1. **Improving Outcomes Assessment in Chronic GVHD, Protocol 2192**
2. **2192 data capture guide for analysis**
3. **Chronic GVHD Response Measures Validation, Protocol 2710**
4. **2710 data capture guide for analysis**
5. **Longitudinal Study of Immune Mediated Disorders after Allogeneic HCT, Protocol 2342 RDCRN 6501**
6. **6501 data capture guide for analysis**
7. **A Randomized Phase II Study of Imatinib and Rituximab for Cutaneous Sclerosis after Allogeneic Hematopoietic Cell Transplantation, Protocol 2343 RDCRN 6502**
8. **6502 data capture guide for analysis**
9. **Targeted Therapy of Bronchiolitis Obliterans Syndrome, Protocol 2367, RDCRN 6503**
10. **6503 data capture guide for analysis**
11. **Repository Access & Publication Request v1.0**

Study Name/Hutch Protocol Number	**Improving Outcomes Assessment in Chronic GVHD, Protocol 2192, "old R01"**
Participating institutions	Fred Hutchinson Cancer Research Center University of Minnesota Stanford University Dana-Farber Cancer Institute Vanderbilt University Medical College of Wisconsin Washington University School of Medicine H. Lee Moffitt Cancer Center and Research Institute Memorial Sloan Kettering Cancer Center
Years of accrual	4.5, from 2007 to 2012
Number with chronic GVHD	601 (only FHCRC patients with samples: 261)
Are controls included?	Yes, 60 with samples
Duration of follow up	Active 2 years, continuing to collect long term data, most recently collected Jan 2019
Samples collected	EDTA plasma, PBMC, serum, DNA from EDTA and Grey Top tubes, trizol RNA from PBMC (will need to be extracted) Urine Leftover clinical biopsies
Timepoints for samples	Incident cases (within 3mo of diagnosis) • Enrollment • 3 months • Every 6 months up to 4.5 years Prevalent cases (within 3 years of SCT) • Enrollment • Every 6 months up to 4 years Controls (confirmed 6mo later) • Enrollment
Location of samples	FHCRC,
Patient reported outcomes	• NIH Patient Self Report (PSR) • Lee symptom scale (LSS) • Functional Assessment of Cancer Therapy – Bone Marrow Transplant (FACT-BMT) • Medical Outcomes Study Short-Form 36 (SF-36) • Human Activities Profile (HAP) or Activity Scale for Kids (ASK) All PROs given at all sample timepoints listed above
Functional assessment	Walk, schirmer's, grip strength tests, and pulmonary function tests or portable spirometers performed at every study visit.
Availability of medication data	Current medications with dose/frequency at each sample timepoint, includes some non-GVHD meds Systemic and topical medications and treatments for chronic GVHD taken during timepoint intervals from transplant to end of study (no doses or dates, do have max steroid dose)
Description of how the cohort was assembled	Cross sectional study of anyone with NIH defined chronic GVHD regardless of times since transplant

Primary objectives of the parent study	Testing of all the NIH-recommended tools to assess chronic GVHD
Does consent allow broad use of samples?	Yes
Clinicaltrials.gov number	NCT00637689
Grant funding	NIH/NCI R01 CA118953
Cost/procedure for retrieving samples	~$2-25 per sample depending on size of batch Contact Kate Chilson (kchilson@fredhutch.org) and she will coordinate shipment from FHCRC
Contact for more information	Dr. Stephanie Lee (sjlee@fredhutch.org)
Notes	

Table 1 Patient Characteristics

Variable	Category	N	Count (%)
Study site	Dana-Farber Cancer Institute	601	65 (11%)
	Fred Hutchinson Cancer Research Center	.	261 (43%)
	H. Lee Moffitt Cancer Center and Research Institute	.	39 (6%)
	Medical College of Wisconsin	.	23 (4%)
	NW Children's	.	13 (2%)
	Stanford University	.	74 (12%)
	University of Minnesota	.	66 (11%)
	Vanderbilt University Medical Center	.	48 (8%)
	Washington University	.	4 (1%)
	Memorial Sloan Kettering	.	8 (1%)
Case type	Incident	.	348 (58%)
	Prevalent	.	241 (40%)
	Late acute	.	9 (1%)
	Incident/late acute	.	3 (<1%)
Recipient age at HCT in years	Median: 50.6 Range: 1-78.9		
	<= 10	601	8 (1%)
	11-20	.	20 (3%)
	21-30	.	50 (8%)
	31-40	.	68 (11%)
	41-50	.	158 (26%)
	51-60	.	197 (33%)
	61-70	.	93 (15%)
	>=70	.	7 (1%)
Patient gender	Female	601	251 (42%)
	Male	.	350 (58%)
Diagnosis	Aplastic anemia	601	7 (1%)
	Acute lymphocytic leukemia	.	72 (12%)
	Acute myeloid leukemia	.	198 (33%)

	Chronic lymphocytic leukemia	.	48 (8%)
	Chronic myeloid leukemia	.	28 (5%)
	Hodgkins disease	.	17 (3%)
	Myelodysplastic syndrome	.	94 (16%)
	Multiple myeloma	.	31 (5%)
	Non Hodgkins Lymphoma	.	86 (14%)
	Other	.	20 (3%)
Disease stage at transplant	Early	601	199 (33%)
	Intermediate	.	255 (42%)
	Advanced	.	147 (24%)
Graft Type	Bone Marrow	601	40 (7%)
	Cord Blood	.	31 (5%)
	Peripheral Blood	.	530 (88%)
Donor type	HLA identical sibling	601	243 (40%)
	HLA-matched other relative	.	6 (1%)
	HLA-matched unrelated donor	.	251 (42%)
	HLA-mismatched relative (single antigen or allele mismatched)	.	13 (2%)
	HLA-mismatched unrelated donor	.	88 (15%)
Conditioning Intensity	Myeloablative	597	312 (52%)
	Not myeloablative	.	285 (48%)
Donor-recipient sex match	Female into male	595	172 (29%)
	Other	.	423 (71%)
Donor CMV status	Negative / Indeterminate	587	360 (61%)
	Positive	.	227 (39%)
Recipient CMV status	Negative / Indeterminate	594	265 (45%)
	Positive	.	329 (55%)
Prior grade II-IV acute GVHD	Yes	601	328 (55%)
	No	.	273 (45%)
Time from HCT to study consent (months)	Median: 12 Range: 3-295		

