

TN-01 Natural History Subject Consort Diagram

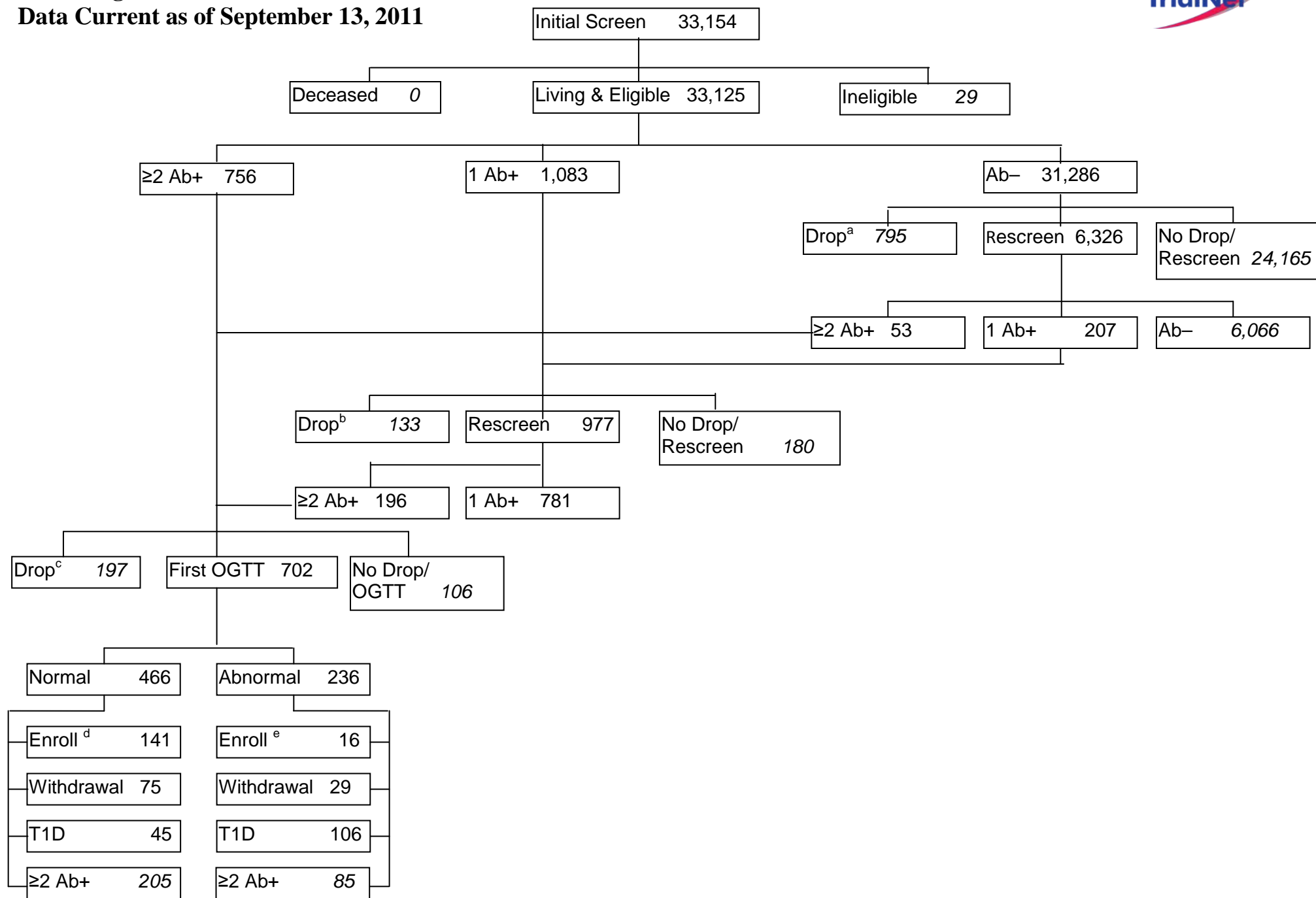
Description:

The current disposition (as of 9-13-2011) of all participants in the TrialNet Natural History study is described in the consort diagram provided here. Of note, the flow of the diagram follows all subjects monitored at North American Clinical Centers through all possible pre-diabetic states, towards the endpoint of Type 1 Diabetes diagnosis. This includes metabolic (glucose tolerance) and immunological (biochemical autoantibodies) changes.

