

ITN Clinical Team Teleconference Report



Date: May 6, 2026

Invitees:

ITN Seattle Aaron Gannon, Jared Hennessy, Jesse Forrest, Mary Roy, Michael Konieczny, Nabil Morad, Philip Bernstein

ITN CTG Allison Dias, Audrey Plough, Carolyn Bromstead, Dawn Smilek, Geo Gaile, Karen Chia, Kristin Ryker, Laurie Kost, Lijo Neelankavil, Lynn Serizawa, MacKenzie Cox, Michele DesMarais, Michelle Huffaker, Pardeep Singh, Patti Tosta, Sadeed Rashid, Sharon Chung, Sindhu Chandran

ITN BDR Carolyn Baloh (BWH), Cindy Breeden (Emory), Juliete Francisco da Silva (Emory), Laura Cooney (U Michigan), Lauren Higdon (UCSF), Ryan Doan

NIAID Adora Lin, Afrah Zia, Angela Kibiy, Ashlyn Nam, Brittney Penn, Bruce Burnett, Caeden Dempsey, Ellen Goldmuntz, Jaclyn Evans, James McNamara, Julia Goldstein, Kathy Zephir, Leighton Thomas, Linda Griffith, Ling Li, Lyudmila Lyakh, Maggie Hafer, Maria Veri, Mark Robien, Martin MacPhee, Matthew Sherman, Megan Morsheimer, Melissa Greenleaf, Nancy Bridges, Padmaja Juvvadi, Patrice Becker, Patricia Fulkerson, Patricia Rohan, Paul Price, Rija John, Stuart Sweet, Tatyana Vaysman, Taylor Poor, Tina Sledge, Tomeka Granderson, Tyhis Coates, Wendy Gao, Yvonne Morrison

DAIT Pharmacy Charlene Kaplowitz, Kinara Yang, Ousmane Toure, Sanaz Hamrah, Shivali Singh

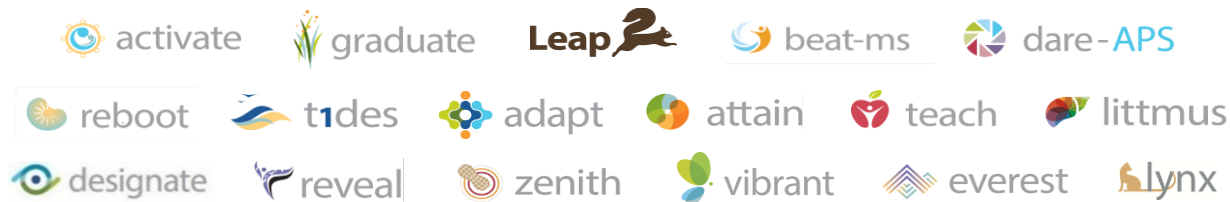
NIDDK Beena Akolkar

Rho Bill Barry, Julie Vick, Karen Boyle, Kelly Penke, Lars Dunaway, Lasonia Morgan, Nicole Rogers

PPD Bettina Junghahn, Cheryl Wilmoth, Darrel Westbrook, Katie Spencer, Jamie Reese, Michelle Sever

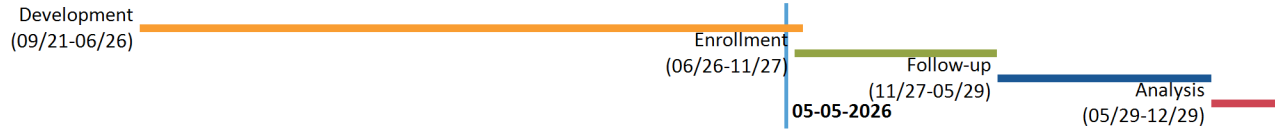
Agenda: Announcements, trial review, and discussion

Next Call: Wednesday, June 3, 2026



ITN Study Management Report May 2026										
Therapeutic Area	Phase	Trial Number	Brand Name	Project Manager	Regulatory Officer	Medical Monitor	Pharmaceutical Specialist	Clinical Operations Manager	Biomarker Discovery Research Scientist	Clinical Trial Physician
Allergy	D	ITN097AD	Zenith	C Dempsey	P Price	A Lin	S Hamrah	M Cox, A Dias	C Baloh	M Huffaker
	E	ITN102AD	Lynx	T Vaysman	P Price	T Poor		C Bromstead	C Baloh	M Huffaker
	F	ITN079AD	Activate	C Dempsey	L Li	A Lin		C Bromstead	C Baloh	S Chung
	A	ITN070AD	Leap Trio		L Lyakh			A Plough	C Baloh	M Huffaker
	A	ITN084AD	Graduate	C Dempsey	L Li	A Toggias	S Hamrah	K Chia	C Baloh	M Huffaker
Autoimmune	E	ITN077AI	BEAT-MS	W Gao	J Goldstein	L Griffith		A Dias, M Cox	L Cooney	D Smilek
	E	ITN080AI	REBOOT Part B	W Gao	P Price	M Sherman	O Toure	C Bromstead, L Kost	L Cooney	S Chung
	E	ITN091AI	Vibrant	W Gao	L Li	M Sherman	O Toure	K Ryker, K Chia	L Cooney	D Smilek
	E	ITN093AI	DARE-APS	M Greenleaf	L Li	P Rohan	S Hamrah	K Chia	L Cooney	S Chung
	A	ITN086AI	REVEAL	W Gao	L Li	M Sherman	O Toure	C Bromstead	L Cooney	D Smilek
Transplan-tation	E	ITN101ST	Everest	J Evans	P Price	N Bridges	K Yang	G Gaile	J Silva	S Chandran
	F	ITN089ST	ADAPT	T Sledge	P Price	N Bridges	O Toure	M DesMarais	C Breeden	S Chandran
	F	ITN090ST	ATTAIN	T Sledge	P Price	M Morsheimer	O Toure	G Gaile	C Breeden	S Chandran
	A	ITN062ST	TEACH	J Evans	L Lyakh	N Bridges	O Toure	A Dias	C Breeden	S Chandran
	A	ITN073ST	LITTMUS MGH	Y Morrison	J Goldstein	M Robien		M DesMarais	C Breeden	S Chandran
Type 1 Diabetes	D	ITN104AI	INTENT	R John	L Lyakh	J McNamara	K Yang	L Kost	L Higdon	D Smilek
	F	ITN066AI	TIDES	R John	L Lyakh	M Sherman		A Dias	L Higdon	D Smilek
	A	ITN095AI	DESIGNATE	R John	L Lyakh	M Sherman	K Yang	G Gaile	L Higdon	D Smilek
Mechanistic	F	ITN832AI	UST1D2					L Higdon	L Higdon	D Smilek
	F	ITN833AD	SUNBEAM	S Perry	M Veri	P Fulkerson		R Doan	C Baloh	M Huffaker
Phase Key:		D	Development	E	Enrollment	F	Follow-up	A	Analysis	

Efficacy of Tezepelumab in Peanut Allergy



Study Design Summary	This is a proof-of-concept Phase 2, double-blind, randomized placebo-controlled clinical trial using tezepelumab and peanut OIT for the treatment of peanut allergy. The trial design is an 8-week monotherapy period, followed by a 56-week combination therapy period, and a 12-week tezepelumab and OIT treatment withdrawal period.
Primary Endpoint Summary	The primary endpoint is persistent desensitization to peanut at week 76, following the tezepelumab/OIT withdrawal period. The PE is assessed by an OFC to 4000 mg of peanut protein without dose-limiting symptoms.

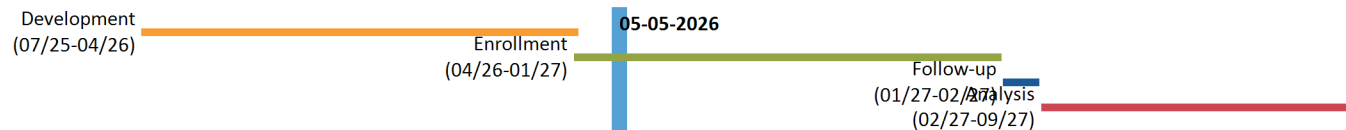
Key Indicators	
Target Screened	124
Target Enrollment	62
Target Enrollment Duration (mo)	16
Target Number of Sites	10
Target Participants/Site/Month	1.00
Money Spent-Lifetime (UM1) (in 000s)	\$1,045

Task	Target Finish	Finish
Conduct Kick-off Meeting	10/11/21	10/11/21
Conduct SMT Review 1	01/07/22	01/07/22
Conduct SMT Review 2	02/01/22	02/01/22
Conduct SMT Review 3	06/03/22	06/03/22
Conduct Pre-IND	07/15/22	07/15/22
Obtain NEC Approval	06/28/24	09/26/24
Distribute Protocol V1.0	12/09/24	08/06/25
Submit IND to FDA	12/09/24	08/06/25
Complete EDC	02/17/25	06/01/26
Distribute Materials and Conduct Training	03/21/25	03/17/26
Activate Site	04/04/25	05/11/26
FPFV (First Patient First Visit)	05/22/25	06/15/26

Development Progress Comments
Project Update: 9 of the 10 selected ZENITH sites have completed DRMC site registration and fulfilled their training requirements for site activation. 4 of 10 sites are expected to activate within the month.
Protocol Update: Protocol V3.0 was submitted to the sIRB on 16Apr26 and is under review. Once approved it will be distributed to sites.
Regulatory Update: Clinical hold response submitted 1/16/26. FDA granted Okay to Proceed on 2/18/26.

