HELPFUL TIPS & COMMON ERRORS

DATA MANAGEMENT

Alliance for Clinical Trials in Oncology

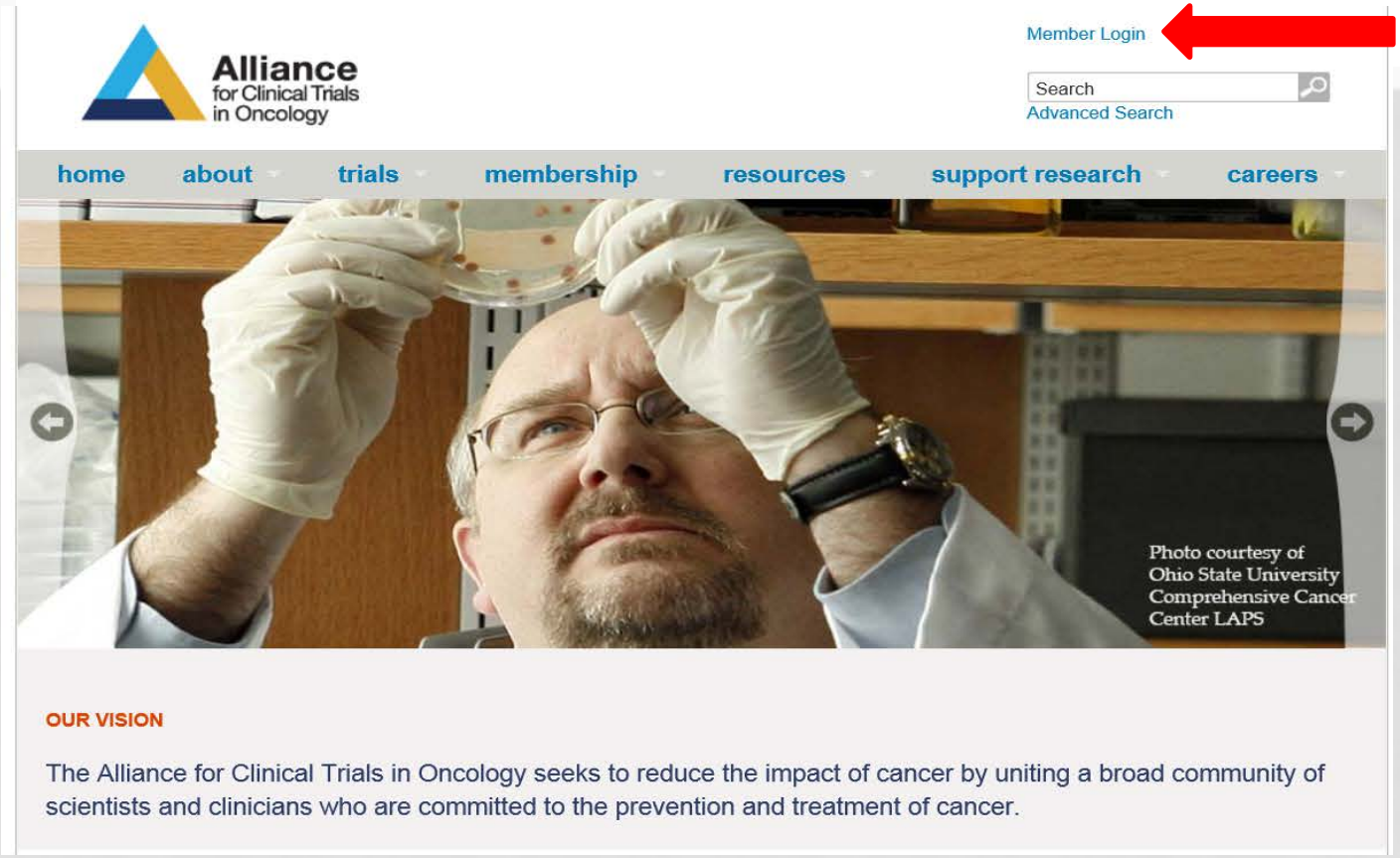
ALLIANCE FALL MEETING 2016

QUESTIONS? CONTACT KRISTIN HONER
KRISTIN.HONER@ESSENTIAHEALTH.ORG
OR THE ALLIANCE STATISTICAL & DATA CENTER

AGENDA

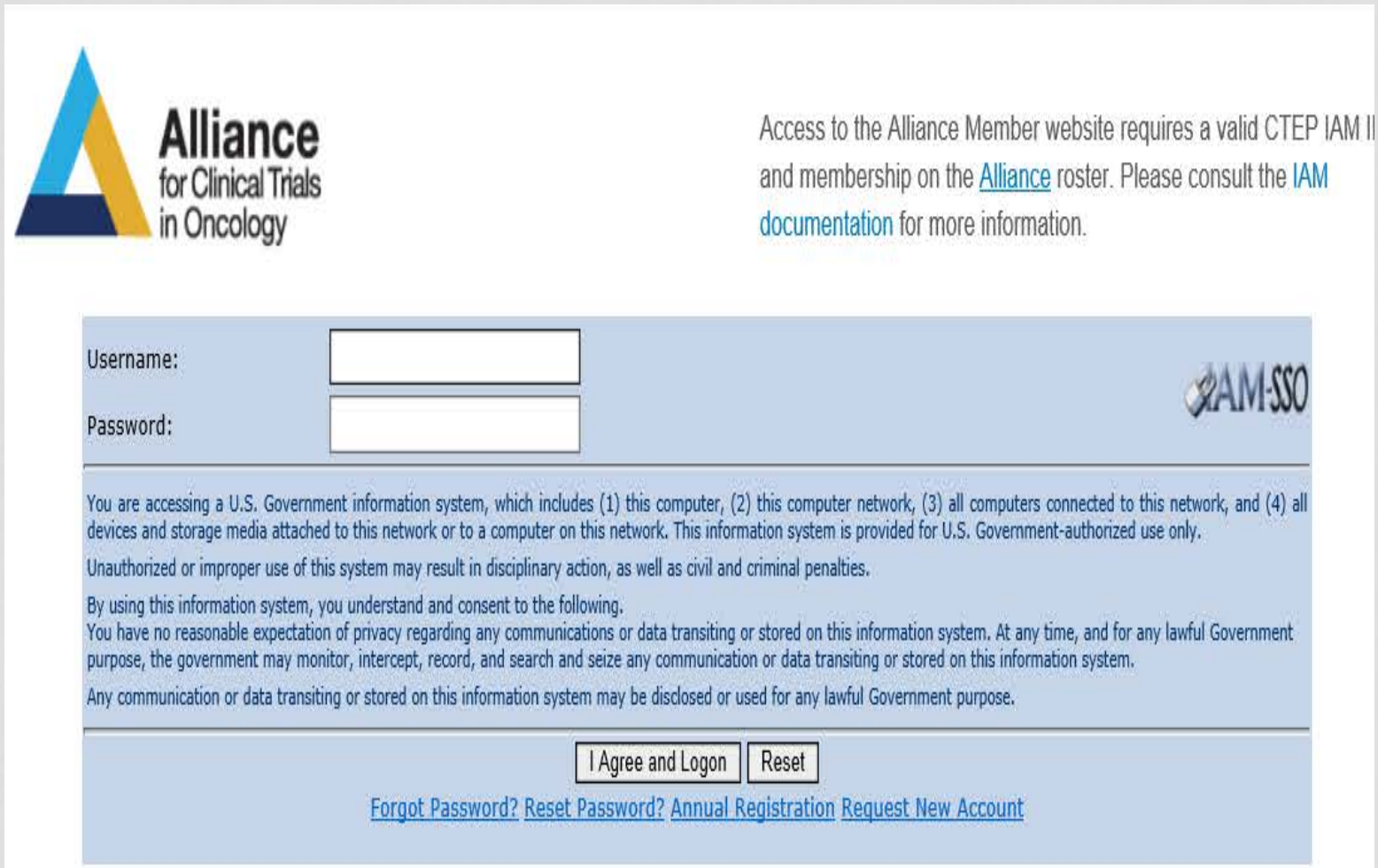
- Teleforms, Paper Case Report Forms, Data Submission Schedule
- On study forms
  - Contacts
  - Adverse events
  - RECIST
  - Supporting documentation
  - Specimen Submission
  - Patient status
- Cycles
  - Treatment & Dose Mods
  - Adverse Events
  - RECIST
  - Patient status
- Off treatment
- Follow up

TELEFORMS



- Found on the Alliance website (for older studies that are not in Rave) https://www.allianceforclinicaltrialsinoncology.org/main/
- Internet Explorer is the only recommended browser.

