

Num	Variable	Type	Len	Format	Label
622	Date_At_Assessment18	Num	8	MMDDYY10.	Date at Assessment #18
623	Date_At_Assessment19	Num	8	MMDDYY10.	Date at Assessment #19
624	Date_At_Assessment20	Num	8	MMDDYY10.	Date at Assessment #20
625	Date_At_Assessment21	Num	8	MMDDYY10.	Date at Assessment #21
626	Date_At_Assessment22	Num	8	MMDDYY10.	Date at Assessment #22
627	Date_At_Assessment23	Num	8	MMDDYY10.	Date at Assessment #23
628	Date_At_Assessment24	Num	8	MMDDYY10.	Date at Assessment #24
629	Date_At_Assessment25	Num	8	MMDDYY10.	Date at Assessment #25
630	Date_At_Assessment26	Num	8	MMDDYY10.	Date at Assessment #26
631	Date_At_Assessment27	Num	8	MMDDYY10.	Date at Assessment #27
632	Date_At_Assessment28	Num	8	MMDDYY10.	Date at Assessment #28
633	Date_At_Assessment29	Num	8	MMDDYY10.	Date at Assessment #29
634	Date_At_Assessment30	Num	8	MMDDYY10.	Date at Assessment #30
635	Date_At_Assessment31	Num	8	MMDDYY10.	Date at Assessment #31
636	Date_At_Assessment32	Num	8	MMDDYY10.	Date at Assessment #32
637	Date_At_Assessment33	Num	8	MMDDYY10.	Date at Assessment #33
638	Date_At_Assessment34	Num	8	MMDDYY10.	Date at Assessment #34
639	Date_At_Assessment35	Num	8	MMDDYY10.	Date at Assessment #35
640	Date_At_Assessment36	Num	8	MMDDYY10.	Date at Assessment #36
641	Date_At_Assessment37	Num	8	MMDDYY10.	Date at Assessment #37
642	Date_At_Assessment38	Num	8	MMDDYY10.	Date at Assessment #38
643	Date_At_Assessment39	Num	8	MMDDYY10.	Date at Assessment #39
644	Date_At_Assessment40	Num	8	MMDDYY10.	Date at Assessment #40
645	Date_At_Assessment41	Num	8	MMDDYY10.	Date at Assessment #41
646	Date_At_Assessment42	Num	8	MMDDYY10.	Date at Assessment #42
647	Date_At_Assessment43	Num	8	MMDDYY10.	Date at Assessment #43
648	Date_At_Start1	Num	8	MMDDYY10.	Date at Start #1
649	Date_At_Start2	Num	8	MMDDYY10.	Date at Start #2
650	Date_At_Start3	Num	8	MMDDYY10.	Date at Start #3
651	Date_At_Start4	Num	8	MMDDYY10.	Date at Start #4
652	Date_At_Start5	Num	8	MMDDYY10.	Date at Start #5
653	Date_At_Start6	Num	8	MMDDYY10.	Date at Start #6
654	Date_At_Start7	Num	8	MMDDYY10.	Date at Start #7
655	Date_At_Start8	Num	8	MMDDYY10.	Date at Start #8
656	Date_At_Start9	Num	8	MMDDYY10.	Date at Start #9
657	Date_At_Start10	Num	8	MMDDYY10.	Date at Start #10
658	Date_At_Start11	Num	8	MMDDYY10.	Date at Start #11
659	Date_At_Start12	Num	8	MMDDYY10.	Date at Start #12
660	Date_At_Start13	Num	8	MMDDYY10.	Date at Start #13

Num	Variable	Type	Len	Format	Label
661	Date_At_Start14	Num	8	MMDDYY10.	Date at Start #14
662	Date_At_Start15	Num	8	MMDDYY10.	Date at Start #15
663	Date_At_Start16	Num	8	MMDDYY10.	Date at Start #16
664	Date_At_Start17	Num	8	MMDDYY10.	Date at Start #17
665	Date_At_Start18	Num	8	MMDDYY10.	Date at Start #18
666	Date_At_Start19	Num	8	MMDDYY10.	Date at Start #19
667	Date_At_Start20	Num	8	MMDDYY10.	Date at Start #20
668	Date_At_Start21	Num	8	MMDDYY10.	Date at Start #21
669	Date_At_Start22	Num	8	MMDDYY10.	Date at Start #22
670	Date_At_Start23	Num	8	MMDDYY10.	Date at Start #23
671	Date_At_Start24	Num	8	MMDDYY10.	Date at Start #24
672	Date_At_Start25	Num	8	MMDDYY10.	Date at Start #25
673	Date_At_Start26	Num	8	MMDDYY10.	Date at Start #26
674	Date_At_Start27	Num	8	MMDDYY10.	Date at Start #27
675	Date_At_Start28	Num	8	MMDDYY10.	Date at Start #28
676	Date_At_Start29	Num	8	MMDDYY10.	Date at Start #29
677	Date_At_Start30	Num	8	MMDDYY10.	Date at Start #30
678	Date_At_Start31	Num	8	MMDDYY10.	Date at Start #31
679	Date_At_Start32	Num	8	MMDDYY10.	Date at Start #32
680	Date_At_Start33	Num	8	MMDDYY10.	Date at Start #33
681	Date_At_Start34	Num	8	MMDDYY10.	Date at Start #34
682	Date_At_Start35	Num	8	MMDDYY10.	Date at Start #35
683	Date_At_Start36	Num	8	MMDDYY10.	Date at Start #36
684	Date_At_Start37	Num	8	MMDDYY10.	Date at Start #37
685	Date_At_Start38	Num	8	MMDDYY10.	Date at Start #38
686	Date_At_Start39	Num	8	MMDDYY10.	Date at Start #39
687	Date_At_Start40	Num	8	MMDDYY10.	Date at Start #40
688	Date_At_Start41	Num	8	MMDDYY10.	Date at Start #41
689	Date_At_Start42	Num	8	MMDDYY10.	Date at Start #42
690	Date_At_Start43	Num	8	MMDDYY10.	Date at Start #43
691	Date_At_Stop1	Num	8	MMDDYY10.	Date at Stop #1
692	Date_At_Stop2	Num	8	MMDDYY10.	Date at Stop #2
693	Date_At_Stop3	Num	8	MMDDYY10.	Date at Stop #3
694	Date_At_Stop4	Num	8	MMDDYY10.	Date at Stop #4
695	Date_At_Stop5	Num	8	MMDDYY10.	Date at Stop #5
696	Date_At_Stop6	Num	8	MMDDYY10.	Date at Stop #6
697	Date_At_Stop7	Num	8	MMDDYY10.	Date at Stop #7
698	Date_At_Stop8	Num	8	MMDDYY10.	Date at Stop #8
699	Date_At_Stop9	Num	8	MMDDYY10.	Date at Stop #9

Num	Variable	Type	Len	Format	Label
700	Date_At_Stop10	Num	8	MMDDYY10.	Date at Stop #10
701	Date_At_Stop11	Num	8	MMDDYY10.	Date at Stop #11
702	Date_At_Stop12	Num	8	MMDDYY10.	Date at Stop #12
703	Date_At_Stop13	Num	8	MMDDYY10.	Date at Stop #13
704	Date_At_Stop14	Num	8	MMDDYY10.	Date at Stop #14
705	Date_At_Stop15	Num	8	MMDDYY10.	Date at Stop #15
706	Date_At_Stop16	Num	8	MMDDYY10.	Date at Stop #16
707	Date_At_Stop17	Num	8	MMDDYY10.	Date at Stop #17
708	Date_At_Stop18	Num	8	MMDDYY10.	Date at Stop #18
709	Date_At_Stop19	Num	8	MMDDYY10.	Date at Stop #19
710	Date_At_Stop20	Num	8	MMDDYY10.	Date at Stop #20
711	Date_At_Stop21	Num	8	MMDDYY10.	Date at Stop #21
712	Date_At_Stop22	Num	8	MMDDYY10.	Date at Stop #22
713	Date_At_Stop23	Num	8	MMDDYY10.	Date at Stop #23
714	Date_At_Stop24	Num	8	MMDDYY10.	Date at Stop #24
715	Date_At_Stop25	Num	8	MMDDYY10.	Date at Stop #25
716	Date_At_Stop26	Num	8	MMDDYY10.	Date at Stop #26
717	Date_At_Stop27	Num	8	MMDDYY10.	Date at Stop #27
718	Date_At_Stop28	Num	8	MMDDYY10.	Date at Stop #28
719	Date_At_Stop29	Num	8	MMDDYY10.	Date at Stop #29
720	Date_At_Stop30	Num	8	MMDDYY10.	Date at Stop #30
721	Date_At_Stop31	Num	8	MMDDYY10.	Date at Stop #31
722	Date_At_Stop32	Num	8	MMDDYY10.	Date at Stop #32
723	Date_At_Stop33	Num	8	MMDDYY10.	Date at Stop #33
724	Date_At_Stop34	Num	8	MMDDYY10.	Date at Stop #34
725	Date_At_Stop35	Num	8	MMDDYY10.	Date at Stop #35
726	Date_At_Stop36	Num	8	MMDDYY10.	Date at Stop #36
727	Date_At_Stop37	Num	8	MMDDYY10.	Date at Stop #37
728	Date_At_Stop38	Num	8	MMDDYY10.	Date at Stop #38
729	Date_At_Stop39	Num	8	MMDDYY10.	Date at Stop #39
730	Date_At_Stop40	Num	8	MMDDYY10.	Date at Stop #40
731	Date_At_Stop41	Num	8	MMDDYY10.	Date at Stop #41
732	Date_At_Stop42	Num	8	MMDDYY10.	Date at Stop #42
733	Date_At_Stop43	Num	8	MMDDYY10.	Date at Stop #43

