Quality Assurance Audits
Preparing for Success

What is your current Position?

A. Data Management
B. Clinical Research Nurse
C. Regulatory Affairs
D. Quality Assurance
E. Administration
F. Other

What is your work setting?

A. NCORP
B. NCORP Component
C. Member Institution
D. Lead Academic Program
E. Affiliate institution

Purpose of the audit program

Verify study data that could affect the interpretation of primary study endpoints by checking compliance to protocol and regulatory requirements and accuracy of submitted data

Assessment of trial related activities and documents for adherence to Good Clinical Practice (GCP)

Provide educational support for data quality and data management practices

Scheduling of Audits

New LAPS, Members, NCORPs – within 18 months of first patient registration

New affiliates, components – at next parent institution audit

Institutions audited at least once every three years but remain at risk for more frequent audits

FDA registration studies – more frequent monitoring

FDA Registration Study Site Visits

- LungMAP – initial audit at three months after first registration to a sub-study (with registration intent), then every six months
- S1418, S1806, S1914 – initial audit at six to nine months after first registration, additional site visits dependent on accrual
- S2302 (Pragmatica) – will be audited on same schedule as treatment audits (every 3 years)

On-Site Versus Off-Site Audits

On-site

- LAPS / Main Member / NCORP
- Component / affiliate with large accrual
- FDA registration study site visits for sites requesting onsite audits

Off-site

- Most NCORP components and Main Member affiliates audited off site with parent institution
- Most FDA registration study site audits can be audited off site (remote)

Notification Process

- Scheduled three to four months prior to the audit.
- Formal notification/case list by email four to six weeks prior to the audit.
- Includes detailed instructions on how to prepare for the audit and Site Questionnaire for audit planning.

Site Questionnaire for SWOG Audit

In preparation for the upcoming visit to your site, please complete and return the questionnaire to the SWOG auditor.

Contact Person:
Name & Title: Click or tap here to enter text.
Email: Click or tap here to enter text.
Phone: Click or tap here to enter text.

PI (name and email) for the registration studies (LUNGMAP, S1418, S1806, S1914): Click or tap here to enter text.

PI (name and email) of Main Member/NCORP: Click or tap here to enter text.

Audit Hours: 8:00 am – 5:00 pm
If unable to accommodate these hours, please list alternative hours: Click or tap here to enter text.

Physical Address for Location of Audit:
Click or tap here to enter text.

FedEx Delivery Address (for receiving packages) if different from physical address:
Click or tap here to enter text.

Does the audit room have a Wi-Fi connection available for the SWOG audit team?
Click or tap here to enter text.

Regulatory Review

1. (IF APPLICABLE) Are all affiliate/component sites covered by a single IRB? Click or tap here to enter text.
   If not, please provide a list outlining all sites and their reviewing IRB. Click or tap here to enter text.
2. Does your local IRB require submission of all external safety reports and internal SAEs or do you have a policy that outlines alternate procedures? Click or tap here to enter text.
   If alternate procedures are followed, please submit a copy of your policy.
3. Are the regulatory records electronic, paper, or a combination? Click or tap here to enter text.
4. Do you have a Site Authority Log for studies not covered by a CTSU DTL? Click or tap here to enter text.

Pharmacy Review

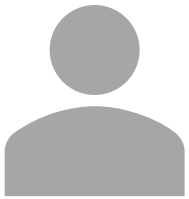
5. Is the investigational drug storage area within walking distance of the audit? Click or tap here to enter text.
6. Does your pharmacy use an electronic system or paper DARFs? Click or tap here to enter text.
7. Does your pharmacy have a written procedure in place to ensure a) the investigator ordering the dispensing of NCI supplied-agents is currently registered with the Pharmaceutical Management Branch (PMB) or b) that the order/prescription is co-signed by a registered investigator? Click or tap here to enter text.
8. Are APPs authorized to prescribe study agents? If allowed, does your pharmacy have a written procedure in place that describes your institutional policy on credentialing and GCP requirements for APPs? Click or tap here to enter text.

Patient Case Review

9. Does your site use an EMR system, paper charts, or a combination? Click or tap here to enter text.

If the records are maintained electronically, there must be a computer for each auditor and a CRA/Nurse available to navigate the system for the audit team, if requested.

The Audit Team



QA auditor

One or more Nurse or CRA auditors

NCI-CTMB observer occasionally in attendance

Site Representatives

- CRAs
- Research Nurses
- Principal Investigator or designate
- Regulatory Representative
- Pharmacy staff

Audit Process

Audit Process

Regulatory review (IRB, consent form content and Delegation of Task Log/Site Authority Log)

Investigational drug accountability (drug accountability, pharmacy visit)

Patient case review

Regulatory Review

- IRB: Regulatory documents for all protocols on the case list
- Informed consent content: minimum of four protocols' consents reviewed
- Delegation of Task Log (DTL) and Site Authority Log
- Trial Master File (TMF): FDA registration studies

IRB Review – Local IRB

- Approvals: initial and continuing reviews, protocol updates
- Reportable external Safety Reports and internal SAEs
- All versions of IRB-approved consent forms or a comprehensive list
- SOPs for alternative procedures (e.g., submission of unanticipated events only)

IRB Review – CIRB

CIRB Approval of the Study-Specific Worksheet

Signatory Institution: **Eastern Maine Medical Center**

Re: **CIRB Approval of the Annual Signatory Institution Worksheet About Local Context**

Signatory Institution: **Trinity Health Michigan**

NCI CIRB Consent tracking sheet							
Study Number	NCI CIRB Approval Date	NCI CIRB Posting Date	NCI CIRB Version Date	Date sent to Reviewer	Reviewer Initials	Date Approved by Reviewer	Initials and Date Uploaded to CREATE
S1800D	02/18/22	[redacted]	v12/17/22 & RevBPH	HB 2/21/22	JD	2/21/2022	HB 2/21/22
	08/10/22	09/02/22	Rev 1 - v06/15/2022	HB 9/6/22	JD	9/6/2022	HB 9/7/22

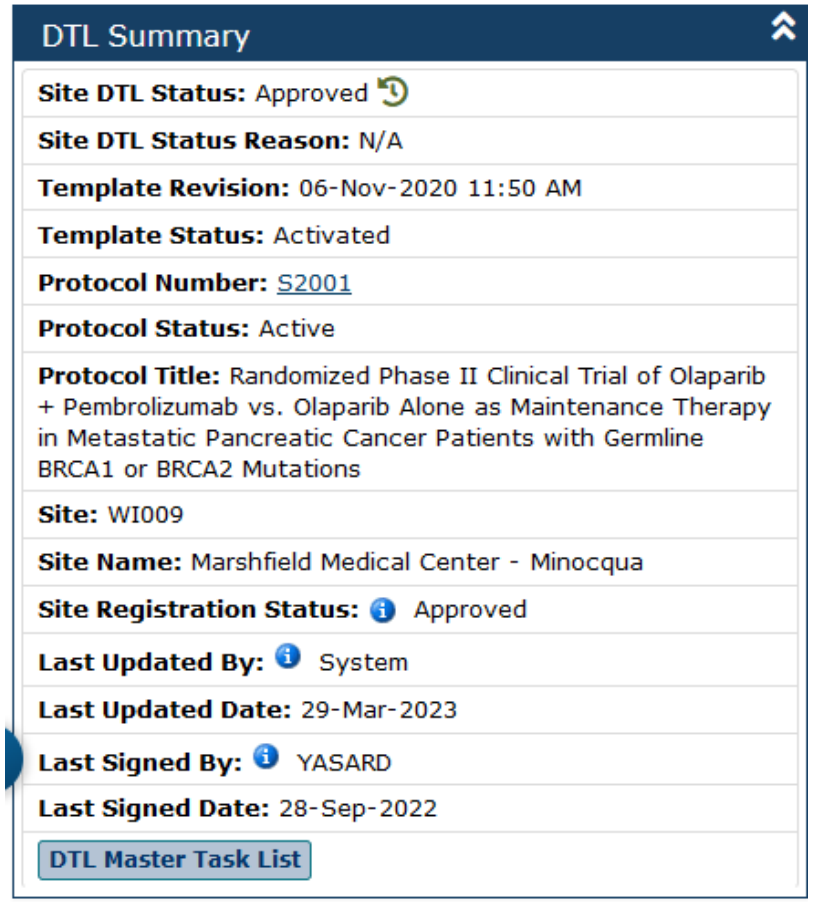
- Documentation that CIRB is the IRB of record (Study Specific Worksheet approval)
- Approved boilerplate language for ICFs
- Date of local implementation of protocol updates and consent versions
- Submission of unanticipated events (e.g., reportable local SAEs)
- NO COPIES OF CIRB APPROVAL DOCUMENTS REQUIRED

Consent Form Content

- Compared to model consent
- Contains all elements required by federal regulations
- Updated by protocol modifications
- Specimen banking/optional studies questions same as model
- CIRB sites: identical to approved boilerplate merged with model

Delegation of Task Log

- Site Authority Log (delegation of authority, signatures, handwriting samples) for key research personnel to cover all NCI sponsored studies
- Delegation of Task Log (CTSU website)
  - LungMAP sub-studies
  - All registration studies (S1418, S1806, S1914)
  - All new studies that use investigational agents (since August 2020 for Ph III studies/since October 2020 for Ph I/II studies)



Trial Master File

- Protocol
- Regulatory documents
- CLIA Certificates and list of normal lab values/range
- List of local SOPs
- Site training documents (GCP, protocol specific, etc.)
- Placeholder for centrally filed documents (e.g., CVs, 1572s)

Investigational Drug Accountability

- Review of Drug Accountability Record Forms: NCI DARF or NCI Oral DARF required for all studies using investigational agents
  - Control and satellite records
  - Complete and timely entries
  - Good documentation practices
  - Patient returns documented on Oral DARF

Investigational Drug Accountability

- Shipping receipts, transfer and return forms
  - Unused or expired drug returned or destroyed within 90 days of end of use
  - No substitution of commercial drug for investigational agent

Investigational Drug Accountability

- Cross reference DARFs against patient records to verify dose and dates of dispensing
- SOP for authorized prescriptions (ordering investigator must have active CTEP account)
- On-site audits: Tour of pharmacy
  - Assess security and storage conditions
  - Verify physical inventory
- Off-site audits: Tour of pharmacy conducted via Teams, FaceTime, WebEx, etc.