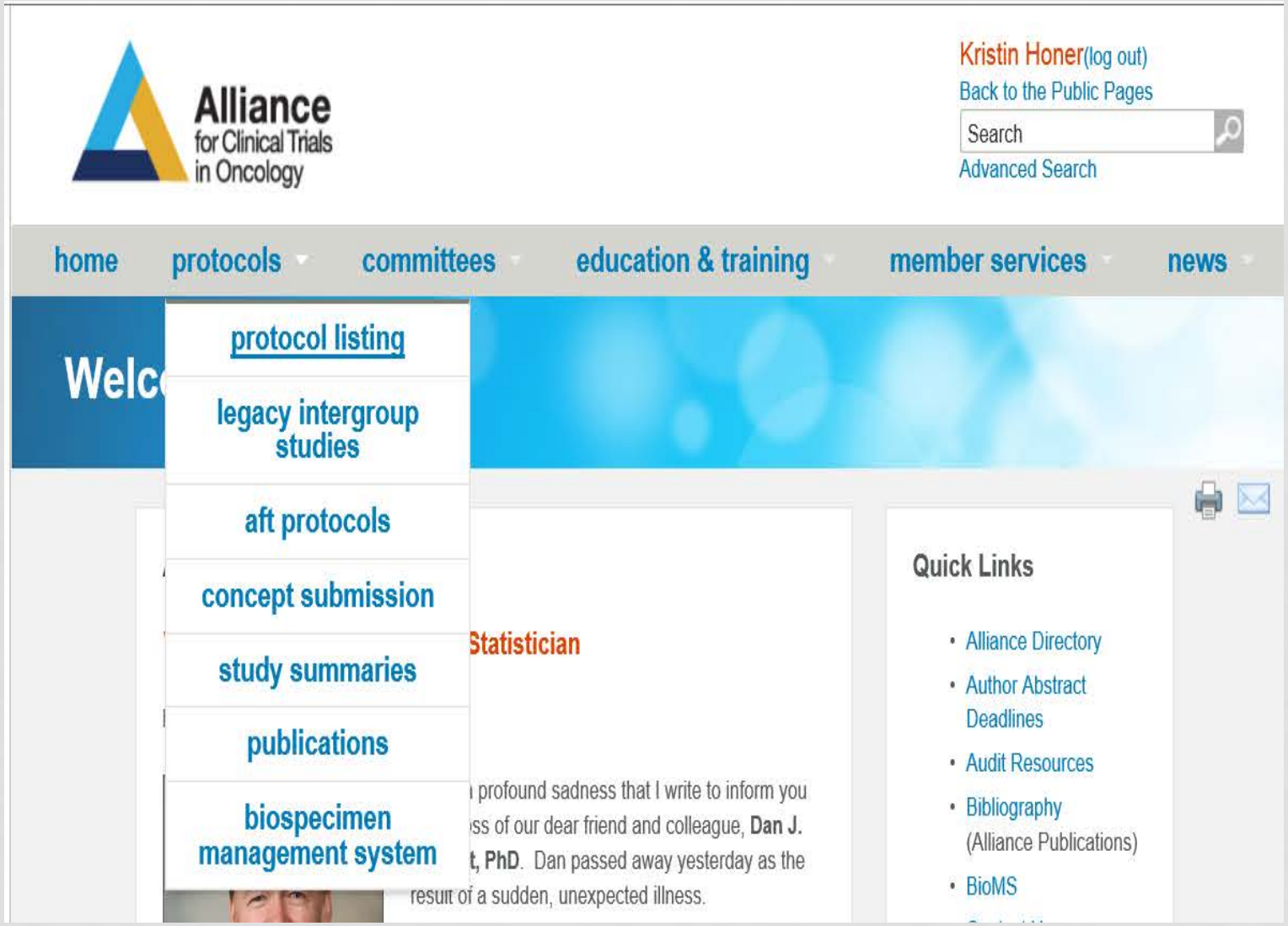
TELEFORMS



Use your CTSU login

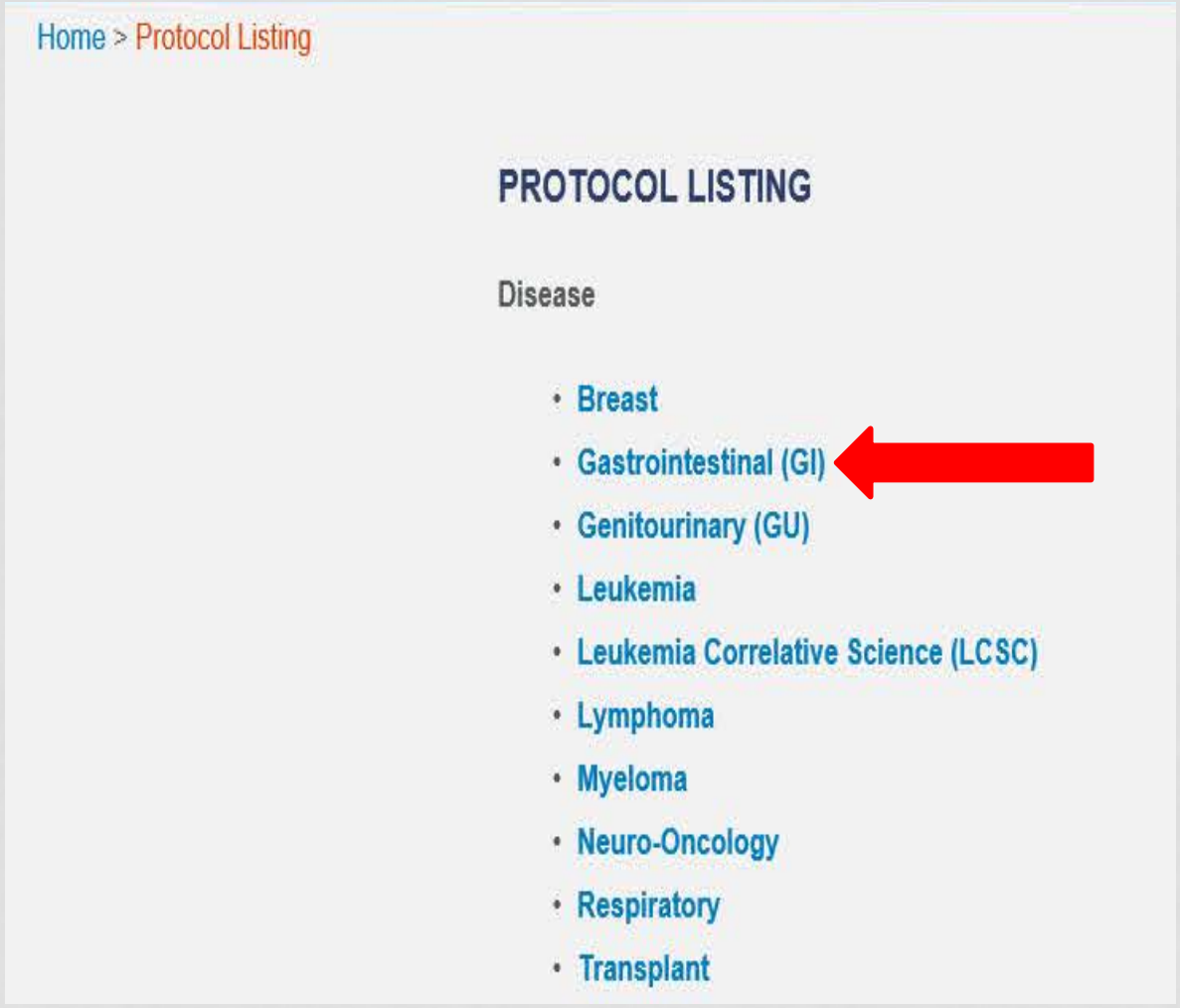
TELEFORMS

Search by protocol listing



TELEFORMS

Pick the disease site



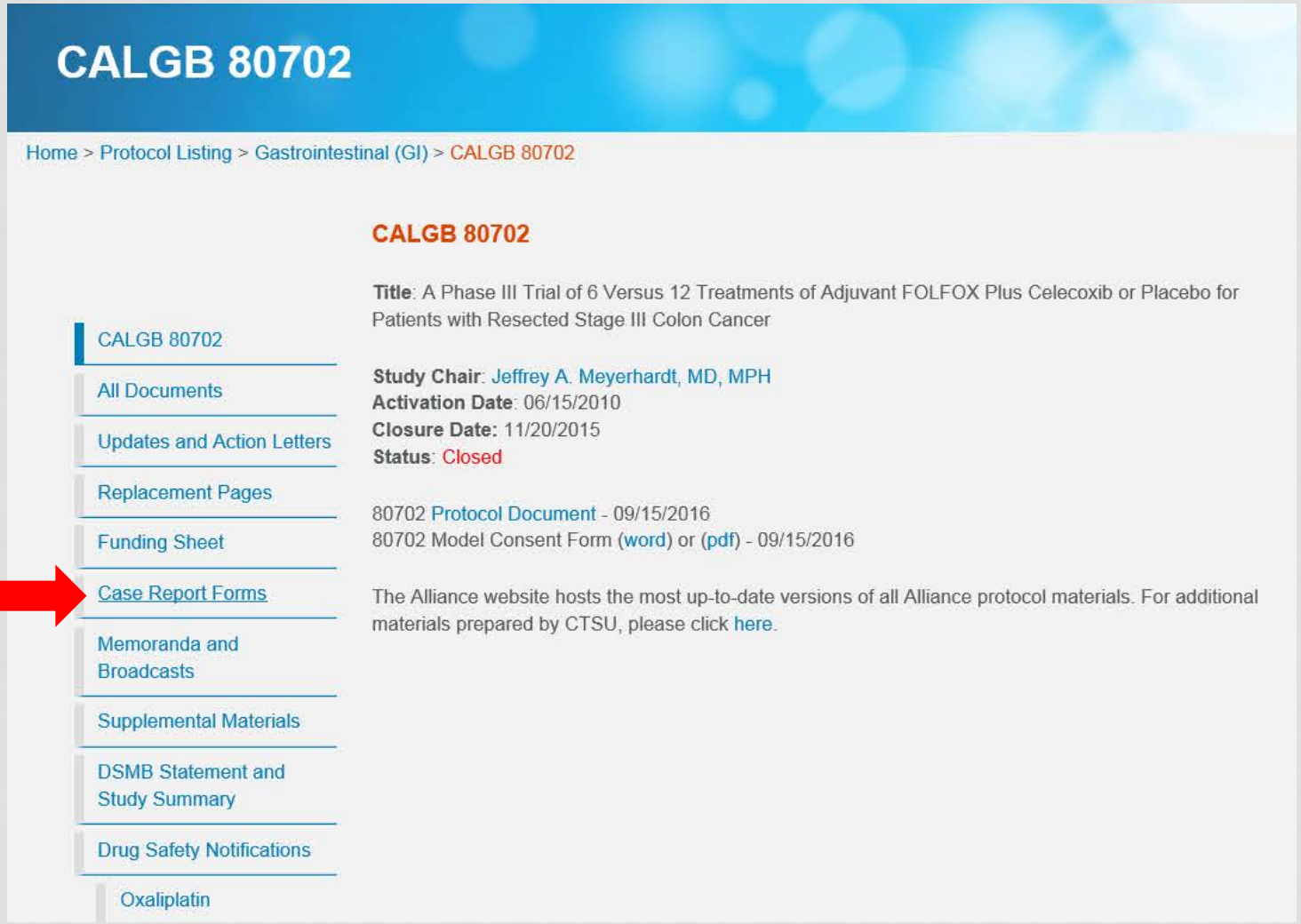
TELEFORMS

Select the specific protocol

CALGB 80405	A phase III trial of irinotecan/5-fu/leucovorin or oxaliplatin/5-fu/leucovorin with bevacizumab, or cetuximab (c225), or with the combination of bevacizumab and cetuximab for patients with untreated metastatic adenocarcinoma of the colon or rectum
CALGB 80701	Randomized phase II study of everolimus alone versus everolimus plus bevacizumab in patients with locally advanced or metastatic pancreatic neuroendocrine tumors
CALGB 80702	A phase III trial of 6 versus 12 treatments of adjuvant FOLFOX plus celecoxib or placebo for patients with resected stage III colon cancer
CALGB 80802	Phase III randomized study of sorafenib plus doxorubicin versus sorafenib in patients with advanced hepatocellular carcinoma(HCC)
CALGB 80803	Randomized phase II trial of PET scan-directed combined modality therapy in esophageal cancer
CALGB 150105	STI571 response predictors in gastrointestinal stromal tumors
CALGB 150705	Correlative science studies in colon cancer: A companion study to CALGB 9581 and 89803
CALGB 150806	Correlative science studies in untreated metastatic adenocarcinoma of the colon or rectum

TELEFORMS

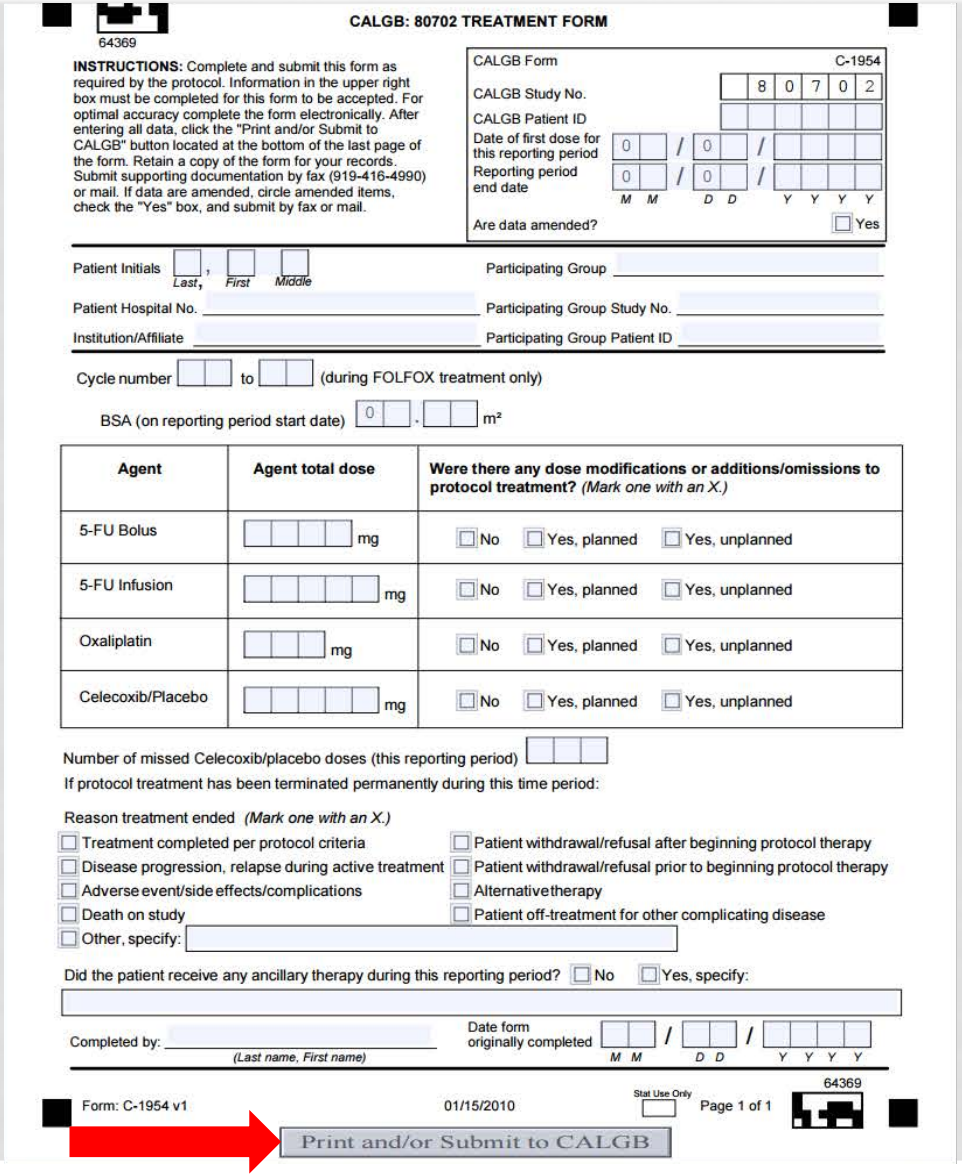
- Select "Case Report Forms"



TELEFORMS

- You will then get a list of all the possible forms

SUBMITTING TELEFORMS



64369

CALGB: 80702 TREATMENT FORM

INSTRUCTIONS: Complete and submit this form as required by the protocol. Information in the upper right box must be completed for this form to be accepted. For optimal accuracy complete the form electronically. After entering all data, click the "Print and/or Submit to CALGB" button located at the bottom of the last page of the form. Retain a copy of the form for your records. Submit supporting documentation by fax (919-416-4990) or mail. If data are amended, circle amended items, check the "Yes" box, and submit by fax or mail.

