CRMS

Data Management Tools

Case Report Forms

Study Schedule Tracking

Coordinating Center Functions

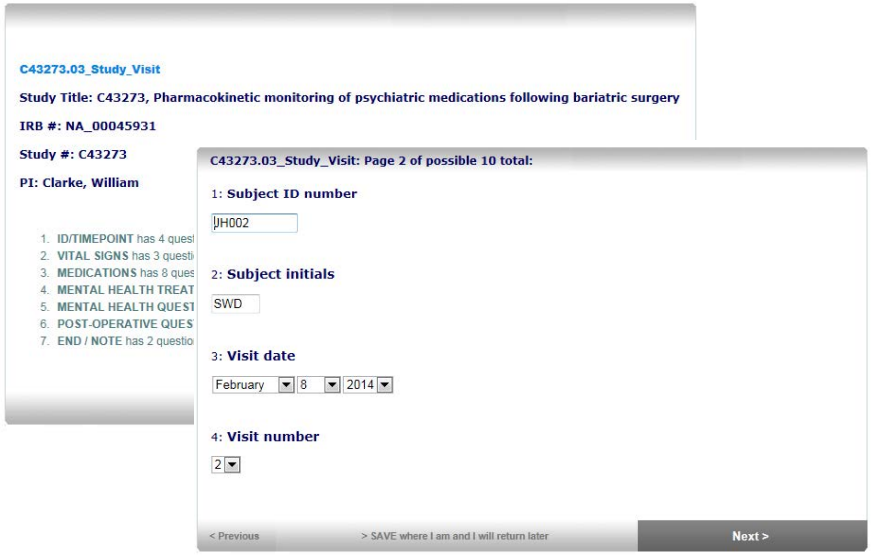
Data Manager Interest Group April 14, 2015

Susan Viles Booker
Research Data Analyst
sbooker2@jhmi.edu

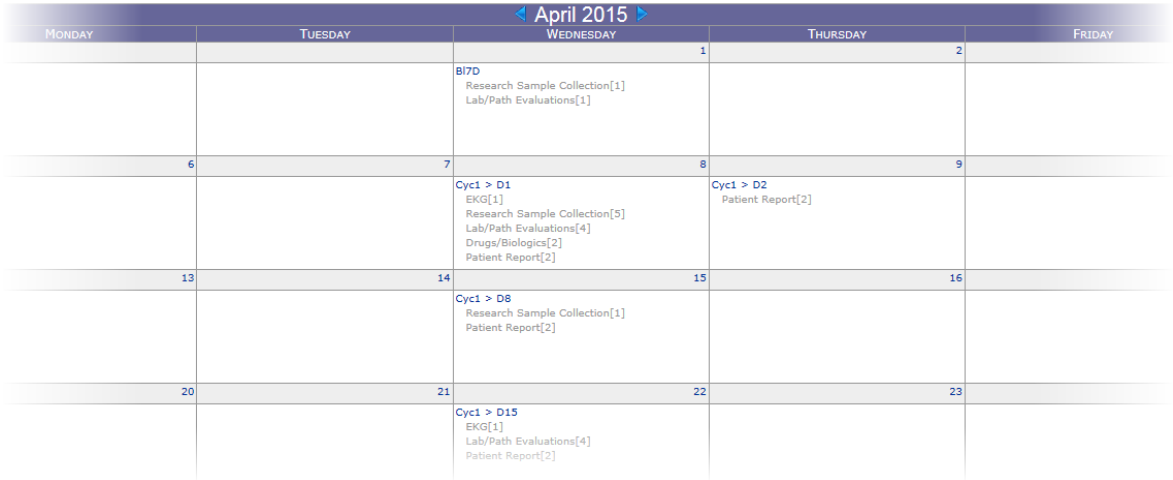
Jessica Wakefield
Coordinating Center Manager
jrober31@jhmi.edu

Clinical Research Office , Sidney Kimmel Comprehensive Cancer Center

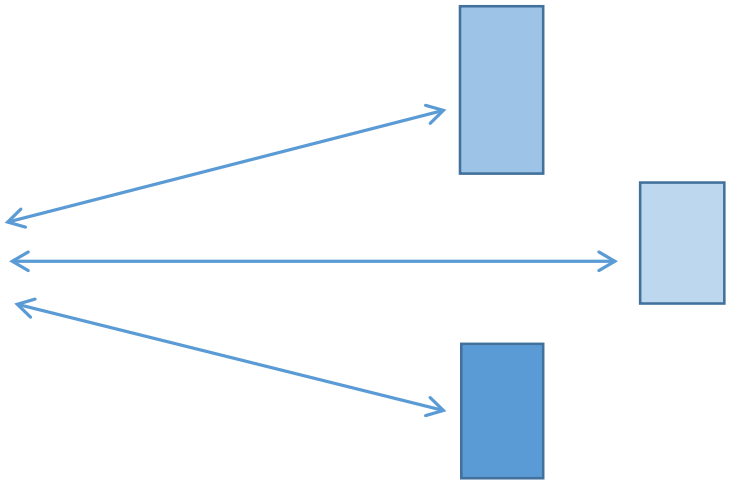
Case Report Forms / Database Development



Study Schedule Tracking

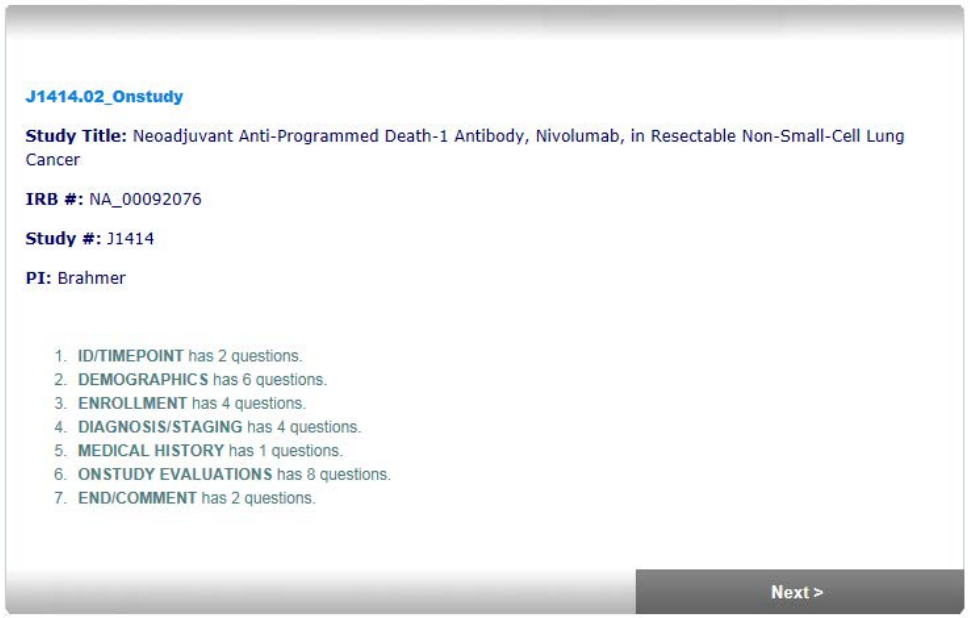


Coordinating Center Functions



Case Report Forms

1



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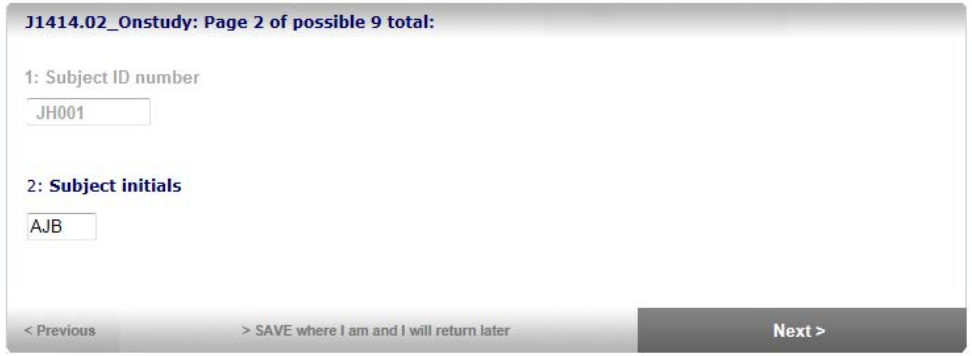
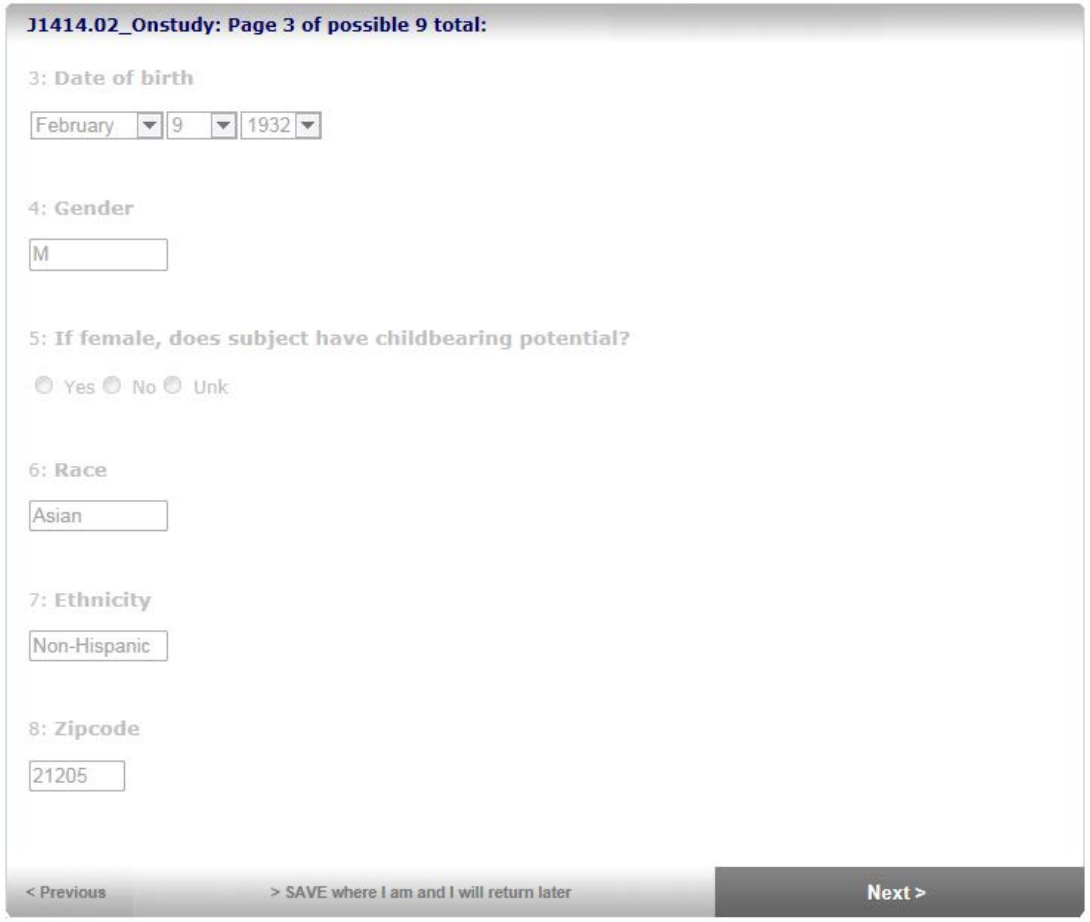


Q1. Subject ID # has been populated directly from CRMS. The field is grayed-out and may not be edited.

Q2. Subject initials are normally entered only on the Onstudy form. This field is auto-populated on all of the subject's remaining forms.

