EXN ADVERSE EVENT

Subject ID	Page 1 of 5
Report Number	
A. ADVERSE EVENT	
1. Date of adverse event/	
(dd/mmm/yyyy) 2. Date site became aware of AE/(dd/mmm/yyyy) (dd/mmm/yyyyy)	
3. Adverse Event Term	
4. Describe event or problem. (Include any details relating to diagnosis.)	
No Yes	
5. O Is this an exacerbation of a pre-existing condition (existing prior to enrollment)?	•
6. Describe relevant tests/laboratory data, including dates.	
7. Describe other relevant history, including preexisting medical conditions. (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)	

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Report Number	
8. Outcomes attributed to adverse event (Check all that apply) (ALL choices below represent an SAE except "None of the above") Death:	
If outcome changes to an SAE during a postcomplete change, Q8a and 8b pop-up. 8a. Date the Adverse Event became a Serious Adverse Event: (dd/mmm/yyyy) 8b. Date the site became aware that the Adverse Event became a Serious Adverse Event: (dd/mmm/yyyy)	
9. Intensity - Please follow the guidelines in the "TCAE in Trials of Adult Pancreatic Islet Transplantation (Select one) OMild/Grade I OModerate/Grade II OSevere/Grade III OLife-threatening/Grade IV ODeath/Grade V (If question 9 is Death/Grade V, then go to question 10)	n"
10. Was/will an autopsy be performed? (select one) O No O Yes Please provide a de-identified copy to the DCC OUnknown	
11. Indicate outcome of the event O Continuing O Resolved (or resolved with sequelae) -If resolved, give date of resolution	

Subject ID			f 5
Report Nu	mber		
	No	Yes	
12.	0	Was a study-related islet transplant procedure ever initiated for this subject? a. Relationship to islet transplantation ODefinite OProbable OPossible OUnlikely OUnrelated, Explain:	
	No	b. Action taken regarding islet transplantation O Infusion not started O None O Interrupted but completed O Prematurely terminated Yes	
13.	0	Has the subject <u>ever</u> received immunosuppression and/or infection prophylaxis?	
		a. Relationship to immunosuppression/infection prophylaxis ODefinite OProbable OPossible OUnlikely OUnrelated, Explain: b. Action taken regarding immunosuppression/infection prophylaxis ONone ODose reduced OInterrupted ODiscontinued ODose increased	
1.4	No	Yes	
14.	0	Has the subject ever received the investigational drug, Exenatide? a. Relationship to Exenatide Operinite Oprobable Opossible Ounlikely Ounrelated, Explain: b. Action taken regarding Exenatide One Opose reduced Ointerrupted Oiscontinued Obose increased	

Subject ID	
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B. SUSPECT MEDICATION(S)

	Suspect Medication 1	Suspect Medication 2	Suspect Medication 3
1. Name	i.Islet Transplantation □Puified Human Pancreatic Islets (check if ever received islets) □Transplant Procedure (check if ever had transplant procedure initiated)	Immunosuppression and infection prophylaxis	Exenatide
2. Dose	i.		ii.
3. Therapy dates (if unknown, give best estimate)	i. Date of most recent islet transplantation/// (dd/mmm/yyyy)		ii. Introduction date iii. Date of last dose // (dd/mmm/yyyy)
4. Diagnosis for use	Type I Diabetes Mellitus	Islet Transplant/Immunosuppression	Islet Transplant/Immunosuppression
5. Event abated after use stopped or dose reduced	i. O No O Yes O Doesn't apply	ii. O No O Yes O Doesn't apply	iii. O No O Yes O Doesn't apply
6.Event reappeared after reintroduction?	i. O No O Yes O Doesn't apply	ii. O No O Yes O Doesn't apply	iii. O No O Yes O Doesn't apply
7. Lot number	i.		ii.
8. Expiration Date (if known)	i. N/A		ii//(dd/mmm/yyyy)

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Subject ID Report Number	
C. OTHER MEDICATIONS	
What concomitant medications was the subject receiving at the time of the event? (Exclude treatment of event)	
INSTRUCTIONS:	
1. Select the buttons below to add data to the Other Medications text box.	
O Select to add data that has been entered into the subject's Concomitant Meds eCRF	
O Select to add data that has been entered into the subject's Study Treatment Regimen eCRF	
2. Please review added data carefully for accuracy and modify this form and the Concomit Meds eCRF and/or the Study Treatment Regimen eCRF as needed.	ant
3. If the subject was on insulin therapy at the time of the event , their insulin therapy must be added to the text box below .	
4. Add any additional medication information, if applicable.	