CALGB Form C-1954
CALGB Study No. 80702
CALGB Patient ID
Date of first dose for this reporting period 0_ / 0_ / ____ (M M / D D / Y Y Y Y)
Reporting period end date 0_ / 0_ / ____ (M M / D D / Y Y Y Y)
Are data amended? ☐ Yes

Patient Initials ____ , ____ ____ (Last, First Middle)
Participating Group
Patient Hospital No.
Participating Group Study No.
Institution/Affiliate
Participating Group Patient ID

Cycle number ____ to ____ (during FOLFOX treatment only)

BSA (on reporting period start date) 0_._____ m²

Agent	Agent total dose	Were there any dose modifications or additions/omissions to protocol treatment? *(Mark one with an X.)*
5-FU Bolus	_____ mg	☐ No ☐ Yes, planned ☐ Yes, unplanned
5-FU Infusion	_____ mg	☐ No ☐ Yes, planned ☐ Yes, unplanned
Oxaliplatin	_____ mg	☐ No ☐ Yes, planned ☐ Yes, unplanned
Celecoxib/Placebo	_____ mg	☐ No ☐ Yes, planned ☐ Yes, unplanned

Number of missed Celecoxib/placebo doses (this reporting period) ____

If protocol treatment has been terminated permanently during this time period:

Reason treatment ended *(Mark one with an X.)*

☐ Treatment completed per protocol criteria
☐ Disease progression, relapse during active treatment
☐ Adverse event/side effects/complications
☐ Death on study
☐ Other, specify:
☐ Patient withdrawal/refusal after beginning protocol therapy
☐ Patient withdrawal/refusal prior to beginning protocol therapy
☐ Alternative therapy
☐ Patient off-treatment for other complicating disease

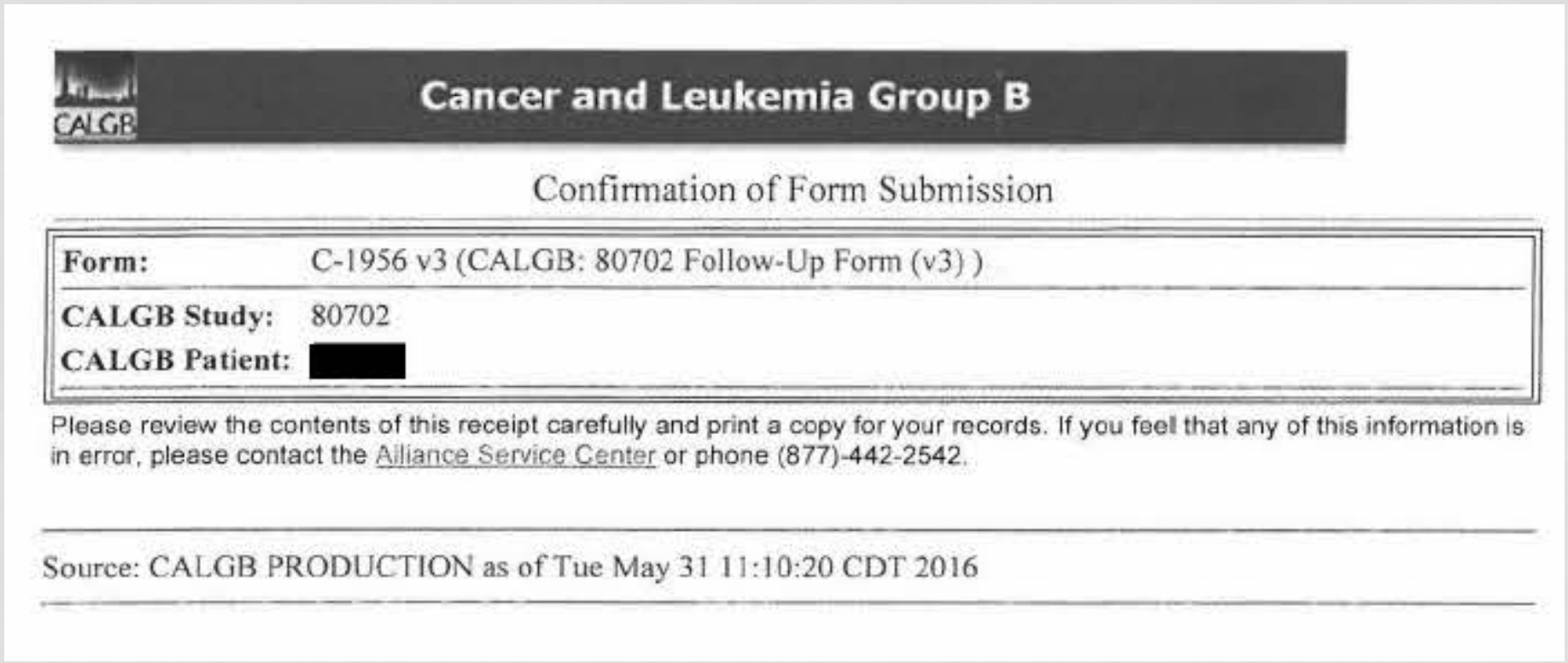
Did the patient receive any ancillary therapy during this reporting period? ☐ No ☐ Yes, specify:

Completed by: _____ (Last name, First name)
Date form originally completed ____ / ____ / ____ (M M / D D / Y Y Y Y)

Form: C-1954 v1 01/15/2010 Stat Use Only ☐ Page 1 of 1 64369

Print and/or Submit to CALGB

SUBMITTING TELEFORMS



Cancer and Leukemia Group B

Confirmation of Form Submission

Form:	C-1956 v3 (CALGB: 80702 Follow-Up Form (v3))
CALGB Study:	80702
CALGB Patient:	[redacted]

Please review the contents of this receipt carefully and print a copy for your records. If you feel that any of this information is in error, please contact the Alliance Service Center or phone (877)-442-2542.

Source: CALGB PRODUCTION as of Tue May 31 11:10:20 CDT 2016

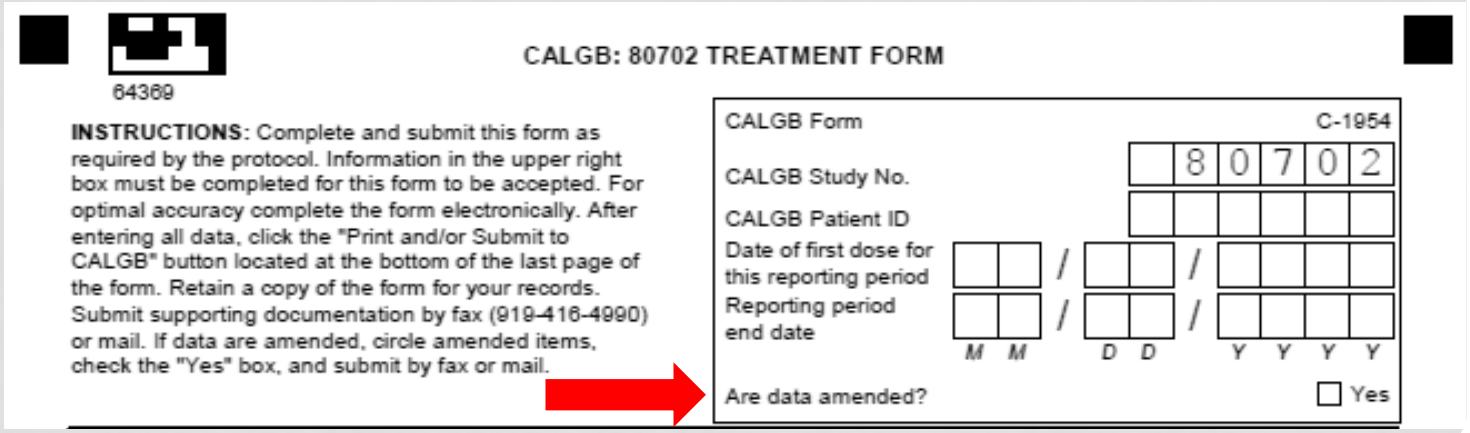
Print the confirmation page!

HOW TO CORRECTLY AMEND

- **Amended forms should <u>not</u> be submitted electronically**, but can be faxed to 507-284-1902 or mailed (our preference) to:

  Alliance Data Center
  Attention: Quality Assurance Office
  RO FF-3-24-CC/NW Clinic
  200 First Street SW
  Rochester, MN 55905

- To submit "amended data" place an "X" (with a pen) in the amended data box in the upper right corner of the form, draw a line through data you wish to delete, add and circle the amended data, and initial and date the change.
- On forms lacking a box, write "amended" at the top of the copy of the form, circle amended data, and initial and date the change. Everyone handling forms should follow these rules in order to track any changes that are made to the original notations.



64369

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CALGB Form C-1954

CALGB Study No. 80702

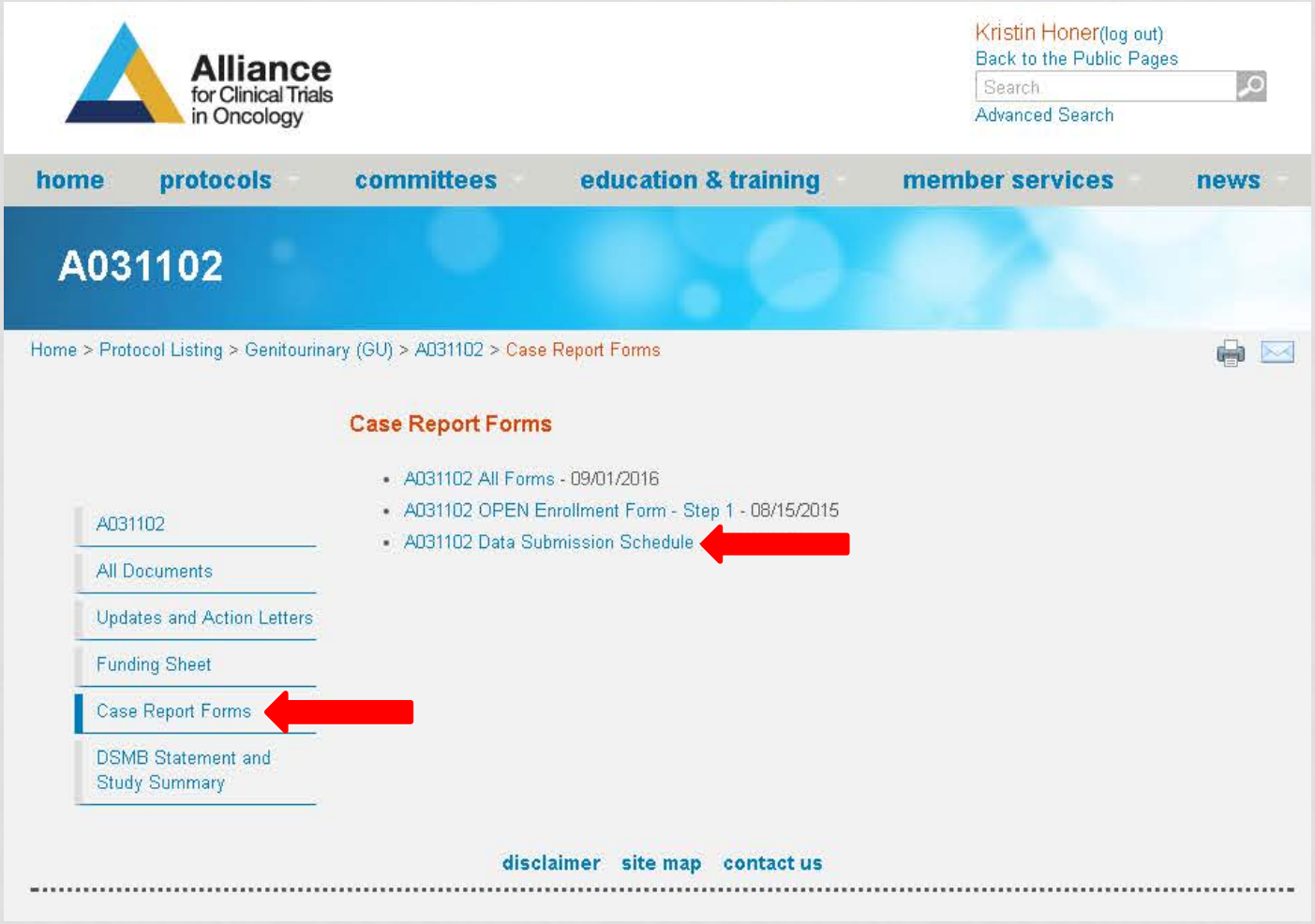
CALGB Patient ID

Date of first dose for this reporting period M M / D D / Y Y Y Y

Reporting period end date M M / D D / Y Y Y Y

Are data amended? ☐ Yes

DATA SUBMISSION SCHEDULE



- You can also find the Data Submission Schedule under CRFs on the Alliance website.
- Helpful so you know what forms to submit at what time points.

DATA SUBMISSION SCHEDULE

Data Submission Schedule – A031201, PHASE III TRIAL OF ENZALUTAMIDE (NSC # 766085) VERSUS ENZALUTAMIDE, ABIRATERONE AND PREDNISONE FOR CASTRATION RESISTANT METASTATIC PROSTATE CANCER

This schedule reflects case report form expectations and requirements based on parameters defined in the A031201 protocol document. Additional case report forms may become available and therefore required, based on responses to trigger questions within individual forms as described in the footnotes.