3

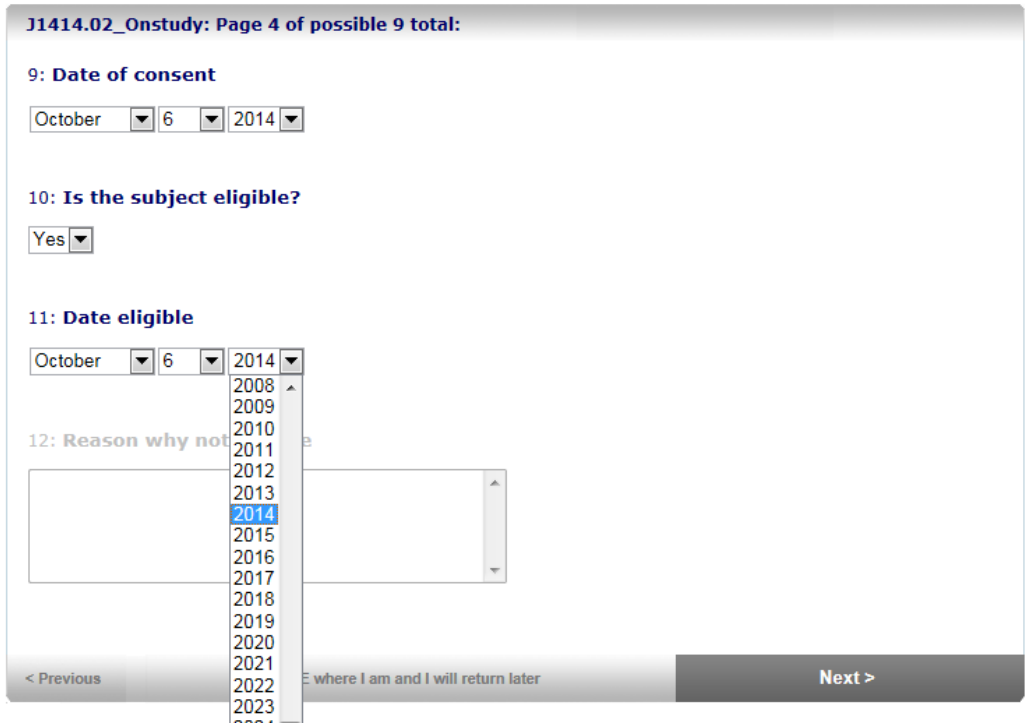


Demographic fields are pulled from CRMS and may not be edited.

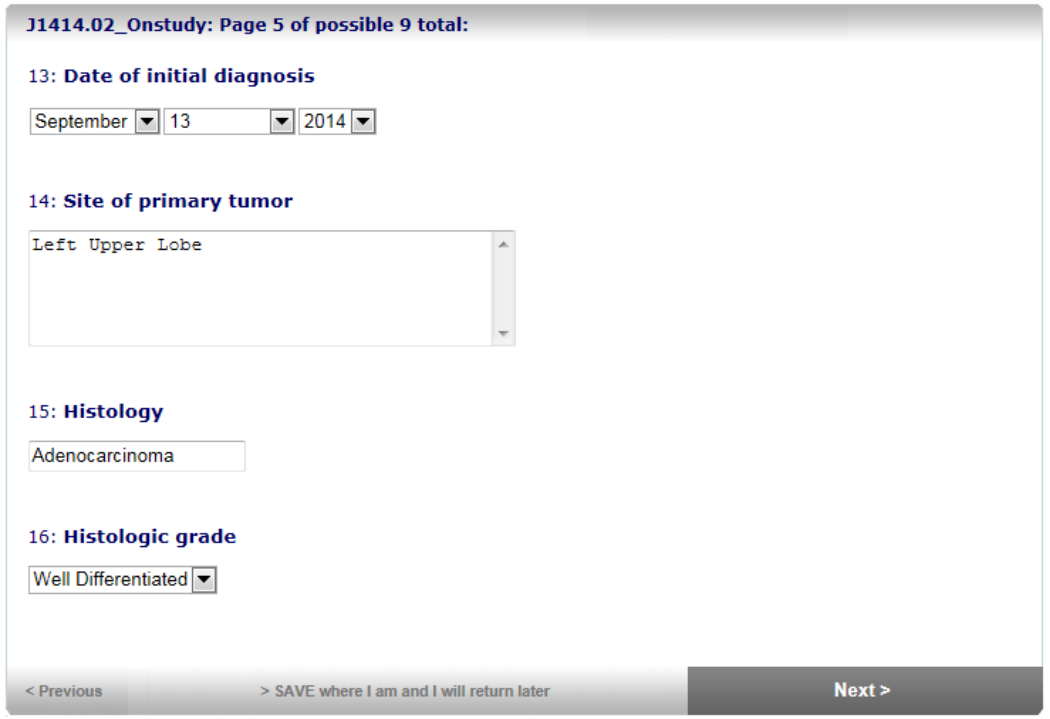
Q5. This question has been skipped (disabled) because the subject is male.

CASE REPORT FORMS

4

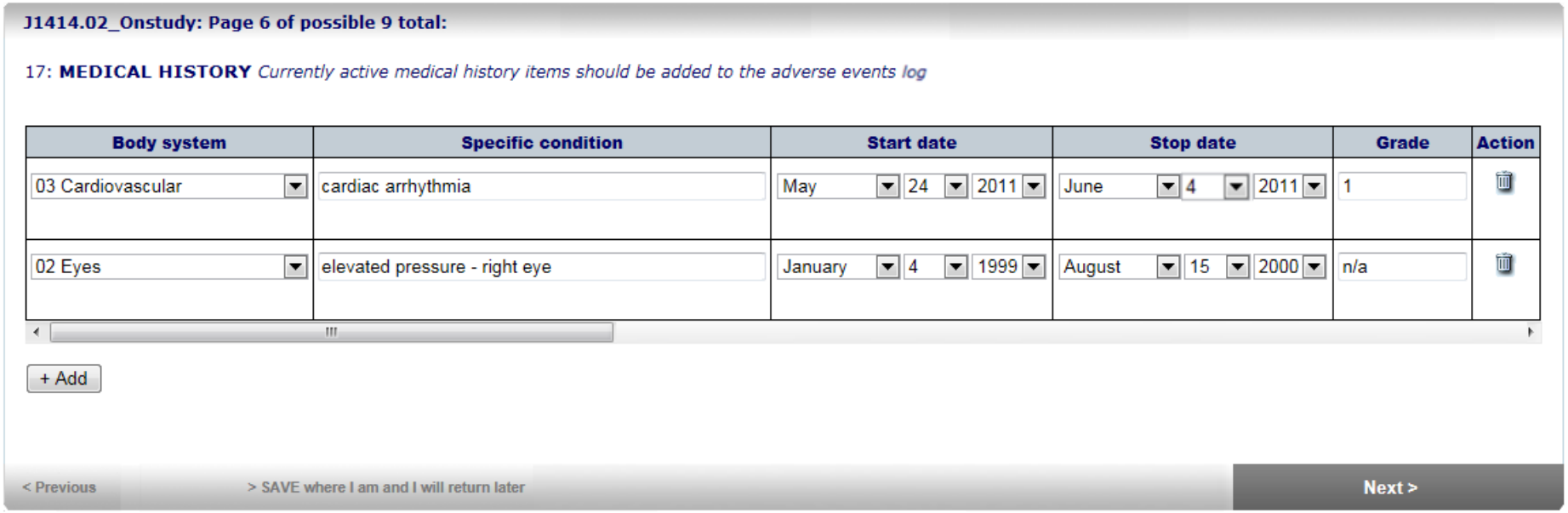


5



CASE REPORT FORMS

6



This is a* Tabular Field.** ***It may contain a variable number of rows of data.

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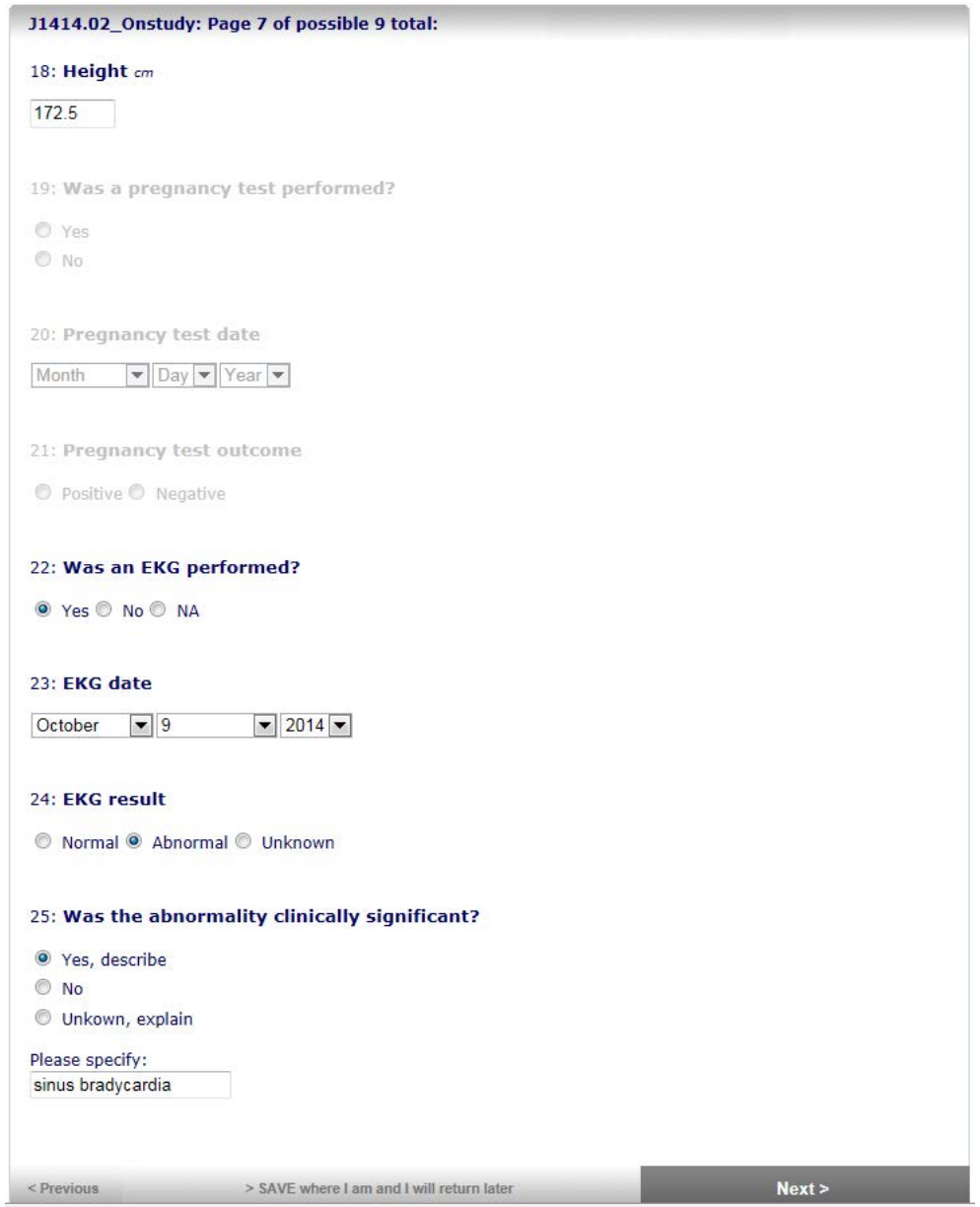
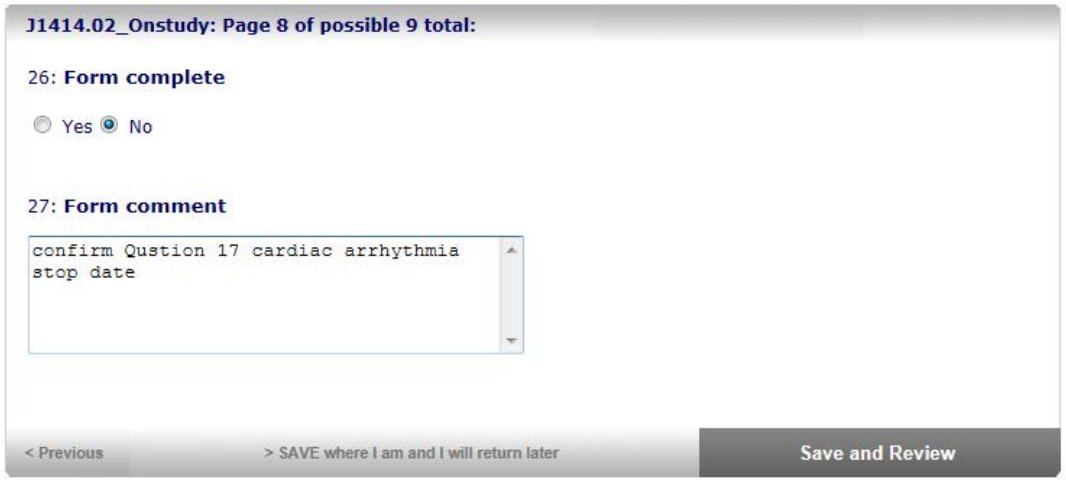
Case Report Forms

