

HELPFUL TIPS & COMMON ERRORS



DATA MANAGEMENT

ALLIANCE FALL MEETING 2016

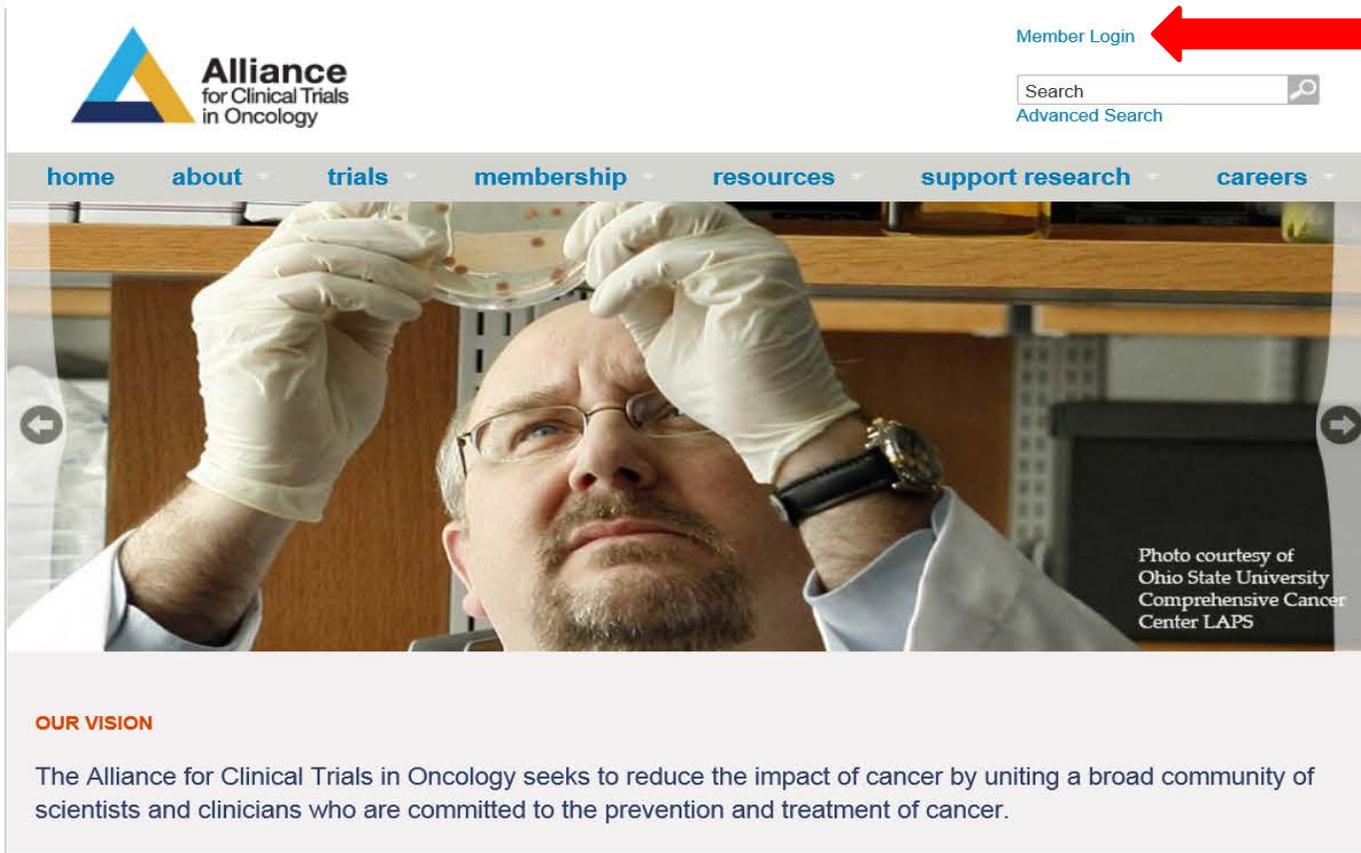


QUESTIONS? CONTACT KRISTIN HONER
KRISTIN.HONER@ESSENTIAHEALTH.ORG
OR THE ALLIANCE STATISTICAL & DATA CENTER

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



Alliance
for Clinical Trials
in Oncology

Member Login

Search
Advanced Search

home about trials membership resources support research careers

Photo courtesy of
Ohio State University
Comprehensive Cancer
Center LAPS

OUR VISION

The Alliance for Clinical Trials in Oncology seeks to reduce the impact of cancer by uniting a broad community of scientists and clinicians who are committed to the prevention and treatment of cancer.

