University of CINCINNATI

IDS (Investigational Pharmacy) A great drug interaction

Thursday, October 20th, 2022

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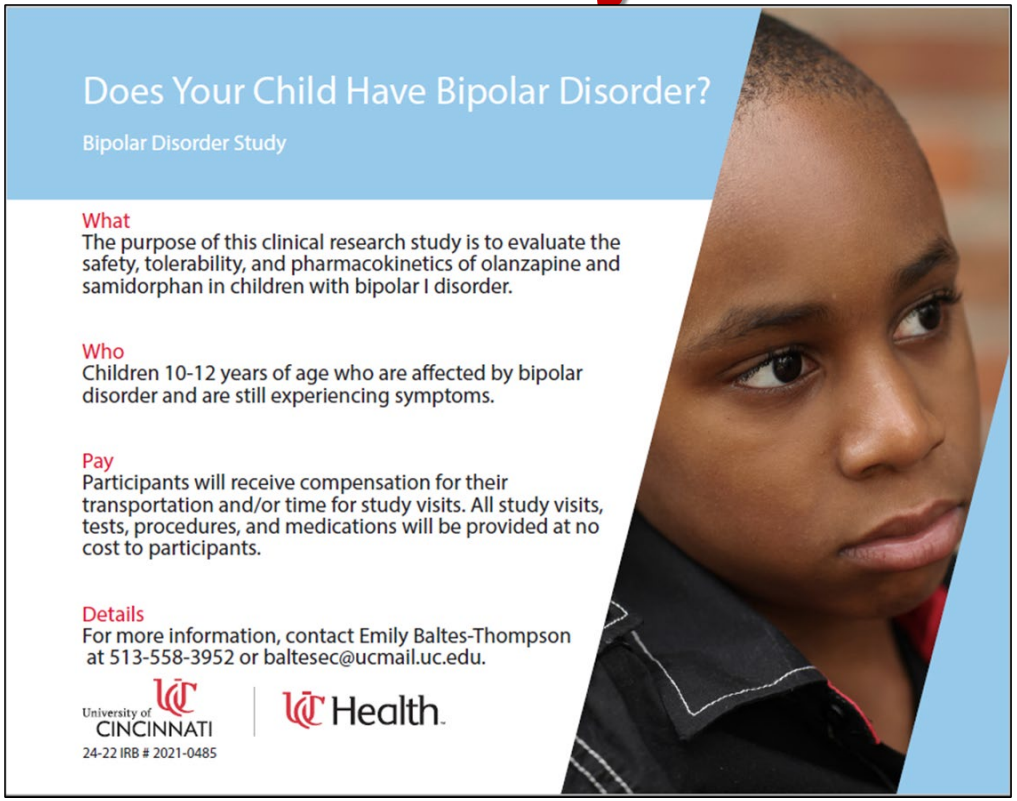
October 2022 Study of the Month



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UC Health Annual Flu Campaign

The UCH annual flu campaign starts the week of October 3rd, 2022.

The flu vaccine is a mandatory requirement and of utmost importance this year with the continued challenge of COVID-19.

UC Health Employee Health will be providing the flu vaccine, free of charge, to employees and affiliates but also willingly accept documentation of the vaccine received elsewhere.

If you are a UCH Employee, or a UCP employee hired prior to April1, 2022, the survey (consent form) will be in Readyset. ***This survey must be filled out prior to receiving your vaccine, and also if you receive the vaccine elsewhere.***

All UC Health employees and clinicians are required to receive an annual flu vaccination by Friday, Nov. 11, at 5 p.m

Please contact UCH Employee Health for any questions

Friday, November 4th, 2022

CCTST/CHI Research Tools

Brett Harnett, MS-IS

Asst. Professor, Field Service | Director, Center for Health Informatics | Department of Biomedical Informatics (BMI) | VA Research Affiliate | Adjunct Faculty CCHMC

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Today's Presentation:

IDS (Investigational Pharmacy)
A great drug interaction

Please join us for a look into the world of Investigational Drug Services and its relationship to other research areas. Discover the innovations propelling the growth of IDS and refresh pharmacy tips and tricks for IDS requests.

Mary Burns, PharmD
IDS Pharmacist

Dorice Smith, BA, CPhT
IDS Pharmacy Technician

Investigational Pharmacy Services (IDS)

A Great Drug Interaction!

Dorice Smith, CPhT, CSPT
Mary Burns, PharmD, RPH

Objectives

- Provide an overview of what IDS does
  - Who, What, Where, When, How and WHY
- What is Vestigo
- What is Versatrak
- Prescriptions!?
- Epic
- Fee Schedule
- Success Stories

Who

Personnel

- Technicians: Dorice Smith, Dan Lechuga,
- Pharmacists: Mary Burns, Tazeen Fatima, Judy Houston, Kelli Johnson
- Supervisor: Eric Mueller, Pharm.D., FCCM, FCCP

Service Email: IDS-Pharmacy@uchealth.com

Location: Medical Science Building G253, G255, G257

Contact Numbers

During IDS Office Hours (Monday - Friday 0700-1630) 513-584-1766

After Hours Pharmacist Pager: 513-343-1046

Where

- Medical Sciences Building: G253, G255, G257
  - Turn left when exiting central pharmacy or right when leaving resident office
  - Go up stairs in Medical Sciences Building to G floor. Walk to the end of the hallway and turn right in last corridor
- Refrigerators with drug in IDS, central pharmacy, 7E

- Study Sites:
  - UCMC
  - UCGNI
  - Barrett
- Satellite Sites:
  - WCH
  - Mobile Stroke Unit

What is IDS Pharmacy?

- IDS = Investigational Drug Services
  - A division of pharmacy services that is responsible for facilitating (procuring, storing, preparing and dispensing) investigational agents for trials conducted at University of Cincinnati Medical Center
- Licensed Pharmacy focused on dispensing “investigational agents”
  - Novel agents (all drugs not approved by the FDA)
  - FDA approved agents being studied for a new labeled indication (Metformin being studied in cancer)
  - Substances placed in the body for research purposes (IV contrast dye for a CT scan that would not be ordered were it not for the research protocol)

What oversight does IDS have?

- FDA
- Institutional Review Board (IRB): A committee formally designated to review, approve and monitor biomedical research involving humans in order to protect the rights and welfare of research subjects.
- Office of Clinical Research (OCR): Internal regulatory system
- CRO
- Pharmacy Management
- Must follow rules outlined by the Ohio Board of Pharmacy

What types of studies does IDS participate in?

- Approximately 400 active studies; Phase 0-4
- Every discipline: Oncology, hematology, neurology, trauma, psychology, NICU, cardiology, pulmonology, vaccine, transplant, surgery…
- Industry (Pfizer, Amgen, Roche)
- Consortium (NCI, PANCAN, ECOG, ALLIANCE)
- Investigator Initiated (lead by UC physicians)

How does a clinical trial work?

Clinical trials occur in four phases, and each phase has a different purpose.

Cancer®

Phase I

Focus on **safety** and the proper dose.

15 to 50 patients

Phase II

Focus on **effectiveness** and side effects.

Less than 100 patients

Phase III

Compares the **new treatment** to existing treatment.

Hundreds of people

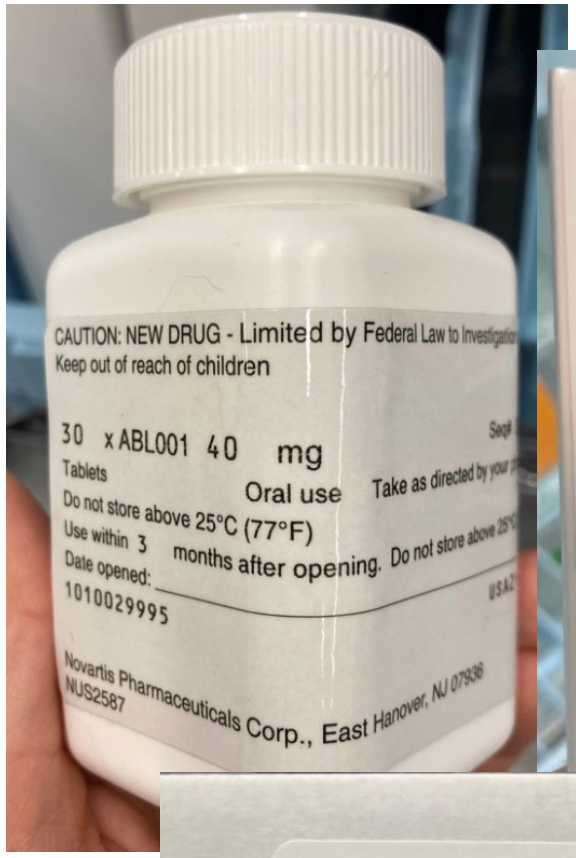
Phase IV

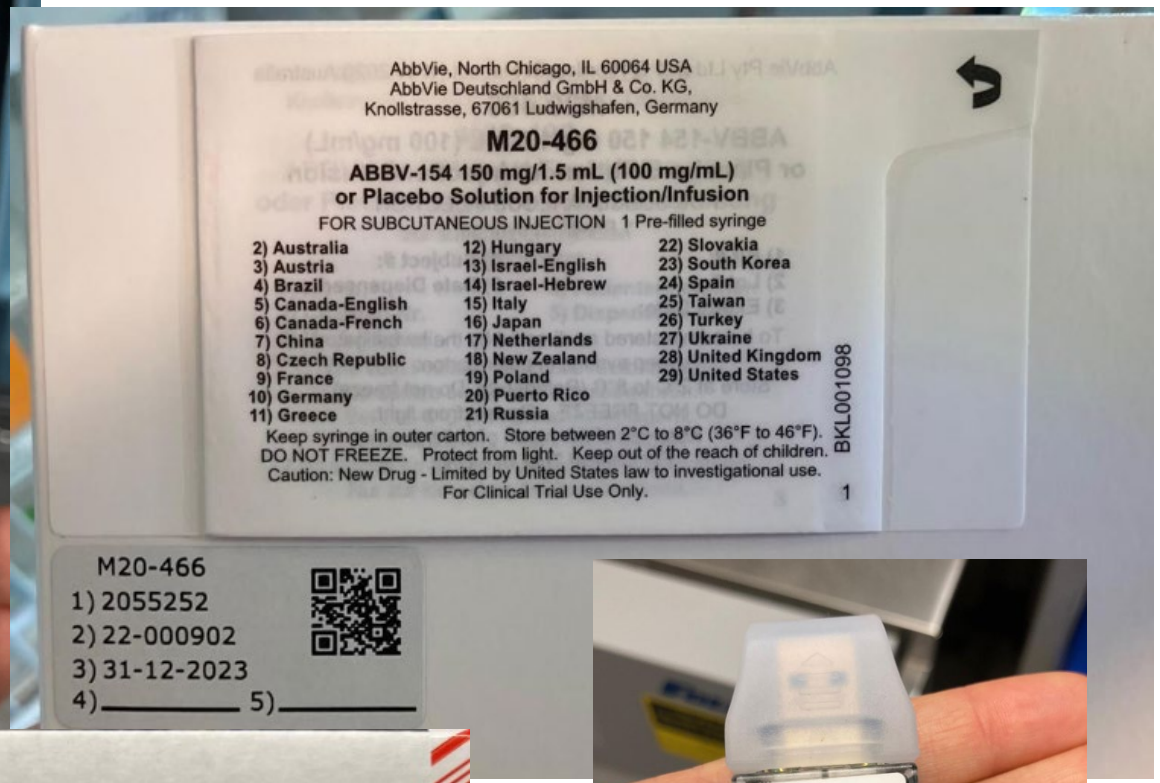
Treatment is **approved and available**. Long-term effects are observed.

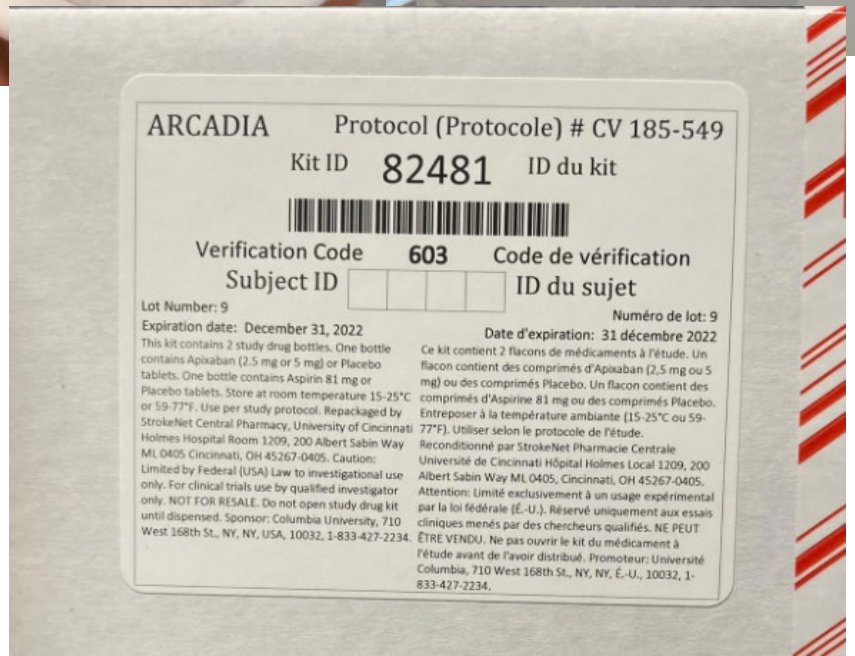
Thousands of people

How do studies come to be?

- **Planning Phase:** feasibility (time, storage, drug preparation, workflow), cost estimates, detailed reading of protocols/pharmacy manuals.
  - Initial creation of internal Fact Sheets, Dispensing Guidelines, and drug prep Work Cards
- **Start Up Phase:** IRB submission, SOAR meetings, Site initiation Visits, meeting with study teams
- **Open Enrollment Phase:** Study drug is available on site and ready to dispense, Monitoring visits
  - Drug Sources: Sponsor, internal purchase
  - Protocol Updates
  - Temperature monitoring
  - Drug accountability: Vestigo
- **Close Enrollment Phase:** Enrollment is complete, but patients remain on study or in follow-up
- **Study Closure Phase:** Time after last patient, last visit. Reconciliation of all documents and data.