Lymph Node examination in cat allergen immunotherapy

Protocol Version 1.0



No trial performance or site activation data are available for this study. No key visit achievement data are available for this study.

Mechanistic Specimens: % Collected

Screened-Enrolled by Site (mos. open)

No Data Available

No Data Available

[Performance Report - Clinical](#)

[Performance Report - Mechanistic](#)

[Study Level Specimen Inventory Report \(click here\)](#)

Task	Target	Finish	Finish
Conduct Kick-off Meeting	07/21/25	07/21/25	
FPFV (First Patient First Visit)	02/09/26	04/10/26	
LPFV (Last Patient First Visit)	12/28/26	01/14/27	
LP PE (Last Patient Primary Endpoint)	01/19/27	02/05/27	
LPLV (Last Patient Last Visit)	01/19/27	02/05/27	

No Experimental Plans are being reported for this study.

Enrollment Progress Comments
Site registration was completed 3/31 and the site was activated 4/8. The first Screening Visit occurred on 4/10; the participant has now completed Visits 0 and Visit 1.
The SMT kick-off occurred 7/21/25. Protocol v1.0 finalized 1/20/26. IRB approval received 3/17.

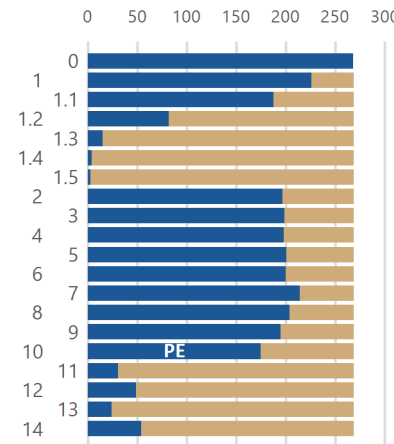
Key Indicators	
Target Screened	32
Total Screened	
Target Enrollment	16
Current Enrollment	-
Screen Failure Percent	100.0%
Target Enrollment Duration (mo)	10
Target Participants/Site/Month	1.45
Actual Participants/Site/Month	-
Percent Discontinued or Early Term	-
Expected Specimens	-
Collected Specimens	-
Percent Collected Specimens	0.0%
Money Spent-Lifetime (UM1) (in 000s)	\$103

Report run on:
5/5/2026

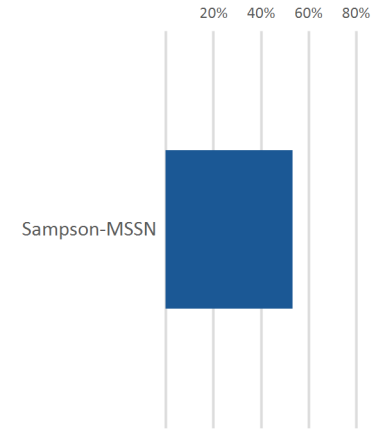


Count of Participants by Specimen Type by Visit									
Visit Num	PIDs / Visit	Breast Milk	PBMC- Na Hep	Placenta Biopsy	Plasma- CD	Plasma- Na Hep	Seeding Gauze	Stool	Vag Fluid Gauze
0	132		57	96	14	58	88	132	92
1	67							67	
2	95	72						95	
3	93							93	
4	86							86	
5	97	77						97	
6	92	71						92	
7	178	73	56		7	64		178	
8	157	57						157	
9	158							158	
10	138		69		5	85		138	
11	34							34	
12	36		27					36	
13	27							27	
14	32		31				32	24	

Key Visit Completion / Expected Visits



Mechanistic Specimens: % Collected



Performance Report - Clinical

Task	Target	Finish	Finish
Conduct Kick-off Meeting	11/29/16	11/29/16	11/29/16
LP PE (Last Patient Primary Endpoint)	03/04/22	01/30/25	01/30/25
LPLV (Last Patient Last Visit)	03/11/22	01/22/27	01/22/27

Performance Report - Mechanistic

Follow-up Progress Comments
LPPE occurred 30Jan2025. A total of 114 pairs (mother + infant) were accrued; 69 infants consented to continue in the extended follow-up, with 5 active participants remaining. LPLV expected January 2027.
Database for primary endpoint locked 4/16/25. 4 abstracts presented at 2026 AAAAI: the clinical results as a featured poster, Electrical Impedance Spectroscopy, CyTOF, and Microbiome assessments abstracts as oral presentations. Manuscript planning meeting held at AAAAI on 3/1/26. Clinical and mechanistic analyses and manuscripts in process.
Planned publications and presentations:

Study Level Specimen Inventory Report (click here)

Key Indicators	
Target Screened	171
Total Screened	289
Target Enrollment	120
Current Enrollment	155
Screen Failure Percent	46.4%
Enrollment Duration (mo)	57
Target Participants/Site/Month	1.50
Actual Participants/Site/Month	1.78
Percent Discontinued or Early Term	45.81%
Expected Specimens	10,131
Collected Specimens	5,469
Percent Collected Specimens	54.0%
Money Spent-Lifetime (UM1) (in 000s)	\$13,262

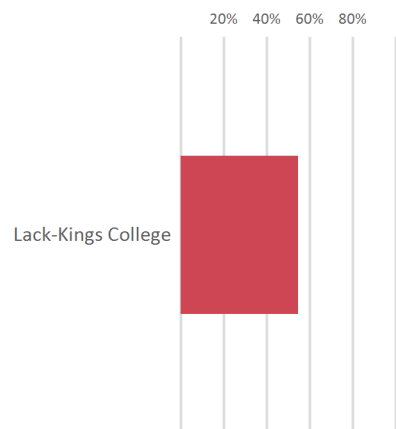
Experimental Plan Status (ST) Key: DV = In Development / DA = Data Analysis / SA = Sample Analysis / DP = Results Data Processing / RT = Real Time

Experimental Plans (Click link to EP page)	EP#	Lab	ST	Comments
Microbiome viability assessment	262	Clemente Lab	RT	RT microbiome viability assay.
Sample processing for ACTIVATE	261	Northwestern - Berin L	RT	RT blood processing



Visit Num	Count of Participants by Specimen Type by Visit			
	PIDs / Visit	PBMC-Li Hep	PBMC-Na Hep	Plasma-CD
144	1486	99	1	1486

Mechanistic Specimens: % Collected



Publications and Presentations
Working Title/Target Journal:
Comment:
Working Title/Target Journal:
Comment:

SharePoint SMT Site: [SharePoint SMT Site \(click here\)](#)

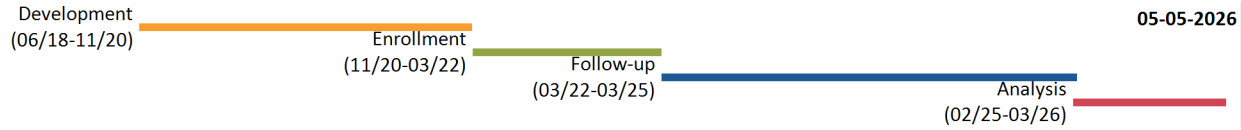
Task	Target	Finish	Finish	Analysis Progress Comments
Conduct Kick-off Meeting	02/03/16	02/03/16		Finalizing LEAP TRIO Siblings manuscript revisions for submission to the Lancet. Multivariate analysis on sibling data was a featured abstract at the AAAAI. LEAP TRIO genetic analyses are underway. CSR pending per completion of manuscripts.
LPLV (Last Patient Last Visit)	06/26/19	08/30/22		
Submit for Publication	12/25/19	07/10/23		
Create Clinical Study Report	03/18/20	03/31/26		

[Study Level Specimen Inventory Report \(click here\)](#)

Key Indicators	
Target Screened	2321
Total Screened	1869
Target Enrollment	1973
Current Enrollment	1869
Screen Failure Percent	0.0%
Enrollment Duration (mo)	49
Actual Participants/Site/Month	32.79
Percent Discontinued or Early Term	-
Collected Specimens	815
Percent Collected Specimens	54.7%
Trial Duration	49
Money Spent-Lifetime (UM1) (in 000s)	\$6,832

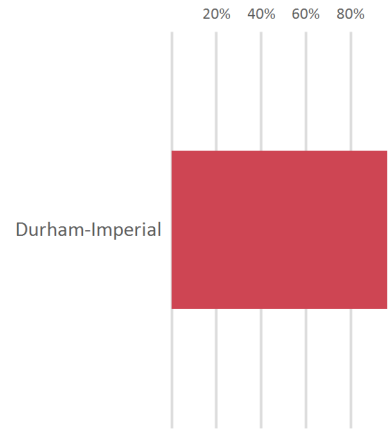
Experimental Plan Status (ST) Key: DV = In Development / DA = Data Analysis / SA = Sample Analysis / DP = Results Data Processing / RT = Real Time

Experimental Plans (Click link to EP page)	EP#	Lab	ST	Comments
LEAP Trio Genetics	563	Johns Hopkins CIDR	DA	



Count of Participants by Specimen Type by Visit						
Visit Num	PIDs / Visit	Nasal Brushing	Nasal Fluid	PBMC-Li Hep	Plasma-Li Hep	Serum-Clot
-2	107	107	106	106	106	106
-1	114	113	114			114
0	107	106	107	106	105	106
S1	105		105			105
S3	101	100	101	101	101	101
S4	100	98	100			100
S5	95	94	94	95	95	95
S6	94		94			93
S8	93	92	93	93	93	93
S9	95	92	95			95
S10	92	91	91	92	92	92
S11	91		91			91
S13	92	91	92	92	92	92
S14	97	93	97			96
S15	90	90	89	90	90	90