- 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



Access to the Alliance Member website requires a valid CTEP IAM ID and membership on the [Alliance](#) roster. Please consult the [IAM documentation](#) for more information.

Username:

Password:



You are accessing a U.S. Government information system, which includes (1) this computer, (2) this computer network, (3) all computers connected to this network, and (4) all devices and storage media attached to this network or to a computer on this network. This information system is provided for U.S. Government-authorized use only.

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Use your
CTSU login

TELEFORMS

Search by
protocol listing

The screenshot shows the website for the Alliance for Clinical Trials in Oncology. At the top left is the logo, a stylized triangle with blue and yellow sections, followed by the text "Alliance for Clinical Trials in Oncology". At the top right, it says "Kristin Honer(log out)" and "Back to the Public Pages". Below this is a search bar with the text "Search" and a magnifying glass icon, with a link to "Advanced Search" underneath. A horizontal navigation bar contains the following items: "home", "protocols", "committees", "education & training", "member services", and "news". A vertical dropdown menu is open under "protocols", listing: "protocol listing", "legacy intergroup studies", "aft protocols", "concept submission", "study summaries", "publications", and "biospecimen management system". The "protocol listing" item is highlighted with a blue background. To the right of the dropdown menu, there is a blue banner with a blurred image. Below the banner, there is a section titled "Quick Links" with a list of links: "Alliance Directory", "Author Abstract Deadlines", "Audit Resources", "Bibliography (Alliance Publications)", and "BioMS". There is also a "Statistician" section with a partial view of a text block starting with "a profound sadness that I write to inform you...".

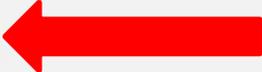
TELEFORMS

Pick the disease site

[Home](#) > [Protocol Listing](#)

PROTOCOL LISTING

Disease

- [Breast](#)
- [Gastrointestinal \(GI\)](#) 
- [Genitourinary \(GU\)](#)
- [Leukemia](#)
- [Leukemia Correlative Science \(LCSC\)](#)
- [Lymphoma](#)
- [Myeloma](#)
- [Neuro-Oncology](#)
- [Respiratory](#)
- [Transplant](#)

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”

CALGB 80702

[Home](#) > [Protocol Listing](#) > [Gastrointestinal \(GI\)](#) > [CALGB 80702](#)

CALGB 80702

Title: A Phase III Trial of 6 Versus 12 Treatments of Adjuvant FOLFOX Plus Celecoxib or Placebo for Patients with Resected Stage III Colon Cancer

Study Chair: [Jeffrey A. Meyerhardt, MD, MPH](#)

Activation Date: 06/15/2010

Closure Date: 11/20/2015

Status: **Closed**

80702 [Protocol Document](#) - 09/15/2016

80702 Model Consent Form ([word](#)) or ([pdf](#)) - 09/15/2016

The Alliance website hosts the most up-to-date versions of all Alliance protocol materials. For additional materials prepared by CTSU, please click [here](#).

[CALGB 80702](#)

[All Documents](#)

[Updates and Action Letters](#)

[Replacement Pages](#)

[Funding Sheet](#)

[Case Report Forms](#)

[Memoranda and
Broadcasts](#)

[Supplemental Materials](#)

[DSMB Statement and
Study Summary](#)

[Drug Safety Notifications](#)

[Oxaliplatin](#)



TELEFORMS

CALGB 80702

Home > Protocol Listing > Gastrointestinal (GI) > CALGB 80702 > Case Report Forms