Improving Outcome Assessment in Chronic GVHD Biomarker Bibliography:
Updated 1/23/20

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4. Kitko CL, Levine JE, Storer BE, Chai X, Fox DA, Braun TM, Martin PJ, Flowers ME, Hansen JA, Chang L, Conlon M, Fiema BJ, Morgan R, Pongtornpipat P, Lamiman K, Ferrara JLM, Lee SJ, Paczesny S. Plasma CXCL9 elevations correlate with chronic GVHD diagnosis. Blood 2014 Jan 30; 123(5):786-793. PMID: 24363401, PMCID: PMC3966477

5. Pidala J, Sarwal M, Roedder S, Lee SJ. Biologic markers of chronic graft vs. host disease. Bone Marrow Transplant. 2014 Mar; 49(3): 324-331. PMID: 23872737, PMCID: PMC3976639

6. Kariminia A, Holtan SG, Ivison S, Rozmus J, Hebert MJ, Martin PJ, Lee SJ, Wolff D, Subrt P, Abdossamadi S, Sung S, Storek J, Levings M, Aljurf M, Arora M, Cutler C, Gallagher G, Kuruvilla J, Lipton J, Nevill TJ, Newell LF, Panzarella T, Pidala J, Popradi G, Szwajcer D, Tay J, Toze CL, Walker I, Couban S, Storer BE, Schultz KR. Heterogeneity of chronic graft vs. host disease biomarkers: association with CXCL10 and CXCR3+ NK cells. Blood 2016 Jun; 127(24): 3082-91. PMID: 27020088

7. Lui X, Yue Z, Daguindau E, Kushekhar K, Zhang Q, Ogata Y, Gafken PR, Inamoto Y, Gracon A, Wilkes DS, Hansen JA, Lee SJ, Chen JY, Paczesny S. Proteomic Characterization Reveals That MMP-3 Correlates With Bronchiolitis Obliterans Syndrome Following Allogeneic Hematopoietic Cell and Lung Transplantation. Am J Transplant. 2016 Aug; 16(8): 2342-51. PMID: 26887344

8. Yu J, Storer BE, Kushekhar K, Abu Zaid M, Zhang Q, Gafken PR, Ogata Y, Martin PJ, Flowers ME, Hansen JA, Arora M, Cutler C, Jagasia M, Pidala J, Hamilton BK, Chen GL, Pusic I, Lee SJ, Paczesny S. Biomarker Panel for Chronic Graft vs. Host Disease. J Clin Oncol. 2016 Aug; 34(22): 2583-90. PMID: 27217465

9. Pidala J Sigdel T Wang A Hsieh S Inamoto Y Martin PJ Flowers MED Hansen JA Lee SJ Sarwal M. A combined biomarker and clinical panel for chronic graft versus host disease diagnosis. J Path: Clin Res. 2016 Nov 29; 3(1):3-16. PMID: 28138397

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Data Collection for 2192:

Timepoints: Enrollment, 3mo (incident cases only), every 6mo for approx. 5 years

Baseline chart abstraction: transplant date, hypertension pre-tx y/n, PFT* pre-tx, height, weight pre-tx, age at tx, disease status, tx source, tx type, CMV, donor age/gender/match, conditioning, GVH prophy, acute GVH scores and rx,

cGVHD onset form: dx date, type of GVH, weight, dx PFT*, performance score, BSA, lichen planus, sclerotic, diarrhea, oral, bili, plt

Chart abstraction: ROM report, blood pressure, weight, PFT*, WBC, neu, eos, lym, plt, bili, ALT, alk phos, alb, cr, glu, chol, trig, HDL, LDL, urine creatinine/microalbumin, blood in urine, protein in urine, current medications (dose regimen included), DLI y/n, 2 min walk test, grip strength, schirmer's, portable spirometer FEV-1, Follow-up version: biopsies, hospitalizations, # of visits with providers during interval

*Pulmonary function testing: FVC, FEV1, FVC/FEV1, DLCO adj, preference given for post bronchodilation

cGVHD medications: chronic GVH meds given from diagnosis to end of study, no doses (do have max dose of steroids during study visit intervals), no dates (can approximate from study visit intervals)

Patient survey: NIH GVH patient self-report, Lee GVH sx scale, FACT-BMT QOL, KPS, Short Form 36, HAP, Enrollment version: employ, race, ethnicity, gender, age, marital, education, income pre-tx, Follow-up version: mouth, skin, eye, joint, overall change scores

Provider survey: NIH skin BSA scale, sclerotic score, skin score, fascia score, skin features, Vienna skin scale, ROM shoulder, elbow, wrist, ankle, mouth score, mouth eryth, lichenoid, ulcers, mucoceles, mouth pain, GI score, esophagus, upper GI, lower GI, eye score, joint score, genital score, lung score, mild/mod/sev, 1-10 scale, GVH type, infx, edema, other GVH manifestations (14), Enrollment version: rx change reason, sentinel organ, Follow-up version: mouth, skin, eye, joint, overall change scores

Comorbidities: cardiovascular, gastrointestinal, pulmonary, endocrine, neuropsychiatric, bone/joint, other (*completed at diagnosis, enrollment and death/relapse only*)

