"Making the Job Your Own"

A Hands-On Workshop for Protocol Organization and Compliance

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Essentia Health Cancer Center-NCORP

Thursday, May 11th, 2017

Presentation Objectives

- Input on Various Institutional Models
  - Who does what at your institution?
- Study Feasibility Tools
- Patient Tracking Tools
- Briefing a Protocol
  - Protocol Binder Contents
- Other Helpful Tools

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“Let’s Get Organized”

“I’m the Clutter Fairy. I’ll come back ...
I’m gonna need a much bigger wand!”

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Protocol Checklist

NCORP New Protocol Checklist

Protocol: _____ Sponsor: _____ PI: _____

Disease Site: _____ Study Team: _____

CRC Approval Date: _____ **IRB of Record:** ☐ CIRB ☐ Essentia Health

☐ Enrollment Goal _____ **IRB Submission Date:** _____

☐ Preliminary Proposal Form **IRB Approval Date:** _____

Notify: ☐ Beacon ☐ Pharmacy

CREDIT ☐ Review History ☐ Revision History

CTSU Outcome Letter & IRB Cert Form (local)

IRB Submission Materials:
- ☐ CIRB SSW
- ☐ Protocol
- ☐ Consent(s)
- ☐ Patient Materials
- ☐ QOLs
- ☐ IBs

Study Start Up

Ancillary Credentialing Completed: _____
- ☐ Lab/Path _____
- ☐ Radiology _____
- ☐ Radiation _____
- ☐ Extra Regulatory Forms
- ☐ IND Pharmacy _____
- ☐ Beacon _____
- ☐ Training _____

CREDIT/MCA
- ☐ Upload Protocol
- ☐ Build Template
- ☐ Input NCCN Guidelines
- ☐ Create MCA document
- ☐ Tammie double check
- ☐ MCA signed

Request RSH Record to be built in EPIC: _____ ☐ Completed
- ☐ OCT Booklet Page (email Tammie)
- ☐ Add to CancerHelp spreadsheet

Briefing Completed: _____
- ☐ Schedule Briefing with Research Staff + Tammie + Pharmacy

Materials	Binder	CREDIT
Protocol		
Consent(s)		
IBs	---	
QOLs/Patient Materials		
Lab Order Sheet		
Lab Instructions		
Lab Manual		
Pharmacy Manual		
AE Assessment Form		
Reproductive Risks Sheet		
Funding Sheet		
MCA/Budget	---	
Highlighted test schedule		---
Pharmacy green sheet		---
Other: registration sheet(s)/forms		---

Notes:

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Study Feasibility Tools

- Laboratory
- Pathology
- Radiology
- Pharmacy

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Lab Orders with CPT Codes

- Lab Orders with CPT Codes
  - Created and updated by the Research Lab Coordinator
  - Gives most cost effective labs to order for patient on protocol

A071401 (Oncology) w/Sub-Study A071401-ST1 (per Update 6)

Reviewed by: MAM 11/10/2015; 2/24/16 (Ver. 2); 4/20/17 (Update 6)

PI: Bret Friday, MD

TEST	EPIC	CPT	Proc. Code	Pre-Registration	Day 1 of Each Cycle	Post-Tx Follow-Up	At Progression
CBC w/Diff	Lab2998	85025	9248	X	X		
Creatinine	Lab11	82565	7916	X	X		
AST	Lab7	84450	7911	X	X		
ALT	Lab8	84460	7912	X	X		
Alk P'Tase	Lab4	84075	7908	X	X		
T Bili	Lab5	82247	7909	X	X		
Glucose	Lab11	82947	7904	X	X		
Urine Protein	Lab4074	82570 + 84156	6951 + 84156	X	X		
Serum HCG (WOCBP only)	Lab2624	84703	7752	X	X (for vismodegib arm)		
HBSAg	Lab1116	87340	7044	X			
Hep C RNA	Lab1090	86803	7039	X			
Cholesterol (fasting)	Lab14	82465	7919	X	X (q6 cycles)		
Triglyceride (fasting)	Lab15	84478	7920	X	X (q6 cycles)		
RSEND (H&E & Unstained Slides from Tumor Block--Mandatory)	Lab1214	99001	7200	X			
RSEND (Blood & Tissue Block for Substudy--Optional)				X	X (blood only = every 4 cycles)		FFPE Tumor Block & 1 H&E slide at Recurrence

For patients with NF2 mutation on GSK2256098 arm only

At MD discretion (not required)

Protocol indicates either serum or urine HCG; strongly urge serum HCG due due high teratogenicity of study drug

These Chemistries are required by protocol; if MD usually performs a larger Chem panel, Lab4532 (CPT 80053 & Proc. Code 80053) would cover these labs

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Lab Instructions

A071401 (Oncology) with Optional Sub-study A071401-ST1(per Update #6)

Study Contacts: Deb Ronding, RN (ext. 63105; pager 788-0177)
Aaron Dunphy-Knighten, CRA (ext. 63868)
Main Lab Sendouts (ext. 18157)
Mary Ann Miller, MT (pager 218-788-6580)

Oncology Clinical Trials: Place routine orders and RSEND order under local lab appointment. No appointments on Friday if RSEND visit. Morning appointments are best to allow local staff ample time for handling.
Fax patient info (using Research coversheet) and study lab instructions to local lab contact. Send "kit" and supplies via courier to allow lab staff time to review materials.

