Lung-MAP Protocol Updates

CRYSTAL MIWA, BS
LUNG-MAP PROJECT MANAGER
SWOG | LEADING CANCER RESEARCH. TOGETHER.
CMIWA@SWOG.ORG

Overview

Sponsored by the Lung-MAP Site Coordinators Committee

Objective:

- Update on Lung-MAP activates
  - Sub-study/Revisions, Common Errors, Data Entry Tips
- Management of irAEs
- Useful Tips and Tricks for coordinating and running Lung-MAP

Protocol Updates:

- Sub-Study Status/Revisions
- New Studies
  - S1400K
  - S1400GEN
- Opening to all histologies

S1400 Update Meeting
Fri 4/13, at 2:30pm
Seacliff Room (Bay Level)
Featuring presentations on S1400K and S1400GEN

Sub-Study Status

Revisions Approved since last Group Meeting	
Revision #12 [S1400GEN and S1400K]	Released: 2/5/2018
Revision #14 [S1400A – Admin Edits]	Released: 2/5/2018
Revision #15 [S1400I – Admin Edits]	Released: 4/1/2018

Revisions Under CTEP/CIRB Review	
Revision #16 [S1400F – Responses to FDA Comments]	CTEP Approval on Hold, next CIRB meeting 4/5
Revision #17 [S1400A – Admin Edits]	CTEP Approval on Hold, next CIRB meeting 4/5

NOTE: Revision 13 is no longer relevant and will not be released

Main Screening Protocol (Rev #12)

Section	Change	Previous
5 – Eligibility	c-Met testing, S1400GEN for US sites & English speaking	
7 – Follow-Up Period	Until sub-study registration or death	Until death or 3 years after screening/pre-screening registration
13 – Registration Timing	Tissue submission lengthened to **5 calendar** days	Tissue submission in 1 working day
	Planned treatment lengthened to **10 calendar** days	Planned treatment in 7 working days

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Main Screening Protocol (Rev #12)

Section	Change
18 – On Site Monitoring Plan	Reduced to sites with **patients registered to a sub-study**. Exceptions to on site monitoring requirement: • Sites that use a **centralized** pharmacy and data management team may be monitored at this central location. • Sites that had an acceptable **pharmacy audit** in the last year may be audited off site at a central location. • Sites that had an acceptable **patient case** review outcome at their last audit and have **not enrolled** patients to any new sub-studies may be put on an annual schedule.

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New Sub-Study, S1400K (Rev #12)

- Single-Arm Phase II Trial evaluating overall response rate with **ABBV-399** in patients with **c-MET positive squamous cell lung cancer**.
- S1400K – Activated 2/5/18, First patient enrolled 3/16/18
- Total accrual goal is **44 pts**, prevalence **30%**

Frequently Asked Questions:

- **Investigator's Brochures**: Available through CTSU. Complete the CTSU Request for Clinical Brochure form located under Documents > Site Registration. Complete and return form to ctsucontact@westat.com.
- **Pre-Medications**: No requirements. Follow ASCO guidelines.
- **Retrospective c-MET testing:** Available in the near future.

Study Chairs: Dr. Saiama Waqar (NRG) and Dr. Susanne Arnold (SWOG)

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New Ancillary Study, S1400GEN (Rev #12)

Evaluate Patient and Physician Knowledge, Attitudes, and Preferences Related to Return of Genomic Results

- Sites are required to **offer** the optional study to patients when consenting for screening or pre-screening. If consented, fax the consent page to Fred Hutch.
- The S1400GEN consent **cannot be altered**.
  - The **bracketed language** regarding an online survey was intended to be included for an easy switch from the survey being conducted via phone to online.
  - Fred Hutch is purchasing and mailing **gift cards** directly to patients. Consent for patient/physician cannot be modified to remove gift card language.
- The **physician consent** is intended for use by Fred Hutch team, not by the site. Site boilerplate language is not applicable and should not be added.

Study Chairs: Dr. Josh Roth and Dr. Scott Ramsey

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S1400A (Rev # 14 & 17)

Section	Change
9 – Calendar	TSH/Free T3/T4 laboratory footnote has been modified to clarify that the laboratory tests, **if clinically indicated,** should be repeated every 4 weeks during treatment, then **every 8 weeks** prior to progression, or more often as clinically indicated. Justification: to reduce burden on patient if they are asymptomatic or off treatment.