LSFADVERSE EVENT

Subject ID	Page 1 of 5
Report Number	
A. ADVERSE EVENT	
1. Date of adverse event/	
(dd/mmm/yyyy) 2. Date site became aware of AE////	
3. Adverse Event Term	
4. Describe event or problem. (Include any details relating to diagnosis.)	
No Yes 5. O O Is this an exacerbation of a pre-existing condition (existing prior to enrollment)?	
6. Describe relevant tests/laboratory data, including dates.	
7. Describe other relevant history, including preexisting medical conditions. (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)	
	_

Subject ID	Page 2 of 5
Report Number	
8. Outcomes attributed to adverse event (Check all that apply) (ALL choices below represent an SAE except "None of the above") Death:/	
If outcome changes to an SAE during a postcomplete change, Q8a and 8b pop-up. 8a. Date the Adverse Event became a Serious Adverse Event: (dd/mmm/yyyy) 8b. Date the site became aware that the Adverse Event became a Serious Adverse Event: (dd/mmm/yyyy)	
9. Intensity - Please follow the guidelines in the "TCAE in Trials of Adult Pancreatic Islet Transplanta (Select one) OMild/Grade I OModerate/Grade II OSevere/Grade III OLife-threatening/Grade IV ODeath/Grade V (If question 9 is Death/Grade V, then go to question 10)	tion"
10. Was/will an autopsy be performed? (select one) O No O Yes Please provide a de-identified copy to the DCC OUnknown	
11. Indicate outcome of the event O Continuing O Resolved (or resolved with sequelae) -If resolved, give date of resolution (dd/mmm/yy)	

Subject ID)	Page 3 of 5	5
Report Nu	ımber		
	No	Yes	
12.	0	O Was a study-related islet transplant procedure ever initiated for this subject?	
		a. Relationship to islet transplantation	
		ODefinite OProbable	
		OPossible	
		O Unlikely	
		OUnrelated, Explain:	
		b. Action taken regarding islet transplantation	
		O Infusion not started O None	
		OInterrupted but completed	
	N. T	OPrematurely terminated	
13.	No O	Yes O Has the subject ever received immunosuppression and/or infection prophylaxis?	
15.	O	a. Relationship to immunosuppression/infection prophylaxis	
		ODefinite	
		O Probable O Possible	
		O Unlikely	
		OUnrelated, Explain:	
		b. Action taken regarding immunosuppression/infection prophylaxis	
		O None	
		O Dose reduced O Interrupted	
		ODiscontinued	
		O Dose increased	
1.4	No	Yes	
14.	0	Has the subject <u>ever</u> received the investigational drug, Lisofylline? a. Relationship to Lisofylline	
		ODefinite	
		OProbable	
		OPossible OUnlikely	
		OUnrelated, Explain:	
		b. Action taken regarding Lisofylline	
		O None	
		O Dose reduced	
		OInterrupted ODiscontinued	
		O Dose increased	

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Subject ID	
Report Number	Page 4 of 5
B. SUSPECT MEDICATION(S)	

	Suspect Medication 1	Suspect Medication 2	Suspect Medication 3
	i.Islet Transplantation	Immunosuppression and infection	Lisofylline
1. Name	 □ Purified Human Pancreatic Islets (check if ever received islets) □ Transplant Procedure (check if ever had transplant procedure initiated) 	prophylaxis	
2. Dose	i.		ii.
3. Therapy dates (if unknown, give best estimate)	i. Date of most recent islet transplantation///		ii. Introduction date iii. Date of last dose (dd/mmm/yyyy)
4. Diagnosis for use	Type I Diabetes Mellitus	Islet Transplant/Immunosuppression	Islet Transplant/Immunosuppression
5. Event abated after use stopped or dose reduced?	i. O No O Yes O Doesn't apply	ii. O No O Yes ODoesn't apply	iii. O No O Yes O Doesn't apply
6.Event reappeared after reintroduction?	i. O No OYes O Doesn't apply	ii. O No O Yes O Doesn't apply	iii. O No O Yes O Doesn't apply
7. Lot number	i.		ii.
8. Expiration Date (if known)	i. N/A		ii//(dd/mmm/yyyy)

Subject ID	Page 5 of 5
Report Number	
C. OTHER MEDICATIONS	
What concomitant medications was the subject receiving at the time of the event? (Exclude treatment of event)	
INSTRUCTIONS:	
1. Select the buttons below to add data to the Other Medications text box.	
O Select to add data that has been entered into the subject's Concomitant Meds eCRF	
O Select to add data that has been entered into the subject's Study Treatment Regimen eCRI	F
2. Please review added data carefully for accuracy and modify this form and the Concomi Meds eCRF and/or the Study Treatment Regimen eCRF as needed.	tant
3. If the subject was on insulin therapy at the time of the event , their insulin therapy must be added to the text box below .	
4. Add any additional medication information, if applicable.	