Phlebotomy: No urine collection required for Sendouts, but check for routine orders (GSK arm for NF2 mutations must have Urine Protein at Baseline and Day 1 of each cycle).
Patients on GSK treatment arm must be fasting every 6 cycles for Cholesterol and Triglyceride.

Most draws will be local, routine labs, but note the following:
At Pre-Registration, all patients will have mandatory Sendout of all diagnostic H&E slides (recuts OK) plus 15-25 unstained slides (containing at least 1 cm^2 viable tumor) shipped to the following address:

Darrell Borger, PhD
c/o Nancy Higgins
Massachusetts General Hospital
55 Fruit Street, GRJ-1028
Boston, MA 02114

All specimens and outer bag must be labeled with:

Protocol Number (A071401)
Alliance Patient Number
Patient's Initials
Accession Number

Ship ambient Monday-Thursday only by overnight service, and include de-identified Pathology report, Central Pathology and Biomarker Results Form and BioMS shipping manifest. Study coordinator will work with Histo/Path to gather specimens (see pp. 32-36 of protocol for details).

Patients may choose to participate in an optional sub-study (A071401-ST1). If so, there will be RSEND orders at Pre-Registration and every 4 cycles during treatment.
Draw tubes contained in "kit" (30mls EDTA blood at Pre-Registration (10mls for germline DNA and 20mls for ctDNA); 20mls EDTA blood (for ctDNA) q4cycles during treatment). Mix tubes gently, but thoroughly, and label with:

Patient Information Label
Name of Study: A071401-ST1
Date & Time Drawn & Initials

Place RSEND label around tops of tubes. Send specimens and paperwork STAT to Lab Sendouts area.
Processing is as follows:

1. Germline DNA: 10mls EDTA whole blood is required (Pre-Registration only). No further processing necessary, except peel off all patient demographics and replace with study label containing the following information:

   Protocol Number (A071401-ST1)
   Alliance Patient Number
   Patient's Initials
   Date Collected
   Type of Specimen (EDTA WB)

   Place sample in a biohazard bag per IATA guidelines. Immediately refrigerate sample until shipment. Obtain BioMS shipping manifest from study coordinator. Ship on cold pack same day as draw via overnight courier to:

   Alliance BAP Freezer
   ST-SL-16
   150 Third Street SW
   Rochester, MN 55902

2. ctDNA: 20mls EDTA blood is required (at Pre-Registration and every 4 cycles while on study). Centrifuge EDTA tubes at RT for 15 minutes at 1500g (call Main Sendouts for assistance in conversion to RPMs). After first spin (no brakes), pipper off plasma from all EDTA tubes (avoiding buffy coat) and place into a 15ml conical tube. Cap and centrifuge plasma ("double spin") at RT for 15 minutes at 1500g. After second spin, aliquot clear plasma into labeled 2ml cryovials (~1.5ml plasma per tube; up to 8 cryovials). Label each aliquot tube as follows:

   Protocol Number (A071401-ST1)
   Alliance Patient Number
   Patient's Initials
   Date Collected
   Type of Specimen (EDTA plasma)

   Freeze aliquots at -80C until shipment. Regional labs may quick freeze cryovials on dry ice, and ship to Main lab Sendouts via courier. Sendouts, see p. 37 of protocol for shipping details. May batch ship every 30 days (on dry ice via overnight courier to Alliance BAP Freezer at address above).

If patient has recurrence and is participating in the sub-study, see p. 36 of protocol for submission of one H&E slide plus FFPE tumor block from recurrence (or 15 unstained slides). Label as follows:

Protocol Number (A071401)
Alliance Patient Number
Patient Initials
Accession Number
Order of Sections and Thickness (slides only)

Ship tissue samples to:

Alliance Biorepository at Mayo Clinic FFPE Tissue
Attn: PC Office (Study A071401)
RO-FF-03-24-CC/NW Clinic
200 First Street Southwest
Rochester, MN 55905

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Pathology Instructions

A071101 (Heat-Shock Vaccine in GBM) Study—Tumor Procurement, Preparation and Shipment

Study Coordinators: Deb Ronding, RN (ext. 63105; pager 788-0177)
Wilma Knutson, RN (ext. 63111; pager 788-0188)
Amy Van Hecke, CRA (ext. 63088)
O.R. Contact: Marcie Hunker, RN (ext. 64977)
Lab Contacts: Mary Ann Miller, MT (pager 788-6580)
Sheila Tapper, Anatomic Path Supervisor (ext. 65472)
Lab Sendouts (ext. 18157)

Surgery will be scheduled through Oncology Clinical Trials, and information communicated to Mary Ann Miller, who will disseminate information to Pathology.
If possible, surgery should be scheduled Monday-Wednesday (morning case) to optimize tissue viability. Tumor harvested on Friday must be stored frozen at -80°C (± 20°C) for Monday shipment to Agenus. Agenus will not accept Saturday delivery.
Oncology Clinical Trials will deliver Agenus kit to Histology the day before scheduled procedure. The kit contains all supplies required for tumor processing and shipment. OCT staff should fill out labels and patient information on the Tissue Procurement Form (TPF).