7



8

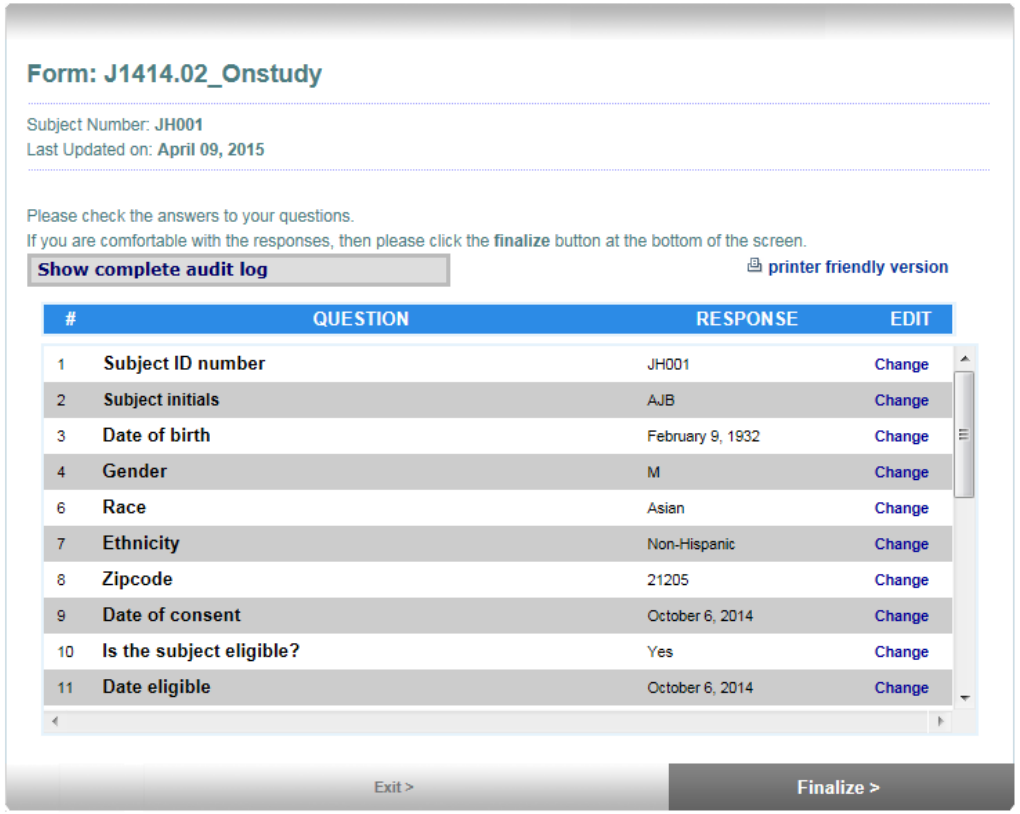


On the last screen of the form, Save and Review appears as an option.
Selecting this displays data in a more consolidated form.
It also moves you to the screen where Finalize is an option.

Case Report Forms

After **Save and Review** has been selected, data items appear in summary format.

Until the form is **Finalized**, any item may be edited by selecting **Change**.



Form: J1414.02_Onstudy

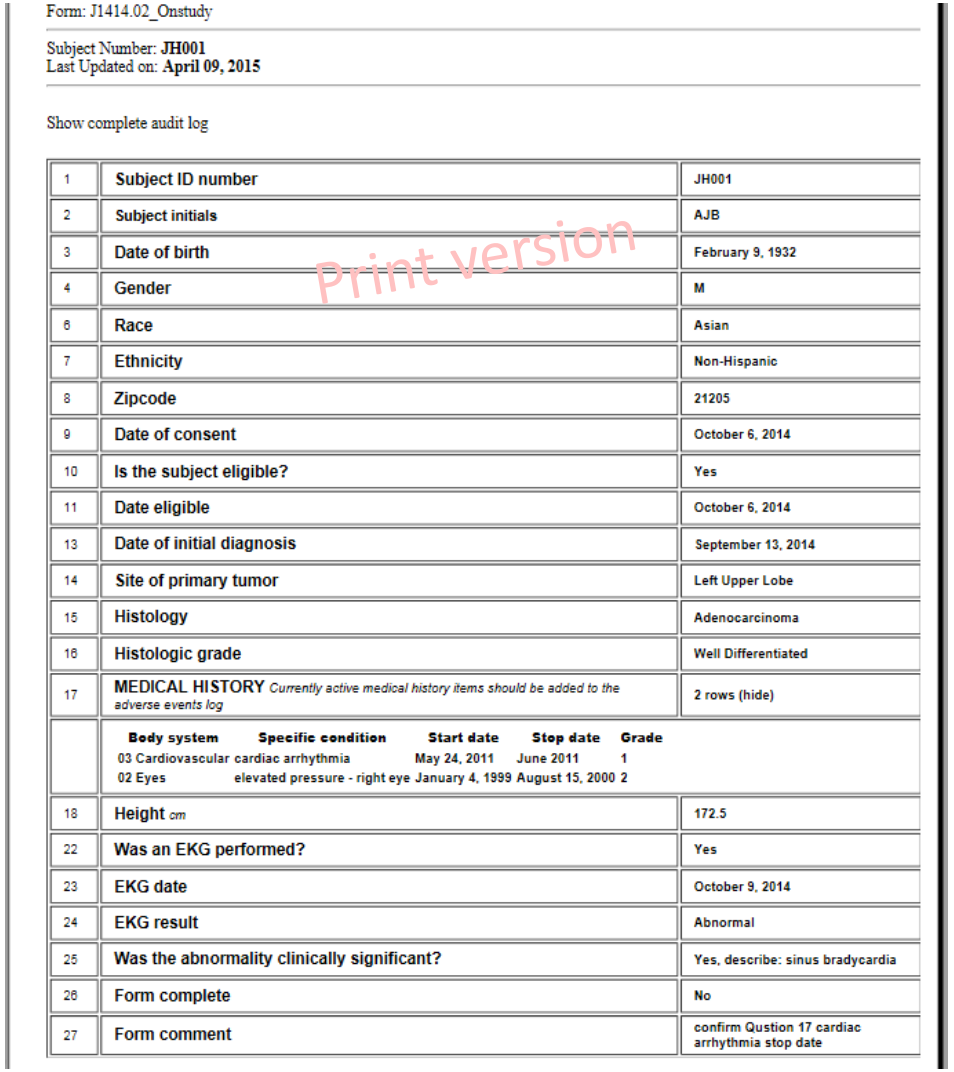
Subject Number: **JH001**
Last Updated on: **April 09, 2015**

Please check the answers to your questions.
If you are comfortable with the responses, then please click the **finalize** button at the bottom of the screen.

Show complete audit log printer friendly version

#	QUESTION	RESPONSE	EDIT
1	Subject ID number	JH001	Change
2	Subject initials	AJB	Change
3	Date of birth	February 9, 1932	Change
4	Gender	M	Change
6	Race	Asian	Change
7	Ethnicity	Non-Hispanic	Change
8	Zipcode	21205	Change
9	Date of consent	October 6, 2014	Change
10	Is the subject eligible?	Yes	Change
11	Date eligible	October 6, 2014	Change

Exit > Finalize >



Form: J1414.02_Onstudy

Subject Number: **JH001**
Last Updated on: **April 09, 2015**

Show complete audit log

Print version

1	Subject ID number	JH001
2	Subject initials	AJB
3	Date of birth	February 9, 1932
4	Gender	M
6	Race	Asian
7	Ethnicity	Non-Hispanic
8	Zipcode	21205
9	Date of consent	October 6, 2014
10	Is the subject eligible?	Yes
11	Date eligible	October 6, 2014
13	Date of initial diagnosis	September 13, 2014
14	Site of primary tumor	Left Upper Lobe
15	Histology	Adenocarcinoma
16	Histologic grade	Well Differentiated
17	MEDICAL HISTORY *Currently active medical history items should be added to the adverse events log*	2 rows (hide)
	Body system / **Specific condition** / **Start date** / **Stop date** / **Grade** 03 Cardiovascular / cardiac arrhythmia / May 24, 2011 / June 2011 / 1 02 Eyes / elevated pressure - right eye / January 4, 1999 / August 15, 2000 / 2	
18	Height *cm*	172.5
22	Was an EKG performed?	Yes
23	EKG date	October 9, 2014
24	EKG result	Abnormal
25	Was the abnormality clinically significant?	Yes, describe: sinus bradycardia
26	Form complete	No
27	Form comment	confirm Qustion 17 cardiac arrhythmia stop date

CASE REPORT FORMS

Features

Multiple data types supported	Text, string, integer, float, option-select one, option- select multi, visual scale, date, time, tabular (matrix)
Initial value source	Fields can be autopopulated with system values, text and responses from another form
Field mask	The appearance of a field can be customized – special characters can be automatically inserted. ###/###
Data validation	Validate range, data type, date.
Validation control – prevent invalid data	Has both warning and error (hard stop) preventing invalid data
Branching logic	Provide skip (disable) rules using standard operators. Questions modified by disable rules only accept data if condition is met. Web forms also provides a jump rule, allowing bypass of an entire section of a form
Calculated fields	
Logging	Onscreen display of audit trail for fields, either as a summary or on roll-over of individual fields. Log of all status changes to a subject's form
Record/Form locking	Allows locking/unlocking by anyone with locking permission.
Form/Field design	Online design systems that create two types of forms: a form with questions listed vertically and a form that can be formatted to have any appearance.
Code book / Data dictionary	A data dictionary is created in CRMS as a form is developed.