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S1400I (Rev #15)

Section	Change	Previous
Throughout	SWOG and CTSU links have been updated due to changes on the websites	
5 – Eligibility	**Canadian sites** – Allow for the collection of lipase only	All sites to collect both Amylase and Lipase
7 – Follow-Up Period	Patients who enroll on a new sub-study following progression **must continue follow-up on this sub-study**, in addition to follow-up on the new sub-study.	Patients that enroll on a new sub-study following progression may discontinue follow-up on this sub-study and proceed per protocol of new sub-study.
9 – Calendar	EQ-5D Questionnaire should be completed within **14 days** prior to registration. Frequency of Brain CT/MRI scans reduced to **12 weeks** (for patients with brain mets at baseline)	Brain CT/MRI scans every 6 weeks (for patients with brain mets at baseline)
13 – Registration Timing	Planned treatment lengthened to **10 calendar** days	Planned treatment in 7 working days

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S1400F (Rev #16)

Response to FDA comments to ensure patients continuing treatment beyond radiologic disease progression are not exposed to unreasonable risks.

Section	Change
7 – Removal from Protocol	Additional criteria has been added: • absence of symptoms and signs indicating clinically significant progressive disease; • no decline in Zubrod performance status; • absence of symptomatic rapid disease progression requiring urgent medical intervention [e.g., symptomatic pleural effusion, spinal cord compression]
Consent Addendum	Consent must be obtained from patients who progress and wish to continue to receive treatment on study.

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Lung-MAP Opening to all histologies

- Current design consists of a biomarker platform for evaluating genomically-matched therapies as well as therapies irrespective of biomarker status.
- Proposed Changes:
  - Allow all histologies to enroll
  - Establish an immunotherapy combination (IO) platform for PD/L-1 resistance
  - Better serve the changing needs of patients and provide patients with more options after lines of therapy have stopped working

New Sub-Studies Coming
LungMAP – New Lung-MAP Screening Protocol – CIRB only
S1800A – Pembro/Ramucirumab. First sub-study in the IO platform.
S1400L – Rucaparib. Biomarker driven sub-study enrolling all histologies.

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QA Common Errors and Concerns

LAURA GONZALES, BSN, MA, RN, OCN
QA NURSE AUDITOR
SWOG | LEADING CANCER RESEARCH. TOGETHER.
LGONZALES@SWOG.ORG

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QA Auditing Common Problems

- **Regulatory: For sites using the CIRB:**
  - Consent forms deviate from the approved boilerplate language
  - Unable to determine when consent versions were implemented
- **Boilerplate Document**
  - Protocol Specific
  - Annual Signatory
- **DTL – New requirement**

QA Auditing Common Problems

- **Patient Case Review: Eligibility**
  - **S1400**: Failure to confirm ≥ 20% tumor cells by local pathologist
    - Much better – we are seeing less of this
  - **S1400G:** – Must have achieved stable disease, a partial response, or a complete response at their first disease assessment after initiating first-line platinum-based chemotherapy
  - **S1400I**: Must not have received systemic treatment with corticosteroids (> 10 mg daily prednisone or equivalent) or other immunosuppressive medications within 14 days prior to sub-study registration.

QA Auditing Common Problems

- **Patient Case Review: Treatment**
  - Failure to dose reduce per protocol
  - Failure to document compliance to oral drugs
- **Patient Case Review: Adverse Events**
  - Failure to report adverse events
  - See CRF Guidelines page 27

QA Auditing Common Problems

- **Patient Case Review: Data Quality**

Data entry errors (Data Submission Guidelines under 'Other Study Materials' and CRA Workbench-ORP Manual)

- Current date of staging (Pg 3)
- TNM staging (Pg 3)
- # of prior systemic treatments for Stage IV (Pg 4)
- Date on uploaded reports (Pg 5)
- Measured Creatinine Clearance (Pg 15)
- RECIST (Pg 21 & 22)

Disease Assessment

- **Target Lesions**
  - Choose up to 2 lesions per organ & 5 lesions total
  - For lymph nodes, record the smallest (short axis) diameter (must be > 1.5 cm to be a measurable lesion).
  - Nodules are generally not considered lymph nodes.

Disease Assessment

- **Non-Target Lesions**
  - Measurable lesions that were not selected as target lesions. Since only two lesions per organ and five lesions in total can be selected as target lesions, any additional lesions should be followed as non-target disease.
  - Small lesions (longest diameter < 1.0 cm or pathologic lymph nodes with ≥ 1.0 cm to <1.5 cm short axis). Note: Lymph nodes that have a short axis < 1.0 cm (10 mm) are considered non-pathological and should not be recorded or followed.
  - Bone lesions, leptomeningeal disease, ascites, pleural/pericardial effusions, lymphangitis cutis, pulmonis, inflammatory breast disease, and abdominal masses (not followed by CT or MRI).
  - Previously radiated lesions that have not progressed.

