

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: comorbidities_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

6502

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.

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

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)		

Transplant Date

registration-revised

* These fields are required in order to SAVE the form	
* These fields are required in order to COMPLETE the form	
Date of Visit:	* 11 Mar 2011 <u>Date</u>
Interviewer User ID:	* 2970
Note: By updating the Transplant date, you will change all of the due date windows for the follow-up visits. Please verify the participant's Transplant date before proceeding.	
Date of Transplant:	* 15 Dec 2010 <u>Date</u> <i>Start dt</i>

Save Print Close Window

Protocol # 6501 - Longitudinal Study of Immune Mediated Disorders after Allogeneic

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:* Date
Interviewer User ID:* User ID is required

1. Participant Age (either Date of Birth or Age is required, use Date of Birth unless disallowed by your local institution's IRB):

Date of Birth:

OR

Age at registration:

dob {
 date of birth day
 date of birth month
 date of birth year

age at registration

2. Gender:*

Male Female

gender

3. Race (check all that apply): *

0, 1

American Indian or Alaska Native

race - American Indian or AK native

Asian

race - Asian

Black or African American

race - black or african american

race - native or pacific islander

Native Hawaiian or Other Pacific Islander

White

race - white

Unknown

race - unknown or not reported

Refused

race - refused

4. Ethnicity (select one): *

Hispanic, Latino, or Spanish origin

ethnicity

Not Hispanic, Latino or Spanish origin

Unknown or not reported

Refused

DEMO

Save Print Close Window

Protocol # 6501 - Longitudinal Study of Immune Mediated Disorders after Allogeneic

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 Sociodemographics

patient_sociodem_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

Section 1:

1. Employment status (check all that apply)

- Employed full-time
- Employed part-time
- Homemaker
- Student
- Retired
- On medical leave from work
- Disabled, unable to work
- Unemployed, looking for work
- Unemployed, not looking for work
- Unknown

2. Marital status *sd - marital*

- Currently married
- Separated
- Divorced
- Widowed
- Never married
- Unknown

3. Living with a spouse or partner? *sd - spouse*

- Yes
- No
- Unknown

4. Highest level of school completed or the highest degree received *sd - educ*

- Didn't go to school
- Grade school
- Some high school (9-11 years)
- High school diploma or GED
- Vocational or training school
- Some college or Associate Degree
- College graduate or Baccalaureate Degree
- Some post-graduate or professional
- Master's Degree
- Doctoral Degree (Ph.D., M.D., J.D., etc)
- Unknown

DEMO

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

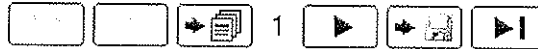
Protocol # 6501 - Longitudinal Study of Immune Mediated Disorders after Allogeneic

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 Abstraction

blvsvitchatabstract-revised

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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

Date of Visit:* Date

Interviewer User ID:* User ID is required

TRANSPLANT CHARACTERISTICS

1. Date of transplant:

TX-DT [*TX-DD*
TX-YY
TX-mm]

2. Height pre-transplant:

cm

HT-PRE
HT-pre-unit

Unknown *HT-pre-unlc*

3. Weight pre-transplant:

kg

WT-pre
WT-pre-unit

Unknown *WT-pre-unlc*

Disease Status	Early	Intermediate	Advanced
<i>DIS STATUS</i> - AML	<input type="radio"/> CR1	<input type="radio"/> CR2	<input type="radio"/> CR3+, rel, ref, IF
<i>DIS STATUS</i> - ALL	<input type="radio"/> CR1	<input type="radio"/> CR2	<input type="radio"/> CR3+, rel, ref, IF
<i>DIS STATUS</i> - CML	<input type="radio"/> CP	<input type="radio"/> AP	<input type="radio"/> BC or after BC
CLL		<input type="radio"/> CR, PR, CS	<input type="radio"/> Rel, ref, CI
MDS	<input type="radio"/> RA, RARS	<input type="radio"/> RAEB, RAEBT	<input type="radio"/> Rel, ref, IF
MPD		<input type="radio"/> All others	<input type="radio"/> Rel, ref, IF
NHL		<input type="radio"/> CR, PR, CS	<input type="radio"/> Rel, ref, CI
DEMO HD		<input type="radio"/> CR, PR, CS	<input type="radio"/> Rel, ref, CI
MM		<input type="radio"/> CR, PR, CS	<input type="radio"/> Rel, ref, CI
AA	<input type="radio"/> Without ATG/TG	<input type="radio"/> With ATG/TG	
Other	<input type="radio"/> Early (non-malignant)	<input type="radio"/> Intermed (CR, PR)	<input type="radio"/> Adv. (Rel, ref, CI)

13. Age of Donor *Dnr-age* years *Dnr-age-unk*
 Unknown

14. Donor Gender (choose 2 genders if double cord) *Dnr-gen*

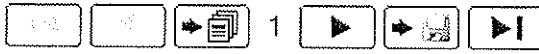
- Male
- Female
- Female/Female
- Male/Male
- Male/Female

15. 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

16. Donor CMV Antibodies *Dnr-cmv*

- Yes
- No
- Indeterminate
- Not tested



Save ... Print ... Close Window

Protocol # 6501 - Longitudinal Study of Immune Mediated Disorders after Allogeneic

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)		

Acute GVHD p6501-17083 - acute gvhd - revised

* These fields are required in order to SAVE the form

* These fields are required in order to COMPLETE the form

Date of data entry:* Date

Interviewer User ID:* User ID is required

Date of Acute GVHD Diagnosis	<input type="checkbox"/> No Acute GVHD agrhd-no	<input type="checkbox"/> Unknown agrhd-unk
Maximum Acute GVHD Grade		
Overall	<input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> Not done	agrhd-over
Liver	<input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> Not done	agrhd-liv
GI	<input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> Not done	agrhd-GI
Skin	<input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> Not done	agrhd-skin

Save Print Close Window

→ agrhd_DT [agrhd-DD
agrhd-MM
agrhd-YY

DEMO

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*

* 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 IMD Onset: * Date

Interviewer User ID:*

CHARACTERISTICS OF IMMUNE MEDIATE DISORDER (e.g., CHRONIC GVHD) AT ONSET

- 1. Date of immune mediated disorder onset Date *IMD-0-DD
IMD-0-MM
IMD-0-YY*
- 2. Name of immune mediated disorder *IMD-0*
 - Late, recurrent or persistent acute GVHD
 - Chronic GVHD (classic chronic or overlap)
 - Other immune mediated disorder

If Other, specify: *IMD-0-OTH*
- 3. Acute GVHD present the week before immune mediated disorder diagnosis? Yes No Unknown *onset*
- 4. Weight *WT-0* Kgs *WT-0-UNIT* Unknown *WT-0-unk*
- 5. Performance score *Perf-0* % Karnofsky *KPS-LPS-0* Unknown *Perf-0-unk*
- 6. Percent BSA *BSA-0* % Unknown *BSA-0-unk*
- 7. Lichen-planus-like changes of skin *LICH-0* Yes No Unknown
- 8. Sclerotic changes of skin *SCL-0* Yes No Unknown
- 9. Bronchiolitis obliterans syndrome *BOS-0* Yes No Unknown
- 10. Chronic diarrhea *DIA-0* Yes No Unknown
- 11. Oral involvement *ORAL-0* Yes No Unknown
- 12. Total bilirubin *Bili-0* Unknown *Bili-0-unk*
- 13. Platelet count *Plt-0* Unknown *Plt-0-unk*

Save Print Close Window

Protocol # 6501 - Longitudinal Study of Immune Mediated Disorders after Allogeneic

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

* 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

Metabolic Panel

Not Done
Meta-nd

Date of Test

Meta-DD
 Meta-MM
 Meta-YY

Test Name	Result	Units
Creatinine* CR	CR-unit	<input type="checkbox"/> Not Done CR-nd
BUN* BUN	BUN-unit	<input type="checkbox"/> Not Done BUN-nd
Glucose* Glu	Glu-unit	<input type="checkbox"/> Not Done Glu-nd

CBC with Differential

Not Done
CBC-nd

Date of Test

CBC-DD
 CBC-MM
 CBC-YY

Test Name	Result	Units
Hemoglobin (Hgb)* HGB	HGB-unit	<input type="checkbox"/> Not Done HGB-nd
Hematocrit (Hct)* HCT	HCT-unit	<input type="checkbox"/> Not Done HGB-nd
WBC* WBC	WBC-unit	<input type="checkbox"/> Not Done WBC-nd
Neutrophils* Neu	Neu-unit	<input type="checkbox"/> Not Done Neu-nd
Bands* Bands	Bands-unit	<input type="checkbox"/> Not Done Bands-nd
Lymphocytes* Lym	Lym-unit	<input type="checkbox"/> Not Done Lym-nd
Eosinophils* Eos	Eos-unit	<input type="checkbox"/> Not Done Eos-nd
Platelets* Plt	Plt-unit	<input type="checkbox"/> Not Done Plt-nd

Liver Function Tests

Not Done
LFT-nd

Date of Test

LFT-DD
 LFT-MM
 LFT-YY

DEMO

Test Name	Result	Units
Total bilirubin* Bili	Bili-unit	<input type="checkbox"/> Not Done Bili-nd
Direct bilirubin* BilID	BilID-unit	<input type="checkbox"/> Not Done BilID-nd
AST* AST	AST-unit	<input type="checkbox"/> Not Done AST-nd
ALT* ALT	ALT-unit	<input type="checkbox"/> Not Done ALT-nd

Alkaline Phosphatase*	ALP	ALK-unit	<input type="checkbox"/> Not Done	ALK-nd
Albumin*	ALB	ALB-unit	<input type="checkbox"/> Not Done	ALB-nd

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 Research Center (cGVHD)		

IMD Medication Form

IMD_medications_revised

* 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	Start Date	Currently Taking?	If no, Stop Date
Search term	RxNorm Code				
IMD_Med#	IMD_Med_Code#		IMD_Med_Start	Y N	
Code:		Chronic Acute Prophylaxis Unknown Other			
Add					IMD_Med_take#

Save Print Close Window

= 1 - 32

o/1 indication-chronic#
 ↓
 indication-acute#
 ↓
 indication-prophylaxis#
 ↓
 indication-unknown#
 ↓
 indication-other#

IMD_Med_Start_DD#
 IMD_Med_Start_MM#
 IMD_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 Allogeneic

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 *CoMorbidity_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

Comorbidity	Definition	Present
1. CARDIOVASCULAR		
Arrhythmia* <i>CMB-ARR</i>	Atrial fibrillation or flutter, sick sinus syndrome or ventricular arrhythmias	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Coronary artery disease <i>CMB-CAD</i>	Coronary artery disease (one or more vessel-coronary artery stenosis requiring medical treatment, stent, or bypass graft), angina	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
History of MI <i>CMB-MI</i>	History of myocardial infarction	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Heart valve disease <i>CMB-HVD</i>	Except asymptomatic mitral valve prolapse	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Hypertension <i>CMB-HTN</i>		<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Congestive heart failure <i>CMB-CHF</i>	EF ≤ 50%	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Cerebrovascular disease <i>CMB-CVD</i>	Transient ischemic attack or history of cerebrovascular accident, or neurologic impairment consequent to CVA	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Peripheral vascular disease <i>CMB-PVD</i>		<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
DEMO Venous thrombosis <i>CMB-VT</i>	Confirmed radiographically and requiring anticoagulation	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
2. GASTROINTESTINAL		
Peptic ulcer/hernia/reflux <i>CMB-ULC</i>	Requiring treatment	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U

Mild hepatic <i>CMB-HEPM</i>	Chronic hepatitis, bilirubin > ULN to 1.5 X ULN, or AST/ALT > ULN to 2.5 X ULN	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Moderate/severe hepatic <i>CMB-HEPS</i>	Liver cirrhosis, bilirubin > 1.5 times ULN or AST/ALT > 2.5 ULN	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Inflammatory bowel disease <i>CMB-IBS</i>	Crohn's disease or ulcerative colitis	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
3. PULMONARY		
Moderate pulmonary <i>CMB-PULMM</i>	DLCO and/or FEV-1 66%-80% or dyspnea on slight activity	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Severe pulmonary <i>CMB-PULMS</i>	DLCO and/or FEV-1 65% or lower or dyspnea at rest or requiring oxygen	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Asthma <i>CMB-AST</i>	Asthma symptoms for which inhaled steroids or other daily treatments are needed chronically to prevent or manage attacks	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
4. ENDOCRINE		
Diabetes <i>CMB-DB</i>	Requiring treatment with insulin or oral hypoglycemic agents but not diet alone	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Hypothyroidism <i>CMB-HT</i>	Including compensated hypothyroidism	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Adrenal Insufficiency <i>CMB-AI</i>	Including compensated adrenal insufficiency	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
5. NEUROPSYCHIATRIC		
Psychiatric disturbance- Depression <i>CMB-DEP</i>	Depression requiring psychiatric consult or treatment	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Psychiatric disturbance- Anxiety or panic disorder <i>CMB-ANX</i>	Anxiety or panic disorder requiring psychiatric consult or treatment	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Neurologic disease (peripheral neuropathy, MS, Parkinson's disease or other chronic neurologic disease <i>CMB-ND</i>	Symptomatic and requiring treatment to control or manage symptoms/disease process	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Visual impairment secondary to cataracts, glaucoma or macular degeneration <i>CMB-VIS</i>	Unilateral or bilateral, and unrepaired	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Hearing impairment <i>CMB-EAR</i>	Very hard of hearing, even with hearing aids	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
6. BONE/JOINT		

Osteoarthritis <i>CMB-DA</i>	Symptomatic and requiring treatment or with osteoarthritic changes noted on radiographic studies	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U	
Degenerative disc disease (spinal stenosis or severe chronic back pain) <i>CMB-DISC</i>	Symptomatic and requiring treatment or symptomatic and with degenerative disc disease noted on radiographic studies	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U	
Avascular necrosis <i>CMB-AVN</i>	Symptomatic with pain secondary to AVN or joint replacement	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U	
Osteopenia/Osteoporosis <i>CMB-OP</i>	T Score < or equal to minus 1.5 or on treatment with a bisphosphonate	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U	
Rheumatologic <i>CMB-RA</i>	Lupus, mixed connective tissue disorder, rheumatoid arthritis, polymyalgia rheumatica	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U	
7. OTHER COMORBIDITIES			
Infection <i>CMB-INFX</i>	Requiring current treatment with antimicrobial (not prophylaxis)	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U	
Moderate/severe renal <i>CMB-REN</i>	Serum creatinine > 2 mg/dL, on dialysis, or prior renal transplantation	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U	
Prior solid malignancy <i>CMB-ST</i>	Treated at any time point in the patient's past history, excluding nonmelanoma skin cancer	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U	
8: PHYSICAL EXAM - Anthropometry			
Height	<i>HT-CMB-cm</i> cm	<i>HT-CMB-in</i> in	<i>HT-CMB-nd</i> <input type="checkbox"/> Not Done
Weight	<i>WT-CMB-kg</i> kg	<i>WT-CMB-lb</i> lbs	<i>WT-CMB-nd</i> <input type="checkbox"/> Not Done

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 Research Center (cGVHD)		

Medication-Steroids Form *imd_13174-medications_revised*

* 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

Patient is not on any steroids

	Medication	Dose	Units	Frequency	Route
	Search term	RxNorm Code	<i>Ster-Dose#</i>	<i>Ster-Freq #</i>	(PO,IV)
Code	<i>IMD_Med #</i>	<i>IMD-Med-Code #</i>	<i>Ster-Units#</i>		<i>Ster-Route#</i>
Add					

Save | Print | Close Window

DEMO

Specimen Collection – Aliquots Sampling Form

Protocol Number: 6501

Participant ID: _____

Site: _____

Person Completing Form: _____

*Which Visit Type?

research - labs - revised

- d100
- d180
- d365

- IMD Onset
- 3 mo post onset
- 6 mo post onset

cGVHD 6501 visit type

drawnode = site

Specimen Name	Barcode Number	Box Number	Insufficient Volume	Volume	Cell Count	Location in Box	Comments
PBMC aliquots – Tube 1			<input type="checkbox"/>	mL	$\times 10^6$		
PBMC aliquots – Tube 2			<input type="checkbox"/>	mL	$\times 10^6$		
PBMC aliquots – Tube 3			<input type="checkbox"/>	mL	$\times 10^6$		
PBMC aliquots – Tube 4			<input type="checkbox"/>	mL	$\times 10^6$		
PBMC aliquots – Tube 5			<input type="checkbox"/>	mL	$\times 10^6$		
PBMC aliquots – Tube 6			<input type="checkbox"/>	mL	$\times 10^6$		
PBMC aliquots – Tube 7			<input type="checkbox"/>	mL	$\times 10^6$		
PBMC aliquots – Tube 8			<input type="checkbox"/>	mL	$\times 10^6$		

aliquot_type aliquot_barcode box insufficient_vol cell_count box_loc comments

Status = tube broken

*delayed processing
hemolyzed
low cell count*

Specimen Collection –Aliquots Sampling Form

Protocol Number: 6501

Participant ID: _____

Site: _____

Person Completing Form: _____

Heparin Plasma aliquots – Tube 1			<input type="checkbox"/>	mL	$\times 10^6$		
Heparin Plasma aliquots – Tube 2			<input type="checkbox"/>	mL	$\times 10^6$		
Heparin Plasma aliquots – Tube 3			<input type="checkbox"/>	mL	$\times 10^6$		
Heparin Plasma aliquots – Tube 4			<input type="checkbox"/>	mL	$\times 10^6$		
Heparin Plasma aliquots – Tube 5			<input type="checkbox"/>	mL	$\times 10^6$		
Heparin Plasma aliquots – Tube 6			<input type="checkbox"/>	mL	$\times 10^6$		
Heparin Plasma aliquots – Tube 7			<input type="checkbox"/>	mL	$\times 10^6$		
Heparin Plasma aliquots – Tube 8			<input type="checkbox"/>	mL	$\times 10^6$		
Heparin Plasma aliquots – Tube 9			<input type="checkbox"/>	mL	$\times 10^6$		
Heparin Plasma aliquots – Tube 10			<input type="checkbox"/>	mL	$\times 10^6$		
Heparin Plasma aliquots – Tube 11			<input type="checkbox"/>	mL	$\times 10^6$		
Heparin Plasma aliquots – Tube 12			<input type="checkbox"/>	mL	$\times 10^6$		

Specimen Collection – Aliquots Sampling Form

Protocol Number: 6501

Participant ID: _____

Site: _____

Person Completing Form: _____

Serum aliquots – Tube 1			<input type="checkbox"/>	mL	$\times 10^6$		
Serum aliquots – Tube 2			<input type="checkbox"/>	mL	$\times 10^6$		
Serum aliquots – Tube 3			<input type="checkbox"/>	mL	$\times 10^6$		
Serum aliquots – Tube 4			<input type="checkbox"/>	mL	$\times 10^6$		
Urine aliquots – Tube 1			<input type="checkbox"/>	mL	$\times 10^6$		
Urine aliquots – Tube 2			<input type="checkbox"/>	mL	$\times 10^6$		
Urine aliquots – Tube 3			<input type="checkbox"/>	mL	$\times 10^6$		
Urine aliquots – Tube 4			<input type="checkbox"/>	mL	$\times 10^6$		
Urine aliquots – Tube 5			<input type="checkbox"/>	mL	$\times 10^6$		
Urine aliquots – Tube 6			<input type="checkbox"/>	mL	$\times 10^6$		
EDTA Plasma aliquots – Tube 1			<input type="checkbox"/>	mL	$\times 10^6$		
EDTA Plasma aliquots – Tube 2			<input type="checkbox"/>	mL	$\times 10^6$		

Specimen Collection – Aliquots Sampling Form

Protocol Number: 6501

Participant ID: _____

Site: _____

Person Completing Form: _____

EDTA Plasma aliquots – Tube 3			<input type="checkbox"/>	mL	$\times 10^6$		
EDTA Plasma aliquots – Tube 4			<input type="checkbox"/>	mL	$\times 10^6$		
Granulocytes			<input type="checkbox"/>	mL	$\times 10^6$		

Protocol # 6501 - Longitudinal Study of Immune Mediated Disorders after Allogeneic

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-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

Date of Test :	PFT-DT [PFT-DD PFT-mm PFT-YY		
Participant Information			
Height :	HT	cm	HT_PFT-unit
Weight :	WT-PFT	Kgs	WT-unit
Participant Hb	Hb	gm/dl	Hb-nd <input type="checkbox"/> Not Done

PRE-BRONCHODILATOR

Spirometry

FVC - pre	Liters	FVC-pre-nd <input type="checkbox"/> Not Done
FEV1 - pre	Liters	FEV1-pre-nd <input type="checkbox"/> Not Done
FEV1/FVC	%	FEV1 - FVC - R - pre
FEF25-75%	L/sec	FEF-pre <input type="checkbox"/> Not Done FEF-pre-nd

Lung Volumes

TLC - pre	Liters	TLC-pre-nd <input type="checkbox"/> Not Done
RV - pre	Liters	RV-pre-nd <input type="checkbox"/> Not Done
DEMO: (SVC) VC - pre	Liters	VC - pre-nd <input type="checkbox"/> Not Done

Diffusion

Raw DLCO DLCO-pre	mL/mmHg/min	DLCO-pre-nd <input type="checkbox"/> Not Done
DLCO Adj DLCOadj-pre	mL/mmHg/min	DLCOadj-pre-nd <input type="checkbox"/> Not Done

POST-BRONCHODILATOR Not Done

Spirometry

FVC_post	Liters	FVC_post_nd	<input type="checkbox"/> Not Done
FEV1_post	Liters	FEV1_post_nd	<input type="checkbox"/> Not Done
FEV1/FVC	FEV1-FVC_post %	FEV1-FVC_post_nd	
FEF25-75	FEF_post L/sec	FEF_post_nd	<input type="checkbox"/> Not Done

Lung Volumes

TLC_post	Liters	TLC_post_nd	<input type="checkbox"/> Not Done
RV_post	Liters	RV_post_nd	<input type="checkbox"/> Not Done
VC (SVC) ₂₅	VC_post Liters	VC_post_nd	<input type="checkbox"/> Not Done

Diffusion

Raw DLCO	DLCO_post mL/mmHg/min	DLCO_post_nd	<input type="checkbox"/> Not Done
DLCO Adj	DLCO_adj_post mL/mmHg/min	DLCO_adj_post_nd	<input type="checkbox"/> Not Done

Save Print Close Window

Protocol # 6501 - Longitudinal Study of Immune Mediated Disorders after Allogeneic

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)		

Follow-up Visit Chart Abstraction *FU_Visit_Chart_Abstraction*

* 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. Type of Follow-up Visit (check all that apply):
- In person at site
 - In person elsewhere (outside medical records review)
 - Telephone visit

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_none*

Area of Body	Date of Biopsy	Location	Findings
<i>BX_Area #</i>	<i>BX_DD#</i>	<i>BX_Loc #</i>	<i>BX_Find #</i>
	<input type="radio"/> At center <input type="radio"/> Outside center	<i>Code</i>	<i>SNOMED Code</i> <i>BX_Find_Code #</i>

3. Was an immune mediated disorder diagnosed since last report? *IMD_Dx*
- Yes No (If yes, complete 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:**