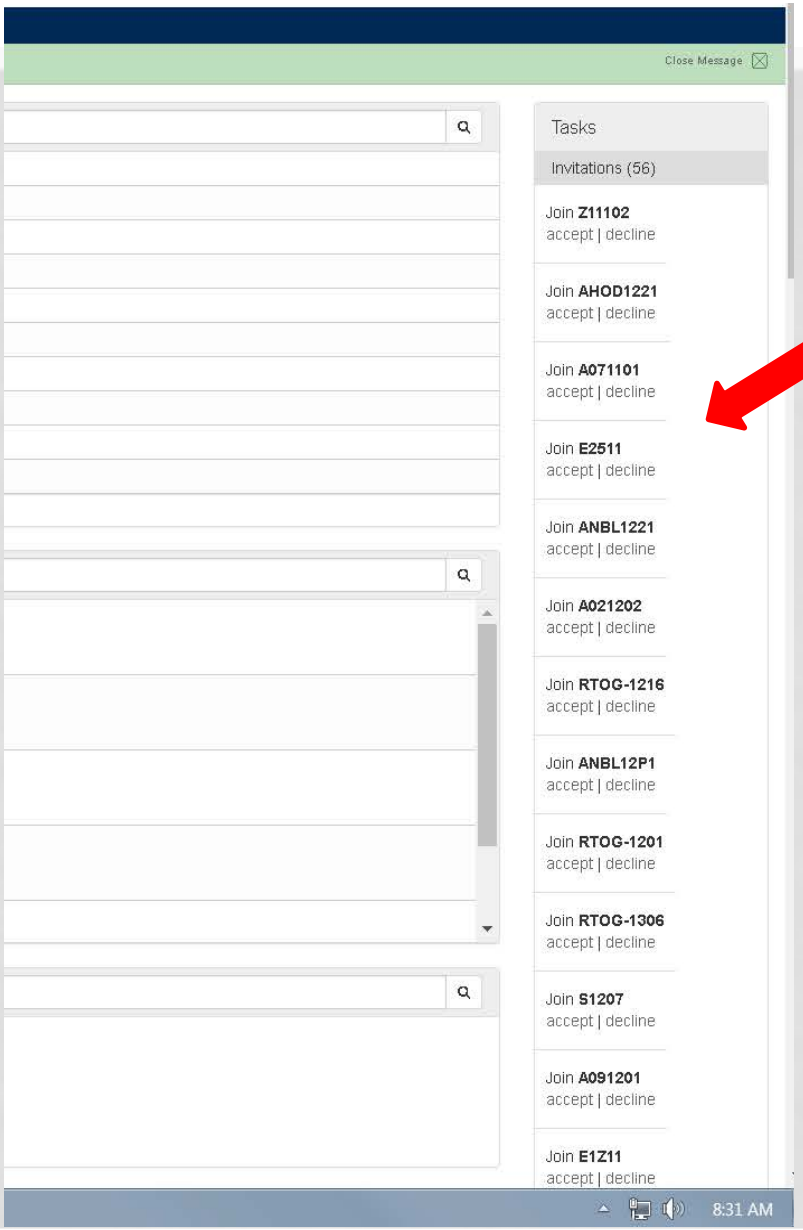
Folder Name in the Data Entry System		Baseline	Treatment	Off Treatment	Clinical Follow Up	Survival and Disease Status Follow Up	Concomitant Medications	Early Termination of Follow-Up	Unscheduled Evaluations	Confirmatory Scans	Unequivocal Clinical Progression
		On Study	Each cycle	End of treatment							
Form Name and Time of Form Submission	Institutional Contacts	X									
	On-Study	X									
	On-Study: Prior Therapy to Treat the Primary Tumor[1]	X									
	On-Study: Prior Therapy to Treat Biochemical Relapse[2]	X									
	On-Study: Prior Therapy to Treat Metastatic Disease[3]	X									
	Laboratory Tests and Results: Baseline	X									
	Laboratory Tests and Results: Baseline - PSA	X									
	Specimen Submission: Blood (Baseline - Substudies)[4]	X									
	Adverse Events: Baseline	X									
	Measureable Disease: Baseline[5]	X									
	PCW2 Bone Scan Assessment: Baseline	X									
	Measurements (Non-Measurable Disease Only): Baseline[6]	X									
	Supporting Documentation: Baseline[7]	X									
	Registration Fatigue/Uniscale Assessment	X									
	Registration Fatigue/Uniscale Assessment Compliance[8]	X									
	Patient Status: Baseline	X									
	Treatment (Intervention)		X								
	Treatment (Intervention): Dose Modifications[9]		X								
	Adverse Events: Solicited		X								
	Adverse Events: Other[10]		X								
	Measureable Disease[11]		X		X						
	PCWG2 Bone Scan Assessment[12]		X		X						

CASE REPORT FORMS

- You can follow the same process to find paper CRFs of studies that are submitted exclusively through Rave.
  - These are helpful to use when you are new so you can complete all the data by hand before entering in Rave.
  - Also helpful when activating a new study so you know what to expect and what data points need to be collected.

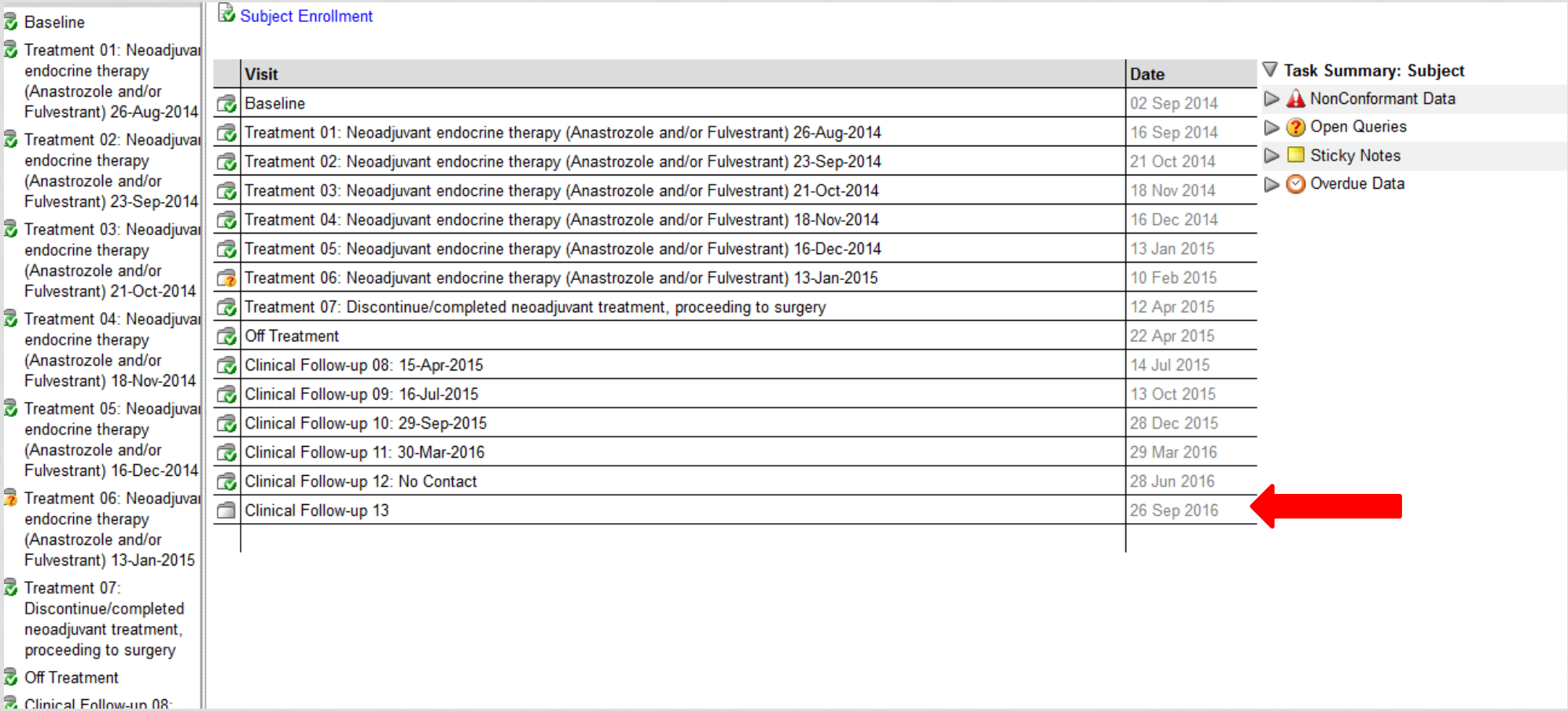
RAVE

Studies you have been invited to and accepted show up here.



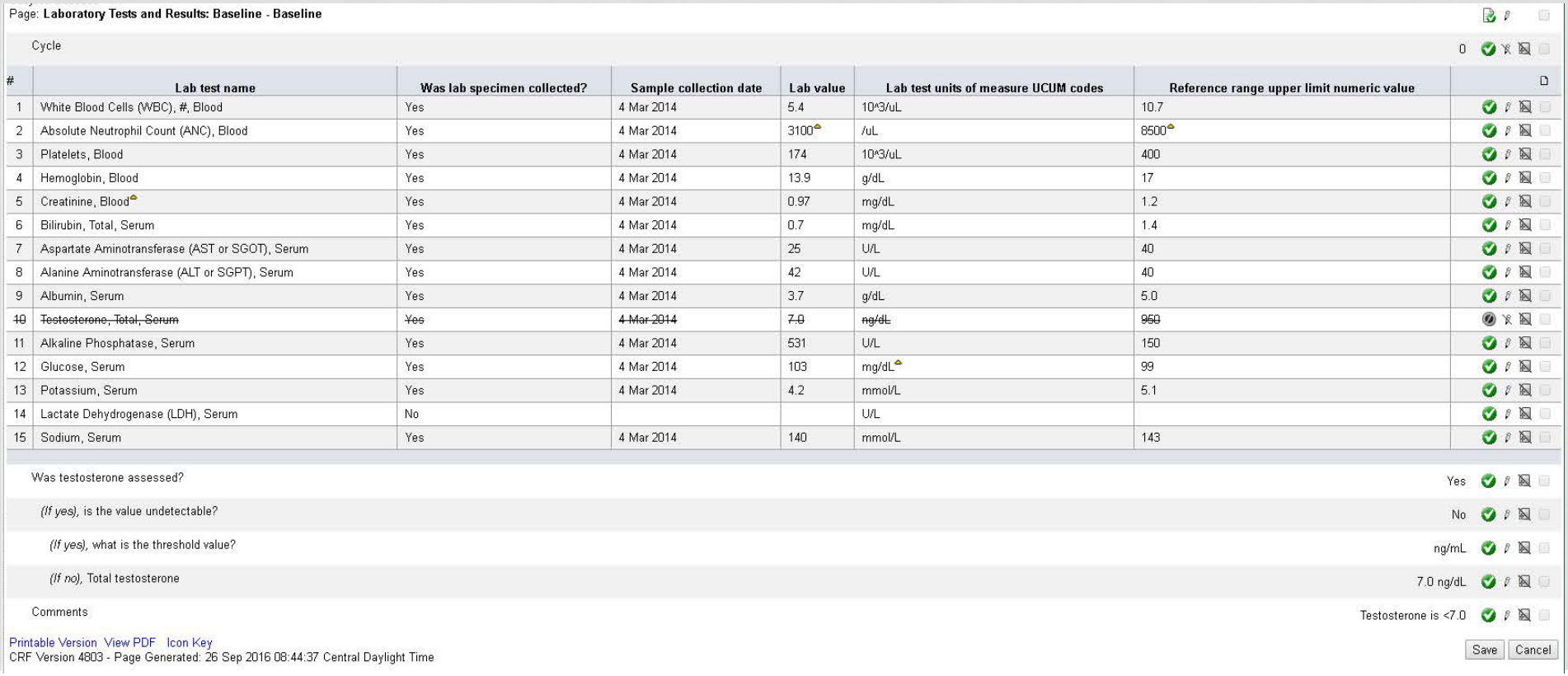
Studies you have been invited to but haven't accepted show up on the right side.

HOW PATIENTS ARE SET UP



ON STUDY FORMS

- Disease site/Study specific
- May ask you about stratification factors, stage/grade of disease, prior therapies, comorbidities, and QoLs completed
- Will ask baseline height, weight, performance status.
- Baseline lab results – WATCH units, ULN, LLN



Page: **Laboratory Tests and Results: Baseline - Baseline**

Cycle 0

#	Lab test name	Was lab specimen collected?	Sample collection date	Lab value	Lab test units of measure UCUM codes	Reference range upper limit numeric value
1	White Blood Cells (WBC), #, Blood	Yes	4 Mar 2014	5.4	10^3/uL	10.7
2	Absolute Neutrophil Count (ANC), Blood	Yes	4 Mar 2014	3100	/uL	8500
3	Platelets, Blood	Yes	4 Mar 2014	174	10^3/uL	400
4	Hemoglobin, Blood	Yes	4 Mar 2014	13.9	g/dL	17
5	Creatinine, Blood	Yes	4 Mar 2014	0.97	mg/dL	1.2
6	Bilirubin, Total, Serum	Yes	4 Mar 2014	0.7	mg/dL	1.4
7	Aspartate Aminotransferase (AST or SGOT), Serum	Yes	4 Mar 2014	25	U/L	40
8	Alanine Aminotransferase (ALT or SGPT), Serum	Yes	4 Mar 2014	42	U/L	40
9	Albumin, Serum	Yes	4 Mar 2014	3.7	g/dL	5.0
~~10~~	~~Testosterone, Total, Serum~~	~~Yes~~	~~4 Mar 2014~~	~~7.0~~	~~ng/dL~~	~~950~~
11	Alkaline Phosphatase, Serum	Yes	4 Mar 2014	531	U/L	150
12	Glucose, Serum	Yes	4 Mar 2014	103	mg/dL	99
13	Potassium, Serum	Yes	4 Mar 2014	4.2	mmol/L	5.1
14	Lactate Dehydrogenase (LDH), Serum	No			U/L	
15	Sodium, Serum	Yes	4 Mar 2014	140	mmol/L	143

Was testosterone assessed? Yes

(If yes), is the value undetectable? No

(If yes), what is the threshold value? ng/mL

(If no), Total testosterone 7.0 ng/dL

Comments Testosterone is <7.0

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Save Cancel

ON STUDY – INSTITUTIONAL CONTACTS

Page: **Institutional Contacts - Baseline**

INSTRUCTIONS: Use this form to identify who the Data Manager should contact for quality assurance purposes. Please update this information if there are any changes to the contact information while the patient is still on study.

