Protocol ID: PERL001 Study Name: PERL Site:																						Study	Subject	DOB:							
	Source Documents	Visit 1	Visit 1a	Eligibility Run-In	Visit 2	Visit 3	Visit 4	Visit 4a	Eligibility Randomization	Visit 5 - V6	Visit 5 Call - V7	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10	Visit 11	Visit 12	Visit 13	Visit 14	Visit 15	Visit 16	Visit 17	Unscheduled Visit	Final Status	Unmasking	Initial Complications and Screening eGFR	AE, Con Med, Compliance, BP Med, and Deviation	SAE	Pilot Unscheduled Visit	ESF
PERL_000_Source Document Uploads - V1.0	x																											Logs			-
PERL_000-022_Source Document Uploads - V1.0	x																														+
PERL_000_Additional Source Document Uploads - V1.0	x																														-
PERL_002_Demographics - V3.0		х	х																												
PERL_003_Medical History - V2.0		х			х		х																								
PERL_006_Blood Pressure and Measurements - P1.1																														x	+
PERL_006_Blood Pressure and Measurements - V1.0		х	х		х	x	х	x		х		х	х	х	x	х	х	х	х	х	x	х	х	x							+
PERL_008_Local Laboratory Results - V5.0		x	x			x	x	x		x		х	x	x	х	x	x	х	х	х	x	х	х	x						х	-
PERL_009_ECG Report - V1.0		х			x		x	x					x		-	-	x					х		x							+
PERL_010 Central Lab Specimen Collection - V4.0		x	x			х	x	x		x		х	x	x	x	x	x	х	x	х	x	х	х	x							T
PERL_016_ACR/AER Screening - V4.0		x	x																												1
PERL_001S_Eligibility_RunIn - V3.0				x		-																									+
PERL_001RS_Eligibility Re Screen - V1.0				х																											+
PERL_015_Exemption Request - V2.0				x					x																						
PERL_007_Physical Examination - V1.0					x		x	x					x				x					x		x							-
PERL_010A_Central Lab Specimen Collection - V5.0						x	x	x																							-
PERL_019_iGFR Procedures Form - V3.0							х	x					х				х					х	х	x							-
PERL_019_iGFR Procedures Form - P2.1																														x	+
PERL_014_Family History - V1.0							x	x		х																					
PERL_011_Skin Assessment - V3.0							x					х	х	х	х	х	х	х	х	х	х	х	х	х						х	
PERL_011_Skin Assessment - V2.0										х																					-
PERL_001R_Eligibility_Randomization - V3.0									x																						-
PERL_021_Telephone_Visit - V1.0											х																				
PERL_022_Study Drug Compliance and Exposure - V3.0												х	x	x	х	x	x	х	x	х	x	х								x	-
PERL_023F_Follow Up_Complication Questionnaire - 1.0																							x								1
PERL_025 Unscheduled Visit Reason - V1.0							-																	x							+
PERL_035_Final Status Form - 2.0						-																			х						+
PERL_041_Unmasking Report - V1.0																										х					
PERL_023I_Initial_Complication Questionnaire - 1.0																											x				T
PERL_026_Historical eGFR Slope - 2.0																											x				1
PERL_012_RAS and BP Medication Log - V3.0							-																					x			+
PERL_013_Concomitant Medication Log - V2.0																												x			+
PERL_013_pg2 Concomitant Medications Contd - 1.0																												x			+
PERL_020_Adverse Event Log - V1.0						-	-	-			-				-	-		-										x			+
PERL_040_Protocol Deviation Log - V1.0							-																					x			+
PERL_045_Serious Adverse Event - V5.0																													x		+
PERL_028_ESRD - 1.0					-	-	-		-																						×

PERL_000_Source Document Uploads - V1.0 PERL_000-022_Source Document Uploads - V1.0 PERL_000_Additional Source Document Uploads - V1.0

Investigator Name: _____ Date: _____ Date: _____

Protocol ID: PERL001 Study Name: PERL	Study Subject ID: Study Subject DOB:
Ster	300/ 300/ct to/8
Event Name: Source Documents	
Event Date:	
	PERL_000_Source Document Uploads - V1.0
Section Title: Source Documents Uploads	
A1. Visit 1: Please upload original source documents associated with: Form 006, Form 008, Form 009, Form 016 and Slope Work	rsheet if required
A2. Visit 2: Please upload original source documents associated with: Form 006, Form 007, Form 008, and Form 009	
A3. Visit 3: Please upload original source documents associated with: Form 006, Form 008	
A4. Visit 4/4a: Please upload original source documents associated with: Form 006, Form 007, Form 008, Form 009, Form 019	
A6. Visit 6: Please upload original source documents associated with: Form 006, Form 008	
A7. Visit 7: Please upload original source documents associated with: Form 006, Form 007, Form 008, Form 009, Form 019	
A8. Visit 8: Please upload original source documents associated with: Form 006, Form 008	
A9. Visit 9: Please upload original source documents associated with: Form 006, Form 008	
A10. Visit 10: Please upload original source documents associated with: Form 006, Form 008	
A11. Visit 11: Please upload original source documents associated with: Form 006, Form 007, Form 008, Form 009, Form 019	
A12. Visit 12: Please upload original source documents associated with: Form 006, Form 008	
A13. Visit 13: Please upload original source documents associated with: Form 006, Form 008	
A14. Visit 14: Please upload original source documents associated with: Form 006, Form 008	
A15. Visit 15: Please upload original source documents associated with: Form 006, Form 008	
A16. Visit 16: Please upload original source documents associated with: Form 006, Form 007, Form 009, Form 019	
A17. Visit 17: Please upload original source documents associated with: Form 006, Form 008, Form 019	

Protocol ID: PSRU001 Study Name: FRL	Study Subject ID: Study Subject DOB:
Ster. Event Name: Source Documents Event Name: Source Documents Event Name: Source Documents	
PERL_000-022_Source Document Uploads - V1.0	
Section Title: Source Documents Uploads	
A6. Visit 6: Please upload original source documents associated with Form 022	
A7. Visit 7: Please upload original source documents associated with Form 022	
A8. Visit 8: Please upload original source documents associated with Form 022	
A9. Visit 9: Please upload original source documents associated with Form 022	
A10. Visit 10: Please upload original source documents associated with Form 022	
A11. Visit 11: Please upload original source documents associated with Form 022	
A12. Visit 12: Please upload original source documents associated with Form 022	
A13. Visit 13: Please upload original source documents associated with Form 022	
A14. Visit 14: Please upload original source documents associated with Form 022	
A15. Visit 15: Please upload original source documents associated with Form 022	
A16. Visit 16: Please upload original source documents associated with Form 022	
A17. Visit 17: Please upload original source documents associated with Form 022	

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Source Documents Event Date:		Study Subject ID: Study Subject DOR:
	PERL_000_Additional Source Document Uploads - V1.0	
Section Title: Source Documents Uploads		
1. Additional Source Document Upload		
	Please include a description of upload file:	
2. Additional Source Document Upload		
	Please include a description of upload file:	
3. Additional Source Document Upload		
	Please include a description of upload file:	
4. Additional Source Document Upload		
	Please include a description of upload file:	
5. Additional Source Document Upload		
	Please include a description of upload file:	
6. Additional Source Document Upload		
	Please include a description of upload file:	
7. Additional Source Document Upload		
	Please include a description of upload file:	
8. Additional Source Document Upload		
	Please include a description of upload file:	
9. Additional Source Document Upload		
	Please include a description of upload file:	
10. Additional Source Document Upload		
	Please include a description of upload file:	
Visit 1:		
PERL_002_Demographics - V3.0 PERL_003_Media Hetory - V2.0 PERL_005_Bood Pressure and Measurements - V1.0 PERL_008_Local Laboratory Results - V5.0 PERL_009_ECG Report - V1.0 PERL_001_Contal Lab Spectime Collection - V4.0 PERL_016_ACR/AER Screening - V4.0		

Investigator Name: _____ Date: _____ Date: _____

Protocol ID: PERL001				Study Subject ID:
Study Name: PERL				Study Subject DOB:
Site: Event Name: Visit 1				
Event Date:	_			
			PERL_002_Demographics - V3.0	
Section Title: Demograph	hics			
Instructions:				
Date of Consent:				
A1. Date of Consent:				
Date of Birth:				
A2. Date of Birth:				
Age: A3.				
A3.	(yrs)			
Gender:				
A4. Gender: *	 Male Female of childbearing potential 			
	Female not of childbearing potential			
	Female			
A4a. Reason: (Please select all that apply)	Hysterectomy			
	Tubal Ligation			
	Post-menopausal			
	Other If Othe	er, Specify:		
Ethnicity:				
A5. Ethniticy:	 Hispanic or Latino Non-Hispanic or Non-Latino 			
	 Unknown/Undisclosed 			
Race:				
A6. Please select all that apply:	American Indian or Alaska Native			
	Asian			
	African-American or Black			
	Native Hawaiian or Other Pacific Islander			
	White			
	Unknown or not reported			
	Prefer not to answer			
Marital Status: A7. Marital Status:	○ Single			
A7. Hailta status.	 Married 			
	 Divorced/Separated 			
	 Widowed Unknown 			
History of Smoking: A8. Does the participant have a hist of smoking?	tory O Yes			
of smoking?	⊖ No			
A8a. Smoking status:	O Current			
	 Past 			
	 Not in Last 30 Days In Last 30 Days 			
A8b. Quit Date:				
A8c. How many years has the participant smoked?	years			
A8d. On average, during that time,	how cigarettes/day			
A8d. On average, during that time, many cigarettes per day did th participant smoke?	he			
Alcohol Consumption:				
A9. Does the participant consume alcohol?	ा Yes			
arcohol?	⊖ No			
A9a. Average number of drinks/wee	ek: drinks/week			

Protocol ID: PERL001		Study Subject ID:
Study Name: PERL		Study Subject DOB:
Site:		
Event Name: Visit 1		
Event Date:		
	PERL_003_Medical History - V2.0	
Section Title: Diabetes/GI		

Subtitle:	
Instructions:	
Complete each section Check all conditions th	A-H. At the participant has had in the past five years. I present, indicate if it is ongoing at the time of consent.
	d present, indicate if it is ongoing at the time of consent.
A1. Year of Type I Diabetes Diagnosis: *	(****)
Gastrointestinal Probl	ans
	□A2.680
Ongoing?	C Yes O No
Ongoing?	○Yes ○No
	IAA Appendidas
Ongoing?	CYes
	©No
	TAS. Celac Disease
Ongoing?	©?#s ⊙No
	DAS Celles
Ongoing?	ाभड
	©No
	□ A7. Colon Polyps
Ongoing?	이 Yes
	A& Constipation
Ongoing?	े Yes
	⊖No
	□A3- Grohns Dosase
Ongoing?	©Yes ○No
Ongoing?	े भिड
	○No
Ongoing?	OYes ONo
	□A12.0kes
Ongoing?	CYes
	○No
	□A13. Oxychegia
Ongoing?	CYes ONo
	□A14. Galittones
Ongoing?	O'Yes
	○No
	IA15. Gastrointestinal Beecking
Ongoing?	○Yes ○No
	□A16. Hemia
Ongoing?	O'Yes
	0N6
Ongoing?	O Yes O No
	TAIR Peptic Uces
Ongoing?	े Үड
	©No
	LIA13. Other
If Other, Specify:	
Ongoing?	CYes No
	TA20. None

Protocol ID: PERL001 Study Name: PERL Site: ______ Event Name: Visit 1 Event Date: _____ Study Subject ID:_____ Study Subject DOB:_____ Section Title: Brain/Nervous System Subtitle: Brain & Nervous System Ongoing? ⊖Yes ⊖No B2. Tremors Ongoing? ⊖Yes ⊖No B3. Bells Palsy ⊖Yes ⊖No Ongoing? □B4. Embolism Ongoing? ିYes ିNo B5. Stroke ି Yes ି No Ongoing? 🗆 B6. Dementia ⊖Yes ⊖No Ongoing? B7. Epilepsy Ongoing? ି Yes ି No B8. Guilain-Barre Syndrome Ongoing? ି Yes ି No B9. Migraines Ongoing? ⊖Yes ⊖No 🗆 B10. Meningitis Ongoing? ⊖Yes ⊖No B11. Neuropathy Ongoing? ୁ Yes ି No 🗆 B12. TIA ⊖Yes ⊖No Ongoing? B13. Other If Other, Specify: Ongoing? ⊖Yes ⊖No B14. None

Protocol ID: PERL001 Study Name: PERL Site: ______ Event Name: Visit 1 Event Date: _____ Study Subject ID:_____ Study Subject DOB:_____ Section Title: Skin/Musculoskeletal Subtitle: Skin □C1. Rash ⊖Yes ⊖No Ongoing? C2. Skin Cancer Ongoing? ⊖Yes ⊖No C3. Psoriasis ⊖Yes ⊖No Ongoing? □C4. Rosacea Ongoing? ିYes ିNo C5. Eczema ି Yes ି No Ongoing? C6. Ulcers Ongoing? ⊖Yes ⊖No C7. Hives Ongoing? ି Yes ି No C8. Celluitis Ongoing? ି Yes ି No C9. Other If Other, Specify: ି Yes ି No Ongoing? C10. None Musculoskeletal/Joints Ongoing? ି Yes ି No C12. Back Pain ⊖Yes ⊖No Ongoing? C13. Carpal Tunnel Syndrome Ongoing? ⊖Yes ⊖No □C14. Fibromyalgia Ongoing? ିYes ିNo C15. Joint Pain or Swelling Ongoing? ⊖Yes ⊖No C16. Arthritis Ongoing? ⊖Yes ⊖No C17. Gout Ongoing? ିYes ିNo C18. Osteoarthritis Ongoing? ⊖Yes ⊖No C19. Other If Other, Specify: Ongoing? ⊖Yes ⊖No □C20. None

Protocol ID: PERL001 Study Name: PERL Site: ______ Event Name: Visit 1 Event Date: _____ Study Subject ID:_____ Study Subject DOB:_____ Section Title: Cardiovascular/Pulmonary Subtitle: Cardiovascular System Ongoing? ⊖Yes ⊖No D2. Percutaneous coronary intervention Ongoing? ⊖Yes ⊖No D3. Peripheral artery disease Ongoing? ⊖Yes ⊖No D4. Congestive heart failure Ongoing? ୁ Yes ି No D5. Arrhythmia Ongoing? ି Yes ି No 🗆 D6. MI Ongoing? ⊖Yes ⊖No D7. Congenital heart failure Ongoing? ି Yes ି No DB. Cardiomyopathy Ongoing? ୁ Yes ୁ No D9. Vascular Disease Ongoing? ⊖Yes ⊖No 🗆 D10. Angina Ongoing? ⊖Yes ⊖No D11. Hypertension Ongoing? ୁ Yes ୁ No D12. Hypotension Ongoing? ⊖Yes ⊖No D13. Other If Other, Specify: Ongoing? ⊖Yes ⊖No D14. None Pulmonary System D15. COPD Ongoing? ⊖Yes ⊖No D16. Asthma Ongoing? ⊖Yes ⊖No D17. Pulmonary Embolism Ongoing? ିYes ିNo D18. Pneumonia Ongoing? ⊖Yes ⊖No D19. Pulmonary Edema Ongoing? ⊖Yes ⊖No D20. Emphysema Ongoing? ୁ Yes ି No D21. Shortness of Breath Ongoing? ⊖Yes ⊖No D22. Seasonal/Environmental Allergies Ongoing? ି Yes ି No D23. Other If Other, Specify: Ongoing? ⊖Yes ⊖No D24. None

Protocol ID: PERL001		Study Subject ID:
Study Name: PERL Site:		Study Subject DOB:
Event Name: Visit 1 Event Date:		
Section Title: Autoimm	nune //bitesse	
Subtitle:	une, ormer y	
Autoimmune Disease	IE1. Hashinoto thyroidtis	
Ongoing?	∴ EL restinado trynolotis	
Ungaing?	O'Yes O'No	
	E2. Rheumatoid Arthritis	
Ongoing?	○Yes ○No	
	UNO ⊡E3. Lupus	
Ongoing?	OYes	
ongung.	⊖No	
	E4. Other	
If Other, Specify:		
Ongoing?	⊖Yes ⊖No	
	ES. None	
Urinary System		
	E6. Kidney Stones	
Ongoing?	⊖Yes ⊖No	
	E7. Cystitis	
Ongoing?	0Yes 0No	
	□E& Dysuria	
Ongoing?	OYes ONo	
	□F0. Incontinence	
0		
Ongoing?	⊖Yes ⊖No	
	E10. Urethväs	
Ongoing?	୍ର Yes ାଧ	
	Πειι. υπ	
Ongoing?	ेYes	
	No □E12.08er	
If Other, Specify:		
If Other, Specify: Ongoing?	0 Yes	
ongullig:	ONo	
	E13. None	

Protocol ID: PERL001		Study Subject ID:
Study Name: PERL Site:		Study Subject DOB:
Event Name: Visit 1 Event Date:	_	
Section Title: Endocri	ne/Mental Health	
Subtitle:		
Endocrine System	F1. Adrenal Insufficiency	
Ongoing?	OYes ONo	
	F2. Growth Disorder	
Ongoing?	⊖Yes ⊖No	
	F3. Hyperthyrodism	
Ongoing?	ିYes ୁNo	
	P4. Hypothyroidiam	
Ongoing?	⊖Yes ⊖No	
	F5. Polycystic Overy Syndrome	
Ongoing?	⊖Yes ⊖No	
	F6. Other	
If Other, Specify:		
Ongoing?	O'Yes O'No	
	EF7. None	
Mental Health	F8. Depression	
Ongoing?	OYes ONo	
	P9. 8poler	
Ongoing?	○Yes ○No	
	□F10. Ansiety	
Ongoing?	⊖Yes ○No	
	IF11. Schizophrenia	
Ongoing?	⊖Yes ⊖No	
	P12. Obsessive Compulsive Disorder	
Ongoing?	ିYes ଠNo	
	IP13. Exting disorder	
Ongoing?	OYes ONe	
	IF14. Post-traumatic stress syndrome	
Ongoing?	ିYes ଠNo	
	DFIS.08er	
If Other, Specify:		
Ongoing?	ିYes ାଧ	
	IF16. None	

Protocol ID: PERL001		Study Subject ID:
Study Name: PERL Site:		Study Subject 008:
Event Name: Visit 1 Event Date:		
Section Title: Hepati Subtitle:	ic/Cancer/Eye	
Hepatic		
Ongoing?	□G1. Jaundice ○Yes	
	○ No	
Ongoing?	□G2. Girhois) Yes	
ongoing.	⊖ No	
Ongoing?	□G3. Fatty Liver Disease	
ongunge	⊖ No	
1000	□G4. Other	
If Other, Specify: Ongoing?	○ Yes	
	⊙ No	
Cancer		
Ongoing?	□G6. Head/Neck Cancer ○Yes	
ongoing.	○ No	
Ongoing?	□G7. Renal/Urinary Tract Cancer	
ongung:	○ No	
Oranian ²	□G8. Leukemia/Lymphoma	
Ongoing?	○ No	
	G9. Solid Tumor	
Ongoing?	⊖Yes ⊖No	
	G10. Other	
Ongoing?	○ Yes	
	○No	
Eye		
Ongoing?	⊡G12. Conjunctivitis ∵Yes	
	⊖ No	
Ongoing?	□G13. Cataract ○Yes	
	⊖ No	
Ongoing?	□G14. Cataract Removal	
ongoing.	○ No	
Ongoing?	□G15. Vitrectomy Yes	
ongung:	⊖ res ⊖ No	
Ongoing?	G16. Retinopathy	
Ungang?	⊖Yes ⊖No	
	G17. Laser Therapy	
Ongoing?	⊖Yes ⊖No	
Onwine?	G18. Bindness	
Ongoing?	⊖Yes ⊖No	
Onavina?	G19. Glaucoma	
Ongoing?	⊖Yes ⊖No	
Oranian ²	G20. Myopia	
Ongoing?	⊖Yes ⊖No	
Oracian ²	G21. Hyperopia	
Ongoing?	⊖Yes ⊖No	
0	G22. Macular Degeneration	
Ongoing?	⊖Yes ⊖No	
	□G23. Other	
If Other, Specify: Ongoing?	○Yes	
	⊖ No	
Date of Last Eye Exam:	□G24. None	
	□ Never Examined	
	Eye Exam Date Unknown	

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 1		Study Subject IDc
Event Date:		
Section Title: Hospitalizati	ons/Allergies/Pregnancies	
Allergies	O Yes	
H1. Do you have any food, drug or environmental allergies?		
-	O Noiso O Unkirowan	
	O Unknown	
List allergens:		
Pregnancies		
H2. Has participant ever been pregnant?	○Yes	
pregnant?	○ No	
	O NA	
Number of pregnancies:		
Number of live births:		
Hospitalizations		
H3. Has the participant had a	ny Hospitalizations in the last 5 years requiring overnight stay?	
	Yes	
C	No	

Protocol ID: PERL001 Study Name: PERL Site: _____ Event Name: Visit 1 Event Date: _____

Study Subject ID:_____ Study Subject DOB:_____

Reason:	If Other or non-elective surgery, specify:	Month:	Year:	Length of Stay (days)
Elective Surgery		 January 		
Cardiovascular		O February		
 Diabetes 		O March		
Renal		 April 		
Accident		O May		
Non-Elective Surgery		 June 		
Pulmonary		O July		
Psychiatric		O August		
Other		O September		
		October		
		 November 		
		O December		

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 1			Study Subject ID: Study Subject IDB:
Event Date:	_	PERL_006_Blood Pressure and Measurements - V1.0	
Section Title: Blood Pr	ressure and Heart Rate		
Subtitle:			
Measurements:			
A1. Weight:	(kg)	Not Done	
A2. Height:	(cm)	IN Not Done	
Upload Source Documen	ts:		
Blood Pressure:			
B1. First Reading			
B1a. Systolic:	(mmHg)		
B1b. Diastolic:	(mmHg)	BP Not Dane	
B1c. Heart Rate:	(bpm)	HR Not Done	
B2. Second Reading			
B2a. Systolic:	(mmHg)		
B2b. Diastolic:	(mmHg)	BP Not Done	
B2c. Heart Rate:	(bpm)	HR Not Done	
B3. Third Reading			
B3a. Systolic:	(mmHg)		
B3b. Diastolic:	(mmHg)	BP Not Done	
B3c. Heart Rate:	(bpm)	HR Not Dane	

Protocol ID: PERL001		Study Subject ID:			
Study Name: PERL		Study Subject ID: Study Subject DOB:			
Site:					
Event Name: Visit 1					
Event Date:	-				
Section Title: Average B	lood Pressure and Heart Rate				
Subtitle:					
Calculated Fields:	Calculated Fields:				
BMI					
BMI:					
Blood Pressure					
Systolic:	(mmHg)				
Diastolic:	(mmHg)				
Heart Rate:	(bpm)				

Protocol ID: PERL001		Study Subject ID:
Study Name: PERL		Study Subject DOB:
Site:		
Event Name: Visit 1		
Event Date:		
	PERL_008_Local Laboratory Results - V5.0	
Section Title: Section A. Chemistry		
Subtitle:		
Instructions: Enter the lab values in the units indicated with the date of co	ollection for each field. Use the "Not Done" checkbox provided if data is unobtainable.	
Upload source documents:		
Chemistry:		
A1 Dataceiums (concel/l) Data Cellesteds	This Dana	

Protocol ID: PERL001 Study Name: PERL Site: ______ Event Name: Visit 1 Event Date: _____ Study Subject ID:_____ Study Subject DOB:_____ Section Title: Section B. CBC Subtitle: Date Collected: B1. Hemoglobin: (gm/dl) □ Not Done B2. Hematocrit: (%) Date Collected: □ Not Done B3. Platelets: (mmol) Date Collected: □ Not Done (million cells/mcL) B4. RBC: Date Collected: Not Done B5. WBC: (cells/mcL) Date Collected: □ Not Done B5a. Neutrophils: (%) Not Done B5b. Lymphocytes: (%) Not Done B5c. Monocytes: (%) Not Done B5d. Eosinophils: (%) Not Done (%) B5e. Basophils: Not Done

Protocol ID: PERL001 Study Name: PERL Ste: Event Name: Visit 1 Event Date:			Study Subject ID: Study Subject DOR:
Section Title: Section C. P	regnancy Test		
C1. Urine Pregnancy Test Result:	 Positive Negative Not Done Not Applicable 	Date of test:	
C2. Serum Pregnancy Test Result:	 Positive Negative Not Done Not Applicable 	Date of test:	

Protocol ID: PERL001			Study Subject ID:
Study Name: PERL			Study Subject DO8:
Site:			
Event Name: Visit 1			
Event Date:	_		
Section Title: Section D.	Uning Multiplie		
	onne multisux		
Date Urine Collected:		Not Done	
D1. Leukocytes:	O Negative		
	Trace		
	Small		
	O Moderate		
	Large		
D2. Nitrites:	O Negative		
	O Positive		
D3. Protein:	O Negative		
	 Trace 		
	O 30		
	100		
	O 300		
	O 2000+		
D4. Blood	O Negative		
	O Positive		
D4a. Blood - Non Hemolyzed:	 None 		
	 Trace 		
	O Moderate		
D4b. Blood - Hemolyzed:	None		
DHD. Bloba - Heinbiyzea.	O Trace		
	○ Irace ○ Small		
	O Moderate		
	O Large		
	Olarge		
D6. Ketones:	O Negative		
	O Trace		
	O Small		
	 Moderate 		
	Large		

Protocol ID: PERL001	Study Subject ID:
Study Name: PERL	Study Subject DOB:
Site:	
Event Name: Visit 1	
Event Date:	
Section Title: Section E. eGFR	
Subtitle:	
E1. Indicate visit for which this eGFR values applies:	
○Visit 1	
○ Visits 6-15	
E2. Use central lab creatinine value to calculate eGFR	
Click Here to Calculate eGFR	
Central lab creatinine value	
E3. Use local lab creatinine value to calculate eGFR	
Click Here to Calculate eGFR	
Local Jab creatinine value	

□ Not Done

E4. eGFR: (mls/min/1.73m²) Date Collected:

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 1		Study Subject ID: Study Subject DOB:
Event Date:	PERL_009_ECG Report - V1.0	
Section Title: ECG Rep	nt	
ECG Completed? *	ेCompleted ेNet Completed	
Upload Source Document:		
A1. Date of ECG:		
A2. Heart Rate:	(mqd)	
A3. ECG Findings:	O Normal O Aenomal	
A3a. If abnormal (select	ll that apply): □ST Beation	
	□ Atrial Fib	
	Inversion	
	□Q Wave	
	□ AV Block	
	UMI Changes	
	∏ Bradycardia	
	□ Other	
If Other, Specify:		
A3b. Is this abnormality clinical significant?	 Yes ** If yes, report on AE Log No 	

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 1 Event Date:				Study Subject IDR: Study Subject IDDR:	
			PERL_010 Central Lab Specimen Collection - V4.0		
Section Title: Section A. B Instructions: Please indicate the collected s		date of collection.			
A1. Serum Uric Acid, Creatinine, Cystatin C Collected	⊖ Yes ⊖ No	Date Collected			
A2. HbA1c Collected	⊖Yes ⊙No ⊙NA-if visit 6	Date Collected			

A3. Shipped to ARDL O Yes Date Shipped No

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 1 Event Date:	_					Study Subject ID: Study Subject IDO8:
Section Title: Section B	. Urine Specimens					
B1. ACR/AER Collected	ਂ Yes ਂ No ਂ NA-ਜੋਂ visit 6_8_10_12 or 14					
Overnight	⊖Yes ⊖No	Date Ended Collection				
First Morning	⊖Yes ⊖No	Date Collected				
Spot Urine	⊖Yes ⊖No	Date Collected	Additional Date Collected	If necessary	Additional Date Collected	И песезану
B2. Shipped to ARDL	○ Yes ○ No	Date Shipped				

Protocol ID: PERL001 Study Name: PERL				Study Subject ID: Study Subject DOB:
Site: Event Name: Visit 1 Event Date:				
		· · · · · · · · · · · · · · · · · · ·	 	
Section Title: Section C	. Biospecimens	for Repository		
Is this Visit 4, 11, 16 or 17	⊖Yes ⊖No			
C1. Serum Collected	ି Yes ୁ No	Date Collected		
C2. Plasma Collected	ି Yes ଼ No	Date Collected		
C3. Urine Collected	⊙ Yes ⊙ No	Date Collected		
C3a. Protease Inhibitor Added	○ Yes ○ No			
C4. Shipped to ARDL	⊖ Yes ○ No	Date Shipped		

Protocol ID: PERL001	Study Subject ID:		
Study Name: FERL Site:	Study Subject DOB:		
Event Name: Visit 1			
Event Date:			
PERL_016_ACR/AER Screening - V4.0			
Section Title: ACR/AER Screening			

Section Title: ACR/AE	Section Title: ACR/AER Screening					
Which of the criteria was used to document microalbuminuria or moderate macroalbuminuria at screening? (Check all that apply)						
Ala.	Uniary albumin excretion rates					
Select RASB status:	Net en RAS9 30-5000 mg/24tr or 20-3133 g/min or 30-5000 mg/g On RAS9 18-5000 mg/24tr or 12-3333 g/min or 16-5000 mg/g					
	Albumin creatinine ratios					
Select RASB status:	O Not on RASB 36-5000 mg/24th or 216-3333 g/min or 316-5000 mg/9 O On RASB 18-5000 mg/24th or 12-3333 g/min or 18-5000 mg/9					

If A1c checkbox is selected, provide Slope Calculation Result:

Date of Test: ACR Res	ult: AER Result: ACR/AER Unit	EGFR: Enter values for the last 3-5 years (ml/min/1.73 m ²)
	O Mg/24 hr	
	O Mcg/min	
	O Mg/24 hr	
	O Mcg/min	
	O Mg/24 hr	
	O Mog/min	

Visit 1a:

PERL_016_ACR/AER Screening - V4.0 PERL_002_Demographics - V3.0 PERL_006_Blood Pressure and Measurements - V1.0 PERL_008_Local Laboratory Results - V5.0 PERL_010 Central Lab Specimen Collection - V4.0

Investigator Name: _____ Investigator Signature: ____ ____ Date: __

Protocol ID: PERL001 Study Name: PERL	Study Subject ID: Study Subject DOB:
Site: Event Name: Visit 1a	sauf sujes 0.00
Event Date:	_016_ACR/AER Screening - V4.0
PE	_UID_ACK/ACK Screening - V4.U

Section Title: ACR/A	AER Screening	
	ia was used to document microalbuminuria albuminuria at screening? Ny)	
Ala.	Uninery abounts excetion rates	
Select RASB status:	ামt on RASB 30-5000 mg/24r or 20-3333 g/min or 30-5000 mg/g ি On RASB 18-5000 mg/24r or 12-3333 g/min or 18-5000 mg/g	
	Abumin creatinire ratios	

 Select RASB status:
 O Not on RASB 30-5000 mg/24hr or 20-3333 g/min or 30-5000 mg/g

 O N RASB 18-5000 mg/24hr or 12-3333 g/min or 18-5000 mg/g

If A1c checkbox is selected, provide Slope Calculation Result:

Date of Test:	ACR Result:	AER Result:		GFR: Enter values for the last 3-5 years (ml/min/1.73 m ²)
			O Mg/24 hr	
			O Mog/min	
			O Mg/24 hr	
			O Mog/min	
			O Mg/24 hr	
			O Mcg/min	

Protocol ID: PERL001					Study Subject ID:
Study Name: PERL Site:					Study Subject DOB:
Event Name: Visit 1a					
Event Date:					
			PERL_002_De	mographics - V3.0	
Section Title: Demograp	phics				
Instructions:					
Date of Consent:					
A1. Date of Consent:					
Date of Birth:					
A2. Date of Birth:					
Age: A3.					
	(yrs)				
Gender: A4. Gender: *	 Male 				
A4. Gender: *	 Female of childbearing potential 				
	Female not of childbearing pote	ntial			
	 Female 				
A4a. Reason: (Please select all that apply)	Hysterectomy				
	Tubal Ligation				
	□ Post-menopausal				
	Other	If Other, Specify:			
	UOther	If Other, Specify:			
Ethnicity:					
A5. Ethniticy:	 Hispanic or Latino Non-Hispanic or Non-Latino 				
	 Unknown/Undisclosed 				
Race:					
A6. Please select all that apply:	American Indian or Alaska Nativ	e			
	□Asian				
	African-American or Black				
	Native Hawaiian or Other Pacific Isla	ander			
	□ White				
	Unknown or not reported				
	Prefer not to answer				
Marital Status: A7. Marital Status:	○ Single				
A7. Hairtai Status.	Married				
	 Divorced/Separated 				
	 Widowed Unknown 				
History of Smoking: A8. Does the participant have a his of smoking?	istory O Yes				
of smoking?	○ No				
A8a. Smoking status:	O Current				
	 Past 				
	 Not in Last 30 Days In Last 30 Days 				
	U III Last 30 Days				
A8b. Quit Date:					
A8c. How many years has the participant smoked?	years				
A8d. On average, during that time	e, how cigarettes/day				
A8d. On average, during that time many cigarettes per day did t participant smoke?	the				
Alcohol Consumption:					
A9. Does the participant consume alcohol?	e ⊖Yes ⊙No				
	0160				
A9a. Average number of drinks/we	reek: drinks/week				

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 1a			Study Subject ID: Study Subject DDB:
Event Date:			PERL_006_Blood Pressure and Measurements - V1.0
	ressure and Heart Rate		
Subtitle:			
Measurements:			
A1. Weight:	(kg)	Not Done	
A2. Height:	(cm)	Not Done	
Upload Source Documer	nts:		
Blood Pressure:			
B1. First Reading B1a. Systolic:	(mmHg)		
B1b. Diastolic:	(mmHg)	BP Not Done	
B1c. Heart Rate:	(bpm)	HR Not Done	
B2. Second Reading			
B2a. Systolic:	(mmHg)		
B2b. Diastolic:	(mmHg)	BP Not Done	
B2c. Heart Rate:	(bpm)	HR Not Done	
B3. Third Reading			
B3a. Systolic:	(mmHg)		
B3b. Diastolic:	(mmHg)	BP Not Done	
B3c. Heart Rate:	(bpm)	HR Not Done	

Protocol ID: PERL001 Study Name: PERL		Study Subject ID: Study Subject DOB:
Site:		
Event Name: Visit 1a		
Event Date:	-	
Section Title: Average B	ood Pressure and Heart Rate	
Subtitle:		
Calculated Fields:		
BMI		
BMI:		
Blood Pressure		
Systolic:	(mmHg)	
Diastolic:	(mmHg)	
Didstonc.	(mm2)	
Heart Rate:	(bpm)	

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 1a Event Date:	_			ID coce:
			PERL_008_Local Laboratory Results - V5.0	
Section Title: Section A. Subtitle: Instructions: Enter the la Upload source document	b values in the units i	indicated with the date of co	lection for each field. Use the "Not Done" checkbox provided if data is unobtainable.	
Chemistry:				
A1. Potassium:	(mmol/L)	Date Collected:	□ Not Dane	
A2. Creatinine:	(mg/dl)	Date Collected:	□ Not Dane	
A3. ALT (SGPT):	(U/L)	Date Collected:	□ Not Done	

. Potassium:	(mmol/L)	Date Collected:	□ Not Done
. Creatinine:	(mg/dl)	Date Collected:	□ Not Done
I. ALT (SGPT):	(U/L)	Date Collected:	□ Not Done

Protocol ID: PERL001 Study Name: PERL Site: ______ Event Name: Visit 1a Event Date: ______ Study Subject ID:_____ Study Subject DOB:_____ Section Title: Section B. CBC Subtitle: B1. Hemoglobin: (gm/dl) Date Collected: □ Not Done B2. Hematocrit: (%) Date Collected: □ Not Done B3. Platelets: (mmol) Date Collected: □ Not Done (million cells/mcL) B4. RBC: Date Collected: Not Done B5. WBC: (cells/mcL) Date Collected: □ Not Done B5a. Neutrophils: (%) 🗆 Not Done B5b. Lymphocytes: (%) 🗆 Not Done B5c. Monocytes: (%) Not Done B5d. Eosinophils: (%) Not Done (%) B5e. Basophils: Not Done

Protocol ID: PERL001 Study Name: PERL Ste: Event Name: Visit 1a Event Date:			Study Subject ID Study Subject DOR
Section Title: Section C. P	regnancy Test		
C1. Urine Pregnancy Test Result:	 Positive Negative Not Done Not Applicable 	Date of test:	
C2. Serum Pregnancy Test Result:	 Positive Negative Not Done Not Applicable 	Date of test:	

Protocol ID: PERL001			Study Subject ID:
Study Name: PERL			Study Subject DO8:
Site:			
Event Name: Visit 1a			
Event Date:	_		
Section Title: Section D.	11-1		
Section Title: Section D.	Unne Multistix		
Date Urine Collected:		Not Done	
D1. Leukocytes:	O Negative		
	O Trace		
	○ Small		
	 Moderate 		
	⊖ Large		
	Orange		
D2. Nitrites:	O Negative		
	 Positive 		
	o reasine		
D3. Protein:	O Negative		
	⊖ Trace		
	O 30		
	○ 100		
	O 300		
	C 2000+		
	0.2001		
D4. Blood	O Negative		
	O Positive		
D4a. Blood - Non Hemolyzed:	O None		
	O Trace		
	 Moderate 		
D4b. Blood - Hemolyzed:	None		
.,	O Trace		
	○ Small		
	O Moderate		
	○ Large		
D6. Ketones:	O Negative		
	O Trace		
	O Small		
	O Moderate		
	⊖ Large		

Protocol ID: PERL001	Study Subject ID:
Study Name: PERL	Study Subject ID: Study Subject DO8:
Site:	
Event Name: Visit 1a	
Event Date:	
Section Title: Section E. eGFR	
Subtitle:	
E1. Indicate visit for which this eGFR values applies:	
O Visit 1	
○ Visits 6-15	
E2. Use central lab creatinine value to calculate eGFR	
Click Here to Calculate eGFR	
Central lab creatinine value	
E3. Use local lab creatinine value to calculate eGFR	
Click Here to Calculate eGFR	
Local lab creatining value	

□ Not Done

E4. eGFR: (mls/min/1.73m²) Date Collected:

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 1a Event Date:					Study Subject ID: Study Subject DOR:
PERL_010 Central Lab Specimen Collection - V4.0					
Section Title: Section A. Blood Specimens Instructions: Please inducts the collected specimens and provide the date of collection. Please inducts the collected specimens and provide the date of collection.					
A1. Serum Uric Acid, Creatinine, Cystatin C Collected	⊖ Yes ⊖ No	Date Collected			
A2. HbA1c Collected	○ Yes ○ No ○ NA-if visit 6	Date Collected			

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 1a Event Date:	_					Study Subject ID®
Section Title: Section B	. Urine Specimens					
B1. ACR/AER Collected	ਂ Yes ਂ No ਂ NA-ਜੋਂ visit 6_8_10_12 or 14					
Overnight	○Yes ○No	Date Ended Collection				
First Morning	⊖Yes ⊖No	Date Collected				
Spot Urine	⊖Yes ⊖No	Date Collected	Additional Date Collected	If necessary	Additional Date Collected	II necessary
B2. Shipped to ARDL	○ Yes ○ No	Date Shipped				

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 1a Event Date:	_			Study Subject IDC	
Section Title: Section C.	Biospecimens for Repos	itory			
Is this Visit 4, 11, 16 or 17	⊖Yes ⊖No				
C1. Serum Collected	⊖ Yes ○ No	Date Collected			
C2. Plasma Collected	⊖ Yes ⊖ No	Date Collected			
C3. Urine Collected	⊖ Yes ⊖ No	Date Collected			
C3a. Protease Inhibitor Added	○ Yes ○ No				
C4. Shipped to ARDL	⊖ Yes ⊖ No	Date Shipped			
Eligibility Run-In:					
PERL_0015_Eligibility_RunI PERL_001RS_Eligibility Re S PERL_015_Exemption Requ	creen - V1.0				
Investigator Name:	Investiga	tor Signature:	Date:		

Protocol ID: PERL001	Study Subject ID:
Study Name: PERL	Study Subject DOB:
Ste:	
Event Name: Eligibility Run-In	
Event Date:	
PERL_001S_Eligibility_RunIn - V3.0	
Section Title: PERL Pilot	

Is this participant active in the PERL Pilot Study? Yes No Enter Pilot Subject ID If Pilot Study Participant, Skip to Eligibility Status.

Protocol ID: PERL001	Study Subject ID:
Study Name: PERL	Study Subject DO8:
Ste	
Event Name: Eligibility Run-In	
Event Date:	
Section Title: Inclusion Criteria	
Section nue: Inclusion Criteria	
A1. Between 18 and 70 years of age, inclusive.	
⊆ Yes No Not Done	
A3. Continuously treated with insulin within one year of T1D diagnosis.	
○ Yes ○ No ○ Not Done	
A5. Duration of T1D ≥ 8 years	
⊖Yes ⊡ No	
A6. History or presence of microalbuminuria, moderate macroalbuminuria or evidence of declining kidney function according to the specific protoco	I requirements.
A7. Estimated GFR based on serum creatinine between 40 and 99.9 ml/min/1.73 m ² at screening according to the specific protocol requirements.	
⊖ Yes ⊖ No	
A8. Serum UA \ge 4.5 mg/dl at the screening visit.	
○Yes ○No ○Not Done	
A9. Willing to comply with schedule of events and protocol requirements.	
○ Yes ○ No ○ Not Done	
A10. Participant signed informed consent.	
○ Yes ○ No ○ Not Done	
A11. Male or female T1D patient.	
A12. Was T1D diagnosis after age 35?	
○ Yes ○ No ○ NA	
17 Marca along to display which additional activity and	
A12a. If yes, please indicate which additional criteria was met:	Reema C-pentide below the limit of detection with Standard areas (durant blood obscess >100mo/d)
A13. Participant eligible to skip to Visit 4.	
○ Yes ○ Not Applicable	

Protocol ID: PERL001	Study Subject ID:
Study Name: PERL Stee:	Study Subject DOB:
ster: Eigibilty Run-In	
Event Date:	
Section Title: Exclusion Criteria	
B1. History of gout requiring allopurinol therapy or xanthinuria or other indications for uric acid lowering therapy such as cancer chemotherapy or extremely high serum uric acid values (>12 mg/dl).	
Yes No	
B2. Recurrent renal calculi (history of more than 1 episode).	
Characteric feature default of the factor of	
B3. Use of urate-lowering agents within 3 months prior to screening.	
DS. Use of under-wweining agents within 5 monus prior to Screening.	
B4. Current use of drugs known to interact with allopurinol. OYes O No ONat Dane	
B5. Known allergy to xanthine-oxidase inhibitors or iodine containing substances. ○ \(\cons	
B7. Renal transplant ○ Yes ○ No ○ Not Done	
B8. Non-diabetic kidney disease as indicated by medical history and/or laboratory findings.	
B9. SBP>160 or DBP>100 mmHg at screening.	
B11. Cancer treatment (excluding non-melanoma skin cancer treated by excision) within two years before screening.	
○Yes ○ No ○Not Done	
B12. History of clinically significant hepatic disease including hepatitis B or C and/or ALT >2.50 ULN at screening and/or history of HBV/HCV antibody positivity.	
○ Yes ○ No ○ Not Done	
B13. History of acquired immune deficiency syndrome or human immunodeficiency virus (HIV) infection	
○Yes No OND Done	
B14. Hemoglobin concentration <11 g/dL (males), <10 g/dL (females) at screening.	
○Yes ○ No ○ Not Done	
B15. Platelet count <100,000/mm ³ at screening.	
⊖Yes ⊖ No ⊖ Not Done	
B16. Ongoing alcohol or drug abuse or history of treatment for these conditions in the past 6 months.	
○Yes ○No ○Not Done	
B17. Blood donation in the 3 months before screening.	
○Yes O No O Not Done	
B18. Breastfeeding or pregnancy or unwillingness to be on contraception if fertile.	
⊖Yes ONo ONOt Done	
B19. Poor mental function or any other reason to expect patient difficulty in complying with the requirements of the study.	
City is the next initiation of the start of the Dene	
B20. Serious pre-existing medical problems (except T1D).	
D20. Je log pre-existing indexical proteins (concept 120). O'Yes O'No O'No Oho Dato	

Protocol ID: PERL001		Study Subject ID:			
Study Name: PERL		Study Subject DOB:			
Site:					
Event Name: Eligibility Run-In					
Event Date:	_				
Section Title: Eligibility	Section Title: Eligibility Status				
	a are 'No' or if any Exclusion Criteria are 'Yes', the participant is not eligible.				
Participant Is:	C Eligible for Run-In				
	 Eligible (Pilot Participant) 				
	O Ineligible for Run-In				
	C Eligible for Run-In by Exemption				

Protocol ID: PERL001	Study Subject ID:
Study Name: PERL	Study Subject DOB:
Site:Eiqbilty Rum-In	
Event Date	
PERL_001RS_Eligibilit	ty Re Screen - V1.0
Section Title: Eligibility ReScreen	
A1. Date participant considered for re-screening assessments	
A2. Which eligibility criteria was not met at Visit 1 Screening? Preser refer to the Inclusion and Exclusion Criteria sections of Form 0015 Eligibility RunIn CRF and select the appropriate question number(2) that the subject did not meet at Visit 1 Screening.	
□A6	
□ A7	
□A8	
383	
□ 84	
□ 89	
0611	
B12	
□ 614	
B15	
□1816	
□B17	
A3. Projected date of re-screen visit	

Protocol ID: PERL001		Study Subject ID:
Study Name: PERL		Study Subject DOB:
Site:		Suby Subject Dob.
Event Name: Eligibility Run-In		
Event Date:		
	PERL_015_Exemption Re	quest - V2.0
Section Title: Exempt	on Request	
Instructions: Completion of items Please enter relevant	41-A3 will send an email to the Exemption Review Committee. details into A3 below. This is required in order to send the alert and for the Exemption Committee to make a decision.	
A1. Select Inclusion crit	eria not met:	
Select criteria for review:	○ Male or female between 18 and 70 years of age	
	T1D diagnosed after age 35 and additional criteria not met	
	O Continuously treated with insulin within one year of T1D diagnosis	
	Our think of T1D 2 8 years	
	Itstory or presence of microalbuminuria or moderate macroalbuminuria or evidence of declining kidney function according to the specific protocol requirements	
	Estimated GR between 40 and 99.9 ml/min/1.73 m2. The upper limit should be decreased by 1 ml/min/1.73 m2 for each year over age 60	
	\odot Securities of the electric in the spectral matrix in the epper numerical and the decreased by 1 mining 1.5 min is then year over age of \odot Securities 4.5 mg/dl at the screening visit	
A2. Select Exclusion crit	ada udalatada	
A2. Select Exclusion cn Select criteria for review:	ena violated: O History of gout requiring allopurinol therapy or xanthinuria or other indications for uric acid lowering therapy such as cancer chemotherapy or extremely high serum uric acid	value (~12 m/d)
and a mana for remem.	Onsoling indicating and a manufacture and a second seco	converte (see military
	Use of urate-lowering agents within 3 months prior to screening	
	Current use of drugs known to interact with allopurinol	
	Chrown allergy to sample inhibitors or indexe inhibitors or indexe containing substances	
	O Non-diabetic kidney disease as indicated by medical history and/or laboratory findings	
	SBP>160 or DBP >100mmHg at screening	
	O SBP>150 or DBP >95mmHg at the end of the run-in period	
	Cancer treatment within two years before screening	
	 Hemoglobin concentration <11 _tmplitem="755" g/dL (males) or <10 g/dL (females) at screening 	
	Platelet count <10000/mm3	
	Ongoing alcohol or drug abuse or history of treatment for these conditions in the past 6 months	
	Blood donation in the 3 months before screening	
	Serious pre-existing medical problems (except TID)	
	Other	
If Other, Specify:		
A3. Reason this particip Please Provide: *	ant should be considered for the study:	
A4. Exemption Gram Please Select One:	oYes	
manac socce one.	ONe Contraction of the second se	
	Ond	
A4a. If No, Reason:		
A5. Date of Decision		
Date:		
Visit 2:		
PERI 006 Blood Process	e and Measurements - V1.0	
PERL_008_Blobu Plessul PERL_007_Physical Exan		
PERL_007_Physical Exam PERL_003_Medical Histo	v - √2.0	
PERL_009_ECG Report -		
Investigator Name:	Investigator Signature: Date:	
	Date	

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 2			Study Subject ID: Study Subject DOR:
Event Date:			PERL_006_Blood Pressure and Measurements - V1.0
Section Title: Blood F	Pressure and Heart Rate		
Subtitle:			
Measurements:			
A1. Weight:	(kg)	Not Done	
A2. Height:	(cm)	Not Done	
Upload Source Docume	ents:		
Blood Pressure:			
B1. First Reading			
B1a. Systolic:	(mmHg)		
B1b. Diastolic:	(mmHg)	BP Not Done	
B1c. Heart Rate:	(bpm)	HR Not Done	
B2. Second Reading			
B2a. Systolic:	(mmHg)		
B2b. Diastolic:	(mmHg)	BP Not Done	
B2c. Heart Rate:	(bpm)	U HR Not Done	
B3. Third Reading			
B3a. Systolic:	(mmHg)		
B3b. Diastolic:	(mmHg)	BP Not Done	
B3c. Heart Rate:	(bpm)	HR Not Done	

Protocol ID: PERL001		Study Subject ID: Study Subject DDB:
Study Name: PERL		Study Subject DOB:
Site:		
Event Name: Visit 2 Event Date:		
Event Date:	-	
Section Title: Average B	ood Pressure and Heart Rate	
Subtitle:		
Calculated Fields:		
BMI		
BMI:		
Blood Pressure		
Systolic:	(mmHq)	
Systole.	(umað)	
Diastolic:	(mmHg)	
Heart Rate:	(bpm)	