Case Report Forms

	Form #	Version	Form Name
CALGB 80702	80702	---	All Forms For 80702
All Documents	80702	1.0	CALGB: OPEN Registration For 80702
Updates and Action Letters			
Replacement Pages	---	1.0	CALGB: Patient Race and Ethnicity Form
Funding Sheet	C-1953	4.0	CALGB: 80702 On-Study Form (TeleForm)
Case Report Forms	C-1954	1.0	CALGB: 80702 Treatment Form (TeleForm)
Memoranda and Broadcasts	C-1955	4.0	CALGB: 80702 Adverse Event Form
Supplemental Materials	C-1956	3.0	CALGB: 80702 Follow-up Form
DSMB Statement and Study Summary	S-067	1.0	CALGB: 80702 Medication Calendar (TeleForm)
Drug Safety Notifications			
Oxaliplatin	C-113	5.0	CALGB: Notification of Death Form
	C-1742	5.0	CALGB: Confirmation of Lost to Follow-up Form

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

SUBMITTING TELEFORMS


CALGB: 80702 TREATMENT FORM

64369

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.
 CALGB Patient ID
 Date of first dose for this reporting period / /
 Reporting period end date / /
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) m²

Agent	Agent total dose	Were there any dose modifications or additions/omissions to protocol treatment? (Mark one with an X.)
5-FU Bolus	<input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> mg	<input type="checkbox"/> No <input type="checkbox"/> Yes, planned <input type="checkbox"/> Yes, unplanned
5-FU Infusion	<input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> mg	<input type="checkbox"/> No <input type="checkbox"/> Yes, planned <input type="checkbox"/> Yes, unplanned
Oxaliplatin	<input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> mg	<input type="checkbox"/> No <input type="checkbox"/> Yes, planned <input type="checkbox"/> Yes, unplanned
Celecoxib/Placebo	<input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> mg	<input type="checkbox"/> No <input type="checkbox"/> Yes, planned <input type="checkbox"/> 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.)

<input type="checkbox"/> Treatment completed per protocol criteria	<input type="checkbox"/> Patient withdrawal/refusal after beginning protocol therapy
<input type="checkbox"/> Disease progression, relapse during active treatment	<input type="checkbox"/> Patient withdrawal/refusal prior to beginning protocol therapy
<input type="checkbox"/> Adverse event/side effects/complications	<input type="checkbox"/> Alternative therapy
<input type="checkbox"/> Death on study	<input type="checkbox"/> Patient off-treatment for other complicating disease
<input type="checkbox"/> Other, specify: <input type="text" value=""/>	

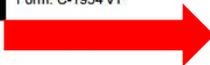
Did the patient receive any ancillary therapy during this reporting period? No Yes, specify:

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



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:	██████████

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 not 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

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.

8	0	7	0	2
---	---	---	---	---

CALGB Patient ID

--	--	--	--	--	--	--	--

Date of first dose for this reporting period

--	--

 /

--	--

 /

--	--	--	--

Reporting period end date

--	--

 /

--	--

 /

--	--	--	--

M M D D Y Y Y Y

Are data amended? Yes



DATA SUBMISSION SCHEDULE



Kristin Honer (log out)
Back to the Public Pages
Search
Advanced Search

[home](#) [protocols](#) [committees](#) [education & training](#) [member services](#) [news](#)

A031102

Home > Protocol Listing > Genitourinary (GU) > A031102 > Case Report Forms



Case Report Forms

- [A031102 All Forms - 09/01/2016](#)
- [A031102 OPEN Enrollment Form - Step 1 - 08/15/2015](#)
- [A031102 Data Submission Schedule](#) ←

[A031102](#)

[All Documents](#)

[Updates and Action Letters](#)

[Funding Sheet](#)

[Case Report Forms](#) ←

[DSMB Statement and Study Summary](#)

[disclaimer](#) [site map](#) [contact us](#)

- 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

medidata



iMedidata now offers two-factor authentication as an additional security enhancement. Click here to learn more.

Apps

- RAVE EDC
- ECOG-ACRIN SWOG
- Mayo Clinic (Mayo)

Studies (18)

A031201	Rave EDC
A041202	Rave EDC
A151216	Rave EDC

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

The screenshot shows the RAVE interface with a search bar at the top. Below the search bar is a list of studies. On the right side, there is a 'Tasks' sidebar with a sub-section for 'Invitations (56)'. A red arrow points to the 'Join A071101' invitation in this list.