Cycle	0
CRA	
Name *(first, last)*	Kristin, Honer
Email	kristin.honer@essentiahealth.org
Phone *(example: 999-999-9999)*	218-786-8141
LEAD CRA	
Name *(first, last)*	Wilma, Knutson
Email	Wilma.Knutson@EssentiaHealth.org
Phone *(example: 999-999-9999)*	218-785-3111
SITE INVESTIGATOR	
Name *(first, last)*	Bret, Friday
Email	Bret.Friday@EssentiaHealth.org
Phone *(example: 999-999-9999)*	218-786-1048
Is the reference radiologist or local investigator available for bone imaging interpretation?	Yes
Comments	

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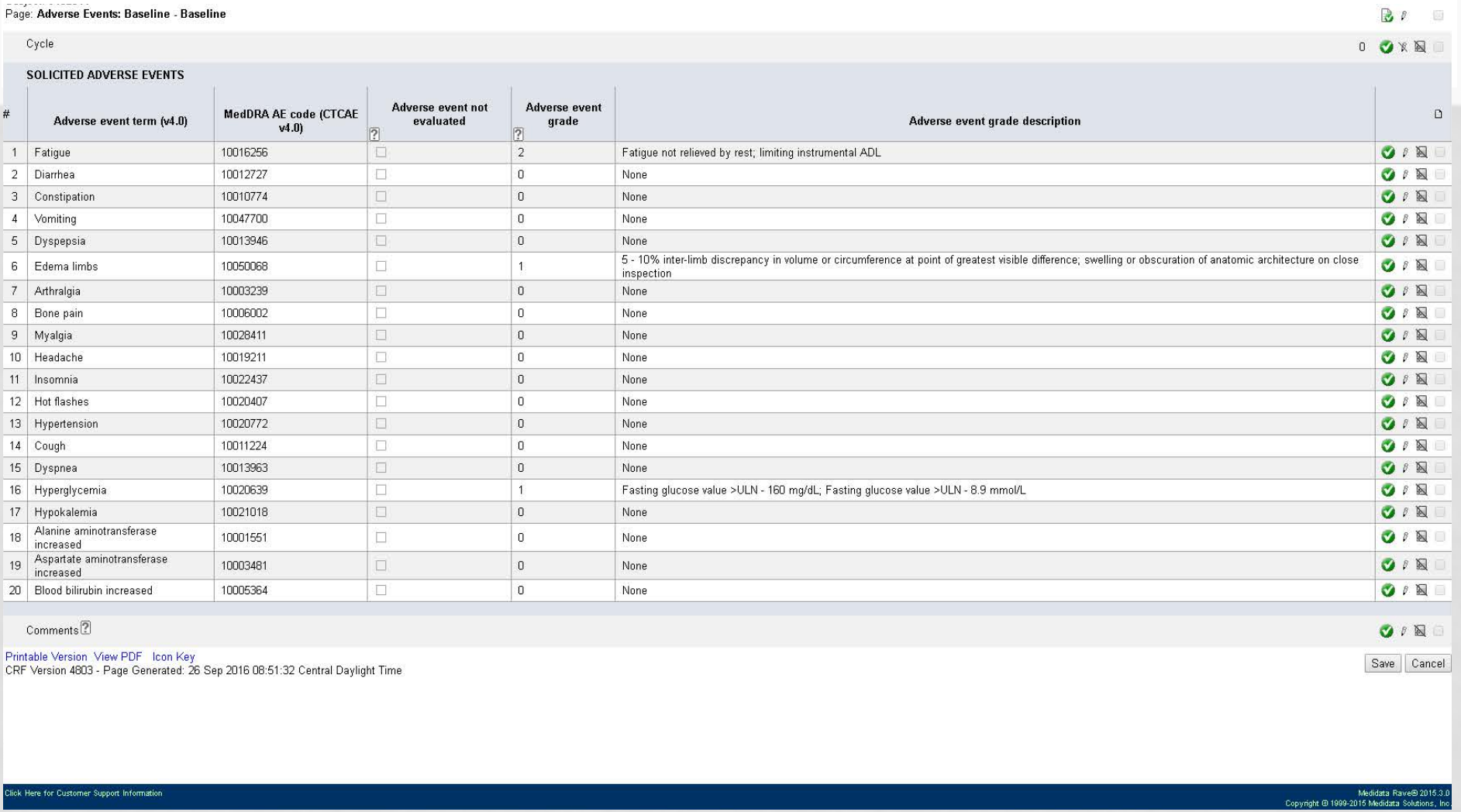
Save Cancel

Keep updated!

ON STUDY – BASELINE ADVERSE EVENTS



Page: **Adverse Events: Baseline - Baseline**

Cycle 0

SOLICITED ADVERSE EVENTS

#	Adverse event term (v4.0)	MedDRA AE code (CTCAE v4.0)	Adverse event not evaluated	Adverse event grade	Adverse event grade description
1	Fatigue	10016256		2	Fatigue not relieved by rest; limiting instrumental ADL
2	Diarrhea	10012727		0	None
3	Constipation	10010774		0	None
4	Vomiting	10047700		0	None
5	Dyspepsia	10013946		0	None
6	Edema limbs	10050068		1	5 - 10% inter-limb discrepancy in volume or circumference at point of greatest visible difference; swelling or obscuration of anatomic architecture on close inspection
7	Arthralgia	10003239		0	None
8	Bone pain	10006002		0	None
9	Myalgia	10028411		0	None
10	Headache	10019211		0	None
11	Insomnia	10022437		0	None
12	Hot flashes	10020407		0	None
13	Hypertension	10020772		0	None
14	Cough	10011224		0	None
15	Dyspnea	10013963		0	None
16	Hyperglycemia	10020639		1	Fasting glucose value >ULN - 160 mg/dL; Fasting glucose value >ULN - 8.9 mmol/L
17	Hypokalemia	10021018		0	None
18	Alanine aminotransferase increased	10001551		0	None
19	Aspartate aminotransferase increased	10003481		0	None
20	Blood bilirubin increased	10005364		0	None

Comments

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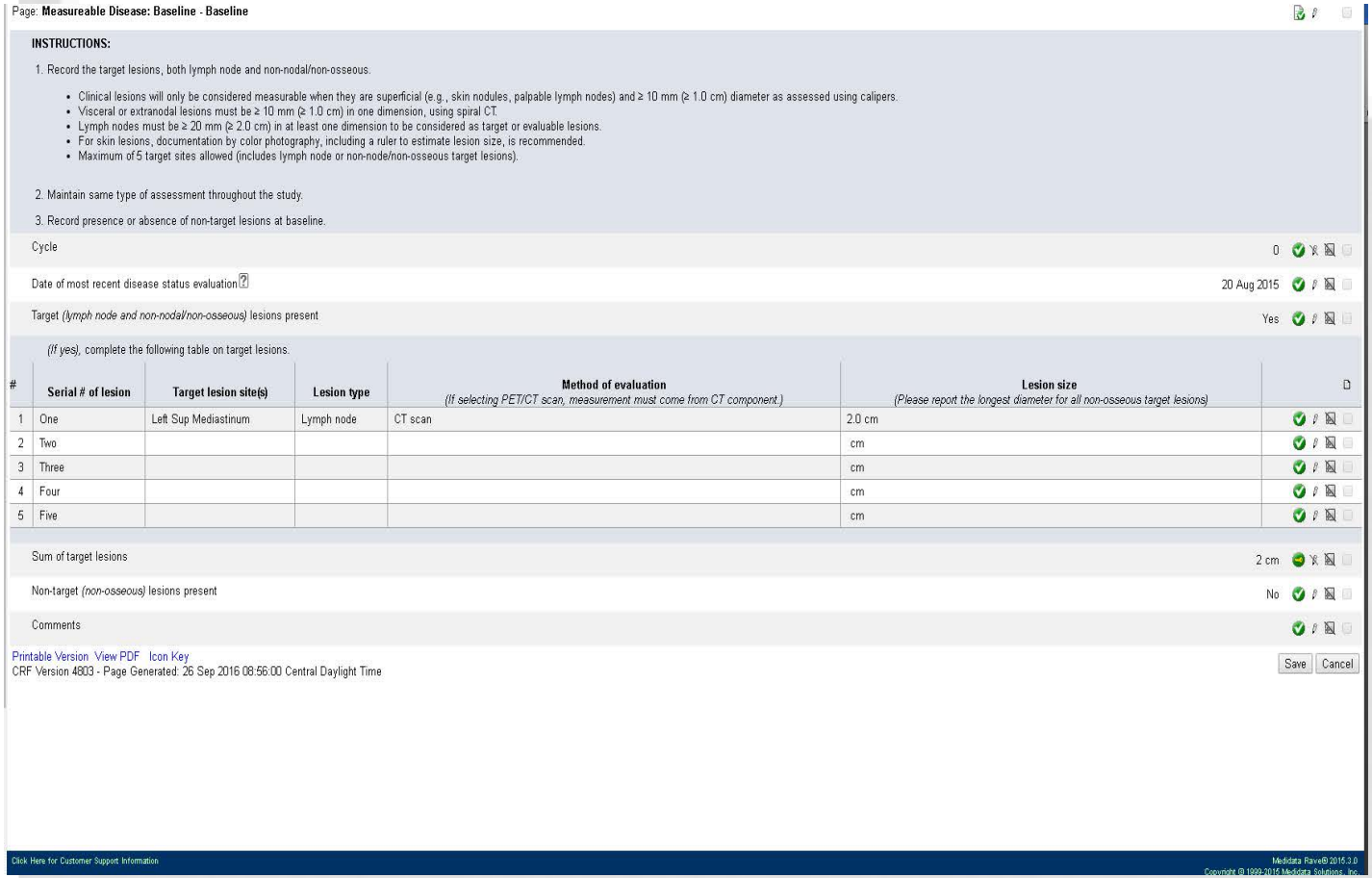
May be “solicited” as above. May be an empty form where you have to add log lines.

ON STUDY – RECIST MEASUREMENTS



Page: **Measureable Disease: Baseline - Baseline**

INSTRUCTIONS:

1. Record the target lesions, both lymph node and non-nodal/non-osseous.
   - Clinical lesions will only be considered measurable when they are superficial (e.g., skin nodules, palpable lymph nodes) and ≥ 10 mm (≥ 1.0 cm) diameter as assessed using calipers.
   - Visceral or extranodal lesions must be ≥ 10 mm (≥ 1.0 cm) in one dimension, using spiral CT.
   - Lymph nodes must be ≥ 20 mm (≥ 2.0 cm) in at least one dimension to be considered as target or evaluable lesions.
   - For skin lesions, documentation by color photography, including a ruler to estimate lesion size, is recommended.
   - Maximum of 5 target sites allowed (includes lymph node or non-node/non-osseous target lesions).
2. Maintain same type of assessment throughout the study.
3. Record presence or absence of non-target lesions at baseline.

Cycle	0
Date of most recent disease status evaluation	20 Aug 2015
Target *(lymph node and non-nodal/non-osseous)* lesions present	Yes

(If yes), complete the following table on target lesions.

#	Serial # of lesion	Target lesion site(s)	Lesion type	Method of evaluation *(If selecting PET/CT scan, measurement must come from CT component.)*	Lesion size *(Please report the longest diameter for all non-osseous target lesions)*
1	One	Left Sup Mediastinum	Lymph node	CT scan	2.0 cm
2	Two				cm
3	Three				cm
4	Four				cm
5	Five				cm

Sum of target lesions	2 cm
Non-target *(non-osseous)* lesions present	No
Comments	

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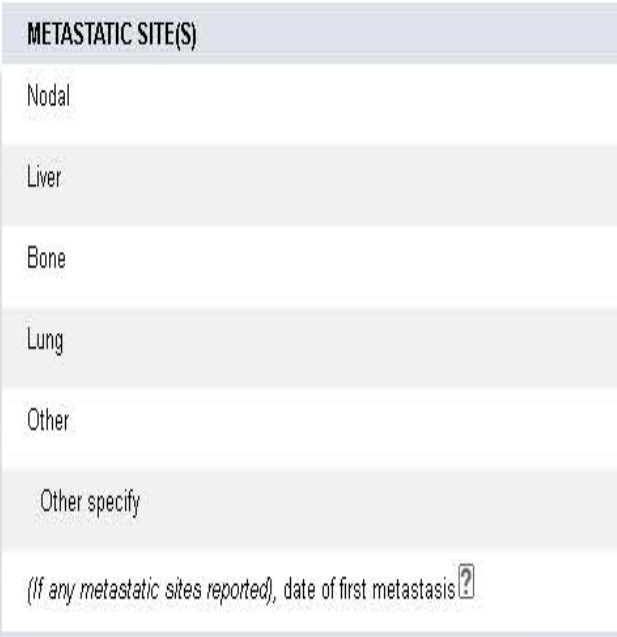
Measureable lesions – have to enter lesion site, method of evaluation, and lesion size.