DARF Examples – Good DARF

National Institutes of Health
National Cancer Institute

Division of Cancer Treatment and Diagnosis
Cancer Therapy Evaluation Program

Investigational Agent Accountability Record

PAGE NO.
CONTROL RECORD ☒
SATELLITE RECORD ☐

Name of Institution: Fabulous Cancer Center

NCI Protocol No.: S9999

Agent Name: Drug Z

Dose Form and Strength: 100 mg/vial

Protocol Title: Phase II Lung

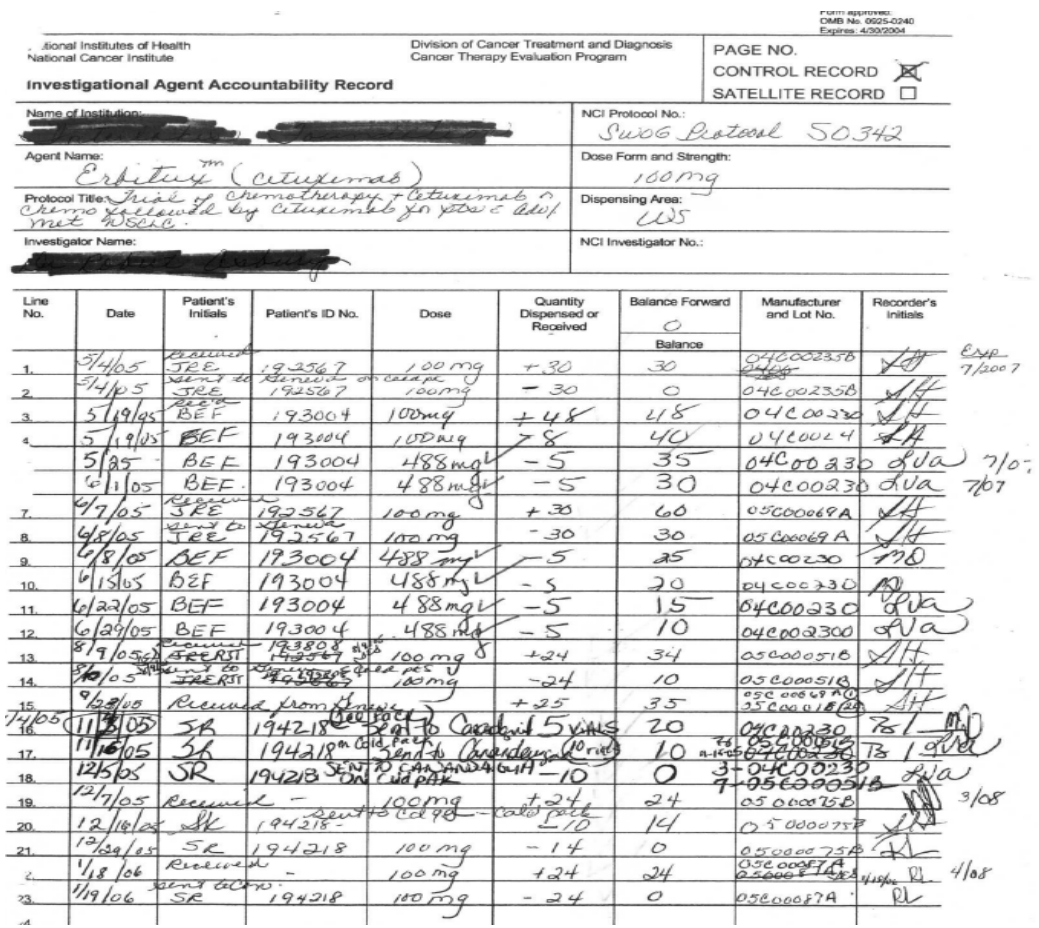
Dispensing Area: IDS Pharmacy

Investigator Name: Dr Jane Smith

CTEP Investigator ID: 123456

Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward / Balance	Manufacturer and Lot No.	Recorder's Initials
1.	5/18/23	RECEIVED FROM NCI			+30	30	ABC 98765	RG
2.	5/19/23	SENT	TO XYZ		-10	20	ABC 98765	RG
3.	5/22/23	RG	223344	175 mg	-2	18	ABC 98765	RG
4.	5/30/23	RG	223344	175mg	-2	16	ABC 98765	RG
5.	6/5/23	RG	223344	170mg	-2	14	ABC 98765	RG
6.	6/12/23	RG	223344	170mg	-2	12	ABC 98765	RG
7.	6/15/23	RECEIVED FROM NCI			+30	42	DEF 44317	RG
8.	6/16/23	SENT	TO XYZ		-10	32	ABC 98765	RG
9.	6/19/23	RG	223344	170mg	-2	30	ABC 98765	RG

DARF Examples – "So-So" DARF



Investigational Agent Accountability Record

Division of Cancer Treatment and Diagnosis, Cancer Therapy Evaluation Program

PAGE NO. | CONTROL RECORD ☒ | SATELLITE RECORD ☐

Name of Institution: [redacted]

NCI Protocol No.: SWOG Protocol S0342

Agent Name: Erbitux™ (cetuximab)

Dose Form and Strength: 100mg

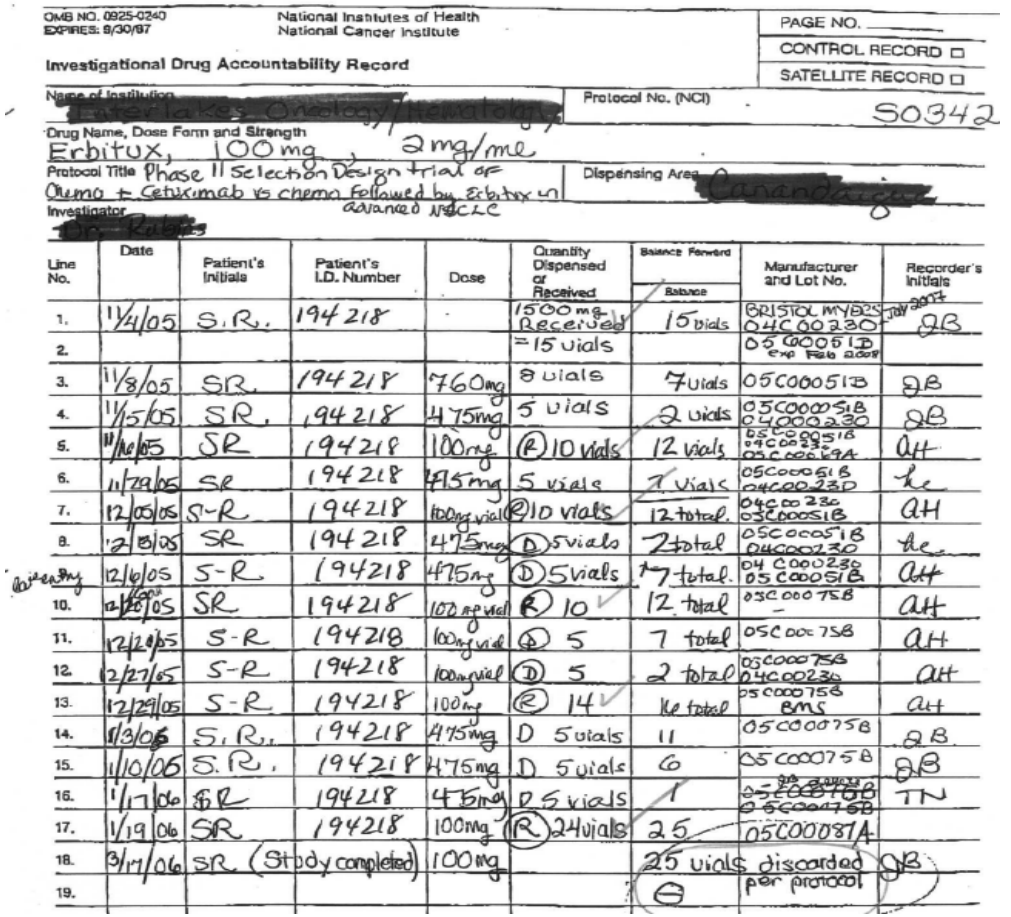
Protocol Title: Trial of chemotherapy + Cetuximab vs chemo followed by Cetuximab for Pts w/ Adv/Met NSCLC

Dispensing Area: WS

Investigator Name: [redacted]

NCI Investigator No.:

Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward / Balance	Manufacturer and Lot No.	Recorder's Initials
						0		
1.	5/4/05	Received JRE	192567	100 mg	+30	30	04C00233B	JRE
2.	5/4/05	Sent to JRE	Returned 192567	100mg	−30	0	04C00233B	JRE
3.	5/19/05	Rec'd BEF	193004	100mg	+48	48	04C00230	BEF
4.	5/19/05	BEF	193004	100mg	−8	40	04C00230	BEF
	5/25	BEF	193004	488mg	−5	35	04C00230	dVa
	6/1/05	BEF	193004	488mg	−5	30	04C00230	dVa
7.	4/7/05	Received JRE	192567	100 mg	+30	60	05C00069A	JRE
8.	4/8/05	Sent to JRE	Returned 192567	100 mg	−30	30	05C00069A	JRE
9.	6/8/05	BEF	193004	488 mg	−5	25	04C00230	BEF
10.	6/15/05	BEF	193004	488mg	−5	20	04C00230	BEF
11.	6/22/05	BEF	193004	488mg	−5	15	04C00230	dVa
12.	6/29/05	BEF	193004	488mg	−5	10	04C00230	dVa
13.	8/9/05	Received JRE/RST	193808	100 mg	+24	34	05C00051B	JRE
14.	8/10/05	Sent to JRE/RST	[illegible]	100mg	−24	10	05C00051B	JRE
15.	9/29/05	Received from [illegible]			+25	35	05C00069A 05C00051B	AH
16.	11/3/05	SR	194218	Sent to Cardwell	5 VIALS	20	04C00230	RL
17.	11/16/05	SR	194218	Sent to Cardwell	(10 vials)	10	05C00051B 04C00230	dVa
18.	12/5/05	SR	194218	SENT TO CARDWELL	−10	0	3-04C00230 7-05C00051B	dVa
19.	12/7/05	Received	–	100mg	+24	24	05C00075B	3/08
20.	12/16/05	SR	194218	Sent to Cardwell	−10	14	05C00075B	
21.	12/29/05	SR	194218	100 mg	−14	0	05C00075B	
	1/18/06	Received	–	100 mg	+24	24	05C00087A	4/08
23.	1/19/06	Sent back to SR	194218	100 mg	−24	0	05C00087A	RL