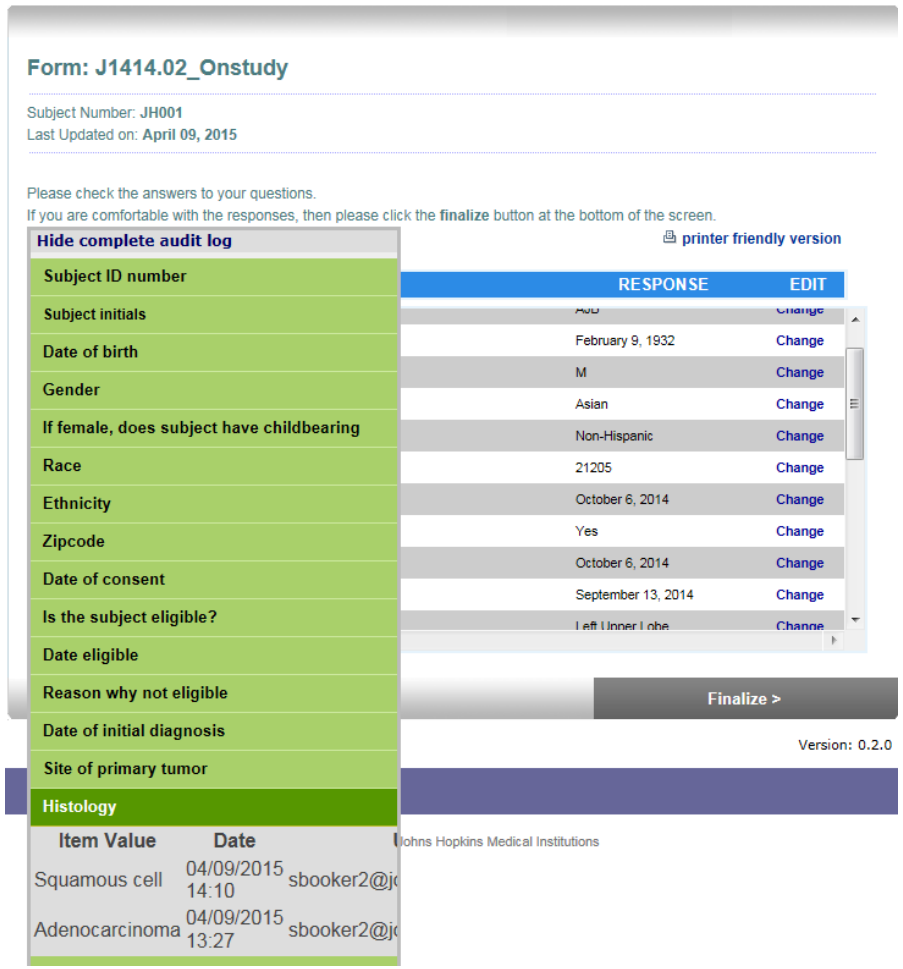
Case Report Forms

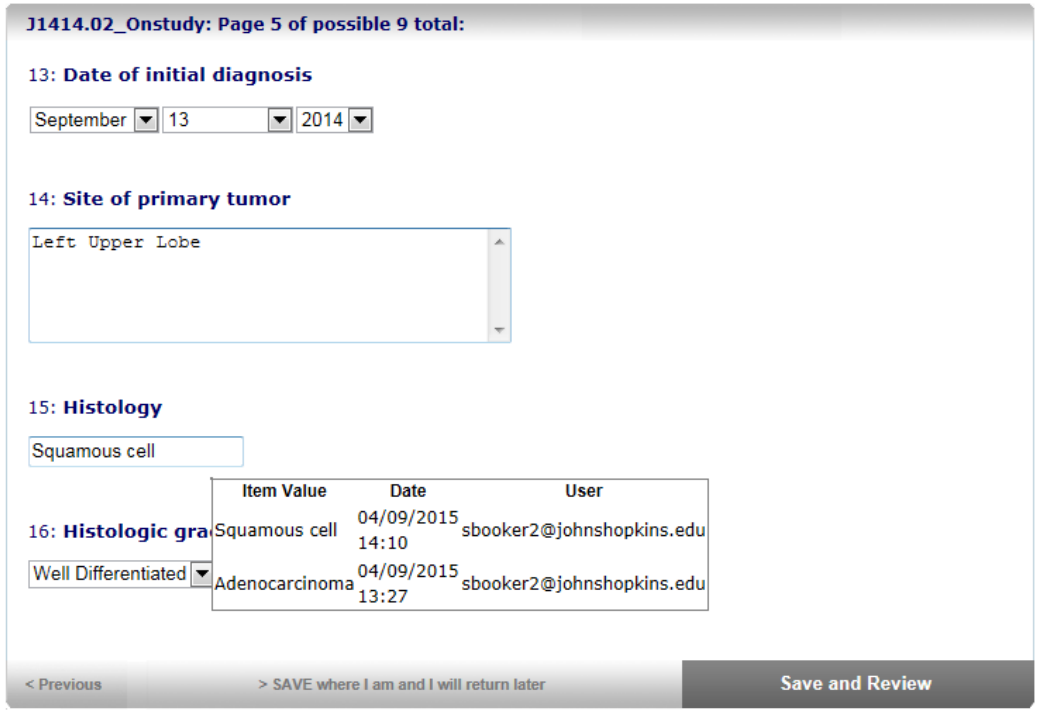
Features

Code book / Data dictionary	A data dictionary is created in CRMS as a form is developed.
Ability to copy and modify forms and variables	
Form Library	A library of standard CRMS forms is available to use.
View/Print case report forms	
Pre-activation form testing	Forms can be fully tested before switching to production mode.
Versioning	Form and field versioning is supported
Data export	Exports to CSV file
Configurable user rights	Individual user rights are programmed by a system administrator.
Support for multi-site studies	Full Coordinating Center functions are in place, giving outside sites study-level access to only their subjects.
File repository	Store documents and other files with the project/study

Case Report Forms

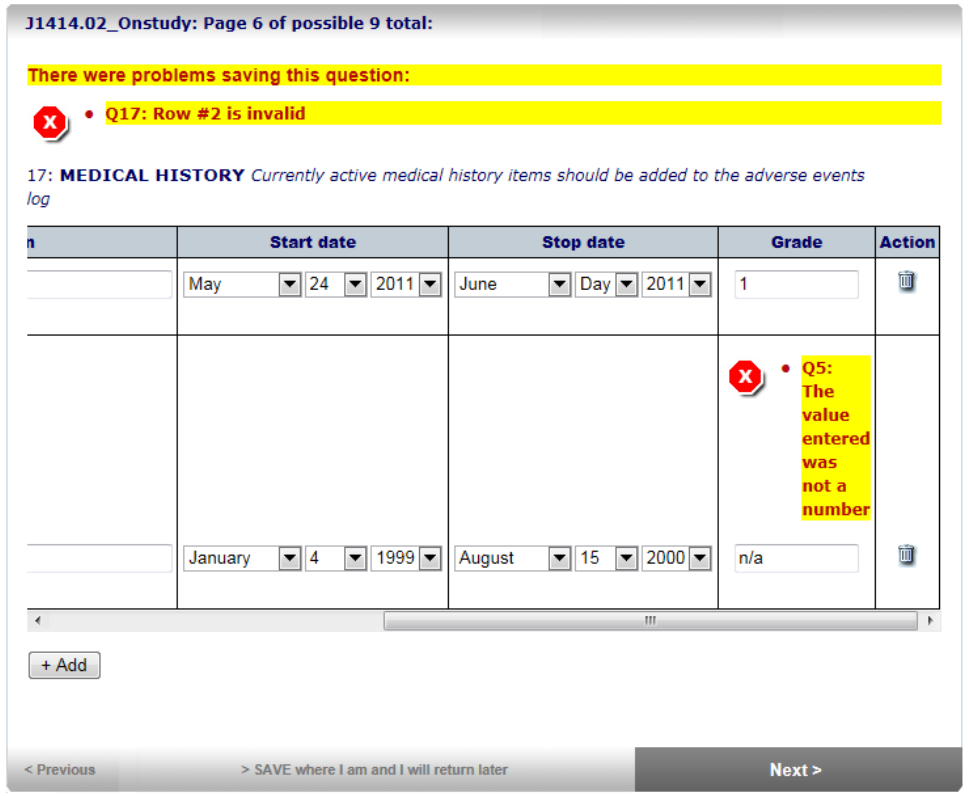
Features: Audit Log





CASE REPORT FORMS

Features: Validation



Case Report Forms

Requesting and Creating Case Report Forms

1. **Contact the Development Team** at CRMSHelp@jhmi.edu, noting that you are requesting CRFs and providing the study ID number.

2. **Initial Review and Planning** The Development Team will respond shortly after that to review the request, help define required forms, if necessary, and complete the CRMS **CRF Request Summary**.

3. **Data Definition** The Study Team then defines all data items to be included in the forms by modifying available standard form templates, modifying forms from previous or current studies, providing an existing database structure, or by defining new forms using CRMS **CRF Request Forms**.

4. **Form Creation and First Sign-off** After the Development Team has created the CRFs in CRMS, the Study Team reviews them for completeness and signs off on this stage of development.

5. **Data Test and Final Sign-off** The Development Team then runs a data test on the forms and provides the results to the Study Team. After review, both teams give their final sign-off.

6. **Form Activation** The Development Team activates the forms and moves them to the live system.

CRFs and Study Calendars are created for all departments by the Development Team in the SKCCC Clinical Research Office.

Case Report Forms

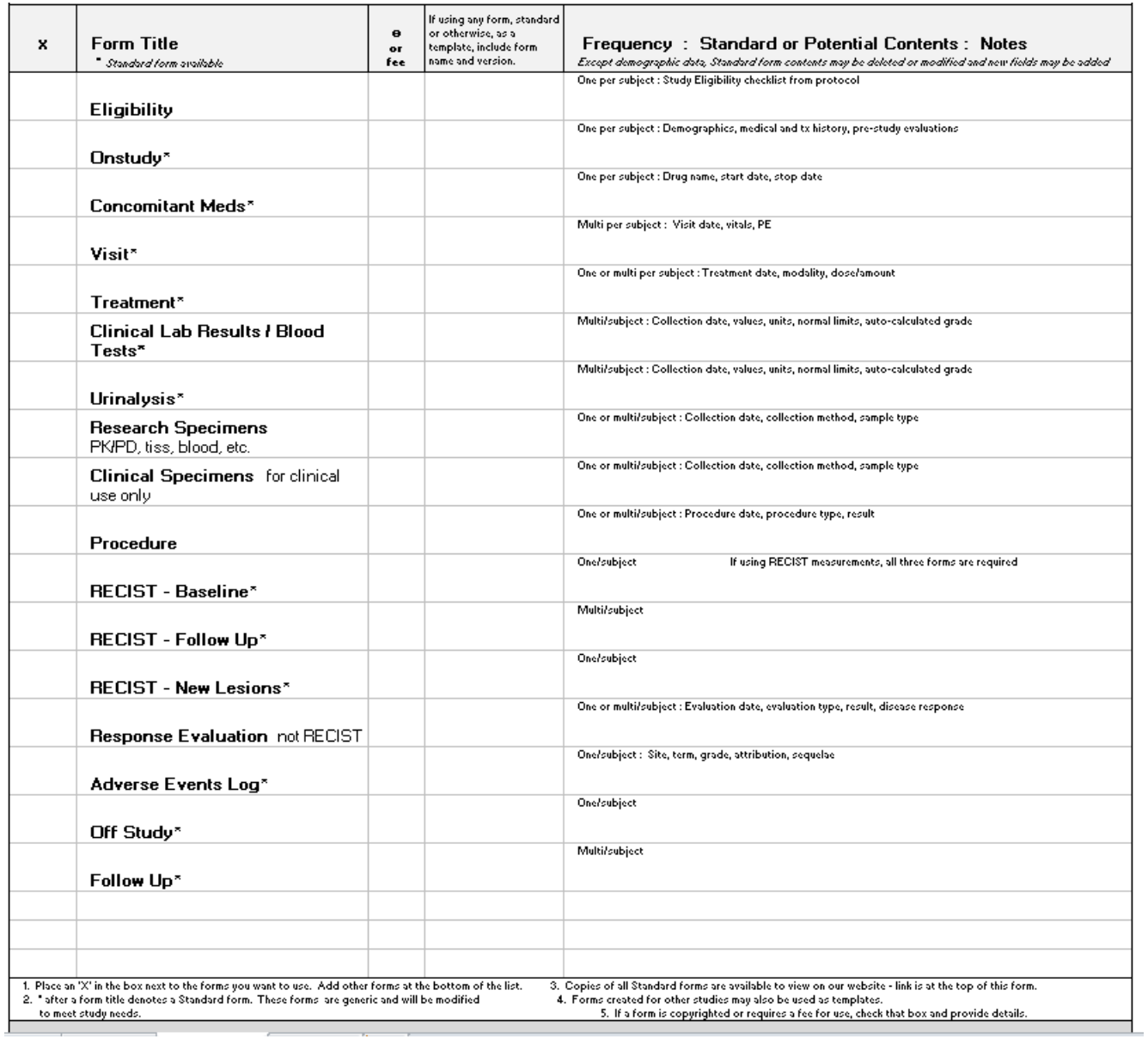
CRF Request Summary

While this list represents the most commonly used CRFs in Oncology studies, many of the forms are relevant to non-Onc studies.

1. Standard forms serve as templates, to be modified to meet the needs of any study.

2. Studies are not required to use any of the standard forms. CRFs may be created using previously defined forms, forms that are currently in use on other studies, existing database structure, or newly designed using the CRMS **CRF Request Form.**

3. Most importantly, the entire Study Team, including the PI and Statistician, should have input at this stage of f development. This is an opportunity for everyone to become familiar with study structure and goals and to ensure that nothing is overlooked, avoiding form changes mid-study to correct errors that could have been caught before the forms went into use.



x	Form Title * Standard form available	e or fee	If using any form, standard or otherwise, as a template, include form name and version.	Frequency : Standard or Potential Contents : Notes Except demographic data, Standard form contents may be deleted or modified and new fields may be added
	Eligibility			One per subject : Study Eligibility checklist from protocol
	Onstudy*			One per subject : Demographics, medical and tx history, pre-study evaluations
	Concomitant Meds*			One per subject : Drug name, start date, stop date
	Visit*			Multi per subject : Visit date, vitals, PE
	Treatment*			One or multi per subject : Treatment date, modality, dose/amount
	Clinical Lab Results / Blood Tests*			Multi/subject : Collection date, values, units, normal limits, auto-calculated grade
	Urinalysis*			Multi/subject : Collection date, values, units, normal limits, auto-calculated grade
	Research Specimens PK/PD, tiss, blood, etc.			One or multi/subject : Collection date, collection method, sample type
	Clinical Specimens for clinical use only			One or multi/subject : Collection date, collection method, sample type
	Procedure			One or multi/subject : Procedure date, procedure type, result
	RECIST - Baseline*			One/subject If using RECIST measurements, all three forms are required
	RECIST - Follow Up*			Multi/subject
	RECIST - New Lesions*			One/subject
	Response Evaluation not RECIST			One or multi/subject : Evaluation date, evaluation type, result, disease response
	Adverse Events Log*			One/subject : Site, term, grade, attribution, sequelae
	Off Study*			One/subject
	Follow Up*			Multi/subject

1. Place an 'X' in the box next to the forms you want to use. Add other forms at the bottom of the list.
2. * after a form title denotes a Standard form. These forms are generic and will be modified to meet study needs.
3. Copies of all Standard forms are available to view on our website - link is at the top of this form.
4. Forms created for other studies may also be used as templates.
5. If a form is copyrighted or requires a fee for use, check that box and provide details.