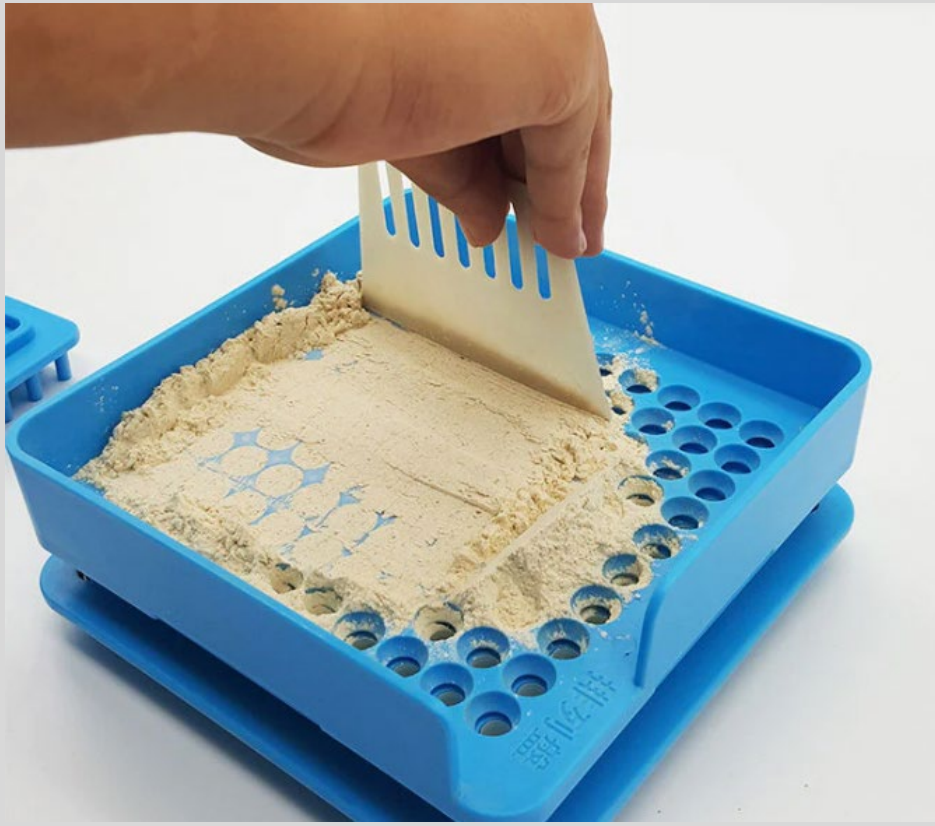


How is Dispensing Different?

- Which study?
- Study training needed?
- Patient name, MRN, Subject ID
- IWRS/vial assignments?
- Dose verification
- Primary/Sub-Investigator
- Lot, Kit #, Expiration (Why isn't there an expiration!?)
- Time dispensed
- Drug accountability
- Inventory?
- How to find drug information

Compounding Blinded Capsules

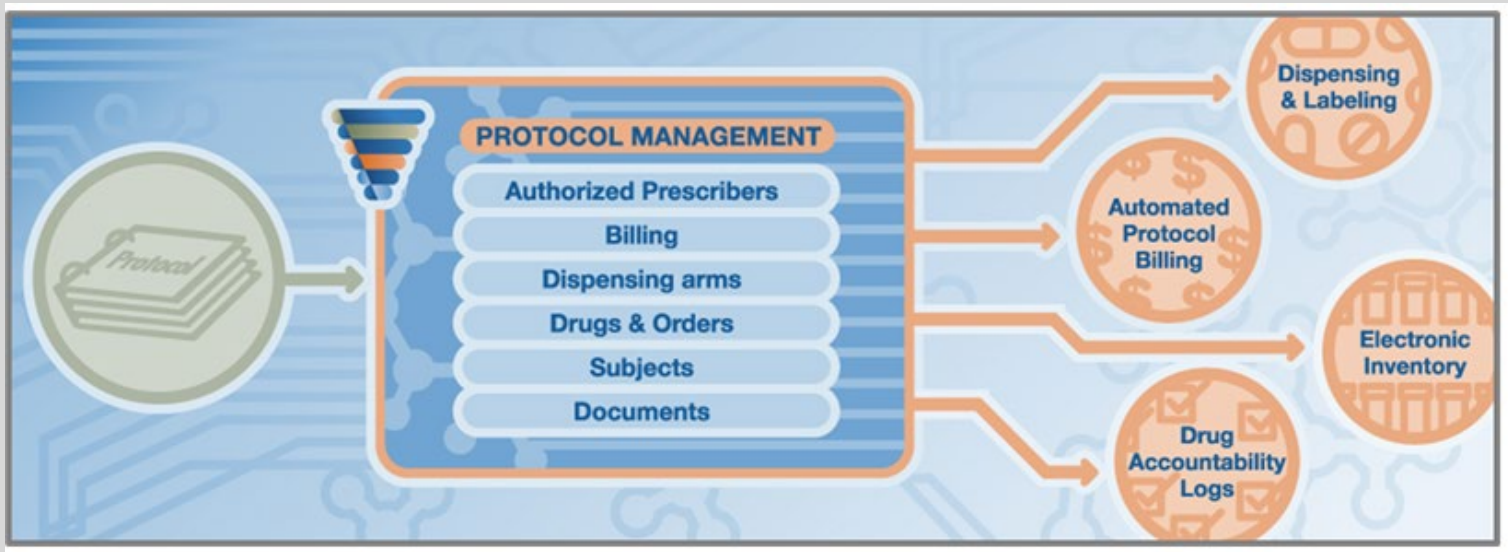
- Special service offered by IDS
- IDS orders drug, avicel powder, empty capsules
- Process results in blinded capsules that look identical (Ex: 2 batches of “Blue” capsules compounded; one batch contains Lexapro one contains placebo)
- Time consuming process
- Typically shorter expiration dating
- Communication is key!



How do we organize our studies?

Vestigo™ (http://www.mccreadiegroup.com/vestigo/)

- Automated platform to improve accuracy, efficiency, and safety
- Web-based supports 'remote' users and system-wide access



http://www.mccreadiegroup.com/vestigo/ (Accessed 2/3/2016)

Industry

Protocol Numbers: mRNA-1273-P301 | Moderna; 2020-0603 | 2819-20 | P598
PI: Carl Fichtenbaum (Carl.Fichtenbaum@uc.edu)
Title: A Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older

IRB: 2020-0603 (IRB status is active)
Exp: 7/27/2021
Sponsor Site Number: No site number found

Protocol | Inventory | Patients/Subjects | Protocol Documents | Transaction Documents | Temperature Documents | Competency Access | Billing | Workload | Contacts | Access Codes | Reports | Monitor Visits

IDS Options: Edit Protocol Close Out Protocol View Audit Trail

Protocol Identifiers | +

Name	Identifier	Protocol (NCI) Order on DARF	Protocol (Local) Order on DARF
Vestigo ProtocolNumber	mRNA-1273-P301	1	Do not display on DARF
Vestigo SecondID	Moderna; 2020-0603	2	Do not display on DARF
Vestigo IRB Number	2020-0603	Do not display on DARF	Do not display on DARF
Vestigo ProtocolID	P598	Do not display on DARF	Do not display on DARF
Vestigo ThirdID	2819-20	Do not display on DARF	Do not display on DARF

Protocol Status:	Recruiting: participants are currently being recruited and enrolled
Lead Sponsor:	ModernaTX, Inc.
Phase:	Phase 3
Intervention Type:	Drug
Study Design:	This is a Phase 3, randomized, stratified, observer-blind, placebo-controlled study to evaluate the efficacy, safety, and immunogenicity of mRNA-1273 SARS-CoV-2 vaccine compared to placebo in adults 18 years of age and older who have no known history of SARS-CoV-2 infection but whose locations or circumstances put them at appreciable risk of acquiring COVID-19 and/or SARS-CoV-2 infection. Figure 1 shows the study flow.
Protocol Group:	Infectious Diseases
Protocol Binder Location:	Pending
Sponsor Type:	Industry
Facilities:	(Main) UCMC Investigational Pharmacy
Print:	Protocol Binder Cover Sheet Print Protocol Label Protocol Summary Report
Summary:	Investigational product will be administered as an IM injection into the deltoid muscle on a 2-dose injection schedule on Days 1 and 29, with at least a 28-day interval between doses. Each injection will have a volume of 0.5 mL and contain mRNA-1273 100 mcg, or saline placebo. Preferably, vaccine should be administered into the nondominant arm. The second dose of IP should be administered in the same arm as the first dose.

Cooperative Group/Consortium

Protocol Numbers: NCI-2019-02186 | NRG-GY018 | IDS# 2782-20 | P537
PI: Amanda Jackson (jacks2a6@ucmail.uc.edu)
Title: A Phase III Randomized, Placebo-Controlled Study of Pembrolizumab (MK-3475, NSC #776864) in Addition to Paclitaxel and Carboplatin for Measurable Stage III or IVA, Stage IVB or Recurrent Endometrial Cancer

IRB: 2020-0075 (IRB status is active)
Exp: 4/20/2022
Sponsor Site Number: OH-070

Protocol | Inventory | Patients/Subjects | Protocol Documents | Transaction Documents | Temperature Documents | Competency Access | Billing | Workload | Contacts | Access Codes | Reports | Monitor Visits

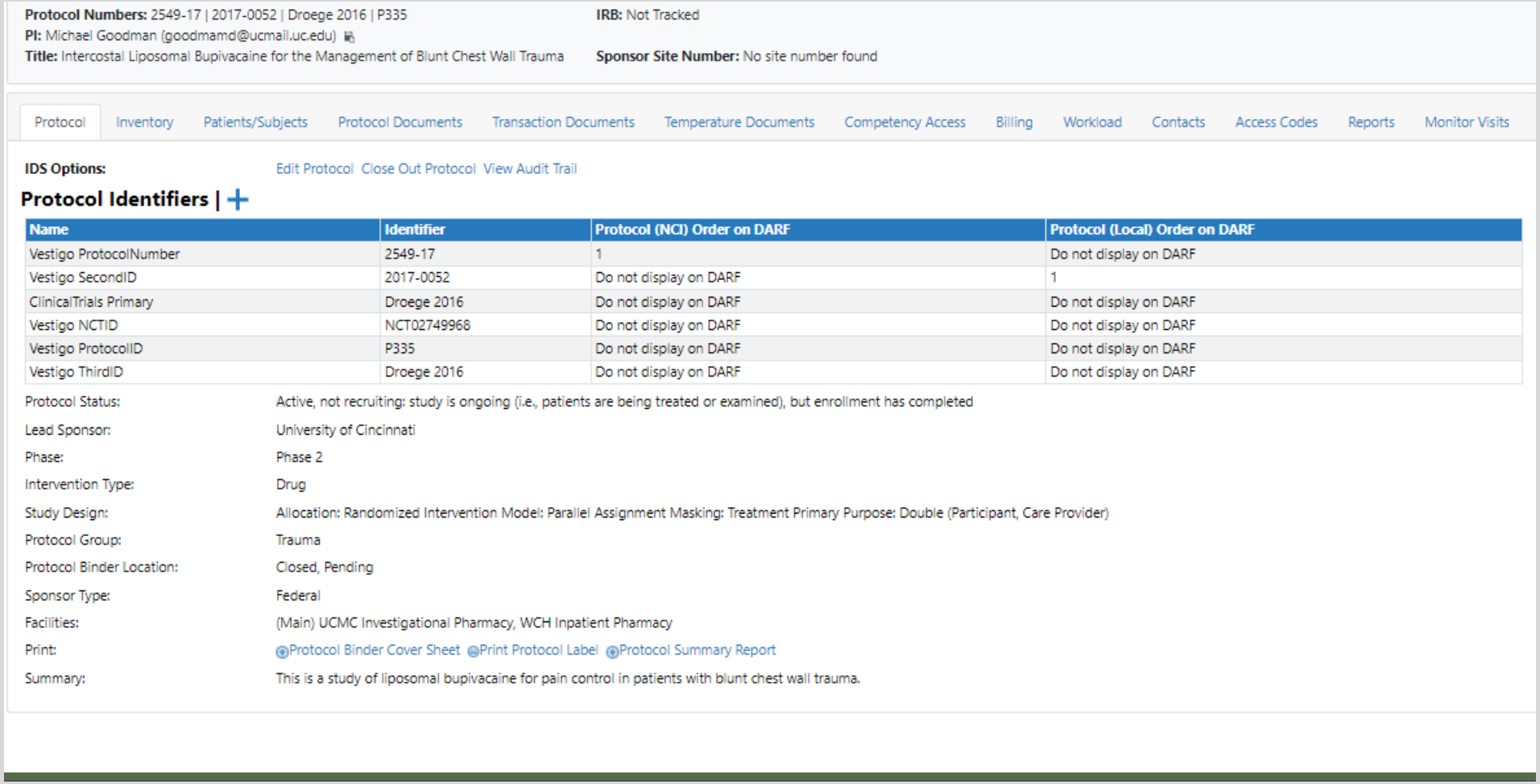
IDS Options: Edit Protocol Close Out Protocol View Audit Trail

Protocol Identifiers | +

Name	Identifier	Protocol (NCI) Order on DARF	Protocol (Local) Order on DARF
Vestigo ProtocolNumber	NCI-2019-02186	1	Do not display on DARF
Vestigo SecondID	NRG-GY018	2	Do not display on DARF
ClinicalTrials Primary	NCI-2019-02186	Do not display on DARF	Do not display on DARF
Vestigo IRB Number	2020-0075	Do not display on DARF	Do not display on DARF
Vestigo NCTID	NCT03914612	Do not display on DARF	Do not display on DARF
Vestigo ProtocolID	P537	Do not display on DARF	Do not display on DARF
Vestigo ThirdID	IDS# 2782-20	Do not display on DARF	Do not display on DARF

Protocol Status:	Recruiting: participants are currently being recruited and enrolled
Lead Sponsor:	National Cancer Institute (NCI) (Sponsor Site Study Number: OH-070)
Phase:	Phase 3
Intervention Type:	Drug
Study Design:	Observational Model: Allocation: Randomized Intervention Model: Parallel Assignment Primary Purpose: Treatment Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Protocol Group:	Hem/Onc
Protocol Binder Location:	Open
Sponsor Type:	Cooperative Group
Facilities:	(Main) UCMC Investigational Pharmacy
Print:	Protocol Binder Cover Sheet Print Protocol Label Protocol Summary Report
Summary:	This phase III trial studies how well the combination of pembrolizumab, paclitaxel and carboplatin, works compared with paclitaxel and carboplatin alone in treating patients with endometrial cancer that is stage III or IV, or has come back (recurrent). Immunotherapy with monoclonal antibodies, such as pembrolizumab, may help the body's immune system attack the cancer, and may interfere with the ability of tumor cells to grow and spread. Paclitaxel and carboplatin are chemotherapy drugs used as part of the usual treatment approach for this type of cancer. This study aims to assess if adding immunotherapy to these drugs is better or worse than the usual approach for treatment of this cancer.

