

CASE REPORT FORMS GRID

CIT04: ISLET TRANSPLANTATION IN TYPE 1 DIABETES

Time points (specified in Days relative to transplant)	0	3	4	7	14	21	28	56	75	84	112	140	168	196	224	252	280	308	336	365
Visit Number	03	3a	04	05	06	07	08	09	10	11	12	13	14	15	16	17	18	19	20	21
Visit Windows (specified in days)	N/A	N/A	N/A	+/-2	+/-2	+/-2	+/-3	+/-3	+/-3	+/-3	+/-3	+/-3	+/-3	+/-5	+/-5	+/-5	+/-5	+/-5	+/-5	+/-5
Equivalent Week	N/A	N/A	N/A	W1	W2	W3	W4	W8	N/A	W12	W16	W20	W24	W28	W32	W36	W40	W44	W48	W52
General Assessment				X																X
Retinopathy																				X
Physical Examination	X			X	X	X	X	X	X		X	X		X			X			X
Laboratory	X			X	X	X	X	X	X		X	X		X			X			X
Pregnancy Test			X		X		X	X		X	X	X	X	X	X	X	X	X	X	X
Serology									X				X							X
C-Peptide		X		X																
CGMS									X											X
Clarke Survey														X						X
Full Hypo																				X
Belatacept Trough Level and Immunogenicity Sample	X ¹		X ²	X ²	X ²	X ²	X ²	X ²	X ²	X ²	X ²	X ²	X ³	X ²	X ²	X ²	X ²	X ²	X ²	X ³
Islet Transplantation	X																			

1 Immunogenicity Sample only prior to dosing with immunosuppression medications. Please note in the SOE Immunogenicity sample is listed as Visit 02.

2 Belatacept Trough Level only

3 Draw both Belatacept Trough Level and Immunogenicity Sample

Event Driven Forms: Adverse Event / Study Treatment Regimen / Major Protocol Deviation / Minor Protocol Deviation / CIT-04 Study Termination /

Concomitant Meds / Reduced Follow-Up / Second Transplant Qualification / Third Transplant Qualification / CIT-04 Premature Discontinuation /

Blood Sugar Record and HYPO/Belatacept Trough Level and Immunogenicity Sample

Note: Forms in red are CIT 04 specific forms – All other forms are CIT core forms

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Continuation of Appendix 1 Schedule of Events (Subjects with Subsequent CIT Transplants)

Time points (specified in Days relative to 1 st transplant)	392	420	448	476	504	532	560	588	616
Visit Number	22	23	24	25	26	27	28	29	30
Visit Windows (specified in days)	+/-5	+/-5	+/-5	+/-5	+/-5	+/-5	+/-5	+/-5	+/-5
Equivalent Week	W56	W60	W64	W68	W72	W76	W80	W84	W88
Physical Examination			X			X			X
Laboratory			X			X			X
Pregnancy Test	X	X	X	X	X	X	X	X	X
Clarke Survey						X			
Full HYPO									
Belatacept Trough Level and Immunogenicity Sample	X ²	X ²	X ²	X ²	X ²	X ³	X ²	X ²	X ²

2 Belatacept Trough Level only

3 Draw both Belatacept Trough Level and Immunogenicity Sample

Event Driven Forms: Adverse Event / Study Treatment Regimen / Major Protocol Deviation / Minor Protocol Deviation / CIT-04 Study Termination/ Concomitant Meds / Reduced Follow-Up / Second Transplant Qualification / Third Transplant Qualification / CIT-04 Premature Discontinuation/ Blood Sugar Record and HYPO / Belatacept Trough Level and Immunogenicity Sample

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Subsequent Transplant Schedule of Events

Time points (specified in Days relative to most recent transplant)	0 ¹	3	4	7	75	365
Visit Number	TBD	TBD	TBD	TBD	TBD	TBD
Visit Windows (specified in days)	N/A	N/A	N/A	+/-3	+/-5	+/-14
Equivalent Week (post most recent infusion)						
General Assessment				X		X
Physical Examination	X			X	X	X
PRA	X					
Blood Type	X					
Crossmatch	X					
Islet Transplant	X					
CGMS					X	X
Laboratory	X			X	X	X
Pregnancy Test	X					X
C-Peptide		X		X		
Clarke Survey						X
Full HYPO						X
Belatacept Trough Level and Immunogenicity Sample			X ²	X ²	X ²	X ³
Serology					X	

2 Belatacept Trough Level only

3 Draw both Belatacept Trough Level and Immunogenicity Sample

Event Driven Forms: Adverse Event / Study Treatment Regimen / Major Protocol Deviation / Minor Protocol Deviation / CIT-04 Study Termination / Concomitant Meds / Reduced Follow-Up / Second Transplant Qualification/ Third Transplant Qualification / CIT-04 Premature Discontinuation / Blood Sugar Record and HYPO/ Belatacept Trough Level and Immunogenicity Sample

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Schedule of Events for 2-year additional Follow-up

Time points (specified in Days relative to transplant)	W4 (AY)	W8 (AY)	W12 (AY)	W16 (AY)	W20 (AY)	W24 (AY)	W28 (AY)	W32 (AY)	W36 (AY)	W40 (AY)	W44 (AY)	W48 (AY)	W52 (AY)	Y2
Visit Number	51	52	53	54	55	56	57	58	59	60	61	62	63	64
Visit Windows (specified in days)	+/-5	+/-5	+/-5	+/-5	+/-5	+/-5	+/-5	+/-5	+/-5	+/-5	+/-5	+/-5	+/-5	+/-30
Physical Examination						X							X	X
Laboratory			X			X				X			X	
Pregnancy Test	X	X	X	X	X	X	X	X	X	X	X	X	X	
CGMS													X	X
Clarke Survey						X							X	
Belatacept Trough Level and Immunogenicity Sample	X	X	X	X	X	X	X	X	X	X	X	X	X	X

AY – Additional Year; example W4 (AY) = 4 weeks after the subject has completed the 1 Year post final transplant.