Data Delinquency & Failure to Collect Specimens

All data is submitted electronically:

Medidata Rave®	TRIAD application	SWOG Specimen Tracking System
All case report forms & specified source documentation	**Radiology images**	**All specimens**
Protocol Section 14 for submission schedule	Protocol Section 14 for schedule Protocol Section 15 for details	Protocol Section 15 for details and schedule
Baseline forms due within 7 days of registration	Scan images to be uploaded within 7 days of the disease assessment	Specimens can be batched, but enter the date drawn in Specimen tracking
For Baseline Forms: • > 30 days late is a lesser • > 90 days late is a major	For Baseline Forms: • > 30 days late is a lesser • > 90 days late is a major	

Timely submission of data is critical to trial success!

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Adverse Events Overview

- Monitoring of adverse events (AEs) is critical to the patient's safety (i.e., human subjects protection) and data integrity.
  - Define what constitutes an AE.
  - Describe the elements required to document AEs.
  - How to distinguish between AEs & irAEs

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Adverse Event

- Multiple clinical terms have been used to convey an Adverse Event (AE) including:
  - toxicity
  - side effect
  - acute or late effect
  - Complication
    - all essentially pointing to a change possibly caused by treatment

All of the terms above imply that an intervention caused the event which is not the definition of an AE.

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Definition

- **Adverse Event:** Any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related.
- **Immune Related AE:** Side effects, due to the immune system activation by CTLA-4 blockade.

21CFR 312.3222
2018: M.A. Postow & J.D Wolchok

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QA Auditing Common Problems

- Patient Case Review: Adverse Events
  - Reporting of baseline toxicities
  - Failure to report adverse events

CRF Guidelines page 27

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Reporting of Baseline Toxicities

- Do not report a condition existing prior to registration.
  - This includes any condition occurring up to the time of the first infusion.
  - If a baseline toxicity resolves and then re-occurs, it is then reported.
  - If a baseline increases, it then is reported. However, when it returns to the baseline grade, it is not considered a toxicity and should not be reported.

e.g. Hyponatremia is grade 1 at baseline, it is reported when it increases to grade 3, when it returns to grade 1, an end date is reported for the grade 3 & the grade 1 is not reported.

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Non-Clinically Significant AEs

- The protocol states to report all adverse events, 1 – 5 unless present at baseline. Some pharmaceutical studies may exclude the reporting of NCS AEs.
- As S1400 does not state to exclude these, all must be reported. This includes NCS laboratory value abnormalities.

AE Progress Note

- All AEs should be documented in the patient's medical record. Include any workup or treatment provided.
  - Date the AE began
  - Treatment for the AE
  - Description of the event
  - Attribution of the AE
  - Date the AE resolved
  - Immune-relationship

CTCAE

- The CTCAE is set up in a table format using the Medical Dictionary for Regulatory Activities (MedDRA) System Organ Class (SOC).
- Within each SOC, AEs are listed and accompanied by descriptions of severity: Grades 1 – 5

Determining Attribution

- Determining the attribution is done by the investigator with input from the research team.
  - What do we already know about the drug/therapy, or classification of drug?
  - Does the AE improve or disappear when drug/therapy is stopped?
  - If re-challenged with the drug/therapy, does the AE reappear? At the same severity? At the same time point?
  - Is the AE a worsening of baseline symptom(s)?

E. Ness AE documenting, recording & reporting (NIH)

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Documentation Example

Patient Name:_____ Study # _____

AE	Grade	Relationship	Start	Stop	Immune Related	Not Immune related	Medication to Treat
					☐	☐	
					☐	☐	
					☐	☐	
					☐	☐	
					☐	☐	
					☐	☐	
					☐	☐	
					☐	☐	
					☐	☐	

