

***TrialNet - TN10***  
***Analytic Datasets - ProventionBio***  
***Data Dictionary***  
***Data Through November 30, 2018***  
***Current as of January 31, 2019***

***Table of Contents***

<b>Form</b>	<b>File Name</b>
Adverse Events	AE
Autoantibody	AUTOAB
BMI	BMI
Complete Blood Count	CBC
Cytomegalovirus Viral Load	CMV
Cytomegalovirus & Epstein-Barr Virus Viral Load	CMVEBV
Epstein-Barr Virus Viral Load	EBV
HbA1c	HBA1C
Human Leukocyte Antigen	HLA
Mastable	MASTABLE
OGTT C-Peptide	OGTT_CPEP
OGTT Glucose	OGTT_GLU
Relationship	RELATION
Status	STATUS
Treatment	TREATMENT

***TrialNet - TN10***  
***Analytic Datasets - ProventionBio***  
***Data Dictionary***  
***Data Through November 30, 2018***  
***Current as of January 31, 2019***

***Form: Adverse Events***

***File Name: AE***

***Number of Observations: 272***

***Number of Variables: 23***

Variable Name	Variable Type	Variable Length	Variable Label
MaskID	Num	8	Participant Mask ID#
Eventabateafterstoppingdrug	Char	14	Did the eventreaction abate after stopping drug
AECategory	Char	35	Category
AECausalityByReporter	Char	22	Causality by reporter
AEAssociations_Death	Num	8	AEAssociations: Death
AEAssociations_Isanotherconditio	Char	12	AEAssociations: Is another condition which investigators judge to represent significant hazards
AEPatientOutcome	Char	35	AE Patient Outcome
AEexpected	Char	12	AE Expected
AEPrimarySecondary	Char	12	Is this event a primary or secondary event?
AESelectTermstr	Char	25	AE Select Term
seriousae	Num	8	Serious AE
ae_eval_id	Num	8	AE Initial AEID
AECausalityByReviewer	Char	22	Causality by reviewer
CTCAE_VERSION	Num	8	CTCAE Version
AETerm	Char	88	AE Term
AE_Submitted	Num	8	Date AE Submitted
severity	Num	8	Severity
dtfollow	Num	8	Date at Follow-Up
dtreported	Num	8	Date Event Reported
dtresolved	Num	8	Date Event Resolved
dte	Num	8	Date Event Occurred
aedetails_abbr	Char	400	Adverse Event Details
new_aedetails_abbr	Char	200	New Adverse Event Details

***TrialNet - TN10***  
***Analytic Datasets - ProventionBio***  
***Data Dictionary***  
***Data Through November 30, 2018***  
***Current as of January 31, 2019***

***Form: Autoantibody***

***File Name: AUTOAB***

***Number of Observations: 156***

***Number of Variables: 13***

Variable Name	Variable Type	Variable Length	Variable Label
MaskID	Num	8	Participant Mask ID#
DateOfDraw	Num	8	Date of Draw
DateSampleEvaluation	Num	8	Date of Sample Evaluation
znt8	Num	8	Zinc Transporter 8
miaa	Num	8	Micro Insulin autoantibody
ia2h	Num	8	Anti-IA-2 autoantibody (NIDDK Harmonized Assay)
ica	Num	8	Islet Cell Antigen
gad65h	Num	8	Anti-GAD65 autoantibody (NIDDK Harmonized Assay)
gad65h_pos	Num	8	GAD65H Outcome (1=positive 0=negative)
ia2h_pos	Num	8	IA-2H Outcome (1=positive 0=negative)
ica_pos	Num	8	ICA Outcome (1=positive 0=negative)
miaa_pos	Num	8	MIAA Outcome (1=positive 0=negative)
znt8_pos	Num	8	ZNT8 Outcome (1=positive 0=negative)

***TrialNet - TN10***  
***Analytic Datasets - ProventionBio***  
***Data Dictionary***  
***Data Through November 30, 2018***  
***Current as of January 31, 2019***

***Form: BMI***

***File Name: BMI***

***Number of Observations: 76***

***Number of Variables: 5***

Variable Name	Variable Type	Variable Length	Variable Label
MaskID	Num	8	Participant Mask ID#
DateofExam	Num	8	Date of Exam
HeightCM	Num	8	Height (cm)
WeightKG	Num	8	Weight (kg)
bmi	Num	8	Body Mass Index

***TrialNet - TN10***  
***Analytic Datasets - ProventionBio***  
***Data Dictionary***  
***Data Through November 30, 2018***  
***Current as of January 31, 2019***