OR/Pathology/Histology: Follow instructions provided by Agenus. Key points for tumor processing:

- OR staff should wrap the tumor tissue in a sterile cloth and place in a basin on ice. Tissue should be transported STAT to Pathology (agreed-upon location per Dr. Carter).
- Use sterile technique and avoid cross-contamination with tissue or fluid from other patients.
- Pathologist should assess tumor viability—do not submit necrotic or cystic components of tumor to Agenus.
- Within 30 minutes, using sterile technique, section tumor tissue into 1-2 cm^2 sections. At least 7gms tumor should be sent. Place carefully, maintaining sterility, into the 50ml tubes provided in Agenus kit. Fill no more than ½-2/3 full.
- Label tubes with Agenus labels—make sure all required information is documented using a ballpoint pen.
- Freeze tissue immediately at -80°C (within 30 minutes of removal).
- Prep sections of tumor per routine local path. Also obtain a sample of at least 5mm^3, fix in 4-10% neutral buffered formalin and prepare an FFPE block for biomarker analysis (per pp. 20-22 of protocol). The FFPE block will be shipped to the Alliance Biorepository at Mayo, NOT to Agenus.
- Notify Lab Sendouts (ext. 18157)—they will complete shipping process.

Sendouts: Communicate with Pathology and Oncology Clinical Trials to ship tumor ASAP per printed instructions from Agenus lab (Research file under A071101). Make sure all labels and forms are completed, that there are no discrepancies, and that sufficient dry ice is used (8kg).

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Radiology

- Communicate radiology portion of protocol via:
  - E-mail
  - Radiology Summary Forms
  - Meetings (optional)

- Send protocol with Radiology Summary form to Radiology manager
- Radiology manager forwards information to radiologists to approve at their scheduled meetings

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ONCOLOGY CLINICAL STUDY SUMMARY

Name of study: A071401: Phase II Trial of SMO/AKT/NF2 Inhibitors in Progressive Meningiomas with SMO/AKT/NF2 Mutations

Study Summary: To determine the activity of a SMO inhibitor in patients with meningiomas harboring SMO mutations as measured by 6-month PFS and response rate. To determine the activity of a FAK inhibitor in patients with meningiomas harboring NF2 mutations as measured by 6-month PFS and response rate. To evaluate dynamic contrast enhanced MRI during treatment with SMO and FAK inhibitors for meningioma.

Modality involved: MRI of Brain; CT of Brain (only if patient is unable to undergo MR)

Modality protocol needed, technical parameters: Per Section 11.3.2 of protocol for general MRI. Please see Appendix II and section 14.2 of protocol to see if DCE MRI is feasible at our site.

Conventional CT and MRI: This guideline has defined measurability of lesions on CT scan based on the assumption that CT slice thickness is 5 mm or less. If CT scans have slice thickness greater than 5 mm, the minimum size for a measurable lesion should be twice the slice thickness.

As with CT, if an MRI is performed, the technical specifications of the scanning sequences used should be optimized for the evaluation of the type and site of disease. The lesions should be measured on the same pulse sequence. Ideally, the same type of scanner should be used and the image acquisition protocol should be followed as closely as possible to prior scans. Body scans should be performed with breath-hold scanning techniques, if possible.

DCE MRI: If patient consents to **DCE MRI** (and our site is able to meet the radiology protocol criteria), please see Appendix II and section 14.2 of protocol for necessary criteria.

Radiologist dictation requirements: Dictate per RECIST guidelines.

Radiology Summary

Technical charge: This will always be billed to patient and we will direct to study or patient insurance on the billing side by research coder.

Professional charge: This will always be billed to patient and we will direct to study or patient insurance on the billing side by research coder.

Do we get a copy of report if our radiologists are not reading? N/A Essentia Health Radiologist will complete the read.