OMB NO. 0925-0240 EXPIRES: 9/30/97

National Institutes of Health, National Cancer Institute

Investigational Drug Accountability Record

PAGE NO. | CONTROL RECORD ☐ | SATELLITE RECORD ☐

Name of Institution: [redacted] Protocol No. (NCI) S0342

Drug Name, Dose Form and Strength: Erbitux, 100 mg 2 mg/ml

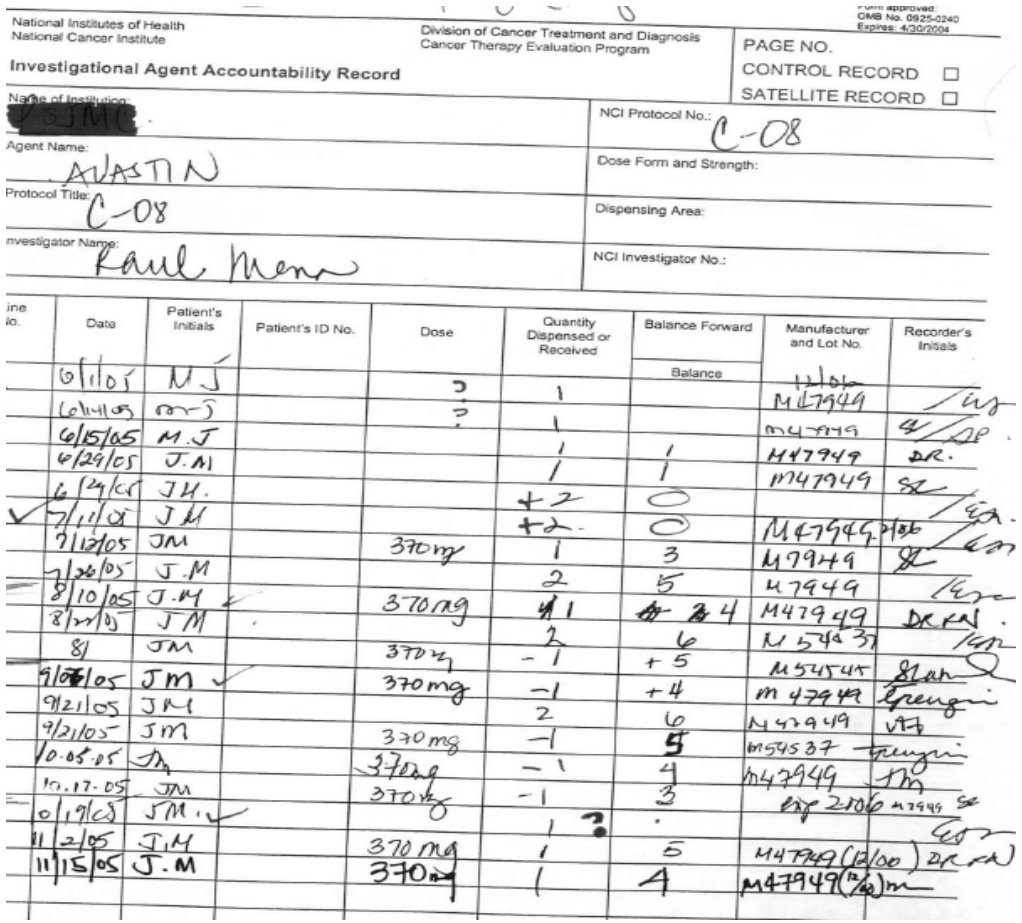
Protocol Title: Phase II Selection Design trial of Chemo + Cetuximab vs chemo followed by Erbitux in advanced NSCLC

Dispensing Area: [redacted]

Investigator: [redacted]

Line No.	Date	Patient's Initials	Patient's I.D. Number	Dose	Quantity Dispensed or Received	Balance Forward / Balance	Manufacturer and Lot No.	Recorder's Initials
1.	11/4/05	S.R.	194218		1500 mg Received = 15 vials	15 vials	BRISTOL MYERS 04C00230 05C00051B	QB
2.								
3.	11/8/05	SR.	194218	760mg	8 vials	7 vials	05C00051B	QB
4.	11/15/05	SR.	194218	475mg	5 vials	2 vials	05C00051B 04C00230	QB
5.	11/16/05	SR	194218	100mg	(R) 10 vials	12 vials	05C00051B 04C00230 05C00069A	QH
6.	11/29/05	SR	194218	475mg	5 vials	7 vials	05C00051B 04C00230	he
7.	12/05/05	S-R	194218	100mg/vial	(R) 10 vials	12 total	04C00230 05C00051B	QH
8.	12/8/05	SR	194218	475mg	(D) 5 vials	7 total	05C00051B 04C00230	he
	12/6/05	S-R	194218	475mg	(D) 5 vials	7 total	04C00230 05C00051B	QH
10.	12/20/05	SR	194218	100mg/vial	(R) 10	12 total	05C00075B	QH
11.	12/20/05	S-R	194218	100mg/vial	(D) 5	7 total	05C00075B	QH
12.	12/27/05	S-R	194218	100mg/vial	(D) 5	2 total	05C00075B 04C00230	QH
13.	12/29/05	S-R	194218	100mg	(R) 14	he total	05C00075B BMS	QH
14.	1/3/06	S.R.	194218	475mg	D 5 vials	11	05C00075B	QB
15.	1/10/06	S.R.	194218	475mg	D 5 vials	6	05C00075B	QB
16.	1/17/06	SR	194218	475mg	D 5 vials	1	05C00075B 05C00075B	TN
17.	1/19/06	SR	194218	100mg	(R) 24 vials	25	05C00087A	
18.	3/17/06	SR (Study completed)		100mg		25 vials discarded per protocol		QB
19.								

DARF Examples – Incomplete DARF



National Institutes of Health
National Cancer Institute

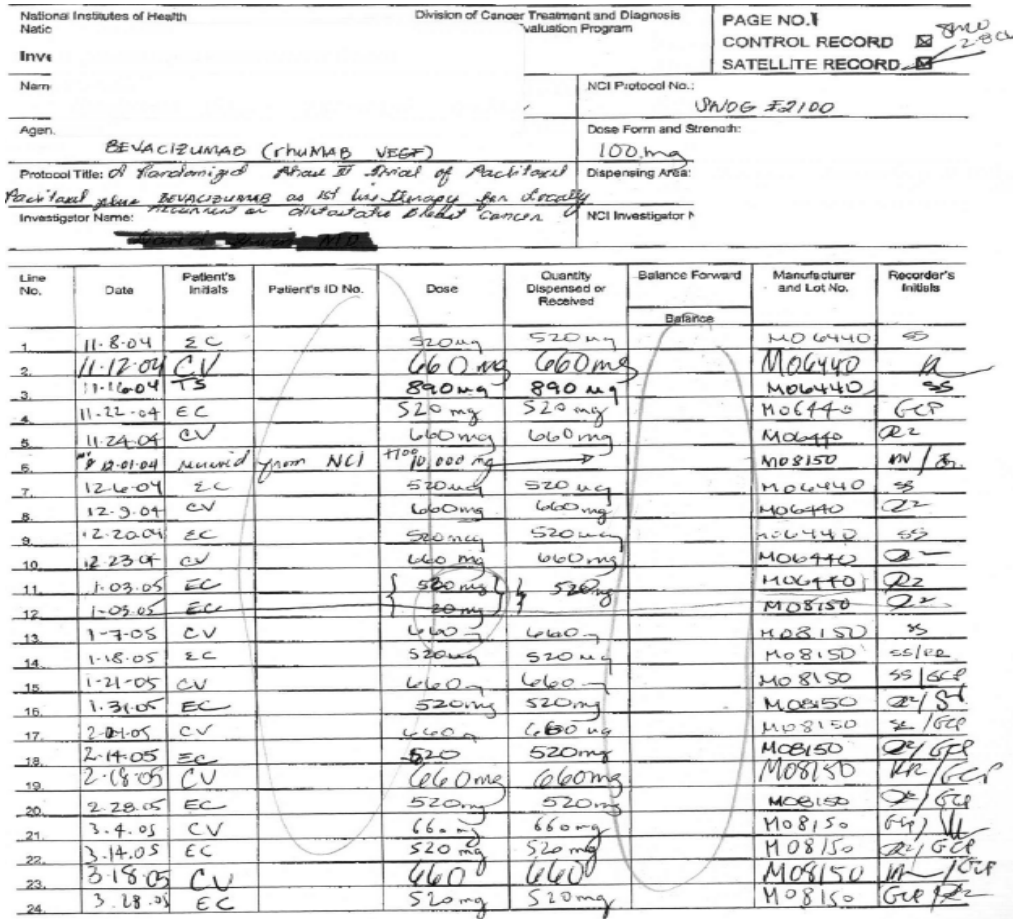
Division of Cancer Treatment and Diagnosis
Cancer Therapy Evaluation Program

Investigational Agent Accountability Record

PAGE NO.
CONTROL RECORD ☐
SATELLITE RECORD ☐

Name of Institution: [redacted]
NCI Protocol No.: C-08
Agent Name: AVASTIN
Dose Form and Strength:
Protocol Title: C-08
Dispensing Area:
Investigator Name: Paul Mena
NCI Investigator No.:

Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward / Balance	Manufacturer and Lot No.	Recorder's Initials
	6/1/05	MJ		?	1		M47949	
	6/14/05	MJ		?	1		M47949	
	6/15/05	M.J			1	1	M47949	DR.
	6/29/05	J.M			1	1	M47949	
	6/29/05	JM			+2	0		
✓	7/11/05	JM			+2	0	M47949 2106	
	7/12/05	JM		370mg	1	3	M47949	
	7/26/05	J.M			2	5	M47949	
	8/10/05	J.M		370mg	1	4	M47949	DR KM
	8/24/05	JM			2	6	M54537	
	8/	JM		370mg	-1	+5	M54547	
	9/07/05	JM		370mg	-1	+4	M47949	
	9/21/05	JM			2	6	M47949	
	9/21/05	JM		370mg	-1	5	M54537	
	10-05-05	JM		370mg	-1	4	M47949	
	10.17.05	JM		370mg	-1	3	M47949	
	10/19/05	JM			1		exp 2106 M7949	
	11/2/05	JM		370mg	1	5	M47949 (2106)	DR KM
	11/15/05	J.M		370mg	1	4	M47949 (2106)	



National Institutes of Health
Natic

Division of Cancer Treatment and Diagnosis
Evaluation Program

PAGE NO. 1
CONTROL RECORD ☒
SATELLITE RECORD ☒

Inve
Nam
NCI Protocol No.: SWOG S0100
Agen. BEVACIZUMAB (rhuMAB VEGF)
Dose Form and Strength: 100 mg
Protocol Title: A Randomized Phase III Trial of Paclitaxel Paclitaxel plus BEVACIZUMAB as 1st line therapy for locally recurrent or disseminate Breast Cancer
Dispensing Area:
Investigator Name: [redacted] MD
NCI Investigator N

Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward / Balance	Manufacturer and Lot No.	Recorder's Initials
1.	11-8-04	EC		520mg	520mg		M06440	
2.	11-12-04	CV		660mg	660mg		M06440	
3.	11-16-04	TS		890mg	890mg		M06440	
4.	11-22-04	EC		520mg	520mg		M06440	
5.	11-24-04	CV		660mg	660mg		M06440	
6.	12-01-04	Mailed	from NCI	+700 10,000mg	→		M08150	
7.	12-6-04	EC		520mg	520mg		M06440	
8.	12-9-04	CV		660mg	660mg		M06440	
9.	12-20-04	EC		520mg	520mg		M06440	
10.	12-23-04	CV		660mg	660mg		M06440	
11.	1-03-05	EC		520mg	520mg		M06440	
12.	1-03-05	EC		20mg			M08150	
13.	1-7-05	CV		660mg	660mg		M08150	
14.	1-18-05	EC		520mg	520mg		M08150	
15.	1-21-05	CV		660mg	660mg		M08150	
16.	1-31-05	EC		520mg	520mg		M08150	
17.	2-04-05	CV		660mg	660mg		M08150	
18.	2-14-05	EC		520	520mg		M08150	
19.	2-18-05	CV		660mg	660mg		M08150	
20.	2-28-05	EC		520mg	520mg		M08150	
21.	3-4-05	CV		660mg	660mg		M08150	
22.	3-14-05	EC		520mg	520mg		M08150	
23.	3-18-05	CV		660	660		M08150	
24.	3-28-05	EC		520mg	520mg		M08150	

Patient Case Review

SWOG QUALITY ASSURANCE AUDIT
UC IRVINE HEALTH/CHAO FAMILY COMPREHENSIVE CANCER CENTER
ORANGE, CA
JANUARY 25-27, 2022

UC IRVINE HEALTH/CHAO FAMILY COMPR CANCER CENTER — *NCI Code: CA088*
Orange, CA

Case #	Study #	Disease Site	Patient #	Registered	Treatment
1.	A011502	BREAST	9133067	16NOV20	**Aspirin/Placebo**
2.	A041501	LEUKEMIA	9131686	29AUG20 29SEP20	Remission Induction Remission Consolidation +/- **Inotuzumab**
3.	EA8174	MELANOMA	16108	11FEB21	Observation
4.	S1602	BLADDER	706396	28APR20	**Prime +Tokyo-172 BCG**
5.	S1801	MELANOMA	285300	09APR21 09JUN21	Neoadjuvant **Pembrolizumab** Surgery
6.	S1803	MYELOMA	286666	19JUL21 18AUG21	Screening Lenalidomide
7.	S1820	PEOLC	281746	24JUL20 07AUG20	Run-In Diet Modification Coaching
8.	S1823	PREVENTION	287279	03SEP21	Observation

UC IRVINE HEALTH CANCER CENTER-NEWPORT — *NCI Code: CA814*
Costa Mesa, CA

9.	S0820	PREVENTION	283539	11DEC20	**Eflornithine/Sulindac +/-Placebo**

UC IRVINE HEALTH/CHAO FAMILY COMPR CANCER CENTER — *NCI Code: CA088*

UNANNOUNCED CASE (consent form and eligibility review only)

Case #	Study #	Disease Site	Patient #	Registered	Treatment Arm
10.	EA8174	MELANOMA	16055	01MAY20	Observation

PRESBYTERIAN INTERCOMMUNITY HOSPITAL — *NCI Code: CA030*
Whittier, CA

1.	EA8143	RENAL	38194	22FEB19	Nephrectomy-> Observation
2.	EAY131 EAY131-Z1K	ERLYTX	17026	14APR20 21APR20	Screening **Ipatasertib**
3.	S1826	LYMPHOMA	279015	14OCT19	**Nivolumab** + AVD

SAINT JUDE MEDICAL CENTER — *NCI Code: CA084*
Fullerton, CA

1. 1a.	A151216 EA5142	LUNG LUNG	9123932 25771	11APR19 10MAY19	Specimen submission Observation
2.	EAY131 EAY131-T	ERLYTX ERLYTX	17045 17045	10JUN20 15JUN20	Screening **GDC-0449 (Vismodegib)**

List of SWOG and CTSU accrual credited to SWOG over last three years

- 10% SWOG treatment and 10% SWOG non-treatment
- 10% non-SWOG treatment and 10% non-SWOG non-treatment
- Minimum of one case for each non-SWOG FDA registration study
- Minimum of three cases
- One unannounced case for on-site audits

Patient Case Review: Categories

- Informed consent
- Eligibility
- Treatment administration
- Disease / endpoint assessment
- Toxicity assessment
- General data quality – to include specimen submission and QOLs

Case Review: Categories

Chart preparation prior to audit

Shadow chart is acceptable

Recommended chart organization: Consent and screening/eligibility, then chronological by cycle / reporting period - H&P, labs, disease assessments, etc.

Color coded flagging of sections/cycles (for paper/shadow charts)

Specimen submission documents flagged (print out of specimen tracking documents)

If auditor will review records in EMR, EMR Source Documentation Locator Form must be completed prior to the audit

PATIENT CASE REVIEW

The following should be performed **prior** to the audit:

- Medical records and research charts must be obtained and all major study parameters tagged in the source documents to facilitate the review of eligibility, treatment administration, toxicity evaluations, disease assessment and supplemental documents (i.e., consent forms, questionnaire, specimen submission, etc.)

  Examples of Color-Coding for Patient Charts

White	Operative and Pathology Reports: label tab with Op or Path and date
Purple	H&P, Weight, Performance Status: label tab with Pre-study or Cycle # and date
Orange	Treatment Records: label tab with Cycle # and date
Yellow	Toxicity Evaluations: label tab with date range
Red	Lab Tests: label tab with Pre-study or Cycle # and date
Green	Tumor Measurements/Disease Assessment: label tab with Pre-study or Cycle # and date
Blue	Specimen submission: label with pre-study or Cycle #

- If auditors will review data in the electronic medical record (EMRs), a computer must be made available for each auditor and access obtained prior to the audit. ***See Policy on Review of EMRs.***
- A review of all patient records being audited to verify that the following documents are available:
  - **Eligibility Criteria**
    - Documentation to support all eligibility criteria including operative and pathology reports, radiology reports, lab reports, medical history, doctor's notes, etc.
  - **Treatment**
    - Drug orders, prescriptions, chemo flowsheets, progress notes, intake calendars or other documentation of treatment administration;
    - Documentation to support and provide an explanation of modifications or delays in study treatment.
  - **Disease Outcome/Response Determination**
    - Documentation to support disease assessment/response evaluations as outlined in the protocol (physician notes, radiology reports, tumor measurement grids, lab reports, etc.).
  - **Toxicity Assessment**
    - Documentation to support assessment of toxicities (i.e., signed AE logs with grade and attribution).
    - Supporting laboratory reports;
    - Copies of CTEP-AERs forms for reportable SAEs.
  - **Data Quality**
    - All records including the subject's primary care chart and copies of medical records from outside sources that are considered relevant to the subject's study participation must be accessible for review during an audit. If records are missing, all attempts to secure the records must be documented;
    - Supporting research documents (i.e., questionnaires, specimen submission);
    - Original records are preferred but shadow charts are acceptable if unable to obtain original records;
  - **Consent Forms**
    - Signed consent forms;
    - If applicable, documentation to verify patient was reconsented or notified of new information as instructed by the sponsor and/or local IRB.

Informed Consent

- Most current version signed prior to registration
- Contains all required signatures
- Informed of new findings in a timely manner
- Specimen banking/optional studies offered and intent reported correctly in OPEN at time of registration
- HIPAA authorization signed

Eligibility

- Verify diagnosis by review of pathology or other diagnostic reports
- Review medical history for exclusion criteria
- Verify pre-study assessments meet protocol requirements and performed within specified time limits
- Eligibility affirmation signed prior to registration/randomization
- NO EXCEPTIONS GRANTED per Section 5.0

Treatment Administration

- BSA / dose calculations verified
- Verification of both drug orders and drug administration
- Appropriate dose modifications
- Patient diaries or other supporting documentation of compliance to oral medications
- Documentation to support delays or deviations in treatment

Endpoint Assessment

- Disease/endpoint assessments performed per protocol
- Review of radiology reports, pathology reports, lab reports, records of physical examinations, etc.
- Same method of measuring the disease at baseline and at each assessment
- Tumor measurements documented
- Off treatment follow-up conducted per protocol

Adverse Event Assessment

- Required baseline and follow-up studies performed
- Grade and attribution of AEs documented, signed off by investigator/qualified practitioner
- Documentation of immune-related status, if applicable
- Adverse events reported appropriately.
- Serious Adverse Events (SAEs) reported in a timely manner

General Data Quality

ALCOA + C to achieve data quality:
If it is not documented, it did not happen

A: Attributable

L: Legible

C: Contemporaneous

O: Original

A: Accurate

C: Complete

Adequate source documentation

Data accurately reported on the data collection forms

Timely submission of data

Specimens/images/questionnaires submitted per protocol

Good documentation practices

References:

ICH GCP E6R2 4.9.0 and ICH GCP E6R2 4.9.1

Exit Interview

- Meet with PI and staff
- Summarize findings
- Clear up any questions
- Preliminary Report indicating any major deficiencies submitted within one working day to the NCI

Audit Ratings

- Acceptable
  - See you in three years

- Acceptable, Follow-up Needed
  - A written response including a corrective and preventive action plan must be submitted.

