Best Practices:
Communications between Clinical Research Study teams and Clinical Care staff for Clinical Research Best Outcomes

Thursday, October 19th, 2023

Friday, November 3rd, 2023

EFIC Studies

This First Friday Session will be offered IN PERSON, MSB Rm E684, along with a virtual option to join as well

University of CINCINNATI

October 2023 Study of the month:

Binge Eating Disorder Study

Are you struggling with overeating?

What
A twelve week study assessing an investigational medication for binge eating disorder.

Who
Adults aged 18-65 years of age with binge eating disorder.

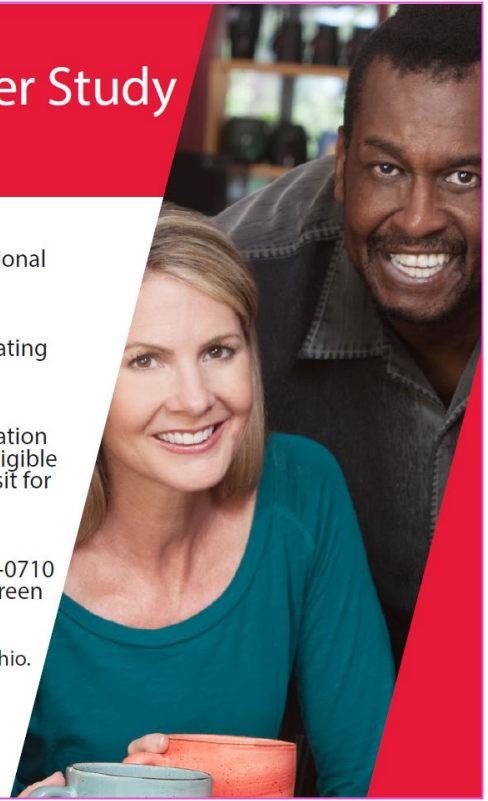
Pay
All study visits, tests, procedures, and medication will be provided at no cost to participants. Eligible participants will be compensated $50 per visit for their time and travel.

Details
For more information, contact us at 513-536-0710 or visit www.LCOH.info to complete a pre-screen questionnaire.

Located at the Lindner Center of HOPE, Mason, Ohio.

UC Health | UC Health Lindner Center of HOPE

12-20 IRB # PENDING



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Today's Presentation:

Best Practices:
Communications between Clinical Research Study teams and Clinical Care staff for Clinical Research Best Outcomes

A discussion of best practices and proven methods of research study team communication and collaboration with clinical care teams and departments for the successful execution of research studies, visits, and procedures, and increased research study awareness among clinical staff.

Mary St. John
Jennifer Waters
Kelly Acker
Bethany Fuhrman
University of Cincinnati Cancer Center
UC Health

Best Practices: Communication Between Study Teams and Clinical Care Staff

- Bethany Fuhrman, Clinical Research Manager
- Mary St. John, Infusion Manager, Barrett Center
- Jennifer Waters, Director of ClinOps, Barrett Center
- Kelly Acker, System Service Line Director, Oncology

University of CINCINNATI CANCER CENTER

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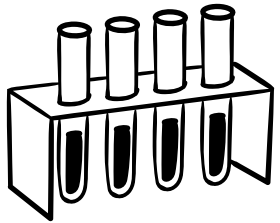
General Overview:

- Involve clinical teams in study start up
- Include clinical teams in patient planning
- Streamline communications
- Collaborate with clinical department leads during research workflow development



Involve Clinical Teams in Study Start Up

- Cross-Functional Feasibility Committee
- Implementation Meetings
- Shared Biopsy Spreadsheet for Interventional Radiology