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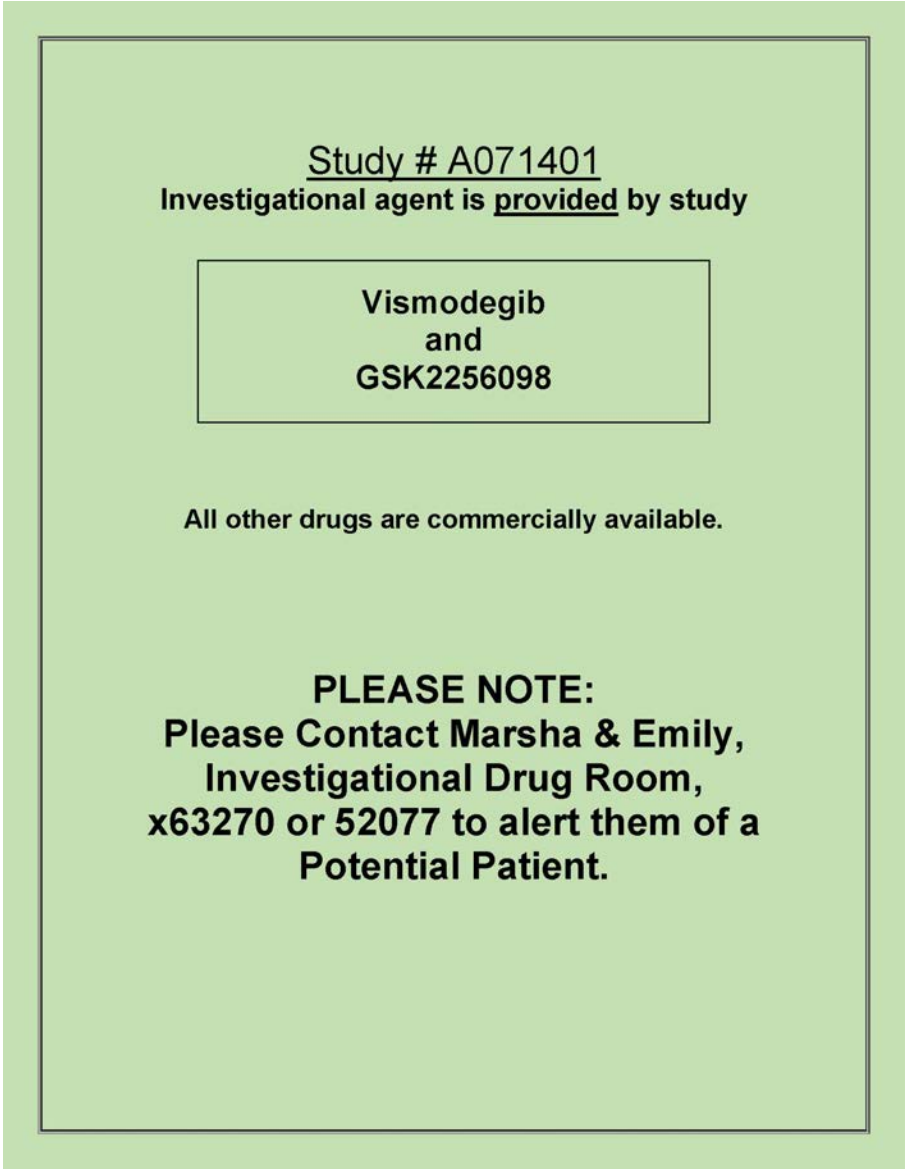
Pharmacy

- Feasibility
  - Components
  - Sub-Components



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Patient Tracking Tools

- AE Assessment Sheet
- Reproductive Risks Sheet
- Study Calendar for Billing Purposes