Audit Ratings

Unacceptable

- A written response including a corrective and preventive action plan must be submitted.
- Repeat audit within 6 - 12 months.
- If repeat offender: Site Improvement Plan required / possible suspension of registration privileges.

Final Report and Follow-up Response/CAPA

Final Report sent to site and submitted to NCI within 70 days of audit

For FDA Registration Studies, Final Report must be submitted within 45 days of audit

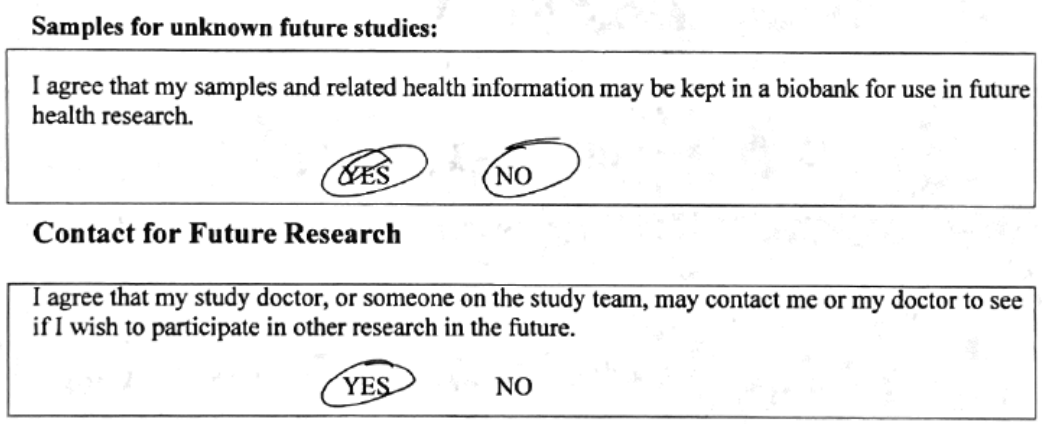
- Site must submit Follow-up Response/CAPA for any component with Acceptable-needs follow up or Unacceptable finding
- Once Follow-up Response/CAPA reviewed and approved, site will be placed back into normal audit rotation

A Walk Through an Audit

Common things that found during the Patient Case Review

Informed Consent

Unclear specimen choice, with no documented explanation.



Samples for unknown future studies:

I agree that my samples and related health information may be kept in a biobank for use in future health research.

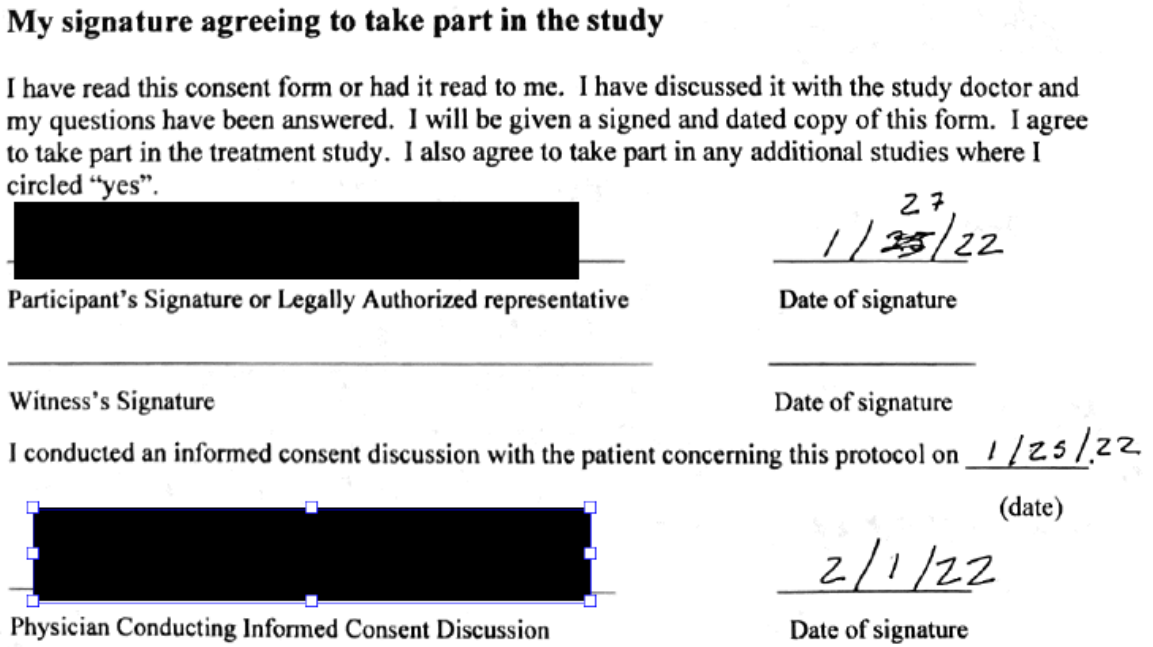
YES NO

Contact for Future Research

I agree that my study doctor, or someone on the study team, may contact me or my doctor to see if I wish to participate in other research in the future.

YES NO

No initials or date next to change, no explanation.



My signature agreeing to take part in the study

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed and dated copy of this form. I agree to take part in the treatment study. I also agree to take part in any additional studies where I circled "yes".

[redacted] 1/27/22

Participant's Signature or Legally Authorized representative — Date of signature

Witness's Signature — Date of signature

I conducted an informed consent discussion with the patient concerning this protocol on 1/25/22 (date)

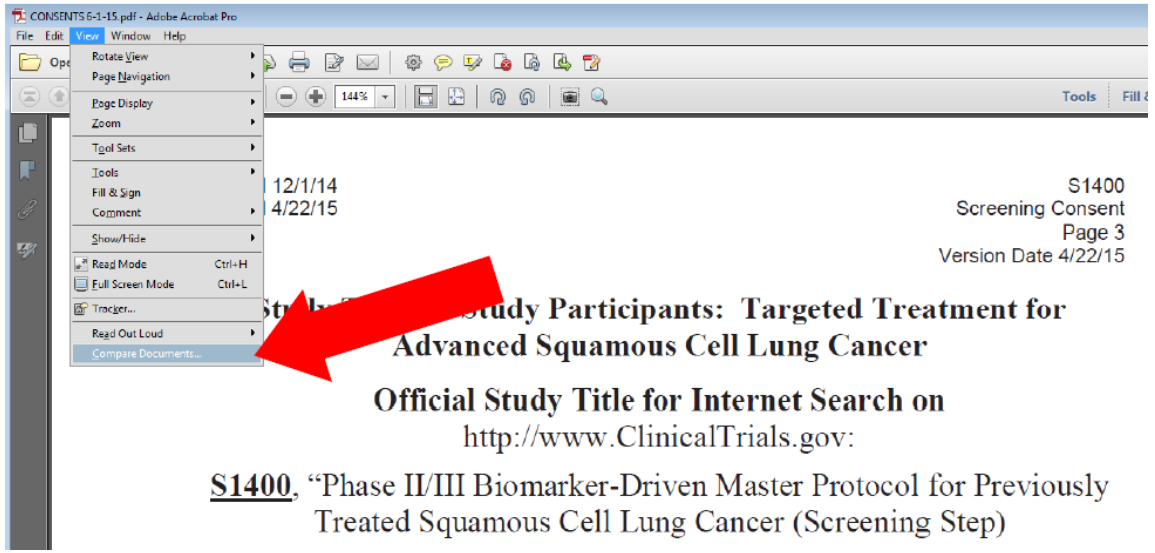
[redacted] 2/1/22

Physician Conducting Informed Consent Discussion — Date of signature

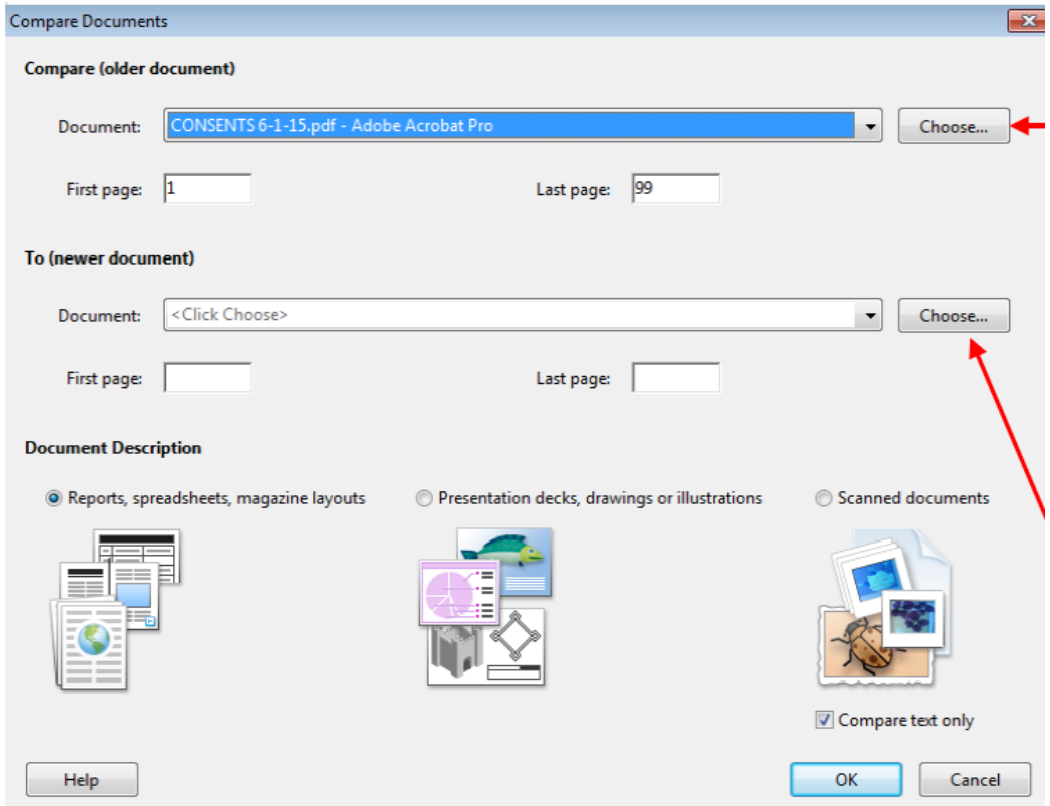
No explanation of different dates.