DEMO

		Medical Record
Abnormal skin color <i>5X1</i>	<input type="radio"/> Not at all <input type="radio"/> Slightly <input type="radio"/> Moderately <input type="radio"/> Quite a bit <input type="radio"/> Extremely	<input type="checkbox"/> Present <input type="checkbox"/> Absent <input type="checkbox"/> Not Discussed
Rashes <i>5X2</i>	<input type="radio"/> Not at all <input type="radio"/> Slightly <input type="radio"/> Moderately <input type="radio"/> Quite a bit <input type="radio"/> Extremely	<input type="checkbox"/> Present

5X1 - Not Discussed
5X1 - Present
5X1 - Absent

	all			bit		<input type="checkbox"/> Absent <input type="checkbox"/> Not Discussed
Thickened skin <i>SX3</i>	<input type="radio"/> Not at all	<input type="radio"/> Slightly	<input type="radio"/> Moderately	<input type="radio"/> Quite a bit	<input type="radio"/> Extremely	<input type="checkbox"/> Present <input type="checkbox"/> Absent <input type="checkbox"/> Not Discussed
Sores on skin <i>SX4</i>	<input type="radio"/> Not at all	<input type="radio"/> Slightly	<input type="radio"/> Moderately	<input type="radio"/> Quite a bit	<input type="radio"/> Extremely	<input type="checkbox"/> Present <input type="checkbox"/> Absent <input type="checkbox"/> Not Discussed
Itchy skin <i>SX5</i>	<input type="radio"/> Not at all	<input type="radio"/> Slightly	<input type="radio"/> Moderately	<input type="radio"/> Quite a bit	<input type="radio"/> Extremely	<input type="checkbox"/> Present <input type="checkbox"/> Absent <input type="checkbox"/> Not Discussed

SX2 - Not Discussed
SX2 - Present
SX2 - Absent
 ...
SX# - Not Discussed
SX# - Present
SX# - Absent

5. **BREATHING:**

						Medical Record
Frequent cough <i>SX12</i>	<input type="radio"/> Not at all	<input type="radio"/> Slightly	<input type="radio"/> Moderately	<input type="radio"/> Quite a bit	<input type="radio"/> Extremely	<input type="checkbox"/> Present <input type="checkbox"/> Absent <input type="checkbox"/> Not Discussed
Colored sputum <i>SX13</i>	<input type="radio"/> Not at all	<input type="radio"/> Slightly	<input type="radio"/> Moderately	<input type="radio"/> Quite a bit	<input type="radio"/> Extremely	<input type="checkbox"/> Present <input type="checkbox"/> Absent <input type="checkbox"/> Not Discussed
Shortness of breath with exercise <i>SX14</i>	<input type="radio"/> Not at all	<input type="radio"/> Slightly	<input type="radio"/> Moderately	<input type="radio"/> Quite a bit	<input type="radio"/> Extremely	<input type="checkbox"/> Present <input type="checkbox"/> Absent <input type="checkbox"/> Not Discussed
Shortness of breath at rest <i>SX15</i>	<input type="radio"/> Not at all	<input type="radio"/> Slightly	<input type="radio"/> Moderately	<input type="radio"/> Quite a bit	<input type="radio"/> Extremely	<input type="checkbox"/> Present <input type="checkbox"/> Absent <input type="checkbox"/> Not Discussed

Need to use oxygen <i>5X16</i>	<input type="radio"/> Not at all <input type="radio"/> Slightly <input type="radio"/> Moderately <input type="radio"/> Quite a bit <input type="radio"/> Extremely	<input type="checkbox"/> Present <input type="checkbox"/> Absent <input type="checkbox"/> Not Discussed
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6. EYES AND MOUTH:

		Medical Record
Dry eyes <i>5X6</i>	<input type="radio"/> Not at all <input type="radio"/> Slightly <input type="radio"/> Moderately <input type="radio"/> Quite a bit <input type="radio"/> Extremely	<input type="checkbox"/> Present <input type="checkbox"/> Absent <input type="checkbox"/> Not Discussed
Need to use eye drops frequently <i>5X7</i>	<input type="radio"/> Not at all <input type="radio"/> Slightly <input type="radio"/> Moderately <input type="radio"/> Quite a bit <input type="radio"/> Extremely	<input type="checkbox"/> Present <input type="checkbox"/> Absent <input type="checkbox"/> Not Discussed
Difficulty seeing clearly <i>5X8</i>	<input type="radio"/> Not at all <input type="radio"/> Slightly <input type="radio"/> Moderately <input type="radio"/> Quite a bit <input type="radio"/> Extremely	<input type="checkbox"/> Present <input type="checkbox"/> Absent <input type="checkbox"/> Not Discussed
Need to avoid certain foods due to mouth pain <i>5X9</i>	<input type="radio"/> Not at all <input type="radio"/> Slightly <input type="radio"/> Moderately <input type="radio"/> Quite a bit <input type="radio"/> Extremely	<input type="checkbox"/> Present <input type="checkbox"/> Absent <input type="checkbox"/> Not Discussed
Ulcers in mouth <i>5X10</i>	<input type="radio"/> Not at all <input type="radio"/> Slightly <input type="radio"/> Moderately <input type="radio"/> Quite a bit <input type="radio"/> Extremely	<input type="checkbox"/> Present <input type="checkbox"/> Absent <input type="checkbox"/> Not Discussed
Receiving nutrition from an intravenous line or feeding tube <i>5X11</i>	<input type="radio"/> Not at all <input type="radio"/> Slightly <input type="radio"/> Moderately <input type="radio"/> Quite a bit <input type="radio"/> Extremely	<input type="checkbox"/> Present <input type="checkbox"/> Absent <input type="checkbox"/> Not Discussed

7. EATING AND DIGESTION:

5X# - Not Discussed
 5X# - Present
 5X# - Absent

		Medical Record
Difficulty swallowing solid foods <i>SX17</i>	<input type="radio"/> Not at all <input type="radio"/> Slightly <input type="radio"/> Moderately <input checked="" type="radio"/> Quite a bit <input type="radio"/> Extremely	<input type="checkbox"/> Present <input type="checkbox"/> Absent <input type="checkbox"/> Not Discussed
Difficulty swallowing liquids <i>SX18</i>	<input type="radio"/> Not at all <input type="radio"/> Slightly <input type="radio"/> Moderately <input checked="" type="radio"/> Quite a bit <input type="radio"/> Extremely	<input type="checkbox"/> Present <input type="checkbox"/> Absent <input type="checkbox"/> Not Discussed
Vomiting <i>SX19</i>	<input type="radio"/> Not at all <input type="radio"/> Slightly <input type="radio"/> Moderately <input checked="" type="radio"/> Quite a bit <input type="radio"/> Extremely	<input type="checkbox"/> Present <input type="checkbox"/> Absent <input type="checkbox"/> Not Discussed
Weight loss <i>SX20</i>	<input type="radio"/> Not at all <input type="radio"/> Slightly <input type="radio"/> Moderately <input checked="" type="radio"/> Quite a bit <input type="radio"/> Extremely	<input type="checkbox"/> Present <input type="checkbox"/> Absent <input type="checkbox"/> Not Discussed

SX# - Not Discussed
SX# - Present
SX# - Absent

8. **MUSCLES AND JOINTS:**

		Medical Record
Joint and muscle aches <i>SX21</i>	<input type="radio"/> Not at all <input type="radio"/> Slightly <input type="radio"/> Moderately <input checked="" type="radio"/> Quite a bit <input type="radio"/> Extremely	<input type="checkbox"/> Present <input type="checkbox"/> Absent <input type="checkbox"/> Not Discussed
Limited joint movement <i>SX22</i>	<input type="radio"/> Not at all <input type="radio"/> Slightly <input type="radio"/> Moderately <input checked="" type="radio"/> Quite a bit <input type="radio"/> Extremely	<input type="checkbox"/> Present <input type="checkbox"/> Absent <input type="checkbox"/> Not Discussed
Muscle cramps <i>SX23</i>	<input type="radio"/> Not at all <input type="radio"/> Slightly <input type="radio"/> Moderately <input checked="" type="radio"/> Quite a bit <input type="radio"/> Extremely	<input type="checkbox"/> Present <input type="checkbox"/> Absent <input type="checkbox"/> Not Discussed
Weak muscles <i>SX24</i>	<input type="radio"/> Not at all <input type="radio"/> Slightly <input type="radio"/> Moderately <input checked="" type="radio"/> Quite a bit <input type="radio"/> Extremely	<input type="checkbox"/> Present <input type="checkbox"/> Absent

SX# - Not Discussed
SX# - Present
SX# - Absent

9. ENERGY:

		<input type="checkbox"/> Not Discussed
		Medical Record
Loss of energy <i>SX25</i>	<input type="radio"/> Not at all <input type="radio"/> Slightly <input type="radio"/> Moderately <input type="radio"/> Quite a bit <input type="radio"/> Extremely	<input type="checkbox"/> Present <input type="checkbox"/> Absent <input type="checkbox"/> Not Discussed
Need to sleep more/take naps <i>SX26</i>	<input type="radio"/> Not at all <input type="radio"/> Slightly <input type="radio"/> Moderately <input type="radio"/> Quite a bit <input type="radio"/> Extremely	<input type="checkbox"/> Present <input type="checkbox"/> Absent <input type="checkbox"/> Not Discussed
Fevers <i>SX27</i>	<input type="radio"/> Not at all <input type="radio"/> Slightly <input type="radio"/> Moderately <input type="radio"/> Quite a bit <input type="radio"/> Extremely	<input type="checkbox"/> Present <input type="checkbox"/> Absent <input type="checkbox"/> Not Discussed

10. MENTAL AND EMOTIONAL:

		Medical Record
Depression <i>SX28</i>	<input type="radio"/> Not at all <input type="radio"/> Slightly <input type="radio"/> Moderately <input type="radio"/> Quite a bit <input type="radio"/> Extremely	<input type="checkbox"/> Present <input type="checkbox"/> Absent <input type="checkbox"/> Not Discussed
Anxiety <i>SX29</i>	<input type="radio"/> Not at all <input type="radio"/> Slightly <input type="radio"/> Moderately <input type="radio"/> Quite a bit <input type="radio"/> Extremely	<input type="checkbox"/> Present <input type="checkbox"/> Absent <input type="checkbox"/> Not Discussed
Difficulty sleeping <i>SX30</i>	<input type="radio"/> Not at all <input type="radio"/> Slightly <input type="radio"/> Moderately <input type="radio"/> Quite a bit <input type="radio"/> Extremely	<input type="checkbox"/> Present <input type="checkbox"/> Absent <input type="checkbox"/> Not Discussed

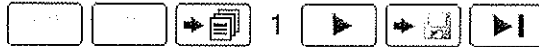
Save | Print | Close Window

Protocol # 6501 - Longitudinal Study of Immune Mediated Disorders after Allogeneic

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)		

Physician Assessment - IMD

p 6501-13176 - physician revised



* 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 WT-MD-nd

How was the following data obtained?*

MRR-MD

Physician or midlevel provider completed form Completed from medical record

Date form completed:

MD-compi-DD
 MD-compi-MM
 MD-compi-YY

2. **Skin Score** SC-skin

SC-skin-gv
 SC-skin-nd

Not due to chronic GVHD No symptoms

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

Mouth Score SC-mouth

SC-mouth-gv
 SC-mouth-nd

Not due to chronic GVHD No symptoms

Not done Mild symptoms with disease signs but not limiting oral intake significantly

Moderate symptoms with signs with **partial** limitation of oral intake

Severe symptoms with disease signs on examination with **major** limitation of oral intake

GI Tract Score SC-GI

SC-gi-gv

Not due to chronic GVHD No symptoms

DEMO

SC-gi-nd

<input type="checkbox"/> Not done	<ul style="list-style-type: none"> <input type="radio"/> Symptoms such as dysphagia, anorexia, nausea, vomiting, abdominal pain or diarrhea without significant weight loss (<5%) <input type="radio"/> Symptoms associated with mild to moderate weight loss (5-15%) <input type="radio"/> Symptoms associated with significant weight loss (>15%), requires nutritional supplement for most calorie needs OR esophageal dilation
-----------------------------------	--

Eye Score SC-eye

SC-eye-gv
SC-eye-nd

<input type="checkbox"/> Not due to chronic GVHD <input type="checkbox"/> Not done	<ul style="list-style-type: none"> <input type="radio"/> No symptoms <input type="radio"/> Mild dry eye symptoms not affecting ADL (requiring eye drops <3x per day) OR asymptomatic signs of kerato-conjunctivitis sicca <input type="radio"/> Moderate dry eye symptoms partially affecting ADL (requiring eye drops >3x per day or punctual plugs) WITHOUT vision impairment <input type="radio"/> 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 SC-joint

SC-joint-gv
SC-joint-nd

<input type="checkbox"/> Not due to chronic GVHD <input type="checkbox"/> Not done	<ul style="list-style-type: none"> <input type="radio"/> No symptoms <input type="radio"/> Mild tightness of arms or legs, normal or mild decreased range of motion (ROM) AND not affecting ADL <input type="radio"/> Tightness of arms or legs OR joint contractures, erythema thought due to fasciitis, moderate decrease ROM AND mild to moderate limitation of ADL <input type="radio"/> Contracture WITH significant decrease of ROM AND significant limitation of ADL (unable to tie shoes, button shirts, dress self etc.)
---	---

Genital Tract Score SC-genital

SC-genital-nd

<input type="checkbox"/> No GYN Exam	<ul style="list-style-type: none"> <input type="radio"/> No symptoms <input type="radio"/> Symptomatic with mild distinct signs on exam AND no effect on coitus and minimal discomfort with GYN exam <input type="radio"/> Symptomatic with distinct signs on exam AND with mild dyspareunia or discomfort with GYN exam <input type="radio"/> 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

SC-lung-gv
SC-lung-nd

<input type="checkbox"/> Not due to chronic GVHD <input type="checkbox"/> Not done	<ul style="list-style-type: none"> <input type="radio"/> No symptoms <input type="radio"/> Mild symptoms (shortness of breath after climbing one flight of steps) <input type="radio"/> Moderate symptoms (shortness of breath after walking on flat ground)
---	---

Severe symptoms (shortness of breath at rest; requiring O2)

Performance Score *SC-perf*

KPS
 ECOG
 LPS

Not done

Asymptomatic and fully active (ECOG 0; KPS or LPS 100%)
 Symptomatic, fully ambulatory, restricted only in physical strenuous activity (ECOG 1, KPS or LPS 80-90%)
 Symptomatic, ambulatory, capable of self-care, >50% of waking hours out of bed (ECOG 2, KPS or LPS 60-70%)
 Symptomatic, limited self-care, >50% of waking hours in bed (ECOG 3-4, KPS or LPS <60%)

SC-perf-nd

3. **Clinical Skin Features**

Maculopapular rash
 Lichen planus-like lesions
 Poikiloderma

Nail involvement
 Hair involvement

Sclerosis
 Fasciitis

Clinical Skin Features - Maculopapular rash
Clinical Skin Features - Lichen planus-like lesions
Clinical Skin Features - Poikiloderma
Clinical Skin Features - Nail involvement
Clinical Skin Features - Hair involvement
Clinical Skin Features - Sclerosis
Clinical Skin Features - Fasciitis

4. **Please rate the severity of this person's GVHD**

on this scale	<input type="radio"/> None (1)	<input type="radio"/> Mild (2)	<input type="radio"/> Moderate (3)	<input type="radio"/> Severe (4)							
and on this scale (select one)	cGVHD Symptoms are not at all severe (0)		cGVHD Symptoms are most severe possible (10)								
	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5	<input type="radio"/> 6	<input type="radio"/> 7	<input type="radio"/> 8	<input type="radio"/> 9	<input type="radio"/> 10

MD-sev-MMS

MD-sev10

5. **Does this person currently have:** *GVHD-current*

Late acute GVHD (1)
 Overlap acute and chronic GVHD (2)
 Classic chronic GVHD (3)
 No GVHD (0)

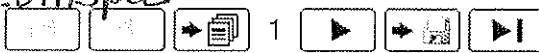
6. **Infection** *J-inf*

0 - None
 1 - Mild, topical or no therapy required
 2 - Moderate, localized, requiring oral treatment *J-inf-ID*
 3 - Severe, systemic infection requiring IV anti-infective, mold-active oral antifungal or hospitalization
 4 - Life-threatening infection

For 2-4:	<input type="radio"/> Pending lab report (1) <input type="radio"/> Unidentified organism (2) <input type="radio"/> Identified organism (3)
	If Identified organism(3), specify: <i>J-inf-spec</i>

7.

Clinical Manifestations or Severe Complications	
1. Pleural Effusion(s) <i>CM1</i>	<input type="radio"/> Never <input type="radio"/> Past, not now <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
2. Bronchiolitis obliterans <i>CM2</i>	<input type="radio"/> Never <input type="radio"/> Past, not now <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
3. Bronchiolitis obliterans organizing pneumonia <i>CM3</i>	<input type="radio"/> Never <input type="radio"/> Past, not now <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
4. Nephrotic syndrome <i>CM4</i>	<input type="radio"/> Never <input type="radio"/> Past, not now <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
5. Malabsorption <i>CM5</i>	<input type="radio"/> Never <input type="radio"/> Past, not now <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
6. Esophageal stricture or web <i>CM6</i>	<input type="radio"/> Never <input type="radio"/> Past, not now <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
7. Ascites (serositis) <i>CM7</i>	<input type="radio"/> Never <input type="radio"/> Past, not now <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
8. Myasthenia Gravis <i>CM8</i>	<input type="radio"/> Never <input type="radio"/> Past, not now <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
9. Peripheral Neuropathy <i>CM9</i>	<input type="radio"/> Never <input type="radio"/> Past, not now <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
10. Polymyositis <i>CM10</i>	<input type="radio"/> Never <input type="radio"/> Past, not now <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
11. Pericardial Effusion <i>CM11</i>	<input type="radio"/> Never <input type="radio"/> Past, not now <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
12. Cardiomyopathy <i>CM12</i>	<input type="radio"/> Never <input type="radio"/> Past, not now <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
13. Cardiac conduction defects <i>CM13</i>	<input type="radio"/> Never <input type="radio"/> Past, not now <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
14. Coronary artery involvement <i>CM14</i>	<input type="radio"/> Never <input type="radio"/> Past, not now <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe
15. Other, please specify : <i>CM15-oth</i> <i>CM15-oth-spec</i>	<input type="radio"/> Never <input type="radio"/> Past, not now <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe



Save Print Close Window

Protocol # 6501 - Longitudinal Study of Immune Mediated Disorders after Allogeneic HSCT

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 Research Center (cGVHD)		

Sclerosis, Fasciitis, BOS Capture p6501-20282_sclerosis_revised

* 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:*

1a. Was this person diagnosed with **BOS** on this study visit or anytime between this study visit and the last study visit? *Diagnosed With BOS* Yes No

1b. If yes, what is the date of Bronchiolitis Obliterans Syndrome Diagnosis:
Please consider this person for participation in 6503.
 BOS D+DD
 BOS D+MM
 BOS D+YY

2a. Was this person diagnosed with **cutaneous sclerosis** on this study visit or anytime between this study visit and the last study visit? *Diag With Sclerosis* Yes No

2b. If yes, what is the date of Cutaneous Sclerosis Diagnosis:
Please consider this person for participation in 6502.
 sclerosis D+DD
 sclerosis D+MM
 sclerosis D+YY

3a. Was this person diagnosed with **fasciitis** on this study visit or anytime between this study visit and the last study visit? *Diag With Fasciitis* Yes No

3b. If yes, what is the date of Fasciitis Diagnosis:
Please consider this person for participation in 6502.
 Fasciitis D+DD
 Fasciitis D+MM
 Fasciitis D+YY

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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)		

Participant Status Form imd-17919-patientstat-revised

* 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. Date of last contact or most recent medical note *DOLE-DD*
DOLE-MM
DOLE-YY
- 2. Select all events that have occurred to date:

Patient was never transplanted *Event_NoTx*

Graft loss *Event_Graft*

DLI *Event_DLI*

Additional stem cell transplant *Event_add-SCT*

Relapse *Event_Rel*

Death *Event_Death*

Cause of Death *COD*

None of the above has occurred. *Event_None*

Patient is alive (confirmed within past 6 months) *Event_Alive*

- Graft-DD*
- Graft-MM*
- Graft-YY*
- DLI-DD, DLI-MM*
- DLI-YY*
- Add-SCT-DD*
- Add-SCT-MM*
- Add-SCT-YY*
- Rel-DD, Rel-MM*
- Rel-YY*

DEMO

Save | Print | Close Window

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

Participant ID	122600	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

Treatment Start Date *treatment table - revised*

* 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 <u>Date</u>
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 <u>Date</u> <i>treatment_start_date</i>

Save Print Close Window

treatment name = imatinib or rituximab

Protocol # 6501 - Longitudinal Study of Immune Mediated Disorders after Allogeneic

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:* Date

Interviewer User ID:* User ID is required

1. Participant Age (either Date of Birth or Age is required, use Date of Birth unless disallowed by your local institution's IRB):

Date of Birth:

OR

Age at registration:

dob [date of birth day
date of birth month
date of birth year

age at registration

2. Gender:*

Male Female

gender

3. Race (check all that apply): * 0, 1

- American Indian or Alaska Native *race - American Indian or AK native*
- Asian *race - asian*
- Black or African American *race - black or african american*
- Native Hawaiian or Other Pacific Islander
- White *race - white*
- Unknown *race - unknown or not reported*
- Refused *race - refused*

race - native HI or pacific islander

4. Ethnicity (select one): *

- Hispanic, Latino, or Spanish origin
- Not Hispanic, Latino or Spanish origin
- Unknown or not reported
- Refused.

ethnicity

DEMO

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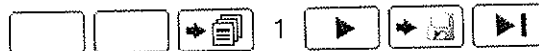
Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

Participant ID	121393	Date of Registration	11 Mar 2013
Local ID	0201011		
Status	Eligible		
Site ID	Fred Hutchinson Cancer 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

Page: 1 of 2

BL_Visit_chart_Abstraction



* 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

- Date of transplant: 22 Feb 2011
- Height pre-transplant: 172 cm
- Weight pre-transplant: 77.3 kg

*Tx-DD
Tx-MM
Tx-YY*

HT-pre, HT-unit Unknown HT-pre-unk

WT-pre, WT-unit Unknown WT-pre-unk

Disease Status	Early	Intermediate	Advanced
<i>Dis-status-AML</i> AML	CR1	CR2	CR3+, rel, ref, IF
<i>Dis-status-ALL</i> ALL	CR1	CR2	CR3+, rel, ref, IF
<i>Dis-status-CML</i> CML	CP	AP	BC or after BC
<i>Dis-status-CLL</i> CLL		CR, PR, CS	Rel, ref, CI
<i>Dis-status-MDS</i> MDS	RA, RARS	RAEB, RAEBT	Rel, ref, IF
<i>Dis-status-MPD</i> MPD		All others	Rel, ref, IF
<i>Dis-status-NHL</i> NHL		CR, PR, CS	Rel, ref, CI
<i>Dis-status-HD</i> HD		CR, PR, CS	Rel, ref, CI
<i>Dis-status-MM</i> MM		CR, PR, CS	Rel, ref, CI
<i>Dis-status-AA</i> AA	Without ATG/TG	With ATG/TG	

Dis-status-oth

Other	<input type="radio"/> Early (non-malignant) <input type="radio"/> Intermed (CR, PR) <input type="radio"/> Adv. (Rel, ref, CI)
Other, specify	Dis-status-oth-spec