Data Set Name: demographics.sas7bdat

Num	Variable	Type	Len	Format	Label
1	Ethnicity	Char	37	\$37.	Ethnicity
2	Sex	Char	6	\$6.	Sex
3	BirthMonth	Char	3	\$3.	Date of Birth Month
4	Age	Num	8		Age years
5	BirthDay	Num	8		Date of Birth DAY
6	BirthYear	Num	8		Date of Birth Year
7	Race_AmericanIndianorAlaskaNat	Num	8		Race: American Indian or Alaska Native
8	Race_Asian	Num	8		Race: Asian
9	Race_BlackorAfricanAmerican	Num	8		Race: Black or African American
10	Race_NativeHawaiianorOtherPaci	Num	8		Race: Native Hawaiian or Other Pacific Islander
11	Race_Refused	Num	8		Race: Refused
12	Race_Unknownornotreported	Num	8		Race: Unknown or not reported
13	Race_White	Num	8		Race: White
14	MaskID	Num	8		Participant Mask ID#
15	Visit	Char	100		Visit
16	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit
17	DOB_Month	Num	8		Date of Birth - Month
18	DOB_Year	Num	8		Date of Birth - Year

Data Set Name: diabetes_management.sas7bdat

Num	Variable	Type	Len	Format	Label
1	AreThere3GlucoseValuesAvailabl	Char	7	\$7.	Are there atleast three glucose values available for atleast three days
2	AvgAllRecordedGlucosesMmoll	Char	6	\$6.	Average of all recorded glucoses over three days units
3	AvgRecordedFastingGlucosesmmol	Char	6	\$6.	Average of recorded fasting glucoses over three days units
4	ExperiencedAnyHypoglycemicEven	Char	3	\$3.	Have you experienced any sevre hypoglycemic events loss of consciousness seizure or assistance required from another person due to an altered state or consciousness since trhe last visit
5	HighestGlucosemmol	Char	6	\$6.	Highest recorded glucose over three days units
6	InsulDoseInfoAvailableFor3Days	Char	7	\$7.	Is the insulin dose information available for atleast three days
7	InsulinRoutineDaily	Char	27	\$27.	Daily insulin routines check one
8	LowestGlucosemmoll	Char	6	\$6.	Lowest recorded glucose over three days units
9	RecordedGlucoseDuringFirstSeve2	Char	6	\$6.	What was the recorded glucose during the first severe hypoglycemic event units
10	RecordedGlucoseDuringSecondSev2	Char	1	\$1.	What was the recorded glucose during the second severe hypoglycemic event units Record
11	RecordedGlucoseDuringThirdSeve2	Char	1	\$1.	What was the recorded glucose during the third severe hypoglycemic event units Record
12	SubjectUsingCGMS	Char	7	\$7.	Is the person using a Continuous Glucose Monitoring System CGMS
13	InsulinInjectionSite	Char	121	\$121.	diabetes mgmt insulin 2 Site location of most recent last 24 hour period insulin injection eg left tricep
14	AverageUnitsOfftermediateInsul	Num	8		Average unitsday of intermediatelong acting insulin average over 3 day period
15	AvgAllRecordedGlucosesMgDL	Num	8		Average of all recorded glucoses over three days
16	AvgRecordedFastingGlucosesmgdl	Num	8		Average of recorded fasting glucoses over three days
17	AvgUnitsShortActingInsulin	Num	8		Average unitsday of short acting insulin
18	DiabetesEducator	Num	8		Study associated Diabetes Educator
19	Endocrinologist	Num	8		Study associated Endocrinologist
20	HighestGlucosemgdl	Num	8		Highest recorded glucose over three days
21	HowManyHypoglycemicEvents	Num	8		If Yes How many severe hypoglycemic events have ocured since the last visit
22	LowestGlucosemgdl	Num	8		Lowest recorded glucose over three days
23	NonStudyDiabetesEducator	Num	8		NonStudy associated Diabetes Educator
24	NonStudyEndocrinologist	Num	8		NonStudy associated Endocrinologist
25	NonStudyOtherHealthCareProvide	Num	8		NonStudy associated other health care provider
26	OtherHealthCareProvider	Num	8		Study associatedother health care provider
27	RecordedGlucoseDuringFirstSeve	Num	8		What was the recorded glucose during the first severe hypoglycemic event
28	RecordedGlucoseDuringSecondSev	Num	8		What was the recorded glucose during the second severe hypoglycemic event units

Num	Variable	Type	Len	Format	Label
29	RecordedGlucoseDuringThirdSeve	Num	8		What was the recorded glucose during the third severe hypoglycemic event
30	TotalOfHBGMonitoringsLessThan6	Num	8		Number of home blood glucose monitorings over three days that were less than 65mgdl
31	TotalOfHomeBloodGlucoseOver3Da	Num	8		Total number of home blood glucose monitorings over three days
32	MaskID	Num	8		Participant Mask ID#
33	Visit	Char	100		Visit
34	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit

Data Set Name: *eligibility.sas7bdat*

Num	Variable	Type	Len	Format	Label
1	AnticipatePregnantWithin24Mont	Char	2	\$2.	Subject anticipates becoming pregnant within 24 months after first injection
2	ChronicUseOfSteroidsOrImmunosu	Char	3	\$3.	Subject requires chronic use of systemic steroids or other immunosuppressive agents for other conditions
3	CpepLevelsGE0point2pmolml	Char	8	\$8.	Subject has stimulated Cpeptide levels 02 pmolml
4	EligibilityCommitteeOverride	Char	3	\$3.	Subject is eligible per eligibility committee
5	HasAbnormalLabTests	Char	3	\$3.	Subject has abnormal laboratory tests that in the opinion of the investigator would interfere with study conduct
6	HasActiveInfectionOrPositivePP	Char	3	\$3.	Subject has an active infection or positive PPD test result
7	HasComplicatingMedicalIssues	Char	3	\$3.	Subject has acute or chronic complicating medical issues that in the opinion of the investigator would interfere with study conduct or cause increased risk including neurological abnormalities
8	HasCurrentOrPastHIVHepatitisBO	Char	8	\$8.	Subject has serologic evidence of current or past HIV Hepatitis B or C infection
9	HasHistoryOfEpimepsyHeadTrauma	Char	3	\$3.	Subject has a history of epilepsy significant head trauma or cerebrovascular accident or clinical features of continuous motor unit activity in proximal muscles
10	HasReproductivePotentialAndRef	Char	2	\$2.	Subject has reproductive potential and refuses to undergo pregnancy testing during the course of study
11	HasReproductivePotentialAndRef2	Char	2	\$2.	Subject has reproductive potential and refuses to promptly report possible or confirmed pregnancies during the course of the study
12	IsPregnant	Char	2	\$2.	Subject is currently pregnant
13	IsSexuallyActiveAndRefuseUseBi	Char	2	\$2.	Subject is sexually active and refuses to use an effective form of birth control
14	NoCompletingPregnancyTestAtThi	Char	3	\$3.	Subject refused or did not complete the pregnancy test at this visit
15	NotAbleToComplyWithProtocol	Char	3	\$3.	Subject has inability or unwillingness to comply with the provisions of this protocol
16	PermissionSampleStorage	Char	3	\$3.	If yes was permission given for samples of the participants blood to be stored for other tests
17	PermissionSampleStorageDNA	Char	11	\$11.	If yes with or without DNA
18	SubjectHasHistoryOfMalignancie	Char	2	\$2.	Subject has a history of malignancies
19	TakingMedsThatInfluenceGlucose	Char	3	\$3.	Subject is taking any medications that are known to influence glucose tolerance
20	UsingNonInsulinPharmaceuticals	Char	3	\$3.	Subject is currently using noninsulin pharmaceuticals to affect glycemic control
21	Within3mosOfT1Ddiagnosis	Char	3	\$3.	Subject is within 3 months 100 days of diagnosis of type 1 diabetes based on ADA criteria
22	_3to45yearsAge	Char	3	\$3.	Subject is between 3 and 45 years of age inclusive
23	detectableGAD65autoantibodies	Char	8	\$8.	Subject has detectable GAD65 autoantibodies
24	maleorfemale	Char	6	\$6.	Is patient male or female