Investigators Signature: _____ Date: _____ Page: ____ of ____

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Resources

- Code of Federal Regulations, Food and Drugs, 21 CFR 312: IND Application
- COMMON TOXICITY CRITERIA ADVERSE EVENTS v.4: https://evs.nci.nih.gov/ftp1/CTCAE/CTCAE_4.03/CTCAE_4.03_2010-06-14_QuickReference_5x7.pdf
- FDA (2009) *Guidance for Clinical Investigators, Sponsors, and IRBs Adverse Event Reporting to IRBs — Improving Human Subject Protection* https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126572.pdf
- Gordon, R. (2017) Checkpoint Inhibitors; common immune-related adverse events and their management. 21(2) CJON.
- Grier, M. (2017). How to manage Immunotherapy-related Endocrinopathies. ONS Voice, July 2017.
- ONS CTN Toolkit on patient management: http://www.clinicaltrialtools.vc.ons.org/190168
- S1400 CRF Guidelines (on the protocol abstract page of website): https://crawb.crab.org/txwb/CRA_MANUAL/Vol1/chapter%2016e_Data_Entry_Guidelines_S1400.pdf
- Therasse, P., Arbuck, S. G., et. al. (2000). New Guidelines to Evaluate the Response to Treatment of Solid Tumors. *Journal of the National Cancer Institute: JNCI, Volume 92* (3), pp. 205-216.

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Data Management & eCRF Completion

LOUISE HIGHLEYMAN
S1400 LUNG-MAP DATA COORDINATOR
SWOG STATISTICS AND DATA MANAGEMENT CENTER
S1400QUESTION@SWOG.ORG

"This is a potential FDA registration study…"

- In general, data procedures are the same
- Increased data submission requirements
  - More detailed adverse event reporting
  - Increased reporting of laboratory values
- Radiology image submission (TRIAD)

"This is a potential FDA registration study…"

- Increased attention to EDC and source documentation
  - Data coordinators, centralized monitoring, auditing
- Data reporting requirements might be adjusted to gather additional information for further analysis, or in reaction to a changing medical landscape
  - Ex.: Retrospective data collection on irAE's (S1400I)

Data Coordinator Review

- Higher frequency of review; more data fields to review
- This means you may see more queries more often than you are used to on other SWOG/NCTN trials
- Rave also generates queries for missing information
  - Important to wait until the end of a cycle to enter data

S1400 Sub-Study: Common Queries
TNM staging (Onstudy)
Reporting period dates (Treatment, AEs)
Treatment doses and dates (Treatment)
Adverse event dates (AE: Report)
Lab dates (Laboratory Values)
Lab value units (Laboratory Values)
Source documentation upload

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General Data Management Resources

- Documents available on the protocol page at SWOG.org and CTSU.org
  - Master Forms Sets
- SWOG Reports
  - SWOG CRA Workbench
  - Available to both SWOG & CTSU members
- CTSU Data Quality Portal (DQP)

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S1400 Data Management Resources

- SWOG Data Coordinators (S1400question@crab.org)
- "Your Institution's Lung-Map Status Update"
  - Emailed quarterly to your institution's head CRA
- **Rave Data Entry Guidelines**
  - Chapter 16e of the ORP Manual or as a link on the protocol abstract page

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S1400 Rave Data Entry Guidelines

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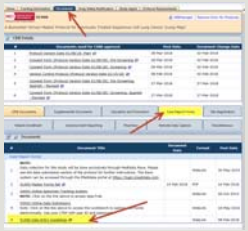
S1400 Rave Data Entry Guidelines

Lives on the SWOG ORP Manual…

…with links on the SWOG protocol page…

…and the CTSU S1400 > Documents tab.



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Forms Changes Going Forward

Applies to S1400F, S1400K and new sub-studies developed in the future:

➢**New forms:**
- *Eligibility Criteria*
- *Immune-Related Adverse Event* (S1400F and future sub-studies with IO drugs)
- *End of Study*

➢**Form updates:**
- *Onstudy* (Comments)
- *Treatment*
- *Adverse Events: Report*
- *Laboratory Values*
- *Late Effects*
- *Notice of Death*

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Forms Changes Going Forward

Eligibility Criteria
This form contains the sub-study protocol section 5 eligibility criteria. A response must be provided for each criterion listed; none should be left blank.

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Forms Changes Going Forward

Onstudy: Patient and Disease Description

If any of the data points on this form require clarification with additional comments, the comments **must** have the corresponding "question number" selected in the log line.

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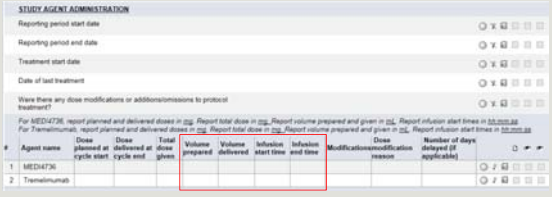
Forms Changes Going Forward

Treatment Form



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Forms Changes Going Forward

Adverse Events: Report

For sub-studies w/ IO drugs (S1400F):
For each AE listed on this form, please indicates "Yes" or "No" in the "Is the AE immune-related?" field. For each adverse event where "Yes" in this field is selected, a new "Immune-Related Adverse Event" form will generate in the cycle folder.