Mechanistic Specimens: % Collected



Publications and Presentations
Working Title/Target Journal: Novel Weekly Combined Symptom Medication Score to Assess Seasonal Allergic Rhinitis
Comment: To be submitted to JACI in May 2025
Working Title/Target Journal:
Comment:

SharePoint SMT Site: [SharePoint SMT Site \(click here\)](#)

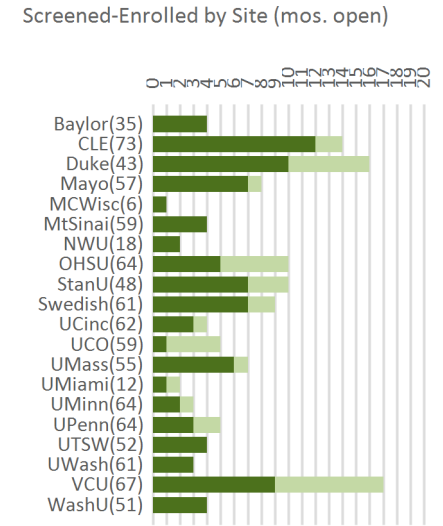
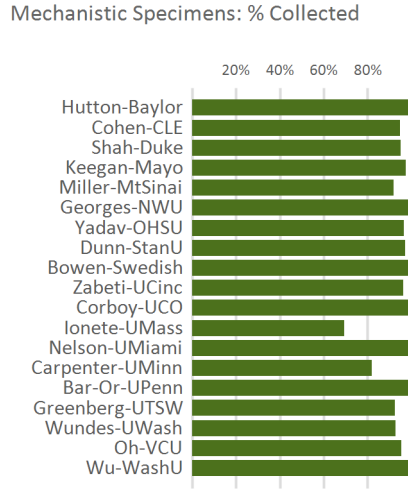
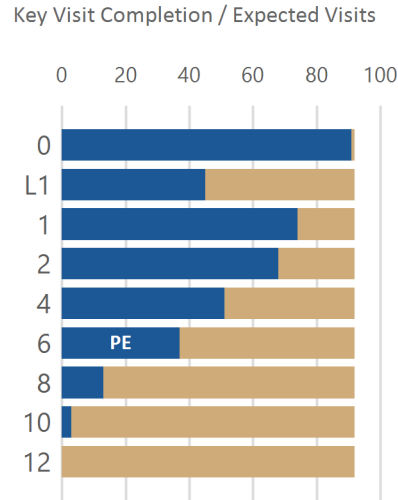
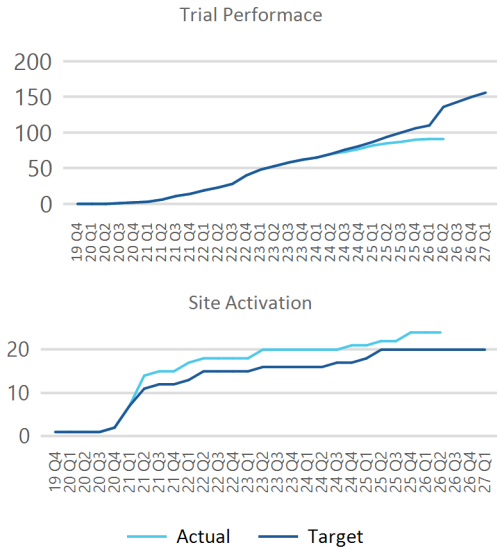
Task	Target Finish	Finish	Analysis Progress Comments
Conduct Kick-off Meeting	07/02/18	08/13/18	Manuscript rejected from JAMA. Team plans to submit to JACI.
LPLV (Last Patient Last Visit)	05/31/23	02/20/25	3 abstracts (oral) accepted at EAACI. One late breaking abstract accepted as a poster.
Submit for Publication	12/08/23	02/16/26	
Create Clinical Study Report	03/06/24	03/27/26	Mech projects and secondary clinical manuscripts underway

[Study Level Specimen Inventory Report \(click here\)](#)

Key Indicators	
Target Screened	240
Total Screened	198
Target Enrollment	108
Current Enrollment	112
Screen Failure Percent	43.4%
Enrollment Duration (mo)	14
Actual Participants/Site/Month	1.62
Percent Discontinued or Early Term	17.86%
Collected Specimens	3,924
Percent Collected Specimens	96.3%
Trial Duration	14
Money Spent-Lifetime (UM1) (in 000s)	\$8,297

Experimental Plan Status (ST) Key: DV = In Development / DA = Data Analysis / SA = Sample Analysis / DP = Results Data Processing / RT = Real Time

Experimental Plans (Click link to EP page)	EP#	Lab	ST	Comments
GRADUATE T cell studies	636	MSSM - Wambre Lab	DV	
	624	BRI - Altman Lab	DV	
Nasal transcriptomics in GRADUATE study	594	BRI - Altman Lab	DV	
GRADUATE Real-time Assays	349	Imperial - Shamji Lab	RT	RT blood processing and BAT.



[Performance Report - Clinical](#)

Task	Target	Finish
Conduct Kick-off Meeting	01/20/17	01/20/17
FPFV (First Patient First Visit)	09/02/20	09/02/20
LPFV (Last Patient First Visit)	04/24/24	08/09/27
LP PE (Last Patient Primary Endpoint)	04/21/27	08/06/30
LPLV (Last Patient Last Visit)	04/24/30	08/09/33

[Performance Report - Mechanistic](#)

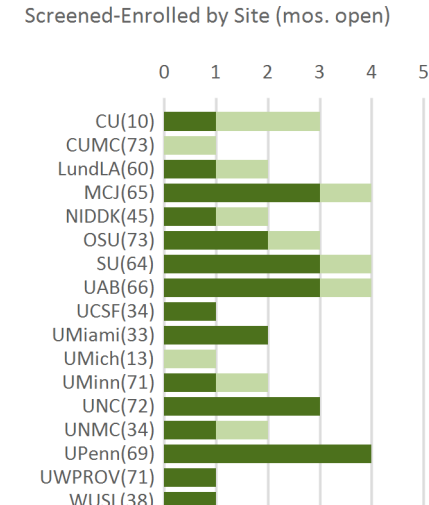
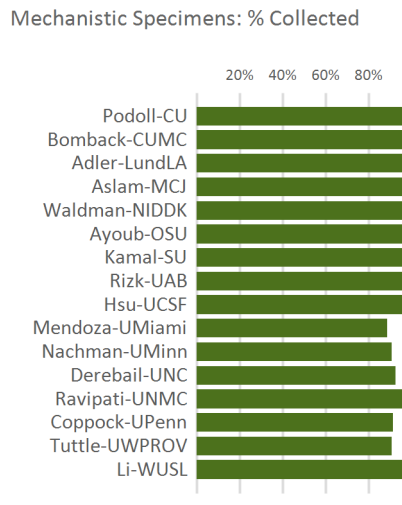
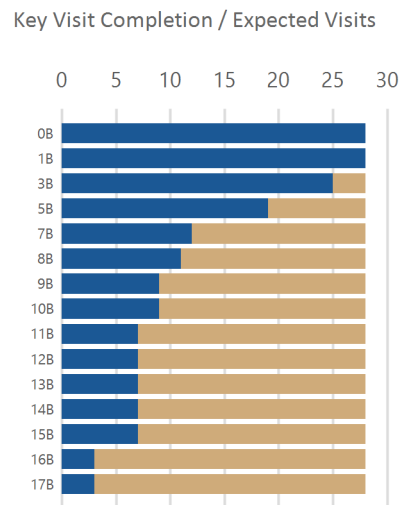
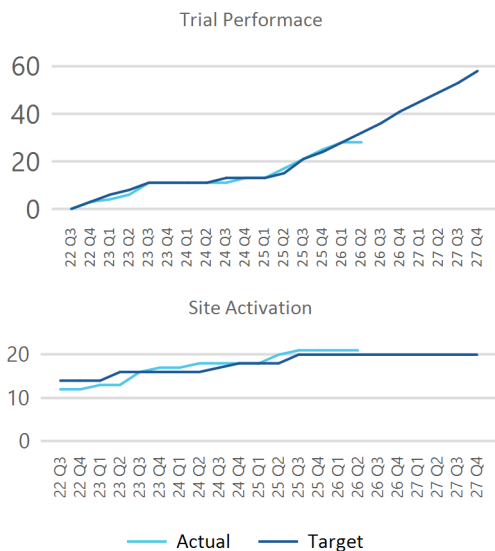
Enrollment Progress Comments
 137 participants have been screened and 92 have been randomized. One participant is in screening at OHSU. Henry Ford/Wayne State site activation is pending site registration.
 Protocol V6.0 distributed to sites on 1/29/2026. BEAT-MS reviewed at the April DSMB meeting.