Implementation Meetings

III. Admission/Treatment Logistics:

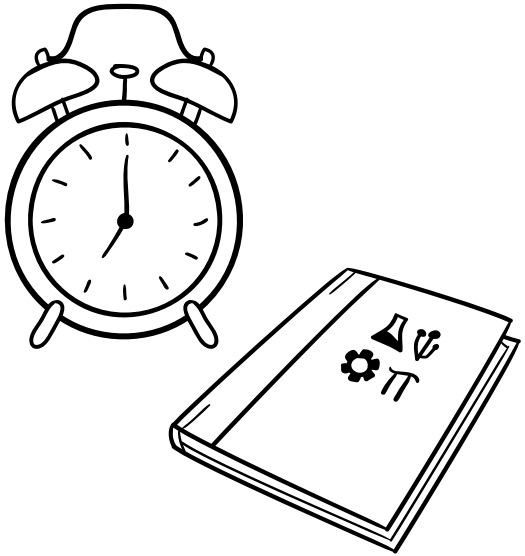
a. Although this is not a cellular therapy, all patients enrolled during the dose escalation cohorts will be admitted to BMT/8NW for at least their first treatment (C1D1) due to the high likelihood of IRRs. This admission is mandatory.
   i. Patients will be admitted the afternoon prior to treatment (around 3:30pm).
   ii. On treatment days, 1:1 nursing is recommended through the first 4 hours post-treatment.
   iii. RNs should use CARTOX documentation flowsheet for monitoring

b. On Cycle 1, Day 1, labs and physical will be needed prior to dosing

c. On Cycle 1, Day 1, patients will not be getting their full assigned dose of [redacted]. They will be receiving a Step-Up dose of 30mg.
   i. Patient will get pre-medications 30-60 minutes prior to the start of [redacted]
   ii. [redacted] 30mg will be given over 2 hours.
   iii. When/if patient is ready to receive cemiplimab, there must be at least a 30-minute wait from the end of [redacted] then it can be administered over 30 minutes

d. On Cycle 1, Day 22, the patient will receive their first full dose of [redacted] (600mg)
   i. Due to the incidence of IRRs for doses over 100mg of [redacted] the sponsor states that the 600mg dose should be given over **10 hours.** For this reason, we will admit the patient for dosing. This admission is option per sponsor, but the sponsor has agreed to pay for this admission.
   ii. They suggest the patient be in a **supine** position for the full 10 hours. We responded asking if the patient could take periodic "breaks" and sit up. They said they will continually review the safety data and try to get us an updated recommendation before C1D22 for our current patient **(May 17 for current patient)**
      1. D/t concern with orthostatic hypotension, so we should educate the patient about this risk, potentially make a fall risk note
   iii. Pre-medications will be given 30-60 minutes prior to the start of [redacted]
   iv. IDS pharmacy will need to prepare the [redacted] in two separate bags/batches to avoid drug expiration during infusion
      1. Question – if we get labs and approval to treat the night prior (day 21), how early could we possibly start the [redacted] infusion?
         a. For example, if we start at 9am, then the infusion will end around 7pm, so cemiplimab will be due at 7:30pm, and IDS is not typically open this late
            i. IDS is typically open from 7am, but can come early if needed
            ii. Cemiplimab is typically good for 8 hours, so they can prepare it earlier in the day
            iii. BF will need to look into IRT/vial assignments - 3 vials vs. 4 for split bags
   v. If the [redacted] treatment is interrupted and not restarted, it can be administered the following day, but all PKs/research blood samples should be repeated

Include Clinical Teams in Patient Planning



- Initial Consent Email Notifications to Cross-Functional Groups
- Continued Updates to the Patient's Care Team regarding Screening and Enrollment Status
- Attend Care Team Meetings

New Consent Email Notification

Hi all,

Patient [redacted] consented to the [redacted] Pharmaceuticals protocol, [redacted] on 07/31/23. Attached is signed ICF for IDS and nursing. This ICF was also submitted to the scanning bin. Patient has been added to SignalPath. Her patient ID is 840012-012. Per the sponsor, the patient is ***required to start on trial on Aug 9.*** Due to this, SOC PE and CT CAP from earlier in July can be used for screening. Her screening ECG and labs were completed yesterday. She does need a screening biopsy if medically possible, so I've entered that as STAT and touched base with the IR APPs and let them know that this needs to happen prior to Aug 9 if at all.

The patient will be enrolling into the dose-finding portion of the protocol, assigned to **Dose Level 10 (900mg), dosing Q3W with [redacted] and Cemiplimab concurrently (NO run-in).** She will be admitted on Aug 8 for her first dose (30mg [redacted] + cemiplimab) on Aug 9. She will be admitted again on Aug 29 for her second dose (900mg [redacted] + cemiplimab) on Aug 30.