Subject states included in the consort:

1. Eligible/Ineligible for Phase 2/3 monitoring in the TN Natural History study.
2. Number of T1D autoantibodies present.
3. Re-screen status for autoantibody negative and single autoantibody positive subjects.
4. Oral Glucose Tolerance Test (OGTT) presence and results for multiple autoantibody positive subjects.
5. Number of subjects with a given OGTT result as compared to specific autoantibody positivity combinations.

TrialNet — Natural History Study
Flow Diagram for North American Clinical Centers
Data Current as of September 13, 2011



Autoantibody Combinations (POS=1, NEG=0)				First OGTT Result	
mIAA	Gad65/Gad65H ^f	ICA512/IA-2H ^f	ICA	Normal	Abnormal
1	1	1	1	12	7
1	1	1	0	8	5
1	1	1	.	0	0
1	1	0	1	6	3
1	1	0	0	24	13
1	1	0	.	1	0
1	1	.	1	0	0
1	1	.	0	0	0
1	1	.	.	0	0
1	0	1	1	0	2
1	0	1	0	3	1
1	0	1	.	0	1
1	0	0	1	6	2
1	0	.	1	0	0
1	.	1	1	0	2
1	.	1	0	0	0
1	.	1	.	0	0
1	.	0	1	1	0
1	.	.	1	0	0
0	1	1	1	31	18
0	1	1	0	26	11
0	1	1	.	1	0
0	1	0	1	73	18
0	1	.	1	0	0
0	0	1	1	13	2
0	.	1	1	0	0
.	1	1	1	0	0
.	1	1	0	0	0
.	1	1	.	0	0
.	1	0	1	0	0
.	1	.	1	0	0
.	0	1	1	0	0
.	.	1	1	0	0
<i>Total</i>				205	85

Data Current as of September 13, 2011

TN:	TrialNet.
NH:	Natural History.
T1D:	Type 1 Diabetes.
Deceased:	When TNCC is notified of a participant's death, the participant is listed directly under Initial Screen, regardless of NH progress.
Enroll:	Participant enters either a new TN protocol or a non-TN study.
Withdrawal:	Participant leaves NH. Reasons for withdrawal include, but are not limited to: lost to follow-up; maximum follow-up reached; pregnancy; withdrawn consent; adverse event; other.
Drop:	Participant withdraws from NH, enrolls in either a new TN protocol or a non-TN study, or develops T1D.
No Rescreen:	Participant completes the initial screen, but has neither dropped out nor been rescreened for NH.
Normal OGTT:	Fasting plasma glucose <110 mg/dL <i>and</i> 2 hour plasma glucose <140 mg/dL <i>and</i> 30, 60, and 90 minute plasma glucose <200 mg/dL.
Abnormal OGTT:	Fasting plasma glucose \geq 110 mg/dL <i>and</i> 2 hour plasma glucose \geq 140 mg/dL <i>and</i> 30, 60, and 90 minute plasma glucose \geq 200 mg/dL.

^aOf the 795 participants who dropped out after an Ab–: 15 enrolled in either a new TN protocol or a non-TN study; 763 withdrew; and 17 developed T1D.

^bOf the 133 participants who dropped out after 1 Ab+: 1 enrolled in either a new TN protocol or a non-TN study; 124 withdrew; and 8 developed T1D.

^cOf the 197 participants who dropped out after 2 or more Ab+: 6 enrolled in either a new TN protocol or a non-TN study; 128 withdrew; and 65 developed T1D.

^dApproximately 141 participants who had \geq 2 Ab+ and an initial Normal OGTT result subsequently enrolled in a TN protocol or a non-TN study: 2 in TN10; and 139 in TN07.

^eApproximately 16 participants who had \geq 2 Ab+ and an initial Abnormal OGTT result subsequently enrolled in a TN protocol or a non-TN study: 1 in TN10; 4 in TN14; and 11 in TN07.

^fFor participants who are tested using both the standard and harmonized methods, a positive result on *either* the standard *or* the harmonized method is counted as a single positive.