[Study Level Specimen Inventory Report \(click here\)](#)

Key Indicators	
Target Screened	155
Total Screened	129
Target Enrollment	121
Current Enrollment	92
Screen Failure Percent	28.7%
Target Enrollment Duration (mo)	43
Target Participants/Site/Month	0.15
Actual Participants/Site/Month	0.09
Percent Discontinued or Early Term	23.91%
Expected Specimens	4,538
Collected Specimens	4,275
Percent Collected Specimens	94.2%
Money Spent-Lifetime (UM1) (in 000s)	\$17,570

Experimental Plan Status (ST) Key: DV = In Development / DA = Data Analysis / SA = Sample Analysis / DP = Results Data Processing / RT = Real Time

Experimental Plans (Click link to EP page)	EP#	Lab	ST	Comments
Real-time flow cytometry analysis of CSF cells sta	338	UPenn TCL - Bar-Or Lab	RT	Composition of major leukocyte populations in CSF samples stabilized using TransFix tubes is being acquired in real-time



[Performance Report - Clinical](#)

Task	Target	Finish
Conduct Kick-off Meeting	04/25/17	04/25/17
FPFV (First Patient First Visit)	02/03/20	03/06/20
LPFV (Last Patient First Visit)	04/03/23	12/31/27
LP PE (Last Patient Primary Endpoint)	03/31/25	12/28/29
LPLV (Last Patient Last Visit)	03/30/26	12/27/30

[Performance Report - Mechanistic](#)

Enrollment Progress Comments

Part B: 28 of 58 participants randomized and one participant is in screening. Multiple recruitment initiatives remain ongoing. An Investigator Call is scheduled for 5/20. The 4/13 DSMB memo recommended proceeding as planned.

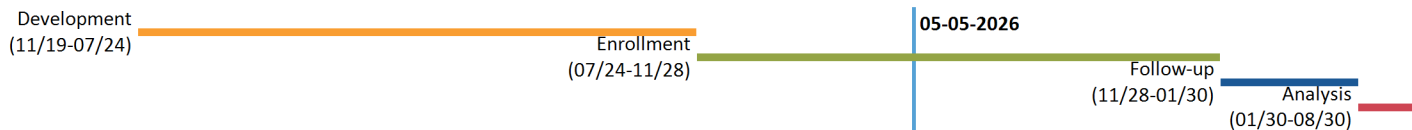
The revised Part A Manuscript is currently under team review prior to submission to Kidney International Reports. Part A data cleaning (through week 156) in final stages.

[Study Level Specimen Inventory Report \(click here\)](#)

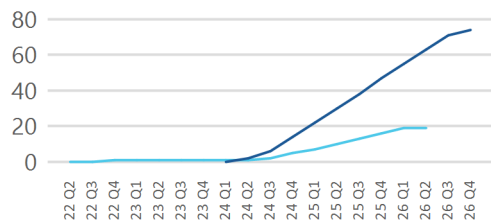
Key Indicators	
Target Screened	90
Total Screened	40
Target Enrollment	58
Current Enrollment	28
Screen Failure Percent	30.0%
Target Enrollment Duration (mo)	38
Target Participants/Site/Month	0.07
Actual Participants/Site/Month	0.03
Percent Discontinued or Early Term	7.14%
Expected Specimens	3,971
Collected Specimens	3,853
Percent Collected Specimens	97.0%
Money Spent-Lifetime (UM1) (in 000s)	\$3,949

Experimental Plan Status (ST) Key: DV = In Development / DA = Data Analysis / SA = Sample Analysis / DP = Results Data Processing / RT = Real Time

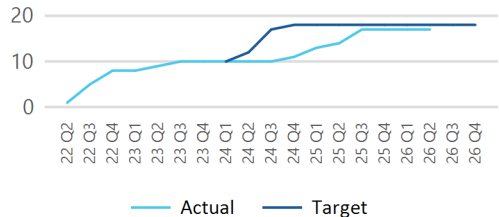
Experimental Plans (Click link to EP page)	EP#	Lab	ST	Comments
REBOOT Part A PBMC flow cytometry	559	BRI - Wiedeman Lab	DA	Flow analysis completed successfully, publication in progress.



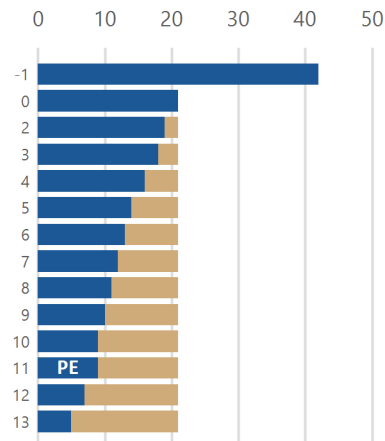
Trial Performance



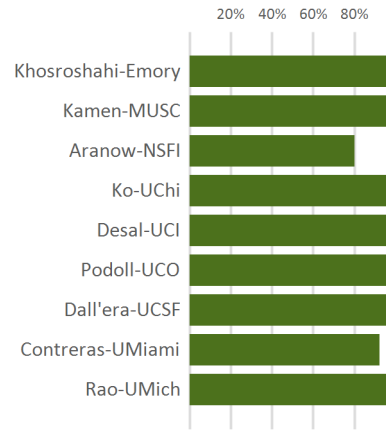
Site Activation



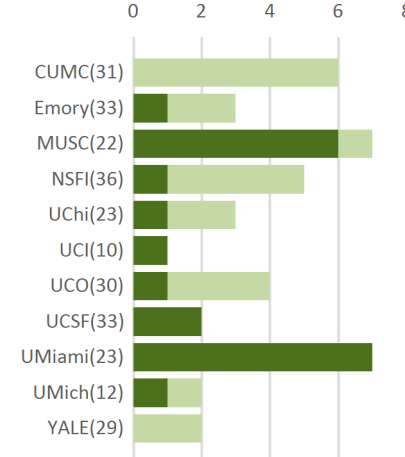
Key Visit Completion / Expected Visits



Mechanistic Specimens: % Collected



Screened-Enrolled by Site (mos. open)



[Performance Report - Clinical](#)

Task	Target	Finish	Finish
Conduct Kick-off Meeting	12/16/19	12/16/19	
FPFV (First Patient First Visit)	02/04/21	08/13/24	
LPFV (Last Patient First Visit)	11/23/23	11/28/28	
LP PE (Last Patient Primary Endpoint)	08/01/24	08/07/29	
LPLV (Last Patient Last Visit)	10/31/24	01/22/30	

[Performance Report - Mechanistic](#)

Enrollment Progress Comments
UAB site start-up activities initiated. Site intro call occurred on 4/20. Colorado close-out activities in process.
31 participants screened; 20 randomized; 1 in screening (Michigan), 10 screen failures.

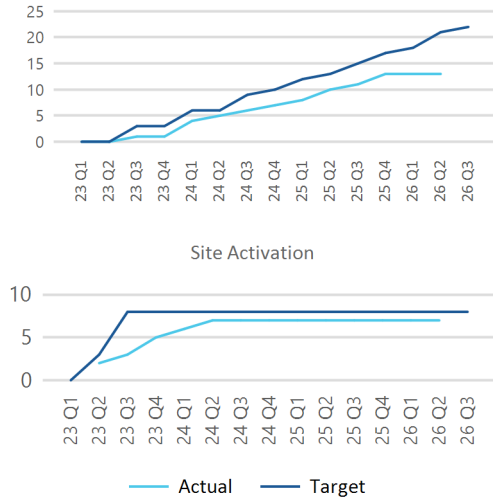
[Study Level Specimen Inventory Report \(click here\)](#)

Key Indicators	
Target Screened	96
Total Screened	42
Target Enrollment	74
Current Enrollment	21
Screen Failure Percent	50.0%
Target Enrollment Duration (mo)	33
Target Participants/Site/Month	0.10
Actual Participants/Site/Month	0.05
Percent Discontinued or Early Term	38.10%
Expected Specimens	308
Collected Specimens	301
Percent Collected Specimens	97.7%
Money Spent-Lifetime (UM1) (in 000s)	\$3,582

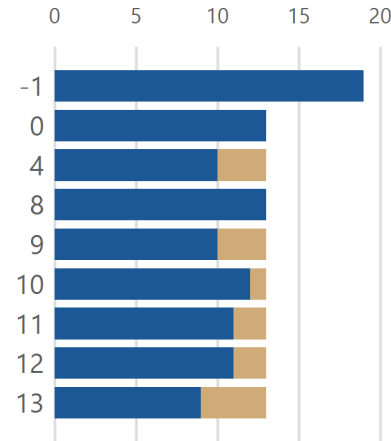
No Experimental Plans are being reported for this study.



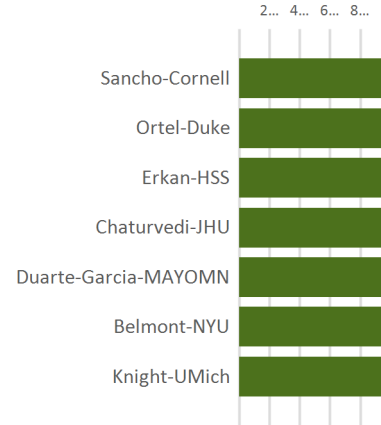
Trial Performance



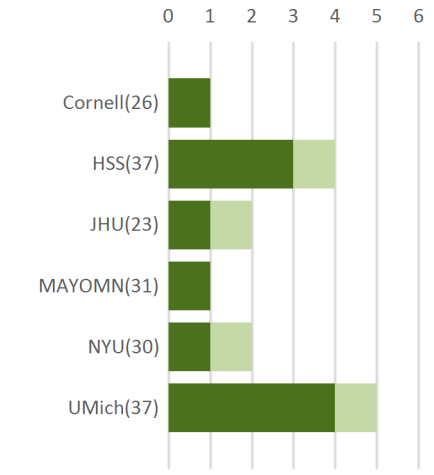
Key Visit Completion / Expected Visits



Mechanistic Specimens: % Collected



Screened-Enrolled by Site (mos. open)



[Performance Report - Clinical](#)

Task	Target Finish	Finish
Conduct Kick-off Meeting	08/31/20	08/31/20
FPFV (First Patient First Visit)	07/06/23	07/06/23
LPFV (Last Patient First Visit)	02/12/26	12/11/26
LP PE (Last Patient Primary Endpoint)	05/07/26	03/05/27
LPLV (Last Patient Last Visit)	01/14/27	11/15/27

[Performance Report - Mechanistic](#)

Enrollment Progress Comments
4mg/kg dosing cohort: Enrollment completed Feb 2024. 8mg/kg dosing cohort: Enrollment completed in Oct 2024.
16mg/kg dosing cohort: Enrollment of first 3 subjects completed in May. Screening/enrollment resumed in August (6 required for Highest Safe Dose); 2 enrolled out of 3. 1 recent screen failure (JHU) and 1 screening visit scheduled on 5/19 (NYU).