Patient status: date of last contact, death date/cause, relapse date

Specimen collection: EDTA plasma, PBMC, serum, urine

Study Name/Hutch Protocol Number	**Chronic GVHD Response Measures Validation** **Protocol 2710, "new R01"**
Participating institutions	Fred Hutchinson Cancer Research Center University of Minnesota Dana-Farber Cancer Institute Stanford University Vanderbilt University H. Lee Moffitt Cancer Center Roswell Park Cancer Institute Cleveland Clinic Foundation Ohio State University Vancouver General Hospital Duke University M.D. Anderson Cancer Center
Years of accrual	5.25, from 2013 to 2019
Number with chronic GVHD	383
Are controls included?	Yes, 62, under protocol 2732 at FHCRC only
Duration of follow up	Active 18 months, will continue to collect long term data, last collected Oct 2019
Samples collected	PBMC and heparin plasma
Timepoints for samples	Cases (chronic GVHD only) • Enrollment • 3 months • 6 months • 18 months • when first systemic treatment is added after enrollment Controls (confirmed 6mo later) • Enrollment
Location of samples	National Marrow Donor Program
Patient reported outcomes	• NIH Patient Self Report (PSR) • Lee symptom scale (LSS) • Functional Assessment of Cancer Therapy – Bone Marrow Transplant (FACT-BMT) • Medical Outcomes Study Short-Form 36 (SF-36) • Human Activities Profile (HAP) All PROS collected at each sample timepoint listed above, except the HAP is excluded at a treatment change visit.
Functional assessment	Two-minute walk test at enrollment and follow-up visits (not performed at treatment change visit)
Availability of medication data	Current medications dose/frequency collected at each sample timepoint Running log of systemic medications and treatments for chronic GVHD from diagnosis to end of study with start and stop dates for each med
Description of how the cohort was assembled	Enrolled patients who are starting new systemic treatment +/- 4 weeks.

Primary objectives of the parent study	Test the NIH response criteria
Does consent allow broad use of samples?	Yes
Clinicaltrials.gov number	NCT01902576
Grant funding	NIH CA118953
Cost/procedure for retrieving samples	~$2-25 per sample depending on size of batch Contact Kate Chilson (kchilson@fredhutch.org) and she will coordinate shipment from FHCRC
Contact for more information	Dr. Stephanie Lee (sjlee@fredhutch.org)
Notes	

Table 1 Patient Characteristics , n=383

Variable	Category	N	Count (%)
Male		383	240 (63%)
Adult		383	381 (99%)
White		383	342 (89%)
Study Site	Fred Hutchinson Cancer Research Center	383	166 (43%)
	Vanderbilt University Medical Center	.	42 (11%)
	Cleveland Clinic Foundation	.	30 (8%)
	Roswell Park Cancer Institute	.	27 (7%)
	Dana-Farber Cancer Institute	.	25 (7%)
	Vancouver General Hospital	.	23 (6%)
	University of Minnesota	.	21 (5%)
	H. Lee Moffitt Cancer Center and Research Institute	.	19 (5%)
	Stanford University	.	10 (3%)
	M.D. Anderson Cancer Center	.	11 (3%)
	Duke University	.	7 (2%)
	Ohio State University	.	2 (1%)
Graft source	PBSC	383	348 (91%)
	BM	.	24 (6%)
	Cord	.	9 (2%)
	Missing	.	2 (1%)
Donor type	Matched related	383	127 (33%)
	Other related	.	8 (2%)
	Unrelated/cord	.	247 (64%)
	Missing	.	1 (0%)
Conditioning	Myeloablative	383	178 (46%)
	Reduced Intensity	.	112 (29%)
	Not myeloablative	.	92 (24%)
	Missing	.	1 (0%)
Chronic GVHD type	Incident	383	161 (42%)
	Prevalent	.	222 (58%)

2710 Published Biomarker Studies

As of 1/23/20

none

Data Collection for 2710:

Timepoints: Enrollment, Rx Change, 3mo, 6mo, 18mo

Baseline chart abstraction: transplant date, PFT* pre-tx, height, weight pre-tx, age at tx, disease status, tx source, tx type, CMV, donor age/gender/match, conditioning, GVH prophy, acute GVH scores and rx, t-cell depletion

cGVHD onset form: dx date, type of GVH, weight, dx PFT*, performance score, WBC, neu, eos, lym, plt, bili, AST, ALT, alk phos, alb

Chart abstraction: ROM report, blood pressure, weight, PFT*, WBC, neu, eos, lym, plt, bili, AST, ALT, alk phos, alb, LDL, current medications (dose regimen included), 2 min walk test, Follow-up version: biopsies during interval

> *Pulmonary function testing: FVC, FEV1, FVC/FEV1, TLC, RV, DLCO adj, preference given for post bronchodilation

cGVHD medications: chronic GVH meds given from diagnosis to end of study, start and stop dates, start and stop reasons, no doses

Steroid log: prednisone/methylprednisone/dexamethasone po, start/stop dates of dose category changes during study

Patient survey: NIH GVH patient self-report, Lee GVH sx scale, FACT-BMT QOL, KPS, Short Form 36, HAP, Enrollment version: employ, race, ethnicity, gender, age, marital, education, income pre-tx, Follow-up version: mouth, skin, eye, joint, overall change scores

Provider survey: sclerotic score, 0-10 sclerotic severity, skin score, fascia score, skin features, ROM shoulder, elbow, wrist, ankle, mouth score, mouth eryth, lichenoid, ulcers, mucoceles, GI score, esophagus, upper GI, lower GI, eye score, joint score, genital score, lung score, mild/mod/sev, 1-10 scale, GVH type, GVH response, other manifestations (7), Enrollment version: rx change reason, sentinel organ, Follow-up version: mouth, skin, eye, joint, lung, liver, ugi, lgi, overall change scores