Num	Variable	Type	Len	Format	Label
25	noVaccinationsInPastMonth	Char	3	\$3.	Subject has not had any vaccinations in the preceding month
26	signedInformedConsent	Char	3	\$3.	Subject has signed written informed consent for participation
27	weighsAtLeast20kg	Char	3	\$3.	Subject weighs at least 20 kg 44 lb at study entry
28	willComplyWithIntensiveDiabete	Char	3	\$3.	Subject is willing to comply with intensive diabetes management
29	willingToBeRandomized	Char	3	\$3.	Subject is willing to be randomized to either group
30	willingToForgoImmunizations100	Char	3	\$3.	Subject is willing to forgo immunizations for 100 days after first injection
31	InformedConsentDateMonth	Char	3	\$3.	Informed consent date month
32	InformedConsentDateDay	Num	8		Informed consent date day
33	InformedConsentDateYear	Num	8		Informed consent date year
34	MaskID	Num	8		Participant Mask ID#
35	Visit	Char	100		Visit
36	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit

Data Set Name: family_history.sas7bdat

Num	Variable	Type	Len	Format	Label
1	AnyRelativesDiagnosedwithAIoth	Char	3	\$3.	Have any of your first and second degree relatives been diagnosed with an autoimmune AI disease other than type 1 diabetes
2	HalfSiblingIndicateSameMoth1	Char	11	\$11.	If Half Sibling Indicate same Mother or same Father
3	HalfSiblingIndicateSameMoth2	Char	11	\$11.	If Half Sibling Indicate same Mother or same Father
4	HalfSiblingIndicateSameMoth3	Char	11	\$11.	If Half Sibling Indicate same Mother or same Father
5	HalfSiblingIndicateSameMoth4	Char	1	\$1.	If Half Sibling Indicate same Mother or same Father
6	HalfSiblingIndicateSameMoth5	Char	1	\$1.	If Half Sibling Indicate same Mother or same Father
7	HalfSiblingIndicateSameMoth6	Char	1	\$1.	If Half Sibling Indicate same Mother or same Father
8	HalfSiblingIndicateSameMoth7	Char	1	\$1.	If Half Sibling Indicate same Mother or same Father
9	HalfSiblingIndicateSameMoth8	Char	1	\$1.	If Half Sibling Indicate same Mother or same Father
10	HalfSiblingIndicateSameMoth9	Char	1	\$1.	If Half Sibling Indicate same Mother or same Father
11	SexOfRelativewithAIDisease1	Char	6	\$6.	Sex of Relative
12	SexOfRelativewithAIDisease2	Char	6	\$6.	Sex of Relative
13	SexOfRelativewithAIDisease3	Char	6	\$6.	Sex of Relative
14	SexOfRelativewithAIDisease4	Char	6	\$6.	Sex of Relative
15	SexOfRelativewithAIDisease5	Char	6	\$6.	Sex of Relative
16	SexOfRelativewithAIDisease6	Char	6	\$6.	Sex of Relative
17	SexOfRelativewithAIDisease7	Char	4	\$4.	Sex of Relative
18	SexOfRelativewithAIDisease8	Char	6	\$6.	Sex of Relative
19	SexOfRelativewithAIDisease9	Char	6	\$6.	Sex of Relative
20	relativehavet1d1	Char	3	\$3.	4 Does Relative have Type 1 Diabetes
21	relativehavet1d2	Char	3	\$3.	4 Does Relative have Type 1 Diabetes
22	relativehavet1d3	Char	3	\$3.	4 Does Relative have Type 1 Diabetes
23	relativehavet1d4	Char	3	\$3.	4 Does Relative have Type 1 Diabetes
24	relativehavet1d5	Char	3	\$3.	4 Does Relative have Type 1 Diabetes
25	relativehavet1d6	Char	3	\$3.	4 Does Relative have Type 1 Diabetes
26	relativehavet1d7	Char	3	\$3.	4 Does Relative have Type 1 Diabetes
27	relativehavet1d8	Char	2	\$2.	4 Does Relative have Type 1 Diabetes
28	relativehavet1d9	Char	2	\$2.	4 Does Relative have Type 1 Diabetes
29	Relativewitht1d1	Char	17	\$17.	3 Relative with Type 1 Diabetes or Other AI Disease
30	Relativewitht1d2	Char	22	\$22.	3 Relative with Type 1 Diabetes or Other AI Disease
31	Relativewitht1d3	Char	17	\$17.	3 Relative with Type 1 Diabetes or Other AI Disease
32	Relativewitht1d4	Char	17	\$17.	3 Relative with Type 1 Diabetes or Other AI Disease
33	Relativewitht1d5	Char	17	\$17.	3 Relative with Type 1 Diabetes or Other AI Disease
34	Relativewitht1d6	Char	17	\$17.	3 Relative with Type 1 Diabetes or Other AI Disease
35	Relativewitht1d7	Char	13	\$13.	3 Relative with Type 1 Diabetes or Other AI Disease
36	Relativewitht1d8	Char	13	\$13.	3 Relative with Type 1 Diabetes or Other AI Disease

Num	Variable	Type	Len	Format	Label
37	RelativewithT1d9	Char	14	\$14.	3 Relative with Type 1 Diabetes or Other AI Disease
38	TypeOfAutoImmune11	Char	26	\$26.	1Type of Autoimmune Disease
39	TypeOfAutoImmune12	Char	26	\$26.	1Type of Autoimmune Disease
40	TypeOfAutoImmune13	Char	26	\$26.	1Type of Autoimmune Disease
41	TypeOfAutoImmune14	Char	26	\$26.	1Type of Autoimmune Disease
42	TypeOfAutoImmune15	Char	26	\$26.	1Type of Autoimmune Disease
43	TypeOfAutoImmune16	Char	26	\$26.	1Type of Autoimmune Disease
44	TypeOfAutoImmune17	Char	1	\$1.	1Type of Autoimmune Disease
45	TypeOfAutoImmune18	Char	15	\$15.	1Type of Autoimmune Disease
46	TypeOfAutoImmune19	Char	26	\$26.	1Type of Autoimmune Disease
47	TypeOfAutoImmune21	Char	35	\$35.	2Type of Autoimmune Disease
48	TypeOfAutoImmune22	Char	26	\$26.	2Type of Autoimmune Disease
49	TypeOfAutoImmune23	Char	24	\$24.	2Type of Autoimmune Disease
50	TypeOfAutoImmune24	Char	24	\$24.	2Type of Autoimmune Disease
51	TypeOfAutoImmune25	Char	5	\$5.	2Type of Autoimmune Disease
52	TypeOfAutoImmune26	Char	1	\$1.	2Type of Autoimmune Disease
53	TypeOfAutoImmune27	Char	1	\$1.	2Type of Autoimmune Disease
54	TypeOfAutoImmune28	Char	1	\$1.	2Type of Autoimmune Disease
55	TypeOfAutoImmune29	Char	1	\$1.	2Type of Autoimmune Disease
56	NumRelativesWithT1D	Num	8		How many of your first and second degree relatives have type 1 diabetes including deceased
57	AgeAtDiagnosis1	Num	8		Age at Diagnosis
58	AgeAtDiagnosis2	Num	8		Age at Diagnosis
59	AgeAtDiagnosis3	Num	8		Age at Diagnosis
60	AgeAtDiagnosis4	Num	8		Age at Diagnosis
61	AgeAtDiagnosis5	Num	8		Age at Diagnosis
62	AgeAtDiagnosis6	Num	8		Age at Diagnosis
63	AgeAtDiagnosis7	Num	8		Age at Diagnosis
64	AgeAtDiagnosis8	Num	8		Age at Diagnosis
65	AgeAtDiagnosis9	Num	8		Age at Diagnosis
66	MaskID	Num	8		Participant Mask ID#
67	Visit	Char	100		Visit
68	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit

Data Set Name: followup_eligible_participant.sas7bdat

Num	Variable	Type	Len	Format	Label
1	BiweeklyInjectionVisitSchedule	Char	1	\$1.	Biweekly Injection Visit Schedule
2	ConcernsAboutReceivingPlaceboR	Char	20	\$20.	Concerns about receiving placebo Rank
3	ConflictingResponsibilitiesRan	Char	20	\$20.	Conflicting Responsibilities Rank
4	DoesNotTolerateOGTTRank	Char	20	\$20.	Does not tolerate OGTTIVGTTs well Rank
5	DoesNotWantToBeBlindedRank	Char	16	\$16.	Does not want to be blinded to individual test results during the study Rank
6	FamilyWishesToWaitUntilOlderRa	Char	16	\$16.	Family wishes to wait until participant is older Rank
7	FearOfStudyDrugRisksRank	Char	20	\$20.	Fear of Study Drug Risks Rank
8	IndicateTheStudyParticipantWas	Char	31	\$31.	Please indicate which TrialNet Study this participant was offered
9	IsParticipantCurrentlyEligible	Char	20	\$20.	If participant was offered an intervention study please indicate if participant is currently eligible or potentially eligible
10	IsTheParticipantInterested	Char	8	\$8.	Is the participant interested in participating in the above study
11	LostToFollowUp	Char	16	\$16.	Lost to FollowUp
12	MonetaryCompensationRank	Char	16	\$16.	Monetary Compensation Rank
13	MonthlyInfusionVisitScheduleRa	Char	20	\$20.	Monthly Infusion Visit Schedule Rank
14	OtherRank	Char	20	\$20.	Other Rank
15	PregnantNursingOrPlanningChild	Char	16	\$16.	Pregnant nursing or planning children in the future Rank
16	TimeCommitmentRank	Char	20	\$20.	Time Commitment Rank
17	UnableUnwillingToTravelRank	Char	20	\$20.	Unable Unwilling to Travel Rank
18	UnwillingToTakeInvestigational	Char	16	\$16.	Unwilling to take investigational drug Rank
19	_2DayInfusionPeriod	Char	1	\$1.	2 Day Infusion Period
20	_2WeekIfusionPeriodRank	Char	20	\$20.	2 week Infusion Period Rank
21	willingToConsiderAtALaterTime	Char	3	\$3.	Did the participant indicate they may be willing to consider participating in the study at a later time
22	AdditionalComments	Char	948	\$948.	Additional comments describing participants Situation
23	ParticipantWasContactedByOther	Char	48	\$48.	Participant was contacted by Other Specify
24	ReasonsNotInterestedOtherSpeci	Char	1289	\$1289.	Reasons the participant is not currently interested Other Specify
25	ParticipantWasContac_Other	Num	8		ParticipantWasContac: Other
26	ParticipantWasContac_SiteCoordin	Num	8		ParticipantWasContac: Site Coordinator
27	ParticipantWasContac_SitePI	Num	8		ParticipantWasContac: Site PI
28	ReasonsNotInterested_2DayInfusio	Num	8		ReasonsNotInterested: 2 Day Infusion Period
29	ReasonsNotInterested_2weekInfusi	Num	8		ReasonsNotInterested: 2 week Infusion Period
30	ReasonsNotInterested_BiweeklyInj	Num	8		ReasonsNotInterested: Biweekly Injection Visit Schedule
31	ReasonsNotInterested_Concernsabo	Num	8		ReasonsNotInterested: Concerns about receiving placebo
32	ReasonsNotInterested_Conflicting	Num	8		ReasonsNotInterested: Conflicting Responsibilities (Work, School, Family)

Num	Variable	Type	Len	Format	Label
33	ReasonsNotInterested_Doesnotwant	Num	8		ReasonsNotInterested: Does not want to be blinded to individual test results during the study
34	ReasonsNotInterested_Familywishe	Num	8		ReasonsNotInterested: Family wishes to wait until participant is older
35	ReasonsNotInterested_FearofStudy	Num	8		ReasonsNotInterested: Fear of Study Drug Risks
36	ReasonsNotInterested_LosttoFollo	Num	8		ReasonsNotInterested: Lost to Follow-Up
37	ReasonsNotInterested_MonetaryCom	Num	8		ReasonsNotInterested: Monetary Compensation
38	ReasonsNotInterested_MonthlyInfu	Num	8		ReasonsNotInterested: Monthly Infusion Visit Schedule
39	ReasonsNotInterested_Other	Num	8		ReasonsNotInterested: Other
40	ReasonsNotInterested_Participant	Num	8		ReasonsNotInterested: Participant does not tolerate OGTT/IVGTTs well
41	ReasonsNotInterested_Pregnantnur	Num	8		ReasonsNotInterested: Pregnant, nursing or planning children in the future
42	ReasonsNotInterested_Refusednore	Num	8		ReasonsNotInterested: Refused; no reason given
43	ReasonsNotInterested_TimeCommitm	Num	8		ReasonsNotInterested: Time Commitment
44	ReasonsNotInterested_UnableUnwil	Num	8		ReasonsNotInterested: Unable/ Unwilling to Travel
45	ReasonsNotInterested_Unwillingto	Num	8		ReasonsNotInterested: Unwilling to take investigational drug
46	MaskID	Num	8		Participant Mask ID#
47	Visit	Char	100		Visit
48	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit

Data Set Name: h1n1_vacc_form.sas7bdat

Num	Variable	Type	Len	Format	Label
1	DidSubjectReceiveH1N1Vaccinati	Char	3	\$3.	H1N1 Vaccination Did subject receive H1N1 Vaccination
2	DidSubjectReceiveH1N1Vaccinati2	Char	3	\$3.	H1N1 Vaccination Did subject receive H1N1 Vaccination booster
3	H1N1VaccinationBoosterType	Char	16	\$16.	H1N1 Vaccination Receive H1N1 Vaccination booster If yes type
4	H1N1VaccinationType	Char	16	\$16.	H1N1 Vaccination Received H1N1 Vaccination If yes type
5	MaskID	Num	8		Participant Mask ID#
6	Visit	Char	100		Visit
7	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit
8	Date_At_H1N1VaccBooster	Num	8	MMDDYY10.	Date at H1N1V Vacc Booster
9	Date_At_H1N1Vacc	Num	8	MMDDYY10.	Date at H1N1V Vacc

Data Set Name: nh07_changeofstatus.sas7bdat

Num	Variable	Type	Len	Format	Label
1	ChangeOfStatusOccuring	Char	98	\$98.	Change in status that has occurred
2	IsParticipantWillingBeContacte	Char	1	\$1.	Is the participant still willing to be contacted
3	ParticipantCompletedEntireStud	Char	3	\$3.	Participant completed entire study
4	ReasonForWithdrawal	Char	45	\$45.	Record the primary reason for withdrawal
5	WillingToBeContacted	Char	3	\$3.	Is the subject still willing to be contacted
6	WillingToContinueAfterPregnanc	Char	3	\$3.	Is the participant willing to continue participation as a Control after completion of pregnancy
7	WithdrewConsentWhy	Char	1	\$1.	If withdrew consent selected record the reason why
8	ReasonAdverseEventSpecify	Char	106	\$106.	Reason Adverse Event specify
9	ReasonForWithdrawalOTHER	Char	789	\$789.	If OTHER Specify
10	ReasonWithdrewConsentSpecify	Char	770	\$770.	Reason Withdrew Consent specify
11	WithdrewConsentWhyIfOther	Char	1	\$1.	If withdrew consent selected record the reason why If OTHER specify
12	DateCompletionMM	Char	3	\$3.	Date of completionMM
13	DateCompletionDD	Num	8		Date of completionDD
14	DateCompletionYYYY	Num	8		Date of completionYYYY
15	PhiX174VisitNumber	Num	8		If PhiX174 Visit ONLY ie Weeks 6 7 8 13 14 16 53 54 58 60 or 62 Record week number
16	MaskID	Num	8		Participant Mask ID#
17	Visit	Char	100		Visit
18	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit
19	Date_at_Change_of_Status	Num	8	MMDDYY10.	Date at Change of Status
20	Date_at_Reactivation	Num	8	MMDDYY10.	Date at Reactivation
21	Date_at_Withdrawal	Num	8	MMDDYY10.	Date at Withdrawal
22	Date_at_Last_Visit	Num	8	MMDDYY10.	If Other, Date of Last Visit
23	Date_at_Pregnancy_Completion	Num	8	MMDDYY10.	Date at Pregnancy Completion