5. Transplant Source SOURCE
 Peripheral Blood Bone Marrow Cord Blood
6. Transplant Type Tx-type
 Myeloablative Not myeloablative (non-myeloablative or reduced intensity)
7. Recipient CMV Antibodies Pt-CMV
 Yes No Indeterminate Not tested

8. Hepatitis B sAb	<input type="radio"/> Reactive <input type="radio"/> Not performed <input type="radio"/> Nonreactive	HepB-SAB
Hepatitis B sAg	<input type="radio"/> Reactive <input type="radio"/> Not performed <input type="radio"/> Nonreactive	HepB-SAG
Hepatitis B cAb	<input type="radio"/> Reactive <input type="radio"/> Not performed <input type="radio"/> Nonreactive	HepB-CAB
Hepatitis C	<input type="radio"/> Reactive <input type="radio"/> Not performed <input type="radio"/> Nonreactive	HepC

9. HLA : HLA
 Fully matched at all tested loci
 Mismatched at one or more loci

HLA-A
 HLA-B
 HLA-C
 HLA-DRB1
 HLA-DQ
 HLA-DP

A	<input type="radio"/> Not tested HLA-A-nd <input type="radio"/> Antigen mm <input type="radio"/> Allele mm <input type="radio"/> Matched
B	<input type="radio"/> Not tested HLAB-nd <input type="radio"/> Antigen mm <input type="radio"/> Allele mm <input type="radio"/> Matched
C	<input type="radio"/> Not tested HLA-C-nd <input type="radio"/> Antigen mm <input type="radio"/> Allele mm <input type="radio"/> Matched
DRB1	<input type="radio"/> Not tested HLADRBI-nd <input type="radio"/> Antigen mm <input type="radio"/> Allele mm <input type="radio"/> Matched
DQ	<input type="radio"/> Not tested HLA-DQ-nd <input type="radio"/> Antigen mm <input type="radio"/> Allele mm <input type="radio"/> Matched
DP	<input type="radio"/> Not tested HLADP-nd <input type="radio"/> Antigen mm <input type="radio"/> Allele mm <input type="radio"/> Matched

10. Date of Acute GVHD Diagnosis: AGVH-DD, AGVH-MM, AGVH-YY
 No Acute GVHD AVGH-no
 Unknown AVGH-UNK

11. Maximum Acute GVHD Grade

Overall	0	1	2	3	4	Not done	AGVH-OVER
Liver	0	1	2	3	4	Not done	AGVH-LIV
GI	0	1	2	3	4	Not done	AGVH-GI
Skin	0	1	2	3	4	Not done	AGVH-SKIN

TRANSPLANT MEDICATIONS

12. Conditioning Regimen

Code regimen	Modifier 1	Modifier 2
21 TX_CODE#	4 TX_MOD#	TX_MOD#

Add

13. T-cell Depletion? *Tcell* Yes 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) *Dnr_gen*

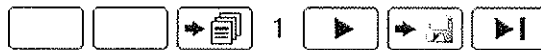
- Male
- Female
- Female/Female
- Male/Male
- Male/Female

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
- No
- Indeterminate
- Not tested



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Protocol # **6501** - Longitudinal Study of Immune Mediated Disorders after Allogeneic HSCT

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 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 IMD Onset: * Date

Interviewer User ID:*

CHARACTERISTICS OF IMMUNE MEDIATED DISORDER (e.g., CHRONIC GVHD) AT ONSET

1. Date of immune mediated disorder onset Date *IMD-O-DD*
IMD-O-MM
IMD-O-YY
2. Name of immune mediated disorder *IMD-O*
 - Late, recurrent or persistent acute GVHD
 - Chronic GVHD (classic chronic or overlap)
 - Other immune mediated disorder

If Other, specify: *IMD-O-OTH*
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 *Perf-O* % Karnofsky *KPS-LPS-O* Unknown *Perf-O-unk*
6. Percent BSA *BSA-O* % Unknown *BSA-O-unk*
7. Lichen-planus-like changes of skin *LICH-O* Yes No Unknown
8. Sclerotic changes of skin *SCL-O* Yes No Unknown
9. Bronchiolitis obliterans syndrome *BOS-O* Yes No Unknown
10. Chronic diarrhea *DIA-O* Yes No Unknown
11. Oral involvement *ORAL-O* Yes No Unknown
12. Total bilirubin *Bili-O* Unknown *Bili-O-unk*
13. Platelet count *PIT-O* Unknown *PIT-O-unk*

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 Research Center (cGVHD)		

Lab Results Form *Lab-Results-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

Metabolic Panel Not Done **Date of Test** *Meta-DD*
Meta-nd *Meta-MM*
Meta-YY

Test Name	Result	Units	
Creatinine* <i>CR</i>	<i>CR-unit</i>		<input type="checkbox"/> Not Done <i>CR-nd</i>
BUN* <i>BUN</i>	<i>BUN-unit</i>		<input type="checkbox"/> Not Done <i>BUN-nd</i>
Glucose* <i>Glu</i>	<i>Glu-unit</i>		<input type="checkbox"/> Not Done <i>Glu-nd</i>

CBC with Differential Not Done **Date of Test** *CBC-DD*
CBC-nd *CBC-MM*
CBC-YY

Test Name	Result	Units	
Hemoglobin (Hgb)* <i>HGB</i>	<i>HGB-unit</i>		<input type="checkbox"/> Not Done <i>HGB-nd</i>
Hematocrit (Hct)* <i>HCT</i>	<i>HCT-unit</i>		<input type="checkbox"/> Not Done <i>HGB-nd</i>
WBC* <i>WBC</i>	<i>WBC-unit</i>		<input type="checkbox"/> Not Done <i>WBC-nd</i>
Neutrophils* <i>Neu</i>	<i>Neu-unit</i>		<input type="checkbox"/> Not Done <i>Neu-nd</i>
Bands* <i>Bands</i>	<i>Bands-unit</i>		<input type="checkbox"/> Not Done <i>Bands-nd</i>
Lymphocytes* <i>Lym</i>	<i>Lym-unit</i>		<input type="checkbox"/> Not Done <i>Lym-nd</i>
Eosinophils* <i>Eos</i>	<i>Eos-unit</i>		<input type="checkbox"/> Not Done <i>Eos-nd</i>
Platelets* <i>PIT</i>	<i>PIT-unit</i>		<input type="checkbox"/> Not Done <i>PIT-nd</i>

Liver Function Tests Not Done **Date of Test** *LFT-DD*
LFT-nd *LFT-MM*
LFT-YY

DEMO

Test Name	Result	Units	
Total bilirubin* <i>Bili</i>	<i>Bili-unit</i>		<input type="checkbox"/> Not Done <i>Bili-nd</i>
Direct bilirubin* <i>BiliD</i>	<i>BiliD-unit</i>		<input type="checkbox"/> Not Done <i>BiliD-nd</i>
AST* <i>AST</i>	<i>AST-unit</i>		<input type="checkbox"/> Not Done <i>AST-nd</i>
ALT* <i>ALT</i>	<i>ALT-unit</i>		<input type="checkbox"/> Not Done <i>ALT-nd</i>

Alkaline Phosphatase*	ALP	ALK-unit	<input type="checkbox"/> Not Done	ALK-nd
Albumin*	ALB	ALB-unit	<input type="checkbox"/> Not Done	ALB-nd

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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)		

IMD Medication Form

IMD_medications_revised

* 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	Start Date	Currently Taking?	If no, Stop Date
Search term	RxNorm Code				
<i>IMD_Med#</i>	<i>IMD_Med_Code#</i>		<i>IMD_Med_Start</i>	<i>IMD_Med-Take#</i>	
Code		Chronic Acute Prophylaxis Unknown Other		Y N	
Add					

Save Print Close Window

= 1 - 32

0/1 indication-chronic#
 ↓
 indication-acute#
 ↓
 indication-prophylaxis#
 ↓
 indication-unknown#
 ↓
 indication-other#

IMD_Med_Start_DD#
IMD_Med_Start_MM#
IMD_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	Fred Hutchinson Cancer Research Center (cGVHD)		

Comorbidities *CoMorbidityes_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

Comorbidity	Definition	Present
1. CARDIOVASCULAR		
Arrhythmia* <i>CMB-ARR</i>	Atrial fibrillation or flutter, sick sinus syndrome or ventricular arrhythmias	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Coronary artery disease <i>CMB-CAD</i>	Coronary artery disease (one or more vessel-coronary artery stenosis requiring medical treatment, stent, or bypass graft), angina	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
History of MI <i>CMB-MI</i>	History of myocardial infarction	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Heart valve disease <i>CMB-HVD</i>	Except asymptomatic mitral valve prolapse	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Hypertension <i>CMB-HTN</i>		<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Congestive heart failure <i>CMB-CHF</i>	EF ≤ 50%	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Cerebrovascular disease <i>CMB-CVD</i>	Transient ischemic attack or history of cerebrovascular accident, or neurologic impairment consequent to CVA	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Peripheral vascular disease <i>CMB-PVD</i>		<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
DEMO Venous thrombosis <i>CMB-VT</i>	Confirmed radiographically and requiring anticoagulation	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
2. GASTROINTESTINAL		
Peptic ulcer/hernia/reflux <i>CMB-ULC</i>	Requiring treatment	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U

Mild hepatic <i>CMB-HEPM</i>	Chronic hepatitis, bilirubin > ULN to 1.5 X ULN, or AST/ALT > ULN to 2.5 X ULN	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Moderate/severe hepatic <i>CMB-HEPS</i>	Liver cirrhosis, bilirubin > 1.5 times ULN or AST/ALT > 2.5 ULN	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Inflammatory bowel disease <i>CMB-IBS</i>	Crohn's disease or ulcerative colitis	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
3. PULMONARY		
Moderate pulmonary <i>CMB-PULMM</i>	DLCO and/or FEV-1 66%-80% or dyspnea on slight activity	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Severe pulmonary <i>CMB-PULMS</i>	DLCO and/or FEV-1 65% or lower or dyspnea at rest or requiring oxygen	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Asthma <i>CMB-AST</i>	Asthma symptoms for which inhaled steroids or other daily treatments are needed chronically to prevent or manage attacks	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
4. ENDOCRINE		
Diabetes <i>CMB-DB</i>	Requiring treatment with insulin or oral hypoglycemic agents but not diet alone	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Hypothyroidism <i>CMB-HT</i>	Including compensated hypothyroidism	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Adrenal Insufficiency <i>CMB-AI</i>	Including compensated adrenal insufficiency	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
5. NEUROPSYCHIATRIC		
Psychiatric disturbance- Depression <i>CMB-DEP</i>	Depression requiring psychiatric consult or treatment	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Psychiatric disturbance- Anxiety or panic disorder <i>CMB-ANX</i>	Anxiety or panic disorder requiring psychiatric consult or treatment	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Neurologic disease (peripheral neuropathy, MS, Parkinson's disease or other chronic neurologic disease <i>CMB-ND</i>	Symptomatic and requiring treatment to control or manage symptoms/disease process	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Visual impairment secondary to cataracts, glaucoma or macular degeneration <i>CMB-VIS</i>	Unilateral or bilateral, and unrepaired	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Hearing impairment <i>CMB-EAR</i>	Very hard of hearing, even with hearing aids	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
6. BONE/JOINT		

Osteoarthritis <i>CMB-OA</i>	Symptomatic and requiring treatment or with osteoarthritic changes noted on radiographic studies	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U	
Degenerative disc disease (spinal stenosis or severe chronic back pain) <i>CMB-DISC</i>	Symptomatic and requiring treatment or symptomatic and with degenerative disc disease noted on radiographic studies	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U	
Avascular necrosis <i>CMB-AVN</i>	Symptomatic with pain secondary to AVN or joint replacement	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U	
Osteopenia/Osteoporosis <i>CMB-OP</i>	T Score < or equal to minus 1.5 or on treatment with a bisphosphonate	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U	
Rheumatologic <i>CMB-RA</i>	Lupus, mixed connective tissue disorder, rheumatoid arthritis, polymyalgia rheumatica	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U	
7. OTHER COMORBIDITIES			
Infection <i>CMB-INFX</i>	Requiring current treatment with antimicrobial (not prophylaxis)	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U	
Moderate/severe renal <i>CMB-REN</i>	Serum creatinine > 2 mg/dL, on dialysis, or prior renal transplantation	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U	
Prior solid malignancy <i>CMB-ST</i>	Treated at any time point in the patient's past history, excluding nonmelanoma skin cancer	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U	
8. PHYSICAL EXAM - Anthropometry			
Height	<i>HT-CMB-cm</i> cm	<i>HT-CMB-in</i> in	<i>HT-CMB-nd</i> <input type="checkbox"/> Not Done
Weight	<i>WT-CMB-kg</i> kg	<i>WT-CMB-lb</i> lbs	<i>WT-CMB-nd</i> <input type="checkbox"/> Not Done

Save Print Close Window

Protocol # 6501 - Longitudinal Study of Immune Mediated Disorders after Allogeneic

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_revised*

* 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

Patient is not on any steroids

	Medication	Dose	Units	Frequency	Route
	Search term	RxNorm Code	<i>ster_Dose#</i>	<i>ster_Freq #</i>	(PO,IV)
Code	<i>IMD_Med #</i>	<i>IMD_Med_Code #</i>	<i>ster_Units#</i>		<i>ster_Route#</i>
Add					

Save | Print | Close Window

DEMO

Specimen Collection – Aliquots Sampling Form

Protocol Number: 6502

Participant ID: _____

Site: _____

Person Completing Form: _____

research_labs_revised

drawmode = site

Specimen Name	Barcode Number	Box Number	Insufficient Volume	Volume	Cell Count	Location in Box	Comments
NMDP PBMC aliquots – Tube 1			<input type="checkbox"/>	mL	x10 ⁶		
NMDP PBMC aliquots – Tube 2			<input type="checkbox"/>	mL	x10 ⁶		
NMDP PBMC aliquots – Tube 3			<input type="checkbox"/>	mL	x10 ⁶		
NMDP PBMC aliquots – Tube 4			<input type="checkbox"/>	mL	x10 ⁶		
NMDP PBMC aliquots – Tube 5			<input type="checkbox"/>	mL	x10 ⁶		
NMDP PBMC aliquots – Tube 6			<input type="checkbox"/>	mL	x10 ⁶		
NMDP PBMC aliquots – Tube 7			<input type="checkbox"/>	mL	x10 ⁶		
NMDP PBMC aliquots – Tube 8			<input type="checkbox"/>	mL	x10 ⁶		
NMDP Heparin Plasma aliquots – Tube 1			<input type="checkbox"/>	mL	x10 ⁶		
NMDP Heparin Plasma aliquots – Tube 2			<input type="checkbox"/>	mL	x10 ⁶		

aliquot_type aliquot_barcode box insufficient_vol volume cell-count box_loc Comments

*Status = tube broken
 delayed processing
 hemolyzed
 low cell count*

Specimen Collection – Aliquots Sampling Form

Protocol Number: 6502

Participant ID: _____

Site: _____

Person Completing Form: _____

NMDP Heparin Plasma aliquots – Tube 3			<input type="checkbox"/>	mL	$\times 10^6$		
NMDP Heparin Plasma aliquots – Tube 4			<input type="checkbox"/>	mL	$\times 10^6$		
NMDP Heparin Plasma aliquots – Tube 5			<input type="checkbox"/>	mL	$\times 10^6$		
NMDP Heparin Plasma aliquots – Tube 6			<input type="checkbox"/>	mL	$\times 10^6$		
NMDP Heparin Plasma aliquots – Tube 7			<input type="checkbox"/>	mL	$\times 10^6$		
NMDP Heparin Plasma aliquots – Tube 8			<input type="checkbox"/>	mL	$\times 10^6$		
NMDP Heparin Plasma aliquots – Tube 9			<input type="checkbox"/>	mL	$\times 10^6$		
NMDP Heparin Plasma aliquots – Tube 10			<input type="checkbox"/>	mL	$\times 10^6$		
NMDP Heparin Plasma aliquots – Tube 11			<input type="checkbox"/>	mL	$\times 10^6$		
Miklos Heparin Plasma aliquots – Tube 1			<input type="checkbox"/>	mL	$\times 10^6$		
UNC EDTA Plasma aliquots – Tube 1			<input type="checkbox"/>	mL	$\times 10^6$		

Specimen Collection – Aliquots Sampling Form

Protocol Number: 6502 _____

Participant ID: _____

Site: _____

Person Completing Form: _____

UNC EDTA Plasma aliquots – Tube 2			<input type="checkbox"/>	mL	$\times 10^6$		
UNC EDTA Plasma aliquots – Tube 3			<input type="checkbox"/>	mL	$\times 10^6$		
UNC EDTA Plasma aliquots – Tube 4			<input type="checkbox"/>	mL	$\times 10^6$		

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

more than 3 months #

Concomitant Medications *Concomitant - Meets*

* 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: *

con continuing #

Assess Date	Medication	Dose	Units	Frequency	Route	Indication	Start Date	>3 months since prescribed	Continuing ?
	Search term/RxNorm Code		(mg,ml)	(BID,TID)	(PO,IV,etc.)	Search term/SNOMED Code			Y/N
	Code					Code			
	<i>Con R med # /</i>			<i>Con freq #</i>	<i>Con route #</i>	<i>Con S med # /</i>			
	<i>Con R code #</i>					<i>Con S code #</i>			

Con assess DD #
Con assess MM #
Con assess YY #
Con Add

Con Dose #

Con units #

Con start DD #
Con start MM #
Con start YY #

if no, stop date

Con stop DD #
Con stop MM #
Con stop YY #

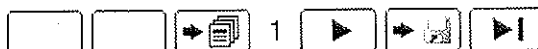
Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

Participant ID	121393	Date of Registration	11 Mar 2013
Local ID	0201011		
Status	Eligible		
Site ID	Fred Hutchinson Cancer 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

Provider Survey Enrollment

Provider_Survey

Page: 1 of 8



* 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

Date completed: *MD-compl-DD, MD-compl-MM, MD-compl-YY*

SKIN

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 <i>SL1-1</i>	<i>Eskin1%</i>	<i>Mskin1%</i>	<i>Fskin1%</i>
2. Anterior torso <i>SL1-2</i>	<i>Eskin2%</i>	<i>Mskin2%</i>	<i>Fskin2%</i>
3. Posterior torso <i>SL1-3</i>	<i>Eskin3%</i>	<i>Mskin3%</i>	<i>Fskin3%</i>
4. Left upper extremity <i>SL1-4</i>	<i>Eskin4%</i>	<i>Mskin4%</i>	<i>Fskin4%</i>
5. Right upper extremity <i>SL1-5</i>	<i>Eskin5%</i>	<i>Mskin5%</i>	<i>Fskin5%</i>
6. Left lower extremity, (incl. L buttock) <i>SL1-6</i>	<i>Eskin6%</i>	<i>Mskin6%</i>	<i>Fskin6%</i>
7. Right lower extremity, (incl. R buttock) <i>SL1-7</i>	<i>Eskin7%</i>	<i>Mskin7%</i>	<i>Fskin7%</i>
8. Genitalia <i>SL1-8</i> Not examined	<i>Eskin8%</i>	<i>Mskin8%</i>	<i>Fskin8%</i>

SL1-8 Gen-BSA

2.

	0	1	2	3	4
Skin sclerotic changes J-skin	Normal	Thickened with pockets of normal skin	Thickened over majority of skin	Thickened, unable to move	Hidebound, unable to pinch

3.

	0	1	2	3
Skin Score SC-skin	No symptoms	< 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
Fascia J-fascia	Normal	Tight with normal areas	Tight	Tight, unable to move

4.

Ulcer

Clinical Skin Features

Ulcer Location: *Ulc-loc* Largest dimension (cm): *Ulc-sz*

Maculopapular rash *MPrash* Keratosis pilaris *Kpil*

Lichen planus-like lesions *Lich* Papulosquamous lesions or ichthyosis *Ichth*

Poikiloderma *Poik* Hair involvement *Hair*

Pruritus *Prur* Nail involvement *Nail*

Other, specify: *Othskin, Othskin-spec* Other, specify: *Othskin2, Othskin2-spec*

3L2-1

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	%		6. Right Hand	0	%	
	T351-0				T356-0		

3L2-6

T351-1	1	%	<p>T351-3a</p> <p>0 1/4 1/2 3/4 1</p> <p>0 1/4 1/2 3/4 1</p>	T356-1	1	%	<p>T356-3a</p> <p>0 1/4 1/2 3/4 1</p> <p>0 1/4 1/2 3/4 1</p>
T351-2	2	%		T356-2	2	%	
T351-3	3	%		T356-3	3	%	
T351-4	4	%		T356-4	4	%	
Total=	100%			Total=	100%		
T352-0	0	%	<p>T352-3a</p> <p>0 1/4 1/2 3/4 1</p> <p>0 1/4 1/2 3/4 1</p> <p>T352-4a</p>	T357-0	0	%	<p>T357-2</p> <p>0 1/4 1/2 3/4 1</p> <p>0 1/4 1/2 3/4 1</p> <p>T357-4a</p>
T352-1	1	%		T357-1	1	%	
SL2-2 2. Chest T352-2	2	%		7. Left Arm T357-3	3	%	
T352-3	3	%		T357-4	4	%	
T352-4	4	%		Total=	100%		
Total=	100%		Total=	100%			
T353-0	0	%	<p>T353-2</p> <p>0 1/4 1/2 3/4 1</p> <p>0 1/4 1/2 3/4 1</p> <p>T353-4a</p>	T358-0	0	%	<p>T358-2</p> <p>0 1/4 1/2 3/4 1</p> <p>0 1/4 1/2 3/4 1</p> <p>T358-4a</p>
T353-1	1	%		T358-1	1	%	
SL2-3 3. Abdomen and Genitals T353-3	2	%		8. Left Hand T358-3	3	%	
T353-4	4	%		T358-4	4	%	
Total=	100%			Total=	100%		
Total=	100%		Total=	100%			
T354-0	0	%	<p>T354-1</p> <p>0 1/4 1/2 3/4 1</p> <p>0 1/4 1/2 3/4 1</p> <p>T354-4a</p>	T359-0	0	%	<p>T359-1</p> <p>0 1/4 1/2 3/4 1</p> <p>0 1/4 1/2 3/4 1</p> <p>T359-4a</p>
T354-1	1	%		T359-1	1	%	
SL2-4 4. Back and Buttocks T354-2	2	%		9. Right Leg and Foot T359-2	2	%	
T354-2	2	%		T359-2	2	%	
Total=	100%			Total=	100%		
Total=	100%		Total=	100%			

SL2-7
T357-3a

SL2-8
T358-3a

SL2-9

T354-3	3	%		T359-3	3	%	
T354-4	4	%		T359-4	4	%	
Total=		100%		Total=		100%	
T355-0	0	%		T3510-0	0	%	
T355-1	1	%		T3510-1	1	%	
5. Right Arm	2	%		10. Left Leg and Foot	2	%	
T355-3	3	%		T3510-3	3	%	
T355-4	4	%		T3510-4	4	%	
Total=		100%		Total=		100%	

Handwritten notes:
 SL2-5 (next to T355-2)
 T355-2 - T355-3a
 T355-2
 0 1/4 1/2 3/4 1
 T355-4a
 T3510-2 - T3510-3a
 T3510-2
 0 1/4 1/2 3/4 1
 T3510-4a
 SL2-10 (next to T3510-2)

ROM & MOUTH

6. ROM

	1	2	3	4	5	6	7
Shoulder ROM_shr							
Elbow ROM_elb							
Wrist and Fingers ROM_wri							
Foot Dorsiflexion ROM_foot							

7.

