RDCRN 6501: Longitudinal Study of Immune Mediated Disorders after Allogeneic HCT

RDCRN 6502: A Randomized Phase II Study of Imatinib and Rituximab for Cutaneous Sclerosis after Allogeneic Hematopoietic Cell Transplantation

RDCRN 6503: Targeted Therapy of Bronchiolitis Obliterans Syndrome

This file is a list of the forms for each U54 protocol organized by which time points they were completed. See the schedule of events in the protocol for a detailed list of time points.

The name of the form is in blue, the title of the csv file containing the data is in black. See next page for a guide to the forms that shows what's unique and what's duplicated among protocols.

Please refrain from printing these as they are large documents. Each pdf is bookmarked for ease of searching forms.

Forms that are found in 6501, 6502, 6503:

Demographics

Baseline chart abstraction

Lab results

IMD medications

Comorbidities

Medication-steroids

IMD onset form

Primary tube collection

Specimen collection-aliquots sampling

Conclusion of study participation

Patient status

Protocol deviation

Serious adverse event

Pulmonary function testing (not 6502)

Forms that are found in 6502 and 6503:

Treatment start date

Concomitant meds

Serum/urine pregnancy test

Provider survey

Patient survey

Forms that are unique to 6501:

Transplant

Patient sociodemographics

Follow-up chart abstraction

Physician assessment

Sclerosis, fasciitis, BOS capture

Forms that are unique to 6502:

SHAQ

Specific lab results

Goniometer

Skin biopsy tracking

Coordinator collection

Study medications-rituximab

Treatment failure

Forms that are unique to 6503:

FEV1 absolute value

HRCT and pathology

PFT interpretation form

FAM meds

Six minute walk test

6501:

Enrollment:

Transplant: registration_revised.csv
Demographics: demographics revised.csv

Patient sociodemographics: patient_sociodem_revised.csv Baseline chart abstraction: blvisitchartabstrac_revised.csv and

p6501_17083_acutegvhd_revised.csv

Disease diagnosis:

IMD onset form: imd_onset_form_revised.csv

Control and IMD (case) followup:

Lab results: lab results revised.csv

IMD medications: imd medications revised.csv

Comorbidities: comorbities revised.csv

Medication-steroids: imd_13174_medications_revised.csv Primary tube collection: p6501_13994_researchs_revised.csv

Specimen collection-aliquots sampling: specimen6501_revised.csv and

specimen_collection_revised.csv and research_labs_revised.csv Pulmonary function testing: pulm_function_test_revised.csv Follow-up chart abstraction: fu_visit_chrtabstr_revised.csv

IMD (case) followup:

Physician assessment: p6501_13176_physician_revised.csv Sclerosis, fasciitis, BOS capture: p6501_20282_sclerosis_revised.csv

PRN:

Conclusion of study participation: conclstudypartic_revised.csv

Patient status: imd_17919_patientstat_revised.csv Protocol deviation: imd14013_protdev_revised.csv

Adverse event: adverse_event_revised.csv

Enrollment:

Treatment start date (crossover from same): treatmenttable revised.csv and

p6502_16984_crossover_revised (duplicate)
Demographics: demographics_revised.csv

Baseline chart abstraction: blvisitchartabstrac_revised.csv

IMD onset form: imd_onset_form_revised.csv

Serum/urine pregnancy test: pregnancy_test_revised.csv

Followup:

Lab results: lab_results_revised.csv

IMD medications: imd_medications_revised.csv

Comorbidities: comorbidities_revised.csv

Medication-steroids: imd_13174_medications_revised.csv Primary tube collection: imd_14879_researchsam_revised.csv

Specimen collection-aliquots sampling: research_labs_revised.csv and

specimen6502_revised.csv

Concomitant meds: concomitant_meds_revised.csv Provider survey: provider_survey_revised.csv Patient survey: patient_survey_revised.csv SHAQ: p6502 15613 shaq revised.csv

Specific lab results: p6502_15612_specificl_revised.csv Goniometer: p6502_17061_goniomete_revised.csv Skin biopsy tracking: p6502_15618_skinbiops_revised.csv

Coordinator collection: research labs revised.csv and specimen6502 revised.csv

Study medications-rituximab: p6502_15623_studymedi_revised.csv

PRN:

Treatment failure: p6502_15619_treatment_revised.csv Conclusion of study participation: conclstudypartic revised.csv

Patient status: imd_17919_patientstat_revised.csv Protocol deviation: imd14013 protdev revised.csv

Adverse event: adverse_event_revised.csv and ae_mro_review_revised.csv

Snomed 6502 revised.csv is the coding for meds used on the IMD and con meds forms.

6503:

Enrollment:

Treatment start date: treatmenttable_revised.csv

Demographics: demographics_revised.csv

Baseline chart abstraction: blvisitchartabstrac_revised.csv

IMD onset form: imd_onset_form_revised.csv

Serum/urine pregnancy test: pregnancy_test_revised.csv FEV1 absolute value: p6503_17918_fev1absol_revised.csv

HRCT and pathology: pathology revised.csv

Followup:

Lab results: lab results revised.csv

IMD medications: imd_medications_revised.csv

Comorbidities: comorbidities revised.csv

Medication-steroids: imd_13174_medications_revised.csv Primary tube collection: imd_14879_researchsam_revised.csv

Specimen collection-aliquots sampling: research_labs_revised.csv and

specimen6503 revised.csv

Concomitant meds: concomitant_meds_revised.csv Provider survey: provider_survey_revised.csv Patient survey: patient survey revised.csv

Pulmonary function testing: pulm_function_test_revised.csv PFT interpretation form: pft interpretation form revised.csv

FAM meds: fam medications revised.csv

Six minute walk test: six minute walk test revised.csv

PRN:

Conclusion of study participation: conclstudypartic_revised.csv

Patient status: imd_17919_patientstat_revised.csv Protocol deviation: imd14013_protdev_revised.csv

Adverse event: adverse_event_revised.csv and ae_mro_review_revised.csv

Snomed_6503_revised.csv is the coding for meds used on the IMD and con meds forms.

Participant ID	108195	Date of Registration	14 Mar 2011		
Local ID	0101001	Date of Baseline Exam	15 Dec 2010		
Status	Eligible				
Site ID	Fred Hutchinson Cancer Research Center (cGVHD)				

			Trar	isplant	: Date	registration_verised
THE REAL PROPERTY AND ADDRESS OF THE PROPERTY ADDRESS OF THE PROPERTY AND ADDRESS OF THE PROPERTY ADDRESS OF THE PROPERTY AND ADDRESS OF THE PROPERTY ADDRESS					* These fi	ields are required in order to SAVE the form
				* Th	ese fields a	ire required in order to COMPLETE the form
Date of Visit:	*	11	Mar	2011	<u>Date</u>	
Interviewer User ID:	*	2970)			
Note: By updating the Tra follow-up visits. Please v	ansplar erify th	nt da e pa	ate, yo articipa	u will c ant's Tr	hange all ansplant	of the due date windows for the date before proceeding.
Date of Transplant:	*	15	Dec	2010	<u>Date</u>	Startat
		Save	Pri	int C	lose Wind	low.

1 of 2

Participant ID	101106	Date of Registration	26 Nov 2013
Local ID	0101100	Date of Baseline Exam	26 Sep 2013
Status	Eligible		
Site ID	Fred Hutchinson Cancer Research Center (cGVHD)		

Demographics _ revised

	* These fields are required in order to SAVE the form
	* These fields are required in order to COMPLETE the form
Date of Visit:* Da	<u>te</u>
Interviewer User ID:* Us	ser ID is required
1. Participant Age (either Date of Birt your local institution's IRB):	h or Age is required, use Date of Birth unless disallowed by
Date of Birt	h: OR Age is required, use Date of Birth unless disallowed by date of boirth day date of boirth much date of boirth much
	OR
Age at registration	can al vearshator
2. Gender:*	Male Female gender
3. Race (check all that apply): *	Asian MCL-ASIAN OF AMERICAN ARCHARING
race_natureHlorpacificishing	
	Unknown race_white
	Refused race_rcfused
4. Ethnicity (select one): *	Hispanic, Latino, or Spanish origin
	Not Hispanic, Latino or Spanish origin
	Unknown or not reported
	Refused.
MO	

Protocol # 6501 - Longitudinal Study of Immune Mediated Disorders after Alloge...

Participant ID	101106	Date of Registration	26 Nov 2013	
Local ID	0101100	Date of Baseline Exam	26 Sep 2013	
Status	Eligible			
Site ID	Fred Hutchinson Cancer Research Center (cGVHD)			

		Patient S	ociodemographics	patient_socioder
				required in order to SAVE the form
	All questions sh	ould be filled out f	or eCRF to be "COMPLETE" in	n tracking system
Date	of Visit:*	<u>Date</u>		1
Inte	viewer User ID:*	User ID	is required	
Sec	tion 1:			
1.	Employment status (chec	ck all that apply)		
	Employed full-time	C)	On medical leave from w	vork
	Employed part-time	ET.	Disabled, unable to work	<
	Homemaker	13	Unemployed, looking for	work
	Student	O	Unemployed, not looking	g for work
	Retired	O	Unknown	
2.	Marital status Sd -	martal		
	Currently married	() (0)	Widowed	
	Separated	-Žir	Never married	
	Divorced	73	Unknown	
3.	Living with a spouse or p	partner? Sd-	spouse	
	Yes			
	· No			
	Unknown			
4.	Highest level of school of	ompleted or the	highest degree received	Sd-educ
	Didn't go to school		College graduate	or Baccalaureate Degree
EMO L	Grade school		ା Some post-gradu	ate or professional
	Some high school (9-11 years)	Master's Degree	
	 High school diploma 	a or GED	Doctoral Degree	(Ph.D., M.D., J.D., etc)
	Vocational or training	ng school	Unknown	
	Some college or As	sociate Degree		
1				

Section 2: Health and Well Being					
5. Karnofsky performance status Sd_ kPS					
Normal, no difficulties with daily activities (100%)					
Able to carry on normal activities, minor problems (90%)					
Normal activity with effort (80%)					
Able to care for self, but unable to carry on normal activity or active work (70%)					
Require occasional assistance, but able to care for most of needs (60%)					
Require considerable assistance and frequent medical care (50%)					
Disabled, require special care and assistance (40%)					
Severely disabled, hospitalized (30%)					
Very sick, hospitalized (<30%)					
○ Unknown					
6. Overall health SF2					
୍ Excellent ୍ Very good ୍ Good ୍ Fair ୍ Poor ୍ Unknown					
Save Print Close Window					

2 of 2

Participant ID	101106	Date of Registration	26 Nov 2013		
Local ID	0101100	Date of Baseline Exam	26 Sep 2013		
Status	Eligible				
Site ID	Fred Hutchinson Cancer Research Center (cGVHD)				

Baseline Visit Chart Abstract	ion
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blusitchatalostradirevised

		Pag	ge: 1 of 2	61 MSITCH AT MOST MAG
			1 • •	<u> </u>
				re required in order to SAVE the form
	All questio	ns should be filled out for	eCRF to be "COMPLETE"	in tracking system
Dat	e of Visit:*	<u>Date</u>		
Int	erviewer User ID:*	User ID is	required	
TR	ANSPLANT CHARAC	CTERISTICS	[TX_DD	
1.	Date of transplant:	TX-I	$ \begin{array}{ccc} TX - DD \\ TX - YY \\ TX - VN & \end{array} $	PM
2.	Height pre-transplant;		IT-PRE	Unknown HT_pre_und
3.	Weight pre-transplant:	kg L	T-pre-unit t-pre ur-pre-unit	Unknown HT_pre_und
4.	Disease Status	Early	Intermediate	Advanced
ors st	ans_ AML	CR1	CR2	CR3+, rel, ref, IF
) TS _ S	Hadus ALL	CR1	CR2	CR3+, rel, ref, IF
275_ 8	tatis_ ALL Statis_CML	СР	⊖ АР	BC or after BC
	CLL		CR, PR, CS	Rel, ref, CI
	MDS	RA, RARS	RAEB, RAEBT	Rel, ref, IF
	MPD		All others	Rel, ref, IF
	NHL		CR, PR, CS	Rel, ref, CI
DEMO	HD		CR, PR, CS	Rel, ref, CI
	ММ		CR, PR, CS	Rel, ref, CI
	AA	Without ATG/TG	With ATG/TG	
	Other	Early (non-malignant)	Intermed (CR, PR)	Adv. (Rel, ref, CI)

	Other, sp	ecify	Dis-status-oth-spec				
5.	Transplant S	ource	Peripheral Blood Bone Marrow Cord Blood Souce				
6.	Transplant T	уре	Myeloablative Not myeloablative TX-+176 (non-myeloablative or reduced intensity)				
7.	Recipient CM Antibodies	V	Yes	No Indeterminate Not tested P+- CmV			
8.	Hepatitis B	sAb	Reactiv	ve Not performed Nonreactive HepB_SAB			
	Hepatitis B	sAg	Reactiv	ve Not performed Nonreactive Hep B _ SAG			
	Hepatitis B	cAb	Reactiv				
Hepatitis C Re				Not performed Nonreactive HepB_CAB Not performed Nonreactive HepC			
9.	, HLA:			natched at all tested loci tched at one or more loci			
	A	Not tes	ted	Antigen mm Allele mm Matched HLA_A			
	B h	Not tes	ted	Antigen mm Allele mm Matched HLA_B			
	C	Not tes	ted	Antigen mm Allele mm Matched LA_C			
	DRB1	Not test	ted	Antigen mm Allele mm Matched ALA DRE			
	DQ Not tested		ted	Antigen mm Allele mm Matched HLA - DQ			
	DP 3		-	Antigen mm Allele mm Matched			

TRANSPLANT MEDICATIONS

10. Conditioning Regimen

Code regimen	Modifier 1	Modifier 2	
TXLODEI	TX_MODII	TX_mon 21	< orlyones
TX-CODE 2	TX_mod 12	TX_moo 22	w/ Lata
TX CODE 3	1X-1100 13	TX_MSD 23	
		Ą	\dd

11. T-cell Depletion?

Yes No Talk

12. GVHD prophylaxis (please complete the IMD medication form)

DONOR CHARACTERISTICS

13.	Age of Donor Dnr-age	years Unknown
14.	Donor Gender (choose 2 genders if double cord) Dov-gen	Male Female Female/Female Male/Male Male/Female
15.	Donor Match Dry match	HLA identical sibling HLA-matched other relative HLA-mismatched relative (single antigen or allele mismatched) Haplo-identical relative (2 or more antigen or allele mismatched) HLA-mismatched unrelated donor HLA-matched unrelated donor
16.	Donor CMV Antibodies Dor- CmV	YesNoIndeterminateNot tested

1 ***** | ***** | ***** | ***** | ***** |

Save Print Close Window

Participant ID	101106	Date of Registration	26 Nov 2013		
Local ID	0101100	Date of Baseline Exam	26 Sep 2013		
Status	Eligible				
Site ID	Fred Hutchinson Cancer Research Center (cGVHD)				

			A	cute GVI	1D Plo	001-1708	3- autequ
		777107411141		;	* These fie	lds are required in	order to SAVE the form
	***************************************			* Thes	se fields are	e required in order	to COMPLETE the form
Date of data en	itry:*		D	<u>ate</u>			
nterviewer Us	er ID:*		User ID	is required	İ		17777 1777
Date of Acute G	VHD Diagı	nosis				No Acute GVHD GVトーロロ	Unknown
			Maximun	Acute GV	HD Grade	U	
Overall	0	(°) 1	-0.2	⊘ 3	·) 4	○ Not done	agrh-or
Liver	0	· 1	⇒ 2	⊕ 3	/ · 4	Not done	agrh-liv
GI	<i>-</i> 0	·* 1	ಿ 2	<i>⊕</i> 3		Not done	agrh-or agrh-lir agrh-GI agrh-ski
Skin	- O	· 1	÷ 2	⊕ 3	· 4	Not done	aavh_ska

Ly agih_DT [agrh_DD]
agrh_mm
agrh_YY

DEMO

Participant ID	129179	Date of Registration	29 May 2014		
Local ID	0101245	Date of Baseline Exam	07 Mar 2014		
Status	Eligible				
Site ID	Fred Hutchinson Cancer Research Center (cGVHD)				

IMD Onset Form IMD - Onset - Form - revised

			* These fi	ields are requ	uired in order	to SAVE the for	m
	All questions should	be filled out for eCRF to	o be "COMF	PLETE" in tra	cking system		
Dat	e of IMD Onset: *	<u>Date</u>					
Inte	erviewer User ID:*						
СН	ARACTERISTICS OF IMMU	NE MEDIATE DISOI	RDER (e.	g., CHRON	IC GVHD)	AT ONSET	:
1.	Date of immune mediated di onset	sorder		<u>Date</u>	IMD_0- IMD_0- IMD-0-	DD MM VV	
2.	Name of immune mediated of	lisorder 💢 Late	, recurren	t or persiste	ent acute GV		
	IMD_0	ි Chrc	nic GVHD	(classic chi	ronic or over	lap)	
				mediated of MI)O			
3.	Acute GVHD present the wee	VAC	୍ No ୍	Unknown	onset		
4.	Weight $WT_{-}O$		Kgs	WT-	O-UNIT	☐ Unknown	WT_0_UNK
5.	Performance score Perf_	.0	% Karno	ofsky KP5	LP3 - O	Unknown	Perf_O-unk
6.	Percent BSA BSA = 0		%			□ Unknown	BSA_O_UNK
7.	Lichen-planus-like changes o	f skin LICH O Yes	ି No	ି Unkno	wn		
8.	Sclerotic changes of skin 50	೭L - ೧ Yes	ି No	ି Unkno	wn		
9.	Bronchiolitis obliterans syndr		ି No	ି Unkno	wn		
10.	Chronic diarrhea DIA_0	ි Yes	ି No	ି Unkno	wn		
11.	Oral involvement ORAL -	<i>Ö</i> Yes	ି No	ି Unkno	wn		
12.	Total bilirubin $Bili0$					□ Unknown	Bili-O-UNK
13.	Platelet count PIF_O					Unknown	PIt_O_UNK

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Protocol # 6501 - Longitudinal Study of Immune Mediated Disorders after Alloge...

	[
Participant ID	101106	Date of Registration	26 Nov 2013
Local ID	0101100	Date of Baseline Exam	26 Sep 2013
Status	Eligible	*	1
Site ID Fred Hutchinson Cancer Research Center (cGVHD)			

Lab Results Form Lab-Results_revised

			m - Vc2m12 - Louiscol
All questions should			re required in order to SAVE the form
Date of Visit:*	be filled out for eCRF to be	"COMPLETE"	ın tracking system
	<u>Date</u>		
Interviewer User ID:*	User ID is required		
Metabolic Panel Not	Done Date of Test		J-Mela-DD J-Mela-MM Mela-YY
Meta Test Name	. Nd Result	Units	Meta-YY
Creatinine* CR	CR-unit		□ Not Done CR_nd
BUN* (3UN	BUN_UNI		-
	•		□ Not Done BUN_no
Glucose* 4 lu	Glu-unit	•	Not Done Glu - nd
CBC with Differential Not			JCBC- DD CBC- MM
では Name CBC - nc	∤ Result	Units	CBC-AA
Hemoglobin (Hgb)* 니식B	HGB.	.unit	□ Not Done HGBnx
Hematocrit (Hct)* HCT	HCT-uni		Not Done HGB-no
WBC* WBC	WBC_un	•	Not Done WBC-ne
Neutrophils* Neu	Neu-uni		Not Done Neu - ne
Bands* 13and5	Bands-	•	Not Done Bands
Lymphocytes* Lym	Lym - Ur		Not Done Lym_n
Eosinophils* Eo5	E05-UN		Not Done E05-No
Platelets* P/+	PIF_ uni	+	Not Done PIF_nd
Liver Function Tests Not [JLFT- DD
MO LFT_N Test Name	() Result	Huita	LFT-YY
Total bilirubin* Bili	Bili_unit	Units	Not Done Bili nd
Direct bilirubin* BiliD	Bili D- unit		Not Done Bili D- n
ACT* ACT	AST_Unit		Not Done AST_na
AST* AST	ガントー・レロコ		™ NOUDONE //C// INCA

Alkaline Phosphatase* ALP

ALK _ unit

Albumin*

ALB _ unit

Not Done ALK _ nd

Not Done ALB _ nd

Save Print Close Window

P	F			
Participant ID	101106	Date of Registration	26 Nov 2013	
Local ID	0101100	Date of Baseline Exam	26 Sep 2013	
Status	Eligible			
Site ID	red Hutchinson Cancer Research Center (cGVHD)			

IMD_ medications revised **IMD Medication Form** * These fields are required in order to SAVE the form All fields should be filled out for each Medication for eCRF to be "COMPLETE" in tracking system Date of Visit:* **Date** Interviewer User ID:*

User ID is required

Medication Indication Currently If no, Date IMD_Med_Start Taking? Search term **RxNorm Code** IMD_Med# IMD_Med_Code# Chronic Acute Prophylaxis Unknown Other Code Add

#=1-32

Close Window indication_chronic# indication-acute #mdication-prophylaxi8#
mdication-ununun#

Save

Print

IMD-Med-Start_DD# IMD_ Med_Stat_ MM# IND_ med_Start_ yy # IMD-med-Stop-DD# IMD-med-Stop-MM# IMD-med-Stop-YY#

DEMO

Protocol # 6501 - Longitudinal Study of Immune Mediated Disorders after Alloge...

Participant ID	101106	Date of Registration	26 Nov 2013		
Local ID	0101100	Date of Baseline Exam	26 Sep 2013		
Status	Eligible				
Site ID	Site ID Fred Hutchinson Cancer Research Center (cGVHD)				

Comorbidities CoMorbidities_revised

February Community Communi	
	* These fields are required in order to SAVE the form
All questions sho	uld be filled out for eCRF to be "COMPLETE" in tracking system
Date of Visit:*	Date
Interviewer User ID:*	User ID is required

Comorbidity	Definition	Present
1. CARDIOVASCULAR		1
Arrhythmia* CMB_ARR	Atrial fibrillation or flutter, sick sinus syndrome or ventricular arrhythmias	OY ON OU
Coronary artery disease	Coronary artery disease (one or more vessel- coronary artery stenosis requiring medical treatment, stent, or bypass graft), angina	n Y ko N ok U
History of MI <u>CMB_MI</u>	History of myocardial infarction	OY ON OU
Heart valve disease <u> とMB -</u> HVD	Except asymptomatic mitral valve prolapse	OY ON OU
Hypertension <u> </u>		OY ON OU
Congestive heart failure	EF ≤ 50%	OY ON OU
Cerebrovascular disease	Transient ischemic attack or history of cerebrovascular accident, or neurologic impairment consequent to CVA	оу од од
Peripheral vascular disease CMB — PVD		OY ON OU
O ous thrombosis	Confirmed radiographically and requiring anticoagulation	OY ON OU
2. GASTROINTESTINAL		
Peptic ulcer/hernia /reflux CMB_ULC	Requiring treatment	SY ON OU

Mild hepatic CMB_HEPM	Chronic hepatitis, bilirubin > ULN to 1.5 X ULN, or AST/ALT > ULN to 2.5 X ULN	OY ON OU
Moderate/severe hepatic AST/ALT > 2.5 ULN		OY ON OU
Inflammatory bowel disease	Crohn's disease or ulcerative colitis	OY ON OU
3. PULMONARY		
Moderate pulmonary	DLCO and/or FEV-1 66%-80% or dyspnea on slight activity	the Yourse North U
Severe pulmonary CMI3_PULM5	DLCO and/or FEV-1 65% or lower or dyspnea at rest or requiring oxygen	+4 Y +4 N +4 U
Asthma <i>ごMB-A</i> ろて	Asthma symptoms for which inhaled steroids or other daily treatments are needed chronically to prevent or manage attacks	OY ON OU
4. ENDOCRINE		
Diabetes CMB_DB	Requiring treatment with insulin or oral hypoglycemic agents but not diet alone	AY AN AU
Hypothyroidism <i>CMB</i> _ HT	Including compensated hypothyroidism	** Y - ** N - * * U
Adrenal Insufficiency CMB_AL	Including compensated adrenal insufficiency	AY ANDU
5. NEUROPSYCHIATRIC		
Psychiatric disturbance- Depression CMB_D트P	Depression requiring psychiatric consult or treatment	OY ON OU
Psychiatric disturbance- Anxiety or panic disorder CMB-ANX	Anxiety or panic disorder requiring psychiatric consult or treatment	»Υ⊖N »U
Neurologic disease (peripheral neuropathy, MS, Parkinson's disease or other chronic neurologic disease (MB_N)	Symptomatic and requiring treatment to control or manage symptoms/disease process)γ ⊹N ⊖U
Visual impairment secondary to cataracts, glaucoma or macular degeneration どれみニンパラ	Unilateral or bilateral, and unrepaired	OYON OU
Hearing impairment	Very hard of hearing, even with hearing aids	OY ON OU

	P. T.	
Osteoarthritis	Symptomatic and requiring treatment or with osteoarthritic changes noted on radiographic studies	AY AN AU
Degenerative disc disease (spinal stenosis or severe chronic back pain)	Symptomatic and requiring treatment or symptomatic and with degenerative disc disease noted on radiographic studies	⊘γ ⊹η ∴υ
Avascular necrosis CMB_AVN	Symptomatic with pain secondary to AVN or joint replacement	OYON OU
Osteopenia/Osteoporosis	T Score < or equal to minus 1.5 or on treatment with a bisphosphonate	OY ON OU
Rheumatologic CMB_RA	Lupus, mixed connective tissue disorder, rheumatoid arthritis, polymyalgia rheumatica	OY AN OU
7. OTHER COMORBIDITIE	S	
Infection CMB_INFX	Requiring current treatment with antimicrobial (not prophylaxis)	⊕Y ≜ N → U
Moderate/severe renal	Serum creatinine > 2 mg/dL, on dialysis, or prior renal transplantation	AY AN AU
Prior solid malignancy CMB_5T	Treated at any time point in the patient's past history, excluding nonmelanoma skin cancer	$\cap Y \oplus N \oplus U$
8. PHYSICAL EXAM - Anth	ropometry	
Height Weight	HT_CMB_em HT_CMB_in cm in WT_CMB_kg WT_CMB_ib kg lbs	HT_CMB_n Not Done WT_CMB-n Not Done

Save Print Close Window

Participant ID	101106	Date of Registration	26 Nov 2013	
Local ID	0101100	Date of Baseline Exam	26 Sep 2013	
Status	Eligible			
Site ID	Fred Hutchinson Cancer Research Center (cGVHD)			

Medication-Steroids Form imd_13174_medications_versed

	311 104 4 4 4 4 4 4
	* These fields are required in order to SAVE the form
All fields should be filled	out for each Medication for eCRF to be "COMPLETE" in tracking system
Date of Visit:*	<u>Date</u>
Interviewer User ID:*	User ID is required

Patient is not on any steroids Medication Dose Units Frequency Route RxNorm Code Ster_ Dose# ster-Freq # (PO,IV) Search term (mg,ml) IMD_Med_Code# IMD_Med# Code Ster_Units# Ster_Roule# Add

Save Print Close Window

DEMO

Participant D:	RARE DISEASES CLINICAL RESEARCH NETWORK		Specime	en Collection –A	Aliquots Sar	npling Forn	n		25May201: Version 2.0 Page 1 of 3
*Which Visit Type? d100	Protocol Number: Site:	6501			Participant I	D:		-	
d100	Person Completing Fo	orm:							
□ d180 □ d365 □ d365 □ d mo post onset	*Which Visit Type	?			researc	ch-lab	S_vevis	ed	
Specimen Name Barcode Number Number Volume Cell Location in Box Comments	□ d180 □ d365				3	mo post onse		HD 6501 vi	sittyf
Number Number Volume Count in Box	drawnode =	sife							
Tube 1	Specimen Name		ſ		Volume		1	Comments	
Tube 2					mL	x10 ⁶	1		
Tube 3					mL	x10 ⁶			
Tube 4					mL	x10 ⁶			
Tube 5 PBMC aliquots – Tube 6 PBMC aliquots – Tube 7 Tube 8					mL	x10 ⁶			
Tube 6 mL x10 ⁶ PBMC aliquots – x 10 ⁶	•				mL	x10 ⁶			A
					mL	x10 ⁶			
	PBMC aliquots – Tube 7				mL	x10 ⁶			
PBMC aliquots – Tube 8 mL x10 ⁶					mL	x10 ⁶			

Dox

Vol

volume

Status = tube broken

delayed processing hemoly zed low cell count

RARE DISEASES CLINICAL RESEARCH NETWORK ecimen Collection –Aliquots Sampling Form	25May2012 Version 2.0 Page 2 of 3	
Protocol Number:6501 Site: Person Completing Form:	Participant ID:	

Heparin Plasma aliquots – Tube 1		mL	x10 ⁶	
Heparin Plasma aliquots – Tube 2		mL	x10 ⁶	
Heparin Plasma aliquots – Tube 3		mL	x10 ⁶	
Heparin Plasma aliquots – Tube 4		mL	x10 ⁶	
Heparin Plasma aliquots – Tube 5		mL	x10 ⁶	
Heparin Plasma aliquots – Tube 6		mL	x10 ⁶	
Heparin Plasma aliquots – Tube 7		mL	x10 ⁶	
Heparin Plasma aliquots – Tube 8		mL	x10 ⁶	
Heparin Plasma aliquots – Tube 9		mL	x10 ⁶	
Heparin Plasma aliquots – Tube 10		mL	$x10^{6}$	
Heparin Plasma aliquots – Tube 11		mL	x10 ⁶	
Heparin Plasma aliquots – Tube 12		mL	x10 ⁶	

RARE DISEASES CLINICAL RESEARCH NETWORK THE WORK THE STATE OF THE STAT	Specimen Collection –Aliquots Sampling Form	25May2012 Version 2.0 Page 3 of 3
Protocol Number:6501 Site: Person Completing Form:	Participant ID:	

Serum aliquots — Tube 1	mL	x10 ⁶		
Serum aliquots – Tube 2	mL	x10 ⁶		
Serum aliquots — Tube 3	mL	x10 ⁶		
Serum aliquots – Tube 4	mL	x10 ⁶		
Urine aliquots – Tube 1	mL	x10 ⁶		
Urine aliquots – Tube 2	mL	x10 ⁶		
Urine aliquots — Tube 3	mL	x10 ⁶	·	
Urine aliquots – Tube 4	mL	x10 ⁶		
Urine aliquots – Tube 5	mL	x10 ⁶		
Urine aliquots – Tube 6	mL	x10 ⁶		
EDTA Plasma aliquots – Tube 1	mL	x10 ⁶		
EDTA Plasma aliquots – Tube 2	mL	x10 ⁶		

Specimen Collection –Aliquots Sampling Form CLINICAL RESEARCH NETWORK THE COLUMN National Institutes of Health						25May2012 Version 2.0 Page 4 of 3	
Protocol Number: Site:	6501			Participant ID):	***************************************	
Person Completing Fo	orm:						
EDTA Plasma aliquots – Tube 3				mL	x10 ⁶		
EDTA Plasma aliquots – Tube 4				mL	x10 ⁶		
Granulocytes				mL	x10 ⁶		

Protocol # 6501 - Longitudinal Study of Immune Mediated Disorders after Alloge...