METASTATIC SITE(S)

Nodal

Liver

Bone

Lung

Other

Other specify

(If any metastatic sites reported), date of first metastasis

Studies may ask about metastatic sites of disease. What is reported here must match what is on the baseline RECIST measurements form!

ON STUDY- SUPPORTING DOCUMENTATION

Page: **Supporting Documentation: Baseline - Baseline**

Cycle 0

#	Serial # of Supporting Documentation	Date of assessment	Report type	Specify report type	Attachment *(max file size 10 MB)*
1	#1	05 Feb 2014	Imaging report	Bone Scan Whole Body	9100008 Bone Scan.pdf
2	#2	05 Feb 2014	Imaging report	CT Chest Abd Pelvis w/contrast	9100008 CT.pdf
3	#3	12 Jul 2011	Pathology report	Path for Prostate Biopsies	9100008 Path.pdf
4	#4				
5	#5				
6	#6				
7	#7				
8	#8				
9	#9				
10	#10				

May have to upload radiology reports, pathology reports, etc

What about Protected Health Information (PHI)??

ON STUDY – SPECIMEN SUBMISSION

Page: **Specimen Submission: Blood (Baseline - Substudies) - Baseline**

Cycle 0

INSTRUCTIONS:

1. See Section 6.2 of the protocol for specimen requirements and shipment.
2. Please do not submit this form with specimen shipment.

#	Specimen type	Was specimen submitted?	Not submitted reason	Not submitted reason other, specify	Number of specimens submitted	Date specimen collected	Date specimen shipped
1	Serum (red top)	Yes			5	09 Mar 2015	10 Mar 2015
2	Whole blood (PAXgene)	Yes			2	09 Mar 2015	10 Mar 2015
3	Plasma EDTA (lavender)	Yes			4	09 Mar 2015	10 Mar 2015
4	Plasma Citrate (light blue)	Yes			5	09 Mar 2015	10 Mar 2015
5	Whole Blood EDTA (lavender)	Yes			2	09 Mar 2015	09 Mar 2015
6	Plasma (lavender)	Yes			1	09 Mar 2015	10 Mar 2015

REMINDER: All specimens must be logged in BioMS. Please see the protocol for further instructions.

BASELINE (PRETREATMENT) PK BLOOD SAMPLE

Time collected 09:30 AM (example: 11 30 AM)

Comments

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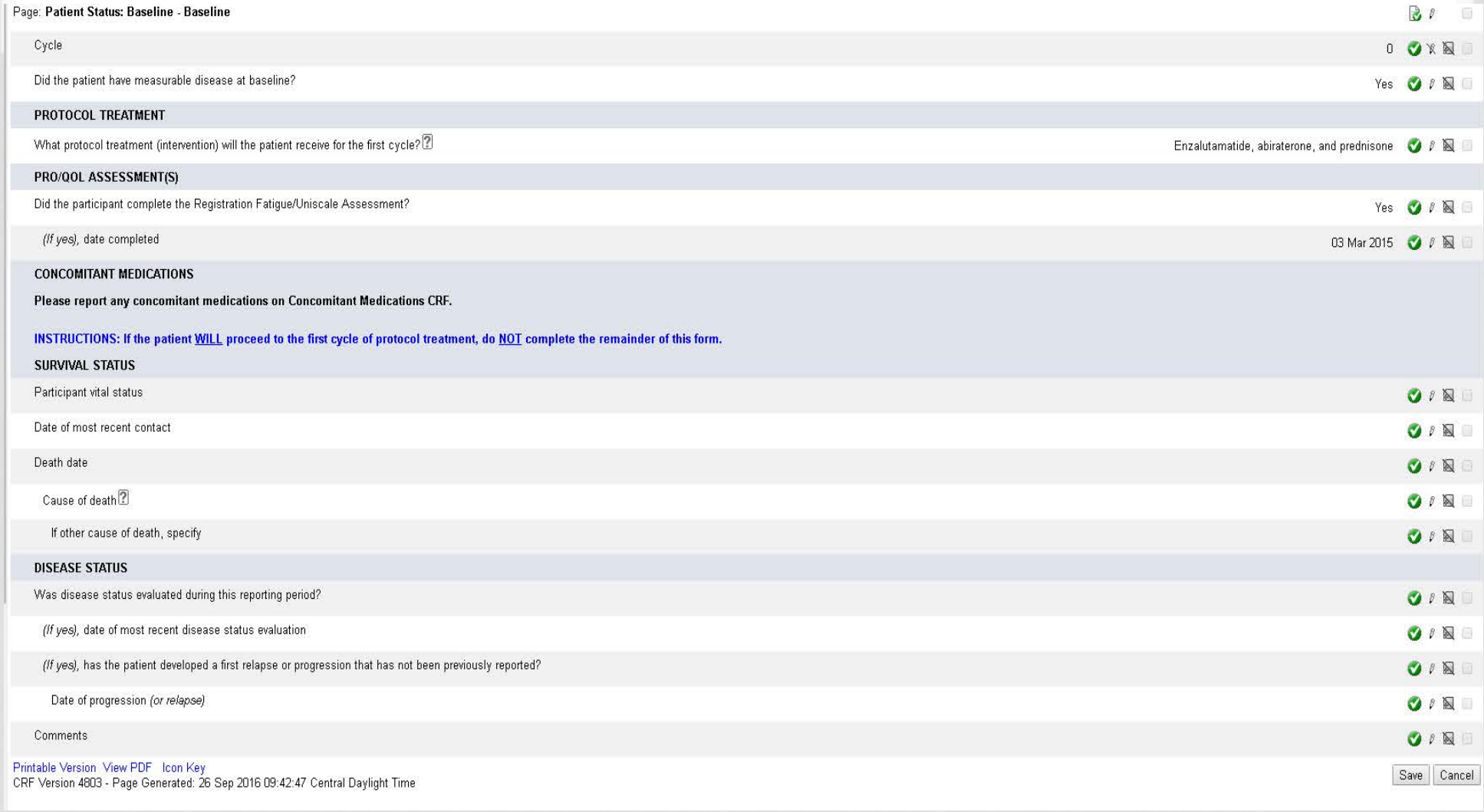
Don't forget about BioMs!

ON STUDY – PATIENT STATUS



Page: **Patient Status: Baseline - Baseline**

Cycle	0
Did the patient have measurable disease at baseline?	Yes
PROTOCOL TREATMENT	
What protocol treatment (intervention) will the patient receive for the first cycle?	Enzalutamatide, abiraterone, and prednisone
PRO/QOL ASSESSMENT(S)	
Did the participant complete the Registration Fatigue/Uniscale Assessment?	Yes
(If yes), date completed	03 Mar 2015
CONCOMITANT MEDICATIONS	
Please report any concomitant medications on Concomitant Medications CRF.	
INSTRUCTIONS: If the patient WILL proceed to the first cycle of protocol treatment, do NOT complete the remainder of this form.	
SURVIVAL STATUS	
Participant vital status	
Date of most recent contact	
Death date	
Cause of death	
If other cause of death, specify	
DISEASE STATUS	
Was disease status evaluated during this reporting period?	
(If yes), date of most recent disease status evaluation	
(If yes), has the patient developed a first relapse or progression that has not been previously reported?	
Date of progression *(or relapse)*	
Comments	

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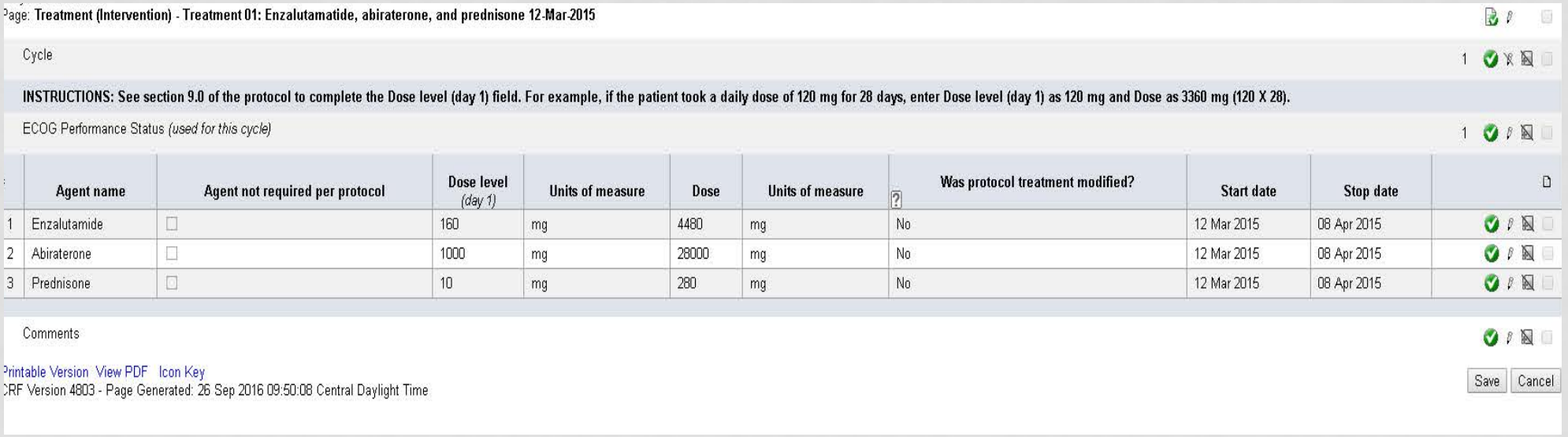
What treatment will the patient receive? Did the patient complete any QoLs (if applicable)?

CYCLES - TREATMENT FORMS

- Will ask for dose level, total dose, units, modifications, start and end dates. May also ask for weight, BSA, performance status.



Page: **Treatment (Intervention) - Treatment 01: Enzalutamatide, abiraterone, and prednisone 12-Mar-2015**

Cycle 1

INSTRUCTIONS: See section 9.0 of the protocol to complete the Dose level (day 1) field. For example, if the patient took a daily dose of 120 mg for 28 days, enter Dose level (day 1) as 120 mg and Dose as 3360 mg (120 X 28).

ECOG Performance Status *(used for this cycle)* 1

	Agent name	Agent not required per protocol	Dose level *(day 1)*	Units of measure	Dose	Units of measure	Was protocol treatment modified?	Start date	Stop date
1	Enzalutamide	☐	160	mg	4480	mg	No	12 Mar 2015	08 Apr 2015
2	Abiraterone	☐	1000	mg	28000	mg	No	12 Mar 2015	08 Apr 2015
3	Prednisone	☐	10	mg	280	mg	No	12 Mar 2015	08 Apr 2015

Comments

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CYCLES - DOSE MODIFICATIONS

NOTE: "Dose level (day 1)" refers to the measured amount of each study agent expected to be administered on the first day of this cycle. "Dose (total this cycle)" refers to the total dose taken over the course of this cycle.

#	Agent name	Dose level *(day 1)*	Units of measure	Dose *(total this cycle)*	Units of measure	Was protocol treatment modified?	Was protocol treatment omitted?	Was protocol treatment delayed?	Start date
1	Temozolomide	150	mg/m2	1500	mg	Yes, planned	No	Yes	12 Jun 2015
2	Veliparib (ABT-888) or placebo	60	mg	420	mg	Yes, planned	No	Yes	12 Jun 2015

Modifications:

- Yes, planned – if according to protocol guidelines (e.g AEs, lab values)
- Yes, unplanned – if not according to protocol guidelines (e.g. mistake, vacation)
- No

If you select "Yes" a new form opens up to enter the reason

Page: **Treatment (Intervention): Dose Modifications, Omissions and Delays - Treatment 03: 12-Jun-2015**

Cycle 3

#	Agent name	Dose modification reason	Dose omission reason	Dose delay reason
1	Temozolomide	investigations		investigations
2	Veliparib (ABT-888) or placebo	investigations		investigations

Reasons come from the CTCAE book. "Other, not per protocol" is a choice.