Comorbidities: cardiovascular, gastrointestinal, pulmonary, endocrine, neuropsychiatric, bone/joint, other (*completed at every visit except 3mo*)

Specimen collection: heparin plasma, PBMC

Patient status: date of last contact, death date/cause, relapse date

Study Name/Hutch Protocol Number	**Longitudinal Study of Immune Mediated Disorders after Allogeneic HCT, Protocol 2342 RDCRN 6501**
Participating institutions	Fred Hutchinson Cancer Research Center University of Minnesota Dana-Farber Cancer Institute Stanford University Vanderbilt University Medical College of Wisconsin Washington University St. Louis H. Lee Moffitt Cancer Center University of North Carolina at Chapel Hill Weill Cornell Medical College Roswell Park Cancer Institute Mayo Clinic-Scottsdale Cleveland Clinic Foundation
Years of accrual	3, from 2011 to 2014
Number with chronic GVHD	413
Number with late acute GVHD	97 (30 also have chronic GVHD)
Number with other immune mediated disorders	11 (4 also have chronic GVHD)
Are controls included?	Yes, 403 (doesn't include those with chronic GVHD, late acute GVHD or other IMD; does include 15 controls who later developed chronic GVHD)
Duration of follow up	2 years active for controls, 5 years active intended for cases, however the median follow up is 3 years because we got a late start. We are continuing to collect long term data, most recently collected Oct 2019
Samples collected	PBMC, heparin plasma, EDTA plasma, granulocytes, serum, urine
Timepoints for samples	**Controls**: • Day 100 • Day 180 **Cases:** • Diagnosis of chronic or late acute GVHD • 3 month **OR** 6 month after dx (If no diagnosis sample obtained, then both 3 AND 6 month samples collected)
Location of samples	National Marrow Donor Program
Patient reported outcomes	None
Functional assessment	PFTs captured when performed clinically
Availability of medication data (at visit, interval history)	Current steroid dose/frequency collected at each sample timepoint Running log of systemic medications and treatments for GVHD from transplant to end of study, includes start/stop dates but no doses
Description of how the cohort was assembled	Patients are enrolled before onset of chronic GVHD with the first sample taken day 80-121.
Primary objectives of the parent study	To create a large cohort of prospectively followed patients.
Does consent allow broad use of samples?	Yes

Clinicaltrials.gov number	NCT01206309
Grant funding	NIH U54CA163438
Cost/procedure for retrieving samples	$10 per sample, contact Kate Chilson kchilson@fredhutch.org and she will coordinate shipment from NMDP
Contact for more information	Dr. Stephanie Lee (sjlee@fredhutch.org)
Notes	

Longitudinal Study of Immune-Mediated Disorders Patient Characteristics

Variable	Category	N	Count (%)
Recipient age at HCT in years Median (range)	Median: 53.7 Range: 19-77.9	890	
	< 10	890	0 (0)
	10-19	.	2 (<1)
	20-29	.	90 (10)
	30-39	.	118 (13)
	40-49	.	146 (16)
	50-59	.	261 (29)
	60-69	.	242 (27)
	>=70	.	31 (3)
Donor type	HLA identical sibling	885	290 (33)
	HLA-matched other relative	.	8 (1)
	HLA-matched unrelated donor	.	388 (44)
	HLA-mismatched relative (single antigen or allele mismatched)	.	3 (<1)
	HLA-mismatched unrelated donor	.	180 (20)
	Haplo-identical relative (2 or more antigen or allele mismatched)	.	16 (2)
Graft Type	Bone Marrow	890	75 (8)
	Cord Blood	.	102 (11)
	Peripheral Blood	.	713 (80)
Conditioning Intensity	Myeloablative	890	395 (44)
	Not myeloablative	.	495 (56)
GVHD prophylaxis	CNI + mtx	890	389 (44)
	CNI + MMF	.	307 (34)
	CNI + sirolimus	.	264 (30)
	ATG	.	51 (6)
	T-cell depletion	882	23 (3)
Center	Cleveland Clinic Foundation	890	35 (4)
	Dana-Farber Cancer Institute	.	190 (21)
	Fred Hutchinson Cancer Research Center	.	235 (26)
	H. Lee Moffitt Cancer Center and Research Institute	.	69 (8)
	Mayo Clinic - Scottsdale	.	4 (<1)
	Medical College of Wisconsin	.	16 (2)
	Roswell Park Cancer Center	.	42 (5)
	Stanford University	.	34 (4)

	University of Minnesota	.	105 (12)
	University of North Carolina, Chapel Hill	.	4 (<1)
	Vanderbilt University Medical Center	.	113 (13)
	Washington University	.	20 (2)
	Weill Cornell Medical College	.	23 (3)
Diagnosis	Aplastic anemia	890	14 (2)
	Acute lymphocytic leukemia	.	135 (15)
	Acute myeloid leukemia	.	303 (34)
	Chronic lymphocytic leukemia	.	42 (5)
	Chronic myeloid leukemia	.	42 (5)
	Hodgkins disease	.	27 (3)
	Myelodysplastic syndrome	.	124 (14)
	Multiple myeloma	.	31 (3)
	Myeloproliferative disorder	.	47 (5)
	Non Hodgkins Lymphoma	.	86 (10)
	Other	.	39 (4)
Disease stage at transplant	Early	890	414 (47)
	Intermediate	.	368 (41)
	Advanced	.	108 (12)
Donor CMV status	Negative / Indeterminate	875	519 (59)
	Positive	.	356 (41)
Recipient CMV status	Negative / Indeterminate	886	432 (49)
	Positive	.	454 (51)
Donor-recipient sex match	Female into male	885	187 (21)
	Other	.	698 (79)
Time from HCT to study consent (months)	Median: 2.0 Range: -5.5 ~ 4.0	890	
Frequency of each disorder		890	
	Late acute GVHD	.	97 (11)
	Chronic GVHD	.	413 (46)
	BOS	.	34 (4)
	Cutaneous sclerosis	.	92 (10)

