2021 Research Pharmacy Summit

Session Details

October 1-2, 2021

Friday, October 1, 2021

10:00 – 11:15 am (EDT)

Knock, Knock - FDA is Here. Being Prepared for a Regulatory Inspection **UAN: | 0.1CEU/1.0 hours**

Understanding and preparing for regulatory inspections is vital for compliance, data integrity, and continued research support. This session will explore the proceedings of an audit and discuss the available toolkit of items to be used by clinical researchers and clinical pharmacists to ensure a successful audit.

Upon completion of the session, Pharmacists and Pharmacy Technicians will be able to:

- Identify the key resources and locations to find inspectional information.
- Understand the meaning of an FDA-483 and support the formulation of appropriate responses.
- Define and recognize BIMO Metrics and commonly cited observations during an audit.

SPEAKER

Eric S. Pittman, MBA
Director of the FDA/ORA Bioresearch Monitoring Program Division II (BIMO-W)
Chicago, IL

11:15 am – 12:30 pm (EDT)

CONNECT

Visit the RPS Exhibit Hall, join a discussion, or network with your colleagues.

12:30 – 1:45 (EDT)

Off the Beaten Path: Exploring Opportunities for Technicians within IDS Pharmacy

UAN: | 0.1CEU/1.0 hours

IDS Pharmacies are confronted with staffing and workflow challenges due to a unique niche practice. Examining different roles of the IDS pharmacy technician can help to optimize the use

of technology and improve overall workflow efficiency of the IDS team. This session will explore novel opportunities within the IDS pharmacy where technicians can play a leading role.

Upon completion of the session, Pharmacists and Pharmacy Technicians will be able to:

- Identify common areas of workflow inefficiencies within the IDS pharmacy where the skills of an IDS Technician can be utilized to lead improvement processes.
- Discuss the key tasks associated with these workflows where the IDS Technician can play a pivotal role.
- Examine the needs associated with advancing technology in the IDS pharmacy, such as the EMR, electronic drug accountability software, and CTMS systems, and discuss where the IDS Technician can be utilized to support integration initiatives.

SPEAKER

Mindy Suttlemyre, BS, CPhT
Lead Technician, Investigational Drug Service
University of Utah/Huntsman Cancer Hospital
Salt Lake City, Utah

1:45 – 3:00 (EDT)

CONNECT

Visit the RPS Exhibit Hall, join a discussion, or network with your colleagues.

3:00 – 5:15 (EDT)

One Size Doesn't Fit All – Aspects of Site Infrastructure on Clinical Trial Management in Investigational Pharmacies, a Panel Discussion

UAN: | 0.2CEU/2.0 hours

Differences in clinical trial set-up, physical site organization and infrastructure, and varying requirements from sponsors create logistical challenges for IDS Pharmacies in the storage, transport, training, and management of inventory and patients. Stringent restrictions and definitions from NCI/NIH & Consortium Groups on trial set-up and conduct, along with compliance to USP-800, add dimension to this challenge. Recent events, such as the COVID-19 pandemic, has further highlighted the need for 24/7 access to clinical trial participation across multiple sites including remote locations. This session will explore various solutions from clinical trial sites to guide and educate practitioners on best practices and procedures.

Upon completion of the session, Pharmacists and Pharmacy Technicians will be able to:

- Describe medication distribution models for implementation of clinical trials across multiple sites, including remote locations.
- Differentiate various strategies in the implementation and support of clinical trials during IDS off-hours.

- Identify key policies associated with successful implementation of research across multiple locations, such as Delegation of Authority, training, and transport.
- Compare and contrast solutions for compliance with USP800 at various sites, including IP classification, storage, and workflows.

SPEAKERS

Hallie Barr, PharmD, BCOP
Pharmacy Manager - Investigational Drug Service
PGY2 Investigational Drugs and Research Residency Program Director
The Ohio State University Wexner Medical Center and James Cancer Hospital
Columbus, OH

Alison Grimsley, PharmD, BCPS, BCPPS
Investigational Drug Service Research Clinical Pharmacist
PGY2 Pediatric Residency Program Director
Cone Health Moses H Cone Memorial Hospital
Greensboro, NC

Kim Redic, PharmD
Manager, Research Pharmacy and Clinical Assistant Professor
Residency Program Director
Michigan Medicine
Ann Arbor, MI

Mindy Waggoner, PharmD, BCOP
Oncology & Investigational Drug Services Pharmacy Manager
Froedtert & Medical College of Wisconsin
Milwaukee, WI

5:15 – 6:30 pm (EDT)

CONNECT

Visit the RPS Exhibit Hall, join a discussion, or network with your colleagues.

Saturday, October 2, 2021

10:00 am – 12:15 pm (EDT)

Turning Adversity to Opportunity: Investigational Drug Services 2021 and Beyond

UAN: | 0.2CEU/2.0 hours

The COVID-19 pandemic has had a profound effect on how we care for patients on clinical trials. Our innovation in performing telehealth visits, allowing local laboratory assessments, and introducing wearable technology has forged a new frontier in the oversight and operation of

clinical trials. This session will examine challenges faced during the Coronavirus Disease 2019 (COVID-19) pandemic and adaptations that occurred to care for the clinical trial patient. Efficiencies gained by pharmacists and pharmacy technicians in investigational drug services during COVID-19 by will allow for enhanced clinical trial visibility and accessibility across the globe. Opportunities for advancement of pharmacy services, inclusivity of a diverse clinical trial population, and preparedness for future emergencies will be discussed.