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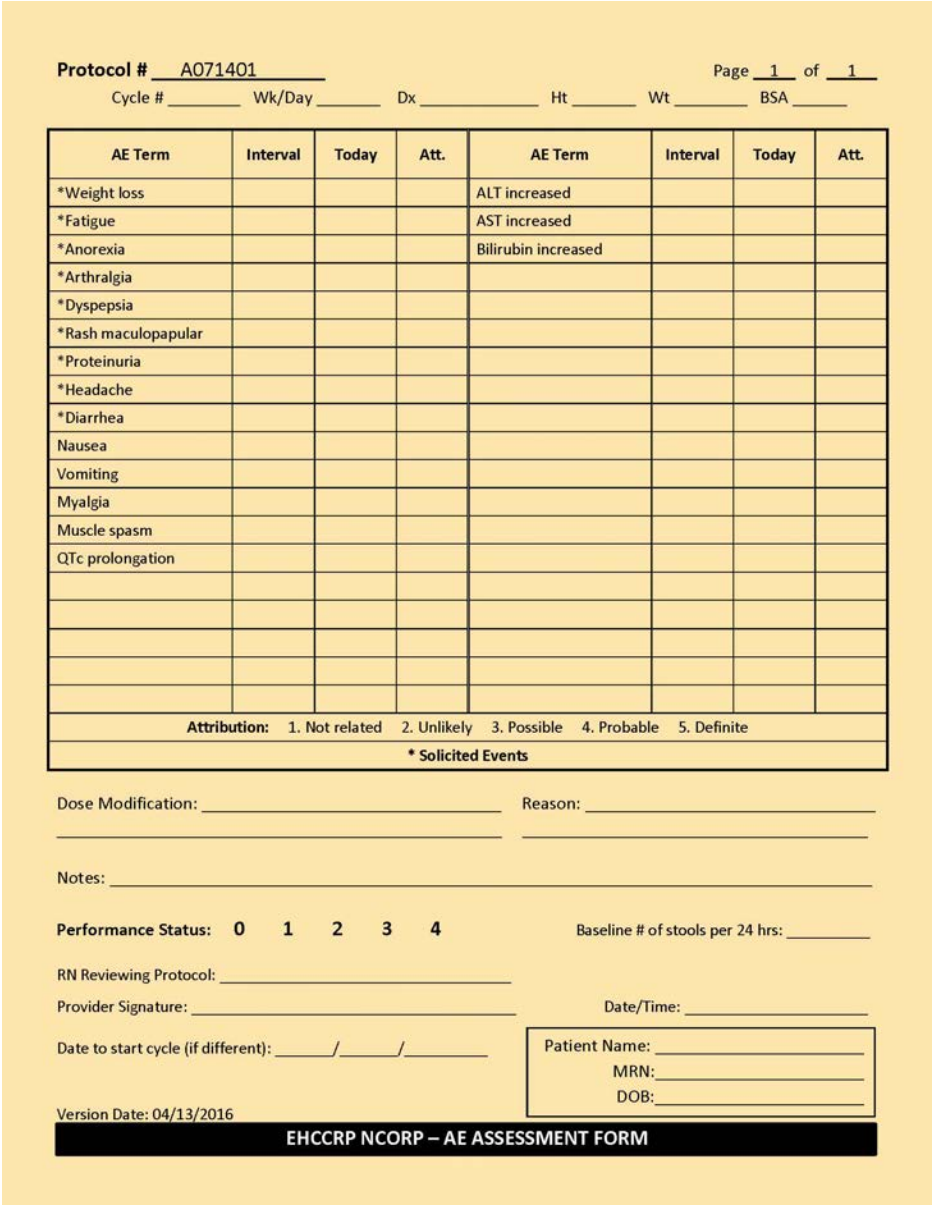
AE Assessment Sheet

- Solicited events
- Events from Dose Mods
- Events from CAEPR
- Start and Stop Dates (if applicable)
- Dose Mods listed
- Signed by RN and MD



Protocol # A071401 Page 1 of 1

Cycle # _____ Wk/Day _____ Dx _____ Ht _____ Wt _____ BSA _____

AE Term	Interval	Today	Att.	AE Term	Interval	Today	Att.
*Weight loss				ALT increased			
*Fatigue				AST increased			
*Anorexia				Bilirubin increased			
*Arthralgia							
*Dyspepsia							
*Rash maculopapular							
*Proteinuria							
*Headache							
*Diarrhea							
Nausea							
Vomiting							
Myalgia							
Muscle spasm							
QTc prolongation							