Participant ID	101106	Date of Registration	26 Nov 2013
Local ID	0101100	Date of Baseline Exam	26 Sep 2013
Status	Eligible		
Site ID	Fred Hutchinson Cancer Research Center (cGVHD)		

Pulmonary Function Testing (PFT) pulm-fuction test revised * These fields are required in order to SAVE the form All questions should be filled out for eCRF to be "COMPLETE" in tracking system Date of Visit:* <u>Date</u> Interviewer User ID:* User ID is required PFT_DT PFT_DD PFT_mm PFT_YY Date of Test: **Participant Information** HT_PFT-unit Height: HT cm WT-Unit WT-PFT Weight: Kas Hb Hb-nd Not Done Participant Hb gm/dl PRE-BRONCHODILATOR Spirometry FVC-pre- nd Not Done FVC - Pre Liters FEVI-pre-nd 11 Not Done FEVI ~ Pre Liters % FEVI_FVC_R_pre FEV1/FVC 17 Not Done FEF_pre_nd L/sec FEF_pre FEF25-75% **Lung Volumes** Liters TC-pre-nd Not Done

Liters RV-pre-nd Not Done

Liters VC-pre-nd Not Done TLC_pre RV_pre DEMO: (SVC) VC-pre Diffusion Raw DLCO DLCO_pre mL/mmHg/min DLCO_pre_Nd Not Done

DLCO Adj DL CO adj-pre mL/mmHg/min DLCO adj-pre-nd 13 Not Done

POST-BRONCHODILATOR Not Done				
Spirometry				
FVC_post	Liters	FVC-post-nd	○ Not Done	
FEV1_post	Liters	FeVI-post-nd	○ Not Done	
FEV1/FVC FEVI_FVC_ POST	- %	FEVI-FUC_post_1	nd	
FEF25-75 FEF-POSH	L/sec \(FEF-post-nd	Not Done	
Lung Volumes				
TLC - POST	Liters	TLC-post-nd	Not Done	
RV_post	Liters	RV-post-nd	○ Not Done	
VC (SVC) NC-post	Liters	VC-post-nd	Not Done	
Diffusion				
Raw DLCO DLCO - POST	mL/mmHg/n	nin DLCO-post- no	Not Done	
DLCO Adj DLCO adj-post	mL/mmHg/n	nin Dlcoady_post-	《 Not Done	

Close Window

Save

Print

2 of 2

Protocol # 6501 - Longitudinal Study of Immune Mediated Disorders after Alloge...

Participant ID	101106	Date of Registration	26 Nov 2013		
Local ID	0101100	Date of Baseline Exam	26 Sep 2013		
Status	Eligible				
Site ID	Fred Hutchinson Cancer Research Center (cGVHD)				

1. Type of Follow-up Visit (check all that apply): In person at site In person elsewhere (outside medical records review) Telephone visit 2. Biopsy samples taken (for day 100 only) since transplant or (for all other follow-up visits) during interval between study visits: Area of Body BX Area # BX DD# BX Find # BX Find # BX Find # Add 3. Was an immune mediated disorder diagnosed since last report? IMD DX If previous or current IMD, complete questions 4-10 How bothered has the participant been by the following problems in the past month? Medical Record		Follow-up Visit Cha	art Abstraction	FU_Visit_Chart
Date Interviewer User ID:* User ID is required 1. Type of Follow-up Visit (check all that apply): □ In person at site □ In person elsewhere (outsion medical records review) □ Telephone visit 2. Biopsy samples taken (for day 100 only) since transplant or (for all other follow-up visits) during interval between study visits: None BX_rone Area of Body Visits: Date of Biopsy BX_Loc.# Search term BX_Find #			* These fields are re-	quired in order to SAVE the form
1. Type of Follow-up Visit (check all that apply): In person at site In person elsewhere (outside medical records review) Telephone visit 2. Biopsy samples taken (for day 100 only) since transplant or (for all other follow-up visits) during interval between study visits: Area of Body BX Area # BX DD# BX Findings BX Find # BX Find # BX Find # BX Find # Add 3. Was an immune mediated disorder diagnosed since last report? IMD DX If previous or current IMD, complete questions 4-10 How bothered has the participant been by the following problems in the past month? 4. SKIN: Medical Record		* 7	hese fields are required	I in order to COMPLETE the form
1. Type of Follow-up Visit (check all that apply): In person at site In person at site In person elsewhere (outside medical records review) Telephone visit Telephone visit Telephone visit Telephone visit None BX _ rune SX _ Area of Body Date of Biopsy Location Findings BX _ Area # Search term SNOMED Code BX _ DD# BX _ Find # BX _ Find # BX _ Find # Add ate of Visit:*	<u>Date</u>			
In person elsewhere (outside medical records review) Telephone visit 2. Biopsy samples taken (for day 100 only) since transplant or (for all other follow-up visits) during interval between study visits: Area of Body BX Arca # BX Loc # BX Loc # BX Loc # BX Loc # BX Findings BX Findings BX Find # Add 3. Was an immune mediated disorder diagnosed since last report? IMD DX If previous or current IMD, complete questions 4-10 How bothered has the participant been by the following problems in the past month? Medical Record	iterviewer User ID:	User ID is requir	red	
medical records review) Telephone visit 2. Biopsy samples taken (for day 100 only) since transplant or (for all other follow-up visits) during interval between study visits: Area of Body BX _ Area # BX _ DD# BX _ Find # Add 3. Was an immune mediated disorder diagnosed since last report? IMD _ DX If previous or current IMD, complete questions 4-10 How bothered has the participant been by the following problems in the past month? Medical Record	. Type of Follow-u	Visit (check all that apply):	il Ir	n person at site
2. Biopsy samples taken (for day 100 only) since transplant or (for all other follow-up visits) during interval between study visits: Area of Body BX Area # Date of Biopsy BX Location BX Loc # Search term BX DD# BX Loc # Search term BX Find # BX Find # Add 3. Was an immune mediated disorder diagnosed since last report? IMD DX If previous or current IMD, complete questions 4-10 How bothered has the participant been by the following problems in the past month? 4. SKIN: Medical Record				
2. Biopsy samples taken (for day 100 only) since transplant or (for all other follow-up visits) during interval between study None BX_rone visits: Area of Body BX_Area # BX_DD# BX_Find # Search term BX_Find # BX_Find = Code BX_Find # Add 3. Was an immune mediated disorder diagnosed since last report? IMD_DX If previous or current IMD, complete questions 4-10 How bothered has the participant been by the following problems in the past month? 4. SKIN: Medical Record				· /
Area of Body Biopsy BX Loc# Search term BX DD# BX Loc# Search term BX Find # BX	(for all other follo		-	one BX_rone
Add 3. Was an immune mediated disorder diagnosed since last report? IMD DX Yes IMD onset form) If previous or current IMD, complete questions 4-10 How bothered has the participant been by the following problems in the past month? 4. SKIN: SNOWED Code BX _ Find _ C BX _	•	Biopsy	k	_
At Outside center Code Add 3. Was an immune mediated disorder diagnosed since last report? IMD_DX Yes IMD onset form) If previous or current IMD, complete questions 4-10 How bothered has the participant been by the following problems in the past month? 4. SKIN: Medical Record	JA	•	Search term	
 Was an immune mediated disorder diagnosed since last report? IMD_DX Yes IMD onset form) If previous or current IMD, complete questions 4-10 How bothered has the participant been by the following problems in the past month? SKIN: Medical Record 	Add	Вх-ИМИ At Outside center center	Code	
report? IMD_DX Yes IMD onset form) If previous or current IMD, complete questions 4-10 How bothered has the participant been by the following problems in the past month? 4. SKIN: Medical Record				
How bothered has the participant been by the following problems in the past month? 4. SKIN: Medical Record		-		
4. SKIN: Medical Record	If previous or c	rrent IMD, complete quest	tions 4-10	
Medical Record	How bothered ha	the participant been by the fo	ollowing problems in	the past month?
	. SKIN:			
				Medical Record
MO	O	JAMARA L. L. A. JAMARA L.		
Abnormal State of the State of	Abnormal	NI-L-L	S 0	
Abnormal skin color all Slightly Moderately bit Extremely SXI Absent Not Discussed	skin color a			mely Not

🤄 Quite a

Extremely

Not at

Slightly

Moderately

Rashes

3XZ

Present

	all		bit		Absent Not Discussed
Thickened skin <i>5</i> ×3	े Not at all Slight	y Moderately	ି Quite a bit	Extremely	Absent Not Discussed
Sores on skin	ಿ Not at ು all Slightl	y Moderately	े Quite a bit	Extremely	Present Absent Not Discussed
Itchy skin ろそち	ಿ Not at ು all Slightl	y Moderately	ି Quite a bit	Extremely	Present Absent Not Discussed
BREATHIN	G: 				Medical Record
Frequent cough	ି Not at ା all Slight	o ly Moderately	· Quite a bit	Extremely	Present Absent Not Discussed
Colored sputum <i>ざX13</i>		y Moderately		Extremely	Present Absent Not Discussed
Shortness of breath with exercise		y Moderately		Extremely	Present Absent Not Discussed
Shortness of breath at		y Moderately		် Extremely	☐ Present ☐ Absent ☐ Not

Need to use oxygen			n Moderately			Absent Not Discussed	\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\
EYES AND N	моитн:	· · · · , , , , , , , , 					185
						Medical Record	bsent
Dry eyes			् Moderately			☐ Present ☐ Absent ☐ Not Discussed	
Need to use eye drops frequently			Moderately			☐ Present ☐ Absent ☐ Not Discussed	
Difficulty seeing clearly ろX8			n Moderately			☐ Present ☐ Absent ☐ Not Discussed	
Need to avoid certain foods due to mouth pain			্ Moderately			Present Absent Not Discussed	
Ulcers in mouth ろXIO			Moderately		Extremely	Present Absent Not Discussed	
Receiving nutrition from an intravenous line or feeding tube 5 XII			n Moderately	ି Quite a bit	ි Extremely	Present Absent Not Discussed	

8.

· · · · · · · · · · · · · · · · · · ·				Medical Record
Difficulty swallowing solid foods	○ Not at ○ all Slightly	o Moderately	ੇ Quite a ਂ bit Extrem	Present Absent Not Discussed
Difficulty swallowing liquids ろな18	े Not at ं all Slightly		ି Quite a ୍ର bit Extrem	Present Absent Not Discussed
Vomiting	Not at all Slightly			Present Absent Not Discussed
Weight loss <i>らXZO</i>	Not at all Slightly			Present Absent Not Discussed
MUSCLES A	ND JOINTS:			Medical Record
Joint and muscle aches ろメとし	Not at all Slightly		ି Quite a ୍ bit Extrem	Present Absent
Limited joint movement ゴンススス	Not at all Slightly	ි Moderately	Ouite a Obit Extrem	ely Present Not Discussed
Muscle cramps 5X23	Not at all Slightly		ି Quite a ା bit Extreme	
Neak	O Not at			□ Present

					Not Discussed	
ENERGY:						
					Medical Record	
Loss of energy	Not at all Slightly	ാ Moderately	Quite a	Extremely	Present Absent Not Discussed	
Need to sleep more/take naps	Not at all Slightly	Moderately	Quite a	Extremely	Present Absent Not Discussed	Suscession and the Confession of the Confession
Fevers	Not at all Slightly	n Moderately	े Quite a bit	Extremely	☐ Present ☐ Absent ☐ Not Discussed	
MENTAL AI	ND EMOTIONAL:	Port Port I Self A Cold II Access to 1 and Access to the Access to the Access to 1 and Access			<u> </u>	
					Medical Record	
Depression 5XZ8	Not at all Slightly	ं Moderately	ି Quite a bit		☐ Present ☐ Absent ☐ Not Discussed	
Anxiety 5X29	Not at sall Slightly	् Moderately	Quite a bit	© Extremely	Present Absent Not Discussed	
Difficulty sleeping	Not at all Slightly	n Moderately	े Quite a bit	Extremely	Present Absent Not Discussed	77

Save Print Close Window

Protocol # 6501 - Longitudinal Study of Immune Mediated Disorders after Alloge...

Participant ID	101106	Date of Registration	26 Nov 2013
Local ID	0101100	Date of Baseline Exam	26 Sep 2013
Status	Eligible		
Site ID	Fred Hutchinson Cancer Res	earch Center (cGV	HD)

Physician Assessment - IMD p6501-13176-physician Page: 1 of 2 **→** 🗐 1 * These fields are required in order to SAVE the form * These fields are required in order to COMPLETE the form Date of Visit:* Date Interviewer User ID:* User ID is required 1. Weight kg Not done WT_MD-rd WT-MD How was the following data obtained?* $MRR_{-}MD$ Physician or midlevel provider completed form Completed from medical record Date form completed: 2. Skin Score SC_SKIN SC_Skin-gr Not due to chronic GVHD No symptoms 3C.skin nd □ Not done <18% BSA with disease signs but NO sclerotic features 19-50% BSA OR involvement with superficial sclerotic features 'not hidebound' (able to pinch) >50% BSA OR deep sclerotic features 'hidebound' (unable to pinch) OR impaired mobility, ulceration or severe pruritus SC-mouth Mouth Score &-mouth-gr Not due to chronic GVHD No symptoms 5C-mouth Ind Not done Mild symptoms with disease signs but not limiting oral intake significantly Moderate symptoms with signs with partial limitation of oral **DEMO** intake Severe symptoms with disease signs on examination with major limitation of oral intake 5C-G1 **GI Tract Score** Not due to chronic GVHD No symptoms

SC-gi-ra	1	1
00-3,1-13	Not done	Symptoms such as dysphagia, anorexia, nausea, vomiting, abdominal pain or diarrhea without significant weight loss (<5%)
		Symptoms associated with mild to moderate weight loss (5-15%)
		Symptoms associated with significant weight loss (>15%), requires nutritional supplement for most calorie needs OR esophageal dilation
	Eye Score SC-eye	
5c-eye-gv 5c-eye-nd	Not due to chronic GVHD	ি No symptoms
oc_eye_na	Not done	Mild dry eye symptoms not affecting ADL (requiring eye drops <3x per day) OR asymptomatic signs of keratoconjunctivitis sicca
		Moderate dry eye symptoms partially affecting ADL (requiring eye drops >3x per day or punctual plugs) WITHOUT vision impairment
		Severe dry eye symptoms significantly affecting ADL (special eyewear to relieve pain) OR unable to work because of ocular symptoms OR loss of vision caused by kerato-conjunctivitis sicca
	Joints and Fascia Score 56	-joint
sc-joint-gr sc-joint-nd	Not due to chronic GVHD	No symptoms
30-joint nd	Not done	Mild tightness of arms or legs, normal or mild decreased range of motion (ROM) AND not affecting ADL
		Tightness of arms or legs OR joint contractures, erythema thought due to fasciitis, moderate decrease ROM AND mild to moderate limitation of ADL
		Contracture WITH significant decrease of ROM AND significant limitation of ADL (unable to tie shoes, button shirts, dress self etc.)
	•	genital
<i>SC_genital_</i> n	No GYN Exam	No symptoms
		Symptomatic with mild distinct signs on exam AND no effect on coitus and minimal discomfort with GYN exam
		Symptomatic with distinct signs on exam AND with mild dyspareunia or discomfort with GYN exam
		Symptomatic WITH advanced signs (stricture, labia agglutination or severe ulceration) AND severe pain with coitus or inability to insert vaginal spectrum
	Lung Score SC_lung	
5c_lung-gr 5c_lung-nd	Not due to chronic GVHD	No symptoms
se_lung_ind	Not done	Mild symptoms (shortness of breath after climbing one flight of steps)
		Moderate symptoms (shortness of breath after walking on flat ground)
	I	

		Severe symptoms (shortness of breath at i	rest; requiring O2)	
	Performance Score 50	c-perf		
	○ KPS	Asymptomatic and fully active (ECOG 0; KI	PS or LPS 100%)	
	© ECOG	Symptomatic, fully ambulatory, restricted of strenuous activity (ECOG 1, KPS or LPS 80-90%)		
Λ.	○ LPS	Symptomatic, ambulatory, capable of self- waking hours out of bed (ECOG 2, KPS or LPS 6		
5c-perf-nd	Not done	Symptomatic, limited self-care, >50% of w bed (ECOG 3-4, KPS or LPS <60%)	vaking hours in	
3.	Clinical Skin Features			
Clinical		Nail involvement Sclerosis-Clinicals Kin Features Nail involvement Sclerosis-Clinicals Kin Features Nail involve ensapri Seasciitis Clinicals Kin Features Hair involve	nicalskin Features. nicalskin Feature	-sclcrosis es - Fasciiti
4.	Please rate the severity of			
1D_5ev_mi	on this scale	None (1) Mild (2) Moderate (3)	Severe (4)	
UD-5ev O	and on this scale (select one)	cGVHD Symptoms are not at all severe (0)	cGVHD Symptoms are most severe possible (10)	
		00 01 02 03 04 05 06 07	8 7 9 7 10	l
5.	Does this person currently	have: GVHD_current		
	Late acute GVHD (1)		; ;	
	Overlap acute and chro	onic GVHD (2)		
	Classic chronic GVHD ((3)		
	No GVHD (0)	70° (170) (1		
6.	Infection J_inf			
	🤊 0 - None			
	1 - Mild, topical or no t	herapy required		
	2 - Moderate, localized	, requiring oral treatment J_inf_1D		
	3 - Severe, systemic in hospitalization	fection requiring IV anti-infective, mold-active oral	antifungal or	
	4 - Life-threatening inf	ection		
			,	

For 2-4:	0 Unide	ing lab rep entified org tified organ	anism (2)			
	If Identifie	ed organisn	n(3), specify:			Jinfe
Clinical Manifesta	ntions or Se	vere Comp	lications	***************************************		
1. Pleural Effusion	n(s) CMI	Never	Past, not now	Mild	Moderate	Severe
2. Bronchiolitis ob	oliterans	Never	Past, not now	○ Mild	Moderate	Severe
3. Bronchiolitis ob organizing pneum	oliterans onia 0/4/3	Never	Past, not now	் Mild	Moderate	Severe
4. Nephrotic synd	rome M4	Never	Past, not now	· Mild	Moderate	Severe
5. Malabsorption	M5	Never	Past, not now	⊕ Mild	Moderate	Severe
6. Esophageal stri		Never	Past, not now	Mild	Moderate	Severe
7. Ascites (serosit	is) CM 7	Never	Past, not now	□ Mild	Moderate	Severe
8. Myasthenia Gra	avis M8	Never	Past, not now	ା Mild	் Moderate	Severe
9. Peripheral Neu	ropathy MQ	ि Never	Past, not now	⊕ Mild	Moderate	Severe
L0. Polymyositis	Mio	Never	Past, not now	· Mild	Moderate	Severe
l.1. Pericardial Effu		Never	Past, not now	Mild	Moderate	Severe
ا2. Cardiomyopath آ/	NIZ.	Never	Past, not now	ं Mild	Moderate	Severe
3. Cardiac conduc		Never	Past, not now	Mild	Moderate	Severe
14. Coronary arter nvolvement じ	y Mit	े Never	Past, not now	் Mild	Moderate	Severe
.5. Other, please s	specify:	0 Never	Past, not now	Mild	Moderate	Severe
	5 oth 5	pec ►] 1 • 64	I ► I		

Protocol # 6501 - Longitudinal Study of Immune Mediated Disorders after Alloge...

Participant ID	124250	Date of Registration	22 Aug 2013
Local ID	0101200	Date of Baseline Exam	21 May 2013
Status	Eligible		
Site ID	Fred Hutchinson Cancer Res	earch Center (cGV	HD)

S	Sclerosis, Fasciitis, BOS Capture $\rho 650(-20282-506)$
	* These fields are required in order to SAVE the form
	* These fields are required in order to COMPLETE the form
Date of Visit:	<u>Date</u>
Interviewer User ID:*	
	vith BOS on this study visit or anytime between this
study visit and the last study visi	it? Diagnosed With BOS Yes No
	onchiolitis Obliterans Syndrome Diagnosis: 805 Dt
Please cor	nsider this person for participation in 6503.
2a. Was this person diagnosed v	vith cutaneous sclerosis on this study visit or
anytime between this study visit	and the last study visit? With Sclerools Yes No
2b. If yes, what is the date of Co	With Sclerosis With Sclerosis Diagnosis: Sclerosis Dt D Sclerosis Dt M Sclerosis Dt M Sclerosis Dt Y with fasciitis on this study visit or anytime between
Please cor	nsider this person for participation in 6502.
3a. Was this person diagnosed v	vith fasciitis on this study visit or anytime between
this study visit and the last study Diag	y visit? Yes No
3b. If yes, what is the date of Fa	asciitis Diagnosis: Fascii tis Dt MM
Please cor	nsider this person for participation in 6502.

Close Window

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6/26/2014 10:56 AM

Protocol # 6501 - Longitudinal Study of Immune Mediated Disorders after Alloge...

Participant ID	101106	Date of Registration	26 Nov 2013
Local ID	0101100	Date of Baseline Exam	26 Sep 2013
Status	Eligible		
Site ID	Fred Hutchinson Cancer Res	earch Center (cGV	HD)

Participant Status Form ind_17919-patientstat-rensed

		* These fields are required in ord	er to SAVE the form
	* *	These fields are required in order to	COMPLETE the form
Date of Visit:*	<u>Date</u>		
Interviewer User ID:*	User ID is requ	uired	
1. Date of last contact or most	recent medical note	DOLC DD DOLC MM DOLC YY	
2. Select all events that have o	ccurred to date:	DOLC-AA	
Patient was never tra	nsplanted Event_1	NoTX	
Graft loss Event_	Graft		Graft_DD Graft_MM
O DLI Event_DLI			Graft-YY DLI-UD, DLI-
Additional stem cell t	ransplant Event_	add-SCT	DLI_YY
Relapse Event-1	lel		Add-SCT-DI Add-SCT-M Add-SCT-Y
Death Event_D	eath		Rel-DD, Rel- Rel-XY
Cause of Death COL	י י		(())
None of the above h	as occured. Event_	-None	
Patient is alive (confir	med within past 6 mo	onths) Event_Alive	

Save Print

Close Window

Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

	Date of	
22600	Registration	23 Jun 2014
201020		
igible		
red Hutchinson Cancer Res	search Center (cGV	HD)
matinib Dose: 200 mg PO (-19)	daily (Age > 19) or	130 mg/m2 PO daily (Age
3 Jun 2014	Treatment Start Date	26 Jun 2014
	igible red Hutchinson Cancer Res natinib Dose: 200 mg PO (igible red Hutchinson Cancer Research Center (cGV natinib Dose: 200 mg PO daily (Age > 19) or 19)

Treatment Start Date treatment table - vensed

* These fields are required in order to SAVE the form

* These fields are required in order to COMPLETE the form

Date of Visit:

* 25 Jun 2014 Date

Interviewer User ID:

* 4442

Note: By updating the treatment start date, you will change all of the due date windows for the follow-up visits. Please verify the participant's treatment start date before proceeding.

Date treatment started: * 26 Jun 2014 Date treatment_Start_date

Save Print Close Window

treatment name = matrib or vitiximab

Protoco 4#6501 - Longitudinal Study of Immune Mediated Disorders after Alloge...

Protocol#6501 -	Longitudinai Stud	y of minimic integrated a	
Participant ID	101106	Date of Registration	26 Nov 2013
Local ID	0101100	Date of Baseline Exam	26 Sep 2013
	Eligible		
Site ID	Fred Hutchinson Ca	ncer Research Center (cGV	HD)

Demographics _ revised

	Demographics
	* These fields are required in order to SAVE the form
	* These fields are required in order to COMPLETE the form
Date of Visit:* Da	te
	ser ID is required
1. Participant Age (either Date of Birt	th or Age is required, use Date of Birth unless disallowed by
your local institution's IRB):	date of borth day
Date of Birt	th: dob (date of birth day date of birth month day)
Age at registration	on: age at regretration
2. Gender:*	on: Male Female gender GAGE CHARLETTERS
3. Race (check all that apply): *	O. I American Indian or Alaska Native
	Asian Mul-asian
	Black or African American Vacl black or African
race_nativeHlorpauticiskin	Native Hawaiian or Other Pacific Islander
•	White VALL-WWR
	Unknown race_unlenous anotreported
	Refused race_refused
4. Ethnicity (select one): *	Hispanic, Latino, or Spanish origin
, (55.55)	Not Hispanic,Latino or Spanish origin
	Unknown or not reported
	Refused.
 EMO	I WI WAR

1 of 2

Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

7010coi # 0502 =	A Randonnized Frasc II 5	tudy of finatime	W110 1 111000
Participant ID	121393	Date of Registration	11 Mar 2013
Local ID	0201011		
Status	Eligible		
Site ID	Fred Hutchinson Cancer Res	earch Center (cGV	HD)
Treatment	Rituximab Dose: 375 mg/m2	2 IV weekly x 4	-
Treatment Assign Date	11 Mar 2013	Treatment Start Date	20 Mar 2013

Baseline Visit Chart Abstraction

BL_Visit_chart_Abstraction Page: 1 of 2

	1 > • •
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* These fields are required in order to SAVE the form All questions should be filled out for eCRF to be "COMPLETE" in tracking system 2013 Date Date of Visit:* 8 Mar Interviewer User ID:* 2970

TR	ANSPLANT CHARAC	TER	ISTICS		Tx-DD
1.	Date of transplant:	22	Feb	2011	TX-DD TX-MM TX-YY

TX-YY

HT-pre, HT-unit unknown HT-pre-unk Height 172 cm pre-transplant:

WT-pre, WT_Unit a Unknown WT-pre_Unk Weight 77.3 pre-transplant:

	4.	Disease Status	Early	Intermediate	Advanced
Dis-status.	AMA	· AML	CR1.	CR2	CR3+, rel, ref, IF
nis status.	ALL	ALL	CR1	CR2	CR3+, rel, ref, IF
013-5/21/113	5 - CA	1L CML	° CP	· AP	BC or after BC
D15_3 talus				CR, PR, CS	Rel, ref, CI
Dis-status			RA, RARS	RAEB, RAEBT	Rel, ref, IF
Dis-spatu	5-M	PD MPD		All others	Rel, ref, IF
715-statu	ł.			° CR, PR, CS	Rel, ref, CI
DIX STATE	15_ H	D HD		CR, PR, CS	Rel, ref, CI
DIS-Statu	15_M	U MM		CR, PR, CS	Rel, ref, CI
015-31414	1	AA AA	Without ATG/TG	With ATG/TG	

s-status	ot	n Othe	er	Eai (no	rly on-malig	ınant)	Interm (CR, PR		Adv. (Rel, ref, CI)
-	1	Other, s	pecify	Dis	_stal	V3-	oth -sp	oec_	
	5.	Transplant :		° Pe	eripheral	Blood	Bone M	arrow Co	ord Blood
	6.	Transplant		М	yeloabla	itive	Not myelo (non-myel	ablative oablative or	reduced intensity)
	7.	Recipient C Antibodies	мv _ <i>СМV</i>		es ° N	lo I	(ndetermina	te Not te	
	8.	Hepatitis			active	• Not	performed	Nonreact	ive HepB_SAB
		Hepatitis	B sAg	Re	active	Not	performed	• Nonreact	tive $HepB-5AB$ tive $HepB-5AG$ tive $HepB-CAB$
		Hepatitis	B cAb	Re	eactive	Not	performed	• Nonreac	tive HepB-CAB
		Hepatitis	С	Re	eactive	Not	performed	• Nonreac	2 0
HI A		HLA	Not	tested			one or more gen mm	ALEXANDER OF THE PROPERTY OF T	P Matched
		HLH		14	IISITIALCI	ieu at c	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	IOCI	
HLA_	A	L		tested HL4A		Antig		Allele mm	• Matched • Matched
HLA-	A B	L	⊖ Not	tested HLAA tested HLAB tested	-nd -nd	Antig Antig	gen mm	Allele mm	
HLA- HLA- HLA-	A B	L	Not Not	tested HLAA tested HLAB tested HLAB tested	-nei -nd -nd	Antig Antig	gen mm	Allele mm Allele mm	• Matched
HLA- HLA- HLA-	A B C DRB	A B C DRB1	Not Not Not Not	tested tested tested tested HLAG tested ADRGI	-nd -nd -nd	Antig Antig Antig Antig	gen mm gen mm gen mm	Allele mm Allele mm	MatchedMatchedMatched
HLA- HLA- HLA- HLA- HLA-	A B C DRB DQ PP	L	Not Not Not Not Not Not Not	tested HLAA tested HLAG tested ADGG tested LADG	and and and and	Antig Antig Antig Antig	gen mm gen mm gen mm	Allele mm Allele mm Allele mm	MatchedMatchedMatched
HLA- HLA- HLA- HLA- HLA-	A B C DRB DQ - pP	A B C DRB1 DQ DP	Not Not Not Not Not Not Not Not	tested HLAB tested HLAB tested HLAC tested LADC tested	and and and and	Antig Antig Antig Antig	gen mm gen mm gen mm gen mm gen mm	Allele mm Allele mm Allele mm Allele mm Allele mm Allele mm	Matched Matched Matched Matched Matched
HLA- HLA- HLA- HLA- HLA-	DQ - PP	A B C DRB1 DQ DP Date of Addingnosis	Not Not Not Not Not Not Not Not Cute GVI	tested HLAB tested HLAC tested ADRGI tested LADR tested	and and and and	Antig Antig Antig Antig Antig	gen mm gen mm gen mm gen mm gen mm gen mm AGI AGI	Allele mm Allele mm Allele mm Allele mm Allele mm	Matched Matched Matched Matched Matched Matched Matched Matched
HLA- HLA- HLA- HLA-	DQ - PP 10.	A B C DRB1 DQ DP Date of Addingnosis	Not Not Not Not Not Not Not Cute GVI	tested HLAB tested HLAC tested ADKGI tested LADC tested	and and and and and	Antig Antig Antig Antig Antig	gen mm gen mm gen mm gen mm gen mm gen mm AGI AGI	Allele mm	Matched
HLA- HLA- HLA- HLA- HLA-	DQ - PP 10.	A B C DRB1 DQ DP Date of Addingnosis	Not Not Not Not Not Not Not Cute GVI	tested HLAA tested HLAC tested ADREI tested LADR tested LADR Tested	and	Antig Antig Antig Antig Antig	gen mm gen mm gen mm gen mm gen mm gen mm AGI AGI	Allele mm	Matched Matched Matched Matched Matched Matched Matched More GVHD AVGI Unknown AVGII-U
HLA- HLA- HLA- HLA- HLA-	DQ - PP 10.	A B C DRB1 DQ DP Date of Ac Diagnosis Overall	Not Not Not Not Not Not H Not H O Not	tested HLAA tested HLAC tested ADREI tested LADR tested LADR Tested	and	Antig Antig Antig Antig Antig	gen mm gen mm gen mm gen mm gen mm AGI AGI AGI	Allele mm	Matched Matched Matched Matched Matched Matched Matched More GVHD AVGI Unknown AVGII-U

12. Conditioning Regimen

	Code regimen		Modifier 1	Modifier 2
21	TX_CODE#	4	TX-MOD#	TX_MOL
				# TO SECOND SECO
	ANNE METTER NE 118 des nécestros en la meso en en en estados en estados en estados en estados en entre en esta			
		./-//- != \$ \$! \$ \$ = = \ \ •		
		***********************	1000	

- 13. T-cell Depletion? Tcell
- Yes O No
- 14. GVHD prophylaxis (please complete the IMD medication form)

DONOR CHARACTERISTICS

15. Age of Donor DAC- 29e 39

years

Unknown Dnr_age_unk

- 16. Donor Gender (choose 2 genders if double cord) Dnr_gen
- Male

Female

Female/Female

Male/Male

Male/Female

17. Donor Match

HLA identical sibling

10nr-match

HLA-matched other relative

HLA-mismatched relative (single antigen or allele mismatched)

Haplo-identical relative (2 or more antigen or allele mismatched)

HLA-mismatched unrelated donor

HLA-matched unrelated donor

18. Donor CMV Antibodies

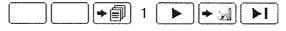
Yes

DRY_ CMV

9: No

Indeterminate

Not tested



Save

Print

Close Window

Protocol #6501 - Longitudinal Study of Immune Mediated Disorders after Alloge...