***Form: Complete Blood Count***

***File Name: CBC***

***Number of Observations: 1414***

***Number of Variables: 6***

Variable Name	Variable Type	Variable Length	Variable Label
MaskID	Num	8	Participant Mask ID#
DateofDraw	Num	8	Date of Draw
Type	Char	12	Type
LymphocytesResults	Num	8	Lymphocytes results (%)
LymphocytesResultsOR	Num	8	Lymphocytes results (10 <sup>3</sup> cells/ $\mu$ l)
WBCResults	Num	8	WBC results (10 <sup>3</sup> cells/ $\mu$ l)

***TrialNet - TN10***  
***Analytic Datasets - ProventionBio***  
***Data Dictionary***  
***Data Through November 30, 2018***  
***Current as of January 31, 2019***

***Form: Cytomegalovirus Viral Load***

***File Name: CMV***

***Number of Observations: 473***

***Number of Variables: 3***

Variable Name	Variable Type	Variable Length	Variable Label
MaskID	Num	8	Participant Mask ID#
DateOfDraw	Num	8	Date of Draw
cmvvl	Char	6	CMV Viral Load

***TrialNet - TN10***  
***Analytic Datasets - ProventionBio***  
***Data Dictionary***  
***Data Through November 30, 2018***  
***Current as of January 31, 2019***

***Form: Cytomegalovirus & Epstein-Barr Virus Viral Load***

***File Name: CMVEBV***

***Number of Observations: 91***

***Number of Variables: 7***

Variable Name	Variable Type	Variable Length	Variable Label
MaskID	Num	8	Participant Mask ID#
DateOfDraw	Num	8	Date of Draw
cmviggg	Char	5	CMV IgG Result
cmvigmm	Char	5	CMV IgM Result
ebna	Char	5	EBNA Result
ebvvcaigm	Char	5	EBV IgM Result
ebvvcaigg	Char	5	EBV IgG Result

***TrialNet - TN10***  
***Analytic Datasets - ProventionBio***  
***Data Dictionary***  
***Data Through November 30, 2018***  
***Current as of January 31, 2019***

***Form: Epstein-Barr Virus Viral Load***

***File Name: EBV***

***Number of Observations: 455***

***Number of Variables: 3***

Variable Name	Variable Type	Variable Length	Variable Label
MaskID	Num	8	Participant Mask ID#
DateOfDraw	Num	8	Date of Draw
ebvvl	Char	10	EBV Viral Load



***TrialNet - TN10***  
***Analytic Datasets - ProventionBio***  
***Data Dictionary***  
***Data Through November 30, 2018***  
***Current as of January 31, 2019***

***Form: HbA1c***

***File Name: HBA1C***

***Number of Observations: 76***

***Number of Variables: 3***

Variable Name	Variable Type	Variable Length	Variable Label
MaskID	Num	8	Participant Mask ID#
DateOfDraw	Num	8	Date of Draw
HbA1c	Num	8	HbA1c Result

***TrialNet - TN10***  
***Analytic Datasets - ProventionBio***  
***Data Dictionary***  
***Data Through November 30, 2018***  
***Current as of January 31, 2019***

***Form: Human Leukocyte Antigen***

***File Name: HLA***

***Number of Observations: 75***

***Number of Variables: 7***

Variable Name	Variable Type	Variable Length	Variable Label
MaskID	Num	8	Participant Mask ID#
DateOfDraw	Num	8	Date of Draw
DR3	Char	9	DR3 Result
DR4	Char	9	DR4 Result
HLA	Char	8	HLA Result
HLAA	Char	16	HLA Alpha Result
HLAB	Char	16	HLA Beta Result

***TrialNet - TN10***  
***Analytic Datasets - ProventionBio***  
***Data Dictionary***  
***Data Through November 30, 2018***  
***Current as of January 31, 2019***

***Form: Mastable***

***File Name: MASTABLE***

***Number of Observations: 76***

***Number of Variables: 20***

Variable Name	Variable Type	Variable Length	Variable Label
MaskID	Num	8	Participant Mask ID#
TreatmentDate	Num	8	Date of Treatment
RxDesc	Char	9	Treatment Description
Sex	Char	8	Sex
dtbirth	Num	8	Date of Birth
race	Char	7	Race
ethnic	Char	10	Ethnicity
dtfollowup	Num	8	Date of Follow-up (maximum of last OGTT and last PE)
dtexam	Num	8	Date of Most Recent Physical Exam
dtiddm	Num	8	Date of First Diabetic OGTT
dtiddm2	Num	8	Date of Confirmatory Diabetic OGTT
dtlast	Num	8	Date of Last Treatment
T1D	Num	8	T1D Diagnosis (1=yes 0=no)
timT1D	Num	8	Time between Treatment Date to Diagnosis Date (days)
age	Num	8	Age at Treatment Start
day_start	Num	8	Number of days therapy started after randomization
degree	Num	8	Relationship Degree
no_first	Num	8	Number of first degree relatives
which_first	Char	37	Relationship to case of all first degree relatives with T1D
strata	Char	14	Eligibility categories (< 18 confirmed abnormal OGTT, < 18 not confirmed, 18+ confirmed)