Investigator Initiated



Protocol Numbers: 2549-17 | 2017-0052 | Droege 2016 | P335
IRB: Not Tracked
PI: Michael Goodman (goodmamd@ucmail.uc.edu)
Title: Intercostal Liposomal Bupivacaine for the Management of Blunt Chest Wall Trauma
Sponsor Site Number: No site number found

Protocol | Inventory | Patients/Subjects | Protocol Documents | Transaction Documents | Temperature Documents | Competency Access | Billing | Workload | Contacts | Access Codes | Reports | Monitor Visits

IDS Options: Edit Protocol Close Out Protocol View Audit Trail

Protocol Identifiers | +

Name	Identifier	Protocol (NCI) Order on DARF	Protocol (Local) Order on DARF
Vestigo ProtocolNumber	2549-17	1	Do not display on DARF
Vestigo SecondID	2017-0052	Do not display on DARF	1
ClinicalTrials Primary	Droege 2016	Do not display on DARF	Do not display on DARF
Vestigo NCTID	NCT02749968	Do not display on DARF	Do not display on DARF
Vestigo ProtocolID	P335	Do not display on DARF	Do not display on DARF
Vestigo ThirdID	Droege 2016	Do not display on DARF	Do not display on DARF

Protocol Status:	Active, not recruiting: study is ongoing (i.e., patients are being treated or examined), but enrollment has completed
Lead Sponsor:	University of Cincinnati
Phase:	Phase 2
Intervention Type:	Drug
Study Design:	Allocation: Randomized Intervention Model: Parallel Assignment Masking: Treatment Primary Purpose: Double (Participant, Care Provider)
Protocol Group:	Trauma
Protocol Binder Location:	Closed, Pending
Sponsor Type:	Federal
Facilities:	(Main) UCMC Investigational Pharmacy, WCH Inpatient Pharmacy
Print:	Protocol Binder Cover Sheet Print Protocol Label Protocol Summary Report
Summary:	This is a study of liposomal bupivacaine for pain control in patients with blunt chest wall trauma.

What types of Services Do We Provide?

- Study Setup
- Randomizations
- Budgetary consultation and Feasibility
- Regulatory guidance and support (SOP's and Site Blinding Plans)
- Multiple site coordination of pharmacy services
- EPIC protocol build and maintenance
- Drug procurement, storage, inventory management, accountability, preparation, compounding, dispensing, monitoring
  - Oral dosage forms to hazardous drugs to stem cell therapies
  - Sterile product preparation and compounding
  - Capsule/masked product compounding
  - Drug Devices
- Coordination within and across UC Health Pharmacy Services
- Training upon request

Temperature Monitoring

UC Health

VersaTrak

VERSATRAK™ WIRELESS

VersaTrak is the second generation product brought to you by the creat
system in Healthcare, back in 2009. Our experience and knowledge bas
VersaTrak is the **next generation** in wireless technology. We have creat
compliant, intuitive and user friendly software interface available. We a
technologies to benefit your Healthcare system. This allows you to mix
or cellular) hardware needs within the same system and even within the
bring you the most innovative software solution, we also provide our *pa*
technology that allows you to test and re-certify your transmitters to a
you already have an existing wireless system — allow us to upgrade it to

With your VersaTrak system you can monitor:

- Temperatures
- Relative humidity
- Equipment and door status
- Differential pressures
- Real time particle count
- Gas levels and flow
- Steam traps
- Water leaks
- Just about anything else you want to monitor, document and alarm!

Daily Detail Report

University

Wednesday, October 12, 2022 thru Tuesday, October 18, 2022

IDC Room 1209 Ultra-Low Freezer Contact Anna Poston--Blahnik 1-859-512-6028 or 513-543-9739 Eric Mueller in alarm / Temperature

Alert Range: IDS ULTRA LOW [-80.0°C - -70.2°C]

	Daily			AM	PM	12 AM - 2 AM	2 AM - 4 AM	4 AM - 6 AM	6 AM - 8 AM	8 AM - 10 AM	10 AM - 12 PM	12 PM - 2 PM	2 PM - 4 PM	4 PM - 6 PM	6 PM - 8 PM	8 PM - 10 PM	10 PM - 12 AM
Date	Readings	Avg Min/Max	% In Range	Avg Min/Max	Avg Min/Max	Avg Min/Max	Avg Min/Max	Avg Min/Max	Avg Min/Max	Avg Min/Max	Avg Min/Max	Avg Min/Max	Avg Min/Max	Avg Min/Max	Avg Min/Max	Avg Min/Max	Avg Min/Max
0/12/2022	48	-79.8 -82.4 / -77.8°C	63%	-79.5 -82.2 / -77.8°C	-80.2 -82.4 / -78.3°C	-79.2 -79.4 / -79.0°C	-79.9 -80.1 / -79.6°C	-79.4 -79.9 / -78.5°C	-79.5 -80.4 / -77.9°C	-80.0 -82.2 / -77.8°C	-79.0 -79.7 / -78.4°C	-80.3 -82.2 / -78.4°C	-80.5 -81.9 / -78.9°C	-79.7 -82.2 / -78.3°C	-80.2 -82.4 / -78.8°C	-80.2 -81.3 / -78.4°C	-80.2 -81.8 / -78.8°C
0/13/2022	48	-78.8 -81.6 / -77.3°C	88%	-79.1 -81.6 / -77.5°C	-78.6 -80.6 / -77.3°C	-80.1 -81.6 / -78.9°C	-79.9 -81.4 / -78.0°C	-79.8 -80.7 / -78.7°C	-78.5 -79.2 / -77.5°C	-78.2 -78.9 / -77.8°C	-78.1 -79.0 / -77.6°C	-78.6 -79.8 / -77.3°C	-78.0 -79.3 / -77.5°C	-79.1 -80.6 / -77.9°C	-78.2 -79.2 / -77.6°C	-78.6 -79.6 / -77.7°C	-78.9 -79.5 / -77.4°C
0/14/2022	48	-78.6 -80.6 / -77.1°C	98%	-78.4 -79.7 / -77.1°C	-78.8 -80.6 / -77.4°C	-78.4 -79.0 / -78.0°C	-78.3 -79.1 / -77.6°C	-78.7 -79.3 / -78.2°C	-78.2 -79.7 / -77.4°C	-78.7 -79.3 / -78.4°C	-78.1 -78.7 / -77.1°C	-78.5 -79.0 / -78.0°C	-77.9 -78.9 / -77.4°C	-78.3 -79.3 / -77.8°C	-79.4 -79.7 / -79.1°C	-79.7 -80.6 / -79.1°C	-79.2 -79.6 / -78.9°C
0/15/2022	48	-79.1 -80.2 / -77.3°C	96%	-79.0 -80.2 / -77.5°C	-79.3 -80.1 / -77.3°C	-79.4 -79.4 / -79.4°C	-79.1 -80.2 / -77.5°C	-79.2 -79.4 / -78.5°C	-79.2 -79.8 / -78.6°C	-78.9 -79.6 / -78.1°C	-78.4 -79.1 / -77.5°C	-78.4 -79.9 / -77.3°C	-78.8 -79.2 / -78.2°C	-79.5 -79.6 / -79.4°C	-79.6 -80.0 / -79.5°C	-79.8 -79.9 / -79.6°C	-79.4 -80.1 / -78.9°C
0/16/2022	48	-79.2 -81.6 / -77.4°C	79%	-78.4 -79.7 / -77.4°C	-79.9 -81.6 / -78.7°C	-78.7 -79.7 / -77.4°C	-78.4 -79.0 / -77.7°C	-77.7 -78.5 / -77.4°C	-78.7 -79.7 / -77.7°C	-78.7 -79.5 / -77.8°C	-78.4 -79.1 / -77.5°C	-79.8 -80.8 / -79.0°C	-80.3 -81.0 / -79.6°C	-79.5 -79.9 / -78.8°C	-80.2 -81.6 / -79.3°C	-79.5 -80.2 / -78.9°C	-80.0 -81.4 / -78.7°C
0/17/2022	48	-78.6 -82.6 / -76.0°C	85%	-79.3 -82.6 / -76.8°C	-77.9 -79.6 / -76.0°C	-79.2 -80.9 / -77.4°C	-80.3 -82.6 / -77.6°C	-79.3 -82.6 / -77.5°C	-79.4 -79.7 / -79.0°C	-79.1 -80.8 / -77.5°C	-78.2 -80.3 / -76.8°C	-77.4 -78.3 / -76.6°C	-77.8 -79.4 / -76.0°C	-77.9 -78.0 / -77.8°C	-77.4 -77.8 / -76.6°C	-78.3 -79.6 / -77.4°C	-78.3 -78.8 / -77.7°C
0/18/2022	47	-77.6 -80.5 / -76.2°C	98%	-77.9 -80.5 / -76.5°C	-77.4 -78.4 / -76.2°C	-78.8 -79.4 / -77.8°C	-78.4 -79.0 / -77.9°C	-77.1 -77.8 / -76.6°C	-77.3 -77.5 / -76.9°C	-77.9 -78.7 / -76.6°C	-77.9 -80.5 / -76.5°C	-77.4 -78.2 / -76.2°C	-77.8 -78.4 / -77.4°C	-77.2 -77.3 / -77.1°C	-77.3 -77.8 / -77.1°C	-77.3 -77.5 / -77.2°C	-77.3 -77.6 / -76.7°C

Daily Summary Report

University

Wednesday, October 12, 2022 thru Tuesday, October 18, 2022

C Room 1209 Ultra-Low Freezer Contact Anna Poston--Blahnik 1-859-512-6028 or 513-543-9739 Eric Mueller in alarm / Temperature

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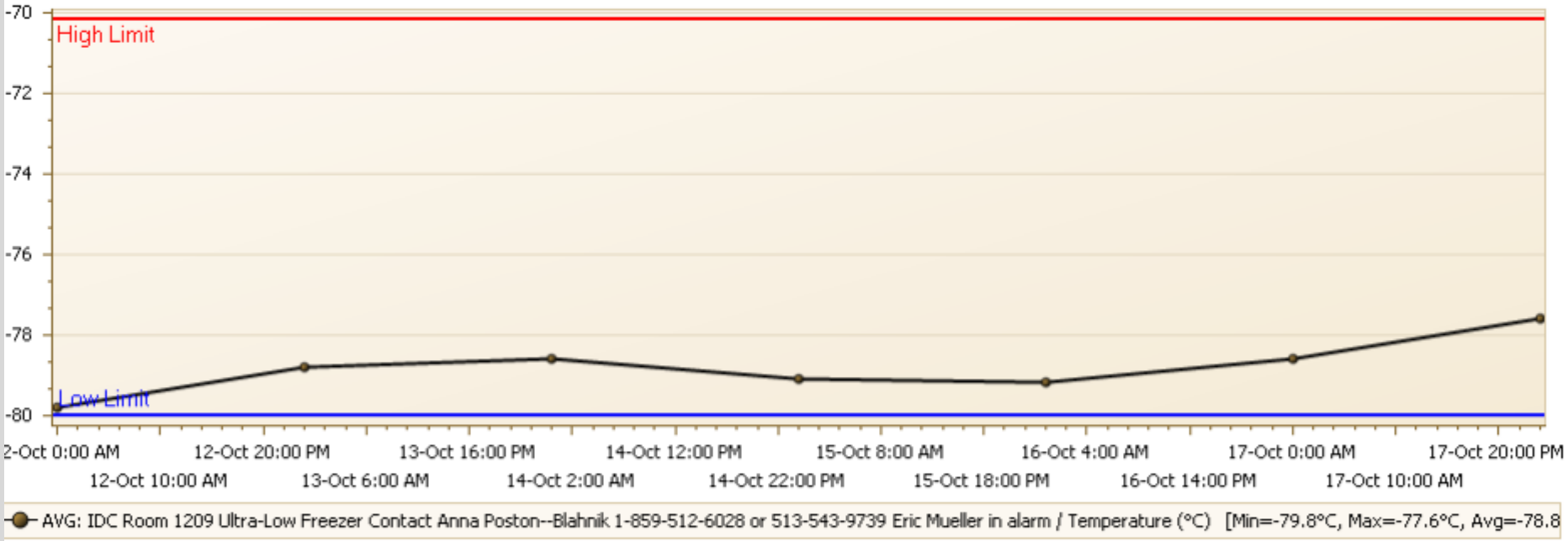
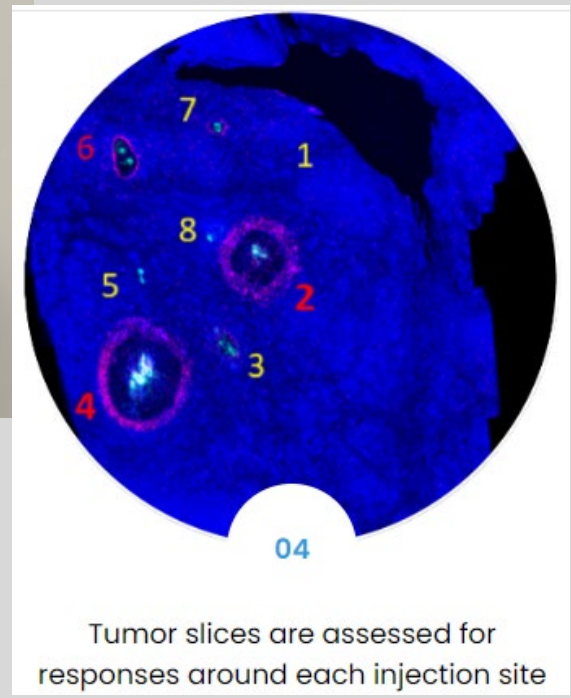


	Low	Avg	Hi
22	-82.4°C	-79.8°C	-77.8°C
22	-81.6°C	-78.8°C	-77.3°C
22	-80.6°C	-78.6°C	-77.1°C
22	-80.2°C	-79.1°C	-77.3°C

When

- Scheduled infusions in GNI and Barrett
  - Q6 months, bi-weekly, 3x weekly
  - GNI: MS, Adult onset Pompe Disease, Alzheimer's studies
  - Barrett: All varieties of hematologic and solid cancer types
    - Oral therapies: PK lab draws
    - Infusions
    - Intratumoral Injections (RP1, CIVO device)
- Same day randomization and treatment
    - Study for kidney transplant: first infusion no later than 7 days post transplant
    - TXA study for hip fractures
    - COVID studies
- STAT
    - STROKE studies
    - 10 minutes or less to prepare drug



Tumor slices are assessed for responses around each injection site

What does IDS need to start a trial?