@UCH-Peterson, Stephanie (Stephanie.Peterson), @Faber, Ed (fabered), and @Kostuik Neidhard, Paula (kostuipa) I submit the admission request this morning for the admission next week. I will submit for the second admission as well.

@UCH-Tippenhauer, Becky (Becky.Tippenhauer) and @UCH-Shirley, MaryBeth (MaryBeth.Shirley) can you please add this patient on for the Monday Morning Inpatient meeting for next Monday Aug 7.

@XTR-UCH IDS Pharmacy (idspharmacy-c) I will submit the build update requests today to remove the cohort name from the builds. She will be following Dosing Schedule D.

@managedcarealerts@uchealth.com: can you please add the Complex Care Plan flag to this patient's chart with the following:

Phase I Clinical Trial Patient. Please notify an Experimental Therapeutics team member of ER/hospital admission and before adding new medications or undergoes any procedure (unless emergent). Contact 1st: The Hematology/Oncology Fellow on call. Experimental Therapeutics attendings for questions or for specifics of clinical study M-F 8am-5pm: Dr. Wise-Draper [redacted] or Dr. Sohal [redacted] If after hours, please call the Hematology/Oncology fellow on call. Any adverse events, especially deaths, must be reported immediately to Experimental Therapeutics team (even on the weekends).

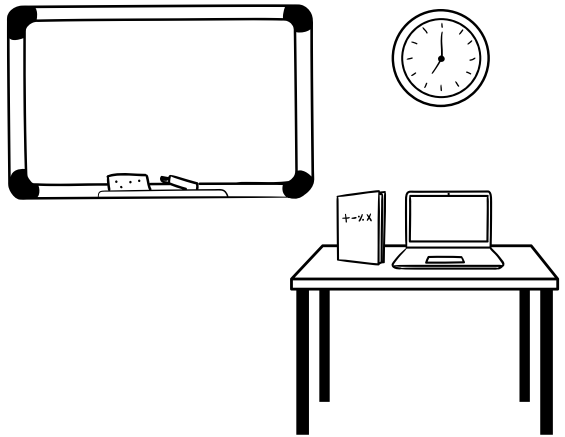
@Mohamoud, Ikram (mohamoij) this patient has colorectal cancer, so will be assigned to you.

Please let me know if you have any additional recommendations, questions, or concerns, and I will keep everyone updated on the patient's status.

If needed, contact me at my cell [redacted]. Thank you!

Streamline Communications

- Utilize Epic Notes for Direct Communication
- Standardizing Research Epic Notes for Passive Communication
- Research Care Flag for Phase 1 Patients



Outpatient Infusion Care Sheet (Direct Communication)

Subject ID: 121-032
Protocol Number: [redacted]
Treatment Group: Part 1A, Monotherapy, Dose Level 3
Study Visit: C1D1
Treating MD: Trisha Wise-Draper

Infusion Care Information for this Visit:

Research coordinator to contact for questions and OK to treat (per provider): **Bethany Fuhrman**
Research coordinator phone number: [redacted]

Are research blood draws required at this visit? Yes
If yes, can the samples be drawn from the same line used to infuse drug? No
Are ECGs required to be collected by RN at this visit? Yes
If yes, are they single or triplicate? Single
If yes, how many sets of ECGs are required? 4
Estimated/Planned total chair time: 8 hours

See Treatment Plan for Infusion Care Order specifics, with the additional clarifications/procedures below. If no additional requirements to the treatment plan, CRC to indicate N/A:

Pre-Dose Requirements:
If patient was seen in-clinic prior to infusion, can clinical vitals be used as "pre-dose vitals"? No -

Treatment Requirements:
- Do not initiate treatment until after the OK to treat was obtained by coordinator
- Document time that OK to treat was obtained by coordinator
- Treat any infusion/drug reactions per treatment plan, and notify provider and CRC
- Alert provider, clinical pharmacist, and/or CRC of any non-urgent patient complaints (e.g. nausea, vomiting, etc.)
- N/A

Post-Dose Requirements:
- Prior to patient discharge, confirm with patient that there are no questionnaires, diaries, oral drug, etc. that still needs to be handed off to patient
- N/A