Case Report Forms

New CRF – Completing the CRF Request Form

If a new form is being created ,start with the CRF Request Form.

This is similar to the REDCap data definition form, but it doesn't automatically generate a CRF.

For CRMS purposes, this form is used for documentation and for communication within the Study Team and with CRF developers.

When complete, this form will serve as a data dictionary to be shared with Statisticians and others involved in data analysis.

CRMS Case Report Form Request Johns Hopkins Medical Institutions Clinical Research Management System

Last saved: 9/5/13 11:32 AM
File name: CRF Request Form v.5 BLANK TEMPLATE.xltm
Help ! CRMS Help

Study Title:
IRB #:
Study #: J#####
Contact:
Email:
Phone:
Form #: 01
Title: form title
File name: J#####.01_form title

Instructions version 5.0

1. Submit only one CRFon this form.
2. List questions in the order in which they should appear on the online form.
3. When entering multiple codes or response options, separate each item with **[Alt][Enter]** to create a list in a single cell.
4. **Adding a Section Title or other text**
   Place the cursor in the row above the row in which you want the text to appear. Insert a blank row by striking **[Ctrl] [Shft] [I]**. Enter the section title in the new row.
5. **Naming and Saving this form**
   A filename for this form is automatically created when you enter the basic information to the left. The first time you save this form, use the Excel **Save As** command and give it this filename, located in the cell beneath the Form Title.

Item #	Text	Data Type	Field Name	Data Format Mask	Data Units	Field Length	Response Format	Response Codes	Response Choices	Code List *CRC use only*	**Validation Rule** syntax: warning|error *if dummy_field < 1*	**Disable Rule** syntax: disable *if dummy_field != 1*
Header/ Section	**ID**											
A	**Subject ID number**	CRMS	subject_id_CRMS									
B	**Subject initials** *replace missing initial with '-'*	String	subject_initials_J#####	XXX		3						
Header/ Section												
1												
2												
3												
4												
5												
6												

Item #	Text	Data Type	Field Name	Data Format/ Mask	Data Units	Field Length	Response	Response Codes	Response Choices	Code List Name	Validation Rule syntax: warning/error if... *dummy_field* <> *1*	Skip Rule syntax: skip if... *dummy_field* != *1*
	ID / TIMEPOINT											
1	**Subject ID number**	CRMS	subject_number_crms_SKCCC									
2	**Subject initials** *replace missing initial with '-'*	String	subject_initials_J1414	XXX		3						
	DEMOGRAPHICS											
3	**Date of birth**	CRMS	date_of_birth_crms_SKCCC									
4	**Gender**	CRMS	gender_crms_SKCCC				Radio button		Female Male Not reported Undifferentiated			
5	**If female, does subject have childbearing potential?**	Select one	child_bearing_potential_SKCCC				Radio button	Y N U	Yes No Unk	yesnounk		gender != F
6	**Race** *select all that apply*	CRMS	race_crms_SKCCC				Radio button		Am Indian or AK Native Asian Black or African American Native HI /Pacific Islander Other Unknown White Two or more Races Declined to Answer			
7	**Ethnicity**	CRMS	ethnicity_crms_SKCCC				Radio button		Hispanic Non-Hispanic Unknown Pt Refused			
8	**Zipcode**	CRMS	zipcode_crms_SKCCC									
	ELIGIBILITY / CONSENT											
9	**Consent date**	CRMS	consent_date_CRMS_SKCCC									
10	**Is the subject eligible?**	Select one	eligible_SKCCC				Drop down	Y N	Yes No			
11	**Date eligibility determined**	Date	date_subject_eligible_SKCCC									
12	**Reason why not eligible**	Text	reason_not_eligible_SKCCC									
13	**Arm Assignment**	Select one	patient_cohort_J1414				Drop down	A B	A B	patient_cohort_alva		
	DIAGNOSIS / STAGING											
14	**Date of first diagnosis**	Date	date_initial_diagnosis_SKCCC									

CASE REPORT FORMS

Defining a Variable using the CRF Request Form

Item #	Text	Data Type	Field Name	Data Format Mask	Data Units	Field Length	Response Format	Response Codes	Response Choices	Code List *CRO use only*	**Validation Rule** syntax: warning/error *if dummy_field < 1*	**Disable Rule** syntax: disable if *dummy_field != 1*
1	**Height**											

Defining a Float Variable

Item #	Text	Data Type	Field Name	Data Format Mask	Data Units	Field Length	Response Format	Response Codes	Response Choices	Code List *CRO use only*	**Validation Rule** syntax: warning/error *if dummy_field < 1*	**Disable Rule** syntax: disable if *dummy_field != 1*
1	**Height**											

CRMS
Date
Float (dec)
Integer
String
Text
Select one
Select multi

Case Report Forms

Defining a Float Variable

Item #	Text	Data Type	Field Name	Data Format Mask	Data Units	Field Length	Response Format	Response Codes	Response Choices	Code List *CRO use only*	**Validation Rule** syntax: warning/error *if dummy_field < 1*	**Disable Rule** syntax: disable if *dummy_field != 1*
1	**Height**	**Float**										

Case Report Forms

Defining a Float Variable

Item #	Text	Data Type	Field Name	Data Format Mask	Data Units	Field Length	Response Format	Response Codes	Response Choices	Code List *CRO use only*	**Validation Rule** syntax: warning/error *if dummy_field < 1*	**Disable Rule** syntax: disable if *dummy_field != 1*
1	**Height**	**Float**	**height_cm_J1414**	**###.##**								

Case Report Forms

Defining a Float Variable

Item #	Text	Data Type	Field Name	Data Format Mask	Data Units	Field Length	Response Format	Response Codes	Response Choices	Code List *CRO use only*	**Validation Rule** syntax: warning/error *if dummy_field < 1*	**Disable Rule** syntax: disable if *dummy_field != 1*
1	**Height**	**Float**	**height_cm_J1414**	**###.##**	**cm**							

Defining a Float Variable

Item #	Text	Data Type	Field Name	Data Format Mask	Data Units	Field Length	Response Format	Response Codes	Response Choices	Code List *CRO use only*	**Validation Rule** syntax: warning/error *if dummy_field < 1*	**Disable Rule** syntax: disable if *dummy_field != 1*
1	**Height**	**Float**	**height_cm_J1414**	**###.##**	**cm**	**6**						

Case Report Forms

Defining a Float Variable

Item #	Text	Data Type	Field Name	Data Format Mask	Data Units	Field Length	Response Format	Response Codes	Response Choices	Code List *CRO use only*	**Validation Rule** syntax: warning/error *if dummy_field < 1*	**Disable Rule** syntax: disable if *dummy_field != 1*
1	**Height**	**Float**	**height_cm_J1414**	**###.##**	**cm**	**6**					**Warn if height > 243**	

CASE REPORT FORMS

Defining an Option Variable

Item #	Text	Data Type	Field Name	Data Format/ Mask	Data Units	Field Length	Response Format	Response Codes	Response Choices	Code List Name	Validation Rule syntax: warning/error if... *dummy_field* < *1*	Skip Rule syntax: skip if... *dummy_field* != *1*
	Best response	Select one	prior_chemotherapy_best_response_SKCCC				Drop down	CR PR SD PD UNK	Complete response Partial response Stable disease Progressive disease Unknown	prior_chemotherapy_best_response_SKCCC		

Drop down
Radio button

CASE REPORT FORMS

Creating a New CRF from a Standard Template

If a Standard Template is close to your needs, make any modifications on the form's CRF Request Form that was supplied .

In this example, changes appear in red.

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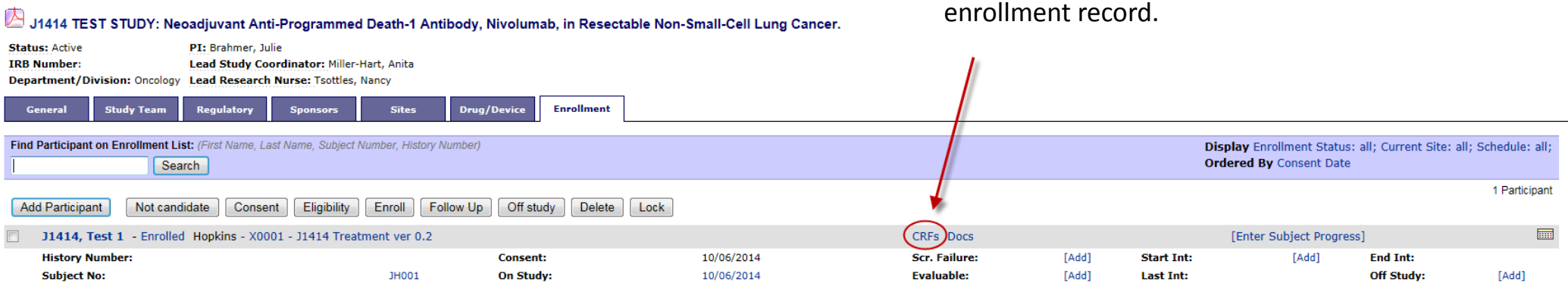
Item #	Text	Data Type	Field Name	Data Format/ Mask	Data Units	Field Length	Response Format	Response Codes	Response Choices	Code List Name	syntax: warning/error if... *dummy_field < 1*	syntax: skip if... *dummy_field != 1*
MEDICAL HISTORY												
21	**Medical history**	Tabular	medical_history_**J1414**									
	Body system	Select one	history_body_system_**J1414**				Drop down	01 ENMT 02 Eye 03 Cardio 04 Resp 05 GI 06 GU 07 MS 08 Skin 09 Neuro 10 Psych 11 Endo 12 Heme/Lym 13 All/Imm 14 Con 15 Oth	01 Ear / Nose / Mouth / Throat 02 Eyes 03 Cardiovascular 04 Respiratory 05 Gastrointestinal 06 Genitourinary 07 Musculoskeletal 08 Skin / Breasts 09 Neurologic 10 Psychiatric 11 Endocrine 12 Hematologic / Lymphatic 13 Allergy / Immunologic 14 Constitutional 15 Other, specify	body_system_code_**J1414**		
	Specific condition	Text	history_condition_SKCCC			50						
	Start date	Date	history_start_date_SKCCC									
	Stop date	Date	history_stop_date_SKCCC									
	Grade	Integer	history_grade_SKCCC			1						
ONSTUDY EVALUATIONS												
22	**Height**	Float (dec)	height_cm_SKCCC	###.#	cm	5					Warn if <122.0 or >243.0	
23	**Was a pregnancy test performed?**	Select one	pregnancy_test_done_SKCCC				Radio button	Y N	Yes No	yes_no_na		gender_crms_SKCCC != "Female"
24	**Pregnancy test date**	Date	pregnancy_test_date_SKCCC									pregnancy_test_done_ != "Y"

Case Report Forms

Accessing Forms

Forms for an individual subject can be accessed by selecting the **Enrollment** tab.

Then by selecting **CRFs** on the subject's enrollment record.



Case Report Forms

Accessing Forms and Entering Data

Forms may be grouped by study time point on the CRFs page.
CRFs that have been finalized give the option to View only.