Study ID	Action
Join Z11102	accept decline
Join AHOD1221	accept decline
Join A071101	accept decline
Join E2511	accept decline
Join ANBL1221	accept decline
Join A021202	accept decline
Join RTOG-1216	accept decline
Join ANBL12P1	accept decline
Join RTOG-1201	accept decline
Join RTOG-1306	accept decline
Join S1207	accept decline
Join A091201	accept decline
Join E1Z11	accept decline

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

HOW PATIENTS ARE SET UP

Visit	Date	Task Summary: Subject
Baseline	02 Sep 2014	<ul style="list-style-type: none"> NonConformant Data Open Queries Sticky Notes Overdue Data
Treatment 01: Neoadjuvant endocrine therapy (Anastrozole and/or Fulvestrant) 26-Aug-2014	16 Sep 2014	
Treatment 02: Neoadjuvant endocrine therapy (Anastrozole and/or Fulvestrant) 23-Sep-2014	21 Oct 2014	
Treatment 03: Neoadjuvant endocrine therapy (Anastrozole and/or Fulvestrant) 21-Oct-2014	18 Nov 2014	
Treatment 04: Neoadjuvant endocrine therapy (Anastrozole and/or Fulvestrant) 18-Nov-2014	16 Dec 2014	
Treatment 05: Neoadjuvant endocrine therapy (Anastrozole and/or Fulvestrant) 16-Dec-2014	13 Jan 2015	
Treatment 06: Neoadjuvant endocrine therapy (Anastrozole and/or Fulvestrant) 13-Jan-2015	10 Feb 2015	
Treatment 07: Discontinue/completed neoadjuvant treatment, proceeding to surgery	12 Apr 2015	
Off Treatment	22 Apr 2015	
Clinical Follow-up 08: 15-Apr-2015	14 Jul 2015	
Clinical Follow-up 09: 16-Jul-2015	13 Oct 2015	
Clinical Follow-up 10: 29-Sep-2015	28 Dec 2015	
Clinical Follow-up 11: 30-Mar-2016	29 Mar 2016	
Clinical Follow-up 12: No Contact	28 Jun 2016	
Clinical Follow-up 13	26 Sep 2016	



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	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
2	Absolute Neutrophil Count (ANC), Blood	Yes	4 Mar 2014	3100	/uL	8500	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
3	Platelets, Blood	Yes	4 Mar 2014	174	10 ³ /uL	400	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
4	Hemoglobin, Blood	Yes	4 Mar 2014	13.9	g/dL	17	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
5	Creatinine, Blood	Yes	4 Mar 2014	0.97	mg/dL	1.2	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
6	Bilirubin, Total, Serum	Yes	4 Mar 2014	0.7	mg/dL	1.4	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
7	Aspartate Aminotransferase (AST or SGOT), Serum	Yes	4 Mar 2014	25	U/L	40	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
8	Alanine Aminotransferase (ALT or SGPT), Serum	Yes	4 Mar 2014	42	U/L	40	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
9	Albumin, Serum	Yes	4 Mar 2014	3.7	g/dL	5.0	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
10	Testosterone, Total, Serum	Yes	4 Mar 2014	7.0	ng/dL	960	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
11	Alkaline Phosphatase, Serum	Yes	4 Mar 2014	531	U/L	150	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
12	Glucose, Serum	Yes	4 Mar 2014	103	mg/dL	99	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
13	Potassium, Serum	Yes	4 Mar 2014	4.2	mmol/L	5.1	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
14	Lactate Dehydrogenase (LDH), Serum	No			U/L		<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
15	Sodium, Serum	Yes	4 Mar 2014	140	mmol/L	143	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

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

Printable Version View PDF Icon Key
 CRF Version 4803 - Page Generated: 26 Sep 2016 08:44:37 Central Daylight Time

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

[Printable Version](#) [View PDF](#) [Icon Key](#)