	0	1	2	3
Mouth Score sc_mouth	No symptoms	Mild symptoms with disease signs but not limiting oral intake significantly	Moderate symptoms with signs with partial limitation of oral intake	Severe symptoms with disease signs on examination with major limitation of oral intake
Mouth R_mouth_E	Erythema None	Mild erythema OR Moderate	Moderate (≥25%) OR	Severe erythema (≥25%)

			erythema (<25%)	Severe erythema (<25%)
Lichenoid	None	Hyperkeratotic changes (<25%)	Hyperkeratotic changes (25-50%)	Hyperkeratotic changes (>50%)
<i>R-mouth-L</i>				
Ulcers	None	None	Ulcers involving (≤20%)	Severe ulcerations (>20%)
<i>R-mouth-U</i>				
Mucoceles (of lower labia and soft palate only)	None	1-5 mucoceles	6-10 scattered mucoceles	Over 10 mucoceles
<i>R-mouth-M</i>				
Mouth Pain	No symptoms	Food sensitivity	Pain requiring narcotics	Unable to eat
<i>J-mouth</i>				

GASTROINTESTINAL

8.

		0	1	2	3
GI Tract Score		No symptoms	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
	<i>SC-GI</i>				
Gastro-intestinal	Esophagus Dysphagia OR Odynophagia	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
	<i>R-eso</i>				
	Upper GI Early satiety	No symptoms	Mild, occasional	Moderate,	More severe or
<i>R-UGI</i>					

OR Anorexia		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	persistent symptoms throughout the day, with marked reduction in oral intake, on almost every day of the past week
OR Nausea & vomiting				
Lower GI Diarrhea <i>R-LGI</i>	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 <i>SC-eye</i>	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	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 <i>SC-joint</i>	No symptoms	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 Tract Score <i>SC-genital</i>	No symptoms	Symptomatic with mild distinct signs	Symptomatic with distinct signs on	Symptomatic WITH advanced

GYN_exam No GYN 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)
-------------	--	--	---

sc-oth11

Other Organ Score, specify:
sc-oth1-spec1

No effect on ADL	Mild effect on ADL	Moderate effect on ADL	Severe effect on ADL
------------------	--------------------	------------------------	----------------------

sc-oth12

Other Organ Score, specify:
sc-oth1-spec2

No effect on ADL	Mild effect on ADL	Moderate effect on ADL	Severe effect on ADL
------------------	--------------------	------------------------	----------------------

Add Other

OVERALL STATUS

10.

Please rate the severity of this person's GVHD

MD-sev-MMS

on this scale	None(0)	Mild(1)	Moderate(2)	Severe(3)
<i>MD-sev10</i> and on this scale (select one)	cGVHD Symptoms are not at all severe			cGVHD Symptoms are most severe possible
	0	1	2	3

11.

Reasons for changing therapeutic regimen (check all that apply)

- Not applicable, no changes made *Rxchg-na*
- Adjust levels of medications *Rxchg-level*
- Enroll on clinical trial *Rxchg-trial*
- Worsening of symptoms *Rxchg-worse*
- No improvement in symptoms *Rxchg-noimprov*
- Toxicity *Rxchg-tox*
- New symptoms *Rxchg-newsx*
- Improvement in symptoms *Rxchg-improve*
- Disease relapse *Rxchg-rel*
- Stable *Rxchg-stable*

12.

Sentinel Organ
 Response in which organ system will guide your treatment decisions (If more than one, please rank)

	If ranked, please provide number
<input type="checkbox"/> Skin <i>SOR-skin</i>	
<input type="checkbox"/> Joints <i>SOR-joint</i>	
<input type="checkbox"/> Fascia <i>SOR-fascia</i>	
<input type="checkbox"/> Lung <i>SOR-lung</i>	
<input type="checkbox"/> Urogenital <i>SOR-genital</i>	
<input type="checkbox"/> Liver <i>SOR-liver</i>	
<input type="checkbox"/> Mouth <i>SOR-mouth</i>	
<input type="checkbox"/> Esophagus <i>SOR-eso</i>	
<input type="checkbox"/> Lower GI <i>SOR-LGI</i>	
<input type="checkbox"/> Other <i>SOR-oth</i>	
If Other, specify: <i>SO-othspec</i>	

13.

Does this person currently have:

GVHD-current

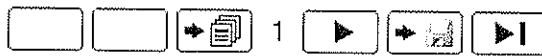
- Late acute GVHD (1)
- Overlap acute and chronic GVHD (2)
- Classic chronic GVHD (3)
- No GVHD (0)

14.

Infection	0	1	2	3	4
<i>J-inf</i>	None	Mild, topical or no therapy required	Moderate, localized, requiring oral treatment <i>J-inf-ID</i>	Severe, systemic infection requiring IV anti-infective, mold-active oral antifungal or hospitalization	Life-threatening infection
	For 2-4:	Pending lab report (1)	Unidentified organism (2)	Identified organism (3)	
Identified organism(3), specify: <i>J-inf-spec</i>					

15.

Peripheral Edema?	None (0)	Tr (9)	1+	2+	3+	4+
16.						
Other indicators, clinical manifestations or severe complications related to chronic GVHD						
	Never (0)	Past, not now (1)	Mild (2)	Moderate (3)	Severe (4)	
1. Pleural Effusion(s) <i>CM1</i>						
2. Bronchiolitis obliterans <i>CM2</i>						
3. Bronchiolitis obliterans organizing pneumonia <i>CM3</i>						
4. Nephrotic syndrome <i>CM4</i>						
5. Malabsorption <i>CM5</i>						
6. Esophageal stricture or web <i>CM6</i>						
7. Ascites (serositis) <i>CM7</i>						
8. Myasthenia Gravis <i>CM8</i>						
9. Peripheral Neuropathy <i>CM9</i>						
10. Polymyositis <i>CM10</i>						
11. Pericardial Effusion <i>CM11</i>						
12. Cardiomyopathy <i>CM12</i>						
13. Cardiac conduction defects <i>CM13</i>						
14. Coronary artery involvement <i>CM14</i>						
15. Other, please specify: <i>CM15-oth#</i>						
16. Other, please specify: <i>CM15-othspec#</i>						
17. Other, please specify: <i>CM15-othspec#</i>						
Add Other						



Save Print Close Window

OVERALL STATUS

ON FOLLOW-UP VERSION ONLY

14.

Since the last study visit three months ago on _____, how would you say this patient's chronic GVHD has changed?

	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)
chg- Mouth	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
chg- Skin	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
chg- Eyes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
chg- Joints	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
chg- Chronic GVHD Overall	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

What are your reasons for how you rated "chronic GVHD overall"?
 Write in → (For example, has an organ or symptom improved or worsened?)

chg-reason

15.

	0	1	2	3	4
Infection	<input type="radio"/> None	<input type="radio"/> Mild, topical or no therapy required	<input type="radio"/> Moderate, localized, requiring oral treatment	<input type="radio"/> Severe, systemic infection requiring IV anti-infective, mold-active oral antifungal or hospitalization	<input type="radio"/> Life-threatening infection
	For 2-4:	<input type="radio"/> Pending lab report (1)	<input type="radio"/> Unidentified organism (2)	<input type="radio"/> Identified organism, specify (3): _____	

16.

Peripheral Edema?	<input type="checkbox"/> None (0)	<input type="checkbox"/> Tr (9)	<input type="checkbox"/> 1+	<input type="checkbox"/> 2+	<input type="checkbox"/> 3+	<input type="checkbox"/> 4+
--------------------------	-----------------------------------	---------------------------------	-----------------------------	-----------------------------	-----------------------------	-----------------------------

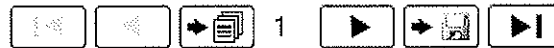
Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

Participant ID	129841	Date of Registration	23 Jun 2014
Local ID	0201020		
Status	Eligible		
Site ID	Fred Hutchinson Cancer Research Center (cGVHD)		
Treatment	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



* These fields are required in order to SAVE the form

* These fields are required in order to COMPLETE the form

Date of Visit: * Date Invalid Date of Visit

Interviewer User ID:* User ID is required

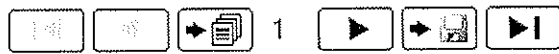
Pt-Compl-DD
Pt-Compl-MM
Pt-Compl-YY

Date completed: Date not valid

Section 1: Your Chronic Graft vs. Host Disease (GVHD) Symptoms

	Not Present	As Bad As You Can Imagine
1. Your chronic GVHD symptoms overall? <i>PSR1</i>	<input type="radio"/> 0	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> 6 <input type="radio"/> 7 <input type="radio"/> 8 <input type="radio"/> 9 <input type="radio"/> 10
2. Your skin itching at its WORST? <i>PSR2</i>	<input type="radio"/> 0	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> 6 <input type="radio"/> 7 <input type="radio"/> 8 <input type="radio"/> 9 <input type="radio"/> 10
3. Your mouth dryness at its WORST? <i>PSR3</i>	<input type="radio"/> 0	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> 6 <input type="radio"/> 7 <input type="radio"/> 8 <input type="radio"/> 9 <input type="radio"/> 10
4. Your mouth pain at its WORST? <i>PSR4</i>	<input type="radio"/> 0	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> 6 <input type="radio"/> 7 <input type="radio"/> 8 <input type="radio"/> 9 <input type="radio"/> 10
5. Your mouth sensitivity at its WORST? <i>PSR5</i>	<input type="radio"/> 0	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> 6 <input type="radio"/> 7 <input type="radio"/> 8 <input type="radio"/> 9 <input type="radio"/> 10
6. Your eye problem at its WORST? <i>PSR6</i>	<input type="radio"/> 0	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> 6 <input type="radio"/> 7 <input type="radio"/> 8 <input type="radio"/> 9 <input type="radio"/> 10
7. What is your main complaint with regard to your eyes? <i>PSR7</i>		

<p>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?</p> <p style="text-align: right;">PSR8</p>	<p><input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not applicable</p>
<p>9. Overall, how would you rate the severity of your chronic graft versus host disease?</p> <p style="text-align: right;">PSR9</p>	<p><input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe</p>
<p>10. Do you think your chronic GVHD symptoms are in good enough control to decrease your immunosuppressive medications?</p> <p style="text-align: right;">PSR10</p>	<p><input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Not applicable</p>



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ON FOLLOW-UP VERSION ONLY

		Not involved with GVHD	Completely gone	Very much better	Moderately better	A little better	About the same	A little worse	Moderately worse	Very much worse
PSR	11. GVHD symptoms overall	--	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5	<input type="radio"/> 6	<input type="radio"/> 7	<input type="radio"/> 8
PSR	12. Mouth	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5	<input type="radio"/> 6	<input type="radio"/> 7	<input type="radio"/> 8
PSR	13. Skin	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5	<input type="radio"/> 6	<input type="radio"/> 7	<input type="radio"/> 8
PSR	14. Eye	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5	<input type="radio"/> 6	<input type="radio"/> 7	<input type="radio"/> 8
PSR	15. Joints	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5	<input type="radio"/> 6	<input type="radio"/> 7	<input type="radio"/> 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)

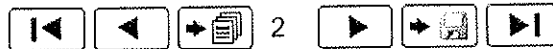
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Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

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

Patient Survey Enrollment

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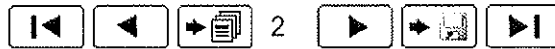
Interviewer User ID: *

Section 2:

By circling one (1) number per line, please indicate how much you have been bothered by the following problems in the past month:

SKIN:	Not at all	Slightly	Moderately	Quite a bit	Extremely
1. Abnormal skin color SX1	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
2. Rashes SX2	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
3. Thickened skin SX3	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
4. Sores on skin SX4	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
5. Itchy skin SX5	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
EYES AND MOUTH:	Not at all	Slightly	Moderately	Quite a bit	Extremely
6. Dry eyes SX6	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
7. Need to use eye drops frequently SX7	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
8. Difficulty seeing clearly SX8	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4

9. Need to avoid certain foods due to mouth pain <i>SX9</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
10. Ulcers in mouth <i>SX10</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
11. Receiving nutrition from an intravenous line or feeding tube <i>SX11</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
BREATHING:	Not at all	Slightly	Moderately	Quite a bit	Extremely
12. Frequent cough <i>SX12</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
13. Colored sputum <i>SX13</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
14. Shortness of breath with exercise <i>SX14</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
15. Shortness of breath at rest <i>SX15</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
16. Need to use oxygen <i>SX16</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4



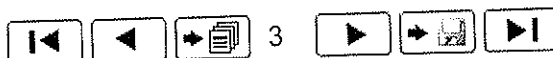
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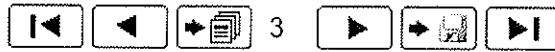
Date of Visit: * Date

Interviewer User ID: *

Section 2: (cont.)

EATING AND DIGESTION:	Not at all	Slightly	Moderately	Quite a bit	Extremely
17. Difficulty swallowing solid foods <i>SX17</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
18. Difficulty swallowing liquids <i>SX18</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
19. Vomiting <i>SX19</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
20. Weight loss <i>SX20</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
MUSCLES AND JOINTS:	Not at all	Slightly	Moderately	Quite a bit	Extremely
21. Joint and muscle aches <i>SX21</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
22. Limited joint movement <i>SX22</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
23. Muscle cramps <i>SX23</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
24. Weak muscles <i>SX24</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
ENERGY:	Not at all	Slightly	Moderately	Quite a bit	Extremely

25. Loss of energy <i>SX25</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
26. Need to sleep more/ take naps <i>SX26</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
27. Fevers <i>SX27</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
MENTAL AND EMOTIONAL:	Not at all	Slightly	Moderately	Quite a bit	Extremely
28. Depression <i>SX28</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
29. Anxiety <i>SX29</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
30. Difficulty sleeping <i>SX30</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4



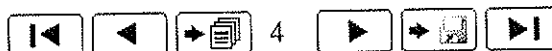
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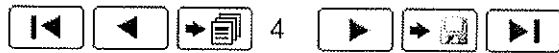
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Section 3:

Have you experienced any of the following during the last week?	All of the time	Most of the time	Half of the time	Some of the time	None of the time
1. Eyes that are sensitive to light? <i>OD1</i>	<input type="radio"/> 4	<input type="radio"/> 3	<input type="radio"/> 2	<input type="radio"/> 1	<input type="radio"/> 0
2. Eyes that feel gritty? <i>OD2</i>	<input type="radio"/> 4	<input type="radio"/> 3	<input type="radio"/> 2	<input type="radio"/> 1	<input type="radio"/> 0
3. Painful or sore eyes? <i>OD3</i>	<input type="radio"/> 4	<input type="radio"/> 3	<input type="radio"/> 2	<input type="radio"/> 1	<input type="radio"/> 0
4. Blurred vision? <i>OD4</i>	<input type="radio"/> 4	<input type="radio"/> 3	<input type="radio"/> 2	<input type="radio"/> 1	<input type="radio"/> 0
5. Poor vision? <i>OD5</i>	<input type="radio"/> 4	<input type="radio"/> 3	<input type="radio"/> 2	<input type="radio"/> 1	<input type="radio"/> 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 of the time	Some of the time	None of the time	Not applicable
6. Reading? <i>OD6</i>	<input type="radio"/> 4	<input type="radio"/> 3	<input type="radio"/> 2	<input type="radio"/> 1	<input type="radio"/> 0	<input type="radio"/> N/A
7. Driving at night? <i>OD7</i>	<input type="radio"/> 4	<input type="radio"/> 3	<input type="radio"/> 2	<input type="radio"/> 1	<input type="radio"/> 0	<input type="radio"/> N/A
8. Working with a computer or bank machine (ATM)? <i>OD8</i>	<input type="radio"/> 4	<input type="radio"/> 3	<input type="radio"/> 2	<input type="radio"/> 1	<input type="radio"/> 0	<input type="radio"/> N/A

9. Watching TV? <i>009</i>	<input type="radio"/> 4	<input type="radio"/> 3	<input type="radio"/> 2	<input type="radio"/> 1	<input type="radio"/> 0	<input type="radio"/> 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? <i>0D10</i>	<input type="radio"/> 4	<input type="radio"/> 3	<input type="radio"/> 2	<input type="radio"/> 1	<input type="radio"/> 0	<input type="radio"/> N/A
11. Places or areas with low humidity (very dry)? <i>0D11</i>	<input type="radio"/> 4	<input type="radio"/> 3	<input type="radio"/> 2	<input type="radio"/> 1	<input type="radio"/> 0	<input type="radio"/> N/A
12. Areas that are air conditioned? <i>0D12</i>	<input type="radio"/> 4	<input type="radio"/> 3	<input type="radio"/> 2	<input type="radio"/> 1	<input type="radio"/> 0	<input type="radio"/> N/A



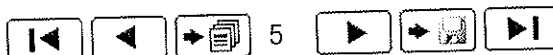
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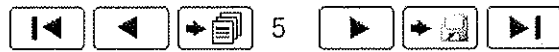
Date of Visit: * Date

Interviewer User ID:*

Section 4: Quality of Your Life After Your Transplant

PHYSICAL WELL-BEING:	Not at all	A little bit	Some-what	Quite a bit	Very much
1. I have a lack of energy F1	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
2. I have nausea F2	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
3. Because of my physical condition, I have trouble meeting the needs of my family F3	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
4. I have pain F4	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
5. I am bothered by side effects of treatment F5	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
6. I feel ill F6	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
7. I am forced to spend time in bed F7	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 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	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4

9. I get emotional support from my family <i>F9</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
10. I get support from my friends <i>F10</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
11. My family has accepted my illness <i>F11</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
12. I am satisfied with family communication about my illness <i>F12</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
13. I feel close to my partner (or the person who is my main support) <i>F13</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please check this box and go to the next section.					<input type="checkbox"/> <i>F14 - skip</i>
14. I am satisfied with my sex life <i>F14</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4



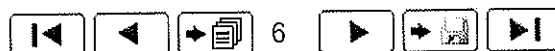
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**Patient Survey
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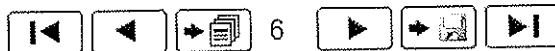
Date of Visit: * Date

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 F15	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
16. I am satisfied with how I am coping with my illness F16	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
17. I am losing hope in the fight against my illness F17	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
18. I feel nervous F18	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
19. I worry about dying F19	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
20. I worry that my condition will get worse F20	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 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) F21	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
22. My work (include work at home) is fulfilling F22	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4

23. I am able to enjoy life F23	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
24. I have accepted my illness F24	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
25. I am sleeping well F25	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
26. I am enjoying the things I usually do for fun F26	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
27. I am content with the quality of my life right now F27	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 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	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
29. I feel distant from other people F29	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
30. I worry that the transplant will not work F30	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
31. The effects of treatment are worse than I had imagined F31	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
32. I have a good appetite F32	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
33. I like the appearance of my body F33	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
34. I am able to get around by myself F34	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
35. I get tired easily F35	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
36. I am interested in sex F36	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
37. I have confidence in my nurse(s) F37	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4



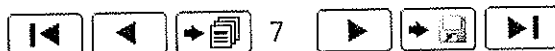
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Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

Participant ID	129841	Date of Registration	23 Jun 2014
Local ID	0201020		
Status	Eligible		
Site ID	Fred Hutchinson 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: * Date

Interviewer User ID:*

Section 5: Your Health and Well-Being

1. Which statement describes how you feel most of the time? (please check one) *KPS I*

- 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 *SF2*

Excellent	Very good	Good	Fair	Poor
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

3. Compared to one year ago, how would you rate your health in general now? *SF3*

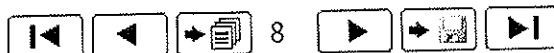
Much better now than one year ago	Somewhat better now than one year ago	About the same now as one year ago	Somewhat worse now as one year ago	Much worse now as one year ago
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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

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Patient Survey Enrollment

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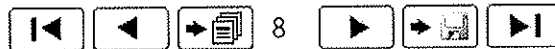
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Section 5: Your Health and Well-Being (cont.)

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 heavy objects, participating in strenuous sports <i>SF4</i>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3
5. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf. <i>SF5</i>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3
6. Lifting or carrying groceries <i>SF6</i>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3
7. Climbing several flights of stairs <i>SF7</i>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3
8. Climbing one flight of stairs <i>SF8</i>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3
9. Bending, kneeling, or stopping <i>SF9</i>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3
10. Walking more than a mile <i>SF10</i>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3
11. Walking several hundred yards <i>SF11</i>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3
12. Walking one hundred yards <i>SF12</i>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3

13. Bathing or dressing yourself	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3				
<i>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?</i>					
	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	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
15. Accomplished less than you would like	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
16. Were limited in the kind of work or other activities	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
17. Had difficulty performing the work or other activities (for example, it took extra effort)	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5



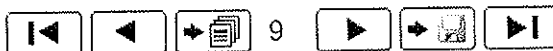
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Section 5: Your Health and Well-Being (cont.)

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 any emotional problems (such as feeling depressed or anxious)?

	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 time you spent on work or other activities as a result of any emotional problems <i>SF18</i>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
19. Accomplished less than you would like as a result of any emotional problems <i>SF19</i>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
20. Did work or other activities less carefully than usual <i>SF20</i>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5

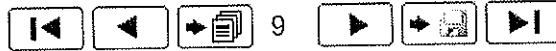
21. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? *SF21*

Not at all	Slightly	Moderately	Quite a bit	Extremely
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

22. How much bodily pain have you had during the past 4 weeks? *SF22*

None	Very Mild	Mild	Moderate	Severe	Very Severe
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

<input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/> <input type="radio"/>										
23. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)? <i>SF23</i>										
<table border="1"><tr><th>Not at all</th><th>A little bit</th><th>Moderately</th><th>Quite a bit</th><th>Extremely</th></tr><tr><td><input type="radio"/></td><td><input type="radio"/></td><td><input type="radio"/></td><td><input type="radio"/></td><td><input type="radio"/></td></tr></table>	Not at all	A little bit	Moderately	Quite a bit	Extremely	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Not at all	A little bit	Moderately	Quite a bit	Extremely						
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>						



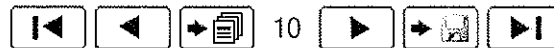
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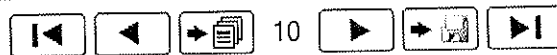
Section 5: Your Health and Well-Being (cont.)

