SWOG | CANCER RESEARCH NETWORK

Clinical Research Associates (CRA)

Clinical Trials Training Course Manual

Seattle, WA
April 6, 2022

SWOG Clinical Trials Training Course (CTTC)

Hybrid Agenda for Oncology Research Professionals

Hyatt Regency Seattle

Wednesday, April 6, 2022

Morning Session		**Location: Columbia A**
7:00 – 7:20	Registration ***(continental breakfast provided)***	
7:20 – 7:30	Introduction	Rodney Sutter, CCRP
7:30 – 7:55	Clinical Trials and Protocol Development	Dana Sparks, MAT
7:55 – 8:20	Data Submission	Tonya Johnson, BS
8:20 – 8:30	Patient Reported Outcomes	Monica Yee, BA, CCRP
8:30 – 8:55	Reports to Support Quality Data	Phyllis Goodman, MS
8:55 – 9:10	***BREAK***	
9:10 – 9:35	Long Term Follow-Up	Connie Szczepanek, RN, BSN
9:35 – 10:00	Adverse Event Reporting	Amy Johnson, BA, CCRP
10:00 – 10:30	Serious Adverse Events	Maggie Spillers, BSN, RN
10:30 – 10:45	***BREAK***	
10:45 – 11:10	Audits/Quality Assurance	Elaine Armstrong, MS
11:10 – 11:35	Specimen Tracking System	Hannah Hale, BS
11:35 – 11:45	Tips for Specimen Submission	Hannah Brown, BS
11:45 – 12:10	Scientific Impact of the CRA	Michael LeBlanc, PhD
12:10 – 1:45	***LUNCH (on your own)***	
Afternoon Session		**Location: Columbia A**
1:45 – 2:00	Introduction to the Practicum	Christine Magner
2:00 – 4:00	Practicum Session	Data Operations Center Staff

SWOG CANCER RESEARCH NETWORK

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The planning and implementation of the SWOG Clinical Trials Training Course involves the diligent efforts of a group of dedicated people. Their time, energy and commitment are sincerely appreciated. We would like to acknowledge the following people for their valuable contribution to the Spring 2022 CRA Clinical Trials Training Course.

• **Administrative Support**	Caylene Castagno	Riley Williamson
• **Certificates**	Caylene Castagno	Riley Williamson
• **Registrations**	Dave Law Caylene Castagno	Connie Barnes Riley Williamson
• **Slides, Signage, and Photos**	Authors with support from and Caylene Castagno	Riley Williamson
• **Training Course Manual**	Caylene Castagno	Riley Williamson
• **Practicum Session**	Christine Magner Leah Everhart	Larry Kaye Tracy Maher
• **SWOG Support**	Connie Barnes Courtney Wille Dana Sparks Elaine Armstrong Hannah Brown Jo Horn	Jamie Myers Kari Williams Keisha Humphries Mike LeBlanc Phyllis Goodman

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Spring 2022

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GLOSSARY

ACTIVATION: The decision by a Group/Institution to open a study for patient entry (which occurs after CTEP approval).

ACTIVATION AMENDMENT: An amendment sent to CTEP detailing any protocol change that occurs after CTEP approval and prior to local activation. Examples: The study is approved by CTEP with recommendations which are incorporated prior to activation; these changes must be listed and submitted by CTEP as an Activation Amendment.

ADR/ Adverse Drug Reaction: (see SAE/Serious Adverse Event)

ADVERSE EVENT: Any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporarily associated with the use of a medical treatment or procedure regardless of whether it is considered related to the medical treatment or procedure. For NCI-sponsored clinical trials, reportable adverse events are enumerated in published criteria, currently Common Terminology Criteria for Adverse Events (CTCAE) version 4.0 and version 5.0.

AFFILIATE PROGRAM: Membership program for small physician consortia or individual MDs requiring affiliation with full member institutions.

ALLIANCE: The Alliance for Clinical Trials in Oncology. An adult clinical trial group sponsored by the NCI, supporting research as one of the 5 Lead Protocol Organizations (LPO) within the NCTN.

AMENDMENT: Changes to the protocol which directly affect patient care or treatment and have the potential to adversely affect patient risk; these changes usually constitute a change in the treatment plan, dosage modifications or study parameters. Examples of amendments include an increase or decrease in the dose of a drug and addition or deletion of a study parameter. Justification for the amendment is required; amendments require NCI approval. The amendment date appears in the upper right-hand corner of amended protocol pages. Amendments will almost always require full board IRB review.

APPROVAL: CTEP approves the protocol in writing when the science and informed consent are acceptable, the IRB documentation is on file (not applicable to Groups), and the drugs to be supplied are specified by the Drug Management and Authorization Section. If recommendations are specified, CTEP expects an "Activation Amendment" to indicate any changes to the approved document.

CaDSR: Cancer Data Standards Registry and Repository.

CANCER CENTER: An institution which is designated by NCI as a comprehensive or clinical cancer center and is eligible to conduct IND drug studies.

CCD: Cancer Care and Delivery (Committee within Cancer Control and Prevention).

CCP: Cancer Control and Prevention.

CCIRC: Cancer Clinical Investigations Review Committee: The committee which is responsible for peer reviews of Group Competing grant applications (Site Visit).

CCTG: Canadian Cancer Trials Group.

CDMS: The NCTN centralized Clinical Data Management System (e.g. Medidata Rave).

CDUS: Clinical Data Update System.

CIRB: NCI's Central Institutional Review Board.

CLINICAL/INVESTIGATORS BROCHURE: This document contains all relevant information about the drug, including animal screening, preclinical toxicology, and detailed pharmaceutical data. Also included if available is a summary of current knowledge about pharmacology and mechanism of action and a full description of the clinical toxicities.

CLINICAL NETWORK GROUPS: Cancer clinical network groups are composed of investigators who join together to develop and implement common protocols. The distinguishing characteristic of network groups is the group chairs office, operations, data collection and statistical offices which support the administrative requirements of the research and perform central data collection and analysis.

CLINICAL TRIALS MONITORING SERVICE: The Theradex organization receives, reviews, and performs data management service on individual patient case report forms for Phase I and some Phase II NCI investigational drug studies.

CLOSED: The decision by a Group, Institution, or NCI to close a study to new patient entries; previously entered patients will continue treatment.

COG: Children's Oncology Group. A pediatric clinical trial group sponsored by the NCI, supporting research as one of the 5 Lead Protocol Organizations (LPO) within the NCTN.

COMMERCIAL DRUG: A drug, given on an NCI study, for which no IND has been filed.

COMPLETED: The study is closed and no patients are being treated or followed for data collection.

CRA: The Clinical Research Associate (currently known as ORP, Oncology Research Professional) at the institution responsible for clinical and data record collection and data submission to the SDMC. The Head CRA is responsible for receiving information from the Group, disseminating it and responding to requests.

CRAB: Cancer Research And Biostatistics, an administrative arm of the SWOG Statistical Center.

CTCAE: Common Terminology Criteria for Adverse Events (current version is 5.0).

CTEP: Cancer Therapy Evaluation Program, DCTD, NCI. A division of the NCI which funds cancer treatment trials.

CTEP-AERS: CTEP Adverse Event Reporting System, NCI's on-line SAE reporting mechanism (formerly AdEERS: Adverse Event Expedited Reporting System).

CTEP LETTER: Newsletter which announces the approval of new drugs for clinical trials and other drug development information.

CTMB: Clinical Trials Monitoring Branch, CTEP.

CTSU: The Cancer Trials Support Unit (CTSU) is sponsored by the National Cancer Institute (NCI) for the support of a national network of physicians to participate in NCI-sponsored cancer treatment trials.

CTTC: Clinical Trials Training Course.

DC: The Statistical Center Data Coordinator who performs full data evaluation on patient data received.

DCP: Division of Cancer Prevention. A division of the NCI that funds cancer control research and the NCORP Program.

DCTD: Division of Cancer Treatment and Diagnosis, NCI.

DHHS: The United States Department of Health and Human Services.

DRAS: Drug Regulatory Affairs Section, RAB, CTEP, DCTD, NCI.

DRUG ACCOUNTABILITY RECORD FORM (DARF): Form used to maintain records of disposition of NCI investigational drugs. NIH Form-2564.

DRUG MONITOR: A physician in IDB assigned to coordinate the clinical development of specific IND drugs.

DSMC: Data and Safety Monitoring Committee.

DTP: Developmental Therapeutics Program, DCTD, NCI.

ECOG-ACRIN: Eastern Cooperative Oncology Group and American Radiology Imaging Network. An adult clinical trial group sponsored by the NCI, supporting research as one of the 5 Lead Protocol Organizations (LPO) within the NCTN.

EORTC: European Organization for Research and Treatment of Cancer. An international non-profit organization the NCI collaborates with to promote cooperation and coordination of cancer research in the United States and Europe.

FDA: Food and Drug Administration, DHHS.

FDA-1572: Also referred to as a "Statement of Investigator," it is a requirement of section 505(l) of the Food, Drug, and Cosmetic Act and §312.1 of Title 21 CFR, that an investigator complete this form as a condition for receiving and conducting clinical studies involving investigational drug(s). For CTEP sponsored studies, the PMB is responsible for collecting this form annually. It includes the investigator's training and experience and provides for legal certifications.

FEDERALWIDE ASSURANCE (FWA): A formal written agreement with the Office for Human Research Protections (on behalf of the Secretary of DHHS) and an institution which conducts or supports DHHS sponsored research involving human subjects.

GCO: Group Chair's Office located at Oregon Health & Science University in Portland.

HHS 310: Protection of Human Subjects Assurance/Certification/Declaration. An HHS Form 310 is an optional form used by an institution to document the initial and annual re-review of protocols by its Institutional Review Board (IRB).

HIPAA: Health Insurance Portability and Accountability Act.

ICS: Investigator/Clinical Research Associate/Nurse Contribution Sheets.

IDB: Investigational Drug Branch, CTEP, DCTD, NCI.

IND: Investigational New Drug Application. The IND is the legal mechanism under which experimental drug research is performed in the United States. An IND is submitted to the Food and Drug Administration in order to receive an exception from premarketing approval requirements so that experimental clinical trials may be conducted.

IND-EXEMPT: Use of a drug in a research study that meets the criteria outlined in the Code of Federal Regulations 21 CFR 312.2. See also COMMERCIAL DRUG.

INVESTIGATIONAL DRUG: A drug, given on an NCI study, for which an IND has been filed.

INVESTIGATOR: Any physician who assumes full responsibility for the treatment and evaluation of patients on research protocols as well as the integrity of the research data.

LAPS: Lead Academic Participating Sites.

LOI: The Letter of Intent is an investigator's declaration of interest in conduction a Phase II trial with a specific CTEP-supplied investigational drug in a particular disease. Approval of the LOI by CTEP commits an investigator to submit a protocol within a specified timeframe.

LPO: Lead Protocol Organization within the NCTN.

LUNG-MAP: SWOG-coordinated "Master Protocol" (S1400). A Biomarker-Targeted Second-Line Therapy in Treating Patients With Recurrent Stage IV Squamous Cell Lung Cancer. This screening and multi-sub-study randomized phase II/III trial will establish a method for genomic screening of similar large cancer populations followed by assigning and accruing simultaneously to a multi-sub-study hybrid.

MedDRA: Medical Dictionary for Regulatory Activities Terminology.

MEDIDATA RAVE: Commercial software purchased by the NCI that provides a single electronic data capture platform accommodating the same look and feel for the CRA across network group sponsored trials they manage.

METADATA: Data about data. Metadata is structured information that describes, explains, locates, or otherwise makes it easier to retrieve, use or manage an information resource.

NCAB: National Cancer Advisory Board.

NCI: National Cancer Institute, NIH, DHHS.

NCIC: National Cancer Institute of Canada (now known as the Canadian Cancer Trials Group, CCTG).

NCORP: NCI Community Oncology Research Program. NCORP is a community-based program that builds upon the scope and activities of NCI's previously supported community networks.

NCTN: National Clinical Trials Network.

NDA: New Drug Application is the formal process by which the FDA makes a drug commercially available to patients and physicians for specific medications.

NDI: National Death Index.

NEW DRUG STUDY GROUP: A group of highly qualified clinical researchers at an institution approved by IDB to participate in NCI's drug development program.

NIA: Non-institutional Investigator Agreement. An OHRP-authorized document entered into between a signatory institution and a non-institutional affiliate investigator (e.g., private practitioner), which assures compliance with 45 CFR 46 for a specified activity (e.g., network oncology group trials).

NIH: National Institutes of Health, DHHS.

NRG: An adult clinical trial group sponsored by the NCI, supporting research as one of the 5 Lead Protocol Organizations (LPO) within the NCTN.

OFFICIALLY FILED: At the time of CTEP approval, the protocol document, the informed consent, or amendment is placed in the "approved" PIO file and is distributed to the Clinical Trials Monitoring Services, the Food and Drug Administration, and/or PDQ.