Baseline > Screening (09/01/2014)

	Scheduled	Event Status	Due	Updated	Finalized	Data Available	
View Screening > J1414.02_Onstudy	09/01/2014	Projected	09/01/2014	04/09/2015 14:17	04/09/2015 14:16	04/09/2015 14:17	Reopen Lock Print History
Resume Screening > J1414.03_Study_Visit	09/01/2014	Projected	09/01/2014	04/13/2015 07:57	—	04/13/2015 07:57	Reset Print History
Start Screening > J1414.05_Treatment	09/01/2014	Projected	09/01/2014	—		—	—
Start Screening > J1414.08_Research_Specimens	09/01/2014	Projected	09/01/2014	—		—	—
Start Screening > J1414.09_Procedures	09/01/2014	Projected	09/01/2014	—		—	—

Baseline > Ongoing Forms (09/07/2014)

	Scheduled	Event Status	Due	Updated	Finalized	Data Available	
Start Ongoing Forms > J1414.04_Concomitant_Medications	09/07/2014	Projected	09/07/2014	—		—	—

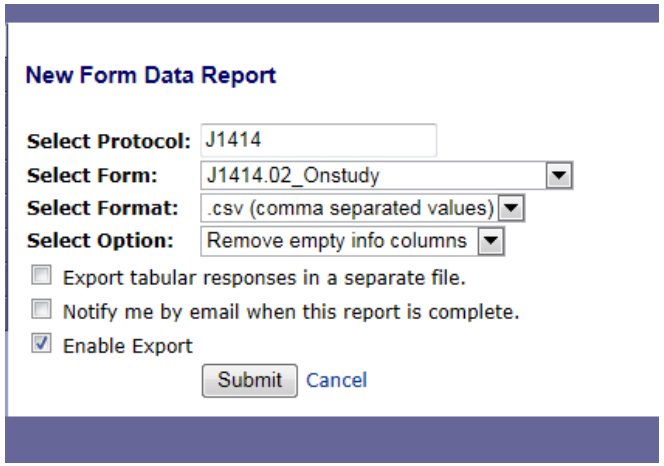
Baseline > Pre Op Day -28 (09/08/2014)

	Scheduled	Event Status	Due	Updated	Finalized	Data Available	

Case Report Forms

Retrieving Data

- Data from a single form or from all forms within a study may be exported to a csv file.
- No filters or other qualifiers can be applied.
- Data from Tabular fields may be exported to separate tables, displaying data by row rather than horizontally
- Reporting functions are being developed which, initially, will require submitting a report request to the Oncology CRO.
- Future development will include a more flexible reporting system.



subject_number_crms_SKCCC	subject_initials_J1414	date_of_birth_crms_SKCCC	gender_crms_SKCCC	child_bearing_potential_J1414
JH001	AJB	2/9/1932	M	null:-666

race_crms_SKCCC	ethnicity_crms_SKCCC	zipcode_crms_SKCCC	consent_date_crms_SKCCC	eligible_SKCCC
Asian	Non-Hispanic	21205	10/6/2014	Y

date_subject_ eligible_SKCCC	reason_not_eligible_SKCCC	date_initial_diagnosis_SKCCC
10/6/2014	null:-666	9/13/2014

site_tumor_SKCCC	histology_SKCCC	histologic_grade_SKCCC
Left Upper Lobe	Squamous cell	WD

Case Report Forms

Neat Things - Internal Data Dictionary and Emails Triggered by Form Responses

pregnancy_test_done_J1414 (Option) - Was a pregnancy test performed?

Header:	
Footer:	
Category:	
Comment:	
Version:	1
Validation Level:	Form Level
Display Mode:	Radio buttons
Alignment:	Vertical
Option List:	yes_no
Can Clear All:	false
Initial Value Source:	

Description	Coded Val.	Score	Other Specify	Exclusive
Yes	Y		No	No
No	N		No	No

Disable Rules: Expression: child_bearing_potential_J1414 != "Y"

height_cm_J1414 (Float) - Height cm

Header:	
Footer:	
Category:	
Comment:	
Version:	1
Validation Level:	Form Level
Field Size:	5
Max Length:	5
Input Mask:	###.#
Initial Value Source:	

Grading Scale: sodium_mEq_L_hyper_scale_JHH

Version: 1
Inputs: sodium_mEq_L_JHH, sodium_mEq_L_high_JHH

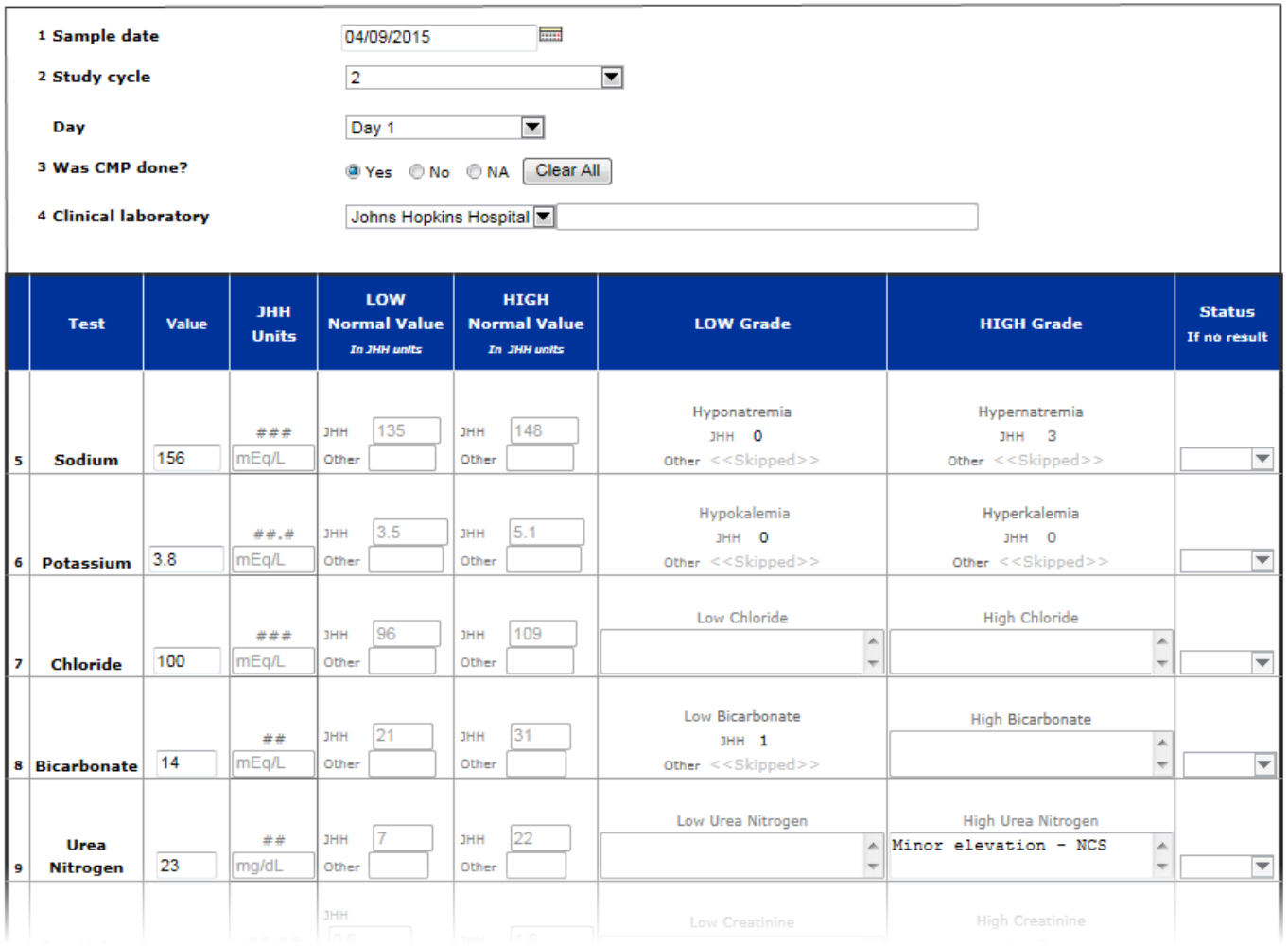
Grade	Expression
4	sodium_mEq_L_JHH>160
3	sodium_mEq_L_JHH>155
2	sodium_mEq_L_JHH>150
1	(sodium_mEq_L_JHH>sodium_mEq_L_high_JHH)
0	(sodium_mEq_L_JHH<=sodium_mEq_L_high_JHH)

sodium_mEq_L_hypo_grade_JHH_v8 (Scoring) - Hyponatremia grade

Category:	
Comment:	
Version:	7
Validation Level:	Form Level
Scoring Expression:	grade("sodium_mEq_L_hypo_scale_JHH_v2",sodium_mEq_L_JHH,sodium_mEq_L_low_JHH)
Initial Value Source:	
Disable Rules:	Expression: clinical_laboratory_site_GENERIC != "1" or cmp_done_JHH != "Y" or sodium_mEq_L_JHH=null or sodium_mEq_L_JHH >=sodium_mEq_L_low_JHH and sodium_mEq_L_low_OTHER =null or sodium_mEq_L_JHH >=sodium_mEq_L_low_OTHER and sodium_mEq_L_low_JHH=null

Case Report Forms

Auto-Calculated Clinical Laboratory CTCAE Toxicity Grades



1 Sample date: 04/09/2015

2 Study cycle: 2

Day: Day 1

3 Was CMP done? Yes / No / NA — Clear All

4 Clinical laboratory: Johns Hopkins Hospital

	Test	Value	JHH Units	LOW Normal Value (In JHH units)	HIGH Normal Value (In JHH units)	LOW Grade	HIGH Grade	Status (If no result)
5	Sodium	156	### mEq/L	JHH 135 / Other	JHH 148 / Other	Hyponatremia JHH 0 / Other <<Skipped>>	Hypernatremia JHH 3 / Other <<Skipped>>	
6	Potassium	3.8	##.# mEq/L	JHH 3.5 / Other	JHH 5.1 / Other	Hypokalemia JHH 0 / Other <<Skipped>>	Hyperkalemia JHH 0 / Other <<Skipped>>	
7	Chloride	100	### mEq/L	JHH 96 / Other	JHH 109 / Other	Low Chloride	High Chloride	
8	Bicarbonate	14	## mEq/L	JHH 21 / Other	JHH 31 / Other	Low Bicarbonate JHH 1 / Other <<Skipped>>	High Bicarbonate	
9	Urea Nitrogen	23	## mg/dL	JHH 7 / Other	JHH 22 / Other	Low Urea Nitrogen	High Urea Nitrogen: Minor elevation - NCS	
				JHH		Low Creatinine	High Creatinine	

Johns Hopkins Laboratory normal values are populated and maintained by SKCCC CRO. If a lab other than Johns Hopkins is selected in Q4, the Hopkins normal values are removed.

Since we do not support auto-population of Outside Laboratory (Other) normal values*, normal values must be entered manually on every form that is completed for an Outside Lab.

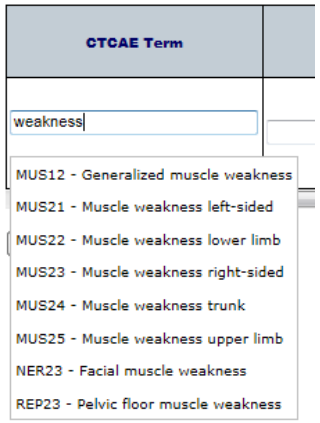
*Because subjects on Hopkins clinical trials live throughout the country and internationally, the number of outside normal values that would require monitoring and updating is very large, and the maintenance of these values would be prone to error.

CASE REPORT FORMS

Adverse Events Log – Lookup Functions

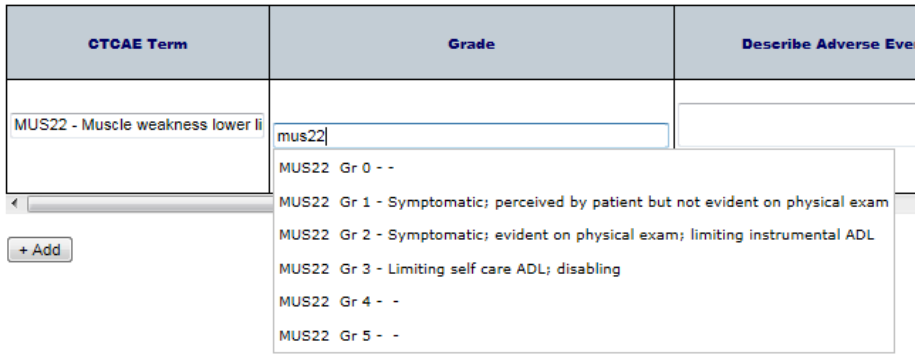
Look up CTCAE Term

- Subject reports feeling weakness in left leg.
- Locate the CTCAE term for leg weakness by entering 'weakness' or other key term in CTCAE Term field.
- Identify term as 'Muscle weakness lower limb' CRMS code MUS22.