Data Set Name: *physical_exam.sas7bdat*

Num	Variable	Type	Len	Format	Label
1	AbnormalitiesAtPreviousDrugAdm	Char	7	\$7.	Were there any abnormalities at the previous drug administration site
2	AbnormalitiesOnThePhysicalExam	Char	7	\$7.	Were there any abnormalities on the physical exam
3	ClinicallySignificantAbnormali	Char	7	\$7.	were there any clinically significant abnormalities
4	CompletedNeurologicalAssessmen	Char	7	\$7.	Was a neurological assessment completed at this visit
5	CurrentlyTakingBirthControlMed	Char	3	\$3.	Are you currently taking birth control medication
6	CurrentlyUseBirthControl	Char	3	\$3.	Do you currently use a form of birth control Females of reproductive age are expected to sue a form of birth control or practice abstinence
7	IsFemaleWithReproductivePotent	Char	3	\$3.	If FEMALE does the participant have reproductive or childbearing potential
8	PlanOnBecomingPregnant	Char	3	\$3.	Do you plan on becoming pregnant before the study end
9	PregnancyTestAtVisit	Char	3	\$3.	Was a urine pregnancy test completed at this visit
10	TannerGenitalia	Char	18	\$18.	Genitalia male
11	TannerPubicHair	Char	18	\$18.	Pubic Hair both
12	TannerStageBreast	Char	18	\$18.	Tanner Stage Breast
13	UrinePregnancyTestResultPositi	Char	2	\$2.	If YES was the test result positive
14	SpecifyAbnormalitiesOnThePhysi	Char	312	\$312.	If YES specify
15	SpecifyClinicallySignificantAb	Char	111	\$111.	If YES specify
16	SpecifyPreviousAbnormalities	Char	230	\$230.	If YES specify
17	BloodPressureNotDone	Num	8		BloodPressure not done
18	HeartRateNotDone	Num	8		heartRate not done
19	HeightNotDone	Num	8		Height not done
20	RespiratoryRateNotDone	Num	8		respiratory rate not done
21	TemperatureNotDone	Num	8		temperature not done
22	WeightNotDone	Num	8		weight not done
23	BPDiatolic	Num	8		Seated arm blood pressure diatolic
24	BPSystolic	Num	8		Seated arm blood pressure Systolic
25	HeartRateBPM	Num	8		heartRate count
26	HeightCM	Num	8		Height CM
27	RespiratoryRatePerMin	Num	8		respiratory rate per min
28	TemperatureC	Num	8		temperature C
29	WeightKG	Num	8		WeightKGDoube
30	MaskID	Num	8		Participant Mask ID#
31	Visit	Char	100		Visit
32	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit

Data Set Name: pregnancy_confirmation.sas7bdat

Num	Variable	Type	Len	Format	Label
1	CodedMedStopped	Char	1	\$1.	Has the coded medication been stopped
2	HadComplicationOfPreg	Char	7	\$7.	Has the participant ever experienced a complication of pregnancy
3	NeonatalDeath	Char	2	\$2.	Has the participant ever experienced a pregnancy that resulted in neonatal death
4	ParticipantCarryingPregnancyTo	Char	7	\$7.	Is the participant planning on carrying the pregnancy to term
5	ParticpantsObCareProviderInfor	Char	7	\$7.	Has the participants obstetric care provider been informed of her participation in this study
6	PostTermDelivryGT37GWeeks	Char	2	\$2.	Has the participant ever experienced a postterm delivery 37 gestational weeks
7	PostTermDelivryLT42GWeeks	Char	2	\$2.	Has the participant ever experienced a postterm delivery 42 gestational weeks
8	SpontaneousMiscarage	Char	3	\$3.	Has the participant ever experienced a spontaneous miscarage
9	StillBirth	Char	2	\$2.	Has the participant ever experienced a pregnancy that resulted in a still birth
10	WillingToContinueFUVisits	Char	7	\$7.	Is the participant willing to continue with future followup visits
11	LastAttendedVisit	Char	8	\$8.	Last attended study visit prior to the confirmed pregnancy
12	DateDeliveryUnknown	Num	8		Estimated date of delivery unknown
13	DateMenCycleUnknown	Num	8		Date of last menstrual cycle unknown
14	DatePregTestUnknown	Num	8		Date of positive pregnancy test unknown
15	PriorPregnancyNumberUnkown	Num	8		record total number of prior pregnancies unkown
16	PhiX174VisitNumber	Num	8		If PhiX174 Visit ONLY ie weeks 6 7 8 13 14 16 53 54 58 59 60 or 62 Record week number
17	TotalNumOfPregNotIncluThisOne	Num	8		Indicate the total number of prior pregnancies not including this one
18	MaskID	Num	8		Participant Mask ID#
19	Visit	Char	100		Visit
20	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit
21	Date_At_EstDelivery	Num	8	MMDDYY10.	Date at Estimated date of delivery
22	Date_At_LastMenstrualCycle	Num	8	MMDDYY10.	Date at last menstrual cycle
23	Date_At_PositivePregTest	Num	8	MMDDYY10.	Date at positive pregnancy test
24	Date_At_OtherVisit	Num	8	MMDDYY10.	Date at Other Visit

Data Set Name: pregnancy_outcome.sas7bdat

Num	Variable	Type	Len	Format	Label
1	BreastFeeding	Char	7	\$7.	Is the participant currently breastfeeding
2	ComplicationsInDelivery	Char	7	\$7.	Were there any complications during the delivery
3	HbA1cMeasure	Char	7	\$7.	Was an HbA1c measured at any time during the pregnancy
4	LiveBirths	Char	3	\$3.	Did the pregnancy result in a live birth or multiple live births
5	Miscarriage	Char	3	\$3.	Did the pregnancy result in a miscarriage
6	OutcomeUKNDueToLossOfParticpan	Char	2	\$2.	Is the outcome of the pregnancy unknown due to loss of participant to followup
7	PregnancyAbortion	Char	3	\$3.	Was the pregnancy terminated as a result of an induced abortion
8	ReasonForAbortionMedicallyIndi	Char	2	\$2.	Was the reason for the abortion medically indicated
9	StillBirth	Char	2	\$2.	Did the pregnancy result in a stillbirth
10	StillBirthHaveAnyOtherComplica	Char	1	\$1.	Did the stillbirth have any other complications
11	StillBirthHaveMalformations	Char	1	\$1.	Did the stillbirth have any congenital malformations
12	InfantBornCongenitalMalform1	Char	7	\$7.	Was the infant born with any congenital malformations
13	InfantBornCongenitalMalform2	Char	1	\$1.	Was the infant born with any congenital malformations
14	InfantBornCongenitalMalform3	Char	1	\$1.	Was the infant born with any congenital malformations
15	InfantBornOtherComplication1	Char	7	\$7.	Was the infant born with other complications
16	InfantBornOtherComplication2	Char	1	\$1.	Was the infant born with other complications
17	InfantBornOtherComplication3	Char	1	\$1.	Was the infant born with other complications
18	InfantDischargedFromHopsita1	Char	3	\$3.	Was the infant discharged from the hospital alive
19	InfantDischargedFromHopsita2	Char	1	\$1.	Was the infant discharged from the hospital alive
20	InfantDischargedFromHopsita3	Char	1	\$1.	Was the infant discharged from the hospital alive
21	InfantInNICU1	Char	7	\$7.	Was the infant admitted to the Neonatal Intensive Care Unit NICU at any time
22	InfantInNICU2	Char	1	\$1.	Was the infant admitted to the Neonatal Intensive Care Unit NICU at any time
23	InfantInNICU3	Char	1	\$1.	Was the infant admitted to the Neonatal Intensive Care Unit NICU at any time
24	Sex1	Char	4	\$4.	Sex
25	Sex2	Char	1	\$1.	Sex
26	Sex3	Char	1	\$1.	Sex
27	ReasonForAbortionMedicallyIndi2	Char	1	\$1.	Specify reason
28	StillBirthHaveAnyOtherComplica2	Char	1	\$1.	If YES Specify
29	StillBirthHaveMalformationsSpe	Char	1	\$1.	If YES Specify
30	InfantBornCongenitalMalformS1	Char	1	\$1.	Was the infant born with any congenital malformations Specify
31	InfantBornCongenitalMalformS2	Char	1	\$1.	Was the infant born with any congenital malformations Specify