[Study Level Specimen Inventory Report \(click here\)](#)

Key Indicators	
Target Screened	36
Total Screened	19
Target Enrollment	22
Current Enrollment	13
Screen Failure Percent	31.6%
Target Enrollment Duration (mo)	31
Target Participants/Site/Month	0.13
Actual Participants/Site/Month	0.06
Percent Discontinued or Early Term	76.92%
Expected Specimens	816
Collected Specimens	813
Percent Collected Specimens	99.6%
Money Spent-Lifetime (UM1) (in 000s)	\$1,815

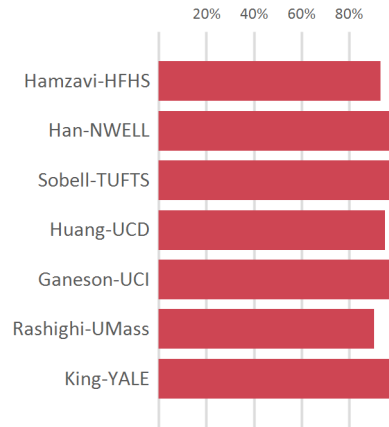
Experimental Plan Status (ST) Key: DV = In Development / DA = Data Analysis / SA = Sample Analysis / DP = Results Data Processing / RT = Real Time

Experimental Plans (Click link to EP page)	EP#	Lab	ST	Comments
APS disease-specific assessments at APS Core Lab f	469	APS CORE UTMB	RT	Assays for anti-CL antibody, anti-B2GPI antibody, and lupus anticoagulant. Results of these assays are critical to the c



Visit Num	Count of Participants by Specimen Type by Visit				
	PIDs / Visit	PBMC- EDTA	PBMC- Na Hep	Serum- Clot	Skin Biopsy
0	59		57	59	59
3	55		53	55	1
6	56		56	55	56
8	54		53	54	53
9	52	1	51	52	
10	50	1	45	50	49

Mechanistic Specimens: % Collected



Publications and Presentations
Working Title/Target Journal:
Comment:
Working Title/Target Journal:
Comment:

SharePoint SMT Site: [SharePoint SMT Site \(click here\)](#)

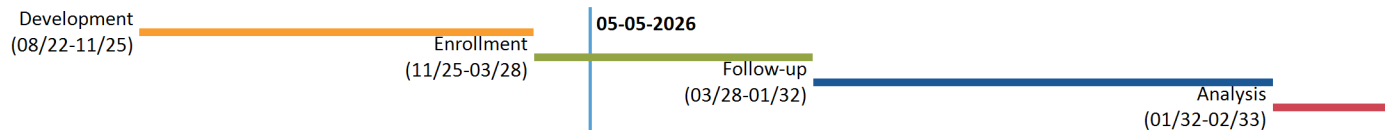
[Study Level Specimen Inventory Report \(click here\)](#)

Task	Target	Finish	Finish	Analysis Progress Comments
Conduct Kick-off Meeting	07/04/18		07/26/18	Enrollment N= 59 completed April 2024. LPLV occurred 4/2/25 and all COVs completed. Database hard lock occurred 4/24/25.
Submit for Publication	02/21/22		08/29/25	
LPLV (Last Patient Last Visit)	09/22/22		04/02/25	A abstract has been selected for a plenary talk and for the Society for Investigative Dermatology (SID) meeting in May. Additional mechanistic analyses are underway and the primary manuscript is in development.
Create Clinical Study Report	06/29/23		01/29/26	

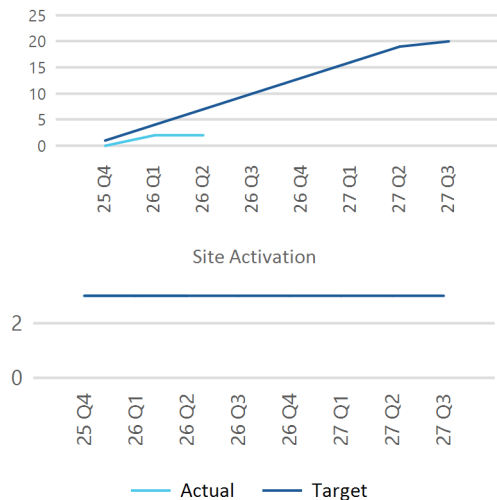
Key Indicators	
Target Screened	74
Total Screened	89
Target Enrollment	57
Current Enrollment	60
Screen Failure Percent	32.6%
Enrollment Duration (mo)	39
Actual Participants/Site/Month	0.15
Percent Discontinued or Early Term	16.67%
Collected Specimens	2,888
Percent Collected Specimens	96.7%
Trial Duration	39
Money Spent-Lifetime (UM1) (in 000s)	\$3,746

Experimental Plan Status (ST) Key: DV = In Development / DA = Data Analysis / SA = Sample Analysis / DP = Results Data Processing / RT = Real Time

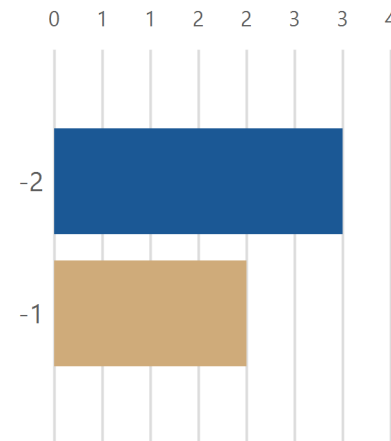
Experimental Plans (Click link to EP page)	EP#	Lab	ST	Comments
Spatial transcriptomics of REVEAL skin biopsies	622	Gudjonsson - Universit	DA	A combination of single cell and spatial transcriptomics analysis of skin biopsies to determine effects of treatment.
REVEAL: effects of treatment on serum cytokines	612	UCSF - Core Immunology	DA	High quality data received. Results show persistent depletion of serum IL-15 in both responders and nonresponders.
Skin spatial transcriptomics pilot	560	Gudjonsson - Universit	DA	Pilot study completed successfully, high quality single cell and spatial transcriptomics data was generated. Plans for expansion are under development.
REVEAL PBMC flow	558	BRI - Wiedeman Lab	DA	Flow cytometry analysis successfully demonstrated effects of IL-15 blockade on CD8 memory T cell subsets.



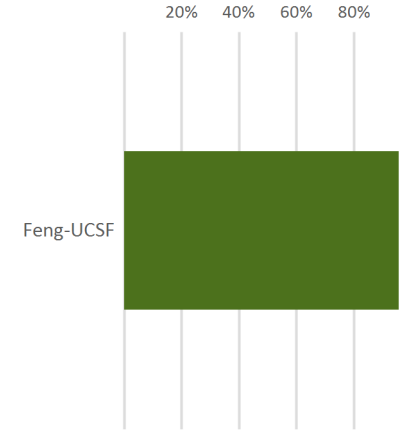
Trial Performance



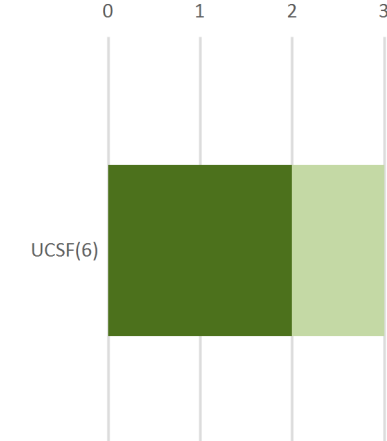
Key Visit Completion / Expected Visits



Mechanistic Specimens: % Collected



Screened-Enrolled by Site (mos. open)



[Performance Report - Clinical](#)

Task	Target	Finish	Finish
Conduct Kick-off Meeting	09/12/22	09/12/22	
FPFV (First Patient First Visit)	11/21/23	01/21/26	
LPFV (Last Patient First Visit)	06/22/27	03/17/28	
LP PE (Last Patient Primary Endpoint)	04/24/29	01/04/30	
LPLV (Last Patient Last Visit)	04/22/31	01/16/32	

[Performance Report - Mechanistic](#)

Enrollment Progress Comments
UCSF enrolled the study's first 3 participants; Penn and Northwestern are pre-screening candidates. Refresher trainings for Northwestern and Penn will occur before consent of their first participants. Last PI/SC call occurred on 4/16/26; next one will be 5/12/26.
Protocol v 2.0 received sIRB approval on 8/5/25.