Protocol ID: PERL001 Study Name: PERL	Study Subject ID: Study Subject DOB:	
Site: Event Name: Visit 2		
Event Name: Visit 2 Event Date:		
	PERL_007_Physical Examination - V1.0	
Section Title: Body Sys	y System	
A0. Was a physical exam	exam performed at this visit? O're	
	Ute No	
Upload source documents	ments:	
A1. Eyes: Eyes (including fundoscopy):		
Eyes (including fundoscopy):	Abnormal	
	O Not Dane	
If abnormal, describe find Select all that apply:	e findings: □Retiropathy	
	Macular Degeneration	
	_ 08er	
If other, specify:		
A2. Cardiovascular: Cardiovascular:	 Normal 	
	Abnormal Not Done	
If abnormal, describe find Select all that apply:	□ Antytmia	
If other, specify:		
A3. Extremities:	ON mod	
Extremities:	O Normal O Anormal O Anormal O hoto Done	
If abnormal, describe find		
Select all that apply:	Amputation	
Amputation, specify:		
	- Terdemes	
Pulses:	0+	
	01+ 02+	
	01- 03- 04-	
	00ter	
If other, specify:		
A4. Lymph Nodes: Lymph Nodes:	() Kornal	
	Oktomal Oktoba	
If abnormal, describe find	e findings:	
Select all that apply:	Sweling	
If other, specify:	□ Other	
A5. Pulmonary:		
Pulmonary:	Normal Advormal	
If abnormal, describe find		
Select all that apply:	E munitys. Reduced breath sounds	
If other, specify:		
A6. Skin: Skin:	O Normal O Atmormal	
	○ Next Minut ○ Not Done	
If abnormal, describe find Select all that apply:	e findings: □Ref or purple paint/ rash	
	□Sær	
	□Ecema	
	Portess	
	Ulces	
	Encessive Bruising	
	- Other	
If other, specify:		
A7. Gastrointestinal: Gastrointestinal:	Okomat Oktomat	
	○Atromal ○Not Done	
If abnormal, describe find Select all that apply:	e findings: □Acdes	
	□ Abdominal Mass	
	□ Organomegaly	
Organomegaly, specify:		
	Stona	
	□0ter	
If other, specify:		
A8. Musculoskeletal Musculoskeletal:	O Normal	
	Abnormal Oktobene	
If abnormal, describe find	e findings:	

Select all that apply:	□ Stiffees
	□Tendemes
Injury, specify:	
	□ Reduced strength
	CReduced range of motion
	Clober Clober
If other, specify:	
A9. Genitourinary:	
Genitourinary:	○ Normal
	O Abnormal
	Net Done
If abnormal, describe find	ing:
Specify:	
A10. Neurological:	
Neurological:	○ Normal
	OAbnormal
	(Net Done
If abnormal, describe find	ings:
Select all that apply:	
Abnormal reflex response, speci	V. O hooffesia
	CHypothesia
	[]Diminished sensation
	□ Canial Kenes
Abnormal, specify:	
	□ Other
If other, specify:	

Study Subject ID:_____ Study Subject DOB:_____

Protocol ID: PERL001 Study Name: PERL Site: ______ Event Name: Visit 2 Event Date: _____

Section Title: Other Body System

Other Body System
A11. Other Body System: Describe

Protocol ID: PERLODI	Study Subject ID:
Study Name: PERL	Study Subject DOB:
Site:	
Event Name: Visit 2	
Event Date:	
PERL_003_Medical History - V2.0	
Section Title: Diabetes/GI	

nstructions:	
	k-H. L'hte participant has had in the past five years. present, indicate if it is ongoing at the time of consent.
f a condition is marked I. Year of Type I Diabetes agnosis: *	present, indicate if it is ongoing at the time of consent.
astrointestinal Proble	
astronitestinal Proble	BA2.680
ngaing?	016 -
	ONo
ngaing?	○Yes ○No
	A. Appendix
igaing?	OYes
	□A5. Gelic Disease
ngaing?	0Yes 0No
ngaing?	ore
	○ No
ngaing?	0 Yes 0 No
	AL Constpation
ngaing?	™et
	⊖ No
	A9. Gohns Diesse
igaing?	0Yes 0No
	DAIb Durhes
gaing?	ore
	○No
ngaing?	0 Yes 0 No
	DA2 Ukes
ngaing?	O'res
	O No
	□A13. Dysphage O'tes
igaing?	⊖ tes ⊖No
	DA4 Galitones
ngoing?	Ores
ngaing?	□AIS. Gastrointestind Bleeding O'tes
gung.	O Ma O No
	□A16. Hemia
ngaing?	ି Yes ିାର
gaing?	0Yes
	O No
	Alß. Peptic Ucers
gaing?	○Yes ○No
0.0	and the
	O'Yes
Other, Specify: 1going?	CYes ○No □A20 None

Protocol ID: PERL001 Study Name: PERL Site: ______ Event Name: Visit 2 Event Date: _____ Study Subject ID:_____ Study Subject DOB:_____ Section Title: Brain/Nervous System Subtitle: Brain & Nervous System Ongoing? ⊖Yes ⊖No B2. Tremors Ongoing? ⊖Yes ⊖No B3. Bells Palsy ⊖Yes ⊖No Ongoing? □B4. Embolism Ongoing? ିYes ିNo B5. Stroke ି Yes ି No Ongoing? 🗆 B6. Dementia ⊖Yes ⊖No Ongoing? B7. Epilepsy Ongoing? ି Yes ି No B8. Guilain-Barre Syndrome Ongoing? ି Yes ି No B9. Migraines Ongoing? ⊖Yes ⊖No 🗆 B10. Meningitis Ongoing? ⊖Yes ⊖No B11. Neuropathy Ongoing? ୁ Yes ି No 🗆 B12. TIA ⊖Yes ⊖No Ongoing? B13. Other If Other, Specify: Ongoing? ⊖Yes ⊖No B14. None

Protocol ID: PERL001 Study Name: PERL Site: ______ Event Name: Visit 2 Event Date: _____ Study Subject ID:_____ Study Subject DOB:_____ Section Title: Skin/Musculoskeletal Subtitle: Skin □C1. Rash ⊖Yes ⊖No Ongoing? C2. Skin Cancer Ongoing? ⊖Yes ⊖No C3. Psoriasis ⊖Yes ⊖No Ongoing? □C4. Rosacea Ongoing? ୁ Yes ି No C5. Eczema ି Yes ି No Ongoing? C6. Ulcers Ongoing? ⊖Yes ⊖No C7. Hives Ongoing? ି Yes ି No C8. Celluitis Ongoing? ି Yes ି No C9. Other If Other, Specify: ି Yes ି No Ongoing? C10. None Musculoskeletal/Joints Ongoing? ି Yes ି No C12. Back Pain ⊖Yes ⊖No Ongoing? C13. Carpal Tunnel Syndrome Ongoing? ⊖Yes ⊖No □C14. Fibromyalgia Ongoing? ି Yes ି No C15. Joint Pain or Swelling Ongoing? ⊖Yes ⊖No C16. Arthritis Ongoing? ⊖Yes ⊖No C17. Gout Ongoing? ିYes ିNo C18. Osteoarthritis Ongoing? ⊖Yes ⊖No C19. Other If Other, Specify: Ongoing? ⊖Yes ⊖No □C20. None

Protocol ID: PERL001 Study Name: PERL Site: ______ Event Name: Visit 2 Event Date: _____ Study Subject ID:_____ Study Subject DOB:_____ Section Title: Cardiovascular/Pulmonary Subtitle: Cardiovascular System Ongoing? ⊖Yes ⊖No D2. Percutaneous coronary intervention Ongoing? ⊖Yes ⊖No D3. Peripheral artery disease Ongoing? ⊖Yes ⊖No D4. Congestive heart failure Ongoing? ୁ Yes ି No D5. Arrhythmia Ongoing? ି Yes ି No 🗆 D6. MI Ongoing? ⊖Yes ⊖No D7. Congenital heart failure Ongoing? ି Yes ି No DB. Cardiomyopathy Ongoing? ୁ Yes ୁ No D9. Vascular Disease Ongoing? ⊖Yes ⊖No 🗆 D10. Angina Ongoing? ⊖Yes ⊖No D11. Hypertension Ongoing? ୁ Yes ୁ No D12. Hypotension Ongoing? ⊖Yes ⊖No D13. Other If Other, Specify: Ongoing? ⊖Yes ⊖No D14. None Pulmonary System D15. COPD Ongoing? ⊖Yes ⊖No D16. Asthma Ongoing? ⊖Yes ⊖No D17. Pulmonary Embolism Ongoing? ିYes ିNo D18. Pneumonia Ongoing? ⊖Yes ⊖No D19. Pulmonary Edema Ongoing? ⊖Yes ⊖No D20. Emphysema Ongoing? ୁ Yes ି No D21. Shortness of Breath Ongoing? ⊖Yes ⊖No D22. Seasonal/Environmental Allergies Ongoing? ି Yes ି No D23. Other If Other, Specify: Ongoing? ⊖Yes ⊖No D24. None

Protocol ID: PERL001		Study Subject ID:
Study Name: PERL Site:		Study Subject DOB:
Event Name: Visit 2 Event Date:		
Section Title: Autoimn Subtitle:	uune/Urinary	
Autoimmune Disease		
Autoimmune Disease	E1. Heshimoto thyroiditis	
Ongoing?	OYes ONo	
	Z. Rheumstaid Arthritis	
Ongoing?	OYes	
	○No	
	E3. Lupus	
Ongoing?	OYes ONo	
	□E4.0ther	
If Other, Specify:		
Ongoing?	OYes	
	0 No	
	CES. None	
Urinary System	E6. Kidney Stones	
Ongoing?	ा भूम े २०	
	E7. Gystös	
Ongoing?	⊖Yes ⊖No	
	E8. Dysuria	
Ongoing?	⊖Yes ⊖No	
	E9. Incontinence	
Ongoing?	0Yes 0No	
	E10. Urethrüs	
Ongoing?	ି Yes ି No	
	E11. UTI	
Ongoing?	OYes ONo	
	□E12.0ther	
If Other, Specify:		
Ongoing?	0 Yes 0 No	
	E13. None	

Protocol ID: PERL001 Study Name: PERL Site: ______ Event Name: Visit 2 Event Date: _____ Study Subject ID:_____ Study Subject DOB:_____ Section Title: Endocrine/Mental Health Subtitle: Endocrine System F1. Adrenal Insufficiency Ongoing? ⊖Yes ⊖No F2. Growth Disorder Ongoing? ⊖Yes ⊖No F3. Hyperthyroidism Ongoing? ି Yes ି No F4. Hypothyroidism Ongoing? ୁ Yes ି No F5. Polycystic Ovary Syndrome ି Yes ି No Ongoing? F6. Other If Other, Specify: ⊖Yes ⊖No Ongoing? □F7. None Mental Health F8. Depression ⊖Yes ⊖No Ongoing? 🗆 F9. Bipolar ୁ Yes ୁ No Ongoing? F10. Anxiety Ongoing? ି Yes ି No 🗆 F11. Schizophrenia Ongoing? ି Yes ି No F12. Obsessive Compulsive Disorder ⊖Yes ⊖No Ongoing? F13. Eating disorder Ongoing? ⊖Yes ⊖No F14. Post-traumatic stress syndrome Ongoing? ⊖Yes ⊖No F15. Other If Other, Specify: Ongoing? ି Yes ି No □F16. None

Protocol ID: PERL001		Study Subject ID:				
Study Name: PERL Site:	-	Study Subject DOB:				
Event Name: Visit 2 Event Date:						
Section Title: Hepatic/Cancer/Eye Subtite:						
Hepatic						
Ongoing?	□G1. Jaundice ○Yes					
	○ No					
Ongoing?	□G2. Cirrhosis ○Yes					
	⊖ No					
Ongoing?	□G3. Fatty Liver Disease ○ Yes					
	⊖ No					
If Other, Specify:	□G4. Other					
Ongoing?	ି Yes ଼ No					
	GS. None					
Cancer	G6. Head/Neck Cancer					
Ongoing?	⊖Yes					
	○ No					
Ongoing?	⊖Yes					
	○ No					
Ongoing?	⊖Yes					
	⊙ No □ G9. Solid Tumor					
Ongoing?	⊖Yes ⊙No					
	G10. Other					
Ongoing?	⊖ Yes ⊖ No					
	G11. None					
Еуе	G12. Conjunctivitis					
Ongoing?	⊖Yes ⊖No					
	G13. Cataract					
Ongoing?	⊖ Yes ○ No					
	G14. Cataract Removal					
Ongoing?	⊖Yes ⊖No					
	GIS. Vitrectomy					
Ongoing?	⊖Yes ⊖No					
	G16. Retinopathy					
Ongoing?	ି Yes No					
	G17. Laser Therapy					
Ongoing?	⊖Yes ⊖No					
Ongoing?	⊡G18. Bindness ⊖Yes					
- 	⊖ No					
Ongoing?	⊡G19. Glaucoma ⊖Yes					
	⊖ No					
Ongoing?	⊡G20. Myopia ⊖Yes					
	⊂ No □G21. Hyperopia					
Ongaing?	⊖Yes					
	○ No					
Ongoing?	्Yes					
	○ No					
If Other, Specify:	an ann Mille					
Ongoing?	⊖Yes ⊜No					
	G24. None					
Date of Last Eye Exam:						
	□Never Examined					

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 2	udy Name: FRL Study Subject DOB:					
Event Date:						
Section Title: Hospitalizati	ions/Allergies/Pregnancies					
Allergies						
H1. Do you have any food, drug or environmental allergies?	○Yes ○ No					
List allergens:						
Pregnancies						
H2. Has participant ever been pregnant?	○Yes ○No ○No					
Number of pregnancies:						
Number of live births:						
Hospitalizations						
H3. Has the participant had any Hospitalizations in the last 5 years requiring overnight stay?						
0	Yes No					

 Petcol IP FER.001
 Study Subject ID._____

 Study Name: FER.
 Study Subject ID._____

 Ster ______
 Study Subject ID._____

 Ster ______
 Study Subject ID._____

 Ster Name: Vol 2
 Study Subject ID._____

Reason:	If Other or non-elective surgery, specify:	Month:	Year:	Length of Stay (days):
C Elective Surgery		 January 		
Cardiovascular		O February		
O Diabetes		O March		
Renal		 April 		
O Accident		O May		
O Non-Elective Surgery		 June 		
O Pulmonary		 July 		
O Psychiatric		 August 		
O Other		O September		
		October		
		 November 		
		O December		

Protocol ID: PERL001 Study Name: PERL		Study Subject ID: Study Subject D08:				
Site:		,				
Event Name: Visit 2 Event Date:						
	PERL_009_ECG Report - V1.0					
Section Title: ECG Rep						
ECG Completed? *	Completed Okto Completed					
Upload Source Document:						
A1. Date of ECG:						
A2. Heart Rate:	(tepm)					
A3. ECG Findings:	O Normal					
A3a. If abnormal (select	al that apply): ST Beation					
	□Atrial Fb					
	T Inversion					
	□Q Wave					
	□ AV Block					
	I MI Changes					
	□ Tachycardia					
	Resycardia					
	Other					
If Other, Specify:						
A3b. Is this abnormality clinica significant?	Ny Orge ** If yes, report on AE Log O No					
Visit 3:						
PERL_008_Local Laborato PERL_010 Central Lab Sp	PERL_006_Blood Pressure and Measurements - V1.0 PERL_006_Local Laboratory Results - V5.0 PERL_010Central Lab Specimen Collection - V4.0 PERL_010Lab Specimen Collection - V5.0					
Investigator Name:	Investigator Signature: Date:					

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 3			Study Subject ID:
Event Date:	_	PERL_006_Blood Pressure and Measurements - V1.0	
Section Title: Blood Pre	ssure and Heart Rate		
Subtitle:			
Measurements:			
A1. Weight:	(kg)	Not Done	
A2. Height:	(cm)	Not Done	
Upload Source Documents	50 50		
Blood Pressure:			
B1. First Reading			
B1a. Systolic:	(mmHg)		
B1b. Diastolic:	(mmHg)	BP Not Done	
B1c. Heart Rate:	(bpm)	HR Not Done	
B2. Second Reading			
B2a. Systolic:	(mmHg)		
B2b. Diastolic:	(mmHg)	BP Not Done	
B2c. Heart Rate:	(bpm)	HR Not Done	
B3. Third Reading			
B3a. Systolic:	(mmHg)		
B3b. Diastolic:	(mmHg)	BP Not Done	
B3c. Heart Rate:	(bpm)	HR Not Done	

Protocol ID: PERL001 Study Name: PERL		Study Subject ID: Study Subject DOB:						
Site: Event Name: Visit 3 Event Date:								
	lood Pressure and Heart Rate							
Subtitle:	uou rressure anu neart Kate							
Calculated Fields: BMI								
BMI:								
Blood Pressure Systolic:	(mode)							
Diastolic: Heart Rate:	(mmHg) (cpm)							
neart kate:	(opm)							

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 3 Event Date:	_				Study Subject ID: Study Subject DOB:	
			PERL_008_Local	Laboratory Results - V5.0		
Section Title: Section A Subtitle:	. Chemistry					
Instructions: Enter the la	b values in the units i	indicated with the date of co	llection for each field. Use the "Not Done" checkbox provided it	data is unobtainable.		
Upload source docume	nts:					
Chemistry:						
A1. Potassium:	(mmol/L)	Date Collected:	□ Not Do	ne		
A2. Creatinine:	(mg/dl)	Date Collected:	Not Do	ne		
A3. ALT (SGPT):	(U/L)	Date Collected:	□ Not Do	ne		

. Potassium:	(mmol/L)	Date Collected:	Not Done
t. Creatinine:	(mg/dl)	Date Collected:	□ Not Done
I. ALT (SGPT):	(U/L)	Date Collected:	□ Not Done

Protocol ID: PERL001 Study Name: PERL Site: ______ Event Name: Visit 3 Event Date: _____ Study Subject ID:_____ Study Subject DOB:_____ Section Title: Section B. CBC Subtitle: Date Collected: B1. Hemoglobin: (gm/dl) □ Not Done B2. Hematocrit: (%) Date Collected: □ Not Done B3. Platelets: (mmol) Date Collected: □ Not Done (million cells/mcL) B4. RBC: Date Collected: Not Done B5. WBC: (cells/mcL) Date Collected: □ Not Done B5a. Neutrophils: (%) Not Done B5b. Lymphocytes: (%) 🗆 Not Done B5c. Monocytes: (%) Not Done B5d. Eosinophils: (%) Not Done (%) B5e. Basophils: Not Done

Protocol ID: PERL001 Study Name: PERL Ste: Event Name: Visit 3 Event Date:			Study Subject ID: Study Subject DOR:
Section Title: Section C. P	regnancy Test		
C1. Urine Pregnancy Test Result:	 Positive Negative Not Done Not Applicable 	Date of test:	
C2. Serum Pregnancy Test Result:	 Positive Negative Not Done Not Applicable 	Date of test:	

Subjer: FBI, Subject DBE Subject DDE Subject DDESubject DDE Subject DDE Subject DDE S	
Event Nume: Val 3 Event Date:	
Event Date:	
Section Title: Section J. Urier Multistix Date Urine Colectat: I Ladeopte: I Ladeopte: I Repate I Trace I Moderite I Mode	
Date Unite Colected: INite Done D1. Leologytes: Oregative Onde: Oregative Onde	
Date Unite Colected: INite Done D1. Leologytes: Oregative Onde: Oregative Onde	
Date Urine Collected: INAX Done D1. Laskaptes: Inter- Carlot Collected:	
D1. Leskoptes: O liegative O Tace O Small O Modorate	
⊂Trace ⊂Small ⊖Nodorate	
Small	
○ Moderate	
○ Large	
D2. Nirites: O Regative	
○ Positive	
D3. Protein: O Negative	
○ Trace ○ 30	
0.100	
330	
2000+	
D4. Blood O Negative	
O Positive	
D4a. Blood – Non Hemolyzed: 🕐 None	
O Trace	
 Moderate 	
DHb. Blood – Hemalyzed: O None	
O Trace	
○ Small	
○ Maderate	
⊂ Large	
D5. Ketones: O Negative	
Da Assules. O regative O Tace	
0 Intec 0 Small	
⊖smal ⊘ Modrate	
⊖ Moorate Clarge	
⊖ Laiye	

Protocal ID: FERL001 Study Hame: FRL	Study Subject ID: Study Subject DOB:
Site:	
Event Name: Visit 3	
Event Date:	
Section Title: Section E. eGFR	
Subtitle:	
E1. Indicate visit for which this eGFR values applies:	
○Visit 1	
○ Vielts 6-15	
E2. Use central lab creatinine value to calculate eGFR Click Here to Calculate eGFR Click Here to Calculate eGFR	
E3. Use local lab creatinine value to calculate eGFR	
Cick Here to Calculate eGFR Local to creation value	
Local tab Creatifier Value	

Not Done

E4. eGFR: (mls/min/1.73m²) Date Collected:

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 3 Event Date:					Study Subject IDC Study Subject DDR:
			PERL_010 Central Lab Specimen Collection - V	/4.0	
Section Title: Section A. Blood Specimens Instructions: Plasse indicate the collected specimens and provide the date of collection.					
A1. Serum Uric Acid, Creatinine, Cystatin C Collected	⊖ Yes ⊖ No	Date Collected			
A2. HbA1c Collected	○ Yes ○ No ○ NA-if visit 6	Date Collected			

A3. Shipped to ARDL O Yes Date Shipped No

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 3 Event Date:	_					Study Subject ID: Study Subject IDO8:
Section Title: Section B	. Urine Specimens					
B1. ACR/AER Collected	○ Yes ○ No ○ NA-#Fvisit 6_8_10_12 or 14					
Overnight	⊖Yes ⊖No	Date Ended Collection				
First Morning	○Yes ○No	Date Collected				
Spot Urine	⊖Yes ⊖No	Date Collected	Additional Date Collected	If necessary	Additional Date Collected	И песезану
B2. Shipped to ARDL	○ Yes ○ No	Date Shipped				

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 3 Event Date:	-		Study Subject DD: Study Subject DD®:
Section Title: Section C.	Biospecimens for Reposit	ory	
	⊙Yes ⊙No		
C1. Serum Collected	⊖ Yes ○ No	Date Collected	
C2. Plasma Collected	○ Yes ○ No	Date Collected	
C3. Urine Collected	⊖ Yes ⊖ No	Date Collected	
C3a. Protease Inhibitor Added	○ Yes ○ No		
C4. Shipped to ARDL	⊖ Yes ○ No	Date Shipped	

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 3 Event Date:				Study Subject ID: Study Subject OD8:	
			PERL_010A_Central Lab Specimen Collection - V5.0		
Section Title: Section A. Blood Specimens Instructions: Please indicate the collected specimers and provide the date of collection.					
A1. Serum for Uric Acid, Creatinine, Cystatin C Collected	⊖Yes ⊖ No	Date Collected			
A3. HLA B*5810 Collected	⊖ Yes ⊖ No	Date Collected			
A4. Shipped to ARDL	⊖Yes ○No	Date Shipped			

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 3 Event Date:	_		Study Subject ID: Study Subject ID08:
Section Title: Section E	3. Urine Specimens		
B1. ACR/AER Collected	ି Yes ୦ No		
Overnight	⊙Yes ⊙No	Date Ended Collection	
First Morning	⊖Yes ⊙No	Date Collected	
Spot Urine	⊙Yes ⊙No	Date Collected	
B2. Shipped to ARDL	⊖ Yes ⊙ No	Date Shipped	
Visit 4:			
PERL_006_Blood Pressure and Measurements - V1.0 PERL_008_Loca Laboratory Results - V5.0 PERL_0108_Certral Lab Specimen Collection - V5.0 PERL_0107_Procedures Form - V3.0 PERL_0107_Projecial Examination - V1.0 PERL_011_Skin Assessment - V3.0 PERL_011_Skin Assessment - V3.0 PERL_011_Skin Assessment - V3.0 PERL_011_Skin Assessment - V3.0 PERL_0101_Central Lab Specimen Collection - V4.0			

Investigator Name: _____ Date: _____ Date: _____

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 4 Event Date:			Study Subject IDR: Study Subject DDR:
Event Date:		PERL_006_Blood Pressure and Measurements - V1.0	
Section Title: Blood Pr	ressure and Heart Rate		
Subtitle:			
Measurements:			
A1. Weight:	(kg)	Not Done	
A2. Height:	(cm)	Not Done	
Upload Source Document	ts:		
Blood Pressure:			
B1. First Reading B1a. Systolic:	(mmHg)		
B1b. Diastolic:	(mmHg)	BP Not Done	
B1c. Heart Rate:	(bpm)	HR Not Done	
B2. Second Reading			
B2a. Systolic:	(mmHg)		
B2b. Diastolic:	(mmHg)	BP Not Done	
B2c. Heart Rate:	(bpm)	HR Not Done	
B3. Third Reading			
B3a. Systolic:	(mmHg)		
B3b. Diastolic:	(mmHg)	BP Not Done	
B3c. Heart Rate:	(bpm)	HR Not Done	

Protocol ID: PERL001		Study Subject ID: Study Subject DDB:
Study Name: PERL Site:		Study Subject DOB:
Event Name: Visit 4		
Event Date:		
Event bute.	-	
	lood Pressure and Heart Rate	
Subtitle:		
Calculated Fields:		
Calculated Fields.		
BMI		
BMI:		
Blood Pressure		
Systolic:	(minila)	
Diastolic:	(mmHg)	
Heart Rate:	(bpm)	

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 4 Event Date:	_				Study Subject ID: Study Subject DOB:	
			PERL_008_Lo	cal Laboratory Results - V5.0		
Section Title: Section A Subtitle:	. Chemistry					
Instructions: Enter the la	b values in the units i	indicated with the date of c	ollection for each field. Use the "Not Done" checkbox provid	ed if data is unobtainable.		
Upload source docume	nts:					
Chemistry:						
A1. Potassium:	(mmol/L)	Date Collected:		at Done		
A2. Creatinine:	(mg/dl)	Date Collected:		at Done		
A3. ALT (SGPT):	(U/L)	Date Collected:		at Done		

. Potassium:	(mmol/L)	Date Collected:	I Not Done
. Creatinine:	(mg/dl)	Date Collected:	□ Not Done
ALT (SGPT):	(U/L)	Date Collected:	□ Not Done

Protocol ID: PERL001 Study Name: PERL Site: ______ Event Name: Visit 4 Event Date: _____ Study Subject ID:_____ Study Subject DOB:_____ Section Title: Section B. CBC Subtitle: Date Collected: B1. Hemoglobin: (gm/dl) □ Not Done B2. Hematocrit: (%) Date Collected: □ Not Done B3. Platelets: (mmol) Date Collected: □ Not Done (million cells/mcL) B4. RBC: Date Collected: Not Done B5. WBC: (cells/mcL) Date Collected: □ Not Done B5a. Neutrophils: (%) 🗆 Not Done B5b. Lymphocytes: (%) 🗆 Not Done B5c. Monocytes: (%) Not Done B5d. Eosinophils: (%) Not Done (%) B5e. Basophils: Not Done

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 4 Event Date:			Study Subject ID: Study Subject DOR:
Section Title: Section C. P	regnancy Test		
C1. Urine Pregnancy Test Result:	 Positive Negative Not Done Not Applicable 	Date of test:	
C2. Serum Pregnancy Test Result:	 Positive Negative Not Done Not Applicable 	Date of test:	

Protocol ID: PERL001			Study Subject ID:
Study Name: PERL			Study Subject DOB:
Site:			
Event Name: Visit 4			
Event Date:	_		
Section Title: Section D.	Urine Multistix		
Date Urine Collected:		Not Done	
Date office concerca.			
D1. Leukocytes:	O Negative		
	O Trace		
	 Small 		
	O Moderate		
	⊖ Large		
	0		
D2. Nitrites:	O Negative		
	O Positive		
D3. Protein:	O Negative		
	⊖ Trace		
	O 30		
	0 100		
	O 300		
	O 2000+		
	0.20001		
D4. Blood	O Negative		
	 Positive 		
D4a. Blood - Non Hemolyzed:	O None		
one. bloba man nemaryaea.	O Trace		
	 Moderate 		
	- Production		
D4b. Blood - Hemolyzed:	None		
	O Trace		
	○ Small		
	○ Moderate		
	O Large		
D6. Ketones:	O Negative		
	O Trace		
	O Small		
	 Moderate 		
	O Large		
	- Luge		

Protocal ID: FERL001 Study Hame: FRL	Study Subject ID: Study Subject DOB:
Site:	
Event Name: Visit 4	
Event Date:	
Section Title: Section E. eGFR	
Subtitle:	
E1. Indicate visit for which this eGFR values applies:	
○Visit 1	
○ Visits 6-15	
E2. Use central lab creatinine value to calculate eGFR Click Here to Calculate eGFR Click Here to Calculate eGFR	
Central Borachine value	
E3. Use local lab creatinine value to calculate eGFR	
Citck Here to Calculate eGFR	
Local lab creatinine value	

Not Done

E4. eGFR: (mis/min/1.73m²) Date Collected:

Protocol ID: PERL001 Study Name: PERL		Study Subject ID: Study Subject DOB:
Site:		study studget to de
Event Name: Visit 4 Event Date:		
		PERL_009_ECG Report - V1.0
		FERL_009_ECG REPORT VI.V
Section Title: ECG Rep	ort	
ECG Completed? *	Completed Not Completed	
Upload Source Document:		
A1. Date of ECG:		
A2. Heart Rate:	(bpm)	
A3. ECG Findings:	 Normal Abromal 	
A3a. If abnormal (select	all that apply):	
Tou. If up to the locate	ST Bevation	
	□Atrial Fib	
	T Inversion	
	□Q Wave	
	AV Block	
	II MI Changes	
	□ Tachycardia	
	🗆 Bradycardia	
	□ Other	
If Other, Specify:		
A3b. Is this abnormality clinica significant?	ly O Yes ** If yes, report on AE Log O No	

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 4				Study Subject ID: Study Subject DOR:
Event Date:			PERL_010A_Central Lab Specimen Collection - V5.0	
Section Title: Section A. Ble Instructions:	ood Specimens			
Please indicate the collected s	pecimens and provide the a	date of collection.		
A1. Serum for Uric Acid, Creatinine, Cystatin C Collected	⊖ Yes ⊖ No	Date Collected		
A3. HLA B*5810 Collected	ः Yes	Date Collected		
	⊖ No			
A4. Shipped to ARDL	⊖ Yes	Date Shipped		
	⊖ No			

Protocol ID: PERL001 Study Name: PERL Site:			Study Subject ID: Study Subject DOB:
Event Name: Visit 4			
Event Date:			
Section Title: Section B	. Urine Specimens		
B1. ACR/AER Collected	⊙ Yes ⊙ No		
Overnight	⊖Yes ○No	Date Ended Collection	
First Morning	⊖Yes ⊖No	Date Collected	
Spot Urine	○Yes ○No	Date Collected	
B2. Shipped to ARDL	○ Yes ○ No	Date Shipped	

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 4				Study Subject ID: Study Subject DOB:	
Event Date:					
		PERL_019_iGFR Procedure	es Form - V3.0		
Section Title: I. iGFR	Procedure				
Upload source docume	nts:				
A1. Was the iGFR Perfo	umod2				
Please Select:)Yes				
	○ No				
If No, Reason: (check all that apply)	πυα				
	□ BP too high				
	Positive pregnancy test				
	Hyperglycemia				
	Hypoglycemia				
	□ Vamiting				
	□ Febrile				
	Other				
If Other, Specify:					

Protocol ID: PERL001 Study Name: PERL Site:						Study Stolpet IDC Study Stolpet DOR
Start clock at end of Omnipaque injection* (No Sample)	"0" time 00:00					
A4. 120 minutes						
Projected draw time for sample:		Actual draw time of sample (24 hour clock):	(00:00)	Glucose value	(mg/dl)	Not Done
A5. 150 minutes						
Projected draw time for sample:		Actual draw time of sample (24 hour clock):	(00:00)	Glucose value	(mg/dl)	□ Not Done
A6. 180 minutes						
Projected draw time for sample:		Actual draw time of sample (24 hour clock):	(00:00)	Glucose value	(mg/dl)	Not Done
A7. 210 minutes						
Projected draw time for sample:		Actual draw time of sample (24 hour clock):	(00:00)	Glucose value	(mg/dl)	□ Not Done
A8. 240 minutes						
Projected draw time for sample:		Actual draw time of sample (24 hour clock):	(00:00)	Glucose value	(mg/dl)	Not Done
A9. Samples shipped to ce	ntral lab?					
Please Select:	○Yes ○No	Date Samples Shipped:				
A10. Backup samples ship	ped to central lab?					
Please Select:	○Yes ○No ○NA	Date Backup Samples Shipped:				

Protocol ID: PERL001	Study Subject ID:
Study Name: PERL	Starty Subject 10: Starty Subject 10:
Site: Event Name: Visit 4	
Event Date:	_
	PERL_007_Physical Examination - V1.0
Section Title: Body Sys	tan
A0. Was a physical exam	performe at this visat?
	ONE CONTRACTOR OF
Upload source documents	5°
A1. Eyes:	
Eyes (including fundoscopy):	O Normal Abnormal
	Over Done
If abnormal, describe find Select all that apply:	dags Definition
Select all that apply:	
	Li Oher
If other, specify:	
A2. Cardiovascular: Cardiovascular:	O Normal
cardonacaa.	Abnormal
	O Not Done
If abnormal, describe find Select all that apply:	lings:
	∏Marnur
If other, specify:	
A3. Extremities: Extremities:	Okrmal
	O Abonal Ohct Done
If abnormal, describe find	
Select all that apply:	IIIgs. ∐Amputation
Amputation, specify:	
	IT Testemes
	_ Edema
Pulses:	00+
	01+
	02+ 03+
	04+
	□0her
If other, specify:	
A4. Lymph Nodes: Lymph Nodes:	Okamat
-,,	O National O Not Done
If abnormal, describe find Select all that apply:	lings: Seetro
	Other
If other, specify:	
A5. Pulmonary:	
Pulmonary:	Normal Abcomal
	O Not Done
If abnormal, describe find	ing:
Select all that apply:	
	□ Oher
If other, specify:	
A6. Skin: Skin:	Okamal
	O Abromal O Not Done
If abnormal, describe find	
Select all that apply:	nngi: Diktor purple pairkaf reak
	USer
	□Ezema
	∏ Ukes
	LExessive Brushing
	□ Oher
If other, specify:	
A7. Gastrointestinal: Gastrointestinal:	○Normal
	Oktoma Oktomat Oktome
If abnormal, describe find Select all that apply:	ling: ∏axies
	Abdominal Mas
	□ Organomegely
	Lucy genergy y
Organomegaly, specify:	
	∐ Stome
	□ Ober
If other, specify:	
A8. Musculoskeletal	Oterest
	Otternal O Abromal
A8. Musculoskeletal	Abromal Not Due

Select all that apply:	□ Stiffees
	□Tendemes
Injury, specify:	
	□ Reduced strength
	CReduced range of motion
	Clober Clober
If other, specify:	
A9. Genitourinary:	
Genitourinary:	○ Normal
	O Abnormal
	Net Done
If abnormal, describe find	ing:
Specify:	
A10. Neurological:	
Neurological:	○ Normal
	OAbnormal
	(Net Done
If abnormal, describe find	ings:
Select all that apply:	
Abnormal reflex response, speci	V. O hooffesia
	CHypothesia
	[]Diminished sensation
	□ Canial Kenes
Abnormal, specify:	
	□ Other
If other, specify:	

Study Subject ID:_____ Study Subject DOB:_____

Protocol ID: PERL001 Study Name: PERL Site: ______ Event Name: Visit 4 Event Date: _____

Section Title: Other Body System

Other Body System
A11. Other Body System: Describe

Protocol ID: PERL001 Study Name: PERL Site: ______ Event Name: Visit 4 Event Date: _____

Study Subject ID: ______ Study Subject DOB: _____

PERL_014_Family History - V1.0

Please complete the o	hart for Mother	ather Materna	Grand	ther and C	randfather and	Daternal Con	ndmother -	nd Grande	ther					
Relative:	Alive/Deceased:		If Other,		Hypertension:		Stroke:		Type I	Obesity:	Hyperlipidemia	: Kidney Disease	End Stage Renal Disease	Othe
) Mother	 Alive 	 Cardiovascular 		No History	 Yes 	O Yes	⊖Yes	O Yes	⊖ Yes	O Yes	ं Yes	0 Yes	() Yes	
Maternal Grandmother	O Deceased	Cancer			⊖ No	O No	○ No	No	No	O No	No	No	O No	
Maternal Grandfather	 Unknown 	 Accident 			 Unknown 	Unknown	 Unknown 							
) Father		O Other												
Paternal Grandmother		 Unknown 												
Paternal Grandfather														
O Mother	O Alive	Cardiovascular		No History	 Yes 	O Yes	୍ୟଟ	ं Yes	ाes	े Yes	ं Yes	⊖ Yes	O Yes	
Maternal Grandmother	C Deceased	Cancer			O No									
Maternal Grandfather	 Unknown 	 Accident 			 Unknown 									
) Father		O Other												
O Paternal Grandmother		 Unknown 												
O Paternal Grandfather														
) Mother	O Alive	Cardiovascular		No History	O Yes	ं Yes	୍ୟର	ं Yes	ाes	ं Yes	े Yes	ा Yes	ं Yes	-
Maternal Grandmother	O Deceased	Cancer			○ No	○ No	○ No	No	No	No	○ No	○ No	No	
Maternal Grandfather	 Unknown 	 Accident 			 Unknown 									
O Father		Other												
Paternal Grandmother		Unknown												
Paternal Grandfather														
O Mother	O Alive	 Cardiovascular 		No History	 Yes 	Yes	୍ୟଟ	ं Yes	୍ୟଟ	े Yes	ं Yes	⊖ Yes	 Yes 	
Maternal Grandmother	O Deceased	Cancer			O No	O No	⊖ No	○ No	No	O No	No	No	O No	
Maternal Grandfather	 Unknown 	 Accident 			 Unknown 									
) Father		Other												
Paternal Grandmother		Unknown												
O Paternal Grandfather														
Mother	0.000	 Cardiovascular 	1	No History	O Yes	O Yes) Yes) Yes	े Yes) Yes	ं Yes	0 Yes	O Yes	
Maternal Grandmother	O Deceased	Cancer			O No	⊖ No	⊖ No	○ No	No	O No	⊖ No	O No	O No	
Maternal Grandfather	 Unknown 	 Accident 			 Unknown 									
O Father		O Other												
Paternal Grandmother		 Unknown 												
Paternal Grandfather														
O Mother		Cardiovascular		No History		O Yes	○Yes	○ Yes		0 Yes	े Yes	○ Yes	O Yes	-
Maternal Grandmother	 Deceased 	 Cancer 			O No	O No	⊖ No	No	No	O No	No	O No	O No	
Maternal Grandfather	 Unknown 	 Accident 			 Unknown 									
Father		Other												
Paternal Grandmother		Unknown												
O Paternal Grandfather														

Protocol ID:	ERLO01	Study Subject ID:	
Study Name		Study Subject DOB:	
Site:			
Event Name	Asit 4		
Event Date:			
Section	tle: Section B. Brothers		
	lete the chart for all full biological brothers.		

Relative:	Alive/Deceased:			No History:	Hypertension:	Heart Attack:				Obesity:	Hyperlipidemia:			Other:
		cause of death:	Specify:						Diabetes:				Renal Disease	
O Brother1	 Alive 	 Cardiovascular 		No History	O Yes	Yes	O Yes	O Yes	O Yes	O Yes	O Yes	O Yes	O Yes	
O Brother2	 Deceased 	Cancer			O No	No	O No	O No	O No	O No	O No	○ No	O No	
O Brother3	Unknown	 Accident 			Unknown	Unknown	O Unknown	 Unknown 	O Unknown	 Unknown 	Unknown	O Unknown	O Unknown	
O Brother4		O Other												
 Brother5 		 Unknown 												
O Brother6														
O Brother7														
O Brother8														
O Brother9														
O Brother10														
O Brother11														
O Brother12														
O Brother13														
OBrother14														
O Brother15														

Protocol ID: FERLIDI	Study Subject ID:
Study Name: PERL	Study Subject DOB:
Site:	
Event Name: Visit 4	
Event Date:	
Section Title: Section C. Sisters	
Please complete the chart for all full biological sisters.	
Relative: Alive/Deceased. If Orber, No History: Hypertension Heart Attack Stroke. Type II Type I Type II Type I Desity. Hyperlipidemia: Kidney Disease: End Stage Other: Cause of desht:Specify: Cause of desht:Specify: Cause Disease	

Relative:	Alive/Deceased:	If Deceased, cause of death:		Hypertension:	Heart Attack:		Type II Diabetes:		Obesity:	Hyperlipidemia:		End Stage Renal Disease	Other:
O Sister1	 Alive 	 Cardiovascular 	No History	O Yes	ି Yes	O Yes	O Yes	⊖ Yes	⊖Yes	O Yes	Yes	 Yes 	
O Sister2	O Deceased	Cancer		O No	No	O No	O No	⊖ No	⊖ No	O No	No	No	
Sister3	 Unknown 	 Accident 		 Unknown 	 Unknown 	 Unknown 	 Unknown 	ି Unknown	 Unknown 	O Unknown	 Unknown 	 Unknown 	
O Sister4		O Other											
Sister5		 Unknown 											
Sister6													
O Sister7													
O Sister8													
 Sister9 													
O Sister10													
O Sister11													
O Sister12													
O Sister13													
O Sister14													
 Sister15 													

Study Subject ID: _____ Study Subject DOB: _____

Protocol ID: PERL001 Study Name: PERL Site: ______ Event Name: Visit 4 Event Date: _____

Section Title: Section D. Children

 Please complete the chart for all full biological children.
 Participation
 Non Non

Protocol ID: PERL001 Study Name: PERL					Study Subject ID: Study Subject ID:
Site: Event Name: Visit 4					
Event Date:	_		PERL	011_Skin Assessment - V3.0	
Section Title: Skin Asse	ssment				
Indicate who performed the Select: *	○ Participant Self-Assessment				
Was any rash present of	Clinician Assessment				
*	OYes ONo				
A1. Has the participant	Not Assessed	ens-Johnson Syndrome (SJS	s) symptoms?		
Select:	○Yes ○No ○Not Assessed				
Select all that apply:	O Not Assessed				
Fever	□ Fever				
Duration:	(days)				
Maximum temperature:	Celsius or Faren	nheit: O °C O °F		Unknown temperature	
Skin tenderness	Skin tenderness				
Sore throat	□ Sore throat				
Photophobia	□ Photophobia				
Burning eyes	Photophobia				
Itching eyes	Burning eyes				
	□ Itching eyes				
	ick and purulent sputum				
Headache	Headache				
Malaise	□ Malaise				
Arthralgia	□ Arthralgia				
A2. During assessment Select:	, was any swelling or rash noted?				
Socu.	No Not Assessed				
Select all that apply:					
Burning rash	□Burning rash				
Skin pain	□Skin pain				
Facial swelling	Facial swelling				
Tongue swelling	□ Tongue swelling				
Red or purple skin rash	1				
Area of rash (select all	Red or purple skin rash that apply):				
	□ Face	Chest		Abdomen	
	□Arms	🗆 Legs		Palms	
Target lesions surroun	Soles	□ Back			
Hives	Target lesions				
	Hives				
Area of hives (select al	<i>that apply):</i>	Chest		Abdomen	
	Arms	🗆 Legs		Paims	
	□ Soles	🗆 Back			
Blisters	Bisters				
Area of blisters (select	all that apply):	🗆 Chest		Abdomen	
	Arms	🗆 Legs		Paims	
	□ Soles	Genitals		Anal	
	Back				
Shedding	Shedding (sloughing) of skin				
Area of shedding (sele	ct all that apply):	□ Chest		Abdomen	
	Arms	□ Legs		Pains	
	□ Soles	Back			
Denuded skin areas	Denuded skin areas				
Area of denudation (se					
	Face Arms	Chest		Abdomen Palms	
	□ Arms	Back			

A3. During assessment was any mucous membrane involvement noted?