Informed Consent

- The wrong version signed, when taken home to review.
- Physician or institutional HIPAA signed in place of the Research HIPAA.
- Unapproved wording in consent.



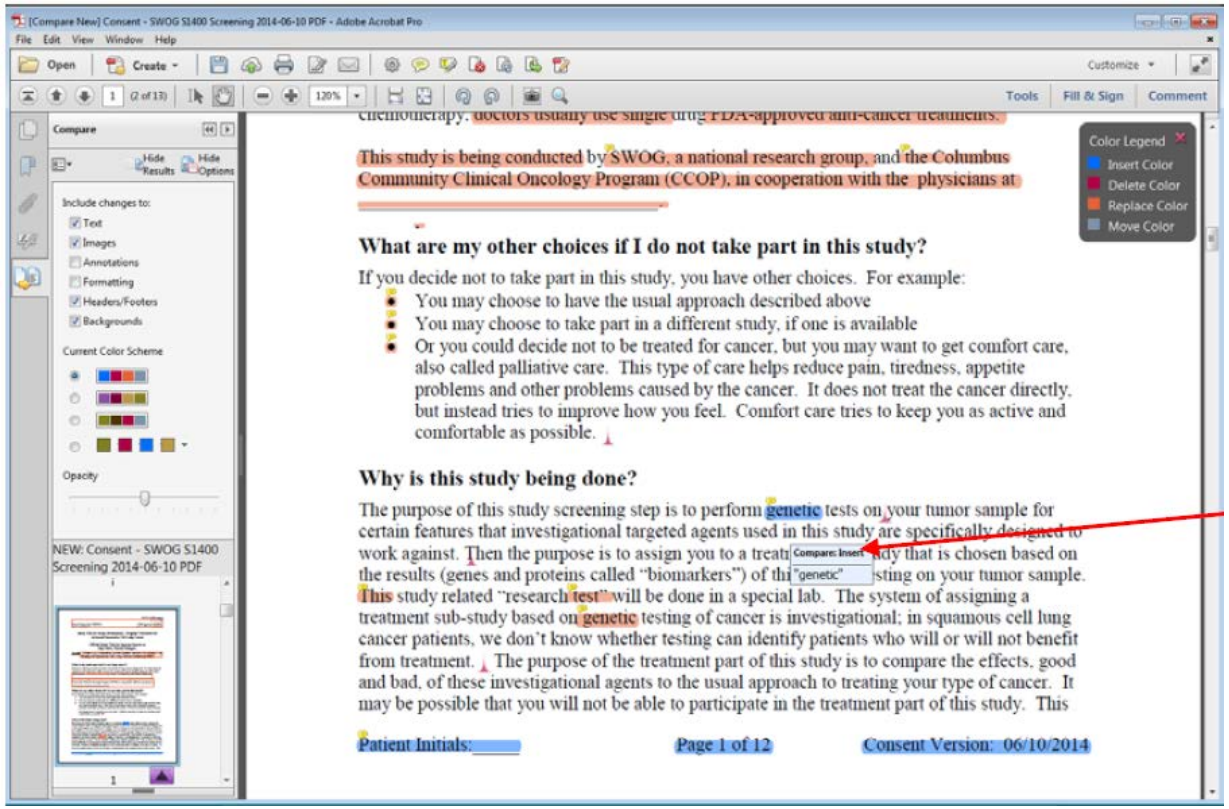
Consent Comparison



Model Consent

Site Consent

Consent Comparison



Orange highlight wording was changed.

Pink triangle means something was deleted.

Blue highlight means something was added that is not in the model consent.

Eligibility

- Performance Status (closest to registration date).

> Participants' most recent Zubrod performance status must be 0-1 (Section 10.4) and be documented within **28 days** prior to sub-study randomization.

- Lack of attribution for residual adverse events.

> Patients must have resolution of adverse event(s) of the most recent prior chemotherapy to Grade 1 or less, except alopecia and ≤ Grade 2 neuropathy which are allowed.

Anemia	Grade 2
Dyspnea	Grade 1
Fatigue	Grade 1
HTN	Grade 2
Diarrhea	Grade 1

- Lack of documentation related to prior malignancy

> No other prior invasive malignancy is allowed except for the following: adequately treated basal (or squamous cell) skin cancer, in situ breast or cervical cancer. Stage I or II invasive cancer treated with a curative intent without evidence of disease recurrence for at least five years.

Medical History:

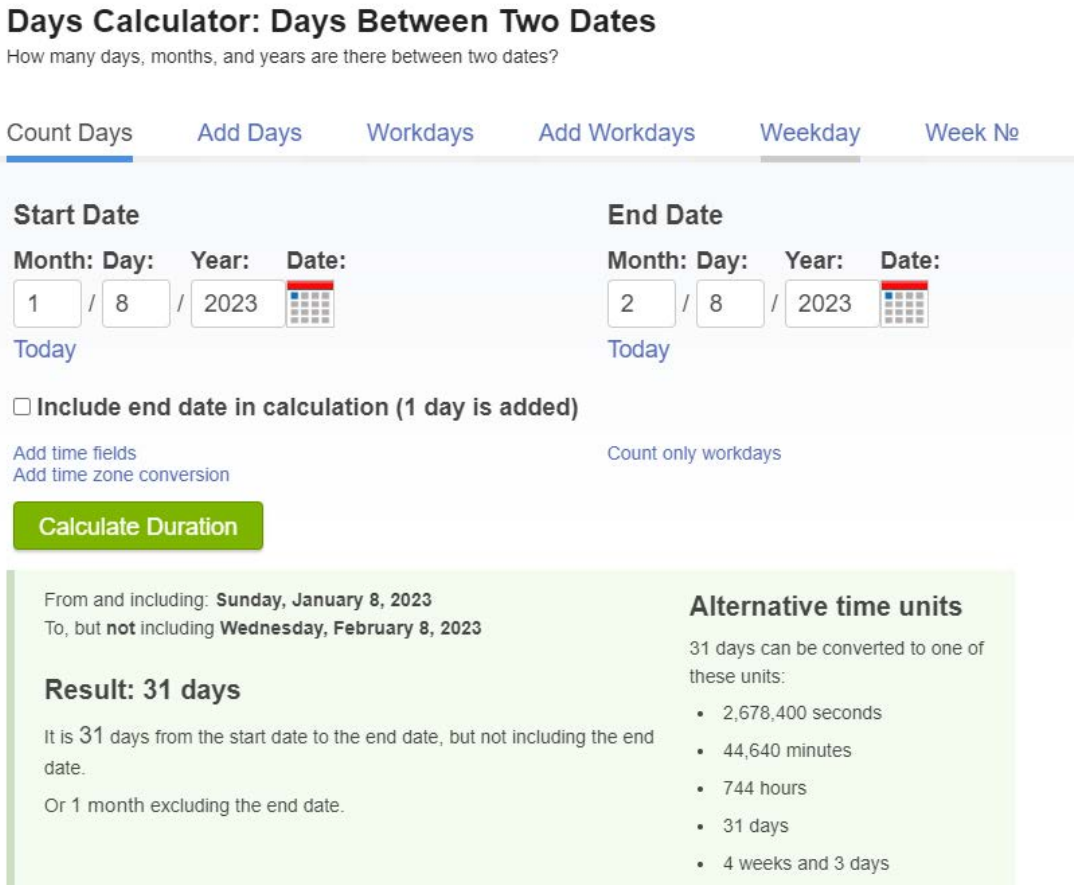
Arthritis
GERD
CAD
Prostate Cancer
Hip replacement

Eligibility

- Timing of tests outside the required window.

> Participants must have history and physical exam must be obtained within 28 days prior to sub-study randomization.

https://www.timeanddate.com/date/duration.htm



Eligibility

- No physical or height documented in the H&P note.

Date of Service 9/1/21

Interval History
Met with patient to consider participation in S1803. We discussed the study and side effects; patient is agreeable to participation.

Subjective:
Patient complains of some fatigue. Diarrhea resolved. Denies fever, shortness of breath, nausea, vomiting or weight loss.

Objective:
B/P: 132/82, Pulse 78, Temp 97.8, Resp. 18 Weight 91.6 kg

Assessment/Plan:
Patient agreeable to participation in S1803. Required tests ordered. Plan to register next week and start treatment on 2/12/23. Return visit per research.

Height	170 cm (xxx)
Weight	91.6 kg (xxx.x)
Date of history and physical exam	01 Sep 2021

Eligibility

- Childbearing potential:
  - Considered to be of reproductive potential if has had menses at any time in the preceding 12 consecutive months.
  - Don’t assume a participant is post-menopausal based on age or tubal ligation.
  - Missing a negative pregnancy test.
  - Missing documentation that the patient, whether female or male, agrees to contraception use as specified in the protocol.

Eligibility

- Common missing documentation:
  - TNM staging.
  - Last date/dose of systemic treatment with corticosteroids.

> Participants with spinal cord compression or brain metastases must not have residual neurological dysfunction, unless no further recovery is expected, and the participant has been stable on weaning doses of corticosteroids (≤ 10 mg daily prednisone or equivalent) prior to sub-study randomization.

  - Start and stop dates of prior therapies.

Adjuvant Chemotherapy	☑
Date started:	29 Mar 2019
Date completed:	12 Sep 2019

  - Whether or not the patient had a live vaccine.

Treatment

- Patient compliance with oral medication not documented.