CRF Version 4803 - Page Generated: 26 Sep 2016 08:36:57 Central Daylight Time

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	<input type="checkbox"/>	2	Fatigue not relieved by rest; limiting instrumental ADL	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
2	Diarrhea	10012727	<input type="checkbox"/>	0	None	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
3	Constipation	10010774	<input type="checkbox"/>	0	None	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
4	Vomiting	10047700	<input type="checkbox"/>	0	None	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
5	Dyspepsia	10013946	<input type="checkbox"/>	0	None	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
6	Edema limbs	10050068	<input type="checkbox"/>	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	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
7	Arthralgia	10003239	<input type="checkbox"/>	0	None	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
8	Bone pain	10006002	<input type="checkbox"/>	0	None	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
9	Myalgia	10028411	<input type="checkbox"/>	0	None	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
10	Headache	10019211	<input type="checkbox"/>	0	None	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
11	Insomnia	10022437	<input type="checkbox"/>	0	None	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
12	Hot flashes	10020407	<input type="checkbox"/>	0	None	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
13	Hypertension	10020772	<input type="checkbox"/>	0	None	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
14	Cough	10011224	<input type="checkbox"/>	0	None	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
15	Dyspnea	10013963	<input type="checkbox"/>	0	None	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
16	Hyperglycemia	10020639	<input type="checkbox"/>	1	Fasting glucose value >ULN - 160 mg/dL; Fasting glucose value >ULN - 8.9 mmol/L	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
17	Hypokalemia	10021018	<input type="checkbox"/>	0	None	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
18	Alanine aminotransferase increased	10001551	<input type="checkbox"/>	0	None	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
19	Aspartate aminotransferase increased	10003481	<input type="checkbox"/>	0	None	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
20	Blood bilirubin increased	10005364	<input type="checkbox"/>	0	None	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

Comments

Printable Version View PDF Icon Key
 CRF Version 4803 - Page Generated: 26 Sep 2016 08:51:32 Central Daylight Time

Save Cancel

Click Here for Customer Support Information

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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:

- 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).
- Maintain same type of assessment throughout the study.
- 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 <i>(If selecting PET/CT scan, measurement must come from CT component.)</i>	Lesion size <i>(Please report the longest diameter for all non-osseous target lesions)</i>	
1	One	Left Sup Mediastinum	Lymph node	CT scan	2.0 cm	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
2	Two				cm	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
3	Three				cm	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
4	Four				cm	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
5	Five				cm	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

Sum of target lesions: 2 cm

Non-target (non-osseous) lesions present: No

Comments:

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METASTATIC SITE(S)

Nodal

Liver

Bone

Lung

Other

Other specify

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

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

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

#	Serial # of Supporting Documentation	Date of assessment	Report type	Specify report type	Attachment <small>(max file size 10 MB)</small>	
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

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	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
2	Whole blood (PAXgene)	Yes			2	09 Mar 2015	10 Mar 2015	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
3	Plasma EDTA (lavender)	Yes			4	09 Mar 2015	10 Mar 2015	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
4	Plasma Citrate (light blue)	Yes			5	09 Mar 2015	10 Mar 2015	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
5	Whole Blood EDTA (lavender)	Yes			2	09 Mar 2015	09 Mar 2015	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
6	Plasma (lavender)	Yes			1	09 Mar 2015	10 Mar 2015	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