Select:	Yes		
	No Not Assessed		
	Chier Addata		
Select all that apply:			
Oral mucosa			
	Oral mucosa		
Oral mucosa (select a	ll that apply):		
	□Erythema	Edema	Skughing
	Blistering	Ulceration/erosion	Necrosia/aust
Nasal mucosa			
	Nasal mucosa		
Nasal mucosa (select	all that apply):		
	□Erythema	Edema	
	Blistering	Ulceration/erosion	□ Necrois/aust
Eyes			
	Eyes		
Eyes (select all that a	oply):		
	□ Excessive tearing	Hyperemia	
	□Scarring		
Urinary tract			
	Urinary tract		
Urinary Tract (select a	all that apply):		
	□ Dysuria	Urinary retention	
Pulmonary			
	Pulmonary		
Pulmonary (select all	that apply):		
	Dyspnea	Productive cough	Pumorary edema

Protocol ID: PERL001	Study Subject ID:
Study Name: PERL	Study Subject DOB:
Ste:	
Event Name: Visit 4	
Event Date:	
PERL_003_Medical History - V2.0	
Section Title: Diabetes/GI	
Subtitle	

Subtitle:	
Instructions:	
Complete each section	AH.
Check all conditions the If a condition is marked	A-H. It the participant has had in the past five years. I present, indicate if it is ongoing at the time of consent.
A1. Year of Type I Diabetes Diagnosis: *	(111)
Gastrointestinal Proble	me
	TA2. 680
Ongoing?	이전: 'No
	A3. Hemorhods
Ongoing?	©Yes ©No
Ongoing?	O Yes O No
	A5. Celuc Deese
Ongoing?	0Yes
	CNo
	□A5. Golds
Ongoing?	O'Ya
	© No
	IA7. Calon Polypes
Ongoing?	0Yes
	© No
Ongoing?	°Yes ♡No
	A3. Gohns Disease
Ongoing?	○Yes ○No
	TA12. Darhes
Ongoing?	C Yes O No
	A11. Diverticultis
Ongoing?	O'Yes
	□A12. Ukes
Ongoing?	O'Yes
	□A13. Dysphagie
Ongoing?	O'Yes
	□A44. Galitone
Ongoing?	O'Yes
	IA15. Gatrointestind Bleeding
Omenine?	
Ongoing?	©™s ○№
Ongoing?	O Yes
ongung:	Che
	JA77. IBS
Ongoing?	
	CY4 CNo
	□All Pepte Uors
Ongoing?	O'Yes
	Che
	ARS. Other
If Other, Specify:	
If Other, Specify: Ongoing?	CYes
ungulig:	○Yes ○No
	□A20. None

Protocol ID: PERL001 Study Name: PERL Site: ______ Event Name: Visit 4 Event Date: _____ Study Subject ID:_____ Study Subject DOB:_____ Section Title: Brain/Nervous System Subtitle: Brain & Nervous System Ongoing? ⊖Yes ⊖No B2. Tremors Ongoing? ⊖Yes ⊖No B3. Bells Palsy ⊖Yes ⊖No Ongoing? □B4. Embolism Ongoing? ିYes ିNo B5. Stroke ି Yes ି No Ongoing? 🗆 B6. Dementia ⊖Yes ⊖No Ongoing? B7. Epilepsy Ongoing? ି Yes ି No B8. Guilain-Barre Syndrome Ongoing? ି Yes ି No B9. Migraines Ongoing? ⊖Yes ⊖No 🗆 B10. Meningitis Ongoing? ⊖Yes ⊖No B11. Neuropathy Ongoing? ୁ Yes ି No 🗆 B12. TIA ⊖Yes ⊖No Ongoing? B13. Other If Other, Specify: Ongoing? ⊖Yes ⊖No B14. None

Protocol ID: PERL001 Study Name: PERL Site: ______ Event Name: Visit 4 Event Date: _____ Study Subject ID:_____ Study Subject DOB:_____ Section Title: Skin/Musculoskeletal Subtitle: Skin □C1. Rash ⊖Yes ⊖No Ongoing? C2. Skin Cancer Ongoing? ⊖Yes ⊖No C3. Psoriasis ⊖Yes ⊖No Ongoing? □C4. Rosacea Ongoing? ୁ Yes ି No C5. Eczema ି Yes ି No Ongoing? C6. Ulcers Ongoing? ⊖Yes ⊖No C7. Hives Ongoing? ି Yes ି No C8. Celluitis Ongoing? ି Yes ି No C9. Other If Other, Specify: ି Yes ି No Ongoing? C10. None Musculoskeletal/Joints Ongoing? ି Yes ି No C12. Back Pain ⊖Yes ⊖No Ongoing? C13. Carpal Tunnel Syndrome Ongoing? ⊖Yes ⊖No C14. Fibromyalgia Ongoing? ିYes ିNo C15. Joint Pain or Swelling Ongoing? ⊖Yes ⊖No C16. Arthritis Ongoing? ⊖Yes ⊖No C17. Gout Ongoing? ିYes ିNo C18. Osteoarthritis Ongoing? ⊖Yes ⊖No C19. Other If Other, Specify: Ongoing? ⊖Yes ⊖No □C20. None

Protocol ID: PERL001 Study Name: PERL Site: ______ Event Name: Visit 4 Event Date: _____ Study Subject ID:_____ Study Subject DOB:_____ Section Title: Cardiovascular/Pulmonary Subtitle: Cardiovascular System Ongoing? ⊖Yes ⊖No D2. Percutaneous coronary intervention Ongoing? ⊖Yes ⊖No D3. Peripheral artery disease Ongoing? ⊖Yes ⊖No D4. Congestive heart failure Ongoing? ୁ Yes ି No D5. Arrhythmia Ongoing? ି Yes ି No 🗆 D6. MI Ongoing? ⊖Yes ⊖No D7. Congenital heart failure Ongoing? ି Yes ି No DB. Cardiomyopathy Ongoing? ୁ Yes ୁ No D9. Vascular Disease Ongoing? ⊖Yes ⊖No 🗆 D10. Angina Ongoing? ⊖Yes ⊖No D11. Hypertension Ongoing? ୁ Yes ୁ No D12. Hypotension Ongoing? ⊖Yes ⊖No D13. Other If Other, Specify: Ongoing? ⊖Yes ⊖No D14. None Pulmonary System D15. COPD Ongoing? ⊖Yes ⊖No D16. Asthma Ongoing? ⊖Yes ⊖No D17. Pulmonary Embolism Ongoing? ିYes ିNo D18. Pneumonia Ongoing? ⊖Yes ⊖No D19. Pulmonary Edema Ongoing? ⊖Yes ⊖No D20. Emphysema Ongoing? ୁ Yes ି No D21. Shortness of Breath Ongoing? ⊖Yes ⊖No D22. Seasonal/Environmental Allergies Ongoing? ି Yes ି No D23. Other If Other, Specify: Ongoing? ⊖Yes ⊖No D24. None

Protocol ID: PERL001		Study Subject ID:
Study Name: PERL Site:		Study Subject DDB:
Event Name: Visit 4 Event Date:		
Section Title: Autoimm Subtitle:	nune/Urinary	
Autoimmune Disease		
Autominune Disease	E1. Hashimoto thyroidits	
Ongoing?	O Yes O No	
	E2. Rheumstoid Arthritis	
Ongoing?	0 Yes 0 No	
	CE3. Lupus	
Ongoing?	⊖Yes ⊖No	
	E4. Other	
If Other, Specify:		
Ongoing?	OYes ONo	
	ES. None	
Urinary System	[E6. Kidney Stones	
Ongoing?	○Yes ○No	
	□E7. Cystils	
Ongoing?	OYes ONo	
	E8. Dysuria	
Ongoing?	O'Yes O'No	
	E9. Incontinence	
Ongoing?	OYes ONo	
	E10. Urethvitis	
Ongoing?	ः Ves ेNo	
	E11. UTI	
Ongoing?	0Yes 0No	
	E12. Other	
If Other, Specify:		
Ongoing?	⊖Yes ⊖No	
	E13. Kone	

Protocol ID: PERL001 Study Name: PERL Site: ______ Event Name: Visit 4 Event Date: _____ Study Subject ID:_____ Study Subject DOB:_____ Section Title: Endocrine/Mental Health Subtitle: Endocrine System F1. Adrenal Insufficiency Ongoing? ⊖Yes ⊖No F2. Growth Disorder Ongoing? ⊖Yes ⊖No F3. Hyperthyroidism Ongoing? ି Yes ି No F4. Hypothyroidism Ongoing? ୁ Yes ି No F5. Polycystic Ovary Syndrome ି Yes ି No Ongoing? F6. Other If Other, Specify: ⊖Yes ⊖No Ongoing? □F7. None Mental Health F8. Depression ⊖Yes ⊖No Ongoing? 🗆 F9. Bipolar ୁ Yes ୁ No Ongoing? F10. Anxiety Ongoing? ି Yes ି No 🗆 F11. Schizophrenia Ongoing? ି Yes ି No F12. Obsessive Compulsive Disorder ⊖Yes ⊖No Ongoing? F13. Eating disorder Ongoing? ⊖Yes ⊖No F14. Post-traumatic stress syndrome Ongoing? ⊖Yes ⊖No F15. Other If Other, Specify: Ongoing? ି Yes ି No □F16. None

Protocol ID: PERL001 Study Name: PERL Site: ______ Event Name: Visit 4 Event Date: _____ Study Subject ID:_____ Study Subject DOB:_____ Section Title: Hepatic/Cancer/Eye Subtitle: Hepatic G1. Jaundice Ongoing? ⊖Yes ⊖No □G2. Cirrhosis Ongoing? ⊖Yes ⊖No G3. Fatty Liver Disease Ongoing? ି Yes ି No □G4. Other If Other, Specify: Ongoing? ⊖Yes ⊖No G5. None Cancer G6. Head/Neck Cancer Ongoing? ୁ Yes ୦ No G7. Renal/Urinary Tract Cancer Ongoing? ⊖Yes ⊖No G8. Leukemia/Lymphoma ⊖Yes ⊖No Ongoing? G9. Solid Tumor ୁ Yes ୁ No Ongoing? G10. Other ି Yes ୦ No Ongoing? G11. None Eye □G12. Conjunctivitis Ongoing? ି Yes ି No G13. Cataract Ongoing? ି Yes ି No □G14. Cataract Removal Ongoing? ⊖Yes ⊖No G15. Vitrectomy Ongoing? ⊖Yes ⊖No G16. Retinopathy Ongoing? ି Yes ି No G17. Laser Therapy Ongoing? ି Yes ୦ No □G18. Blindness Ongoing? ⊖Yes ⊖No G19. Glaucoma Ongoing? ିYes ⊖No 🗆 G20. Myopia ⊖Yes ⊖No Ongoing? 🗆 G21. Hyperopia Ongoing? ⊖Yes ⊖No G22. Macular Degeneration Ongoing? ି Yes ି No G23. Other If Other, Specify: Ongoing? ⊖Yes ⊖No G24. None Date of Last Eye Exam: □ Never Examined Eye Exam Date Unknown

Protocol ID: PERL001		Study Subject ID:
Study Name: PERL		Study Subject ID:
Site:		Study Studjett Dots
Event Name: Visit 4		
Event Date:		
Event Date.		
Section Title: Hospitalizat	ions/Allergies/Pregnancies	
Allergies		
H1. Do you have any food, drug or environmental allergies?	0 Yes	
	○ Unknown	
List allergens:		
List and gens.		
Pregnancies		
H2. Has participant ever been pregnant?	○ Yes	
pregnant?	○ No	
	○ NA	
Number of pregnancies:		
Number of live births:		
Number of live birtis.		
Hospitalizations		
	ad any Hospitalizations in the last 5 years requiring overnight stay?	
	No	

 Petcol II: PERL 001
 Study Subject ID:_____

 Study Name: PERL
 Study Subject ID:_____

 Ster

 Ster

 Event Name: Vol 4

 Event Name: Vol 4

Reason:	If Other or non-elective surgery, specify:	Month:	Year:	Length of Stay (days):
C Elective Surgery		 January 		
Cardiovascular		O February		
 Diabetes 		O March		
Renal		 April 		
O Accident		O May		
O Non-Elective Surgery		 June 		
O Pulmonary		 July 		
O Psychiatric		O August		
O Other		O September		
		October		
		 November 		
		O December		

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 4 Event Date:				Study Subject IDc Study Subject DOB:
		PERL_010 Central Lab Specimen Collect	tion - V4.0	
Section Title: Section A. B	lood Specimens			
Instructions: Please indicate the collect	ted specimens and prov	de the date of collection.		
A1. Serum Uric Acid, Creatinine, Cystatin C Collected	⊖ Yes ⊖ No	Date Collected		
A2. HbA1c Collected	○Yes ○No ○NA-if visit 6	Date Calected		
A3. Shipped to ARDL	ି Yes ି No	Date Shipped		

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 4 Event Date:	_					Study Subject ID: Study Subject DOB:
Section Title: Section B	. Urine Specimens					
B1. ACR/AER Collected	○ Yes ○ No ○ NA-if visit 6_8_10_12 or 14					
Overnight	⊖Yes ⊖No	Date Ended Collection				
First Morning	⊖Yes ⊙No	Date Collected				
Spot Urine	⊖Yes ⊖No	Date Collected	Additional Date Collected	If necessary	Additional Date Collected	II necessary
B2. Shipped to ARDL	○ Yes ○ No	Date Shipped				

Protocol ID: PERL001 Study Name: PERL Site: ______ Event Name: Visit 4 Event Date: _____ Study Subject ID:_____ Study Subject DOB:_____ Section Title: Section C. Biospecimens for Repository Is this Visit 4, 11, 16 or 17 OYes No ି Yes ି No C1. Serum Collected Date Collected C2. Plasma Collected O Yes O No Date Collected ⊖ Yes ⊖ No C3. Urine Collected Date Collected C3a. Protease Inhibitor Added O Yes O No ⊖ Yes ⊖ No Date Shipped C4. Shipped to ARDL Visit 4a: PERL_006_Blood Pressure and Measurements - V1.0 PERL_007_Physical Examination - V1.0 PERL_008_Local Laboratory Results - V5.0 PERL_009_ECG Report- V1.0 PERL_0102_ECG Report- V1.0 PERL_0102_ECG Report- V1.0 PERL_010_ECG Report- V1.0 PERL_010_EGG Reported Resonance Collection - V4.0 PERL_014_Family History - V1.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 4a	-		Study Subject ID: Study Subject DOB:
Event Date:			PERL_006_Blood Pressure and Measurements - V1.0
Section Title: Blood	Pressure and Heart Rate		
Subtitle:			
Measurements:			
A1. Weight:	(kg)	Not Done	
A2. Height:	(cm)	Not Done	
Upload Source Doc	uments:		
Blood Pressure:			
B1. First Reading			
B1a. Systolic:	(mmHg)		
B1b. Diastolic:	(mmHg)	BP Not Done	
B1c. Heart Rate:	(bpm)	HR Not Done	
B2. Second Reading	g		
B2a. Systolic:	(mmHg)		
B2b. Diastolic:	(mmHg)	BP Not Done	
B2c. Heart Rate:	(bpm)	HR Not Done	
B3. Third Reading			
B3a. Systolic:	(mmHg)		
B3b. Diastolic:	(mmHg)	BP Not Done	
B3c. Heart Rate:	(bpm)	HR Not Done	

Protocol ID: PERL001 Study Name: PERL		Study Subject ID: Study Subject DOB:
Site: Event Name: Visit 4a		
Event Date:	-	
C	ood Pressure and Heart Rate	
Subtitle:	ood Pressure and Heart Rate	
Calculated Fields:		
вмі		
BMI:		
Blood Pressure		
Systolic:	(mmHg)	
Diastolic:	(mmHg)	
Heart Rate:	(čpm)	

Protocol ID: PERL001		Study Subject ID:
Study Name: PERL Site:		Study Subject DOB:
Event Name: Visit 4a Event Date:		
	PERL_007_Physical Examination -	/1 0
Section Title: Body Sys		
A0. Was a physical exa	xxam performed at this visit? O'res ONo	
Upload source docume	nems:	
A1. Eyes: Eyes (including fundoscopy):	() Nermal	
	⊖ Abnormal ○ Not Done	
If abnormal, describe	ve findings:	
Select all that apply:	C Retinopathy	
	☐ Macular Degeneration	
	∐ Other	
If other, specify:		
A2. Cardiovascular: Cardiovascular:	Olormal Abnormal	
	Not Done	
If abnormal, describe Select all that apply:	e findings: 	
	□ Marnur	
	U Mumor	
If other, specify:		
A3. Extremities:		
Extremities:	O Normal	
	O Not Done	
If abnormal, describe Select all that apply:	Amputation	
Amputation, specify:		
	Tendemess	
	- Puloes	
Pulses:	00+ 01+	
	02+	
	03+ 04+	
	Other	
If other, specify:		
A4. Lymph Nodes: Lymph Nodes:	⊖ Normal	
	Abnormal Not Done	
If abnormal, describe	ve findings:	
Select all that apply:	□Sweling	
	□ Other	
If other, specify: A5. Pulmonary:		
Pulmonary:	Normal Aknormal	
	O Not Done	
If abnormal, describe Select all that apply:	e findings: Reduced breath sounds	
	- Other	
If other, specify:		
A6. Skin:		
Skin:	○Normal ○Abromal ○Net.Done	
T - b - c - c - b - c -		
If abnormal, describe Select all that apply:	le rindings: ☐Red or purple painful rash	
	□ Scar	
	□Eczema	
	□ Psoriasis	
	□Ucers	
	Excessive Bruising	
	□ Other	
If other, specify:		
A7. Gastrointestinal: Gastrointestinal:	O Normal	
	O Abnormal ⊖Not Done	
If abnormal, describe	e findings:	
Select all that apply:	Asches	
	Abdominal Mass	
	□ Organomegaly	
Organomegaly, specify:	∐ Stoma	
If other enables	□ Other	
If other, specify: A8. Musculoskeletal		
Musculoskeletal:	Abnormal	
	○ Not Done	
If abnormal, describe	e findings:	

Select all that apply:	□Sifres
	□Tendanes
	⊡Injary
Injury, specify:	
	Reduced strength
	□Reduced range of motion
	□ Oher
If other, specify:	
A9. Genitourinary:	
Genitourinary:	ONemal
	Abnormal
	o Net Done
If abnormal, describe	findings:
Specify:	
A10. Neurological:	
Neurological:	Normal
	○ Abnormal
	O Net Done
If abnormal, describe	findings:
Select all that apply:	□ Abromal Refex Reporce
Abnormal reflex response, speci	fr: O Hyperfields
	Ohypothesis
	Diminished sension
Abnormal, specify:	
	□Ober
If other, specify:	

Study Subject ID:_____ Study Subject DOB:_____

Protocol ID: PERL001 Study Name: PERL Site: ______ Event Name: Visit 4a Event Date: _____

Section Title: Other Body System

Other Body System A11. Other Body System: Describe

Protocol ID: PERL001 Study Name: PERL Ste: Event Name: Visit 4a Event Date:	-				Study Subject ID: Study Subject ID@:	
				PERL_008_Local Laboratory Result	sults - V5.0	
Section Title: Section A. Subtitle:	Chemistry					
	ab values in the units in	dicated with the date of	collection for each field. Use the "Not Do	one" checkbox provided if data is unobtainab	inable.	
Upload source documen	Upload source documents:					
Chemistry:						
A1. Potassium:	(mmol/L)	Date Collected:		□ Not Done		

A1. Potassium:	(mmol/L)	Date Collected:	□ Not Done
A2. Creatinine:	(mg/dl)	Date Collected:	□ Not Done
A3. ALT (SGPT):	(U/L)	Date Collected:	□ Not Done

Protocol ID: PERL001 Study Name: PERL Site: ______ Event Name: Visit 4a Event Date: _____ Study Subject ID:_____ Study Subject DOB:_____ Section Title: Section B. CBC Subtitle: B1. Hemoglobin: Date Collected: (gm/dl) □ Not Done B2. Hematocrit: (%) Date Collected: □ Not Done B3. Platelets: (mmol) Date Collected: □ Not Done (million cells/mcL) B4. RBC: Date Collected: Not Done B5. WBC: (cells/mcL) Date Collected: □ Not Done B5a. Neutrophils: (%) Not Done B5b. Lymphocytes: (%) Not Done B5c. Monocytes: (%) Not Done B5d. Eosinophils: (%) Not Done (%) B5e. Basophils: Not Done

Protocol ID: PERL001 Study Name: PERL Ste: Event Name: Visit 4a Event Date:			Study Subject ID: Study Subject DOR:
Section Title: Section C. P	regnancy Test		
C1. Urine Pregnancy Test Result:	 Positive Negative Not Done Not Applicable 	Date of test:	
C2. Serum Pregnancy Test Result:	 Positive Negative Not Done Not Applicable 	Date of test:	

Protocol ID: PERL001			Study Subject ID:
Study Name: PERL			Study Subject DOB:
äte:			
Event Name: Visit 4a			
Event Date:	_		
Section Title: Section D.	Urino Multictiv		
Section The. Section D.	onne Huitibux		
Date Urine Collected:		Not Done	
D1. Leukocytes:	O Negative		
	O Trace		
	○ Small		
	O Moderate		
	Large		
D2. Nitrites:	O Negative		
	O Positive		
3. Protein:	 Negative 		
	 Trace 		
	O 30		
	100		
	300		
	O 2000+		
D4. Blood	O Negative		
	 Positive 		
	0.000		
Ma. Blood – Non Hemolyzed:	O None		
	 Trace 		
	O Moderate		
4b. Blood – Hemolyzed:	None		
	 Trace 		
	Small		
	O Moderate		
	 Large 		
6. Ketones:	○ Negative		
	○ Trace		
	O Small		
	 Moderate 		
	⊖ Large		

Protocol ID: PERL001	Study Subject ID:
Study Name: PERL	Study Subject DOB:
Site:	
Event Name: Visit 4a	
Event Date:	
Section Title: Section E. eGFR	
Subtitle:	
E1. Indicate visit for which this eGFR values applies:	
⊖Vis≹ 1	
○ Visits 6-15	
E2. Use central lab creatinine value to calculate eGFR	
Click Here to Calculate eGFR	
Central lab creatinine value	
72 Understatisk service and a second state of 72	
E3. Use local lab creatinine value to calculate eGFR <u>Click Here to Calculate eGFR</u>	
Local to reating value	
E4. eGFR: (mls/min/1.73m ²) Date Collected:	Not Done

(mls/min/1.73m²) Date Collected: E4. eGFR:

Protocol ID: PERL001 Study Name: PERL Site:		Study Subject ID: Study Subject DOR					
Event Name: Visit 4a Event Date:							
	PERL_	09_ECG Report - V1.0					
Section Title: ECG Re	Section Title: ECG Report						
ECG Completed? *	Completed Net Completed						
Upload Source Document:							
A1. Date of ECG:							
A2. Heart Rate:	(bpm)						
A3. ECG Findings:	O Normal						
A3a. If abnormal (se							
ASa. II abnormai (se	ST Bevation						
	□Atrial Fib						
	T Inversion						
	□ Q Wave						
	□ AV Block						
	IMI Granges						
	□ Tachycardia						
	□ Bradycardia						
	□ Other						
If Other, Specify:							
A3b. Is this abnormality clinic significant?	ally Oves ** If yes, report on AE Log ONo						

Protocol ID: PERL001 Study Name: PERL Ste: Event Name: Visit 4a Event Date:				Study Subject ID: Study Subject DOR
			PERL_010A_Central Lab Specimen Collection - V5.0	
Section Title: Section A. Bl Instructions: Please indicate the collect		ide the date of collection.		
A1. Serum for Uric Acid, Creatinine, Cystatin C Collected	⊖ Yes ⊖ No	Date Collected		
A3. HLA B*5810 Collected	⊖ Yes ⊖ No	Date Collected		
A4. Shipped to ARDL	⊖ Yes ⊙ No	Date Shipped		

Protocol ID: PERL001 Study Name: PERL			Study Subject ID: Study Subject DOB:
Site:			
Event Name: Visit 4a			
Event Date:			
Section Title: Section B	. Urine Specimens		
B1. ACR/AER Collected	ं Yes		
	No		
Overnight	⊖Yes	Date Ended Collection	
	○ No		
First Morning	⊖Yes	Date Collected	
	⊖ No		
Spot Urine	ा Yes	Date Collected	
Spaconne	⊙No	our conclud	
	0.12		
B2. Shipped to ARDL	ा Yes	Date Shipped	
	No		

Other

If Other, Specify:

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 4a			Study Subject ID: Study Subject DOB:	
Event Date:				
		PERL_019_iGFR Procedures Form - V3.0		
Section Title: I. iGFR	Procedure			
Upload source docum	ients:			
A1. Was the iGFR Per Please Select:	OYes			
	O No			
If No, Reason: (check all that apply)	□υπ			
	BP too high			
	Positive pregnancy test			
	Hyperglycemia			
	□Hypoglycemia			
	□ Vamiting			
	□ Febrile			

Protocol ID: PERL001						Study Subject ID:
Study Name: PERL						Study Subject DOB:
Site:						
Event Name: Visit 4a						
Event Date:						
Section Title: II. iGFR	Draw Times					
A2. Date of iGFR:						
Date of iGFR:						
A3. iGFR Collections:						
Start clock at end of Omnipaque injection* (No Sample)	"0" time 00:00					
A4. 120 minutes						
Projected draw time for sample		Actual draw time of sample (24 hour clock):	(00:00)	Glucose value	(mg/dl)	Not Done
A5. 150 minutes						
Projected draw time for sample		Actual draw time of sample (24 hour clock):	(00:00)	Glucose value	(mg/dl)	Not Dane
A6. 180 minutes						
Projected draw time for sample		Actual draw time of sample (24 hour clock):	(00:00)	Glucose value	(mg/dl)	Not Dane
A7. 210 minutes						
Projected draw time for sample		Actual draw time of sample (24 hour clock):	(00:00)	Glucose value	(mg/dl)	Not Done
A8. 240 minutes						
Projected draw time for sample		Actual draw time of sample (24 hour clock):	(00:00)	Glucose value	(mg/dl)	Not Done
A9. Samples shipped t	o central lab?					
Please Select:	⊖Yes	Date Samples Shipped:				
	○ No					
A10. Backup samples	shipped to central lab?					
Please Select:	⊖Yes	Date Backup Samples Shipped:				
	O No					
	ONA					

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 4a Event Date:				Study Subject DDR			
			PERL_010 Central Lab Specimen Collection - V4.0				
Section Title: Section A. B	lood Specimens						
Instructions: Please indicate the collect	Instructions: Please indicate the collected specimens and provide the date of collection.						
A1. Serum Uric Acid, Creatinine, Cystatin C Collected	⊖ Yes ⊖ No	Date Collected					
A2. HbA1c Collected	े Yes	Date Collected					

A2. IPAJC Caleted Ures ONIO NA-If visit 6 A3. Shipped to AROL Yes Date Shipped No

Protocol ID: PERL001						Study Subject ID:
Study Name: PERL						Study Subject DOB:
Site:						
Event Name: Visit 4a						
Event Date:						
Section Title: Section B	. Urine Specimens					
B1. ACR/AER Collected	ः Yes					
	O No					
	O NA-if visit 6_8_10_12 or 14					
Overnight	ारङ	Date Ended Collection				
	○ No					
First Morning	⊖Yes	Date Collected				
	○ No					
Spot Urine	⊖Yes	Date Collected	Additional Date Collected	If necessary	Additional Date Collected	If necessary
Sportonic	O No	Duc concecto	Additional Date collected	11 The GLADANY	Addona bate concerta	ar raunadan y
	OND					
B2. Shipped to ARDL	O Yes	Date Shipped				
	No					

Protocol ID: PERL001 Study Name: PERL				Study Subject ID: Study Subject DOB:
Site: Event Name: Visit 4a				
Event Date:				
Section Title: Section C	. Biospecimens	for Repository		
Is this Visit 4, 11, 16 or 17	⊙Yes ⊙No			
C1. Serum Collected	ି Yes ି No	Date Collected		
C2. Plasma Collected	ି Yes ୁ No	Date Collected		
C3. Urine Collected	⊖ Yes ⊖ No	Date Collected		
C3a. Protease Inhibitor Added	○ Yes ○ No			
C4. Shipped to ARDL	⊖ Yes ⊖ No	Date Shipped		

Protocol ID: PERL001 Study Name: PERL Site: ______ Event Name: Visit 4a Event Date: _____

Study Subject ID:_____ Study Subject DOB:_____

PERL_014_Family History - V1.0

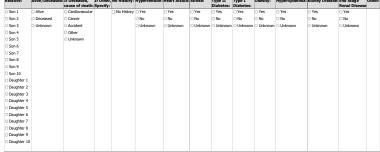
Please complete the o	hart for Mother	ather Materna	Grand	ther and C	randfather and	Daternal Con	ndmother -	nd Grande	ther					
Relative:	Alive/Deceased:		If Other,		Hypertension:		Stroke:		Type I	Obesity:	Hyperlipidemia	: Kidney Disease	End Stage Renal Disease	Othe
) Mother	 Alive 	 Cardiovascular 	1	No History	 Yes 	O Yes	⊖Yes	O Yes	⊖ Yes	O Yes	ं Yes	0 Yes	() Yes	
Maternal Grandmother	O Deceased	Cancer			⊖ No	O No	○ No	No	No	O No	No	No	O No	
Maternal Grandfather	 Unknown 	 Accident 			 Unknown 	Unknown	 Unknown 							
) Father		O Other												
Paternal Grandmother		 Unknown 												
Paternal Grandfather														
O Mother	O Alive	Cardiovascular		No History	 Yes 	O Yes	୍ୟଟ	ं Yes	ाes	े Yes	ं Yes	⊖ Yes	O Yes	
Maternal Grandmother	C Deceased	Cancer			O No									
Maternal Grandfather	 Unknown 	 Accident 			 Unknown 									
) Father		Other												
O Paternal Grandmother		Unknown												
O Paternal Grandfather														
) Mother	O Alive	Cardiovascular		No History	O Yes	ं Yes	୍ୟର	ं Yes	ाes	ं Yes	े Yes	ा Yes	ं Yes	-
Maternal Grandmother	O Deceased	Cancer			○ No	○ No	○ No	○ No	No	No	○ No	No	No	
Maternal Grandfather	 Unknown 	 Accident 			 Unknown 									
O Father		Other												
Paternal Grandmother		Unknown												
Paternal Grandfather														
O Mother	O Alive	 Cardiovascular 		No History	 Yes 	Yes	୍ୟଟ	ं Yes	୍ୟଟ	े Yes	ं Yes	⊖ Yes	O Yes	
Maternal Grandmother	O Deceased	Cancer			O No	O No	⊖ No	○ No	No	O No	No	No	O No	
Maternal Grandfather	 Unknown 	 Accident 			 Unknown 									
) Father		Other												
Paternal Grandmother		Unknown												
O Paternal Grandfather														
Mother	0.000	 Cardiovascular 	1	No History	O Yes	O Yes) Yes) Yes	े Yes) Yes	ं Yes	0 Yes	O Yes	
Maternal Grandmother	 Deceased 	Cancer			O No	⊖ No	⊖ No	No	No	O No	⊖ No	O No	O No	
Maternal Grandfather	 Unknown 	 Accident 			 Unknown 									
O Father		O Other												
Paternal Grandmother		 Unknown 												
Paternal Grandfather														
O Mother		Cardiovascular		No History		O Yes	○Yes	○ Yes		0 Yes	े Yes	○ Yes	O Yes	-
Maternal Grandmother	 Deceased 	 Cancer 			O No	O No	⊖ No	No	No	O No	No	O No	O No	
Maternal Grandfather	 Unknown 	 Accident 			 Unknown 									
Father		Other												
Paternal Grandmother		Unknown												
O Paternal Grandfather														

Protocol ID: PERL001	Study Subject ID: Study Subject DOB:
Study Name: PERL. Site:	Study Subject DOB:
Site:	
Event Name: Visit 4a	
Event Date:	
Section Title: Section B. Brothers	
Please complete the chart for all full biological brothers.	

Relative:	Alive/Deceased:	If Deceased, cause of death:			Hypertension:	Heart Attack:			Type I Diabetes:	Obesity:	Hyperlipidemia:		End Stage Renal Disease	Other:
O Brother1) Alive	 Cardiovascular 	Specify.	No History	O Yes) Yes	0 Yes	O Yes	O Yes) Yes	ा Yes		O Yes	_
O Brother2	O Deceased	O Cancer			O No	○ No	O No	O No	O No	O No	O No	O No	O No	
O Brother3	Unknown	 Accident 			O Unknown	Unknown	O Unknown	 Unknown 	O Unknown	Unknown	O Unknown	O Unknown	O Unknown	
O Brother4		Other												
 Brother5 		 Unknown 												
 Brother6 														
O Brother7														
O Brother8														
O Brother9														
O Brother10														
O Brother11														
O Brother12														
O Brother13														
O Brother14														
 Brother15 														

Protocol ID: PERL001		Study Subject ID:
Study Name: PERL		Study Subject DOB:
Site:		
Event Name: Visit 4a		
Event Date:		
Section Title: Section C. Sisters		
Please complete the chart for all full biological sisters.		
Relative: Alive/Deceased: If Deceased, If Other, No History: Hypertension: Heart Attack: Stroke: cause of death: Specify:	Type II Type I Obesity: Hyperlipidemia: Kidney Disease: End Stage Other Diabetes: Diabetes: Renal Disease	

Relative:	Alive/Deceased:	If Deceased, cause of death:		Hypertension:	Heart Attack:			Type I Diabetes:	Obesity:	Hyperlipidemia	Kidney Disease:	End Stage Renal Disease	Other:
O Sister1	 Alive 	 Cardiovascular 	No History	O Yes	ି Yes	O Yes	O Yes	⊖ Yes	⊖Yes	O Yes	Yes	O Yes	
Sister2	O Deceased	Cancer		O No	⊖ No	O No	No	⊖ No	○ No	O No	No	O No	
Sister3	O Unknown	 Accident 		O Unknown	 Unknown 	 Unknown 	 Unknown 	Unknown	 Unknown 	 Unknown 	Unknown	 Unknown 	
Sister4		O Other											
 Sister5 		 Unknown 											
Sister6													
Sister7													
Sister8													
Sister9													
Sister10													
Sister11													
Sister12													
Sister13													
Sister14													
Sister15													



Eligibility Randomization:

PERL_001R_Eligibility_Randomization - V3.0 PERL_015_Exemption Request - V2.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: PERL001
Study Name: PERL
Site:
Event Name: Eligibility Randomization
Event Date:

Section Title: Inclusion

Study Subject ID:_____ Study Subject DOB:_____

PERL_001R_Eligibility_Randomization - V3.0

A2. Valid baseline (Visit 4) iGFR measurement.

Protocol ID: PERL001	Study Subject ID:						
Study Name: PERL	Study Subject DOB:						
Ste:							
Event Name: Eligibility Randomization							
Event Date:							
Section Title: Exclusion							
B6. HLA B* 58:01 genotype indicating increased risk of Stevens-Johnson syndrome in response to allopurinol.							
 ^o Yes O No O Not Done 							

B10. SBP>150 or DBP>95mmHg at the end of the Run-In period. * \bigcirc Yes \bigcirc No

Protocol ID: PERL001		Study Subject ID:
Study Name: PERL		Study Subject DOB:
Site:		
Event Name: Eligibility Randomization		
Event Date:		
Section Title: Eligibility		
Section Title: Eligibility		
	re 'No' or if any Exclusion Criteria are 'Yes', the participant is not eligible.	
C1. Subject is: *	Eligible for Randomization	
	Ineligible for Randomization	
	Eligible for Randomization by Exemption	

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Protocol ID: PERL001		Study Subject ID:
Study Name: PERL		Study Subject DOB:
site:		
Event Name: Eligibility Random	zation	
Event Date:		
	PERL_015_Exemptio	n Request - V2.0
Section Title: Exempti	on Request	
Instructions:		
	1-A3 will send an email to the Exemption Review Committee. details into A3 below. This is required in order to send the alert and for the Exemption Committee to make a decision.	
A1. Select Inclusion c	riteria not met:	
Select criteria for review:	O Male or female between 18 and 70 years of age	
	T1D diagnosed after age 35 and additional criteria not met	
	O Continuously treated with insulin within one year of T1D diagnosis	
	Ouration of TID ≥ 8 years	
	History or presence of microalbuminuria or moderate macroalbuminuria or evidence of declining kidney function according to the specific protocol requirements	
	Estimated GFR between 40 and 99.9 ml/min/1.73 m2. The upper limit should be decreased by 1 ml/min/1.73 m2 for each year over age 60	
	○ Serum UA ≥ 4.5 mg/dl at the screening visit	
A2. Select Exclusion of	riteria violated:	
Select criteria for review:	History of gout requiring allopurinol therapy or xanthinuria or other indications for uric acid lowering therapy such as cancer chemotherapy or extremely high serum of the second se	uric acid values (>12 mg/dl)
	 Recurrent renal calculi (history of more than 1 episode) 	
	Use of urate-lowering agents within 3 months prior to screening	
	Current use of drugs known to interact with allopurinol	
	O Known allergy to xanthine-oxidase inhibitors or iodine containing substances	
	O Non-diabetic kidney disease as indicated by medical history and/or laboratory findings	
	SBP>160 or DBP >100mmHg at screening	
	© SBP>150 or DBP >95mmHg at the end of the run-in period	
	Cancer treatment within two years before screening	
	 Hemoglobin concentration <11 _tmplitem="2513" g/dL (males) or <10 g/dL (females) at screening 	
	OPlatelet count <100000/mm3	
	Ongoing alcohol or drug abuse or history of treatment for these conditions in the past 6 months	
	Blood donation in the 3 months before screening	
	Serious pre-existing medical problems (except TID)	
	Other	
If Other, Specify:		
A3. Reason this partic Please Provide: *	ipant should be considered for the study:	
A4. Exemption Grante	d?	
Please Select One:	○Yes	
	0 No	
A4a. If No, Reason:		
A5. Date of Decision		
Date:		
Visit 5 - V6:		
PERL_008_Local Labor	Specimen Collection - V4.0	
PERL_014_Family Hist		
Investigator Name:	Investigator Signature: Date:	

Protocol ID: PERL001			Study Subject ID:
Study Name: PERL Site:			Study Subject DO8:
Event Name: Visit 5 - V6	-		
Event Date:			
			PERL_006_Blood Pressure and Measurements - V1.0
Section Title: Blood	Pressure and Heart Rate		
Subtitle:			
Measurements:			
A1. Weight:	(kg)	🗆 Not Done	
A2. Height:	(cm)	🗆 Not Done	
Upload Source Doc	uments:		
Blood Pressure:			
B1. First Reading			
B1a. Systolic:	(mmHg)		
B1b. Diastolic:	(mmHg)	BP Not Done	
B1c. Heart Rate:	(bpm)	I HR Not Done	
B2. Second Reading			
B2a. Systolic:	(mmHg)		
B2b. Diastolic:	(mmHg)	BP Not Done	
B2c. Heart Rate:	(bpm)	🗆 HR Not Done	
B3. Third Reading			
B3a. Systolic:	(mmHg)		
B3b. Diastolic:	(mmHg)	BP Not Done	
B3c. Heart Rate:	(bpm)	HR Not Done	

Protocol ID: PERL001 Study Name: PERL Site:		Study Subject ID: Study Subject DO8:
Event Name: Visit 5 - V6 Event Date:	-	
Section Title: Average B Subtitle:	ood Pressure and Heart Rate	
Calculated Fields:		
BMI: BMI:		
Blood Pressure		
Systolic:	(mmHg)	
Diastolic:	(mmHg)	
Heart Rate:	(čpm)	

Protocol ID: PERL001						Study Subject ID:	
Study Name: PERL						Study Subject DOB:	
Site:							
Event Name: Visit 5 - V6							
Event Date:	_						
			F	ERL_008_Local Laboratory Results - V	5.0		
Section Title: Section A.	Chemistry						
Subtitle:							
Instructions: Enter the l	lab values in the units indi	cated with the date of collec	tion for each field. Use the "Not Done"	checkbox provided if data is unobtainable.			
Upload source document	nts:						
Chemistry:							
A.1. Destructioners	(mmol/l)	Data Collected		T Net Dana			

A1. Potassium:	(mmal/L)	Date Collected:	□ Not Done
A2. Creatinine:	(mg/dl)	Date Collected:	□ Not Done
A3. ALT (SGPT):	(U/L)	Date Collected:	□ Not Done

Protocol ID: PERL001 Study Name: PERL Site: ______ Event Name: Visit 5 - V6 Event Date: _____ Study Subject ID:_____ Study Subject DOB:_____ Section Title: Section B. CBC Subtitle: B1. Hemoglobin: Date Collected: (gm/dl) □ Not Done B2. Hematocrit: (%) Date Collected: □ Not Done B3. Platelets: (mmol) Date Collected: □ Not Done (million cells/mcL) B4. RBC: Date Collected: Not Done B5. WBC: (cells/mcL) Date Collected: □ Not Done B5a. Neutrophils: (%) Not Done B5b. Lymphocytes: (%) 🗆 Not Done B5c. Monocytes: (%) Not Done B5d. Eosinophils: (%) Not Done (%) B5e. Basophils: Not Done

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 5 - V6 Event Date:			Study Subject IDC
Section Title: Section C. P			
C1. Urine Pregnancy Test Result:	 Positive Negative Not Done Not Applicable 	Date of test:	
C2. Serum Pregnancy Test Result:	 Positive Negative Not Done Not Applicable 	Date of test:	

Protocol ID: PERL001			Study Subject ID:
Study Name: PERL			Study Subject DO8:
Site:			
Event Name: Visit 5 - V6			
Event Date:	-		
Section Title: Section D.	Urine Multistix		
Date Urine Collected:		Not Done	
D1. Leukocytes:	O Negative		
	O Trace		
	 Small 		
	O Moderate		
	 Large 		
D2. Nitrites:	O Negative		
	O Positive		
D3. Protein:	O Negative		
	 Trace 		
	O 30		
	100		
	○ 300 ○ 2000+		
	0 2000+		
D4. Blood	O Negative		
	 Positive 		
D4a. Blood - Non Hemolyzed:	 None 		
	 Trace 		
	O Moderate		
D4b. Blood – Hemolyzed:	None		
	 Trace 		
	 Small Moderate 		
	 Moderate Large 		
	Olarge		
D6. Ketones:	O Negative		
	O Trace		
	O Small		
	O Moderate		
	O Large		

Protocol ID: FERL001 Study Name: FERL	Study Subject ID: Study Subject DOB:
Ster	study study. tota
Event Name: Visit 5 - V6	
Event Name: visit 3 - vio	
Even Dote.	
Section Title: Section E. eGFR	
Subtitle:	
E1. Indicate visit for which this eGFR values applies:	
○ Visit 1	
○ Visits 6-15	
E2. Use central lab creatinine value to calculate eGFR	
Click Here to Calculate eGFR	
Central lab creatinine value	
E3. Use local lab creatinine value to calculate eGFR	
Click Here to Calculate GFR	
Local lab creatinine value	
E4. eGFR: (mls/min/1.73m ²) Date Collected:	Not Done

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 5 - V6 Event Date:				Study Subject ID:			
PERL_010 Central Lab Specimen Collection - V4.0							
Section Title: Section A. B Instructions: Please indicate the collect		ide the date of collection.					
A1. Serum Uric Acid, Creatinine, Cystatin C Collected A2. HbA1c Collected	⊖Yes ⊜No ⊙Yes	Date Collected					
AL TURIC CONCICU	0 No	Suc concello					

 No

 NA-if vist 6

 A3. Shipped to ARDL
 Viss

 No

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit S - V6 Event Date:	_					Study Subject ID: Study Subject 0008:
Section Title: Section B	. Urine Specimens					
B1. ACR/AER Collected	ਂ Yes ਂ No ਂ NA-≆rvisit 6_8_10_12 or 14					
Overnight	⊖Yes ⊖No	Date Ended Collection				
First Morning	○Yes ○No	Date Collected				
Spot Urine	⊖Yes ⊖No	Date Collected	Additional Date Collected	If necessary	Additional Date Collected	If necessary
B2. Shipped to ARDL	⊖ Yes ○ No	Date Shipped				

Protocol ID: PERL001 Study Name: PERL				Study Subject ID: Study Subject DOB:	
Site: Event Name: Visit 5 - V6 Event Date:	_				
Section Title: Section C	. Biospecimens for	Repository			
Is this Visit 4, 11, 16 or 17	⊙Yes ⊙No				
C1. Serum Collected	⊖ Yes ⊙ No	Date Collected			
C2. Plasma Collected	ିYes ଼No	Date Collected			
C3. Urine Collected	⊖ Yes ⊖ No	Date Collected			
C3a. Protease Inhibitor Added	○ Yes ○ No				
C4. Shipped to ARDL	⊖ Yes ⊖ No	Date Shipped			

Protocol ID: PERL001 Study Name: PERL					Study Subject ID: Study Subject DOB:
Site: Event Name: Visit 5 - V6 Event Date:					
event bale.	_		PERL	011_Skin Assessment - V2.0	
Section Title: Skin Asse	ssment				
Indicate who performe Select: *	 Participant Self-Assessment 				
Was any rash present d	Clinician Assessment				
•	○Yes ○No ○Not Assessed				
A1. Has the participant Select:	had any of the following pre-	-rash Stevens-Johnson S	Syndrome (SJS) symptoms?		
Social	O No O Not Assessed				
Select all that apply: Fever					
Duration:	Gever				
Maximum temperature:			○ °C ○ °F	Unknown temperature	
Skin tenderness			04		
Sore throat	□ Skin tenderness				
Photophobia	Sore throat				
Burning eyes	Photophobia				
	Burning eyes				
Itching eyes	□ Itching eyes				
	ick and purulent sputum				
Headache	Headache				
Malaise	□Malaise				
Arthralgia	□ Arthralgia				
A2. During assessment, Select:	, was any swelling or rash not OYes	ted?			
	No Not Assessed				
Select all that apply: Burning rash					
Skin pain	Burning rash				
	□Skin pain				
Facial swelling	□ Facial swelling				
Tongue swelling	□ Tongue swelling				
Red or purple skin rash	Red or purple skin rash				
Area of rash (select all	That apply):		Chest	Abdomen	
	Arms		Legs	Palms	
	□Soles				
Target lesions surround	ded by macular erythema Target lesions				
Hives	Hives				
Area of hives (select al	☐ Face		Chest	Abdomen	
	□Arms		□ Legs	Palms	
	Soles				
Blisters	Blisters				
Area of blisters (select	all that apply):		. Chest	Abdomen	
	□Arms		C Legs	Paims	
	□Soles		□ Genitals	□ Anal	
Shedding	Shedding (sloughing) of skin				
Area of shedding (selec	Ct all that apply):		□ Chest	Abdomen	
	□Arms		□ Legs	Paims	
_	□Soles				
Denuded skin areas	Denuded skin areas				
Area of denudation (se	□Face		Chest	Abdomen	
	□Arms		□ Legs	- Palms	
	Soles				
A3. During assessment Select:	was any mucous membrane i Yes No	involvement noted?			
	○ Not Assessed				

Select all that apply	•		
Oral mucosa			
oral macosa	Oral mucosa		
Oral mucosa (select	t all that apply):		
		Edema	
	□ Erythema	□ Edema	Sloughing
	Blistering	Ulceration/erosion	Necrosis/crust
Nasal mucosa			
	Nasal mucosa		
Nasal mucosa (sele	ct all that apply):		
	Erythema	Edema	□ Sloughing
	Blistering	Ulceration/erosion	□ Necrosis/crust
Eyes			
	□ Eyes		
Eyes (select all that	apply):		
	Excessive tearing	Hyperemia	Congestion
	□ Scarring		
Urinary tract	□ Urinary tract		
Urinary Tract (selec	t all that apply):		
	Dysuria	Urinary retention	
Pulmonary			
	Pulmonary		
Pulmonary (select a	all that apply):		
	Dyspnea	Productive cough	Pulmonary edema
	uyspnéa	Productive cough	Pulmonary edema

Protocol ID: PERL001 Study Name: PERL Site: ______ Event Name: Visit 5 - V6 Event Date: _____

Study Subject ID:_____ Study Subject DOB:_____

PERL_014_Family History - V1.0

Please complete the o	hart for Mother	ather Materna	Grand	ther and C	randfather and	Daternal Con	ndmother -	nd Grande	ther					
Relative:	Alive/Deceased:		If Other,		Hypertension:		Stroke:		Type I	Obesity:	Hyperlipidemia	: Kidney Disease	End Stage Renal Disease	Othe
) Mother	 Alive 	 Cardiovascular 	1	No History	 Yes 	O Yes	⊖Yes	O Yes	⊖ Yes	O Yes	ं Yes	0 Yes	() Yes	
Maternal Grandmother	O Deceased	Cancer			⊖ No	O No	○ No	No	No	O No	No	No	O No	
Maternal Grandfather	Unknown	 Accident 			 Unknown 	Unknown	 Unknown 							
) Father		O Other												
Paternal Grandmother		 Unknown 												
Paternal Grandfather														
O Mother	O Alive	Cardiovascular		No History	 Yes 	O Yes	୍ୟଟ	ं Yes	ाes	े Yes	ं Yes	⊖ Yes	O Yes	
Maternal Grandmother	C Deceased	Cancer			O No									
Maternal Grandfather	 Unknown 	 Accident 			 Unknown 									
) Father		O Other												
O Paternal Grandmother		 Unknown 												
O Paternal Grandfather														
) Mother	O Alive	Cardiovascular		No History	O Yes	ं Yes	୍ୟର	ं Yes	ाes	ं Yes	े Yes	ा Yes	ं Yes	-
Maternal Grandmother	O Deceased	Cancer			○ No	○ No	○ No	No	No	No	○ No	No	No	
Maternal Grandfather	 Unknown 	 Accident 			 Unknown 									
O Father		Other												
Paternal Grandmother		Unknown												
Paternal Grandfather														
O Mother	O Alive	 Cardiovascular 		No History	 Yes 	Yes	୍ୟଟ	ं Yes	୍ୟଟ	े Yes	ं Yes	⊖ Yes	O Yes	
Maternal Grandmother	O Deceased	Cancer			O No	O No	⊖ No	○ No	No	O No	No	No	O No	
Maternal Grandfather	 Unknown 	 Accident 			 Unknown 									
) Father		Other												
Paternal Grandmother		Unknown												
O Paternal Grandfather														
Mother	0.000	 Cardiovascular 	1	No History	O Yes	O Yes) Yes) Yes	े Yes) Yes	ं Yes	0 Yes	O Yes	
Maternal Grandmother	O Deceased	Cancer			O No	⊖ No	⊖ No	No	No	O No	⊖ No	O No	O No	
Maternal Grandfather	 Unknown 	 Accident 			 Unknown 									
O Father		O Other												
Paternal Grandmother		 Unknown 												
Paternal Grandfather														
O Mother		Cardiovascular		No History		O Yes	○Yes	○ Yes		0 Yes	े Yes	○ Yes	O Yes	-
Maternal Grandmother	 Deceased 	 Cancer 			O No	O No	⊖ No	No	No	O No	No	O No	O No	
Maternal Grandfather	 Unknown 	 Accident 			 Unknown 									
Father		Other												
Paternal Grandmother		Unknown												
O Paternal Grandfather														

Protocol ID: PERLO01	Study Subject ID:
Study Name: PERL	Study Subject ID: Study Subject DOB:
Site:	
Event Name: Visit 5 - V6	
Event Date:	
Section Title: Section B. Brothers	
Please complete the chart for all full biological brothers.	

Please complete the chart for all full biological brothers. Relative: Allvier Deceased, If Other, No History: Hypertension: Heart Attack: Stroke: Type II Type I Obesity: Hypertipidemia: Kidney Disease: End Stage														Other:
Kelauve.		cause of death:		no history.	nypercension.	ricart Attack.			Diabetes:	obesity.	nypempidenna.		Renal Disease	
O Brother1	 Alive 	 Cardiovascular 		No History	ा Yes) Yes	O Yes	O Yes	O Yes	O Yes	O Yes	⊖ Yes	O Yes	
O Brother2	 Deceased 	O Cancer			O No	⊖ No	O No	O No	O No	O No	O No	O No	O No	
Brother3	 Unknown 	 Accident 			 Unknown 	Unknown	 Unknown 	 Unknown 	 Unknown 	 Unknown 	🗆 Unknown	O Unknown	O Unknown	
O Brother4		O Other												
 Brother5 		 Unknown 												
Brother6														
O Brother7														
O Brother8														
Brother9														
OBrother10														
O Brother11														
Brother12														
OBrother13														
OBrother14														
O Brother15														

Protocol ID: PFRL001	Study Subject ID:
Study Name: PERL	Study Subject DOB:
Site:	
Event Name: Visit 5 - V6	
Event Date:	
Section Title: Section C. Sisters	
Please complete the chart for all full biological sisters.	
Relative: Alive/Decassed; II/ Decassed; II/ Other, No History; Hypertension: Heart Attack; Stroke: Type II Type; I Typ	
cause of death: Specify: Diabetes: Diabetes: Renal Disease	

Relative:	Alive/Deceased:	If Deceased, cause of death:		Hypertension:	Heart Attack:			Type I Diabetes:	Obesity:	Hyperlipidemia		End Stage Renal Disease	Other
O Sister1	 Alive 	 Cardiovascular 	No History	O Yes	ୁ Yes	O Yes	() Yes	े Yes	⊖Yes	O Yes	Yes	O Yes	
Sister2	 Deceased 	Cancer		No	⊖ No	O No	O No	⊖ No	O No	O No	No	No	
Sister3	 Unknown 	 Accident 		Unknown	 Unknown 	 Unknown 	O Unknown	ं Unknown	O Unknown	 Unknown 	Unknown	Unknown	
Sister4		O Other											
 Sister5 		 Unknown 											
Sister6													
Sister7													
Sister8													
Sister9													
Sister10													
Sister11													
Sister12													
Sister13													
Sister14													
Sister15													

Investigator Name: _

____ Investigator Signature: ____

___ Date: _

<form><form>

			PER	L_021_Telephone_Visit - V1.0		
Section Title: Tele						
A0. Was contact r	nade with the participant vi O Yes O No	a telephone?				
A1. If No, reason	for no contact:					
	Phone number no longer v	alid				
	□No response from participa	ant after multiple contact attempts				
	Participant no longer intere	ested in participating in the study				
	Participant moved					
	□Other	If Other, Specify				
12. Date of Contact						
A3. Is subject elig	ible to continue in the stud	γ?				
	⊖Yes ⊙No					
A4. Were any AE's	s identified when speaking v	with subject?				
	○ No					
A5. Was participa	nt randomized immediately	after the telephone visit?				
	⊖Yes ⊙No					
A6. Was study me	dication prescription sent t ාප	o the Study Pharmacy?				
	○ No					
isit 6:						
Visit 0						

Investigator Name: _____ Date: _____ Date: _____

Protocol ID: PERL001 Study Name: PERL Site:			Study Subject ID: Study Subject 000:
Event Name: Visit 6			
Event Date:			
			PERL_006_Blood Pressure and Measurements - V1.0
Section Title: Blood	Pressure and Heart Rate		
Subtitle:			
Measurements:			
A1. Weight:	(kg)	Not Done	
A2. Height:	(cm)	Not Done	
Upload Source Docu	uments:		
Blood Pressure:			
B1. First Reading			
B1a. Systolic:	(mmHg)		
B1b. Diastolic:	(mmHg)	BP Not Done	
B1c. Heart Rate:	(bpm)	🗆 HR Not Done	
B2. Second Reading			
B2a. Systolic:	(mmHg)		
B2b. Diastolic:	(mmHg)	BP Not Done	
B2c. Heart Rate:	(bpm)	HR Not Done	
B3. Third Reading			
B3a. Systolic:	(mmHg)		
B3b. Diastolic:	(mmHg)	BP Not Done	
B3c. Heart Rate:	(bpm)	HR Not Done	

Protocol ID: PERL001 Study Name: PERL		Study Subject ID: Study Subject DOB:
Site:		
Event Name: Visit 6		
Event Date:	-	
Section Title: Average Bl	ood Pressure and Heart Rate	
Subtitle:		
Calculated Fields:		
Calculated Fields:		
BMI		
BMI:		
Blood Pressure		
Systolic:	(mmHg)	
Diastolic:	(mmhg)	
Heart Rate:	(bpm)	

Protocol ID: PERL001	Study Subject ID:
Study Name: PERL	Study Subject DOB:
Site:	
Event Name: Visit 6	
Event Date:	
PERL_008_Local Laboratory Results - V5.0	
Section Title: Section A. Chemistry	
Subtitle:	
Instructions: Enter the lab values in the units indicated with the date of collection for each field. Use the "Not Done" checkbox provided if data is unobtainable.	
Upload source documents:	
Chemistry:	

Protocol ID: PERL001 Study Name: PERL Site: ______ Event Name: Visit 6 Event Date: _____ Study Subject ID:_____ Study Subject DOB:_____ Section Title: Section B. CBC Subtitle: B1. Hemoglobin: Date Collected: (gm/dl) □ Not Done B2. Hematocrit: (%) Date Collected: □ Not Done B3. Platelets: (mmol) Date Collected: □ Not Done (million cells/mcL) B4. RBC: Date Collected: Not Done B5. WBC: (cells/mcL) Date Collected: □ Not Done B5a. Neutrophils: (%) Not Done B5b. Lymphocytes: (%) Not Done B5c. Monocytes: (%) Not Done B5d. Eosinophils: (%) Not Done (%) B5e. Basophils: Not Done

Protocol ID: PERL001 Study Name: PERL Ste: Event Name: Visit 6 Event Date:			Study Subject ID: Study Subject DOR:
Section Title: Section C. P	regnancy Test		
C1. Urine Pregnancy Test Result:	 Positive Negative Not Done Not Applicable 	Date of test:	
C2. Serum Pregnancy Test Result:	 Positive Negative Not Done Not Applicable 	Date of test:	

Protocol ID: PERL001			Study Subject ID:
Study Name: PERL			Study Subject DOB:
Site:			
Event Name: Visit 6			
Event Date:	_		
Section Title: Section D.	Urine Multistix		
Date Urine Collected:		Not Done	
D1. Leukocytes:	 Negative 		
	O Trace		
	Small		
	O Moderate		
	 Large 		
D2. Nitrites:	O Negative		
	O Positive		
D3. Protein:	O Negative		
	 Trace 		
	O 30		
	0 100		
	O 300		
	O 2000+		
D4. Blood	O Negative		
	O Positive		
D4a. Blood - Non Hemolyzed:	O None		
	 Trace 		
	O Moderate		
D4b. Blood - Hemolyzed:	None		
	 Trace 		
	Small		
	O Moderate		
	 Large 		
D6. Ketones:	O Negative		
	O Trace		
	O Small		
	 Moderate 		
	⊖ Large		

Protocol ID: PERL001 Study Name: PERL	Study Subject ID: Study Subject DOB:
	study studject DUB:
Site: Event Name: Visit 6	
Event Date:	
Section Title: Section E. eGFR	
Subtitle:	
E1. Indicate visit for which this eGFR values applies:	
○Visit 1	
○ Visits 6-15	
E2. Use central lab creatinine value to calculate eGFR	
Click Here to Calculate eGFR	
Central lab creatinine value	
E3. Use local lab creatinine value to calculate eGFR	
Click Here to Calculate eGFR	
Local lab creatinine value	
E4. eGrR: (mls/min/1.73m ²) Date Collected:	Not Done

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Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 6 Event Date:				Study Subject ID: Study Subject 008:
		PERL_010 Central Lab S	pecimen Collection - V4.0	
Section Title: Section A. B	lood Specimens			
Instructions: Please indicate the collect	ted specimens and prov	de the date of collection.		
A1. Serum Uric Acid, Creatinine, Cystatin C Collected	⊖ Yes ⊖ No	Date Collected		
A2. HbA1c Collected	○Yes ○No ○NA-if visit 6	Date Collected		
A3. Shipped to ARDL	⊖ Yes ○ No	Date Shipped		

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 6 Event Date:	_					Study Subject DOR
Section Title: Section B	. Urine Specimens					
B1. ACR/AER Collected	○ Yes ○ No ○ NA-if visit 6_8_10_12 or 14					
Overnight	○Yes ○No	Date Ended Collection				
First Morning	⊖Yes ⊖No	Date Collected				
Spot Urine	⊖Yes ⊖No	Date Collected	Additional Date Collected	If necessary	Additional Date Collected	If necessary
B2. Shipped to ARDL	○ Yes ○ No	Date Shipped				

Protocol ID: PERL001 Study Name: PERL Site:			Study Subject ID: Study Subject DOB:
Event Name: Visit 6			
Event Date:			
Section Title: Section C	. Biospecimens for Reposit	ory	
Is this Visit 4, 11, 16 or 17	⊖Yes ⊖No		
C1. Serum Collected	⊖ Yes ○ No	Date Collected	
C2. Plasma Collected	⊖ Yes ⊖ No	Date Collected	
C3. Urine Collected	⊖ Yes ⊖ No	Date Collected	
C3a. Protease Inhibitor Added	○ Yes ○ No		
C4. Shipped to ARDL	⊖ Yes ○ No	Date Shipped	

Protocol ID: PERL001 Study Name: PERL					Study Subject ID: Study Subject ID::
Site: Event Name: Visit 6 Event Date:					
Event Date:	_		PERL	_011_Skin Assessment - V3.0	
Section Title: Skin Asse	ssment				
Indicate who performe Select: *					
Was any rash present of	Clinician Assessment				
•	○Yes ○No ○Not Assessed				
A1. Has the participant Select:		re-rash Stevens-Johnson	Syndrome (SJS) symptoms?		
	No Not Assessed				
Select all that apply:					
Fever	□Fever				
Duration: Maximum temperature:	(days)	Celsius or Farenheit:	0 °C	Unknown temperature	
Skin tendemess			0 °F		
	□ Skin tenderness				
Sore throat	□ Sore throat				
Photophobia	Photophobia				
Burning eyes	Burning eyes				
Itching eyes	□ Itching eyes				
Cough productive of th	ick and purulent sputum				
Headache	- Headache				
Malaise	□Malaise				
Arthralgia	Arthralgia				
A2. During assessment	, was any swelling or rash r	noted?			
Select:	O Yes No No Not Assessed				
Select all that apply:					
Burning rash	Burning rash				
Skin pain	□Skin pain				
Facial swelling	Facial swelling				
Tongue swelling	Tongue swelling				
Red or purple skin rash	Red or purple skin rash				
Area of rash (select all					
	□ Face		Chest	Abdomen Paims	
	□Soles		Back		
Target lesions surround	ded by macular erythema				
Hives	Hives				
Area of hives (select al					
	□ Face		Chest	Abdomen Palms	
	Soles		Back		
Blisters	Blisters				
Area of blisters (select					
	□ Face		Chest	Abdomen Palms	
	□Soles		Genitals	Anal	
Chadding	Back				
Shedding	Shedding (sloughing) of skin				
Area of shedding (selec	ct all that apply):		Chest	Abdamen	
	□Arms		Legs	Palms	
Donuded alda	Soles		Back		
Denuded skin areas	Denuded skin areas				
Area of denudation (se			Chest	Abdamen	
	□Ams		Legs	Palms	
	□ Soles		Back		

A3. During assessment was any mucous membrane involvement noted?