[Study Level Specimen Inventory Report \(click here\)](#)

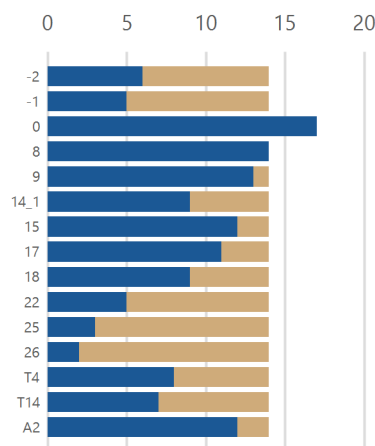
Key Indicators	Value
Target Screened	40
Total Screened	3
Target Enrollment	20
Current Enrollment	2
Screen Failure Percent	33.3%
Target Enrollment Duration (mo)	43
Target Participants/Site/Month	0.28
Actual Participants/Site/Month	0.13
Percent Discontinued or Early Term	-
Expected Specimens	24
Collected Specimens	22
Percent Collected Specimens	91.7%
Money Spent-Lifetime (UM1) (in 000s)	\$575

No Experimental Plans are being reported for this study.

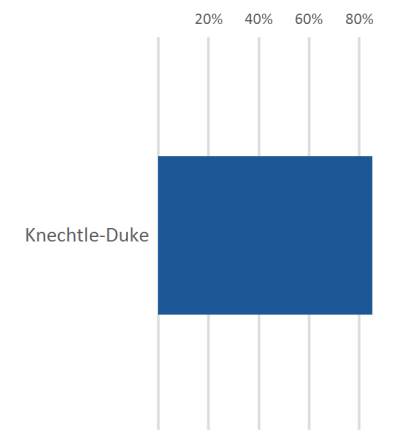


Visit Num	Count of Participants by Specimen Type by Visit				
	PIDs / Visit	Bone Marrow	PBMC- EDTA	PBMC- Na Hep	Serum- None
-2	6			5	6
-1	5			5	5
0	17	15		17	17
8	14			13	14
9	12				12
14_1	8		1	8	8
15	10	7		8	10
17	11			11	10
18	6		1	6	5
22	4				4
25	3			3	3
26	2			2	1
T0	8	7		6	8
T4	8		1	7	8
T14	7				7

Key Visit Completion / Expected Visits



Mechanistic Specimens: % Collected



[Performance Report - Clinical](#)

Task	Target	Finish	Finish
Conduct Kick-off Meeting	09/27/19		09/27/19
LP PE (Last Patient Primary Endpoint)	09/05/25		08/05/26
LPLV (Last Patient Last Visit)	05/15/26		04/14/27

[Performance Report - Mechanistic](#)

Follow-up Progress Comments
Cohort 2 – of 10 accrued participants, 5 have been transplanted (2/29/24, 7/26/24, 1/20/25, 9/5/25, 5/4/26) from previously incompatible donors & 3 of 5 have completed study; 1 lost to f/u; 1 completed study; 3 who completed carfilzomib treatment are in follow-up & awaiting transplant offers.
Cohort 1 – of 5 accrued participants, 4 were transplanted (1 with previously incompatible donor)
Planned publications and presentations: Manuscript development underway

[Study Level Specimen Inventory Report \(click here\)](#)

Key Indicators	
Target Screened	25
Total Screened	22
Target Enrollment	15
Current Enrollment	14
Screen Failure Percent	36.4%
Enrollment Duration (mo)	48
Target Participants/Site/Month	1.00
Actual Participants/Site/Month	0.33
Percent Discontinued or Early Term	7.14%
Expected Specimens	1,432
Collected Specimens	1,219
Percent Collected Specimens	85.1%
Money Spent-Lifetime (UM1) (in 000s)	\$4,680

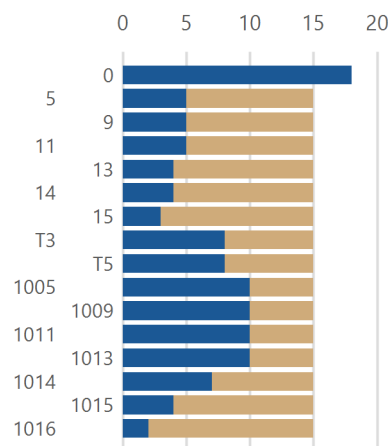
Experimental Plan Status (ST) Key: DV = In Development / DA = Data Analysis / SA = Sample Analysis / DP = Results Data Processing / RT = Real Time

Experimental Plans (Click link to EP page)	EP#	Lab	ST	Comments
ITN089ST/ITN090ST Lymph node handling	508	UPMC - Liver Lab	RT	
memory B cell pilot assays for ADAPT	397	Duke - Song Lab	RT	in data analysis
real-time flow cytometry for ADAPT	394	Duke - Jackson Lab	RT	
plasma cell assays for desensitization protocols	393	Emory - Lee Lab	RT	

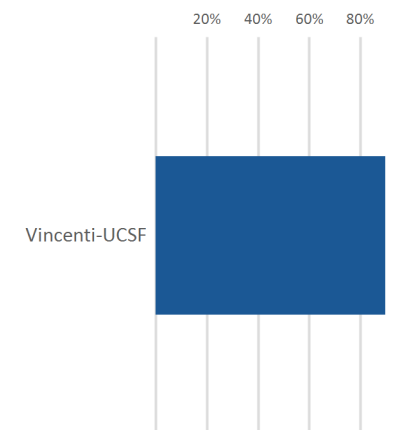


Visit Num	Count of Participants by Specimen Type by Visit				
	PIDs / Visit	Bone Marrow	PBMC- EDTA	PBMC- Na Hep	Serum- None
0	17	16	1	16	17
5	14		2	14	12
9	15			15	12
11	15	11		15	12
13	11			4	11
14	8			6	8
15	4				4
T0	10	1	1	8	10
T3	7		2	7	7
T5	8				8
DT0	4		1	4	
1005	3				3
1009	3				3
1011	3	3			3
1013	2				2
1014	3			1	3
1015	2				2
1016	2				2

Key Visit Completion / Expected Visits



Mechanistic Specimens: % Collected



[Performance Report - Clinical](#)

Task	Target	Finish	Finish
Conduct Kick-off Meeting	10/10/19	10/10/19	
LP PE (Last Patient Primary Endpoint)	06/25/25	04/02/26	
LPLV (Last Patient Last Visit)	12/24/25	04/05/27	

[Performance Report - Mechanistic](#)

Follow-up Progress Comments
Accrual completed. Cohort 2 (n=10): 10 accrued (6 transplanted, 2 completed study, 1 in follow-up, 1 withdrew from study). Last subject completed PE visit and is in follow-up. Protocol v5.0 distributed on 3/3/26.
Cohort 1 (n=5): All subjects completed study participation. 5 accrued completed treatment. 3 met primary endpoint. 2 transplanted.
Planned publications and presentations:

[Study Level Specimen Inventory Report \(click here\)](#)

Key Indicators	
Target Screened	25
Total Screened	19
Target Enrollment	15
Current Enrollment	15
Screen Failure Percent	21.1%
Enrollment Duration (mo)	45
Target Participants/Site/Month	1.00
Actual Participants/Site/Month	0.34
Percent Discontinued or Early Term	6.67%
Expected Specimens	1,432
Collected Specimens	1,285
Percent Collected Specimens	89.7%
Money Spent-Lifetime (UM1) (in 000s)	\$4,065

Experimental Plan Status (ST) Key: DV = In Development / DA = Data Analysis / SA = Sample Analysis / DP = Results Data Processing / RT = Real Time

Experimental Plans (Click link to EP page)	EP#	Lab	ST	Comments
Pathogen-specific beads development	661	Emory - Lee Lab	DV	
ITN089ST/ITN090ST Lymph node handling	508	UPMC - Liver Lab	RT	
real-time flow cytometry for ATTAIN	395	UCSF ITL	RT	
plasma cell assays for desensitization protocols	393	Emory - Lee Lab	RT	

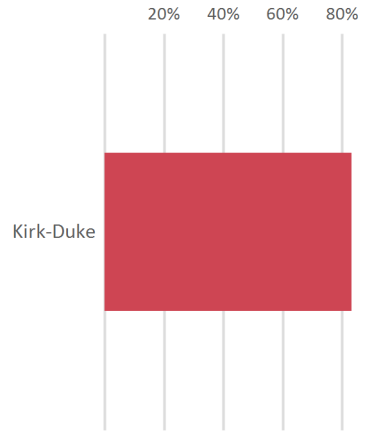
Tolerance by engaging antigen during cellular homeostasis

Protocol Version 5.0



Count of Participants by Specimen Type by Visit								
Visit Num	PIDs / Visit	Kidney Biopsy	PBMC- Na Hep	Plasma	Plasma- Na Hep	Serum- None	Stool	Urine pellet
101	8		8	1		8		
102	6	4				6	5	5
106	3		3	3				
107	3		3	2	1			
109	3		3	2				
110	3		3	3				
111	4		4	4				
112	3		3	3				
113	3		3	2	1			
114	4		4	3	1			
115	3		3	3				
116	4		4	3	1			
117	3		3	3				
118	2		2	2				
119	3		3	3		2	1	3
199A	2	2	2	1	1	2		2
301	1					1		

Mechanistic Specimens: % Collected



Publications and Presentations
Working Title/Target Journal: Donor-specific Mesenchymal Stem Cell Infusion in Human and Non-human Primate Kidney Transplantation
Comment: AJT, October 2025
Working Title/Target Journal:
Comment:

SharePoint SMT Site: [SharePoint SMT Site \(click here\)](#)

Task	Target	Finish	Finish
Conduct Kick-off Meeting	10/06/14	10/06/14	
LPLV (Last Patient Last Visit)	10/28/25	09/16/25	
Create Clinical Study Report	02/03/26	06/23/26	
Submit for Publication	09/15/26	06/23/26	

Analysis Progress Comments

Database locked November 2025 and study close-out memo issued December 2025. CSR in progress.