			\mathcal{C}
Participant ID	129179	Date of Registration	29 May 2014
Local ID	0101245	Date of Baseline Exam	07 Mar 2014
Status	Eligible		
Site ID	Fred Hutchinson Cancer Research Center (cGVHD)		

IMD Onset Form IMD_Onset_Form_revised

			······································			to SAVE the form	- 1
	All questions should be filled out	for eCRF t	o be "COMI	PLETE" in trac	king system		-
Dat	e of IMD Onset: *	<u>Date</u>					7.
Inte	erviewer User ID:*						
СН	ARACTERISTICS OF IMMUNE MEDIA	TE DISO	RDER (e.	g., CHRON	-		
1.	Date of immune mediated disorder onset			<u>Date</u>	IMD_0-1 IMD_0-1 IMD-0-	DD MM VV	
2.	Name of immune mediated disorder	் Late	e, recurren	t or persiste	nt acute GVI		
	IMO_0	ි Chro	onic GVHD	(classic chr	onic or overl	ap)	
		Other immune mediated disorder					
		If Other	, specify:	IMD.O.	-014		
3.	Acute GVHD present the week before immune mediated disorder diagnosis?	ି Yes	ି No ା	Unknown	onset		
4.	Weight $WT_{-}O$		Kgs	WT-	O-UNIT	Unknown	WT_O_UNK
5.	Performance score Parf _ O		% Karno	ofsky KP5.	LP5-0	□ Unknown	Perf_O-unk
6.	Percent BSA BSA - 0		%			[□] Unknown	BSA_O_UNK
7.	Lichen-planus-like changes of skin / i/U-	LO Yes	ି No	ି Unknov	vn		
8.	Sclerotic changes of skin SCL_O	ି Yes	ି No	ି Unknov	vn		
9.	Bronchiolitis obliterans syndrome	ି Yes	ି No	ି Unknov	vn		
10.	Chronic diarrhea DIA_0	ି Yes	ି No	ି Unknov	vn		
11.	Oral involvement ORAL - O	ି Yes	ି No	ି Unknov	vn		
12.	Total bilirubin $Bili = 0$					□ Unknown	Bili-O-UNK
13.	Platelet count PIF_0					□ Unknown	H-O-UNK

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Protocol # 6501 - Longitudinal Study of Immune Mediated Disorders after Alloge...

Participant ID	101106	Date of Registration	26 Nov 2013	
Local ID	0101100	Date of Baseline Exam	26 Sep 2013	
Status	Eligible			
Site ID	Fred Hutchinson Cancer Research Center (cGVHD)			

Lab Results Form Lab-Results_revised

Bands* Bands Lymphocytes* Lym Eosinophils* Eos Platelets* PI+ Liver Function Tests Total billirubin* Bill Direct billirubin* Bill Not Done Bands Lym_unit Lym_unit Not Done Lym_no Not Done Lym_no Not Done Fos_no Not Done PIt - nol LFT_DD LFT_DD LFT_MM LFT_YY Not Done Billind Not Done Astrance		Lad Kesuit	C/	b - Kesulis - Conse	
Date of Visit:* Interviewer User ID:* User ID is required Metabolic Panel Test Name Result Creatinine* CR Result Units Creatinine* CR CR-unit Not Done BUN- nd Glucose* Glu CBC with Differential Not Done Date of Test Test Name CBC-nd Result Units Not Done GR-nd Not Done BUN- nd CBC- MM CBC- Nd Result Units Hematocrit (Hct)* HCT HCT- Unit Not Done HGB- nd Not Done HGB- nd Not Done MBC- nd Not Done MBC- nd Not Done HGB- nd Not Done HGB- nd Not Done Lym- nd Eosinophils* Fos Lym- Unit Eosinophils* Fos Fos- Unit Not Done Fos- nd Not Done Fos- nd Not Done Billi - nd Test Name Total billirubin* Billi Billi - Unit Not Done Billi - nd	All - ··				form
Interviewer User ID:* User ID is required Metabolic Panel Test Name Result Units Creatinine* CR BUN* BUN Glucose* Glu CBC with Differential Test Name Result Units CBC with Differential Test Name CBC with Differential Test Name CBC - nd Result Units Not Done CBC - nd C					
Metabolic Panel Test Name Test Name Creatinine* CR BUN* BUN Glucose* Glu CBC with Differential Test Name CBC with Test Not Done Test Test Name CBC with Test Name CBC with Test Name Not Done Test Test Test Test Test Test Test Tes		<u>Date</u>			
Creatinine* CR CR-unit BUN* BUN BUN BUN BUN BUN Not Done BUN not BuN not Bun Glucose* Glu CBC with Differential Not Done Date of Test Test Name Hemoglobin (Hgb)* HGB Hematocrit (Hct)* HCT WBC* WBC Neutrophils* Neu Bands* Bands Lymphocytes* Lym Eosinophils* Eos Platelets* PIt Liver Function Tests Total billirubin* Billi Direct billirubin* Billi Direct billirubin* Billi Direct billirubin* Billi Billi - unit Not Done CR-nd Result Units Not Done BUN not Not Done BUN not Not Done HGB not Not Done HGB not Not Done WBC not Not Done Neu not Bands* Lym - unit Not Done Lym not Left Direct billirubin* Billi Billi - unit Not Done Billi - nd	Interviewer User ID:*	User ID is requi	red		
Creatinine* CR CR-unit BUN* BUN Glucose* Glu Glucose* Glu Greatinine* CR Glucose* Glu Greatinine* CR BUN* BUN Glucose* Glu Greatinine* CR Greatinine* CR CR-unit Not Done Glucose* Glu Greatinine* CR Greatinine* CR Greatinine* CR CR-unit Not Done Glucose* Glu Not Done Glucose Glucose* Glu Not Done Glucose* Glu Not Done HGB- Not Done Not Don	Metabolic Panel		st	J-Mela-DD Mela-MM	
BUN* BUN BUN_vnit Glucose* Glu CBC with Differential Not Done Date of Test Test Name Result Hemoglobin (Hgb)* HGB Hematocrit (Hct)* HCT WBC* WBC Not Done HGB-nc Not Done Bill - nd	Test Name		Units	Nata yy	
Glucose* Glu Glucose* Glucose* Glucose* Glucose* Glucose* Glucose* Glucose* Glucose* Glucose* Glucose* Glucose* Glucose* Glucose* Glucose* Glucose* Glucose* Glucose* Glucose* Glucose*	Creatinine* CR	CR-U	init	□ Not Done CR -	.nd
Test Name Result Test Name Result Hemoglobin (Hgb)* HqB Hematocrit (Hct)* HcT WBC* WBC Neutrophils* Neu Bands* Bands Lymphocytes* Lym Eosinophils* Eos Platelets* PI+ Liver Function Tests Total bilirubin* Bili Direct bilirubin* Bili	BUN* 13 UN	BUN_	unit	Not Done BUN	_na
Hemoglobin (Hgb)* HGB Hematocrit (Hct)* HCT WBC* WBC Neutrophils* Neu Bands* Bands Lymphocytes* Lym Eosinophils* Eos Platelets* PI+ Liver Function Tests MO Test Name Total bilirubin* Bili Direct bilirubin* Bili Direct bilirubin* Bili AST* AST AST* AST HCT-unit HGB-unit HGB-unit Not Done HGB-no Not Done WBC-no Not Done WBC-no Not Done WBC-no Not Done Bands Lym-no Eos-unit Not Done Eos-no LFT-DD LFT-MM LFT-YY Not Done Bili-nd	Glucose* G 14	G10-1	unit		nd
Hemoglobin (Hgb)* HGB Hematocrit (Hct)* HCT WBC* WBC Neutrophils* Neu Bands* Bands Lymphocytes* Lym Eosinophils* Eos Platelets* PI+ Liver Function Tests MOT Done Result Total billirubin* Billi Direct billirubin* Billi AST* AST Not Done HGB-not HGB-not Not Done HGB-not Not Done HGB-not HGB-not Not Done HGB-not Not Done HGB-not HGB-not Not Done HGB-not HGB-not Not Done HGB-not HGB-not HGB-not Not Done HGB-not HGB-n			st	TCBC-DD	
Hematocrit (Hct)* HCT WBC* WBC Neutrophils* Neu Neutrophils* Neu Bands* Bands Lymphocytes* Lym Eosinophils* Eos Platelets* PI+ Liver Function Tests Test Name Total bilirubin* Bili Direct bilirubin* Bili Not Done HGB-no Not Done WBC-no Not Done Neu-no Not Done Bands Lym-Unit Not Done Lym-no Los-no Not Done Eos-no LFT-DD LFT-MM LFT-YY Not Done Bili-nd	Test Name	1BC-nd Result	Units	CBC-YV	
WBC* WBC Neutrophils* Neu Neu-unit Not Done WBC-ne Not Done Neu-ne Not Done Neu-ne Not Done Bands Lymphocytes* Lym Eosinophils* Eos Platelets* PIt Liver Function Tests Not Done Plate of Test Total bilirubin* Bili Direct bilirubin* Bili Not Done Bili - nd AST* AST Not Done Bili - nd	Hemoglobin (Hgb)* H	4B H	IGB_unit	□ Not Done HGB	- n
Neutrophils* Neu Neu-unit Neu-unit Not Done Neu-ne Neu-unit Not Done Neu-ne Not Done Bands Lymphocytes* Lym Lym-unit Not Done Lym-ne Not Done Lym-ne Not Done Lym-ne Not Done Fos-ne Not Done Fos-ne Not Done PIt-nd Liver Function Tests Not Done Date of Test Units Total bilirubin* Bili Not Done Bili-nd Not Done AST-ne	Hematocrit (Hct)* HC7	- HCT_	unit	□ Not Done H4B	- ŋ(
Neutrophils* Neu Bands* Bands Lymphocytes* Lym Eosinophils* Eos Platelets* PI+ Liver Function Tests Not Done Bands Date of Test Total bilirubin* Bili Direct bilirubin* Bili Not Done Not Done Date of Test Direct bilirubin* Bili Not Done Bili Junit Not Done Not Done Bili Junit Bi	WBC* WBC		•	□ Not Done WBC	-ne
Bands* Bands Bands Unit Not Done Bands Lymphocytes* Lym Eosinophils* Eos Eos Unit Not Done Lym_no Platelets* PI+ PI+ Unit Not Done PI+ not Liver Function Tests Not Done Date of Test Total bilirubin* Bili Direct bilirubin* Bili AST* AST AST AST Not Done AST-not	Neutrophils* Neu	•			
Lymphocytes* Lym Lym - Unit Bosinophils* E05 E05 - Unit Not Done Lym - not Not Done E05 - not Platelets* PI+ Liver Function Tests Not Done Date of Test LFT - DD LFT - MM LFT - MM LFT - YY Direct bilirubin* Bili Not Done Bili - not Not Done AST - not Not Done AST - not	Bands* Bands	•		1 Not Done Band	15
Platelets* PI+ PIL Unit Not Done PIT - nd Liver Function Tests Not Done Date of Test Test Name Test Name Total bilirubin* Bili Direct bilirubin* Bili AST* AST Not Done Bili - nd	Lymphocytes* Lym			13 Not Done Lym	_n
Liver Function Tests Not Done Date of Test Test Name Result Units Total bilirubin* Bili Direct bilirubin* Bili AST* AST AST-Unit Total Direct Done Date of Test TLFT_DD LFT_MM LFT_YY Not Done Bili - nd Not Done Bili D- n	Eosinophils* EoS	E05-	-unit	Not Done Eos.	-ne
Test Name Result Units Total bilirubin* Bili Direct bilirubin* Bili AST* AST AST-Unit Direct Name LFT-MM LFT-YY Not Done Bili-nd Not Done Bili-nd Not Done Bili-nd Not Done AST-name	Platelets* PI+	PIL	. unit	□ Not Done P/+	- nd
Total bilirubin* Bili Direct bilirubin* Bili AST* AST AST-Unit Not Done Bili - nd Not Done Bili D- n	Liver Function Tests	Not Done Date of Tes	t	7 LFT_ DD	
Direct bilirubin* BiliD BiliD unit Not Done BiliD n AST* AST AST AST Not Done AST no	Test Name	Result	Units	LFT_YY	
Direct bilirubin* BiliD BiliD unit Not Done BiliD n AST* AST AST AST Not Done AST no	Total bilirubin* Bili	Bili - unin		Not Done Bili.	nd
	Direct bilirubin* BiliD	Bilib. uni	t		l l
ALT_UNIT Not Done ALT_N	AST* AST	AST_unit	-	□ Not Done AST-	-ng
	ALT* ALT	ALT_Unit	اسا	Not Done ALT	.nd

Alkaline Phosphatase* ALP Albumin*

ALB

ALK - unit ALB-unit

Not Done ALK_nd
Not Done ALB_nd

Save

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Protoce 6501 - Longitudinal Study of Immune Mediated Disorders after Alloge... Date of Participant ID 101106 26 Nov 2013 Registration Date of Local ID 0101100 **Baseline Exam** Status Eligible Site ID Fred Hutchinson Cancer Research Center (cGVHD) IMD_ medications_revised **IMD Medication Form** * These fields are required in order to SAVE the form All fields should be filled out for each Medication for eCRF to be "COMPLETE" in tracking system Date of Visit: Date Interviewer User ID:* User ID is required Medication Indication IMD_Med_Start Taking? **RxNorm Code** Search term IMD_ Med# IMD_Med_Code# Chronic Acute Prophylaxis Unknown Other
Y
N Code Add Save Print Close Window IMD Med-Start_DD# indication_chronic# IMD_ Med-Stat_ MM# indication-acute #indication-prophylaxi8#

mdication-unknown#
indication-other# #=1-32 IND_ med_Start_ YY # IMD-med-Stop-DD# IMD-med-Stop-MM#

DEMO

IMD_med_stop-YY #

Protocol #6501 - Longitudinal Study of Immune Mediated Disorders after Alloge...

	<u> </u>		
Participant ID	101106	Date of Registration	26 Nov 2013
Local ID	0101100	Date of Baseline Exam	26 Sep 2013
Status	Eligible		
Site ID	Fred Hutchinson Cancer Research Center (cGVHD)		

Comorbidities CoMorbidities_revised

	0
	* These fields are required in order to SAVE the form
All questions sho	ould be filled out for eCRF to be "COMPLETE" in tracking system
Date of Visit:*	Date
Interviewer User ID:*	User ID is required

Comorbidity	Definition	Present
1. CARDIOVASCULAR		
Arrhythmia* CMI3_ARR	Atrial fibrillation or flutter, sick sinus syndrome or ventricular arrhythmias	OY ON OU
Coronary artery disease	Coronary artery disease (one or more vessel- coronary artery stenosis requiring medical treatment, stent, or bypass graft), angina	Y ON D
History of MI CMB - Mi	History of myocardial infarction	Y AN OU
Heart valve disease £MBHVD	Except asymptomatic mitral valve prolapse	OY MN WU
Hypertension <u>CMB_HTN</u>		OY ON OU
Congestive heart failure	EF ≤ 50%	OY ON OU
Cerebrovascular disease	Transient ischemic attack or history of cerebrovascular accident, or neurologic impairment consequent to CVA	Y 'N EU
Peripheral vascular disease (M/3 — I ² VD		ay an au
ous thrombosis	Confirmed radiographically and requiring anticoagulation	OY ON OU
2. GASTROINTESTINAL		
Peptic ulcer/hernia /reflux CMB_ULC	Requiring treatment	OY ON OU

Mild hepatic CMB_HEPM	Chronic hepatitis, bilirubin > ULN to 1.5 X ULN, or AST/ALT > ULN to 2.5 X ULN	Y N DU
Moderate/severe hepatic <u>CMB_ HEPS</u>	Liver cirrhosis, bilirubin > 1.5 times ULN or AST/ALT > 2.5 ULN	$\oplus \ A \oplus M \oplus \Omega$
Inflammatory bowel disease	Crohn's disease or ulcerative colitis	*Y ON SU
3. PULMONARY		
Moderate pulmonary CMB_PULMM	DLCO and/or FEV-1 66%-80% or dyspnea on slight activity	OY ON NOU
Severe pulmonary (MI3 PULM5	DLCO and/or FEV-1 65% or lower or dyspnea at rest or requiring oxygen	5 Y> N U
Asthma CMB-AST	Asthma symptoms for which inhaled steroids or other daily treatments are needed chronically to prevent or manage attacks	OY ON OU
4. ENDOCRINE		A STATE OF THE STA
Diabetes CMB - DB	Requiring treatment with insulin or oral hypoglycemic agents but not diet alone	PY PN PU
Hypothyroidism CMB_I-IT	Including compensated hypothyroidism	SY ON OU
Adrenal Insufficiency CMB_AL	Including compensated adrenal insufficiency	YAN TU
5. NEUROPSYCHIATRIC		
Psychiatric disturbance- Depression CMB_DEP	Depression requiring psychiatric consult or treatment	OY ON OU
Psychiatric disturbance- Anxiety or panic disorder CMi3_ANX	Anxiety or panic disorder requiring psychiatric consult or treatment	oy on ou
Neurologic disease (peripheral neuropathy, MS, Parkinson's disease or other chronic neurologic disease CMB-ND	Symptomatic and requiring treatment to control or manage symptoms/disease process	AYAN AU
Visual impairment secondary to cataracts, glaucoma or macular degeneration	Unilateral or bilateral, and unrepaired	OY ON OU
Hearing impairment <i>CMB_iEAR</i>	Very hard of hearing, even with hearing aids	OY ON OU

		
Osteoarthritis	Symptomatic and requiring treatment or with osteoarthritic changes noted on radiographic studies	°Y °N ∾U
Degenerative disc disease (spinal stenosis or severe chronic back pain) CMB_DISC	Symptomatic and requiring treatment or symptomatic and with degenerative disc disease noted on radiographic studies	oy on ou
Avascular necrosis CMB_AVN	Symptomatic with pain secondary to AVN or joint replacement	OYONOU
Osteopenia/Osteoporosis	T Score < or equal to minus 1.5 or on treatment with a bisphosphonate	OY ON OU
Rheumatologic <u>CMB_RA</u>	Lupus, mixed connective tissue disorder, rheumatoid arthritis, polymyalgia rheumatica	m Y M N O U
7. OTHER COMORBIDITIE	S	
Infection CMB_INFX	Requiring current treatment with antimicrobial (not prophylaxis)	ay Yan Naha
Moderate/severe renal	Serum creatinine > 2 mg/dL, on dialysis, or prior renal transplantation	OY ON OU
Prior solid malignancy	Treated at any time point in the patient's past history, excluding nonmelanoma skin cancer	OY ON OU
8. PHYSICAL EXAM - Anth	ropometry	
Height Weight	HT_CMB_em HT_CMB_in cm in WT_CMB_kg WT_CMB_1b kg lbs	HT_CMB- ne Not Done WT_CMB-で Not Done

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Protocol # 6501 - Longitudinal Study of Immune Mediated Disorders after Alloge...

Participant ID	101106	Date of Registration	26 Nov 2013
Local ID	0101100	Date of Baseline Exam	26 Sep 2013
Status	s Eligible Fred Hutchinson Cancer Research Center (cGVHD)		
Site ID			

Medication-Steroids Form imd_13174_medications_verised

	11104
	* These fields are required in order to SAVE the form
All fields should be filled	out for each Medication for eCRF to be "COMPLETE" in tracking system
Date of Visit:*	<u>Date</u>
Interviewer User ID:*	User ID is required

Patient is not on any steroids

Medication

Dose
Units
Frequency
Route
Search term
RxNorm Code
SFer_Dose# (mg,ml)

Ster_Freq # (PO,IV)

Code IMD_Med # IMD_Med_Code#

Ster_Units#

Ster_Vnits#

Ster_Route#

Save Print Close Window

DEMO

RARE DISEASES CLINICAL RESEARCH NETWORK TO SEASON NATIONAL Institutes of Health	Specimen Collection –Aliquots Sampling Form	24May2012 Version 1.1 Page 1 of 3
Protocol Number:6502Site:	Participant ID:	
Person Completing Form:	research - labs-revised	

drannode = site

Specimen Name	Barcode Number	Box Number	Insufficient Volume	Volume	Cell Count	Location in Box	Comments
NMDP PBMC aliquots – Tube 1				mL	x10 ⁶		
NMDP PBMC aliquots – Tube 2				mL	x10 ⁶		
NMDP PBMC aliquots – Tube 3				mL	x10 ⁶		
NMDP PBMC aliquots – Tube 4				mL	x10 ⁶		
NMDP PBMC aliquots – Tube 5				mL	x10 ⁶		
NMDP PBMC aliquots – Tube 6				mL	x10 ⁶		
NMDP PBMC aliquots – Tube 7				mL	x10 ⁶		
NMDP PBMC aliquots – Tube 8				mL	x10 ⁶		
NMDP Heparin Plasma aliquots – Tube 1				mL	x10 ⁶		
NMDP Heparin Plasma aliquots – Tube 2				mL	x10 ⁶		

alicant Lane.	alianot barcode	box	insufficient_	Volume Cell-count	box-loc	Comment S
and and singles	D	,	Vol	cell-cont		

Status = tube broken

delayed processing

hemoly zed

low cell count

RARE DISEASES CLINICAL RESEARCH NETWORK Mattheward Institutes of Health	Specimen Collection –Aliquots Sampling Form	24May2012 Version 1.1 Page 2 of 3
Protocol Number:6502 Site: Person Completing Form:	Participant ID:	

NMDP Heparin	T		
Plasma aliquots –	mL	$x10^{6}$	
Tube 3			
NMDP Heparin			
Plasma aliquots –	mL	$x10^{6}$	
Tube 4			
NMDP Heparin			
Plasma aliquots –	mL	$x10^{6}$	
Tube 5			
NMDP Heparin			
Plasma aliquots –	mL	$x10^{6}$	
Tube 6			
NMDP Heparin		,	
Plasma aliquots –	mL	$x10^{6}$	
Tube 7			
NMDP Heparin		6	
Plasma aliquots –	mL	$x10^{6}$	
Tube 8			
NMDP Heparin		6	
Plasma aliquots –	mL	$x10^{6}$	
Tube 9			
NMDP Heparin		. 6	
Plasma aliquots –	mL	$x10^{6}$	
Tube 10			
NMDP Heparin	_	6	
Plasma aliquots –	mL	$x10^{6}$	
Tube 11			
Miklos Heparin	Į	1.06	
Plasma aliquots –	mL	$x10^{6}$	
Tube 1			
UNC EDTA Plasma	and T	$x10^{6}$	
aliquots – Tube 1	mL	X10	

RARE DISEASES CLINICAL RESEARCH NETWORK POSICES IN National Institutes of Health	24May2012 Version 1.1 Page 3 of 3		
Protocol Number:6502 Site:	 Participant ID: _		
Person Completing Form:			
UNC EDTA Plasma aliquots – Tube 2	mL	x10 ⁶	
UNC EDTA Plasma aliquots – Tube 3	mL	x10 ⁶	
UNC EDTA Plasma aliquots – Tube 4	mL	x10 ⁶	

		Par	ticipant IC	129841		Date of Registration	23 Jun 2014	,				
			Local II	0201020		Registration						
			Statu	Eligible								
			Site II	Fred Hutchins	on Cancer Resear	ch Center (cGVI	HD)		200	other	3mor	HAS井
			Treatmen	2-19)	e: 200 mg PO daily		•		1410	MC I FINA	, -	
		Treatm	ent Assigr Date	23 Jun 2014	٦	reatment Start Date	26 Jun 2014	,				
				C	oncomitant M			mitant.				1
		 			* Th	a comment of the second of the second	5	order to SAVE the to COMPLETE the			Co	an contin
		Date of Visi	t:	x	Date				·····			
		Interviewer	User ID	:*								
Assess Date	Medication	D	ose	Units	Frequency	Route		Indicatio	n	Start Date	>3 months	Continuin ?
	Search term/RxNorm Co	de		(mg,ml)	(BID,TID)	(PO,IV,etc.)) S	earch term/SNC	MED Code	Ducc	since	
5DD#	Code					Conrou	1c#	<u> </u>	Code		prescriber	OY N
XX #	Con Rmed#		í	1	Confreq			Smcai#	/			
: Add	ConReade#					N Mr. d	COX	15code	t			
	commune.		!	Sav	ve Print (lose Window	()		Const Const	n Sta	of DD	林
		Can	Dosc	· HŁ						MIC IV	. IL	
		CON	17000						Const	-crtmm	144	ifno,
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Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

Participant ID	121393	Date of Registration	11 Mar 2013
Local ID	0201011		
Status	Eligible		
Site ID	Fred Hutchinson Cancer Res	earch Center (cGV	HD)
Treatment	Rituximab Dose: 375 mg/m2	2 IV weekly x 4	POWER THE PROPERTY OF THE PROP
Treatment Assign Date	11 Mar 2013	Treatment Start Date	20 Mar 2013

Provider Survey Enrollment

Provider_Survey

* These fields are required in order to SAVE the form

Page:	1	of 8	
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Pate of Visit:*	<u>Dat</u>	e		
nterviewer User ID:*	Use	er ID is required		
Date completed:	, g ₁ , g ₂ , g ₃ g ₄	MD_compl -	DD, MD-com	1PI-MM, MD-0
SKIN				
1.			,	
Check ONE area of the body as the sentinel lesion		Erythematous rash of any sort	Moveable sclerosis	Non-moveable subcutaneous sclerosis or fasciitis
1. Head/neck/scalp 5L1_1	.: -)	Eskin1%	Mskin1%	Fokin1%
2. Anterior torso SL1_2	:1	Eskin2%	Mskin2%	F3kin2%
3. Posterior torso SL1_3	3	E3kin3 [%]	Mskin3°	F5kin3%
4. Left upper extremity		Eskin4%	Mskinto	F5Kin4%
5. Right upper extremity 51.1.5	(*)	Eskin5°	Mskin5°	Fskin5%
6. Left lower extremity, (incl. L buttock) SL1_6	: 1	Eskin6	Uskin6	Eskin6
7. Right lower extremity, (incl. R buttock) SL1_7		Eskin7°	Uskin7	Fskin7"
8. Genitalia Not examined		Eskin8%	Mskin'8	Eskin8%

3L1_8 Gen_B3A

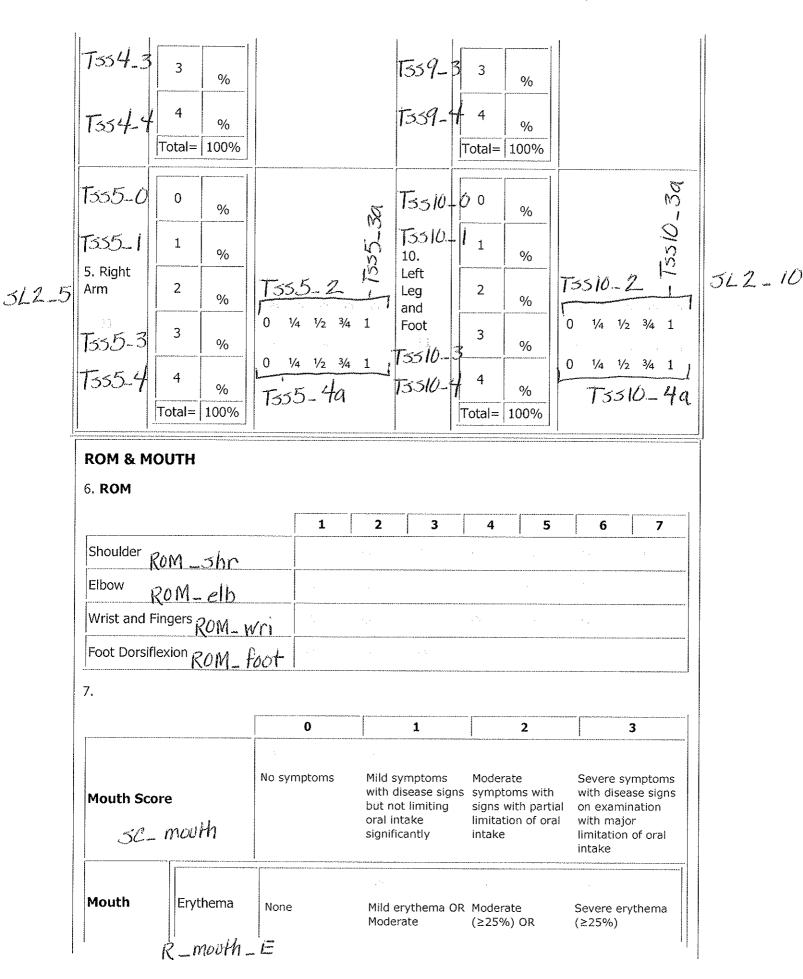
	0	1		2	3		4
kin sclerotic hanges しっぷばれ	Normal	Thickened wit pockets of normal skin	h Thicke majori skin		Thickened, unable to move		lidebound, inable to pincl
		And primarily defined a standard bandle had a fact of the desirable data company to company to the standard data company to the stan					
	0	1			2		3
in Score SC_5KiN	No symptoms	< 18% BSA w disease signs sclerotic featu	but NO in sires significant for the significan	uperficial eatures "r	nt with sclerotic not " (able to	sclerot "hideb to pind impair	ed mobility, tion or severe
cia _fascia	Normal	Tight with nor areas	mal T	ïght		Tight, move	unable to
		Clinical Skin F	onturoc		THE PROPERTY OF THE PROPERTY OF THE PARTY OF	******************	
Icer				· · · · · · · · · · · · · · · · · · ·			
Jlcer Locatio	0.1001 = 100			ion (cm)		.52	
	rash MPrash		Keratos	is pilaris	Kpil	4.1	
Lichen planus-li	ke lesions Lich	:	Papulos	quamou	s lesions o	r icthy	osis 1cH
Poikiloderma	Poik		Hair inv	olvemen	t Hair	~	Committee of the second
Pruritus	Prur	: ;	Nail inv	olvement		00000 ATOCS 14 TO FASTE A ST	
Other, specify:	Othskin, O	thain apec	Other,	specify:		an 2	, Othski

5.								
Region	Grade	% Area of Grade	Fraction of Grade 3 or 4 Areas with Erythema (indicate up to what fraction is involved)	Region	Grade	% Area of Grade	Fraction of Grade 3 or 4 Areas with Erythema (indicate up to what fraction is involved)	
1. Head, Neck and Scalp	0 T <i>5</i> 51	% -0		6. Right Hand	0 T55	% 6-0		JL2-0

562-

2 of 9

	•					
	T351_1 T351_2 T331-3 T351_4		T551_3Q 0 1/4 1/2 3/4 1 0 1/4 1/2 3/4 1	T556-1 1 % T556-3 3 % T556-4 4 % Total= 100%	T556_30 0 1/4 1/2 3/4 1 0 1/4 1/2 3/4 1	
512-2	T552-1 2. Chest T552-2 T552-3 T552-4	1 % 2 % 3 %	T552_3a 0 1/4 1/2 3/4 1 0 1/4 1/2 3/4 1 T552_4a		7557-2 0 1/4 1/2 3/4 1 0 1/4 1/2 3/4 1 1557_49	SLZ-7 T357-39
3L2_3	T353_0 T353_1 3. Abdomen and Genitals T353_3	2 %	T553-215 10 1/4 1/2 3/4 1	7358_0 0 % 7358_1 1 % 8.Left Hand 2 % 7358_3 3 % 7558_4 4 % Total= 100%	T358-2 0 1/4 1/2 3/4 1 10 1/4 1/2 3/4 1 T358-49	SLZ-8 T558-3a
SL2-4	7.554-0 4. Back and Buttocks 7.554-2	0 % 1 %	7354-1 19 0 1/4 1/2 3/4 1 0 1/4 1/2 3/4 1 7554-40	7.559-0 0 % Right Leg 1 % Foot 2 % T559-2	T559-1 1 1 0 1/4 1/2 3/4 1 1 T559-49	5L2-9



			erythema (<25%)	Severe erythema (<25%)	
	A 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1				
	Lichenoid	None	Hyperkeratotic changes	Hyperkeratotic changes	Hyperkeratotic changes
	R_mouth	<u> </u>	(<25%)	(25-50%)	(>50%)
			·.		.*
	Ulcers R_movH	None	None	Ulcers involving (≤20%)	Severe ulcerations (>20%)
	Mucoceles (of lower			. :	1
	labia and soft palate	None	1-5 mucoceles	6-10 scattered mucoceles	Over 10 mucoceles
	only) R_m	outh_M			
			*:	n,	+ N
louth Pain J_n	naith	No symptoms	Food sensitivity	Pain requiring narcotics	Unable to eat

GASTROINTESTINAL

8.