Select:	Yes		
	No Not Assessed		
	Chier Addata		
Select all that apply:			
Oral mucosa			
	Oral mucosa		
Oral mucosa (select a	ll that apply):		
	□Erythema	Edema	Skughing
	Blistering	Ulceration/erosion	Necrosia/aust
Nasal mucosa			
	Nasal mucosa		
Nasal mucosa (select	all that apply):		
	□Erythema	Edema	
	Blistering	Ulceration/erosion	□ Necrois/aust
Eyes			
	Eyes		
Eyes (select all that a	oply):		
	□ Excessive tearing	Hyperemia	
	□Scarring		
Urinary tract			
	Urinary tract		
Urinary Tract (select a	all that apply):		
	□ Dysuria	Urinary retention	
Pulmonary			
	Pulmonary		
Pulmonary (select all	that apply):		
	Dyspnea	Productive cough	Pumorary edema

Protocol ID: PERL001 Study Nume: PERL Ster Fern Nume: Visk 6 Event Date:					bject ID: bject DOB:			
Event Late.		PERL_022_Study Drug Compliance a	nd Exposure -	V3.0				
Section Title: Study Medication Log Instructions: Refer to the MOG for detailed instructions and examples. All dosages and discontinuations must be listed for the entire Dosing Period. The Dosing Period starts with the date the subject takes the first pill from the shipment received after the prior visit and ends with the date the subject takes the last pill from that shipment tecause they received a new shipment of pills. Has the subject premanently discontinued the study drug prior to this dosing period? *								
াও Will be the previous line Stop Date plus 1 day.")" emmouseout="UnTip()">Start Date	Start Date Unknown	taking pills of the same does or the last day not taking pills."	Stop Date Unknown	Dosage Dispensed by Pharmacy 0 0 0 100 0 200 0 300 0 400 (mg/day)	Type. of Change No change Permanently discontinued Temporarily discontinued Change in dosage Started treatment Restarted treatment Other Specify	Other Type of Change	Reason for Change (select all that apph) abdry assessment results Adjouring contraindicated (Fride aligopring the self-self-self- progravy present/self-self- progravy present/self-self- progravy present/self-self- progravy present/self-self- progravy present/self- progravy present/self- progravy present/self- self-self-self-self- (ber-specify)	Other Reason for Change

Protocol ID: PERL001	Study Subject ID:
Study Name: PERL Site:	Study Subject DOB:
Event Name: Visit 6	
Event Date:	
Section Title: Study Drug Exposure	
Instructions: For the entire Dosing Period. The Dosing Period starts with the date the subject takes the first pill from the sl ends with the date the subject takes the last pill from that shipment because they received a new shipment of pills.	hipment received after the prior visit and
1a. Date started using drug vials:	
Unknown	
1b. Date stopped using drug vials:	
🗌 Unknown	
Difference in days:	
1c. Number of pills should have taken if there were no Discontinuations:	
🗆 Unknown	
Please explain why the number of pills the subject should have taken is Unknown:	
Please explain why the number of plils the subject should have taken is Unknown;	
2. Number of pills instructed not to take: (by vial because the number can be different for each vial)	
(by vial because the number can be different for each vial) Vial A: *	
Vial B: *	
Vial C *	
Vial D: *	
Total number of pills instructed not to take:	
3. Number of pills should have taken: (by vial because the number can be different for each vial)	
(by via because the number can be unreferent for each vial) Vial A:	
Vial B:	
Vial C	
Vial D:	
Total number of pills should have taken:	
4. Number of pills dispensed: (by vial because the number can be different for each vial)	
Vial A: *	
Vial B: *	
Vial C.*	
Vial D: *	
Total number of pills dispensed:	
 These selfs externed to back these selfs. 	
5. Were pills returned in individual vials: * OYes	
○ No ○ Pills not returned	
Number of Pills Returned: (by vial because the number can be different for each vial)	
Vial A:	
Vial B:	
Vial C	
Vial D:	
Total number of pills returned:	
Total number of pills returned:	
And a second sec	
<u>6. Number of pills taken:</u> (by vial because the number can be different for each vial)	
(by via because the number can be different for each via) Via A:	
Vial B:	
Vial C:	
Vial D:	
Total number of pills taken:	
Total number of pills taken:	
7. Select the reason Drug Compliance cannot be calculated at this visit:	
 Subject did not return pills 	
 Pils were thrown away Pils were lost 	
○Start date and/or Stop date unknown ○ Not applicable	
Other	
If Other, Specify:	

Protocol ID: PERL001	Study Subject ID:
Study Name: PERL	Study Subject DDB:
Site:	
Event Name: Visit 6	
Event Date:	
Section Title: % Compliant Calculation	
B1. Percent Compliant (if total pills taken reported by the 4 individual vials)	
B2. Percent Compliant (if vials not returned and total pills taken reported as a total only)	

Protocol ID: PERL001 Study Name: PERL Site: ______ Event Name: Visit 6 Event Date: _____ Study Subject ID:_____ Study Subject DOB:_____ Section Title: Upload Your Form 022 Source Document Instructions: Don't forget to upload your source document! Go to the Source Document event
 Open the PERL_022_Source Documents form
 Upload your source document to the appropriate visit field You can now return to the Compliance tab to review subject's compliance and if you wish, the Exposure tab to review pill counts and calculations. .

Confirm form is complete and source document uploaded.

Visit 7: PERL_006_Blood Pressure and Measurements - V1.0 PERL_007_Physical Examination - V1.0 PERL_008_LCo1 Laboretory Results - V5.0 PERL_009_ECG Report - V1.0 PERL_010_Central Lab Specimen Collection - V4.0 PERL_011_Skin Assessment - V3.0 PERL_022_Study Drug Compliance and Exposure - V3.0 PERL_022_Study Drug Compliance and Exposure - V3.0

Investigator Name: _____ Investigator Signature: _____ ____ Date: ____

Protocol ID: PERL001 Study Name: PERL Site:	_		Study Subject ID: Study Subject DOB
Event Name: Visit 7 Event Date:			
Event Date.			PERL_006_Blood Pressure and Measurements - V1.0
Section Title: Blood	Pressure and Heart Rate		
Subtitle:			
Measurements:			
A1. Weight:	(kg)	Not Done	
A2. Height:	(cm)	Not Done	
Upload Source Doc	uments:		
Blood Pressure:			
B1. First Reading B1a. Systolic:	(mmHg)		
B1b. Diastolic:	(mmHg)	BP Not Done	
B1c. Heart Rate:	(bpm)	U HR Not Done	
B2. Second Reading B2a. Systolic:	(mmHg)		
B2b. Diastolic:	(mmHg)	BP Not Done	
B2c. Heart Rate:	(bpm)	HR Not Done	
B3. Third Reading			
B3a. Systolic:	(mmHg)		
B3b. Diastolic:	(mmHg)	BP Not Done	
B3c. Heart Rate:	(bpm)	🗆 HR Not Done	

Protocol ID: PERL001 Study Name: PERL		Study Subject ID: Study Subject DOB:
Site: Event Name: Visit 7		
Event Date:	-	
Section Title: Average Bl Subtitle:	ood Pressure and Heart Rate	
Calculated Fields:		
BMI BMI:		
Blood Pressure Systolic:	(mmit)	
Diastolic:	(mmHg)	
Heart Rate:	(bpm)	

Protocol ID: PERL001		Study Subject ID:
Study Name: PERL Site:		Study Subject DOB:
Event Name: Visit 7 Event Date:		
	PERL_007_Physical Examination - V1.0	
C		
Section Title: Body Sys	tem im performed at this visit?	
AU. Was a physical exa	In performed at this visit? OYes ONo	
Upload source docume		
A1. Eyes: Eyes (including fundoscopy):	⊖ Normal	
	O Abromal O Not Done	
If abnormal, describe	findings:	
Select all that apply:	□ Retinopathy	
	Macular Degeneration	
	□ Other	
If other, specify: A2. Cardiovascular:		
Cardiovascular:	O Normal Abnormal	
	O Not Done	
If abnormal, describe the Select all that apply:	findings: □Arhytmia	
	□Marmur	
	□ Other	
If other, specify:		
A3. Extremities: Extremities:	Olfermal	
- Arternova.	ONormal O'Abnormal ONEDone	
If abnormal, describe		
Select all that apply:	Interings:	
Amputation, specify:		
	□ Tendemois	
	∐ Edema	
	□ Pulses	
Pulses:	00+ 01+	
	02+ 03+	
	04+	
	□ Ober	
If other, specify: A4. Lymph Nodes:		
Lymph Nodes:	O Normal O Abnormal	
	() Not Done	
If abnormal, describe to Select all that apply:	findings: □Sweling	
	□ Other	
If other, specify:		
A5. Pulmonary: Pulmonary:	○ Nermal	
	Athromal Ond Done	
If abnormal, describe		
Select all that apply:	□ Reduced breath sounds	
	□ Other	
If other, specify:		
A6. Skin: Skin:	O Normal O Abnormal	
	○ Not Done	
If abnormal, describe the Select all that apply:	findings: □Red or purple painful rash	
	∐Scar	
	□ Ezzema	
	□ Psoriatis	
	() Ulces	
	Excessive Bruising	
	□Other	
If other, specify:		
A7. Gastrointestinal: Gastrointestinal:	ONormal	
	Orema O'Abromat ONE Done	
If abnormal, describe		
Select all that apply:	International Control of Control	
	Abdominal Mass	
	□ Organamegały	
Organomegaly, specify:		
	□ Stoma	
	□ Other	
If other, specify:		
A8. Musculoskeletal Musculoskeletal:	O Normal	
	O Abnormal O Not Done	
If abnormal, describe	findings:	

Select all that apply:	CSIfies
	□ Injury
	- ungay
Injury, specify:	
	Reduced strength
	Reduced range of motion
If other, specify:	
A9. Genitourinary:	
Genitourinary:	○ Nernal
	Akomal
	\ NXLORE
If abnormal, describe	e findings:
Specify:	
A10. Neurological:	
Neurological:	O Normal
	Abnormal
	⊖Not Dane
If abnormal, describe	e findings:
Select all that apply:	Abnormal Reflex Response
Abnormal reflex response, spec	vite - O khowflexia
маналла телек тезратас, арс	Ohladesia
	Diminished sensation
	Crank Menes
Abnormal, specify:	
If other, specify:	

Study Subject ID:_____ Study Subject DOB:_____

Protocol ID: PERL001 Study Name: PERL Site: ______ Event Name: Visit 7 Event Date: _____

Section Title: Other Body System

Other Body System A11. Other Body System: Describe

Protocol 107- PGKL001 Stody Name: FSRL Stre: Event Name: Vist 7	Study Subject ID: Study Subject ID:R:
Event Date:	
	PERL_008_Local Laboratory Results - V5.0
Section Title: Section A. Chemistry	
Subtitle:	
Instructions: Enter the lab values in the units indicated with the date of collection for each field. Use the "N	Not Done" checkbox provided if data is unobtainable.
Upload source documents:	
Chemistry:	

Protocol ID: PERL001 Study Name: PERL Site: ______ Event Name: Visit 7 Event Date: _____ Study Subject ID:_____ Study Subject DOB:_____ Section Title: Section B. CBC Subtitle: B1. Hemoglobin: Date Collected: (gm/dl) □ Not Done B2. Hematocrit: (%) Date Collected: □ Not Done B3. Platelets: (mmol) Date Collected: □ Not Done (million cells/mcL) B4. RBC: Date Collected: Not Done B5. WBC: (cells/mcL) Date Collected: □ Not Done B5a. Neutrophils: (%) Not Done B5b. Lymphocytes: (%) Not Done B5c. Monocytes: (%) Not Done B5d. Eosinophils: (%) Not Done (%) B5e. Basophils: Not Done

Protocol ID: PERL001 Study Name: PERL Ste: Event Name: Visit 7 Event Date:			Study Subject ID: Study Subject DOR:
Section Title: Section C. P	regnancy Test		
C1. Urine Pregnancy Test Result:	 Positive Negative Not Done Not Applicable 	Date of test:	
C2. Serum Pregnancy Test Result:	 Positive Negative Not Done Not Applicable 	Date of test:	

Protocol ID: PERL001			Study Subject ID:
Study Name: PERL			Study Subject DOB:
Site:			
Event Name: Visit 7			
Event Date:	-		
Section Title: Section D.	Urine Multistix		
Date Urine Collected:		Not Done	
bate onlie collected.		Linot bone	
D1. Leukocytes:	O Negative		
Dr. concerca.	O Trace		
	○ Small		
	O Moderate		
	 Large 		
	O Large		
D2. Nitrites:	- No. 19		
D2. NUILES.	O Negative		
	O Positive		
D3. Protein:	- Normality		
D3. Protein:	 Negative 		
	 Trace 		
	O 30		
	100		
	O 300		
	O 2000+		
D4. Blood			
DA. Blood	O Negative		
	O Positive		
D4a. Blood - Non Hemolyzed:	O None		
	 Trace 		
	O Moderate		
D4b. Blood - Hemolyzed:	 None 		
	○ Trace		
	 Small 		
	 Moderate 		
	 Large 		
D6. Ketones:	0.000		
DO. NEUHES.	O Negative		
	O Trace		
	O Small		
	 Moderate 		
	C Large		

Protocol ID: PERLO01	Study Subject ID:
Study Name: PERL	Study Subject DOB:
Site:	
Event Name: Visit 7	
Event Date:	
Section Title: Section E. eGFR	
Subtitle:	
E1. Indicate visit for which this eGFR values applies:	
○Visit 1	
○ Visits 6-15	
E2. Use central lab creatinine value to calculate eGFR	
Click Here to Calculate eGFR	
Central lab creatinine value	
E3. Use local lab creatinine value to calculate eGFR	
Click Here to Calculate eGFR	
Local lab creatinine value	
E4. eGFR: (mls/min/1.73m ²) Date Collected:	Not Dane

Protocol ID: PERL001 Study Name: PERL Site:		Study Subject ID: Study Subject ID0:
Event Name: Visit 7 Event Date:		
	PERL_009_ECG Report - V1.0	
Section Title: ECG Re	port	
ECG Completed? *	Completed Not Completed	
Upload Source Document:		
A1. Date of ECG:		
A2. Heart Rate:	(bpm)	
A3. ECG Findings:	() Normal () Abnomal	
A3a. If abnormal (se		
A3a. If abnormal (se	Ct all that apply):	
	□ Atrial Fb	
	T Inversion	
	□Q Wave	
	AV Block	
	I MI Oranges	
	□ Tachycardia	
	Bradycardia	
	Other	
If Other, Specify:		
A3b. Is this abnormality clinics significant?	Ny OYes ** If yes, report on AE Log ⊖No	

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 7 Event Date:				Study Subject IDC Study Subject DDB:
		Р	ERL_010 Central Lab Specimen Collection - V4.0	
Section Title: Section A. B	lood Specimens			
Instructions: Please indicate the collect	ted specimens and prov	de the date of collection.		
A1. Serum Uric Acid, Creatinine, Cystatin C Collected	⊖ Yes ⊖ No	Date Collected		
A2. HbA1c Collected	○ Yes ○ No ○ NA-if visit 6	Date Collected		
A3. Shipped to ARDL	○ Yes ○ No	Date Shipped		

Protocol ID: PERL001						Study Subject ID:
Study Name: PERL						Study Subject DOB:
Site:						
Event Name: Visit 7						
Event Date:						
Section Title: Section B	. Urine Specimens					
B1. ACR/AER Collected	 Yes 					
	O No					
	O NA-if visit 6_8_10_12 or 14					
Overnight	ा es	Date Ended Collection				
	○ No					
First Morning) Yes	Date Collected				
	○ No					
Spot Urine		Date Collected	Additional Date Collected	If necessary	Additional Date Collected	If necessary
Spot Unne	OYes	Date Collected	Additional Date Collected	If necessary	Additional Date Collected	Ir necessary
	⊖ No					
B2. Shipped to ARDL	 Yes 	Date Shipped				
	O No					

Protocol ID: PERL001 Study Name: PERL Site:			Study Subject ID: Study Subject DOB:
Event Name: Visit 7			
Event Date:	_		
Section Title: Section C.	Biospecimens for Reposit	ory	
	⊖Yes ⊖No		
C1. Serum Collected	⊖ Yes ○ No	Date Collected	
C2. Plasma Collected	⊖ Yes ⊙ No	Date Collected	
C3. Urine Collected	○ Yes ○ No	Date Collected	
C3a. Protease Inhibitor Added	○ Yes ○ No		
C4. Shipped to ARDL	⊖ Yes ○ No	Date: Shipped	

Protocol ID: PERL001 Study Name: PERL					Study Subject ID: Study Subject DOB:
Site: Event Name: Visit 7 Event Date:					
Event Date:	_		PERL	_011_Skin Assessment - V3.0	
Section Title: Skin Asse	ssment				
Indicate who performe Select: *					
Was any rash present of	Clinician Assessment				
	⊖Yes ⊙No				
A1. Has the participant	Not Assessed	ore-rash Stevens-Johnson	Syndrome (SJS) symptoms?		
Select:	○Yes ○No ○Not Assessed				
Select all that apply:	Cine Aucasa				
Fever	□Fever				
Duration:	(days)				
Maximum temperature:		Celsius or Farenheit:	0 °C 0 °F	Unknown temperature	
Skin tenderness	□Skin tenderness				
Sore throat	□Sore throat				
Photophobia	Photophobia				
Burning eyes					
Itching eyes	Burning eyes				
	□ Itching eyes				
Cough productive of th	ick and purulent sputum				
Headache	Headache				
Malaise	□Malaise				
Arthralgia	□ Arthralgia				
A2. During assessment	, was any swelling or rash	noted?			
Select:	○Yes ○No ○Not Assessed				
Select all that apply:					
Burning rash	Burning rash				
Skin pain	□Skin pain				
Facial swelling	□ Facial swelling				
Tongue swelling					
Red or purple skin rash	□Tongue swelling				
Area of rash (select all	Red or purple skin rash that apply):				
	Face		Chest	Abdomen	
	□Arms		Legs	□ Palms	
Target lesions surrous	□Soles ded by macular erythema		Back		
Hives	Target lesions				
	Hives				
Area of hives (select al	Face		Chest	D Abdomen	
	□Arms		Legs	Patms	
	□ Soles		Back		
Blisters	Blisters				
Area of blisters (select					
	Gace		Chest	Abdomen Patms	
	Soles		Genitals	□ Anel	
	Back				
Shedding	Shedding (sloughing) of skin				
Area of shedding (sele					
	□ Face		Chest	Abdomen Patms	
	Soles		Back		
Denuded skin areas	Denuded skin areas				
Area of denudation (se					
	Face		Chest	Abdomen	
	□ Arms		🗆 Legs	D Palms	

A3. During assessment was any mucous membrane involvement noted?

Select:	Yes		
	No Not Assessed		
Select all that apply:			
Oral mucosa			
	□ Oral mucosa		
Oral mucosa (select a	ll that apply):		
	□Erythema	Edema	Skughing
	Blistering	Ulceration/erosion	Necrosia/aust
Nasal mucosa			
	Nasal mucosa		
Nasal mucosa (select	all that apply):		
	□Erythema	Edema	
	Blistering	Ulceration/erosion	□ Necrois/aust
Eyes			
	□ Eyes		
Eyes (select all that a	pply):		
	Excessive tearing	Hyperemia	
	□Scarring		
Urinary tract			
	Urinary tract		
Urinary Tract (select a	all that apply):		
	Dysuria	Urinary retention	
Pulmonary			
	Pulmonary		
Pulmonary (select all	that apply):		
	Dyspnea	Productive cough	Pumorary edema

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 7 Event Date:				Study Subject ID: Study Subject DO8:	
Event Date:		PERL_019_iGFR Procedures	Form - V3.0		
Section Title: I. iGFR	Procedure				
Upload source docum	nents:				
A1. Was the iGFR Per					
Please Select:	OYes				
	○ No				
If No, Reason: (check all that apply)	ппп				
	BP too high				
	Positive pregnancy test				
	Hyperglycemia				
	□ Hypoglycemia				

If Other, Specify:

□Vomiting □Febrile □Other

Protocol ID: PERL001						Study Subject ID:
Study Name: PERL						Study Subject DOB:
Site:						
Event Name: Visit 7						
Event Date:						
Section Title: II. iGFR	Draw Times					
A2. Date of iGFR:						
Date of iGFR:						
A3. iGFR Collections:						
Start clock at end of Omnipaque injection* (No Sample)	"0" time 00:00					
A4. 120 minutes						
Projected draw time for sample		Actual draw time of sample (24 hour clock):	(00:00)	Glucose value	(mg/dl)	Not Dane
A5. 150 minutes						
Projected draw time for sample		Actual draw time of sample (24 hour clock):	(00:00)	Glucose value	(mg/df)	Not Dane
A6. 180 minutes						
Projected draw time for sample		Actual draw time of sample (24 hour clock):	(00:00)	Glucose value	(mg/dl)	□ Not Done
A7. 210 minutes						
Projected draw time for sample		Actual draw time of sample (24 hour clock):	(00:00)	Glucose value	(mg/df)	□ Not Done
A8. 240 minutes						
Projected draw time for sample		Actual draw time of sample (24 hour clock):	(00:00)	Glucose value	(mg/dl)	□ Not Done
A9. Samples shipped t	o central lab?					
Please Select:	⊙Yes	Date Samples Shipped:				
I INARA JANAN	O No	ouse sumples Shipped.				
A10. Backup samples	shipped to central lab?					
Please Select:	0 Yes	Date Backup Samples Shipped:				
	⊙No					
	ONA					

rotocol ID: PERL001 kudy Name: PERL ite: ite: vent Name: Visit 7					ubject ID:			
vent Date:								
		PERL_022_Study Drug Compli	iance and Exposure -	V3.0				
Section Title: Study Medication Log								
instructions: Refer to the MOO for deta	ailed instructions and examples. All do	sages and discontinuations must be listed for the entire Dosing Pe	riod.					
The Dosing Period starts with the date ands with the date the subject takes the	the subject takes the first pill from the last pill from the	e shipment received after the prior visit and they received a new shipment of pills.						
Has the subject permanently discontine	used the study drug prior to this dosin	n mania d'A						
01/11	inco the stady drug prior to this dosh	penour:						
• Yes No		i penoura						
		i periour:						
• No		taking pills of the same dose or the last day not taking pills."," omnosteout="UnTig()">Stop Date	Stop Date Unknown	Dosage Dispensed by Pharmacy	Type of Change	Other Type of Change	Reason for Change (select all that apply)	Other Reason for Change
○ No	onmouseout="UnTip()">Start Start Date	taking pills of the same dose or the last day not taking pills.")"	Stop Date Unknown	Pharmacy 0	Type of Change	Other Type of Change	(select all that apply) Lab safety assessment results	
○ No	<u>onmouseout="UnTip()">Start</u> Start Date Unknown	taking pills of the same dose or the last day not taking pills.")"	Unknown	Pharmacy 0 100	 No change Permanently 	Other Type of Change	(select all that apply) Lab safety assessment results Allopurinol contraindicated	Change
○No	<u>onmouseout="UnTip()">Start</u> Start Date Unknown	taking pills of the same dose or the last day not taking pills.")"	Unknown	Pharmacy 0 100 200	No change Permanently discontinued Temporarily	Other Type of Change	(select all that apply) Lab safety assessment results Aliopurinol contraindicated Off-label aliopurinol treatment requi	Change
○ No	<u>onmouseout="UnTip()">Start</u> Start Date Unknown	taking pills of the same dose or the last day not taking pills.")"	Unknown	Pharmacy 0 100 200 300	No change Permanently discontinued Temporarily discontinued	Other Type of Change	(select all that apply) (Lab safety assessment results Allopurinol contraindicated Off-label allopurinol treatment requi Pregnancy or breastfeeding	Change
○ No	<u>onmouseout="UnTip()">Start</u> Start Date Unknown	taking pills of the same dose or the last day not taking pills.")"	Unknown	Pharmacy 0 0 100 200 300 400	No change Permanently discontinued Temporarily discontinued Change in dosage	Other Type of Change	(select all that apply) Lab safety assessment results Allopurinol contraindicated Off-label allopurinol treatment requil Pregnancy or breastfeeding End-stage renal disease	Change ired
○ No	<u>onmouseout="UnTip()">Start</u> Start Date Unknown	taking pills of the same dose or the last day not taking pills.")"	Unknown	Pharmacy 0 100 200 300	No change Permanently discontinued Temporarily discontinued Change in dosage Started treatment	Other Type of Change	Select all that apply □ Lab safety assessment results □ Allopurinol contraindicated □ Off-label allopurinol treatment requir □ Pregnancy or breastfeeding □ End-stage renal disease □ Per protocol change dose after 1st month	Change ired
• No	<u>onmouseout="UnTip()">Start</u> Start Date Unknown	taking pills of the same dose or the last day not taking pills.")"	Unknown	Pharmacy 0 0 100 200 300 400	No change Permanently discontinued Temporarily discontinued Change in dosage Started treatment Restarted treatment	Other Type of Change	[celect all that apph) I lab safety assessment results Alloparino contraindicated Off-label alloparinol treatment requi Pregnancy or breastfeeding IEnd-stage read disease Per protocol change dose after 1st month Change in eGFR	Change ired
• No	<u>onmouseout="UnTip()">Start</u> Start Date Unknown	taking pills of the same dose or the last day not taking pills.")"	Unknown	Pharmacy 0 0 100 200 300 400	No change Permanently discontinued Temporarily discontinued Change in dosage Started treatment	Other Type of Change	[celect all that septy) Lab safey assessment results Alepurinol contraindicated Off-label allopurinol restment requi Pregnancy or breastfeeding Pregnancy or breastfeeding Per protocol change dose after 1st month Change in cGFR Started treatment	Change ired
	<u>onmouseout="UnTip()">Start</u> Start Date Unknown	taking pills of the same dose or the last day not taking pills.")"	Unknown	Pharmacy 0 0 100 200 300 400	No change Permanently discontinued Temporarily discontinued Change in dosage Started treatment Restarted treatment	Other Type of Change	[celect all that apph) I lab safety assessment results Alloparino contraindicated Off-label alloparinol treatment requi Pregnancy or breastfeeding IEnd-stage read disease Per protocol change dose after 1st month Change in eGFR	ired

Protocol ID: PERL001	Study Subject ID:
Study Name: PERL Site:	Study Subject DD8:
Event Name: Visit 7 Event Date:	
Event Date:	
Section Title: Study Drug Exposure	
Instructions: For the entire Dosing Period. The Dosing Period starts with the date the subject takes the first pill from the shipn ends with the date the subject takes the last pill from that shipment because they received a new shipment of pills.	nent received after the prior visit and
1a. Date started using drug vials:	
🗆 Unknown	
1b. Date stopped using drug vials:	
Unknown	
Difference in days:	
1c. Number of pills should have taken if there were no Discontinuations;	
Unknown	
Please explain why the number of pills the subject should have taken is Unknown:	
Prease explain why the number of plus the subject should have taken is Unknown:	
2. Number of pills instructed not to take:	
2. Number of pills instructed not to take: (by vial because the number can be different for each vial) Vial k^+	
Vial B: *	
Vial C *	
Vial D: *	
Total number of pills instructed not to take:	
3. Number of pills should have taken: (by vial because the number can be different for each vial)	
(by via because the number can be different for each via) Via A:	
Vial B:	
Vial C	
Vial D:	
Total number of pills should have taken:	
4. Number of pills dispensed: (by vial because the number can be different for each vial) $_{\rm Vid\;A^{-*}}$	
Vial B: *	
Vial C *	
Vial D: *	
Total number of pills dispensed:	
5. Were pills returned in individual vials:	
* 0Ys	
○ No ○ Pills not returned	
Number of Pills Patron of	
Number of Pills Returned: (by vial because the number can be different for each vial)	
Via A:	
Vial C	
Vial D:	
Total number of pills returned:	
Total number of pills returned:	
<u>6. Number of pills taken:</u> (by vial because the number can be different for each vial)	
Vial A:	
Vial B:	
Vial C:	
Vial D:	
Total number of pills taken:	
Total number of pills taken:	
7. Select the reason Drug Compliance cannot be calculated at this visit:	
* Osubject di not return pils	
○ Pils were lost	
Start date and/or Stop date unknown Not applicable	
O Other	
If Other, Specify:	

Protocol ID: PERLO01	Study Subject ID:
Study Name: PERL	Study Subject DOB:
Site:	
Event Name: Visit 7	
Event Date:	
Section Title: % Compliant Calculation	
B1. Percent Compliant (ff total pills taken reported by the 4 individual vials)	

.

You can now return to the Compliance tab to review subject's compliance and if you wish, the Exposure tab to review pill counts and calculations.

□ Confirm form is complete and source document uploaded.

Visit 8: PERL_006_Blood Pressure and Measurements - V1.0 PERL_008_Local Laboratory Results - V5.0 PERL_012_Central Lab Specimen Collection - V4.0 PERL_013_Skin Assessment - V3.0 PERL_022_Skind Porg Compliance and Exposure - V3.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 8	-		Study Subject ID Study Subject DOB
Event Date:			PERL_006_Blood Pressure and Measurements - V1.0
Section Title: Blood	Pressure and Heart Rate		
Subtitle:			
Measurements:			
A1. Weight:	(kg)	Not Done	
A2. Height:	(cm)	Not Done	
Upload Source Docu	uments:		
Blood Pressure:			
B1. First Reading			
B1a. Systolic:	(mmHg)		
B1b. Diastolic:	(mmHg)	BP Not Done	
B1c. Heart Rate:	(bpm)	HR Not Done	
B2. Second Reading	g		
B2a. Systolic:	(mmHg)		
B2b. Diastolic:	(mmHg)	BP Not Done	
B2c. Heart Rate:	(bpm)	HR Not Done	
B3. Third Reading			
B3a. Systolic:	(mmHg)		
B3b. Diastolic:	(mmHg)	BP Not Done	
B3c. Heart Rate:	(bpm)	HR Not Done	

Protocol ID: PERL001 Study Name: PERL		Study Subject ID: Study Subject DOB:
Site: Event Name: Visit 8		
Event Date:	-	
Section Title: Average B Subtitle:	ood Pressure and Heart Rate	
Calculated Fields:		
BMI BMI:		
Blood Pressure		
Systolic:	(mmHg)	
Diastolic:	(mmHg)	
Heart Rate:	(bpm)	

Protocol ID: PERL001	Study Subject ID:					
Study Name: PERL	Study Subject DOB:					
Site:						
Event Name: Visit 8						
Event Date:						
PERL 008 Local Laboratory Results - V5.0						
FERL_006_LOCAL LABORATOR Y RESULTS - 43.0						
Section Title: Section A. Chemistry						
Subtitle:						
Instructions: Enter the lab values in the units indicated with the date of collection for each field. Use the "Not Done" checkbox provided if data is unobtainable.						
Upload source documents:	Upload source documents:					
Chemistry:						

A1. Potassium:	(mmol/L)	Date Collected:	□ Not Done
A2. Creatinine:	(mg/dl)	Date Collected:	□ Not Done
A3. ALT (SGPT):	(U/L)	Date Collected:	Not Done

Protocol ID: PERL001 Study Name: PERL Site: ______ Event Name: Visit 8 Event Date: _____ Study Subject ID:_____ Study Subject DOB:_____ Section Title: Section B. CBC Subtitle: B1. Hemoglobin: Date Collected: (gm/dl) □ Not Done B2. Hematocrit: (%) Date Collected: □ Not Done B3. Platelets: (mmol) Date Collected: □ Not Done (million cells/mcL) B4. RBC: Date Collected: Not Done B5. WBC: (cells/mcL) Date Collected: □ Not Done B5a. Neutrophils: (%) Not Done B5b. Lymphocytes: (%) Not Done B5c. Monocytes: (%) Not Done B5d. Eosinophils: (%) Not Done (%) B5e. Basophils: Not Done

Protocol ID: PERL001 Study Name: PERL Ste: Event Name: Visit 8 Event Date:			Study Subject ID: Study Subject DOR:
Section Title: Section C. P	regnancy Test		
C1. Urine Pregnancy Test Result:	 Positive Negative Not Done Not Applicable 	Date of test:	
C2. Serum Pregnancy Test Result:	 Positive Negative Not Done Not Applicable 	Date of test:	

Protocol ID: PERL001			Study Subject ID:
Study Name: PERL			Study Subject DOB:
äte:			
Event Name: Visit 8			
Event Date:	_		
Section Title: Section D.	Urino Multistix		
Section file. Section D.	onne Huitibux		
Date Urine Collected:		Not Done	
D1. Leukocytes:	O Negative		
	O Trace		
	○ Small		
	O Moderate		
	 Large 		
D2. Nitrites:	O Negative		
	O Positive		
3. Protein:	O Negative		
	 Trace 		
	O 30		
	100		
	○ 300		
	O 2000+		
D4. Blood	O Negative		
	 Positive 		
	Oreanic		
Ma. Blood – Non Hemolyzed:	 None 		
	 Trace 		
	O Moderate		
4b. Blood – Hemolyzed:	 None 		
	 Trace 		
	Small		
	O Moderate		
	 Large 		
6. Ketones:	0. Hu Hu -		
na mutana.	 Negative Trace 		
	O Irace		
	O Small O Moderate		
	 Large 		
	U Laige		

Protocol ID: PERL001	Study Subject ID:
Study Name: PERL	Study Subject DOB:
Site:	
Event Name: Visit 8	
Event Date:	
Section Title: Section E. eGFR	
Subtitle:	
E1. Indicate visit for which this eGFR values applies:	
O Visit 1	
○ Visits 6-15	
E2. Use central lab creatinine value to calculate eGFR	
Click Here to Calculate eGFR	
Central lab creatinine value	
E3. Use local lab creatinine value to calculate eGFR Click Here to Calculate eGFR	
Loca lab creatine vole	
E4. eGFR: (mls/min/1.73m ²) Date Collected:	Not Done

(mls/min/1.73m²) Date Collected: E4. eGFR:

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 8 Event Date:				Study Subject IDC Study Subject DOB:
		PERL_010 Central Lab Specimen Co	llection - V4.0	
Section Title: Section A. B	lood Specimens			
Instructions: Please indicate the collect	ted specimens and prov	de the date of collection.		
A1. Serum Uric Acid, Creatinine, Cystatin C Collected	⊖ Yes ⊖ No	Date Collected		
A2. HbA1c Collected	○Yes ○No ○NA-if visit 6	Date Calected		
A3. Shipped to ARDL	ି Yes ି No	Date Stipped		

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 8 Event Date:	_					Study Subject IDC Study Subject DDB:
Section Title: Section B	. Urine Specimens					
B1. ACR/AER Collected	ਂ Yes ਂ No ਂ NA-ਜੋfvisit 6_8_10_12 or 14					
Overnight	⊖Yes ⊖No	Date Ended Collection				
First Morning	○Yes ○No	Date Collected				
Spot Urine	⊖Yes ⊖No	Date Collected	Additional Date Collected	If necessary	Additional Date Collected	If necessary
B2. Shipped to ARDL	⊖ Yes ○ No	Date Shipped				

Protocol ID: PERL001 Study Name: PERL Site:			Study Subject ID: Study Subject DOB:
Event Name: Visit 8			
Event Date:	_		
Section Title: Section C	Biospecimens for Reposit	ory	
Is this Visit 4, 11, 16 or 17	⊖Yes ⊖No		
C1. Serum Collected	⊖ Yes ○ No	Date Collected	
C2. Plasma Collected	⊖ Yes ⊖ No	Date Collected	
C3. Urine Collected	⊖ Yes ⊖ No	Date Collected	
C3a. Protease Inhibitor Added	○ Yes ○ No		
C4. Shipped to ARDL	⊖ Yes ⊙ No	Date: Shipped	

Protocol ID: PERL001 Study Name: PERL					Study Subject ID: Study Subject ID::
Site: Event Name: Visit 8 Event Date:					
Event Date:	_		PERL_	011_Skin Assessment - V3.0	
Section Title: Skin Asse	ssment				
Indicate who performe Select: *					
Was any rash present of	Clinician Assessment				
•	⊖Yes ⊙No				
A1. Has the participant	Not Assessed	-rash Stevens-Johnson	Syndrome (SJS) symptoms?		
Select:	○Yes ○No ○Not Assessed				
Select all that apply:					
Fever	□Fever				
Duration:	(days)				
Maximum temperature:		Celsius or Farenheit:	○ °C ○ °F	Unknown temperature	
Skin tenderness	Skin tenderness				
Sore throat	□ Sore throat				
Photophobia					
Burning eyes	Photophobia				
	Burning eyes				
Itching eyes	□ Itching eyes				
Cough productive of th	ick and purulent sputum				
Headache	Headache				
Malaise	□Malaise				
Arthralgia	□ Arthralgia				
A2. During assessment	, was any swelling or rash no	ted?			
Select:	○ Yes ○ No ○ Not Assessed				
Select all that apply:					
Burning rash	Burning rash				
Skin pain	⊡Skin pain				
Facial swelling	Facial swelling				
Tongue swelling					
Red or purple skin rash	Tongue swelling				
Area of rash (select all	Red or purple skin rash				
Alles of fusin (select all	Face		Chest	Abdomen	
	□Arms		🗆 Legs	Paims	
	□ Soles		Back		
	ded by macular erythema Target lesions				
Hives	Hives				
Area of hives (select al	That apply): Face		Chest	□ Abdomen	
	□ Arms			Pains	
	□ Soles		Back		
Blisters	Blisters				
Area of blisters (select					
	Face Arms		Chest	Abdomen Palms	
	Soles		Genitals	- Anal	
	Back				
Shedding	Shedding (sloughing) of skin				
Area of shedding (selec					
	□ Face		Chest	□ Abdomen	
	□ Arms		🗆 Legs	Palms	
Denuded skin areas	Denuded skin areas				
Area of denudation (se					
	Face		Chest	Abdomen	
	□ Arms		🗆 Legs	Palms	
	□ Soles		Back		

A3. During assessment was any mucous membrane involvement noted?

Select:	Yes		
	No Not Assessed		
Select all that apply:			
Oral mucosa			
	Oral mucosa		
Oral mucosa (select a	ll that apply):		
	□Erythema	Edema	Skughing
	Blistering	Ulceration/erosion	Necrosia/aust
Nasal mucosa			
	Nasal mucosa		
Nasal mucosa (select	all that apply):		
	□Erythema	Edema	
	Blistering	Ulceration/erosion	□ Necrois/aust
Eyes			
	Eyes		
Eyes (select all that a	oply):		
	□ Excessive tearing	Hyperemia	
	□Scarring		
Urinary tract			
	Urinary tract		
Urinary Tract (select a	all that apply):		
	□ Dysuria	Urinary retention	
Pulmonary			
	Pulmonary		
Pulmonary (select all	that apply):		
	Dyspnea	Productive cough	Pumorary edema

Protocol ID: PERL001 Study Name: PERL Stee: Event Name: Viol 8 Event Oate:					bject ID: bject DOB:			
Event Date:		PERL_022_Study Drug Compliance	and Exposure -	V3.0				
Section Title: Study Medication Log Instructions: Refer to the MOO for detailed instructions and en The Dosing Period starts with the date the subject takes the first ends with the date the subject takes the last pill from that shill Has the subject permanently discontinued the study drug prior "Vis ONo	rst pill from the soment because the	ey received a new shipment of pills.						
will be the previous line. Stop Date plus 1 day.'," annouseout="UnTip(1">Sta Date	t Start Date Unknown	iaking allic of the same does or the last day not taking alls. 12 ormouseout="UnTip(1">Stop Date	Stop Date Unknown	Dosage: Dispensed by Pharmacy 0 100 200 300 400 (mg/day)	Type of Change No change Permanently discontinued Temporarily discontinued Change in dosage Started treatment Restarted treatment Restarted treatment College	Other Type of Change	Ceclect all that apply) Lab safety assessment results Allopurinol contraindicated OfF-label allopurinol treatment required Pregrancy or breastfeeding End-stage rend disease Per protocol change dose after 1st month Change in eGRR	Other Reason for Change
					Uther specify		Started treatment Restarted treatment Other Specify	

Protocol ID: PERL001	Study Subject ID:
Study Name: PERL Site:	Study Subject DOB:
Event Name: Visit 8 Event Date:	
Event Date:	
Section Title: Study Drug Exposure	
Instructions: For the entire Dosing Period. The Dosing Period starts with the ends with the date the subject takes the last nill from that shipment because	te the subject takes the first pill from the shipment received after the prior visit and ey received a new shipment of pills.
1a. Date started using drug vials:	a reason a subscription of the second s
	nkoovn
1b. Date stopped using drug vials:	
	nkrown
Difference in days:	
1c. Number of pills should have taken if there were no Discontinuations:	
	rakowa
Please explain why the number of pills the subject should have taken is Unk	
Frease explain why the number of pills the subject should have taken is onk	
2. Number of pills instructed not to take: (by vial because the number can be different for each vial) Vial k *	
(by vial because the number can be different for each vial) Vial A: *	
Vial B: *	
Vial C: *	
Vial D: *	
Total number of pills instructed not to take:	
3. Number of pills should have taken: (by vial because the number can be different for each vial)	
Vial A:	
Vial B:	
Vial C:	
Viel D:	
Total number of pills should have taken:	
4. Number of pills dispensed: (by vial because the number can be different for each vial) ${\rm Via} {\cal K}^*$	
Vial B: *	
Vial C: *	
Vial D: *	
Total number of pills dispensed:	
5. Were pills returned in individual vials:	
* Yes	
No Pills not returned	
Number of Dills Determined	
Number of Pills Returned: (by vial because the number can be different for each vial)	
Vial A:	
Vial B:	
Vial C:	
Vial D:	
Total number of pills returned:	
Total number of pills returned:	
 S. Number of pills taken: (by vial because the number can be different for each vial) 	
Vial A:	
Vial B:	
Vial C:	
Vial D:	
Total number of pills taken:	
Total number of pills taken:	
7. Select the reason Drug Compliance cannot be calculated at this visit:	
Subject did not return pills Osubject did not return pills Opilis were thrown away	
Pills were lost	
 Start date and/or Stop date unknown Not applicable 	
Other	
If Other, Specify:	

Protocol ID: PERL001	Study Subject ID:
Study Name: PERL	Study Subject DOB:
Site:	
Event Name: Visit 8	
Event Date:	
Section Title: % Compliant Calculation	
B1. Percent Compliant (if total pills taken reported by the 4 individual vials)	

.

You can now return to the Compliance tab to review subject's compliance and if you wish, the Exposure tab to review pill counts and calculations.

□ Confirm form is complete and source document uploaded.