S1400F, S1400K:
Serious adverse events as defined in S1400F protocol section 16 should have "Yes" indicated in the "Serious" field. Associated CTEP-AERS report ticket numbers should be added in the corresponding field.

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Forms Changes Going Forward

End of Study

Please only complete this form if the patient has gone off study, which is defined as:

- reaching or expiring prior to maximum protocol-defined follow-up of 3 years, or
- being documented as lost to follow-up per SWOG Policy #30, or
- patient withdrawal of consent to all protocol treatment *and* follow-up on the study, per SWOG Policy #30.

This is not the same as removal from protocol treatment, which should be documented in the "Off Treatment Notice."

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Management of irAE's

LAVINIA DOBREA, RN, MS, OCN
LUNG-MAP SCC CO-CHAIR
ST. JOSEPH HOSPITAL | THE CENTER FOR CANCER PREVENTION AND TREATMENT
LAVINIA.DOBREA@STJOE.ORG

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Overview

- Examples of irAE Guidelines
- Management of irAE's:
  - Prevention
  - Treatment
- irAE Reporting
- irAE Resources

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Guidelines

JOURNAL OF CLINICAL ONCOLOGY ASCO SPECIAL ARTICLE

Management of Immune-Related Adverse Events in Patients Treated With Immune Checkpoint Inhibitor Therapy: American Society of Clinical Oncology Clinical Practice Guideline

Julie R. Brahmer, Christina Lacchetti, Bryan J. Schneider, Michael B. Atkins, Kelly J. Brassil, Jeffrey M. Caterino, Ian Chau, Marc S. Ernstoff, Jennifer M. Gardner, Pamela Ginex, Sigrun Hallmeyer, Jennifer Holter Chakrabarty, Natasha B. Leighl, Jennifer S. Mammen, David F. McDermott, Aung Naing, Loretta J. Nastoupil, Tanyanika Phillips, Laura D. Porter, Igor Puzanov, Cristina A. Reichner, Bianca D. Santomasso, Carole Seigel, Alexander Spira, Maria E. Suarez-Almazor, Yinghong Wang, Jeffrey S. Weber, Judd D. Wolchok, and John A. Thompson in collaboration with the National Comprehensive Cancer Network

ABSTRACT

Purpose

To increase awareness, outline strategies, and offer guidance on the recommended management of immune-related adverse events in patients treated with immune checkpoint inhibitor (ICPI) therapy.

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Guidelines

NCCN National Comprehensive Cancer Network

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) in partnership with the American Society of Clinical Oncology (ASCO)

Management of Immunotherapy-Related Toxicities

(Immune Checkpoint Inhibitor-Related Toxicities)

Version 1.2018 — February 14, 2018

NCCN.org

Continue

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Prevention: Patient & family HISTORY:

S1400F Eligibility

- 5.1e "Patients must not have any prior documented autoimmune or inflammatory disease (including inflammatory bowel disease, diverticulitis with the exception of diverticulosis, celiac disease, irritable bowel disease; Wegner syndrome; Hashimoto syndrome) within 3 years prior to sub-study registration. Patients with vitiligo, immune-mediated alopecia, Grave's disease, or psoriasis requiring systemic treatment within the past 2 years are not eligible. Patients with hypothyroidism (e.g. post Hashimoto syndrome) who are stable on hormone replacement therapy are eligible."
- 5.1e "Patients must not have any history of primary immunodeficiency."

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Prevention: no concomitant medications

S1400F 3.0 Drug Information- Durvalumab

- 3.1.c.1 AE, Drug Interactions:

"…There are no known clinically significant interactions of MEDI4736 (Durvalumab) with other medicinal products."

S1400F 5.1 & 5.2 ELIGIBILITY

- Ensure patients current and past treatments meet eligibility:
  - 5.1b. No Prior PD-1/PD-L1 combination therapy
  - 5.1c. No prior exposure to CTLA-4 inhibitors (ipilimumab and tremelimumab)
  - 5.1d. No nitrosoureas or mitomycin-c within 42 days prior to sub-study registration.