***TrialNet - TN10***  
***Analytic Datasets - ProventionBio***  
***Data Dictionary***  
***Data Through November 30, 2018***  
***Current as of January 31, 2019***

***Form: OGTT C-Peptide***

***File Name: OGTT\_CPEP***

***Number of Observations: 664***

***Number of Variables: 9***

Variable Name	Variable Type	Variable Length	Variable Label
MaskID	Num	8	Participant Mask ID#
DateOfDraw	Num	8	Date of Draw
mu_cpep	Num	8	C-peptide 2-hour AUC mean = AUC/120 minutes
PEP0	Num	8	0 Minute C-Peptide
PEP30	Num	8	30 Minute C-Peptide
PEP60	Num	8	60 Minute C-Peptide
PEP90	Num	8	90 Minute C-Peptide
PEP120	Num	8	120 Minute C-Peptide
MAXPEP	Num	8	Maximum C-Peptide

***TrialNet - TN10***  
***Analytic Datasets - ProventionBio***  
***Data Dictionary***  
***Data Through November 30, 2018***  
***Current as of January 31, 2019***

***Form: OGTT Glucose***

***File Name: OGTT\_GLU***

***Number of Observations: 664***

***Number of Variables: 11***

Variable Name	Variable Type	Variable Length	Variable Label
MaskID	Num	8	Participant Mask ID#
DateOfDraw	Num	8	Date of Draw
gluI	Num	8	Abnormal OGTT (1=yes 0=no)
gluT1	Num	8	Diabetic Levels OGTT (1=yes 0=no)
mu_glucose	Num	8	Glucose 2-hour AUC mean = AUC/120 minutes
GLUM10	Num	8	-10 minute Glucose
GLU0	Num	8	0 minute Glucose
GLU30	Num	8	30 minute Glucose
GLU60	Num	8	60 minute Glucose
GLU90	Num	8	90 minute Glucose
GLU120	Num	8	120 minute Glucose

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***Analytic Datasets - ProventionBio***  
***Data Dictionary***  
***Data Through November 30, 2018***  
***Current as of January 31, 2019***

***Form: Relationship***

***File Name: RELATION***

***Number of Observations: 96***

***Number of Variables: 3***

Variable Name	Variable Type	Variable Length	Variable Label
MaskID	Num	8	Participant Mask ID#
relation	Char	23	Relationship
degree	Num	8	Relationship Degree

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***Analytic Datasets - ProventionBio***  
***Data Dictionary***  
***Data Through November 30, 2018***  
***Current as of January 31, 2019***

***Form: Status***

***File Name: STATUS***

***Number of Observations: 40***

***Number of Variables: 9***

Variable Name	Variable Type	Variable Length	Variable Label
MaskID	Num	8	Participant Mask ID#
dtevent	Num	8	Date of Event
dtstatuschange	Num	8	Date of Status Change
dtwithdrawal	Num	8	Date of Withdrawal
dtreactivate	Char	1	Date of Reactivation
ReasonForWithdrawal	Char	19	Reason for Withdrawal
ReasonForWithdrawalOTHER	Char	20	Reason for Withdrawal Other
ReasonWithdrewConsentSpecify	Char	62	Reason Withdrew Consent Specify
changestatus	Char	12	Status Change Reason

***TrialNet - TN10***  
***Analytic Datasets - ProventionBio***  
***Data Dictionary***  
***Data Through November 30, 2018***  
***Current as of January 31, 2019***

***Form: Treatment***

***File Name: TREATMENT***

***Number of Observations: 1050***

***Number of Variables: 5***

Variable Name	Variable Type	Variable Length	Variable Label
MaskID	Num	8	Participant Mask ID#
dtadministered	Num	8	Date of Drug Administration
WasIVInfusionOfStudyDrugGiven	Char	5	Was IV Infusion of Study Drug Given?
ReasonNoInfusionOfStudyDrugOth	Char	1	Reason No Infusion of Study Drug Given
TotalDoseOfStudyDrugInfused	Num	8	Total Dose of Study Drug Infused