		0	1	2	3
			\$		
GI Tract Sco ろと -		No symptoms	Symptoms such as dysphagia, anorexia, nausea, vomiting, abdominal pain or diarrhea without significant weight loss (<5%)	associated with mild to moderate weight loss	Symptoms associated with significant weight loss >15%, requires nutritional supplement for most calorie needs OR esophageal dilation
			· :		
Gastro- intestinal	Esophagus Dysphagia OR Odynophagia K_eso	No esophageal symptoms	Occasional dysphagia or odynophagia with solid food or pills during the past week	Intermittent dysphagia or odynophagia with solid food or pills (but not for liquids or soft foods) during the past week	Dysphagia or odynophagia for almost all oral intake, on almost every day of the past week
	Upper GI Early satiety R_UGI	No symptoms	Mild, occasional	Moderate,	More severe or

OR Anorexia OR Nausea & vomiting		symptoms with little reduction in oral intake during the past week	day, with some reduction in oral	persistent symptoms throughout the day, with marked reduction in oral intake, on almost every day of the past week
Lower GI Diarrhea $R = LGI$	No loose or liquid stools during the past week	Occasional loose or liquid stools, on some days during the past week	Intermittent loose or liquid stools through-out the day, on almost every day of the past week without requiring intervention to prevent or correct volume depletion	Voluminous diarrhea on almost every day of the past week requiring intervention to prevent or correct volume depletion

OTHER ORGANS

9.

	0	1	2	3
Eye Score SC-CYC	No symptoms	Mild dry eye symptoms not affecting ADL (requiring eye drops <3x per day) OR asymptomatic signs of kerato- conjunctivitis sicca	Moderate dry eye symptoms partially affecting ADL (requiring eye drops >3x per day or punctual plugs) WITHOUT vision impairment	
		MANAGEMENT AND		conjunctivitis sicca
		· .		*.
Joints and Fascia Score	No symptoms	Mild tightness of arms or legs, normal or mild decreased range of motion (ROM)	Tightness of arms or legs OR joint contractures, erythema thought due to fasciitis,	Contracture WITH significant decrease of ROM AND significant limitation of ADL
SC-joint		AND not affecting ADL	moderate decrease ROM AND mild to moderate limitation of ADL	(unable to tie shoes, button shirts, dress self etc.)
Genital Tract Score			1	
○ No GYN Exam	No symptoms	Symptomatic with mild distinct signs	Symptomatic with distinct signs on	Symptomatic WITH advanced
3C-genital				

6 of 9

	NB: score still required		on exam AND no effect on coitus and minimal discomfort with GYN exam	exam AND with mild dyspareunia or discomfort with GYN exam	signs (stricture, labia agglutination or severe ulceration) AND severe pain with coitus or inability to insert vaginal spectrum
	Lung Score 5C – lung	No symptoms	Mild symptoms (shortness of breath after climbing one flight of steps)	Moderate symptoms (shortness of breath after walking on flat ground)	Severe symptoms (shortness of breath at rest; requiring O2)
c_oth 11	Other Organ Score, specify: \$\sigma_0 + 1 - spec Other Organ Score,	No effect on ADL	Mild effect on ADL	Moderate effect on ADL	Severe effect on ADL
:-oth 12	Other Organ Score, specify: Sc_o+1 - spec 2 Add Other	No effect on ADL	Mild effect on ADL	Moderate effect on ADL	Severe effect on ADL

OVERALL STATUS

10.

Please rate the severity of this person's GVHD ### AD 561 MM5											
on this scale	None(0)	Mild(1)	Moderate(2)	Severe(3)							
MD_5CV10 and on this scale	cGVHD Symptoms are not at all severe			cGVHI Symptome are mos severe possible							
(select one)	0 1	2 3 4	5 - 6 7	8 9 10							

11.

Reasons for changing therapeutic regimen (c	heck all that apply)
Not applicable, no changes made Rxc hg - No	a Toxicity Richg-tox

- New symptoms Rxchg newsx Adjust levels of medications Rxchg—level
- | Enroll on clinical trial Rxchg-trial | Improvement in symptoms Rxchg-improve | Worsening of symptoms Rxchg-worse | Disease relapse Rxchg-rel | No improvement in symptoms Rxchg-noimprov | Stable Rxchg-stable

12.

Sentinel Organ Response in which rank)	n organ system w	vill guide your trea	itment decisions	(If more than o	one, please
,			If ranked, p	lease provide nu	mber
Skin 50K_	skin				ALL
\Box Joints $50R$					
Fascia 5012	fascia				
□ Lung <i>ろの</i> 尺 _ □ Urogenital ろん	lung OR-genital				
□ Liver <i>30R</i> -	liver				
□ Mouth づりR -					
Esophagus 5	- 4				
□ Lower GI <i>≾0</i> □ Other <i>≾0尺</i> .					
If Other, specify:		ሳ <i>ል</i> ነለ <i>ጋድ</i>			
13.					
Does this persor 名り	HD-curren	+	Classic chror	te and chronic G nic GVHD (3)	VHD (2)
14.					INNOVINO TOTAL TO
Infection	0	1	2	3	4
J-inf					- :
	None	Mild, topical or no therapy required	Moderate, localized, requiring oral treatment	Severe, systemic infection requiring IV	Life-threatening infection
	ł I		J-inf-10	anti-infective, mold-active oral	
		,		antifungal or hospitalization	an.
	For 2-4:		**************************************	~	
	For 2-4:	Pending lab report (1)		hospitalization	

15.

.6.						
Other indicators, clinic	cal manifesta	tions or sev	ere compl	ications re	ated to ch	ronic GVH
		Never (0)	Past, not now (1)	Mild (2)	Moderate (3)	Severe (4
1. Pleural Effusion(s) C	MI					
2. Bronchiolitis obliterans						
3. Bronchiolitis obliterans pneumonia		1 :	:			
4. Nephrotic syndrome	CM4	1.2	-	***************************************		
5. Malabsorption	CM5			* 1		
5. Esophageal stricture o	r web		T s			
7. Ascites (serositis)	CM7		:			
3. Myasthenia Gravis	CM8					
9. Peripheral Neuropathy	CMG		71174/A1444			
.0. Polymyositis	CMID	* .				
1. Pericardial Effusion	CMII					
2. Cardiomyopathy	CM12	· .				
3. Cardiac conduction de	efects M13	13	,	1,4	······································	
4. Coronary artery involv			.',			
5. Other, please specify:	M15-0H	#	7777-7-04-2-04-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-			A
.6. Other, please specify:	CM 15_0th	SPEC#				
7. Other, please specify:	CM15 oth	5pec#		· .		
Add Other			of the Hart Color Color of the	e de la composition		

_______1 **▶** | **▶** | **▶** | **▶** | **▶** | **▶** | **▶** | **▶** | **♦** | **⊘** | **▶** | **♦** | **⊘** | **⊘** | **∀** | **⊘** | **∀** | **⊘** | **∀** | **⊘** | **∀** | **⊘** | **∀** | **⊘** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀** | **∀**

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14.

Since th	e last study	visit three n	nonths ago	on, how would you say this patient's chronic GVHD ha changed?					VHD has
	Not involved (0)	Resolved (1)	Very much better (2)	Moderately better (3)	A little better (4)	About the same (5)	A little worse (6)	Moderately worse (7)	Very much worse (8)
Mouth	0	0	0	0	0	0	0	0	0
Skin	0	0	0	0	0	0 .	0	0	0
Eye \$	0	0	0	0	0	0	0	0	0
Joints	0	0	0	0	0	0	0	0	0
Chronic GVHD(Overall		0	0	0	0	0	0	0	0
Overall What are your reasons for how you rated "chronic GVHD overall"? Write in (For example, has an organ or symptom improved or worsened?)				chg-ve.	NOS				

15.

	0	1	2	3	4
Infection	O None	O Mild, topical or no therapy required	O Moderate, localized, requiring oral treatment	O Severe, systemic infection requiring IV anti-infective, mold-active oral antifungal or hospitalization	O Life- threatening infection
	For 2-4:	O Pending lab report (1)	O Unidentified organis	sm (2) O Identified or	rganism, specify (3):

Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

Participant ID	129841	Date of Registration				
Local ID	0201020					
Status	Eligible					
l .	l .	Fred Hutchinson Cancer Research Center (cGVHD)				
Treatment	Imatinib Dose: 200 mg PO o 2-19)	Imatinib Dose: 200 mg PO daily (Age > 19) or 130 mg/m2 PO daily (Age 2-19)				
Treatment Assign Date	23 Jun 2014	Treatment Start Date	26 Jun 2014			

Patient Survey Enrollment

Patient_Survey

Page: 1 of 16

Date of Visit: *	*		***************************************	Date	Inva	lid Dat	o of V	icit				***************************************
		<u>Date</u> Invalid Date of Visit										
Interviewer User ID:*	k		User I	D is re	quired							
Date completed:)ate n	ot vali	d 							
Section 1: Your Ch	ronic	Graft '	vs. H	ost D	iseas	e (GV	/HD)	Symj	otom	S		
		Not Present										d As You Imagine
1. Your chronic GVHD symptoms overall?	5RI	் 0	ୀ 1	் 2	் 3	୍ 4	් 5	் 6	୍ 7	ි 8	୍ର 9	් 10
2. Your skin itching at it WORST?	its 5RZ	് 0	ා 1	் 2	୍ 3	୍ 4	் 5	் 6	ି 7	ଃ	் 9	் 10
3. Your mouth dryness WORST?	at its 5 <u>K3</u>	் 0	ி 1	் 2	் 3	୍ 4	ි 5	ି 6	୍ 7	ଃ	் 9	© 10
4. Your mouth pain at i WORST?	its SR4	್ 0	్ 1	் 2	<u> </u>	୍ 4	் 5	ి 6	ි 7	ଃ	୍ 9	ୀ0
5. Your mouth sensitivitits WORST?	ty at 5 <u>R5</u>	் 0	் 1	· 2	୍ 3	୍ 4	் 5	ି 6	୍ 7	୍ଚ 8	୍ 9	ି 10
6. Your eye problem at WORST?	: its 5R6	் 0	ୀ 1	் 2	ି 3	୍ 4	ି 5	ି 6		ଃ	9	ୁ 10
7. What is your main complaint with regard to your eyes?	to 5R 7											

8. Vulvovaginal Symptoms (females only): Do you have any burning, pain or discomfort in the area of your vagina, vulva or labia? - OR - Do you have any discomfort or pain with sexual intercourse?	୍ Yes ା No ା Not applicable
9. Overall, how would you rate the severity of your chronic graft versus host disease? $P5R^{9}$	○ None ○ Mild ○ Moderate ○ Severe
10. Do you think your chronic GVHD symptoms are in good enough control to decrease your immunosuppressive medications? $\rho s \approx 10000000000000000000000000000000000$	୍ No ୍ Yes ୍ Not applicable

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6/26/2014 10:33 AM

ON FOLLOW-UP VERSION ONLY

-			Not involved with GVHD	Compl- etely gone	Very much better	Moder- ately better	A little better	About the same	A little worse	Moder- ately worse	Very much worse
PSR	11.	GVHD symptoms overall		0 1	0 2	0 3	0 4	0 5	0 6	0 7	0 8
PSR	12.	Mouth	0 0	0 1	0 2	0 3	0 4	0 5	0 6	0 7	0 8
PSR	13.	Skin	00	0 1	0 2	0 3	0 4	O 5	0 6	0 7	0 8
PSR	14.	Eye	00	0 1	0 2	O 3	0 4	0 5	0 6	0 7	0 8
PSR	15.	Joints	0 0	0 1	0 2	0 3	0 4	0 5	0 6	0 7	0 8

PSR 16. What are your reasons for saying your chronic GVHD is better or worse overall? (Is there a symptom of particular concern to you that has changed?

(Write in)

Free text	

Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

		· · · · · · · · · · · · · · · · · · ·					
Participant ID	129841	Date of Registration	23 Jun 2014				
Local ID	0201020						
Status	Eligible Eli						
Site ID	Fred Hutchinson Cancer Res	earch Center (cGV	HD)				
Treatment	Imatinib Dose: 200 mg PO o 2-19)	matinib Dose: 200 mg PO daily (Age > 19) or 130 mg/m2 PO daily (Age 2-19)					
Treatment Assign Date		Treatment Start Date					

Patient Survey Enrollment

		* These f	ields are require	ed in order to	SAVE the forr
	* -	These fields a	are required in c	order to COM	PLETE the form
Date of Visit:	<u>Date</u>				
interviewer User ID:*					
Section 2:					
By circling one (1) number per line, please problems in the past month:	indicate how n	nuch you hav	re been bothered	d by the follo	wing
SKIN:	Not at all	Slightly	Moderately	Quite a bit	Extremely
1. Abnormal skin color ろんし	0	ୀ	் 2	் 3	0 4
2. Rashes	် 0	் 1	ି 2	୍ 3	୍ 4
3. Thickened skin	၀	္ 1	∜ 2	<i>-</i> 3	0 4
4. Sores on skin	୍ 0	ୀ	2	் 3	ି 4
5. Itchy skin られち	് 0	ି 1	் 2	<i></i> 3	ି 4
EYES AND MOUTH:	Not at all	Slightly	Moderately	Quite a bit	Extremely
6. Dry eyes	၀	ୀ	ं 2	୍ 3	ं 4
7. Need to use eye drops frequently	ം 0	୍ 1	் 2	୍ 3	୍ 4
8. Difficulty seeing clearly 5X8	0	89 1	○ 2	⊕ 3	ି 4

9. Need to avoid certain foods due to mouth pain	் 0	ୀ	் 2	3	୍ 4
10. Ulcers in mouth	် 0	្ 1	O 2	୍ 3	୍ 4
11. Receiving nutrition from an intravenous line or feeding tube	္ 0	ା 1	<> 2	ି 3	ି 4
BREATHING:	Not at all	Slightly	Moderately	Quite a bit	Extremely
12. Frequent cough	<i>○</i> 0	ୀ	△ 2	் 3	ି 4
13. Colored sputum	் 0	୍ 1	⊘ 2	் 3	୍ 4
14. Shortness of breath with exercise	் 0	·· 1	⊘ 2	⊕ 3	<u> </u>
15. Shortness of breath at rest	ာ ၀	1	ି 2	୍ 3	0 4
16. Need to use oxygen	ം 0	ୀ 1	் 2	୍ 3	୍ 4

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Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

Participant ID	129841	Date of Registration	23 Jun 2014			
Local ID	0201020					
Status	Eligible					
Site ID	Fred Hutchinson Cand	cer Research Center (cGV	HD)			
Treatment	Imatinib Dose: 200 m 2-19)	ng PO daily (Age > 19) or	130 mg/m2 PO daily (Age			
Treatment Assign Date		Treatment Start Date	26 Jun 2014			

Patient Survey Enrollment

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Interviewer User ID:*	
Date of Visit: *	<u>Date</u>
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	* These fields are required in order to SAVE the form

Section 2: (cont.)

EATING AND DIGESTION:	Not at all	Slightly	Moderately	Quite a bit	Extremely
17. Difficulty swallowing sold foods	0	୍ଷ 1	ି 2	े 3	୍ 4
18. Difficulty swallowing liquids	୍ 0	୍ର 1	ି 2	3	ି 4
19. Vomiting	ି 0	ಿ 1	ି 2	୍ 3	ି 4
20. Weight loss SX 20	് 0	ୀ	⊕ 2	୍ 3	୍ 4
MUSCLES AND JOINTS:	Not at all	Slightly	Moderately	Quite a bit	Extremely
21. Joint and muscle aches	೦ 0	୍ର 1	୍ 2	୍ 3	ិ 4
22. Limited joint movement	് 0	O 1	் 2	் 3	ି 4
23. Muscle cramps 5X23	ം 0	ୀ	் 2	୍ 3	୍ 4
24. Weak muscles SXZ4	0	ୀ	ି 2	୍ 3	<u> </u>
ENERGY:	Not at all	Slightly	Moderately	Quite a bit	Extremely

25. Loss of energy $5X25$	ా 0	் 1	% 2	୍ 3	© 4
26. Need to sleep more/ take naps	ಿ 0	் 1	÷ 2	୍ 3	୍ 4
27. Fevers <i>SX2-</i> 7	് 0	ୀ 1	் 2	் 3	ି 4
MENTAL AND EMOTIONAL:	Not at all	Slightly	Moderately	Quite a bit	Extremely
28. Depression	ം 0	© 1	◇ 2	⊕ 3	ି 4
29. Anxiety <i>5X29</i>	∅ 0	្រា	் 2	୍ 3	୍ 4

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Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

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Participant ID	129841	Date of Registration	23 Jun 2014		
Local ID	0201020		A STATE OF THE STA		
Status	Eligible				
Site ID	Fred Hutchinson Cancer Research Center (cGVHD)				
Treatment	Imatinib Dose: 200 mg PO daily (Age > 19) or 130 mg/m2 PO daily (Age 2-19)				
Treatment Assign Date		Treatment Start Date			

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					***************************************	o SAVE the for
		* These fie	lds are re	quired in o	order to CO	MPLETE the for
eate of Visit:	<u>Dat</u>	<u>te</u>				
nterviewer User ID:*						
Section 3:						
Have you experienced any of the following during the last week?	All of the	1		Half of ne time	Some o	1
1. Eyes that are sensitive to light?	0 4	் 3	\(\)	2	ୀ 1	် 0
2. Eyes that feel gritty? ODZ	0 4	் 3	()	2	0 1	⊗ 0
3. Painful or sore eyes?	୍ 4	୍ 3	<	2	୍ର 1	் 0
4. Blurred vision?	୍ 4	୍ 3	ζ.	2	ୀ	⊹ 0
5. Poor vision?	୍ 4	3	ė.	2	្រាំ	00
Have problems with your eyes limited you in performing any of the following during the last week?	All of the time	Most of the time	Half of the time	Some of the time	e the	applicable
6. Reading?	୍ 4	୍ 3	் 2	ា 1	္ 0	ି N/A
7. Driving at night?	୍ 4	் 3	ි 2	<u> </u>	္ 0	୍ N/A
8. Working with a computer or bank machine (ATM)?	ି 4	୍ 3	் 2	ୀ	္ 0	ି N/A

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9. Watching TV?	ୀ 4	⊕ 3	ି 2	0 1	೦೦ ೮	N/A
Have your eyes felt uncomfortable in any of the following situations during the last week?	All of the time	Most of the time	Half of the time	Some of the time	None of the time	Not applicable
10. Windy conditions?	ं 4	୍ 3	ి 2	ಿ 1	⊘0 (N/A
11. Places or areas with low humidity (very dry)?	୍ 4	ୁ 3	் 2	ୀ	୍ 0 ୍	N/A
12. Areas that are air conditioned?	ି 4	் 3	ି 2	ಿ 1	OO (N/A

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Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

Participant ID	129841	Date of Registration	23 Jun 2014
Local ID	0201020		
	Eligible		
Site ID	Fred Hutchinson Cand	er Research Center (cGV	HD)
Treatment	Imatinib Dose: 200 m 2-19)	ng PO daily (Age > 19) or	но) 130 mg/m2 PO daily (Age
reatment Assign Date		Treatment Start Date	26 Jun 2014

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		* Th	nese fields are	required in o	rder to COMP	LETE the for
ate of Visit: *		<u>Date</u>				
nterviewer User ID:*						
Section 4: Quality of Your L	ife Afte	er Your Ti	ansplant			
PHYSICAL WELL-BEING:		Not at all	A little bit	Some- what	Quite a bit	Very much
1. I have a lack of energy	-	္ 0	୍ 1	⊕ 2	ି 3	0 4
2. I have nausea	2	୦ ୦	ୀ 1	ි 2	୍ଷ 3	୍ 4
3. Because of my physical condition have trouble meeting the needs of family	on, I of my	O 0	0 1	<i>^</i> 2	∅ 3	∜ 4
4. I have pain	4	் 0	0 1	ି 2	े 3	0 4
5. I am bothered by side effects of treatment	of 5	္ ၀	0 1	் 2	୍ 3	0 4
6. I feel ill	6	ି 0	୍ 1	் 2	் 3	0 4
7. I am forced to spend time in b	ed 7	ಿ 0	் 1	2	் 3	் 4
SOCIAL/FAMILY WELL-BEING:		Not at all	A little bit	Some- what	Quite a bit	Very much
8. I feel close to my friends	F8	் 0	ି 1	ି 2	ି 3	ି 4

9. I get emotional support from my family	ံ 0	୍ର 1	் 2	୍ 3	୍ 4
10. I get support from my friends	் 0	0 1	୍ 2	୍ 3	∜> 4
11. My family has accepted my illness	் 0	0 1	○ 2	் 3	O 4
12. I am satisfied with family communication about my illness	ి 0	0 1	en 2	୍ 3	◇ 4
13. I feel close to my partner (or the person who is my main support)	్ 0	∅ 1	⊖ 2	୍ 3	O 4
Regardless of your current level of sexual If you prefer not to answer it, please cha	• •	•			n. [
14. I am satisfied with my sex life	ာ 0	୍ର 1	ୁ 2	் 3	0 4
I4 (4)+	<u></u> 5 [> (*)			

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Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

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Participant ID	129841	Date of Registration	23 Jun 2014	
Local ID	0201020		to a state of the	
Status	Eligible			
Site ID	Fred Hutchinson Cancer Research Center (cGVHD)			
Treatment	Imatinib Dose: 200 mg PO daily (Age > 19) or 130 mg/m2 PO daily (Age 2-19)			
Treatment Assign Date		Treatment Start Date		

Interviewer Use	r ID:*	
Date of Visit:	*	<u>Date</u>
		* These fields are required in order to COMPLETE the form
		* These fields are required in order to SAVE the form

Section 4: Quality of Your Life After Your Transplant (cont.)

EMOTIONAL WELL-BEING:	Not at all	A little bit	Some- what	Quite a bit	Very much
15. I feel sad F15	ာ 0	ୀ 1	் 2	୍ 3	© 4
16. I am satisfied with how I am coping with my illness	் 0	∅ 1	ି 2	ಿ 3	<i>-</i> 4
17. I am losing hope in the fight against my illness	ಿ 0	1	் 2	୍ 3	ି 4
18. I feel nervous FI8	ံ 0	୍ର 1	் 2	் 3	୍ 4
19. I worry about dying FI9	் 0	ୀ 1	ି 2	୍ 3	<i></i> 4
20. I worry that my condition will get worse F20	္ ၀	் 1	் 2	୍ 3	୍ 4
FUNCTIONAL WELL-BEING:	Not at all	A little bit	Some- what	Quite a bit	Very much
21. I am able to work (include work at home)	် 0	ୀ 1	ି 2	் 3	ି 4
22. My work (include work at home) is fulfilling	် 0	1	ි 2	୍ 3	0 4

23. I am able to enjoy life	F23	୍ 0	் 1	୍ 2	⊹ 3	୍ 4
24. I have accepted my illnes	is F24	၀	ି 1	÷ 2	୍ 3	04
25. I am sleeping well	F25	୍ 0	ା 1	் 2	୍ 3	<u> </u>
26. I am enjoying the things do for fun	I usually F26	் 0	୍ 1	© 2	୍ 3	ి 4
27. I am content with the qu my life right now	ality of F27	O 0	O 1	<i></i> 2	୍ 3	9 4
ADDITIONAL CONCERNS:		Not at all	A little bit	Some- what	Quite a bit	Very much
28. I am concerned about ke job (include work at home)		ံ 0	0 1	் 2	ి 3	୍ 4
29. I feel distant from other	people F29	ം 0	୍ 1	் 2	் 3	୍ 4
30. I worry that the transplawork	int will not	் 0	ୀ 1	○ 2	୍ 3	୍ 4
31. The effects of treatment than I had imagined	are worse	© 0	ୀ 1	் 2	் 3	ି 4
32. I have a good appetite	F32	ာ 0	ୀ 1	୍ 2	் 3	୍ 4
33. I like the appearance of	my body F 33	ಿ 0	ୀ 1	ි 2	୍ 3	្ 4
34. I am able to get around	by myself	© 0	் 1	⊕ 2	ି 3	ି 4
35. I get tired easily	F35_	ಿ 0	01	· 2	୍ 3	<i>்</i> 4
36. I am interested in sex	F36	· 0	ୀ 1	ି 2	3	୍ 4
37. I have confidence in my	nurse(s) ドろフ	္ ၀	ୀ	் 2	୍ 3	ំ 4

Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

Participant ID	129841	Date of Registration	23 Jun 2014		
Local ID	0201020				
Status	Eligible				
Site ID	Fred Hutchinson Cancer Research Center (cGVHD)				
Treatment	Fred Hutchinson Cancer Research Center (cGVHD) Imatinib Dose: 200 mg PO daily (Age > 19) or 130 mg/m2 PO daily (Age 2-19)				
Treatment Assign Date		Treatment Start Date			

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Interviewer Use	r ID: *	
Date of Visit:	*	Date
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		[◀ ←

Section 5: Your Health and Well-Being

- 1. Which statement describes how you feel most of the time? (please check one) KPS
 - 1. Normal, no difficulties with daily activities
 - 2. Able to carry on normal activities, minor problems
 - 3. Normal activity with effort
 - 4. Able to care for self, but unable to carry on normal activity or active work
 - 5. Require occasional assistance, but able to care for most of needs
 - 6. Require considerable assistance and frequent medical care
 - 7. Disabled, require special care and assistance
 - 8. Severely disabled, hospitalized
 - 9. Very sick, hospitalized
- 2. In general, would you say your health is $5 \vec{F} \hat{Z}$

Excellent	Very good	Good	Fair	Poor
.**	//	<i>#</i> }	6)	i)

3. Compared to one year ago, how would you rate your health in general now? 5F3

Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

Participant ID	129841	Date of Registration	23 Jun 2014
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Status	Eligible		
Site ID	Fred Hutchinson Cancer R	esearch Center (cGV	HD)
Treatment	Fred Hutchinson Cancer R Imatinib Dose: 200 mg PC 2-19)	daily (Age > 19) or	130 mg/m2 PO daily (Ag
reatment Assign Date		Treatment Start Date	26 Jun 2014

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Interviewer Use	r ID: *		
Date of Visit:	*	<u>Date</u>	
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Section 5: Your Health and Well-Being (cont.)