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?	Enzalutamide, 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 <u>WILL</u> proceed to the first cycle of protocol treatment, do <u>NOT</u> 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: Enzalutamide, 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	<input type="checkbox"/>	160	mg	4480	mg	No	12 Mar 2015	08 Apr 2015	  
2	Abiraterone	<input type="checkbox"/>	1000	mg	28000	mg	No	12 Mar 2015	08 Apr 2015	  
3	Prednisone	<input type="checkbox"/>	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: Enzalutamide 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	<input type="checkbox"/>	1	Fatigue relieved by rest	Probable	No	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2	Diarrhea	10012727	<input type="checkbox"/>	0	None		No	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3	Constipation	10010774	<input type="checkbox"/>	1	Occasional or intermittent symptoms; occasional use of stool softeners, laxatives, dietary modification, or enema	Unlikely	No	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4	Vomiting	10047700	<input type="checkbox"/>	0	None		No	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5	Dyspepsia	10013946	<input type="checkbox"/>	1	Mild symptoms; intervention not indicated	Unrelated	No	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6	Edema limbs	10050068	<input type="checkbox"/>	0	None		No	<input checked="" type="checkbox"/>	<input type="checkbox"/>
7	Arthralgia	10003239	<input type="checkbox"/>	1	Mild pain	Unlikely	No	<input checked="" type="checkbox"/>	<input type="checkbox"/>
8	Bone pain	10006002	<input type="checkbox"/>	0	None		No	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9	Myalgia	10028411	<input type="checkbox"/>	0	None		No	<input checked="" type="checkbox"/>	<input type="checkbox"/>
10	Headache	10019211	<input type="checkbox"/>	0	None		No	<input checked="" type="checkbox"/>	<input type="checkbox"/>
11	Insomnia	10022437	<input type="checkbox"/>	0	None		No	<input checked="" type="checkbox"/>	<input type="checkbox"/>
12	Hot flashes	10020407	<input type="checkbox"/>	2	Moderate symptoms; limiting instrumental ADL	Possible	No	<input checked="" type="checkbox"/>	<input type="checkbox"/>
13	Hypertension	10020772	<input type="checkbox"/>	0	None		No	<input checked="" type="checkbox"/>	<input type="checkbox"/>
14	Cough	10011224	<input type="checkbox"/>	0	None		No	<input checked="" type="checkbox"/>	<input type="checkbox"/>
15	Dyspnea	10013963	<input type="checkbox"/>	0	None		No	<input checked="" type="checkbox"/>	<input type="checkbox"/>
16	Hyperglycemia	10020639	<input type="checkbox"/>	1	Fasting glucose value >ULN - 160 mg/dL; Fasting glucose value >ULN - 8.9 mmol/L	Unrelated	No	<input checked="" type="checkbox"/>	<input type="checkbox"/>
17	Hypokalemia	10021018	<input type="checkbox"/>	0	None		No	<input checked="" type="checkbox"/>	<input type="checkbox"/>
18	Alanine aminotransferase increased	10001551	<input type="checkbox"/>	0	None		No	<input checked="" type="checkbox"/>	<input type="checkbox"/>
19	Aspartate aminotransferase increased	10003481	<input type="checkbox"/>	0	None		No	<input checked="" type="checkbox"/>	<input type="checkbox"/>
20	Blood bilirubin increased	10005364	<input type="checkbox"/>	0	None		No	<input checked="" type="checkbox"/>	<input type="checkbox"/>

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?
4	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.

CYCLES - RECIST MEASUREMENTS

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

INSTRUCTIONS:

- 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).
- Maintain same type of assessment throughout the study.
- Record presence or absence of non-target lesions at each required evaluation.
- 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 <i>(if selecting PET/CT scan, measurement must come from CT component.)</i>	Lesion size <i>(Please report the longest diameter for all non-osseous target lesions)</i>	<input type="checkbox"/>
1	One	Left Sup Mediastinum	Lymph node	CT scan	1.3 cm	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
2	Two				cm	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
3	Three				cm	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
4	Four				cm	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
5	Five				cm	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

Sum of target lesions 1.3 cm

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

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

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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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

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

Cycle	4	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SURVIVAL STATUS					
Participant vital status	Alive	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Date of most recent contact	22 Jan 2016	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Death date		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cause of death [?]		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If other cause of death, specify		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DISEASE STATUS					
Was disease status evaluated during this reporting period?	Yes	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(If yes), date of most recent disease status evaluation	22 Jan 2016	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(If yes), was a scan for soft tissue lesions performed?	Yes	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(If yes), was a bone scan performed?	Yes	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(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? <i>(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.)</i>	No	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Date of progression (or relapse)		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PROTOCOL TREATMENT					
What protocol treatment (intervention) will the patient receive in the subsequent cycle? [?]	Enzalutamatide, abiraterone, and prednisone	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PRO/QOL ASSESSMENT(S)					
Did the participant complete the assessment (Population Pharmacokinetics Questionnaire)?		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(If yes), date completed	24 Dec 2015	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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

Page: Off Treatment - Off Treatment



Last date protocol treatment/intervention (any modality) given?