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Prevention: patient identification/provider awareness

S1400K 7.2b- Study Drug Information Wallet Card

STUDY DRUG INFORMATION WALLET CARD

You are enrolled on a clinical trial using the experimental study drug ABBV-339 (Process II). This clinical trial is sponsored by the NCI. ABBV-339 (Process II) may interact with drugs that are processed by your liver, or use certain transport proteins in your body. Because of this, it is very important to:

- Tell your doctors if you stop taking any medicines or if you start taking any new medicines.
- Tell all your health care providers (doctors, physician assistants, nurse practitioners, or pharmacists) that you are taking part in a clinical trial.
- Check with your doctor or pharmacist whenever you need to use an over-the-counter medicine or herbal supplement.
- Avoid ingesting grapefruit, grapefruit juice and Seville oranges and avoid herbal tea/medicines while on trial.

- ABBV-339 (Process II) may interact with CYP 3A4 and transport protein P-gp, and must be used very carefully with other medicines that interact with this enzyme and transport protein.
- Before you enroll onto the clinical trial, your study doctor will work with your regular health care providers to review any medicines and herbal supplements that are considered "strong inducers/inhibitors of CYP 3A4 and transport protein P-gp."
- Before prescribing new medicines, your regular health care providers should go to a frequently-updated medical reference for a list of drugs to avoid, or contact your study doctor.
- Your study doctor's name is _____

and can be contacted at _____.

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Prevention: patient identification/provider awareness

Ex. Non-protocol Wallet Card

IMPORTANT INFORMATION

I am receiving or have received
IMMUNOTHERAPY.

Nurse/Doctor
Please read the information on the reverse side of this card.

Oncologist: _____
Contact number: _____

St.JosephHealth
St. Joseph Hospital
Cancer Prevention and Treatment

ADVICE TO HEALTH CARE PROFESSIONALS

Autoimmune side effects:
- Diarrhea and Colitis
- Hepatotoxicities
- Pneumonitis
- Addison's Disease
- Endocrinopathies
- Neuropathies
- Renal Toxicities
- Skin Rashes

Required blood tests:
- CBC
- Complete Metabolic Panel
- Random Cortisol/ACTH
- Thyroid function test
- If patient has dyspnea, order Chest CT

Steroids are frequently indicated in the management of side effects and may be given.

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IrAE Management: prevention

S1400F 7.0 -TREATMENT PLAN

- **7.1 Pre-Medication & Supportive Care**
  - –Premedication & supportive care (including anti-diarrheals, antibiotics, diuretics or other medications) may be given as indicated by the current ASCO guidelines.
  - –Protocol treatment specific pre-medication is not required for routine infusions.
  - –If during any infusion, a reaction occurs, pre-medication (e.g. acetaminophen) and/or antihistamine (e.g. diphenhydramine) may be used for subsequent infusions.
  - –Intranasal and inhaled corticosteroids are allowed during protocol therapy.
  - –Corticosteroids to manage immune-related adverse events during protocol therapy will be permitted.

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IrAE Management: toxicities

S1400F 8.3.a –Dose Interruptions and Management Guidelines for irAE's

Toxicity	Dose Interruptions	Toxicity Management
Immune-Related Adverse Events (irAEs) for toxicities not noted below		
In addition to the criteria for permanent discontinuation of study drug/regimen based on CTCAE grade/severity (table below) , permanently discontinue study drug/study regimen for the following conditions: • Inability to reduce corticosteroid to a dose of ≤10 mg of prednisone per day (or equivalent) **within 28 days** after last dose of study drug/regimen • **Recurrence of a previously experienced Grade 3 treatment-related AE following resumption of dosing.**		
Grade 1	No dose modifications	It is recommended that management of irAEs follow these guidelines. - Thoroughly evaluate patients to rule out any alternative etiology (e.g., disease progression, concomitant medications, infections, etc.) - In the absence of a clear alternative etiology, all events should be considered potentially immune related. - Symptomatic and topical therapy should be considered for low-grade (Grade 1 or 2, unless otherwise specified) events - For persistent (> 3 or 5 days) low-grade (Grade 2) or severe (Grade ≥3) events promptly start prednisone PO 1-2mg/kg/day or IV equivalent - If symptoms recur or worsen during corticosteroid tapering (> 28 days
Grade 2	Hold protocol therapy until resolution to ≤ Grade 1 and after completion of steroid taper then resume protocol therapy administration at next scheduled dose	
≥ Grade 3	Discontinue protocol therapy and remove from protocol therapy	

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IrAE Reporting:

Ensure Providers Document:

- Causality of the AE **(Is the AE immune-related?)**
- Grade per CTCAE v.5.0 **(As of 01 April 2018)**

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Resources of irAE management:

- Dr. Bazhenova's Presentation Slides **"Lung-MAP Webinar (12/7/2017)"** https://www.swog.org/lung-map-s1400-resources
- Checkpoint Inhibitors: **Common Immune-Related Adverse Events and Their Management (Paper in Clinical Journal of Oncology Nursing)** https://cjon.ons.org/cjon/21/2-0/supplement/checkpoint-inhibitors-common-immune-related-adverse-events-and-their
- CTSU Video: **"Harnessing the Power of the Human Immune System Against Cancer" video**
  Click Immunotherapy (Checkpoint Inhibitors) Video – April 26, 2017 or sign into the CTSU members' website with your CTEP-IAM account, go to the Resources Tab > Educational Multimedia > Videos
- NCCN immunotherapy teaching/monitoring tool for clinicians and patients: https://www.nccn.org/immunotherapytool/pdf/NCCN_Immunotherapy_Teaching_Monitoring_Tool.pdf

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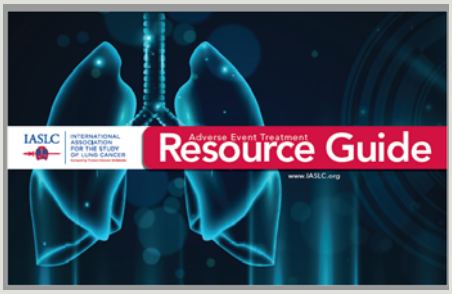
Resources of irAE management:



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Recruitment and Best Practices

JESSICA JORDAN, BA
LUNG-MAP SCC CHAIR
VA CONNECTICUT HEALTHCARE SYSTEM
JESSICA.JORDAN@VA.GOV

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Recruitment to S1400 Lung-Map

- When Should we approach patients?
  - Pre-Screening
- When should the providers be approached?
  - During discussions of the patients treatment
  - During team meetings/ tumor boards
- What are the best ways to keep the Lung-Map Trial in the forefront of everyone's minds?
  - LungMap Newsletters
  - Protocol Cheat Sheets with information on what is open at this time.

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Template for a Note Documenting Trial Eligibility

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The Lung-Map Newsletter

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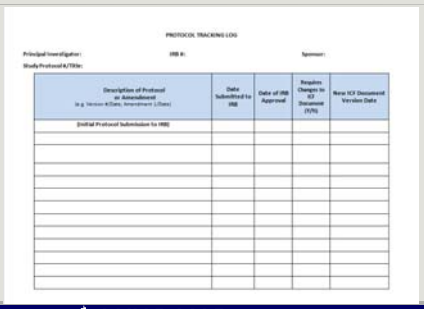
Best Practices for Lung-Map

How do you organize a trial that is ever evolving?



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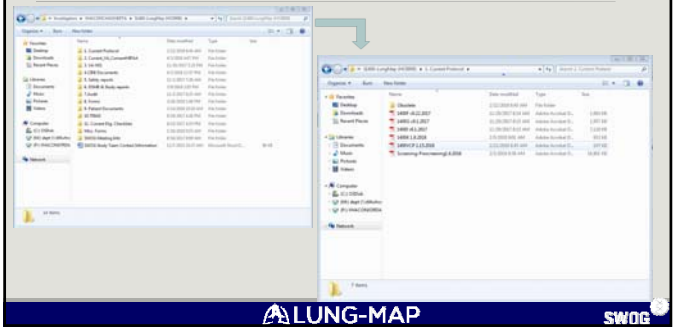
How to Organize Study Documentation