IT-02		EXN	STUDY TRE	ATMENT RI	EGIMEN
ubject ID					
					Page 1 of 2
A. INVESTIGAT	IONALAGENT				
Drug	Date	Total D	ose on this Date (µg)	Add new Entry	
O EXN	/ /		1		
	(dd/mmm/yyyy)				
<u> </u>					
-B. INDUCTION M	EDICATIONS				
Drug	Date	Total Do	se on this Date (mg)	Add new Entry	
O ATG	/			7	
Other ((dd/mmm/yyyy)				
C. SUBSEQUENT	TRANSPLANT INDU	UCTION M	IEDICATION		
Drug	Date	Total Do	se on this Date (mg)	Add new Entry	
O Daclizumab	/				
O Basiliximab	(dd/mmm/xxxxx)				
Dasinximato	(dd/mmm/yyyy)				
D. IMMUNUSUPI	PRESSIVE/ANTI-IN	FLAMMA	TORY MEDICATIO	NS	
Drug	Date	Total D	ose on this Date (mg)	Add new Entry	
Diug		Total D	ose on this Date (mg)	Add new Entry	
© Etanercept	(dd/mmm/yyyy)				
	will be available for l l be available for first		•		
	l be available for seco	-	•		
TO INTA INTUITATA N	CE IMMUNOSUPPI	DECCION	MEDICATIONS		
E. WAINTENAN	CE IMMUNOSUPPI	KESSION	Add new Entry		
Drug	Total Dose (m	ng) / Day	Start Date	Stop Date	
OTacrolimus					
○ Sirolimus				/	
OCyclosporin	ne		(dd/mmm/yyyy)	(dd/mmm/yyyy)	

ROUGH LEVELS						
Drug O Tacrolimus O Sirolimus O Cyclosporine	Date of Dra // (dd/mmm/y			(ng/mL)	Add ne	ew Entry
G. OTHER MAINT	ENANCE I	MMUNOSUPPRI Total Dose (mg) /		N MEDIC Start Date		Add new Entry Stop Date
Orug O Mycophenolate s O Mycophenolate s O Other		Total Dose (IIIg)		/	_/ nm/yyyy)	/(dd/mmm/yy
	, please	complete M	ajor	Protoc	col De	viation forn
	-	•	is	Protoc	col De	viation forn Add new entry Stop Date
If Other,	OPHYLAX S=1 tab)* oche)	IS MEDICATION	y Star			Add new entry
Drug O TMP/SMX (SSO Clotrimazole (tro	GPHYLAX S=1 tab)* oche) ng) gth TMP = 80	Total Dose / Day Omg SMX = 400mg	y Star	rt Date		Add new entry Stop Date //_ (dd/mmm/yyyy)
If Other, H. INFECTION PR Drug O TMP / SMX (SSO Clotrimazole (tro O Valganciclovir (month) *Single Streng	S=1 tab)* oche) ng) gth TMP = 80	Total Dose / Day Omg SMX = 400mg	y Star	rt Date		Add new entry Stop Date

CIT-02		LSF S	STUDY TREA	TMENT REC	HIMEN
Subject ID					
					Page 1 of 2
A. INVESTIGA	ATIONALAGENT				
Drug	Date	Total D	ose on this Date (mg)	Add new Entry	
O LSF	/ /		(8)		
	(dd/mmm/yyyy)				
<u> </u>		I			
-B. INDUCTION	MEDICATIONS				
Drug	Date	Total Do	se on this Date (mg)	Add new Entry	
O ATG	/				
O Other	(dd/mmm/yyyy)				
C. SUBSEQUEN	T TRANSPLANT INI	DUCTION M	IEDICATION		
Drug	Date	Total Do	se on this Date (mg)	Add new Entry	
ODaclizumab					
O Basiliximab	(dd/mmm/yyy	v)			
Bushinan	(dell'illinia yyy	<i>37</i>			
D. IMMUNUSU	PPRESSIVE/ANTI-I	NFLAMMA	TORY MEDICATIO	NS	
Drug	Date	Total D	ose on this Date (mg)	Add new Entry	
5				·	
○ Etanercept	t (dd/mmm/yyyy	y)			
Sections A-	D will be available for	r Induction o	only.		
Section B v	vill be available for fi	rst transplani	t only.		
Section C v	vill be available for se	cond and thi	rd transplants only.		
E. MAINTENA	ANCE IMMUNOSUP	PRESSION	MEDICATIONS Add new Entry		
Drug	Total Dose	(mg) / Day	Start Date	Stop Date	
OTacrolim:	us				
○ Sirolimus				/]
O Cyclospo	orine		(dd/mmm/yyyy)	(dd/mmm/yyyy)	

Drug						
O Tacrolimus O Sirolimus O Cyclosporine	Date of Dra // (dd/mmm/y				Add new	v Entry
G. OTHER MAINT Drug	ENANCE II	MMUNOSUPPRE Total Dose (mg) /		N MEDICA' Start Date	TIONS	Add new Entry Stop Date
O Mycophenolate s O Mycophenolate s O Other				(dd/mmm	 /yyyy)	// (dd/mmm/yyyy
	, piease (complete Ma	ajor	Protoco	l Dev	iation form.
H. INFECTION PR	•	•	S	rt Date	ol Dev	Add new entry Stop Date
H. INFECTION PR	OPHYLAX S=1 tab)* che)	IS MEDICATION	S Star			Add new entry
Drug O TMP / SMX (SSO) Clotrimazole (troo) Valganciclovir (m	OPHYLAX S=1 tab)* che) gg) gth TMP = 80	Total Dose / Day	S Star	rt Date		Add new entry Stop Date
Drug O TMP / SMX (SSO Clotrimazole (troe) Valganciclovir (most) *Single Streng	OPHYLAXI S=1 tab)* che) gg) gth TMP=80	Total Dose / Day	S Star	rt Date	 yy)	Add new entry Stop Date // (dd/mmm/yyyy)