CYCLES – ADVERSE EVENTS

Page: **Adverse Events: Solicited - Treatment 03: Enzalutamatide alone 07-May-2014**

Cycle: 3

Reporting period end date: 03 Jun 2014

SOLICITED ADVERSE EVENTS

#	Adverse event term (v4.0)	MedDRA AE code (CTCAE v4.0)	Adverse event not evaluated	Adverse event grade	Adverse event grade description	AE attribution *(if grade > 0)*	Has an adverse event expedited report been submitted?
1	Fatigue	10016256	☐	1	Fatigue relieved by rest	Probable	No
2	Diarrhea	10012727	☐	0	None		No
3	Constipation	10010774	☐	1	Occasional or intermittent symptoms; occasional use of stool softeners, laxatives, dietary modification, or enema	Unlikely	No
4	Vomiting	10047700	☐	0	None		No
5	Dyspepsia	10013946	☐	1	Mild symptoms; intervention not indicated	Unrelated	No
6	Edema limbs	10050068	☐	0	None		No
7	Arthralgia	10003239	☐	1	Mild pain	Unlikely	No
8	Bone pain	10006002	☐	0	None		No
9	Myalgia	10028411	☐	0	None		No
10	Headache	10019211	☐	0	None		No
11	Insomnia	10022437	☐	0	None		No
12	Hot flashes	10020407	☐	2	Moderate symptoms; limiting instrumental ADL	Possible	No
13	Hypertension	10020772	☐	0	None		No
14	Cough	10011224	☐	0	None		No
15	Dyspnea	10013963	☐	0	None		No
16	Hyperglycemia	10020639	☐	1	Fasting glucose value >ULN - 160 mg/dL; Fasting glucose value >ULN - 8.9 mmol/L	Unrelated	No
17	Hypokalemia	10021018	☐	0	None		No
18	Alanine aminotransferase increased	10001551	☐	0	None		No
19	Aspartate aminotransferase increased	10003481	☐	0	None		No
20	Blood bilirubin increased	10005364	☐	0	None		No

Were *(other)* adverse events assessed during most recent period? Yes, but no reportable adverse events occurred

Comments

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Solicited AEs will be listed. If event was evaluated but not present, record a grade 0. Enter attribution and answer whether an expedited report was done.

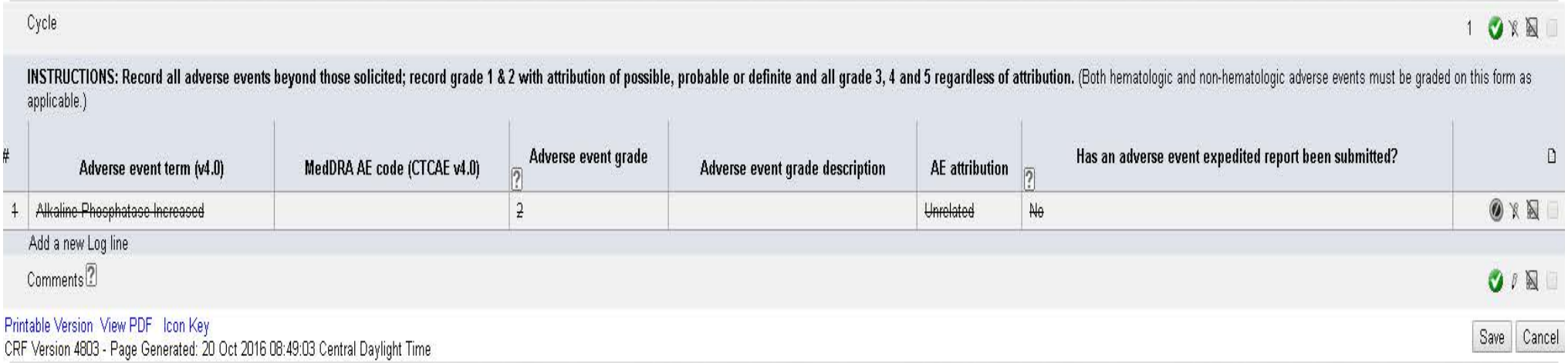
Were (other) AE's assessed?

- Yes, but no reportable events occurred
- Yes, and reportable events occurred
- No

Start and stop dates?

CYCLES – OTHER ADVERSE EVENTS

- Log line to add each additional AE. It will ask all the same questions as the solicited AE form.



Cycle 1

INSTRUCTIONS: Record all adverse events beyond those solicited; record grade 1 & 2 with attribution of possible, probable or definite and all grade 3, 4 and 5 regardless of attribution. (Both hematologic and non-hematologic adverse events must be graded on this form as applicable.)

#	Adverse event term (v4.0)	MedDRA AE code (CTCAE v4.0)	Adverse event grade	Adverse event grade description	AE attribution	Has an adverse event expedited report been submitted?
1	~~Alkaline Phosphatase Increased~~		~~2~~		~~Unrelated~~	~~No~~

Add a new Log line

Comments

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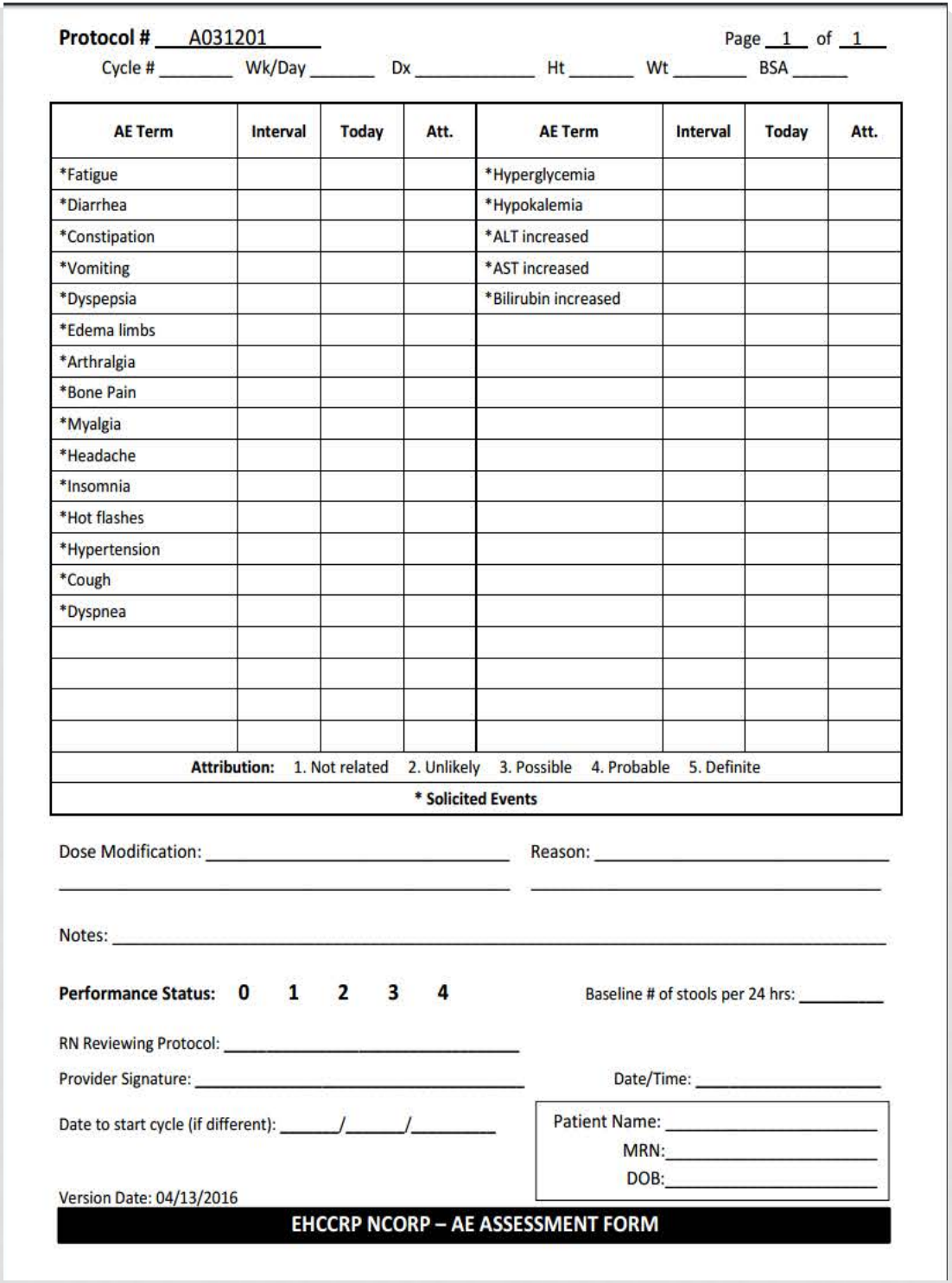
Read the instructions!
Otherwise you may have to "inactive" lines.

- Each study may have it's own set of solicited AEs
- To make sure we capture them we use study specific AE assessment forms at my site



Protocol # A031201 Page 1 of 1

Cycle # _____ Wk/Day _____ Dx _____ Ht _____ Wt _____ BSA _____

AE Term	Interval	Today	Att.	AE Term	Interval	Today	Att.
*Fatigue				*Hyperglycemia			
*Diarrhea				*Hypokalemia			
*Constipation				*ALT increased			
*Vomiting				*AST increased			
*Dyspepsia				*Bilirubin increased			
*Edema limbs							
*Arthralgia							
*Bone Pain							
*Myalgia							
*Headache							
*Insomnia							
*Hot flashes							
*Hypertension							
*Cough							
*Dyspnea							

Attribution: 1. Not related 2. Unlikely 3. Possible 4. Probable 5. Definite

*** Solicited Events**

Dose Modification: _____ Reason: _____

_____ _____

Notes: _____

Performance Status: 0 1 2 3 4 Baseline # of stools per 24 hrs: _____

RN Reviewing Protocol: _____

Provider Signature: _____ Date/Time: _____

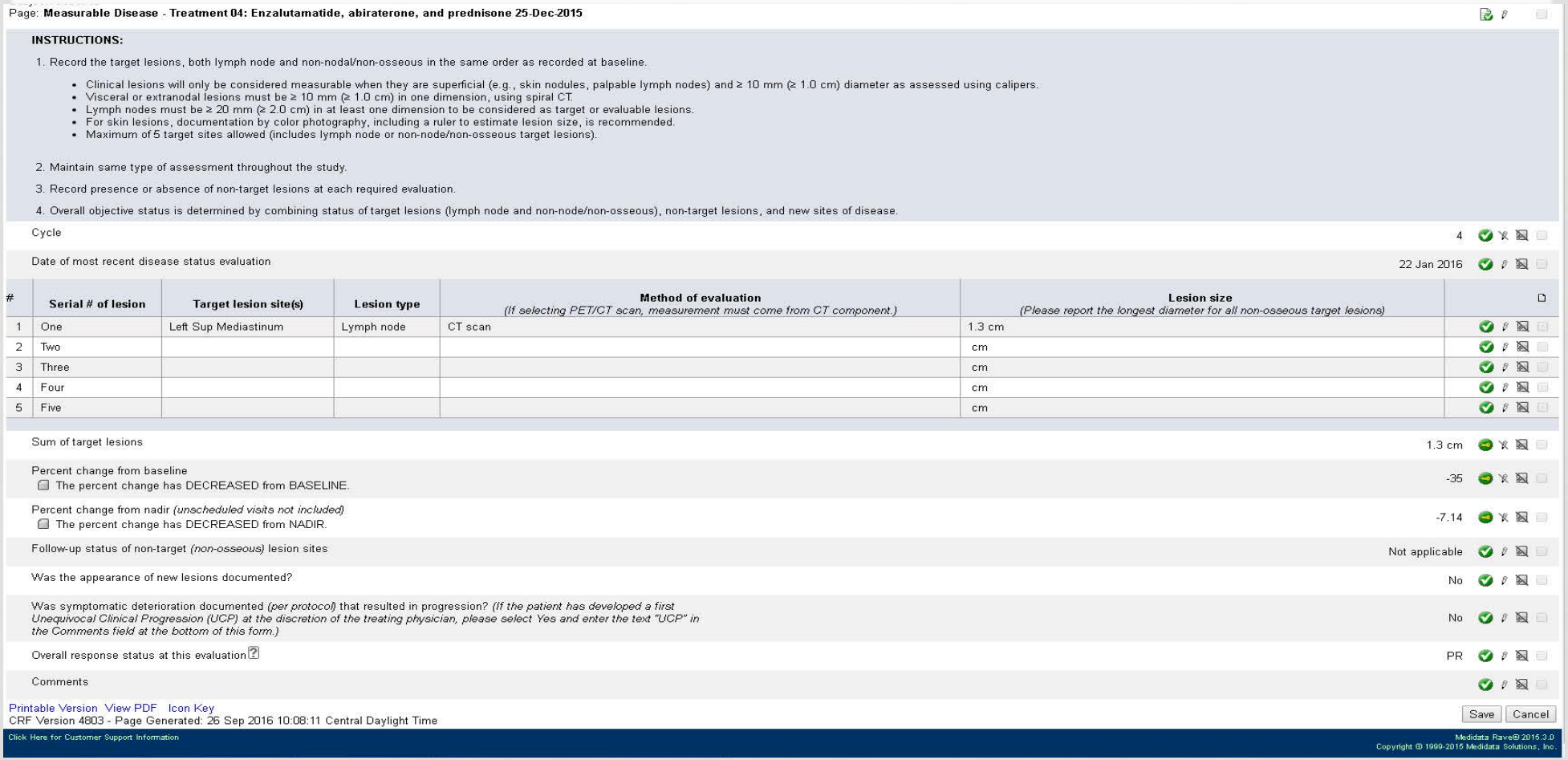
Date to start cycle (if different): _____/_____/_____

Patient Name: _____
MRN: _____
DOB: _____

Version Date: 04/13/2016

EHCCRP NCORP – AE ASSESSMENT FORM

CYCLES – RECIST MEASUREMENTS



Page: **Measurable Disease - Treatment 04: Enzalutamatide, abiraterone, and prednisone 25-Dec-2015**

INSTRUCTIONS:

1. Record the target lesions, both lymph node and non-nodal/non-osseous in the same order as recorded at baseline.
   - Clinical lesions will only be considered measurable when they are superficial (e.g., skin nodules, palpable lymph nodes) and ≥ 10 mm (≥ 1.0 cm) diameter as assessed using calipers.
   - Visceral or extranodal lesions must be ≥ 10 mm (≥ 1.0 cm) in one dimension, using spiral CT.
   - Lymph nodes must be ≥ 20 mm (≥ 2.0 cm) in at least one dimension to be considered as target or evaluable lesions.
   - For skin lesions, documentation by color photography, including a ruler to estimate lesion size, is recommended.
   - Maximum of 5 target sites allowed (includes lymph node or non-node/non-osseous target lesions).
2. Maintain same type of assessment throughout the study.
3. Record presence or absence of non-target lesions at each required evaluation.
4. Overall objective status is determined by combining status of target lesions (lymph node and non-node/non-osseous), non-target lesions, and new sites of disease.