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? <i>SF24</i>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
25. Have you been very nervous? <i>SF25</i>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
26. Have you felt so down in the dumps that nothing could cheer you up? <i>SF26</i>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
27. Have you felt calm and peaceful? <i>SF27</i>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
28. Did you have a lot of energy? <i>SF28</i>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
29. Have you felt downhearted and depressed? <i>SF29</i>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
30. Did you feel worn out? <i>SF30</i>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5

31. Have you been happy? <i>SF31</i>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
32. Did you feel tired? <i>SF32</i>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
33. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)? <i>SF33</i>					
All of the time	Most of the time	Some of the time	A little of the time	None of the time	
<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5	
	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
34. I seem to get sick a little easier than other people <i>SF34</i>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
35. I am as healthy as anybody I know <i>SF35</i>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
36. I expect my health to get worse <i>SF36</i>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
37. My health is excellent <i>SF37</i>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5



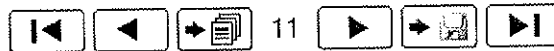
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Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

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Patient Survey Enrollment

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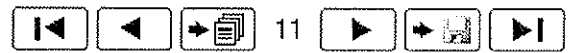
Date of Visit: * Date

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) H1	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. Listening to the radio H2	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. Reading books, magazines or newspapers H3	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. Writing (letters, notes) H4	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. Working at a desk or table H5	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. Standing (for more than one minute) H6	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. Standing (for more than five minutes) H7	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8. Dressing or undressing (without assistance) H8	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9. Getting clothes from drawers or closets H9	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

10. Getting in or out of a car (without assistance)	H10	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11. Dining at a restaurant	H11	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12. Playing cards/table games	H12	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13. Taking a bath (no assistance needed)	H13	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
14. Putting on shoes, stockings or socks (no assistance needed)	H14	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
15. Attending a movie, play, church event or sports activity	H15	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
16. Walking 30 yards (27 meters)	H16	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>



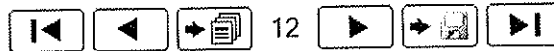
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Patient Survey Enrollment

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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) H17	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
18. Dressing/undressing (no rest or break needed) H18	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
19. Using public transportation or driving a car (100 miles or less) H19	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
20. Using public transportation or driving a car (99 miles or more) H20	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
21. Cooking your own meals H21	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
22. Washing or drying dishes H22	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
23. Putting groceries on shelves H23	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
24. Ironing or folding clothes H24	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
25. Dusting/polishing furniture or polishing cars H25	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

26. Showering	H26	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
27. Climbing six steps	H27	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
28. Climbing six steps (non-stop)	H28	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
29. Climbing nine steps	H29	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
30. Climbing 12 steps	H30	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
31. Walking 1/2 block on level ground	H31	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
32. Walking 1/2 block on level ground (non-stop)	H32	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
33. Making a bed (not changing sheets)	H33	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
34. Cleaning windows	H34	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
35. Kneeling, squatting to do light work	H35	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
36. Carrying a light load of groceries	H36	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
37. Climbing nine steps (non-stop)	H37	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

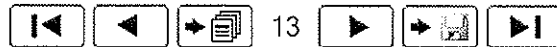
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Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

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Section 6: Your Activity Level (cont.)

		Still Doing This Activity (1)	Have Stopped Doing This Activity (2)	Never Did This Activity (3)
38. Climbing 12 steps (non-stop)	H38	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
39. Walking ½ block uphill	H39	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
40. Walking ½ block uphill (non-stop)	H40	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
41. Shopping (by yourself)	H41	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
42. Washing clothes (by yourself)	H42	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
43. Walking one block on level ground	H43	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
44. Walking two blocks on level ground	H44	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
45. Walking one block on level ground (non-stop)	H45	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
46. Walking two blocks on level ground (non-stop)	H46	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

47. Scrubbing (floors, walls or cars)	H47	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
48. Making beds (changing sheets)	H48	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
49. Sweeping	H49	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
50. Sweeping (five minutes non-stop)	H50	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
51. Carrying a large suitcase or bowling (one line)	H51	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
52. Vacuuming carpets	H52	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
53. Vacuuming carpets (five minutes non-stop)	H53	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
54. Painting (interior/exterior)	H54	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
55. Walking six blocks on level ground	H55	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
56. Walking six blocks on level ground (non-stop)	H56	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
57. Carrying out the garbage	H57	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
58. Carrying a heavy load of groceries	H58	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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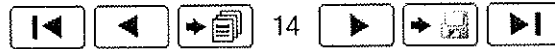
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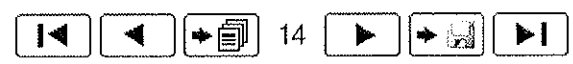
Date of Visit: * Date

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)
59. Climbing 24 steps	H59	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
60. Climbing 36 steps	H60	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
61. Climbing 24 steps (non-stop)	H61	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
62. Climbing 36 steps (non-stop)	H62	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
63. Walking one mile	H63	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
64. Walking one mile (non-stop)	H64	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
65. Running 110 yards (100 meters) or playing softball/baseball	H65	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
66. Dancing (social)	H66	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
67. Doing calisthenics or aerobic dancing (5 minutes non-stop)	H67	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

68. Mowing the lawn (power mower, but not a riding mower)	H68	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
69. Walking two miles	H69	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
70. Walking two miles (non-stop)	H70	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
71. Climbing 50 steps	H71	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
72. Shoveling, digging or spading	H72	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
73. Shoveling, digging or spading (five minutes non-stop)	H73	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
74. Climbing 50 steps (non-stop)	H74	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
75. Walking three miles or golfing 18 holes without a riding cart	H75	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
76. Walking three miles (non-stop)	H76	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
77. Swimming 25 yards	H77	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
78. Swimming 25 yards (non-stop)	H78	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>



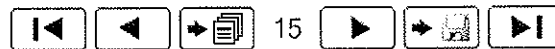
Save Print Close Window

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		
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

Patient Survey Enrollment

Page: 15 of 16



* These fields are required in order to SAVE the form

* These fields are required in order to COMPLETE the form

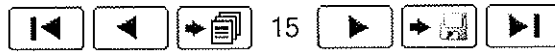
Date of Visit: * Date

Interviewer User ID: *

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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
80. Bicycling two miles	H80	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
81. Bicycling one mile (non-stop)	H81	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
82. Bicycling two miles (non-stop)	H82	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
83. Running or jogging ¼ mile	H83	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
84. Running or jogging ½ mile	H84	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
85. Playing tennis or racquetball	H85	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
86. Playing basketball (game play)	H86	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
87. Running or jogging ¼ mile (non-stop)	H87	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

88. Running or jogging 1/2 mile (non-stop)	H88	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
89. Running or jogging one mile	H89	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
90. Running or jogging two miles	H90	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
91. Running or jogging three miles	H91	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
92. Running or jogging one mile in 12 minutes or less	H92	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
93. Running or jogging two miles in 20 minutes or less	H93	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
94. Running or jogging three miles in 30 minutes or less	H94	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>



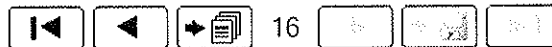
Save Print Close Window

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		
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

Patient Survey Enrollment

Page: 16 of 16



* 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: *

Section 7: About Yourself

1. What is your current work status? (check all that apply)

- In school full time *SD-work-Inschoolfulltime*
- In school part time *SD-work-Inschoolparttime*
- Working full time *SD-work-Workingfulltime*
- Working part time *SD-work-Workingparttime*
- Homemaker *SD-work-Homemaker*
- Retired *SD-work-Retired*
- On medical leave from work *SD-work-Onmedicalleavefromwork*
- Disabled, unable to work *SD-work-Disabledunabletowork*
- Unemployed, looking for work *SD-work-Unemployedlookingforwork*
- Unemployed, not looking for work *SD-work-Unemployednotlookingforwork*
If other, specify:
- Other *SD-work-Other* *SD-work-oth*

2. Do you consider yourself to be Latino (a) or Hispanic? *SD-eth*

- Not Hispanic or Latino
- Hispanic or Latino

3. How would you best describe your race? (check all that apply) *SD-raceDescribe*

- Black *SD_race - Black*
- American Indian or Alaska Native *SD_race - American Indian or Alaska Na*
- Asian *SD_race - Asian*
- Native Hawaiian or Other Pacific Islander *SD_race - Native Hawaiian or Other Pac*
- White *SD_race - White*
- Other *SD_race - Otherspecifg*

If Other, specify:

4. What is your gender? *SD_gen*

- Male
- Female

5. How old are you? *SD_age*

years

6. How much did you weigh before your transplant?

(Please be sure to indicate it in pounds (lbs) or kilograms (kg)) *SD-WT* Weigh unit: kg

SD-WT-unit

7. What is your marital status? *SD_marital*

- Married/Living with partner
- Single, never married
- Divorced, Separated
- Widowed
- Other

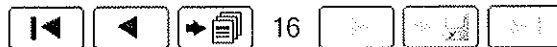
If Other, specify: *SD-marital-oth*

8. What is the highest grade of school you have completed? *SD_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? *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 is your current work status? (check **all** that apply)

- In school full time SD-work - inschoolfulltime
- In school part time SD-work - inschoolparttime
- Working full time SD-work - workingfulltime
- Working part time SD-work - workingparttime
- Homemaker SD-work - homemaker
- Retired
- On medical leave from work
- Disabled, unable to work
- Unemployed, looking for work
- Unemployed, not looking for work
- Other, specify: _____

SD-work - homemaker

SD-work - on medical leave from work

SD-work - disabled unable to work

SD-work - unemployed looking for work

SD-work - unemployed not looking for w

SD-work - other

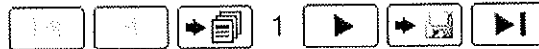
Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

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

p6502-15613-shaq



* These fields are required in order to SAVE the form

* These fields are required in order to COMPLETE the form

Date of Visit: * Date Invalid Date of Visit

Interviewer User ID: * User ID is required

Date completed: Date not valid

SHAQ Page 1

In the past seven (7) days,	Without any difficulty	With some difficulty	With much difficulty	Unable to do
1. Are you able to				
<i>shaq 1a</i> Dress yourself, including tying shoelaces and doing buttons?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<i>shaq 1b</i> Shampoo your hair?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. Are you able to				
<i>shaq 2a</i> Stand up from an armless straight chair?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<i>shaq 2b</i> Get in and out of bed?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. Are you able to				
<i>shaq 3a</i> Cut your meat?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<i>shaq 3b</i> Lift a full cup or glass to your mouth?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<i>shaq 3c</i> Open a new carton of milk?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

4. Are you able to

Walk outdoors on flat ground?

Climb up 5 steps?

5. Are you able to

Wash and dry your entire body?

Take a tub bath?

Get on and off the toilet?

6. Are you able to

Reach and get down a 5 pound object (such as a bag of sugar) from just above your head?

Bend down and pick up clothing from the floor?

7. Are you able to

Open car doors?

Open jars which have previously opened?

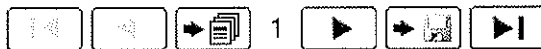
Turn regular taps on and off?

8. Are you able to

Run errands and shop?

Get in and out of a car?

Do chores such as vacuuming or yard work?



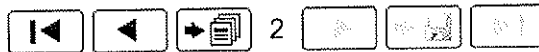
Save Print Close Window

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		
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: 2 of 2



* 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: *

SHAQ Page 2

Please check any Aids or Devices that you usually use:

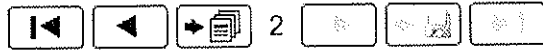
- Cane *shaq101* Dressing Devices (button hook, long shoe horn, etc.) *shaq108*
- Walker *shaq102* Built up or Special Utensils *shaq109*
- Bathtub seat *shaq103* Long Handled Appliances for reach *shaq110*
- Bathtub Bar *shaq104* Long Handled Appliances for Bathroom *shaq111*
- Jar Opener *shaq105* Raised Toilet seat *shaq112*
- Crutches *shaq106* Special or Built-up Chair *shaq113*
- Wheelchair *shaq107* Other (Specify) *shaq114*

Please check any categories for which you usually need help from another person:

- Hygiene *shaq115* Gripping and Opening Things *shaq119*
- Reach *shaq116* Errands and Chores *shaq120*
- Arising *shaq117* Dressing and Grooming *shaq121*
- Eating *shaq118* Walking *shaq122*

Enter a score from 0 to 100 to indicate the severity of the pain and interference.

1. How much pain have you had because of your illness in the past week? *Shaq9*
2. In the past week, how much has your Raynaud's Phenomenon interfered with your activities? *Shaq10*
3. In the past week, how much has/have your finger ulcer(s) interfered with your activities? *Shaq11*
4. In the past week, how much have your intestinal problems interfered with your activities? *Shaq12*
5. In the past week, how much have your breathing problems interfered with your activities? *Shaq13*
6. Overall, considering how much pain, discomfort, limitations in your daily life and other changes in your body and life, how severe would you rate your disease today? *Shaq14*



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		
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

Specific Lab Results

p6502 - 15012 - specific1 - revised

* 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	<input checked="" type="radio"/> Done <i>HepB-done</i> <input type="radio"/> Required but not done <input type="radio"/> Not required	HepB-mm HepB-DD HepB-YY	Positive <i>HepB-result</i> Negative Not Interpretable
Hepatitis B core antibody	<input checked="" type="radio"/> Done <i>HepBcore-done</i> <input type="radio"/> Required but not done <input type="radio"/> Not required	hepBcore-mm DD YY	Positive Negative HBV DNA detectable <i>HBV-DNA</i> HBV DNA undetectable <i>hepBcore-result</i>
Hepatitis C antibody	<input checked="" type="radio"/> Done <i>HepC-done</i> <input type="radio"/> Required but not done <input type="radio"/> Not required	hepC-DD hepC-mm hepC-YY	Positive Negative HCV RNA detectable HCV RNA undetectable <i>hepC-result</i> <i>HCV-RNA</i>
Phosphate	<input checked="" type="radio"/> Done <i>phos-done</i> <input type="radio"/> Required but not done <input type="radio"/> Not required	phos-DD phos-mm phos-YY	mg/dl <i>phos-result</i>
Vitamin D	<input checked="" type="radio"/> Done <i>vitD-done</i> <input type="radio"/> Required but not done <input type="radio"/> Not required	vitD-mm vitD-DD vitD-YY	ng/ml Vit D2 (250HD2) <i>vitD-D2</i> ng/ml Vit D3 (250HD3) <i>vitD-D3</i> ng/ml Total Vit D <i>vitD-total</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		
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

Goniometer Measurement Results

p6502-17dd - goniometer - revised

* These fields are required in order to SAVE the form																	
* These fields are required in order to COMPLETE the form																	
Date of Visit:	* <input type="text"/> <u>Date</u>																
Interviewer User ID: *																	
<table border="1"> <thead> <tr> <th>Name of Joint</th> <th>Left or Right</th> <th>Measurement</th> <th>Comments</th> </tr> </thead> <tbody> <tr> <td></td> <td><input type="radio"/> Left <input type="radio"/> Right</td> <td>degree</td> <td></td> </tr> <tr> <td></td> <td><input type="radio"/> Left <input type="radio"/> Right</td> <td>degree</td> <td></td> </tr> <tr> <td></td> <td><input type="radio"/> Left <input type="radio"/> Right</td> <td>degree</td> <td></td> </tr> </tbody> </table>		Name of Joint	Left or Right	Measurement	Comments		<input type="radio"/> Left <input type="radio"/> Right	degree			<input type="radio"/> Left <input type="radio"/> Right	degree			<input type="radio"/> Left <input type="radio"/> Right	degree	
Name of Joint	Left or Right	Measurement	Comments														
	<input type="radio"/> Left <input type="radio"/> Right	degree															
	<input type="radio"/> Left <input type="radio"/> Right	degree															
	<input type="radio"/> Left <input type="radio"/> Right	degree															
Add ..																	

Save Print Close Window

Gon_joint #

Gon_joint_meas #

Gon_joint_oth #

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/m ² IV weekly x 4		
Treatment Assign Date	10 Jun 2014	Treatment Start Date	16 Jun 2014

Study Medications - Rituximab

p6502 - 15623 - study medi-revised

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

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

Date of Visit: * 09 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)
<i>ritux-cld1-DD</i>	<i>ritux-cld1-dose</i>	<i>ritux-cld1-units</i>	Day 1	QWK	IV
<i>-mm</i>					
<i>-YY</i>	<i>ritux-cld8-dose</i>		Day 8	QWK	IV
<i>and</i>					
<i>ritux-cld1-DT</i>	<i>ritux-cld15-dose</i>		Day 15	QWK	IV
	<i>ritux-cld22-dose</i>		Day 22	QWK	IV

Save Print Close Window

2nd cycle

<i>ritux-c2d1-DT</i>	<i>ritux-c2d1-dose</i>	<i>ritux-c2d1-units</i>
<i>ritux-c2d8-DT</i>	<i>ritux-c2d8-dose</i>	<i>ritux-c2d8-units</i>
<i>ritux-c2d15-DT</i>	<i>ritux-c2d15-dose</i>	<i>ritux-c2d15-units</i>
<i>ritux-c2d22-DT</i>	<i>ritux-c2d22-dose</i>	<i>ritux-c2d22-dose</i>

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

Treatment Failure

pl6502 - 15619 - treatment_reversed

* 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:*

Which version of the protocol is your site currently operating under?

V0.8, V1.0 or V2.0 V3.0 or later *version number*

V3.0 or later

1. Did patient experience treatment failure to the first study medication? Yes No *cross-failure*

No response at 6 months
 Progression of sclerosis before 6 months
 Treatment intolerance before 6 months *cross-failure-type*

2. Did patient cross over to the other study medication? *crossover* Yes No

3. Date of last dose of first study medication *cross-last-DD*
cross-last-mm
cross-last-YY

4. If crossover due to treatment intolerance and toxicity present, did toxicity resolve before crossover?
 Yes No Not applicable *cross-resolve*

5. Date of crossover visit (complete Crossover Treatment Start Date form to create the crossover visit schedules and data collection): *cross-DD*
cross-mm
cross-YY

Save Print Close Window

Protocol # 6501 - Longitudinal Study of Immune Mediated Disorders after Allogeneic

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-patientstat-revised*

* 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
<p>1. Date of last contact or most recent medical note <i>DOLC-DD</i></p> <p>2. Select all events that have occurred to date: <i>DOLC-MM</i></p> <p style="margin-left: 150px;"><i>DOLC-YY</i></p> <ul style="list-style-type: none"> <input type="checkbox"/> Patient was never transplanted <i>Event_NoTx</i> <input type="checkbox"/> Graft loss <i>Event_Graft</i> <input type="checkbox"/> DLI <i>Event-DLI</i> <input type="checkbox"/> Additional stem cell transplant <i>Event_add-SCT</i> <input type="checkbox"/> Relapse <i>Event_Rel</i> <input type="checkbox"/> Death <i>Event_Death</i> <li style="margin-left: 40px;">Cause of Death <i>COD</i> <input type="checkbox"/> None of the above has occurred. <i>Event_None</i> <input type="checkbox"/> Patient is alive (confirmed within past 6 months) <i>Event_Alive</i> <div style="float: right; margin-top: 20px;"> <i>Graft-DD</i> <i>Graft-MM</i> <i>Graft-YY</i> <i>DLI-DD, DLI-MM</i> <i>DLI-YY</i> <i>Add-SCT-DD</i> <i>Add-SCT-MM</i> <i>Add-SCT-YY</i> <i>Rel-DD, Rel-MM</i> <i>Rel-YY</i> </div>	

DEMO

Save Print Close Window

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

Initial Report

* These fields are required in order to SAVE the form

A. INTERVIEW INFORMATION

Adverse event report date
(date site was notified of event) *

(DD MMM YYYY) ae.report.dt

B. ADVERSE EVENT REPORT

Adverse event occurrence date *

(DD MMM YYYY) ae.date

Is this a primary or secondary event? * (required only for initial report)

 Primary Secondary primary or 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 + treatmentlocationother

D. EVENT ASSESSMENT

Expected *

 Yes No

Expected

Causality (by reporter) *

causality by reporter

Was the adverse event associated with any of the following?
(check all that apply)

prefix assoc -

- Development of a congenital anomaly or birth defect
- Development of a permanent, serious, disabling or incapacitating condition
- Death
- Hospitalization or prolonged hospitalization
- Life threatening
- Is another condition which investigators judge to represent significant hazards

Patient status (at time of this report): *

patient outcome

Adverse event resolved date

(DD MMM YYYY)

AE resolved

Date of death

(DD MMM YYYY)

Additional comments

Comments

E. Study Drug Activity

Study Drug Start Date
(dd/MMM/yyyy)Study Drug Stop Date
(dd/MMM/yyyy)

study drug start date

study drug stop date

Add More

Did the event/reaction abate after stopping drug?

 Yes No Not Applicable

event abate after stopping drug

Did the event/reaction reappear after reintroduction?

 Yes No Not Applicable

event reappear after reintroduction

F. CONCOMITANT MEDICATIONS

* If applicable, please ensure the concomitant medications log was updated prior to adverse event submission.