Num	Variable	Type	Len	Format	Label
32	InfantBornCongenitalMalformS3	Char	1	\$1.	Was the infant born with any congenital malformations Specify
33	InfantBornOtherComplicationS1	Char	1	\$1.	Was the infant born with other complications Specify
34	InfantBornOtherComplicationS2	Char	1	\$1.	Was the infant born with other complications Specify
35	InfantBornOtherComplicationS3	Char	1	\$1.	Was the infant born with other complications Specify
36	InfantDeathCause1	Char	1	\$1.	Specify cause of death
37	InfantDeathCause2	Char	1	\$1.	Specify cause of death
38	InfantDeathCause3	Char	1	\$1.	Specify cause of death
39	NumberOfinfantsUnknown	Num	8		Record number of infants the birth resulted in Unknown
40	RecordHbA1cUnknown	Num	8		Record HbA1c unknown
41	BirthWeightGMUnknown1	Num	8		Birth weight gm unknown
42	BirthWeightGMUnknown2	Num	8		Birth weight gm unknown
43	BirthWeightGMUnknown3	Num	8		Birth weight gm unknown
44	BirthWeightLBUnknown1	Num	8		Birth weight lb unknown
45	BirthWeightLBUnknown2	Num	8		Birth weight lb unknown
46	BirthWeightLBUnknown3	Num	8		Birth weight lb unknown
47	FiveMinuteAPGARScoreUnknown1	Num	8		Five minute APGAR score unknown
48	FiveMinuteAPGARScoreUnknown2	Num	8		Five minute APGAR score unknown
49	FiveMinuteAPGARScoreUnknown3	Num	8		Five minute APGAR score unknown
50	GestationalAgeUnknown1	Num	8		Gestational age unknown
51	GestationalAgeUnknown2	Num	8		Gestational age unknown
52	GestationalAgeUnknown3	Num	8		Gestational age unknown
53	OneMinuteAPGARScoreUnknown1	Num	8		One minute APGAR score unknown
54	OneMinuteAPGARScoreUnknown2	Num	8		One minute APGAR score unknown
55	OneMinuteAPGARScoreUnknown3	Num	8		One minute APGAR score unknown
56	BirthWeightLBS	Num	8		Birth Weight lbs oz
57	HbA1cMeasure2	Num	8		Indicate HbA1c
58	NumberOfInfants	Num	8		Record number of infants both living and deceased the birth resulted in
59	PregnancyIDNumber	Num	8		Record the Pregnancy Identification Number
60	BirthWeight1	Num	8		Birth weight gm
61	BirthWeight2	Num	8		Birth weight gm
62	BirthWeight3	Num	8		Birth weight gm
63	BirthWeightLbs1	Num	8		Birth weight lbs
64	BirthWeightLbs2	Num	8		Birth weight lbs
65	BirthWeightLbs3	Num	8		Birth weight lbs
66	BirthWeightOz1	Num	8		Birth weight oz
67	BirthWeightOz2	Num	8		Birth weight oz
68	BirthWeightOz3	Num	8		Birth weight oz

Num	Variable	Type	Len	Format	Label
69	GestationalAge1	Num	8		Gestational age
70	GestationalAge2	Num	8		Gestational age
71	GestationalAge3	Num	8		Gestational age
72	_1MinAPGARScore1	Num	8		One minute APGAR score
73	_1MinAPGARScore2	Num	8		One minute APGAR score
74	_1MinAPGARScore3	Num	8		One minute APGAR score
75	_5MinAPGARScore1	Num	8		Five minute APGAR score
76	_5MinAPGARScore2	Num	8		Five minute APGAR score
77	_5MinAPGARScore3	Num	8		Five minute APGAR score
78	MaskID	Num	8		Participant Mask ID#
79	Visit	Char	100		Visit
80	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit
81	Date_At_PregnancyEnd	Num	8	MMDDYY10.	Date at Pregnancy End
82	Date_At_InfantDeath1	Num	8	MMDDYY10.	Date at Infant Death #1
83	Date_At_InfantDeath2	Num	8	MMDDYY10.	Date at Infant Death #2
84	Date_At_InfantDeath3	Num	8	MMDDYY10.	Date at Infant Death #3
85	Date_At_HbA1c	Num	8	MMDDYY10.	Date at HbA1c
86	Date_At_InfantHospDisch1	Num	8	MMDDYY10.	Date at Infant Hospital Discharge #1
87	Date_At_InfantHospDisch2	Num	8	MMDDYY10.	Date at Infant Hospital Discharge #2
88	Date_At_InfantHospDisch3	Num	8	MMDDYY10.	Date at Infant Hospital Discharge #3

Data Set Name: protocol_deviation.sas7bdat

Num	Variable	Type	Len	Format	Label
1	Deviation	Char	1	\$1.	Protocol Deviation
2	DeviationError	Char	49	\$49.	Protocol deviationprocedural error
3	DeviationReportedFor	Char	6	\$6.	Protocol deviation reported for
4	PNotified	Char	3	\$3.	Was PI notified
5	ProtocolDeviation	Char	87	\$87.	Protocol Deviation
6	ProtocolDeviation2	Char	83	\$83.	Protocol Deviation
7	ProtocolDeviationApprovedByElg	Char	3	\$3.	Was protocol deviation approved by the Eligibility Committee
8	RequiredBloodCollectionProcedu	Char	1	\$1.	Required procedureblood collection not completed Specify
9	SubjectRandomizedIneligibilityA	Char	3	\$3.	If Ineligible subject randomized checked approved by Eligibility Committee
10	TN16ProtocolDeviation	Char	88	\$88.	TN16 Protocol deviation
11	TestingErrorProcedure	Char	1	\$1.	Testing procedure error
12	DescribeCorrectionAction	Char	175	\$175.	Describe corrective action taken if necessary depending on circumstances
13	DescribeDeviation	Char	204	\$204.	Describe Deviation procedural error and circumstances
14	DeviationOccurenceSpecify	Char	1	\$1.	IF OTHER Specify Deviation
15	ExlcudedMedicationSpecify	Char	1	\$1.	Excluded Medications Specify
16	ExplanProtocolDeviation	Char	1	\$1.	Explanation for protocol deviation
17	OtherSpecify	Char	116	\$116.	Other Specify
18	OtherSpecify2	Char	159	\$159.	If Other Specify
19	OtherSpecify3	Char	1	\$1.	Other Specifiy
20	ProtocolChair	Char	1	\$1.	If yes who was the protocol chair
21	ProtocolDeviationSpecify	Char	119	\$119.	If OTHER Specify deviation
22	ProtocolDeviationOtherSubcateg	Char	53	\$53.	Protocol Deviation Other subcategory
23	StudyVisitCompletedFor	Char	13	\$13.	Study visit this form being completed for
24	PhiX174WeekNumber	Num	8		If PhiX174 Visit ONLY ie Weeks 6 7 8 13 14 16 53 54 58 59 60 62 Record week number
25	MaskID	Num	8		Participant Mask ID#
26	Visit	Char	100		Visit
27	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit
28	Date_at_Deviation	Num	8	MMDDYY10.	Date at Deviation
29	Date_at_Other	Num	8	MMDDYY10.	Date at Other
30	Date_at_Protocol_Deviation	Num	8	MMDDYY10.	Date at Protocol Deviation

Data Set Name: registration.sas7bdat

Num	Variable	Type	Len	Format	Label
1	status	Char	20		Participant Status
2	MaskID	Num	8		Participant Mask ID#
3	Date_of_Study_Start	Num	8	MMDDYY10.	Date of Study Start
4	Date_of_Registration	Num	8	MMDDYY10.	Date of Registration

Data Set Name: research_labs.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	MaskID	Num	8			Participant Mask ID#
2	Date_of_Draw	Num	8	MMDDYY10.		Date of Draw
3	Event_Title	Char	100			Specimen Collection Form
4	SPEC_NAME	Char	250			Specimen Name
5	SampleMaskID	Char	10			Sample Mask ID#
6	TEST_NAME	Char	150	\$150.	\$150.	Test Name
7	RESULT	Char	1000	\$1000.	\$1000.	Result
8	ResultType	Char	6			Result Type
9	Visit	Char	100			Visit
10	Date_at_Test_Results_Reported	Num	8	MMDDYY10.		Date at Test Results Reports
11	Date_at_Evaluation	Num	8	MMDDYY10.		Date at Sample Evaluation
12	Date_Received	Num	8	MMDDYY10.		Date when Sample Received at Lab
13	Date_Shipped	Num	8	MMDDYY10.		Date when Sample Shipped
14	LabID	Num	8			LabID

Data Set Name: screening_informed_consent.sas7bdat

Num	Variable	Type	Len	Format	Label
1	PermissionSampleStorageDNA	Char	11	\$11.	If yes with or without DNA
2	WasPermissionGivenForBloodSamp	Char	14	\$14.	On the consent form was permission given for samples of the participants blood to be stored for other tests
3	InformedConsentMonth	Char	3	\$3.	Date written informed consent for screening was obtained month
4	InformedConsentDay	Num	8		Date written informed consent for screening was obtained day
5	InformedConsentYear	Num	8		Date written informed consent for screening was obtained year
6	MaskID	Num	8		Participant Mask ID#
7	Visit	Char	100		Visit
8	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit

Data Set Name: screening_medical_history.sas7bdat

Num	Variable	Type	Len	Format	Label
1	AddisonsDisease	Char	2	\$2.	Addisons Disease Adrenal Insufficiency
2	AllergiesEver	Char	7	\$7.	Ever had allergies
3	Alopecia	Char	2	\$2.	Alopecia
4	AsthmaEver	Char	7	\$7.	Ever had asthma
5	AutoimmuneThyroidDisease	Char	3	\$3.	Autoimmune Thyroid Disease Hypothyroidism or Hashimotos Disease
6	CardiovascularFindings	Char	12	\$12.	Cardiovascular findings
7	CeliacDisease	Char	3	\$3.	Celiac Disease Gluten Allergy or Celiac Sprue
8	DKAatDiagnosis	Char	7	\$7.	Did you have Diabetic Ketoacidosis DKA at time of diagnosis
9	DKAsinceDiagnosis	Char	7	\$7.	Since diagnosis have you ever experienced Diabetic Ketoacidosis
10	DiagnosedAutoimmuneDiseaseEver	Char	7	\$7.	Have you ever ben diagnosed with an autoimmune diseases
11	EndocrineFindings	Char	12	\$12.	Endocrine other than T1D findings
12	FrequentOtherInfectionsEver	Char	7	\$7.	Ever had frequent other infections
13	GastrointestinalFindings	Char	12	\$12.	Gastrointestinal findings
14	GravesDisease	Char	1	\$1.	Graves Disease Hyperthyroidism
15	HEENTfindings	Char	12	\$12.	HEENT findings
16	HealthChangesSinceLastVisit	Char	3	\$3.	Have there been any changes in your health since the last visit
17	HospitalizedDuringDiagnosis	Char	7	\$7.	Were you admitted to a hospital during the diagnosis period
18	HospitalizedOtherThanDiabetes	Char	7	\$7.	Have you ever been hospitalized other than for diabetes
19	HypogonadismOrPrematureMenopau	Char	2	\$2.	Hypogonadism or Premature Menopause
20	Hypoparathyroidism	Char	2	\$2.	Hypoparathyroidism
21	ICUDuringDiagnosis	Char	7	\$7.	If yes were you admitted to an Intensive Care Unit ICU while in the hospital
22	InflammatoryBowelDisease	Char	2	\$2.	Inflammatory Bowel Disease
23	IntegumentFindings	Char	12	\$12.	Integument Findings
24	LeukopeniaOrNeutropeniaEver	Char	7	\$7.	Ever had leukopenianeutropenia
25	Lupus	Char	2	\$2.	Lupus
26	MultipleSclerosis	Char	2	\$2.	Multiple Sclerosis
27	MusculoskeletalFindings	Char	12	\$12.	Musculoskeletal findings
28	NeurologicalFindings	Char	12	\$12.	Neurological Findings
29	OtherConditionsDiseasesEver	Char	7	\$7.	Ever had other conditionsdiseases
30	PerniciousAnemia	Char	2	\$2.	Pernicious Anemia
31	Psoriasis	Char	2	\$2.	Psoriasis
32	PulmonaryFindings	Char	12	\$12.	Pulmonary findings
33	ReproductiveFindings	Char	12	\$12.	Reproductive findings

Num	Variable	Type	Len	Format	Label
34	RheumatologicDisease	Char	2	\$2.	Rheumatologic Disease
35	VaccinationsOtherThanStudyMed	Char	3	\$3.	Since the last scheduled visit have you had any vaccinations other than those administered as part of the study
36	Vitiligo	Char	3	\$3.	Vitiligo
37	OtherAutoimmuneDisease1	Char	3	\$3.	Other autoimmune disease
38	OtherAutoimmuneDisease2	Char	1	\$1.	Other autoimmune disease
39	OtherFindings1	Char	12	\$12.	Other findings
40	OtherFindings2	Char	12	\$12.	Other findings
41	OtherFindings3	Char	1	\$1.	Other findings
42	CardiovascularAbnormalExplain	Char	302	\$302.	Cardiovascular abnormal explain
43	FrequentOtherInfectionsSpecify	Char	59	\$59.	Ever had frequent other infections specify
44	GastrointestinalAbnormalExplai	Char	495	\$495.	Gastrointestinal abnormal explain
45	HospitalizedOtherThanDiabetesW	Char	156	\$156.	If yes what for
46	MusculoskeletalAbnormalExplain	Char	481	\$481.	Musculoskeletal abnormal explain
47	NeurologicalAbnormalExplain	Char	217	\$217.	Neurological Abnormal Explain
48	OtherConditionsDiseasesSpecify	Char	219	\$219.	Ever had other conditionsdiseases specify
49	PulmonaryAbnormalExplain	Char	199	\$199.	Pulmonary abnormal explain
50	ReproductiveAbnormalExplain	Char	236	\$236.	Reproductive abnormal explain
51	OtherAbnormalExplain2	Char	56	\$56.	Other abnormal explain
52	OtherAbnormalExplain3	Char	1	\$1.	Other abnormal explain
53	OtherAutoimmuneDiseaseSpeci1	Char	29	\$29.	Other autoimmune disease specify
54	OtherAutoimmuneDiseaseSpeci2	Char	1	\$1.	Other autoimmune disease specify
55	VaccinationTypeSpecify1	Char	51	\$51.	Vaccination type specify
56	VaccinationTypeSpecify2	Char	52	\$52.	Vaccination type specify
57	VaccinationTypeSpecify3	Char	31	\$31.	Vaccination type specify
58	VaccinationTypeSpecify4	Char	11	\$11.	Vaccination type specify
59	VaccinationTypeSpecify5	Char	8	\$8.	Vaccination type specify
60	AddisonsDiseaseDiagnosisDateMo	Char	1	\$1.	Addisons Disease Adrenal Insufficiency diagnosis date month
61	AlopeciaDiagnosisDateMonth	Char	1	\$1.	Alopecia diagnosis date month
62	AutoimmuneThyroidDiseaseDiagno2	Char	3	\$3.	Autoimmune Thyroid Disease Hypothyroidism or Hashimotos Disease diagnosis date month
63	CeliacDiseaseDiagnosisDateMont	Char	1	\$1.	Celiac Disease Gluten Allergy or Celiac Sprue diagnosis date month
64	DateOfT1DdiagnosisMonth	Char	3	\$3.	Date of diagnosis of T1D month
65	GravesDiseaseDiagnosisDateMont	Char	1	\$1.	Graves Disease Hyperthyroidism diagnosis date month
66	HypogonadismOrPrematureMenopau3	Char	1	\$1.	Hypogonadism or Premature Menopause diagnosis date month
67	HypoparathyroidismDiagnosisDat2	Char	1	\$1.	Hypoparathyroidism diagnosis date month
68	InflammatoryBowelDiseaseDiagno2	Char	1	\$1.	Inflammatory Bowel Disease diagnosis date month