Visit 9: PERL_006_Blood Pressure and Measurements - V1.0 PERL_008_Local Laboratory Results - V5.0 PERL_012_Central Lab Specimen Collection - V4.0 PERL_013_Skin Assessment - V3.0 PERL_022_Skind Porg Compliance and Exposure - V3.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: PERL001 Study Name: PERL Site:			Study Subject ID: Study Subject DOB:
Event Name: Visit 9			
Event Date:			
			PERL_006_Blood Pressure and Measurements - V1.0
Section Title: Blood	Pressure and Heart Rate		
Subtitle:			
Measurements:			
A1. Weight:	(kg)	Not Done	
A2. Height:	(cm)	Not Done	
Upload Source Doc	uments:		
Blood Pressure:			
B1. First Reading			
B1a. Systolic:	(mmHg)		
B1b. Diastolic:	(mmHg)	BP Not Done	
B1c. Heart Rate:	(bpm)	U HR Not Done	
B2. Second Reading			
B2a. Systolic:	(mmHg)		
B2b. Diastolic:	(mmHg)	BP Not Done	
B2c. Heart Rate:	(bpm)	HR Not Done	
B3. Third Reading			
B3a. Systolic:	(mmHg)		
B3b. Diastolic:	(mmHg)	BP Not Done	
B3c. Heart Rate:	(bpm)	HR Not Done	

Protocol ID: PERL001 Study Name: PERL		Study Subject ID: Study Subject DOB:
Site:		Sudy Sudjett DOB
Event Name: Visit 9		
Event Date:	-	
	ood Pressure and Heart Rate	
Subtitle:		
Calculated Fields:		
BMI		
BMI:		
Blood Pressure		
Systolic:	(mmHg)	
Diastolic:	(mmhg)	
Heart Rate:	(topm)	

Protocol ID: FERLIDO1 Study Name: FRR State	Study Subject ID: Study Subject DO8:
Event Date:	
PERL_008_Local Laboratory Results - V5.0	
Section Title: Section A. Chemistry	
Subtitle:	
Instructions: Enter the lab values in the units indicated with the date of collection for each field. Use the "Not Done" checkbox provided if data is unobtainable.	
Upload source documents:	
Chemistry:	

Protocol ID: PERL001 Study Name: PERL Site: ______ Event Name: Visit 9 Event Date: _____ Study Subject ID:_____ Study Subject DOB:_____ Section Title: Section B. CBC Subtitle: B1. Hemoglobin: Date Collected: (gm/dl) □ Not Done B2. Hematocrit: (%) Date Collected: □ Not Done B3. Platelets: (mmol) Date Collected: □ Not Done (million cells/mcL) B4. RBC: Date Collected: Not Done B5. WBC: (cells/mcL) Date Collected: □ Not Done B5a. Neutrophils: (%) 🗆 Not Done B5b. Lymphocytes: (%) 🗆 Not Done B5c. Monocytes: (%) Not Done B5d. Eosinophils: (%) Not Done (%) B5e. Basophils: Not Done

Protocol ID: PERL001 Study Name: PERL Ste: Event Name: Visit 9 Event Date:			Study Subject ID: Study Subject DOR:
Section Title: Section C. P	regnancy Test		
C1. Urine Pregnancy Test Result:	 Positive Negative Not Done Not Applicable 	Date of test:	
C2. Serum Pregnancy Test Result:	 Positive Negative Not Done Not Applicable 	Date of test:	

Protocol ID: PERL001			Study Subject ID:
Study Name: PERL			Study Subject DOB:
Site:			
Event Name: Visit 9			
Event Date:	_		
Section Title: Section D.	Urine Multistix		
Date Urine Collected:		Not Done	
D1. Leukocytes:	O Negative		
	 Trace 		
	○ Small		
	O Moderate		
	 Large 		
D2. Nitrites:	O Negative		
	 Positive 		
D3. Protein:	Negative		
	⊖ Trace		
	O 30		
	0 100		
	0 300		
	C 2000+		
	0.20001		
D4. Blood	O Negative		
	 Positive 		
	Ordanic		
D4a. Blood - Non Hemolyzed:	 None 		
ona. bibba mannenia yaca.	O Trace		
	 Moderate 		
	O Houerate		
D4b. Blood - Hemolyzed:	None		
	O Trace		
	○ Small		
	 Moderate 		
	O Large		
	Ar		
D6. Ketones:	O Negative		
	O Trace		
	O Small		
	O Moderate		
	O Large		
	- Laige		

Protocol ID: PERLOD1	Study Subject ID:
Study Name: PERL	Study Subject DOB:
Site:	
Event Name: Visit 9	
Event Date:	
Section Title: Section E. eGFR	
Subtitle:	
E1. Indicate visit for which this eGFR values applies:	
○Visit 1	
○ Visits 6-15	
E2. Use central lab creatinine value to calculate eGFR	
Click Here to Calculate eGFR	
Central lab creatinine value	
E3. Use local lab creatinine value to calculate eGFR	
Click Here to Calculate eGFR	
Local lab creatinine value	
E4. eGFR: (mls/min/1.73m ²) Date Collected:	Not Done

Protocol ID: PERL001 Study Name: PERL Stte: Event Name: Visit 9 Event Date:				Study Subject ID: Study Subject DD8:
		PERL_010 Central Lab Specimen Colleg	ction - V4.0	
Section Title: Section A. B	lood Specimens			
Instructions: Please indicate the collect	ted specimens and prov	de the date of collection.		
A1. Serum Uric Acid, Creatinine, Cystatin C Collected	⊖ Yes ⊖ No	Date Callected		
A2. HbA1c Collected	○Yes ○No ○NA-if visit 6	Date Collected		
A3. Shipped to ARDL	ି Yes ି No	Date Shipped		

Protocol ID: PERL001						Study Subject ID:
Study Name: PERL						Study Subject DOB:
Site:						
Event Name: Visit 9						
Event Date:						
Section Title: Section B.	. Urine Specimens					
B1. ACR/AER Collected	ः Yes					
	O No					
	O NA-if visit 6_8_10_12 or 14					
Overnight	⊖Yes	Date Ended Collection				
	⊖ No					
First Morning	⊖Yes	Date Collected				
-	⊖ No					
Spot Urine	⊖Yes	Date Collected	Additional Date Collected	If necessary	Additional Date Collected	If necessary
	⊙ No					
B2. Shipped to ARDL	ा Yes	Date Shipped				
B2. Shipped to ARDL	0 No	Date Shipped				

Protocol ID: PERL001 Study Name: PERL Site:		
Event Name: Visit 9 Event Date:		
Section Title: Section C	. Biospecimens fo	or Repository
Is this Visit 4, 11, 16 or 17	⊖Yes ⊙No	
C1. Serum Collected	ି Yes ି No	Date Collected
C2. Plasma Collected	⊖ Yes ⊖ No	Date Collected
C3. Urine Collected	⊖ Yes ⊙ No	Date Collected
C3a. Protease Inhibitor Added	○ Yes ○ No	
C4. Shipped to ARDL	⊖ Yes ⊙ No	Date Shipped

Protocol ID: PERL001 Study Name: PERL					Study Subject ID: Study Subject ID::
Site: Event Name: Visit 9 Event Date:					
Event Date:	_		PERL	_011_Skin Assessment - V3.0	
Section Title: Skin Asse	ssment				
Indicate who performe Select: *					
Was any rash present of	Clinician Assessment				
	⊖Yes ⊙No				
A1. Has the participant	Not Assessed t had any of the following p	ore-rash Stevens-Johnson	Syndrome (SJS) symptoms?		
Select:	○Yes ○No ○Not Assessed				
Select all that apply:	Cinc Addata				
Fever	□Fever				
Duration:	(days)				
Maximum temperature:		Celsius or Farenheit:	0 °C 0 °F	Unknown temperature	
Skin tenderness	□Skin tenderness				
Sore throat	□Sore throat				
Photophobia					
Burning eyes	Photophobia				
Itching eyes	Burning eyes				
	□ Itching eyes				
Cough productive of th	ick and purulent sputum				
Headache	Headache				
Malaise	□Malaise				
Arthralgia	□ Arthralgia				
A2. During assessment	, was any swelling or rash	noted?			
Select:	○Yes ○No ○Not Assessed				
Select all that apply:					
Burning rash	Burning rash				
Skin pain	□Skin pain				
Facial swelling	□ Facial swelling				
Tongue swelling					
Red or purple skin rash	□Tongue swelling				
Area of rash (select all	Red or purple skin rash that apply):				
	Face		Chest	Abdomen	
	□Arms		Legs	□ Palms	
Target lesions surrous	□Soles ded by macular erythema		Back		
	□ Target lesions				
Hives	Hives				
Area of hives (select al	Face		Chest	D Abdomen	
	□Arms		Legs	Patms	
	□ Soles		Back		
Blisters	Blisters				
Area of blisters (select					
	Gace		Chest	Abdomen Patms	
	Soles		Genitals	□ Anel	
	Back				
Shedding	Shedding (sloughing) of skin				
Area of shedding (selec					
	□ Face		Chest	Abdomen Patms	
	Soles		Back		
Denuded skin areas	Denuded skin areas				
Area of denudation (se					
	Face		Chest	Abdomen	
	□ Arms		🗆 Legs	Paims	

A3. During assessment was any mucous membrane involvement noted?

Select:	Yes		
	No Not Assessed		
Select all that apply:			
Oral mucosa			
	□ Oral mucosa		
Oral mucosa (select a	ll that apply):		
	□Erythema	Edema	Skughing
	Blistering	Ulceration/erosion	Necrosia/aust
Nasal mucosa			
	Nasal mucosa		
Nasal mucosa (select	all that apply):		
	□ Erythema	Edema	
	Blistering	Ulceration/erosion	□ Necrois/aust
Eyes			
	□ Eyes		
Eyes (select all that a	pply):		
	Excessive tearing	Hyperemia	
	□Scarring		
Urinary tract			
	Urinary tract		
Urinary Tract (select a	all that apply):		
	Dysuria	Urinary retention	
Pulmonary			
	Pulmonary		
Pulmonary (select all	that apply):		
	Dyspnea	Productive cough	Pumorary edema

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit. 9					ubject ID:ubject DOB:			
Event Date:		PERL_022_Study Drug Compli	ance and Exposure -	V3.0				
Section Title: Study Medication Log Instructions: Refer to the MOO for detailed instructions as The Dosing Period starts with the date the subject takes ends with the date the subject takes the last pill from this Has the subject permanently discontinued the study dru Oto	the first pill from the at shipment because	they received a new shipment of pills.	iod.					
ill be the previous line Stop Date plus 1 day.')" onmouseout="UnTip[ate)"≥Start Start Date Unknown	taking pills of the same dose or the last day not taking pills.")" onmouscout="UnTip()">Stop Date	Stop Date Unknown	Dosage Dispensed by Pharmacy	Type of Change	Other Type of Change	Reason for Change (select all that apply)	Other Reason fo
	Unknown		Unknown	0 100 200 300	 No change Permanently discontinued Temporarily discontinued Change in dosage 		Lab safety assessment results Allopurinol contraindicated Off-label allopurinol treatment requires Pregnancy or breastfeeding LEnd-stage renal disease	

Protocol ID: PERL001 Study Name: PERL	Study Subject ID Study Subject DOB:
Site:	July supply box
Event Nate:	
Section Title: Study Drug Exposure	
Instructions: For the entire Dosing Period. The Dosing Period starts with the date ends with the date the subject takes the last pill from that shipment because the	e subject takes the first pill from the shipment received after the prior visit and eceived a new shipment of pills.
1a. Date started using drug vials:	
⊡ Uri	vn
1b. Date stopped using drug vials:	
	vn
Difference in days:	
1c. Number of pills should have taken if there were no Discontinuations:	
	n
Please explain why the number of pills the subject should have taken is Unknow	
2. Number of pills instructed not to take: (by vial because the number can be different for each vial)	
Vial A: *	
Vial B: *	
Vial C: * Vial D: *	
Total number of pills instructed not to take:	
3. Number of pills should have taken: (by vial because the number can be different for each vial) Visl λ:	
Vial B:	
Vial C:	
Vial D:	
Total number of pills should have taken:	
4. Number of pills dispensed:	
4. Number of pills dispensed: (by vial because the number can be different for each vial) Vial k *	
Vial B: *	
Vial C *	
Vial D: *	
Total number of pills dispensed:	
5. Were pills returned in individual vials: * OYes	
○ No ○ Pilis not returned	
Number of Pills Returned: (by vial because the number can be different for each vial)	
(by vial because the number can be different for each vial) Vial A:	
Vial B:	
Vial C:	
Vial D:	
Total number of pills returned:	
Total number of pills returned:	
6. Number of pills taken: (by vial because the number can be different for each vial)	
(by vial because the number can be different for each vial) Vial A:	
Vial B:	
Vial C:	
Vial D:	
Total number of pills taken:	
Total number of pills taken:	
7. Select the reason Drug Compliance cannot be calculated at this visit:	
O Subject did not return pills Pills were thrown away	
 Pills were lost Start date and/or Stop date unknown 	
O Not applicable Other	
If Other, Specify:	

Protocol ID: PERL001	Study Subject ID:
Study Name: PERL	Study Subject DOB:
Site:	
Event Name: Visit 9	
Event Date:	
Section Title: % Compliant Calculation	
B1. Percent Compliant (if total pills taken reported by the 4 individual vials)	
B2. Percent Compliant (if vials not returned and total pills taken reported as a total only)	

.

You can now return to the Compliance tab to review subject's compliance and if you wish, the Exposure tab to review pill counts and calculations.

□ Confirm form is complete and source document uploaded.

Visit 10: PERL_006_Blood Pressure and Measurements - V1.0 PERL_008_Local Laboratory Results - V5.0 PERL_012_Central Lab Specimen Collection - V4.0 PERL_021_Skin Assessment - V3.0 PERL_022_Skind Porg Compliance and Exposure - V3.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 10			Study Subject ID: Study Subject DOB:
Event Date:			PERL_006_Blood Pressure and Measurements - V1.0
Section Title: Blood I	Pressure and Heart Rate		
Subtitle:			
Measurements:			
A1. Weight:	(kg)	Not Done	
A2. Height:	(cm)	Not Done	
Upload Source Docu	ments:		
Blood Pressure:			
B1. First Reading			
B1a. Systolic:	(mmHg)		
B1b. Diastolic:	(mmHg)	BP Not Done	
B1c. Heart Rate:	(bpm)	HR Not Done	
B2. Second Reading			
B2a. Systolic:	(mmHg)		
B2b. Diastolic:	(mmHg)	BP Not Done	
B2c. Heart Rate:	(bpm)	HR Not Done	
B3. Third Reading			
B3a. Systolic:	(mmHg)		
B3b. Diastolic:	(mmHg)	BP Not Done	
B3c. Heart Rate:	(bpm)	HR Not Done	

Protocol ID: PERL001 Study Name: PERL		Study Subject ID: Study Subject DOB:
Site:		
Event Name: Visit 10		
Event Date:	-	
Section Title: Average B	ood Pressure and Heart Rate	
Subtitle:		
Calculated Fields:		
BMI		
BMI:		
Blood Pressure		
Systolic:	(mmHg)	
Diastolic:	(mmHg)	
Heart Rate:	(čpm)	

Protocol ID: PERL001	Study Subject ID:
Study Name: PERL	Study Subject DOB:
Site:	
Event Name: Visit 10	
Event Date:	
	PERL_008_Local Laboratory Results - V5.0
Section Title: Section A. Chemistry	
Subtitle:	
Instructions: Enter the lab values in the units indicated with the date of col	on for each field. Use the "Not Done" checkbox provided if data is unobtainable.
Upload source documents:	
Chemistry:	
chamba ji	
At Patronica (and 12) Data Calendaria	

A1. Potassium:	(mmal/L)	Date Collected:	□ Not Done
A2. Creatinine:	(mg/dl)	Date Collected:	□ Not Done
A3. ALT (SGPT):	(U/L)	Date Collected:	□ Not Done

Protocol ID: PERL001 Study Name: PERL Site: ______ Event Name: Visit 10 Event Date: ______ Study Subject ID:_____ Study Subject DOB:_____ Section Title: Section B. CBC Subtitle: B1. Hemoglobin: Date Collected: (gm/dl) □ Not Done B2. Hematocrit: (%) Date Collected: □ Not Done B3. Platelets: (mmol) Date Collected: □ Not Done (million cells/mcL) B4. RBC: Date Collected: Not Done B5. WBC: (cells/mcL) Date Collected: □ Not Done B5a. Neutrophils: (%) 🗆 Not Done B5b. Lymphocytes: (%) 🗆 Not Done B5c. Monocytes: (%) Not Done B5d. Eosinophils: (%) Not Done (%) B5e. Basophils: Not Done

Protocol ID: PERL001 Study Name: PERL Ste: Event Name: Visit 10 Event Date:			Study Subject ID: Study Subject DOR:
Section Title: Section C. P	regnancy Test		
C1. Urine Pregnancy Test Result:	 Positive Negative Not Done Not Applicable 	Date of test:	
C2. Serum Pregnancy Test Result:	 Positive Negative Not Done Not Applicable 	Date of test:	

Protocol ID: PERL001			Study Subject ID:
Study Name: PERL			Study Subject DOB:
Site:			
Event Name: Visit 10			
Event Date:	_		
Section Title: Section D.	Urine Multistix		
Date Urine Collected:		Not Done	
D1. Leukocytes:	O Negative		
	○ Trace		
	○ Small		
	O Moderate		
	Large		
D2. Nitrites:	O Negative		
	O Positive		
D3. Protein:	O Negative		
	 Trace 		
	O 30		
	○ 100		
	O 300		
	C 2000+		
D4. Blood	O Negative		
	 Positive 		
D4a. Blood - Non Hemolyzed:	O None		
	 Trace 		
	O Moderate		
D4b. Blood – Hemolyzed:	None		
	 Trace 		
	 Small 		
	O Moderate		
	 Large 		
D6. Ketones:	O Negative		
and material	⊖ Trace		
	O Small		
	O Moderate		
	O Large		
	O mige		

Protocol ID: PERL001	Study Subject ID:
Study Name: PERL	Study Subject DOB:
Site:	
Event Name: Visit 10	
Event Date:	
Section Title: Section E. eGFR	
Subtitle:	
E1. Indicate visit for which this eGFR values applies:	
○ Visit 1	
○ Visits 6-15	
E2. Use central lab creatinine value to calculate eGFR	
Click Here to Calculate GFR	
Central lab creatinine value	
E3. Use local lab creatinine value to calculate eGFR	
Click Here to Calculate eGFR	
Local lab creatinine value	
E4. eGFR: (mls/min/1.73m ²) Date Collected:	Not Done

E4. eGFR: (mls/min/1.73m²) Date Collected:

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 10 Event Date:				Study Subject DD8
		PERL_010 Central Lab Specimen Collection - V	4.0	
Section Title: Section A. B	lood Specimens			
Instructions: Please indicate the collect	ted specimens and prov	ide the date of collection.		
A1. Serum Uric Acid, Creatinine, Cystatin C Collected	⊖ Yes ⊖ No	Date Collected		
A2. HbA1c Collected	○Yes ○No ○NA-if visit 6	DiteCalected		
A3. Shipped to ARDL	ି Yes ି No	Date Shipped		

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 10 Event Date:	_					Study Subject DOR
Section Title: Section E	. Urine Specimens					
B1. ACR/AER Collected	○ Yes ○ No ○ NA-if visit 6_8_10_12 or 14					
Overnight	○Yes ○No	Date Ended Collection				
First Morning	⊖Yes ⊖No	Date Collected				
Spot Urine	⊖Yes ⊖No	Date Collected	Additional Date Collected	If necessary	Additional Date Collected	If necessary
B2. Shipped to ARDL	○ Yes ○ No	Date Shipped				

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 10 Event Date:	-		Study Subject DD: Study Subject DDR:
Section Title: Section C.	Biospecimens for Reposit	ory	
	⊖Yes ⊖No		
C1. Serum Collected	⊖ Yes ⊙ No	Date Collected	
C2. Plasma Collected	⊖ Yes ⊙ No	Date Collected	
C3. Urine Collected	○ Yes ○ No	Date Collected	
C3a. Protease Inhibitor Added	○ Yes ○ No		
C4. Shipped to ARDL	⊖ Yes ⊙ No	Date Stipped	

Protocol ID: PERL001 Study Name: PERL					Study Subject ID: Study Subject DOB:
Site: Event Name: Visit 10 Event Date:					
Event Date:	_		PERL	_011_Skin Assessment - V3.0	
Section Title: Skin Asse	ssment				
Indicate who performe Select: *					
Was any rash present of	O Clinician Assessment				
•	○Yes ○No ○Not Assessed				
A1. Has the participant Select:		re-rash Stevens-Johnson	Syndrome (SJS) symptoms?		
	No Not Assessed				
Select all that apply:					
Fever	□Fever				
Duration: Maximum temperature:	(days)	Celsius or Farenheit:	0 °C	Unknown temperature	
Skin tendemess			0 °F		
	Skin tenderness				
Sore throat	□ Sore throat				
Photophobia	Photophobia				
Burning eyes	Burning eyes				
Itching eyes	□ Itching eyes				
Cough productive of th	ick and purulent sputum				
Headache	🗆 Headache				
Malaise	□ Malaise				
Arthralgia	Arthralgia				
A2. During assessment	, was any swelling or rash (noted?			
Select:	○Yes ○No ○Not Assessed				
Select all that apply:					
Burning rash	□Burning rash				
Skin pain	⊡Skin pain				
Facial swelling	□ Facial swelling				
Tongue swelling	Tongue swelling				
Red or purple skin rash	Red or purple skin rash				
Area of rash (select all					
	□ Face		Chest	Abdomen Paims	
	Soles		Back		
Target lesions surround	ded by macular erythema				
Hives	□Hives				
Area of hives (select al					
	□ Face		Chest	Abdomen Paims	
	Soles		Back		
Blisters	Blisters				
Area of blisters (select					
	□ Face		Chest	Abdomen	
	Soles		Genitals	□ Anal	
	Back				
Shedding	Shedding (sloughing) of skin				
Area of shedding (selec	□ Face		Chest	Abdomen	
	□Arms			Palms	
	□Soles		Back		
Denuded skin areas	Denuded skin areas				
Area of denudation (se	lect all that apply): □Face		Chest	Abdomen	
	Arms			□ Paims	
	□Soles		Back		

A3. During assessment was any mucous membrane involvement noted?

Select:	Yes		
	No Not Assessed		
Select all that apply:			
Oral mucosa			
	Oral mucosa		
Oral mucosa (select a	ll that apply):		
	□Erythema	Edema	Skughing
	Blistering	Ulceration/erosion	Necrosia/aust
Nasal mucosa			
	Nasal mucosa		
Nasal mucosa (select	all that apply):		
	□Erythema	Edema	
	Blistering	Ulceration/erosion	□ Necrois/aust
Eyes			
	Eyes		
Eyes (select all that a	oply):		
	□ Excessive tearing	Hyperemia	
	□Scarring		
Urinary tract			
	Urinary tract		
Urinary Tract (select a	all that apply):		
	□ Dysuria	Urinary retention	
Pulmonary			
	Pulmonary		
Pulmonary (select all	that apply):		
	Dyspnea	Productive cough	Pumorary edema

Rudy Name: PERL Site: Event Name: Visit 10					ubject ID:ubject DOB:			
Event Date:		PERL 022 Study Drug Compli	ance and Exposure -	V3.0				
Section Title: Study Medication Log Instructions: Refer to the MOO for detailed instructions	s and examples. All do	ages and discontinuations must be listed for the entire Dosing Per						
The Dosing Period starts with the date the subject takes ends with the date the subject takes the last pill from the	es the first pill from the	shipment received after the prior visit and						
Has the subject permanently discontinued the study dr	rug prior to this dosing	period?:						
○ No								
ill be the previous line Stop Date plus 1 day.`)" onmouseout="UnTip ate	ip()">Start Start Date Unknown	taking pills of the same dose or the last day not taking pills.)" onmouseout="UnTip()">Stop Date	Stop Date Unknown	Dosage Dispensed by Pharmacy	Type of Change	Other Type of Change	Reason for Change (select all that apply)	Other Reason for Change

Protocol ID: PERL001 Study Name: PERL	Study Subject ID: Study Subject DOB:
Site:	Suby Subject Ood
Event Name: Visit 10 Event Date:	
Section Title: Study Drug Exposure Instructions: For the entire Dosing Period. The Dosing Period starts with the date the subject takes the first pill from the shipm ends with the date the subject takes the last pill from that shipment because they received a new shipment of pills.	ent received after the prior visit and
1a. Date started using drug vials:	
Unknown	
1b. Date stopped using drug vials:	
🗋 Unknown	
Difference in days:	
1c. Number of pills should have taken if there were no Discontinuations:	
🖂 Unknown	
Please explain why the number of pills the subject should have taken is Unknown:	
2. Number of nills instructed not to take:	
2. Number of pills instructed not to take: (by vial because the number can be different for each vial) Vial k *	
Vial B: *	
Vial C *	
Vial D: *	
Total number of pills instructed not to take:	
3. Number of pills should have taken: (by vial because the number can be different for each vial) Vial A:	
Via A:	
Vial C	
Vial D:	
Total number of pills should have taken:	
4. Number of pills dispensed: (by vial because the number can be different for each vial) Via k *	
Vial B: * Vial C: *	
Via D: *	
Total number of pills dispensed:	
5. Were pills returned in individual vials: * OYes	
○ No ○ Pils not returned	
Number of Pills Returned; (by vial because the number can be different for each vial) Via A:	
Via R	
Vial C	
Vial D:	
Total number of pills returned:	
Total number of pills returned:	
6. Number of pills taken: (by vial because the number can be different for each vial)	
(by vial because the number can be different for each vial) Via A:	
Vial B:	
Vial C:	
Vial D:	
Total number of pills taken:	
Total number of pills taken:	
Select the reason Drug Compliance cannot be calculated at this visit: Subject did not return pils	
○PIIs were thrown away ○PIIs were lost	
Stat date and/or Stop date unknown	
⊖ not applicable ○ Other	
If Other, Specify:	

Protocol ID: PERL001	Study Subject ID:
Study Name: PERL	Study Subject DOB:
Site:	
Event Name: Visit 10	
Event Date:	
Section Title: % Compliant Calculation	
B1. Percent Compliant (if total pills taken reported by the 4 individual vials)	
B2. Percent Compliant	

.

You can now return to the Compliance tab to review subject's compliance and if you wish, the Exposure tab to review pill counts and calculations.

Confirm form is complete and source document uploaded.

Visit 11: PERL_005_Blood Pressure and Measurements - V1.0 PERL_005_Loog_Local Laboratory Results - V5.0 PERL_005_LEC6 Report - V1.0 PERL_0101 Central Lab Specimen Collection - V4.0 PERL_011 Central Lab Specimen Collection - V4.0 PERL_0112_EC7 Assessment - V3.0 V3.0 PERL_022_Study Drug Compliance and Exposure - V3.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 11			Study Subject ID0 Study Subject D00
Event Date:			PERL_006_Blood Pressure and Measurements - V1.0
Section Title: Blood	Pressure and Heart Rate		
Subtitle:			
Measurements:			
A1. Weight:	(kg)	Not Done	
A2. Height:	(cm)	Not Done	
Upload Source Docu	uments:		
Blood Pressure:			
B1. First Reading B1a. Systolic:	(mmHg)		
B1b. Diastolic:	(mmHg)	BP Not Done	
B1c. Heart Rate:	(bpm)	III HR Not Done	
B2. Second Reading			
B2a. Systolic:	(mmHg)		
B2b. Diastolic:	(mmHg)	BP Not Done	
B2c. Heart Rate:	(bpm)	HR Not Done	
B3. Third Reading			
B3a. Systolic:	(mmHg)		
B3b. Diastolic:	(mmHg)	BP Not Done	
B3c. Heart Rate:	(bpm)	HR Not Done	

Protocol ID: PERL001 Study Name: PERL Site:		Study Subject ID: Study Subject DOB:
Event Name: Visit 11 Event Date:		
Subtitle:	ood Pressure and Heart Rate	
Calculated Fields:		
BMI BMI:		
Blood Pressure		
Systolic:	(mmHg)	
Diastolic:	(mmhg)	
Heart Rate:	(lapm)	

Protocol ID: PERL001		Study Subject ID:
Study Name: PERL Site:		Study Subject DOB:
Event Name: Visit 11 Event Date:		
Event Date:		
	PERL_007_Physical Examination - V1.0	
Section Title: Body Sys		
A0. Was a physical exa	exam performed at this visit? OYes	
	○ No	
Upload source docume	uments:	
A1 Fyes		
A1. Eyes: Eyes (including fundoscopy):): ONormal OAbnormal	
	Not Done	
If abnormal, describe the select all that apply:	Districtions:	
Select all that apply:		
	Macular Degeneration	
	□ Other	
If other, specify:		
A2. Cardiovascular: Cardiovascular:	O Normal	
	Abnormal Not Done	
If abnormal, describe	be findings:	
Select all that apply:	□ Anthythmia	
	□ Murmur	
	Other	
If other, specify:		
A3. Extremities: Extremities:	⊖Normal	
	Akormal Oktobe	
If abnormal, describe		
Select all that apply:	□ Amputation	
Amputation, specify:		
	Tendemess	
	_ Edema	
	- Pulses	
Pulses:	00+	
	01+ 02+	
	03+ 04+	
	□ Other	
If other, specify:		
A4. Lymph Nodes: Lymph Nodes:		
Lymph Nodes:	O Abnormal	
	○ Not Done	
If abnormal, describe the Select all that apply:	be findings:	
	□ Other	
If other, specify:		
A5. Pulmonary:		
Pulmonary:	Normal Abnormal	
	○ Not Dane	
If abnormal, describe the Select all that apply:	be findings: □Reduced breath sounds	
	- Other	
If other, specify:		
A6. Skin:		
Skin:	O Normal O Abnormal	
	○ Not Done	
If abnormal, describe the select all that apply:	Ced or purple painful rash	
	□Sar	
	- Ecena	
	Portasis	
	Cluces	
	Excessive Bruising	
	□ Other	
If other, specify:	h	
A7. Gastrointestinal: Gastrointestinal:	 Normal 	
	O Abnormal O Not Done	
If abnormal, describe	be findings:	
Select all that apply:	□Axtes	
	Abdominal Mass	
	□ Organomegely	
Organomegaly, specify:		
	Stona	
	□ Other	
If other, specify:		
A8. Musculoskeletal Musculoskeletal:	O Normal	
	O Abnormal Not Done	
If abnormal, describe		
describe		

Select all that apply:	□Sifres
	□Tendanes
	⊡lajay
Injury, specify:	
	Reduced strength
	Reduced range of motion
	□Ober
If other, specify:	
A9. Genitourinary:	
Genitourinary:	Onemal
	○ Abnormal
	Net Done
If abnormal, describe	findings:
Specify:	
A10. Neurological:	
Neurological:	O Normal
	OAbornal
	O Net Done
If abnormal, describe	findings:
Select all that apply:	Abroma Refex Reporte
Abnormal reflex response, spec	fy: Otherstein
) Hypothesia
	Diminished sensition
Abnormal, specify:	
	□Ober
If other, specify:	
,iy.	

Study Subject ID:_____ Study Subject DOB:_____

Protocol ID: PERL001 Study Name: PERL Site: ______ Event Name: Visit 11 Event Date: _____

Section Title: Other Body System

Other Body System A11. Other Body System: Describe

Protocol ID: PERLOD1	Study Subject ID:
Study Name: PERL	Study Subject DOB:
Site:	
Event Name: Visit 11	
Event Date:	
PERL_00	8_Local Laboratory Results - V5.0
Section Title: Section A. Chemistry	
Subtitle:	
Instructions: Enter the lab values in the units indicated with the date of collection for each field. Use the "Not Done" checkbox	x provided if data is unobtainable.
	·
Upload source documents:	
Chemistry:	
Cremiso y:	

A1. Potassium:	(mmal/L)	Date Collected:	□ Not Done
A2. Creatinine:	(mg/dl)	Date Collected:	□ Not Done
A3. ALT (SGPT):	(U/L)	Date Collected:	□ Not Done

Protocol ID: PERL001 Study Name: PERL Site: ______ Event Name: Visit 11 Event Date: ______ Study Subject ID:_____ Study Subject DOB:_____ Section Title: Section B. CBC Subtitle: B1. Hemoglobin: (gm/dl) Date Collected: □ Not Done B2. Hematocrit: (%) Date Collected: □ Not Done B3. Platelets: (mmol) Date Collected: □ Not Done (million cells/mcL) B4. RBC: Date Collected: Not Done B5. WBC: (cells/mcL) Date Collected: □ Not Done B5a. Neutrophils: (%) 🗆 Not Done B5b. Lymphocytes: (%) 🗆 Not Done B5c. Monocytes: (%) Not Done B5d. Eosinophils: (%) Not Done (%) B5e. Basophils: Not Done

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 11 Event Date:			Study Subject ID: Study Subject DOR:
Section Title: Section C. P	regnancy Test		
C1. Urine Pregnancy Test Result:	 Positive Negative Not Done Not Applicable 	Dete of test:	
C2. Serum Pregnancy Test Result:	 Positive Negative Not Done Not Applicable 	Date of test:	

Protocol ID: PERL001			Study Subject ID:
Study Name: PERL			Study Subject DOB:
Site:			
Event Name: Visit 11			
Event Date:	_		
Section Title: Section D.	11.1		
Section Title: Section D.	Unne Multistix		
Date Urine Collected:		Not Done	
D1. Leukocytes:	O Negative		
	O Trace		
	⊖ made		
	 Moderate 		
	⊖ Large		
	Charge		
D2. Nitrites:	O Negative		
	 Positive 		
	ortable		
D3. Protein:	O Negative		
	 Trace 		
	0 30		
	O 100		
	O 300		
	C 2000+		
	0.2001		
D4. Blood	O Negative		
	O Positive		
D4a. Blood - Non Hemolyzed:	O None		
	 Trace 		
	 Moderate 		
D4b. Blood - Hemolyzed:	None		
.,	○ Trace		
	O Small		
	O Moderate		
	○ Large		
	-		
D6. Ketones:	O Negative		
	O Trace		
	O Small		
	 Moderate 		
	○ Large		

Protocol ID: PERL001	Study Subject ID:			
Study Name: PERL	Study Subject DOB:			
Site:				
Event Name: Visit 11				
Event Date:				
Section Title: Section E. eGFR				
Subtitle:				
E1. Indicate visit for which this eGFR values applies:				
○ Visit 1				
⊖ Visits 6-15				
E2. Use central lab creatinine value to calculate eGFR				
Click Here to Calculate eGFR				
Central lab creatinine value				
53 Has band lak searching up to be selected a 255				
E3. Use local lab creatinine value to calculate GFR Cick Here to Calculate GFR Cick Here to Calculate GFR				
Local lab creatinine value				
E4 #GE9- (mis/min/1 73m ²) Data Collector/	Done			
	Done			

E4. eGFR: (mls/min/1.73m²) Date Collected:

Protocol ID: PERL001 Study Name: PERL Site:		Study Subject ID: Study Subject ID:
Event Name: Visit 11 Event Date:	_	
	PERL_009_ECG Report - V1.0	
Section Title: ECG Rep	ort	
ECG Completed? *	○Completed ○Not Completed	
Upload Source Document:		
A1. Date of ECG:		
A2. Heart Rate:	(bpm)	
A3. ECG Findings:	O Normal Abrormal	
A3a. If abnormal (sel	xct all that apply): □ST Bevelon	
	□ Atrial Fib	
	Inversion	
	□Q Wave	
	AV Block	
	□ MI Ohanges	
	□Tachycardia	
	Rradycardia	
	Other	
If Other, Specify:		
A3b. Is this abnormality clinica significant?	y CYes ** If yes, report on AE Log No	

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 11 Event Date:				Study Subject ID: Study Subject DD8:
		PERL_010 Central Lab Sp	ecimen Collection - V4.0	
Section Title: Section A. B	lood Specimens			
Instructions: Please indicate the collect	ted specimens and prov	de the date of collection.		
A1. Serum Uric Acid, Creatinine, Cystatin C Collected	⊖ Yes ⊖ No	Date Callected		
A2. HbA1c Collected	○ Yes ○ No ○ NA-if visit 6	Date Collected		
A3. Shipped to ARDL	⊖Yes ○No	Date Shipped		

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 11 Event Date:	_					Study Subject DOB:
Section Title: Section B	. Urine Specimens					
B1. ACR/AER Collected	○ Yes ○ No ○ NA-if visit 6_8_10_12 or 14					
Overnight	○Yes ○No	Date Ended Collection				
First Morning	⊖Yes ⊖No	Date Collected				
Spot Urine	⊖Yes ⊖No	Date Collected	Additional Date Collected	If necessary	Additional Date Collected	II necessary
B2. Shipped to ARDL	○ Yes ○ No	Date Shipped				

Protocol ID: PERL001 Study Name: PERL				Study Subject ID: Study Subject DOB:	
Site: Event Name: Visit 11 Event Date:					
Section Title: Section C		for Repository			
Is this Visit 4, 11, 16 or 17	⊖Yes ⊙No				
C1. Serum Collected	⊖ Yes ○ No	Date Collected			
C2. Plasma Collected	⊖ Yes ⊙ No	Date Collected			
C3. Urine Collected	⊖ Yes ⊖ No	Date Collected			
C3a. Protease Inhibitor Added	○ Yes ○ No				
C4. Shipped to ARDL	⊖ Yes ⊖ No	Date Shipped			

Protocol ID: PERL001 Study Name: PERL					Study Subject ID: Study Subject ID::
Site: Event Name: Visit 11 Event Date:					
Event Date:	_		PERL	_011_Skin Assessment - V3.0	
Section Title: Skin Asse	ssment				
Indicate who performe Select: *					
Was any rash present of	Clinician Assessment				
•	○Yes ○No ○Not Assessed				
A1. Has the participant Select:		re-rash Stevens-Johnson	Syndrome (SJS) symptoms?		
	No Not Assessed				
Select all that apply:					
Fever	□Fever				
Duration: Maximum temperature:	(days)	Celsius or Farenheit:	°℃	Unknown temperature	
Skin tendemess			⊖ oF		
	□Skin tenderness				
Sore throat	□ Sore throat				
Photophobia	Photophobia				
Burning eyes	Burning eyes				
Itching eyes	□ Itching eyes				
Cough productive of th	ick and purulent sputum				
Headache	- Headache				
Malaise	□ Malaise				
Arthralgia	□ Arthralgia				
A2. During assessment	, was any swelling or rash	noted?			
Select:	○ Yes ○ No ○ Not Assessed				
Select all that apply:					
Burning rash	Burning rash				
Skin pain	⊡Skin pain				
Facial swelling	□ Facial swelling				
Tongue swelling	Tongue swelling				
Red or purple skin rash	Red or purple skin rash				
Area of rash (select all					
	□ Face		Chest	Abdomen Paims	
	Soles		Back		
Target lesions surround	ded by macular erythema				
Hives	Hives				
Area of hives (select al					
	□ Face		Chest	Abdomen Paims	
	Soles		Back		
Blisters	Blisters				
Area of blisters (select					
	Face Arms		Chest	Abdomen Palms	
	Soles		Genitals	□ Anal	
	Back				
Shedding	Shedding (sloughing) of skin				
Area of shedding (selec	□ Face		Chest	Abdomen	
	Arms			Palms	
	□ Soles		Back		
Denuded skin areas	Denuded skin areas				
Area of denudation (se	lect all that apply): □Face		- Chest	Abdomen	
	Arms			□ Paims	
	□ Soles		Back		

A3. During assessment was any mucous membrane involvement noted?

Select:	Yes		
	No Not Assessed		
Select all that apply:			
Oral mucosa			
	□ Oral mucosa		
Oral mucosa (select a	ll that apply):		
	□Erythema	Edema	Skughing
	Blistering	Ulceration/erosion	Necrosia/aust
Nasal mucosa			
	Nasal mucosa		
Nasal mucosa (select	all that apply):		
	□ Erythema	Edema	
	Blistering	Ulceration/erosion	□ Necrois/aust
Eyes			
	□ Eyes		
Eyes (select all that a	pply):		
	Excessive tearing	Hyperemia	
	□Scarring		
Urinary tract			
	Urinary tract		
Urinary Tract (select a	all that apply):		
	Dysuria	Urinary retention	
Pulmonary			
	Pulmonary		
Pulmonary (select all	that apply):		
	Dyspnea	Productive cough	Pumorary edema

Protocol ID: PERL001 Study Name: PERL Site:				Study Subject ID: Study Subject DOB:	
Event Name: Visit 11					
Event Date:					
		PERL_019_iGFR Procedures Form -	V3.0		
Section Title: I. iGFR P	rocedure				
Upload source docume	ents:				
A1. Was the iGFR Perf	ormed?				
Please Select:	⊖Yes				
	⊙ No				
If No, Reason: (check all that apply)	υπ				
	BP too high				
	Positive pregnancy test				
	Hyperglycemia				
	Hypoglycemia				
	□Vamiting				

If Other, Specify:

□Febrile □Other

Protocol ID: PERL001 Study Name: PERL Ster Event Name: Visk 11 Event Date: Section Title: IL iGFR Draw Time	4			Study Subject DOB Study Subject DOB	_
A2. Date of iGFR:	-				
Date of iGFR:					
A3. iGFR Collections: Start clock at <u>end</u> of Omnipaque "0" tim injection* (No Sample)	e 00:00				
A4. 120 minutes					
Projected draw time for sample:	Actual draw time of sample (24 hour clock):	(00:00) Glucose va	lue (mg/dl)	Not Done	
A5. 150 minutes					
Projected draw time for sample:	Actual draw time of sample (24 hour clock):	(00:00) Glucose va	lue (mg/dl)	□ Not Done	
A6. 180 minutes					
Projected draw time for sample:	Actual draw time of sample (24 hour clock):	(00:00) Glucose va	lue (mg/di)	Not Done	
A7. 210 minutes					
Projected draw time for sample:	Actual draw time of sample (24 hour clock):	(00:00) Glucose va	lue (mg/dl)	Not Done	
A8. 240 minutes					
Projected draw time for sample:	Actual draw time of sample (24 hour clock):	(00:00) Glucose va	lue (mg/dl)	Not Done	
A9. Samples shipped to central la	ab?				
Please Select: O Yes No	Date Samples Shipped:				
A10. Backup samples shipped to	central lab?				
Please Select: O Yes No NA	Date Backup Samples Shipped:				

Study Name: PERL Site: Event Name: Visit 11					ubject ID:ubject DOB:		
Event Date:		PERL_022_Study Drug Compli	ance and Exposure -	V3.0			
Section Title: Study Medication Log Instructions: Refer to the MOO for detailed instructions an The Dosing Period starts with the date the subject takes the ends with the date the subject takes the last pill from that Has the subject permanently discontinued the study drug i Ve No	e first pill from the shipment because	they received a new shipment of pills.	iod.				
ill be the previous line Stop Date plus 1 day.')" onmouseout="UnTip()": ate	Start Start Date	taking pills of the same dose or the last day not taking pills.')" onmouseout="UnTip()">Stop Date	Stop Date	Dosage Dispensed by			
			Unknown	Pharmacy	Type of Change	Other Type of Change	Other Reason for Change

Protocol ID: PERL001 Study Name: PERL	Study Subject ID: Study Subject DOB:
Site:Event Name: Visit 11	Jacky Jacky Landon
Event Date:	
Section Title: Study Drug Exposure	
Instructions: For the entire Dosing Period. The Dosing Period starts with the date the subject t ends with the date the subject takes the last pill from that shipment because they received a m	akes the first pill from the shipment received after the prior visit and ew shipment of pills.
1a. Date started using drug vials:	
Unknown	
1b. Date stopped using drug vials:	
[] Unknown	
Difference in days:	
1c. Number of pills should have taken if there were no Discontinuations:	
🗆 Unknown	
Please explain why the number of pills the subject should have taken is Unknown:	
2. Number of pills instructed not to take: (by vial because the number can be different for each vial)	
Vial A: *	
Vial B: * Vial C: *	
Vial C: *	
Total number of pills instructed not to take:	
3. Number of pills should have taken: (by vial because the number can be different for each vial) Vid A:	
Vial B:	
Vial C:	
Vial D:	
Total number of pills should have taken:	
4. Number of pills dispensed: (by vial because the number can be different for each vial) Vial b *	
(by vial because the number can be different for each vial) Vial A: *	
Vial B: *	
Vial C: * Vial D: *	
Total number of pills dispensed:	
5. Were pills returned in individual vials: • O're No	
 No Pills not returned 	
<u>Number of Pills Returned:</u> (by vial because the number can be different for each vial)	
Vial A:	
Vial B:	
Vial C.	
Total number of pills returned:	
Total number of pills returned:	
5. Number of pills taken: (by vial because the number can be different for each vial)	
Vial A:	
Vial B:	
Vial C:	
Total number of pills taken:	
Total number of pills taken:	
jotai numuer OT DIIS Taken;	
Subject the reason Drug Compliance cannot be calculated at this visit: Osubject did not return pils	
 Pils were thrown away Pils were lost 	
 Start date and/or Stop date unknown Not applicable 	
○ Other	
If Other, Specify:	

Protocol ID: PERL001	Study Subject ID:
Study Name: PERL	Study Subject DDB:
Site:	
Event Name: Visit 11	
Event Date:	
Section Title: % Compliant Calculation	
B1. Percent Compliant (if total pills taken reported by the 4 individual vials)	

.

You can now return to the Compliance tab to review subject's compliance and if you wish, the Exposure tab to review pill counts and calculations.

□Confirm form is complete and source document uploaded.

Visit 12: PERL_006_Blood Pressure and Measurements - V1.0 PERL_008_Local Laboratory Results - V5.0 PERL_012_Central Lab Specimen Collection - V4.0 PERL_021_Skin Assessment - V3.0 PERL_021_Skin Assessment - V3.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 12			Study Subject ID Study Subject DOR
Event Date:			PERL_006_Blood Pressure and Measurements - V1.0
Section Title: Blood	Pressure and Heart Rate		
Subtitle:			
Measurements:			
A1. Weight:	(kg)	Not Done	
A2. Height:	(cm)	Not Done	
Upload Source Docu	uments:		
Blood Pressure:			
B1. First Reading			
B1a. Systolic:	(mmHg)		
B1b. Diastolic:	(mmHg)	BP Not Done	
B1c. Heart Rate:	(bpm)	HR Not Done	
B2. Second Reading	1		
B2a. Systolic:	(mmHg)		
B2b. Diastolic:	(mmHg)	BP Not Done	
B2c. Heart Rate:	(bpm)	HR Not Done	
B3. Third Reading			
B3a. Systolic:	(mmHg)		
B3b. Diastolic:	(mmHg)	BP Not Done	
B3c. Heart Rate:	(bpm)	HR Not Done	

Protocol ID: PERL001 Study Name: PERL		Study Subject ID: Study Subject DOB:
Site: Event Name: Visit 12		
Event Date:	-	
Section Title: Average B Subtitle:	ood Pressure and Heart Rate	
Calculated Fields:		
BMI BMI:		
Blood Pressure		
Systolic: Diastolic:	(mmig) (mmig)	
Heart Rate:	(čpm)	

Protocol ID: FERLIOI Study Name: FERL Ster Even Name: Volt 12	Study Subject ID: Study Subject DOB:
Event bate:	
PERL_008_Local Laboratory Results - V5.0	
Section Title: Section A. Chemistry	
Subtitle:	
Instructions: Enter the lab values in the units indicated with the date of collection for each field. Use the "Not Done" checkbox provided if data is unobtainable.	
Upload source documents:	

A1. Potassium:	(mmol/L)	Date Collected:	□ Not Done
A2. Creatinine:	(mg/dl)	Date Collected:	□ Not Done
A3. ALT (SGPT):	(U/L)	Date Collected:	Not Done

Protocol ID: PERL001 Study Name: PERL Site: ______ Event Name: Visit 12 Event Date: _____ Study Subject ID:_____ Study Subject DOB:_____ Section Title: Section B. CBC Subtitle: B1. Hemoglobin: Date Collected: (gm/dl) □ Not Done B2. Hematocrit: (%) Date Collected: □ Not Done B3. Platelets: (mmol) Date Collected: □ Not Done (million cells/mcL) B4. RBC: Date Collected: Not Done B5. WBC: (cells/mcL) Date Collected: □ Not Done B5a. Neutrophils: (%) 🗆 Not Done B5b. Lymphocytes: (%) 🗆 Not Done B5c. Monocytes: (%) Not Done B5d. Eosinophils: (%) Not Done (%) B5e. Basophils: Not Done

Protocol ID: PERL001 Study Name: PERL Ste: Event Name: Visit 12 Event Date:			Study Subject ID: Study Subject DOR:
Section Title: Section C. P	regnancy Test		
C1. Urine Pregnancy Test Result:	 Positive Negative Not Done Not Applicable 	Date of test:	
C2. Serum Pregnancy Test Result:	 Positive Negative Not Done Not Applicable 	Date of test:	

Protocol ID: PERL001			Study Subject ID:
Study Name: PERL			Study Subject DOB:
Site:			
Event Name: Visit 12			
Event Date:	-		
Section Title: Section D.	Urine Multistix		
Date Urine Collected:		Not Done	
D1. Leukocytes:	O Negative		
	O Trace		
	 Small 		
	 Moderate 		
	Large		
D2. Nitrites:	O Negative		
	O Positive		
D3. Protein:	O Negative		
	 Trace 		
	O 30		
	100		
	C 300		
	O 2000+		
D4. Blood	O Negative		
	 Positive 		
D4a. Blood – Non Hemolyzed:	 None 		
	 Trace 		
	O Moderate		
D4b. Blood - Hemolyzed:	None		
	 Trace 		
	Small		
	 Moderate 		
	 Large 		
D6. Ketones:			
DO. NEIDIRS.	Negative		
	 Trace Small 		
	 Small Moderate 		
	 Large 		
	O mige		

Protocol ID: PERL001 Study Name: PERL	Study Subject ID: Study Subject DOB:
Ster	
Event Name: Visit 12	
Event Date:	
Liter bole.	
Section Title: Section E. eGFR	
Subtitle:	
E1. Indicate visit for which this eGFR values applies:	
○ Visit 1	
○ Visits 6-15	
E2. Use central lab creatinine value to calculate eGFR	
Click Here to Calculate eGFR Central lab greatinine value	
E3. Use local lab creatinine value to calculate eGFR	
Click Here to Calculate eGFR	
Local lab creatinine value	
The second	
E4. eGFR: (mls/min/1.73m ²) Date Collected:	Not Done

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 12 Event Date:				by Subject ID: by Subject 008:
		PERL_010 Central Lab Specin	en Collection - V4.0	
Section Title: Section A. B	lood Specimens			
Instructions: Please indicate the collect	ted specimens and prov	de the date of collection.		
A1. Serum Uric Acid, Creatinine, Cystatin C Collected	⊖ Yes ⊖ No	Date Collected		
A2. HbA1c Collected	⊖Yes ⊙No ⊙NA-if visit 6	Date Catected		
A3. Shipped to ARDL	⊖ Yes ○ No	Date Shipped		

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 12 Event Date:	_					Study Subject ID: Study Subject DDB:
Section Title: Section B	. Urine Specimens					
B1. ACR/AER Collected	○ Yes ○ No ○ NA-if visit 6_8_10_12 or 14					
Overnight	∵Yes ⊖No	Date Ended Collection				
First Morning	⊖Yes ⊙No	Date Collected				
Spot Urine	⊖Yes ⊖No	Date Collected	Additional Date Collected	If necessary	Additional Date Collected	If necessary
B2. Shipped to ARDL	○ Yes ○ No	Date Shipped				

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 12 Event Date:			Study Subject ID: Study Subject DOR:
Section Title: Section C.	Biospecimens for Reposit	ory	
	⊙Yes ⊙No		
C1. Serum Collected	⊖ Yes ○ No	Date Collected	
C2. Plasma Collected	⊖ Yes ⊖ No	Date Collected	
C3. Urine Collected	⊖ Yes ⊖ No	Date Collected	
C3a. Protease Inhibitor Added	○ Yes ○ No		
C4. Shipped to ARDL	⊖ Yes ○ No	Date Shipped	

Protocol ID: PERL001 Study Name: PERL					Study Subject ID: Study Subject ID::
Site: Event Name: Visit 12 Event Date:					
Event Date:	_		PERL	_011_Skin Assessment - V3.0	
Section Title: Skin Asse	ssment				
Indicate who performe Select: *					
Was any rash present of	O Clinician Assessment				
•	○Yes ○No ○Not Assessed				
A1. Has the participant Select:		re-rash Stevens-Johnson	Syndrome (SJS) symptoms?		
	No Not Assessed				
Select all that apply:					
Fever	□Fever				
Duration: Maximum temperature:	(days)	Celsius or Farenheit:	0 °C	Unknown temperature	
Skin tendemess			0 °F		
	□ Skin tenderness				
Sore throat	□ Sore throat				
Photophobia	Photophobia				
Burning eyes	Burning eyes				
Itching eyes	□ Itching eyes				
Cough productive of th	ick and purulent sputum				
Headache	- Headache				
Malaise	□ Malaise				
Arthralgia	Arthralgia				
A2. During assessment	, was any swelling or rash (noted?			
Select:	O Yes No No Not Assessed				
Select all that apply:					
Burning rash	Burning rash				
Skin pain	□Skin pain				
Facial swelling	□ Facial swelling				
Tongue swelling	Tongue swelling				
Red or purple skin rash	Red or purple skin rash				
Area of rash (select all					
	□ Face		Chest	Abdomen Paims	
	□ Soles		Back		
Target lesions surround	ded by macular erythema				
Hives	Hives				
Area of hives (select al					
	□ Face		Chest	Abdomen Palms	
	Soles		Back		
Blisters	Blisters				
Area of blisters (select					
	□ Face		Chest	Abdomen Palms	
	□Soles		Genitals	Anal	
Chaddin	Back				
Shedding	Shedding (sloughing) of skin				
Area of shedding (selec	Ct all that apply):		Chest	Abdamen	
	□Arms		Legs	Palms	
Donuded alda	Soles		Back		
Denuded skin areas	Denuded skin areas				
Area of denudation (se			Chest	Abdamen	
	□Ams		Legs	Palms	
	□ Soles		Back		

A3. During assessment was any mucous membrane involvement noted?