OHRP: Office for Human Research Protections, DHHS.

OPEN: Oncology Patient Enrollment Network; the centralized portal for patient registrations to NCTN trials.

ORP: Oncology Research Professional.

P01: Funding mechanisms for Program Project Grants (PPGs) (investigator initiated).

PCPT: Prostate Cancer Prevention Trial, SWOG-9217.

PDQ: The Physician Data Query is an on-line data base which makes state-of-the art treatment information, directory information, and protocol information available to primary care physicians. This data base is maintained by the International Cancer Research Data Base Branch, International Cancer Information Center, NCI.

PHS: Public Health Service, DHHS.

PIO: The Protocol and Information Office, CTEP, DCTD manages the protocol and amendment review process and maintains the official record of all NCI sponsored protocols as well as voluntary protocols for PDQ.

PMB: Pharmaceutical Management Branch, CTEP.

PRC: The CTEP Protocol Review Committee reviews and approves all studies involving DCTD investigational drugs, network group, or CCOP credit.

PRINCIPAL INVESTIGATOR (PI): Name of physician who has organizational and fiscal responsibility for the use of federal funds to conduct a plan of research which frequently includes several clinical trials, i.e., Contract PI, Group Chairman, R01/P01 PI, etc.

PROTOCOL CHAIRMAN: See Study Chair.

PC: Operations Office Protocol Coordinator responsible for the development and maintenance of protocol documents for the Group.

QACS: Quality Assurance and Compliance Section, RAB, CTEP, DCTD, NCI.

QARC: The Quality Assurance Review Center reviews all SWOG protocols containing a significant radiation therapy component, performs rapid reviews of radiation therapy treatment records and serves as a central repository for these records.

QOL: Quality of Life.

QUALITY ASSURANCE: A method to assure the quality of the data which supports scientific conclusions through the routine auditing of clinical trial data.

R01: Funding mechanism for new research proposals (investigator initiated).

RAB: Regulatory Affairs Branch, CTEP, DCTD, NCI, NIH.

RECIST: Response Evaluation Criteria In Solid Tumors (current version is 1.1).

RESEARCH BASE: An institution or network group which assumes a broad range of responsibilities and functions for the support of clinical trials conducted under its name. It supports the investigator in developing, organizing, implementing, and analyzing clinical trials. It assumes responsibility for the quality of the research, both in concept and execution, and has an important role in assuring patient safety.

REVISIONS: Administrative changes to a protocol which do not have the potential to adversely affect patient risk. Examples of revisions include change of study chair, addition or deletion of a participating institution, or correction of an error. The revision date appears in the upper right hand corner of revised protocol pages.

RFA: Request for Applications. NCI sends out a request for studies dealing with their priority research areas that they have specifically put money aside for funding if high quality applications are received and approved.

ROS: Report of Studies.

SAE/SERIOUS ADVERSE EVENT: An SAE is a serious, fatal, or life-threatening clinical experience in a patient which is thought to be drug related. Specific guidelines for SAE definitions and reporting requirements are shown in Section 16 of each SWOG protocol. (Formerly called ADR [Adverse Drug Reaction])

SDMC: Statistics and Data Management Center.

SELECT: Selenium and Vitamin E Cancer Prevention Trial (S0000).

SPONSOR: An organization or individual who assumes legal responsibilities for supervising or overseeing clinical trials with investigational agents.

STUDY CHAIR: The scientific chair of a SWOG study responsible for developing and monitoring the study as well as analyzing, reporting, and publishing its results.

SWOG: An adult clinical trial group sponsored by the NCI, supporting research as one of the 5 Lead Protocol Organizations (LPO) within the NCTN.

TEMPORARILY CLOSED: The decision by a Group, Institution, or NCI to stop patient entry pending study evaluation.

TRIAD: Transmission of Imaging and Data. Provides seamless exchange of images and data for accreditation of clinical trials and registries. TRIAD is the only image management workflow system tightly integrated with NCTN core systems allowing research personnel at NCTN research sites to submit data and images for the trials that are part of NCTN.

WUA: Web User Administrator. A designee at the institution level who is responsible for assigning permissions to web applications.

VITAL INFORMATION EVERY CRA SHOULD KNOW

This section contains a brief orientation, tips and guidelines for the following topics:

- SWOG Contact Reference Sheets
- Studies Coordinated by other Lead Protocol Organizations (LPO)

CONTACT REFERENCE SHEET

Data Operations Center:	SWOG Data Operations Center c/o Cancer Research And Biostatistics 1505 Westlake Ave N, STE 750
Hours: 6:30-4:00 PT	Seattle, WA 98109
Data Submission Fax Line:	800-892-4007
Study-Specific Questions:	Email
Breast	breastquestion@crab.org
Cancer Control	cancercontrolquestion@crab.org
GI	giquestion@crab.org
GU	guquestion@crab.org
GYN	gynquestion@crab.org
Leukemia	leukemiaquestion@crab.org
Lung	lungquestion@crab.org
Lymphoma	lymphomaquestion@crab.org
Melanoma	melanomaquestion@crab.org
Myeloma	myelomaquestion@crab.org
Sarcoma	sarcomaquestion@crab.org
Rare Tumors	raretumors@crab.org
General Questions:	datamanagement@crab.org
Phone:	206-652-2267

Contact the SWOG Data Operations Center for assistance with:

CRA Clinical Trials Training Course (CTTC): Questions pertaining to the planning of or attendance at the training course should be directed to the Data Operations Center.

Forms Completion, Data Submission, Queries and Expectation Reports: All data are submitted electronically via Medidata Rave® or the CRA Workbench. Information regarding the proper forms to complete and when to submit them is outlined in the Data Submission section of the protocol. Questions about forms, the Expectation Report or outstanding queries for SWOG-coordinated studies should be directed to the committee-specific email address above. Questions regarding multiple studies on your Expectation Report should be directed to expectationreportquestion@crab.org.

Oncology Research Professional (ORP) Manual: This manual is available online at www.swog.org. (Go to the CRA Workbench, then click on ORP Manual).

Pathology and Radiotherapy Material Submission: The Discipline Review section of the protocol provides details on whether pathology and/or radiotherapy review are required, and, if so, which specific materials are to be submitted, and where to send them. Questions regarding these requirements should be directed to the study Data Coordinator.

Patient Registration/Patient Eligibility: Patient registrations to all SWOG studies are detailed in Section 13 of each protocol. Nearly all SWOG studies now use the OPEN application accessed at https://open.ctsu.org or from the OPEN Patient Registration link on the SWOG CRA workbench. Eligibility criteria are always in Section 5 of the protocol. Questions pertaining to patient eligibility for SWOG-coordinated protocols should be directed to the study Data Coordinator.

Specimen Tracking System (SpecTrack): General questions in how to access or use the Specimen Tracking System should be directed to the study Data Coordinator. Errors or technical issues resulting in a failed submission should be emailed to us at technicalquestion@crab.org and include a screen shot or copy of the error received.

CONTACT REFERENCE SHEET

Operations Office:

Hours: 8:00-4:30 CT

SWOG Operations Office
4201 Medical Drive, Suite 250
San Antonio, Texas 78229-5631

Phone: 210-614-8808

Contact the SWOG Operations Office for assistance with:

Adverse Drug Reactions: When a patient experiences an adverse drug reaction you will file Serious Adverse Events according to protocol specifications and via CTEP-AERS. Should you need assistance with this process or are unclear if the event needs to be reported, contact the SAE Coordinator.

Audits: Any items related to past, present or future audits should be referred to the Quality Assurance Manager or other available Auditors.

Credits: If you need to obtain information on Credit assignments for treatment and cancer control trials, contact the Operations Office.

Membership/Institution Assurances: Questions about membership or updates/changes to SWOG Roster information should be directed to the Programs Manager.

Protocol Mailings/Updates: Notifications for protocol mailings and updates are sent electronically the 1st and 15th of each month. Contact the disease site Protocol Coordinator for assistance.

SWOG Group Meeting: Questions pertaining to the conduction of or attendance at the spring or fall group-wide meetings should be directed to the Meetings Manager.

CONTACT REFERENCE SHEET

Group Chair's Office:

Hours: 8:00-4:00 PT

SWOG Group Chairs Office
3181 SW Sam Jackson Park Road
MC: L586
Oregon Health & Science University
Portland, OR 97239

Phone: 503-494-5586

Contact the SWOG Group Chair's Office for assistance with:

Funding/Payments/Reimbursement: If you have questions about funding, payments you have received, status of reimbursements or need assistance in reconciling your records with these payments you should contact the group Financial Administrator.

SWOG Newsletter: Do you have an idea or suggestions for the SWOG Newsletter? Would like to provide feedback or inquiry on a current edition? Contact our Group Chair's Office for assistance.

Statistical Center:

Hours: 8:00-5:00 PT

SWOG Statistical Center
Fred Hutchinson Cancer Research Center
1100 Fairview Ave N, MC-C102
PO Box 19024
Seattle, Washington 98109-1024

Phone: 206-667-4623

Contact the SWOG Statistical Center for assistance with:

Institutional Performance Review Reports: These reports are distributed monthly to institutions. Questions concerning the Institutional Performance Review Report are handled by Phyllis Goodman, Managing Statistician at the Statistical Center.

Meeting Report: The Group *Report of Studies* is prepared by the Statistical Center. You may download a copy of the Report at the SWOG website: www.swog.org. Questions with regard to contents of the Report should be directed to the Statistical Center.

Protocol Accrual and Statistical Analysis: Questions regarding accrual and statistical analysis of Group protocols should be directed to the committee Statistician at the Statistical Center.

REFERENCE SHEET – OTHER CONTACTS

Medidata Rave®: All new studies require the use of Medidata Rave® as the common electronic data capture (EDC) software mandated for use by all groups within the NCTN. Questions regarding user access, passwords, study invitations or technical issues with the site should be directed to the CTSU Helpdesk by email (ctsucontact@westat.com) or phone (888-823-5923). Form or study-specific questions should always be sent by email using the committee-specific distribution lists on page 4.

Treatment Modification or Interpretation: Questions which require medical judgment should be directed to the physician assigned as the Study Chair for that protocol. Prior to contacting the Study Chair, the protocol should be reviewed and a physician within your institution should be consulted. Phone numbers for Study Chairs are provided on the title page of each protocol. Typically, a back-up contact is also provided here and at the end of Section 8.0 if the primary Study Chair is not available. If neither is available, you can contact the disease site chair, then the Executive Officer at the Group Chair's Office.

Trials Conducted by Another Group: Questions regarding protocols coordinated by a different LPO should be directed to that coordinating group or the CTSU.

REFERENCE SHEET – INTERGROUP STUDIES

Refer to the ORP Manual for complete information. The ORP Manual can be accessed or downloaded from the SWOG website; Go to www.swog.org, click on Policies & Manuals, CRA Manual or go to the CRA Workbench, then click on ORP Manual.

Definitions:

- *Intergroup Studies:* studies involving more than one LPO (e.g., SWOG and ECOG-ACRIN). It is important to note that only one LPO coordinates the study.
- *Coordinating group*: the LPO conducting the study. This group writes the study, dictates eligibility, randomizes the patient to a specific treatment, collects and analyzes the data, and publishes the results of the study.

Purpose:

The purpose of an intergroup study is to hasten the accrual of patients so that the study results may be obtained in a timelier manner. This is achieved by having several LPO's participate in the study. Generally, intergroup studies are large Phase III studies in which two or more treatments are being compared.

The NCI has implemented the Clinical Trials Support Unit (CTSU), through which most Phase III intergroup trials are conducted. Please see the CTSU website at www.ctsu.org for additional information.

Identifying intergroup studies:

Both the title page of the protocol and the priority list specify the participants of the study. For intergroup studies, these participants will include more than one LPO.

Determining the coordinating group:

The coordinating LPO of an intergroup study will be capitalized or boldfaced and is almost always at the top of the title page of the protocol.

Steps to follow when enrolling a patient to a non-SWOG coordinated study:

(All of these steps must be completed before the registration is considered final and treatment can begin).

1) *Determine Eligibility.* Use the eligibility criteria provided in the protocol. Some LPO's do not provide a separate checklist so it is the institution's responsibility to work through the eligibility criteria stated in the body of the protocol before completing the registration.
2) *Fill out all required paper work* (e.g., eligibility checklists, randomization worksheets) and have them on hand when you initiate the enrollment in OPEN.

Data Flow and Expectation System for Intergroups:
SWOG Institutions are responsible for submission of all information required by the individual intergroup protocols. Required forms and follow-up information should be sent directly to the responsible LPO conducting the study.

SWOG does not post expectations for studies coordinated by other LPO's. (Exceptions to this policy are for selected studies that require pathology submissions directly to SWOG. In these rare cases, expectations will continue to be posted). Institutional Performance Review (IPR) statistics only reflect data for SWOG coordinated trials.