REPORTER INFORMATION

Reporter User ID

2439

Save Draft

Submit for Review

Print

Close Window

on follow-up report:

Specify the adverse event = select term

date of follow up = AE follow up date

reason for follow up = reason for follow up

also not on forms:

AE causality by reviewer

Supra ordinate term (if other specify, options per CTCAE)

CTCAE version

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

Participant ID	128647	Date of Registration	01 May 2014
Local ID	0311004		
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

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

* These fields are required in order to SAVE the form	
* These fields are required in order to COMPLETE the form	
Date of Visit:	* 30 Apr 2014 <u>Date</u>
Interviewer User ID:	* 4338
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 Start:	* 3 May 2014 <u>Date</u> <i>treatment_start_date</i>

Save Print Close Window

Protocol # 6501 - Longitudinal Study of Immune Mediated Disorders after Allogeneic

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:* Date

Interviewer User ID:* User ID is required

1. Participant Age (either Date of Birth or Age is required, use Date of Birth unless disallowed by your local institution's IRB):

Date of Birth:

OR

Age at registration:

dob [date of birth day
date of birth month
date of birth year

age at registration

2. Gender:*

Male Female

gender

3. Race (check all that apply): *

0, 1

- American Indian or Alaska Native
- Asian
- Black or African American
- Native Hawaiian or Other Pacific Islander
- White
- Unknown
- Refused

race - American Indian or AK native

race - Asian

race - black or African American

race - native H or Pacific Islander

race - white

race - unknown or not reported

race - refused

4. Ethnicity (select one): *

- Hispanic, Latino, or Spanish origin
- Not Hispanic, Latino or Spanish origin
- Unknown or not reported
- Refused

ethnicity

DEMO

Save Print Close Window

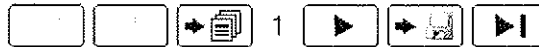
Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

Participant ID	121393	Date of Registration	11 Mar 2013
Local ID	0201011		
Status	Eligible		
Site ID	Fred Hutchinson Cancer 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

Page: 1 of 2

BL_Visit_chart_Abstraction



* 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

1. Date of transplant: 22 Feb 2011

*Tx-DD
Tx-MM
Tx-YY*

2. Height pre-transplant: 172 cm

HT-pre, HT-unit Unknown *HT-pre-unk*

3. Weight pre-transplant: 77.3 kg

WT-pre, WT-unit Unknown *WT-pre-unk*

Disease Status	Early	Intermediate	Advanced
<i>Dis-status-AML</i> AML	<input type="checkbox"/> CR1	<input type="checkbox"/> CR2	<input type="checkbox"/> CR3+, rel, ref, IF
<i>Dis-status-ALL</i> ALL	<input type="checkbox"/> CR1	<input type="checkbox"/> CR2	<input type="checkbox"/> CR3+, rel, ref, IF
<i>Dis-status-CML</i> CML	<input type="checkbox"/> CP	<input type="checkbox"/> AP	<input type="checkbox"/> BC or after BC
<i>Dis-status-CLL</i> CLL		<input type="checkbox"/> CR, PR, CS	<input type="checkbox"/> Rel, ref, CI
<i>Dis-status-MDS</i> MDS	<input type="checkbox"/> RA, RARS	<input type="checkbox"/> RAEB, RAEBT	<input type="checkbox"/> Rel, ref, IF
<i>Dis-status-MPD</i> MPD		<input type="checkbox"/> All others	<input type="checkbox"/> Rel, ref, IF
<i>Dis-status-NHL</i> NHL		<input type="checkbox"/> CR, PR, CS	<input type="checkbox"/> Rel, ref, CI
<i>Dis-status-HD</i> HD		<input type="checkbox"/> CR, PR, CS	<input type="checkbox"/> Rel, ref, CI
<i>Dis-status-MM</i> MM		<input type="checkbox"/> CR, PR, CS	<input type="checkbox"/> Rel, ref, CI
<i>Dis-status-AA</i> AA	<input type="checkbox"/> Without ATG/TG	<input type="checkbox"/> With ATG/TG	

Dis-status-oth

Other	<input type="radio"/> Early (non-malignant)	<input type="radio"/> Intermed (CR, PR)	<input type="radio"/> Adv. (Rel, ref, CI)
Other, specify	Dis-status-oth-spec		

5. Transplant Source SOURCE
 Peripheral Blood Bone Marrow Cord Blood
6. Transplant Type Tx-type
 Myeloablative Not myeloablative
 (non-myeloablative or reduced intensity)
7. Recipient CMV Antibodies Pt-CMV
 Yes No Indeterminate Not tested

8. Hepatitis B sAb	<input type="radio"/> Reactive <input type="radio"/> Not performed <input type="radio"/> Nonreactive	HepB-SAB
Hepatitis B sAg	<input type="radio"/> Reactive <input type="radio"/> Not performed <input type="radio"/> Nonreactive	HepB-SAG
Hepatitis B cAb	<input type="radio"/> Reactive <input type="radio"/> Not performed <input type="radio"/> Nonreactive	HepB-CAB
Hepatitis C	<input type="radio"/> Reactive <input type="radio"/> Not performed <input type="radio"/> Nonreactive	HepC

9. HLA : HLA
 Fully matched at all tested loci
 Mismatched at one or more loci

HLA-A
 HLA-B
 HLA-C
 HLA-DRB1
 HLA-DQ
 HLA-DP

A	<input type="radio"/> Not tested HLA-A-nd	<input type="radio"/> Antigen mm <input type="radio"/> Allele mm <input type="radio"/> Matched
B	<input type="radio"/> Not tested HLA-B-nd	<input type="radio"/> Antigen mm <input type="radio"/> Allele mm <input type="radio"/> Matched
C	<input type="radio"/> Not tested HLA-C-nd	<input type="radio"/> Antigen mm <input type="radio"/> Allele mm <input type="radio"/> Matched
DRB1	<input type="radio"/> Not tested HLA-DRB1-nd	<input type="radio"/> Antigen mm <input type="radio"/> Allele mm <input type="radio"/> Matched
DQ	<input type="radio"/> Not tested HLA-DQ-nd	<input type="radio"/> Antigen mm <input type="radio"/> Allele mm <input type="radio"/> Matched
DP	<input type="radio"/> Not tested HLA-DP-nd	Antigen mm Allele mm Matched

10. Date of Acute GVHD Diagnosis: AGVH-DD
 AGVH-MM
 AGVH-YY
 No Acute GVHD AVGH-no
 Unknown AVGH-unk

11. Maximum Acute GVHD Grade

Overall	0	1	2	3	4	Not done	AGVH-OVER
Liver	0	1	2	3	4	Not done	AGVH-LIV
GI	0	1	2	3	4	Not done	AGVH-GI
Skin	0	1	2	3	4	Not done	AGVH-SKIN

TRANSPLANT MEDICATIONS

12. Conditioning Regimen

Code regimen	Modifier 1	Modifier 2
21 TX_CODE#	4 TX_MOD#	TX_MOD#

Add

13. T-cell Depletion? *Tcell* Yes 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) *Dnr_gen*

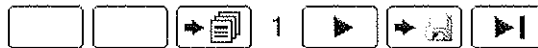
- Male
- Female
- Female/Female
- Male/Male
- Male/Female

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
- No
- Indeterminate
- Not tested



Save Print Close Window

Protocol # 6501 - Longitudinal Study of Immune Mediated Disorders after Allogeneic

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 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 IMD Onset: * Date

Interviewer User ID: *

CHARACTERISTICS OF IMMUNE MEDIATED DISORDER (e.g., CHRONIC GVHD) AT ONSET

- Date of immune mediated disorder onset Date *IMD_0-DD*
IMD_0-MM
IMD_0-YY
- Name of immune mediated disorder *IMD_0*
 - Late, recurrent or persistent acute GVHD
 - Chronic GVHD (classic chronic or overlap)
 - Other immune mediated disorder

If Other, specify: *IMD_0-OTH*
- Acute GVHD present the week before immune mediated disorder diagnosis? Yes No Unknown *onset*
- Weight *WT_0* Kgs *WT_0-UNIT* Unknown *WT_0-unk*
- Performance score *Perf_0* % Karnofsky *KPS_LPS_0* Unknown *Perf_0-unk*
- Percent BSA *BSA_0* % Unknown *BSA_0-unk*
- Lichen-planus-like changes of skin *LICH_0* Yes No Unknown
- Sclerotic changes of skin *SCL_0* Yes No Unknown
- Bronchiolitis obliterans syndrome *BOS_0* Yes No Unknown
- Chronic diarrhea *DIA_0* Yes No Unknown
- Oral involvement *ORAL_0* Yes No Unknown
- Total bilirubin *Bili_0* Unknown *Bili_0-unk*
- Platelet count *PIT_0* Unknown *PIT_0-unk*

Save Print Close Window

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

Participant ID	128647	Date of Registration	01 May 2014
Local ID	0311004		
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

FEV₁ Absolute Value *p6503-17918 - fev1absol - revised*

* These fields are required in order to SAVE the form			
* These fields are required in order to COMPLETE the form			
Date of Visit:	* 30	Apr	2014 <u>Date</u>
Interviewer User ID:	* 4338		
1. Baseline FEV ₁ Absolute Value	3.67	liters	<i>base-FEV1</i>
2. FEV ₁ Absolute Value which indicates 10% decrease	1.58	liters	<i>fall-FEV1</i>

Save Print Close Window

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 *Pathology*

* 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:*	
1. Did subject have a HRCT confirming diagnosis of BOS?	<i>BOS - HRCT</i> <input type="radio"/> Yes <input type="radio"/> No
Date of HRCT:	<i>HRCT-DD HRCT-MM HRCT-YY</i>
2. Did subject have a biopsy and a pathology report confirming diagnosis of BOS?	<input type="radio"/> Yes <input type="radio"/> No
Date of biopsy:	<i>BOS-Bx-DD BOS-bx BOS-Bx-MM BOS-Bx-YY</i>

Save Print Close Window

Protocol # 6501 - Longitudinal Study of Immune Mediated Disorders after Allogeneic

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*

* 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

Metabolic Panel	<input type="checkbox"/> Not Done <i>Meta-nd</i>	Date of Test	
Test Name	Result	Units	
Creatinine* <i>CR</i>	<i>CR-unit</i>		<input type="checkbox"/> Not Done <i>CR-nd</i>
BUN* <i>BUN</i>	<i>BUN-unit</i>		<input type="checkbox"/> Not Done <i>BUN-nd</i>
Glucose* <i>Glu</i>	<i>Glu-unit</i>		<input type="checkbox"/> Not Done <i>Glu-nd</i>

*Meta-DD
Meta-MM
Meta-YY*

CBC with Differential	<input type="checkbox"/> Not Done <i>CBC-nd</i>	Date of Test	
Test Name	Result	Units	
Hemoglobin (Hgb)* <i>HGB</i>	<i>HGB-unit</i>		<input type="checkbox"/> Not Done <i>HGB-nd</i>
Hematocrit (Hct)* <i>HCT</i>	<i>HCT-unit</i>		<input type="checkbox"/> Not Done <i>HGB-nd</i>
WBC* <i>WBC</i>	<i>WBC-unit</i>		<input type="checkbox"/> Not Done <i>WBC-nd</i>
Neutrophils* <i>Neu</i>	<i>Neu-unit</i>		<input type="checkbox"/> Not Done <i>Neu-nd</i>
Bands* <i>Bands</i>	<i>Bands-unit</i>		<input type="checkbox"/> Not Done <i>Bands-nd</i>
Lymphocytes* <i>Lym</i>	<i>Lym-unit</i>		<input type="checkbox"/> Not Done <i>Lym-nd</i>
Eosinophils* <i>Eos</i>	<i>Eos-unit</i>		<input type="checkbox"/> Not Done <i>Eos-nd</i>
Platelets* <i>PIT</i>	<i>PIT-unit</i>		<input type="checkbox"/> Not Done <i>PIT-nd</i>

*CBC-DD
CBC-MM
CBC-YY*

DEMO

Liver Function Tests	<input type="checkbox"/> Not Done <i>LFT-nd</i>	Date of Test	
Test Name	Result	Units	
Total bilirubin* <i>Bili</i>	<i>Bili-unit</i>		<input type="checkbox"/> Not Done <i>Bili-nd</i>
Direct bilirubin* <i>BiliD</i>	<i>BiliD-unit</i>		<input type="checkbox"/> Not Done <i>BiliD-nd</i>
AST* <i>AST</i>	<i>AST-unit</i>		<input type="checkbox"/> Not Done <i>AST-nd</i>
ALT* <i>ALT</i>	<i>ALT-unit</i>		<input type="checkbox"/> Not Done <i>ALT-nd</i>

*LFT-DD
LFT-MM
LFT-YY*

Alkaline Phosphatase*	ALP	ALK-unit	<input type="checkbox"/> Not Done	ALK-nd
Albumin*	ALB	ALB-unit	<input type="checkbox"/> Not Done	ALB-nd

Save Print Close Window

Protocol # 6501 - Longitudinal Study of Immune Mediated Disorders after Allogeneic

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)		

IMD Medication Form

IMD_medications_revised

* 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	Start Date	Currently Taking?	If no, Stop Date
Search term	RxNorm Code		IMD_Med_Start	Y N	Stop Date
IMD_Med#	IMD_Med_Code#	<input type="checkbox"/> Chronic <input type="checkbox"/> Acute <input type="checkbox"/> Prophylaxis <input type="checkbox"/> Unknown <input type="checkbox"/> Other			
Code					
Add					

IMD-med-take#

Save Print Close Window

= 1 - 32

o/1 indication-chronic#
 ↓
 indication-acute#
 ↓
 indication-prophylaxis#
 ↓
 indication-unknown#
 ↓
 indication-other#

IMD-med-start-DD#
 IMD-med-start-mm#
 IMD-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 Allogeneic

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 *CoMorbidityes_rensed*

* 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* <i>CMB-ARR</i>	Atrial fibrillation or flutter, sick sinus syndrome or ventricular arrhythmias	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Coronary artery disease <i>CMB-CAD</i>	Coronary artery disease (one or more vessel-coronary artery stenosis requiring medical treatment, stent, or bypass graft), angina	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
History of MI <i>CMB-MI</i>	History of myocardial infarction	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Heart valve disease <i>CMB-HVD</i>	Except asymptomatic mitral valve prolapse	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Hypertension <i>CMB-HTN</i>		<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Congestive heart failure <i>CMB-CHF</i>	EF ≤ 50%	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Cerebrovascular disease <i>CMB-CVD</i>	Transient ischemic attack or history of cerebrovascular accident, or neurologic impairment consequent to CVA	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Peripheral vascular disease <i>CMB-PVD</i>		<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
DEMO Venous thrombosis <i>CMB-VT</i>	Confirmed radiographically and requiring anticoagulation	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
2. GASTROINTESTINAL		
Peptic ulcer/hernia/reflux <i>CMB-ULC</i>	Requiring treatment	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U

Mild hepatic <i>CMB-HEPM</i>	Chronic hepatitis, bilirubin > ULN to 1.5 X ULN, or AST/ALT > ULN to 2.5 X ULN	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Moderate/severe hepatic <i>CMB-HEPS</i>	Liver cirrhosis, bilirubin > 1.5 times ULN or AST/ALT > 2.5 ULN	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Inflammatory bowel disease <i>CMB-IBS</i>	Crohn's disease or ulcerative colitis	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
3. PULMONARY		
Moderate pulmonary <i>CMB-PULMM</i>	DLCO and/or FEV-1 66%-80% or dyspnea on slight activity	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Severe pulmonary <i>CMB-PULMS</i>	DLCO and/or FEV-1 65% or lower or dyspnea at rest or requiring oxygen	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Asthma <i>CMB-AST</i>	Asthma symptoms for which inhaled steroids or other daily treatments are needed chronically to prevent or manage attacks	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
4. ENDOCRINE		
Diabetes <i>CMB-DB</i>	Requiring treatment with insulin or oral hypoglycemic agents but not diet alone	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Hypothyroidism <i>CMB-HT</i>	Including compensated hypothyroidism	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Adrenal Insufficiency <i>CMB-AI</i>	Including compensated adrenal insufficiency	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
5. NEUROPSYCHIATRIC		
Psychiatric disturbance- Depression <i>CMB-DEP</i>	Depression requiring psychiatric consult or treatment	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Psychiatric disturbance- Anxiety or panic disorder <i>CMB-ANX</i>	Anxiety or panic disorder requiring psychiatric consult or treatment	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Neurologic disease (peripheral neuropathy, MS, Parkinson's disease or other chronic neurologic disease <i>CMB-ND</i>	Symptomatic and requiring treatment to control or manage symptoms/disease process	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Visual impairment secondary to cataracts, glaucoma or macular degeneration <i>CMB-VIS</i>	Unilateral or bilateral, and unrepaired	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
Hearing impairment <i>CMB-EAR</i>	Very hard of hearing, even with hearing aids	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U
6. BONE/JOINT		

Osteoarthritis <i>CMB-OA</i>	Symptomatic and requiring treatment or with osteoarthritic changes noted on radiographic studies	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U	
Degenerative disc disease (spinal stenosis or severe chronic back pain) <i>CMB-DISC</i>	Symptomatic and requiring treatment or symptomatic and with degenerative disc disease noted on radiographic studies	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U	
Avascular necrosis <i>CMB-AVN</i>	Symptomatic with pain secondary to AVN or joint replacement	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U	
Osteopenia/Osteoporosis <i>CMB-OP</i>	T Score < or equal to minus 1.5 or on treatment with a bisphosphonate	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U	
Rheumatologic <i>CMB-RA</i>	Lupus, mixed connective tissue disorder, rheumatoid arthritis, polymyalgia rheumatica	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U	
7. OTHER COMORBIDITIES			
Infection <i>CMB-INFX</i>	Requiring current treatment with antimicrobial (not prophylaxis)	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U	
Moderate/severe renal <i>CMB-REN</i>	Serum creatinine > 2 mg/dL, on dialysis, or prior renal transplantation	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U	
Prior solid malignancy <i>CMB-ST</i>	Treated at any time point in the patient's past history, excluding nonmelanoma skin cancer	<input type="radio"/> Y <input type="radio"/> N <input type="radio"/> U	
8. PHYSICAL EXAM - Anthropometry			
Height	<i>HT-CMB-cm</i> cm	<i>HT-CMB-in</i> in	<i>HT-CMB-nd</i> <input type="checkbox"/> Not Done
Weight	<i>WT-CMB-kg</i> kg	<i>WT-CMB-lb</i> lbs	<i>WT-CMB-nd</i> <input type="checkbox"/> Not Done

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 Research Center (cGVHD)		

Medication-Steroids Form *imd_13174-medications_revised*

* 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

Patient is not on any steroids

Medication	Dose	Units	Frequency	Route
Search term	RxNorm Code	<i>ster-Dose#</i>	<i>ster-Freq #</i>	(PO,IV)
Code	<i>IMD_Med #</i>	<i>IMD_Med_Code #</i>	<i>ster_Units#</i>	<i>ster_Route #</i>
Add				

Save | Print | Close Window

DEMO

Specimen Collection – Aliquots Sampling Form

Protocol Number: 6503

Participant ID: _____

Site: _____

Person Completing Form: _____

research - labs - revised

drawnode = site

Specimen Name	Barcode Number	Box Number	Insufficient Volume	Volume	Cell Count	Location in Box	Comments
PBMC aliquots – Tube 1			<input type="checkbox"/>	mL	$\times 10^6$		
PBMC aliquots – Tube 2			<input type="checkbox"/>	mL	$\times 10^6$		
PBMC aliquots – Tube 3			<input type="checkbox"/>	mL	$\times 10^6$		
PBMC aliquots – Tube 4			<input type="checkbox"/>	mL	$\times 10^6$		
PBMC aliquots – Tube 5			<input type="checkbox"/>	mL	$\times 10^6$		
PBMC aliquots – Tube 6			<input type="checkbox"/>	mL	$\times 10^6$		
PBMC aliquots – Tube 7			<input type="checkbox"/>	mL	$\times 10^6$		
PBMC aliquots – Tube 8			<input type="checkbox"/>	mL	$\times 10^6$		
Heparin Plasma aliquots – Tube 1			<input type="checkbox"/>	mL	$\times 10^6$		
Heparin Plasma aliquots – Tube 2			<input type="checkbox"/>	mL	$\times 10^6$		
Heparin Plasma aliquots – Tube 3			<input type="checkbox"/>	mL	$\times 10^6$		

aliquot-type aliquot-barcode box insufficient_vol volume cell-count box_loc comments

*Status = tube broken
 delayed processing
 hemolyzed
 low cell count*

Specimen Collection – Aliquots Sampling Form

Protocol Number: 6503

Participant ID: _____

Site: _____

Person Completing Form: _____

Heparin Plasma aliquots – Tube 4			<input type="checkbox"/>	mL	$\times 10^6$		
Heparin Plasma aliquots – Tube 5			<input type="checkbox"/>	mL	$\times 10^6$		
Heparin Plasma aliquots – Tube 6			<input type="checkbox"/>	mL	$\times 10^6$		
Heparin Plasma aliquots – Tube 7			<input type="checkbox"/>	mL	$\times 10^6$		
Heparin Plasma aliquots – Tube 8			<input type="checkbox"/>	mL	$\times 10^6$		
Heparin Plasma aliquots – Tube 9			<input type="checkbox"/>	mL	$\times 10^6$		
Heparin Plasma aliquots – Tube 10			<input type="checkbox"/>	mL	$\times 10^6$		
Heparin Plasma aliquots – Tube 11			<input type="checkbox"/>	mL	$\times 10^6$		
Heparin Plasma aliquots – Tube 12			<input type="checkbox"/>	mL	$\times 10^6$		
Urine aliquots – Tube 1			<input type="checkbox"/>	mL	$\times 10^6$		
Urine aliquots – Tube 2			<input type="checkbox"/>	mL	$\times 10^6$		
Urine aliquots – Tube 3			<input type="checkbox"/>	mL	$\times 10^6$		

Specimen Collection –Aliquots Sampling Form

Protocol Number: 6503

Participant ID: _____

Site: _____

Person Completing Form: _____

Urine aliquots – Tube 4			<input type="checkbox"/>	mL	$\times 10^6$		
Urine aliquots – Tube 5			<input type="checkbox"/>	mL	$\times 10^6$		
Urine aliquots – Tube 6			<input type="checkbox"/>	mL	$\times 10^6$		
EDTA Plasma aliquots – Tube 1			<input type="checkbox"/>	mL	$\times 10^6$		
EDTA Plasma aliquots – Tube 2			<input type="checkbox"/>	mL	$\times 10^6$		
EDTA Plasma aliquots – Tube 3			<input type="checkbox"/>	mL	$\times 10^6$		
EDTA Plasma aliquots – Tube 4			<input type="checkbox"/>	mL	$\times 10^6$		
Granulocytes			<input type="checkbox"/>	mL	$\times 10^6$		

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

more than 3 months #

Concomitant Medications *Concomitant - Meeds*

* 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: *

con continuing #

Assess Date	Medication	Dose	Units	Frequency	Route	Indication	Start Date	>3 months since prescribed	Continuing?
	Search term/RxNorm Code		(mg,ml)	(BID,TID)	(PO,IV,etc.)	Search term/SNOMED Code			Y/N
	Code				Con route #	Code			

Con assess DD #
Con assess MM #
Con assess YY #

Con Rmed # /
Con Rcode #

Con freq #

Con Smed # /

Con Scode #

Con Dose #

Con units #

Con start DD #
Con start MM #
Con start YY #

if no,
stop
date

Con stop DD #
Con stop MM #
Con stop YY #

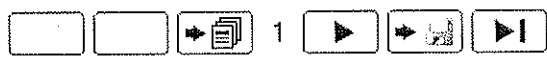
Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

Participant ID	121393	Date of Registration	11 Mar 2013
Local ID	0201011		
Status	Eligible		
Site ID	Fred Hutchinson Cancer 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

Provider Survey Enrollment

Provider_Survey

Page: 1 of 8



* 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

Date completed: MD_compl-DD, MD_compl-MM, MD_compl-YY

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 SL1-1	Eskin1%	Mskin1%	Fskin1%
2. Anterior torso SL1-2	Eskin2%	Mskin2%	Fskin2%
3. Posterior torso SL1-3	Eskin3%	Mskin3%	Fskin3%
4. Left upper extremity SL1-4	Eskin4%	Mskin4%	Fskin4%
5. Right upper extremity SL1-5	Eskin5%	Mskin5%	Fskin5%
6. Left lower extremity, (incl. L buttock) SL1-6	Eskin6%	Mskin6%	Fskin6%
7. Right lower extremity, (incl. R buttock) SL1-7	Eskin7%	Mskin7%	Fskin7%
8. Genitalia <input type="checkbox"/> Not examined	Eskin8%	Mskin8%	Fskin8%

SL1-8 Gen-BSA

2.					
	0	1	2	3	4
Skin sclerotic changes <i>J-skin</i>	Normal	Thickened with pockets of normal skin	Thickened over majority of skin	Thickened, unable to move	Hidebound, unable to pinch

3.				
	0	1	2	3
Skin Score <i>SC-skin</i>	No symptoms	< 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
Fascia <i>J-fascia</i>	Normal	Tight with normal areas	Tight	Tight, unable to move

4.	
Clinical Skin Features	
<input checked="" type="checkbox"/> Ulcer	Location: <i>Ulc-loc</i> Largest dimension (cm): <i>Ulc-sz</i>
<input checked="" type="checkbox"/> Maculopapular rash <i>MPrash</i>	<input checked="" type="checkbox"/> Keratosis pilaris <i>Kpil</i>
<input checked="" type="checkbox"/> Lichen planus-like lesions <i>Lich</i>	<input checked="" type="checkbox"/> Papulosquamous lesions or ichthyosis <i>Ich</i>
<input checked="" type="checkbox"/> Poikiloderma <i>Poik</i>	<input checked="" type="checkbox"/> Hair involvement <i>Hair</i>
<input checked="" type="checkbox"/> Pruritus <i>Prur</i>	<input checked="" type="checkbox"/> Nail involvement <i>Nail</i>
<input checked="" type="checkbox"/> Other, specify: <i>Othskin, Othskin-spec</i>	<input checked="" type="checkbox"/> Other, specify: <i>Othskin2, Othskin2-spec</i>

SL2-1

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	%		6. Right Hand	0	%	
	<i>T351-0</i>				<i>T356-0</i>		

SL2-6

T351-1	1	%	<p>T351-3a</p> <p>0 1/4 1/2 3/4 1</p> <p>0 1/4 1/2 3/4 1</p>	T356-1	1	%	<p>T356-3a</p> <p>0 1/4 1/2 3/4 1</p> <p>0 1/4 1/2 3/4 1</p>
T351-2	2	%		T356-2	2	%	
T351-3	3	%		T356-3	3	%	
T351-4	4	%		T356-4	4	%	
Total=	100%			Total=	100%		
T352-0	0	%	<p>T352-3a</p> <p>0 1/4 1/2 3/4 1</p> <p>0 1/4 1/2 3/4 1</p> <p>T352-4a</p>	T357-0	0	%	<p>T357-2</p> <p>0 1/4 1/2 3/4 1</p> <p>0 1/4 1/2 3/4 1</p> <p>T357-4a</p>
T352-1	1	%		T357-1	1	%	
2. Chest T352-2	2	%		7. Left Arm T357-3	3	%	
T352-3	3	%		T357-4	4	%	
T352-4	4	%		Total=	100%		
Total=	100%		Total=	100%			
T353-0	0	%	<p>T353-2</p> <p>0 1/4 1/2 3/4 1</p> <p>0 1/4 1/2 3/4 1</p> <p>T353-4a</p>	T358-0	0	%	<p>T358-2</p> <p>0 1/4 1/2 3/4 1</p> <p>0 1/4 1/2 3/4 1</p> <p>T358-4a</p>
T353-1	1	%		T358-1	1	%	
3. Abdomen and Genitals T353-3	3	%		8. Left Hand T358-3	3	%	
T353-4	4	%		T358-4	4	%	
Total=	100%			Total=	100%		
Total=	100%		Total=	100%			
T354-0	0	%	<p>T354-1</p> <p>0 1/4 1/2 3/4 1</p> <p>0 1/4 1/2 3/4 1</p> <p>T354-4a</p>	T359-0	0	%	<p>T359-1</p> <p>0 1/4 1/2 3/4 1</p> <p>0 1/4 1/2 3/4 1</p> <p>T359-4a</p>
T354-1	1	%		9. Right Leg and Foot T359-2	2	%	
4. Back and Buttocks T354-2	2	%		T359-2	2	%	
T354-2	2	%		T359-2	2	%	
Total=	100%			Total=	100%		
Total=	100%		Total=	100%			

SL2-2

SL2-3

SL2-4

SL2-7
T357-3a

SL2-8
T358-3a

SL2-9

T334-3	3	%		T339-3	3	%	
T334-4	4	%		T339-4	4	%	
	Total=	100%			Total=	100%	
T335-0	0	%		T3310-0	0	%	
T335-1	1	%		T3310-1	1	%	
5. Right Arm	2	%	T335-2	10. Left Leg and Foot	2	%	T3310-2
	3	%	0 1/4 1/2 3/4 1		3	%	0 1/4 1/2 3/4 1
T335-3	3	%	0 1/4 1/2 3/4 1	T3310-3	3	%	0 1/4 1/2 3/4 1
T335-4	4	%	T335-4a	T3310-4	4	%	T3310-4a
	Total=	100%			Total=	100%	

SL2-5

SL2-10

ROM & MOUTH

6. ROM

	1	2	3	4	5	6	7
Shoulder ROM_shr							
Elbow ROM_elb							
Wrist and Fingers ROM_wri							
Foot Dorsiflexion ROM_foot							

7.