Next Study Visit Date: C1D8 on 8/9/23
Next Treatment Date: C2D1 on 8/22/23

Inpatient Admission Care Sheet (Direct Communication)

ubject ID: 840012-010
Protocol Number: [redacted]
Treatment Group: Dose Schedule A (DL9aw - 600mg Weekly With Lead-In and Step Up)
Study Visit: C1D8
Treating MD: Dr. Trisha Wise-Draper MD, PhD

PLAN TO START INFUSION AROUND 8 AM WITH PREMEDS AROUND 7:30 AM

Research Patient Admission Care Sheet:

Date of admission: 14AUG2023
Date of treatment initiation: 15AUG2023
Post-Dose Observation Requirements prior to discharge: 24 hours post [redacted] observation
Estimated Discharge Date: 16AUG2023

Research coordinator to contact for questions and OK to treat (per provider): **Deanne Lu**
Research coordinator phone number: [redacted]

Treating MD/NP phone number for reactions: Dr. Wise-Draper ([redacted]) / Lisa Gebhart CNP [redacted]

Link to the Protocol in Complion: https://app.complion.com/binder/f1391ee1-f72c-4f46-9ac6-b4ac9e6c0dbb/files/6408b709692a75f6e44aa3b9
Schedule of Events to follow for this patient (group or page number): p116
Details on Dose(s) Receiving During this Admission: 600mg of [redacted] over 6 hours

Has the patient had an infusion reaction to prior doses: Yes
If yes, on what date, and what was the dose received?: 18JUL2023 30mg of [redacted]- Patient had hypotens
hypoxia, burning sensation on chest wall lesion, lightheaded, itchiness on both feet, redness on both eyes; 25JUL2023
300mg (out of 600mg) of [redacted] - same IRR symptoms as 18JUL2023. Patient's first symptom is usually itchiness
symptoms follow after 5 minutes.

To Do upon arrival to unit (labs, ECGs, etc.): Safety Labs can be drawn 72 hours prior to infusion (**CBCWD, CMP, CR**
Please place PIV on day of admission as patient will need continous IVF on the day of infusion

See Treatment Plan for care and order specifics, with the additional clarifications/procedures below. If there are no requirements (other than what is in the treatment plan), CRC to indicate N/A:

Was Visit Flowsheet/Checklist emailed from CRC to Nursing Educator prior to the patient's admission? Yes
If no, will the CRC be brining one to the unit, and when? Yes

Are research blood draws required during this admission? Yes
If yes, can any post-dose samples be drawn from the same line that was used to infuse drug? No, PIV needed; Patient has lympedema on LUE. *Please place PIV on day of admission 14AUG2023*

Are ECGs required to be collected by RN at this admission? No
If yes, are they single or triplicate? NA
If yes, how many sets of ECGs are required?NA

Pre-Dose Requirements:
Is a pre-dose physical exam required? Yes,
If yes, will the inpatient team be responsible for physical exam? No
If the patient's primary hemonc will complete the physical exam, what is the time/date plan for completion?
Lisa Gebhart CNP will see the patient on the day of admission 14AUG2023 for a PE

Treatment Requirements:
- Do not initiate treatment until after the OK to treat was obtained by coordinator
- Document time that OK to treat was obtained by coordinator
- Treat any infusion/drug reactions per treatment plan, and notify attending physician, primary hemonc, and CRC
- Alert provider, clinical pharmacist, and/or CRC of any non-urgent patient complaints
- 600mg of [redacted] over 6 hours

Discharge Requirements:
- Prior to patient discharge, confirm with coordinator that there are no questionnaires, diaries, oral drug, etc. that still needs to be handed off to patient
- Vitals and research labs draws at the end of [redacted] and Cemiplimab infusion, 1 hour, 2 hours and 4 hours post dose
- Pt has to stay 24 hours post [redacted] for observation

For questions related to scheduling of follow up appointments, contact the CRC listed above.