Intergroup treatment start policies:
Depending on the LPO that is coordinating the study, there is a different time frame allowed between patient registration and the projected date of start of treatment. When doing a registration for a study not coordinated by SWOG, please make sure that the date on which treatment is planned to begin falls within the appropriate time frame stated in the protocol.

Questions related to an intergroup study:
Questions about an intergroup study must always be directed to the coordinating LPO. If the study is not coordinated by SWOG, the SWOG Data Operations Center is not authorized to answer protocol related questions, including those pertaining to eligibility, treatment plan, or dosage modification. Be sure to follow up directly with the other group's data management department.

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Welcome to the Spring 2022 Clinical Trials Training Course Practicum Session!

The purpose of the practicum is to provide you with a good foundation and understanding of the protocol policies and procedures you will encounter as a SWOG Clinical Research Associate (CRA). Please note that we use the term "CRA" very broadly. In this practicum, "CRA" means anyone responsible for submitting data for SWOG Protocols.

For this practicum session, we have presenters on site and virtually from the Data Operations Center in Seattle that will go through the exercises with you and answer any questions you may have. It is important to note that due to circumstances around the pandemic and holding a hybrid meeting with remote and in-person attendees, the training you receive today is different than the Practicum available on the SWOG website (www.swog.org). A link to this document is available in an email sent to virtual attendees, as well as on the SWOG Group Meeting site. It is highly recommended and encouraged that our virtual attendees download the document to follow along and take notes.

The correct answers for each exercise are pre-filled in your manual and located at the bottom of the page in small type. Additional information about each topic can be found in the Oncology Research Professional (ORP) Manual. The ORP Manual can be accessed or downloaded from the SWOG website, just click on the **ORP Manual link within the CRA Workbench.**

Our aim is to give you a practical understanding of the importance of correct and complete documentation of each patient's experience on a SWOG Clinical Trial. Accurate and timely data submission is essential in fulfilling the objectives of any study.

Today, we will go through the exercises on the following pages. For virtual attendees, please feel free to download and mark-up your own version of this document. For those attending in person, please feel free to write in your manual.

Discussion Points

- Online data submission is required for all SWOG studies. Studies activated after 08/01/2012 will be in Medidata Rave. Older studies still use the SWOG system – forms for these studies can be accessed by going to www.SWOG.org, CRA Workbench and clicking on "Rave Data Submission" or "Pre-Rave Data Submission".
- Data submission requirements are found in the online version of the protocol also available at www.SWOG.org and on CTSU.
- Only the most current versions of forms are online. Samples of current forms can be found in the Master Form Set available on the CTSU website.

* Asterisks are used throughout the Practicum to lead you to referenced documents.

Background Information: Patient A, BC

You are preparing to register patient A, BC to a fictitious SWOG Study: S2525. Other patients at your institution are already enrolled.

S2525 is a one step, Phase III randomized trial of Drug X vs. Drug X plus Drug Y for post-menopausal women with metastatic breast cancer.

The objectives as stated in Section 1 of the protocol are the following:

- To compare time to tumor progression in post- menopausal women with metastatic breast cancer treated with Drug X vs. Drug X plus Drug Y.
- To assess the clinical benefit (CR, PR, or Stable disease > 24 weeks) and overall survival for this cohort of patients.
- To assess the adverse events of Drug X as compared to Drug X plus Drug Y.

Patient A, BC was previously registered to a SWOG neo-adjuvant treatment protocol when she was initially diagnosed with breast cancer. If she is eligible for S2525 she will be registered under her existing SWOG patient ID number which is 123456.

Discussion Points

- It is important to understand the study objectives because this helps to motivate compliance with data submission requirements.
- If a patient is registered to more than one SWOG therapeutic trial they will retain the same SWOG patient ID number, otherwise they are registered as a "new patient".
  One exception to this is for FDA registration studies in which each patient will receive their own unique patient ID number.
- Patient ID numbers assigned by the Specimen Tracking System: when a pre-registration specimen submission is required, you will use that same patient ID number to register the patient to the study and for all **subsequent** registrations to SWOG protocols.

Eligibility – Section 5 of the Protocol: Patient A, BC

On the next page is a copy of Section 5 (the eligibility section) of the protocol. This section may be used as a worksheet by the CRA to determine the eligibility of the study participant.

This patient was registered to a prior SWOG study. Therefore, you will always use her SWOG patient number, (123456), regardless of how many additional SWOG therapeutic trials she enters. (Except FDA Registration Trials, such as S1605 & S1404). For patients enrolled to a Registration Trial, they will receive a new Patient ID # for each study.

The patient has met Sections 5.1.a and 5.1.b criteria.

There are several useful tools to help determine the number of days that separate two known dates. For example, the "date wheel" or the online date counters found on the CRA Workbench https://crawb.crab.org/TXWB/DateCounter.aspx, and www.TimeandDate.com.

Exercise 1 (Section 5.1.c)

You have a report of a CT scan done for measurable disease on 04OctYY and a bone scan done for non-measurable disease on 17SepYY. Let's complete Section 5.1.c and determine what was the LAST date the patient may have been registered in order to be eligible according to this criterion. _29Oct, 42 days after bone scan and less than 28 days after CT scan.

Discussion Points

- It is important to understand each time restriction in Section 5, since each eligibility criterion must be met exactly as written. **No exceptions to Section 5 criteria are granted.**
- Make sure to refer to Section 5, not the study calendar, for baseline requirements.
- If using a date wheel, please note that it may not have 29Feb, so a day must be added in leap years.
- Submission of the Pathology Report confirming the diagnosis is usually required with the Initial Forms Set. Remember to include SWOG patient ID number, patient initials, and SWOG Study ID number on at least one page. Remember to redact patient identifiers such as name, MRN, SSN, address, etc. See protocol Section 14 for data submission requirements and timing. Please also include all pages of the source document you are submitting, even if the final page is blank.

Answers: **Ex 1.** 29Oct, 42 days after bone scan and less than 28 days after CT scan.

5.0 ELIGIBILITY CRITERIA

Each of the criteria in the following section must be met in order for a patient to be considered eligible for registration. Use the spaces provided to confirm a patient's eligibility. For each criterion requiring test results and dates, please record this information on the Onstudy Form and submit via Medidata Rave ® (see Section 14.0). Any potential eligibility issues should be addressed to the SWOG Data Operations Center in Seattle at 206/652-2267 or by the appropriate disease site distribution list prior to registration.

In calculating days of tests and measurements, the day a test or measurement is done is considered Day 0. Therefore, if a test is done on a Monday, the Monday 4 weeks later would be considered Day 28. This allows for efficient patient scheduling without exceeding the guidelines. **If Day 28 or 42 falls on a weekend or holiday, the limit may be extended to the next working day.**

SWOG Patient No. _____

Patient's Initials (L, F, M) _____

5.1 Disease Related Criteria

_____ a. Patients must be female with a pathologically confirmed diagnosis of metastatic breast cancer (M1) or multiple sites of new disease that is clinically obvious metastatic disease (e.g. multiple sites of new osseous lesions).

_____ b. Patients must be postmenopausal as defined by one of the following criteria:

_____a. Prior bilateral oophorectomy OR

__√ b.> 12 months since LMP with no prior hysterectomy OR

____ c. Patients >= 55 years of age with prior hysterectomy OR

____ d. For patients < 55 years of age and with a prior hysterectomy without oophorectomy, estradiol and FSH levels must be consistent with the patient being post-menopausal.

Estradiol _____ FSH _____

Institutional cutoff values for postmenopausal status (Estradiol) ___ (FSH) ___

_____ c. Patients must have measurable or non-measurable disease (see Section 10.1). Chest x-ray and any x-rays and scans for assessment of measurable disease must be performed within 28 days prior to registration. Non-measurable disease must be assessed within 42 days prior to registration.

Date of x-rays/scans for measurable disease _____

Date of other x-rays/scans for non-measurable disease _____

_____ d. Prior radiation is allowed as long as it encompassed no more than 25% of the bone marrow (see Appendix 19.1).

SWOG Patient No. _____

Patient's Initials (L, F, M) _____

5.2 Clinical/Laboratory Criteria

_____ a. Patients must have an ANC ≥ 1500 cells/mm^3 and platelets ≥ 100,000/mm^3. Patients must have a hemoglobin ≥ 10 g/dL. These tests must be performed within 14 days prior to registration.

_____ b. Patients must have a serum creatinine performed and a calculated creatinine clearance ≥ 50 ml/min by the formula below performed within 28 days prior to registration:

$$\frac{(140 - \text{age}) \times \text{wt (kg)} \times 0.85 \text{ (if female)}}{72 \times \text{creatinine (mg/dl)}}$$

_____ c. Patients must have a Performance Status of 0 – 2 by Zubrod criteria (see Section 10.4).

_____ d. Patients must have total bilirubin ≤ the institutional upper limit of normal, SGOT (AST) or SGPT (ALT) ≤1.5 x institutional upper limit of normal and alkaline phosphatase ≤2.5 x institutional upper limit of normal within 28 days prior to registration.

_____ e. Prestudy history and physical must be obtained with 28 days prior to registration.

. _____ f. Patients must not have known brain or CNS disease or evidence of brain or CNS metastases.

5.3 Regulatory Criteria

_____ a. Patients or their legally authorized representative must *be informed of the investigational nature of this study and must sign and give written informed consent in accordance with institutional and federal guidelines.*

_____ b. As a part of the OPEN registration process (see Section 13.4 for OPEN access instructions) the treating institution's identity is provided in order to ensure that the current (within 365 days) date of institutional review board approval for this study has been entered in the system.

Eligibility – Section 5 of the Protocol: Patient A, BC

Lab values are often required to determine the patient's eligibility and are necessary for assessing some toxicities. The following Lab Report was sent for patient A, BC: From CBC done 20OctYY for patient A,BC.

Exercise 2

Please determine the last date patient A, BC may be registered according to section 5.2.a
____03Nov _____
Taking the 04OctYY date of the CT Scan and the 17SepYY date of the Bone Scan into consideration, if you tried to register her on the above date would she be eligible?
_____No, the last date available for this patient is still 29Oct per Section 5_____

Exercise 3 (Section 5.2.a)

If patient, A, BC had her labs done 14Oct. Would she be eligible for registration on 29Oct according to Section 5.2.a? __No__ Why? _It is 15 days between labs and registration date

Discussion Points

- The timing of each criterion must be considered when determining eligibility. For example, in Exercise 3 Section 5.1.c must also be considered when determining the date of registration.
- It is vital that all lab tests and scans are done within the times specified in Section 5. For example, in Exercise 3 the labs must be done again for this patient to be eligible.
- Eligibility criteria are determined by the study design and objectives and are protocol specific. For example, the formula used here for creatinine clearance is for female patients only (includes "multiply result by 0.85"). Other protocols may use the more generic formula
- Your lab may report values in various ways. For example, 3.5 k/uL vs. 3500 /uL. However, it is very important to translate values into the format specified on the form. Formulas or units of measurements specified in the protocol must be used whether or not they are your institutional standard.
- All questions regarding Section 5 of the protocol should be directed to the study Data Coordinator at the SWOG SDMC in Seattle, WA

Answers: **Ex 2.** 03Nov, NO, the last date available for this patient is still 29Oct per Section 5.; **Ex 3.** No, It is 15 days

INITIAL FORMS SET (IFS): Patient A, BC

The Onstudy Form

The Onstudy Form is study specific and collects data that the statistician will use in study analysis. It also collects data from Section 5 that will confirm whether the patient met the eligibility requirements set in the protocol at study enrollment. Even if some of the information on the Onstudy Form is provided elsewhere or repeated on other forms, it is important to complete all sections of the form. Furthermore, **all** SWOG study forms must be filled out completely so that the data is properly recorded in the database.

ANC = 2.1 K/uL
HgB = 11.6 g/dL
Platelets = 210 K/uL
Serum Creatinine = 1.0 mg/dL, IULN = 1.5 mg/dL
Calculated Creatinine Clearance = 68 ml/min (derived from serum creatinine value)

Discussion Point

- ANC is reported as thousands (K) per microliter in the report above, however the Onstudy Lab Values form required this to be reported in cells per microliter. If 2.1 is entered as the value on the Onstudy Laboratory Values form, then the patient would be marked as Ineligible.
- Please make sure to not include any commas when you are un-abbreviating to the appropriate lab test units on the form. (For example, ANC = 2.1 K/uL should read as "2100" in the field instead of "2,100")

Subject: **123456**
Page: **Onstudy: Laboratory Values - Baseline**

#	Lab test	Lab test units	Lab value	LLN	ULN	Sample collection date
1	Absolute Neutrophil Count (ANC)	uL (x,xxx)	2100			
2	Platelets	uL (xxx,xxx)	210000			
3	Hemoglobin (Hgb)	g/dL (xx.x)	11.6			
4	Serum total bilirubin	mg/dL (xxx.x)				
5	Aspartate Aminotransferase (AST or SGOT), serum	U/L (xxx)				
6	Alanine Aminotransferase (ALT or SGPT), serum	U/L (xxx)				
7	Alkaline phosphatase, serum	U/L (xxx.x)				
8	Creatinine, serum	mg/dL (xx.xx)	1.0			
9	Measured creatinine clearance	ml/min (xxx.x)				
10	Calculated creatinine clearance (derived)	ml/min (xxx.x)	68			
11	Thyrotropin (Thyroid Stimulating Hormone or TSH), serum	U/mL (x.x)				

Discussion Point

- The Patient and Disease Description form is unique to each study and will ask for specific protocol related data. It's important to complete this form in its entirety and accurately to ensure eligibility is properly assessed.
- Unless otherwise specified, data entered on the Onstudy forms should be current as of date of study enrollment.