[Study Level Specimen Inventory Report \(click here\)](#)

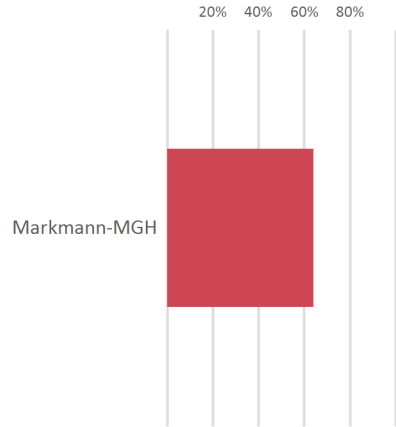
Key Indicators	
Target Screened	8
Total Screened	8
Target Enrollment	6
Current Enrollment	8
Screen Failure Percent	0.0%
Enrollment Duration (mo)	45
Actual Participants/Site/Month	0.09
Percent Discontinued or Early Term	62.50%
Collected Specimens	667
Percent Collected Specimens	83.2%
Trial Duration	45
Money Spent-Lifetime (UM1) (in 000s)	\$4,397

No Experimental Plans are being reported for this study.



Visit Num	Count of Participants by Specimen Type by Visit			
	PIDs / Visit	PBMC- Na Hep	Serum- None	WBC
-1	30	30	30	
101	5	5	5	
T-5	5		5	5
T0	5		5	
T1	4		4	

Mechanistic Specimens: % Collected



Publications and Presentations
Working Title/Target Journal:
Comment:
Working Title/Target Journal:
Comment:

SharePoint SMT Site: [SharePoint SMT Site \(click here\)](#)

Task	Target	Finish	Finish	Analysis Progress Comments
Create Clinical Study Report			10/06/26	5/36 enrolled were accrued (received Tregs). All experienced acute rejection and completed the study in safety follow-up.
Conduct Kick-off Meeting	07/06/16	07/06/16		
LPLV (Last Patient Last Visit)	01/11/28	02/06/26		DSMB review January 2026. CSR publication planned Q3 2026 Database lock April 2026.
Submit for Publication	01/11/28	07/09/26		

[Study Level Specimen Inventory Report \(click here\)](#)

Key Indicators	
Target Screened	34
Total Screened	36
Target Enrollment	9
Current Enrollment	5
Screen Failure Percent	86.1%
Enrollment Duration (mo)	53
Actual Participants/Site/Month	0.06
Percent Discontinued or Early Term	-
Collected Specimens	815
Percent Collected Specimens	65.7%
Trial Duration	53
Money Spent-Lifetime (UM1) (in 000s)	\$2,747

Experimental Plan Status (ST) Key: DV = In Development / DA = Data Analysis / SA = Sample Analysis / DP = Results Data Processing / RT = Real Time

Experimental Plans (Click link to EP page)	EP#	Lab	ST	Comments
DNA storage at UCLA	315	UIC	RT	

TYK2i in Type 1 Diabetes



Study Design Summary	A multi-center, phase 2a open-label clinical trial in adult participants aged 18-45 years diagnosed with stage 3 T1DM within 100 days of the baseline visit (V0). 39 adult participants will receive envudeucitinib PO 40 mg twice daily for 24 weeks followed by 28 weeks of follow-up.
Primary Endpoint Summary	The difference between the observed C-peptide response and the expected response at 24 weeks as defined by the Quantitative Response (QR).

Key Indicators	
Target Screened	51
Target Enrollment	39
Target Enrollment Duration (mo)	16
Target Number of Sites	15
Target Participants/Site/Month	0.20
Money Spent-Lifetime (UM1) (in 000s)	\$28

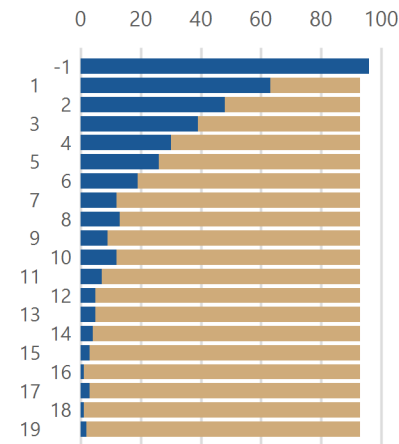
Task	Target Finish	Finish
Conduct Kick-off Meeting	09/19/25	09/19/25
Conduct SMT Review 1	11/14/25	12/19/25
Conduct SMT Review 2	01/23/26	03/05/26
Conduct Pre-IND	02/19/26	07/24/26
Conduct SMT Review 3	05/08/26	08/10/26
Obtain NEC Approval	06/19/26	08/31/26
Distribute Protocol V1.0	06/26/26	09/07/26
Submit IND to FDA	06/26/26	09/07/26
Complete EDC	09/18/26	11/16/26
Establish and setup cores	09/18/26	12/14/26
Distribute Materials and Conduct Training	10/02/26	11/23/26
Activate Site	10/16/26	12/07/26
FPFV (First Patient First Visit)	11/16/26	01/05/27

Development Progress Comments
Project Update: DSMB and DCRC reviews completed the week of March 23rd. Site selection in progress.
Protocol Update: V0.21 distributed on April 29.
Regulatory Update: Pre-IND package submission pending CTA finalization per company request. CTA negotiations underway.

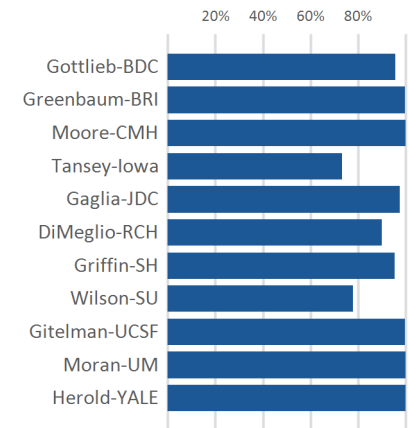


Visit Num	Count of Participants by Specimen Type by Visit				
	PIDs / Visit	PBMC- Na Hep	Plasma- K Oxalate	plasma- K2 EDTA	Serum- Clot
-1	91	90	90	91	91
1	64	61	62	64	64
2	49	48	49	49	48
3	39	39	38	38	38
4	30	27	30	30	30
5	27	27	27	27	27
6	19	19	19	19	19
7	13	13	13	13	13
8	13	12	13	13	13
9	10	10	10	10	10
10	12	12	12	12	12
11	6	6	5	6	6
19	2	2	2	2	2

Key Visit Completion / Expected Visits



Mechanistic Specimens: % Collected



Performance Report - Clinical

Task	Target	Finish
Conduct Kick-off Meeting	07/28/15	07/28/15
LP PE (Last Patient Primary Endpoint)	01/07/27	01/07/27
LPLV (Last Patient Last Visit)	01/07/27	01/07/27

Performance Report - Mechanistic

Follow-up Progress Comments

To date, there are 5 active AbATE (3) and T1DAL (2) participants across 3 sites. T1DES reviewed at the April DSMB meeting.

Analysis completed for the long-term follow up immunophenotyping after immunotherapy for T1D. Waiting for TN10 analysis to start manuscript.

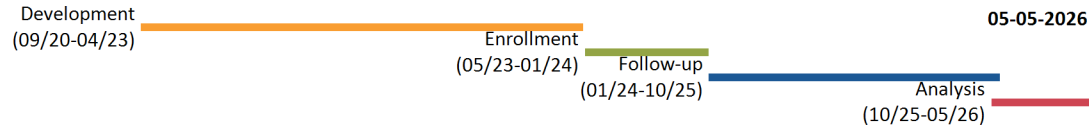
Planned publications and presentations: Manuscript submitted to Diabetes Care 3/24/2026: Extended Follow-Up of Type 1 Diabetes Immunotherapy Trial Participants Suggests Benign Side Effect Profile.

Study Level Specimen Inventory Report (click here)

Key Indicators	
Target Screened	111
Total Screened	96
Target Enrollment	111
Current Enrollment	93
Screen Failure Percent	3.1%
Enrollment Duration (mo)	90
Target Participants/Site/Month	0.08
Actual Participants/Site/Month	0.08
Percent Discontinued or Early Term	70.97%
Expected Specimens	7,640
Collected Specimens	7,273
Percent Collected Specimens	95.2%
Money Spent-Lifetime (UM1) (in 000s)	\$2,558

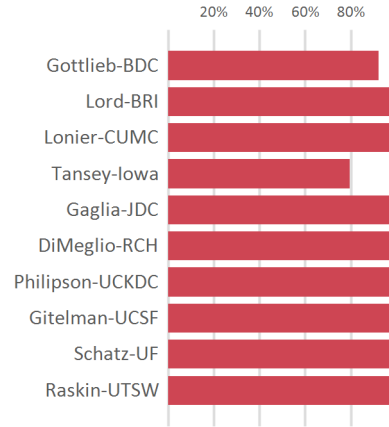
Experimental Plan Status (ST) Key: DV = In Development / DA = Data Analysis / SA = Sample Analysis / DP = Results Data Processing / RT = Real Time

Experimental Plans (Click link to EP page)	EP#	Lab	ST	Comments
T1D metabolomics collaboration - data analysis	601	UFL - Garrett Lab	DV	Follow-up analysis on EP536; analysis is ongoing.
Long term changes in immunophenotype after teplizu	546	BRI - Long Lab	DA	Analysis of data from AbATE and TN10 participants in progress.
Longitudinal c-peptide analysis after immunotherapy	517			TrialNet LIFT data request approved; in process of obtaining data.