26 Aug 2014



Off treatment (intervention) date?

27 Aug 2014



Off treatment (intervention) reason

Disease Progression, Relapse During Active Treatment (Intervention)



Off treatment (intervention) reason other, specify?



Comments?



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Save

Cancel

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

The screenshot displays the 'Subject Enrollment' page in the Rave system. It features a table with two columns: 'Visit' and 'Date'. The table lists various visits from Baseline to Survival Follow-up 10. Below the table, a red arrow points to the 'Add Event' dropdown menu, which is open and showing a list of event options. The 'Add' button is visible to the right of the dropdown.

Visit	Date
Baseline	09 Oct 2015
Treatment 01: Enzalutamatide, abiraterone, and prednisone	02-Oct-2015
Treatment 02: Enzalutamatide, abiraterone, and prednisone	30-Oct-2015
Treatment 03: Enzalutamatide, abiraterone, and prednisone	27-Nov-2015
Treatment 04: Enzalutamatide, abiraterone, and prednisone	25-Dec-2015
Treatment 05: Enzalutamatide, abiraterone, and prednisone	22-Jan-2016
Treatment 06: Enzalutamatide, abiraterone, and prednisone	19-Feb-2016
Treatment 07: Enzalutamatide, abiraterone, and prednisone	18-Mar-2016
Treatment 08: Enzalutamatide, abiraterone, and prednisone	15-Apr-2016
Treatment 09: Enzalutamatide, abiraterone, and prednisone	13-May-2016
Off Treatment	10-Jun-2016
Survival Follow-up 10	22-Jun-2016
	15-Dec-2016

Subject Enrollment

Visit Date

Baseline 09 Oct 2015

Treatment 01: Enzalutamatide, abiraterone, and prednisone 02-Oct-2015 23 Oct 2015

Treatment 02: Enzalutamatide, abiraterone, and prednisone 30-Oct-2015 27 Nov 2015

Treatment 03: Enzalutamatide, abiraterone, and prednisone 27-Nov-2015 25 Dec 2015

Treatment 04: Enzalutamatide, abiraterone, and prednisone 25-Dec-2015 21 Jan 2016

Treatment 05: Enzalutamatide, abiraterone, and prednisone 22-Jan-2016 19 Feb 2016

Treatment 06: Enzalutamatide, abiraterone, and prednisone 19-Feb-2016 18 Mar 2016

Treatment 07: Enzalutamatide, abiraterone, and prednisone 18-Mar-2016 15 Apr 2016

Treatment 08: Enzalutamatide, abiraterone, and prednisone 15-Apr-2016 13 May 2016

Treatment 09: Enzalutamatide, abiraterone, and prednisone 13-May-2016 10 Jun 2016

Off Treatment 22 Jun 2016

Survival Follow-up 10 15 Dec 2016

Add Event ... Add

Confirmatory Scan

Consent Withdrawal

Lost to Follow-Up

Mayo CRA Only-Deviation

Measurable Disease: Unscheduled

New Primary

Unequivocal Clinical Progression

Unscheduled Measurements (Non-Measurable Disease Only)

Unscheduled PCWG2 Bone Scan Assessment

CRF Versio...

FOLLOW UP FORMS

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

Cycle	16	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Were you able to obtain any information about the patient since the last report?	Yes	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(If no), date of last attempt to contact patient		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SURVIVAL STATUS				
Participant vital status	Alive	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Date of most recent contact	28 Jul 2016	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Death date		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cause of death?		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If other cause of death, specify		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DISEASE STATUS				
Was disease status evaluated during this reporting period?	No	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(If yes), date of most recent disease status evaluation		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(If yes), was a scan for soft tissue lesions performed?		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(If yes), was a bone scan performed?		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(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?		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(Notes:		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none">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.		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Date of progression (or relapse)		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FIRST NON-PROTOCOL TREATMENT				
Has the patient received non-protocol treatment for this cancer that has not been previously reported?	No	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(If yes), Name(s) of non-protocol therapy		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(If yes), Non-protocol therapy start date		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LATE ADVERSE EVENTS				

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Modified: Rave@2016-2-0

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