Look up Grade

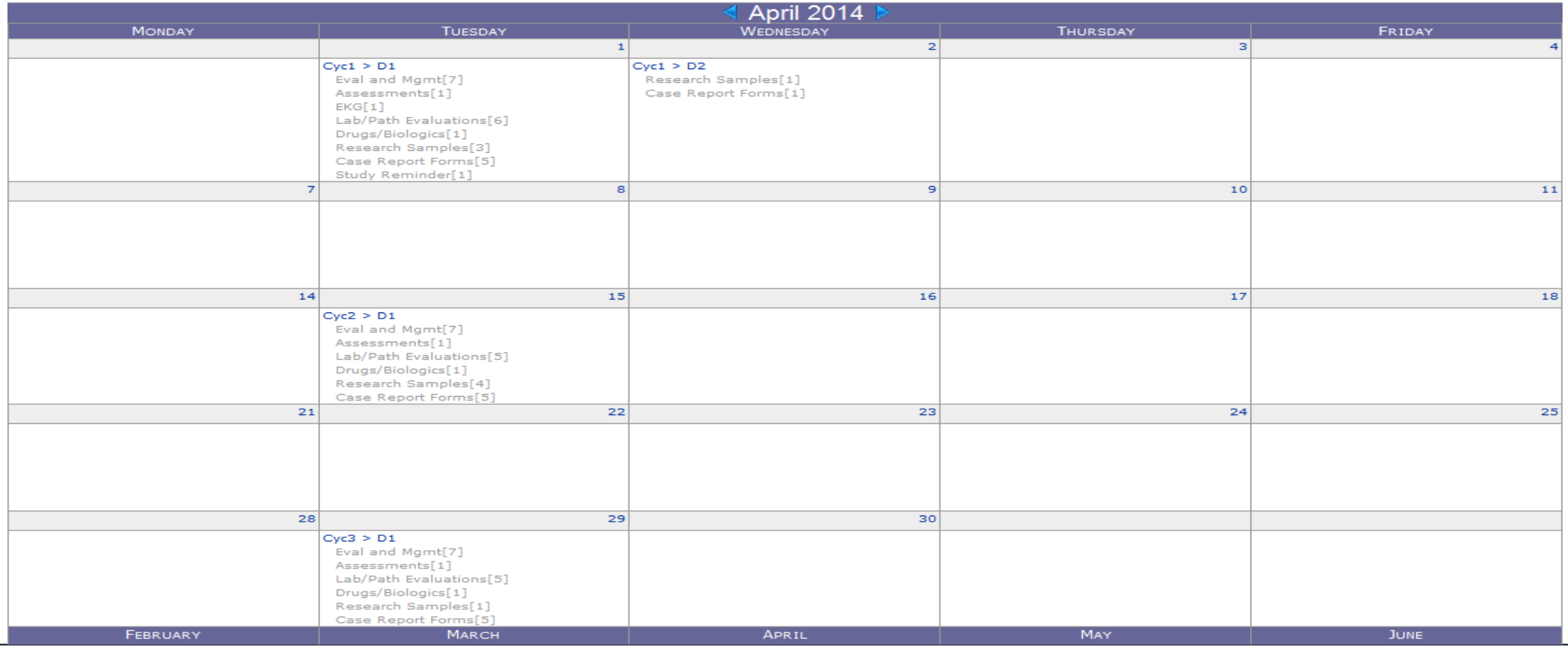
- Enter CRMS code 'MUS22' in Grade field
- Select grade



CTCAE Term	Grade	Describe Adverse Event	Onset date	Stop date	Related to Study Product #1	Related to Study Product #2	Related to Study Product #3	Action Taken	Intervention	Outcome	Dose Limiting Toxicity	Serious AE (SAE)	Action
MUS22 - Muscle weakness lower li	MUS22 Gr 2 - Symptomatic; evident on physical exam	sudden onset loss of strength in left leg	03/16/2015	04/06/2015	1 - Unrelated	2 - Unlikely	4 - Probable	3 - Regimen interrupted		3 - Resolved w/ intervention	Yes / No	Yes / No	

Study Calendar

The CRMS Calendar is a **study-specific patient calendar** based on a protocol's schema and study table.



April 2014

Monday	Tuesday	Wednesday	Thursday	Friday
	1	2	3	4
	Cyc1 > D1 Eval and Mgmt[7] Assessments[1] EKG[1] Lab/Path Evaluations[6] Drugs/Biologics[1] Research Samples[3] Case Report Forms[5] Study Reminder[1]	Cyc1 > D2 Research Samples[1] Case Report Forms[1]		
7	8	9	10	11
14	15	16	17	18
	Cyc2 > D1 Eval and Mgmt[7] Assessments[1] Lab/Path Evaluations[5] Drugs/Biologics[1] Research Samples[4] Case Report Forms[5]			
21	22	23	24	25
28	29	30		
	Cyc3 > D1 Eval and Mgmt[7] Assessments[1] Lab/Path Evaluations[5] Drugs/Biologics[1] Research Samples[1] Case Report Forms[5]			

February | March | April | May | June

Study Calendar

With the Calendar you can:

See what study events the patient needs

See when study events are due to occur

Adjust future due dates

Record the completion of a study event

Find the billing code for an event

Enter notes regarding an individual event

Month View

September 2013

Tuesday	Wednesday	Thursday
3	4	5
10	11	
Cyc1 > D1 Eval and Mgmt[3] EKG[1] Lab/Path Evaluations[6] Drugs/Biologics[1] Research Samples[4]	Cyc1 > D2 Research Samples[1]	
17	18	

Items and Services	Status	Time Scheduled	Time Completed	Notes
Eval and Mgmt				
Physical exam	09/10/2013			
Vital signs - pre-infusion	09/10/2013			
Weight	09/10/2013			
EKG				
ECG - 30 min post-infusion	09/10/2013			
Lab/Path Evaluations				
Pregnancy test - urine - serum	09/10/2013			
CBC with differential	09/10/2013			
Comprehensive Metabolic Panel	09/10/2013			
Serum tumor markers	09/10/2013			
Urinalysis and Microscopic exam	09/10/2013			
Autoimmune and Endocrine Panel	09/10/2013			
Drugs/Biologics				
MK-3475	09/10/2013			

Study Calendar

- For each study that requires an **Calendar**, a **Study Schedule** is created in CRMS by CRO staff. This **Schedule** will be used by the Study Team to create an individual **Calendar** for each subject as they are enrolled on the study.

- The **Schedule** is for this study alone, and includes all of the events required by the study and the schedule on which the events should occur.

- If a study has multiple arms, a separate **Schedule** is created for each arm.

- When a subject is enrolled on the study in CRMS, the Study Team assigns the appropriate **Schedule** to the subject. This creates the subject's **Calendar**.

- The Study Team accesses the subject's calendar through the study's CRMS **Enrollment** screen where they use it to record information about that subject's completion of study-related events.

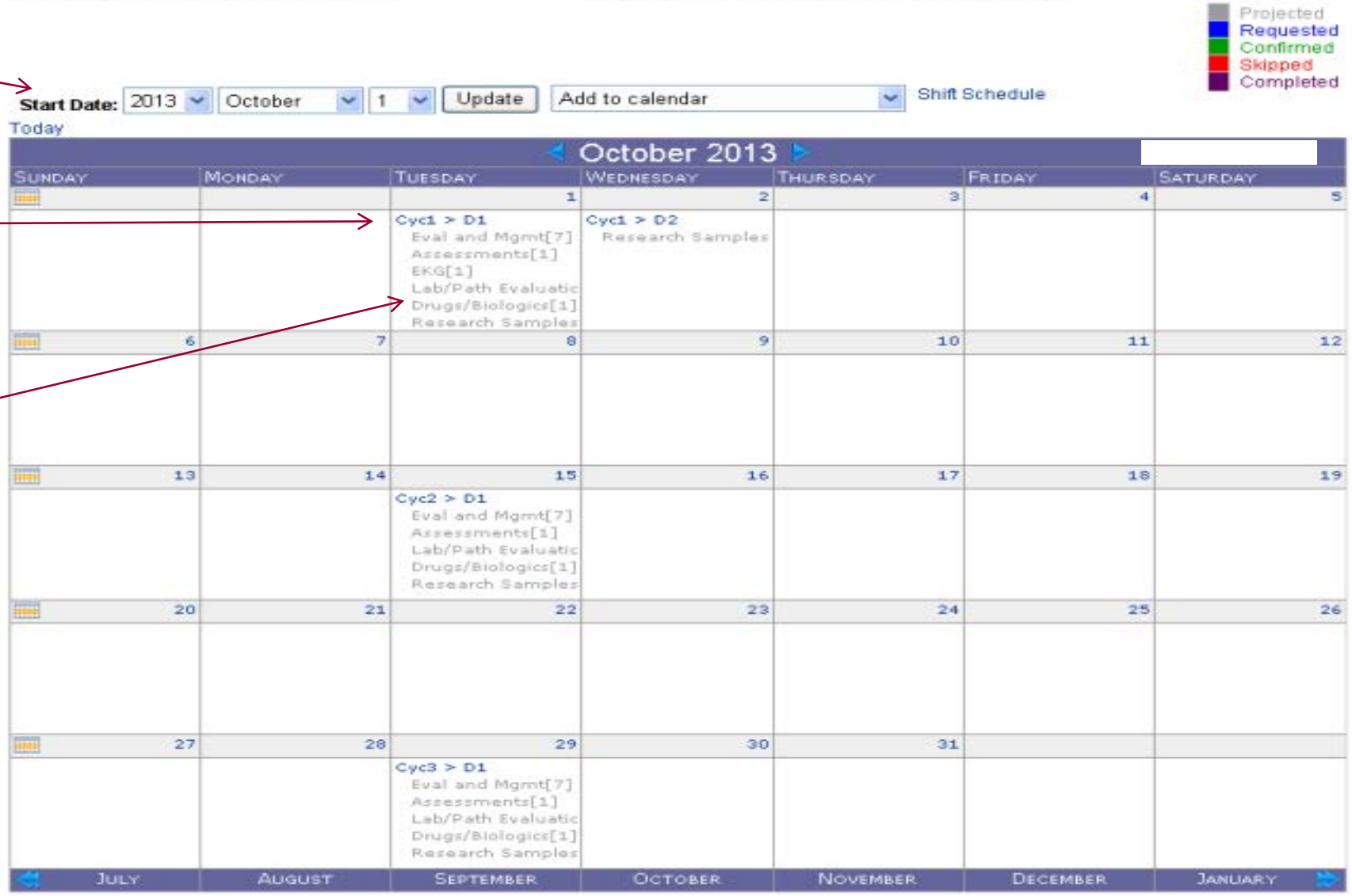
Study Calendar

Month View

The subject's **Start Date** is entered when a calendar is initiated for that subject.

Based on the **Start Date**, study **Timepoints** appear on the calendar on the appropriate dates.

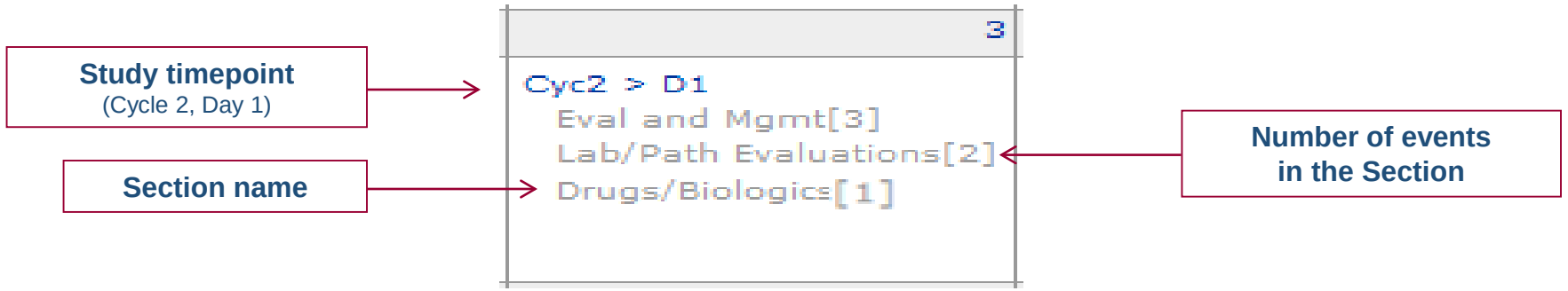
On the **Month View**, protocol **Events** due on that date are summarized by **Section.** The number of **Events** in each **Section** is displayed .



STUDY CALENDAR

The information on the Study Calendar in the **Month View** is a summary of the more complete information found on the **Detail Screen**.

The **Detail Screen** is accessed through the **Month View**.



To document the status of the items listed on the calendar, click on the **Timepoint** or any **Event**. You will be taken to the **Detail Screen** for that day.

STUDY CALENDAR

Detail View

The **Timepoint** bar includes the **Timepoint** and **Date** for the **Events** that are currently displayed, the previous date and the next date that protocol activity is due.

