

HELPFUL TIPS & COMMON ERRORS



Alliance
for Clinical Trials
in Oncology

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**
- **Delinquency Report**

TELEFORMS



Member Login

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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.

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Password:



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Kristin Honer (log out)

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Statistician

I profound sadness that I write to inform you
of the passing of our dear friend and colleague, **Dan J.
t, PhD.** Dan passed away yesterday as the
result of a sudden, unexpected illness.



Quick Links

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Search by
protocol listing

TELEFORMS

PROTOCOL LISTING

Disease

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

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



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](#)

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[Case Report Forms](#)

[Memoranda and
Broadcasts](#)

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[DSMB Statement and
Study Summary](#)

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[Oxaliplatin](#)



TELEFORMS

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

You will then get a list of all the possible forms

Pro Tip: Right click the form you need and select "open in a new tab"

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. 8 0 7 0 2
 CALGB Patient ID
 Date of first dose for this reporting period
 Reporting period end date
 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"/> mg	<input type="checkbox"/> No <input type="checkbox"/> Yes, planned <input type="checkbox"/> Yes, unplanned
5-FU Infusion	<input type="text"/> mg	<input type="checkbox"/> No <input type="checkbox"/> Yes, planned <input type="checkbox"/> Yes, unplanned
Oxaliplatin	<input type="text"/> mg	<input type="checkbox"/> No <input type="checkbox"/> Yes, planned <input type="checkbox"/> Yes, unplanned
Celecoxib/Placebo	<input type="text"/> 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.)
 Treatment completed per protocol criteria Patient withdrawal/refusal after beginning protocol therapy
 Disease progression, relapse during active treatment Patient withdrawal/refusal prior to beginning protocol therapy
 Adverse event/side effects/complications Alternative therapy
 Death on study Patient off-treatment for other complicating disease
 Other, specify: _____

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

Completed by: _____ Date form originally completed / /
 (Last name, First name) 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

Pro Tip: If a field is not known or was not done, leave it blank. This will avoid queries!

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

Pro Tip: Print the confirmation page

Note: if the confirmation page does not show up, the form did not submit properly. Reach out the Alliance Service Center for troubleshooting

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

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](#)

You can also find the Data Submission Schedule under CRFs on the Alliance website. This is helpful so you what forms to submit at what time points

Pro Tip: Look at this when you enroll your first patient on a new study!

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
Form Name and Time of Form Submission	Institutional Contacts	X									
	On-Study	X	Each cycle	End of treatment							
	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.

Pro Tip: Review the case report forms up front when you enroll your first patient on a new study so you what to expect

RAVE

medidata



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

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.

Pro Tip: Never decline a Rave invite

Close Message

Tasks

Invitations (56)

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

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





HOW PATIENTS ARE SET UP


-  Baseline
-  Treatment 01: Neoadjuvant endocrine therapy (Anastrozole and/or Fulvestrant) 26-Aug-2014
-  Treatment 02: Neoadjuvant endocrine therapy (Anastrozole and/or Fulvestrant) 23-Sep-2014
-  Treatment 03: Neoadjuvant endocrine therapy (Anastrozole and/or Fulvestrant) 21-Oct-2014
-  Treatment 04: Neoadjuvant endocrine therapy (Anastrozole and/or Fulvestrant) 18-Nov-2014
-  Treatment 05: Neoadjuvant endocrine therapy (Anastrozole and/or Fulvestrant) 16-Dec-2014
-  Treatment 06: Neoadjuvant endocrine therapy (Anastrozole and/or Fulvestrant) 13-Jan-2015
-  Treatment 07: Discontinue/completed neoadjuvant treatment, proceeding to surgery
-  Off Treatment
-  Clinical Follow-up 08: 15-Apr-2015
-  Clinical Follow-up 09: 16-Jul-2015
-  Clinical Follow-up 10: 29-Sep-2015
-  Clinical Follow-up 11: 30-Mar-2016
-  Clinical Follow-up 12: No Contact
-  Clinical Follow-up 13
-  Treatment 07: Discontinue/completed neoadjuvant treatment, proceeding to surgery
-  Off Treatment
-  Clinical Follow-up 08:

 Subject Enrollment

Visit	Date
 Baseline	02 Sep 2014
 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

▼ Task Summary: Subject

- ▶  NonConformant Data
- ▶  Open Queries
- ▶  Sticky Notes
- ▶  Overdue Data



Rave calculates due dates for you!