Attribution: 1. Not related 2. Unlikely 3. Possible 4. Probable 5. Definite

*** Solicited Events**

Dose Modification: _____ Reason: _____

Notes: _____

Performance Status: 0 1 2 3 4 Baseline # of stools per 24 hrs: _____

RN Reviewing Protocol: _____

Provider Signature: _____ Date/Time: _____

Date to start cycle (if different): _____/_____/_____

Patient Name: _____
MRN: _____
DOB: _____

Version Date: 04/13/2016

EHCCRP NCORP – AE ASSESSMENT FORM

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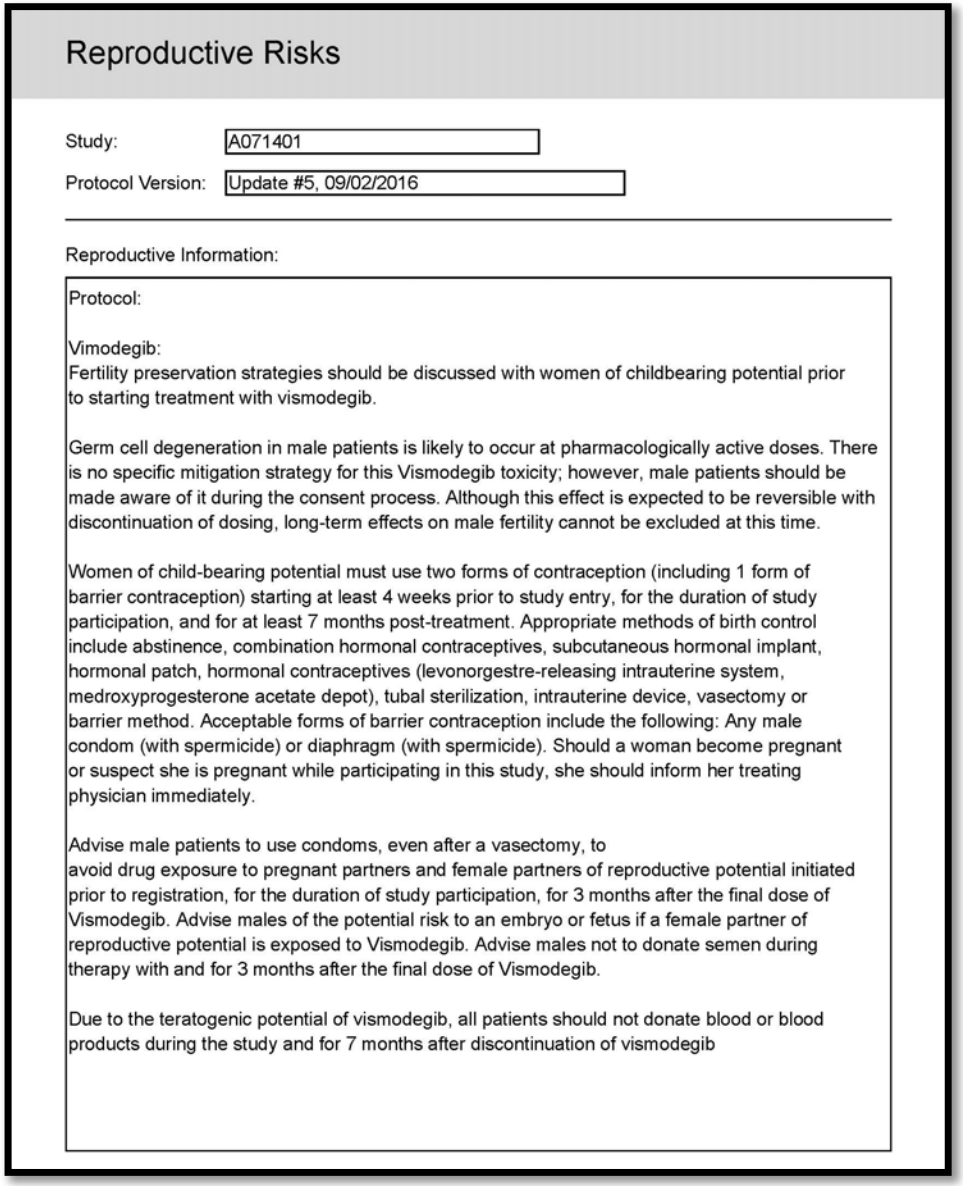
Reproductive Risks Sheet

- Contains information from the protocol regarding reproductive risks, types of birth control, pregnancy prevention, etc.



Reproductive Risks

Study: A071401

Protocol Version: Update #5, 09/02/2016

Reproductive Information:

Protocol:

Vimodegib:
Fertility preservation strategies should be discussed with women of childbearing potential prior to starting treatment with vismodegib.

Germ cell degeneration in male patients is likely to occur at pharmacologically active doses. There is no specific mitigation strategy for this Vismodegib toxicity; however, male patients should be made aware of it during the consent process. Although this effect is expected to be reversible with discontinuation of dosing, long-term effects on male fertility cannot be excluded at this time.

Women of child-bearing potential must use two forms of contraception (including 1 form of barrier contraception) starting at least 4 weeks prior to study entry, for the duration of study participation, and for at least 7 months post-treatment. Appropriate methods of birth control include abstinence, combination hormonal contraceptives, subcutaneous hormonal implant, hormonal patch, hormonal contraceptives (levonorgestre-releasing intrauterine system, medroxyprogesterone acetate depot), tubal sterilization, intrauterine device, vasectomy or barrier method. Acceptable forms of barrier contraception include the following: Any male condom (with spermicide) or diaphragm (with spermicide). Should a woman become pregnant or suspect she is pregnant while participating in this study, she should inform her treating physician immediately.

Advise male patients to use condoms, even after a vasectomy, to
avoid drug exposure to pregnant partners and female partners of reproductive potential initiated prior to registration, for the duration of study participation, for 3 months after the final dose of Vismodegib. Advise males of the potential risk to an embryo or fetus if a female partner of reproductive potential is exposed to Vismodegib. Advise males not to donate semen during therapy with and for 3 months after the final dose of Vismodegib.

Due to the teratogenic potential of vismodegib, all patients should not donate blood or blood products during the study and for 7 months after discontinuation of vismodegib