Availability of Samples

	plasma				EDTA				Granulocyte				PBMC				Serum				Urine			
Timepoint	controls	cGVHD	Ia	other IMD	controls	cGVHD	Ia	other IMD	controls	cGVHD	Ia	other IMD	controls	cGVHD	Ia	other IMD	controls	cGVHD	Ia	other IMD	controls	cGVHD	Ia	other IMD
1: d100	378	359	84	9	378	359	82	9	371	355	82	8	372	350	80	8	380	360	82	9	348	322	79	9
2: d180	225	158	24	5	225	155	23	5	222	157	21	5	222	156	22	5	225	157	23	5	207	143	23	5
3: d365	74	12	3	0	74	12	3	0	74	12	3	0	72	12	3	0	74	12	3	0	62	12	2	0
4: dis dx		241	8	0		243	8	0		242	8	0		238	7	0		240	8	0		205	5	0
5: 3mo post dx		240	6	3		236	6	3		239	5	3		236	6	3		236	6	3		218	5	3
6: 6mo post dx		152	2	2		151	2	2		148	2	2		151	2	2		152	2	2		120	1	2
7: dis dx + 3mo		149	2			146	2			148	1			144	2			145	2			128	2	
8: dis dx + 6mo		65				65				64				65				63				38		
9: dis dx + (3 or 6mo)		204	2			201	2			202	1			199	2			198	2			156	2	
10: dis dx + (3 and 6 mo)		10				10				10				10				10				10		
11: no dis dx, have 3 & 6 mo		56		2		55		2		53		2		54		2		56		2		47		2

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Updated 1/23/20

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6. Kariminia A, Holtan SG, Ivison S, Rozmus J, Hebert MJ, Martin PJ, Lee SJ, Wolff D, Subrt P, Abdossamadi S, Sung S, Storek J, Levings M, Aljurf M, Arora M, Cutler C, Gallagher G, Kuruvilla J, Lipton J, Nevill TJ, Newell LF, Panzarella T, Pidala J, Popradi G, Szwajcer D, Tay J, Toze CL, Walker I, Couban S, Storer BE, Schultz KR. Heterogeneity of chronic graft vs. host disease biomarkers: association with CXCL10 and CXCR3+ NK cells. Blood 2016 Jun; 127(24): 3082-91. PMID: 27020088

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Data Collection for 6501:

Timepoints:
Control: baseline (transplant), d100, d180, d365, d730 (samples at d100 and d180 or d365)
Case: disease diagnosis, 3mo, 6mo, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr *(same person will have baseline and probably other control timepoints)* (samples at onset and 3 or 6mo)

Patient sociodemographics and demographics: race, eth, age, gender, educ, employ, marital, karnofsky

Baseline chart abstraction: transplant date, height, weight pre-tx, disease status, tx source, tx type, CMV, HLA, hepB, donor age/gender/match, conditioning, GVH prophy, acute GVH date and scores

IMD onset form: dx date, type of GVH, weight, performance score, BSA, lichen planus, sclerotic, BOS, diarrhea, oral, bili, plt

Lab results: cr, BUN, glu, hb, hct, WBC, neu, eos, lym, bands, plt, bili, direct bili, AST, ALT, alk phos, alb

IMD medications: immunosuppressive GVH meds given from transplant to now (includes prophy, acute, chronic), dates taken, *no doses*

Medication-steroids: dose of pred/methylpred/dexameth p.o. at date of sample draw or data abstraction

Comorbidities: cardiovascular, gastrointestinal, pulmonary, endocrine, neuropsychiatric, bone/joint, other, height, weight

Pulmonary function testing: height, weight, hb, FVC, FEV1, FVC/FEV1, FEF25-75, TLC, RV, DLCO raw and adj, both pre and post bronchodilation

Specimen collection: heparin plasma, PBMC, granulocyte, EDTA plasma, serum, urine

Follow-up chart abstraction: biopsies, Lee GVHD sx scale (*usually answered by chart review, sometimes by patient)*

Physician assessment: weight, skin score, mouth score, GI score, eye score, joint score, genital score, lung score, perform score, skin features, mild/mod/sev, 1-10scale, GVH type, infx, other GVH manifestations (14) (*usually answered by chart review, sometimes by physician)*

Sclerosis, fasciitis, BOS capture: dx date of any of these

Conclusion of study participation: withdraw date/reason

Patient status: date of last contact, death date/cause, relapse date, chronic GVHD date for controls (off study early d/t DLI, additional SCT, graft loss)

Study Name/Hutch Protocol Number	**A Randomized Phase II Study of Imatinib and Rituximab for Cutaneous Sclerosis after Allogeneic Hematopoietic Cell Transplantation; Protocol 2343 RDCRN 6502**
Participating institutions	Fred Hutchinson Cancer Research Center Stanford University Vanderbilt University Medical College of Wisconsin Washington University St. Louis H. Lee Moffitt Cancer Center University of North Carolina at Chapel Hill Weill Cornell Medical College Roswell Park Cancer Institute Mayo Clinic Ohio State University
Years of accrual	3.5, from 2011-2014
Number with chronic GVHD	72
Are controls included? If yes, number	no
Duration of follow up	1.5 years active, 1.6 years (0.2-4) long term followup
Samples collected	PBMC, heparin plasma, EDTA plasma, skin biopsies
Timepoints for samples	Blood samples 1. Enrollment 2. 6 months or cross over to second arm 3. 12 months or 6 months after cross over
Location of samples	National Marrow Donor Program
Patient reported outcomes (scales and timepoints)	• Scleroderma Health Assessment Questionnaire (SHAQ) • Ocular surface disease index (ODSI) • NIH Patient Self Report (PSR) • Lee symptom scale (LSS) • Functional Assessment of Cancer Therapy – Bone Marrow Transplant (FACT-BMT) • Medical Outcomes Study Short-Form 36 (SF-36) • Human Activities Profile (HAP) PROs collected at all sample timepoints plus 3mo, 9mo and 18mo
Functional assessment	Goniometer
Availability of medication data	Current steroid dose/frequency collected at each sample timepoint Running log of systemic medications and treatments for chronic GVHD from transplant to end of study, includes start/stop dates but no doses Running log of concomitant medications from enrollment to end of study, includes indications, doses and start/stop dates
Description of how the cohort was	Patients with cutaneous sclerosis or fasciitis within 18