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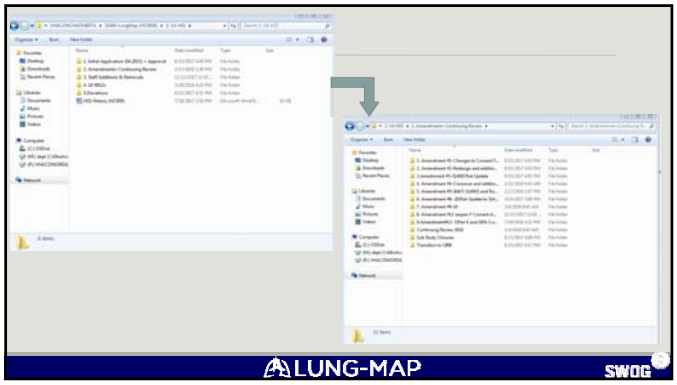
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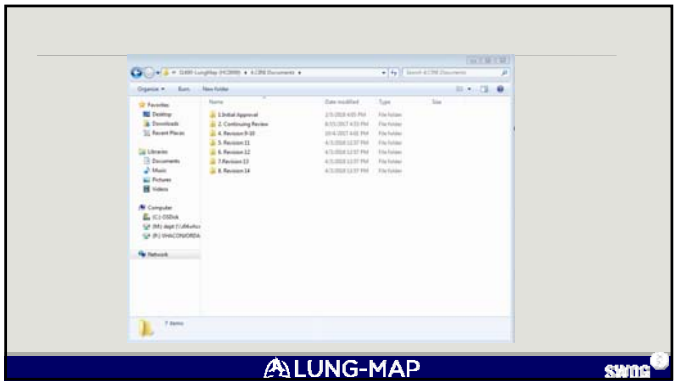
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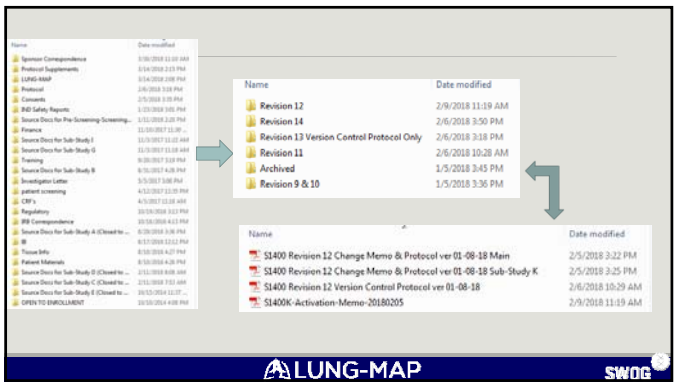
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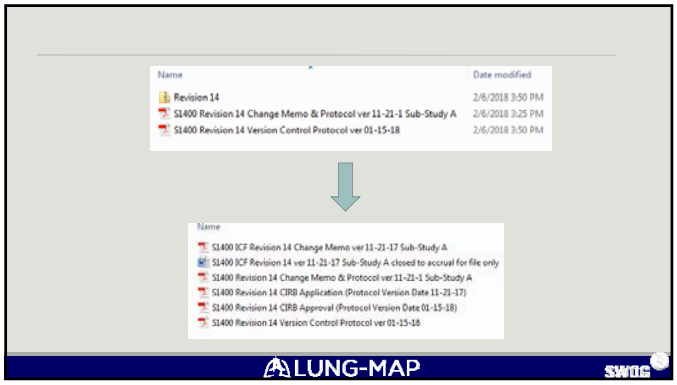
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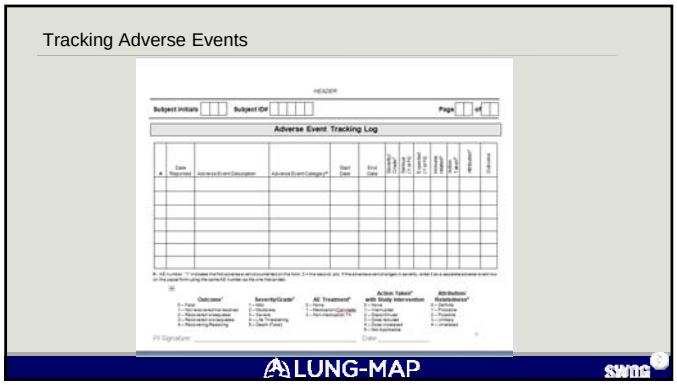
Tracking Adverse Events
Adverse Event Tracking Log
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Contact us: LungmapSCC@crab.org
Joan Aresco
joan.aresco@stjoeshealth.org
734-712-3304
Chair, Jessica Jordan, BA
jessica.jordan@va.gov
203-932-5711 ext 3287
Jamie Arnett, BSN, RN, OCN
arnettj@somc.org
740-356-7594
Steffany Lim, CCRP
sllim@ucdavis.edu
916-734-0561
Wanda M. Burdette RN, OCN, CCRP
wburdette@gibbscc.org
864-560-6810
Joan Moore, MSN, RN, OCN, CCRP
jmoore@wellspan.org
717-339-2638
Co-Chair, Lavinia Dobrea RN, MS, OCN
Lavinia.Dobrea@stjoe.org
714-734-6214
Stephanie Smith, RN, MSN, OCN
smiths1@sjchs.org
912-819-5723
Megan Horne, BSN, RN
mhorne2@umc.edu
601-984-1961
Tyler Workman, RN, MSN
tworkman@queens.org
808-691-8583
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Questions?

Thank you for your time.

The slides presented today will be available on the SWOG website→ S1400 Protocol Abstract page→ Other Study Materials→ **S1400** Group Meeting Materials link

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