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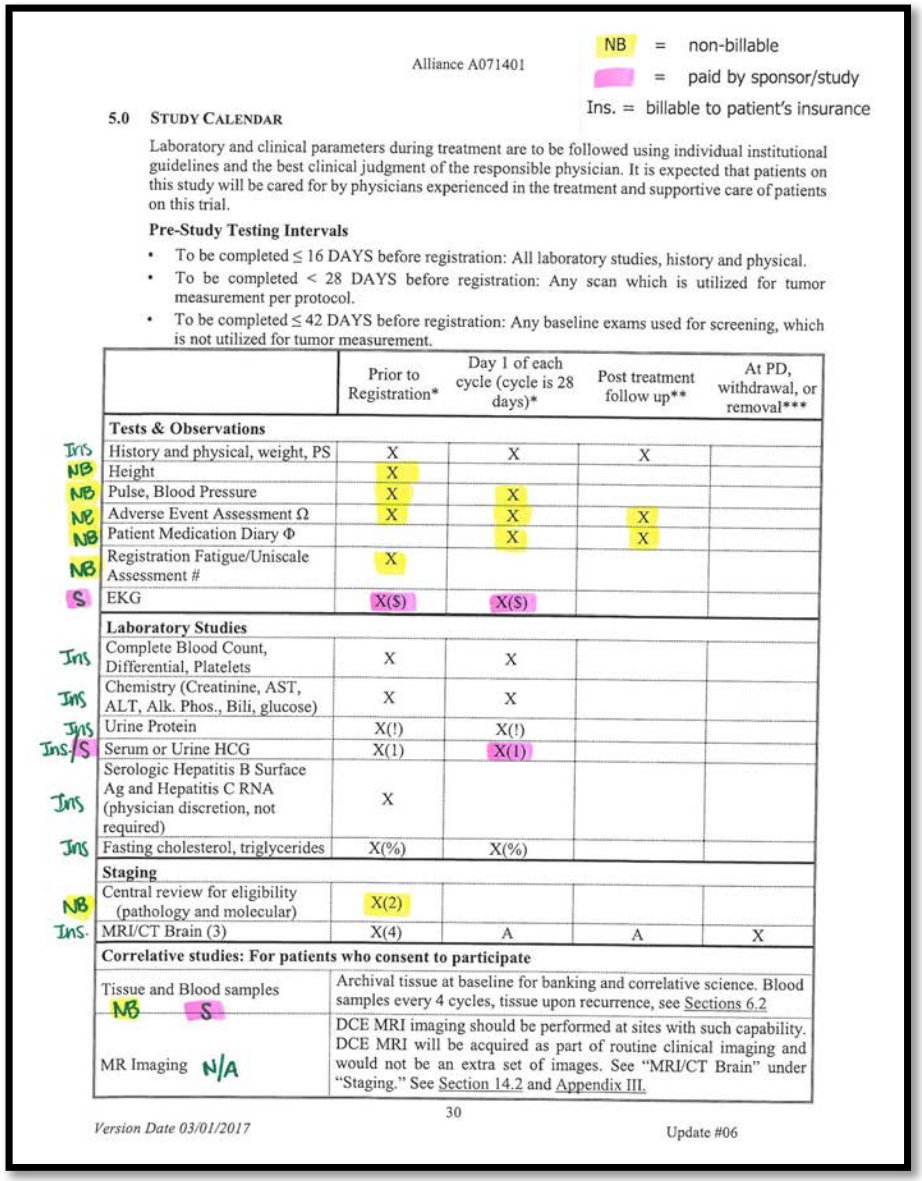
Study Calendar for Billing

- Easy way to show research staff what is:
  - Billable to the patient's insurance
  - Billable to research
  - Nonbillable



NB = non-billable
= paid by sponsor/study
Ins. = billable to patient's insurance

5.0 STUDY CALENDAR

Laboratory and clinical parameters during treatment are to be followed using individual institutional guidelines and the best clinical judgment of the responsible physician. It is expected that patients on this study will be cared for by physicians experienced in the treatment and supportive care of patients on this trial.

Pre-Study Testing Intervals

- To be completed ≤ 16 DAYS before registration: All laboratory studies, history and physical.
- To be completed < 28 DAYS before registration: Any scan which is utilized for tumor measurement per protocol.
- To be completed ≤ 42 DAYS before registration: Any baseline exams used for screening, which is not utilized for tumor measurement.

	Prior to Registration*	Day 1 of each cycle (cycle is 28 days)*	Post treatment follow up**	At PD, withdrawal, or removal***
Tests & Observations				
Ins History and physical, weight, PS	X	X	X	
NB Height	X			
NB Pulse, Blood Pressure	X	X		
NB Adverse Event Assessment Ω	X	X	X	
NB Patient Medication Diary Φ		X	X	
NB Registration Fatigue/Uniscale Assessment #	X			
S EKG	X($)	X($)		
Laboratory Studies				
Ins Complete Blood Count, Differential, Platelets	X	X		
Ins Chemistry (Creatinine, AST, ALT, Alk. Phos., Bili, glucose)	X	X		
Ins Urine Protein	X(!)	X(!)		
Ins/S Serum or Urine HCG	X(1)	X(1)		
Ins Serologic Hepatitis B Surface Ag and Hepatitis C RNA (physician discretion, not required)	X			
Ins Fasting cholesterol, triglycerides	X(%)	X(%)		
Staging				
NB Central review for eligibility (pathology and molecular)	X(2)			
Ins. MRI/CT Brain (3)	X(4)	A	A	X
Correlative studies: For patients who consent to participate				
Tissue and Blood samples NB S	Archival tissue at baseline for banking and correlative science. Blood samples every 4 cycles, tissue upon recurrence, see Sections 6.2			
MR Imaging N/A	DCE MRI imaging should be performed at sites with such capability. DCE MRI will be acquired as part of routine clinical imaging and would not be an extra set of images. See "MRI/CT Brain" under "Staging." See Section 14.2 and Appendix III.			