The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

•	Yes, limited a lot	Yes, limited a little	No, not limited at all
4. Vigorous activities, such as running, lifting heav objects, participating in strenuous sports	<i>x</i> 1	் 2	◇ 3
5. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing gol	5F5	் 2	⇔ 3
6. Lifting or carrying groceries	6 1	© 2	୍ 3
7. Climbing several flights of stairs	= 7 0 1	ි 2	் 3
8. Climbing one flight of stairs	8 ¹	ි 2	୍ର 3
9. Bending, kneeling, or stopping SF	q 0 1	் 2	୍ 3
10. Walking more than a mile	10 ° 1	் 2	୍ଷ 3
11. Walking several hundred yards		⇔ 2	் 3
	12 1	ි 2	୍ 3

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13. Bathing or dressing yourself	SF13	ୀ 1	் 2	ं	3
During the past 4 weeks, how much of the other regular daily activities as a result of ye			e following pro	blems with yo	our work or
	All of the time	Most of the time	Some of the time	A little of the time	None of the time
14. Cut down on the amount of time you spent on work or other activities	1 H4	் 2	୍ 3	் 4	ಿ 5
15. Accomplished less than you would like	ୀ 2	் 2	் 3	୍ 4	் 5
16. Were limited in the kind of work or other activities	* 1	் 2	் 3	୍ 4	் 5
17. Had difficulty performing the work or other activities (for example, it took extra effort)	01	் 2	் 3	் 4	் 5

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Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

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Participant ID	129841	Date of Registration	23 Jun 2014			
Local ID	0201020					
Status	Eligible					
Site ID	Fred Hutchinson Cancer Research Center (cGVHD)					
Treatment	Imatinib Dose: 200 mg PO daily (Age > 19) or 130 mg/m2 PO daily (Age 2-19)					
Treatment Assign Date		Treatment Start Date	1			

Patient Survey Enrollment

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ate of Visit:	<u>Date</u>				
nterviewer User ID:*					
Section 5: Your Health and V	Vell-Being (co	nt.)			
During the past 4 weeks, how much of other regular daily activities as a result	the time have you	had any of the	e following pro n as feeling de	oblems with yo pressed or an	our work or (ious)?
	All of the time	Most of the time	Some of the time	A little of the time	None of the time
18. Cut down on the amount of times you spent on work or other activities as a result of any emotional proble	es │ ○ 1	[⊕] 2	் 3	~ 4	· 5
19. Accomplished less than you wo like as a result of any emotional		© 2	୍ 3	୍ 4	÷ 5
20. Did work or other activities less carefully than usual	§ _ 0 1	ි 2	0 3	ି 4	୍ 5
21. During the past 4 weeks, to whinterfered with your normal social	nat extent has you activities with fam	ır physical he ily, friends,	ealth or emo neighbors, o	tional proble r groups?	ms 5F21
Not at all Slightly	Moderately	Quite	a bit	Extremely	APIRITY .
0 0	43	0	(C)		
	u had during the	nact 4 week	02 SE27		
22. How much bodily pain have yo	u nad during the	past 4 week	3: 1 Lilian		
None Very Mild M	ild Moderat	e Sever	e Ve	ry Severe	

		\$\frac{1}{2}				
	east 4 weeks, ho home and hou		n interfere with you パス	normal v	work (including	g both
Not at all	A little bi			oit	Extremely	·-
NOL at an	Aircic	<u> </u>	29	**************************************		7

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Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

Participant ID	129841	Date of Registration	23 Jun 2014		
Local ID	0201020				
Status	Eligible				
Site ID	Fred Hutchinson Cancer Research Center (cGVHD)				
Treatment	Imatinib Dose: 200 mg PO daily (Age > 19) or 130 mg/m2 PO daily (Age 2-19)				
Treatment Assign Date	23 Jun 2014	Treatment Start Date	26 Jun 2014		

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Interviewer User	ID:*	
Date of Visit:	*	<u>Date</u>
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Section 5: Your Health and Well-Being (cont.)

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks...

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
24. Did you feel full of life? 5F24	୍ର 1	் 2	ं 3	4	் 5
25. Have you been very nervous?	ំ 1	ි 2	୍ 3	୍ 4	ំ 5
26. Have you felt so down in the dumps that nothing could cheer you up?	ି 1	© 2	் 3	0 4	♦ 5
27. Have you felt calm and peaceful?	் 1	ි 2	63	୍ 4	់ 5
28. Did you have a lot of energy?	ា 1	∅ 2	୍ 3	ំ 4	់ 5
29. Have you felt downhearted and depressed?	O 1	் 2	3	୍ 4	் 5
30. Did you feel worn out? 5F30	ୀ	ି 2	© 3	୍ 4	ි 5

31. Have you been	ı happy? ゔFろ	1 21	ୁ 2	୍ 3	୍ 4	∅ 5
32. Did you feel tir	red? 5F3.	2 01	୍ 2	ି 3	© 4	© 5
33. During the pas interfered with you	it 4 weeks, how r ur social activities	much of the time (like visiting frie	has your ph nds, relative	ysical hea s, etc.)?	alth or emotional SF33	problems
All of the time	Most of the time	Some of the time	1	of the me	None of the time	e
^ 1	· 2	⇒ 3	ି 4		⋄ 5	
i		Definitely true	Mostiy true	Don know		Definitely false
34. I seem to get than other people		r 1	2	⊕ 3	<i>-</i> 4	் 5
35. I am as health	ny as anybody I SF35	ं 1	் 2	் 3	୍ 4	் 5
36. I expect my h	ealth to get wors	e 1	© 2	୍ର 3	© 4	ಿ 5
37. My health is e	xcellent SF37	, 1	் 2	୍ 3	<u> </u>	୍ 5

Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

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Participant ID	129841	Date of Registration	23 Jun 2014		
Local ID	0201020				
Status	Eligible				
Site ID	Fred Hutchinson Cancer Research Center (cGVHD)				
Treatment	Imatinib Dose: 200 mg PO daily (Age > 19) or 130 mg/m2 PO daily (Age 2-19)				
Treatment Assign Date		Treatment Start Date	1		

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Date of Visit: * Date	lese fields are requi	Tea in order to ex	JIM LEVE GIOTO
Interviewer User ID:*			
Section 6: Your Activity Level			
	Still Doing This Activity (1)	Have Stopped Doing This Activity (2)	Never Did This Activity (3)
1. Getting in and out of chairs or bed (without assistance)	0	0	Ö
2. Listening to the radio	9	0	0
3. Reading books, magazines or newspapers H3	٥	()	Ĉ.
4. Writing (letters, notes)	139	<u> </u>	0
5. Working at a desk or table	0	0	ť)
6. Standing (for more than one minute) $H \ell$	*>	x3)	Ó
7. Standing (for more than five minutes)	3	Ø	O
8. Dressing or undressing (without assistance) $H8$	O	()	Ö
9. Getting clothes from drawers or closets	\$	0	<.>

10. Getting in or out of a car (without assistance)	\$		6	
11. Dining at a restaurant	()	()	0	
12. Playing cards/table games	()	Ö	()	
13. Taking a bath (no assistance needed)	0	(2)	0	
14. Putting on shoes, stockings or socks (no assistance needed)	0	0	(*)	
15. Attending a movie, play, church event or sports activity	0	<i>(</i>)	٥	
16. Walking 30 yards (27 meters)	(i)	<i>(</i>)	viz	

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Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

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Participant ID	129841	Date of Registration	23 Jun 2014		
Local ID	0201020				
Status	Eligible				
Site ID	Fred Hutchinson Cancer Res	earch Center (cGV	HD)		
Treatment	Imatinib Dose: 200 mg PO daily (Age > 19) or 130 mg/m2 PO daily (Age 2-19)				
Treatment Assign Date		Treatment Start Date			

	* These fields are		
* 7	hese fields are requi	red in order to Co	OMPLETE the for
Date of Visit: * Date			
nterviewer User ID:*			
Section 6: Your Activity Level (cont.)			
	Still Doing This Activity (1)	Have Stopped Doing This Activity (2)	Never Did This Activity (3)
17. Walking 30 yards (non-stop)	0	Č)	Ö
18. Dressing/undressing (no rest or break needed)	3 0	0	
19. Using public transportation or driving a car (100 miles or less)	9		<i>(</i>)
20. Using public transportation or driving a car (99 miles or more)))	W.	(2)
21. Cooking your own meals	77	()	<u> </u>
22. Washing or drying dishes H2:	2 0	<i>*</i> >	Ó
23. Putting groceries on shelves H2	3	0	0
24. Ironing or folding clothes	<i>t</i> °	÷	0
25. Dusting/polishing furniture or polishing cars H^2	25 °	0	0

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26. Showering	H26	(*)	Ö	0	
27. Climbing six steps	1-127	***)	<u> </u>	43	
28. Climbing six steps (non-stop)	H28	13	()	0	
29. Climbing nine steps	1-129	Ð	0	43	
30. Climbing 12 steps	H30	6	٧)	0	
31. Walking ½ block on level ground	H31	i)	©	63	
32. Walking ½ block on level ground (non-	-stop) H32	Ð	O	O	
33. Making a bed (not changing sheets)	H33_	4)	0	Ô	
34. Cleaning windows	H34	9	(3)	6)	
35. Kneeling, squatting to do light work	H35_	4)	123	Ö	
36. Carrying a light load of groceries	H36	f)	C.	- 57	
37. Climbing nine steps (non-stop)	H37	()	0	é)	

Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

Participant ID	129841	Date of Registration	23 Jun 2014		
Local ID	0201020				
Status	Eligible				
	Fred Hutchinson Cancer Res				
Treatment	Imatinib Dose: 200 mg PO daily (Age > 19) or 130 mg/m2 PO daily (Age 2-19)				
Treatment Assign Date	23 Jun 2014	Treatment Start Date	26 Jun 2014		

Page: 13 of 16

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	* These fields are required in order to SAVE the form
	* These fields are required in order to COMPLETE the form

<u>Date</u>

Interviewer User ID:* Section 6: Your Activity Level (cont.)

Date of Visit:

		Still Doing This Activity (1)	Have Stopped Doing This Activity (2)	Never Did This Activity (3)
38. Climbing 12 steps (non-stop)	H38	<>>	Ö	Ō
39. Walking ½ block uphill	H39	O	6	0
40. Walking ½ block uphill (non-stop)	H40	D)	<i>(</i>)	0
41. Shopping (by yourself)	1-141	3"3	0	0
42. Washing clothes (by yourself)	1442	₹ ;>	Ø	ð
43. Walking one block on level ground	H43	9)	0	Ó
44. Walking two blocks on level ground	144	O	()	0
45. Walking one block on level ground (non	-stop) H45	0	A)	6
46. Walking two blocks on level ground (no		:)	0	

47. Scrubbing (floors, walls or cars)	147	57	43	0
48. Making beds (changing sheets)	1448	0	ety.	Ö
49. Sweeping	H49	5 07	0	0
50. Sweeping (five minutes non-stop)	H50	Ø	0	()
51. Carrying a large suitcase or bowling (or	ne line) H51	9	V)	0
52. Vacuuming carpets	H52	0	٥	0
53. Vacuuming carpets (five minutes non-s	stop) H53	£)	<i>(</i>)	¢)
54. Painting (interior/exterior)	H54	÷>	Ö	0
55. Walking six blocks on level ground	H <i>5</i> 5	ಂ	0	<u> </u>
56. Walking six blocks on level ground (no	n-stop) H56	\(\phi\)	6	<i>(</i>)
57. Carrying out the garbage	H57	Ó	Ó	()
58. Carrying a heavy load of groceries	H58	Ø	Ô	()

	13	•	→ [3]	DI
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Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

Participant ID	129841	Date of Registration	23 Jun 2014			
Local ID	0201020					
Status	Eligible	igible				
	Fred Hutchinson Cancer Res					
Treatment	Imatinib Dose: 200 mg PO o 2-19)	matinib Dose: 200 mg PO daily (Age > 19) or 130 mg/m2 PO daily (Age -19)				
Treatment Assign Date	23 Jun 2014	Treatment Start Date	26 Jun 2014			

Page: 14 of 16

Interviewer Useı	r ID:*		
Date of Visit:	*	Date	
		* These fields are required in order to COMPLETE the for	m
		* These fields are required in order to SAVE the fo	m
		[4 + 	

Section 6: Your Activity Level (cont.)

67. Doing calisthenics or aerobic dancing (5 minutes

	Still Doing This Activity (1)	Have Stopped Doing This Activity (2)	Never Did This Activity (3)
59. Climbing 24 steps H59	0	(*)	()
60. Climbing 36 steps	>		()
61. Climbing 24 steps (non-stop)	40	()	0
62. Climbing 36 steps (non-stop) H62	*>	0	·*)
63. Walking one mile H63	%)	6)	<i>"</i>
64. Walking one mile (non-stop)	AT A		Ó
65. Running 110 yards (100 meters) or playing softball/baseball	0	63)	0
66. Dancing (social)	0	O	6

1-166

H67

non-stop)

68. Mowing the lawn (power mower, but mower)	t not a riding	()			
69. Walking two miles	1469	4)	ð	45	
70. Walking two miles (non-stop)	H70	* * * * * * * * * * * * * * * * * * * *	4))	∜>	
71. Climbing 50 steps	H71	0	0	e()	
72. Shoveling, digging or spading	1172			\diamond	
73. Shoveling, digging or spading (five n non-stop)	ninutes 1473	* ()	0	e)	
74. Climbing 50 steps (non-stop)	1174	//y	Pγ	Ó	
75. Walking three miles or golfing 18 ho riding cart	les without a H75	22	<i>(</i> *)	0	
76. Walking three miles (non-stop)	H76	()	ψ	0	
77. Swimming 25 yards	H77	*>	-/)	0	
78. Swimming 25 yards (non-stop)	H78	<i>#</i> }	Ø)	\diamond	

Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

Participant ID	129841	Date of Registration	23 Jun 2014			
Local ID	0201020					
Status	Eligible					
		Fred Hutchinson Cancer Research Center (cGVHD)				
Treatment	Imatinib Dose: 200 mg PO o 2-19)	matinib Dose: 200 mg PO daily (Age > 19) or 130 mg/m2 PO daily (Age -19)				
Treatment Assign Date	23 Jun 2014	Treatment Start Date	26 Jun 2014			

Page: 15 of 16

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 * These fields are required in order to SAVE the form
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Pate of Visit: *	<u>Date</u>			
nterviewer User ID:*				
Section 6: Your Activity Level (cont.)			· · · · · · · · · · · · · · · · · · ·
		Still Doing This Activity (1)	Have Stopped Doing This Activity (2)	Never Did This Activity (3)
79. Bicycling one mile	H79	**>		Ů
80. Bicycling two miles	H80	0		Ó
81. Bicycling one mile (non-stop)	H81	Ö	<i>(</i>)	ś)
82. Bicycling two miles (non-stop)	H82	<u> </u>	()	()
83. Running or jogging ¼ mile	H83	C:	9	Ö
84. Running or jogging ½ mile	H84	ž:	25	Ö
85. Playing tennis or racquetball	H85	<i>*</i>)	173	Ó
86. Playing basketball (game play)	H86	0	<i>(</i>)	0
87. Running or jogging ¼ mile (non-stop)	H87	٥	0	0

			conversation and the second	
88. Running or jogging ½ mile (non-stop) $H88$	(0)	Ö	43	
89. Running or jogging one mile	9	Ø	*>	
90. Running or jogging two miles	Ð	()	0	
91. Running or jogging three miles	Φ	<i>(</i>)	Ø	
92. Running or jogging one mile in 12 minutes or less	6	Ó	(6)	
93. Running or jogging two miles in 20 minutes or less H93	0	ef)	0	
94. Running or jogging three miles in 30 minutes or less	٥	iĝ.	©.	

	15	▶ ♦ □ ▶ I
Save Print		Close Window

Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

Participant ID	129841	Date of Registration	23 Jun 2014		
Local ID	0201020				
Status	Eligible				
	Fred Hutchinson Cancer Research Center (cGVHD)				
Treatment	Imatinib Dose: 200 mg PO daily (Age > 19) or 130 mg/m2 PO daily (Age 2-19)				
Treatment Assign Date	23 Jun 2014	Treatment Start Date	26 Jun 2014		

	* These fields are required in order to SAVE the form
	* These fields are required in order to COMPLETE the form
Date of Visit: *	<u>Date</u>
Interviewer User ID:*	
Section 7: About Yo	urself
1. What is your current	vork status? (check all that apply)
In school part ti Working full tim Working part tin Homemaker 5D Retired 5D-600 On medical leav Disabled, unable Unemployed, loc Unemployed, no	e from work SD_work_On medical kave from work to work JD_work_Disabled unable towork king for work JD_work_Unemployed looking for work t looking for work JD_work_Unemployed not looking for work SD_work
2. Do you consider your	elf to be Latino (a) or Hispanic? 5D-eth
ं Not Hispanic or	_atino
Hispanic or Lati	
3. How would you best	lescribe your race? (check all that apply) 3 D race Describe

Black SD_race_Black American Indian or Alaska Native SD_race_ American Asian SD_race_Asian Native Hawaiian or Other Pacific Islander SD_race_No White SD_race_White. Other	
4. What is your gender? $5D-gen$	ି Male ା Female
5. How old are you? 50-age	years
6. How much did you weigh before your transplant? (Please be sure to indicate it in pounds (lbs) or kilograms (kg)) 7. What is your marital status? 50 marital	, in the second
Married/Living with partner	
Single, never married	
○ Divorced, Separated ○ Widowed	If Other, specify: 3D-mar tal-0th
ं Other	If Other, specify: 5D-11011 That 20111
8. What is the highest grade of school you have completed? $\supset \mathcal{D}$	_educ
Grade school	
Some high school High school graduate	1
Some college	
© College graduate	
Post-graduate degree	
9. What was your approximate annual family income in the year be	efore you had your transplant? SD_ income.
© Under \$15,000	-
\$15,000 - \$24,999	
\$25,000 - \$49,999	
\$50,000 - \$74,999	
\$75,000 - \$99,999	
\$100,000 or above	
	· · ·
Save Print Close Window	

Section 7: About Yourself

1.

What	t is your current work sta	tus? (check all that apply)
	In school full time In school part time Working full time Working part time Homemaker Retired On medical leave from Disabled, unable to wo Unemployed, looking for Unemployed, not looking Other, specify:	rk or work
		SD_work_ homemaker SD_work_ on medical leave from work SD_work_ disabled mable to work SD_work_ memplayed borning for work SD_work_ memployed not looking for a
		SD_ wave_ other

Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

Participant ID	129841	Date of Registration	23 Jun 2014		
Local ID	0201020				
Status	Eligible				
Site ID	Fred Hutchinson Cancer Research Center (cGVHD)				
Treatment	Imatinib Dose: 200 mg PO daily (Age > 19) or 130 mg/m2 PO daily (Age 2-19)				
Treatment Assign Date	23 Jun 2014	Treatment Start Date	26 Jun 2014		

Scleroderma Health Assessment Questionnaire

Page: 1 of 2 $\rho 6502 - 15613 - 5haq$

Page: 1 of 2

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					r to SAVE the form
		* The	se fields are requ	ired in order to C	OMPLETE the form
	Date of Visit:	<u>Date</u> Inv	alid Date of Visi	t	
	Interviewer User ID:*	User ID is require	d		
	Date completed:	Date not valid			
	SHAQ Page 1				4
	In the past seven (7) days,	Without any difficulty	With some difficulty	With much difficulty	Unable to do
	1. Are you able to				
Shaqia Shaqib	Dress yourself, including tying shoelaces and doing buttons?	8	0	♦	O
<i>Shaqib</i>	Shampoo your hair?	0	ð	()	Ö
	2. Are you able to				
Shaq2a Shaq2b	Stand up from an armless straight chair?	. 0	0	Ç	8
5haq2b	Get in and out of bed?	0	Ö	Ø	0
	3. Are you able to				:
5haq3a	Cut your meat?	O	0	0	Ø .
5haq3a Shaq3b 5haq3c	Lift a full cup or glass to your mouth?	40	0	0	· •
5haq3c	Open a new carton of milk?	0	0	0	0

	4. Are you able to					
	·					
5haq44	Walk outdoors on flat ground?	<i>(</i>)	0	<u></u>	0	-
Shaq4a Shaq4b	Climb up 5 steps?	Ø.	0	0	0	
	5. Are you able to					
5haq5a	Wash and dry your entire body?	Üş	©	0	ं	
Shaq5a Shaq5b Shaq5c	Take a tub bath?	₹*7	0	O	0	
Shaq5c	Get on and off the toilet?	0	٥	()	ి	-
	6. Are you able to					
5haq6a	Reach and get down a 5 pound object (such as a bag of sugar) from just above your head?	♦	0	0	٥	
5haq 6b	Bend down and pick up clothing from the floor?	0	೪	0	ి	
	7. Are you able to					
Shaq 7 a	Open car doors?	Ĉ.	٥	Ø	೦	
Shaq7b Shaq7c	Open jars which have previously opened?	\Diamond	٥	¢5	♦	
Shaq7c	Turn regular taps on and off?	O	0	<u>ن</u> -	0	
	8. Are you able to					
Shaq8a	Run errands and shop?	Ø	٥	Ø	0	
5haq8b	Get in and out of a car?	()	9	<i>(</i>)	0	
Shaq8a Shaq8b Shaq8c	Do chores such as vacuuming or yard work?	<∂	0	*27	0	

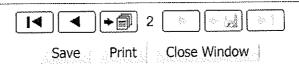
Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

Participant ID	129841	Date of Registration	23 Jun 2014
Local ID	0201020		
Status	Eligible		
Site ID	Fred Hutchinson Cancer Res	search Center (cGV	HD)
Treatment	Imatinib Dose: 200 mg PO (2-19)	daily (Age > 19) or	130 mg/m2 PO daily (Age
Treatment Assign Date		Treatment Start Date	

Scleroderma Health Assessment Questionnaire

		* These fields are required in orde	
		* These fields are required in order to C	OMPLETE the form
Date of Visit:	*	<u>Date</u>	
Interviewer User ID	*		
SHAQ Page 2			
Please check any A	ids or	Devices that you usually use:	
Cane Shaq 101	2	Dressing Devices (button hook, long shoe horn, etc.) 5/100/108	II
Walker Shaq 102	O	Built up or Special Utensils Shaq 109	[7]
Bathtub seat		Long Handled Appliances for reach Shaq110	
Shaq 103 Bathtub Bar		Long Handled Appliances for Bathroom Shaq III	B
Shaqlo4 Jar Opener	E	Raised Toilet seat	11
Sylvery		Shaq112 Special or Built-up Chair shaq113	73
Wheelchair	O	Other (Specify) Shaq 114	
Shaq 107 Please check any c	atego	ries for which you usually need help from another	person:
Hygiene Shaq115		Gripping and Opening Things Thoo 119	
Reach Shaq116	O	Errands and Chores Shaq 120	(***)
Arising Shaq 117	W ()	Dressing and Grooming Shaq 121	100
Eating Shaq 118		Walking Shaq122	ii)
,	0 to 1	.00 to indicate the severity of the pain and interfer	ence.

- 1. How much pain have you had because of your illness in the past week? That q
- 2. In the past week, how much has your Raynaud's Phenomenon interfered with 5haq10 your activities?
- 3. In the past week, how much has/have your finger ulcer(s) interfered with $\frac{1}{2}$ your activities?
- 4. In the past week, how much have your intestinal problems interfered with 5haq12 your activities?
- 5. In the past week, how much have your breathing problems interfered with Shaq 13 your activities?
- 6. Overall, considering how much pain, discomfort, limitations in your daily life shaqiff and other changes in your body and life, how severe would you rate your disease today?



Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

Participant ID	129841	Date of Registration	23 Jun 2014
Local ID	0201020		
Status	Eligible		
Site ID	Fred Hutchinson Cancer F	Research Center (cGV	HD)
Treatment	Imatinib Dose: 200 mg Po 2-19)	O daily (Age > 19) or	130 mg/m2 PO daily (Ag
eatment Assign Date		Treatment Start Date	26 Jun 2014

* These fields are required in order to SAVE the form

* These fields are required in order to COMPLETE the form

Date of Visit:

Date

Interviewer User ID:*

Test Name	Was The Test Done?	Date Done		Result
Hepatitis B surface antigen	Done HepB_done Required but not done Not required	HepB_MM HepB-DD HepB-YY	Positive Negative Not Interpreta	Heps_result
Hepatitis B core antibody	Done HepBare — done Required but not done Not required		Positive Negative	HBV DNA detectable HBV HBV DNA undetectable - hepBcore_rsult
Hepatitis C antibody	Done Hop C - dove Required but not done Not required	hepc-DD hepc-rum hepc-yx	Positive Negative hept -rcs	HCV RNA detectable HCV RNA undetectable は いといっている
Phosphate	Done Phos-done Required but not done Not required	phos_DD phos-mm phos-YY	mg/dl	phos-result
Vitamin D	Done VIT D-Jane Required but not done Not required	VITO_MM VITO_DD VITO_YY	ng/ml	Vit D2 (250HD2) vit D_D2 Vit D3 (250HD3) vit D_D3 Total Vit D vit D_total

Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

Participant ID	129841	Date of Registration	23 Jun 2014
Local ID	0201020		
Status	Eligible		
	Fred Hutchinson Cancer Research Center (cGVHD)		
Treatment	Imatinib Dose: 200 mg PO daily (Age > 19) or 130 mg/m2 PO daily (Age 2-19)		
Treatment Assign Date	23 Jun 2014	Treatment Start Date	26 Jun 2014

		Date		Date		
-		Gonior	neter Measurer	nent Results	p6502 - 1760	ol - gorion
	, LALINI I COMMITTE AND A STATE OF THE STATE		*	These fields are rec	uired in order to SAVE	the form V
			* These	e fields are required	in order to COMPLETE	the form
Date	of Visit:	*	<u>Date</u>			
Inte	viewer User	ID:*				
N	ame of Joint	Left or Right	Measurement	Com	ments	
		○ Left ○ Right	degree			

	ି Left ି Right	degree	
	ಿ Left ಿ Right	degree	
Add		and the second s	

Gon_joint # Save Print Close Window

Gon_joint_meas #

Gon_ comm#

Gon_left_right #

Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

Participant ID	129268	Date of Registration	04 Jun 2014
Local ID	0217003		
Status	Eligible		
Site ID	Ohio State University	(cGVHD)	
Treatment	Rituximab Dose: 375	mg/m2 IV weekly x 4	
Freatment Assign Date	10 Jun 2014	Treatment Start Date	16 Jun 2014

Study Medications - Rituximab p6502 _ 15623 _ Study medi _

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* These fields are required in order to COMPLETE the form

Date of Visit:

Jan

2014 Date

Interviewer User ID:* 1234

Medication Rituximab - 1 st Cycle					
Date Administered	Dose	Units (mg or mg/m ²)	Frequency/ Timepoint	Interval (QWK)	Route (IV)
ritux-eld1-00 -mm	ritux-cld1.	-dose ritux_cldl_1	Day 1	QWK	IV
	ritux-cld8-		Day 8	QWK	IV
and ritux-cld1-DT	ritux_clals	_dose	Day 15	QWK	IV
	nhx-cld22	_dose	Day 22	QWK	IV

Save

Print

Close Window

2nd cycle

ritux-c2d1-DT

ritux_c2d1_dose

ritux_c2d1_units

MAUX-CZd8-DT

nTux-c2d8-dore

n2x-c2d8-units

nhx-c2d15-DT

nhx-c2d15-dose

Whx-c2d15-mits

MWx-c2d22-DT

ribx_c2d22-dose

nilx_c2d22-dose

Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

,			una returnido foi Cu
Participant ID	108548	Date of Registration	07 Apr 2011
Local ID	0201001		
Status	Eligible		
Site ID	Fred Hutchinson Cancer Research Center (cGVHD)		
Treatment	Rituximab Dose: 375 mg/m2 IV weekly x 4		
Treatment Assign Date	26 Oct 2011	Treatment Start Date	26 Oct 2011

		Date	
	Treatment i	Failure Plo502	15619-treatme
		* These fields are requir	ed in order to SAVE the form
The state of the s	* Th	ese fields are required in	order to COMPLETE the form
Date of Visit: *	<u>Date</u>		
Interviewer User ID:*			
Which version of the protoco	ol is your site currently ope	rating under?	
ି V0.8, V1.0 or V2.0	◦ V3.0 or later VerS	nonnumber	
V3.0 or later			
1. Did patient experience tre	eatment failure to the first s	study medication?	Yes No
No response at 6 m	onths		C/ 0302 /MICO
Progression of sclere	osis before 6 months \ C_x	10SS_failure_t	100
Treatment intoleran	ce before 6 months		11
2. Did patient cross over to t	the other study medication	? Crossover	ି Yes ି No
3. Date of last dose of first s	tudy medication	cross-last	
4. If crossover due to treatm crossover?	nent intolerance and toxicity		
ୁ Yes ୁ No ୁ Not a	pplicable Cross_	resolve	
5. Date of crossover visit (co create the crossover visit sch			cross_DD cross_mm
	VARIABLE		Cross-YY

Proteil # 6501 - Longitudinal Study of Immune Mediated Disorders after Alloge...

Participant ID	101106	Date of Registration	26 Nov 2013
Local ID	0101100	Date of Baseline Exam	26 Sep 2013
Status	Eligible		
Site ID	Fred Hutchinson Cancer Research Center (cGVHD)		

Participant Status Form ind_17919_ patients tat_revised

	*	These fields are required in	order to SAVE the form
	* Thes	e fields are required in order	to COMPLETE the form
Date of Visit:*	<u>Date</u>		
nterviewer User ID:*	User ID is required		
1. Date of last contact or most	recent medical note	OLC DD	
2. Select all events that have o	ccurred to date:	OLC-YY	
Patient was never tra	nsplanted Event_NoT	īx	
Graft loss Event_	graft		Graft_DD Graft_MM
DLI Event-DLI			Graft_YY
Additional stem cell	ransplant Event_add	d-SCT	DLI_YY
Relapse Event_6	Pel		Add - 5CT- Add - 5CT-
Death Event_D	eath		Rel-DD, R Rel-YY
Cause of Death (CO)	7		
□ None of the above h	as occured. Event_No	one	
Patient is alive (confi	med within past 6 month	s) Event_Alive	

D.

Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

Participant ID	108548	Date of Registration	07 Apr 2011
Local ID	0201001		
Status	Eligible		
Site ID	Fred Hutchinson Cancer Research Center (cGVHD)		
Treatment	Rituximab Dose: 375 mg/m2 IV weekly x 4		
Treatment Assign Date	26 Oct 2011	Treatment Start Date	26 Oct 2011

Adverse Event Reporting Form

nitial Report	
Thuai Toport	* These fields are required in order to SAVE the form
A. INTERVIEW INFORMATION	These head are required in order
Adverse event report date (date site was notified of event) *	(DD MMM YYYY) rereported
B. ADVERSE EVENT REPORT	
Adverse event occurrence date *	(DD MMM YYYY) aedate
Is this a primary or secondary event? * (required only for initial report)	O Primary O Secondary If secondary event, enter primary Adverse Event ID:
C. EVENT DESCRIPTION	
Event SOC *	Select an Option Category Help
Adverse Event *	AETERM
Severity *	Select an Option Severity
Event Details (Description)	new_aedetails
Location of event treatment	Treatment Location + treatment to cation of
D. EVENT ASSESSMENT	
Expected *	O Yes O No Expected
Causality (by reporter) *	O Yes O No Expected Causality by reporter
Was the adverse event associated with any of the following? (check all that apply)	Development of a congenital anomaly or birth defect Development of a permanent, serious, disabling or incapacitating condition Death Hospitalization or prolonged hospitalization
prefix assoc -	☐ Life threatening ☐ Is another condition which investigators judge to represent significant hazards

on follow-up report:

Specify the adverse event = select term

date of follow up = A E follow up date

reason for follow up = reason for follow up

also not on forms:

A E causality by renewer

Syra or disable term (if other specify, up hons per CTEATE)

CTEATE version

Close Window

Reporter User ID

Save Draft

2439

Submit for Review

Print

Protocol # 6503 - Targeted Therapy of Bronchiolitis Obliterans Syndrome (BOS)...