SWOG
S2525 ONSTUDY FORM

Patient Identifier | | | | | | | **Study Identifier** | S | 2 | 5 | 2 | 5 | **Registration Step** | 1 |

Patient Initials _____ (L, F M)

Registering/Treating Institution _____/_____ Physician _____

Participating Group: Group Name/Study No./Patient ID _____/_____/_____

Instructions: Submit this form within 7 days of registration. All dates are **MONTH, DAY, YEAR**. Explain any blank fields or blank dates in the **Comments** section. Place an ☒ in appropriate boxes.

PATIENT AND DISEASE DESCRIPTION

All disease present at baseline must be reported. Some Patient & Disease Description Onstudy forms collect sites of disease. Data Coordinators will verify consistency across all forms, including the Baseline Tumor Assessment form, and uploaded reports.

Performance status (Zubrod): ☐

Weight: ☐☐☐.☐ kg **Height:** ☐☐☐ cm

Menopausal status (select one):

☐ Pre (< 6 mo since LMP and no prior bilateral oophorectomy

☐ Post (prior bilateral oophorectomy OR > 12 mo since LMP

☐ Above categories not applicable AND current age < 55 (pre

☐ Above categories not applicable AND current age ≥55 (post

Receptor Status: *(negative is considered ≤1% positive nuclear staining)*

ER Status: ☐ Negative ☐ Positive ☐☐☐ % nuclear staining

PgR Status: ☐ Negative ☐ Positive ☐☐☐ % nuclear staining

HER2 results/IHC: ☐ 0 ☐ 1+ ☐ 2+

HER2 results/ISH (gene amplification not required if IHC 0 or 1): ☐ Negative ☐ Positive or Equivocal

Date of initial diagnosis of primary tumor: ☐☐ / ☐☐ / ☐☐☐☐

Date progressive or metastatic disease first diagnosed (radiologic or pathologic): ☐☐ / ☐☐ / ☐☐☐☐

Note: *Involvement of regional nodes or locally advanced disease at original diagnosis is not regarded as metastatic disease.*

Site(s) of disease (at time of study entry; select all involved sites):

☐ Local-regional (including ipsilateral breast; chest wall; axillary, internal mammary, and infraclavicular nodes; local-regional skin an subcutaneous tissue)

☐ Ipsilateral supraclavicular nodes	☐ Bone	☐ Liver
☐ Opposite breast	☐ Bone marrow	☐ Brain
☐ Distant nodes	☐ Lung	☐ Other CNS
☐ Distant skin/subcutaneous tissue	☐ Pleura	

☐ Other, specify: _____

If the patient has brain metastases, **Surgery:** ☐ Yes ☐ No If yes, date: ☐☐ / ☐☐ / ☐☐☐☐

Radiation: ☐ Yes ☐ No If yes, date: ☐☐ / ☐☐ / ☐☐☐☐

Stable neurologic function for at least 14 days prior to registration? ☐ Yes ☐ No

Initial Forms Set (IFS): Patient A, BC

The Baseline Tumor Assessment Form (BTA)

This practicum deals with solid tumor assessment. For response criteria information on Leukemia, Lymphoma and Myeloma, please see the ORP Manual on the SWOG CRA Workbench.

The BTA documents **ALL** disease present at baseline. Identifying "target" lesions does not mean that other lesions can be excluded.

Exercise 4*

Complete the Baseline Tumor Assessment Form on the next page for patient A, BC using the source documents below:

Chest CT 16Oct20YY:
There are extensive interstitial changes with a lesion in the **right upper lung** now measuring **1.8**cm x 1.4cm and a parenchymal density in the **right lung base** measuring **2.5**cm x 1.4cm. Impression: Lung metastasis.

CT abdomen/pelvis 16Oct20YY:
A new low density lesion is present in the **right lobe of the liver** measuring **2.4**cm x 1.6cm. A new focal hypervascular zone is present at the **junction** of the **right & left liver lobe** measuring **2.6**cm x 2.3cm. New focal low density is present adjacent to the **posterior margin** of the **right liver** measuring **0.9cm** x 0.5cm. Impression: Multiple liver metastases.

Whole Body Bone Scan 14Oct20YY:
Foci of abnormal activity are noted in the skull, the left fourth and fifth ribs, and multiple foci in the thoracic and lumbar spine. Impression: **Multiple bony metastases**

MRI Brain 14Oct20YY: **Negative for metastasis.**

Discussion Points

- Using the above scans and the Protocol Section 10, please note there is a difference between "measurable" and "non-measurable" disease (Sect 10.1.a & b) and "target lesions" vs. "non-target" disease (Sect 10.2). There is also a difference between lymph nodes and non-lymph node lesions under RECIST 1.1.
- When completing the "extent" portion under Non-target disease, include as much information as possible. If lesion measurements aren't available, explain the degree of involvement or extent of the disease process. For example; "multiple" "extensive", "localized", etc.
- On older studies, bone scans are reported as "Radioisotope scan". Newer Rave studies may have an option to select "Bone scan" for "Assessment Type". Bone metastases are always "non-measurable" even if measurements are given by the radiologist. Refer to Section 10.1b.
- Documentation of negative tests can be important to note for some studies as an eligibility requirement. Please make sure to include all of the negative baseline reports/scans in the table of the BTA (shown on the next page as an example).
- Lesion measurements should be documented in cm, which may require conversions if they are reported in mm.
- Always reference form instructions, for instance a max of two measurable lesions per organ and five lesions total.
- The "sum of lesions" field is derived once the form is saved, so please make sure all lesions are documented correctly.
- Lastly, make sure the Baseline Tumor Assessment (BTA) is consistent and clean, since this can affect the formatting of Follow Up Tumor Assessment (FUTA) forms and lead to inconsistency in data. If you need to make edits to the lesions being followed, they need to be edited on the BTA.

Baseline Tumor: Assessment - Disease Assessment

RECIST 1.1
Instructions: Record the requested information for all target lesions and all sites of other disease. Please refer to Section 10.0 of the protocol for definitions. Choose all measurable lesions, up to a maximum of two lesions per organ and five lesions in total, to follow as target lesions. Record any remaining measurable lesions and all non-measurable disease as non-target disease. Use the Comments section for any needed explanations. **The same test procedures used for baseline disease assessment must be used for all required subsequent disease assessments.**

Does the patient have target lesions?	Yes
Does the patient have non-target disease?	Yes
Lesions assessment and/or measurements provided by	Radiologist

List all **negative** diagnostic tests/studies used to evaluate patient for malignancy

#	Tests/Studies	Assessment date
1	MRI Brain	14 Oct 20YY

Baseline Tumor: Target Lesions - Disease Assessment

	Target lesion location	Lesion size	Assessment type	Lymph node?	Assessment date
1	Right lung base	2.5 cm	CT scan	No	16 Oct 20YY
2	Right lobe liver	2.4 cm	CT scan	No	16 Oct 20YY
3	Junction rt-lt lobe, liver	2.6 cm	CT scan	No	16 Oct 20YY
4	Right upper lung	1.8 cm	CT scan	No	16 Oct 20YY

Add a new Log line Inactivate

Sum of lesions (derived upon Save) 9.3 cm

Baseline Tumor: Non-target Disease - Disease Assessment

	Non-target disease location	Extent	Assessment type	Assessment date
1	Posterior margin Rt liver	0.9	12	16 Oct 20YY
2	Bone	Multiple	25	14 Oct 20YY

Assessment Types:

01-Palpation
02-Visualization
03-Colposcopy
05-Endoscopy
10-Plain film/X-ray without contrast
11-Plain film/X-ray with contrast
12-CT scan
13-MRI scan
14-Radioisotope scan
15-Ultrasound
16-PET scan
18-Cystoscopy
20-Histologic confirmation
21-Cytologic confirmation
24-PET/ CT
25-Bone scan

Protocol Treatment and Follow-Up: Patient A, BC
Treatment Form

Prior to completing the Treatment form, please complete the Vital Status (On Treatment) Form. This form updates the date of last contact with the patient. If it is not updated prior to entering the treatment form data, there is a high likelihood that a system query will generate. Completing the Vital Status form prior to any other data entry will help keep the data clean, and avoid system queries for you.

The specific information to be collected on a form is determined by the study design and endpoints. Treatment Forms are study specific. The information documented on all forms is entered into study tables and is combined with the data for all participants in the study in order to conduct study analysis. Therefore, it is vital that all required/requested data is recorded on the form. No field on any form is considered "optional" unless it is specified as "optional".

It is also extremely important that the data be in the format that is requested.

Treatment forms frequently ask for BSAs (body surface area). BSA is often used to determine the dose(s) of drugs to be given during treatment. This is commonly referred to in protocols as m^2 (meters squared). So, for example, if the dose is 175 mg/m^2 you would multiply the BSA by 175 to get the correct dose. A link to a BSA calculator can be found on the SWOG website: Go to the CRA workbench on www.swog.org. In the "tools of the trade" link you will find several calculators including the BSA calculator. Be sure to recalculate the BSA after a weight loss or weight gain of ≥10% and always use the actual body weight unless otherwise specified in the protocol. If the BSA is requested on the treatment form you must enter the information on every Treatment Form you submit.

Protocol Treatment and Follow-Up: Patient A, BC
Treatment Form

Exercise 5

Patient A, BC was randomized to arm 2. The dosing instructions from the treatment Section 7.0 of the protocol are listed below. Complete the Cycle 2 Treatment Form using the information below.

> Patient A, BC came in for cycle 2 treatment on 01Dec20YY. Cycle 1 toxicities were assessed and no dose reductions were indicated. Her labs were done prior to infusion of cycle 2 drug X per protocol instructions. She was given **352 mg of drug X** IV infusion over 30 minutes per protocol and a new bottle of Drug Y. On **29Dec20YY** she returned her cycle 2 bottle and pill diary per instructions. **She had missed taking her medication on the last 3 days of treatment and there were 6 pills left in the bottle.** The patient experienced grade 2 nausea after infusion and was treated with antiemetic medication per protocol.

Arm 2 - Drug X plus Drug Y

Agent	Dose	Route	Days	Interval	Notes
Drug X	200 mg/m^2	IV	1	Q 28 days	IV should be given over 30 minutes
Drug Y	50 mg	PO BID (Oral – twice a day)	1 – 21	Q 28 days	Patients should be instructed to complete and return pill diaries and bottles at each visit to monitor compliance

Cycles will be repeated every 28 days to a maximum of 6 cycles or until progression or other criteria for removal per Section 7.5 is met. Further treatment will be at the discretion of the treating physician.

Discussion Points

- Ensure that in a real-world situation, the Vital Status (On Treatment) form is completed before entering any data on the Treatment form.
- Please note that Reporting Period Start date and Reporting Period End dates may not be the same as Treatment start date and Date of last treatment. Reporting periods reflect the length of a cycle, including AE assessments. Treatment dates reflect actual treatment given during the cycle.
- Reporting Period End date should always be day 1 of the next cycle (as the form instructions indicate)
- For weight dependent doses, it is important to weigh the patient prior to each infusion so that the correct amount of drug is administered (refer to Section 7 of the protocol).
- Generally, when a Data Coordinator (DC) is reviewing study data, the dose the patient should have received will be calculated per the protocol. If there is a discrepancy of ±10% the institution will be queried, if no explanation is given on the form. Any questions regarding treatment or dose modifications **must** be directed to the Study Chair. Please refer to protocol contact information page and Sections 7 & 8 of the protocol for Study Chair contact information.

Answers: **Ex5** Drug x =Dose planned = 200mg/m^2, Dose delivered = 200mg/m^2 Total Dose = 352mg, drug Y = (100mg/day x 21 days) – (50mg x 6) = 2100mg – 300mg = 1800 mg. Dose modifications: Yes, unplanned. Modification Code: 10 dose missed. Date of Last Treatment is 18Dec20YY

SWOG
S2525 TREATMENT FORM

SWOG Patient ID: **123456** SWOG Study No.: **S2525** Registration Step: **1**

Patient initials: **A, BC** (L, F M) Current Cycle Number 2

Institution/Affiliate: **General Hospital** Physician: **Dr. Smith**

Instructions: Please complete this form after each cycle *(1 cycle = 28 days)*. All dates are **MONTH, DAY, YEAR.** Explain any blank dates or fields in a **Comments** section.

