

ELECTRONIC CASE REPORT FORMS GRID

CIT03: PERITRANSPLANT DEOXYSPERGUALIN IN ISLET TRANSPLANTATION IN TYPE I DIABETES

YEAR ONE (Y2 on next page)

Time points (specified in Days relative to transplant)	0	1	2	3	5	7	10	14	21	28	42	56	75	120	150	180	270	365	365 post initial tx
Visit Number	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17	18	19	20	1Y
Visit Windows (specified in days)	N/A	N/A	N/A	+/-2	+/-2	+/-3	+/-3	+/-3	+/-3	+/-3	+/-3	+/-7	+/-5	+/-7	+/-7	+/-7	+/-14	+/-14	+/-14
Equivalent Week/Month	N/A	N/A	N/A	N/A	N/A	W1	W1.5	W2	W3	W4	W6	M2	M2.5	M4	M5	M6	M9	M12	Varies
CORE eCRFs																			
General Assessment		X				X												X	
Retinopathy																			X
Physical Examination	X	X	X	X	X	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	X	X	X	X	X	X	
Full HYPO																			X
Serology													X			X			X
C-Peptide				X		X													
CGMS													X					X	X
Clarke Survey																X		X	X
Islet Transplant	X																		

Event Driven Forms:

Adverse Event / Major Protocol Deviation / Minor Protocol Deviation / Study Termination / Blood Sugar Record and HYPO / Concomitant Meds / Reduced Follow-Up / Second Transplant Qualification/ Third Transplant Qualification / PRA / Premature Discontinuation / Informed Consent / ***Study Treatment Regimen***

Note: Forms in *italics* are CIT-03-specific forms. All other forms are CIT core forms.

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CIT03: PERITRANSPLANT DEOXYSPERGUALIN IN ISLET TRANSPLANTATION IN TYPE I DIABETES

YEAR TWO (Y1 on previous page)

Visit Number	21	22	23	24	Y2
Visit Windows (specified in days)	+/- 14	+/- 14	+/- 14	+/- 14	+/- 90
Equivalent Week/Month	M15	M18	M21	M24	Y2
CORE eCRFs					
Physical Examination		X		X	X
Laboratory	X	X	X	X	
CGMS				X	X
Clarke Survey		X		X	

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