Participant ID	128647	Date of Registration	01 May 2014			
Local ID	311004					
Status	Eligible					
Site ID	Experimental Transplantation and Immunology Branch, NIH (cGVHD)					
Treatment	6503 Fluticasone, Azithromy	6503 Fluticasone, Azithromycin and Montelukast (FAM)				
Treatment Assign Date	02 May 2014	Treatment Start Date	03 May 2014			

Treatment Start Date treatment table revised
(First Date All 3 FAM Medications Are Administered)

				* Th			d in order to SAVE the form rder to COMPLETE the form
Date of Visit:	* 3	30	Apr	2014	<u>Date</u>		
Interviewer User ID:	* 4	1338	}				
		t et	art dal	te. vou	will char	ge all of the	due date windowe
Note: By updating the tr for the follow-up visits. proceeding.						_	

Protocol # 6501 - Longitudinal Study of Immune Mediated Disorders after Alloge...

Participant ID	101106	Date of Registration	26 Nov 2013			
Local ID	0101100	Date of Baseline Exam	26 Sep 2013			
Status	Eligible					
Site ID	Fred Hutchinson Cancer Research Center (cGVHD)					

Demographics _ revised

	* These fields are required in order to SAVE the form				
	* These fields are required in order to COMPLETE the form				
Date of Visit:* Dat	<u>e</u>				
Interviewer User ID:* Use	er ID is required				
1. Participant Age (either Date of Birth your local institution's IRB):	or Age is required, use Date of Birth unless disallowed by date of birth day date of birth manth date of birth year				
Date of Birth	: dob date of lovely as				
	OR				
Age at registration	can alivered to the				
2. Gender:*	Male Female gender				
3. Race (check all that apply): *	a Av hative				
race_nativeHlorpacificishand	Black or African American VACL - black or African Native Hawaiian or Other Pacific Islander				
	Unknown race_white				
	Refused race_refused				
4. Ethnicity (se/ect one): *	Hispanic, Latino, or Spanish origin				
	Not Hispanic,Latino or Spanish origin				
	Unknown or not reported				
	Refused.				
MO					

Protoco #6502 -	A Randomized Phase II Study of Imatinib and Rituximab for Cu						
Participant ID	121393	Date of Registration	11 Mar 2013				
Local ID	0201011						
Status	Eligible						
Site ID	Fred Hutchinson Cancer Research Center (cGVHD)						
Treatment	Rituximab Dose: 375 mg/m2 IV weekly x 4						
Treatment Assign Date	11 Mar 2013	Treatment Start Date	20 Mar 2013				

Baseline Visit Chart Abstraction BL_Visit_chart_Abstraction Page: 1 of 2

→ 🗐 1

* These fields are required in order to SAVE the form All questions should be filled out for eCRF to be "COMPLETE" in tracking system Date of Visit:* 8 Mar 2013 Date

Interviewer User ID:* 2970

TRANSPLANT CHARACTERISTICS

TX_DD TX_MM TX-YY

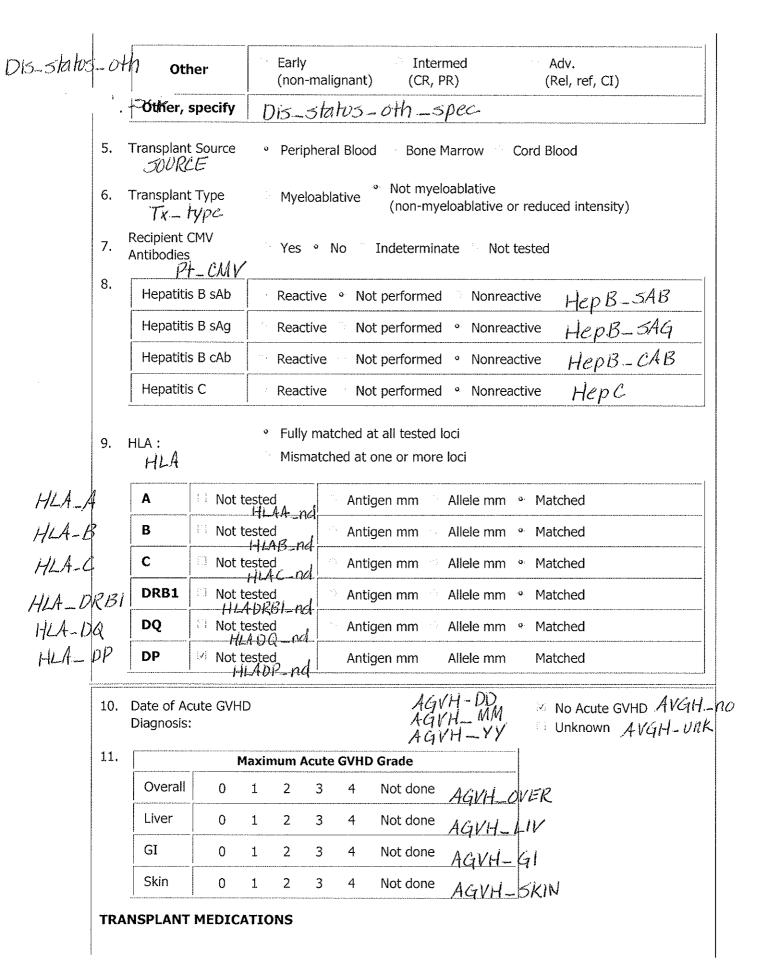
2011 Date of transplant: 22 Feb

HT-pre, HT-unit Unknown HT-pre_unk Height 2. 172 cm pre-transplant:

Weight 3. 77.3 pre-transplant:

WT-pre, WT-Unit Munknown WT-pre-UNK

•	4.	Disease Status	Early	Intermediate	Advanced
is-status.	AMI.	AML	CR1	· CR2	CR3+, rel, ref, IF
15-5hahus-A		ALL	CR1	· CR2	CR3+, rel, ref, IF
13-5tatus	- CM	L CML	· CP	· · AP	BC or after BC
is-status-	24	_ CLL		CR, PR, CS	Rel, ref, CI
15-51alus-			RA, RARS	RAEB, RAEBT	Rel, ref, IF
15-5 Mus-	-M	D MPD		All others	Rel, ref, IF
15-5tatus-	. NH	<u>/</u> NHL		° CR, PR, CS	Rel, ref, CI
013-51atus	- H/) HD		CR, PR, CS	Rel, ref, CI
is_status-	MI	/ MM		CR, PR, CS	Rel, ref, CI
is statu	1.		Without ATG/TG	With ATG/TG	



12. Conditioning Regimen

	Code regimen		Modifier 1	Modifier 2	
21	TX_CODE#	4	TX_MOD#	TX_MOL)#
		. \$ 10 \$ 70 \$ 8 \$ 2 \$ 2 \$ 4 \$ 7 \$ 4 \$ 7 \$ 4 \$ 7 \$ 6 \$ 7 \$ 6 \$ 7 \$ 6 \$ 7 \$ 6 \$ 7 \$ 6 \$ 7 \$ 7	Landrick and the Committee of the Commit		,
				k daarah shakad k dhibaada ka kaada babada adaadk ka a daaraa a saasa	, '

- 13. T-cell Depletion? Tcell
- Yes º No
- 14. GVHD prophylaxis (please complete the IMD medication form)

DONOR CHARACTERISTICS

15. Age of Donor Dnr_age 39

years

Unknown Dnr_age_unk

16. Donor Gender (choose 2 genders if double cord)

• Male

Female

Female/Female

Male/Male

Male/Female

17. Donor Match

Dnr-match

HLA identical sibling

HLA-matched other relative

HLA-mismatched relative (single antigen or allele mismatched)

Haplo-identical relative (2 or more antigen or allele mismatched)

HLA-mismatched unrelated donor

HLA-matched unrelated donor

18. Donor CMV Antibodies

Dnr_ CMV

Yes

o No

110

Indeterminate

Not tested



Save

Print

Close Window

Protocol # 6501 - Longitudinal Study of Immune Mediated Disorders after Alloge...

Participant ID	129179	Date of Registration	29 May 2014			
Local ID	0101245	Date of Baseline Exam	07 Mar 2014			
Status	Eligible					
Site ID	Fred Hutchinson Cancer Research Center (cGVHD)					

IMD Onset Form IMD _ Onset_ Form _ revised

ſ			·		order to SAVE the form	-1
	All questions should be filled ou	t for eCRF to	be "COMF	LETE" in tracking sy	/stem	
Dat	e of IMD Onset: *	<u>Date</u>				
Inte	erviewer User ID:*					
СН	ARACTERISTICS OF IMMUNE MEDIA	ATE DISOF	RDER (e.	J., CHRONIC GV	HD) AT ONSET	
1.	Date of immune mediated disorder onset			Date 1MD.	_O_DD _O_MM _O_YY	
2.	Name of immune mediated disorder	○ Late,	, recurren	t or persistent acu		
	IMD_O	ି Chro	nic GVHD	(classic chronic o	r overlap)	
				mediated disorde		
		If Other,	specify:	IMD_O_OT	17	
3.	Acute GVHD present the week before immune mediated disorder diagnosis?	ି Yes	ି No ା	Unknown UNSC	et	
4.	Weight $WT_{-}O$		Kgs	WT-0-6	Mバー □ Unknown	UT_O_UNK
5.	Performance score Parf _ O		% Karno	ofsky KP5_LP3	<i>_O</i> ☐ Unknown	Perf_O-unt
6.	Percent BSA BSA = 0		%		Unknown	BSA_O_Unl
7.	Lichen-planus-like changes of skin LiC	H.O Yes	ି No	ି Unknown		
8.	Sclerotic changes of skin SCL - O	ି Yes	ି No	ି Unknown		
9.	Bronchiolitis obliterans syndrome	ି Yes	ି No	ි Unknown		
10.	1	ି Yes	⊕ No	ි Unknown		
11.	Oral involvement ORAL - O	ି Yes	ି No	ි Unknown		
12.	Total bilirubin Bili_0				🖺 Unknown	BILL O-UNK
13.	Platelet count PIF_O				🗆 Unknown	PIt_O_UNK

Protocol # 6503 - Targeted Therapy of Bronchiolitis Obliterans Syndrome (BOS)...

Participant ID	128647	Date of Registration	01 May 2014			
Local ID	0311004	311004				
Status	Eligible					
Site ID	Experimental Transplantation and Immunology Branch, NIH (cGVHD)					
Treatment	6503 Fluticasone, Azithromycin and Montelukast (FAM)					
Treatment Assign Date	02 May 2014	Treatment Start Date	03 May 2014			

FEV, Absolute Value pu503-17918 - Fevlabsol - remsed

				*	^k These fields are	required in	n order to SAVE the form
				* Thes	se fields are requi	red in orde	r to COMPLETE the form
Date of Visit:	* 30	Apr	2014	<u>Date</u>			
Interviewer User	ID:* 4338	3					
1. Baseline FEV ₁ A	lue	3.67	liters	base-Fevi			
2. FEV ₁ Absolute \	2. FEV ₁ Absolute Value which indicates 10% decrease						fail-FEVI

Protocol # 6503 - Targeted Therapy of Bronchiolitis Obliterans Syndrome (BOS)...

Participant ID	128187	Date of Registration 03 Apr 2014				
Local ID	0301010					
Status	Eligible					
Site ID	Fred Hutchinson Cancer Research Center (cGVHD)					
Treatment	6503 Fluticasone, Azithromycin and Montelukast (FAM)					
Treatment Assign Date	03 Apr 2014	Treatment Start Date 04 Apr 2014				

High Resolution CT and Local Pathology for Diagnosis of Bronchiolitis Obliterans

		· • · · · · · · · · · · · · · · · · · ·	
		* These fields are required in or	rder to SAVE the form
		* These fields are required in order to	COMPLETE the form
Date of Visit:	*	<u>Date</u>	
Interviewer Use	· ID:*		
1. Did subject hav	e a HRCT cor	nfirming diagnosis of BOS? BOS HRCT	ୁ Yes ୁ No
Date of HI	RCT:	HRCT_DD HRCT_MM HRCT_YY	
2. Did subject hav	ve a biopsy ar	nd a pathology report confirming diagnosis of BOS?	ି Yes 🤚 No
Date of bi	opsy:	1305 - BX - DD BOS - bX 1305 - BX - MM 1305 - BX - XY	

Protocol # 6501 - Longitudinal Study of Immune Mediated Disorders after Alloge...

 (—)			J		
Participant ID	101106	Date of Registration	26 Nov 2013		
Local ID	0101100	Date of Baseline Exam	26 Sep 2013		
Status	Eligible				
Site ID	Fred Hutchinson Cancer Research Center (cGVHD)				

Lab Results Form Lab-Results revised

	Lad Results Fori	m Lab-Kesuns-(moea
		ese fields are required in order to SAVE the form
	ld be filled out for eCRF to be "C	COMPLETE" in tracking system
Date of Visit:*	<u>Date</u>	
Interviewer User ID:*	User ID is required	
Metabolic Panel No	ot Done Date of Test	J-Meta-DD J-Meta-MM Meta-YY
Test Name	Result	Units
Creatinine* CR	CR-unit	□ Not Done CR-nd
BUN* BUN	BUN_unit	□ Not Done BUN_no
Glucose* Glu	Glu-unit	Not Done Glu - nd
CBC with Differential ONG	ot Done Date of Test	J-CBC-YY CBC-YY
Test Name	Result	Units CBC-YY
Hemoglobin (Hgb)* H석B	HGB.	Unit Not Done HGB-n
Hematocrit (Hct)* トピア	HCT_unit	□ Not Done HGB — n
WBC* WBC	WBC-uni	† □ Not Done WBC – ne
Neutrophils* Neu	Neu-unit	Mot Dono William
Bands* Bands	Bands-i	
Lymphocytes* Lym	Lym-un	it Not Done Lym_r
Eosinophils* EoS	Eos- Uni	T Not Done Eos− ∩
Platelets* PI+	PIT_ uni	•
Liver Function Tests No	t Done Date of Test	J LFT_DD LFT_MM LFT_YY
MO LFT_ Test Name	NA Result	Units LFT_YY
Total bilirubin* Billi	Bili - unit	□ Not Done Bili_nd
Direct bilirubin* BiliD	BiliD-unit	□ Not Done BiliD-
AST* AST	AST_unit	□ Not Done <i>A 5T</i> − n
. = · · / 01	101-01/1	Not Done ALT_No

Alkaline Phosphatase* ALP

ALK _ Unit

Not Done ALK_nd

Albumin*

ALB _ Unit

Not Done ALB_nd

	Participant I Local I Statu	- Longitudinal Study of In 101106 0101100 s Eligible Fred Hutchinson Cancer Re	Date of Registration Date of Baseline Exam	26 Nov 2013 26 Sep 2013	
	I		cation Form	IND medication	ns_revised
				re required in order to SAVE the for	rm
		be filled out for each Medicatio	n for eCRF to be "CON	MPLETE" in tracking system	
	Date of Visit:*	Date			
<u></u>	Interviewer User ID	:* User ID is re	quired		
	Medication		Indication	Start Date Currentl	, ,
	A . A . I . I .	exNorm Code ND_Med_Code#	IW	ID_Med_Start Taking?	Stop Date
Code			cute Prophylaxis Unl		me#
# =	- 32	Save Print Close D/1 indication- indication- maication- maication- maication-	acute #1- _prophylaxi; unknownt	IMD_med_S.	at_mm# tart_yy# Stop_DD# Stop_MM#

DEMO

Protocol # 6501 - Longitudinal Study of Immune Mediated Disorders after Alloge...

	[] '			V			
F	Participant ID	101106	Date of Registration	26 Nov 2013			
	Local ID	0101100	Date of Baseline Exam	26 Sep 2013			
	Status	Eligible					
	Site ID	Fred Hutchinson Cancer Research Center (cGVHD)					

* These fields are required in order to SAVE the form
All questions should be filled out for eCRF to be "COMPLETE" in tracking system

Date of Visit:*

Date

Interviewer User ID:*

User ID is required

Comorbidity	Definition	Present	
1. CARDIOVASCULAR			
Arrhythmia* CMI3_ARK	Atrial fibrillation or flutter, sick sinus syndrome or ventricular arrhythmias	OY ON OU	
Coronary artery disease	Coronary artery disease (one or more vessel- coronary artery stenosis requiring medical treatment, stent, or bypass graft), angina	ay an au	
History of MI CMB_M(History of myocardial infarction	OY ON OU	
Heart valve disease CMB - HVD	Except asymptomatic mitral valve prolapse	AY AN AU	
Hypertension <u>CMB_ HTN</u>		OYONOU	
Congestive heart failure	EF ≤ 50%	OY ON OU	
Cerebrovascular disease	Transient ischemic attack or history of cerebrovascular accident, or neurologic impairment consequent to CVA	AY AN AU	
Peripheral vascular disease		OY ON OU	
ous thrombosis	Confirmed radiographically and requiring anticoagulation	OY ON OU	
2. GASTROINTESTINAL			
Peptic ulcer/hernia /reflux CMB_ULC	Requiring treatment	OY ON OU	

Mild hepatic CMB_HEPM		
Moderate/severe hepatic とMB_ HEPS	Liver cirrhosis, bilirubin > 1.5 times ULN or AST/ALT > 2.5 ULN	ay an au
Inflammatory bowel disease cMB~1135	Crohn's disease or ulcerative colitis	⇒γ ⇔N ⊕U
3. PULMONARY		
Moderate pulmonary CMB PULMM	DLCO and/or FEV-1 66%-80% or dyspnea on slight activity	% Y *> N *> U
Severe pulmonary (MI3-PULM3	DLCO and/or FEV-1 65% or lower or dyspnea at rest or requiring oxygen	O Y - O N THU
Asthma CMB-AST	Asthma symptoms for which inhaled steroids or other daily treatments are needed chronically to prevent or manage attacks	ay ay Now A
4. ENDOCRINE		
Diabetes CMB - DB	Requiring treatment with insulin or oral hypoglycemic agents but not diet alone	OY AN AU
Hypothyroidism <i>CMB</i> _ ゴ	Including compensated hypothyroidism	oy an ou
Adrenal Insufficiency CMB_AL	Including compensated adrenal insufficiency	SYNNDU
5. NEUROPSYCHIATRIC		
Psychiatric disturbance- Depression CMB_DEP	Depression requiring psychiatric consult or treatment	oy on ou
Psychiatric disturbance- Anxiety or panic disorder CMB-ANX	Anxiety or panic disorder requiring psychiatric consult or treatment	OYON OU
Neurologic disease (peripheral neuropathy, MS, Parkinson's disease or other chronic neurologic disease CMB-ND	Symptomatic and requiring treatment to control or manage symptoms/disease process	эү эү э
Visual impairment secondary to cataracts, glaucoma or macular degeneration	Unilateral or bilateral, and unrepaired	oy on ou
Hearing impairment	Very hard of hearing, even with hearing aids	оуолоц

	######################################	
Osteoarthritis	Symptomatic and requiring treatment or with osteoarthritic changes noted on radiographic studies	OY UN OU
Degenerative disc disease (spinal stenosis or severe chronic back pain)	Symptomatic and requiring treatment or symptomatic and with degenerative disc disease noted on radiographic studies	⇔Y ⇔N ∻U
Avascular necrosis CMB_AVN	Symptomatic with pain secondary to AVN or joint replacement	OYON OU
Osteopenia/Osteoporosis	T Score < or equal to minus 1.5 or on treatment with a bisphosphonate	OY ON OU
Rheumatologic CMB_RA	Lupus, mixed connective tissue disorder, rheumatoid arthritis, polymyalgia rheumatica	OY ON OU
7. OTHER COMORBIDITIE	es s	
Infection CMB_INFX	Requiring current treatment with antimicrobial (not prophylaxis)	WY AN AU
Moderate/severe renal	Serum creatinine > 2 mg/dL, on dialysis, or prior renal transplantation	OYON OU
Prior solid malignancy	Treated at any time point in the patient's past history, excluding nonmelanoma skin cancer	ary arn ar
8. PHYSICAL EXAM - Anth	ropometry	
Height Weight	HT_CMB_cm HT_CMB_in cm in WT_CMB_Kg WT_CMB_1b kg lbs	HT_CMB - Not Done WT_CMB - r Not Done
i		

Protocol #6501 - Longitudinal Study of Immune Mediated Disorders after Alloge...

Participant ID	101106	Date of Registration	26 Nov 2013		
Local ID	0101100	Date of Baseline Exam	26 Sep 2013		
Status	Eligible				
Site ID	Fred Hutchinson Cancer Research Center (cGVHD)				

Medication-Steroids Form imd_13174-medications_vensed

	11.00						
	* These fields are required in order to SAVE the form						
All fields should be filled out for each Medication for eCRF to be "COMPLETE" in tracking system							
Date of Visit:*	<u>Date</u>						
Interviewer User ID:*	User ID is required						

Patient is not on any steroids

Medication

Dose
Units
Frequency
Route

Search term RxNorm Code Ster_ Dose# (mg,ml) Ster_Freq # (PO,IV)

Code IMD_Med # IMD_Med_Code # Ster_Units #

Ster_Roule#

Add

Save Print Close Window

DEMO

Specimen Collection –Aliquots Sampling Form CLINICAL RESEARCH NETWORK Protocol Number: 6503 Participant ID: ______ Site: _____ Person Completing Form: ______ Sites ______ Person Completing Form: _______ Sites ______

draunode = 87te

Specimen Name	Barcode Number	Box Number	Insufficient Volume	Volume	Cell Count	Location in Box	Comments
PBMC aliquots – Tube 1				mL	x10 ⁶		
PBMC aliquots – Tube 2				mL	x10 ⁶		
PBMC aliquots – Tube 3				mL	x10 ⁶		
PBMC aliquots – Tube 4				mL	x10 ⁶		
PBMC aliquots – Tube 5				mL	x10 ⁶		
PBMC aliquots – Tube 6				mL	x10 ⁶		
PBMC aliquots – Tube 7				mL	x10 ⁶		
PBMC aliquots – Tube 8				mL	x10 ⁶		
Heparin Plasma aliquots – Tube 1				mL	x10 ⁶		
Heparin Plasma aliquots – Tube 2				mL	x10 ⁶		
Heparin Plasma aliquots – Tube 3				mL	x10 ⁶		

aliquet-type aliquet-barade box insufficient-voi volume cell-cont box-loc comments

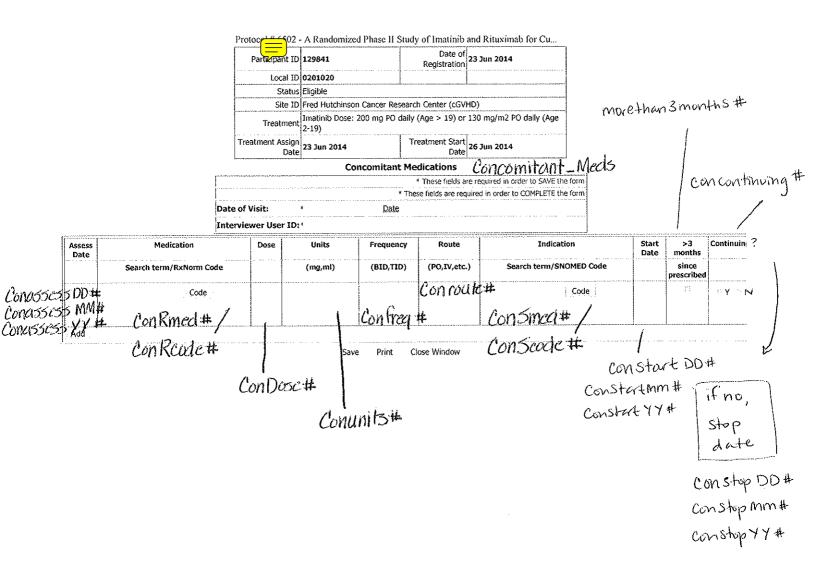
Status = tube broken delayed processins hemoly 3ed low cell count

RARE DISEASES CLINICAL RESEARCH NETWORK reservisor National Institutes of Health	Specimen Collection –Aliquots Sampling Form	24May2012 Version 1.1 Page 2 of 3
Protocol Number:6503	Participant ID:	
Person Completing Form:		

Heparin Plasma aliquots – Tube 4	mL	x10 ⁶	
Heparin Plasma aliquots – Tube 5	mL	x10 ⁶	
Heparin Plasma aliquots – Tube 6	mL	x10 ⁶	
Heparin Plasma aliquots – Tube 7	mL	x10 ⁶	
Heparin Plasma aliquots – Tube 8	mL	x10 ⁶	
Heparin Plasma aliquots – Tube 9	mL	x10 ⁶	
Heparin Plasma aliquots – Tube 10	mL	x10 ⁶	
Heparin Plasma aliquots – Tube 11	mL	x10 ⁶	
Heparin Plasma aliquots – Tube 12	mL	x10 ⁶	
Urine aliquots – Tube 1	mL	x10 ⁶	
Urine aliquots — Tube 2	mL	x10 ⁶	
Urine aliquots – Tube 3	mL	x10 ⁶	

RARE DISEASES CLINICAL RESEARCH NETWORK	Specimen Collection –Aliquots Sampling Form	24May2012 Version 1.1 Page 3 of 3
Protocol Number:6503Site:Person Completing Form:	Participant ID:	

Urine aliquots – Tube 4	mL	x10 ⁶	
Urine aliquots – Tube 5	mL	x10 ⁶	
Urine aliquots – Tube 6	mL	x10 ⁶	
EDTA Plasma aliquots – Tube 1	mL	x10 ⁶	
EDTA Plasma aliquots – Tube 2	mL	$x10^{6}$	
EDTA Plasma aliquots – Tube 3	mL	$x10^{6}$	
EDTA Plasma aliquots – Tube 4	mL	x10 ⁶	
Granulocytes	mL	$x10^{6}$	



Participant ID Partic

Provider Survey Enrollment

Provider_Survey

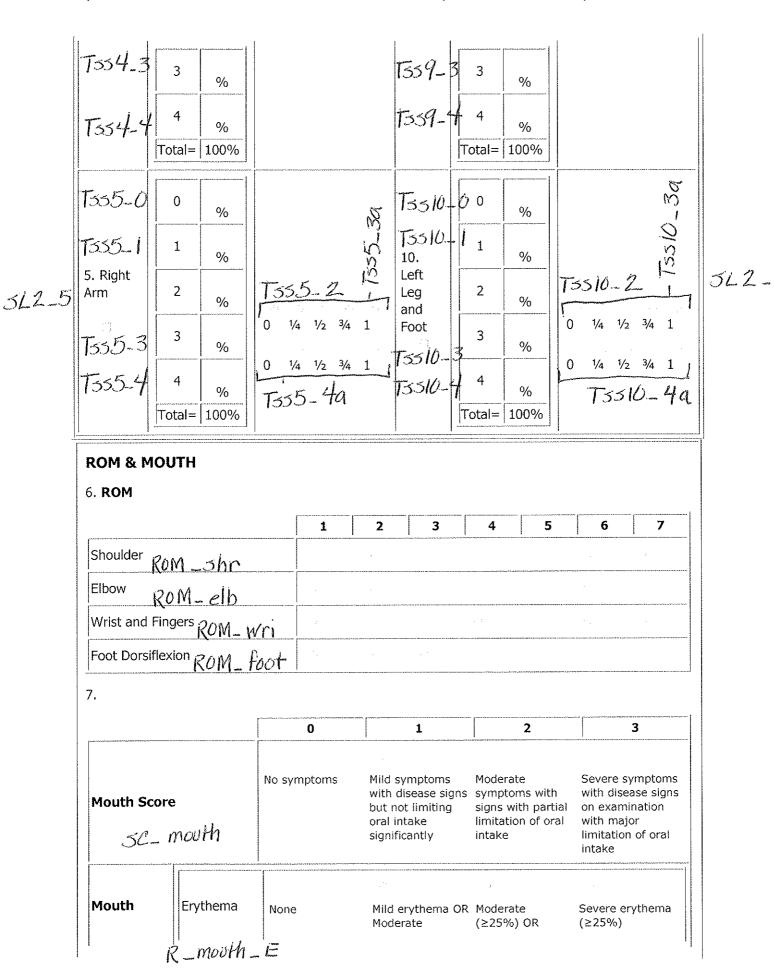
Page: 1 of 8

▶ 1 ▶ ₩ ⅓ ▶ I

		* The	se fields are required	in order to SAVE the form
		* These fiel	ds are required in ord	ler to COMPLETE the form
Date of Visit:*	<u>Dat</u>	e		
Interviewer User ID:*	Use	er ID is required		
Date completed:		MD_compl -	DD, MD-com	pi-MM, MD-co
SKIN				
1.			,	
Check ONE area of the body as the sentinel lesion		Erythematous rash of any sort	Moveable sclerosis	Non-moveable subcutaneous sclerosis or fasciitis
1. Head/neck/scalp 571_1		Eskin1%	Mskin1%	Eskin1%
2. Anterior torso SL1_2	: 3	Eskin2"	Mskin2%	F5kin2%
3. Posterior torso 3L1_3	: 1	Eskin3%	Mskin3°	F3kin3%
4. Left upper extremity	77)	Eskin4%	Mskipy	Fokin4%
5. Right upper extremity 3L1-5	Fl	Eskinso	115Kin5"	Fskin5 [%]
6. Left lower extremity, (incl. L buttock) SL1-6	23	Eskin6	Uskin&	Fskin6
7. Right lower extremity, (incl. R buttock) 5117	in)	Eskin7°	Uskin7	Fskin7°
8. Genitalia Not examined	£3	Eskin8%	Mskin'8	Fskin8%

	0	1		2	3	4
						ı
Skin sclerotic changes J_5KiYI	Normal	Thickened with pockets of normal skin		kened over writy of	Thickened unable to move	, Hidebound, unable to pinch
3.						
	0	1			2	3
		;			-	:
Skin Score SC_5Kin	o symptoms	< 18% BSA wi disease signs b sclerotic featur	out NO res	19-50% Binvolveme superficial features "r hidebound pinch)	nt with sclerotic not	>50% BSA OR deep sclerotic features "hidebound" (unable to pinch) OR impaired mobility, ulceration or severe pruritus
Fascia N.	ormal	Tight with norr areas	mal	Tight		Tight, unable to move
4.				W 10 F		, p. 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1
ulcer		Clinical Skin Fe	ature	S		
Ulcer Location:	ulcer_loc	. Largest	dimer	nsion (cm)	: ille.	_ 5Z
Maculopapular rash	MPrash		Kerato	osis pilaris	Kpil	
Lichen planus-like le	esions / i/h	1 1	Papul	osquamou		or icthyosis IcH
	***************************************		,,	nvolvemer		
	Poik			nvolvemen	1 100	
	rur Whekin ou	hsin_spec			14000	kin2, Othskir
Other, specify: ()	11101011701	113111-0140	Other	, specify.	Orns	KINZ, OTIL-NI
5.	pan —	WALLEY (14 1907)		***************************************		COLLEGE CONTRACTOR CON
	% or Area of	ction of Grade 3 4 Areas with Erythema licate up to what	Reg	ion Grac	% le Area Grad	e (indicate up to w
Region Grade		ction is involved)				fraction is involve

	T351_1 T351_2 T331_3 T351_4	3 06	1551-39 0 1/4 1/2 3/4 1 0 1/4 1/2 3/4 1	T356-1 1 % T356-2 2 % T356-3 3 % T356-4 4 % Total= 100%	T556_3a 0 1/4 1/2 3/4 1 0 1/4 1/2 3/4 1	
312-2	T552-1 2. Chest T552-2 T552-3 T552-4	1 % 2 % 3 %	T552_3a 0 1/4 1/2 3/4 1 0 1/4 1/2 3/4 1 T552_4a	7.557-0 0 % 7. Left 2 % 7.557-3 3 % 7.557-4 4 % Total= 100%	7357-2 0 1/4 1/2 3/4 1 0 1/4 1/2 3/4 1 T557_49	5L2-7 -T357-39
JL2-3	T333_1 3. Abdomen and Genitals T333_3	2 %	T553-210 0 1/4 1/2 3/4 1 1	7558_0 0 % 7558_1 1 % 8.Left Hand 2 % 7558_3 3 % 7558_4 4 % Total= 100%	0 1/4 1/2 3/4 1 10 1/4 1/2 3/4 1 1 T558-49	512-8 T538-30
SL2-4	7.554-0 4. Back and Buttocks 7.554-2	0 % 1 % 2 %	T354-1 1 1 0 1/4 1/2 3/4 1 1 T554-4A	7559-0 0 % Right Leg 1 % Foot 2 %	T559-1 19 0 1/4 1/2 3/4 1 0 1/4 1/2 3/4 1 T559-49	3L2-9



			erythema (<25%)	Severe erythema (<25%)	
	Lichenoid R_movH	None	Hyperkeratotic changes (<25%)	Hyperkeratotic changes (25-50%)	Hyperkeratotic changes (>50%)
	Ulcers R_mout	None	None	Ulcers involving (≤20%)	Severe ulcerations (>20%)
	Mucoceles (of lower labia and soft palate only) R_M	None	1-5 mucoceles	6-10 scattered mucoceles	Over 10 mucoceles
Mouth Pain	nouth	No symptoms	Food sensitivity	Pain requiring narcotics	Unable to eat

GASTROINTESTINAL

8.