- Latest copy of protocol, investigator brochure, pharmacy manual (if available), and general informed consent
- Complion access (if applicable)
- IRB approval letter (including UC's if using an outside IRB)
- UC Health approval letter
- A physician order: this may be a written prescription, infusion plan, treatment plan, or EPIC order set
- List of authorized prescribers (on 1572 or DOA)

What does Pharmacy need to treat a patient?

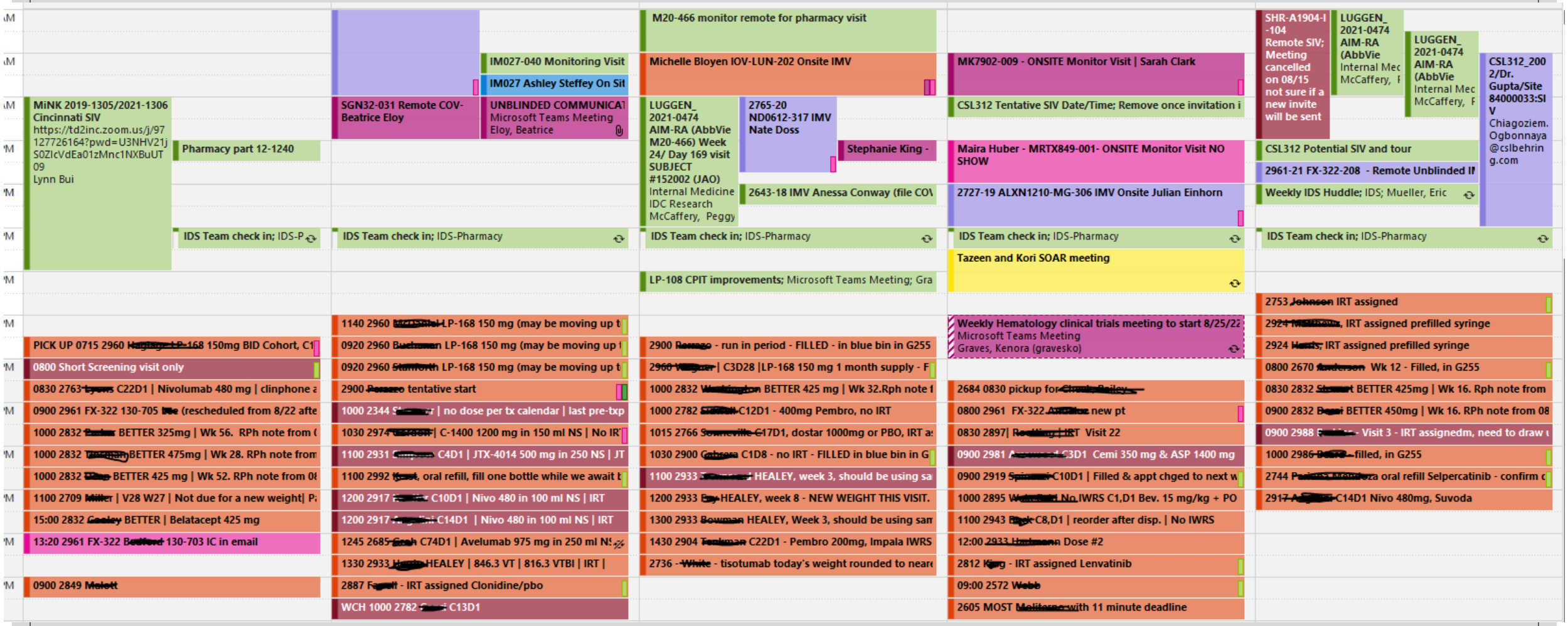
- INFORMED CONSENT (First page with study title + signature of patient)
- Email sent to IDS-Pharmacy (minimum):
  - Participant name
  - Medical record number
  - Subject ID number
  - Date of birth
- **Signed Prescription order for medication**
- TIME TO PREPARE DRUG
- Web assigned vial assignments (if applicable) also known as IRT, IWRS, etc.
- If the patient is in an infusion area, the participant will need an ok to treat order placed (green light)
- If it is an outpatient prescription order, we ask the study coordinator pickup drug from IDS.

SCHEDULING: Investigational Product/Drug Workflow

- **IDS reviews Epic and creates a schedule for the upcoming week on Thursdays/Fridays. Notify IDS when:**
- Screening first patient on study
    - 2 weeks minimum to get a study up and running
- New patient consented
- Last minute additions
- Subject treated outside of protocol window
- Scheduler should put "research" in the notes box in Epic→ helps identify IDS patients
- If there is an appointment where the weight needs to be documented per protocol, please document this weight in Epic.
    - It may also be required to document the weight in an email to IDS if the IRT doesn't capture this
- Research chart notes are encouraged to document study drug administration, infusion related notes, missed infusions, etc.

SCHEDULING: IDS Workflow

UC Health



Why Do We Need a Prescription?

UC Health

OHIO LAWS & ADMINISTRATIVE RULES
LEGISLATIVE SERVICE COMMISSION

HOME | LAWS | ABOUT | CONTACT | RELATED SITES | GO TO 101.01 Go | Keyword Search

The Legislative Service Commission staff updates the Revised Code on an ongoing basis, as it completes its act review of enacted legislation. Updates may be slower during some times of the year, depending on the volume of enacted legislation.

Section 4729.51 | Selling, purchasing, distributing, or delivering dangerous or investigational drugs.

Ohio Revised Code / Title 47 Occupations-Professions / Chapter 4729 Pharmacists; Dangerous Drugs

Previous Next

Effective: *September 23, 2022* ***Latest Legislation:*** *House Bill 193 - 134th General Assembly* ***PDF:*** *Download Authenticated PDF*

(A) No person other than a licensed manufacturer of dangerous drugs, outsourcing facility, third-party logistics provider, repackager of dangerous drugs, or wholesale distributor of dangerous drugs shall possess for sale, sell, distribute, or deliver, at wholesale, dangerous drugs or investigational drugs or products, except as follows:

(1) A licensed terminal distributor of dangerous drugs that is a pharmacy may make occasional sales of dangerous drugs or investigational drugs or products at wholesale.

(2) A licensed terminal distributor of dangerous drugs having more than one licensed location may transfer or deliver dangerous drugs from one licensed location to another licensed location owned by the terminal distributor if the license issued for each location is in effect at the time of the transfer or delivery.

(3) A licensed terminal distributor of dangerous drugs that is not a pharmacy may make occasional sales of the following at wholesale:

(a) Overdose reversal drugs;

(b) Dangerous drugs if the drugs being sold are in shortage, as defined in rules adopted under section 4729.26 of the Revised Code;

(c) Dangerous drugs other than those described in divisions (A)(3)(a) and (b) of this section or investigational drugs or products if authorized by rules adopted under section 4729.26 of the Revised Code.

Outpatient Medication Order

University of Cincinnati Clinical Research | UC Health
Investigational Pharmacy

IDS # 2901-21 Prescription
CTQJ230A12301

Patient Name:_____ Date of Birth: _____

MR # _____ Patient ID # _____ Print Prescribing MD: _____

Patient Allergies: _____

PELACARSEN (TQJ230) 80 mg **or MATCHING PLACEBO** 0.8 mL Prefilled Syringe

SIG: Administer the entire contents of 1 prefilled syringe (0.8 mLs) subcutaneously once every 30 days as directed.

Discard used syringe in sharps container.

Dispense kit(s) as assigned by IWRS

Auxiliary labels: Refrigerate

Refill per protocol. Every year a new prescription is required.

If the EPIC encounter does not allow for ordering and administering medications, then a formal EPIC medication order will not occur. The EPIC order entry is the responsibility of the study staff. On site, administration should be documented in the chart.

DATE: _____ Physician signature: _____

University of Cincinnati, Department of Internal Medicine
Division of Cardiovascular Health and Disease
231 Albert Sabin Way, ML 1555
Cincinnati, Ohio 45267
Phone number (513) 558-1000

GN42272
DOUBLE-BLIND TREATMENT PERIOD

Patient Name: _____ Date of Birth: _____

MR # _____ Subject # _____ Prescribing MD: _____

FENEBRUTINIB 100 mg or Matching Placebo TABLETS
Dispense # 64 tablets/bottle

SIG: Take 2 tablets (PO) twice daily with water, with or without food, as directed. Return bottle at next visit.

Dispense # of bottles assigned by IWRS.
Refill per protocol GN42272

Ancillary labels: Hazardous. Swallow whole. No grapefruit. Plenty of H_2O. Antacids.

AND

TERIFLUNOMIDE 14 mg or Matching Placebo CAPSULES
Dispense # 16 capsules/bottle

SIG: Take 1 capsule (PO) once daily with water, with or without meals, as directed. Return bottle at next visit.

Dispense # of bottles assigned by IWRS.
Refill per protocol GN42272

Ancillary labels: Swallow whole. Plenty of H_2O.

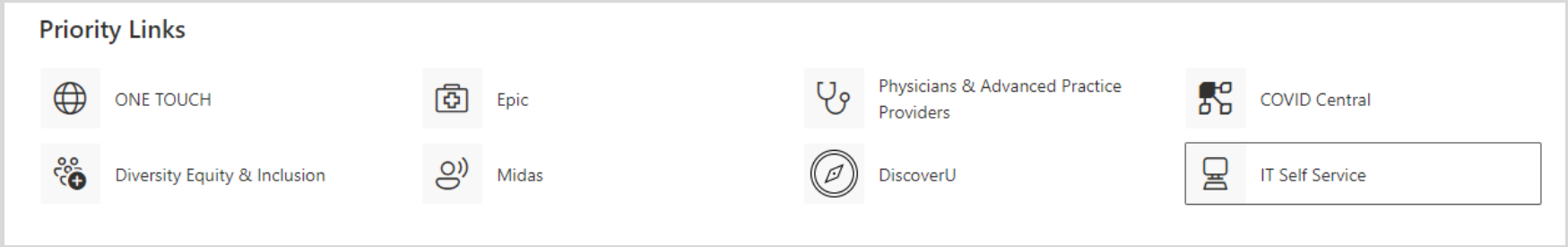
If the dose is changed in any way, a new prescription will need to be signed and provided to IDS Pharmacy.

DATE: _____ Physician's signature: _____

UC Waddell Center for Multiple Sclerosis
University of Cincinnati Medical Center
222 Piedmont Avenue, Suite # 3200

What is the process for Electronic Prescriptions?

- Fill out IDS request for Epic order: Infusion plan (non-oncology), treatment plan (oncology), inpatient order
- Submit a ticket through IT self service link. A manager must approve the ticket. Attach form, protocol and pharmacy manual to ticket.
- EPIC Pharmacy team builds the order
- Once built, Epic team notifies the study coordinator, IDS Pharmacy, Specialist, etc. An extract of the build will be sent to the study staff for review.
- Once the study coordinator and pharmacy have approved, the EPIC team will ask the study coordinator to obtain PI approval of plan.
- After all approvals are obtained, EPIC team migrates the plan into production.
- Any changes to the protocol or pharmacy manual that affect the plan will need to have a new ticket submitted. The process is the same as the original ticket.



UC Health

Request for Infusion Plan for Investigational Protocol

Incident #:	Click here to enter text.	**Requested Completion Date:**	Click here to enter a date.
Date of Request:	Click here to enter a date.	**Type of Request:**	Choose an item.
Anticipated date to begin screening patients:	Click here to enter a date.		
Study Name:	Click here to enter text.		
Abbreviated Study Name and IDS #:			

☐ **Study has received approval from IRB.**

Study Coordinator Contact Information:

Name:	Click here to enter text.	**Phone #:**	Click here to enter text.	**Pager #:**	Click here to enter text.

PI Name: Click here to enter a date.

Internet Links (to be included in Springboard Report) :

Click here to enter text.

# Infusion visits:	Click here to enter text.	**Time between Infusion visits (Days):**	Click here to enter text.
n/a:	Click here to enter text.	**Are all Infusion visits identical?** If yes, please provide details for all treatment days in Infusion Visit 1 only, and specify # Infusion visits to be built. If no, please provide details for each unique infusion visit	Choose an item.

Supportive Care:

☐ Premedications and/or other supportive care medications are specified in protocol

☐ Premedications and/or other supportive care medications NOT specified in protocol. In this case, general UC Health supportive care regimens may be used.

- Premedications and other supportive care meds need to be outlined below only if specified by the study

Additional Notes: Click here to enter text.