Date of last treatment 09 Mar 2021

Were there any dose modifications or additions/omissions to protocol treatment? No

Agent name	Dose planned at cycle start	Units	Dose delivered at cycle end	Units	Total dose given	Units	Modifications	Dose modification reason	Number of days delayed (if applicable)
Lenalidomide	10	mg	10	mg	280	mg	No dose modification		
Daratumumab	1800	mg	1800	mg	7200	mg	No dose modification		

Date of Service 3/10/21

Interval History
Patient tolerating treatment without difficulty. No appreciable side effects, other than mild fatigue.

Assessment/Plan:
Multiple myeloma diagnosed 12/2/20, initial treatment with RVD, followed by transplant. Current treatment with Lenalidomide 10 mg/day, with Daratumumab per S1803. No concerning side effects, continue with treatment.

- When there is no diary required, there still needs to be documentation of any missed pills during the cycle.

Treatment

- Dose modification not per protocol.

Daratumumab/rHuPH20-Related Toxicity Management

If any of the following criteria are met, the daratumumab/rHuPH20 infusion must be held to allow for recovery from toxicity. The criteria for a dose delay are as follows:

- ≥ Grade 3 neutropenia and/or platelet count < 10,000/mm^3

≥ Grade 3 neutropenia	Lenalidomide	Hold therapy (interrupt). Follow CBC on day 8, 15, 22.

Immune-related AEs	Toxicity grade or conditions (CTCAEv4.0)	Action taken to MK-3475 (pembroli-zumab)
Pneumonitis	Grade 2	Withhold
	Grade 3 or 4, or recurrent grade 2	Permanently discontinue
Diarrhea / colitis	Grade 2 or 3	Withhold
	Grade 4	Permanently discontinue
AST / ALT elevation or Increased	Grade 2	Withhold

Treatment:

No documentation of required observation time.

> **Note that patients must remain for observation for at least 6 hours after the first dose of daratumumab (Cycle 1 Day 1).**

Missing vital signs or not all vital signs documented.

> Vital signs (pulse rate, respiratory rate, blood pressure & temperature) are required to be measured within 60 minutes prior to the infusion, during the infusion and within 30 minutes after the infusion.

Response Assessment

- Baseline Lesions – RECIST SECITON 10 of the protocol.
- Mis-categorizing Measurable vs Non-measurable disease.

Measurable Disease

- Lesions you <u>can</u> follow
- Baseline timepoint
- Tumor lesion measured in longest diameter
  - ***EXCEPT*** for lymph nodes: use short axis
- Minimum size of measurable non-nodal lesions
  - CT scan 5 mm slice: ≥10 mm
  - CT scan > 5 mm slice: 2x slice thickness
  - Calibers (clinical exam): ≥10 mm
  - Chest x-ray: ≥20 mm
  - Lymph node ≥ 15 mm

Non-measurable Disease

- All other lesions that do not meet the criteria to be measurable <u>and</u>:
  - Bone lesions
  - Leptomeningeal disease
  - Ascites
  - Pleural/pericardial effusion
  - Inflammatory breast disease
  - Cystic lesions

Response Assessment

- Not obtaining all required scans.

> For studies that use disease progression as an endpoint, all potential sites of metastases should be evaluated at each time point rather than following only sites of disease identified at baseline. It is acceptable to image only the areas of the body most likely to be involved with metastatic disease for the tumor type (chest, abdomen, pelvis, and/or bone scan are typical), with the addition of any areas with suspected involvement based upon clinical symptoms. For study-specific imaging requirements, see the Study Calendar in Section 9.0.

Response Assessment

- Frequency incorrect

CT or MRI (the same method used at pre-study to meet the eligibility criteria must be repeated every 6 weeks (+/- 7 days) for the first year, regardless of treatment delays, then every 12 weeks until disease progression. 6 weeks starts from sub-study registration.

	Pre-Study	Cycle 1	Cycle 2	Cycle 3	Cycle 4	Cycle 5	Cycle 6	Cycle 7
	≤28 d	4/19/22	5/10/22	5/31/22	6/21/22	7/12/22	8/2/22	8/23/22
PHYSICAL								
History & Physical Exam	X	X	X	X	X	X	X	X
Weight & Performance Status	X	X	X	X	X	X	X	X
Participant Diary[D]		X	X	X	X	X	X	X
Toxicity Notation		X	X	X	X	X	X	X
Smoking Status Assessment	X							
LABORATORY	<14 D don't need to repeat					Up to 48 hrs prior to Day 1		
CBC /Diff	X	X	X	X	X	X	X	X
Chemistry Panel (nonfasting)[K]	X	X	X	X	X	X	X	X
Preg test[F]		X[13]						
X-RAYS AND SCANS						plus or minus 7 days		
CT or MRI for Disease Assessment [G]	X[1]			X		X		X
Brain CT/MRI[H]	X[2]				X			

Response Assessment

- Treating past progression
- PD: One or more of the following must occur:
  - 20% ↑ in the sum of appropriate diameters of target measurable lesions over smallest sum observed using the same techniques as baseline, as well as an absolute ↑ of at least 0.5 cm.
  - Unequivocal progression of non-measurable disease
  - Appearance of any new lesion.

Protocol No	Patient ID/Initials	Investigator

Date of Assessment/Scan									
Assessment Time Point	Baseline								
Planned/Unplanned									

TARGET LESIONS

Lesion Number	Lesion Description	Method of Assessment[1]	Diameter[2] (cm)	Diameter[2] (cm)	Diameter[2] (cm)	Diameter[2] (cm)	Diameter[2] (cm)	Diameter[2] (cm)	Diameter[2] (cm)	Diameter[2] (cm)
1										
2										
3										
4										
5										

Sum of Diameters	0	0	0	0	0	0	0	0	0
Smallest sum so far									
% change from Baseline		#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
% Change from the Smallest Sum of Diameters (Nadir)		#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
EVALUATION of TARGET LESIONS[3]									

NON-TARGET LESIONS

Lesion Number	Lesion Description	Method of Assessment[1]	Status	Status[4]	Status[4]	Status[4]	Status[4]	Status[4]	Status[4]	Status[4]
1			Baseline							
2			Baseline							
3			Baseline							
New										
New										

Evaluation of Non-Target Lesions[5]								
New lesions? (Yes or No)								
OVERALL RESPONSE ASSESSMENT[6]								
Worksheet Completed by (Initials/Date)								
Investigator Determining Overall Response Assessment (Initials/Date)								

Response Assessment

- Lymphoma & Deauville scoring

#	Other Sites of Disease	Extent	Method of Assessment	Assessment Date	PET Status	SUV max
1	Lymph Node Mediastinal & Hilar	present	PET/CT	10 Jan 2020	Positive	(xx.xx)
2	Lung Single Site: LUL	present	PET/CT	10 Jan 2020	Positive	(xx.xx)

SUV max of mediastinal blood pool	(xx.xx)
SUV max of liver	(xx.xx)
Are there other FDG avid lesions that are felt to be more likely to represent something other than lymphoma?	No
If yes, describe	
Overall Deauville Score	5

PET 5-Point Scale / Deauville score:

- 1, no FDG uptake above background;
- 2, FDG uptake ≤ mediastinum;
- 3, FDG uptake > mediastinum but ≤ liver;
- 4, FDG uptake moderately >liver;
- 5, FDG uptake markedly higher than liver and/or new lesions;
- X, new areas of uptake unlikely to be related to lymphoma.

Adverse Events

- Documentation of baseline events.
  - Not enough information to determine grade at BL.
  - Events occurring up to the time of the first treatment are considered baseline.

Screening Visit: (5/1/23)

Review of Symptoms:
Patient considering participation in S1802. Complaints of dysuria, shortness of breath & fatigue. Urinalysis shows RBCs. Denies fever, numbness, pain, nausea, vomiting, constipation, or diarrhea. Good appetite.

5/1/23	
WBC	4.0
Hgb	14.0
Platelets	213
ANC	2.0
Creatinine	1.3
T. Bilirubin	0.9
AST	17
ALT	20
Alk Phos	81

Cycle 1 Day 1: (5/13/23)
Patient here to begin treatment on S1802. Complaints of dysuria & fatigue. No more shortness of breath, *pain* noticed in lower back. Denies fever, numbness, nausea, vomiting, constipation, or diarrhea. Good appetite.

5/13/23	
WBC	4.0
Hgb	11.0
Platelets	213
ANC	2.0
Creatinine	1.9
T. Bilirubin	0.9
AST	17
ALT	47
Alk Phos	81

Adverse Events

Non-clinically significant laboratory are required to be reported.

Sodium	137	0
Potassium	3.5	0
Glucose	111	1
Calcium *LLN 8.7*	7.9	0
Albumin	3.0	1
T Bilirubin	1.3	1

- Glucose increase not reported because it was not fasting.

CTCAE Term	Grade 1	Grade 2
Hyperglycemia	Abnormal glucose above baseline with no medical intervention	Change in daily management from baseline for a diabetic; oral antiglycemic agent initiated; workup for diabetes

- Corrected calcium is within normal limits.

Hypocalcemia	Corrected serum calcium of <LLN - 8.0 mg/dL; <LLN - 2.0 mmol/L; Ionized calcium <LLN - 1.0 mmol/L	Corrected serum calcium of <8.0 - 7.0 mg/dL; <2.0 - 1.75 mmol/L; Ionized calcium <1.0 - 0.9 mmol/L; symptomatic

https://globalrph.com/medcalcs/corrected-calcium-calculator-correction-for-serum-albumin-conc/

Adverse Events

Events reported incorrectly

Date 2022		BL	4/18	4/28	5/10	5/20	5/31		
Tx Cycle/Day		4/1	C1/1		C2/1		C3/1		
Hematologic	WBC (x1000)	8.8	8.5	4.0	1.5	3.0	2.9		
	Hgb (gms)	14.0	10.0	9.5	10.1	11.0	13.0		
	Platelets (X1000)	186	166	165	151	150	120		
	Lymphocytes	1.0	1.2	1.1	0.8	0.8	0.3		
	ANC	4.9	4.0	3.5	1.4	4.0	3.5		
	Glucose	104	112	89	90	114	89		
	Albumin	3.6	3.5	3.4	3.1	3.5	3.6		
	Creatinine	0.81	0.75	0.71	0.8	0.8	1.4		
	T. Bilirubin	0.3	0.5	0.5	0.8	0.6	1.0		
	AST	10	13	20	30	44	45		
	ALT	12	10	20	28	35	20		
	Alk Phos	69	70	74	70	74	130		
Other	Wt kg	104	100	102	104	100	101		
	Fatigue	1	1	1	2	2	1		
	Diarrhea	0	0	1	0	0	2		
	Dyspnea	1	1	1	1	1	1		
	Anorexia	0	0	0	1	1	1		

Events occurring on Day 1 of a cycle, PRIOR to treatment being given, are recorded in the previous cycle.

