

Appendix C. Summary of Visit Windows

Table: Visits and Test Windows for entry into the Immune Effects of Oral Insulin Trial			
<u>Test or Visit to be Scheduled</u>	<u>Test/Procedure</u>	<u>Target Window</u>	<u>Maximum Window</u>
OGTT – PTP or TN20 Initial Visit	Eligibility	Within 7 weeks	52 days
Autoantibodies	Eligibility	Confirmed within 6 months	210 days
mIAA	Eligibility	Confirmed within 6 months	210 days
Initial Visit	Eligibility	N/A	N/A
Baseline 0A	Randomization must occur at least 7 days prior to Baseline 0A Initial Treatment Visit	Within 7 weeks (52 days) from normal OGTT; within 6 months (210 days) from confirmed positive mIAA and additional autoantibodies	Cannot be the same day as the Initial Visit; preferably 30 days apart.
Baseline 0B	Initial Treatment Visit	14 days after treatment start date	+/- 3 days
Month 1	Initial Treatment Visit	30 days after treatment start date	+/- 3 days
Month 2	Treatment Phase Visit	60 days after treatment start date	+/- 7 days
Month 3	Treatment Phase Visit	90 days after treatment start date	+/- 7 days
Month 6	Treatment Phase Visit	180 days after treatment start date	+/- 7 days
Month 7	Follow Up Phase Visit	210 days after treatment start date	+/- 7 days
Month 8	Follow Up Phase Visit	240 days after treatment start date	+/- 7 days
Month 9	Follow Up Phase Visit	270 days after treatment start date	+/- 7 days
Month 12	Follow Up Phase Visit	360 days after treatment start date	+/- 14 days