

Case Report Forms Grid
CIT06: Efficacy of Islet after Kidney Transplantation

Time Points (Days relative to transplant)	SCR	IIT	WL	BL	0	3	7	14	21	28	56	75	180	270	365	365 post- initial Tx	450	540	630	730	730 post- initial Tx	810	900	990	1095	1095 post- initial Tx
Visit Number	01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	Y1	16	17	18	19	Y2	20	21	22	23	Y3
Visit Windows (Days)	N/A	+/- 10	N/A	≤ 4	N/A	N/A	+/- 3	+/- 3	+/- 3	+/- 3	+/- 7	+/- 5	+/- 7	+/- 14	+/- 14	+/- 14	+/- 14	+/- 14	+/- 14	+/- 14	+/- 14	+/- 14	+/- 14	+/- 14	+/- 14	+/- 14
Equivalent Week/Month/Yr	N/A	N/A	N/A	N/A	N/A	N/A	W 1	W 2	W 3	W 4	M 2	M 2.5	M 6	M 9	M 12	Varies	M 15	M 18	M 21	M 24	Varies	M 27	M 30	M 33	M 36	Y3
Screening Eligibility	X																									
Transplant Eligibility				X																						
Medical and Diabetes History	X																									
Demographics	X																									
General Assessment	X		X-yrly	X		X									X					X						X
Retinopathy	X		X-yrly												X	X				X						X
Informed Consent	X			X																						
Physical Examination	X	X	X	X	X	X	X	X		X	X	X	X	X	X	X	X	X	X	X		X	X	X	X	
Laboratory	X	X	X-q6mo	X	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	X	X	X	
Pregnancy Test	X			X																						
Serology	X		X-yrly	X								X	X			X				X						X
Blood Type and HLA	X			X																						
Crossmatch				X																						
C-peptide						X	X																			
Local PRA			X-q3mo													X				X						X
CGMS			X-yrly									X	X		X	X		X	X	X	X					X
Clarke Survey	X	X	X-q6mo										X		X	X		X	X	X				X		X
Full HYPO			X-q6mo													X										
Islet Transplant					X																					
Renal History	X																									

Event Driven Forms:

Adverse Event / Blood Sugar Record/ CITR Consent / Concomitant Meds / **Informed Consent** / Major Protocol Deviation / Minor Protocol Deviation / **Outcomes for Adjudication** / **Premature Discontinuation** / Reduced Follow-up / **Second Transplant Qualification** / **Study Termination** / **Study Treatment Regimen** / **Third Transplant Qualification** / Waitlist

Note: Items in red are CIT-06-specific forms and datatables. Italicized CIT-06 forms have core datatables. All other forms are CIT CORE forms and datatables.