	0	1	2	3
Mouth Score sc_mouth	No symptoms	Mild symptoms with disease signs but not limiting oral intake significantly	Moderate symptoms with signs with partial limitation of oral intake	Severe symptoms with disease signs on examination with major limitation of oral intake
Mouth R_mouth_E	Erythema None	Mild erythema OR Moderate	Moderate (≥25%) OR	Severe erythema (≥25%)

			erythema (<25%)	Severe erythema (<25%)
Lichenoid	None		Hyperkeratotic changes (<25%)	Hyperkeratotic changes (25-50%)
<i>R-mouth-L</i>				
Ulcers	None	None	Ulcers involving (≤20%)	Severe ulcerations (>20%)
<i>R-mouth-U</i>				
Mucoceles (of lower labia and soft palate only)	None	1-5 mucoceles	6-10 scattered mucoceles	Over 10 mucoceles
<i>R-mouth-M</i>				
Mouth Pain	No symptoms	Food sensitivity	Pain requiring narcotics	Unable to eat
<i>J-mouth</i>				

GASTROINTESTINAL

8.

	0	1	2	3
GI Tract Score	No symptoms	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
<i>SC-GI</i>				

Gastro-intestinal	Esophagus Dysphagia OR Odynophagia	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
	<i>R-ESO</i>				
	Upper GI Early satiety	No symptoms	Mild, occasional	Moderate,	More severe or
<i>R-UGI</i>					

OR Anorexia		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	persistent symptoms throughout the day, with marked reduction in oral intake, on almost every day of the past week
OR Nausea & vomiting				
Lower GI Diarrhea <i>R-LGI</i>	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 <i>SC-eye</i>	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	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 <i>SC-joint</i>	No symptoms	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 Tract Score <i>GYN_exam</i> <input type="checkbox"/> No GYN Exam <i>SC-genital</i>	No symptoms	Symptomatic with mild distinct signs	Symptomatic with distinct signs on	Symptomatic WITH advanced

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 <i>sc-lung</i>	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)
<i>sc-oth11</i> Other Organ Score, specify: <i>sc-oth1-spec1</i>	No effect on ADL	Mild effect on ADL	Moderate effect on ADL	Severe effect on ADL
<i>sc-oth12</i> Other Organ Score, specify: <i>sc-oth1-spec2</i> 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 *MD-sev-MMS*

on this scale	None(0)	Mild(1)	Moderate(2)	Severe(3)
<i>MD-sev10</i> and on this scale (select one)	cGVHD Symptoms are not at all severe			cGVHD Symptoms are most severe possible
	0	1	2	3

11.

Reasons for changing therapeutic regimen (check all that apply)

<input type="checkbox"/> Not applicable, no changes made <i>Rxchg-na</i>	<input type="checkbox"/> Toxicity <i>Rxchg-tox</i>
<input type="checkbox"/> Adjust levels of medications <i>Rxchg-level</i>	<input type="checkbox"/> New symptoms <i>Rxchg-newsx</i>
<input type="checkbox"/> Enroll on clinical trial <i>Rxchg-trial</i>	<input type="checkbox"/> Improvement in symptoms <i>Rxchg-improve</i>
<input type="checkbox"/> Worsening of symptoms <i>Rxchg-worse</i>	<input type="checkbox"/> Disease relapse <i>Rxchg-rel</i>
<input type="checkbox"/> No improvement in symptoms <i>Rxchg-noimprov</i>	<input type="checkbox"/> Stable <i>Rxchg-stable</i>

12.

Sentinel Organ
 Response in which organ system will guide your treatment decisions (If more than one, please rank)

	If ranked, please provide number
<input type="checkbox"/> Skin <i>SOR-skin</i>	
<input type="checkbox"/> Joints <i>SOR-joint</i>	
<input type="checkbox"/> Fascia <i>SOR-fascia</i>	
<input type="checkbox"/> Lung <i>SOR-lung</i>	
<input type="checkbox"/> Urogenital <i>SOR-genital</i>	
<input type="checkbox"/> Liver <i>SOR-liver</i>	
<input type="checkbox"/> Mouth <i>SOR-mouth</i>	
<input type="checkbox"/> Esophagus <i>SOR-eso</i>	
<input type="checkbox"/> Lower GI <i>SOR-LGI</i>	
<input type="checkbox"/> Other <i>SOR-oth</i>	
If Other, specify: <i>SO-othspec</i>	

13.

Does this person currently have:
GVHD-current

<input type="checkbox"/> Late acute GVHD (1)
<input type="checkbox"/> Overlap acute and chronic GVHD (2)
<input type="checkbox"/> Classic chronic GVHD (3)
<input type="checkbox"/> No GVHD (0)

14.

Infection	0	1	2	3	4
<i>J-inf</i>	None	Mild, topical or no therapy required	Moderate, localized, requiring oral treatment <i>J-inf-ID</i>	Severe, systemic infection requiring IV anti-infective, mold-active oral antifungal or hospitalization	Life-threatening infection
	For 2-4:		Pending lab report (1)	Unidentified organism (2)	Identified organism (3)
Identified organism(3), specify: <i>J-inf-spec</i>					

15.

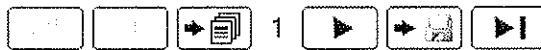
15.

Peripheral Edema?	None (0)	Tr (9)	1+	2+	3+	4+
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16.

Other indicators, clinical manifestations or severe complications related to chronic GVHD

	Never (0)	Past, not now (1)	Mild (2)	Moderate (3)	Severe (4)
1. Pleural Effusion(s) <i>CM1</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Bronchiolitis obliterans <i>CM2</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Bronchiolitis obliterans organizing pneumonia <i>CM3</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Nephrotic syndrome <i>CM4</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Malabsorption <i>CM5</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Esophageal stricture or web <i>CM6</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Ascites (serositis) <i>CM7</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Myasthenia Gravis <i>CM8</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Peripheral Neuropathy <i>CM9</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Polymyositis <i>CM10</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Pericardial Effusion <i>CM11</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Cardiomyopathy <i>CM12</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Cardiac conduction defects <i>CM13</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Coronary artery involvement <i>CM14</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Other, please specify: <i>CM15-othr#</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Other, please specify: <i>CM15-othspec#</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. Other, please specify: <i>CM15-othspec#</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Add Other					



Save Print Close Window

OVERALL STATUS

ON FOLLOW-UP VERSION ONLY

14.

Since the last study visit three months ago on _____, how would you say this patient's chronic GVHD has changed?

	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)
chg- Mouth	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
chg- Skin	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
chg- Eyes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
chg- Joints	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
chg- Chronic GVHD Overall	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

What are your reasons for how you rated "chronic GVHD overall"?
 Write in → (For example, has an organ or symptom improved or worsened?)

chg-reason

15.

	0	1	2	3	4
Infection	<input type="radio"/> None	<input type="radio"/> Mild, topical or no therapy required	<input type="radio"/> Moderate, localized, requiring oral treatment	<input type="radio"/> Severe, systemic infection requiring IV anti-infective, mold-active oral antifungal or hospitalization	<input type="radio"/> Life-threatening infection
	For 2-4:	<input type="radio"/> Pending lab report (1)	<input type="radio"/> Unidentified organism (2)	<input type="radio"/> Identified organism, specify (3): _____	

16.

Peripheral Edema?	<input type="checkbox"/> None (0)	<input type="checkbox"/> Tr (9)	<input type="checkbox"/> 1+	<input type="checkbox"/> 2+	<input type="checkbox"/> 3+	<input type="checkbox"/> 4+
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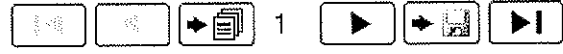
Protocol 502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

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

Patient Survey Enrollment

Patient_Survey

Page: 1 of 16



* These fields are required in order to SAVE the form

* These fields are required in order to COMPLETE the form

Date of Visit: * Date Invalid Date of Visit

Interviewer User ID: * User ID is required

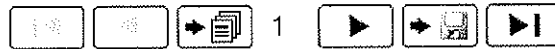
Date completed: Date not valid

PT-Compl-00
PT-Compl-MA
PT-Compl-YY

Section 1: Your Chronic Graft vs. Host Disease (GVHD) Symptoms

	Not Present	As Bad As You Can Imagine
1. Your chronic GVHD symptoms overall? PSR1	<input type="radio"/> 0	<input type="radio"/> 10
2. Your skin itching at its WORST? PSR2	<input type="radio"/> 0	<input type="radio"/> 10
3. Your mouth dryness at its WORST? PSR3	<input type="radio"/> 0	<input type="radio"/> 10
4. Your mouth pain at its WORST? PSR4	<input type="radio"/> 0	<input type="radio"/> 10
5. Your mouth sensitivity at its WORST? PSR5	<input type="radio"/> 0	<input type="radio"/> 10
6. Your eye problem at its WORST? PSR6	<input type="radio"/> 0	<input type="radio"/> 10
7. What is your main complaint with regard to your eyes? PSR7		

<p>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?</p> <p style="text-align: right;">PSR8</p>	<p><input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not applicable</p>
<p>9. Overall, how would you rate the severity of your chronic graft versus host disease?</p> <p style="text-align: right;">PSR9</p>	<p><input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe</p>
<p>10. Do you think your chronic GVHD symptoms are in good enough control to decrease your immunosuppressive medications?</p> <p style="text-align: right;">PSR10</p>	<p><input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Not applicable</p>



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ON FOLLOW-UP VERSION ONLY

		Not involved with GVHD	Completely gone	Very much better	Moderately better	A little better	About the same	A little worse	Moderately worse	Very much worse
PSR	11. GVHD symptoms overall	--	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5	<input type="radio"/> 6	<input type="radio"/> 7	<input type="radio"/> 8
PSR	12. Mouth	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5	<input type="radio"/> 6	<input type="radio"/> 7	<input type="radio"/> 8
PSR	13. Skin	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5	<input type="radio"/> 6	<input type="radio"/> 7	<input type="radio"/> 8
PSR	14. Eye	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5	<input type="radio"/> 6	<input type="radio"/> 7	<input type="radio"/> 8
PSR	15. Joints	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5	<input type="radio"/> 6	<input type="radio"/> 7	<input type="radio"/> 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?)

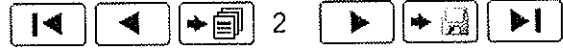
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Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

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

Patient Survey Enrollment



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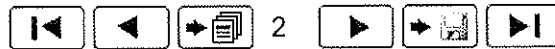
Interviewer User ID: *

Section 2:

By circling one (1) number per line, please indicate how much you have been bothered by the following problems in the past month:

SKIN:	Not at all	Slightly	Moderately	Quite a bit	Extremely
1. Abnormal skin color SX1	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
2. Rashes SX2	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
3. Thickened skin SX3	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
4. Sores on skin SX4	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
5. Itchy skin SX5	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
EYES AND MOUTH:	Not at all	Slightly	Moderately	Quite a bit	Extremely
6. Dry eyes SX6	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
7. Need to use eye drops frequently SX7	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
8. Difficulty seeing clearly SX8	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4

9. Need to avoid certain foods due to mouth pain <i>SX9</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
10. Ulcers in mouth <i>SX10</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
11. Receiving nutrition from an intravenous line or feeding tube <i>SX11</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
BREATHING:	Not at all	Slightly	Moderately	Quite a bit	Extremely
12. Frequent cough <i>SX12</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
13. Colored sputum <i>SX13</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
14. Shortness of breath with exercise <i>SX14</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
15. Shortness of breath at rest <i>SX15</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
16. Need to use oxygen <i>SX16</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4



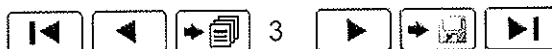
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Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

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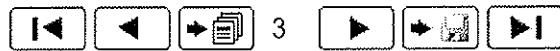
Date of Visit: * Date

Interviewer User ID: *

Section 2: (cont.)

EATING AND DIGESTION:	Not at all	Slightly	Moderately	Quite a bit	Extremely
17. Difficulty swallowing solid foods <i>SX17</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
18. Difficulty swallowing liquids <i>SX18</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
19. Vomiting <i>SX19</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
20. Weight loss <i>SX20</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
MUSCLES AND JOINTS:	Not at all	Slightly	Moderately	Quite a bit	Extremely
21. Joint and muscle aches <i>SX21</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
22. Limited joint movement <i>SX22</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
23. Muscle cramps <i>SX23</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
24. Weak muscles <i>SX24</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
ENERGY:	Not at all	Slightly	Moderately	Quite a bit	Extremely

25. Loss of energy <i>SX25</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
26. Need to sleep more/ take naps <i>SX26</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
27. Fevers <i>SX27</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
MENTAL AND EMOTIONAL:	Not at all	Slightly	Moderately	Quite a bit	Extremely
28. Depression <i>SX28</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
29. Anxiety <i>SX29</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
30. Difficulty sleeping <i>SX30</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4



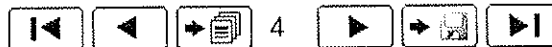
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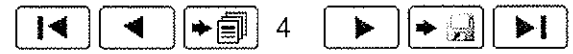
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Section 3:

Have you experienced any of the following during the last week?	All of the time	Most of the time	Half of the time	Some of the time	None of the time
1. Eyes that are sensitive to light? <i>OD1</i>	<input type="radio"/> 4	<input type="radio"/> 3	<input type="radio"/> 2	<input type="radio"/> 1	<input type="radio"/> 0
2. Eyes that feel gritty? <i>OD2</i>	<input type="radio"/> 4	<input type="radio"/> 3	<input type="radio"/> 2	<input type="radio"/> 1	<input type="radio"/> 0
3. Painful or sore eyes? <i>OD3</i>	<input type="radio"/> 4	<input type="radio"/> 3	<input type="radio"/> 2	<input type="radio"/> 1	<input type="radio"/> 0
4. Blurred vision? <i>OD4</i>	<input type="radio"/> 4	<input type="radio"/> 3	<input type="radio"/> 2	<input type="radio"/> 1	<input type="radio"/> 0
5. Poor vision? <i>OD5</i>	<input type="radio"/> 4	<input type="radio"/> 3	<input type="radio"/> 2	<input type="radio"/> 1	<input type="radio"/> 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 of the time	Some of the time	None of the time	Not applicable
6. Reading? <i>OD6</i>	<input type="radio"/> 4	<input type="radio"/> 3	<input type="radio"/> 2	<input type="radio"/> 1	<input type="radio"/> 0	<input type="radio"/> N/A
7. Driving at night? <i>OD7</i>	<input type="radio"/> 4	<input type="radio"/> 3	<input type="radio"/> 2	<input type="radio"/> 1	<input type="radio"/> 0	<input type="radio"/> N/A
8. Working with a computer or bank machine (ATM)? <i>OD8</i>	<input type="radio"/> 4	<input type="radio"/> 3	<input type="radio"/> 2	<input type="radio"/> 1	<input type="radio"/> 0	<input type="radio"/> N/A

9. Watching TV? <i>0D9</i>	<input type="radio"/> 4	<input type="radio"/> 3	<input type="radio"/> 2	<input type="radio"/> 1	<input type="radio"/> 0	<input type="radio"/> 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? <i>0D10</i>	<input type="radio"/> 4	<input type="radio"/> 3	<input type="radio"/> 2	<input type="radio"/> 1	<input type="radio"/> 0	<input type="radio"/> N/A
11. Places or areas with low humidity (very dry)? <i>0D11</i>	<input type="radio"/> 4	<input type="radio"/> 3	<input type="radio"/> 2	<input type="radio"/> 1	<input type="radio"/> 0	<input type="radio"/> N/A
12. Areas that are air conditioned? <i>0D12</i>	<input type="radio"/> 4	<input type="radio"/> 3	<input type="radio"/> 2	<input type="radio"/> 1	<input type="radio"/> 0	<input type="radio"/> N/A



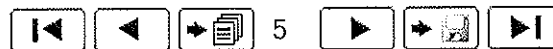
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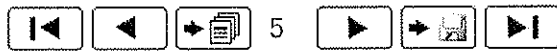
Date of Visit: * Date

Interviewer User ID:*

Section 4: Quality of Your Life After Your Transplant

PHYSICAL WELL-BEING:	Not at all	A little bit	Some-what	Quite a bit	Very much
1. I have a lack of energy F1	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
2. I have nausea F2	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
3. Because of my physical condition, I have trouble meeting the needs of my family F3	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
4. I have pain F4	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
5. I am bothered by side effects of treatment F5	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
6. I feel ill F6	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
7. I am forced to spend time in bed F7	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 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	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4

9. I get emotional support from my family <i>F9</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
10. I get support from my friends <i>F10</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
11. My family has accepted my illness <i>F11</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
12. I am satisfied with family communication about my illness <i>F12</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
13. I feel close to my partner (or the person who is my main support) <i>F13</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please check this box and go to the next section.					<input type="checkbox"/> <i>F14 skip</i>
14. I am satisfied with my sex life <i>F14</i>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4

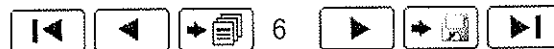
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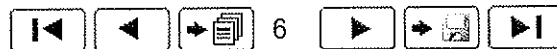
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Section 4: Quality of Your Life After Your Transplant (cont.)

EMOTIONAL WELL-BEING:	Not at all	A little bit	Some-what	Quite a bit	Very much
15. I feel sad F15	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
16. I am satisfied with how I am coping with my illness F16	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
17. I am losing hope in the fight against my illness F17	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
18. I feel nervous F18	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
19. I worry about dying F19	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
20. I worry that my condition will get worse F20	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 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) F21	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
22. My work (include work at home) is fulfilling F22	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4

23. I am able to enjoy life F23	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
24. I have accepted my illness F24	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
25. I am sleeping well F25	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
26. I am enjoying the things I usually do for fun F26	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
27. I am content with the quality of my life right now F27	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 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	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
29. I feel distant from other people F29	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
30. I worry that the transplant will not work F30	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
31. The effects of treatment are worse than I had imagined F31	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
32. I have a good appetite F32	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
33. I like the appearance of my body F33	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
34. I am able to get around by myself F34	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
35. I get tired easily F35	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
36. I am interested in sex F36	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4
37. I have confidence in my nurse(s) F37	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4

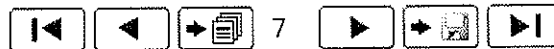


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Section 5: Your Health and Well-Being

1. Which statement describes how you feel most of the time? (please check one) *KPS 1*

- 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 *SF2*

Excellent	Very good	Good	Fair	Poor
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

3. Compared to one year ago, how would you rate your health in general now? *SF3*

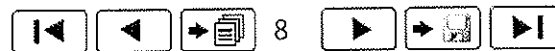
Much better now than one year ago	Somewhat better now than one year ago	About the same now as one year ago	Somewhat worse now as one year ago	Much worse now as one year ago
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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

Patient Survey Enrollment

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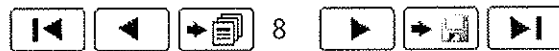
Interviewer User ID: *

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 heavy objects, participating in strenuous sports <i>SF4</i>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3
5. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf <i>SF5</i>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3
6. Lifting or carrying groceries <i>SF6</i>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3
7. Climbing several flights of stairs <i>SF7</i>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3
8. Climbing one flight of stairs <i>SF8</i>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3
9. Bending, kneeling, or stopping <i>SF9</i>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3
10. Walking more than a mile <i>SF10</i>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3
11. Walking several hundred yards <i>SF11</i>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3
12. Walking one hundred yards <i>SF12</i>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3

13. Bathing or dressing yourself	SF13					<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3					
<p><i>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?</i></p>													
		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	SF14								<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
15. Accomplished less than you would like	SF15								<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
16. Were limited in the kind of work or other activities	SF16								<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
17. Had difficulty performing the work or other activities (for example, it took extra effort)	SF17								<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5



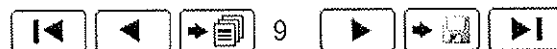
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Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

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Enrollment**

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Section 5: Your Health and Well-Being (cont.)

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 any emotional problems (such as feeling depressed or anxious)?