Cycle: 4

Date of most recent disease status evaluation: 22 Jan 2016

#	Serial # of lesion	Target lesion site(s)	Lesion type	Method of evaluation *(If selecting PET/CT scan, measurement must come from CT component.)*	Lesion size *(Please report the longest diameter for all non-osseous target lesions)*
1	One	Left Sup Mediastinum	Lymph node	CT scan	1.3 cm
2	Two				cm
3	Three				cm
4	Four				cm
5	Five				cm

Sum of target lesions: 1.3 cm

Percent change from baseline
☐ The percent change has DECREASED from BASELINE.: -35

Percent change from nadir *(unscheduled visits not included)*
☐ The percent change has DECREASED from NADIR.: -7.14

Follow-up status of non-target *(non-osseous)* lesion sites: Not applicable

Was the appearance of new lesions documented?: No

Was symptomatic deterioration documented *(per protocol)* that resulted in progression? *(If the patient has developed a first Unequivocal Clinical Progression (UCP) at the discretion of the treating physician, please select Yes and enter the text "UCP" in the Comments field at the bottom of this form.)*: No

Overall response status at this evaluation: PR

Comments

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Click Here for Customer Support Information

The form will ask the status of non-target lesions and for overall response. Report lesions in the SAME order as at baseline. Some fields will automatically populate for you.

CYCLES – PATIENT STATUS

age: **Patient Status: Treatment (Intervention) - Treatment 04: Enzalutamatide, abiraterone, and prednisone 25-Dec-2015**

Cycle	4
SURVIVAL STATUS	
Participant vital status	Alive
Date of most recent contact	22 Jan 2016
Death date	
Cause of death	
If other cause of death, specify	
DISEASE STATUS	
Was disease status evaluated during this reporting period?	Yes
(If yes), date of most recent disease status evaluation	22 Jan 2016
(If yes), was a scan for soft tissue lesions performed?	Yes
(If yes), was a bone scan performed?	Yes
(If yes), has the patient developed first soft tissue relapse/progression or confirmed bone progression *(unequivocal clinical progression, soft tissue relapse/progression, or confirmed bone progression)* that has previously not been reported? *(Notes:* • *If first soft tissue relapse occurs at Week 9 scan, it needs to be confirmed.* • *Unequivocal Clinical Progression (UCPs) are at the discretion of the treating physician; if reporting a UCP please also enter "UCP" in the Comments field at the bottom of this form.* • *If patient experienced more than one form of progression during this reporting period, please report below the date of the earliest progression.)*	No
Date of progression *(or relapse)*	
PROTOCOL TREATMENT	
What protocol treatment (intervention) will the patient receive in the subsequent cycle?	Enzalutamatide, abiraterone, and prednisone
PRO/QOL ASSESSMENT(S)	
Did the participant complete the assessment *(Population Pharmacokinetics Questionnaire)*?	Yes
(If yes), date completed	24 Dec 2015
CONCOMITANT MEDICATIONS	
If there are any new concomitant medications or changes to existing concomitant medications, please report on Concomitant Medications CRF.	
Comments	

CYCLES

- May also have to upload supporting documentation at each time point:
  - Imaging, pathology
  - Make sure PHI is removed. Write study, patient ID, and initials
- Lab results – again watch units, ULN, LLN
- Specimen submission
  - How many samples, if not collected, why, date/time collected, date shipped.

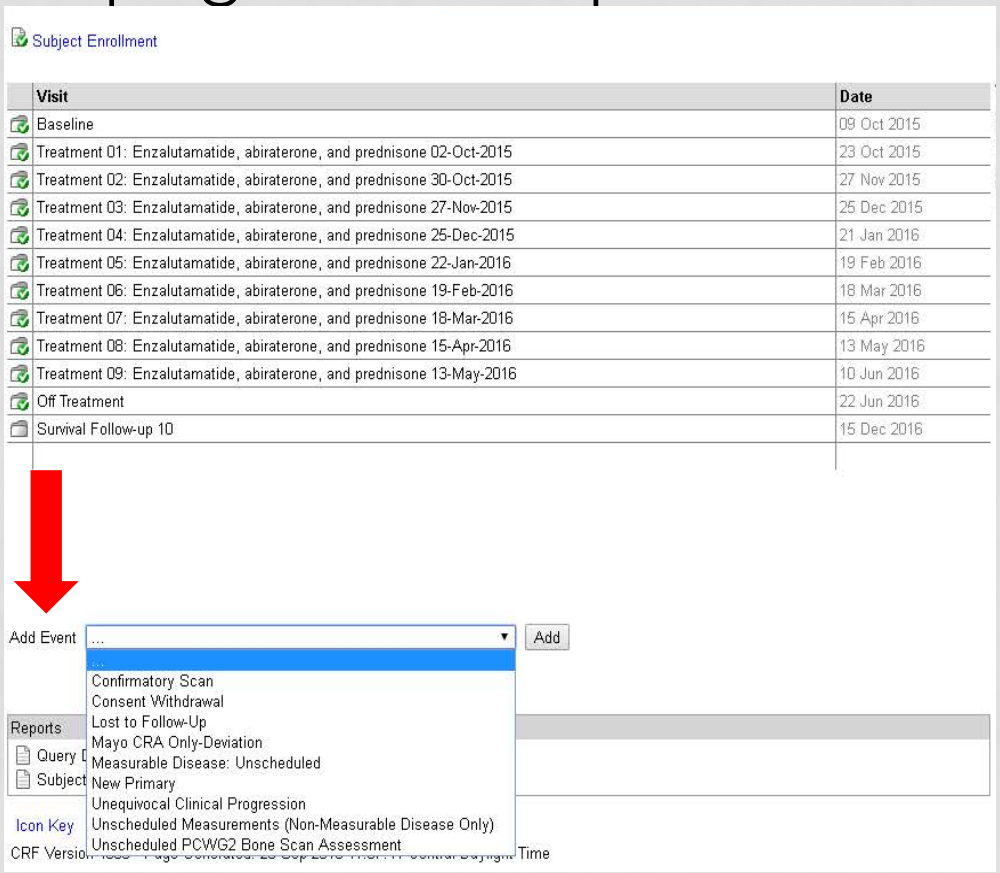
OFF TREATMENT

This form will roll out when you select “none” for what treatment will the patient receive next cycle on the Patient Status form.

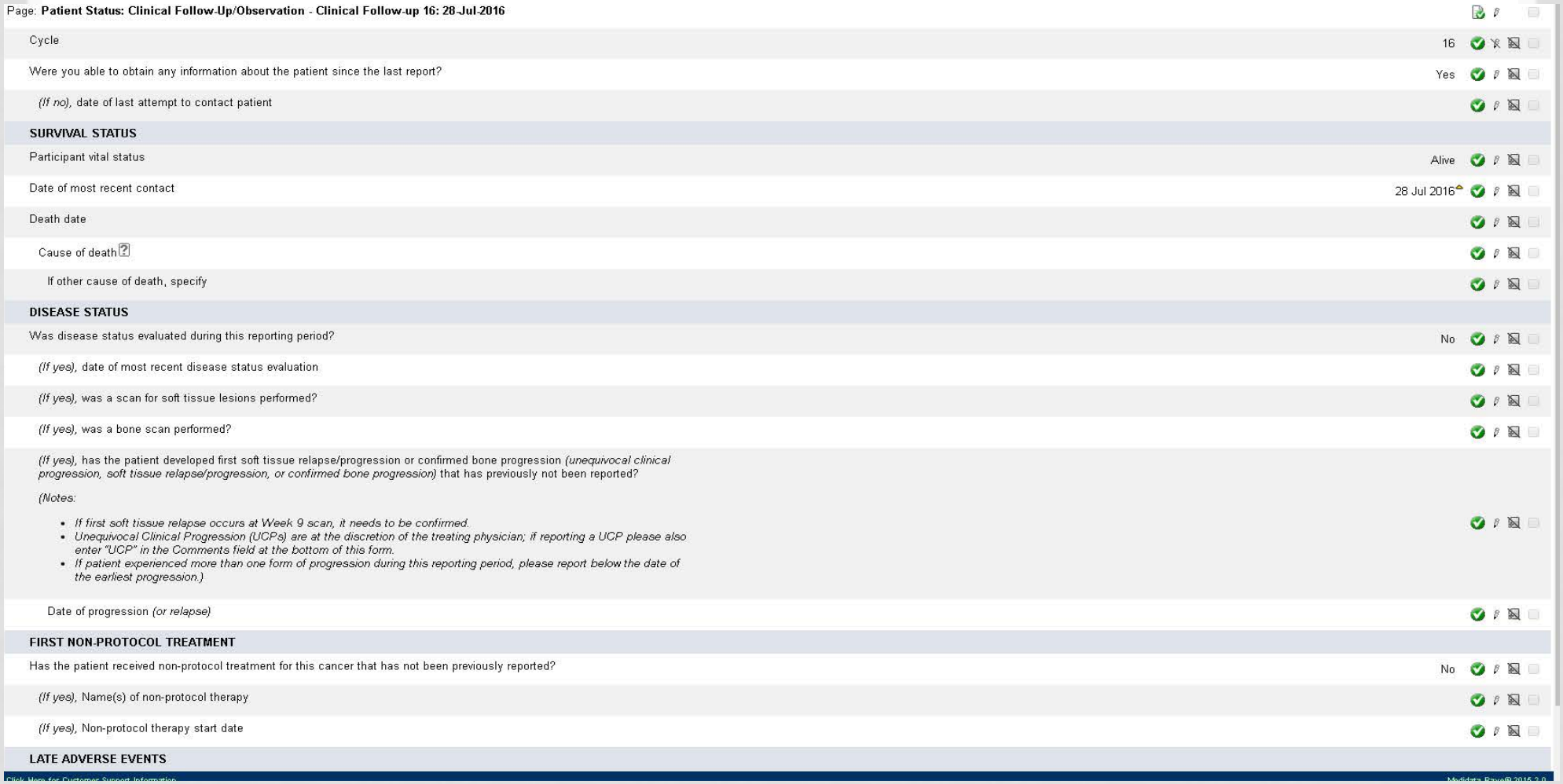
Be as specific as possible for the “off treatment” reason – select from the drop down box.

ADD EVENTS

- If something happens but there doesn't appear to be a form in Rave, check the "Add Event" drop down box on the home page of each patient.
  - Second primary
  - Lost to follow up



FOLLOW UP FORMS



Page: **Patient Status: Clinical Follow-Up/Observation - Clinical Follow-up 16: 28-Jul-2016**

Cycle	16
Were you able to obtain any information about the patient since the last report?	Yes
(If no), date of last attempt to contact patient	
SURVIVAL STATUS	
Participant vital status	Alive
Date of most recent contact	28 Jul 2016
Death date	
Cause of death	
If other cause of death, specify	
DISEASE STATUS	
Was disease status evaluated during this reporting period?	No
(If yes), date of most recent disease status evaluation	
(If yes), was a scan for soft tissue lesions performed?	
(If yes), was a bone scan performed?	
(If yes), has the patient developed first soft tissue relapse/progression or confirmed bone progression *(unequivocal clinical progression, soft tissue relapse/progression, or confirmed bone progression)* that has previously not been reported? *(Notes:* • *If first soft tissue relapse occurs at Week 9 scan, it needs to be confirmed.* • *Unequivocal Clinical Progression (UCPs) are at the discretion of the treating physician; if reporting a UCP please also enter "UCP" in the Comments field at the bottom of this form.* • *If patient experienced more than one form of progression during this reporting period, please report below the date of the earliest progression.)*	
Date of progression *(or relapse)*	
FIRST NON-PROTOCOL TREATMENT	
Has the patient received non-protocol treatment for this cancer that has not been previously reported?	No
(If yes), Name(s) of non-protocol therapy	
(If yes), Non-protocol therapy start date	
LATE ADVERSE EVENTS	

Note: If a patient's last follow up is due on 12/31/2016 and you submit the forms with a contact date of 12/30/2016, Rave will automatically add an additional form


QUESTIONS
?