		0	1	2	3
GI Tract Sco ろと・	ore _ G1	No symptoms	Symptoms such as dysphagia, anorexia, nausea, vomiting, abdominal pain or diarrhea without significant weight loss (<5%)	associated with mild to moderate weight loss	Symptoms associated with significant weight loss >15%, requires nutritional supplement for most calorie needs OR esophageal
Gastro- intestinal	Esophagus Dysphagia OR Odynophagia R_eso	No esophageal symptoms	Occasional dysphagia or odynophagia with solid food or pilis during the past week	–	Dysphagia or odynophagia for
	Upper GI Early satiety R_UGI	No symptoms	: Mild, occasional	Moderate,	More severe or

OR Anorexia OR Nausea & vomiting		symptoms with little reduction in oral intake during the past week	intermittent symptoms throughout the day, with some reduction in oral intake, during the past week	
Lower GI Diarrhea R_LGI	No loose or liquid stools during the past week	Occasional loose or liquid stools, on some days during the past week	Intermittent loose or liquid stools through-out the day, on almost every day of the past week without requiring intervention to prevent or correct volume depletion	Voluminous diarrhea on almost every day of the past week requiring intervention to prevent or correct volume depletion

OTHER ORGANS

9.

	0	1	2	3
				*1
Eye Score SC-eye	No symptoms	Mild dry eye symptoms not affecting ADL (requiring eye drops <3x per day) OR asymptomatic signs of keratoconjunctivitis sicca	Moderate dry eye symptoms partially affecting ADL (requiring eye drops >3x per day or punctual plugs) WITHOUT vision impairment	
		in a larger of the same in the control of the same and th	. Carrier and the control of the con	conjunctivitis sicc
		<i>\$</i>	14	".
Joints and Fascia Score	No symptoms	Mild tightness of arms or legs, normal or mild decreased range of motion (ROM) AND not affecting	Tightness of arms or legs OR joint contractures, erythema thought due to fasciitis, moderate	Contracture WITH significant decrease of ROM AND significant limitation of ADL (unable to tie
5C-joint		ADL	decrease ROM AND mild to moderate limitation of ADL	shoes, button shirts, dress self etc.)
Genital Tract Score	. 11		13	*.
□ No GYN Exam	No symptoms	Symptomatic with mild distinct signs	Symptomatic with distinct signs on	Symptomatic WITH advanced
3C-genital				

GVN_exam

	NB: score still required		on exam AND no effect on coitus and minimal discomfort with GYN exam	exam AND with mild dyspareunia or discomfort with GYN exam	signs (stricture, labia agglutination or severe ulceration) AND severe pain with coitus or inability to insert vaginal spectrum
	Lung Score SC - lung	No symptoms	Mild symptoms (shortness of breath after climbing one flight of steps)	Moderate symptoms (shortness of breath after walking on flat ground)	Severe symptoms (shortness of breath at rest; requiring O2)
&_oth	Other Organ Score, specify: \$\sigma_0 + 0 + 1 - spec 1\$ Other Organ Score,	No effect on ADL	Mild effect on ADL	Moderate effect on ADL	Severe effect on ADL
2-0th 12	Other Organ Score, specify: Sc_oH1 -Spec2 Add Other	No effect on ADL	Mild effect on ADL	Moderate effect on ADL	Severe effect on ADL

OVERALL STATUS

10.

Please rate the severity	y of this person's GVI	1D	MD_5CY_N	M5
on this scale	None(0)	Mild(1)	Moderate(2)	Severe(3)
MD_5eV10 and on this scale	cGVHD Symptoms are not at all severe			cGVHD Symptoms are most severe possible
(select one)	0 1	. 2 - 7 3 - 7	4 5 6 7	7 8 9 10

11.

Reasons for changing therapeutic regimen (check all that apply)

Not applicable, no changes made Rxchg - na Adjust levels of medications Rxchg - level	Toxicity Rxchg-tox New symptoms Rxchg-newsx
Enroll on clinical trial Rxchg—trial	Improvement in symptoms Kxchq_improve
Worsening of symptoms Rxchg - worse	Disease relapse Rxchg - rel
No improvement in symptoms Rxchy-noimprov	Stable Rxchg_stable
12.	

rank)			re	4	
	1		It ranked, p	lease provide nu	imber
Skin 50R_=					
□ Joints 50 R	joint				
Fascia 50R _					
□ Lung SOR_ □ Urogenital SO	lung Propinital				
□ Liver 50R _ 1					
Mouth SOR -					
Esophagus 5					
Lower GI づり					
Other SOR _					
If Other, specify:	50-0H	hopec			
.3.					vog
Does this person currently have: GVHD _ current			Classic chror	te and chronic G nic GVHD (3)	VHD (2)
4.	4				
Infection	0	1	2	3	4
J-inf	None	Mild, topical or no therapy required	Moderate, localized, requiring oral treatment Jainfail	Severe, systemic infection requiring IV anti-infective, mold-active oral antifungal or hospitalization	Life-threatening infection
[For 2-4:		+1	13	
		Pending lab	Unidentified organism (2)	Identified organism (3)	
		report (1)	organism (z)		

Peripheral Edema?	None (0)	‡Tr ((9)	1+ 2+	+ 3+	4+
6.						
Other indicators, clini	ical manifesta	tions or sev	ere compl	ications re	lated to chi	onic GVHI
		Never (0)	Past, not now (1)	Mild (2)	Moderate (3)	Severe (4)
1. Pleural Effusion(s)	 :M1		٠.	· .		AND
2. Bronchiolitis obliteran		vî ş	+ 2	x 3		
3. Bronchiolitis obliteran pneumonia	***************************************	· :	:	v ·	>	
4. Nephrotic syndrome	CM4		*s	٠.		ety.
5. Malabsorption	CM5	· :	· ·			. 3
6. Esophageal stricture			. 3			70
7. Ascites (serositis)	CM 7				13	
8. Myasthenia Gravis	U18					
9. Peripheral Neuropath				··.		· :
10. Polymyositis	CM(I)					
11. Pericardial Effusion	MII			.*.		
12. Cardiomyopathy	CM12	. :	.15	ely.		
13. Cardiac conduction		25	λγ	.')	1	*
14. Coronary artery invo		17)	· ·			
15. Other, please specif	4	#			:	
16. Other, please specif	**************************************		· .			··.
17. Other, please specif	y: <i>CM15-0H</i>	15pec# 			**	* .
Add Other		.1,		en en elemento de la la compania de		

14.

Since th	e last study	visit three n	nonths ago	on, how would you say this patient's chronic GVHD has changed?					VHD has
	Not involved (0)	Resolved (1)	Very much better (2)	Moderately better (3)	A little better (4)	About the same (5)	A little worse (6)	Moderately worse (7)	Very much worse (8)
Mouth	0	0	0	0	0	0	0	0	0
Skin	0	0	0	0	0	0 .	0	0	0
Eye \$	0	0	0	0	0	0	0	0	0
Joints	0	0	0	0	0	0	0	0	0
Chronic GVHD(Overall		0	0	0	0	0	0	0	0
What are your reasons for how you rated "chronic GVHD overall"? Write in (For example, has an organ or symptom improved or worsened?)			chg-ve.	NOS					

15.

	0	1	2	3	4
Infection	O None	O Mild, topical or no therapy required	O Moderate, localized, requiring oral treatment	O Severe, systemic infection requiring IV anti-infective, mold-active oral antifungal or hospitalization	O Life- threatening infection
	For 2-4:	O Pending lab report (1)	O Unidentified organis	sm (2) O Identified or	rganism, specify (3):

 Protoco 502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

Participant ID	129841	Date of Registration	23 Jun 2014				
Local ID	0201020						
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	Fred Hutchinson Cancer Research Center (cGVHD)						
Treatment	Imatinib Dose: 200 mg PO daily (Age > 19) or 130 mg/m2 PO daily (Age 2-19)						
Treatment Assign Date	23 Jun 2014	Treatment Start Date	26 Jun 2014				

Patient Survey Enrollment

Patient_Survey

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Date of Visit:	of Visit: * Date Invalid Date of Visit					
Interviewer User ID:* User ID is required						
Date completed:	Date not valid					
Section 1: Your Chronic	Graft vs. Host Disease (GVHD) Symptoms					
	Not As Bad As Y Present Can Imag					
1. Your chronic GVHD symptoms overall?	0 0 1 02 03 04 05 06 07 08 09 01	0				
2. Your skin itching at its WORST?	00 01 02 03 04 05 06 07 08 09 01	.0				
3. Your mouth dryness at its WORST? PSR3	0 0 1 02 03 04 05 06 07 08 09 01	.0				
4. Your mouth pain at its WORST? PSR4	0 0 1 0 2 0 3 0 4 0 5 0 6 0 7 0 8 0 9 0 1	.0				
5. Your mouth sensitivity at its WORST?	0 0 1 0 2 0 3 0 4 0 5 0 6 0 7 0 8 0 9 0 1	.0				
6. Your eye problem at its WORST?	00 01 02 03 04 05 06 07 08 09 01	.0				
7. What is your main complaint with regard to your eyes?						

8. Vulvovaginal Symptoms (females only): Do you have any burning, pain or discomfort in the area of you vagina, vulva or labia? - OR - Do you have any discomfort or pain with sexual intercourse? PSR	○ Not applicable
9. Overall, how would you rate the severity of your chronic graf versus host disease?	None Mild Moderate Severe
10. Do you think your chronic GVHD symptoms are in good enough control to decrease your immunosuppressive medications?	○ No ○ Yes ○ Not applicable

	+ 1	
Save	Print	Close Window

ON FOLLOW-UP VERSION ONLY

-			Not involved with GVHD	Compl- etely gone	Very much better	Moder- ately better	A little better	About the same	A little worse	Moder- ately worse	Very much worse
PSR	11.	GVHD symptoms overall		0 1	0 2	0 3	0 4	0 5	0 6	0 7	0 8
PSR	12.	Mouth	0 0	0 1	0 2	0 3	0 4	0 5	0 6	0 7	0 8
PSR	13.	Skin	00	0 1	0 2	0 3	0 4	O 5	0 6	0 7	0 8
PSR	14.	Eye	00	0 1	0 2	O 3	0 4	0 5	0 6	0 7	0 8
PSR	15.	Joints	0 0	0 1	0 2	0 3	0 4	0 5	0 6	0 7	0 8

PSR 16. What are your reasons for saying your chronic GVHD is better or worse overall? (Is there a symptom of particular concern to you that has changed?

(Write in)

Free text	

Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

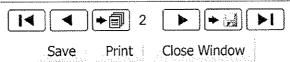
Participant ID	129841	Date of Registration 23 Jun 2014				
Local ID	0201020					
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Patient Survey Enrollment

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			ields are require		
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Date of Visit: *	<u>Date</u>				
Interviewer User ID:*					
Section 2:					
By circling one (1) number per line, please problems in the past month:	indicate how n	nuch you hav	re been bothered	d by the follo	wing
SKIN:	Not at all	Slightly	Moderately	Quite a bit	Extremely
1. Abnormal skin color	· 0	ୀ 1	◇ 2	3	୍ 4
2. Rashes	၀	0 1	் 2	் 3	ି 4
3. Thickened skin	Ø 0	ំ 1	⊗ 2	© 3	୍ 4
4. Sores on skin	ි 0	1	2	் 3	ି 4
5. Itchy skin	် 0	் 1	் 2	3	<u> 4</u>
EYES AND MOUTH:	Not at all	Slightly	Moderately	Quite a bit	Extremely
6. Dry eyes	ಿ 0	ୀ 1	ି 2	~ 3	୍ 4
7. Need to use eye drops frequently	ಿ 0	ି 1	் 2	் 3	୍ 4
8. Difficulty seeing clearly 5X8	் 0	୍ର 1	© 2	ି 3	ं 4

9. Need to avoid certain foods due to mouth pain	் 0	ି 1	୍ 2	் 3	୍ 4
10. Ulcers in mouth	ံ 0	ា 1	் 2	ි 3	ି 4
11. Receiving nutrition from an intravenous line or feeding tube	္ 0	ୀ	୍ 2	÷ 3	୍ 4
BREATHING:	Not at all	Slightly	Moderately	Quite a bit	Extremely
12. Frequent cough	ာ 0	ୀ 1	~ 2	் 3	ି 4
13. Colored sputum	၀	୍ର 1	் 2	் 3	<i>⇔</i> 4
14. Shortness of breath with exercise	ം ര	· 1	o 2	3	÷ 4
15. Shortness of breath at rest	∅ O	ୀ 1	ి 2	୍ 3	୍ 4
16. Need to use oxygen	○ 0	ំ 1	ි 2	୍ 3	୍ 4



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Patient Survey Enrollment

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			* These fields are required in order to SAVE the form
		*	These fields are required in order to COMPLETE the form
Date of Visit:	*	Date	

Interviewer User ID:*

Date of Visit:

Section 2: (cont.)

EATING AND DIGESTION:	Not at all	Slightly	Moderately	Quite a bit	Extremely
17. Difficulty swallowing sold foods	ം 0	○ 1	ి 2	் 3	୍ 4
18. Difficulty swallowing liquids ろれる	് 0	0 1	் 2	் 3	୍ 4
19. Vomiting	ಿ 0	1	் 2	୍ 3	୍ 4
20. Weight loss SX 20	၀	ୀ	ି 2	் 3	
MUSCLES AND JOINTS:	Not at all	Slightly	Moderately	Quite a bit	Extremely
21. Joint and muscle aches	് 0	ି 1	ି 2	் 3	් 4
22. Limited joint movement	၀	ୀ 1	ି 2	் 3	୍ 4
23. Muscle cramps	் 0	ୀ	் 2	୍ 3	ି 4
24. Weak muscles	୦ 0	ି 1	ි 2	3	୍ 4
ENERGY:	Not at all	Slightly	Moderately	Quite a bit	Extremely

25. Loss of energy	္ ၀	୍ 1	் 2	் 3	୍ 4
26. Need to sleep more/ take naps	୍ 0	ୀ 1	ି 2	் 3	୍ 4
27. Fevers <i>SX2.</i> 7	, 0	ା 1	ි 2	୍ 3	୍ 4
MENTAL AND EMOTIONAL:	Not at all	Slightly	Moderately	Quite a bit	Extremely
28. Depression	, ୦୦	୍ 1	் 2	୍ 3	0 4
29. Anxiety SX29	് 0	ୀ 1	ି 2	୍ 3	୍ 4
30. Difficulty sleeping	् । ०	O 1	○ 2	୍ର 3	ି 4

[**4 4 4 3 ▶ 4 3 ▶**

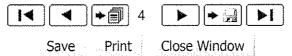
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Date of Visit: *	Dat		ius are i	ецинеи п	order to cor	THE CHE TO
nterviewer User ID:*						haddadd acyst Pattern III ac can a can
Section 3:				Alexandria de la companya de la comp	/ / / / / / / / / / / / / / / / / / / /	
Have you experienced any of the following during the last week?	All of the	ne Mosi the t		Half of the time	Some of the time	
1. Eyes that are sensitive to light? ∂D	4	் 3		ି 2	1	ာ 0
2. Eyes that feel gritty? OD2	, 4	୍ 3		2	ୀ	ံ 0
3. Painful or sore eyes? <i>O</i> D3	୍ 4	் 3		2	÷ 1	° 0
4. Blurred vision?	ి 4	<i>∞</i> 3		÷ 2	ୀ 1	် 0
5. Poor vision?	୍ 4	. ⊹ 3		· 2	ୀ -	் 0
Have problems with your eyes limited you in performing any of the following during the last week?	All of the time	Most of the time	Half o the time	of th	e the	Not
6. Reading? OD 6	0.4	ି 3	் 2	ୀ 1	⇔ 0	ି N/A
7. Driving at night?	୍ 4	୍ 3	ာ 2	<i>0</i> 1	் 0	ି N/A
8. Working with a computer or bank machine (ATM)? DS	୍ 4	0 3	ି 2	ି 1	္ 0	ି N/A

9. Watching TV?	009	୍ 4	03	் 2	୍ 1	೦೦ ೕ	N/A
Have your eyes felt uncom in any of the following situ during the last week?		All of the time	Most of the time	Half of the time	Some of the time	None of the time	Not applicable
10. Windy conditions?	0DIO	୍ 4	⊕ 3	ු 2	୍ର 1	೦೦ ೧	N/A
11. Places or areas with low (very dry)?	w humidity	୍ 4	୍ 3	⊕ 2	ୀ	೦೦ ೮	N/A
12. Areas that are air cond	itioned?	୍ 4	் 3	ු 2	் 1	೦೦ ೧	N/A



Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

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Date of Visit: * Date Interviewer User ID:* Section 4: Quality of Your Life After Your Transplant																
									PHYSICAL WELL-BEING: Not at all A little bit Somewhat Quite a bit much							
									1. I have a lack of energy	் 0	ା 1	் 2	% 3	୍ 4		
2. I have nausea FZ	ಂ 0	ୀ 1	ి 2	୍ 3	୍ 4											
3. Because of my physical condition, I have trouble meeting the needs of my family	Ó 0	1	% 2	<i></i> 3	ି 4											
4. I have pain	္ 0	ୀ 1	் 2	୍ 3	୍ 4											
5. I am bothered by side effects of treatment F5	് 0	ି 1	ି 2	∅ 3	୍ 4											
6. I feel ill F6	് 0	் 1	் 2	্ 3	୍ 4											
7. I am forced to spend time in bed 7	ಿ 0	ି 1	் 2	<i>3</i>	04											
SOCIAL/FAMILY WELL-BEING:	Not at all	A little bit	Some- what	Quite a bit	Very much											
8. I feel close to my friends	ံ 0	0 1	் 2	୍ 3	ී 4											

						1
9. I get emotional support from my family	೦ 0	୍ 1	் 2	୍ 3	े 4	
10. I get support from my friends	் 0	O 1	் 2	ଂ 3	ି 4	
11. My family has accepted my illness	© 0	් 1	⊘ 2	் 3	ି 4	
12. I am satisfied with family communication about my illness	ಿ 0	© 1	் 2	் 3	÷2 4	
13. I feel close to my partner (or the person who is my main support)	் 0	୍ର 1	○ 2	୍ 3	O 4	- Andreas - Andr
Regardless of your current level of sexual If you prefer not to answer it, please ch	•	• •		= '	n. 23 F14_	_ski
14. I am satisfied with my sex life 두너	၀	் 1	ି 2	் 3	94	
[4 4 +	•)	 			
Save	Print	Close Window	V.			

Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

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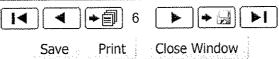
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Date of Visit	*	Date	

Interviewer User ID:*

Section 4: Quality of Your Life After Your Transplant (cont.)

EMOTIONAL WELL-BEING:	Not at all	A little bit	Some- what	Quite a bit	Very much
15. I feel sad	ಿ 0	୍ 1	ි 2	் 3	୍ 4
16. I am satisfied with how I am coping with my illness	் 0	⊕ 1	O 2	் 3	0 4
17. I am losing hope in the fight against my illness	ಾ 0	0.1	∂ 2	3	9.4
18. I feel nervous	ಿ 0	1	⇒ 2	୍ 3	୍ 4
19. I worry about dying FI9	೦ 0	் 1	் 2	୍ 3	<i>-</i> 4
20. I worry that my condition will get worse	் 0	ୀ 1	0 2	ି 3	ି 4
FUNCTIONAL WELL-BEING:	Not at all	A little bit	Some- what	Quite a bit	Very much
21. I am able to work (include work at home)	் 0	ି 1	0 2	୍ 3	୍ 4
22. My work (include work at home) is fulfilling	ి 0	ୀ 1	ි 2	ି 3	ି 4

23. I am able to enjoy life F23	ි 0	1	୍ 2	⊘ 3	0 4
24. I have accepted my illness F24	୍ 0	୍ 1	O 2	· 3	04
25. I am sleeping well F25	೦ 0	ୀ 1	ି 2	୍ 3	ି 4
26. I am enjoying the things I usually do for fun $F26$	೦ 0	0.1	ි 2	் 3	ి 4
27. I am content with the quality of my life right now F27	ಂ	ୀ 1	0 2	3	் 4
ADDITIONAL CONCERNS:	Not at all	A little bit	Some- what	Quite a bit	Very much
28. I am concerned about keeping my job (include work at home) F28	ം 0	் 1	் 2	୍ 3	୍ 4
29. I feel distant from other people	် ၀	୍ଧ 1	் 2	் 3	୍ 4
30. I worry that the transplant will not work	∾ 0	O 1	© 2	O 3	÷ 4
31. The effects of treatment are worse than I had imagined F31	© 0	் 1	் 2	© 3	் 4
32. I have a good appetite F32	ಿ 0	ୀ 1	் 2	୍ 3	ି 4
33. I like the appearance of my body	ံ 0	୍ 1	் 2	் 3	0 4
34. I am able to get around by myself	் 0	ୀ	ି 2	<i>-</i> 3	9 4
35. I get tired easily	ံ ၀	ୀ	் 2	ି 3	÷ 4
36. I am interested in sex	് 0	୍ର 1	⇔ 2	୍ 3	୍ 4
37. I have confidence in my nurse(s)	ි 0	ୀ	ି 2	୍ର 3	0 4



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Date of Visit:	*	<u>Date</u>			
nterviewer User	ID:*				
Section 5: You	r Health and We	ll-Being			
1. Which statement	nt describes how yo	u feel most of the	time? (please che	ck one) KPS (
ା 1. Norma	l, no difficulties with	daily activities			
ି 2. Able to	carry on normal ac	tivities, minor prol	olems		
ි 3. Norma	l activity with effort				
୍ 4. Able to	care for self, but u	nable to carry on i	normal activity or a	ctive work	
🤊 5. Require	e occasional assista	nce, but able to ca	re for most of nee	ds	
ି 6. Requir	e considerable assis	tance and frequen	t medical care		
ି 7. Disable	ed, require special c	are and assistance	:		
ଃ. Severe	ly disabled, hospital	ized			
9. Very si	ck, hospitalized				
2 In general wo	uld you say your he	alth is KE2			
2. In general, wo	ala you say your ne	310110 01 2			
Excellent	Very good	Good	Fair	Poor	
0	ety.	(⁶)	8	10	
3. Compared to o	ne year ago, how w	ould you rate you	r health in general	now? JF3	
Much better now than one year ago	Somewhat better now than one year ago	About the same now as one year ago	Somewhat worse now as one year ago	Much worse now as one year ago	

Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

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				to SAVE the form
	* Thes	se fields are requi	red in order to Co	OMPLETE the form
Date of Visit: *	<u>Date</u>			
Interviewer User ID:*				
Section 5: Your Health and Well-B	eing (cont.)		
The following questions are about activities you these activities? If so, how much?	u might do duri	ing a typical day.	Does your health	now limit you in
		Yes, limited a lot	Yes, limited a little	No, not limited at all
4. Vigorous activities, such as running, lifti objects, participating in strenuous sports	ing heavy <i>ろF</i> 牛	1	ි 2	୍ 3
5. Moderate activities, such as moving a tapushing a vacuum cleaner, bowling, or pla	able, lying golf <u>5</u> F£	ំ 1	் 2	் 3
6. Lifting or carrying groceries	5F6	○ 1	் 2	୍ 3
7. Climbing several flights of stairs	3F7	ା 1	္ 2	ి 3
8. Climbing one flight of stairs	5F8	ି 1	் 2	୍ 3
9. Bending, kneeling, or stopping	5F9	0 1	୍ 2	୍ 3
10. Walking more than a mile	5F10	O 1	୍ 2	ି 3
11. Walking several hundred yards	5F11	୍ର 1	் 2	ं 3
12. Walking one hundred yards	5F12	© 1	ି 2	୍ 3

13. Bathing or dressing yourself	SF13	ୀ	் 2	0	3
During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?					
	All of the time	Most of the time	Some of the time	A little of the time	None of the time
14. Cut down on the amount of time you spent on work or other activities	H4 1	் 2	் 3	0 4	் 5
15. Accomplished less than you would like	⊕ 1	் 2	୍ 3	୍ 4	් 5
16. Were limited in the kind of work or other activities 5F14	- *** 1	O 2	் 3	୍ 4	் 5
17. Had difficulty performing the work or other activities (for example, it took extra effort) 5FI 7	1	் 2	3	୍ 4	் 5

	▶	
Save	Print	Close Window

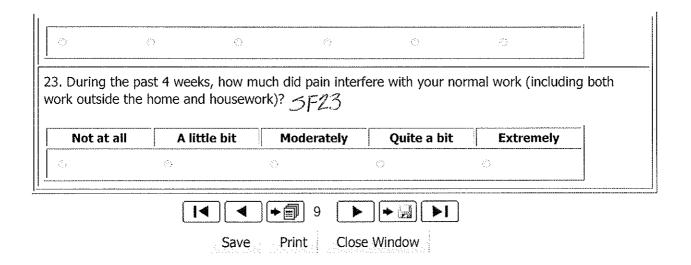
Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

Participant ID	129841	Date of Registration	23 Jun 2014		
Local ID	0201020				
Status	Eligible				
	Fred Hutchinson Cancer Res				
Treatment	Imatinib Dose: 200 mg PO daily (Age > 19) or 130 mg/m2 PO daily (Age 2-19)				
Treatment Assign Date	23 Jun 2014	Treatment Start Date	26 Jun 2014		

Patient Survey Enrollment

Page: 9 of 16

		9	>			
				elds are require		
		*7	hese fields ar	e required in (order to COMF	LETE the fo
ate of Visit: *		<u>Date</u>				
nterviewer User ID:*						
Section 5: Your Healt	n and Well	-Being (co	nt.)			
During the past 4 weeks, how other regular daily activities a	much of the is a result of a	time have you ny emotional p	had any of the roblems (such	e following pro as feeling de	oblems with yo pressed or an	our work or xious)?
		All of the time	Most of the time	Some of the time	A little of the time	None of the time
18. Cut down on the amou you spent on work or othe as a result of any emotion	r activities	ୀ F18	⊕ 2	் 3	୍ 4	÷ 5
19. Accomplished less thar like as a result of any emo problems		© 1	் 2	© 3	୍ 4	∜ 5
20. Did work or other activ		1	் 2	் 3	୍ 4	் 5
21. During the past 4 week interfered with your normal			ily, friends, r	neighbors, or	groups?	
Not at all Sli	ghtly	Moderately	Quite	a bit	Extremely	
0 0	;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;)	Ô	Ö		
22. How much bodily pain	have you ha	d during the	past 4 weeks	? 5F2Z		
None Very Mild	Mild	Moderate	e Sever	e Vei	y Severe	



Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

Participant ID	129841	Date of Registration	23 Jun 2014	
Local ID	0201020			
Status	Eligible			
Site ID	Fred Hutchinson Cancer Research Center (cGVHD)			
Treatment	Imatinib Dose: 200 mg PO daily (Age > 19) or 130 mg/m2 PO daily (Age 2-19)			
Treatment Assign Date	23 Jun 2014	Treatment Start Date	26 Jun 2014	

	* -	* These fie These fields ar		ed in order to order to COMP	
Date of Visit:	<u>Date</u>				
nterviewer User ID:*	,				
Section 5: Your Health and V	Well-Being (co	nt.)			
These questions are about how you fe question, please give the one answer t How much of the time during the past	that comes closest t	ave been with to the way you	you during th have been fe	ne past 4 week eling.	rs. For each
	All of the time	Most of the time	Some of the time	A little of the time	None of the time
24. Did you feel full of life? 5FZ	<i>4</i> 0 1	ି 2	© 3	ି 4	் 5
25. Have you been very nervous?	F25 1	ି 2	் 3	୍ 4	் 5
26. Have you felt so down in the dumps that nothing could cheer you?	ou 1	ି 2	ି 3	୍ 4	் 5
27. Have you felt calm and peacef	ul? 1 F27	ి 2	ି 3	ି 4	் 5
28. Did you have a lot of energy?	ा ।	ି 2	୍ 3	ି 4	் 5
29. Have you felt downhearted and depressed?	d 1	୍ 2	୍ 3	୍ 4	୍ 5
30. Did you feel worn out? 3F	2/) 1	் 2	ి 3	் 4	୍ 5