Has the patient progressed per the definition in Section 10.0 of the protocol?:

○ No ○ Yes *(submit Follow Up Form and Off Treatment Notice)*

TREATMENT FOR THIS CYCLE

Assigned Treatment Arm:
○ Arm 1: **Drug X only**
● Arm 2: **Drug X + Drug Y**

Reporting period begin date: 12 / 01 / 20YY

Reporting period end date: 12 / 29 / 20YY *(Day 1 of next cycle. If final cycle, 14 days after Reporting Period Begin Date.)*

Treatment start date: 12 / 01 / 20YY

Date of last treatment: 18 / Dec / 20YY

BSA (first day this cycle): 1 . 76 m^2 **Weight:** 65 . 9 kg

Were there any dose modifications or additions/omissions to protocol treatment?

○ No
○ Yes, planned (per protocol guidelines), specify in comments
● Yes, unplanned (not per protocol guidelines), specify in comments

For Drug X, report planned and delivered doses in mg/m². Report total dose in mg.
For Drug Y, report planned and delivered doses in mg/day. Report total dose in mg.

Agent Name	Dose Planned at Cycle Start	Dose Delivered at Cycle End	Total Dose Given	Modifications@
Drug X	200 mg/m²	200 mg/m²	352 mg	1
Drug Y	100 mg	50 mg	1800 mg	10

Will the patient continue to receive protocol therapy? ☐ Yes ☐ No

@Agent Dose Modification Codes

1 = No dose modification
2 = Dose held
3 = Dose delayed
4 = Dose reduced
5 = Dose delayed and reduced
6 = Drug discontinued
7 = Drug increased (error)
8 = Drug given too early
9 = Drug re-escalation
10 = Dose missed

Comments:

Protocol Treatment and Follow-Up: Patient A, BC
Treatment Form

Section 8.0 of the protocol specifies which toxicity criteria to use (CTC v.2.0, CTCAE v.3.0, CTCAE v.4.0 or CTCAE v5.0) and it defines anticipated toxicities and dose modifications.

Exercise 6

Complete the Cycle 3 treatment form (on the next page) with the given information below:

Protocol S2525 contains a very simple dose modification table:

Dose Modification Table (DRUG X)	
-1 Level	Starting Dose Level
100 mg/m2	200 mg/m2
Toxicity Grade	Modification
0 – 2	No change
3	Decrease one dose level
4	Discontinue drug

As stated previously, patient A, BC (123456) was randomized to arm 2 treatment (Drug X at 200 mg/m^2 on day 1). Prior to cycle 3, she has a grade 3 ANC. Based on the above table, and her BSA as listed on the opposite form, determine what her dose for cycle 3 should be and finish completing the treatment portion of the form. (Drug Y did not require any dose modification for this toxicity. She received 2100 mg of Drug Y.)

Discussion Points

- This dose modification table requires the treatment for cycle 3 to be dose reduced by one level due to the grade 3 toxicity.
- Note the "complete the modification fields below" after the "yes" answers. Such instruction must be followed or a query will be sent requesting the information. This can be done on the Dose Modification & Dose Modification Reason field and/or additional forms.
- Remember, you must report the **actual** doses given according to your institutional treatment records. Any discrepancy between what should have been given and what was actually given must be explained in the comments section of the form.

Answers: **Ex 6.** Check "yes, planned", Drug X: Dose planned and Delivered are both 100mg, Total Dose = 176mg, Modification Code 4 dose reduced, modification reason 1, Adverse Event Code 2 Blood/Bone Marrow.

Comments:

SWOG

S2525 TREATMENT FORM

SWOG Patient ID: **123456** SWOG Study No.: **S2525** Registration Step: **1**

Patient initials: **A, BC** (L, F M) Current Cycle Number 3

Institution/Affiliate: **General Hospital** Physician: **Dr. Smith**

Instructions: Please complete this form after each cycle *(1 cycle = 28 days)*. All dates are **MONTH, DAY, YEAR.** Explain any blank dates or fields in a **Comments** section.

Reporting period begin date: 12 / 30 / 20YY

Reporting period end date: 01 / 27 / 20YY *(Day 1 of next cycle. If final cycle, date of last treatment.)*

Treatment start date: 12 / 30 / 20YY **Date of last treatment:** / /

BSA (first day this cycle): 1 . 76 m^2 **Weight:** 65 . 9 kg

Were there any dose modifications or additions/omissions to protocol treatment?

- ○ No
- X Yes, planned (per protocol guidelines), specify in comments
- ○ Yes, unplanned (not per protocol guidelines), specify in comments

For Drug X, report planned and delivered doses in mg/m². Report total dose in mg.
For Drug Y, report planned and delivered doses in mg/day. Report total dose in mg.

#	Agent name	Dose planned at cycle start	Dose delivered at cycle end	Total dose given	Modifications	Dose modification reason	Number of days delayed (if applicable)
1	Drug X	100	100	176	Dose Reduced	Adverse Event	
2	Drug Y						

Will the patient continue to receive protocol therapy? ○ Yes ○ No

@Agent dose modification codes

1 = No dose modification
2 = Dose held
3 = Dose delayed
4 = Dose reduced
5 = Dose delayed and reduced
6 = Drug discontinued
7 = Drug increased (error)
8 = Drug given too early
9 = Drug re-escalation
10 = Dose missed

IF DOSE MODIFICATIONS, COMPLETE THE FOLLOWING:

Agent name	Dose modification reason*	Number of days delayed (if applicable)	Modification due to adverse event* *(list all codes that apply)*
Drug X	1		2 - Blood/Bone Marrow

*Agent dose modification reasons (if applicable)

1 = Adverse event
2 = Patient refusal/non-compliance (not due to toxicity)
3 = Scheduling
4 = Dosing error
5 = Alternative therapy for other reasons
6 = Disease progression
7 = Death
8 = Other, specify: _____

*Modification due to AE codes (if applicable)

1 = Allergy/Immunology
2 = Blood/Bone marrow
3 = Cardiac
4 = Coagulation
5 = Gastrointestinal
6 = Hepatobiliary/Pancreas
7 = Infection
8 = Metabolic/Laboratory
9 = Neurology
10 = Pain
11 = Pulmonary/Upper respiratory
12 = Renal/Genitourinary
13 = Vascular
14 = Other, specify: _____

Initial Forms Set (IFS): Patient A, BC
Baseline Abnormalities Form

Some studies use a Baseline Abnormalities Form to document existing conditions or continuing toxicities caused by prior treatment.

Corresponding sections from the CTCAE are included in the handouts.

Exercise 7

Patient A, BC had a physical exam prior to registration.

> Patient is recovering from a cold and presents today with **mild cough with only non-narcotic medication indicated.** She has been experiencing some **shortness of breath, mild fatigue relieved by rest, mild difficulty sleeping** and **mild headaches** that do not affect function.

a) Which condition cannot be graded without further information? ____Dyspnea____

b) What information do you need? __Level of exertion causing the shortness of breath___

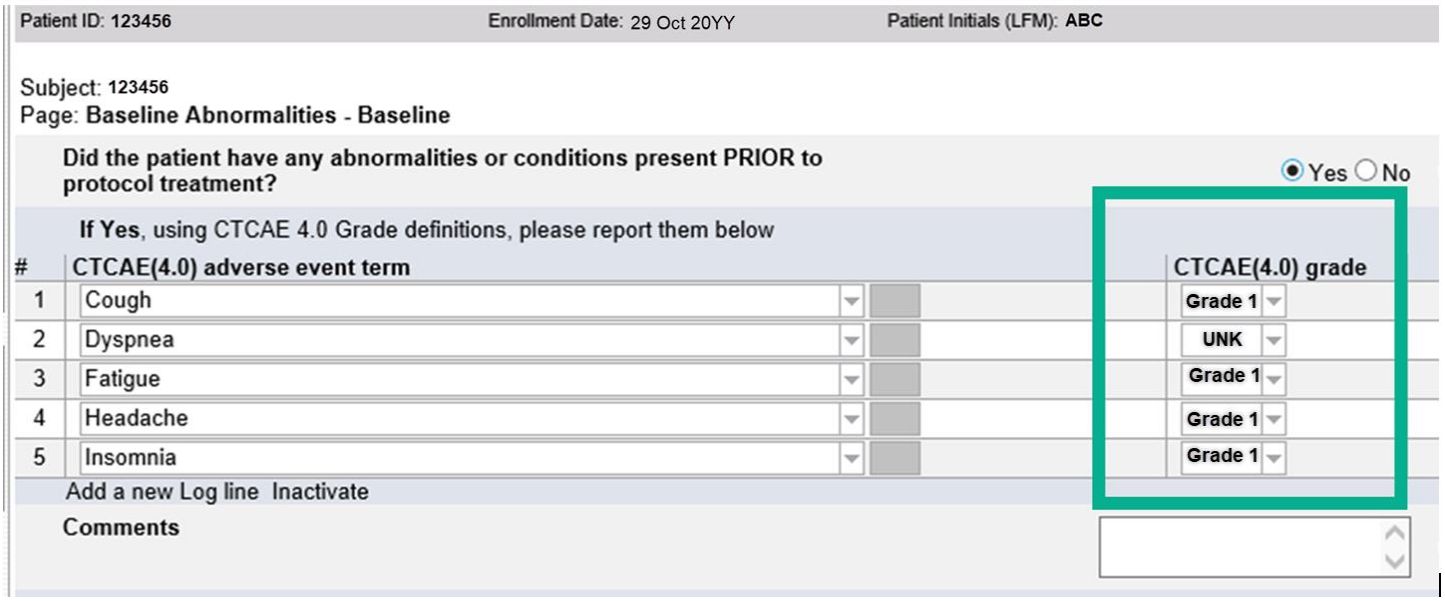
c) Where would you get this information? _From the treating physician or patient__

Discussion Points

- Not all studies require a Baseline Abnormalities or Medical History form. Always refer to protocol Section 14 to determine which forms are needed.
- Clinic notes may not always use the correct terminology to describe an adverse event. For example, "shortness of breath" or "difficulty sleeping". To find the correct terminology, there is a link to the CTCAE terms and CTC on the CRA Workbench under "Tools of the Trade".
- Please use specific CTCAE terms as best as possible, instead of using the "Other" category. When using generic terms, such as "Pain", please specify type/site of pain in the comments section at the bottom of the form. Consult with the PI if you have any questions regarding the AE term.
- The Baseline Abnormalities Form:
  - **Is not** used as a record of the patient's full medical history. For example, prior tonsillectomy or ongoing controlled diabetes should **not** be recorded.
  - **Is used** to record current conditions and existing toxicities only. For example, fever or hypocalcemia **should** be recorded.
- The Medical History Form:
  - Report complete medical history prior to registration, which encompasses all prior conditions and procedures.

Answers: **Ex7.** a) Dyspnea b) level of exertion causing the shortness of breath c) From the treating physician or patient.
AEs: Cough: grade 1, Dyspnea: unknown, Fatigue: grade 1, Headache: grade 1, Insomnia: grade 1.

Complete baseline abnormality information



Patient ID: 123456 Enrollment Date: 29 Oct 20YY Patient Initials (LFM): ABC

Subject: 123456
Page: **Baseline Abnormalities - Baseline**

Did the patient have any abnormalities or conditions present PRIOR to protocol treatment? (●) Yes ( ) No

If Yes, using CTCAE 4.0 Grade definitions, please report them below

#	CTCAE(4.0) adverse event term	CTCAE(4.0) grade
1	Cough	Grade 1
2	Dyspnea	UNK
3	Fatigue	Grade 1
4	Headache	Grade 1
5	Insomnia	Grade 1

Add a new Log line Inactivate

Comments

Protocol Treatment and Follow-Up: Patient A, BC
Adverse Event Form

Adverse Event Forms are used to assess and document toxicities to monitor the effects of treatment. Nearly all protocols require AEs to be assessed within a certain window of the next cycle of treatment beginning. When completing the Adverse Event Assessment form in Rave, please be sure to use the *most recent date* of AE evaluation to ensure all AEs from a cycle are captured.

Exercise 8*

Using the information below and the excerpts from the CTCAE, complete the Cycle 1 Adverse Event Form.

This clinic note refers to patient A, BC for whom the Baseline Abnormalities Form was completed.