Upon completion of the session, Pharmacists and Pharmacy Technicians will be able to:

- Distinguish differences in clinical trial conduct before, during and after the COVID-19 public health emergency.
- Describe advancements in technology that allow for virtual visits and patient-centered care on clinical trials.
- Identify opportunities to enhance diversity, equality and inclusion in clinical trial enrollment.
- Develop efficient investigational drug service (IDS) procedures and clinical touch points to increase safety and efficacy of patients on clinical trials in the post-COVID-19 era.
- Devise strategies for IDS pharmacy services for treatment of patients across the globe and future emergency preparedness.

SPEAKER

Heidi Finnes, PharmD, BCOP, FHOPA
Senior Manager, Pharmacy Cancer Research
Director Pharmacy Shared Resource
Mayo Clinic Cancer Center
Rochester, MN

12:15 – 1:30 pm (EDT)

CONNECT

Visit the RPS Exhibit Hall, join a discussion, or network with your colleagues.

1:30 – 2:45 (EDT)

Good Bill Hunting: Establishing and Tracking IDS Pharmacy Fees

UAN: | 0.1CEU/1.0 hours

IDS best practices define that a budget should be established to support the clinical research pharmacy. Various models may exist for research pharmacy fees and budgeting practices can have a wide variability across sites. This session will review strategies on how to develop, track and utilize data from an IDS fee schedule.

Upon completion of the session, Pharmacists and Pharmacy Technicians will be able to:

- Describe strategies for developing an IDS Pharmacy fee schedule.
- Detail processes for pharmacy billing and charge capture.
- Evaluate current challenges in research pharmacy billing.

SPEAKER

Annie Yi, PharmD
Manager, Investigational Drugs
City of Hope National Medical Center
Duarte, CA

2:45 – 3:00 pm (EDT)

Break

Catch your breath – there's more to come!

3:00 – 4:15 (EDT)

The Wonder Years: Clinical Pearls from IDS Residency

UAN: | 0.1CEU/1.0 hours

Out of Orbit: Optimizing Workflow at IDS Satellite Sites

Many investigational drug service (IDS) systems involve satellite sites. Employing satellite sites and pharmacists who are not formally trained in IDS may present challenges to the health system. This clinical pearl will review some of the training and management techniques used for non-IDS staff.

Upon completion of the session, Pharmacists and Pharmacy Technicians will be able to:

- Describe training and management tools that may be useful in training non-IDS staff at satellite sites.
- Evaluate available opportunities to optimize IDS functions at satellite sites.

SPEAKER

Matthew Murphy, PharmD
Research and Oncology Clinical Pharmacist II
Yale New Haven Health
New Haven, CT

Scan it! Evaluating the Use of Barcodes in the Investigational Drug

Barcode technology can be incorporated into the medication use process to increase patient safety. Multiple organizations, including ISMP, ASHP, and HOPA, have recommended the use of barcode technology for investigational products to help mitigate risks in the clinical research setting. This clinical pearl will review one institution's assessment of barcode scanning practices for standard-of-care medications, determine whether these practices can be applied to

investigational products, and describe some of the unique challenges that exist with barcoding of investigational products.

Upon completion of the session, Pharmacists and Pharmacy Technicians will be able to:

- Describe how barcodes can be used to increase medication and patient safety.
- Identify challenges with barcoding that are unique to investigational products.

SPEAKER
Michelle Yu, PharmD, BCPS
The Johns Hopkins Hospital
Baltimore, MD

Expanding Frontiers: Utilizing Investigational Drugs Outside of Clinical Trials

Investigational medical agents are routinely provided to patients as part of clinical trials for the purpose of clinical research. However, Expanded Access, Right to Try, and Emergency Use Authorization are mechanisms that allow patients to directly obtain investigational agents to treat a condition. This presentation will compare the eligibility criteria, the required stakeholders, the types of investigational agents that can be obtained, and the regulatory requirements for these pathways.

Upon completion of the session, Pharmacists and Pharmacy Technicians will be able to:

- Compare available programs for accessing investigational products outside of clinical trials, including Expanded Access, Right to Try, and Emergency Use Authorization.
- Describe the relevant regulatory obligations for IDS for each of the three pathways.
- Identify roles for pharmacists to assist in the Expanded Access process and the management of patients receiving investigational drugs through Expanded Access.

SPEAKER
Andrew Smith, PharmD
Clinical Pharmacist Specialist
Michigan Medicine
Ann Arbor, MI

4:15 – 6:00 pm (EDT)

CONNECT

Visit the RPS Exhibit Hall, join a discussion, or network with your colleagues.

Course Information

Registration Fee

Pharmacists Registration (Early): $200
Residents and Technicians Registration (Early): $150
Early registration ends on 9/26.

Pharmacists Registration (After 9/26): $250
Residents and Technicians Registration (After 9/26): $200

Contact McCreadie Group at info@mccreadiegroup.com (prior to registering) for a group discount if 4 or more people from your site will be attending.

No refunds will be made.

Continuing Pharmacy Education (CPE) Information

The Research Pharmacy Sessions were developed with the support of the The National Center for Interprofessional Practice and Education's Office of Interprofessional Continuing Professional Development (OICPD). The OICPD is accredited by the Accreditation Council for Pharmacy Education (ACPE) to provide continuing education for the healthcare team.

Following successful participation in the conference, an activity evaluation, and verification of attendance, participant data will be submitted to The Monitor within 60 days.

After the event, course recordings are available for viewing on the Socio platform, but on-demand courses will not be eligible for CE credit.