assembled	months of diagnosis
Primary objectives of the parent study	Test the efficacy of imatinib and rituximab for treatment of cutaneous sclerosis
Does consent allow broad use of samples?	If indicated by subject on the consent form
Clinicaltrials.gov number	NCT01309997
Grant funding	NIH U54 CA163438
Cost/procedure for retrieving samples	$10 per sample, contact Kate Chilson kchilson@fredhutch.org and she will coordinate shipment from NMDP
Contact for more information	Dr. Stephanie Lee (sjlee@fredhutch.org)
Notes	

Rituximab vs Imatinib for Cutaneous Sclerosis Patient Characteristics

Variable	**Category**	**n**	**Count (%)**
Institution Name	Fred Hutchinson Cancer Research Center (cGVHD)	72	20 (28%)
	H. Lee Moffitt Cancer Center and Research Institute (cGVHD)	.	9 (13%)
	Mayo Clinic - Scottsdale (cGVHD)	.	3 (4%)
	Medical College of Wisconsin (cGVHD)	.	3 (4%)
	Ohio State University (cGVHD)	.	3 (4%)
	Roswell Park Cancer Center (cGVHD)	.	3 (4%)
	Stanford University (cGVHD)	.	13 (18%)
	University of North Carolina, Chapel Hill (cGVHD)	.	1 (1%)
	Vanderbilt University Medical Center (cGVHD)	.	2 (3%)
	Washington University (cGVHD)	.	13 (18%)
	Weill Cornell Medical College (cGVHD)	.	2 (3%)
Adult or child	Adult	71	71 (100%)
Gender	Female	71	31 (44%)
	Male	.	40 (56%)
Patient age at registration (years)		71	Median 56 [19-78]
Patient race	Black or African American	71	2 (3%)
	More than one race	.	1 (1%)

Variable	Category	n	Count (%)
	Native Hawaiian or Other Pacific Islander	.	1 (1%)
	Refused/Unknown	.	2 (3%)
	White	.	65 (92%)
Ethnicity	Hispanic,Latino,or Spanish origin	71	3 (4%)
	Not Hispanic,Latino or Spanish origin	.	62 (87%)
	Unknown or not reported	.	6 (8%)
Patient disease diagnosis	ALL	69	9 (13%)
	AML	.	25 (36%)
	CLL	.	8 (12%)
	HD	.	4 (6%)
	MDS	.	7 (10%)
	MM	.	2 (3%)
	NHL	.	10 (14%)
	Other	.	4 (6%)
Patient disease status category	Advanced	69	14 (20%)
	Early	.	25 (36%)
	Intermediate	.	30 (43%)
Transplant Source	Bone Marrow	68	3 (4%)
	Cord Blood	.	1 (1%)
	Peripheral Blood	.	64 (94%)
Transplant Type	Myeloablative	69	40 (58%)
	Not myeloablative	.	29 (42%)
HLA	Fully matched	68	60 (88%)
	Mismatched	.	8 (12%)
Priro acute GVHD?	No	67	21 (31%)
	Yes	.	46 (69%)
Tcell Depletion	No	68	66 (97%)
	Unknown	.	1 (1%)
	Yes	.	1 (1%)
Donor Gender choose 2 genders if double cord	Female	69	29 (42%)

Variable	Category	n	Count (%)
	Male	.	39 (57%)
	Male/Female	.	1 (1%)
Donor Match	HLA identical sibling	68	23 (34%)
	HLA-matched other relative	.	2 (3%)
	HLA-matched unrelated donor	.	34 (50%)
	HLA-mismatched unrelated donor	.	9 (13%)
Recipient CMV Antibodies	No	69	36 (52%)
	Not tested	.	1 (1%)
	Yes	.	32 (46%)
Donor CMV Antibodies	No	68	40 (59%)
	Not tested	.	4 (6%)
	Yes	.	24 (35%)
Reason for early withdrawal	Death	27	7 (26%)
	Intercurrent illness of a nature requiring withdrawal	.	1 (4%)
	Other	.	2 (7%)
	PI removed participant from study	.	11 (41%)
	Participant/Parent request	.	6 (22%)

Rituximab vs. Imatinib for Cutaneous Sclerosis Biomarker Bibliography:
Updated 4/18/17

1. Arai S, Pidala J, Pusic I, Chai X, Jaglowski S, Khera N, Palmer J, Chen GL, Jagasia MH, Mayer SA, Wood W, Green M, Hyun TS, Inamoto Y, Storer BE, Miklos DB, Shulman HM, Martin PJ, Sarantopoulos S, Lee SJ, Flowers ME. A Randomized Phase II Study of Imatinib or Rituximab for Cutaneous Sclerosis after Allogeneic Hematopoietic Stem Cell Transplantation. Clin Cancer Res. 2016 Jan; 22(2): 319-27. PMID: 26378033

Data Collection for 6502:

Timepoints:
Arm 1: enrollment, 1mo, 2mo, 3mo, 4mo, 5mo, 6mo, 9mo, 12mo
Arm 2: crossover, 1mo, 2mo, 3mo, 4mo, 5mo, 6mo, 9mo, 12mo

Demographics: race, eth, age, gender

Baseline chart abstraction: transplant date, height, weight, disease status, tx source, tx type, conditioning, CMV, HLA, hepB, GVH prophy, acute GVH date and scores, donor age/gender/match

IMD onset form: dx date, type of GVH, weight, performance score, BSA, lichen planus, sclerotic, BOS, diarrhea, oral, bili, plt

Lab results: cr, BUN, glu, hb, hct, WBC, neu, eos, lym, bands, plt, bili, direct bili, AST, ALT, alk phos, alb

IMD medications: immunosuppressive GVH meds given from transplant to now (includes prophy, acute, chronic), dates taken, *no doses*

Medication-steroids: dose of pred/methylpred/dexameth p.o. at date of sample draw or visit

Comorbidities: cardiovascular, gastrointestinal, pulmonary, endocrine, neuropsychiatric, bone/joint, other, height, weight

Concomitant meds: all meds other than IST, dates and doses and indication

Provider survey: NIH skin BSA scale, sclerotic score, skin score, fascia score, skin features, Vienna skin scale, ROM shoulder, elbow, wrist, ankle, mouth score, mouth eryth, lichenoid, ulcers, mucoceles, mouth pain, GI score, esophagus, upper GI, lower GI, eye score, joint score, genital score, lung score, mild/mod/sev, 1-10 scale, GVH type, infx, edema, other GVH manifestations (14) Enrollment version: rx change reason, sentinel organ, Follow-up version: mouth, skin, eye, joint, overall change scores *(completed by provider)*

Patient survey: NIH GVH patient self-report, Lee GVH sx scale, FACT-BMT QOL, KPS, Short Form 36, HAP, Enrollment version: employ, race, ethnicity, gender, age, marital, education, income pre-tx, Follow-up version: mouth, skin, eye, joint, overall change scores *(completed by patient)*

Scleroderma health assessment questionnaire *(completed by patient)*

Specific lab results: Hep B, Hep C, Phosphate, Vit D,

Goniometer: Joint measurements

Study medications-rituximab: dose regimen for ritux (*imatinib found in IMD meds*)

Coordinator collection form: skin biopsies in formalin and RNAlater for Miklos and EDTA whole blood for Sarantopoulos

Specimen collection: heparin plasma, PBMC

Arm 1 start date

Treatment failure: why stopped arm 1 (no response, progression, intolerance), arm 2 start date

Adverse event: detailed descriptions of initial and follow up events, review by MRO

Conclusion of study participation: withdraw date/reason,

Patient status: date of last contact, death date/cause, relapse date

Study Name/Hutch Protocol Number	**Targeted Therapy of Bronchiolitis Obliterans Syndrome, Protocol 2367, RDCRN 6503, "FAM"**
Participating institutions	Fred Hutchinson Cancer Research Center University of Minnesota Dana-Farber Cancer Institute Stanford University Vanderbilt University Medical College of Wisconsin Washington University St. Louis H. Lee Moffitt Cancer Center NCI Experimental Transplantation & Immunology Branch Weill Cornell Medical College
Years of accrual	2, from 2011 to 2014
Number with chronic GVHD	36
Are controls included?	No
Duration of follow up	6 months active, median 1.9 years of long term
Samples obtained	PBMC, heparin plasma, EDTA plasma, granulocytes, urine
Timepoints available for samples	Enrollment, 3 months, 6 months
Location of samples	NMDP
Patient reported outcomes	• NIH Patient Self Report (PSR) • Lee symptom scale (LSS) • Functional Assessment of Cancer Therapy – Bone Marrow Transplant (FACT-BMT) • Medical Outcomes Study Short-Form 36 (SF-36) • Human Activities Profile (HAP) • PROs given at all sample timepoints listed above
Functional assessment	PFTs • Baseline • 1 Month* • 2 Months* • 3 Months • 6 Months *Months 1 & 2 only require Spirometry. 6 minute walk test • Enrollment • 3 Months • 6 Months
Availability of medication data	Current steroid dose/frequency collected at each sample timepoint Running log of systemic medications and treatments for GVHD from transplant to end of study, includes start/stop dates but no doses Running log of concomitant medications from enrollment to end of study, includes indications, doses, and start/stop dates

Description of how the cohort was assembled	Patients with BOS per NIH consensus criteria diagnosed within the past 6 months
Primary objectives of the parent study	Test efficacy of inhaled fluticasone, azithromycin, and montelukast (FAM) for the treatment of new onset bronchiolitis obliterans syndrome (BOS).
Does consent allow broad use of samples?	If indicated by subject on the consent form
Clinicaltrials.gov number	NCT01307462
Grant funding	NIH U54CA163438
Cost/procedure for retrieving samples	$10 per sample, contact Kate Chilson kchilson@fredhutch.org and she will coordinate shipment from NMDP
Contact for more information	Dr. Stephanie Lee (sjlee@fredhutch.org)
Notes	There have been no analyses of these samples

Targeted Therapy of Bronchiolitis Obliterans Syndrome, Protocol 2367, RDCRN 6503 Patient Characteristics