ON STUDY FORMS

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

#	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 ^o	/uL	8500 ^o
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 ^o	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 ^o	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

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



CRA

Name *(first, last)* [?] Kristin, Honer

Email kristin.honer@essentiahealth.org

Phone *(example: 999-999-9999)* [REDACTED]

LEAD CRA

Name *(first, last)* [?] Wilma, Knutson

Email Wilma.Knutson@EssentiaHealth.org

Phone *(example: 999-999-9999)* [REDACTED]

Pro Tip: Keep updated

SITE INVESTIGATOR

Name *(first, last)* Bret, Friday

Email Bret.Friday@EssentiaHealth.org

Phone *(example: 999-999-9999)* [REDACTED]

Is the reference radiologist or local investigator available for bone imaging interpretation? Yes

Comments

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

ON STUDY - BASELINE ADVERSE EVENTS

Page: Adverse Events: Baseline - Baseline

Cycle

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	
2	Diarrhea	10012727	<input type="checkbox"/>	0	None	
3	Constipation	10010774	<input type="checkbox"/>	0	None	
4	Vomiting	10047700	<input type="checkbox"/>	0	None	
5	Dyspepsia	10013946	<input type="checkbox"/>	0	None	
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	
7	Arthralgia	10003239	<input type="checkbox"/>	0	None	
8	Bone pain	10006002	<input type="checkbox"/>	0	None	
9	Myalgia	10028411	<input type="checkbox"/>	0	None	
10	Headache	10019211	<input type="checkbox"/>	0	None	
11	Insomnia	10022437	<input type="checkbox"/>	0	None	
12	Hot flashes	10020407	<input type="checkbox"/>	0	None	
13	Hypertension	10020772	<input type="checkbox"/>	0	None	
14	Cough	10011224	<input type="checkbox"/>	0	None	
15	Dyspnea	10013963	<input type="checkbox"/>	0	None	
16	Hyperglycemia	10020639	<input type="checkbox"/>	1	Fasting glucose value >ULN - 160 mg/dL; Fasting glucose value >ULN - 8.9 mmol/L	
17	Hypokalemia	10021018	<input type="checkbox"/>	0	None	
18	Alanine aminotransferase increased	10001551	<input type="checkbox"/>	0	None	
19	Aspartate aminotransferase increased	10003481	<input type="checkbox"/>	0	None	
20	Blood bilirubin increased	10005364	<input type="checkbox"/>	0	None	

Comments

Save Cancel

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

ON STUDY – RECIST MEASUREMENTS

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 <small>(If selecting PET/CT scan, measurement must come from CT component.)</small>	Lesion size <small>(Please report the longest diameter for all non-osseous target lesions)</small>	
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

Printable Version View PDF Icon Key
CRF Version 4603 - Page Generated: 26 Sep 2016 08:56:00 Central Daylight Time

METASTATIC SITE(S)

Nodal

Liver

Bone

Lung

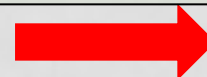
Other

Other specify

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

Measureable lesions – have to enter lesion site, method of evaluation (CT, PET, etc), and lesion size (watch units cm vs mm).

Pro Tip: What is reported on “Metastatic Sites” must match what is on the baseline 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 <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					

May have to upload radiology reports, pathology reports, etc

Pro Tip: Watch out for Protected Health Information (PHI)!