Infusion Visit #	Click here to enter text.	**Day # (if appropriate)**	Click here to enter text.		
Treatment Conditions:	Click here to enter text.				
Standard of Care Labs:	Click here to enter text.				
Standard of Care Labs may be drawn within how many days prior to treatment	Click here to enter text.				
RESEARCH LABS	Click here to enter text.				
Research Labs to be drawn within how many days prior to treatment	Click here to enter text.				
Monitoring:	Click here to enter text.				

Medications to be given (please list in sequence of administration.)

Drug #1:	**Name:**	Click here to enter text.			
Source (Commercial vs. Study Supplied)	Click here to enter text.				
Dosing	Click here to enter text.	**Route:**	Click here to enter text.	**Duration of Infusion**	Click here to enter text.
Drug #2:	**Name:**	Click here to enter text.			
Source (Commercial vs. Study Supplied)	Click here to enter text.				
Dosing	Click here to enter text.	**Route:**	Click here to enter text.	**Duration of Infusion**	Click here to enter text.
Drug #3:	**Name:**	Click here to enter text.			
Source (Commercial vs. Study Supplied)	Click here to enter text.				

Dosing	Click here to enter text.	**Route:**	Click here to enter text.	**Duration of Infusion**	Click here to enter text.
Drug #4:	**Name:**	Click here to enter text.			
Source (Commercial vs. Study Supplied)	Click here to enter text.				
Dosing	Click here to enter text.	**Route:**	Click here to enter text.	**Duration of Infusion**	Click here to enter text.
Duplicate contents of this day for the following Infusion **Visits:**	Click here to enter text.				
Duplicate contents of this day for the following Infusion **Visits:**	Click here to enter text.				

Rescue Medications in the event of adverse reactions (Mark all that apply):

☐ Stop Infusion

☐ Administer Emergency Hypersensitivity Medications::

☐: Diphenhydramine (BENADRYL) injection 25 mg

25 mg, Intravenous, Daily as needed, For urticaria, pruritis, or shortness of breath, starting when released. Administer IV Push at rate of 25mg/minute.

☐: Hydrocortisone sod succ (PF)(SOLU-CORTEF) 100mg injection

100mg, Intravenous, Daily as needed, For urticaria, pruritis, or shortness of breath, starting when released. Administer IV Push over 30 seconds. PROTECT FROM LIGHT.

☐: albuterol (PROVENTIL, VENTOLIN, PROAIR) INHALER 1-2 puff

1-2 puff, inhalation RT every 4 hours PRN. For urticaria, pruritis, or shortness of breath, starting when released. SHAKE WELL.

☐: EPINEPHrine 1mg/ml injection

0.3 mg, subcutaneous, Daily as needed, for Anaphylaxis, Starting when released.

☐ Contact Study coordinator:_____ at pager:_____ if not present at infusion.

ADDITIONAL INFORMATION STUDY COORDINATOR FEELS IMPORTANT FOR THE INFUSION VISIT BUILD:

EPIC TST Environment

UC Health

BB

Burns Beacon
Female, 23 y.o., 5/2/1999
MRN: 07600213,
CSN: 1100150172
Code: Not on file (has ACP docs)

Search

COVID-19 Vaccine: Dose 1 given 7/26/2022, Refer to guidelines

Tahir Latif, MD
Attending

Allergies: Not on File
Active Therapy Plans

ACTIVE TREATMENTS
Other plans (1)

EXPECTED ADMISSION: 5/25/2021
Patient Class: Observation
No active principal problem
Weight: 210 lb 1.6 oz (95.3 kg)

Summary | Chart Review | Results Review | Notes | Allergies | Immunizations | MAR | Medications | Orders | Verify Orders | Plans/Treatment | Admission | Rounding | Discharge | Patient Station

Plans and Treatments

PLANS & TREATMENTS
- Rx Chemo Chec...
- Rx Chemo Prep
- Results Console
- Synopsis
- Supportive Plan
- Treatment Plan
- Infusion Plan
- IP BMT/Hem Ord...
- OP BMT/Hem Or...
- IR Chemo Thera...
- Proton Therapy...
- Clinic Injections

Bb. Treatment Conditions — Move Up

- Treatment Condition — 1/1 remaining
  Routine, Once, Starting when released
  Confirm with study coordinator that patient has met study criteria and it is okay to proceed with study infusion administration.

Cb. Nursing Assessment/Orders — Move Up

- Vital Signs — 1/1 remaining
  Routine, Once, Starting when released
  Obtain patient's weight upon arrival to the infusion area. Vital signs (body temperature, heart rate and blood pressure) will be assessed before starting study drug infusion and 2 hours (+/- 30 minutes) after the end of the study drug infusion.
- Hypersensitivity Reaction Monitoring — 1/1 remaining
  Routine, Once, Starting when released
  Study coordinator will be monitoring patient during the infusion and until the infusion is complete for hypersensitivity reactions. Please do not start study medication until study coordinator is present.
- Nursing Communication
  Routine, Once, Starting when released
  Patient will remain in the infusion area for at least two hours after completion of the study infusion.
- Nursing Communication II
  Routine, Once, Starting when released
  Line will be blinded (covered with an amber sleeve) and primed with study drug by IDS pharmacy. Infusion bag will contain 50 mLs of overfill. DO NOT FLUSH. Sponsor required Alaris pump to be used for infusion will be provided by study team. IDS pharmacy will deliver prepared drug to unblinded nurse. Unblinded nurse will load drug into the pump and cut the blinding sleeve to fit into Alaris pump. Once the drug is loaded, the blinded nurse can enter the room. IDS pharmacist will then provide rate and VTBI to 2 nurses. Nurse #1 will program pump, Nurse #2 will double check info, IDS pharmacist will triple check info; then all 3 will sign chain of custody verifying rate and VTBI were programmed per protocol. In the event of issues with the infusion pump, only unblinded nursing staff is permitted to troubleshoot pump issues. The infusion rate can be reduced if needed for safety reasons. The total infusion duration should not exceed 4 hours.

Pharmacy Communication — Move Up

- Pharmacy Communication
  Routine, Once, Starting when released
  Study drug is provided by Sponsor. For each visit the dose must be calculated based on the patient's body weight measured at the current visit OR the weight from the previous visit (within 2 months) can be used. Weight should be rounded to the nearest 0.5 kg. VTBI will be rounded to the nearest 0.1 mL. Bag will contain 50 mLs of overfill. Drug must be administered with sponsor provided Alaris infusion pump. IDS will prime sponsor provided IV tubing and blind the line. IDS pharmacist will check final product and deliver to UCGNI infusion suite. IDS pharmacy will provide VTBI to 2 nurses at UCGNI. Nurse #1 will program the pump with the provided rate, Nurse #2 will double check the rate programmed on the pump, and IDS pharmacist will confirm and record via Chain of Custody. Call IDS Pharmacy 513-584-1766 with questions. Commercial supply of all other drugs will be used and the patient charged in the usual manner.

Cc. Medications — Move Up

- INVESTIGATIONAL MEDICATION (VOLUME BASED) — 20/20 remaining
  343.08 mL (3.6 mL/kg × 95.3 kg), Intravenous, at 171.5 mL/hr, Once, Starting when released, For 1 dose
  Bag contains 50 mLs of overfill for a total volume (VT) of_______mL. Only administer infusion at rate on label for 120 minutes.
  IDS #: 2945-21 (AH0003)
  IDS Drug: Bepranemab 90 mg/kg OR 45 mg/kg or Placebo in NS
  IDS pharmacist will release order, check final product and manually fill in the total infusion volume in the admin comments section of the label. IDS pharmacy to double check sponsor provided Alaris pump is programmed with the correct rate and VTBI by UCGNI nursing staff.

Da. Line Maintenance — Move Up

- Nursing Communication — 1/1 remaining
  Routine, Once as needed, Starting when released
  Okay to access CVAD to draw labs and administer medications. If patient does not have central line access, nurse to place peripheral IV.
- sodium chloride 0.9 % infusion — 1/1 remaining
  25 mL/hr, Intravenous, Daily as needed, for line maintenance while infusing drug therapy., Starting when released, For 1 day
- sodium chloride flush 10 mL — 1/1 remaining
  10 mL, Intravenous, Daily as needed, Line Care, Use 10-20 ml to flush line., Starting when released, For 1 day
- heparin lock flush Syrg 500 Units — 1/1 remaining
  500 Units, Intracatheter, Daily as needed, For flushing port, Starting when released, For 1 day

IDS 2785-20 Acetaminophen Vs Vitamin C in Patients with Sepsis-Induced Hypotension or Respiratory Failure (ASTER, PETAL04)

✔ Accept

- Acetaminophen and Ascorbate in Sepsis: Targeted Therapy to Enhance Recovery (ASTER)

- ○ IDS 2785-20 ASTER Trial - Select if patient is less than 50 kg
- ○ IDS 2785-20 ASTER Trial - Select if patient is greater than or equal to 50 kg but less than 80 kg
- ○ IDS 2785-20 ASTER Trial - Select if patient is greater than or equal to 80 kg and less than or equal to 180 kg
- ○ IDS 2785-20 ASTER Trial - Select if patient is greater than180 kg

IDS 2785-20 Acetaminophen Vs Vitamin C in Patients with Sepsis-Induced Hypotension or Respiratory Failure (ASTER, PETAL04)

✔ Accept

- Acetaminophen and Ascorbate in Sepsis: Targeted Therapy to Enhance Recovery (ASTER)

- ○ IDS 2785-20 ASTER Trial - Select if patient is less than 50 kg
- ● IDS 2785-20 ASTER Trial - Select if patient is greater than or equal to 50 kg but less than 80 kg
  - ○ IDS 2785-20 Acetaminophen 1000 mg Or D5W 100 mL
    100 mL, Intravenous, Every 6 hours Starting H,, for 20 doses, FOR PATIENTS GREATER THAN AND EQUAL TO 50 KG AND LESS THAN OR EQUAL TO 80 KG. Give via infusion pump. Replace tubing every 24 hours. 24 hour supply will be delivered at one time to nurse. Doses must be given 6 hours apart (+/- 1 hour) from last administered dose for 20 doses or until discharged from the ICU.
  - ○ IDS 2785-20 Vitamin C 50 mg/kg Or Placebo in D5W 50 mL
    Intravenous, Administer over 30 Minutes, Every 6 hours Starting H,, for 20 doses, FOR PATIENTS GREATER THAN OR EQUAL TO 50 KG AND LESS THAN 80 KG. Give via infusion pump. Replace tubing every 24 hours. 24 hour supply will be delivered at one time to nurse. Doses must be given 6 hours apart (+/- 1 hour) from last administered dose for 20 doses or until discharged from the ICU. Do NOT use a glucometer for this patient (Ordering plasma glucose is acceptable)
- ○ IDS 2785-20 ASTER Trial - Select if patient is greater than or equal to 80 kg and less than or equal to 180 kg
- ○ IDS 2785-20 ASTER Trial - Select if patient is greater than180 kg

FOR INVESTIGATIONAL USE ONLY

Beacon, Burns UH 8NW-U8358
DOB: 23 yrs [5/2/1999] CSN # 1100150172
Ord# 154633287 Tahir Latif, MD
investigational medication **100 mL**

Route: **Intravenous** Frequency: **Q6H**
Rate: **200 mL/hr** Volume: **100 mL**
Admin Time: 6/9/22 09:30 Dose: 001

IDS #: 2785-20 (ASTER, PETAL04)
IDS Drug: Acetaminophen 1000 mg or D5W 100 mL

FOR PATIENTS GREATER THAN AND EQUAL TO 50 KG AND LESS THAN OR EQUAL TO 80 KG. Give via infusion pump. Replace tubing every 24 hours. 24 hour supply will be delivered at one time to nurse. Doses must be given 6 hours apart (+/- 1 hour) from last administered dose for 20 doses or until discharged from the ICU.

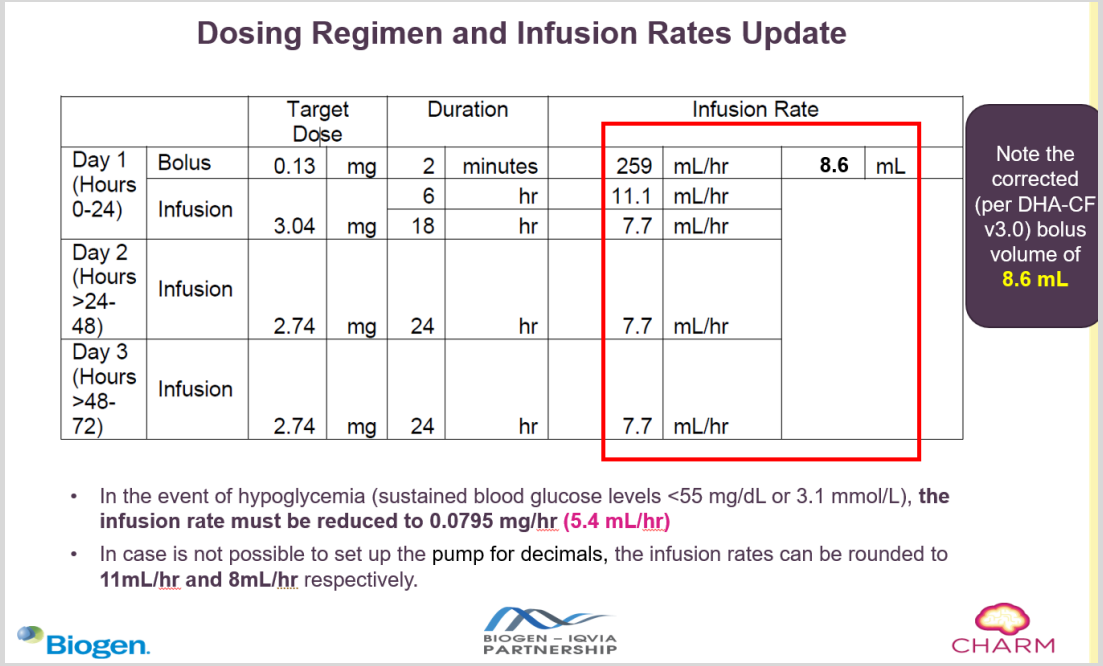
Expires: _____ Prep'd: _____ RPh: _____
[FD] on 6/9/22 09:08 by PW INVESTIGATIONAL
UH MAIN HOSPITAL 234 GOODMAN STREET, CINCINNATI OH 45219-2364