Variable	**Category**	**n**	**Count (%)**
Participant Status	Eligible	36	36 (100%)
Institution Name	Dana-Farber Cancer Institute	36	3 (8%)
	Experimental Transplantation and Immunology Branch, NIH	.	5 (14%)
	Fred Hutchinson Cancer Research Center	.	9 (25%)
	H. Lee Moffitt Cancer Center and Research Institute	.	2 (6%)
	Medical College of Wisconsin	.	2 (6%)
	Stanford University	.	1 (3%)
	University of Minnesota	.	4 (11%)
	Vanderbilt University Medical Center	.	4 (11%)
	Washington University	.	5 (14%)
	Weill Cornell Medical College	.	1 (3%)
Adult or child	Adult	36	36 (100%)
Gender	Female	36	17 (47%)
	Male	.	19 (53%)
Patient age at registration (years)		36	Median 57 [24-72]
Patient race	Black or African American	36	2 (6%)
	Refused/Unknown	.	1 (3%)

Variable	Category	n	Count (%)
	White	.	33 (92%)
Ethnicity	Hispanic,Latino,or Spanish origin	36	1 (3%)
	Not Hispanic,Latino or Spanish origin	.	32 (89%)
	Unknown or not reported	.	3 (8%)
Disease diagnosis	ALL	36	4 (11%)
	AML	.	9 (25%)
	CLL	.	4 (11%)
	CML	.	3 (8%)
	HD	.	1 (3%)
	MDS	.	5 (14%)
	MM	.	1 (3%)
	MPD	.	4 (11%)
	NHL	.	4 (11%)
	Other	.	1 (3%)
Disease status	Advanced	36	7 (19%)
	Early	.	15 (42%)
	Intermediate	.	14 (39%)
Transplant Source	Bone Marrow	36	5 (14%)
	Peripheral Blood	.	31 (86%)
Transplant Type	Myeloablative	36	22 (61%)
	Not myeloablative	.	14 (39%)
HLA	Fully matched	36	29 (81%)
	Mismatched	.	7 (19%)
Prior acute GVHD	No	34	13 (38%)
	Yes	.	21 (62%)
Tcell Depletion	No	36	34 (94%)
	Yes	.	2 (6%)
Donor Gender choose 2 genders if double cord	Female	36	20 (56%)
	Male	.	16 (44%)
Donor Match	HLA identical sibling	36	18 (50%)

Variable	Category	n	Count (%)
	HLA-matched other relative	.	1 (3%)
	HLA-matched unrelated donor	.	8 (22%)
	HLA-mismatched relative (single antigen or allele mismatched)	.	1 (3%)
	HLA-mismatched unrelated donor	.	7 (19%)
	Haplo-identical relative (2 or more antigen or allele mismatched)	.	1 (3%)
Recipient CMV Antibodies	Indeterminate	36	1 (3%)
	No	.	17 (47%)
	Not tested	.	3 (8%)
	Yes	.	15 (42%)
Donor CMV Antibodies	No	36	19 (53%)
	Not tested	.	4 (11%)
	Yes	.	13 (36%)
FEV1 at enrollment	% predicted	36	Median 46.3% [21.4-70.5]
FEV1/FVC			Median 0.50 [0.28-0.75]
Reason for early withdrawal	Death	7	1 (14%)
	Intercurrent illness of a nature requiring withdrawal	.	2 (29%)
	PI removed participant from study	.	1 (14%)
	Participant/Parent request	.	3 (43%)

Targeted Therapy of Bronchiolitis Obliterans Syndrome Biomarker Publications

Updated 4/18/17

None

Data Collection for 6503:

Timepoints: Enrollment, 1mo, 2mo, 3mo, 6mo

Demographics: race, eth, age, gender

Baseline chart abstraction: transplant date, height, weight, disease status, tx source, tx type, conditioning, CMV, HLA, hepB, GVH prophy, acute GVH date and scores, donor age/gender/match

IMD onset form: dx date, type of GVH, weight, performance score, BSA, lichen planus, sclerotic, BOS, diarrhea, oral, bili, plt

FEV1 absolute value: baseline and failure (10% decrease)

BOS confirmed by HRCT and biopsy/pathology?

Lab results: cr, BUN, glu, hb, hct, WBC, neu, eos, lym, bands, plt, bili, direct bili, AST, ALT, alk phos, alb

IMD medications: immunosuppressive GVH meds given from transplant to now (includes prophy, acute, chronic), dates taken, *no doses*

Medication-steroids: dose of pred/methylpred/dexameth p.o. at date of sample draw or visit

Comorbidities: cardiovascular, gastrointestinal, pulmonary, endocrine, neuropsychiatric, bone/joint, other, height, weight

Concomitant meds: all meds other than IST, dates and doses and indication

Provider survey: NIH skin BSA scale, sclerotic score, skin score, fascia score, skin features, Vienna skin scale, ROM shoulder, elbow, wrist, ankle, mouth score, mouth eryth, lichenoid, ulcers, mucoceles, mouth pain, GI score, esophagus, upper GI, lower GI, eye score, joint score, genital score, lung score, mild/mod/sev, 1-10 scale, GVH type, infx, edema, other GVH manifestations (14), Enrollment version: rx change reason, sentinel organ, Follow-up version: mouth, skin, eye, joint, overall change scores *(completed by provider)*

Patient survey: NIH GVH patient self-report, Lee GVH sx scale, FACT-BMT QOL, KPS, Short Form 36, HAP, Enrollment version: employ, race, ethnicity, gender, age, marital, education, income pre-tx, Follow-up version: mouth, skin, eye, joint, overall change scores *(completed by patient)*

Pulmonary function testing: height, weight, hb, FVC, FEV1, FVC/FEV1, FEF25-75, TLC, RV, DLCO raw and adj all values for pre and post bronchodilation

PFT interpretation form: infx sx at PFT, 10% decrease?, if yes, confirmatory PFT

FAM meds: dates, doses of Flu, Azith and Mont

Six minute walk test

Specimen collection: heparin plasma, PBMC, granulocyte, EDTA plasma, urine

Conclusion of study participation: withdraw date/reason

Patient status: date of last contact, death date/cause, relapse date

Adverse event: detailed descriptions of initial and follow up events, review by MRO