ON STUDY – SPECIMEN SUBMISSION

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	
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



Pro Tip: 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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CRF Version 4803 - Page Generated: 26 Sep 2016 09:42:47 Central Daylight Time

Save Cancel

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

#	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

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 <input type="checkbox"/>	Adverse event grade <input type="text"/>	Adverse event grade description	AE attribution (if grade > 0) <input type="text"/>	Has an adverse event expedited report been submitted?	<input type="checkbox"/>
1	Fatigue	10016256	<input type="checkbox"/>	1	Fatigue relieved by rest	Probable	No	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
2	Diarrhea	10012727	<input type="checkbox"/>	0	None		No	<input checked="" type="checkbox"/> <input 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"/> <input type="checkbox"/>
4	Vomiting	10047700	<input type="checkbox"/>	0	None		No	<input checked="" type="checkbox"/> <input 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"/> <input type="checkbox"/>
6	Edema limbs	10050068	<input type="checkbox"/>	0	None		No	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
7	Arthralgia	10003239	<input type="checkbox"/>	1	Mild pain	Unlikely	No	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
8	Bone pain	10006002	<input type="checkbox"/>	0	None		No	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
9	Myalgia	10028411	<input type="checkbox"/>	0	None		No	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
10	Headache	10019211	<input type="checkbox"/>	0	None		No	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
11	Insomnia	10022437	<input type="checkbox"/>	0	None		No	<input checked="" type="checkbox"/> <input 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"/> <input type="checkbox"/>
13	Hypertension	10020772	<input type="checkbox"/>	0	None		No	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
14	Cough	10011224	<input type="checkbox"/>	0	None		No	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
15	Dyspnea	10013963	<input type="checkbox"/>	0	None		No	<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	Unrelated	No	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
17	Hypokalemia	10021018	<input type="checkbox"/>	0	None		No	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
18	Alanine aminotransferase increased	10001551	<input type="checkbox"/>	0	None		No	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
19	Aspartate aminotransferase increased	10003481	<input type="checkbox"/>	0	None		No	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
20	Blood bilirubin increased	10005364	<input type="checkbox"/>	0	None		No	<input checked="" type="checkbox"/> <input 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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Pro Tip: Read the instructions otherwise you may have to inactivate a line

Each study may have it's own set of solicited AEs

Pro Tip: Use study specific AE assessment forms

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

CYCLES - RECIST MEASUREMENTS

Cycle 4 ✓ ↻ 🗑

Date of most recent disease status evaluation 22 Jan 2016 ✓ ↻ 🗑

#	Serial # of lesion	Target lesion site(s)	Lesion type	Method of evaluation <small>(If selecting PET/CT scan, measurement must come from CT component.)</small>	Lesion size <small>(Please report the longest diameter for all non-osseous target lesions)</small>	
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 -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

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
- Lab results – again watch units, ULN, LLN
- Specimen submission
 - How many samples, if not collected, why, date/time collected, date shipped.

Pro Tip: Make sure PHI is removed from all uploaded documentation and study #, patient ID, and patient initials are written on every page

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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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

Subject Enrollment

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	21-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	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 Version: ... Time

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"/>	<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"/>	<input type="checkbox"/>
<i>(If no), date of last attempt to contact patient</i>		<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	28 Jul 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 type="text"/>		<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?	No	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>(If yes), date of most recent disease status evaluation</i>		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>(If yes), was a scan for soft tissue lesions performed?</i>		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>(If yes), was a bone scan performed?</i>		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>(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>		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>(Notes:</i> <ul style="list-style-type: none"><i>If first soft tissue relapse occurs at Week 9 scan, it needs to be confirmed.</i><i>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.</i><i>If patient experienced more than one form of progression during this reporting period, please report below the date of the earliest progression.)</i>		<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"/>
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"/>	<input type="checkbox"/>
<i>(If yes), Name(s) of non-protocol therapy</i>		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>(If yes), Non-protocol therapy start date</i>		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LATE ADVERSE EVENTS					

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Medidata, June 9, 2016, 3.0

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

DELINQUENCY REPORTS

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All sites you submit data for will be listed and you can run a report for each site.

QUESTIONS