Beacon, Burns UH 8NW-U8358
CSN # 1100150172 DOB: 23 yrs [5/2/1999]
Ord# 154633287 Q6H Intravenous
investigational medication

UH 8NW-U8358 **Beacon, Burns**
DUE 6/9/22 09:30 #001 **100 mL**
UH 8NW-U8358
CSN# 1100150172
Ord# 154633287
6/9/22 09:30

Example of Change Requiring Ticket Update

- A current study recently reformulated their product from a 6 mg vial to a 4 mg vial.
- While the overall dose remains the same, this update results in the bolus volume and the infusion rate changing.
- Thus, an update needs to be made to the Epic order to ensure the correct infusion rate and volume occurs**.**
- Orders may need to be changed when: There is a significant change to the protocol resulting in a change in the dose being administered, how the drug is administered, addition of a new therapy, etc.
- **You can always consult IDS regarding whether updates to orders or plans are needed**



Dosing Regimen and Infusion Rates Update

		Target Dose		Duration		Infusion Rate			
Day 1 (Hours 0-24)	Bolus	0.13	mg	2	minutes	259	mL/hr	**8.6**	mL
	Infusion	3.04	mg	6	hr	11.1	mL/hr		
				18	hr	7.7	mL/hr		
Day 2 (Hours >24-48)	Infusion	2.74	mg	24	hr	7.7	mL/hr		
Day 3 (Hours >48-72)	Infusion	2.74	mg	24	hr	7.7	mL/hr		

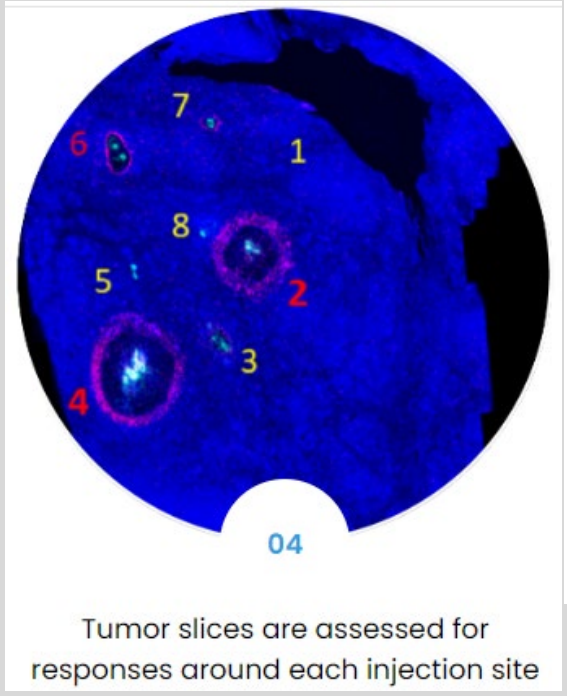
Note the corrected (per DHA-CF v3.0) bolus volume of **8.6 mL**

- In the event of hypoglycemia (sustained blood glucose levels <55 mg/dL or 3.1 mmol/L), **the infusion rate must be reduced to 0.0795 mg/hr (5.4 mL/hr)**
- In case is not possible to set up the pump for decimals, the infusion rates can be rounded to **11mL/hr and 8mL/hr** respectively.

Biogen. BIOGEN – IQVIA PARTNERSHIP CHARM

Why Is It Taking So Long For My Drug!?

- Drug preparation requires 45 vials per dose
- Product is hazardous and biosafety cabinet must be cleaned with special products before and after compounding
- Aliquot study requiring multiple attempts to compound
- FX-322 intratympanic ear injection study example→2 hours minimum required per preparation
- CIVO Device study→2 people x 1 hour
- Priming the line
- Blinding the infusion bag/line
- Documentation requirements from Sponsor



Tumor slices are assessed for responses around each injection site

PBI-MST01-TAK-02 8N Admixing Table

Vehicle/RED (Position #1)
0.1 mL of CIVO GLO RED
0.9 mL 0.9% SALINE
Invert vial 10 times
0.4 mL of this solution loaded to #1

TAK-676/Y (Position #2)
0.1 mL of CIVO GLO YELLOW
0.85 mL 0.9% SALINE
0.05 mL TAK-676 1 mg/mL
Invert vial 10 times
0.4 mL of this solution loaded to #2

CARBO/PACLITAXEL/Y (Position #3)
0.1 mL of CIVO GLO YELLOW
0.3 mL 0.9% SALINE
0.2 mL Carboplatin 10mg/mL
0.4 mL Paclitaxel 6mg/mL
Invert vial 10 times
0.4 mL of this solution loaded to #3

TAK-676/ CARBO/PACLITAXEL/Y (Position #4)
0.1 mL of CIVO GLO YELLOW
0.25 mL 0.9% SALINE
0.05 mL TAK-676 1 mg/mL
0.2 mL Carboplatin 10mg/mL
0.4 mL Paclitaxel 6mg/mL
Invert vial 10 times
0.4 mL of this solution loaded to #4

CARBO/Y (Position #5)
0.1 mL of CIVO GLO YELLOW
0.7 mL 0.9% SALINE
0.2 mL Carboplatin 10mg/mL
Invert vial 10 times
0.4 mL of this solution loaded to #5

TAK-676/ CARBO/5-FU/Y (Position #6)
0.1 mL of CIVO GLO YELLOW
0.25 mL 0.9% SALINE
0.05 mL TAK-676 1 mg/mL
0.2 mL Carboplatin 10mg/mL
0.4 mL Diluted 5-FU
Invert vial 10 times
0.4 mL of this solution loaded to #6

TAK-676/CARBO/Y (Position #7)
0.1 mL of CIVO GLO YELLOW
0.65 mL 0.9% SALINE
0.05 mL TAK-676 1 mg/mL
0.2 mL Carboplatin 10mg/mL
Invert vial 10 times
0.4 mL of this solution loaded to #7

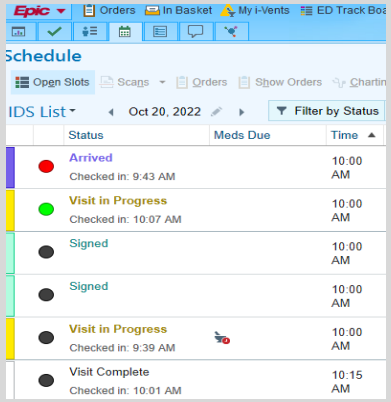
CARBO/5-FU/Y
0.1 mL of CIVO GLO YELLOW
0.3 mL 0.9% SALINE
0.2 mL Carboplatin 10mg/mL
0.4 mL Diluted 5-FU
Invert vial 10 times
0.4 mL of this solution loaded to #8

Version 1.0 Dated 21DEC2021 1

GREEN LIGHTING PROCESS

- We cannot prepare drug until we have an okay to treat order or "GREEN LIGHT"
- Okay to treat: patient is present on campus, eyes on patient, etc.
- Nurse in infusion area will "green light" once patient arrives.
- This "green light" alerts the satellite pharmacists (UCGNI, BARRETT, etc) that the patient has arrived.
- Satellite Pharmacist reviews the treatment/infusion plan in Epic. Double checks dosing, weight, lab parameters, consent, etc
- Pharmacist calls IDS pharmacy to communicate okay to treat. IDS then double checks the information in Epic and enters accountability into our Vestigo system.
- Double check of IDS staff occurs. Pictures are taken of the vials used for compounding.
- Technician walks the vials over the satellite pharmacy for compounding.

- We prepare drug for outpatient infusion visits in our satellite pharmacies adjacent to infusion centers
- Delays entering visit into IRT, getting patient weight (if required), etc can result in IDS delays
- STAT turnaround time once patient is green lit is 2 hours.
- **Communication is key!**



Dispensing Guidelines and Fact Sheets

STUDY FACT SHEET
IDS # 2785-20
ASTER STUDY

PROTOCOL TITLE: A PETAL Network Platform Multi-Center, Phase 2b Randomized, Double-Blind, Placebo-Controlled Trial of Two Different Pharmacologic Therapies (Intravenous Vitamin C or Intravenous Acetaminophen); Acetaminophen and Ascorbate in Sepsis: Targeted Therapy to Enhance Recovery; ASTER.

PHARMACOLOGY: VITAMIN C plays an important role in numerous physiologic functions relevant to patients with septic shock including modulation of inflammatory mediators, catecholamine synthesis, endothelial function, and vasopressor sensitivity. **ACETAMINOPHEN (APAP)** is a potent and specific inhibitor of CFH-mediated oxidative injury, improves lung and renal function in pre-clinical models and seems to be potentially beneficial in humans with hemoprotein-mediated diseases, including in critically ill adults with sepsis.

DOSAGE AND ADMINISTRATION: Eligible, consented patients will be randomized to one of the following treatment groups (in a 2:1:2:1 ratio):

VITAMIN C GROUP: Patients will receive the following for 5 days or until ICU discharge:
- **VITAMIN C** 50 mg/kg (**maximum dose of 9 grams**) IV over 30 minutes every 6 (+/- 1) hours
- **MATCHING PLACEBO** IV over 30 minutes every 6 (+/- 1) hours

APAP GROUP: Patients will receive the following for 5 days or until ICU discharge:
- **APAP** 1 gram (or 15 mg/kg if actual body weight less than 50 kg) IV over 30 minutes every 6 (+/- 1) hours
- **MATCHING PLACEBO** IV over 30 minutes every 6 (+/- 1) hours

TREATMENT WILL CONTINUE FOR 20 DOSES, OR DISCHARGE FROM THE INTENSIVE CARE UNIT, NEW AST/ALT ELEVATION 10 TIMES OR MORE OVER THE NORMAL LIMIT (APAP/Placebo group only), STUDY WITHDRAWAL, OR DEATH, WHICHEVER COMES FIRST.

ADMINISTRATION GUIDELINES:
- Randomized patients should receive their first dose of study medication as soon as possible, but no longer than 4 hours from randomization.
- Doses administered outside of the +/- 1 hour window, or any dose that is skipped, will be considered a protocol deviation.
- **Study medications may be administered through either a peripheral or central IV line. Change IV tubing every 24 hours. A dedicated line is preferred, but not required. Check compatibility before administering another medication through the same line.**
- Patients will receive study infusions while admitted to the ICU or in the ED while awaiting transfer to the ICU. If a patient's level of care changes prior to the final dose of study intervention, remaining doses will be discontinued upon physical transfer from the ICU to another level of care.
- Patients receiving Vitamin C may have falsely elevated glucose levels when measured using point of care glucometers. Glucose monitoring should be made using the Central Core Laboratory; ABG/stat lab devices or point of care hand held glucometers should NOT be used. Blood glucose measurements can resume per institutional practice following 24 hours after completion of final dose of Vitamin C.
- Missed doses may be administered within 3 hours after scheduled administration time. If a dose cannot be administered within 3 hours, the dose should be skipped.
- See Protocol Section 5.5 for information regarding Drug Interruptions.
- See Protocol Section 6.7, 6.8 and 6.9 for Excluded Medications, On-Study Fever Management Recommendations, and Concomitant Medications.
- Research and clinical teams are NOT blinded to the STUDY GROUP (APAP/Placebo; Vitamin C/Placebo) but ARE BLINDED to the active vs. placebo assignments.

UN-BLINDING: In the case of a significant safety concern related to any of the medications administered as part of the ASTER Study, the local PI should evaluate the situation to determine if discontinuing the study intervention is warranted. **The study medication blind shall not be broken**, as breaking the blind will not provide increased safety.

ADVERSE EFFECTS: VITAMIN C: lethargy, fatigue, irritation (pain and swelling) at injection site, nephrolithiasis, hyperglycemia, nausea. **ACETAMINOPHEN:** hepatocellular injury, hypotension, rash/hypersensitivity, nausea, vomiting, headache, insomnia, constipation, pruritis, dry mouth, dizziness.

AUTHORIZED PRESCRIBER: Kristin Hudock and Duncan Hite, MDs.

CONTACT PERSONNEL: Kiersten Rush: Cell: (937) 474-8262.

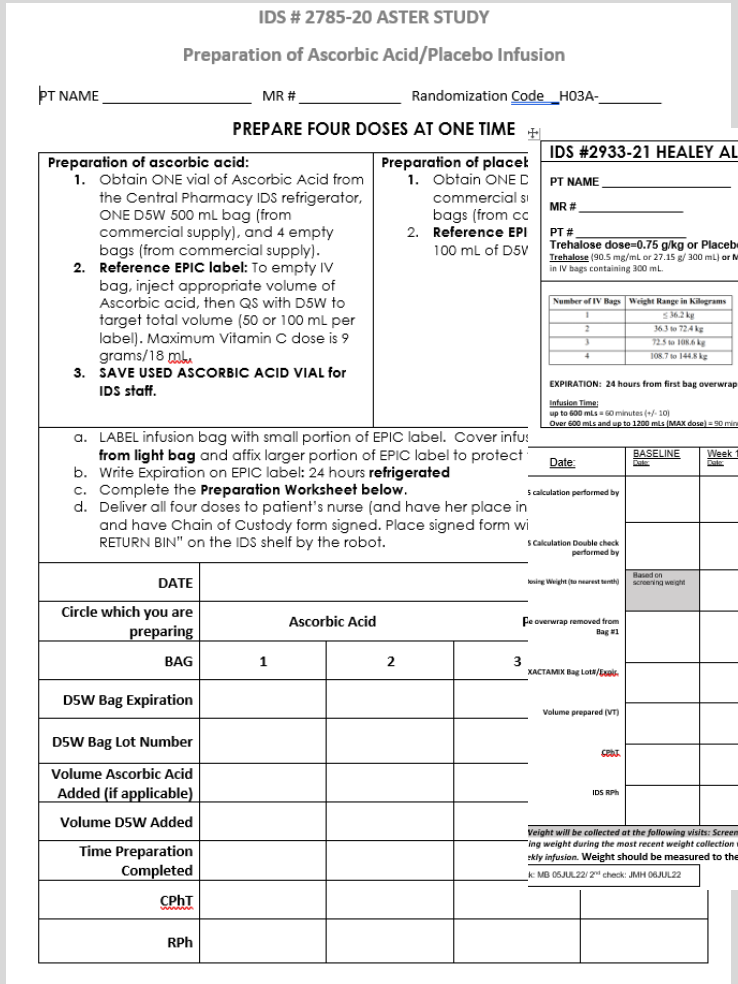
DISPENSING GUIDELINES FOR CENTRAL PHARMACY
IDS # 2785-20
ASTER STUDY

Protocol Title: A PETAL Network Platform Multi-Center, Phase 2b Randomized, Double-Blind, Placebo-Controlled Trial of Two Different Pharmacologic Therapies (Intravenous Vitamin C or Intravenous Acetaminophen); Acetaminophen and Ascorbate in Sepsis: Targeted Therapy to Enhance Recovery; **ASTER.**

Contacts:
- **Pharmacy (text or call):** Mary Burns (513-967-1720), Judy Houston (513-543-6160), Tazeen Fatima (419-967-1665), Kori Truono (913-449-3678)
- **Study Coordinator:** Harshada More (502-439-3712)
- **Physicians:** Kristin Hudock and Duncan Hite, MDs.