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Briefing a Protocol

- Binder Contents
- Training Requirements
- Questionnaires
- PHI Disclosure
- Input From Other Involved Departments
  - Laboratory
  - Pathology
  - Radiology
  - Pharmacy

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Example of Briefing

A071401	Study Briefing

SPECIAL NOTATIONS	REQUIREMENT DETAILS	REQUIREMENT COMPLETED Y/N
LAB REQUIREMENTS Yes	Standard of Care labs Blood samples – optional per patient consent – prior to registration and every 4 cycles	Lab Order Sheet and Instructions completed
QUESTIONNAIRES Yes	Registration Fatigue/Uniscale Assessment	Printable from protocol
TISSUE SUBMISSION Yes	Central Review for Eligibility – Slides Recurrent tumor tissue – optional per patient consent – slide and block	Section 6.0
RT CREDENTIALING No		
RADIOLOGY REQUIREMENTS Yes	CT or MRI; MRI parameters Appendix II **NOT** a DCE imaging site Per RECIST criteria – see "Measurements" case report form for details	Radiology Summary Form submitted with parameters
TRAINING REQUIREMENTS No		
FUNDING/TEMPLATE Yes	EKGs for GSK2256098 Arm – paid by study Monthly Pregnancy Tests for Vismodegib Arm – paid by study Research Sendout (Lab handling) Venipuncture (only if SOC labs are NOT done)	CREDIT build complete
AE ASSESSMENTS Yes	AE Assessment form complete	CRA is responsible for reading instructions on forms to make sure correct information is being reported. CRA is responsible for communicating any changes with the RN coordinator.

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Briefing - continued

A071401	Study Briefing

PHI DISCLOSURE **Yes**	De-identify Path report for central review Patient initials allowed on specimens	
MISC. **No**		
Outreach	Complete review for the following: • Lab – Yes • Radiology – No • Radiation – N/A • Treatment – Yes	Ashland: Lab and Treatment Hibbing: Lab and Treatment Virginia: Lab and Treatment

STUDY BRIEFING ATTENDANCE SIGN-OFF

By signing this debriefing, I attest that I have reviewed all required training modules, protocol, and/or any special requirements listed above for my study role. I agree to follow GCPs and instructions provided in the protocol in the conduct of this study. This briefing was completed prior to any study procedures, and I was given the opportunity to ask questions.

NOTE: The study briefing does not replace the teams (CRC/CRA) responsibility for reading the protocol in its entirety. It is the responsibility of each team (CRC/CRA) to brief/train any staff member who is covering this study in their absence.

PRINT NAME	SIGNATURE	TITLE	DATE

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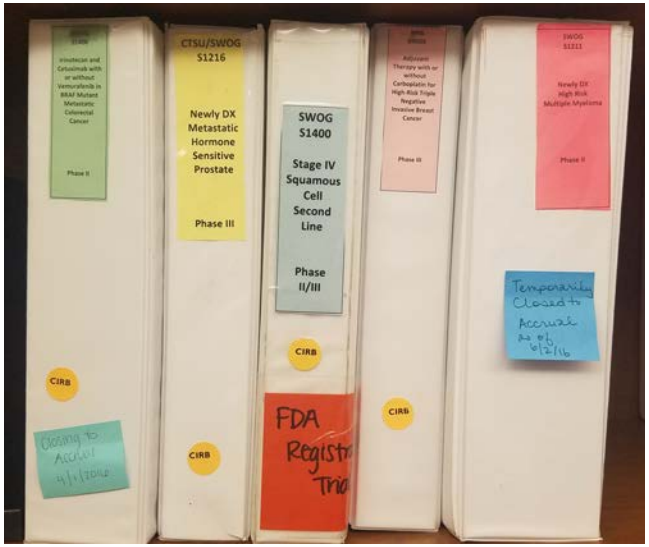
Binder Layout and Contents



- Spine of binder
  - Color coordinated by disease site
  - Acronym and Title
  - CIRB vs Local IRB
  - Closure notes for quick reference
  - FDA Registration Trial note, for applicable trials
- Inside Cover Pocket
  - Funding Sheet
  - Study Correspondence
  - Study Briefing sheet - signed

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Binder Contents – cont'd

- Sleeve Protectors
  - Consent(s)
  - Reproductive Risks sheet
  - Wallet Card, if applicable
  - Registration form(s)
  - AE Assessment Form
  - Special Forms
  - Questionnaires
  - Lab Order Sheet and Instructions
  - MCA
  - Green Investigational Agent Sheet
- Summary of Changes / Memos – most recent on top
- Protocol – flagged with key sections
- Initial IRB Approval(s)
- Protocol Specific Training Certificates and/or other reg documents
- Replaced Pages Pink Sheet
- Replaced Pages – old versions of the protocol labeled with Amd #

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Other Helpful Tools

- Checklists from On Study to Off Study
  - On Study
  - Prep Chart
  - Processing Chart
  - Off Study

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Conclusion

Questions??

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