> Patient A, BC continues to experience **headaches, insomnia** and **fatigue.** All have **increased** to **Grade 2** but are not related to treatment. During cycle 1 she had some **loss of appetite** and **nausea** without alteration of her eating habits during the first few days of treatment. She had **one episode of vomiting** on day 1. IV fluids were not required. All are definitely treatment related. She presented today with **mild ankle edema (<10% change in circumference)** and lab results showing **WBC decreased to 2.5k/uL,** both probably related to treatment. She will start cycle 2 tomorrow.

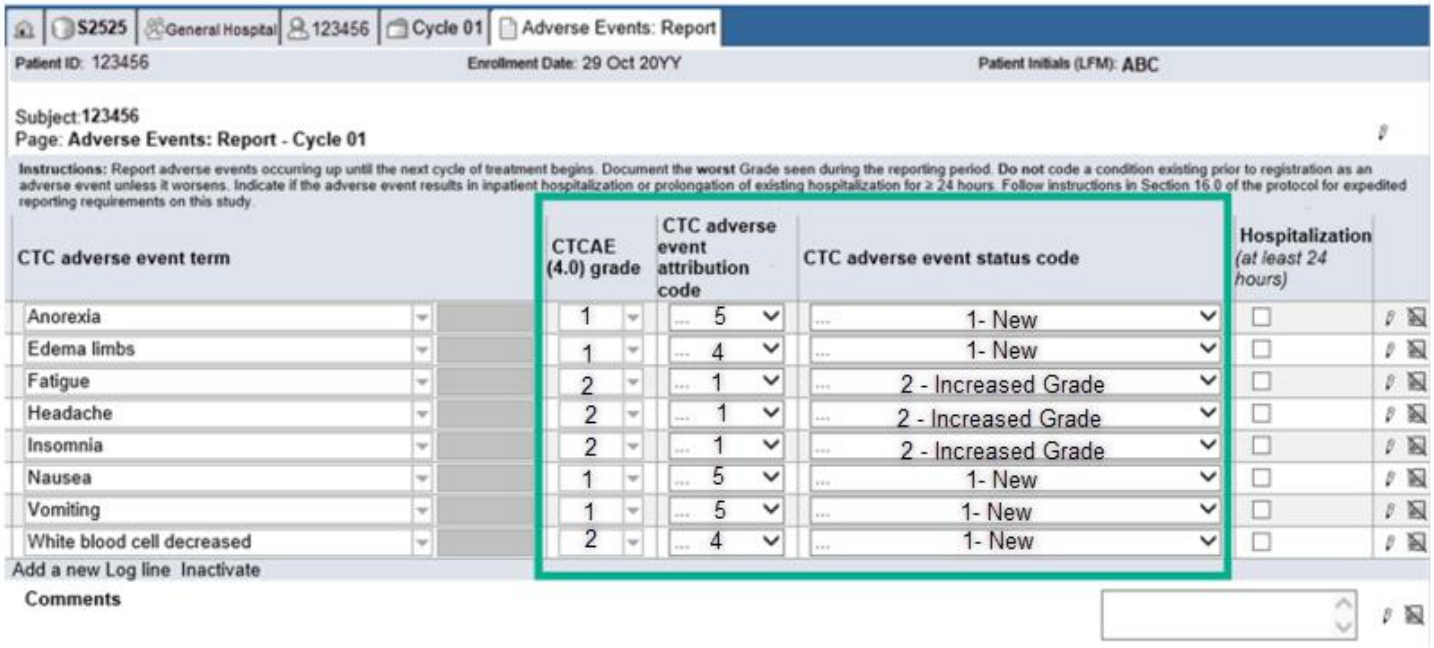
a) Do you have enough information to grade each toxicity? _____Yes_____

b) Can you assign attribution and status codes to each? _____Yes_____

Discussion Points

- Not all protocols will include status codes on the Adverse Event Forms.
- ALWAYS refer to the instructions on the Adverse Event Form. Some studies may only want certain grades reported while others may include/exclude baseline conditions.
- Most protocols require attribution codes which are assigned **only** by the treating physician.
- In the CTCAE, many general terms such as “edema” must now include the site of the toxicity. This form includes edema in her limbs but if the patient had facial edema or edema in her trunk those sites would have to be documented, specified, and graded separately.
- Note that the Adverse Event start & end dates will not always be the same as the start & stop dates of treatment, but should match the treatment reporting period dates.
- AE’s should be assessed at the end of the cycle, ideally on Day 1 of the next Cycle prior to treatment. Please make sure the Reporting Period End date is also Day 1 of the next cycle to avoid any system queries on the form.

Answers: **Ex8.** a) Yes b) Yes



S2525 | General Hospital | 123456 | Cycle 01 | Adverse Events: Report

Patient ID: 123456 Enrollment Date: 29 Oct 20YY Patient Initials (LFM): ABC

Subject:123456
Page: **Adverse Events: Report - Cycle 01**

Instructions: Report adverse events occurring up until the next cycle of treatment begins. Document the **worst** Grade seen during the reporting period. **Do not** code a condition existing prior to registration as an adverse event unless it worsens. Indicate if the adverse event results in inpatient hospitalization or prolongation of existing hospitalization for ≥ 24 hours. Follow instructions in Section 16.0 of the protocol for expedited reporting requirements on this study.

CTC adverse event term	CTCAE (4.0) grade	CTC adverse event attribution code	CTC adverse event status code	Hospitalization *(at least 24 hours)*
Anorexia	1	5	1- New	☐
Edema limbs	1	4	1- New	☐
Fatigue	2	1	2 - Increased Grade	☐
Headache	2	1	2 - Increased Grade	☐
Insomnia	2	1	2 - Increased Grade	☐
Nausea	1	5	1- New	☐
Vomiting	1	5	1- New	☐
White blood cell decreased	2	4	1- New	☐

Add a new Log line Inactivate

Comments

* **Attribution codes:** 1-unrelated 2-unlikely 3-possible 4-probable 5-definite
****Status codes** (since baseline or last cycle): 1-new 2-continues at same or lower grade 3-increased grade OR improved then worsened

Protocol Treatment and Follow-Up: Patient A, BC
Follow-Up Tumor Assessment Form (FUTA)

Background

Response information can be found in Section 10 of the protocol (see example opposite page). Review the definitions below and work through the following exercises.

Response Assessment: A patient's disease response to therapy is the primary endpoint of most Phase II studies and a secondary endpoint of some Phase III studies. To assess a patient's response to therapy correctly, the Study Chair must have accurate tumor assessment on all disease sites. Phase II studies are particularly sensitive to errors in recording response factors. Incorrect response assessment may result in needless exposure of patients to an ineffective agent, early study closure, incorrectly labeling an agent as ineffective, or a biased response rate estimate.

Definition of solid tumors: Solid tumors can be assessed physically by palpation or by using radiography.

Guidelines for assessing both solid tumor and hematologic cancers:

1. **Always** use the response criteria and schedule given in Section 10 of the protocol.
2. **Every** disease assessment called for on the study calendar in Section 9 must be done and done on time.
3. **All disease** present at baseline must be documented to ensure that response can be properly assessed.
4. **Each site** of disease must be assessed at every scheduled disease assessment, unless otherwise specified.
5. The **same method** of measuring the disease used at baseline must be used at each assessment.
6. Usually a **confirmation assessment** is required after an initial observation of response. It should be scheduled according to the protocol instructions.

RECIST – **R**esponse **E**valuation **C**riteria **I**n **S**olid **T**umors

On the opposite page is an abbreviated version of the RECIST 1.1 criteria for evaluation and endpoint definitions for solid tumor response assessment. The next page shows section 10.1 & 10.2 for a study using RECIST 1.1 definitions, as mandated by the NCI starting in 2010.

10.0 Criteria for Evaluation and Endpoint Definitions

10.1 Measurability of lesions:

- **Measurable disease**.
  Measurable disease is defined differently for lymph nodes compared with other disease and will be addressed in a separate section below.
  - Lesions that can be accurately measured in at least one dimension (longest diameter to be recorded) as ≥ 2.0 cm by chest x-ray, by ≥ 1.0 cm with CT or MRI scans, or ≥ 1.0 cm with calipers by clinical exam. All tumor measurements must be recorded in decimal fractions of centimeters (or millimeters).

  - The defined measurability of lesions on CT scan is based on the assumption that CT slice thickness is 0.5 cm or less. It is strongly recommended that CT slice of 0.5 cm be used. If CT scans have slice thickness greater than 0.5 cm, the minimum size for a measurable lesion should be twice the slice thickness.

  - Malignant lymph nodes are to be considered pathologically enlarged and measurable if it measures ≥ 1.5 cm in SHORT AXIS (greatest diameter perpendicular to the long axis of the lymph node) when assessed by scan (CT scan slice recommended being no greater than 0.5 cm).
- **Non-measurable disease**.
  All other lesions (or sites of disease), including small lesions (longest diameter <1.0 cm or pathologic lymph nodes with ≥ 1.0 cm to <1.5 cm short axis), are considered non-measurable disease. Bone lesions, leptomeningeal disease, ascites, pleural/pericardial effusions, lymphangitis cutis/pulmonitis, inflammatory breast disease, and abdominal masses (not followed by CT or MRI), are considered as non-measurable as are previously radiated lesions that have not progressed.

10.2 Objective status at each disease evaluation.

Objective Status is to be recorded at each evaluation. All measurable lesions up to a maximum of 2 lesions per organ, 5 lesions in total, representative of all involved organs, should be identified as *target* lesions at baseline. All other lesions (or sites of disease) including any measurable lesions over and above the 5 target lesions should be identified as *non-target* lesions. Measurements must be provided for target measurable lesions, while presence or absence must be noted for non-target measurable and non-measurable disease.

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.

- **Complete Response (CR):** Complete disappearance of all target and non-target lesions (with the exception of lymph nodes mentioned below). No new lesions. No disease related symptoms. Any lymph nodes (whether target or non-target) must have reduction in short axis to < 1.0 cm. All disease must be assessed using the same technique as baseline.
- **Partial Response (PR):** Applies only to patients with at least one measurable lesion. Greater than or equal to 30% decrease under baseline of the sum of appropriate diameters of all target measurable lesions. No unequivocal progression of non-measurable disease. No new lesions. All target measurable lesions must be assessed using the same techniques as baseline.
- **Stable:** Does not qualify for CR, PR, Progression or Symptomatic Deterioration. All target measurable lesions must be assessed using the same techniques as baseline.
- **Progression**: One or more of the following must occur: 20% increase in the sum of appropriate diameters of target measurable lesions over smallest sum observed (over baseline if no decrease during therapy) using the same techniques as baseline, as well as an absolute increase of at least 0.5 cm. Unequivocal progression of non-measurable disease in the opinion of the treating physician (an explanation must be provided). Appearance of any new lesion/site. Death due to disease without prior documentation of progression and without symptomatic deterioration (see 10.2e).

Protocol Treatment and Follow-Up: Patient A, BC
Follow-Up Tumor Assessment Form (FUTA)

The protocol states that scans for disease assessment should be done after every 3rd cycle of treatment. Patient A, BC had a reassessment of her disease at week 12.

Week 12 Assessment:

Chest CT 20Jan20YY:
There continues to be extensive interstitial changes with the lesion in the **right upper lung** now measuring **2.0**cm x 1.6cm and a parenchymal density in the **right lung base measuring 2.5**cm x 1.5cm.

CT abdomen/pelvis 20Jan20YY:
The low-density lesion in the **right lobe** of the **liver** now measures **2.5**cm x 1.5cm. The hypervascular zone at **the junction of the right & left liver lobe measures 2.5**cm x 2.5cm. Focal low density adjacent to the **posterior margin of the right liver measures 1.5**cm x 1.5cm.

Whole Body Bone Scan 20Jan20YY:
Foci of abnormal activity are noted in the skull, the left fourth and fifth ribs, and multiple foci in the thoracic and lumbar spine. Impression: **Multiple bony metastases, same sites as baseline.**

Exercise 9

Using the information above, complete page one of the FUTA on the opposite page. Then, based on Section 10.0 of the protocol and the summary copy of the BTA below, determine the patient's response at week 12.

Baseline Tumor: Target Lesions - Disease Assessment

	Target lesion location	Lesion size	Assessment type	Lymph node?	Assessment date
1	Right lung base	2.5 cm	CT scan	No	16 Oct 20YY
2	Right lobe liver	2.4 cm	CT scan	No	16 Oct 20YY
3	Junction rt-lt lobe, liver	2.6 cm	CT scan	No	16 Oct 20YY
4	Right upper lung	1.8 cm	CT scan	No	16 Oct 20YY

Baseline Tumor: Non-target Disease - Disease Assessment

	Non-target disease location	Extent	Assessment type	Assessment date
1	Posterior margin Rt liver	1.8 cm	CT scan	16 Oct 20YY
2	Bone	multiple sites	Bone scan	14 Oct 20YY

Discussion Points

- The lesion order on FUTAs should always mirror the order on the BTA.
- All baseline disease **must** be re-assessed at each follow up.
- All disease must be assessed at each time point using the same methods as baseline.
- The presence or absence of non-measurable (and/or non-target) disease must be noted at each assessment time point.
- If this was an unconfirmed response, another assessment must be done at least 4 weeks later to confirm or per Section 10.
- If any changes are made on the BTA form, please make sure to amend all FUTA forms that are inconsistent.