Select:	Yes					
	○ No					
	Not Assessed					
Select all that apply:						
Oral mucosa						
	Oral mucosa					
Oral mucosa (select a	ll that apply):					
	Erythema	Edema	Sloughing			
	Li Ei yu ema	Li Edenia	L accyring			
	Blistering	Ulceration/erosion	□ Necrosis/crust			
Nasal mucosa						
	Nasal mucosa					
Nasal mucosa (select	all that apply):					
	Erythema	Edema	□ Sloughing			
	Blistering	Ulceration/erosion	Necrois/crust			
Eyes						
	□ Eyes					
Eyes (select all that a	pply):					
	Excessive tearing	Hyperemia	Congestion			
	Creating Contraction	Li Typeccina				
	□ Scarring					
Urinary tract						
	Urinary tract					
Urinary Tract (select a	all that apply):					
	Dysuria	Urinary retention				
	Uysana	Li olinary recention				
Pulmonary						
	Pulmonary					
		Professionary Contrast of Marka analysis				
Pulmonary (select all						
Pulmonary (select all		Productive cough	□Pulmorary edema			

Study Name: PERL Site: Event Name: Visit 12					ubject ID:ubject DOB:		
Event Date:		PERL_022_Study Drug Compli	ance and Exposure -	V3.0			
Section Title: Study Medication Log Instructions: Refer to the MOD for detailed instructions and examples. All dosages and discontinuations must be listed for the entire Dosing Period. The Dosing Period Yatrs with the date the subject takes the first pill from the shipment received after the prior wist and ends with the date the subject takes the last pill from the shipment because they received a new shipment of pills. Has the subject Period He study drug prior to this dosing period? CVin CVin CVin CVin CVin CVin CVin CVin							
ill be the previous line Stop Date plus 1 day.')" onmouseout="UnTip()"> ate	Start Start Date	taking pills of the same dose or the last day not taking pills.')" onmouseout="UnTip()">Stop Date	Stop Date Unknown	Dosage Dispensed by	Type of Change	Other Type of	
	Unknown			Pharmacy		Change	Other Reason fo Change

Protocol ID: PERL001 Skudy Name: PERL	Study Subject ID: Study Subject DOB:
Site:	sudy suger too
Event Name: Visit 12 Event Date:	
Section Title: Study Drug Exposure Instructions: For the entire Dosing Period. The Dosing Period starts with the date the subject ta ends with the date the subject takes the last pill from that shipment because they received a m	kes the first pill from the shipment received after the prior visit and
	w shipment of pills.
1a. Date started using drug vials:	
🗆 Unknown	
1b. Date stopped using drug vials:	
🗆 Unknown	
Difference in days:	
1c. Number of pills should have taken if there were no Discontinuations:	
🗆 Unknown	
Please explain why the number of pills the subject should have taken is Unknown;	
2. Number of nills instructed not to take:	
2. Number of pills instructed not to take: (by vial because the number can be different for each vial) Via k *	
Vial B: *	
Vial C *	
Vial D: *	
Total number of pills instructed not to take:	
3. Number of pills should have taken: (by vial because the number can be different for each vial)	
Vial A:	
vial c: Vial C:	
Vial C:	
Total number of pills should have taken:	
4. Number of pills dispensed: (by vial because the number can be different for each vial) Via k *	
Vial B: *	
Vial C: *	
Vial D: *	
Total number of pills dispensed:	
5. Were pills returned in individual vials: * OYes	
No ONIS	
Number of Pills Returned: (by vial because the number can be different for each vial)	
Vial A:	
Vial B:	
Vial C-	
Year D: Total number of pills returned:	
Joannunder of plus retained.	
Total number of pills returned:	
6. Number of pills taken:	
6. Number of pills taken: (by vial because the number can be different for each vial) Vid A:	
Vial B:	
Vial C:	
Vial D:	
Total number of pills taken:	
Total number of pills taken:	
7. Select the reason Drug Compliance cannot be calculated at this visit:	
Osubject did not return pills OPills were thrown away	
 Pils were lost Start date and/or Stop date unknown 	
O Not applicable Other	
If Other, Specify:	
A SUCCEPTION OF SUCCESSION	

Protocol ID: PERLO01	Study Subject ID:
Study Name: PERL	Study Subject DOB:
Site:	
Event Name: Visit 12	
Event Date:	
Section Title: % Compliant Calculation	
B1. Percent Compliant (if total pills taken reported by the 4 individual vials)	
B2. Percent Compliant (if vials not returned and total pills taken reported as a total only)	

.

You can now return to the Compliance tab to review subject's compliance and if you wish, the Exposure tab to review pill counts and calculations.

Confirm form is complete and source document uploaded.

Visit 13: PERL_006_Blood Pressure and Measurements - V1.0 PERL_008_Local Laboratory Results - V5.0 PERL_012_Central Lab Specimen Collection - V4.0 PERL_021_Skin Assessment - V3.0 PERL_021_Skin Assessment - V3.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 13			Study Subject ID Study Subject ID08:
Event Date:			PERL_006_Blood Pressure and Measurements - V1.0
Section Title: Blood	Pressure and Heart Rate		
Subtitle:			
Measurements:			
A1. Weight:	(kg)	Not Done	
A2. Height:	(cm)	Not Done	
Upload Source Docu			
opioud bource boo			
Blood Pressure:			
B1. First Reading			
B1a. Systolic:	(mmHg)		
B1b. Diastolic:	(mmHg)	BP Not Done	
B1c. Heart Rate:	(bpm)	HR Not Done	
B2. Second Reading	1		
B2a. Systolic:	(mmHg)		
B2b. Diastolic:	(mmHg)	BP Not Done	
B2c. Heart Rate:	(bpm)	HR Not Done	
B3. Third Reading			
B3a. Systolic:	(mmHg)		
B3b. Diastolic:	(mmHg)	BP Not Done	
B3c. Heart Rate:	(bpm)	HR Not Done	

Protocol ID: PERL001 Study Name: PERL		Study Subject ID: Study Subject DOB:
Site:		
Event Name: Visit 13 Event Date:		
	-	
Section Title: Average Bl	ood Pressure and Heart Rate	
Subtitle:		
Calculated Fields:		
BMI BMI:		
Blood Pressure Systolic:	(mnHg)	
Diastolic:	(mmHg)	
Heart Rate:	(bpm)	

Protocol ID: PERL001	Study Subject ID:
Study Name: PERL	Study Subject DDB:
Site:	
Event Name: Visit 13	
Event Date:	
PERL_008_Local Laborator	y Results - V5.0
Section Title: Section A. Chemistry	
Subtitle:	
Instructions: Enter the lab values in the units indicated with the date of collection for each field. Use the "Not Done" checkbox provided if data is un	nobtainable.
Upload source documents:	
Chemistry:	

A1. Potassium:	(mmal/L)	Date Collected:	□ Not Done
A2. Creatinine:	(mg/dl)	Date Collected:	□ Not Done
A3. ALT (SGPT):	(U/L)	Date Collected:	□ Not Done

Protocol ID: PERL001 Study Name: PERL Site: ______ Event Name: Visit 13 Event Date: ______ Study Subject ID:_____ Study Subject DOB:_____ Section Title: Section B. CBC Subtitle: B1. Hemoglobin: Date Collected: (gm/dl) □ Not Done B2. Hematocrit: (%) Date Collected: □ Not Done B3. Platelets: (mmol) Date Collected: □ Not Done (million cells/mcL) B4. RBC: Date Collected: Not Done B5. WBC: (cells/mcL) Date Collected: □ Not Done B5a. Neutrophils: (%) 🗆 Not Done B5b. Lymphocytes: (%) 🗆 Not Done B5c. Monocytes: (%) Not Done B5d. Eosinophils: (%) Not Done (%) B5e. Basophils: Not Done

Protocol ID: PERL001 Study Name: PERL Ste: Event Name: Visit 13 Event Date:			Study Subject ID: Study Subject DDB:
Section Title: Section C. P	regnancy Test		
C1. Urine Pregnancy Test Result:	 Positive Negative Not Done Not Applicable 	Date of test:	
C2. Serum Pregnancy Test Result:	 Positive Negative Not Done Not Applicable 	Date of test:	

Protocol ID: PERL001			Study Subject ID:
Study Name: PERL			Study Subject DOB:
Site:			
Event Name: Visit 13			
Event Date:	_		
Section Title: Section D.	11-1		
Section Title: Section D.	Unne Multistix		
Date Urine Collected:		Not Done	
D1. Leukocytes:	Negative		
	O Trace		
	○ Small		
	 Moderate 		
	⊖ Large		
	O talge		
D2. Nitrites:	O Negative		
	 Positive 		
	o roane		
D3. Protein:	Negative		
	⊖ Trace		
	O 30		
	○ 100		
	O 300		
	C 2000+		
	0.2001		
D4. Blood	O Negative		
	O Positive		
D4a. Blood - Non Hemolyzed:	O None		
	O Trace		
	 Moderate 		
D4b. Blood - Hemolyzed:	 None 		
.,	O Trace		
	○ Small		
	O Moderate		
	○ Large		
	-		
D6. Ketones:	O Negative		
	○ Trace		
	O Small		
	 Moderate 		
	⊖ Large		

Protocol ID: PERL001	Study Subject ID:				
Study Name: PERL	Study Subject DOB:				
Site:					
Event Name: Visit 13					
Event Date:					
Section Title: Section E. eGFR					
Subtitle:					
E1. Indicate visit for which this eGFR values applies:					
○ Visit 1					
○ Visits 6-15					
E2. Use central lab creatinine value to calculate eGFR					
Click Here to Calculate eGFR					
Central lab creatinine value					
23. Use local lab creatinine value to calculate GFR Citck teres to calculate sGFR Citck teres to calculate sGFR					
Local lab creatinine value					
E4. eGFR: (mis/min/1.73m ²) Date Collected:	Not Done				

E4. eGFR: (mls/min/1.73m²) Date Collected:

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 13 Event Date:				Study Subject IDC Study Subject DOB:
		PERL_010 Central Lab Specimen Collection -	V4.0	
Section Title: Section A. B	lood Specimens			
Instructions: Please indicate the collect	ted specimens and prov	ide the date of collection.		
A1. Serum Uric Acid, Creatinine, Cystatin C Collected	⊖ Yes ⊖ No	Date Callected		
A2. HbA1c Collected	○Yes ○No ○NA-if visit 6	Date Callected		
A3. Shipped to ARDL	⊖ Yes ○ No	Date Shipped		

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 13 Event Date:	_					Study Subject ID: Study Subject DOB:
Section Title: Section B	. Urine Specimens					
B1. ACR/AER Collected	ਂ Yes ਂ No ਂ NA-ਜੋਂ visit 6_8_10_12 or 14					
Övernight	⊖Yes ⊖No	Date Ended Collection				
First Morning	⊖Yes ⊖No	Date Collected				
Spot Urine	⊖Yes ⊖No	Date Collected	Additional Date Collected	If necessary	Additional Date Collected	If necessary
B2. Shipped to ARDL	○ Yes ○ No	Date Shipped				

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 13 Event Date:			Study Subject ID: Study Subject DOR:
Section Title: Section C. I	Biospecimens for Reposit	ory	
	⊙Yes ⊙No		
C1. Serum Collected	⊖ Yes ○ No	Date Collected	
C2. Plasma Collected	⊖ Yes ⊖ No	Date Collected	
C3. Urine Collected	⊖ Yes ⊖ No	Date Collected	
C3a. Protease Inhibitor Added	○ Yes ○ No		
C4. Shipped to ARDL	⊖ Yes ⊙ No	Date Stipped	

Protocol ID: PERL001 Study Name: PERL					Study Subject ID: Study Subject ID::
Site: Event Name: Visit 13 Event Date:					
Event Date:	_		PERL	_011_Skin Assessment - V3.0	
Section Title: Skin Asse	ssment				
Indicate who performe Select: *					
Was any rash present of	O Clinician Assessment				
•	○Yes ○No ○Not Assessed				
A1. Has the participant Select:		re-rash Stevens-Johnson	Syndrome (SJS) symptoms?		
	No Not Assessed				
Select all that apply:					
Fever	□Fever				
Duration: Maximum temperature:	(days)	Celsius or Farenheit:	0 °C	Unknown temperature	
Skin tendemess			0 °F		
	□ Skin tenderness				
Sore throat	□ Sore throat				
Photophobia	Photophobia				
Burning eyes	Burning eyes				
Itching eyes	□ Itching eyes				
Cough productive of th	ick and purulent sputum				
Headache	- Headache				
Malaise	□ Malaise				
Arthralgia	□ Arthralgia				
A2. During assessment	, was any swelling or rash	noted?			
Select:	○Yes ○No ○Not Assessed				
Select all that apply:					
Burning rash	Burning rash				
Skin pain	⊡Skin pain				
Facial swelling	□ Facial swelling				
Tongue swelling	□Tongue swelling				
Red or purple skin rash	Red or purple skin rash				
Area of rash (select all					
	□ Face		Chest	Abdomen	
	□Soles		Back		
Target lesions surround	ded by macular erythema Target lesions				
Hives	Hives				
Area of hives (select al					
	□ Face		Chest	Abdomen	
	Soles		Back		
Blisters	Blisters				
Area of blisters (select					
	Face Arms		Chest	Abdomen	
	□ Soles		Genitals	Anal	
Chaddin	Back				
Shedding	Shedding (sloughing) of skin				
Area of shedding (selec	ct all that apply):		Chest	Abdomen	
	□Arms		Legs	Palms	
	□Soles		Back		
Denuded skin areas	Denuded skin areas				
Area of denudation (se	□Face		Chest	Abdomen	
	□Arms		Legs	□ Palms	
	□ Soles		Back		

A3. During assessment was any mucous membrane involvement noted?

Select:	Yes		
	No Not Assessed		
Select all that apply:			
Oral mucosa			
	□ Oral mucosa		
Oral mucosa (select a	ll that apply):		
	□Erythema	Edema	Skughing
	Blistering	Ulceration/erosion	Necrosia/aust
Nasal mucosa			
	Nasal mucosa		
Nasal mucosa (select	all that apply):		
	□ Erythema	Edema	
	Blistering	Ulceration/erosion	□ Necrois/aust
Eyes			
	□ Eyes		
Eyes (select all that a	pply):		
	Excessive tearing	Hyperemia	
	□Scarring		
Urinary tract			
	Urinary tract		
Urinary Tract (select a	all that apply):		
	Dysuria	Urinary retention	
Pulmonary			
	Pulmonary		
Pulmonary (select all	that apply):		
	Dyspnea	Productive cough	Pumorary edema

Study Name: PERL Site: Event Name: Visit 13					ubject ID:		
Event Date:		PERL_022_Study Drug Compli	ance and Exposure -	V3.0			
Section Title: Study Medication Log Instructions: Refer to the NOO for detailed instructions and The Dosing Period starts with the date the subject takes the ends with the date the subject takes the last pill from that s Has the subject permanently discontinued the study drug p Ves Into	first pill from the hipment because	they received a new shipment of pills.	iod.				
ill be the previous line Stop Date plus 1 day.')" onmouseout="UnTip()">: ate	itart Start Date Unknown	taking pills of the same dose or the last day not taking pills.") onmouseout="UnTip()">Stop Date	Stop Date Unknown	Dosage Dispensed by Pharmacy	Type of Change	Other Type of Change	1
	Unknown		Unknown				Other Reason for Change

Protacol ID: PERL001 Study Name: PERL	Study Subject ID: Study Subject DDB:
Site:	suby surjex toos
Event Name: Visit 13 Event Date:	
Section Title: Study Drug Exposure Instructions: For the entire Dosing Period. The Dosing Period starts with the date the subject takes the first pil ends with the date the subject takes the last pill from that shipment because they received a new shipment of	I from the shipment received after the prior visit and
	pills.
1a. Date started using drug vials;	
□ Urknown	
1b. Date stopped using drug vials:	
Unknown	
Difference in days:	
1c. Number of pills should have taken if there were no Discontinuations:	
Unknown	
Please explain why the number of pills the subject should have taken is Unknown:	
2. Number of pills instructed not to take:	
2. Number of pills instructed not to take: (by vial because the number can be different for each vial) Via k *	
Vial B: *	
Vial C. *	
Vial D: *	
Total number of pills instructed not to take:	
3. Number of pills should have taken: (by vial because the number can be different for each vial)	
Vial A:	
Vial C:	
Vial D:	
Total number of pills should have taken:	
4. Number of pills dispensed: (by vial because the number can be different for each vial) Via k *	
Vial B: *	
Vial C *	
Vial D: *	
Total number of pills dispensed:	
5. Were pills returned in individual vials:	
* OYes No	
 Pils not returned 	
Number of Pills Returned: (by vial because the number can be different for each vial)	
Vial A:	
Vial B:	
Vial C	
Vial D:	
Total number of pills returned:	
Total number of pills returned:	
6 Number of nille taken:	
6. Number of pills taken: (by vial because the number can be different for each vial) Via A	
Vial B:	
Vial C	
Vial D:	
Total number of pills taken:	
Total number of pills taken:	
7. Select the reason Drug Compliance cannot be calculated at this visit:	
O Subject did not return pills O Pills were thrown away	
 Pills were lost Start date and/or Stop date unknown 	
O Not applicable	
If Other, Specify:	

Protocol ID: PERL001	Study Subject ID:
Study Name: PERL	Study Subject DOB:
Site:	
Event Name: Visit 13	
Event Date:	
Section Title: % Compliant Calculation	
B1. Percent Compliant (if total pills taken reported by the 4 individual vials)	
B2. Percent Compliant (if vials not returned and total pills taken reported as a total only)	

.

You can now return to the Compliance tab to review subject's compliance and if you wish, the Exposure tab to review pill counts and calculations.

□Confirm form is complete and source document uploaded.

Visit 14: PERL_006_Blood Pressure and Measurements - V1.0 PERL_008_Local Laboratory Results - V5.0 PERL_012_Central Lab Specimen Collection - V4.0 PERL_021_Skin Assessment - V3.0 PERL_021_Skin Assessment - V3.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 14	-		Study Subject ID: Study Subject DOB!
Event Date:			PERL_006_Blood Pressure and Measurements - V1.0
Section Title: Blood	Pressure and Heart Rate		
Subtitle:			
Measurements:			
A1. Weight:	(kg)	Not Done	
A2. Height:	(cm)	Not Done	
Upload Source Doc	uments:		
Blood Pressure:			
B1. First Reading			
B1a. Systolic:	(mmHg)		
B1b. Diastolic:	(mmHg)	BP Not Done	
B1c. Heart Rate:	(bpm)	HR Not Done	
B2. Second Reading	g		
B2a. Systolic:	(mmHg)		
B2b. Diastolic:	(mmHg)	BP Not Done	
B2c. Heart Rate:	(bpm)	HR Not Done	
B3. Third Reading			
B3a. Systolic:	(mmHg)		
B3b. Diastolic:	(mmHg)	BP Not Done	
B3c. Heart Rate:	(bpm)	HR Not Done	

Protocol ID: PERL001 Study Name: PERL		Study Subject ID: Study Subject DOB:
Site:		3003 300 j.c. 000
Event Name: Visit 14		
Event Date:	-	
	ood Pressure and Heart Rate	
Subtitle:		
Calculated Fields:		
BMI		
BMI:		
Blood Pressure		
Systolic:	(mmHg)	
Diastolic:	(mmHg)	
Heart Rate:	(čpm)	

Protocol ID: FERLID01 Sudy Name: FERL Sites Frem. Sites Frem. Site 1	Study Subject ID: Study Subject DOR:
Event Date	
PERL_008_Local Laboratory Results - V5.0	
Section Title: Section A. Chemistry	
Subtitle:	
Instructions: Enter the lab values in the units indicated with the date of collection for each field. Use the "Not Done" checkbox provided if data is unobtainable.	
Uplead source documents:	
Chemistry:	

A1. Potassium:	(mmol/L)	Date Collected:	□ Not Done
A2. Creatinine:	(mg/dl)	Date Collected:	□ Not Done
A3. ALT (SGPT):	(U/L)	Date Collected:	Not Done

Protocol ID: PERL001 Study Name: PERL Site: ______ Event Name: Visit 14 Event Date: ______ Study Subject ID:_____ Study Subject DOB:_____ Section Title: Section B. CBC Subtitle: B1. Hemoglobin: Date Collected: (gm/dl) □ Not Done B2. Hematocrit: (%) Date Collected: □ Not Done B3. Platelets: (mmol) Date Collected: □ Not Done (million cells/mcL) B4. RBC: Date Collected: Not Done B5. WBC: (cells/mcL) Date Collected: □ Not Done B5a. Neutrophils: (%) 🗆 Not Done B5b. Lymphocytes: (%) 🗆 Not Done B5c. Monocytes: (%) Not Done B5d. Eosinophils: (%) Not Done (%) B5e. Basophils: Not Done

Protocol ID: PERL001 Study Name: PERL Ste: Event Name: Visit 14 Event Date:			Study Subject ID: Study Subject DOR:
Section Title: Section C. P	regnancy Test		
C1. Urine Pregnancy Test Result:	 Positive Negative Not Done Not Applicable 	Date of test:	
C2. Serum Pregnancy Test Result:	 Positive Negative Not Done Not Applicable 	Date of test:	

Protocol ID: PERL001			Study Subject ID:
Study Name: PERL			Study Subject DO8:
Site:			
Event Name: Visit 14			
Event Date:	-		
Section Title: Section D.	Urine Multistix		
Date Urine Collected:		Not Done	
D1. Leukocytes:	O Negative		
	○ Trace		
	○ Small		
	O Moderate		
	Large		
D2. Nitrites:	O Negative		
	O Positive		
D3. Protein:	O Negative		
	O Trace		
	O 30		
	O 100		
	○ 300		
	O 2000+		
D4. Blood	O Negative		
	 Positive 		
D4a. Blood - Non Hemolyzed:	 None 		
	 Trace 		
	O Moderate		
D4b. Blood - Hemolyzed:	None		
	○ Trace		
	Small		
	 Moderate 		
	 Large 		
D6. Ketones:	O Negative		
	O Trace		
	O Small		
	O Moderate		
	C Large		

Protocol ID: PERL001	Study Subject ID:
Study Name: PERL	Study Subject DOB:
Site:	
Event Name: Visit 14	
Event Date:	
Section Title: Section E. eGFR	
Subtitle:	
E1. Indicate visit for which this eGFR values applies:	
○ Visit 1	
○ Visits 6-15	
E2. Use central lab creatinine value to calculate eGFR	
Click Here to Calculate eGFR	
Central lab creatinine value	
E3. Use local lab creatinine value to calculate eGFR Click Here to Calculate eGFR	
Local lab creatinine value	
E4. eGFR: (mls/min/1.73m ²) Date Collected:	Not Done

E4. eGFR: (mls/min/1.73m²) Date Collected:

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 14 Event Date:				Study Subject DOR
		PERL_010 Central Lab Specimen Collection - V4	4.0	
Section Title: Section A. B	lood Specimens			
Instructions: Please indicate the collect	ted specimens and prov	ide the date of collection.		
A1. Serum Uric Acid, Creatinine, Cystatin C Collected	⊖ Yes ⊖ No	Date Collected		
A2. HbA1c Collected	○Yes ○No ○NA-if visit 6	Date Calended		
A3. Shipped to ARDL	⊖ Yes ○ No	Date Shipped		

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 14 Event Date:	_					Study Subject DOB
Section Title: Section B	. Urine Specimens					
B1. ACR/AER Collected	○ Yes ○ No ○ NA-if visit 6_8_10_12 or 14					
Overnight	⊖Yes ⊖No	Date Ended Collection				
First Morning	⊖Yes ⊖No	Date Collected				
Spot Urine	⊖Yes ⊖No	Date Collected	Additional Date Collected	If necessary	Additional Date Collected	If necessary
B2. Shipped to ARDL	○ Yes ○ No	Date Shipped				

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 14 Event Date:			Study Subject ID: Study Subject DOR:
Section Title: Section C. I	Biospecimens for Reposit	ory	
	⊙Yes ⊙No		
C1. Serum Collected	⊖ Yes ○ No	Date Collected	
C2. Plasma Collected	⊖Yes ⊖No	Date Collected	
C3. Urine Collected	⊖ Yes ⊖ No	Date Collected	
C3a. Protease Inhibitor Added	○ Yes ○ No		
C4. Shipped to ARDL	⊖ Yes ⊙ No	Date Stipped	

Protocol ID: PERL001 Study Name: PERL					Study Subject ID: Study Subject ID::
Site: Event Name: Visit 14 Event Date:					
			PERL	_011_Skin Assessment - V3.0	
Section Title: Skin Asse	ssment				
Indicate who performe Select: *					
Was any rash present of	Clinician Assessment				
	⊖Yes ⊙No				
A1. Has the participant	Not Assessed	re-rash Stevens-Johnson	Syndrome (SJS) symptoms?		
Select:	○Yes ○No ○Not Assessed				
Select all that apply:	Cite Addata				
Fever	□Fever				
Duration:	(days)				
Maximum temperature:		Celsius or Farenheit:	0 °C 0 °F	Unknown temperature	
Skin tenderness	Skin tenderness				
Sore throat	□ Sore throat				
Photophobia	Photophobia				
Burning eyes					
Itching eyes	Burning eyes				
	□ Itching eyes				
Cough productive of th	ick and purulent sputum				
Headache	Headache				
Malaise	□Malaise				
Arthralgia	□ Arthralgia				
A2. During assessment	, was any swelling or rash	noted?			
Select:	○ Yes ○ No ○ Not Assessed				
Select all that apply:					
Burning rash	Burning rash				
Skin pain	□Skin pain				
Facial swelling	□ Facial swelling				
Tongue swelling					
Red or purple skin rash	Tongue swelling				
Area of rash (select all	Red or purple skin rash that apply):				
	□Face		Chest	Abdomen	
	□Arms		Legs	□ Palms	
Target lesions surround	Goles		Back		
	□Target lesions				
Hives	Hives				
Area of hives (select al	That apply): Face		Chest	D Abdomen	
	□Arms		Legs	Patms	
	Soles		Back		
Blisters	Blisters				
Area of blisters (select					
	Face Arms		Chest	Abdomen Patms	
	Soles		□ Genitals	□ Anel	
	Back				
Shedding	Shedding (sloughing) of skin				
Area of shedding (sele					
	□ Face		Chest	Abdomen Patms	
	Soles		Back		
Denuded skin areas	Denuded skin areas				
Area of denudation (se					
	□Face		Chest	Abdomen	
	□ Arms		🗆 Legs	□ Paims	

A3. During assessment was any mucous membrane involvement noted?

Select:	Yes		
	No Not Assessed		
Select all that apply:			
Oral mucosa			
	Oral mucosa		
Oral mucosa (select a	ll that apply):		
	□Erythema	Edema	Skughing
	Blistering	Ulceration/erosion	Necrosia/aust
Nasal mucosa			
	Nasal mucosa		
Nasal mucosa (select	all that apply):		
	□Erythema	Edema	
	Blistering	Ulceration/erosion	□ Necrois/aust
Eyes			
	Eyes		
Eyes (select all that a	oply):		
	□ Excessive tearing	Hyperemia	
	□Scarring		
Urinary tract			
	Urinary tract		
Urinary Tract (select a	all that apply):		
	□ Dysuria	Urinary retention	
Pulmonary			
	Pulmonary		
Pulmonary (select all	that apply):		
	Dyspnea	Productive cough	Pumorary edema

Study Name: PERL Site: Event Name: Visit 14					ubject ID:ubject DOB:		
Event Date:		PERL_022_Study Drug Complia	ance and Exposure -	V3.0			
Section Title: Study Medication Log Instructions: Refer to the MOO for detailed instructions and The Dosing Period starts with the date the subject takes the ends with the date the subject takes the last pill from that the subject permanently discontinued the study drug r Ves UNE	e first pill from the shipment because	they received a new shipment of pills.	iod.				
ill be the previous line Stop Date plus 1 day.')" onmouseout="UnTip()"> ate	Start Start Date	taking pills of the same dose or the last day not taking pills.')" onmouseout="UnTip()">Stop Date	Stop Date	Dosage Dispensed by	Type of Change		
	C Unknown		Unknown	Pharmacy	Tipe of change	Other Type of Change	Other Reason fo Change

Protocol ID: PERL001 Study Name: PERL	Study Subject ID: Study Subject DDB:
Site:	Suby subject Due:
Event Name: Visit 14 Event Date:	
Section Title: Study Drug Exposure Instructions: For the entire Decine Resident The Decine Reside starts with the date the subject takes the first nill from the	the chinesest received after the prior with and
Instructions: For the entire Dosing Period. The Dosing Period starts with the date the subject takes the first pill from t ends with the date the subject takes the last pill from that shipment because they received a new shipment of pills.	
1a. Date started using drug vials:	
🗆 Unknown	
1b. Date stopped using drug vials:	
🗌 Unknown	
Difference in days:	
1c. Number of pills should have taken if there were no Discontinuations;	
□ Unknown	
Please explain why the number of pills the subject should have taken is Unknown:	
riedse explain why the number of pills the subject should have taken is onknown.	
2. Number of pills instructed not to take: (by vial because the number can be different for each vial)	
Vial A: *	
Vial B: *	
Vial C: *	
Vial D: *	
Total number of pills instructed not to take:	
3. Number of pills should have taken:	
3. Number of pills should have taken: (by vial because the number can be different for each vial) Via A	
Vial B:	
Vial C.	
Vial D:	
Total number of pills should have taken:	
4. Number of pills dispensed: (by vial because the number can be different for each vial)	
Vial A: *	
Vial B.*	
Vial C: * Vial D: *	
Total number of pills dispensed:	
5. Were pills returned in individual vials: * OYes	
No Pils not returned	
Number of Pills Returned: (by vial because the number can be different for each vial)	
Vial A:	
Vial B:	
Vial C	
Vial D: Total number of pills returned:	
Total number of plits returned:	
Total number of pills returned:	
6. Number of nills taken:	
6. Number of pills taken: (by vial because the number can be different for each vial) Via k	
Vial B:	
Vial C:	
Vial D:	
Total number of pills taken:	
Total number of pills taken:	
7. Select the reason Drug Compliance cannot be calculated at this visit:	
O Subject did not return pills O Pills were thrown away	
Pills were lost Start date and/or Stop date unknown	
Not applicable	
0 Other	
If Other, Specify:	

Protocol ID: PERL001	Study Subject ID:
Study Name: PERL	Study Subject DOB:
Site:	
Event Name: Visit 14	
Event Date:	
Section Title: % Compliant Calculation	
B1. Percent Compliant (if total pills taken reported by the 4 individual vials)	
B2. Percent Compliant (if vials not returned and total pills taken reported as a total only)	

.

You can now return to the Compliance tab to review subject's compliance and if you wish, the Exposure tab to review pill counts and calculations.

Confirm form is complete and source document uploaded.

Visit 15: PERL_006_Blood Pressure and Measurements - V1.0 PERL_008_Local Laboratory Results - V5.0 PERL_012_Central Lab Specimen Collection - V4.0 PERL_021_Skin Assessment - V3.0 PERL_021_Skin Assessment - V3.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 15	-		Shady Subject ID: Shady Subject DOB:
Event Date:			PERL_006_Blood Pressure and Measurements - V1.0
Section Title: Blood	Pressure and Heart Rate		
Subtitle:			
Measurements:			
A1. Weight:	(kg)	🗆 Not Done	
A2. Height:	(cm)	🗆 Not Done	
Upload Source Doc	cuments:		
Blood Pressure:			
B1. First Reading B1a. Systolic:	(mmHg)		
B1b. Diastolic:	(mmHg)	BP Not Done	
B1c. Heart Rate:	(bpm)	III HR Not Done	
B2. Second Reading	a		
B2a. Systolic:	(mmHg)		
B2b. Diastolic:	(mmHg)	BP Not Done	
B2c. Heart Rate:	(bpm)	HR Not Done	
B3. Third Reading			
B3a. Systolic:	(mmHg)		
B3b. Diastolic:	(mmHg)	BP Not Done	
B3c. Heart Rate:	(bpm)	HR Not Done	

Protocol ID: PERL001 Study Name: PERL		Study Subject ID: Study Subject DOB:
Site:		
Event Name: Visit 15 Event Date:		
	-	
	ood Pressure and Heart Rate	
Subtitle:		
Calculated Fields:		
BMI		
BMI:		
Blood Pressure		
Systolic:	(mmig)	
Diastolic:	(mmHg)	
Heart Rate:	(bpm)	

Protocol ID: PERL001	Study Subject ID:
Study Name: PERL	Study Subject DOB:
Site:	
Event Name: Visit 15	
Event Date:	
PERL_008_Local	Laboratory Results - V5.0
Section Title: Section A. Chemistry	
Subtitle:	
Instructions: Enter the lab values in the units indicated with the date of collection for each field. Use the "Not Done" checkbox provided	if data is unobtainable.
Upload source documents:	
Chemistry:	
chemica y.	

A1. Potassium:	(mmol/L)	Date Collected:	□ Not Done
A2. Creatinine:	(mg/dl)	Date Collected:	□ Not Done
A3. ALT (SGPT):	(U/L)	Date Collected:	Not Done

Protocol ID: PERL001 Study Name: PERL Site: ______ Event Name: Visit 15 Event Date: ______ Study Subject ID:_____ Study Subject DOB:_____ Section Title: Section B. CBC Subtitle: B1. Hemoglobin: Date Collected: (gm/dl) □ Not Done B2. Hematocrit: (%) Date Collected: □ Not Done B3. Platelets: (mmol) Date Collected: □ Not Done (million cells/mcL) B4. RBC: Date Collected: Not Done B5. WBC: (cells/mcL) Date Collected: □ Not Done B5a. Neutrophils: (%) 🗆 Not Done B5b. Lymphocytes: (%) 🗆 Not Done B5c. Monocytes: (%) Not Done B5d. Eosinophils: (%) Not Done (%) B5e. Basophils: Not Done

Protocol ID: PERL001 Study Name: PERL Ste: Event Name: Visit 15 Event Date:			Study Subject ID: Study Subject DOR:
Section Title: Section C. P	regnancy Test		
C1. Urine Pregnancy Test Result:	 Positive Negative Not Done Not Applicable 	Date of test:	
C2. Serum Pregnancy Test Result:	 Positive Negative Not Done Not Applicable 	Date of test:	

Protocol ID: PERL001			Study Subject ID:
Study Name: PERL			Study Subject DOB:
Site:			
Event Name: Visit 15			
Event Date:	-		
Section Title: Section D.	Urine Multistix		
Date Urine Collected:		Not Done	
D1. Leukocytes:	O Negative		
	O Trace		
	O Small		
	 Moderate Large 		
	⊖ Large		
D2. Nitrites:	O Negative		
	O Positive		
D3. Protein:	O Negative		
	O Trace		
	O 30		
	100		
	O 300		
	O 2000+		
D4. Blood	O Negative		
	 Positive 		
D4a. Blood - Non Hemolyzed:	 None 		
	 Trace 		
	O Moderate		
D4b. Blood - Hemolyzed:	None		
	 Trace Small 		
	O Moderate		
	O Large		
D6. Ketones:	O Negative		
	O Trace		
	O Small		
	O Moderate		
	C Large		

Protocol ID: PERL001	Study Subject ID:
Study Name: PERL	Study Subject DOB:
Site:	
Event Name: Visit 15	
Event Date:	
Section Title: Section E. eGFR	
Subtitle:	
E1. Indicate visit for which this eGFR values applies:	
○Visit 1	
○ Visits 6-15	
E2. Use central lab creatinine value to calculate eGFR	
Click Here to Calculate eGFR	
Central lab creatinine value	
E3. Use local lab creatinine value to calculate eGFR	
Click Here to Calculate eGFR	
Local lab creatinine value	
E4. eGFR: (mls/min/1.73m ²) Date Collected:	Not Done

E4. eGFR: (mls/min/1.73m²) Date Collected:

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 15 Event Date:				Study Subject IDC Study Subject IDOE
		PERL_010 Central Lab Specin	nen Collection - V4.0	
Section Title: Section A. E Instructions: Please indicate the collect		de the date of collection.		
A1. Serum Uric Acid, Creatinine, Cystatin C Collected	⊖ Yes ⊖ No	Date Collected		
A2. HbA1c Collected	○ Yes ○ No ○ NA-if visit 6	Date Collected		
A3. Shipped to ARDL	⊙ Yes ○ No	Date Shipped		

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 15 Event Date:						Study Subject ID Study Subject DOB:
Event Date.						
Section Title: Section B	. Urine Specimens					
B1. ACR/AER Collected	ਂ Yes ਂ No ਂ NA-ਜੋਂ visit 6_8_10_12 or 14					
Overnight	⊖Yes ⊖No	Date Ended Collection				
First Morning	⊖Yes ⊖No	Date Collected				
Spot Urine	⊖Yes ⊖No	Date Collected	Additional Date Collected	If necessary	Additional Date Collected	If necessary
B2. Shipped to ARDL	○ Yes ○ No	Date Shipped				

Protocol ID: PERL001 Study Name: PERL Site:			Study Subject ID: Study Subject DOB:
Event Name: Visit 15			
Event Date:	_		
Section Title: Section C.	Biospecimens for Reposit	ory	
	⊖Yes ⊖No		
C1. Serum Collected	⊙ Yes ○ No	Date Callected	
C2. Plasma Collected	○ Yes ○ No	Date Calected	
C3. Urine Collected	⊖ Yes ⊖ No	Date Calented	
C3a. Protease Inhibitor Added	○ Yes ○ No		
C4. Shipped to ARDL	⊖ Yes ⊖ No	Date Shipped	

Protocol ID: PERL001 Study Name: PERL					Study Subject ID: Study Subject DOB:
Site: Event Name: Visit 15 Event Date:					
Event Date:	_		PERL	_011_Skin Assessment - V3.0	
Section Title: Skin Asse	ssment				
Indicate who performe Select: *	this skin assessment:				
Was any rash present of	Clinician Assessment				
*	⊖Yes ⊙No				
A1. Has the participant	Not Assessed t had any of the following p	ore-rash Stevens-Johnson	Syndrome (SJS) symptoms?		
Select:	○Yes ○No ○Not Assessed				
Select all that apply:	U NUL ASSESSED				
Fever	□Fever				
Duration:	(days)				
Maximum temperature:		Celsius or Farenheit:	0 °C 0 °F	Uriknown temperature	
Skin tenderness	□Skin tenderness				
Sore throat	□Sore throat				
Photophobia	Photophobia				
Burning eyes					
Itching eyes	Burning eyes				
	Itching eyes ick and purulent sputum				
Headache	Headache				
Malaise	□Malaise				
Arthralgia	□ Arthralgia				
A2. During assessment Select:	, was any swelling or rash ାଞ	noted?			
	 No Not Assessed 				
Select all that apply:					
Burning rash	Burning rash				
Skin pain	□Skin pain				
Facial swelling	□Facial swelling				
Tongue swelling	Tongue swelling				
Red or purple skin rash	Red or purple skin rash				
Area of rash (select all	that apply):				
	Face		Chest	Abdomen	
	□ Arms		🗆 Legs	Patrus	
Target lesions surround	ded by macular erythema				
Hives					
Area of hives (select al					
	□ Face		Chest	Abdomen	
	□ Arms		□ Legs	Palms	
Blisters			Back		
Area of blisters (select	Blisters				
	- Face		Chest	Abdomen	
	□Arms		□ Legs	□ Paims	
	Soles Back		Genitals	🗆 Anal	
Shedding					
Area of shedding (sele	Shedding (sloughing) of skin ct all that apply):				
	□Face		Chest	Abdomen	
	□Arms		Legs	□ Patrus	
Denuded skin areas	Soles		Back		
Area of denudation (se	Denuded skin areas				
	Face		Chest	Abdomen	
	□Arms		Legs	Paims	
	□ Soles		Back		

A3. During assessment was any mucous membrane involvement noted?

Select:	Yes		
	○ No		
	Not Assessed		
Select all that apply:			
Oral mucosa			
	Oral mucosa		
Oral mucosa (select a	ll that apply):		
	Erythema	Edema	Sloughing
	Li Ei yu ema	Li Edenia	L accounty
	Blistering	Ulceration/erosion	□ Necrosis/crust
Nasal mucosa			
	Nasal mucosa		
Nasal mucosa (select	all that apply):		
	Erythema	Edema	□ Sloughing
	Blistering	Ulceration/erosion	□ Necrois/crust
Eyes			
	□ Eyes		
Eyes (select all that a	pply):		
	Excessive tearing	Hyperemia	Congestion
	Creating Contraction	Li Typeccina	
	□ Scarring		
Urinary tract			
	Urinary tract		
Urinary Tract (select a	all that apply):		
	Dysuria	Urinary retention	
	Uysana	Li olinary recention	
Pulmonary			
	Pulmonary		
Pulmonary (select all	that apply):		
Pulmonary (select all	that apply):	Productive cough	□Rulmovary edama

Study Name: PERL Site: Event Name: Visit 15					ubject ID:ubject DOB:			
Event Date:		PERL_022_Study Drug Compli	ance and Exposure -	V3.0				
Section Title: Study Medication Log Instructions: Refer to the MOO for detailed instructions a The Dosing Period starts with the date the subject takes ends with the date the subject takes the last pill from tha Has the subject permanently discontinued the study drug OVS	the first pill from th at shipment because	they received a new shipment of pills.	riod.					
ill be the previous line Stop Date plus 1 day.')" onmouseout="UnTip() ate	Start Date	taking pills of the same dose or the last day not taking pills.")" onmouseout="UnTip()">Stop Date	Stop Date Unknown	Dosage Dispensed by Pharmacy	Type of Change	Other Type of	Reason for Change	
	□ Unknown					Change		Other Reason for Change

Protocol ID: PERL001 Study Name: PERL	Study Subject ID: Study Subject DOB:
Site:	Suby subject Ords
Event Name: Visit 15 Event Date:	
Section Title: Study Drug Exposure Instructions: For the entire Dosing Period. The Dosing Period starts with the date the subject takes the first pill fr ends with the date the subject takes the last pill from that shipment because they received a new shipment of pill	om the shipment received after the prior visit and
	5.
1a. Date started using drug vials;	
🗆 Unknown	
1b. Date stopped using drug vials:	
🗌 Uriknown	
Difference in days:	
1c. Number of pills should have taken if there were no Discontinuations:	
🗆 Unknown	
Please explain why the number of pills the subject should have taken is Unknown:	
2. Number of pills instructed not to take:	
2. Number of pills instructed not to take: (by vial because the number can be different for each vial) Via A:	
Vial B: *	
Vial C *	
Vial D: *	
Total number of pills instructed not to take:	
3. Number of pills should have taken: (by vial because the number can be different for each vial) Via k	
Vial A:	
Vial C	
Vial D:	
Total number of pills should have taken:	
4. Number of pills dispensed: (by Val because the number can be different for each vial) Val A:	
Vial B: * Vial C: *	
Via D: *	
Total number of pills dispensed:	
5. Were pills returned in individual vials: * OYes	
○ No ○ Pils not returned	
Number of Pills Returned: (by vial because the number can be different for each vial) Vial A	
Via A.	
Vial C	
Vial D:	
Total number of pills returned:	
Total number of pills returned:	
<u>6. Number of pills taken:</u> (by vial because the number can be different for each vial)	
(by vial because the number can be different for each vial) Vial A:	
Vial B:	
Vial C:	
Vial D:	
Total number of pills taken:	
Total number of pills taken:	
Compliance cannot be calculated at this visit: Osubject did not return pils	
Plis were thrown away Plis were lost	
⊖riis wei soa. ⊖Start dete andro Stop date unknown ⊖Not applicable	
Otter	
If Other, Specify:	

Protocol ID: PERL001	Study Subject ID:
Study Name: PERL	Study Subject DOB:
Site:	
Event Name: Visit 15	
Event Date:	
Section Title: % Compliant Calculation	
B1. Percent Compliant (if total pills taken reported by the 4 individual vials)	
B2. Percent Compliant (if vials not returned and total pills taken reported as a total only)	

.

You can now return to the Compliance tab to review subject's compliance and if you wish, the Exposure tab to review pill counts and calculations.

□ Confirm form is complete and source document uploaded.