31. Have you been	n happy? ゔFろし	Ø 1	O 2	୍ 3	୍ 4	் 5
32. Did you feel ti	red? 5F32	୍ର 1	ි 2	୍ 3	୍ 4	○ 5
33. During the past 4 weeks, how much of the time has your physical health or emotional prolinterfered with your social activities (like visiting friends, relatives, etc.)? $5F33$						l problems
All of the time	Most of the time	Some of the time	A little	of the ne No	ne of the tin	ne
1	் 2	3	୍ 4	ė,	5	
		Definitely true	Mostly true	Don't know	Mostly false	Definitely false
34. I seem to get than other people		4 1	் 2	் 3	ି 4	÷ 5
35. I am as health know	ny as anybody I SF35	୍ର 1	் 2	0 3	୍ 4	○ 5
36. I expect my h	ealth to get worse ろドろん	ା 1	୍ 2	୍ 3	୍ 4	ි 5
37. My health is e	xcellent SF37	୍ 1	் 2	் 3	୍ 4	் 5

Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

Participant ID	129841	Date of Registration	23 Jun 2014		
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Treatment Assign Date	23 Jun 2014	Treatment Start Date	26 Jun 2014		

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		* These fields are	required in orde	r to SAVE the for
		* These fields are requi	ed in order to Co	OMPLETE the for
Date of Visit:	*	<u>Date</u>		
interviewer User I	D:*			Market I Marrow type belief before the base I R I Marrow the second
Section 6: Your	Activity Level			AND // PAYAWA
		Still Doing This Activity (1)	Have Stopped Doing This Activity (2)	Never Did This Activity (3)
1. Getting in and ou assistance)	ut of chairs or bed (without	t o	63	े
2. Listening to the r	adio H2		Ö	0
3. Reading books, r	magazines or newspapers	1.12 O	Ö	0

Ö

4)

£)

H8

H9

Ö

(2)

0

 \Diamond

4. Writing (letters, notes)

5. Working at a desk or table

6. Standing (for more than one minute) $H\phi$

8. Dressing or undressing (without assistance)

7. Standing (for more than five minutes)

9. Getting clothes from drawers or closets

10. Getting in or out of a car (without assista	ance) H10		0	0
11. Dining at a restaurant	НП	0	0	0
12. Playing cards/table games	H12	9	<i>*</i> []	<i>(</i>)
13. Taking a bath (no assistance needed)	H13_	Ø	CZ	0
14. Putting on shoes, stockings or socks (no assistance needed)	HIH	٥	179	0
15. Attending a movie, play, church event or activity	sports H15	()	7)	0
16. Walking 30 yards (27 meters)	Hile	<;>	<i>்</i>	(2)

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Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

Participant ID	129841	Date of Registration	23 Jun 2014	
Local ID	0201020			
Status	Eligible			
	Fred Hutchinson Cancer Research Center (cGVHD)			
Treatment	Imatinib Dose: 200 mg PO daily (Age > 19) or 130 mg/m2 PO daily (Age 2-19)			
Treatment Assign Date	23 Jun 2014	Treatment Start Date	26 Jun 2014	

	Page:	12	of 16		
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Date of Visit: * Date			
Interviewer User ID:*			
Section 6: Your Activity Level (cont.)			
	Still Doing This Activity (1)	Have Stopped Doing This Activity (2)	Never Did This Activity (3)
17. Walking 30 yards (non-stop)		0	¢.
18. Dressing/undressing (no rest or break needed)	O	0	()
19. Using public transportation or driving a car (100 miles or less)	20	0	0
20. Using public transportation or driving a car (99 miles or more)	0	0	€.}
21. Cooking your own meals	Ů.	()	0
22. Washing or drying dishes H22	8	Ø.	(*)
23. Putting groceries on shelves H23	<u> </u>	0	0
24. Ironing or folding clothes H24	()	Ö	<u> </u>
25. Dusting/polishing furniture or polishing cars $\mu 25$	0	0	0

	,		,	······································	
26. Showering	H24	Ø3	17	O.	
27. Climbing six steps	1427	₹js	8	<u>(1)</u>	
28. Climbing six steps (non-stop)	H28	ę)	0	0	
29. Climbing nine steps	H29	0	(3)	0	
30. Climbing 12 steps	H30	0	Ó	0	
31. Walking ½ block on level ground	H31	0	Ĉ.	()	
32. Walking ½ block on level ground (non-	-stop) H32	Ű	Ö	0	
33. Making a bed (not changing sheets)	H33	Ó	Ö.	Č.)	
34. Cleaning windows	H34	Ó	/		
35. Kneeling, squatting to do light work	H35	<)	45)	0	
36. Carrying a light load of groceries	H36	0	Ö	0	
37. Climbing nine steps (non-stop)	H37	0	(*)	0	

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Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

Participant ID	129841	Date of Registration	23 Jun 2014		
Local ID	0201020				
Status	Eligible				
	Fred Hutchinson Cancer Research Center (cGVHD)				
Treatment	Imatinib Dose: 200 mg PO daily (Age > 19) or 130 mg/m2 PO daily (Age 2-19)				
Treatment Assign Date	23 Jun 2014	Treatment Start Date	26 Jun 2014		

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	* These fields are required in order to SAVE the for * These fields are required in order to COMPLETE the for			
ate of Visit:	<u>Date</u>			
nterviewer User ID:*				
Section 6: Your Activity Level (con	t.)			
		Still Doing This Activity (1)	Have Stopped Doing This Activity (2)	Never Did This Activity (3)
38. Climbing 12 steps (non-stop)	H38		Ö	Ö
39. Walking ½ block uphill	H39		(5)	6)
40. Walking ½ block uphill (non-stop)	H40	0	<u> </u>	\(\)
41. Shopping (by yourself)	1441		(2)	(*)
42. Washing clothes (by yourself)	1442	Ć.	0	
43. Walking one block on level ground	1443	3	Ó	3)
44. Walking two blocks on level ground	H44	*>	0	0
45. Walking one block on level ground (no	on-stop) H45	0	<i>9</i>)	0
46. Walking two blocks on level ground (n	on-stop)/////		0	0

47. Scrubbing (floors, walls or cars)	147	Ĉ/	Ö	0
48. Making beds (changing sheets)	1448	0	P)	0
49. Sweeping	H49	ξ)	<i>(</i>)	0
50. Sweeping (five minutes non-stop)	H50	\$()	Ó	Ó
51. Carrying a large suitcase or bowling (or	ne line) H51	tb	<i>(</i> 3)	6)
52. Vacuuming carpets	H52	Ø		5
53. Vacuuming carpets (five minutes non-s	top) H53	# 3 	€2	4)
54. Painting (interior/exterior)	H54	÷)	Ó	<u> </u>
55. Walking six blocks on level ground	H55	0		0
56. Walking six blocks on level ground (nor	n-stop) 1156	0	(5)	*>
57. Carrying out the garbage	H57	<u> </u>	ć)	<i>(</i>)
58. Carrying a heavy load of groceries	H58	· •	Ć)	0

Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

Participant ID	129841	Date of Registration	23 Jun 2014		
Local ID	0201020				
Status	Eligible				
Site ID	Fred Hutchinson Cancer Research Center (cGVHD)				
Treatment	Imatinib Dose: 200 mg PO daily (Age > 19) or 130 mg/m2 PO daily (Age 2-19)				
Treatment Assign Date	23 Jun 2014	Treatment Start Date	26 Jun 2014		

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Date of Visit:	*	<u>Date</u>	
Date of Visit:	*		

Section 6: Your Activity Level (cont.)

Interviewer User ID:*

	Still Doing This Activity (1)	Have Stopped Doing This Activity (2)	Never Did This Activity (3)
59. Climbing 24 steps	9	0	0
60. Climbing 36 steps	೦	(2)	0
61. Climbing 24 steps (non-stop)	©	0	\diamond
62. Climbing 36 steps (non-stop)	ర	0	Ó
63. Walking one mile	0	<i>P</i> 3	0
64. Walking one mile (non-stop)	0	0	0
65. Running 110 yards (100 meters) or playing softball/baseball	0	Ö	*
66. Dancing (social)	0	()	O
67. Doing calisthenics or aerobic dancing (5 minutes non-stop)	0	0	0

68. Mowing the lawn (power mower, but mower)	not a riding	9		0
69. Walking two miles	H69	Ó	r)	ř)
70. Walking two miles (non-stop)	H70	fj)	<i>(</i>)	0
71. Climbing 50 steps	H71	ð	19	9
72. Shoveling, digging or spading	H72	0	<i>⇔</i>	0
73. Shoveling, digging or spading (five mi non-stop)	nutes H73	Ó	4)	4)
74. Climbing 50 steps (non-stop)	1174	Ô	43	0
75. Walking three miles or golfing 18 hole riding cart	s without a H75	<i>(</i>)	e ^r is	9
76. Walking three miles (non-stop)	H76	6	e ²)	<u>(†)</u>
77. Swimming 25 yards	H77	<i>.</i>	0	Ö
78. Swimming 25 yards (non-stop)	H78	0	43	Ó

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Save Print Close Window

Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

Participant ID	129841	Date of Registration	23 Jun 2014
Local ID	0201020		
Status	Eligible		
1	Fred Hutchinson Cancer Research Center (cGVHD)		
Treatment	Imatinib Dose: 200 mg PO daily (Age > 19) or 130 mg/m2 PO daily (Age 2-19)		130 mg/m2 PO daily (Age
Treatment Assign Date	23 Jun 2014	Treatment Start Date	26 Jun 2014

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Date of Visit:	*	Date
		* These fields are required in order to COMPLETE the
		* These fields are required in order to SAVE the

Section 6: Your Activity Level (cont.)

		Still Doing This Activity (1)	Have Stopped Doing This Activity (2)	Never Did This Activity (3)
79. Bicycling one mile	H79	(3)	43	(A)
80. Bicycling two miles	H80	3.5	633	**
81. Bicycling one mile (non-stop)	H81	0	69	Ö
82. Bicycling two miles (non-stop)	H82	0	0	0
83. Running or jogging 1/4 mile	H83	Ö	·	<u> </u>
84. Running or jogging ½ mile	H84	Ö	0	61) 61)
85. Playing tennis or racquetball	H85	O	÷	Ö
86. Playing basketball (game play)	H86	O	Ó	<u> </u>
87. Running or jogging ¼ mile (non-stop)	H87	0	0	Ó

88. Running or jogging ½ mile (non-stop)	(2)	(*)	())	
89. Running or jogging one mile	<i>\$</i> 13	()	9	
90. Running or jogging two miles	i).2	0	Ø	
91. Running or jogging three miles	()	()	O	
92. Running or jogging one mile in 12 minutes or less	2.5	43	Å.	
93. Running or jogging two miles in 20 minutes or less	0	ě)	4)	
94. Running or jogging three miles in 30 minutes or less	\$3°	sii:		

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Save	Print	1	Close	Window	

Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

Participant ID	129841	Date of Registration	23 Jun 2014
Local ID	0201020		
Status	Eligible		
	Fred Hutchinson Cancer Research Center (cGVHD)		
Treatment	Imatinib Dose: 200 mg PO c 2-19)	daily (Age > 19) or	130 mg/m2 PO daily (Age
Treatment Assign Date	23 Jun 2014	Treatment Start Date	26 Jun 2014

Page: 16 of 16

* These fields are required in order to SAVE the form * These fields are required in order to COMPLETE the form * These fields are required in order to COMPLETE the form Date Interviewer User ID:* Section 7: About Yourself 1. What is your current work status? (check all that apply) In school full time 3D_work_ inschool full time. In school part time 3D_work_ inschool full time. Working full time 3D_work_ working full time. Working part time 3D_work_ working full time. Working part time 3D_work_ working full time. Retired 3D_work_ Home maker Retired 3D_work_ Retired On medical leave from work 3D_work_ Disabled unable towork. Unemployed, looking for work 3D_work_ Unemployed looking for work 3D_work_ Unemployed fooking for work_ SD_work_ SD_work_ Unemployed fooking for work_ SD_work_ SD_work_ SD_work_ SD_work_ SD_work_ SD_work_ SD_work
Interviewer User ID:* Section 7: About Yourself 1. What is your current work status? (check all that apply) In school full time 3D_work_ Inschool full time. In school part time 3D_work_Inschool part time. Working full time 3D_work_ Working full time. Working part time 3D_work_ Working part time. Homemaker 3D_work_ Home maker Retired 3D_work_ Retired On medical leave from work 3D_work_ On medical kave from work. Disabled, unable to work 3D_work_ Unemployed looking for work. Unemployed, looking for work 5D_work_ Unemployed looking for work. Unemployed, not looking for work 5D_work_ Unemployed looking for work. Unemployed, not looking for work 5D_work_ Unemployed looking for work. Unemployed, not looking for work 5D_work_ Unemployed looking for work.
Interviewer User ID:* Section 7: About Yourself 1. What is your current work status? (check all that apply) In school full time 3D_work_Inschool full time In school part time 3D_work_Inschool part time. Working full time 3D_work_Working full time Working part time 3D_work_Working part time. Homemaker 3D_work_Home maker Retired 3D_work_Retired On medical leave from work 3D_work_On medical kave from work Disabled, unable to work 3D_work_Disabled unable towork Unemployed, looking for work 5D_work_Unemployed tooking for work Unemployed, not looking for work 5D_work_Unemployed tooking for work Unemployed, not looking for work 5D_work_Unemployed tooking for work Unemployed, not looking for work 5D_work_Unemployed tooking for work
Section 7: About Yourself 1. What is your current work status? (check all that apply) In school full time 3D_work_Inschool full time. In school part time 3D_work_Inschool part time. Working full time 3D_work_Working full time. Working part time 3D_work_Working part time. Homemaker 3D_work_Home maker Retired 3D_work_Retired On medical leave from work 3D_work_On medical kave from work. Disabled, unable to work 3D_work_Disabled unable towork. Unemployed, looking for work 3D_work_Unemployed looking for work. Unemployed, not looking for work 3D_work_Unemployed not looking for work. Unemployed, not looking for work 3D_work_Unemployed not looking for work. Unemployed, not looking for work 3D_work_Unemployed not looking for work.
1. What is your current work status? (check all that apply) In school full time 3D_work_Inschool part time. In school part time 3D_work_Inschool part time. Working full time 3D_work_Working full time. Working part time 3D_work_Working part time. Homemaker 3D_work_Home maker Retired 3D_work_Retired On medical leave from work 3D_work_On medical leave from work Disabled, unable to work 3D_work_Disabled unable to work. Unemployed, looking for work 5D_work_Unemployed looking for work. Unemployed, not looking for work 5D_work_Unemployed looking for work. Unemployed, not looking for work 5D_work_Unemployed looking for work. Unemployed, not looking for work 5D_work_Unemployed looking for work.
In school full time 3D_work_Inschool full time. In school part time 3D_work_Inschool part time. Working full time 3D_work_Working full time. Working part time 3D_work_Working part time. Homemaker 3D_work_Home maker Retired 3D_work_Retired On medical leave from work 3D_work_On medical kave from work Disabled, unable to work 3D_work_Disabled unable towork. Unemployed, looking for work 3D_work_Unemployed looking for work. Unemployed, not looking for work 3D_work_Unemployed looking for work. Unemployed, not looking for work 3D_work_Unemployed looking for work. Unemployed, not looking for work 3D_work_Unemployed looking for work.
In school part time 3D_work_Inschool partitime Working full time 3D_work_Working full time Working part time 3D_work_Working partitime. Homemaker 3D_work_Home maker Retired 3D_work_Retired On medical leave from work 3D_work_On medical kave from work Disabled, unable to work 3D_work_Disabled unable to work Unemployed, looking for work 3D_work_Unemployed looking for work Unemployed, not looking for work 3D_work_Unemployed looking for work Unemployed, not looking for work 3D_work_Unemployed looking for work
2. Do you consider yourself to be Latino (a) or Hispanic? 5D-eth

Black SD_race_Black American Indian or Alaska Native SD_race_Al Asian SD_race_Asian Native Hawaiian or Other Pacific Islander SD_race White SD_race_White. Other	
4. What is your gender? 5D-gen	○ Male ○ Female
5. How old are you? 50-age	years
6. How much did you weigh before your transplant? (Please be sure to indicate it in pounds (lbs) or kilograms (kg))	グD-WT Weigh unit: kg ろD_WT_Unit
7. What is your marital status? 50_marital	
্ Married/Living with partner	
ି Single, never married	
ි Divorced, Separated	. 1
ି Widowed	If Other, specify: SD_mar tal_oth
Other	
8. What is the highest grade of school you have completed	? 5D-educ
ି Grade school	
ି Some high school	
் High school graduate	
Some college	
ି College graduate	
Post-graduate degree	
9. What was your approximate annual family income in the	year before you had your transplant? 5D income
୍ Under \$15,000	
্ \$15,000 - \$24,999	
ু \$25,000 - \$49,999	
୍ \$50,000 – \$74,999	
্ \$75,000 - \$99,999	
\$100,000 or above	
<u>[</u>	
Save Print Close Win	ndow

Section 7: About Yourself

1.

What	t is your current work sta	tus? (check all that apply)
	In school full time In school part time Working full time Working part time Homemaker Retired On medical leave from Disabled, unable to wo Unemployed, looking for Unemployed, not looking Other, specify:	rk or work
		SD_work_ homemaker SD_work_ on medical leave from work SD_work_ disabled mable to work SD_work_ memplayed borning for work SD_work_ memployed not looking for a
		SD_ wave_ other

Protocol# 6501 - Longitudinal Study of Immune Mediated Disorders after Alloge...

	•		
Participant ID	101106	Date of Registration	26 Nov 2013
Local ID	0101100	Date of Baseline Exam	26 Sep 2013
Status	Eligible		
Site ID	Fred Hutchinson Cancer Res	search Center (cGV	HD)

Pulmonary Function Testing (PFT) pulm-function test revised * These fields are required in order to SAVE the form All questions should be filled out for eCRF to be "COMPLETE" in tracking system Date of Visit:* Date Interviewer User ID:* User ID is required PFT_DT PFT_DD

rmation PFT_YY Date of Test: **Participant Information** HT PFT- mit Height: HT Kgs wr_unit INT-PFT Weight: Hb-nd Not Done HD Participant Hb gm/dl PRE-BRONCHODILATOR Spirometry FVC-pre- rd Not Done FVC - Pre Liters FEVI-pre-nd Not Done FEVI - Pre Liters % FEVI_FVC_R_pre FEV1/FVC L/sec FEF_pre Not Done FEF_pre_nel FEF25-75% **Lung Volumes** Liters TC-pre-nd Not Done

Liters Ryprend Not Done TLC _ pre RV_pre Liters VC-pre-nd Not Done DEMO: (SVC) VC-pre Diffusion

Raw DLCO DLCO_pre mL/mmHg/min DLCO_pre_nd Not Done

DLCO Adj DL coadj-pre mL/mmHg/min Dcoadj-pre-vd 11 Not Done

11/26/2013 6:00 PM

POST-BRONCHODILATOR Not Done							
Spirometry							
FVC_post	Liters	FVC-post-nd	Not Done				
FEV1_post	Liters	FeVI-post-nd	Not Done				
FEV1/FVC FEVI_FVC_ post	~ %	FEVI-FUC_post_	nd				
FEF25-75 FEF_POST	L/sec	FEF-post-nd	Not Done				
Lung Volumes							
TLC_post	Liters	TLC-POST-Nd	Not Done				
RV_post	Liters	RV-post-nd	Not Done				
VC (SVC) of VC-post	Liters	VC-post-nd	○ Not Done				
Diffusion							
Raw DLCO DLCO POST	mL/mmHg	1/min DLCO_post_n	J∷ Not Done				
DLCO Adj DLCO Adj Post	mL/mmHg	1/min Dlcoady_post_	Not Done				

~ * U < # A A P P 1	mm 0.75 1.1.11.1	01.11	1 /	maan
Protocol # 6503 - Targeted	Therapy of Bronchiolitis	Obliterans S	yndrome (RO2)

Participant ID	128187	Date of Registration	03 Apr 2014				
Local ID	0301010						
Status	Eligible	Eligible					
Site ID	Fred Hutchinson Cancer Res	earch Center (cGV	HD)				
Treatment	6503 Fluticasone, Azithromy	cin and Monteluka	st (FAM)				
Treatment Assign Date	03 Apr 2014	Treatment Start Date	04 Apr 2014				

Dute				
	PFT Interp	retation For	m pft_Interpr	etation_tor
	Page:	1 of 2		
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			elds are required in ord	
		* These fields a	re required in order to	COMPLETE the form
Date of Visit: *	<u>Dat</u>	<u>:e</u>		
Interviewer User ID:*				
1. At the time of the pulm- following? * (Check all tha		this study visit,	did subject have any	of the
Fever PFT_	fever			
□ New cough P				
🗆 Sputum produ	ction PFT_sptum	1 . 1		
🗆 New consolida	tion on chest CT PFT	-consolid		160000
් Change in spu	tum color with positive	culture for puln	nonary pathogen Pf	=1 - parriager
□ None of the at	pove PFT-na			
2. Pulmonary function test	t* PFT_done			
Not done due	to current active pulmo	nary infection (Visit 2, 3 and 4 only))
ं Not done for a	any other reason, pleas	e complete a pr	otocol deviation form	1
# Done		Stucky-P	FT_DD ET 44M	
If done, date of te		Study-P Study-P Study-P	FT-YY	
3. Did subject have a great	ater than 10% decrease	e in FEV1 în com	nparison to the	ୁ Yes ା No
baseline FEV1? * Confir	M_FEVI-TURECT		=T_planned_D	D.
If yes, date of con	ifirmatory test:	Pr Pl	=T_planned-M =T_planned-Y	Ϋ́
4. If confirmatory test wa	s done, was treatment			
	1		►I	

Protocol # 6503 - Targeted Therapy of Bronchiolitis Obliterans Syndrome (BOS)...

Participant ID	128187	Date of Registration	03 Apr 2014				
Local ID	0301010						
Status	Eligible	Eligible					
Site ID	Fred Hutchinson Cancer Res	search Center (cGV	HD)				
Treatment	6503 Fluticasone, Azithromy	cin and Monteluka	st (FAM)				
Treatment Assign Date	03 Apr 2014	Treatment Start Date	04 Apr 2014				

PFT Interpretation Form

Page: 2 of 2

→ 1 2

		* These fields are required in order to SAVE the form	
		* These fields are required in order to COMPLETE the form	
Date of Visit: *	<u>Dat</u>	e	
Interviewer User ID:*			
Date of Test :		PFT_confirm - DD PFT_confirm - MM PFT_confirm - YY	
	articipant		
Height: Confirm - HT	cm	Confirm-HT_PFT_onit	
Weight: Confirm_WT_PFT	Kgs	Confirm_wt_unit	
Participant Hb Confirm_Hb	gm/dl	Not Done Confirm_Hb_nd	
PI	RE-BRON	CHODILATOR	
Spirometry			
FVC Confirm_FVC-pre	Liters	□ Not Done Confirm	FVC-nd
FEV1 Confirm-FEVI-pre	Liters	□ Not Done Confirm -	F-EVI_pre-nd
FEV1/FVC Confirm_FEV1_FVC_R_pre	%		
FEF25-75% Confirm_FEF_pre Lung Volumes	L/sec	□ Not Done <i>Confirm</i> _	FEF. pre-nd
TLC Confirm_TLC_pre	Liters	□ Not Done Confirm _	TLC-pre-nd
RV Confirm - RV- pre	Liters	□ Not Done Confirm -	RV-pre-nd
vc (svc)Confirm_VC-pre	Liters	□ Not Done Confirm -	VC-pre-nd

Diffusion		
Raw DLCO Confirm_DLCO_pre	mL/mmHg/min	Not Done Confirm_Dico_pre-1
DLCO Adj.Confirm_DLCO_adj-pre	Not Done <u>Confirm_DICO_adj</u> _pre_nd	
POST-BRON	ICHODILATOR	Not Done Confirm_dil_nd
Spirometry		
FVC Confirm_FVC-post	Liters	Not Done Confirm - FVC- post - nd
FEV1Confirm_FEVI-post	Liters	Not Done Confirm - FEVI - post - nd
FEV1/FVC Confirm FEVI_FVC_R_post	%	
FEF25-75 Confirm_FEF_post	L/sec	Not Done Confirm_FEF_post_nd
Lung Volumes		`
TLC Confirm_TLL_post	Liters	Not Done Confirm_TLC-past-nd
RV Confirm - RV- post	Liters	Not Done Confirm_RV_post_nd
vc (svc)Confirm_VC-post	Liters	Not Done Confirm_VC-post_nd
Diffusion		
Raw DLCO Confirm_DLCO-post	mL/mmHg/min	Not Done Confirm_DLCO-post
DLCO Adj Confirm_DLCOOdj-pos	tmL/mmHg/min	Not Done Confirm_DLCOadj_post_nd

Protocol # 6503 - Targeted Therapy of Bronchiolitis Obliterans Syndrome (BOS)...

Participant ID	128187	Date of Registration	03 Apr 2014				
Local ID	0301010						
Status	Eligible	Eligible					
Site ID	Fred Hutchinson Cancer Res	Fred Hutchinson Cancer Research Center (cGVHD)					
Treatment	6503 Fluticasone, Azithromy	6503 Fluticasone, Azithromycin and Montelukast (FAM)					
Treatment Assign Date	03 Apr 2014	Treatment Start Date	04 Apr 2014				

FAM Medications FAM_Medications

Interviewer Usei	ID:* 444	2		
Date of Visit:	* 3	Apr	2014	<u>Date</u>
				* These fields are required in order to COMPLETE the for
				* These fields are required in order to SAVE the for
,				

Medication 1: Fluticasone

Flu_a	Dose Dose lose# Other Plu-close-	Units	Frequency Flu_freg#		Flu-start-DU	aking?		W M #
Fluticasone 4	140	mcg	BID-twice/day		2014	M# ★ Y ○ N		XX#
A	Add	Flu-uni	T-54F	Flu_rov	ite#	Flu_current±	(a.	

Medication 2: Azithromycin

	Azith	Dose h_dose		Units Azith_Un	Frequency	Interval Azith -ii		Start Date	Taki	ina?	Stop Date
Azithromy	ycin	250	Azith_dose	mg _spec#	QD-once/day Azith_freq#	TIW Azi	PO Hr. revi	Apr 約014		N H_DD+	Az
		Add	AAAAAAAAA AAAAAA YAAAAA YAAAAA	, ,			,	Azith- Azith- tzith-	start start	AAH WW	<i></i>

Medication 3: Montelukast

Mont	Dose Ldose#	Dose Units Other <i>Mont_uni</i>	Frequency	Route lont_rout	Start _{c#} Date	Currently Taking? Mont_Current	Stop Date	Vant stop 0v#
Montelukast	10		QD-once/day	PO	04 Apr 2014	.Υ ○N	XIII XIII	font stop_00# it_stop_N/I# t_stop-yy#
	Add	Mont-dose_spec#	nont_freq#		Mont-sh	art DD# art NN# art YY#		

Protocol # 6503 - Targeted Therapy of Bronchiolitis Obliterans Syndrome (BOS)...

Participant ID	128187	Date of Registration	03 Apr 2014	
Local ID	0301010			
Status	Eligible			
Site ID	Fred Hutchinson Cancer Research Center (cGVHD)			
Treatment	6503 Fluticasone, Azithromycin and Montelukast (FAM)			
Treatment Assign Date	03 Apr 2014	Treatment Start Date	04 Apr 2014	

Six Minutes Walk Test Six_Minute_Walk_Test

**		in order to COMPLETE the fo
Date of Visit: * Date	These notes are required	
Interviewer User ID:*		
Six Minutes Walk Test	□ Not don	e Walk_nd
1. Supplemental oxygen during the test Walk_02		Yes No
If yes, flow (L/min): Walk-02-		
2. Vital		
	Baseline	End of test
Heart Rate (beats/min)	Walk-pulse-buse	walk-pulse-end
3. Stopped or paused before 6 minutes? Walk - 5h	op :	≻Yes ○ No
If yes, specify reason: Walk - Stop - reas	5	
Number of minutes walked if not 6 minutes: Walk-	minutes	
4. Total Distance walked in 6 minutes		
Number of laps (x 50ft) + Final partial lap: Walk_laps Walk_partial-lacal		walked in 6 minutes - total
5. Tech comments		:
Comments: Walk_comm		
: Save : Print C	lose Window	

Protocol#6501 - Longitudinal Study of Immune Mediated Disorders after Alloge...

	V		
Participant ID	101106	Date of Registration	26 Nov 2013
Local ID	0101100	Date of Baseline Exam	26 Sep 2013
Status	Eligible		
Site ID	Fred Hutchinson Cancer Research Center (cGVHD)		

Participant Status Form imd_17919-patientotat_revised

		* These fields are required in orde	r to SAVE the form
	* .	These fields are required in order to C	OMPLETE the form
Date of Visit:*	<u>Date</u>		
Interviewer User ID:*	User ID is requ	uired	
Date of last contact or most in the second sec	recent medical note	DOLC _ IVM	
2. Select all events that have oc	ccurred to date:	DOLC-YY	
🖾 Patient was never tran	splanted Event_1	VoTx	
Graft loss Event_6	jraft		Graft_DD Graft_MM
OLI Event_DL			GMC+-XY
Additional stem cell tr	ansplant Event_	add-SCT	Di 1 Y Y
□ Relapse Event_R	el		Add-SCT-DL Add-SCT-M Add-SCT-Y)
Death Event_ De	eath		Rel-DD, Rel- Rel-XY
Cause of Death COU)		((2,2))
None of the above ha	s occured. Event.	-None	
	med within past 6 mc	onths) Event_Alive	
MO	ave Print Clo	ose Window	

Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu... Date of Registration 07 Apr 2011 Participant ID 108548 Local ID 0201001 Status Eligible Site ID Fred Hutchinson Cancer Research Center (cGVHD) Treatment Rituximab Dose: 375 mg/m2 IV weekly x 4 Treatment Start Treatment Assign 26 Oct 2011 26 Oct 2011 Date Date **Adverse Event Reporting Form** Initial Report * These fields are required in order to SAVE the form A. INTERVIEW INFORMATION Adverse event report date (DD MMM YYYY) Rereport dt (date site was notified of event) * B. ADVERSE EVENT REPORT Adverse event occurrence acdate (DD MMM YYYY) date * Is this a primary or O Primary O Secondary secondary event? * (required If secondary event, enter primary Adverse Event ID: only for initial report) C. EVENT DESCRIPTION Categor Select an Option Event SOC * Help AETERM Adverse Event * Select an Option Severity Severity * new_ardetails Event Details (Description) Treatment Location + treatment location of her Location of event treatment D. EVENT ASSESSMENT Expected

Causality by reporter O Yes O No Expected * Causality (by reporter) * Was the adverse event Development of a congenital anomaly or birth defect associated with any of the Development of a permanent, serious, disabling or incapacitating condition following? (check all that apply) ☐ Death Hospitalization or prolonged hospitalization Prefix assoc -Life threatening Is another condition which investigators judge to represent significant hazards

on follow-up report:

Specify the adverse event = select term

date of follow up = A E follow up date

reason for follow up = reason for follow up

also not on forms:

A E causality by renewer

Syra or disable term (if other specify, up hons per CTEATE)

CTEATE version

Close Window

Reporter User ID

Save Draft

2439

Submit for Review

Print