

ELECTRONIC CASE REPORT FORMS GRID

CIT-02

YEAR ONE (Y2 on next page)

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
General Assessment			X														X	
Retinopathy																		X
Physical Examination	X		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																	

* Complete only the CMV and EBV data on Serology eCRF.

Event Driven Forms:

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

Note: Forms in red are CIT-02-specific forms.

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CIT-02

YEAR TWO (Y1 on previous page)

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

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