BTA sum of longest diameters:

_____9.3 cm__

FUTA sum of longest diameters:

_____9.5 cm__

Week 12 Response:

_____Stable_____

Follow-up Tumor Assessment: Disease Assessment

Instructions: Record all requested information applicable to this assessment. Use the Comments section for any needed explanations.

Was disease status evaluated during this reporting period?	Yes
Assessment date *(Date 1st scan was done this reporting period. Enter planned assessment date if not done.)*	20 Jan 20YY

New Lesions

#	Site	Assessment type	Assessment date	
1				

Add a new Log line Inactivate

Symptomatic deterioration? (*Global deterioration of health without objective evidence of progression.)*	No
Symptomatic deterioration assessment date	
Has the patient progressed or relapsed (per the definition in the Section 10.0 of the protocol)?	No

Follow-up Tumor Assessment: Target Lesions

#	Target lesion location	Lesion size (cm)	Assessment type	Lymph node?	Assessment date
1	Right lung base	2.5 cm	CT Scan	No	20 Jan 20YY
2	Right lobe liver	2.5 cm	CT Scan	No	20 Jan 20YY
3	Junction rt-lt lobe, liver	2.5 cm	CT Scan	No	20 Jan 20YY
4	Right upper lung	2.0 cm	CT Scan	No	20 Jan 20YY

Add a new Log line Inactivate

Sum of lesions (derived upon Save)	9.5 cm
Lesions assessment and/or measurements provided by	Radiologist

Follow-up Tumor Assessment: Non-target Disease

#	Non-target disease location	Extent	Assessment type	Assessment date
1	Posterior margin Rt liver	Present	CT Scan	20 Jan 20YY
2	Bone	Present	Bone Scan	20 Jan 20YY

Add a new Log line Inactivate

Non-target Disease Extent options:
Complete disappearance
Present
Unequivocal progression (describe in Comments)
Not assessed

Assessment Types:
01-Palpation
02-Visualization
03-Colposcopy
05-Endoscopy
10-Plain film/X-ray without contrast
11-Plain film/X-ray with contrast
12-CT scan
13-MRI scan
14-Radioisotope scan
15-Ultrasound
16-PET scan
17-Spiral CT scan
18-Cystoscopy
20-Histologic confirmation
21-Cytologic confirmation
23-PET/Spiral CT
24-PET/Conventional CT
25-Bone scan

After cycle 6, disease was again re-assessed per protocol.

Week 24 Assessment:

Chest CT 15Apr20YY:
There continues to be extensive interstitial changes with the lesion in the **right upper lung** now measuring **2.0**cm x 1.6cm and a parenchymal density in the **right lung base** measuring **4.5**cm x 2.5cm.

CT abdomen/pelvis 15Apr20YY:
The low density lesion in the **right lobe of the liver** now measures **3.5**cm x 3.0cm. The hypervascular zone at the **junction of the right & left liver lobe** measures **3.0**cm x 2.5cm. Focal low density adjacent to the **posterior margin of the right liver measures 2.0**cm x 1.5cm.

CT abdomen/pelvis 15Apr20YY:
There are multiple **new** hyper vascular **solid masses** scattered throughout the **liver.** The **largest** measuring **5mm.** Impression: Increased liver metastases with new sites of malignancy.

Whole Body Bone Scan 16Apr20YY:
Foci of abnormal activity are again noted in the skull and the left fourth and fifth ribs. There is **increased uptake in the thoracic and lumbar spine.** IMPRESSION: INCREASED uptake in existing bony metastases.

Exercise 10*

Using the above information, complete the FUTA for patient A, BC.
BTA sum of longest diameters = 9.3 cm
12 week assessment sum of longest diameters = 9.5 cm

a) Week 24 sum of longest diameters = _____13.0 cm_____

b) What is the patient's response at this time point? _____Progression_____

c) Comparing this response to previous scans, what is best response overall? _____Stable_____

Discussion Points

- Progression is noted in the target measurable lesions. The sum of longest diameters increased >20% over smallest sum observed.
- Response refers to the patient's objective status at each scheduled evaluation. Best response is the patient's most favorable response over all assessments. This is calculated from the sequence of objective statuses.
- Determination of best response might be required on multi-step protocols. For example, it may be necessary for patients to have stable or better response to continue to the next step.
- The new sites of liver metastases would also be considered progression as well as the increase in the target measurable lesions.
- Note that even though the bone scan reports "increased uptake in existing bone mets", this alone does not constitute unequivocal progression. Therefore, "Present" should be marked. Refer to Section 10.2g.5
- On the Non-target disease form, if unequivocal progression is selected under 'Extent', an explanation to how this is defined must be documented in the Comments section
- New lesions section is only for reporting disease not present at baseline. Entries in this field typically constitute progression, but please refer to section 10 for further clarification.

Answers: **Ex. 10** a) 13.0 cm, b) progression, c) stable.

Follow-up Tumor Assessment: Disease Assessment

Instructions: Record all requested information applicable to this assessment. Use the Comments section for any needed explanations.

Was disease status evaluated during this reporting period?	Yes
Assessment date *(Date 1st scan was done this reporting period. Enter planned assessment date if not done.)*	15 Apr 20YY

New Lesions

#	Site	Assessment type	Assessment date	
1	Liver	CT scan	15 Apr 20YY	

Add a new Log line Inactivate

Symptomatic deterioration? (*Global deterioration of health <u>without</u> objective evidence of progression.*)	No
Symptomatic deterioration assessment date	
Has the patient progressed or relapsed (per the definition in the Section 10.0 of the protocol)?	Yes

Follow-up Tumor Assessment: Target Lesions

#	Target lesion location	Lesion size	Assessment type	Lymph node?	Assessment date
1	Right lung base	4.5 cm	CT Scan	No	15 Apr 20YY
2	Right lobe liver	3.5 cm	CT Scan	No	15 Apr 20YY
3	Junction rt-lt lobe, liver	3.0 cm	CT Scan	No	15 Apr 20YY
4	Right upper lung	2.0 cm	CT Scan	No	15 Apr 20YY

Add a new Log line Inactivate

Sum of lesions (derived upon Save)	13.0 cm
Lesions assessment and/or measurements provided by	Radiologist

Follow-up Tumor Assessment: Non-target Disease

#	Non-target disease location	Extent	Assessment type	Assessment date
1	Posterior margin Rt liver	Unequivocal Progression	CT Scan	15 Apr 20YY
2	Bone	Unequivocal Progression	Bone Scan	16 Apr 20YY

Add a new Log line Inactivate

Non-target Disease Extent options:
Complete disappearance
Present
Unequivocal progression (describe in Comments)
Not assessed

Assessment Types:
01-Palpation
02-Visualization
03-Colposcopy
05-Endoscopy
10-Plain film/X-ray without contrast
11-Plain film/X-ray with contrast
12-CT scan
13-MRI scan
15-Ultrasound
16-PET scan
18-Cystoscopy
20-Histologic confirmation
21-Cytologic confirmation
24-PET CT
25-Bone scan

Protocol Treatment and Follow-Up: Patient A, BC
Follow-Up Tumor Assessment Form (FUTA)

This page contains some further examples of disease assessments and the objective status (response) at each time point.

Example A

Lesion	Assessment Type	Baseline	Week 6	Week 12
LUL lung	CT	6.1cm	4.7cm	4.0cm
LLL lung	CT	4.2cm	2.4cm	measurement not reported
Sum of longest diameters:		10.3	7.1	Unknown
RESPONSE PER SECTION 10			UPR	Inadequate assessment

Note that week 12 assessment is inadequate because at least one of the target measurable lesions was not measured. In order to complete this assessment, the radiologist or Treating physician would need to review the CT to report the measurements for the LLL lung.

Example B

Lesion	Baseline	Week 6	Week 12
RUL lung	2.2x2.3cm by CT	1.0x1.3cm by CT	0x0cm by x-ray
RUL lung	2.0x3.4cm by CT	1.2x1.5cm by CT	0x0cm by x-ray
Sum of longest diameters:	5.7	2.8	0
RESPONSE PER SECTION 10		UPR	Inadequate assessment

Note that week 12 assessment is inadequate because the method used at week 12 is inconsistent with the baseline method.

Example C

Lesion	Assessment Type	Baseline	Week 8	Week 16	Week 20
Neck	Palpation	2.3x2.1cm	2.5x2.1cm	0x0cm	0x0cm
Liver	CT	3.7x2.2cm	1.8x2.0cm	0x0cm	0x0cm
Bone – T2	Scan	Positive	Positive	Positive	Positive
Sum of longest diameters:		6	4.3	0	0
REPONSE PER SECTION 10.0			STA	UPR	PR

Note that week 16 and week 20 are recorded as partial response instead of a complete response. Even though measurable disease had disappeared, the non-measurable bone lesion is still positive. Section 10.2.a defines complete response as complete disappearance of all measurable and non-measurable disease.

Discussion Points

- It is necessary to assess ALL disease at each time point specified in the protocol.
- It is unfortunate when neither a partial response nor a complete response can be declared because of inconsistency or lack of follow up, therefore, it is very important to confirm responses according to protocol Section 10.

Follow-Up Forms: Patient A, BC

The Off Treatment Notice

As you determined when completing the FUTA for patient A, BC she has progressed and protocol treatment will be stopped. The Off-Treatment Notice must be submitted with the FUTA.

It is imperative that **every** section of the Off-Treatment Notice is filled out. That includes reason for going off treatment, planned post protocol treatment, etc. As always, document any unusual or additional information in the comments section.

Discussion Points

- Always refer to Section 7 for Criteria for Removal from Protocol Treatment and Section 14 of the protocol when completing an Off-Treatment Notice as other documentation is usually required.
- When submitting an Off-Treatment Notice make sure that all treatment data, toxicity assessments, and FUTAs are also submitted. EOT specimens may be required to be submitted; refer to Section 15 of the protocol for further clarification.

For studies utilizing the Vital Status form, **prior** to completing the Off-Treatment Notice, the Off Treatment Vital Status form should be completed using the date the patient is notified they will be taken off treatment

SWOG

OFF TREATMENT VITAL STATUS FORM

Patient Identifier 1 2 3 4 5 6 **Study Identifier** S 2 5 2 5 **Registration Step** 1

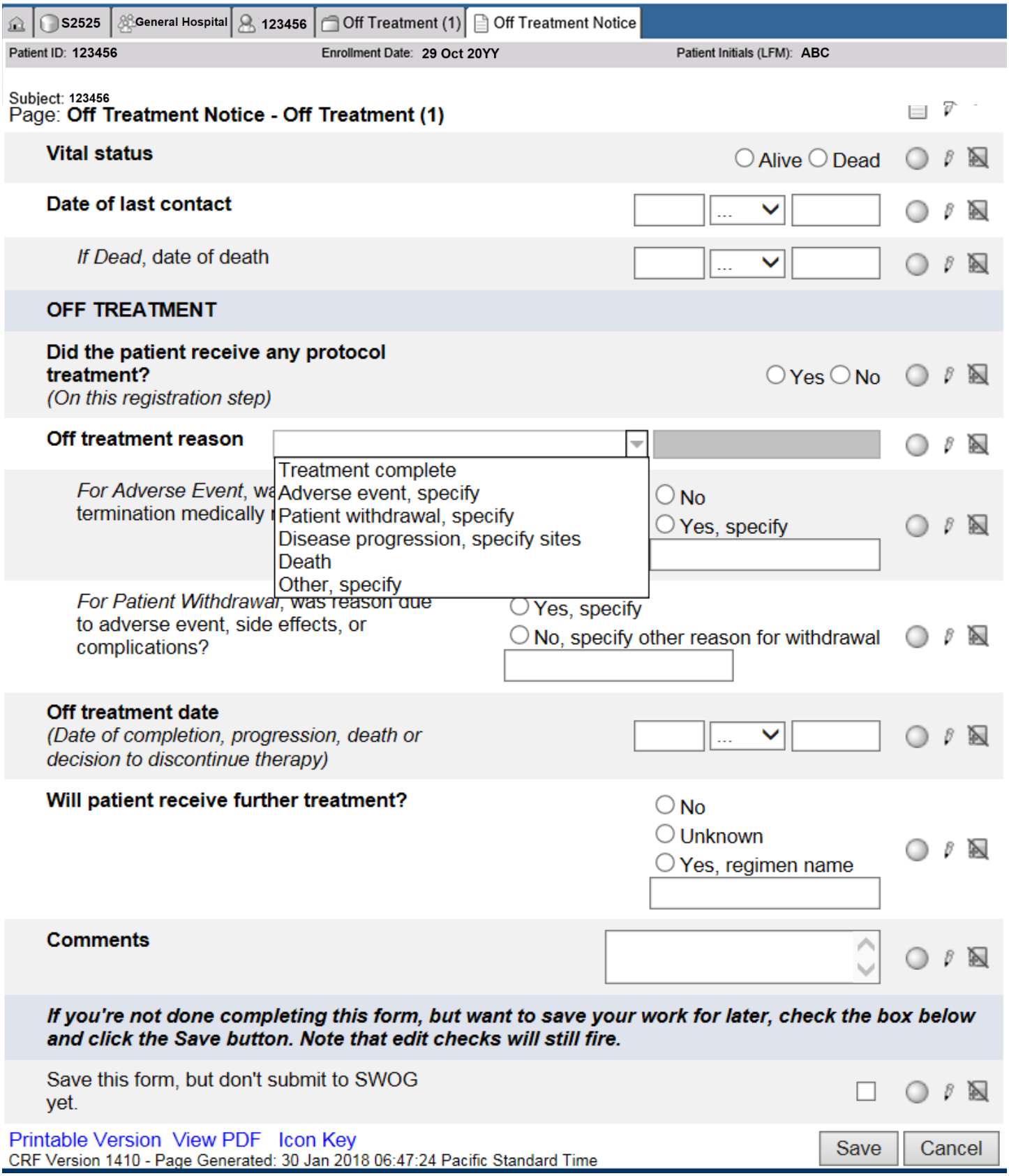
Patient Initials A,BC (L, F M)

Page: Vital Status

Instructions: Please complete this form at required protocol follow-up timepoints at a minimum. This form should be submitted prior to any other data entry related to that visit. Date is in **DD MON YYYY** format.