	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 time you spent on work or other activities as a result of any emotional problems <i>SF18</i>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
19. Accomplished less than you would like as a result of any emotional problems <i>SF19</i>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
20. Did work or other activities less carefully than usual <i>SF20</i>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5

21. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? *SF21*

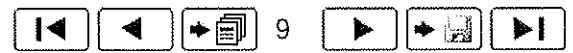
Not at all	Slightly	Moderately	Quite a bit	Extremely
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

22. How much bodily pain have you had during the past 4 weeks? *SF22*

None	Very Mild	Mild	Moderate	Severe	Very Severe
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

23. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)? *SF23*

Not at all	A little bit	Moderately	Quite a bit	Extremely
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>



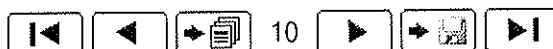
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Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

Participant ID	129841	Date of Registration	23 Jun 2014
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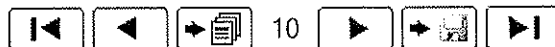
Section 5: Your Health and Well-Being (cont.)

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? SF24	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
25. Have you been very nervous? SF25	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
26. Have you felt so down in the dumps that nothing could cheer you up? SF26	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
27. Have you felt calm and peaceful? SF27	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
28. Did you have a lot of energy? SF28	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
29. Have you felt downhearted and depressed? SF29	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
30. Did you feel worn out? SF30	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5

31. Have you been happy? <i>SF31</i>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
32. Did you feel tired? <i>SF32</i>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
33. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)? <i>SF33</i>					
All of the time	Most of the time	Some of the time	A little of the time	None of the time	
<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5	
	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
34. I seem to get sick a little easier than other people <i>SF34</i>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
35. I am as healthy as anybody I know <i>SF35</i>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
36. I expect my health to get worse <i>SF36</i>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
37. My health is excellent <i>SF37</i>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5



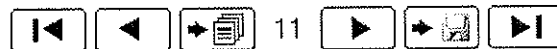
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Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

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

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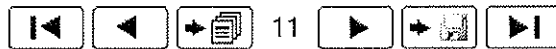
Date of Visit: * Date

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) H1	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. Listening to the radio H2	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. Reading books, magazines or newspapers H3	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. Writing (letters, notes) H4	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. Working at a desk or table H5	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. Standing (for more than one minute) H6	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. Standing (for more than five minutes) H7	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8. Dressing or undressing (without assistance) H8	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9. Getting clothes from drawers or closets H9	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

10. Getting in or out of a car (without assistance)	H10	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11. Dining at a restaurant	H11	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12. Playing cards/table games	H12	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13. Taking a bath (no assistance needed)	H13	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
14. Putting on shoes, stockings or socks (no assistance needed)	H14	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
15. Attending a movie, play, church event or sports activity	H15	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
16. Walking 30 yards (27 meters)	H16	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>



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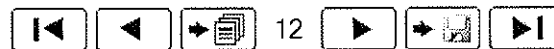
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Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

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

Patient Survey Enrollment

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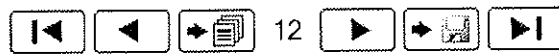
Date of Visit: * Date

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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) H17	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
18. Dressing/undressing (no rest or break needed) H18	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
19. Using public transportation or driving a car (100 miles or less) H19	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
20. Using public transportation or driving a car (99 miles or more) H20	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
21. Cooking your own meals H21	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
22. Washing or drying dishes H22	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
23. Putting groceries on shelves H23	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
24. Ironing or folding clothes H24	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
25. Dusting/polishing furniture or polishing cars H25	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

26. Showering	H26	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
27. Climbing six steps	H27	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
28. Climbing six steps (non-stop)	H28	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
29. Climbing nine steps	H29	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
30. Climbing 12 steps	H30	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
31. Walking 1/2 block on level ground	H31	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
32. Walking 1/2 block on level ground (non-stop)	H32	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
33. Making a bed (not changing sheets)	H33	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
34. Cleaning windows	H34	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
35. Kneeling, squatting to do light work	H35	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
36. Carrying a light load of groceries	H36	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
37. Climbing nine steps (non-stop)	H37	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>



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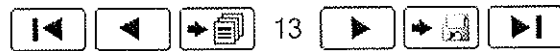
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Protocol # 6502 - A Randomized Phase II Study of Imatinib and Rituximab for Cu...

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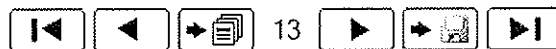
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Date of Visit:	*	<u>Date</u>	
Interviewer User ID:	*		
Section 6: Your Activity Level (cont.)			
		Still Doing This Activity (1)	Have Stopped Doing This Activity (2)
		Never Did This Activity (3)	
38. Climbing 12 steps (non-stop)	H38	<input type="radio"/>	<input type="radio"/>
39. Walking 1/2 block uphill	H39	<input type="radio"/>	<input type="radio"/>
40. Walking 1/2 block uphill (non-stop)	H40	<input type="radio"/>	<input type="radio"/>
41. Shopping (by yourself)	H41	<input type="radio"/>	<input type="radio"/>
42. Washing clothes (by yourself)	H42	<input type="radio"/>	<input type="radio"/>
43. Walking one block on level ground	H43	<input type="radio"/>	<input type="radio"/>
44. Walking two blocks on level ground	H44	<input type="radio"/>	<input type="radio"/>
45. Walking one block on level ground (non-stop)	H45	<input type="radio"/>	<input type="radio"/>
46. Walking two blocks on level ground (non-stop)	H46	<input type="radio"/>	<input type="radio"/>

47. Scrubbing (floors, walls or cars)	H47	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
48. Making beds (changing sheets)	H48	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
49. Sweeping	H49	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
50. Sweeping (five minutes non-stop)	H50	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
51. Carrying a large suitcase or bowling (one line)	H51	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
52. Vacuuming carpets	H52	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
53. Vacuuming carpets (five minutes non-stop)	H53	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
54. Painting (interior/exterior)	H54	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
55. Walking six blocks on level ground	H55	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
56. Walking six blocks on level ground (non-stop)	H56	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
57. Carrying out the garbage	H57	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
58. Carrying a heavy load of groceries	H58	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>



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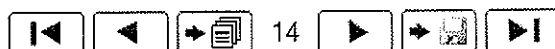
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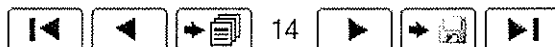
Date of Visit: * Date

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)
59. Climbing 24 steps	H59	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
60. Climbing 36 steps	H60	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
61. Climbing 24 steps (non-stop)	H61	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
62. Climbing 36 steps (non-stop)	H62	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
63. Walking one mile	H63	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
64. Walking one mile (non-stop)	H64	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
65. Running 110 yards (100 meters) or playing softball/baseball	H65	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
66. Dancing (social)	H66	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
67. Doing calisthenics or aerobic dancing (5 minutes non-stop)	H67	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

68. Mowing the lawn (power mower, but not a riding mower)	H68	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
69. Walking two miles	H69	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
70. Walking two miles (non-stop)	H70	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
71. Climbing 50 steps	H71	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
72. Shoveling, digging or spading	H72	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
73. Shoveling, digging or spading (five minutes non-stop)	H73	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
74. Climbing 50 steps (non-stop)	H74	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
75. Walking three miles or golfing 18 holes without a riding cart	H75	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
76. Walking three miles (non-stop)	H76	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
77. Swimming 25 yards	H77	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
78. Swimming 25 yards (non-stop)	H78	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>



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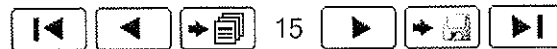
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Enrollment**

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* These fields are required in order to SAVE the form

* These fields are required in order to COMPLETE the form

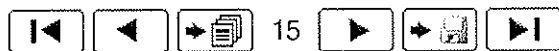
Date of Visit: * Date

Interviewer User ID: *

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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
80. Bicycling two miles	H80	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
81. Bicycling one mile (non-stop)	H81	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
82. Bicycling two miles (non-stop)	H82	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
83. Running or jogging ¼ mile	H83	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
84. Running or jogging ½ mile	H84	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
85. Playing tennis or racquetball	H85	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
86. Playing basketball (game play)	H86	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
87. Running or jogging ¼ mile (non-stop)	H87	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

88. Running or jogging 1/2 mile (non-stop)	H88	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
89. Running or jogging one mile	H89	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
90. Running or jogging two miles	H90	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
91. Running or jogging three miles	H91	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
92. Running or jogging one mile in 12 minutes or less	H92	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
93. Running or jogging two miles in 20 minutes or less	H93	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
94. Running or jogging three miles in 30 minutes or less	H94	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>



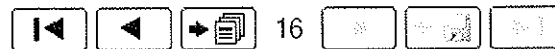
Save Print Close Window

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		
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

**Patient Survey
Enrollment**

Page: 16 of 16



* 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: *

Section 7: About Yourself

1. What is your current work status? (check all that apply)

- In school full time *SD-work-Inschoolfulltime*
- In school part time *SD-work-Inschoolparttime*
- Working full time *SD-work-Workingfulltime*
- Working part time *SD-work-Workingparttime*
- Homemaker *SD-work-Homemaker*
- Retired *SD-work-Retired*
- On medical leave from work *SD-work-Onmedicalleavefromwork*
- Disabled, unable to work *SD-work-Disabledunabletowork*
- Unemployed, looking for work *SD-work-Unemployedlookingforwork*
- Unemployed, not looking for work *SD-work-Unemployednotlookingforwork*
If Other, specify:
- Other *SD-work-Other* *SD-work-oth*

2. Do you consider yourself to be Latino (a) or Hispanic? *SD-eth*

- Not Hispanic or Latino
- Hispanic or Latino

3. How would you best describe your race? (check all that apply) *SD-race Describe*

- Black *SD_race - Black*
- American Indian or Alaska Native *SD_race - American Indian or Alaska Na*
- Asian *SD_race - Asian*
- Native Hawaiian or Other Pacific Islander *SD_race - Native Hawaiian or Other Pac*
- White *SD_race - White*
- Other

If Other, specify:

SD_race - Otherspecify

4. What is your gender? *SD_gen*

- Male
- Female

5. How old are you? *SD_age*

years

6. How much did you weigh before your transplant?

(Please be sure to indicate it in pounds (lbs) or kilograms (kg)) *SD_WT* Weigh unit: kg

SD_WT_unit

7. What is your marital status? *SD_marital*

- Married/Living with partner
- Single, never married
- Divorced, Separated
- Widowed
- Other

If Other, specify:

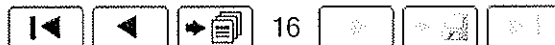
SD_marital - oth

8. What is the highest grade of school you have completed? *SD_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? *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 is your current work status? (check **all** that apply)

- In school full time SD-work - inschoolfulltime
- In school part time SD-work - inschoolparttime
- Working full time SD-work - workingfulltime
- Working part time SD-work - workingparttime
- Homemaker SD-work - homemaker
- Retired
- On medical leave from work
- Disabled, unable to work
- Unemployed, looking for work
- Unemployed, not looking for work
- Other, specify: _____

SD-work - homemaker

SD-work - on medical leave from work

SD-work - disabled unable to work

SD-work - unemployed looking for work

SD-work - unemployed not looking for w

SD-work - other

Protocol # 6501 - Longitudinal Study of Immune Mediated Disorders after Allogeneic

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-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

Date of Test :

PFT-DT [*PFT-DD*
PFT-mm
PFT-YY]

Participant Information

Height : *HT* cm *HT_PFT-unit*
 Weight : *WT-PFT* Kgs *WT-unit*
 Participant Hb *Hb* gm/dl *Hb-nd* Not Done

PRE-BRONCHODILATOR

Spirometry

FVC - pre Liters *FVC-pre-nd* Not Done
 FEV1 - pre Liters *FEV1-pre-nd* Not Done
 FEV1/FVC % *FEV1 - FVC - R - pre*
 FEF25-75% L/sec *FEF-pre* Not Done *FEF-pre-nd*

Lung Volumes

TLC - pre Liters *TLC-pre-nd* Not Done
 RV - pre Liters *RV-pre-nd* Not Done
 DEMO : (SVC) VC - pre Liters *VC-pre-nd* Not Done

Diffusion

Raw DLCO *DLCO-pre* mL/mmHg/min *DLCO-pre-nd* Not Done
 DLCO Adj *DLCOadj-pre* mL/mmHg/min *DLCOadj-pre-nd* Not Done

POST-BRONCHODILATOR <input type="checkbox"/> Not Done			
Spirometry			
FVC_post	Liters	FVC_post_nd	<input type="checkbox"/> Not Done
FEV1_post	Liters	FEV1_post_nd	<input type="checkbox"/> Not Done
FEV1/FVC FEV1-FVC_post %		FEV1-FVC_post_nd	
FEF25-75 FEF_post	L/sec	FEF_post_nd	<input type="checkbox"/> Not Done
Lung Volumes			
TLC_post	Liters	TLC_post_nd	<input type="checkbox"/> Not Done
RV_post	Liters	RV_post_nd	<input type="checkbox"/> Not Done
VC(SVC) VC_post	Liters	VC_post_nd	<input type="checkbox"/> Not Done
Diffusion			
Raw DLCO DLCO_post	mL/mmHg/min	DLCO_post_nd	<input type="checkbox"/> Not Done
DLCO Adj DLCOadj_post	mL/mmHg/min	DLCOadj_post_nd	<input type="checkbox"/> Not Done

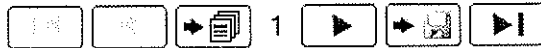
Save Print Close Window

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

PFT Interpretation Form *PFT- Interpretation- Form*

Page: 1 of 2



* 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: *

1. At the time of the pulmonary function test for this study visit, did subject have any of the following? * (Check all that apply)

- Fever *PFT- fever*
- New cough *PFT- cough*
- Sputum production *PFT- sputum*
- New consolidation on chest CT *PFT- consolid*
- Change in sputum color with positive culture for pulmonary pathogen *PFT- pathogen*
- None of the above *PFT- na*

2. Pulmonary function test * *PFT- done*

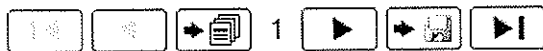
- Not done due to current active pulmonary infection (Visit 2, 3 and 4 only)
- Not done for any other reason, please complete a protocol deviation form
- Done

If done, date of test: *Study- PFT- DD*
Study- PFT- MM
Study- PFT- YY

3. Did subject have a greater than 10% decrease in FEV1 in comparison to the baseline FEV1? * *confirm- FEV1- 10decr* Yes No

If yes, date of confirmatory test: *PFT- planned- DD*
PFT- planned- MM
PFT- planned- YY

4. If confirmatory test was done, was treatment failure confirmed? * *PFT- rx- fail* Yes No



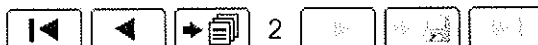
Save Print Close Window

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

PFT Interpretation Form

Page: 2 of 2



* 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 Test :

Participant Information

Height : *Confirm - HT* cm *Confirm - HT - PFT - unit*

Weight : *Confirm - WT - PFT* Kgs *Confirm - wt - unit*

Participant Hb *Confirm - Hb* gm/dl Not Done *Confirm - Hb - nd*

PRE-BRONCHODILATOR

Spirometry

FVC *Confirm - FVC - pre* Liters Not Done *Confirm - FVC - nd*

FEV1 *Confirm - FEV1 - pre* Liters Not Done *Confirm - FEV1 - pre - nd*

FEV1/FVC *Confirm - FEV1 - FVC - R - pre* % Not Done *Confirm - FEF - pre - nd*

FEF25-75% *Confirm - FEF - pre* L/sec

Lung Volumes

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 - DLCO - pre - nd*

DLCO Adj *Confirm - DLCO - adj - pre* mL/mmHg/min Not Done *Confirm - DLCO - adj - pre - nd*

POST-BRONCHODILATOR Not Done *Confirm - dil - nd*

Spirometry

FVC *Confirm - FVC - post* Liters Not Done *Confirm - FVC - post - nd*

FEV1 *Confirm - FEV1 - post* Liters Not Done *Confirm - FEV1 - post - nd*

FEV1/FVC *Confirm FEV1 - FVC - R - post* % Not Done *Confirm - FEF - post - nd*

FEF25-75 *Confirm - FEF - post* L/sec Not Done *Confirm - FEF - post - nd*

Lung Volumes

TLC *Confirm - TLC - post* Liters Not Done *Confirm - TLC - post - nd*

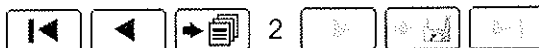
RV *Confirm - RV - post* Liters Not Done *Confirm - RV - post - nd*

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 - nd*

DLCO Adj *Confirm - DLCOadj - post* mL/mmHg/min Not Done *Confirm - DLCOadj - post - nd*



Save Print Close Window

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

FAM Medications *FAM_Medications*

* These fields are required in order to SAVE the form

* These fields are required in order to COMPLETE the form

Date of Visit: * 3 Apr 2014 Date

Interviewer User ID: * 4442

Medication 1: Fluticasone

	Dose	Dose Other	Units	Frequency	Route	Start Date	Currently Taking?	Stop Date	
	<i>Flu_dose#</i>	<i>Flu_dose_spec#</i>		<i>Flu_freq#</i>		<i>Flu_start_DD#</i> <i>MM#</i> <i>YY#</i>	<input checked="" type="radio"/> Y <input type="radio"/> N	<i>Flu_stop_DD#</i> <i>MM#</i> <i>YY#</i>	
Fluticasone	440		mcg	BID-twice/day	IH	04 Apr 2014			
Add			<i>Flu_units#</i>		<i>Flu_route#</i>		<i>Flu_current#</i>		

Medication 2: Azithromycin

	Dose	Dose Other	Units	Frequency	Interval	Route	Start Date	Currently Taking?	Stop Date	
	<i>Azith_dose#</i>		<i>Azith_units#</i>				<i>Azith_start_DD#</i> <i>MM#</i> <i>YY#</i>	<input checked="" type="radio"/> Y <input type="radio"/> N	<i>Azith_stop_DD#</i> <i>MM#</i> <i>YY#</i>	
Azithromycin	250		mg	QD-once/day	TIW	PO	04 Apr 2014			
Add		<i>Azith_dose_spec#</i>		<i>Azith_freq#</i>		<i>Azith_route#</i>		<i>Azith_start_DD#</i> <i>Azith_start_MM#</i> <i>Azith_start_YY#</i>		

Medication 3: Montelukast

	Dose	Dose Other	Units	Frequency	Route	Start Date	Currently Taking?	Stop Date	
	<i>Mont_dose#</i>		<i>Mont_units#</i>			<i>Mont_start_DD#</i> <i>MM#</i> <i>YY#</i>	<input checked="" type="radio"/> Y <input type="radio"/> N	<i>Mont_stop_DD#</i> <i>MM#</i> <i>YY#</i>	
Montelukast	10		mg	QD-once/day	PO	04 Apr 2014			
Add		<i>Mont_dose_spec#</i>		<i>Mont_freq#</i>		<i>Mont_start_DD#</i> <i>Mont_start_MM#</i> <i>Mont_start_YY#</i>			

Save Print Close Window

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*

* 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: *	

Six Minutes Walk Test	<input type="checkbox"/> Not done <i>Walk-nd</i>						
1. Supplemental oxygen during the test <i>Walk-O2</i> <input type="radio"/> Yes <input type="radio"/> No							
If yes, flow (L/min): <i>Walk-O2-flow</i>							
2. Vital							
	<table border="1"> <thead> <tr> <th></th> <th>Baseline</th> <th>End of test</th> </tr> </thead> <tbody> <tr> <td>Heart Rate (beats/min)</td> <td><i>Walk-pulse-base</i></td> <td><i>Walk-pulse-end</i></td> </tr> </tbody> </table>		Baseline	End of test	Heart Rate (beats/min)	<i>Walk-pulse-base</i>	<i>Walk-pulse-end</i>
	Baseline	End of test					
Heart Rate (beats/min)	<i>Walk-pulse-base</i>	<i>Walk-pulse-end</i>					
3. Stopped or paused before 6 minutes? <i>Walk-stop</i> <input type="radio"/> Yes <input type="radio"/> No							
If yes, specify reason: <i>Walk-stop-reas</i>							
Number of minutes walked if not 6 minutes: <i>Walk-minutes</i>							
4. Total Distance walked in 6 minutes							
Number of laps (x 50ft) + Final partial lap: $\text{ft} =$ ft walked in 6 minutes <i>Walk-laps</i> <i>Walk-partial-lap</i> Calculate <i>Walk-total</i>							
5. Tech comments							
Comments: <i>Walk-comm</i>							

Save Print Close Window

Protocol # 6501 - Longitudinal Study of Immune Mediated Disorders after Allogeneic

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_patients_tat_revised*

* 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. Date of last contact or most recent medical note *DOLC_DD*
- 2. Select all events that have occurred to date: *DOLC_MM*
DOLC_YY
- Patient was never transplanted *Event_NoTx*
- Graft loss *Event_Graft*
- DLI *Event_DLI*
- Additional stem cell transplant *Event_add-SCT*
- Relapse *Event_Rel*
- Death *Event_Death*
Cause of Death *COD*
- None of the above has occurred. *Event_None*
- Patient is alive (confirmed within past 6 months) *Event_Alive*

Graft_DD
Graft_MM
Graft_YY
DLI_DD, DLI_MM
DLI_YY
Add-SCT_DD
Add-SCT_MM
Add-SCT_YY
Rel_DD, Rel_MM
Rel_YY

DEMO

Save Print Close Window

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/m ² IV weekly x 4		
Treatment Assign Date	26 Oct 2011	Treatment Start Date	26 Oct 2011

Adverse Event Reporting Form
Initial Report

* These fields are required in order to SAVE the form

A. INTERVIEW INFORMATION

Adverse event report date
(date site was notified of event) *

(DD MMM YYYY) *aereportdt*

B. ADVERSE EVENT REPORT

Adverse event occurrence date *

(DD MMM YYYY) *aedate*

Is this a primary or secondary event? * (required only for initial report)

Primary Secondary *primary or 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 + treatmentlocationother

D. EVENT ASSESSMENT

Expected *

Yes No

Expected

Causality (by reporter) *

Causality by reporter

Was the adverse event associated with any of the following?
(check all that apply)

prefix assoc -

- Development of a congenital anomaly or birth defect
 Development of a permanent, serious, disabling or incapacitating condition
 Death
 Hospitalization or prolonged hospitalization
 Life threatening
 Is another condition which investigators judge to represent significant hazards

Patient status (at time of this report): * patient outcome

Adverse event resolved date (DD MMM YYYY) a resolved dt

Date of death (DD MMM YYYY)

Additional comments Comments

E. Study Drug Activity

Study Drug Start Date
(dd/MMM/yyyy)

Study Drug Stop Date
(dd/MMM/yyyy)

study drug start date

study drug stop date

Add More

Did the event/reaction abate after stopping drug? Yes No Not Applicable event abate after stopping drug

Did the event/reaction reappear after reintroduction? Yes No Not Applicable event reappear after reintroduction

F. CONCOMITANT MEDICATIONS

* If applicable, please ensure the concomitant medications log was updated prior to adverse event submission.

REPORTER INFORMATION

Reporter User ID 2439

Save Draft

Submit for Review

Print

Close Window

on follow-up report:

Specify the adverse event = select term

date of follow up = AE follow up date

reason for follow up = reason for follow up

also not on forms:

AE causality by reviewer

Supra ordinate term (if other specify, options per CTCAE)

CTCAE version