Central Pharmacy's Tasks:
1. **Enrollment:** Study personnel will notify IDS Pharmacy about a patient enrollment and provide IDS Pharmacy with randomization information. IDS Pharmacy will reach out to you with this information and help you with this process. IDS pharmacy can send you Enrollment Confirmations and signed informed consent form if you would like. **DON'T HESTITATE TO CALL/TEXT US.**
2. **EPIC Order:** Pharmacy may need to help enter the order set into EPIC. Search "2785-20" under the Orders tab. Select the corresponding weight group. Then select the correct arm (APAP/Placebo OR VitC/Placebo). Double check dose calculations.
   a. APAP or Placebo Group: 15 mg/kg to MAX of 1000 mg IV Q6H x 20 doses.
   b. Vit C or Placebo Group: 0.1 mL/kg (50 mg/kg) to MAX of 18 mL (9000 mg) IV Q6H x 20 doses.
3. **Verify Order:** Verify order and print 4 labels. Upon verification click box for "patient supplied do not dispense." You will be making 4 doses (24-hour supply) and delivering all 4 doses to the unit at the same time.
4. **Prepare Drug:** Find appropriate work sheet in IDS 2785 Binder behind "Worksheets" tab. There are two choices:
   a. **Preparation of Acetaminophen/Placebo Infusion**
   b. **Preparation of Ascorbic Acid/Placebo Infusion**
5. The only thing that needs saved is the used vial of ascorbic acid (if applicable). Place in IDS RETURN BIN.
6. **Deliver Drug:** Deliver all four doses to patient's nurse (and have them place in Omnicell Refrigerator if Ascorbic Acid/Placebo arm) and have Chain of Custody form signed. Place signed form in "IDS RETURN BIN" on the IDS shelf by the robot.

Preparation Instructions



IDS # 2785-20 ASTER STUDY

Preparation of Ascorbic Acid/Placebo Infusion

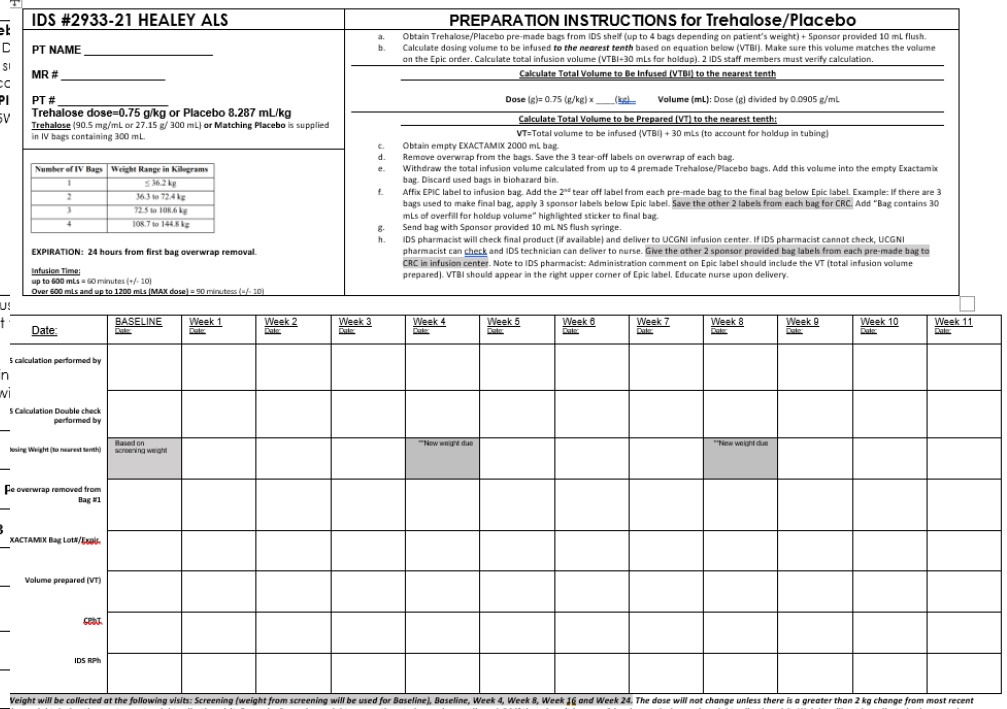
PT NAME _____ MR # _____ Randomization Code H03A-_____

PREPARE FOUR DOSES AT ONE TIME

Preparation of ascorbic acid:	Preparation of placeb
1. Obtain ONE vial of Ascorbic Acid from the Central Pharmacy IDS refrigerator, ONE D5W 500 mL bag (from commercial supply), and 4 empty bags (from commercial supply). 2. **Reference EPIC label:** To empty IV bag, inject appropriate volume of Ascorbic acid, then QS with D5W to target total volume (50 or 100 mL per label). Maximum Vitamin C dose is 9 grams/18 mL. 3. **SAVE USED ASCORBIC ACID VIAL for IDS staff.**	1. Obtain ONE D commercial s bags (from cc 2. **Reference EPI** 100 mL of D5W

a. LABEL infusion bag with small portion of EPIC label. Cover infus **from light bag** and affix larger portion of EPIC label to protect
b. Write Expiration on EPIC label: 24 hours **refrigerated**
c. Complete the **Preparation Worksheet below.**
d. Deliver all four doses to patient's nurse (and have her place in and have Chain of Custody form signed. Place signed form wi RETURN BIN" on the IDS shelf by the robot.

DATE				
Circle which you are preparing	Ascorbic Acid			P
BAG	1	2	3	
D5W Bag Expiration				
D5W Bag Lot Number				
Volume Ascorbic Acid Added (if applicable)				
Volume D5W Added				
Time Preparation Completed				
CPhT				
RPh				



IDS #2933-21 HEALEY ALS

PT NAME _____

MR # _____

PT # _____

Trehalose dose=0.75 g/kg or Placebo 8.287 mL/kg

Trehalose (90.5 mg/mL or 27.15 g/ 300 mL) **or Matching Placebo** is supplied in IV bags containing 300 mL.

Number of IV Bags	Weight Range in Kilograms
1	≤ 36.2 kg
2	36.3 to 72.4 kg
3	72.5 to 108.6 kg
4	108.7 to 144.8 kg

EXPIRATION: 24 hours from first bag overwrap removal.

Infusion Time:
up to 600 mLs = 60 minutes (+/- 10)
Over 600 mLs and up to 1200 mLs (MAX dose) = 90 minutess (+/- 10)

PREPARATION INSTRUCTIONS for Trehalose/Placebo

a. Obtain Trehalose/Placebo pre-made bags from IDS shelf (up to 4 bags depending on patient's weight) + Sponsor provided 10 mL flush.
b. Calculate dosing volume to be infused ***to the nearest tenth*** based on equation below (VTBI). Make sure this volume matches the volume on the Epic order. Calculate total infusion volume (VTBI+30 mLs for holdup). 2 IDS staff members must verify calculation.

Calculate Total Volume to Be Infused (VTBI) to the nearest tenth

Dose (g)= 0.75 (g/kg) x ____ (kg) **Volume (mL):** Dose (g) divided by 0.0905 g/mL

Calculate Total Volume to be Prepared (VT) to the nearest tenth:

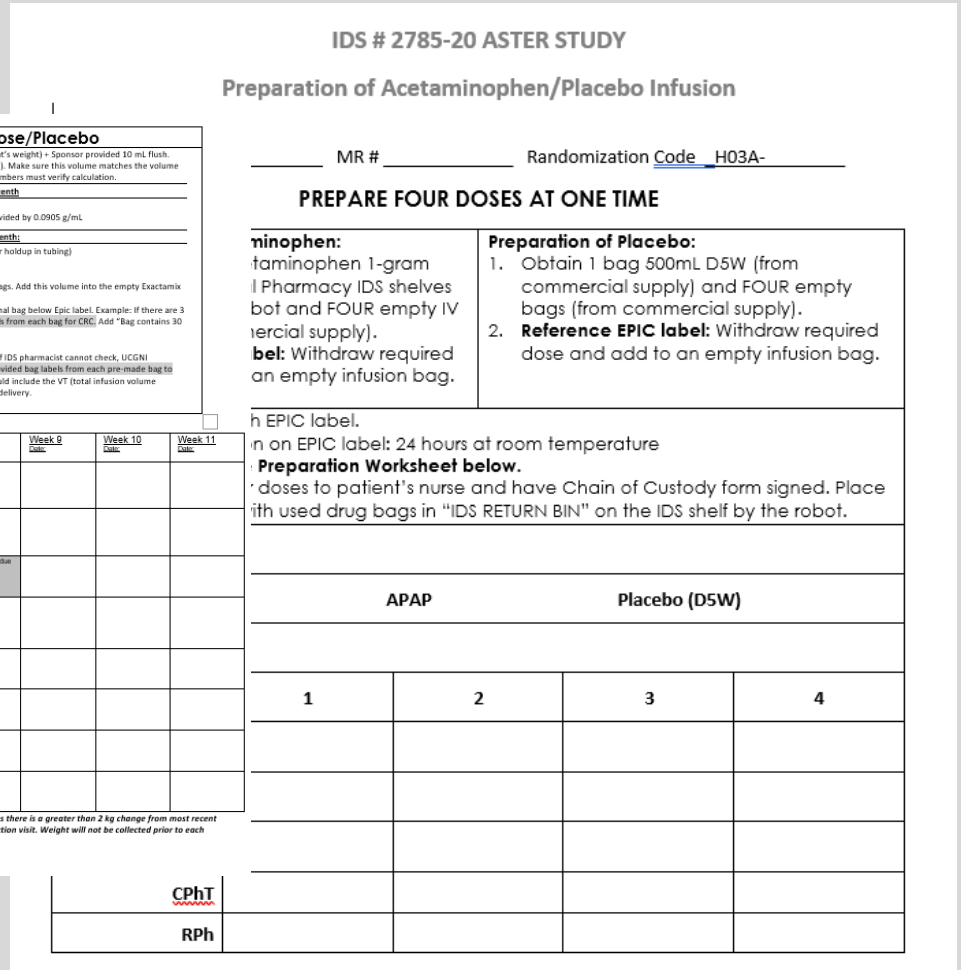
VT=Total volume to be infused (VTBI) + 30 mLs (to account for holdup in tubing)

c. Obtain empty EXACTAMIX 2000 mL bag.
d. Remove overwrap from the bags. Save the 3 tear-off labels on overwrap of each bag.
e. Withdraw the total infusion volume calculated from up to 4 premade Trehalose/Placebo bags. Add this volume into the empty Exactamix bag. Discard used bags in biohazard bin.
f. Affix EPIC label to infusion bag. Add the 2nd tear off label from each pre-made bag to the final bag below Epic label. Example: If there are 3 bags used to make final bag, apply 3 sponsor labels below Epic label. Save the other 2 labels from each bag for CRC. Add "Bag contains 30 mLs of overfill for holdup volume" highlighted sticker to final bag.
g. Send bag with Sponsor provided 10 mL NS flush syringe.
h. IDS pharmacist will check final product (if available) and deliver to UCGNI infusion center. If IDS pharmacist cannot check, UCGNI pharmacist can check and IDS technician can deliver to nurse. Give the other 2 sponsor provided bag labels from each pre-made bag to CRC in infusion center. Note to IDS pharmacist: Administration comment on Epic label should include the VT (total infusion volume prepared). VTBI should appear in the right upper corner of Epic label. Educate nurse upon delivery.

Date:	BASELINE Date:	Week 1 Date:	Week 2 Date:	Week 3 Date:	Week 4 Date:	Week 5 Date:	Week 6 Date:	Week 7 Date:	Week 8 Date:	Week 9 Date:	Week 10 Date:	Week 11 Date:
S calculation performed by												
S Calculation Double check performed by												
losing Weight (to nearest tenth)	Based on screening weight				**New weight due				**New weight due			
e overwrap removed from Bag #1												
XACTAMIX Bag Lot#/Expir.												
Volume prepared (VT)												
CPhT												
IDS RPh												

Weight will be collected at the following visits: Screening (weight from screening will be used for Baseline), Baseline, Week 4, Week 8, Week 16 and Week 24. The dose will not change unless there is a greater than 2 kg change from most recent ing weight during the most recent weight collection visit. Example: Screening weight can continue to be used up until week 24 if there hasn't been a >2 kg change during each weight collection visit. Weight will not be collected prior to each kly infusion. **Weight should be measured to the nearest tenth for dose calculation. The maximum infusion volume is 1200 mL total.**

k: MB 05JUL22/ 2nd check: JMH 06JUL22



IDS # 2785-20 ASTER STUDY

Preparation of Acetaminophen/Placebo Infusion

_____ MR # _____ Randomization Code H03A-_____

PREPARE FOUR DOSES AT ONE TIME

minophen:	Preparation of Placebo:
taminophen 1-gram l Pharmacy IDS shelves bot and FOUR empty IV ercial supply). **bel:** Withdraw required an empty infusion bag.	1. Obtain 1 bag 500mL D5W (from commercial supply) and FOUR empty bags (from commercial supply). 2. **Reference EPIC label:** Withdraw required dose and add to an empty infusion bag.

h EPIC label.
n on EPIC label: 24 hours at room temperature
Preparation Worksheet below.
doses to patient's nurse and have Chain of Custody form signed. Place ith used drug bags in "IDS RETURN BIN" on the IDS shelf by the robot.