Visit 16: PERL_000_Blood Pressure and Measurements - V1.0 PERL_000_Local Laboratory Results - V5.0 PERL_000_LECA Report - V1.0 PERL_010 Central Lab Specimen Collection - V4.0 PERL

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: PERL001			Study Subject ID:
Study Name: PERL			Study Subject DO8:
Site: Event Name: Visit 16			
Event Date:			
Eveni Dale.			
			PERL_006_Blood Pressure and Measurements - V1.0
	Pressure and Heart Rate		
Subtitle:			
Measurements:			
A1. Weight:	(kg)	Not Done	
A2. Height:	(cm)	Not Done	
Upload Source Doc	uments:		
Blood Pressure:			
B1. First Reading			
B1a. Systolic:	(mmHg)		
B1b. Diastolic:	(mmHg)	BP Not Done	
B1c. Heart Rate:	(bpm)	HR Not Done	
B2. Second Reading	q		
B2a. Systolic:	(mmHg)		
B2b. Diastolic:	(mmHg)	BP Not Done	
B2c. Heart Rate:	(bpm)	HR Not Done	
B3. Third Reading			
B3a. Systolic:	(mmHg)		
B3b. Diastolic:	(mmHg)	BP Not Done	
B3c. Heart Rate:	(bpm)	HR Not Done	

Protocol ID: PERL001 Study Name: PERL		Study Subject ID: Study Subject DOB:
Site:		
Event Name: Visit 16 Event Date:		
	ood Pressure and Heart Rate	
Subtitle:		
Calculated Fields:		
BMI		
BMI:		
Blood Pressure		
Systolic:	(mmHg)	
Diastolic:	(mmHg)	
Heart Rate:	(bpm)	

Protocol ID: PERL001	Study Subject ID:
Study Name: PERL	Study subject DOB.
Site: Event Name: Visit 16	
Event Date:	_
	PERL_007_Physical Examination - V1.0
Section Title: Body Sys	tem
	am performed at this visit?
	01%s
Upload source docume	
opioau source uocume	ino.
A1. Eyes: Eyes (including fundoscopy):	Okennal
	Abnormal One
If abnormal, describe to Select all that apply:	Inclings:
	□ Maxuar Degeneration
	_Other
If other, specify:	
A2. Cardiovascular:	
Cardiovascular:	O Normal Associated As
	O Not Done
If abnormal, describe the select all that apply:	findings: Dathdoma
	□Hemur
	□ Other
If other, specify:	
A3. Extremities:	
Extremities:	O Normal O Abromal
	Net Done
If abnormal, describe to Select all that apply:	findings: □Amputtion
Amputation, specify:	
	□Tendenes
	Edema
Pulses:	00+
	01+ 02+
	03+ 04+
	luber
If other, specify: A4. Lymph Nodes:	
Lymph Nodes:	O Normal O Abnormal
	O Nat Date
If abnormal, describe the select all that apply:	findings: □Swelng
Socce on the uppry.	
	□ Ober
If other, specify: A5. Pulmonary:	
Pulmonary:	Okomal Okomal
	ONX Done
If abnormal, describe the select all that apply:	findings: Reduced breefit sounds
If other, specify:	- Gue
A6. Skin:	
Skin:	O Normal O Abornal
	Not Done
If abnormal, describe to Select all that apply:	Findings:
	□ Scar
	□ Pozies
	II Excessive Bruising
	□ Ober
If other, specify: A7. Gastrointestinal:	
Gastrointestinal:	O Normal O Annormal
	○ Abromal ○ Not Done
If abnormal, describe to Select all that apply:	findings:
Scient all unit apply:	
	□ Organamegaky
Organomegaly, specify:	
	□ Ober
If other, specify:	
A8. Musculoskeletal Musculoskeletal:	Okomal Okomal
	O Abnormal O Not Done
If abnormal, describe	findings

Select all that apply:	Stiffes
	□ Terdemes
	Thjury
	ungey
Injury, specify:	
	Reduced strength
	Ceducat range of motion
	Other .
If other, specify:	
A9. Genitourinary:	
Genitourinary:	O Normal
	Akromal
	\ Not core
If abnormal, describe	r findings:
Specify:	
A10. Neurological:	
Neurological:	Onormal
	○ Abnormal
	○Net Done
If abnormal, describe	s findinas:
Select all that apply:	Abnormal Reflex Response
Abnormal reflex response, spec	Alter O Managellacia
маналла телек тезратас, арс	- Ohydrieda
	Diminished sensition
	Canal News
Abnormal, specify:	
	Differ
If other, specify:	

Study Subject ID:_____ Study Subject DOB:_____

Protocol ID: PERL001 Study Name: PERL Site: ______ Event Name: Visit 16 Event Date: _____

Section Title: Other Body System

Other Body System A11. Other Body System: Describe

Protocol ID: PERL001				Study Subject ID:	
Study Name: PERL				Study Subject DOB:	
Site:					
Event Name: Visit 16					
Event Date:					
		PERL_008_L	Local Laboratory Results - V5.0		
Section Title: Section A. Chen	nistry				
Subtitle:					
Instructions: Enter the lab va	lues in the units indicated with the date of	ollection for each field. Use the "Not Done" checkbox pro	ovided if data is unobtainable.		
		· · ·			
Upload source documents:					
Chemistry:					
encanisa j.					
14 Patronicas	(march 10) Data Collected	-			

A1. Potassium:	(mmal/L)	Date Collected:	□ Not Done
A2. Creatinine:	(mg/dl)	Date Collected:	□ Not Done
A3. ALT (SGPT):	(U/L)	Date Collected:	□ Not Done

Protocol ID: PERL001 Study Name: PERL Site: ______ Event Name: Visit 16 Event Date: ______ Study Subject ID:_____ Study Subject DOB:_____ Section Title: Section B. CBC Subtitle: B1. Hemoglobin: Date Collected: (gm/dl) □ Not Done B2. Hematocrit: (%) Date Collected: □ Not Done B3. Platelets: (mmol) Date Collected: □ Not Done (million cells/mcL) B4. RBC: Date Collected: Not Done B5. WBC: (cells/mcL) Date Collected: □ Not Done B5a. Neutrophils: (%) 🗆 Not Done B5b. Lymphocytes: (%) 🗆 Not Done B5c. Monocytes: (%) Not Done B5d. Eosinophils: (%) Not Done (%) B5e. Basophils: Not Done

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 16 Event Date:			Study Subject ID: Study Subject DOR:
Section Title: Section C. P	regnancy Test		
C1. Urine Pregnancy Test Result:	 Positive Negative Not Done Not Applicable 	Dete of test:	
C2. Serum Pregnancy Test Result:	 Positive Negative Not Done Not Applicable 	Date of test:	

Protocol ID: PERL001			Study Subject ID:
Study Name: PERL			Study Subject DO8:
Site:			
Event Name: Visit 16			
Event Date:	_		
Section Title: Section D.	The second states		
Section Title: Section D.	Unne Multistix		
Date Urine Collected:		Not Done	
D1. Leukocytes:	Negative		
	O Trace		
	Small		
	O Moderate		
	⊖ Large		
	-		
D2. Nitrites:	O Negative		
	O Positive		
D3. Protein:	Negative		
	 Trace 		
	0 30		
	O 100		
	O 300		
	O 2000+		
D4. Blood	O Negative		
	 Positive 		
D4a. Blood - Non Hemolyzed:	O None		
	O Trace		
	O Moderate		
D4b. Blood - Hemolyzed:	None		
	○ Trace		
	 Small 		
	O Moderate		
	 Large 		
	-		
D6. Ketones:	O Negative		
	○ Trace		
	O Small		
	 Moderate 		
	○ Large		

Protocol ID: FERL001 Study Name: FERL	Study Subject ID: Study Subject DOB:
Site:	
Event Name: Visit 16	
Event Date:	
Section Title: Section E. eGFR	
Subtitle:	
E1. Indicate visit for which this eGFR values applies:	
○Visit 1	
O Visits 6-15	
E2. Use central lab creatinine value to calculate eGFR <u>Click Here to Calculate eGFR</u>	
Central lab creatinine value	
E3. Use local lab creatinine value to calculate eGFR Click Here to Calculate eGFR	
Local lab creatinine value	
E4. eGFR: (mis/min/1.73m ²) Date Collected:	□Not Done

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 16		Study Subject ID: Study Subject DOB:
Event Name: Visit 16 Event Date:		
		PERL_009_ECG Report - V1.0
Section Title: ECG Re	port	
ECG Completed? *	○ Completed ○ Not Completed	
Upload Source Document:		
A1. Date of ECG:		
A2. Heart Rate:	(bpm)	
A3. ECG Findings:	Normal Abnormal	
A3a. If abnormal (se		
ASa. II abnormai (se	□ST Bevation	
	□Atrial Fib	
	T Inversion	
	□ Q Wave	
	AV Block	
	I MI Changes	
	□Tachycardia	
	Bradycardia	
	Other	
If Other, Specify:		
A3b. Is this abnormality clinic significant?	ally O Yes ** If yes, report on AE Log O No	

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 16 Event Date:				Study Subject DD®
			PERL_010 Central Lab Specimen Collection - V4.0	
Section Title: Section A. Blo Instructions: Please indicate the collected		de the date of collection.		
Cystatin C Collected	○Yes ○No ○Yes	Date Collected Date Collected		

 ○ No

 ○ NA-if vist 6

 A3. Shipped to ARDL
 ○ Yes

 ○ No

Protocol ID: PERL001 Study Name: PERL Site:						Study Subject ID: Study Subject DD8:
Event Name: Visit 16						
Event Date:						
Section Title: Section B	. Urine Specimens					
B1. ACR/AER Collected	⊖ Yes ⊖ No					
	O NA-if visit 6_8_10_12 or 14					
Overnight	○Yes ○No	Date Ended Collection				
First Morning	○Yes ○No	Date Collected				
Spot Urine	⊖Yes ⊖No	Date Collected	Additional Date Collected	If necessary	Additional Date Collected	If necessary
B2. Shipped to ARDL	○ Yes ○ No	Date Shipped				

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 16 Event Date:	-		Study Subject ID: Study Subject DOR
Section Title: Section C.	Biospecimens for Reposit	ory	
	⊖Yes ⊙No		
C1. Serum Collected	⊖ Yes ○ No	Date Collected	
C2. Plasma Collected	○ Yes ○ No	Date Collected	
C3. Urine Collected	⊖ Yes ⊖ No	Date Collected	
C3a. Protease Inhibitor Added	○ Yes ○ No		
C4. Shipped to ARDL	⊖ Yes ⊙ No	Date Stipped	

Protocol ID: PERL001 Study Name: PERL				Study Subject ID: Study Subject ID:
Site: Event Name: Visit 16				
Event Date:	_	PERL	_011_Skin Assessment - V3.0	
Section Title: Skin Asse	ssment		-	
Indicate who performe Select: *	O Participant Self-Assessment			
Was any rash present of	Clinician Assessment during the assessment?			
•	○ Yes ○ No			
A1. Has the participant	Not Assessed	on Syndrome (SJS) symptoms?		
Select:	○ Yes ○ No ○ Not Assessed			
Select all that apply:				
Fever	□Fever			
Duration:	(days)			
Maximum temperature:	Celsius or Farenheit:	○ °C ○ °F	Unknown temperature	
Skin tenderness	Skin tenderness			
Sore throat	□ Sore throat			
Photophobia	□ Photophobia			
Burning eyes				
Itching eyes	Burning eyes			
	Itching eyes ick and purulent sputum			
Headache	⊡Cough			
	Headache			
Malaise	Malaise			
Arthralgia	□ Arthralgia			
A2. During assessment Select:	, was any swelling or rash noted? OYes			
	No Not Assessed			
Select all that apply: Burning rash				
	Burning rash			
Skin pain	□Skin pain			
Facial swelling	□ Facial swelling			
Tongue swelling	Tongue swelling			
Red or purple skin rash	Red or purple skin rash			
Area of rash (select all				
	Grace	Chest	Abdomen Patms	
	□ Soles	Back		
Target lesions surround	ded by macular erythema			
Hives	Hives			
Area of hives (select al				
	□ Face	Chest	Abdomen	
	Arms Soles	Eegs	Paims	
Blisters	Bisters			
Area of blisters (select				
	□ Face	Chest	Abdomen	
	⊡ Arms	□ Legs	Paims	
	Soles	Genitals	🗆 Anal	
Shedding	Shedding (sloughing) of skin			
Area of shedding (sele				
	Face	□ Chest	Abdomen	
	Arms	🗆 Legs	□ Paims	
Denuded skin areas				
Area of denudation (se	Denuded skin areas			
	Face	Chest	Abdomen	
	Arms	🗆 Legs	□ Palms	
	□ Soles	Back		

A3. During assessment was any mucous membrane involvement noted?

Select:	Yes		
	No Not Assessed		
	Chier Addata		
Select all that apply:			
Oral mucosa			
	Oral mucosa		
Oral mucosa (select a	ll that apply):		
	□Erythema	Edema	Skughing
	Blistering	Ulceration/erosion	Necrosia/aust
Nasal mucosa			
	Nasal mucosa		
Nasal mucosa (select	all that apply):		
	□Erythema	Edema	
	Blistering	Ulceration/erosion	□ Necrois/aust
Eyes			
	Eyes		
Eyes (select all that a	oply):		
	□ Excessive tearing	Hyperemia	
	□Scarring		
Urinary tract			
	Urinary tract		
Urinary Tract (select a	all that apply):		
	□ Dysuria	Urinary retention	
Pulmonary			
	Pulmonary		
Pulmonary (select all	that apply):		
	Dyspnea	Productive cough	Pumorary edema

□Febrile □Other

If Other, Specify:

Protocol ID: PERL001 Study Name: PERL Site:			Study Subject ID: Study Subject ID::
Event Name: Visit 16			
Event Date:	_		
		PERL_019_iGFR Procedures Form - V3.0	
Section Title: I. iGFR P	ocedure		
Upload source docume	nts:		
A1. Was the iGFR Perfe	rmed?		
Please Select:	OYes		
	○ No		
If No, Reason: (check all that apply)	ITU		
	BP too high		
	Positive pregnancy test		
	Hyperglycemia		
	Hypoglycemia		
	□ Vamiting		

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 16 Event Date: Section Title: II. iGFR Draw	Times					Study Subject DDR
A2. Date of iGFR:						
Date of iGFR:						
A3. iGFR Collections: Start clock at end of Omnipaque injection* (No Sample)	"0" time 00:00					
A4. 120 minutes						
Projected draw time for sample:	Actual draw t hour clock):	time of sample (24 (0	00:00)	Slucose value	(mg/dl)	Not Done
A5. 150 minutes						
Projected draw time for sample:	Actual draw t hour clock):	time of sample (24 (00:00)	Slucose value	(mg/df)	Not Done
A6. 180 minutes						
Projected draw time for sample:	Actual draw t hour clock):		00:00) 0	Slucose value	(mg/dl)	□ Net Done
A7. 210 minutes						
Projected draw time for sample:	Actual draw t hour clock):		00:00)	Glucose value	(mg/dl)	Not Done
A8. 240 minutes						
Projected draw time for sample:	Actual draw t hour clock):	time of sample (24 (0	00:00)	Slucose value	(mg/dl)	Not Done
A9. Samples shipped to cen	tral lab?					
Please Select: OY		s Shipped:				
A10. Backup samples shipp	ed to central lab?					
Plesse Select: O Y O N O N	0	Samples Shipped:				

Study Name: PERL Site: Event Name: Visit 16					ubject ID:ubject DOB:			
Event Date:		PERL_022_Study Drug Compli	ance and Exposure -	V3.0				
Section Title: Study Medication Log Instructions: Refer to the MOD Core drained instructions and examples. All dosages and discontinuations must be listed for the entire Dosing Period. The Dosing Period starts with the date the subject takes the first pill from the shipment received after the prior visit and ends with the date the subject takes the last pill from the shipment because they received a new shipment of pills. Has the subject permanently discontinued the study drug prior to this dosing period?:								
ill be the previous line Stop Date plus 1 day.')" onmouseout="UnTip(ate)"≥Start Start Date Unknown	taking pills of the same dose or the last day not taking pills.')" onmouseout="UnTip()">Stop Date	Stop Date	Dosage Dispensed by	Type of Change			
			Unknown	Pharmacy		Other Type of Change		Other Reason fo Change

Protocol ID: PERL001 Study Name: PERL	Study Subject ID: Study Subject DDB:
SterEvent Name: Visit 16	and subsc too
Event Date:	
Section Title: Study Drug Exposure	
Instructions: For the entire Dosing Period. The Dosing Period starts with the ends with the date the subject takes the last pill from that shipment becaus	the subject takes the first pill from the shipment received after the prior visit and received a new shipment of pills.
1a. Date started using drug vials:	
	nwa
1b. Date stopped using drug vials:	
Difference in days:	
1c. Number of pills should have taken if there were no Discontinuations;	
	nwa
Please explain why the number of pills the subject should have taken is Un	
2. Number of pills instructed not to take: (by vial because the number can be different for each vial)	
Vial A: *	
Vial B: *	
Vial C: * Vial D: *	
Total number of pills instructed not to take:	
3. Number of pills should have taken: (by vial because the number can be different for each vial) Visl A:	
Vial B:	
Vial C:	
Vial D:	
Total number of pills should have taken:	
4. Number of pills dispensed:	
4. Number of pills dispensed: (by vial because the number can be different for each vial) Vial & *	
Vial B: *	
Vial C: *	
Vial D: *	
Total number of pills dispensed:	
5. Were pills returned in individual vials: * OYes	
 No Pills not returned 	
Number of Pills Returned: (by vial because the number can be different for each vial)	
(by vial because the number can be different for each vial) Vial A:	
Vial B:	
Vial C:	
Vial D:	
Total number of pills returned:	
Total number of pills returned:	
 Number of pills taken: (by vial because the number can be different for each vial) 	
(by vial because the number can be different for each vial) Vial A:	
Vial B:	
Vial C	
Vial D: Total number of pills taken:	
Total number of pills taken:	
7. Select the reason Drug Compliance cannot be calculated at this visit:	
O Subject did not return pills O Pills were thrown away	
 Pills were lost Start date and/or Stop date unknown 	
○ Not applicable ○ Other	
If Other, Specify:	

Protocol ID: PERL001	Study Subject ID:
Study Name: PERL	Study Subject DD8:
Site:	
Event Name: Visit 16	
Event Date:	
Section Title: % Compliant Calculation	
B1. Percent Compliant (if total pills taken reported by the 4 individual vials)	
B2. Percent Compliant	

.

You can now return to the Compliance tab to review subject's compliance and if you wish, the Exposure tab to review pill counts and calculations.

□Confirm form is complete and source document uploaded.

Visit 17: PERL_006_Blood Pressure and Measurements - V1.0 PERL_008_Local Laboratory Results - V5.0 PERL_0101_Entral Lab Specimen Collection - V4.0 PERL_0101_EFR Procedures Form - V3.0 PERL_023F_Follow Up_Complication Questionnaire - 1.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 17	-		Study Subject ID: Study Subject ID:B:
Event Date:			PERL_006_Blood Pressure and Measurements - V1.0
Section Title: Blood	Pressure and Heart Rate		
Subtitle:			
Measurements:			
A1. Weight:	(kg)	Not Done	
A2. Height:	(cm)	Not Done	
Upload Source Doc			
Blood Pressure:			
B1. First Reading			
B1a. Systolic:	(mmHg)		
B1b. Diastolic:	(mmHg)	BP Not Done	
B1c. Heart Rate:	(bpm)	🗆 HR Not Done	
B2. Second Reading	a		
B2a. Systolic:	(mmHg)		
B2b. Diastolic:	(mmHg)	BP Not Done	
B2c. Heart Rate:	(bpm)	🗆 HR Not Done	
B3. Third Reading			
B3a. Systolic:	(mmHg)		
B3b. Diastolic:	(mmHg)	BP Not Done	
B3c. Heart Rate:	(bpm)	III HR Not Done	

Protocol ID: PERL001 Study Name: PERL		Study Subject ID: Study Subject DOB:
Site:		
Event Name: Visit 17		
Event Date:	-	
Section Title: Average B	ood Pressure and Heart Rate	
Subtitle:		
Calculated Fields:		
Calculated Fields:		
BMI		
BMI:		
Blood Pressure		
Systolic:	(mmHg)	
Diastolic:	(mmhg)	
Heart Rate:	(čpm)	

Protocol ID: PERLOL Sudy Name: PERL Site:	Study Subject ID: Study Subject DOR:
Event Name: Vidi 17 Event Name:	
PERL_008_Local Laboratory Results - V5.0	
Section Title: Section A. Chemistry	
Subtitle:	
Instructions: Enter the lab values in the units indicated with the date of collection for each field. Use the "Not Done" checkbox provided if data is unobtainable.	
Upload source documents:	
opioau source documents:	
Chemistry:	

Protocol ID: PERL001 Study Name: PERL Site: ______ Event Name: Visit 17 Event Date: ______ Study Subject ID:_____ Study Subject DOB:_____ Section Title: Section B. CBC Subtitle: B1. Hemoglobin: Date Collected: (gm/dl) □ Not Done B2. Hematocrit: (%) Date Collected: □ Not Done B3. Platelets: (mmol) Date Collected: □ Not Done (million cells/mcL) B4. RBC: Date Collected: Not Done B5. WBC: (cells/mcL) Date Collected: □ Not Done B5a. Neutrophils: (%) 🗆 Not Done B5b. Lymphocytes: (%) 🗆 Not Done B5c. Monocytes: (%) Not Done B5d. Eosinophils: (%) Not Done (%) B5e. Basophils: Not Done

Protocol ID: PERL001 Study Name: PERL Ste: Event Name: Visit 17 Event Date:			Study Subject ID: Study Subject DOR:
Section Title: Section C. P	regnancy Test		
C1. Urine Pregnancy Test Result:	 Positive Negative Not Done Not Applicable 	Date of test:	
C2. Serum Pregnancy Test Result:	 Positive Negative Not Done Not Applicable 	Date of test:	

Protocol ID: PERL001			Study Subject ID:
Study Name: PERL			Study Subject DOB:
Site:			
Event Name: Visit 17			
Event Date:	_		
Section Title: Section D.	Urine Multistix		
Date Urine Collected:		Not Done	
D1. Leukocytes:	Negative		
	O Trace		
	O Small		
	O Moderate		
	 Large 		
D2. Nitrites:	O Negative		
	O Positive		
D3. Protein:	 Negative 		
	 Trace 30 		
	○ 100		
	○ 300		
	C 2000+		
	0.1001		
D4. Blood	O Negative		
	 Positive 		
D4a. Blood - Non Hemolyzed:	 None 		
	 Trace 		
	O Moderate		
D4b. Blood - Hemolyzed:	None		
	 Trace 		
	O Small		
	 Moderate 		
	O Large		
D6. Ketones:	O Negative		
	⊖ Trace		
	O Small		
	 Moderate 		
	⊖ Large		

Protocol ID: FERL001 Study Name: FERL	Study Subject ID: Study Subject DOB:
Ster	
Event Name: Visit 17	
Event Date:	
Section Title: Section E. eGFR	
Subtitle:	
E1. Indicate visit for which this eGFR values applies:	
O Visit 1	
○ Visits 6-15	
E2. Use central lab creatinine value to calculate eGFR	
Click Here to Calculate eGFR Central lab greathine value	
Celtu al lab di edultine value	
E3. Use local lab creatinine value to calculate eGFR	
Click Here to Calculate eGFR	
Local lab creatinine value	
E4. eGFR: (mls/min/1.73m ²) Date Collected:	Not Done

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 17 Event Date:				Study Subject DOR:
		PERL_010 Central Lab Specimen Collection - V4.0	0	
Section Title: Section A. B	lood Specimens			
Instructions: Please indicate the collect	ted specimens and prov	ide the date of collection.		
A1. Serum Uric Acid, Creatinine, Cystatin C Collected	⊖ Yes ⊖ No	Date Collected		
A2. HbA1c Collected	⊖Yes ⊙No ⊙NA-if visit 6	Date Calledad		
A3. Shipped to ARDL	ି Yes ି No	Date Styped		

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Visit 17 Event Date:	_					Study Subject DOR:
Section Title: Section B	. Urine Specimens					
B1. ACR/AER Collected	○ Yes ○ No ○ NA-if visit 6_8_10_12 or 14					
Overnight	⊖Yes ⊖No	Date Ended Collection				
First Morning	⊖Yes ⊖No	Date Collected				
Spot Urine	⊖Yes ⊖No	Date Collected	Additional Date Collected	If necessary	Additional Date Collected	II necessary
B2. Shipped to ARDL	○ Yes ○ No	Date Shipped				

Protocol ID: PERL001 Study Name: PERL Site:			Study Subject ID: Study Subject DOR:
Event Name: Visit 17			
Event Date:	_		
Section Title: Section C.	Biospecimens for Reposit	ory	
Is this Visit 4, 11, 16 or 17	⊙Yes ⊙No		
C1. Serum Collected	ି Yes ି No	Date Collected	
C2. Plasma Collected	⊖ Yes ⊖ No	Date Collected	
C3. Urine Collected	⊖ Yes ⊖ No	Date Collected	
C3a. Protease Inhibitor Added	○ Yes ○ No		
C4. Shipped to ARDL	⊖ Yes ⊙ No	Date Shipped	

Protocol ID: PERL001 Study Name: PERL					Study Subject ID: Study Subject ID::		
Site: Event Name: Visit 17 Event Date:							
Event Date:	_		PERL	_011_Skin Assessment - V3.0			
Section Title: Skin Asse	ssment						
Indicate who performe Select: *	cd this skin assessment: ○ Participant Self-Assessment						
Was any rash present of	Clinician Assessment						
	⊖Yes ⊙No						
A1. Has the participant	Not Assessed	ore-rash Stevens-Johnson	Syndrome (SJS) symptoms?				
Select:	○Yes ○No ○Not Assessed						
Select all that apply:	Cinc Addata						
Fever	□Fever						
Duration:	(days)						
Maximum temperature:		Celsius or Farenheit:	0 °C 0 °F	Unknown temperature			
Skin tenderness	□Skin tenderness						
Sore throat	□Sore throat						
Photophobia							
Burning eyes	Photophobia						
Itching eyes	Burning eyes						
	□ Itching eyes						
Cough productive of th	ick and purulent sputum						
Headache	Headache						
Malaise	□Malaise						
Arthralgia	□ Arthralgia						
A2. During assessment	, was any swelling or rash	noted?					
Select:	○Yes ○No ○Not Assessed						
Select all that apply:							
Burning rash	Burning rash						
Skin pain	□Skin pain						
Facial swelling	□ Facial swelling						
Tongue swelling							
Red or purple skin rash	□Tongue swelling						
Area of rash (select all	Red or purple skin rash						
	Face		Chest	Abdomen			
	Arms		Legs	□ Palms			
Target lesions surround	□Soles ded by macular erythema		Back				
Hives	Target lesions						
	Hives						
Area of hives (select al	Face		Chest	D Abdomen			
	□Arms		Legs	Patms			
	□ Soles		Back				
Blisters	Blisters						
Area of blisters (select							
	Generation Face		Chest	Abdomen Patms			
	Soles		Genitals	□ Anel			
	Back						
Shedding	Shedding (sloughing) of skin						
Area of shedding (selec							
	□ Face		Chest	Abdomen Patms			
	Soles		Back				
Denuded skin areas	Denuded skin areas						
Area of denudation (se							
	Face		Chest	Abdomen			
	□ Arms		🗆 Legs	Paims			

A3. During assessment was any mucous membrane involvement noted?

Select:	Yes		
	No Not Assessed		
Select all that apply:			
Oral mucosa			
	□ Oral mucosa		
Oral mucosa (select a	ll that apply):		
	□Erythema	Edema	Skughing
	Blistering	Ulceration/erosion	Necrosia/aust
Nasal mucosa			
	Nasal mucosa		
Nasal mucosa (select	all that apply):		
	□Erythema	Edema	
	Blistering	Ulceration/erosion	□ Necrois/aust
Eyes			
	□ Eyes		
Eyes (select all that a	pply):		
	Excessive tearing	Hyperemia	
	□Scarring		
Urinary tract			
	Urinary tract		
Urinary Tract (select a	all that apply):		
	Dysuria	Urinary retention	
Pulmonary			
	Pulmonary		
Pulmonary (select all	that apply):		
	Dyspnea	Productive cough	Pumorary edema

Protocol ID: PERL001 Study Name: PERL Site:				Subject ID: Subject DO8:	
Event Name: Visit 17					
Event Date:					
		PERL_019_iGFR Procedures Form - V3.	0		
Section Title: I. iGFR I	Procedure				
Upload source docum	ents:				
A1. Was the iGFR Per					
Please Select:	OYes				
	○ No				
If No, Reason: (check all that apply)	пπ				
	□ BP too high				
	Positive pregnancy test				
	Hyperglycemia				
	Hypoglycemia				

If Other, Specify:

□Vomiting □Febrile □Other

Protocol ID: PERL001						Study Subject ID:
Study Name: PERL						Study Subject DOB:
Site:						
Event Name: Visit 17						
Event Date:						
Section Title: II. iGFR	Draw Times					
A2. Date of iGFR:						
Date of iGFR:						
A3. iGFR Collections:						
Start clock at end of Omnipaque injection* (No Sample)	e "0" time 00:00					
A4. 120 minutes						
Projected draw time for sample	:	Actual draw time of sample (24 hour clock):	(00:00)	Glucose value	(mg/dl)	Not Dane
A5. 150 minutes						
Projected draw time for sample	:	Actual draw time of sample (24 hour clock):	(00:00)	Glucose value	(mg/dl)	Net Dane
A6. 180 minutes						
Projected draw time for sample	:	Actual draw time of sample (24 hour clock):	(00:00)	Glucose value	(mg/dl)	Not Done
A7. 210 minutes						
Projected draw time for sample	:	Actual draw time of sample (24 hour clock):	(00:00)	Glucose value	(mg/dl)	Not Done
A8. 240 minutes						
Projected draw time for sample	:	Actual draw time of sample (24 hour clock):	(00:00)	Glucose value	(mg/dl)	Nkt Dane
A9. Samples shipped	to central lab?					
Please Select:	⊖Yes	Date Samples Shipped:				
Ficase addu.	O No	Date samples snipped:				
	O NO					
A10. Backup samples	shipped to central lab?					
Please Select:	OYes	Date Backup Samples Shipped:				
	○ No					
	ONA					

Event Date:	PERL_023F_Follow Up_Complication Questionnaire - 1.0
Site: Event Name: Visit 17	
Study Name: PERL	Study Subject DOB:
Protocol ID: PERL001	Study Subject ID:

Section Title: Initial Instructions: The PERL_023_Initial Complications Questionnaire should be completed prior to completing the PERL_023 Follow Up Complications Questionnaire. If the subject has progressed to visit 17 prior to implementation of this form, complete only the PERL_023_Initial Complications Questionnaire. A1. Was the PERL_023_Initial Complications Questionnaire completed?
*
OYes
ONo-Complete the Initial form prior to completion of the follow up form

Protocol ID: PERLOD1	Study Subject ID:
Protocol ID: PERLODI Study Name: PERL	Study Subject ID: Study Subject DOB:
Site: Event Name: Violt 17	
Event Name: Visit 17	
Event Date:	
Section Title: CHF	

B1. Select one of the following that best reflects your current health status:
C1 have no instance of my physical activity. Ordering physical activity does not cause me undue falique, palplation (inequiter or strong heart best sensations), or shortness of breath.
C1 have sight fination of physical activity. I an combinate it rest, however ites than ordering yaching activity act

Protocol ID: PEBL001	Study Subject ID:
Sudy Name: FERL Ste:	Study Subject DO8:
Event Name: Vok 17 Event Date:	
Section Title: Neuropathy	
Peripheral Neuropathy Symptoms In the questions below, please select the best answer that reflects your current health status. D3. Are your fest and/or legs numb?	
* OYes No	
D4. Do you ever have any burning pain in your legs and/or feet?	
• • • Yes • No	
D5. Are your symptoms worse at night?	
• OYes ONo	
D6. Does it hurt when the bed covers touch your skin?	
• OYs	
Autonomic neuropathy (SAS) In the questions below, please select the best answer that reflects your current health status. D7. Do you have light headedness?	
* Yes 0No	
D8. Do you have a dry mouth or dry eyes?	
• OYes No	
D9. Are your feet pale or blue?	
* Yes No	
D10. Are your feet colder than the rest of your body?	
* OYes ONo	
D11. Is sweating in your feet decreased or absent (for example, after exercise or during hot weather)?	
• • • • • • • • • • • • • • • • • • •	
D12. Is sweating in your hands increased compared to the rest of your body?	
Cite ONo	
D13. Do you have nausea, vomiting or bloating after eating a small meal?	
_No	
D14. Do you have persistent diarrhea (more than 3 loose bowel movements per day)? * OYes	
∩No	
D15. Do you have persistent constipation (less than 1 bowel movement every other day)? * OYes	
ONo	
D16. Do you have leaking of urine? * OYes	
○No	
D17. Do you have difficulty obtaining an erection?	
No OFensle	
Unscheduled Visit:	
Unscheduled Visit: PERL_006_Blood Pressure and Measurements - V1.0	
PERL_000_Endod Pressure and Measurements * V1.0 PERL_007_Physical Examination • V1.0 PERL_007_Local Laboratory Results • V5.0	
PERL_001_ECG Report - V1.0 PERL_010 Central Lab Specimen Collection - V4.0	
PERL 011 Skin Assessment - V3.0 PERL 019 JGHS Form - V3.0 PERL 019 JGH	
PERL_025 Unscheduled Visit Reason - V1.0	

Investigator Name: ______ Investigator Signature: _____ Date: _____

Protocol ID: PERL001 Study Name: PERL			Study Subject ID: Study Subject D00t:
Site:			
Event Name: Unscheduled Vi			
Event Date:			
			PERL_006_Blood Pressure and Measurements - V1.0
Section Title: Blood I	Pressure and Heart Rate		
Subtitle:			
Measurements:			
A1. Weight:	(kg)	□ Not Done	
A2. Height:	(cm)	Not Done	
Upload Source Docu	ments:		
Blood Pressure:			
B1. First Reading B1a. Systolic:	(mmHg)		
B1b. Diastolic:	(mmHg)	BP Not Done	
B1c. Heart Rate:	(bpm)	U HR Not Done	
B2. Second Reading			
B2a. Systolic:	(mmHg)		
B2b. Diastolic:	(mmHg)	BP Not Done	
B2c. Heart Rate:	(bpm)	III HR Not Done	
B3. Third Reading			
B3a. Systolic:	(mmHg)		
B3b. Diastolic:	(mmHg)	BP Not Done	
B3c. Heart Rate:	(bpm)	I HR Not Done	

Protocol ID: PERL001 Study Name: PERL		Study Subject ID: Study Subject DOB:					
Event Name: Unscheduled Visit							
Event Date:							
Section Title: Average B Subtitle:	ood Pressure and Heart Rate						
Calculated Fields:							
BMI BMI:							
Blood Pressure							
Systolic:	(mmHg)						
Diastolic:	(mmig)						
Heart Rate:	(tpm)						

Protocol ID: PERL001		Study Subject ID:
Study Name: PERL		Study Subject DOB:
Site: Event Name: Unscheduled Visit	- bit	
Event Date:		
	PERL_007_Physical Examination - V1.0	
Section Title: Body Sys	System	
A0. Was a physical exa	exam performed at this visit? Yes	
	© No	
Upload source docume	ments:	
A1. Eyes:		
Eyes (including fundoscopy):	Chormal	
	○ Not Done	
If abnormal, describe to Select all that apply:	De findings:	
Seet all that apply.		
	☐ Macular Degeneration	
	□ Other	
If other, specify:		
A2. Cardiovascular: Cardiovascular:	○ Normal	
	⊖ Abnormal ⊖ Not Done	
If abnormal, describe	be findings:	
Select all that apply:	□Arttythmia	
]]Nurmur	
	∃0ther	
If other, specify:		
A3. Extremities: Extremities:	○ Normal	
	O Abnormal O Not Done	
If abnormal, describe		
Select all that apply:	□ Amputation	
Amputation, specify:		
	Tenderness	
	_ Edema	
	- Pulses	
Pulses:	00+	
	01+ 02+	
	03+ 04+	
	Other	
If other, specify:		
A4. Lymph Nodes:		
Lymph Nades:	O Normal	
	O Not Done	
If abnormal, describe to Select all that apply:	Isweling	
	□ Other	
If other, specify:		
A5. Pulmonary:		
Pulmonary:	O Normal	
	O Not Done	
If abnormal, describe to Select all that apply:	Reduced breath sourds	
	Other	
If other, specify:		
A6. Skin:		
Skin:	O Normal	
	○ Not Dane	
If abnormal, describe to Select all that apply:	lef findings: □Red or purple painful rash	
	Scar	
	□ === □ Eczema	
	□ Footisis	
	Excessive Bruisting	
	□ Other	
If other, specify:		
A7. Gastrointestinal: Gastrointestinal:	Normal	
	O Abnormal O Not Done	
If abnormal, describe	be findings:	
Select all that apply:	Axites	
	□/Abdominal Mess	
	□ Organomegaly	
Organomegaly, specify:		
	Stoma	
	□ Other	
If other, specify:		
A8. Musculoskeletal Musculoskeletal:	O Normal	
	Oket Done Oket	
Tf abae		
If abnormal, describe	pe mongo:	

Select all that apply:	CSIfies
	□ Injury
	- ungay
Injury, specify:	
	Reduced strength
	Reduced range of motion
If other, specify:	
A9. Genitourinary:	
Genitourinary:	○ Nernal
	Akomal
	\ NXLORE
If abnormal, describe	e findings:
Specify:	
A10. Neurological:	
Neurological:	O Normal
	Abnormal
	⊖Not Dane
If abnormal, describe	e findings:
Select all that apply:	Abnormal Reflex Response
Abnormal reflex response, spec	vite - O khowflexia
маналла телек тезратас, арс	Ohladesia
	Diminished sensation
	Crank Menes
Abnormal, specify:	
If other, specify:	

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Study Subject ID:_____ Study Subject DOB:_____

Protocol ID: PERL001 Study Name: PERL Site: _______ Event Name: Unscheduled Visit Event Date:

Section Title: Other Body System

Other Body System
A11. Other Body System: Describe

Protocol ID: PERLIDOI Skudy Name: PERL Sker	Study Subject ID: Study Subject DOR:
PERL_008_Local Laboratory Results - V5.0	
Section Title: Section A. Chemistry	
Subtitle:	
Instructions: Enter the lab values in the units indicated with the date of collection for each field. Use the "Not Done" checkbox provided if data is unobtainable.	
Upload source documents:	
Chemistry:	

A1. Potassium:	(mmol/L)	Date Collected:	□ Not Done
A2. Creatinine:	(mg/dl)	Date Collected:	□ Not Done
A3. ALT (SGPT):	(U/L)	Date Collected:	□ Not Done

Protocol ID: PERL001 Study Name: PERL Site: ______ Event Name: Unscheduled Visit Event Date: _____ Study Subject ID:_____ Study Subject DOB:_____ Section Title: Section B. CBC Subtitle: Date Collected: B1. Hemoglobin: (gm/dl) □ Not Done B2. Hematocrit: (%) Date Collected: □ Not Done B3. Platelets: (mmol) Date Collected: □ Not Done (million cells/mcL) B4. RBC: Date Collected: Not Done B5. WBC: (cells/mcL) Date Collected: □ Not Done B5a. Neutrophils: (%) Not Done B5b. Lymphocytes: (%) Not Done B5c. Monocytes: (%) Not Done B5d. Eosinophils: (%) Not Done (%) B5e. Basophils: Not Done

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Protocol ID: PERL001 Study Name: PERL Site: Event Name: Unscheduled Visit Event Date:			Study Subject ID: Study Subject DOB:
Section Title: Section C. P	regnancy Test		
C1. Urine Pregnancy Test Result:	 Positive Negative Not Done Not Applicable 	Date of test:	
C2. Serum Pregnancy Test Result:	 Positive Negative Not Done Not Applicable 	Date of test:	

Protocol ID: PERL001			Study Subject ID:
Study Name: PERL			Study Subject DOB:
Site:			
Event Name: Unscheduled Visit			
Event Date:			
Event Date.	_		
Section Title: Section D.	Urine Multistix		
Date Urine Collected:		Not Done	
D1. Leukocytes:	 Negative 		
	O Trace		
	 Small 		
	O Moderate		
	 Large 		
D2. Nitrites:	O Negative		
	O Positive		
D3. Protein:	O Negative		
	 Trace 		
	O 30		
	100		
	C 300		
	O 2000+		
D4. Blood	O Negative		
	 Positive 		
	Ordane		
D4a. Blood - Non Hemolyzed:	 None 		
	 Trace 		
	O Moderate		
D4b. Blood - Hemolyzed:	None		
	 Trace 		
	 Small 		
	O Moderate		
	O Large		
D6. Ketones:	O Negative		
	O Trace		
	O Small		
	O Moderate		
	C Large		

Study Kanger FBL Study Kanger KBL Ster Study Kanger KDB. Forent Kanne: Utwachdadi Vall Forent Kanne: Utwachdadi Vall Section Title: Section E. GFR Studtile: I. Indicate visit for which this eGR values applies: Over tail Studtile: I. Subtile: Studie: Citle: Ger Kanger Kange						
Event Name: Usebodied Visit Section Title: Section E. eGFR Subtite: E1. Indicate visit for which this eGFR values applies: Over 1 Over 1:						
Section Title: Section E. eGFR Subtite: Subtite: E1. Indicate visit for which this eGFR values applies: Oven: 1						
Section Title: Section E. eGFR Subtite: E1. Indicate visit for which this eGFR values applies: Vive 1 Vive 1 Vive 1 Vive 1 Vive 1 Vive central lab creatinine value to calculate eGFR E2. Use central lab creatinine value to calculate eGFR Citck Here to Calculate eGFR						
Subtite: E1. Indicate visit for which this eGFR values applies: Visit 1 Visit 6-15 E2. Use central lab creatinine value to calculate eGFR Click Here to Calculate eGFR						
Subtite: E1. Indicate visit for which this eGFR values applies: Visit 1 Visit 6-15 E2. Use central lab creatinine value to calculate eGFR Click Here to Calculate eGFR						
E1. Indicate visit for which this eGFR values applies: Vite 1 Vite 1 Vite 4:5 E2. Use contail ab creatinine value to calculate eGFR Click Here to Calculate eGFR						
Viet: 4 Viets 6-15 E2. Use central lab creatine value to calculate eGFR Click Here to Calculate eGFR Click Here to Calculate eGFR						
Viet: 4 Viets 6-15 E2. Use central lab creatine value to calculate eGFR Click Here to Calculate eGFR Click Here to Calculate eGFR						
Vitas 6-15 E2. Use cartainine value to calculate eGFR Click Here to Calculate eGFR						
E2. Use central lab creatinine value to calculate eGFR Click Here to Calculate eGFR						
Click Here to Calculate eGFR						
Click Here to Calculate eGFR						
Central lab creditine value						
E3. Use local lab creatinine value to calculate eGFR						
Click Here to Calculate eGFR						
Local lab creatinine value						
E4.eGR: (mig/mig/122m ²) Date Collected:						

Protocol ID: PERL001 Study Name: PERL		Study Subject ID: Study Subject DOB:
Site: Event Name: Unscheduled Visi		
Event Date:	—	
	PERL_009_ECG Report - V1.0	
Section Title: ECG Rep	ort	
ECG Completed? *	Completed Not Completed	
Upload Source Document:		
A1. Date of ECG:		
A2. Heart Rate:	(tipm)	
A3. ECG Findings:	O Normal Abnormal	
A3a. If abnormal (sel	ect all that apply):	
	ST Bevation	
	LAtial Fib	
	Inversion	
	Q Wave	
	AV Block	
	I MI Granges	
	□ Techycardia	
	Bradycardia	
	Other	
If Other, Specify:		
A3b. Is this abnormality clinica significant?	ly OYes ** If yes, report on AE Log ONo	

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Unscheduled Visit Event Date:			Shudy Subject ID
		PERL_010 Central Lab Specimen Collection - V4.0	
Section Title: Section A. B Instructions: Please indicate the collect		de the date of collection.	
A1. Serum Uric Acid, Creatinine, Cystatin C Collected	⊖ Yes ⊖ No	Date_Collected	
A2. HbA1c Collected	○Yes ○No ○NA-ifvisit 6	Date Calested	
A3. Shipped to ARDL	ି Yes ି No	Date Stipped	

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Unscheduled Visit Event Date:	_					Study Subject ID: Study Subject DDR:
Section Title: Section B	. Urine Specimens					
B1. ACR/AER Collected	ਂ Yes ਂ No ਂ NA-≆rvisit 6_8_10_12 or 14					
Overnight	⊖Yes ⊖No	Date Ended Collection				
First Morning	⊖Yes ⊖No	Date Collected				
Spot Urine	⊖Yes ⊖No	Date Collected	Additional Date Collected	If necessary	Additional Date Collected	If necessary
B2. Shipped to ARDL	⊖ Yes ○ No	Date Shipped				

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Unscheduled Visit				Study Subject ID: Study Subject DOB:	
Event Name: Unscheduled Visit Event Date:					
Section Title: Section C.	. Biospecimens for R	epository			
Is this Visit 4, 11, 16 or 17	⊙Yes ⊙No				
C1. Serum Collected	⊖ Yes ○ No	Date Collected			
C2. Plasma Collected	⊖ Yes ⊖ No	Date Collected			
C3. Urine Collected	⊖ Yes ⊖ No	Date Collected			
C3a. Protease Inhibitor Added	○ Yes ○ No				
C4. Shipped to ARDL	○ Yes ○ No	Date Shipped			

Protocol ID: PERL001 Study Name: PERL				Study Subject ID: Study Subject DOR:
Site: Event Name: Unscheduled Visit Event Date:				
		PERL_	011_Skin Assessment - V3.0	
Section Title: Skin Asses				
Indicate who performed Select: *	d this skin assessment: Participant Self-Assessment Clinician Assessment			
Was any rash present d				
	○ Tes ○ No ○ Not Assessed			
A1. Has the participant Select:	had any of the following pre-rash Stevens-Johnson	Syndrome (SJS) symptoms?		
	O No Not Assessed			
Select all that apply: Fever				
	Fever			
Duration: Maximum temperature:	(days) Celsius or Farenheit:	°℃	Unknown temperature	
Skin tenderness		⊖∘F		
Sore throat	Skin tenderness			
	□ Sore throat			
Photophobia	□ Photophobia			
Burning eyes	Burning eyes			
Itching eyes	□ Itching eyes			
Cough productive of thi	ick and purulent sputum □Cough			
Headache	- Headache			
Malaise	□Malaise			
Arthralgia	□ Arthralgia			
A2. During assessment,	, was any swelling or rash noted?			
Select:	○Yes ○No ○Not Assessed			
Select all that apply:				
Burning rash	Burning rash			
Skin pain	□Skin pain			
Facial swelling	Facial swelling			
Tongue swelling	Tongue swelling			
Red or purple skin rash	Red or purple skin rash			
Area of rash (select all				
	Face	Chest	Abdomen	
	□ Arms	🗆 Legs	Palms	
Target lesions surround	led by macular erythema			
Hives	□Hives			
Area of hives (select all				
	Face	Chest	Abdomen	
	□ Arms	Legs Back	Paims	
Blisters	Blisters			
Area of blisters (select				
	-Face	Chest	Abdomen	
	□ Arms	Legs Genitals	Palms Anal	
	Back			
Shedding	Shedding (sloughing) of skin			
Area of shedding (selec	t all that apply):			
	□ Face	Chest	Dahns	
	□Arms	Legs Back		
Denuded skin areas	Denuded skin areas			
Area of denudation (see				
	Face	Chest	Abdomen	
	□ Arms	🗆 Legs	Palms	

A3. During assessment was any mucous membrane involvement noted?

Select:	Yes		
	No Not Assessed		
Select all that apply:			
Oral mucosa			
	Oral mucosa		
Oral mucosa (select a	ll that apply):		
	□Erythema	Edema	Skughing
	Blistering	Ulceration/erosion	Necrosia/aust
Nasal mucosa			
	Nasal mucosa		
Nasal mucosa (select	all that apply):		
	□Erythema	Edema	
	Blistering	Ulceration/erosion	□ Necrois/aust
Eyes			
	Eyes		
Eyes (select all that a	oply):		
	□ Excessive tearing	Hyperemia	
	□Scarring		
Urinary tract			
	Urinary tract		
Urinary Tract (select a	all that apply):		
	□ Dysuria	Urinary retention	
Pulmonary			
	Pulmonary		
Pulmonary (select all	that apply):		
	Dyspnea	Productive cough	Pumorary edema

Protocol ID: PERL001 Study Name: PERL Site:				Study Subject ID: Study Subject DOB:	
Event Name: Unscheduled Vis Event Date:					
		PERL_019_iGFR Procedures	s Form - V3.0		
Section Title: I. iGFR	Procedure				
Upload source docum	ients:				
A1. Was the iGFR Pe					
Please Select:	OYes				
	○ No				
If No, Reason: (check all that apply)	□UTI				
	BP too high				
	Positive pregnancy test				
	Hyperglycemia				
	□ Hypoglycemia				
	Vamiting				
	□ Febrile				

Other
 If Other, Specify:

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Unscheduled Visit Event Date:						Study Subject ID: Study Subject ID08:
Section Title: II. iGFR	Draw Times					
A2. Date of iGFR:						
Date of iGFR:						
A3. iGFR Collections:						
Start clock at end of Omnipaque injection* (No Sample)	e "0" time 00:00					
A4. 120 minutes						
Projected draw time for sample		Actual draw time of sample (24 hour clock):	(00:00)	Glucose value	(mg/dl)	Not Done
A5. 150 minutes						
Projected draw time for sample		Actual draw time of sample (24 hour clock):	(00:00)	Glucose value	(mg/dl)	Not Done
A6. 180 minutes						
Projected draw time for sample		Actual draw time of sample (24 hour clock):	(00:00)	Glucose value	(mg/dl)	Not Dane
A7. 210 minutes						
Projected draw time for sample		Actual draw time of sample (24 hour clock):	(00:00)	Glucose value	(mg/dl)	□ Not Done
A8. 240 minutes						
Projected draw time for sample		Actual draw time of sample (24 hour clock):	(00:00)	Glucose value	(mg/dl)	Not Done
A9. Samples shipped t	to central lab?					
Please Select:	⊖Yes ⊖No	Date Samples Shipped:				
A10. Backup samples	shipped to central lab?					
Please Select:	○Yes ○No ○NA	Date Backup Samples Shipped:				

Protocol ID: PERL001 Study Name: PERL			Study Subject ID: Study Subject DOB:
ite: Event Name: Unscheduled Visit			
vent Date:			
		PERL_025 Unscheduled Visit Reason - V1.0	
ection Title: Unschedu	led Visit		
A1. Please select the re	eason for this Unscheduled Visit:		
	Safety Check (Complete form(s) related to the safety check ONLY!)		
	 Other please specify (Complete applicable form(s) ONLY!) 		
If Other reason for visit, please specify: *			
A1a. Please select the	visit where the iGFR procedure was performed or attempted that this p Visit 4	procedure is to replace:	
	⊖ Visit 4a		
	○ Visit 7 ○ Visit 11		
	⊖Visit 16		
	○Visit 17		
A1b. If iGFR repeat or	ceattempt, please select the reason: O Invalid R2		
	Could not be completed		
	Protocol safety check		
A1b1. If Invalid R2, please select which samples: *	Original and Backup sample Orly Original Sample		
Backup sample not tested, please specify why: *			
A1b2. Please select the reason the reason the completed: *	Other		
A1c. If Safety Check, p	lease select all that apply:		
	Physical Exam		
	Lab Result ECG		
	Central Lab Specimen		
	Skin Assessment		
	Other Safety Check please specify		
If Other Safety Check, please specify: *			
A1d. Please select the	visit where something occurred prompting this Safety Check (select No $_{\bigcirc \text{Visit }1}$	one if not related to any visit):	
	○Visit 1a		
	O Eligibility Run-in		
	○ Visit 2 ○ Visit 3		
	○ Visit 4		
	⊖ Visit 4a		
	Eligibility Randomization Visit 5		
	○ Visit 5 ○ Visit 6		
	O Visit 7		
	O Visit 8		
	○ Visit 9 ○ Visit 10		
	O Visit 11		
	O Visit 12		
	○ Visit 13 ○ Visit 14		
	○ Visit 14 ○ Visit 15		
	O Visit 16		
	○ Visit 17 ○ Unscheduled Visit		
	O None		
A1d1. If Unscheduled Visit is	O(1)		
selected, please select which number: *	C(2)		
	ः (3) ः (4)		
	(5)(6)		
inal Status:			
PERL_035_Final Status	Form - 2.0		
nvestigator Name:	Investigator Signature:	Date:	

Study Name: PERL Study Subject DOR Ster Dere Name: Fiel Status	
Event Name: Final Status	
Event Date:	
PERL_035_Final Status Form - 2.0	
Section Title: Final Status Form	
A1. Final Status Date:	
AL. rinal status Jate: Oxte: *	
A2. Primary reason for terminating participation in the study:	
Please select: * O Completed study per protocol	
Oparticipant was determined to be ineligible	
Opticipant withdrew consent	
Investigator withdrew participant	
Study terminated by Sponsor Transferred to authority etc.	
O near the second and O Death	
Clast to followup	
Other	
Transferred to site #:	
New Subject ID:	
If Other, Specify	
Unmasking:	
Investigator Name: Investigator Signature: Date:	

Protocol ID: PERL001						Study Subject ID:	
Study Name: PERL						Study Subject DOB:	
Site: Event Name: Unmasking	-						
Event Name: Unmasking Event Date:							
Liten bate.							
				PERL_041_Unmasking Repor	t - V1.0		
Section Title: A. Uni	nasking Report						
A1. Date unmasking occurre	ed:						
	unmasked (check all tha	t apply)					
A2. a.	Subject						
b.	Coordinator						
с.	Principal Investigator or C	o-Principal Investigator					
d.	Other	If Other, Specify:					
	on or event that caused th	e unmasking? (check all that apply)					
A3. a.	Adverse Event If	checked, please complete AE Log form 020 or Si	E form 045				
b.	Accidental Unblinding						
с.	□ Inadvertent discourse by p	sharmacist					
d.	Other	If Other, Specify:					
How did the unmas	king occur? (check all tha	t apply)					
A4. a.	Pharmacist revealed v	erbally					
b.	Unblinding from website						
с.	□Other	If Other, Specify:					
Initial Complicati and Screening eGFR:	ons						
PERL_023I_Initial_0 PERL_026_Historica	Complication Questionnai leGFR Slope - 2.0	re - 1.0					

Investigator Name: _____ Date: _____ Date: _____

Protocol ID: PERL001 Study Name: PERL Site: Event Name: Initial Co Event Date:	omplications and Screening eGFR		Study Subject ID: Study Subject DOR:
			PERL_023I_Initial_Complication Questionnaire - 1.0
Section Title: M	acrovascular complications		
A1. Date of Init	tial questionnaire completion:		
Have you ever "before PERL"	had any of the following befor means that event or condition	e PERL: first occurred prior to PERL visit 1.	
	ck (myocardial infarction, MI):		
•	○ Yes ○ No ○ Unknown	At what age (first occurrence)? *	
A3. Coronary a	rtery bypass surgery (heart by	pass, CABG):	
•	⊂Yes ○No ○Unknown	At what age (first occurrence)? *	
A4. Angioplast	y or stent in a coronary artery:		
•	○Yes ○No ○Unknown	At what age (first occurrence)? *	
A5. Stroke, "mi	ini-stroke" or TIA (transient is	chemic attack):	
•	○ Yes ○ No ○ Unknown	At what age (first occurrence)? *	
A6. Congestive	e heart failure:		
•	○ Yes ○ No ○ Unknown	At what age (first occurrence)? *	Wee you een kopplalind for O'Yet congestive heart failure? * ONo
A7. Irregular h	eart beat (arrhythmia, atrial fi	brillation)	
•	⊖ Yes ⊖ No ⊖ Unknown	At what age (first occurrence)? *	Were you ever hospitalized for O Yes inequiar heart basit (anrihythmai, O No artival fibrilization)? *
A8. Amputation	n (not related to trauma)		
	⊂ Yes ○ No ○ Unknown	Where was the amputation? * O Toe(s)	Specify: *

Protocol ID: PERL001	Study Subject ID: Study Subject DOB:
	Study Subject DOB:
Ste:	
Event Name: Initial Complications tr>and br>Screening eGFR	
Event Date:	
Section Title: CHF	

B1. Select one of the following that best reflects your current health status:
C1 have no instance of my physical activity. Ordering physical activity does not cause me undue falique, palptation (inequiter or strong heart best sensations), or shortness of breath.
C1 have sight fination of physical activity. I an combinate it rest, however ites than ordering yacking activity causes me falique, palptation (irregular or strong heart best sensations), or shortness of breath.
C1 have sight activity. I an combinate at rest, however ites than ordering yacking activity causes falique, palptation (irregular or strong heart best sensations), or shortness of breath.
C1 have maked limitation of physical activity. I an combinate at rest, however ites than ordering yacking activity causes falique, palptation (irregular or strong heart best sensations), or shortness of breath.
C1 more under activity distribution full however ites than ordering yacking activity causes falique, palptation (irregular or strong heart best sensations), or shortness of breath.
C1 more under activity activity distribution full however ites than ordering yacking activity is under activity than activation in the system of the system activity than activation. The symptom or activity taket rest. If yan yacking activity is undertaken, ynd activity than activation in the system activity than activation for comparison.

