

**ELECTRONIC CASE REPORT FORMS GRID**  
**CIT07: ISLET TRANSPLANTATION IN TYPE 1 DIABETES**

**Year 1**

Time points (specified in Days relative to transplant)	0	3	7	14	21	28	56	75	120	150	180			270			365	365 post initial tx
Visit Number	03	04	05	06	07	08	09	10	11	12	13	13a	13b	14	14a	14b	15	Y1
Visit Windows (specified in days)	N/A	N/A	+/- 3	+/- 3	+/- 3	+/- 3	+/- 7	+/- 5	+/- 7	+/- 7	+/- 7			+/- 14			+/- 14	+/- 14
Equivalent Week/Month	N/A	N/A	W1	W2	W3	W4	M2	M2.5	M4	M5	M6	M7	M8	M9	M10	M11	M12	Varies
CORE eCRFs																		
General Assessment			X														X	
Retinopathy																		X
Physical Examination	X			X		X	X	X	X	X	X			X			X	
Laboratory	X		X	X	X	X	X	X	X	X	X			X			X	
Full HYPO																	X	X
Serology								X			X							X
C-Peptide		X	X															
CGMS								X									X	X
Clarke Survey										X							X	X
Islet Transplant	X																	

**Year 2**

Visit Number	16	17	18	19	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	

**Event Driven Forms:**

*Adverse Event*<sup>2</sup> / Major Protocol Deviation / Minor Protocol Deviation / Study Termination / Concomitant Meds / Blood Sugar Record and HYPO / Reduced Follow-Up / Second Transplant Qualification/ Third Transplant Qualification / Premature Discontinuation / PRA/ Informed Consent / *Study Treatment Regimen*

<sup>1</sup> Granzyme B/ etc. every 2 weeks

<sup>2</sup> Forms in *italics* are CIT-07-specific. All other Event-Driven Forms are CIT core eCRFs.