When a baseline event resolves, then recurs, it then gets reported.

Verbatim term	*Adverse event term (CTCAE v5.0)	*Adverse event grade description *(first 120 characters)*	AE start date	End date

Report all grades if start and end dates are required

Adverse Events

- Failure to document immune relationships or attributions.

AE	Grade	Attribution	Start	Stop	Ongoing	Action taken
Hypotension	1	1	10/28/21	11/18/21	☐	Dose not changed/ no treatment for
					☐	

Verbatim term	CTC adverse event term	CTCAE (4.0) grade	CTC adverse event attribution code	Adverse event status code	Serious?	Onset date	Resolution date	Action taken	Outcome of AE	Hospitalization *(at least 24 hours)*	Is the AE immune-related?	Is the AE radiation-related?	Treatment received for this AE?
hypotension	Hypotension	1	Unrelated	New	No	28 Oct 2021	18 Nov 2021	Dose Not Changed	Recovered/Resolved	☐	No	No	No

Adverse Events

Patient Name:____________________ Study # ___________________ Cycle: ______________

AE	Grade	Attribution	Start	Stop	Ongoing	Immune Related	Is this considered a serious AE needing expedited reporting	Action taken
					☐	☐ Yes ☐ No	☐ Yes ☐ No	
					☐	☐ Yes ☐ No	☐ Yes ☐ No	
					☐	☐ Yes ☐ No	☐ Yes ☐ No	
					☐	☐ Yes ☐ No	☐ Yes ☐ No	
					☐	☐ Yes ☐ No	☐ Yes ☐ No	
					☐	☐ Yes ☐ No	☐ Yes ☐ No	
					☐	☐ Yes ☐ No	☐ Yes ☐ No	
					☐	☐ Yes ☐ No	☐ Yes ☐ No	
					☐	☐ Yes ☐ No	☐ Yes ☐ No	
					☐	☐ Yes ☐ No	☐ Yes ☐ No	
					☐	☐ Yes ☐ No	☐ Yes ☐ No	
					☐	☐ Yes ☐ No	☐ Yes ☐ No	
					☐	☐ Yes ☐ No	☐ Yes ☐ No	
					☐	☐ Yes ☐ No	☐ Yes ☐ No	

Attribution: 1 definitely related; 2 unlikely related; 3 possibly related; 4 probably related; 5 unrelated

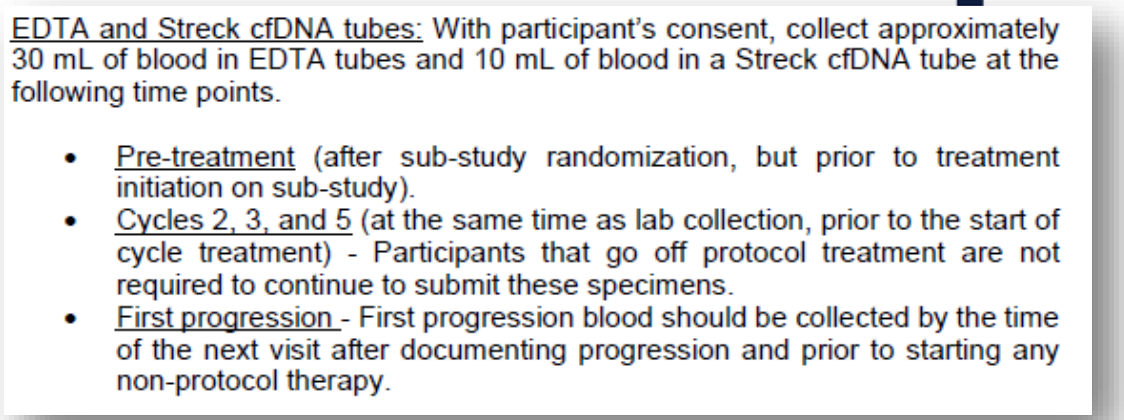
Investigators Signature: ____________________ Date: ______________________ Page: _____ of _____

Data Quality

- Specimens
- Questionnaires
- Data entry errors
- Discrepancies
- Delinquent Data

Specimens & Questionnaires

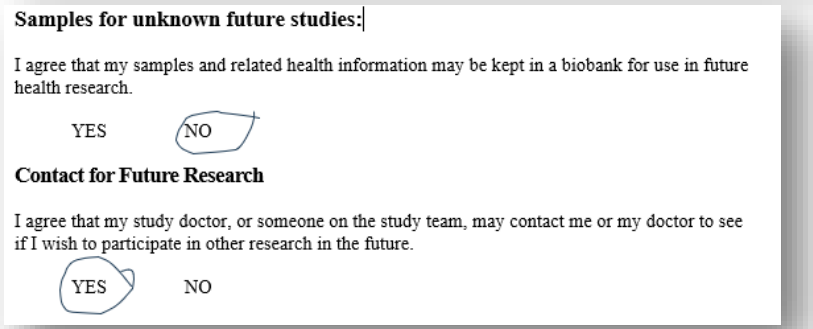
- Section 15 (Section 12 also for specimens).
- Done at the wrong time.
- Optional Specimens not drawn, when patient consented for.
- Specimens drawn and submitted, when patient refused.
- Specimen missed because kit not available.



EDTA and Streck cfDNA tubes: With participant's consent, collect approximately 30 mL of blood in EDTA tubes and 10 mL of blood in a Streck cfDNA tube at the following time points.

- Pre-treatment (after sub-study randomization, but prior to treatment initiation on sub-study).
- Cycles 2, 3, and 5 (at the same time as lab collection, prior to the start of cycle treatment) - Participants that go off protocol treatment are not required to continue to submit these specimens.
- First progression - First progression blood should be collected by the time of the next visit after documenting progression and prior to starting any non-protocol therapy.

If the patient consents, specimens must be submitted as follows



Samples for unknown future studies:

I agree that my samples and related health information may be kept in a biobank for use in future health research.

YES NO

Contact for Future Research

I agree that my study doctor, or someone on the study team, may contact me or my doctor to see if I wish to participate in other research in the future.

YES NO

Data Entry Errors

Date of initial diagnosis

Surgical Pathology Report

Requestion Physician: [redacted]
Patient: [redacted]
Date collected: 10/3/16
Accession#: SS-16-02576
Date Received: 10/3/16
Report Date: 10/7/16

DIAGNOSIS
CONSULTATION CASE
Outside slides and blocks labeled S16-1681, collection date 08/19/2016.
Skin, left perianal lesion, biopsy:
- MALIGNANT MELANOMA, MEASURING APPROXIMATELY 6.50MM IN DEPTH, ULCERATED. See
Discussion and template below.

Date of initial diagnosis of NSCLC (any stage)	8/19/16

Data Entry Errors

Laboratory conversions

FREE KAPPA LIGHT CHAIN	3.3 - 19.4 mg/L	7.5
FREE LAMBDA LIGHT CHAIN	5.7 - 26.3 mg/L	5.5
FREE K/L RATIO	0.26 - 1.65	1.36

Kappa free light chain	0.75 mg/dL (xxxxx.xx)
Lambda free light chain	0.55 mg/dL (xxxxx.xx)
Kappa/lambda ratio *(derived)*	1.36 (xxxxx.xx)

Data Entry Errors

Weight

	1/26/21	2/1/21	2/23/21
Height	168 cm		168 cm
Weight	85.1	81.1	84.0
BSA_M	1.99	1.95	1.98

Page: **Treatment - Cycle 01**

Instructions: Please complete this form after every cycle (1 cycle = 28 days). If any were not administered during this reporting period, please enter "0" for the dose valu

Has the patient progressed or relapsed (per the definition in Section 10.0 of the protocol)?	No
TREATMENT FOR THIS CYCLE	
Weight	85.1 kg (xxx.x)
Reporting period start date	26 Jan 2021
Reporting period end date	23 Feb 2021

Data Discrepancies

Adverse Events unclear

Treatment Unclear

April 6, 2023

Interval History:

Patient here for evaluation prior to Cycle 5. He has been tolerating treatment without many side effects. Continues to complain of right hip pain with some difficulty in walking, but can still play golf. Denies any nausea, vomiting, diarrhea, shortness of breath, fatigue or pain.

Pain Score: 8

Event	Gr	ATT	Start	End	Action
Fatigue	1	3	3/15/23	ongoing	None
Dyspnea	2	3	3/15/23	ongoing	None
Pain	2	1	2/1/23	4/6/23	None

Investigator Signature: _____ Date: 4/6/23

April 6, 2023

Medications at end of visit:

Omeprazole 20 mg
Zocor 20 mg
Immodium
Lenalidomide 15 mg.

Assessment Plan:

Myeloma, continue with treatment on S1803, Daratumumab & Lenalidomide 5 mg.

Delinquent Data

Delinquent data > than 3 months after the due date for baseline & on treatment forms & > than 6 months after the due date for follow-up data.

Section 14.4 for data

Source Doc/RAVE®

14.4 Data Submission Overview and Timepoints

a. WITHIN 15 DAYS OF **S1800A** RANDOMIZATION, SUBMIT:

S1800A Onstudy Form

S1800A Eligibility Criteria Form

Smoking Status Assessment Form

Baseline Tumor Assessment Form (RECIST 1.1)

Radiology reports from all scans performed to assess disease at baseline (NOTE: Upload reports via the Source Documentation: Baseline form in Rave®)

For patients screened under legacy **S1400**: PD-L1 testing (Dako 22C3 PharmDX assay) report.
(NOTE: Upload report via the Source Documentation: Baseline form in Rave®)

Submit to IROC via TRIAD for Central Radiology Review: Images from scans performed to assess disease at baseline as specified in Section 15.5.

b. IF PATIENT CONSENTS, SUBMIT SPECIMENS:

Specimens as specified in Section 15.0 of **S1800A**.

Questions?

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