Visit Num	Count of Participants by Specimen Type by Visit				
	PIDs / Visit	PBMC-Na Hep	Plasma-K Oxalate	plasma-K2 EDTA	Serum-Clot
-1	18	16	18	18	18
0	8	7	1	1	8
2	7	7			7
4	7	7			7
6	7				7
8	6	6			6
10	5				5
12	7	7	7	7	7
13	7	7	7	7	7
14	7	7	7	7	7
15	7	7	7	7	7

Mechanistic Specimens: % Collected



Publications and Presentations
Working Title/Target Journal: CD2 blockade in Type 1 diabetes mellitus: immunophenotyping and safety results from a randomized clinical trial with siplizumab/JCI Insight
Comment: Figures are being finalized now that database is locked.
Working Title/Target Journal:
Comment:

SharePoint SMT Site: [SharePoint SMT Site \(click here\)](#)

Task	Target Finish	Finish	Analysis Progress Comments
Conduct Kick-off Meeting	09/29/20	09/29/20	LPLV occurred 10/20/25. Database lock occurred 1/23/26. Close-out of all 20 sites completed 2/23/26. PI call held 3/20/26 to review study results. DSMB reviewed the study on 3/23/26.
LPLV (Last Patient Last Visit)	01/21/25	10/20/25	
Submit for Publication	10/23/25	05/29/26	SAP and manuscript (planned submission to JCI Insight) are currently being drafted.
Create Clinical Study Report	01/20/26	04/17/26	

Experimental Plan Status (ST) Key: DV = In Development / DA = Data Analysis / SA = Sample Analysis / DP = Results Data Processing / RT = Real Time

Experimental Plans (Click link to EP page)	EP#	Lab	ST	Comments
SNP genotyping - HALT-MS, DESIGNATE part A and oth	592	BRI - General	DA	Analysis is being finalized for the manuscript.
DESIGNATE week 52 CyTOF first seven subjects	583	BRI - Wiedeman Lab	DA	Analysis is being finalized for the manuscript.
Mechanism of lymphodepletion by anti-CD2	577	UMich - Fox Lab	DV	Experiments are in progress!

[Study Level Specimen Inventory Report \(click here\)](#)

Key Indicators	
Target Screened	240
Total Screened	18
Target Enrollment	120
Current Enrollment	8
Screen Failure Percent	55.6%
Enrollment Duration (mo)	5
Actual Participants/Site/Month	0.02
Percent Discontinued or Early Term	100.00%
Collected Specimens	734
Percent Collected Specimens	90.1%
Trial Duration	5
Money Spent-Lifetime (UM1) (in 000s)	\$3,549

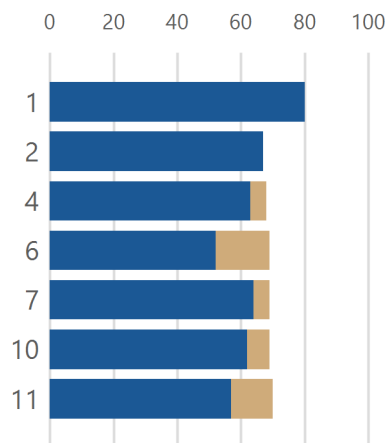
Clinical phase II/III trial of Ustekinumab to treat type 1 diabetes.

Protocol Version 6.0

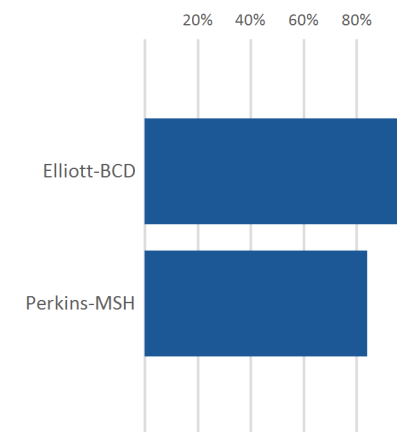


Visit Num	Count of Participants by Specimen Type by Visit			
	PIDs / Visit	PBMC- Na Hep	Plasma- Na Hep	Serum- Clot
1	81			81
2	65	62	65	
4	59	59	59	
6	65			65
7	64	64	63	53
10	62	59	58	62
11	57	45	1	57

Key Visit Completion / Expected Visits



Mechanistic Specimens: % Collected



[Performance Report - Clinical](#)

Task	Target	Finish	Finish
LP PE (Last Patient Primary Endpoint)	05/31/21	01/13/26	
LPLV (Last Patient Last Visit)	07/29/21	07/22/26	

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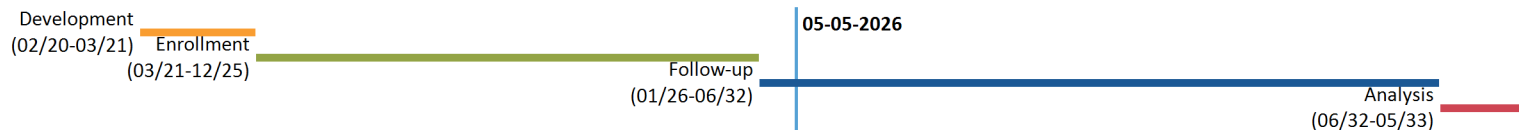
Follow-up Progress Comments
LPLV scheduled for 7/10/26. Final visit for primary outcome completed 1/13/26.
Sample storage at UBC is going as expected.
Planned publications and presentations: Study team is planning to present primary outcomes at the Immunology of Diabetes Society Congress in April.

[Study Level Specimen Inventory Report \(click here\)](#)

Key Indicators	
Target Screened	76
Total Screened	84
Target Enrollment	66
Current Enrollment	70
Screen Failure Percent	16.7%
Enrollment Duration (mo)	48
Target Participants/Site/Month	1.50
Actual Participants/Site/Month	0.58
Percent Discontinued or Early Term	-
Expected Specimens	2,402
Collected Specimens	2,272
Percent Collected Specimens	94.6%

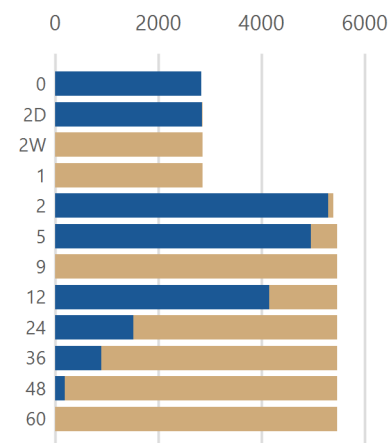
Experimental Plan Status (ST) Key: DV = In Development / DA = Data Analysis / SA = Sample Analysis / DP = Results Data Processing / RT = Real Time

Experimental Plans (Click link to EP page)	EP#	Lab	ST	Comments
C-peptide Testing for UST1D2	402	Mayo_CPep	RT	Week 78 samples are being run.

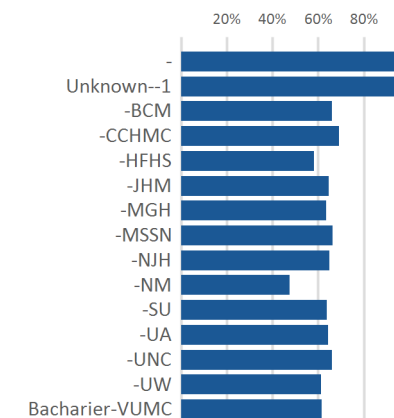


Count of Participants by Specimen Type by Visit											
Visit Num	PIDs / Visit	Breast Milk	CB-PROT1	Nasal Fluid	PBMC-EDTA	Plasma	Saliva	Skin Swab	Stool	urine	WB-PROT1
-1	4355	1			7	4191		4355	3402	2936	3886
0	1551		826		1226	1551		3	7		1
2d	2664				1	2		2664	2363		
2w	2073								2073		
1	2216				2	1			2216		
2	5052	1789		2510	3218	4432	2303	5052	4221	4573	3998
5	2392	1472		2380	1194	1838	2345	2392	1981	1878	1659
9	1462								1462		
12	2004	649		1954	1005	1606	1885	2004	1587	1337	1327
24	1408			1378	867	1211	1313	1408	1093	790	1083
36	814			813	521	696	768	814	560	614	645
48	178			176	128	157	174	178	106	164	154
60	2			1	2	2	1	1		1	2

Key Visit Completion / Expected Visits



Mechanistic Specimens: % Collected



[Performance Report - Clinical](#)

Task	Target Finish	Finish
LP PE (Last Patient Primary Endpoint)	04/06/23	06/28/29
LPLV (Last Patient Last Visit)	04/06/23	06/25/32

[Performance Report - Mechanistic](#)

Follow-up Progress Comments
2,195 kids who remained active through month 12. SUNBEAM II Continuation Rate: 70.5%
Sample collections continuing as expected.
Planned publications and presentations:

[Study Level Specimen Inventory Report \(click here\)](#)

Key Indicators	
Target Screened	8775
Total Screened	7262
Target Enrollment	6750
Current Enrollment	7262
Screen Failure Percent	0.0%
Enrollment Duration (mo)	55
Target Participants/Site/Month	8.00
Actual Participants/Site/Month	9.46
Percent Discontinued or Early Term	22.78%
Expected Specimens	396,091
Collected Specimens	256,355
Percent Collected Specimens	64.7%

Experimental Plan Status (ST) Key: DV = In Development / DA = Data Analysis / SA = Sample Analysis / DP = Results Data Processing / RT = Real Time

Experimental Plans (Click link to EP page)	EP#	Lab	ST	Comments
SUNBEAM PBMC pilot	505	Northwestern - Berin L	DA	