Vital Status *(If dead, please submit Notice of Death)* ☐ Alive ☐ Dead

Date of last contact *(If dead, please enter date of death)* ☐☐ ☐☐☐ ☐☐☐☐


S2525
General Hospital
123456
Off Treatment (1)
Off Treatment Notice
Patient ID: 123456
Enrollment Date: 29 Oct 20YY
Patient Initials (LFM): ABC
Subject: 123456
Page: Off Treatment Notice - Off Treatment (1)
Vital status
Alive
Dead
Date of last contact
If Dead, date of death
OFF TREATMENT
Did the patient receive any protocol treatment?
(On this registration step)
Yes
No
Off treatment reason
Treatment complete
Adverse event, specify
Patient withdrawal, specify
Disease progression, specify sites
Death
Other, specify
For Adverse Event, wa
termination medically
No
Yes, specify
For Patient Withdrawal, was reason due to adverse event, side effects, or complications?
Yes, specify
No, specify other reason for withdrawal
Off treatment date
(Date of completion, progression, death or decision to discontinue therapy)
Will patient receive further treatment?
No
Unknown
Yes, regimen name
Comments
If you're not done completing this form, but want to save your work for later, check the box below and click the Save button. Note that edit checks will still fire.
Save this form, but don't submit to SWOG yet.
Printable Version
View PDF
Icon Key
CRF Version 1410 - Page Generated: 30 Jan 2018 06:47:24 Pacific Standard Time
Save
Cancel

Follow-Up Forms: Patient A, BC

For studies that have the Vital Status form, this form MUST be completed prior to completing the follow-up form. The Date of last contact is derived from the vital status form and cannot be updated any other way than by completing the Vital Status form.

SWOG
OFF TREATMENT VITAL STATUS FORM

Patient Identifier 1 2 3 4 5 6 **Study Identifier** S 2 5 2 5 **Registration Step** 1

Patient Initials A,BC (L, F M)

Page: Vital Status

Instructions: Please complete this form at required protocol follow-up timepoints at a minimum. This form should be submitted prior to any other data entry related to that visit. Date is in **DD MON YYYY** format.

Vital Status *(If dead, please submit Notice of Death)* ☐ Alive ☐ Dead

Date of last contact *(If dead, please enter date of death)* ☐☐ ☐☐☐ ☐☐☐☐

Discussion Points

- Once a patient is off protocol treatment, a Follow-up Form is required at each follow up at the protocol-specified intervals, at first progression and at time of diagnosis of second primary.
- If the study uses a "Vital Status Form," please update the status and date of last contact prior to completing any other forms in RAVE.
- All fields must be completed. Clinical assessment cannot be done by phone.
- In this case, the progression was previously reported when patient was removed from protocol treatment; therefore the "notice of first progression" question is answered as "No".
- When documenting progression on the follow-up form, be as specific as possible when reporting the sites of disease. If patient went off-tx for reasons other than progression, FUTA forms may still be required until progression. You can refer to Section 14.4 for further details.
- When reporting a second primary, verify with the treating physician that it is indeed a new cancer and not a metastasis of the existing disease.
- When documenting the New Primary, it is important to use the date of Histological diagnosis.
- Report if the patient received any non-protocol therapy prior to documentation of progression.
- If reporting date of death, it is important to submit both a Follow-up Form(s) and a Notice of Death Form.
- Under the Notice of New Primary section, please specify the type of cancer for the "site" of new primary. For example, if the new primary is Melanoma, enter that as the "site".

S2525 | General Hospital | 123456 | Follow-up | Follow-up

Patient ID: 123456 Enrollment Date: 29 Oct 20YY Patient Initials (LFM): ABC

Subject: **123456**
Page: **Follow-up - Follow-up**

Instructions: Please submit at each follow-up after completion of treatment until relapse or progression, at time of relapse or progression, and at protocol-specified intervals after relapse or progression. Also submit at time of diagnosis of second primary.

If the patient experienced (prior to treatment for progression or relapse or a second primary, and prior to non-protocol treatment) any severe (Grade ≥ 3) long term toxicity that has not been previously reported, report those on the Late Effects form. Use the Add Event dropdown box on the Subject tab to generate the Late Effects form.

Vital status ☐ Alive ○ Dead

Date of last contact [ ] [...] [ ]

If Dead, date of death [ ] [...] [ ]

DISEASE FOLLOW-UP STATUS

Was disease status (for this cancer) evaluated during this reporting period? ○ Yes ○ No

If Yes, date of last clinical assessment [ ] [...] [ ]

NOTICE OF FIRST RELAPSE OR PROGRESSION

Has the patient developed a first relapse or progression that has not been previously reported? ○ Yes ○ No

If Yes, date of relapse or progression [ ] [...] [ ]

If Yes, site(s) of relapse or progression

NON-PROTOCOL TREATMENT

Has the patient received any non-protocol cancer therapy (prior to progression/relapse) not previously reported? ○ Yes ○ No

If Yes, date of first non-protocol therapy [ ] [...] [ ]

Agent name(s)

NOTICE OF NEW PRIMARY

Has a new primary cancer or MDS (myelodysplastic syndrome) been diagnosed that has not been previously reported? ○ Yes ○ No

If Yes, date of diagnosis [ ] [...] [ ]

If Yes, new primary site

Comments

If you're not done completing this form, but want to save your work for later, check the box below and click the Save button that edit checks will still fire.

Save this form, but don't submit to SWOG yet. ☐

Follow-Up Forms: Patient A, BC

The Notice of Death Form (NOD)

Newer SWOG studies include the Vital Status form. Please use the appropriate Vital Status (On Treatment or Off Treatment version depending on circumstances) form to indicate patient's vital status to have the Notice of Death form roll out.

SWOG
ON TREATMENT VITAL STATUS FORM

Patient Identifier 1 2 3 4 5 6 **Study Identifier** S 2 5 2 5 **Registration Step** 1

Patient Initials A,BC (L, F M)

Page: Vital Status

Instructions: Please complete this form at the required protocol timepoints. This form should be submitted prior to any other data entry related to that visit. If this is the first Registration Step for the Study and the patient has not been seen since registration, please enter the Registration Date for Step 1. Date is in **DD MON YYYY** format.

Vital Status *(If dead, please submit Notice of Death)* ☐ Alive ☐ Dead

Date of last contact *(If dead, please enter date of death)* ☐☐ ☐☐☐ ☐☐☐☐

Discussion Points

- It is crucial to obtain the most complete information possible. It is not sufficient to simply verify a death by accessing the SSDI (social security death index) or confirmation by the tumor registry. Every effort must be made to determine the cause of death and the corresponding details.
- If the cause of death was cancer, it's important to document *which* ~~cancer..~~cancer.
  - If it was the malignancy being followed in the study, "Tumor" should be selected
  - If it was a different primary malignancy, "New Primary" should be selected
- A patient who dies of cancer most likely will have some evidence of progression prior to death and it is important that the progression be documented. If there is no documentation found, the CRA should document the attempts to obtain it and the outcome of those attempts.
- Answering "unknown" to all fields of this form is not a valid response. Unknown should only be used if all other avenues of investigation have been exhausted. If cause of death is truly unknown, use the comments section at the bottom of the form to explain all steps that were taken to try to find the cause of death. For example, was the location of the death certificate attempted to be found, was the tumor registry checked, has the family or primary physician been contacted. If unknown is selected, you will be queried.

SWOG
NOTICE OF DEATH

Patient Identifier 1 2 3 4 5 6 **Study Identifier** S 2 5 2 5 **Registration Step** 1

Patient Initials A,BC (L, F M)

Page: Notice of Death

Instructions: Answer all questions and explain any blank fields or blank dates in the **Comments** section. Date is in **DD MON YYYY** format.

Date of death ☐☐ ☐☐☐ ☐☐☐☐

Cause of death
- ☐ Tumor
- ☐ New primary
- ☐ Infection
- ☐ Drug related
- ☐ Other, specify: _____
- ☐ Unknown

Cancer-related causes
- ☐ No
- ☐ Primary cause, specify: _____
- ☐ Contributory cause, specify: _____
- ☐ Possible, specify: _____
- ☐ Unknown

Toxicity from disease-related treatment
- ☐ No
- ☐ Primary cause, specify: _____
- ☐ Contributory cause, specify: _____
- ☐ Possible, specify: _____
- ☐ Unknown

Non-cancer and non-treatment related causes
- ☐ No
- ☐ Primary cause, specify: _____
- ☐ Contributory cause, specify: _____
- ☐ Possible, specify: _____
- ☐ Unknown

Autopsy performed? ☐ Yes ☐ No ☐ Unknown

Source(s) of death information (select all that apply)

Autopsy report	☐
Medical record/death certificate	☐
Physician	☐
Relative or friend	☐
Other	☐
If Other, specify	_____

Comments

This concludes this year's Practicum!

Thank you for your participation today. We hope this has been an informative session that will help you navigate the SWOG data submission process.

Please take this opportunity to ask any questions at an open microphone or in the chat for those attending virtually.

Again, this Practicum is an abbreviated version of the practicum specifically made for our hybrid training environment. The full practicum and all of the exercises can be found via the SWOG website under the Training link.

If you do have questions or concerns regarding any of the material in this Practicum, please feel free to reach out to the disease site committee email distribution lists for your study at any time.

breastquestion@crab.org
cancercontrolquestion@crab.org
giquestion@crab.org
guquestion@crab.org
leukemiaquestion@crab.org
lungquestion@crab.org
LungMAPquestion@crab.org
lymphomaquestion@crab.org
melanomaquestion@crab.org
myelomaquestion@crab.org
raretumors@crab.org

You may also call the SWOG SDMC at 206-652-2267 to speak to a Data Coordinator.

Thank you again for your time and participation!

SWOG
CLINICAL TRIALS TRAINING COURSE EVALUATION

Spring 2022 – Seattle, WA

You must return a completed evaluation to receive your Certificate of Attendance.

Please Note: Although some of our presenters are professional speakers, we do ask staff or volunteers who are **not**. We appreciate all of our speakers. They have worked beyond their regular workload. Please be sure to let us know if content was unclear, or you feel that there is another issue that we could have explained in a better way. These comments definitely help us improve and prepare for the next course. Thank you!

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1) Evaluate the Clinical Trials Training Course for its overall content **and** presentation style on a scale of 1-5.

Scale: 1 – Poor 2 – Below Average 3 – Average 4 – Good 5 – Excellent

Content: the quality of the information presented (i.e. useable, beneficial, relevant).

1 2 3 4 5

Presentation: the manner in which the information was presented (i.e. clarity, flow, duration).

1 2 3 4 5

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2) Comments pertaining to particular presentations. Please be specific and write your comments as clearly as possible.

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3) Other Comments. Please be specific and write your comments as clearly as possible.

Please turn your completed evaluation form in to your Practicum facilitator. Thank you for your suggestions.

SWOG | CANCER RESEARCH NETWORK

THE HOPE FOUNDATION FOR CANCER RESEARCH

Clinical Research Associate Manual (CRA Manual): Volume I and Volume II may be accessed via the internet at the following address: http://swog.org

SWOG Roster: may be accessed via the internet at the following address: http://swog.org