Protocol DJ. PERLOLI Study Subje Study Hane; PERL Study Subje Stret:	
Site Event Name: Initial Complications-for-and-for-Screening eGR	
Event Name: Initial Complications>and str>screening eGR	
EPUR DOLL	
Section Title: Retinopathy	
C1. Have you ever been diagnosed with diabetic retinopathy (diabetic eye disease)?	
Yes	
○ No	
○ Unknown	
C2. Have you had any of the following treatments for diabetic retinopathy:	
C2a. Laser * OYes	
○No	
C2b. Eye injection * OYes	
ONe Charles Ch	
C2c Other eye surgery for Vier relangably (vierschar)* Other	
retinopathy (vitrectomy) * No	
C3. Have you lost vision or become blind from diabetic retinopathy?	
• OYes	
_No	
C4. When was your last eye exam by an eye specialist (dilated eye exam)?	
Month ◯January Year ⊡Date Unknown	
O February	
O March	
⊖ April	
⊖ May	
○ June	
_ July	
○ August	
○ September	
O October	
○ November	
○ December	

Protocol ID: PERL001	Study Subject ID:
Study Name: PERL Site:	Study Subject DOB:
Event Name: Initial Complications br>and sbr>Screening eGFR	
Event Date:	
Section Title: Neuropathy	
Peripheral Neuropathy Diagnosis	
D1. Have you been diagnosed with diabetic neuropathy? * OYs	
○ No ○ Unknown	
D2. Have you been diagnosed with Charcot foot?	
* ONo	
_ Uno ○ Unicom	
Peripheral Neuropathy Symptoms In the questions below, please select the answers that best reflect your current health status.	
D3. Are your feet and/or legs numb?	
⊖No	
D4. Do you ever have any burning pain in your legs and/or feet? • סיפ	
D5. Does it hurt when the bed covers touch your skin?	
* Yes No	
D6. Are your symptoms worse at night?	
• OVes ONo	
Autonomic neuropathy (SAS) In the questions below, please select the answers that best reflect your current health status. D7. Do you have light headedness?	
* Yes No	
D8. Do you have a dry mouth or dry eyes?	
• OYes ONo	
D9. Are your feet pale or blue?	
* ONo	
D10. Are your feet colder than the rest of your body? * OYes	
⊖No	
D11. Is sweating in your feet decreased or absent (for example, after exercise or during hot weather)?	
No	
D12. Is sweating in your hands increased compared to the rest of your body?	
• Ove	
D13. Do you have nausea, vomiting or bloating after eating a small meal?	
• OYes No	
D14. Do you have persistent diarrhea (more than 3 loose bowel movements per day)?	
* OYes ONo	
D15. Do you have persistent constipation (less than 1 bowel movement every other day)? * Yes	
ON6	
D16. Do you have leaking of urine? * OYes	
○ No	
D17. Do you have difficulty obtaining an erection? * O'Ye	
0 No	
OPenale	

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Protocol ID: PERL001 Study Name: PERL		Study Subject ID: Study Subject ID:
		study subject DOB:
Site:		
Event Name: Initial Complications<	br>and Screening eGFR	
Event Date:	-	
Section Title: Education		
E1. Indicate the highest	level of education	
	○ Some high school	
	□ High school graduate	
	○ Some college	
	College graduate	
	Graduate or professional degree	

Protocol ID: PERL001			Study Subject ID:
Study Name: PERL Site:			Study Subject DOB:
Event Name: Initial Complications br>and<	screening eGFR		
Event Date:			
		PERL_026_Historical eGFR Slope - 2.0	
Section Title: Historical eGFR			
Instructions: COMPLETE THIS	FORM FOR SUBJECTS QUALIFIED BY ALBUMINURIA AT SCREENIN	IG AS INDICATED ON FORM PERL_016_ACR/AER Screening	
	the study using eGFR slope as an eligibility criteria as indicated on I End Form	PERL_016_ACR/AER Screening, selection of A1c?	
	omplete the below eGFR information		
available creatinine measurem 3 serum creatinine measures a values from up to the previous values should be used to calcu • Most recent value is from sci • The oldest value is the value • All other values between the Provide cGR Sace Catalaton	afined as an eGFR (CKD-EPI) decline ≥3.0 ml/min/1.73 m2/year es ensts (including the one at screening assessment) from the previou are not available in the previous 2 years, then the slope can be deri 5 years. An EXCEL-based slope calculator is available on the PERL late the slope according to the following criteria: reening (local lab value) that is closest to 3 years that is GREATER or EQUAL to 3 years ago most recent value and the oldest value should be used	us 3 years. If at least ived from creatinine .website. The eGFR	
Result: *			
Date of Test *	eGFR (mi/min/1.73 m ²) *		
Date of Test *	eGFR (ml/min/1.73 m ²) *		
Date of Test *	eGFR (ml/min/1.73 m ²) *		
Date of Test	eGFR (mi/min/1.73 m²)		
Date of Test	eGFR (ml/min/1.73 m²)		
Date of Test	eGFR (ml/min/1.73 m²)		
Date of Test	eGFR (ml/min/1.73 m²)		
Date of Test	eGFR (ml/min/1.73 m²)		
Date of Test	eGFR (ml/min/1.73 m²)		
Date of Test	eGFR (ml/min/1.73 m²)		
Date of Test	eGFR (ml/min/1.73 m²)		
Date of Test	eGFR (ml/min/1.73 m²)		
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Date of Test	eGFR (ml/min/1.73 m²)		
Date of Test	eGFR (ml/min/1.73 m²)		
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Date of Test	eGFR (ml/min/1.73 m²)		
Date of Test	eGFR (ml/min/1.73 m²)		
Date of Test	eGFR (ml/min/1.73 m²)		
Date of Test	eGFR (ml/min/1.73 m²)		
AE, Con Med, Compliance, I	BP Med, and Deviation Logs:		
PERL_012_RAS and BP Medicat PERL_013_Concomitant Medica PERL_013_pg2 Concomitant Medica	ation Log - V2.0		

PERL_013_pg2 Concomitant Medication Log - V2.0 PERL_013_pg2 Concomitant Medications Contd - 1.0 PERL_020_Adverse Event Log - V1.0 PERL_040_Protocol Deviation Log - V1.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: PERL001		Study Subject ID:
Study Name: PERL		Study Subject DOB:
Site:		
	mpliance, BP Med, and Deviation Logs	
Event Date:		
		PERL_012_RAS and BP Medication Log - V3.0
Section Title: RASB M	edication Status at Enrollment	
	owing questions relate to the subject's RASB medication status at the time of enrollment	n the study.
B1. Was the subject	on a RASB medication at the time of enrollment in the study?	
	ିYs	
	○ No	
B2. Was the RASB m	edication dose at the time of enrollment in the study equivalent to at least 10 mg of Rami	ril?
•	OYes (if Yes, enter RASB medication information in log)	
	○ No	
B3 Was the BASB m	edication dose increased after enrollment in the study?	
*	Yes	
	○ No	
D4 Discus subscribes		
84. Please enter the	Start Date of the RASB dose increase after enrollment in the study: (then enter RASB medication information in log)	
	reason the RASB medication was NOT increased: ed" or "Healthcare provider opposed" confirm a protocol deviation has been submitted)	
*	Contraindications to higher RASB doses (then enter RASB medication information in log)	
	Participant opposed	
	Healthcare provider opposed	
	Other	
If Other, please spec	ífy:	
•		
C1. Was RASB medic	ation therapy initiated as part of the study?	
•	OYes	
	○No	
C2. Was the RASB m	dication dose equivalent to at least 10 mg of Ramipril?	
•	OYes (if Yes, enter RASB medication information in log)	
	○ No	
C3. Please select the	reason the RASB medication was NOT equivalent to at least 10 mg of Ramipril:	
	ed" or "Healthcare provider opposed" confirm a protocol deviation has been submitted)	
•	Contraindications to higher RASB doses (then enter RASB medication information in log)	
	Participant opposed	
	Healthcare provider opposed	
	○ Other	
If Other, please spec	ify:	
•		
C4. Please select the	reason RASB medication therapy was NOT initiated as part of the study:	
(if "Participant oppo	ed" or "Healthcare provider opposed" confirm a protocol deviation has been submitted) Ocntraindications or previous side effects	
	Contraindications or previous side effects Normoalbuminuric and normotensive subject who qualified by slope	
	Normolabuminunc and normotensive subject who qualified by slope Participant opposed	
	Healthcare provider opposed	
	Other	
If Other, please spec	ífy:	
•		

Protocol ID: PERU	001										
Study Name: PERI											
ite:											
Event Name: AE, (Con Med, Compliance, BP	Med, and Der	viation Lo	igs							
Event Date:											
C	: RASB Medication										
Instructions	Enter ONLY RASB	medicati	ons on	this log. Al	I other medications, inclue	ding BP me	eds, are	entered o	on Form 013 - Cor	comitant Medications L	og.
		ha	-								
Name:	If Other RASB Specify Generic Name	Dose:	Units:	Specify:	^{13,} Subject started medication PRIOR to	Start Date:	Ongoing	Stop Date	Stop Date Unknow	n Keason Stopped:	If Other Reason Stopped, Specify:
					enrollment in the study:						
					Yes No						
 Aliskiren 			omg		0 0					Not tolerated/side effects	
Azilsartan			⊖ mcg							Cost prohibitive	
 Benazepril 			O Other	,						Participant's decision	
Candesartan										O Healthcare provider's decision	1
Captopril										Changed dosage	
 Enalapril 										Changed RASB	
C Eprosartan										O Pregnancy or breast-feeding	
Fosinopril										Other	
○ Irbesartan											
 Lisinopril 											
O Losartan											
 Moexipril 											
Olmesartan											
Perindopril											
Quinapril											
 Ramipril 											
 Telmisartan 											
 Trandolapril 											
 Valsartan 											
Other specify											
		1	1	1							

Protocol ID: PERLOD1 Study Hame: FERL Ster	95		I	PERL_013_Concomitant Medicatio	n Log - V2.0		Study Subject ID:_ Study Subject DOB						
Section Title: Concomitant Medication Log Instructions: Enter all medications EXCEPT RAS	B meds on this log.	RASB meds are to be entered on For	m 012 - R <i>l</i>	ASB Medication Log.									
eenendering in the Specify field T. enonmouse de "UnTps/T-Medication Name: *	Nf Other Medication Nana: Specify:	Desci G (comm) mit (com) rel (nummer) c. (colic continentre: same as m) parts (control parts (control) parts (control)	If Other Dose Units, Specify:	TID (Draw times day) (20) (fore times day) (10) (fore times day)	If Other Dose Frequency, Specify:	Indication:	If Other Indication, Specify	Start Date:	Subject started medication PRIOR to enrollment in the study: Yes No	Ongoing	9 Date:	Unknown	If Other Reason, Specify

Acebutolo	്നള	QD	 Allergies 	0 0	Did not tolerate
Acetaminophen Alfuzosin HCl	ි mcg ි G	O BID	 Anxiety Asthma 		Cost prohibitive No longer
○ Alprazolam	⊖ gtt	⊂ QID	O CAD		required
 Amitriptyline HCL 	া	O PRN	CHF		Changed dose Changed medication
Amlodipine Amlodipine and atorvastatin	C cc C drops	ା EOD ା BIW	 Depression Diabetes 		medication
 Amoxicillin 	ා puffs	⊂ TIW	C Embolism		○ Other
Amoxicilin and clavulanate Ampicilin	⊂ sprays ⊖ tabs	⊂ QW ⊂ Q10D	Erectile disfunction Gastritis		
Ampeuin Asprin	⊖ taos ⊖ caps	Q2W	Gastros		
 Atenolol 	ារ	Q3W	GERD		
 Lipitor (atorvastatin) Avanafil 	O Unknown O Other	⊂ QHS ⊂ AC	 Glaucoma Headache 		
 Azithromycin 		0 CC	 Hyperlipidemia 		
 Bacitracin ointment Beclomethasone inhalation aerosol 		□ PC ○ QAM	 Hypertension Hypoglycemia 		
 Betaxolol 		⊂ QPM	 Hypothyroidism 		
 Bisoprolol fumarate Bisoprolol fumarate and hydrochlorothiazide 		 Q12H Q8H 	 Infection Neuropathy 		
O Burnetanide		O Q6H	Nutritional		
Calcitriol Calcium Carbonate and Calcium Citrate		ୁ ପ୍ୟୁମ ୁ ପୁସମ	Supplement Pain-Back		
 Capsaicin cream 		O Q2H	 Pain-Joint Pain-Surgical 		
Carteolol Carvedilol		 Unknown Other 	 Pain-unspecified 		
 Carveolioi Cephalexin 		Odda	 Phiebitis Retinopathy 		
 Cefazolin Cetirizine 			OUTI		
O Chlorthalidone			Other Unknown		
Ciprofloxacin			CONDWI		
Cisapride Citalopram hydrobromide					
 Clindamycin 					
 Clindamycin topical Clopidogrel bisulfate 					
Colsevelam					
 Diltiazem Domperidone 					
O Doxazosin Mesylate					
 Doxycycline Duloxetine 					
C Epoetin alfa and Darbepoetin alfa					
 Erythromycin Esomeprazole 					
 Esterified Estrogens 					
 Estradiol Estradiol transdermal gel 					
 Estradiol transdermal patch 					
Estradiol transdermal solution Estrogens - Conjugated					
 Ethacrynic acid 					
Evening Primrose Oil Ezetimibe					
 Ezetimibe and simvastatin 					
O Fenofibrate					
 Ferrous sulfate Fish oil 					
O Fluconazole					
Fludrocortisone Acetate Fluoxetine					
 Fluticasone propionate 					
Furosemide Gabapentin					
O Gentamicin					
 Glucagon Glucose tablets 					
 Guanabenz acetate 					
Guanethidine monosulfate Guanfacine hydrochloride					
○ Insulin regular					
Hydorcortisone Hydralazine					
 Hydrochlorothiazide 					
 Hydrocodone and acetaminophen 					
Hydroxyzine Ibuprofen					
Insulin (type unknown)					
 Novolog Insulin Degludec 					
 Insulin determin 					
 Lantus Insulin glulisine 					
Insulin NPH					
 Humalog Insulin lispro 					
Isosorbide mononitrate - dinitrate					
 Ketorolac Labetalol HCI 					
 Lansoprazole 					
C Levofloxacin C Levothyroxine					
O Liothyronine					
Coratadine					
C Lovastatin					
 Lovastatin and niacin Metformin 					
O Methimazole					
 Methyldopa Methyldopa and chlorothiazide 					
 Methyldopa and hydrochlorothiazide Methylphenidate 					
 Metodopramide 					
 Metodopramide oral dissolving tablet Metoprolol 					
 Metronidazole 					
 Miconazole Nadolol 					
Nadolol and bendroflumethiazide					
Naproxen Nebivolol					
○ Niacin					
 Nitroglycerin Omeprazole 					
 Oral contraceptive 					
Oxycodone Oxycodone and acetaminophen					
O Pantoprazole					
Paroxetine Penbutolol sulfate					
O Penicillin					
O Phenazopyridine					
 Pindolol Pramlintide Acetate 					
 Pravastatin 					
Prazosin Hydrochloride Prazosin hydrochloride and polythiazide					
O Prednisone					
O Pregabalin					
 Propranolol Propytthiouracil (PTU) 					
O Prost/Phen injectable					
Rabeprazole Ranitidine HCL					
 Reserpine 					
Reserpine and chlorothiazide Reserpine and chlorthalidone					
Reservine and hydralazine and hydrochlorothiazide					
Reservice and hydrochlorothiazide Operational HCI					

Protocol ID: PERLO01 Study Name: PERL Stee: Event Name: AE, Con Med, Compliance, BP Med, and Deviation LC Event Date:	ıgs						Study Subject ID: Study Subject DO						
			PER	L_013_pg2 Concomitant Medica	tions Contd -	1.0							
Section Title: Concomitant Medications Page T Instructions: This form is used ONLY when the	initial Form_013 Co	n Meds form has reached the maxim	um data er	ntry of 40 records.									
Enter all medications EXCEPT RASB meds on the	is log. RASB meds a	re to be entered on Form 012 - RASE	Medicatio	n Log.									
seanchine in the Specify field "." ommosecule-"00 Tip(">Medication Name: *	II O bhe Medication Name, Specify:	Descript (anoma) mit (forse) mit (mittikes) rc. (cable came as mit) drages (att) margane (att) margane (anoma) table. (athieta) case (cases) table. (athieta) table. (athieta) case (cases) table. (athieta) table. (athieta) ta	If Other Dose Units, Specify:	TD: Others times a day) OD: Other times a day) PRN. (owns meeting) ERN. (owns meeting) ERN. (owns films a week) ERN. (owns films a week) Other (owns films a week) Other (owns films a week) Other (owns films) Other (owns films) Other (owns films) C.C. (with meek) C.C. (with meek) C.C. (with meek) C.C. (with meek) C.C. (with meek) C.C. (with meek) C.C. (with meek) Other (owns films) Other (owns films) Oth	If Other Dose Frequency Specify:	Indication:	If Other Indication, Specify	Start Date:	Subject started medication PRIOR enrollment in the study: Yes No	Ongoing St	P Unknov	Vn Reason Stopped	I: If Other Reason, Specify

Acebutalal	mg	QD	 Allergies 	0 0	O Did not tolerate
Acetaminophen Alfuzosin HCl	C mcg	O BID TID	 Anxiety Asthma 		Cost prohibitive
O Alprazolam	o gtt	QID	o cab		required
 Amitriptyline HCL 	⊂ ml	O PRN	CHF		C Changed dose
Amlodipine Amlodipine and atorvastatin	⊂ cc ⊂ drops	⊖ EOD ⊖ BIW	 Depression Diabetes 		○ Changed medication
C Amoxicillin	\odot puffs	ा TIW	C Embolism		O Other
Amovicilin and clavulanate O Ampicilin	⊂ sprays ⊂ tabs	C QW C Q10D	 Erectile disfunction Gastritis 		
○ Asprin	C caps	ः Q2W	 Gastroparesis 		
Atenolol Dipitor (atorvastatin)	iu Unknown	ୁ ପୁ3W ୁ ପ୍ଲାର	GERD		
Avanafil	O Other	AC	Headache		
Azithromycin Bacitracin ointment		O CC □ PC	 Hyperlipidemia Hypertension 		
 Beclomethasone inhalation aerosol 		⊂ QAM	 Hypoglycemia 		
Betaxolol Bisoprolol fumarate		ି QPM ି Q12H	 Hypothyroidism Infection 		
Bisoprotol rumatate Bisoprotol fumarate and hydrochlorothiazide		O QEH	 Neuropathy 		
Bumetanide Calcitriol		⊂ Q6H ⊂ Q4H	 Nutritional Supplement 		
Calcium Carbonate and Calcium Citrate		Q3H	 Pain-Back Pain-Joint 		
Capsalicin cream Carteolol		O Q2H	O Pain-Surgical		
Carvedilol		O Other	 Pain-unspecified Phlebitis 		
Cephalexin Cefazolin			 Phiebitis Retinopathy 		
 Cetrizine 			O UTI		
O Chlorthalidone			Other		
Ciprofloxacin Cisapride					
Citalopram hydrobromide Ciindamycin					
Clindamyon Clindamyon topical					
Clopidogrel bisulfate Colsevelam					
O Dilbiazem					
 Domperidone 					
Doxazosin Mesylate Doxycycline					
Duloxetine Epoetin alfa and Darbepoetin alfa					
C Erythromycin					
C Esomeprazole C Esterified Estrogens					
O Estradiol					
 Estradiol transdermal gel Estradiol transdermal patch 					
 Estradiol transdermal solution 					
C Estrogens - Conjugated					
Ethacrynic acid Evening Primrose Oil					
 Ezetimibe Ezetimibe and simvastatin 					
O Fenofibrate					
 Ferrous sulfate Fish oil 					
O Fish di					
Fludrocortisone Acetate Fluoxetine					
Fluticasone propionate					
O Furosemide					
Gabapentin Gentamicin					
Glucagon					
Glucose tablets Guanabenz acetate					
Guanethidine monosulfate					
Guanfacine hydrochloride Insulin regular					
O Hydorcortisone					
 Hydralazine Hydrochlorothiazide 					
 Hydrocodone and acetaminophen 					
Hydroxyzine Ibuprofen					
 Insulin (type unknown) 					
 Novolog Insulin Degludec 					
 Insulin deternir 					
Lantus Insulin gluisine					
○ Insulin NPH					
 Humalog Insulin lispro 					
Isosorbide mononitrate - dinitrate					
 Ketorolac Labetalol HCI 					
 Lansoprazole 					
Levofloxacin Levothyroxine					
C Liothyronine					
Loratadine Lorazepam					
 Lovastatin 					
 Lovastatin and niacin Metformin 					
O Methimazole					
 Methyldopa Methyldopa and chlorothiazide 					
Methyldopa and hydrochlorothiazide Methylphenidate					
 Metoclopramide 					
Metoclopramide oral dissolving tablet Metoprolol					
 Metronidazole 					
 Miconazole Nadolol 					
Nadolol and bendroflumethiazide					
Naproxen Nebivolo					
○ Niacin					
O Nitroglycerin O Omeprazole					
 Oral contraceptive 					
Oxycodone Oxycodone and acetaminophen					
O Pantoprazole					
Paroxetine Penbutolol sulfate					
 Penicillin 					
O Phenazopyridine					
 Pindolol Pramiintide Acetate 					
 Pravastatin 					
Prazosin Hydrochloride Prazosin hydrochloride and polythiazide					
O Prednisone					
 Pregabalin Propranolol 					
Propylthiouracil (PTU)					
Prost/Phen injectable Rabeprazole					
Ranitidine HCL					
Reserpine Reserpine and chlorothiazide					
Reservine and chlorthalidone					
 Reserpine and hydralazine and hydrochlorothiazide Reserpine and hydrochlorothiazide 					
Reserpine and hydrochlorothiazide Deviational MPI					

Study Subject ID:_____ Study Subject DOB:_____

PERL_020_Adverse Event Log - V1.0

Section Title: Adverse Events									
Instructions:			-						
Adverse Event: Choose an ever Onset Date: Enter the date the	Adverse	e drop down list Event began If	. Enter one even	t per line.	If the event	is not in the l	ist, choose Other an I dates are not acces	d specify the event in sted.	the next
End Date: Enter the date the A	dverse Ev	ent ended. If co	mplete date is u	nknown, e	nter an estin	nate. Partial d	lates are not accepte	ed. (If AE is ongoing, I	eave this
Severity: Indicate the severity Expected or Unexpected: Indic	grade of t	the AE. See MOC) for Grade defin	itions.	in the proto	col.			
Relationship to Allopurinol and	I Ramipril	: For each medic	ation, indicate it	f it had a c	ausal effect	on that Adver	se Event, as reporte	d by the Clinician/Inv	estigato
Action Taken with Allopurinol:	Indicate	the action take v	with allopurinol i	in response	e to the AE. (Report action	taken for ramipril s	uch as dose change o	r discont
Outcome: Indicate the outcom Treatment Required: Indicate i	e of the e if medicat	vent. tion or other trea	atment was requ	uired to tre	at this event	. If yes, enter	details on Concomi	tant Medication Log).	
Adverse Event Adverse Event *	If Other	Onset Date * End Dat	e Severity	Expected or	Relationship	Relationship	Action taken	Outcome	Treatmen
	Specify		-	Unexpected	to Allopurinol	to Ramipril	with Allopurinol		Required
Abnormal ECG changes from baseline				Expected		Definite Probable	None Discontinued	Resolved without sequelae	
Acute Joint/Foot pain Allergic reaction			 Grade 2 Moderate Grade 3 Severe 	Unexpected	 Probable Possible 	 Probable Possible 	 Discontinued Dose Reduced 	 Resolved with sequelae Ongoing 	O NO
Allergic reaction Allergic rhinitis			Usaue 3 Severe		 Not related 		 Dose Reduced Temporarily discontinues 		
ALT elevation							 Meds restarted 		
O Anemia									
 Ascites 									
Bladder infection Bronchial infection									
 Bronchial infection Cold symptoms 									
Cold symptoms Congestion									
Cough									
 Elevated creatinine 									
O Dehydration									
O Dermatitis									
 Diarrhea Difficulty breathing 									
 Difficulty breathing Czema 									
O Edema									
C Elevated bilirubin									
 Elevated transaminases 									
C Emesis									
 Epistaxis Fever 									
Flu-like symptoms									
Gastrointestinal disorder									
○ Gout									
O Headache									
O Hypertension									
O Hypoalbuminemia									
Hypocalcemia Increased sleepiness									
 Irritability 									
C Edema-limbs									
 Leukocytosis 									
C Localized edema									
Low iron Nasal congestion									
O Neutropenia									
O Nocturia									
O Polyuria									
○ Rash									
Reflux Sinus infection									
Sinus infection									
© Sore throat									
 Strep pharyngitis 									
Swelling of lips/tongue/throat/andgiodema									
O Upper respiratory infection									
O Urinary tract infection									
 Urticaria Viral illness 									
O Vorai liness O Vomiting									
O Weight loss									
O Weight gain									
O Wheezing									
 Worsening of diabetes Yellowing of eyes/skin 									

Protocol ID: PERL001						
Study Name: PERL						
Site:						
	led, Compliance, BP Med, and Deviation Logs					
Event Date:						
					PERL_0	40_Protocol Dev
Section Title: Pro	otocol Deviation					
Instructions:						
Please complete	one row for each protocol deviation	. Click "Add" to a	enter additional de	viations.		
Additional Comm	ents are not required and should be	entered only as	necessary.			
	Deviation: *	If Other Deviation	Study Procedure:	If Other Study	Reason for Deviation: *	Additional Comments:
the deviation occur? *		Specify:		Procedure, Specify		
None (not visit related)			○ Vitals		Site error	
⊖ Visit 1	Informed Consent deviation		 Anthropometrics 		 Participant refused 	
O Visit 2	 Study medication dose error 		O Physical Exam		 Participant too ill 	
○ Visit 3	Study procedure not completed		Clinical Lab		Time constraints	
○ Visit 4	Study procedure performed incorrectly		○ iGFR		 Unknown 	
⊖ Visit 4a	 Left arm used for BP 		 Skin Assessment 		 Other (Specify in Comments) 	
O Visit 5	O Participant not seated for 5 minutes prior to BP	>	C ECG			
⊖ Visit 6	 Other (Specify) 		 Randomization 			
O Visit 7			O Blinding			
O Visit 8			O Urine multistix			
O Visit 9			Study Drug Compliance	•		
O Visit 10			Other (Specify)			
○ Visit 11						
○ Visit 12						
O Visit 13						
○ Visit 14						
O Visit 15						
O Visit 16						
O Visit 17						
U THE A						

SAE:

PERL_045_Serious Adverse Event - V5.0

Investigator Name: _____ Date: _____ Date: _____

Protocol ID: PERL001	Study Subject ID:
Study Name: PERL	Sany Subject to: Sany Subject tot:
Site: Event Name: SAE	
Event Date:	—
	PERL_045_Serious Adverse Event - V5.0
Section Title: Serious	Adverse Event
Please upload original	al source documents associated with this SAE
Was SAE expected?	
A1. Please Select:	016 016
This AE fulfills the foll	lowing criteria for being an SAE (check all that apply)
A2. a.	The
b.	_ Duasity
с.	Cargential Anomely
d.	LUE Treatening
е.	Required Intervention to prevent permanent impairment/damage
f.	Choopelatation initial or prolonged
g.	Coter
A2a. If Other, Specify:	
SAE Diagnosis: A3. Please provide brief diagnos	wir *
SAE Description:	
A4. (Includes symptoms and dia tests)	legnotic SHE Description cont:
Specify Treatment for	r SAE:
A5. Please Specify:	Specify Treatment for SAE cost:
Age at time of SAE: ASa. Age	(Yoar)
Start Date:	(rear)
A6. Start Date:	A6. Start Time: Diktroom Start Time
(DD-MMM-YYYY) * Outcome:	(00:00 formal 24 hr clock)
A7. Outcome:	Recovered/resolved without sequelae Orgoing
	Organis Oktoreoreginor teshed ORecovered/resolved with sequelate
	O Reade O Reade U Usknown
End Date:	
A7a. End Date: (DD-MMM-YYYY)	A7b. End Time: Disknown End Time
	(00:90 format 24 fr dock)
Severity: Check MOO t A8. Severity:	for definition Oracle 1 Mid Oracle 2 Moderate
	O ranke 2 Mocente O ranke 2 Source O ran
Causality:	
A9. Causality: (relationship to allopurinol/placebo)	O Definite O Probable
	O Possible O Not related
	O Not assessible
Action Taken with allo A10. Action:	Opcontinued allopuring/jolucebo Date of Treatment Phase
P10. P0001.	Ordexmitted anguantypector Completed Completed Completed Completed Completed Completed
	Allopurinlojbacho interrupted Subject has not yet stanted allopurinlojfacebo
	doubci uto vectorio douporte postedo doubci no vectorio douporte postedo douporte posted douporte postedo
If allopurinol/placebo A10a. Please Select:	o discontinued or reduced, did SAE abate? ି Yବ
	Unes O No C Unicown
If allonuring/placebo	o unation
	o dose was reduced indicate date reduced was instituted and date full dose resumed.
A10c. Date reduced:	Date resumed:
	o dose was interrupted indicate stop/start dates.
A10d. Stop Date: Pilot Unscheduled V	to Start Date:
	Visit: sure and Measurements - P1.1
PERL_019_iGFR Procee PERL_022_Study Drug	dures Form - P2.1 (compliance and Exposure - V3.0
PERL_011_Skin Assess PERL_008_Local Labor	sment - V3.0

Investigator Name: _____ Date: _____ Date: _____

Protocol ID: PERL001 Study Name: PERL			Study Subject D08
Site:			
Event Name: Pilot Unscheduled	Visit		
Event Date:			
			PERL_006_Blood Pressure and Measurements - P1.1
Section Title: Blood Pr	ressure and Heart Rate		
Subtitle:			
Pilot Visit:			
•	O POST-RANDOMIZATION VISITS(V7)		
	O POST-RANDOMIZATION VISITS(V8)		
	O POST-RANDOMIZATION VISITS(V10)		
	O POST-RANDOMIZATION VISITS(V11)		
	O POST-RANDOMIZATION VISITS(V13)		
Measurements:			
A1. Weight:	(kg)	Not Done	
A2. Height:	(cm)	Not Done	
Upload Source Docum	ients:		
Blood Pressure:			
B1. First Reading			
B1a. Systolic:	(mmHg)		
B1b. Diastolic:	(mmHg)	BP Not Done	
B1c. Heart Rate:	(bpm)	HR Not Done	
B2. Second Reading			
B2a. Systolic:	(mmHg)		
B2b. Diastolic:	(mmHg)	BP Not Done	
B2c. Heart Rate:	(bpm)	HR Not Done	
B3. Third Reading			
B3a. Systolic:	(mmHg)		
B3b. Diastolic:	(mmHg)	BP Not Done	
B3c. Heart Rate:	(bpm)	HR Not Done	

Protocol ID: PERL001 Study Name: PERL Site:		Study Subject ID: Study Subject DOR:
Event Name: Pilot Unscheduled Ve Event Date:		
Section Title: Average B Subtitle:	ood Pressure and Heart Rate	
Calculated Fields:		
BMI:		
Blood Pressure		
Systolic:	(mmHg)	
Diastolic:	(mmHg)	
Heart Rate:	(bpm)	

Protocol ID: PERL001				Study Subject ID:
Study Name: PERL				Study Subject DOB:
Site:				
Event Name: Pilot Unschedul	d Visit			
Event Date:				
		PE	RL_019_iGFR Procedures Form - P2.1	
Section Title: I. iGFR	Procedure			
Pilot Visit:				
*	 POST-RANDOMIZATION VISITS(V7) 			
	O POST-RANDOMIZATION VISITS(V8)			
	O POST-RANDOMIZATION VISITS(V10)			
	O POST-RANDOMIZATION VISITS(V11)			
	 POST-RANDOMIZATION VISITS(V13) 			
Upload source docu	nents:			
A1. Was the iGFR Pe				
Please Select:	○Yes			
	○ No			
If No, Reason: (check all that apply)	UTI			
	BP too high			
	Positive pregnancy test			
	Hyperglycemia			
	□ Hypoglycemia			
	Vamiting			
	Febrie			
	Other			
If Other, Specify:				

Protocol ID: PERL001 Study Name: PERL Site:						Study Subject ID: Study Subject DOB:
Event Name: Pilot Unscheduled Event Date:						
Section Title: II. iGFR	Draw Times					
A2. Date of iGFR: Date of iGFR:						
A3. iGFR Collections: Start clock at end of Omnipaque injection* (No Sample)	"0" time 00:00					
A4. 120 minutes						
Projected draw time for sample:		Actual draw time of sample (24 hour clock):	(00:00)	Glucose value	(mg/dl)	Not Done
A5. 150 minutes						
Projected draw time for sample:		Actual draw time of sample (24 hour clock):	(00:00)	Glucose value	(mg/dl)	Not Done
A6. 180 minutes						
Projected draw time for sample:		Actual draw time of sample (24 hour clock):	(00:00)	Glucose value	(mg/dl)	Not Dane
A7. 210 minutes						
Projected draw time for sample:		Actual draw time of sample (24 hour clock):	(00:00)	Glucose value	(mg/dl)	□ Not Done
A8. 240 minutes						
Projected draw time for sample:		Actual draw time of sample (24 hour clock):	(00:00)	Glucose value	(mg/dl)	Not Done
A9. Samples shipped t	o central lab?					
Please Select:	⊖Yes ⊡No	Date Samples Shipped:				
A10. Backup samples	shipped to central lab?					
Please Select:	⊖Yes ⊖No ⊖NA	Date Backup Samples Shipped:				

Protocol ID: PERL001				Shudu S	ubject ID:			
Study Name: PERL					ubject DOB:			
Site:				500475	ubject 000			
Event Name: Pilot Unscheduled Visit								
Event Date:								
		PERL_022_Study Drug Complia	nce and Exposure -	V3.0				
Section Title: Study Medication Log								
Instructions: Refer to the MOO for detailed instructions and ex	amples All doca	ges and discontinuations must be listed for the entire Dosing Peri	od					
The Dosing Period starts with the date the subject takes the fin	st pill from the s	hipment received after the prior visit and	ou.					
ends with the date the subject takes the last pill from that ship	ment because th	ney received a new shipment of pills.						
Has the subject permanently discontinued the study drug prior	to this dosing p	eriod?:						
* 0Yes								
○ No								
rill be the previous line Stop Date plus 1 day.')" onmouseout="UnTip()">Star ate	Start Date	taking pills of the same dose or the last day not taking pills.')" onmouseout="UnTip()">Stop Date	Stop Date Unknown	Dosage Dispensed by Pharmacy	Type of Change	Other Type of Change	Reason for Change (select all that apply)	Other Reason for Change
vill be the previous line Stop Date plus 1 day.')" onmouseout="UnTip()">Star ate	t Start Date Unknown	taking pills of the same dose or the last day not taking pills.")" onmouseout="UnTip()">Stop Date	Stop Date Unknown	Dosage Dispensed by Pharmacy	Type of Change	Other Type of Change	Reason for Change (select all that apply)	Other Reason for Change
vill be the previous line Stop Date plus 1 day.')" onmouseout="UnTip()">Star tate	Unknown	taking pills of the same does or the last day not taking pills.)" omnouseout="Unified">Stop Date	Unknown	Pharmacy	 No change Permanently 	Other Type of Change	(select all that apply)	Other Reason for Change
vill be the previous line Stop Date plus 1 day.]" on mouseout="UnTip(]">Star ate	Unknown	taking pills of the same dose or the last day not taking pills T onnouscout="UnTig()">Stop Date	Unknown	Pharmacy 0	No change Permanently discontinued	Other Type of Change	(select all that apply) Lab safety assessment results	Change
ill be the previous line Stop Date plus 1 day.)" comouseout="UnTip()">Bar all b	Unknown	taking pills of the same does or the last day not taking pills.)" communications: "Unify(r): Stop Date	Unknown	Pharmacy 0 100	 No change Permanently 	Other Type of Change	(select all that apply) Lab safety assessment results Allopurinol contraindicated	Change
(II be the services line Stop Date plus 1 day.)," comesseeout="UnTip()">Sac ats	Unknown	taking allis of the same does or the last day not taking allin.)" composed to "linTip()" > Stop Date	Unknown	Pharmacy 0 100 200	No change Permanently discontinued Temporarily	Other Type of Change	(select all that apply) Lab safety assessment results Allopurinol contraindicated Off-label allopurinol treatment required	Change
ill be the previous line Stop Date plus 1 day.]" comouseout="UnTip()">Sar alla	Unknown	taking pills of the same daw or the last day not taking pills "." annowneed "Un'typ" > Stop bate	Unknown	Pharmacy 0 0 0 100 200 300	No change Permanently discontinued Temporarily discontinued	Other Type of Change	(select all that apply) Lab safety assessment results Allopurinoi contraindicated Off-label allopurinoi treatment requirec Pregnancy or breastfeeding Li End-stage renal disease Per protocol change doss after 1st.	Change
(II be the arrelous line Stop Date plus 1 day.)," comeaseout="UnTip()">Sac ats	Unknown	taking allis of the same does or the last day not taking allin.)" composed to "limTip()" > Stop Date	Unknown	Pharmacy 0 100 200 300 400	No change Permanently discontinued Temporarily discontinued Change in dosage	Other Type of Change	[select all that apply] Lab safety assessment results Altopunion contraindicated Off-label allopurion treatment required Pregnancy or breastfeeding Lend-stage renal disease Per protocol change dose after 1st month	Change
vill ba tha previous line Stop Date plus 1 day.)" enmouseout="UnTip()">Sac Bate	Unknown	laking all is a file same dow or the last day not taking alls."." onmoverout="linitg()">Size bain	Unknown	Pharmacy 0 100 200 300 400	No change Permanently discontinued Temporarily discontinued Change in dosage Started treatment	Other Type of Change	(select all that apply) Lab safety assessment results Allopuindi contraindicated OfF-label allopuindi treatment required Pregrancy or breastfeeding End-stage remail disease Per protocol change dose after 1st month Change in eGFR	Change
vill ba the previous line Slop Date plus 1 day."," comouseout="UnTip()">Sar 2018	Unknown	taking allis of the same does or the last day not taking alls."," composed taking alls."," Stop Date	Unknown	Pharmacy 0 100 200 300 400	No change Permanently discontinued Temporarily discontinued Change Started treatment Restarted treatment	Other Type of Change	Celect all that apply Lab safety assesment recurs Allopurinol contraindicated Off-labed allopurinol treatment required Pregunacy or breastfeeding Product approximation Pregunacy or breastfeeding Product approximation Pregunacy or breastfeeding Product approximation Prognacy or breastfeeding Pregunacy or breastfeeding Breast or breastfeeding Breast or breastfeeding Breast or breastfeeding Breast or breastfeeding	Change
ulli ba the produce line. Stop Date plus 1 day.)" comouseout="UnTip()">Sart Date	Unknown	jaking allin af the same dow or the last day not taking allin ")" ommoneur-"InTip(") > Size Date	Unknown	Pharmacy 0 100 200 300 400	No change Permanently discontinued Temporarily discontinued Change Started treatment Restarted treatment	Other Type of Change	Celect all that apply Lab saffy assesment results Allophind contraindicated Off-Labed allopind transmer required Pregnancy or breastfeeding End-stage renal disease Per protocol change dose after 1st morth Change in eGFR Startod treatment Restartod treatment	Change
vill ba the previous line Stop Date plus 1 day."," comouseout="UnTip()">Sar 1919	Unknown	taking allin of the same does or the last day not taking allin.)" composed to the last day not taking allin.)"	Unknown	Pharmacy 0 100 200 300 400	No change Permanently discontinued Temporarily discontinued Change Started treatment Restarted treatment	<u>Other Type of</u> Change	Celect all that apply Lab safety assesment recurs Allopurinol contraindicated Off-labed allopurinol treatment required Pregunacy or breastfeeding Product approximation Pregunacy or breastfeeding Product approximation Pregunacy or breastfeeding Product approximation Prognacy or breastfeeding Pregunacy or breastfeeding Breast or breastfeeding Breast or breastfeeding Breast or breastfeeding Breast or breastfeeding	Change

Protocol ID: PERL001 Study Name: PERL	Study Subject ID: Study Subject DOB:
Site:Event Name: Pilot Unscheduled Visit	and 1 steps too
Event Date:	
Section Title: Study Drug Exposure	
Instructions: For the entire Dosing Period. The Dosing Period starts with the date ends with the date the subject takes the last pill from that shipment because the	e subject takes the first pill from the shipment received after the prior visit and eceived a new shipment of pills.
1a. Date started using drug vials:	
	n
1b. Date stopped using drug vials:	
Un	n
Difference in days:	
1c. Number of pills should have taken if there were no Discontinuations:	
⊡ Un	n
Please explain why the number of pills the subject should have taken is Unknow	
2. Number of pills instructed not to take: (by vial because the number can be different for each vial)	
Vial A: *	
Vial B: *	
Vial C: * Vial D: *	
Total number of pills instructed not to take:	
3. Number of pills should have taken: (by vial because the number can be different for each vial) Via k:	
Vial B:	
Vial C:	
Vial D:	
Total number of pills should have taken:	
4. Number of pills dispensed:	
(by vial because the number can be different for each vial) Vial A: *	
Vial B: *	
Vial C: *	
Vial D: *	
Total number of pills dispensed:	
5. Were pills returned in individual vials: • OYes	
○ No ○ Pills not returned	
Number of Pills Returned:	
(by vial because the number can be different for each vial) Vial A:	
Vial B:	
Vial C:	
Vial D:	
Total number of pills returned:	
Total number of pills returned:	
<u>5. Number of pills taken:</u> (by vial because the number can be different for each vial)	
(by vial because the number can be different for each vial) Vial A:	
Vial B:	
Vial C:	
Vial D:	
Total number of pills taken:	
Total number of pills taken:	
7. Select the reason Drug Compliance cannot be calculated at this visit:	
Subject did not return pills Oils were thrown away	
Pills were lost Stop date unknown	
 Not applicable Other 	
If Other, Specify:	

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Protocol ID: PERL001	Study Subject ID:
Study Name: PERL	Study Subject DOB:
Site:	
Event Name: Pilot Unscheduled Visit	
Event Date:	
Section Title: % Compliant Calculation	
B1. Percent Compliant (if total pills taken reported by the 4 individual vials)	
B2. Percent Compliant (if vials not returned and total pills taken reported as a total only)	

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https://openclinica.med.umich.edu/OpenClinica/rest/metadata/html/print...

Protocol ID: PERL001 Study Name: PERL Site:______ Event Name: Pilot Unscheduled Visit Event Date: _____

Study Subject ID:_____ Study Subject DOB:_____

Section Title: Upload Your Form 022 Source Document Instructions: Don't forget to upload your source document!

Go to the Source Document event
 Open the PERL_022_Source Documents form
 Upload your source document to the appropriate visit field

You can now return to the Compliance tab to review subject's compliance and if you wish, the Exposure tab to review pill counts and calculations.

Confirm form is complete and source document uploaded.

Protocol ID: PERL001 Study Name: PERL				Study Subject ID: Study Subject ID::
Site: Event Name: Pilot Unscheduled Vi Event Date:	sit			
Event Date:	_	PERL_	011_Skin Assessment - V3.0	
Section Title: Skin Asse	ssment			
Indicate who performed Select: *	d this skin assessment: O Participant Self-Assessment			
Was any rash present d	Clinician Assessment			
•	○Yes ○No ○Not Assessed			
A1. Has the participant Select:	had any of the following pre-rash Stevens-Johnsor OYes	Syndrome (SJS) symptoms?		
Julia.	No Not Assessed			
Select all that apply:				
Fever	Fever			
Duration: Maximum temperature:	(days) Celsius or Farenheit:	°℃	Unknown temperature	
Skin tandomore		⊖ °F		
Skin tendemess	Skin tendemess			
Sore throat	□ Sore throat			
Photophobia	Photophobia			
Burning eyes	Burning eyes			
Itching eyes	Itching eyes			
Cough productive of thi	ick and purulent sputum □Cough			
Headache				
Malaise	□ Headache			
Arthralgia	□Malaise			
	Arthraigia			
Select:	○Yes ○No			
Select all that apply:	Not Assessed			
Burning rash	Burning rash			
Skin pain	□Skin pain			
Facial swelling				
Tongue swelling	□ Facial swelling			
Red or purple skin rash	Tongue swelling			
Area of rash (select all	Red or purple skin rash			
Area or fash (select and		Chest	Abdomen	
	□Arms	□ Legs	🗆 Paims	
Townshipsions surround	Soles	□ Back		
	Target lesions			
Hives	Hives			
Area of hives (select all	□ Face	Chest	Abdomen	
	Arms	□ Legs	□ Paims	
	□ Soles	L Back		
Blisters	Bisters			
Area of blisters (select	all that apply):	Chest	Abdomen	
	□Arms	□ Legs	Palms	
	Soles	Genitals	Anal	
Shedding	Back			
	Shedding (sloughing) of skin			
Area of shedding (selec	t all that apply): □Face	Chest	Abdomen	
	□Arms	□ Legs	Pains	
Depude district	□ Soles	Back		
Denuded skin areas	Denuded skin areas			
Area of denudation (see	lect all that apply): □Face	Chest	Abdomen	
	Arms	□ Legs	□ Paims	
	Soles	Back		

A3. During assessment was any mucous membrane involvement noted?

Select:	Yes		
	No Not Assessed		
Select all that apply:			
Oral mucosa			
	Oral mucosa		
Oral mucosa (select a	ll that apply):		
	□Erythema	Edema	Skughing
	Blistering	Ulceration/erosion	Necrosia/aust
Nasal mucosa			
	Nasal mucosa		
Nasal mucosa (select	all that apply):		
	□Erythema	Edema	
	Blistering	Ulceration/erosion	□ Necrois/aust
Eyes			
	Eyes		
Eyes (select all that a	oply):		
	□ Excessive tearing	Hyperemia	
	□Scarring		
Urinary tract			
	Urinary tract		
Urinary Tract (select a	all that apply):		
	□ Dysuria	Urinary retention	
Pulmonary			
	Pulmonary		
Pulmonary (select all	that apply):		
	Dyspnea	Productive cough	Pumorary edema

Protocol ID: PERL001			Study Subject ID:	
Study Name: PERL			Study Subject DOB:	
Site:				
Event Name: Pilot Unscheduled Visit				
Event Date:				
		PERL_008_Local Laboratory Results - V5	.0	
Section Title: Section A. Chemistry				
Subtitle:				
Instructions: Enter the lab values in the units	s indicated with the date of collection	or each field. Use the "Not Done" checkbox provided if data is unobtainable.		
Upload source documents:				
Chemistry:				

Protocol ID: PERL001 Study Name: PERL Site:______ Event Name: Pilot Unscheduled Visit Event Date: _____ Study Subject ID:_____ Study Subject DOB:_____ Section Title: Section B. CBC Subtitle: B1. Hemoglobin: Date Collected: (gm/dl) □ Not Done B2. Hematocrit: (%) Date Collected: □ Not Done B3. Platelets: (mmol) Date Collected: □ Not Done (million cells/mcL) B4. RBC: Date Collected: Not Done B5. WBC: (cells/mcL) Date Collected: □ Not Done B5a. Neutrophils: (%) 🗆 Not Done B5b. Lymphocytes: (%) 🗆 Not Done B5c. Monocytes: (%) Not Done B5d. Eosinophils: (%) Not Done (%) B5e. Basophils: Not Done

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Protocol ID: PERL001 Study Name: PERL Ste: Event Name: Pilot Unscheduled Visit Event Date:			Study Subject ID: Study Subject DD8:
Section Title: Section C. P	regnancy Test		
C1. Urine Pregnancy Test Result:	 Positive Negative Not Done Not Applicable 	Date of test:	
C2. Serum Pregnancy Test Result:	 Positive Negative Not Done Not Applicable 	Date of test:	

Protocol ID: PERL001 Study Name: PERL			Study Subject ID: Study Subject DOB:
Site:			subjections
Event Name: Pilot Unscheduled Vis			
Event Date:	-		
Section Title: Section D.	Urine Multistix		
Date Urine Collected:		□ Not Done	
D1. Leukocytes:	O Negative		
	O Trace		
	○ Small		
	O Moderate		
	Large		
D2. Nitrites:	O Negative		
	O Positive		
D3. Protein:	O Negative		
	O Trace		
	O 30		
	100		
	○ 300 ○ 2000+		
	0 2000+		
D4. Blood	O Negative		
	 Positive 		
D4a. Blood - Non Hemolyzed:	 None 		
	 Trace 		
	O Moderate		
D4b. Blood - Hemolyzed:	None		
	O Trace		
	○ Small		
	O Moderate		
	 Large 		
D6. Ketones:	O Negative		
	O Trace		
	 Small Moderate 		
	 Moderate Large 		
	C mige		

Protocol ID: FERL001 Study Name: FERL	Study Subject ID: Study Subject ID@:
Ster Event Name: Pilot Unscheduled Volt Event Date:	
Section Title: Section E, eGFR Subtitle:	
E1. Indicate visit for which this eGFR values applies:	
Live central lab creatinie value to calculate eGFR Click times to Calculate aGFR Click times to Calculate aGFR Credit the restrict value to calculate aGFR	
E3. Use local lab creatinine value to calculate eGFR Click Here to Calculate eGFR	
Local lub creatine value E4. cGR: (mls/min/1.72m ²) Date Collected:	Net Done
ESRD:	
Investigator Name: Investigator Signature: Date:	

Protocol ID: PERL001			Study Subject ID:	
Study Name: PERL			Study Subject DOB:	
Site:				
Event Name: ESRD				
Event Date:				
		PERL_028_ESRD - 1.0	I	
Section Title: ESRD				
A1. Date of ESRD diag	maaia			
A1. Date of ESRD diag	nosis			
A2. eGFR at diagnosis				
•				
A3. Form of treatment (check all that apply)	t			
•	Hemodialysis			
	Transplant			
	Peritoneal dialysis			
	□ Other			
A3a. Specify: *				

A3a. Specify: *