Num	Variable	Type	Len	Format	Label
69	LupusDiagnosisDateMonth	Char	1	\$1.	Lupus diagnosis date Month
70	MostRecentHbA1cDateMonth	Char	3	\$3.	Most recent HbA1c date month
71	MultipleSclerosisDiagnosisDate2	Char	1	\$1.	Multiple Sclerosis diagnosis date month
72	PerniciousAnemiaDiagnosisDateM	Char	1	\$1.	Pernicious Anemia diagnosis date month
73	PsoriasisDiagnosisDateMonth	Char	1	\$1.	Psoriasis diagnosis date month
74	RheumatologicDiseaseDiagnosisD2	Char	1	\$1.	Rheumatologic Disease diagnosis date month
75	VitiligoDiagnosisDateMonth	Char	1	\$1.	Vitiligo diagnosis date month
76	OtherAutoimmuneDiseaseDiagn1_2	Char	1	\$1.	Other autoimmune disease diagnosis date month
77	OtherAutoimmuneDiseaseDiagn2_2	Char	1	\$1.	Other autoimmune disease diagnosis date month
78	VaccinationDateMonth1	Char	3	\$3.	Vaccination date month
79	VaccinationDateMonth2	Char	3	\$3.	Vaccination date month
80	VaccinationDateMonth3	Char	3	\$3.	Vaccination date month
81	VaccinationDateMonth4	Char	3	\$3.	Vaccination date month
82	VaccinationDateMonth5	Char	3	\$3.	Vaccination date month
83	AddisonsDiseaseDiagnosisDateDa	Num	8		Addisons Disease Adrenal Insufficiency diagnosis date day
84	AddisonsDiseaseDiagnosisDateYe	Num	8		Addisons Disease Adrenal Insufficiency diagnosis date year
85	AlopeciaDiagnosisDateDay	Num	8		Alopecia diagnosis date day
86	AlopeciaDiagnosisDateYear	Num	8		Alopecia diagnosis date year
87	AutoimmuneThyroidDiseaseDiagno	Num	8		Autoimmune Thyroid Disease Hypothyroidism or Hashimotos Disease diagnosis date day
88	AutoimmuneThyroidDiseaseDiagno3	Num	8		Autoimmune Thyroid Disease Hypothyroidism or Hashimotos Disease diagnosis date year
89	CeliacDiseaseDiagnosisDateDay	Num	8		Celiac Disease Gluten Allergy or Celiac Sprue diagnosis date day
90	CeliacDiseaseDiagnosisDateYear	Num	8		Celiac Disease Gluten Allergy or Celiac Sprue diagnosis date year
91	DateOfT1DdiagnosisDay	Num	8		Date of diagnosis of T1D day
92	DateOfT1DdiagnosisYear	Num	8		Date of diagnosis of T1D year
93	GravesDiseaseDiagnosisDateDay	Num	8		Graves Disease Hyperthyroidism diagnosis date day
94	GravesDiseaseDiagnosisDateYear	Num	8		Graves Disease Hyperthyroidism diagnosis date year
95	HypogonadismOrPrematureMenopau2	Num	8		Hypogonadism or Premature Menopause diagnosis date day
96	HypogonadismOrPrematureMenopau4	Num	8		Hypogonadism or Premature Menopause diagnosis date year
97	HypoparathyroidismDiagnosisDat	Num	8		Hypoparathyroidism diagnosis date day
98	HypoparathyroidismDiagnosisDat3	Num	8		Hypoparathyroidism diagnosis date year
99	InflammatoryBowelDiseaseDiagno	Num	8		Inflammatory Bowel Disease diagnosis date day
100	InflammatoryBowelDiseaseDiagno3	Num	8		Inflammatory Bowel Disease diagnosis date year
101	LupusDiagnosisDateDay	Num	8		Lupus diagnosis date day
102	LupusDiagnosisDateYear	Num	8		Lupus diagnosis date year
103	MostRecentHbA1c	Num	8		Most recent HbA1c
104	MostRecentHbA1cDateDay	Num	8		Most recent HbA1c date day

Num	Variable	Type	Len	Format	Label
105	MostRecentHbA1cDateYear	Num	8		Most recent HbA1c date year
106	MultipleSclerosisDiagnosisDate	Num	8		Multiple Sclerosis diagnosis date day
107	MultipleSclerosisDiagnosisDate3	Num	8		Multiple Sclerosis diagnosis date year
108	PerniciousAnemiaDiagnosisDateD	Num	8		Pernicious Anemia diagnosis date day
109	PerniciousAnemiaDiagnosisDateY	Num	8		Pernicious Anemia diagnosis date year
110	PsoriasisDiagnosisDateDay	Num	8		Psoriasis diagnosis date day
111	PsoriasisDiagnosisDateYear	Num	8		Psoriasis diagnosis date year
112	RheumatologicDiseaseDiagnosisD	Num	8		Rheumatologic Disease diagnosis date day
113	RheumatologicDiseaseDiagnosisD3	Num	8		Rheumatologic Disease diagnosis date year
114	VitiligoDiagnosisDateYear	Num	8		Vitiligo diagnosis date year
115	VitiligoDiagnosisDateday	Num	8		Vitiligo diagnosis date day
116	OtherAutoimmuneDiseaseDiagn1_1	Num	8		Other autoimmune disease diagnosis date day
117	OtherAutoimmuneDiseaseDiagn1_3	Num	8		Other autoimmune disease diagnosis date year
118	OtherAutoimmuneDiseaseDiagn2_1	Num	8		Other autoimmune disease diagnosis date day
119	OtherAutoimmuneDiseaseDiagn2_3	Num	8		Other autoimmune disease diagnosis date year
120	VaccinationDateDay1	Num	8		Vaccination date day
121	VaccinationDateDay2	Num	8		Vaccination date day
122	VaccinationDateDay3	Num	8		Vaccination date day
123	VaccinationDateDay4	Num	8		Vaccination date day
124	VaccinationDateDay5	Num	8		Vaccination date day
125	VaccinationDateYear1	Num	8		Vaccination date year
126	VaccinationDateYear2	Num	8		Vaccination date year
127	VaccinationDateYear3	Num	8		Vaccination date year
128	VaccinationDateYear4	Num	8		Vaccination date year
129	VaccinationDateYear5	Num	8		Vaccination date year
130	InitialDiagnosisBase_Formaltesti	Num	8		InitialDiagnosisBase: Formal testing for diabetes (OGTT)
131	InitialDiagnosisBase_Randomblood	Num	8		InitialDiagnosisBase: Random blood glucose check
132	InitialDiagnosisBase_Routinescre	Num	8		InitialDiagnosisBase: Routine screening for diabetes without presence of symptoms
133	InitialDiagnosisBase_SymptomsofD	Num	8		InitialDiagnosisBase: Symptoms of Diabetes
134	SymptomsAtTimeOfDiag_Blurredvisi	Num	8		SymptomsAtTimeOfDiag: Blurred vision
135	SymptomsAtTimeOfDiag_Frequentinf	Num	8		SymptomsAtTimeOfDiag: Frequent infections
136	SymptomsAtTimeOfDiag_Frequenturi	Num	8		SymptomsAtTimeOfDiag: Frequent urination
137	SymptomsAtTimeOfDiag_IncreasedEa	Num	8		SymptomsAtTimeOfDiag: Increased Eating
138	SymptomsAtTimeOfDiag_Increasedth	Num	8		SymptomsAtTimeOfDiag: Increased thirst
139	SymptomsAtTimeOfDiag_Nosymptoms	Num	8		SymptomsAtTimeOfDiag: No symptoms
140	SymptomsAtTimeOfDiag_Weightloss	Num	8		SymptomsAtTimeOfDiag: Weight loss
141	MaskID	Num	8		Participant Mask ID#
142	Visit	Char	100		Visit

Num	Variable	Type	Len	Format	Label
143	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit

Data Set Name: study_drug_administration.sas7bdat

Num	Variable	Type	Len	Format	Label
1	ExperiencedOtherProblems	Char	3	\$3.	Did the subject experience any other problems during study drug administration
2	ExperiencedProblemFollowingThe	Char	3	\$3.	Did the subject experience any problems following the drug administration
3	ItchingGrade	Char	1	\$1.	Site evaluation Itching grade
4	PainGrade	Char	1	\$1.	Site evaluation pain grade
5	RednessGrade	Char	1	\$1.	Site evaluation Redness grade
6	SwellingGrade	Char	1	\$1.	Site evaluation Swelling grade
7	WasSubcutaneousInjectionGiven	Char	3	\$3.	Was subcutaneous injection given
8	PainDuration	Char	2	\$2.	Site evaluation pain duration
9	PainTimePostInjection	Char	2	\$2.	Site evaluation pain time post injection
10	SpecifyOtherProblemsInDrugAdmi	Char	367	\$367.	If YES specify
11	SpecifyWhySubcutaneousInjectio	Char	1	\$1.	If NO specify why
12	ItchingDuration	Num	8		Site evaluation Itching duration
13	ItchingTimePostInjection	Num	8		Site evaluation Itching time post injection
14	RednessDuration	Num	8		Site evaluation Redness duration
15	RednessTimePostInjection	Num	8		Site evaluation Redness time post injection
16	SwellingDuration	Num	8		Site evaluation Swelling duration
17	SwellingTimePostInjection	Num	8		Site evaluation Swelling time post injection
18	MaskID	Num	8		Participant Mask ID#
19	Visit	Char	100		Visit
20	Date_of_Visit	Num	8	MMDDYY10.	Date of Visit

Data Set Name: treatment_table.sas7bdat

Num	Variable	Type	Len	Format	Label
1	ORDERING_INDEX	Num	8		ORDERING_INDEX
2	CONSUMED	Num	8		CONSUMED
3	TreatmentName	Char	100		
4	RegistrationGroup	Char	100		
5	Treatment_Start_Date	Num	8	MMDDYY10.	
6	Randomization_Date	Num	8	MMDDYY10.	
7	Data_Entry_User_ID	Num	8		User ID of Data Entry Personnel
8	MaskID	Num	8		Participant Mask ID#
9	SequenceNumber	Num	8		