< Cycle 1 > Day 2 10/2/2013 | **Cycle 2 > Day 1 10/15/2013** | Cycle 3 > Day 1 > 10/29/2013

Back to Calendar

Section name

Events

Items and Services	Status	Time Scheduled	Time Completed	Notes	Data Complete	Data to Sponsor
Eval and Mgmt						
Physical exam S	10/15/2013					
Vital signs N	10/15/2013					
Weight N	10/15/2013					
Lab/Path Evaluations						
CBC with diff, plts S	10/15/2013					
Comprehensive Metabolic Panel S	10/15/2013					
Drugs/Biologics						
Pazopanib F	10/15/2013					

Study Calendar

On the **Detail Screen** you can document the completion status (Pending, Completed, Skipped) as well as several other attributes of any event. You can also add a Note to an event.

< Cycle 1 > Day 15 05/20/2013 | **Cycle 2 > Day 1 06/03/2013** | Cycle 2 > Day 15 > 06/17/2013

Back to Calendar

Items and Services	Status	Time Scheduled	Time Completed	Notes	Data Complete	Data to Sponsor
Eval and Mgmt						
Physical exam S	06/03/2013					
Vital signs N	06/03/2013					
Weight N	06/03/2013					
Lab/Path Evaluations						
CBC with diff, plts S	06/03/2013					
Comprehensive Metabolic Panel S	06/03/2013					
Drugs/Biologics						
Pazopanib F	06/03/2013					

Expand/ Close toggle

Event

Billing code

Service Note

Event status icon

Projected/ Completed date

Time

Time-stamped notes

Data completion & submission tracking

Event Status

Statuses are assigned on the Detail Screen and include:

Projected
This is the default status. A projected event appears on the date that was projected when the calendar was generated.

Completed
When an event is done, the event **Status** is changed to *Completed* and the **Date Completed** is entered

Skipped
If an event is not completed on the projected or any other date, the **Status** is changed to *Skipped*.

Requested and **Confirmed** were originally created to reflect appointment statuses. Since CRMS is not yet linked to a clinical appointment system, these two statuses may be used at the discretion of the study team to represent appointment scheduling or any other activity they chose.

STUDY CALENDAR

Entering a study event status

S001 test study

Uzi, test [Documents...]

Projected
Requested
Confirmed
Completed
Skipped
N/A
Cancel

< Cycle 2 > Day 1 03/16/2015 | **Cycle 3 > Day 1 04/08/2015** | Treatment > Day 35 > 04/14/2015

Back to Calendar

Treatment	Status	Time Scheduled	Time Completed	Notes	Data Complete	Data to Sponsor
Evaluation and Management						
Physical exam	04/08/2015					
Weight	04/08/2015					
ECOG Performance Status	04/08/2015					
Concomitant Meds	04/08/2015					
Adverse Events	04/08/2015					
Assessments						
CT Scan	04/08/2015					
RECIST Read	04/08/2015					
Lab/Path Evaluations						
Comprehensive Metabolic Panel	04/08/2015					
CBC and Differential	04/08/2015					
Magnesium	04/08/2015					
Treatment						
MK-3475	04/08/2015					
Research Samples						
Post-infusion serum	04/08/2015					
Case Report Forms						
S001.02_Study_Visit Start	04/08/2015					

S001 test study

Uzi, test [Documents...]

< Cycle 2 > Day 1 03/16/2015 | **Cycle 3 > Day 1 04/08/2015** | Treatment > 04/14/2015

Back to Calendar

Treatment	Status	Time Scheduled	Time Completed	Notes
Evaluation and Management				
Physical exam	04/08/2015			
Weight	04/08/2015			
ECOG Performance Status	04/08/2015			
Concomitant Meds	04/08/2015			
Adverse Events	04/08/2015			
Assessments				
CT Scan	04/08/2015			
RECIST Read	04/08/2015			
Lab/Path Evaluations				
Comprehensive Metabolic Panel	04/08/2015			
CBC and Differential	04/08/2015			

STUDY CALENDAR

Skipped Event : Note

S001 test study

Uzi, test [Documents...]

< Cycle 2 > Day 1 03/16/2015 | **Cycle 3 > Day 1 04/08/2015** | Treatment > Day 35 > 04/14/2015

Back to Calendar

Treatment	Status	Time Scheduled	Time Completed	Notes	Data Complete	Data to Sponsor
Evaluation and Management						
Physical exam	04/08/2015					
Weight	04/08/2015			The patient left the clinic before being weighed		
ECOG Performance Status	04/08/2015					
Concomitant Meds	04/08/2015					
Adverse Events	04/08/2015					
Assessments						
CT Scan	04/08/2015					
RECIST Read	04/08/2015					
Lab/Path Evaluations						
Comprehensive Metabolic Panel	04/08/2015					
CBC and Differential	04/08/2015					
Magnesium	04/08/2015					
Treatment						
MK-3475	04/08/2015					
Research Samples						
Post-infusion serum	04/08/2015					
Case Report Forms						

Save Cancel

S001 test study

Uzi, test [Documents...]

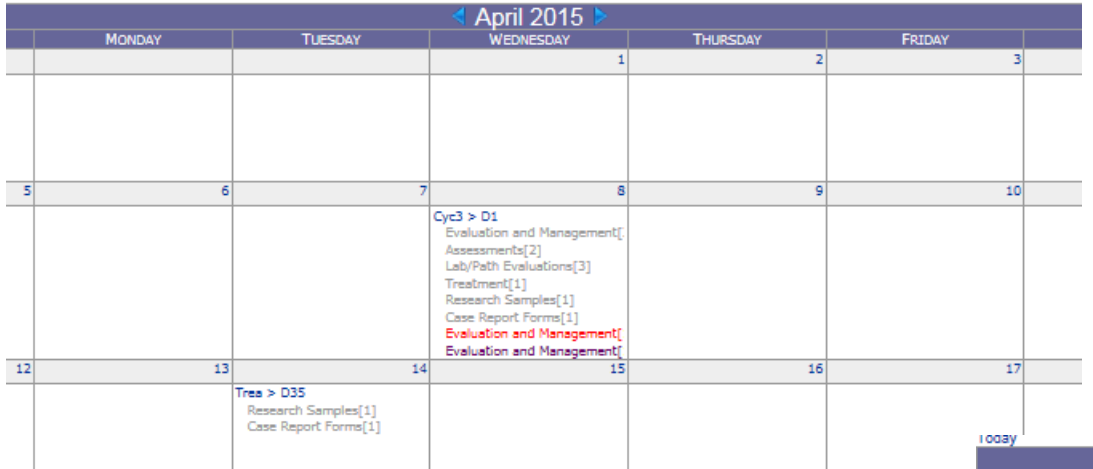
< Cycle 2 > Day 1 03/16/2015 | **Cycle 3 > Day 1 04/08/2015** | Treatment > Day 35 > 04/14/2015

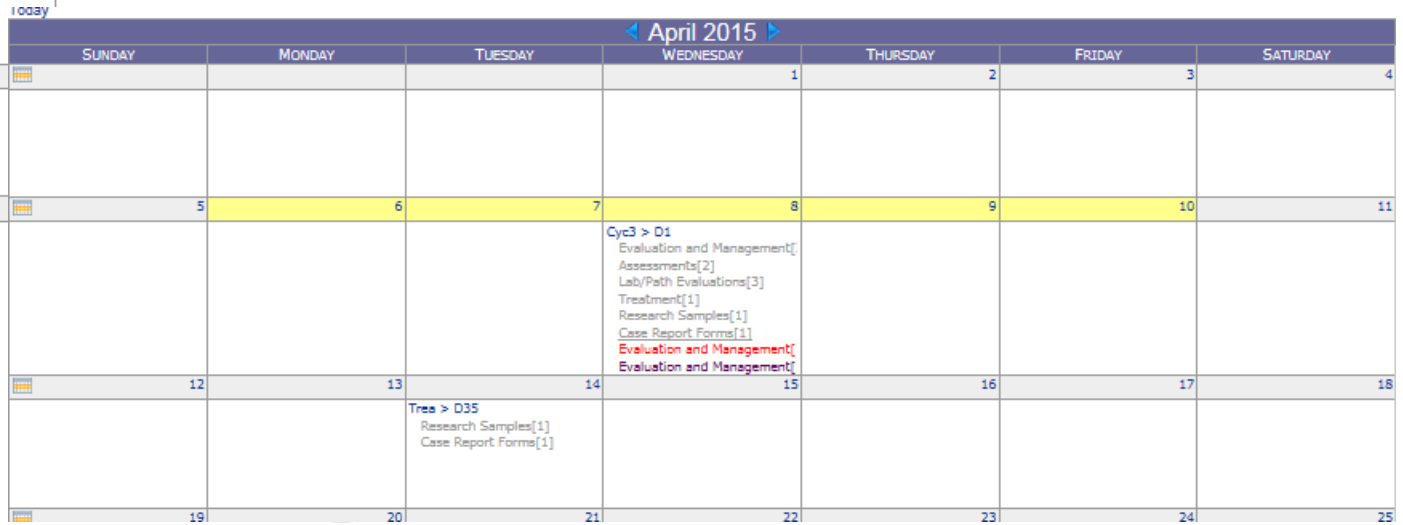
Back to Calendar

Treatment	Status	Time Scheduled	Time Completed	Notes	Data Complete	Data to
Evaluation and Management						
Physical exam	04/08/2015					
Weight	04/08/2015			The patient left the clinic before being weighed --sbooker2@johnshopkins.edu 04/14/15@09:24.		
ECOG Performance Status	04/08/2015					
Concomitant Meds	04/08/2015					
Adverse Events	04/08/2015					
Assessments						
CT Scan	04/08/2015					
RECIST Read	04/08/2015					

STUDY CALENDAR

Ideal Range





STUDY CALENDAR

Protocol Deviation

< Cycle 2 > Day 1 03/16/2015 | **Cycle 3 > Day 1 04/08/2015** | Treatment > Day 35 > 04/14/2015

Back to Calendar

Treatment	Status	Time Scheduled	Time Completed	Notes	Data Complete
Evaluation and Management					
Physical exam	04/08/2015				
Weight	04/08/2015			The patient left the clinic before being weighed --sbooker2@johnshopkins.edu 04/14/15@09:24.	
ECOG Performance Status	04/08/2015				
Concomitant Meds	04/08/2015				
Adverse Events	04/08/2015				
Assessments					
CT Scan	04/08/2015				
RECIST Read	04/08/2015				
Lab/Path Evaluations					
Comprehensive Metabolic Panel	04/08/2015				
CBC and Differential	04/13/2015 Save Cancel				
Magnesium					
Treatment					
MK-3475	04/08/2015				
Research Samples					
Post-infusion serum	04/08/2015				

Lab/Path Evaluations	
Comprehensive Metabolic Panel	04/08/2015
Magnesium	04/08/2015

Today

April 2015

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
			1	2	3	
5	6	7	8	9	10	1
			Cyc3 > D1 Evaluation and Management[Assessments[2] Lab/Path Evaluations[2] Treatment[1] Research Samples[1] Case Report Forms[1] Evaluation and Management[			
12	13	14	15	16	17	1
	Cyc3 > D1 Lab/Path Evaluations[1]	Trea > D35 Research Samples[1] Case Report Forms[1]				
19	20	21	22	23	24	2
			Cyc4 > D1 Evaluation and Management[Lab/Path Evaluations[3] Treatment[1] Research Samples[1] Case Report Forms[1]			
26	27	28	29	30		

STUDY CALENDAR

Service Note : Billing Code

< Treatment > Day 35 04/14/2015 | **Cycle 4 > Day 1 04/22/2015** | Cycle 5 > Day 1 > 05/06/2015

Back to Calendar

Treatment	Status	Time Scheduled	Time Completed	Notes	Data Complet
Evaluation and Management					
▸ **Physical exam** S	— 04/22/2015				
▸ **Weight** N	— 04/22/2015				
▸ **ECOG Performance Status** N	— 04/22/2015				
▸ **Concomitant Meds** N	— 04/22/2015				
▸ **Adverse Events** N	— 04/22/2015				
Lab/Path Evaluations					
▸ **Comprehensive Metabolic Panel** S	— 04/22/2015				
▸ **CBC and Differential** S	— 04/22/2015				
▸ **Magnesium** S	— 04/22/2015				
Treatment					
▸ **MK-3475** F	— 04/22/2015				
Research Samples					
▾ **Post-infusion serum** R	— 04/22/2015				
Treatment > Cycle 4 > Day 1 04/20/2015..04/24/2015 **Service Notes** Collect 3 red top tubes within 30 minutes of completion of infusion. **Additional Notes**					
Case Report Forms					
▸ **S001.02_Study_Visit** N Start	— 04/22/2015				