Standardized Chart Notes (Passive Communication)

Subject ID: 004-001
Protocol Number: [redacted]
Treatment Group: Phase 1, Dose Finding. Dose 20mg QD
Study Visit: C1D1
Treating MD: Davendra Sohal

1. Were inter-current medical history and AE changes reviewed with subject and noted in corresponding log? Yes

2. Were concomitant medications reviewed with the subject and noted in conmed log?: Yes

3. Were safety labs reviewed and signed for CS/NCS prior to subject treatment?: Yes
   If no, which provider reviewed the labs in real time: Jane Temple
   At what time were labs verbally reviewed and approved by the provider above?: 0918
   Was the patient required per protocol to be be fasting prior to labs? No
   If yes, was the patient fasting per protocol requirements? NA

4. Were scans, EKGs, or echocardiograms due at this visit?: Yes
   Date/type of assessment: ECGs due today pre dose and 2 hours post-dose
   Will the patient continue on protocol?: Yes
   If 'Yes', does the study provide an EKG machine: No
   Specify study requirements (e.g.-- single , triplicate, etc.): single
   EKG time collected 0822 and 1344
   Was the patient resting supine for the protocol-specific rest period prior to the ECG(s)?: Yes
   Was the EKG(s) Clinically Significant? No

5. Were correlative labs (PKs, PDs, pharmacogenetics, optional blood draws, etc sent to 3rd party lab) required at this visi
   If yes, were they collected?: Yes
   If not collected, why?: N/A

6. Were dose modifications required at this visit? No
   If yes, list reason for modification: N/A
   If yes, list modification requirements: N/A

7. Were questionnaires required at this visit? No
   If yes, were they collected? NA

8. If subject is on oral IP, was new supply of oral IP required to be provided to the subject this visit? Yes
   IP Name: [redacted]
   IP Dose: 20mg daily (4 x 5 mg capsules)
   Picked up from IDS/WC pharmacy day of visit: yes
   Provided Amount (bottles/packs/how many per each, etc.) to patient: 4 bottles containing 30 capsules each (120 c
   Was subject provided with drug diary?: Yes
   Were IP instructions provided and subject verbalized understanding?: Yes

9. If subject is on oral IP, is IP accountability and compliance required this visit?: No
   (If 'Yes' pull in .uocoralipaccountabilityandcompliance smart phrase)

Narrative Note:

Patient in clinic today for consideration for C1D1 on clinical trial listed above. He is feeling well today, noting only change from baseline is some mild pain on front of his left upper thigh (Gr1). This is a result of an injury while loading a kayak onto his vehicle on Monday 7/24. He is not taking any medications for this at this time, and it's not impacting his ADLs. As this occurred prior to C1D1 (and AE collections begins today per protocol), this has been added to his medical history log.

He is seen today by Jane Temple, NP, who completes physical exam, reviews labs and ECGS, and approves patient for treatment. During visit, it was decided that patient will discontinue his use of curcumin supplement, beginning today (end day added to conmed log). Patient received glucose and ketone monitoring education by pharmacist Moe Schwartz prior to dosing. Patient confirmed fasting since 0630 today prior to dosing. Patient self-administered dose of [redacted] at 1142. He and wife were then again educated on pre-/post-dose fasting requirements, dosing at a consistent time daily, and documenting doses in diary. CRC reviewed all diary instructions with patient, and he and wife confirmed understanding. Patient was provided cooler and ice packs for the transportation and storage of his medication, and both confirmed understanding of the need for refrigeration.

Post-dose lab and ECG collections completed today per protocol. Patient is to RTC tomorrow around 11:30 for 24-hour PK collection as close to 1142 as possible. He confirms understanding to hold his dose until after his PK draw and AE and conmed review with CRC. He and wife have CRC and emergency after-hours contact information should either have any questions, concerns, or changes in the meantime.

Next Study Visit: C1D2
Next Visit Date: 7/27/23

Bethany Fuhrman
Clinical Research Coordinator
[redacted]

Research Care Flag for Phase 1 Patients

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Collaborate with Clinical Leads in Workflow Development

- Ad-Hoc Working Group Meetings

  OR

- Standing Multi-Disciplinary Working Groups

Recap

- You Can Never Overcommunicate
- Streamline And Standardize Wherever Possible
- Collaborate Early and Often

Questions?

Contact: Bethany Fuhrman, fuhrmaba@ucmail.uc.edu