	APAP		Placebo (D5W)	
	1	2	3	4
CPhT				
RPh				

Updated Fee Schedule

Table 1: Research Fee Schedule

Study Type	Study Subtype and Related Activities*	Start-Up Fee	Annual Fee	Closing Fee
Investigator-Initiated (i.e., no direct federal or industry oversight or involvement)	Standard	$750	$500	$500
	Complex	$1,500	$750	$500
	Special Complex	$2,000	$1,000	$500
Cooperative Group Federally-Funded Foundation Industry	Standard	$2,500	$2,000	$750
	Complex	$3,000	$2,250	$1,000
	Special Complex	$4,000	$2,500	$1,000

*Fees may be adjusted for non-funded and intramural-funded studies
#Annual fee will be marked up by $250 for studies with IP requiring refrigeration or freezer storage

Updated Fee Schedule

Electronic Medical Record Builds		
Epic Order Build for All Studies	Individual Order or Order Panel/Set with No More than 3 Options Beacon Infusion Plan	$750
	Order Panel/Set with More than 4 Options Beacon Treatment Plans	$1,000

Updated Fee Schedule

Miscellaneous Fees

- Patient-specific investigational product preparation forms: $20 per required page
- Temperature log requests outside of monitoring visit: $30 per request
- Extended storage of returned/expired inventory: $125 for every 3 months beyond return/expiration date
- Regulatory audit beyond routine study monitoring (e.g., FDA; NCI): $500 per audit

Why

- PRIIDE Values
  - **P**atients and Families First
  - Showing **R**espect
  - Acting with **Integrity**
  - Embracing **I**nclusion
  - Seeking **D**iscovery
  - Offering **E**mpathy
- “In Science Lives Hope”
- Academic Research Institution

Bexion Pharmaceuticals Doses First Patient in Phase I Trial of BXQ-350 For Patients with Advanced Solid Tumors at the University of Cincinnati Cancer Institute

FOR IMMEDIATE RELEASE

Margaret van Gilse
859-757-1652
mvangilse@bexionpharma.com

COVINGTON, KY. September 20, 2016- Bexion Pharmaceuticals, LLC ("Bexion") and the University of Cincinnati Cancer Institute (UCCI) announced today the dosing of the first patient in the Phase I trial of BXQ-350, a novel anti-cancer therapeutic agent.

This open-label trial will include adult patients with advanced solid tumors. The trial is designed to determine the maximum tolerated dose of BXQ-350 and to characterize its safety and pharmacokinetics. In pre-clinical animal studies, BXQ-350 was shown to induce tumor cell death in a variety of

UC, UC Health administer first doses in COVID-19 vaccine trial

Phase 3 clinical trial will evaluate efficacy of Moderna vaccine candidate

Jarelle Marshall, 37, an IT professional who lives in Cincinnati, was the first patient to receive the first dose in Cincinnati in a groundbreaking clinical trial that will evaluate the effectiveness of a vaccine for COVID-19, the respiratory illness caused by the novel coronavirus SARS-CoV-2. Photo/Colleen Kelley/UC Creative + Brand

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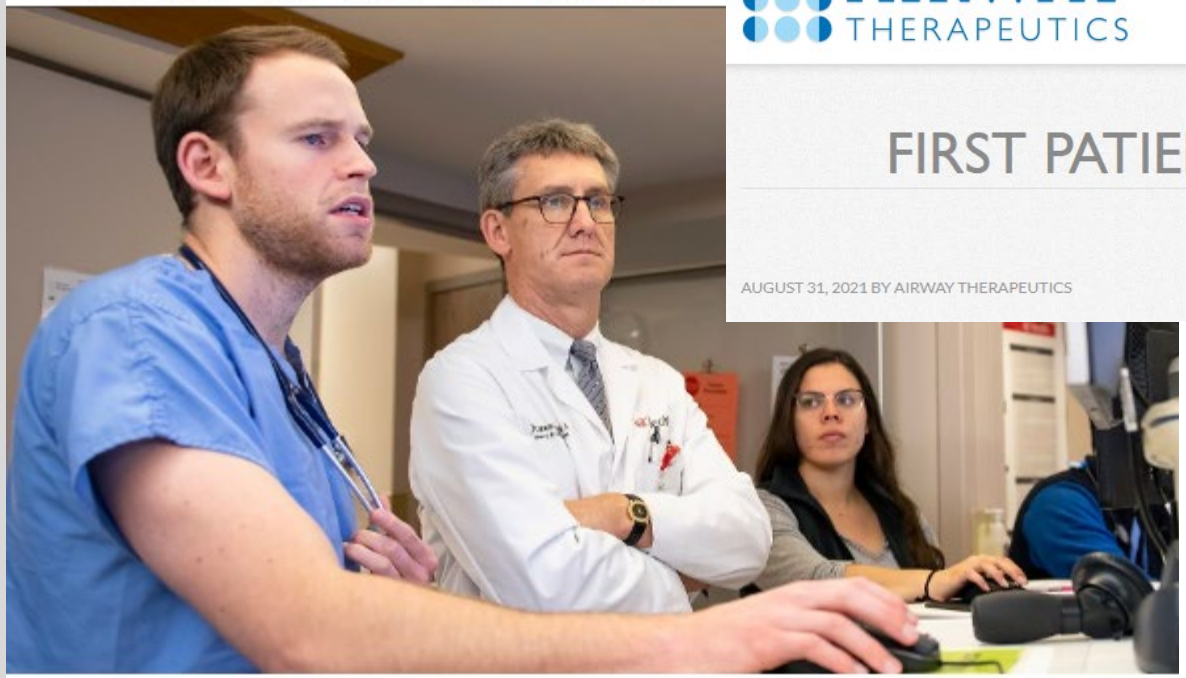


UC researchers administer investigational COVID-19 treatment

This first-of-its-kind therapy could mean a new option for patients severely impacted

AIRWAY THERAPEUTICS

ABOUT US PIPELINE BPD RESPIRATORY & INFLAMMATORY DISEASES NEWS CONTACT

FIRST PATIENT DOSED IN STARTUP'S KEY COVID-19 CLINICAL TRIAL

AUGUST 31, 2021 BY AIRWAY THERAPEUTICS

Airway Therapeutics Announces First Patient Dosed in Phase 1b Trial of AT-100 in Severe COVID-19 Patients

USA - English

Novel therapeutic AT-100 offers potential to reduce inflammation, associated injury and incidence of secondary infection, and inhibit viral replication and promote viral elimination in severely ill, mechanically-ventilated COVID-19 patients

Initial data readout anticipated in Q4 2021

COVID STUDY: TICO ACTIV-3

Tixagevimab–cilgavimab for treatment of patients hospitalised with COVID-19: a randomised, double-blind, phase 3 trial

ACTIV-3–Therapeutics for Inpatients with COVID-19 (TICO) Study Group†*

Summary

Background Tixagevimab–cilgavimab is a neutralising monoclonal antibody combination hypothesised to improve outcomes for patients hospitalised with COVID-19. We aimed to compare tixagevimab–cilgavimab versus placebo, in patients receiving remdesivir and other standard care.

Methods In a randomised, double-blind, phase 3, placebo-controlled trial, adults with symptoms for up to 12 days and hospitalised for COVID-19 at 81 sites in the USA, Europe, Uganda, and Singapore were randomly assigned in a 1:1 ratio to receive intravenous tixagevimab 300 mg–cilgavimab 300 mg or placebo, in addition to remdesivir and other standard care. Patients were excluded if they had acute organ failure including receipt of invasive mechanical ventilation, extracorporeal membrane oxygenation, vasopressor therapy, mechanical circulatory support, or new renal replacement therapy. The study drug was prepared by an unmasked pharmacist; study participants, site study staff, investigators, and clinical providers were masked to study assignment. The primary outcome was time to sustained recovery up to day 90, defined as 14 consecutive days at home after hospital discharge, with co-primary analyses for the full cohort and for participants who were neutralising antibody-negative at baseline. Efficacy and safety analyses were done in the modified intention-to-treat population, defined as participants who received a complete or partial infusion of tixagevimab–cilgavimab or placebo. This study is registered with ClinicalTrials.gov, NCT04501978 and the participant follow-up is ongoing.

Findings From Feb 10 to Sept 30, 2021, 1455 patients were randomly assigned and 1417 in the primary modified intention-to-treat population were infused with tixagevimab–cilgavimab (n=710) or placebo (n=707). The estimated cumulative incidence of sustained recovery was 89% for tixagevimab–cilgavimab and 86% for placebo group participants at day 90 in the full cohort (recovery rate ratio [RRR] 1·08 [95% CI 0·97–1·20]; p=0·21). Results were similar in the seronegative subgroup (RRR 1·14 [0·97–1·34]; p=0·13). Mortality was lower in the tixagevimab–cilgavimab group (61 [9%]) versus placebo group (86 [12%]; hazard ratio [HR] 0·70 [95% CI 0·50–0·97]; p=0·032). The composite safety outcome occurred in 178 (25%) tixagevimab–cilgavimab and 212 (30%) placebo group participants (HR 0·83 [0·68–1·01]; p=0·059). Serious adverse events occurred in 34 (5%) participants in the tixagevimab–cilgavimab group and 38 (5%) in the placebo group.

Interpretation Among patients hospitalised with COVID-19 receiving remdesivir and other standard care, tixagevimab–cilgavimab did not improve the primary outcome of time to sustained recovery but was safe and mortality was lower.

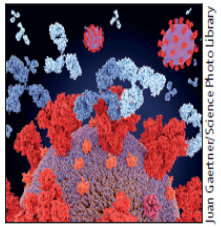
Monoclonals for patients hospitalised with COVID-19

Monoclonal antibodies that neutralise SARS-CoV-2 have consistently reduced hospitalisation or death in outpatients with mild to moderate COVID-19.[1–3] Conversely, results of randomised trials in patients who are hospitalised are mixed.[4–8] In *The Lancet Respiratory Medicine*, Thomas L Holland and colleagues present results of the ACTIV-3 trial comparing intravenous tixagevimab–cilgavimab with placebo for patients hospitalised with COVID-19.[8] Although tixagevimab–cilgavimab did not improve the primary outcome of time to sustained recovery (rate ratio [RR] 1·08 [95% CI 0·97–1·20]; p=0·21), it was associated with improved 28-day (6% *vs* 9%; p=0·02) and 90-day (9% *vs* 12%; p=0·03) mortality.

This study represents the third trial in which intravenous

despite no effect on the ordinal outcome scales, as was the case with tixagevimab–cilgavimab.

The effect of various therapies evaluated for COVID-19 on ordinal outcome scales has been inconsistent, and these scales have plagued findings of pandemic trials for several reasons. First, each step on the scale is not necessarily of equivalent clinical significance. Second, multiple non-clinical and non-COVID-19-related factors can influence recovery, depending on how recovery is defined. Finally, an intervention might halt progression of the disease course to more severe illness (a clinically important endpoint) yet fail to hasten symptom resolution or return to baseline functional status. Therefore, when evaluating COVID-19 therapeutics in patients hospitalised with severe disease, it might be



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See Online/Articles
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ADORE Pre-Natal Study

- IDS mailed out drug each week to patients across the US
- Largest trial to date
- 719 patients!
- We ADORE(D) Thursdays

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Research Paper

Higher dose docosahexaenoic acid supplementation during pregnancy and early preterm birth: A randomised, double-blind, adaptive-design superiority trial

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Early preterm birth
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Docosahexaenoic acid (DHA) amount

ABSTRACT

Background: Several meta analyses have concluded n-3 fatty acids, including docosahexaenoic acid (DHA), reduce early preterm birth (EPB, < 34 weeks), however, the amount of DHA required is unclear. We hypothesized that 1000 mg DHA per day would be superior to 200 mg, the amount in most prenatal supplements.

Methods: This randomised, multicentre, double-blind, adaptive-design, superiority trial was conducted in three USA medical centres. Women with singleton pregnancies and 12 to 20 weeks gestation were eligible. randomization was generated in SAS® by site in blocks of 4. The planned adaptive design periodically generated allocation ratios favoring the better performing dose. Managing study personnel were blind to treatment until 30 days after the last birth. The primary outcome was EPB by dose and by enrolment DHA status (low/high). Bayesian posterior probabilities (pp) were determined for planned efficacy and safety outcomes using intention-to-treat. The study is registered with ClinicalTrials.gov (NCT02626299) and closed to enrolment.

Findings: Eleven hundred participants (1000 mg, n = 576; 200 mg, n = 524) were enrolled between June 8, 2016 and March 13, 2020 with the last birth September 5, 2020. 1032 (n = 540 and n = 492) were included in the primary analyses. The higher dose had a lower EPB rate [1.7% (9/540) vs 2.4% (12/492), pp=0.81] especially if participants had low DHA status at enrolment [2.0% (5/249) vs 4.1%, (9/219), pp=0.93]. Participants with high enrolment DHA status did not realize a dose effect [1000 mg: 1.4% (4/289); 200 mg: 1.1% (3/271), pp = 0.57]. The higher dose was associated with fewer serious adverse events (maternal: chorioamnionitis, premature rupture of membranes and pyelonephritis; neonatal: feeding, genitourinary and neurologic problems, all pp>0.90).

Interpretation: Clinicians could consider prescribing 1000 mg DHA daily during pregnancy to reduce EPB in women with low DHA status if they are able to screen for DHA.

First IDS Study Utilizing MSU Launched in 2022!

IDS has registered over **3075 studies** at UC Health since 1968!!!

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Pharmaceuticals, Inc.

"To Save A Life Is To Save A Universe"

QUESTIONS?