Research Pharmacy Summit
2024 Program

Virtual | September 12-13, 2024

Thursday, September 12, 2024

11:00 am - 12:15 pm (ET)

Oh, the Places You'll Go! Exploring Best Practices Across Institutions

0.1 CEU/1.0 hours

Investigational Drug Service (IDS) practices vary widely across institutions. This session will explore effective strategies for creating and upholding best practices within IDS. Topics will include adhering to current best practice recommendations and guidelines, developing and enforcing policies, establishing successful satellite sites, expanding the roles of IDS personnel, advocating for additional staff, and implementing strategies to streamline daily operations.

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

- Summarize best practices and guidelines for IDS from ASHP, HOPA, and NCCN
- Explore policy development and enforcement strategies within IDS to ensure regulatory compliance
- Outline steps for establishing and operating satellite sites within the IDS framework
- Expand IDS personnel roles and staff numbers using metrics and assessments
- Compare strategies for streamlining IDS operations, including budgeting, standardized forms, electronic accountability, and document organization

SPEAKERS

Erica Gray, PharmD, BCPS
Clinical Pharmacist
Duke University Hospital

Brennen Guzik, PharmD
Clinical Pharmacist
Duke University Hospital

12:15 pm - 12:45 pm (ET)

Keynote Presentation

Non-CE Session

Embracing Technology and Collaboration within IDS Research Services

KEYNOTE SPEAKER

Mathew Ajjarapu, PharmD, MSHI
EPIC Analyst/IT Implementation Clinical Pharmacist
UI Health

12:45 pm - 1:30 pm (ET)

Break

1:30 pm - 2:45 pm (ET)

Stop, Drop and Roll... Out Medication Safety and QI initiatives in IDS

CEU/1.0 hours

Panel Discussion featuring four IDS Pharmacists from two leading institutions on Medication Safety and Quality Improvement.

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

- Discuss recent QI and medication safety projects that were implemented at various sites including barcode validation, smart pump integration, spreadsheet development for eMAR builds, and standardization of emergency medications for infusion reactions
- Explain how these initiatives were implemented and identify notable impacts
- Recognize how quality improvement projects allow for interdepartmental collaboration and growth
- Identify barriers to adoption and implementation, challenges, and lessons learned from QI projects in IDS
- Recognize areas for future safety and potential quality improvements in IDS

SPEAKERS

Kyle W. Richards, PharmD, BCPPS
Manager, Investigational Drug Services
University of Rochester Medical Center

Renee Bailey, PharmD
Pharmacist, Oncology Investigational Drug Service
Wilmot Cancer Center

Obehi Enabulele, PharmD, MBA, MS
Clinical Pharmacist, Investigational Drug Services
Children's Colorado Hospital

Elizabeth Shields, PharmD, BCPS
Clinical Pharmacist
Children's Hospital Colorado

2:45 pm - 3:00 pm (ET)

Break

3:00 pm - 4:15 pm (ET) **Concurrent Session**

A Primer on Regulatory and Best Practice Guidelines for Non-Sterile Compounding Success

0.1 CEU/1.0 hours

The revisions to USP<795> in November 2023 significantly impacted existing non-sterile compounding activities in Investigational Drug Services (IDS). This educational session will cover the relevant regulations concerning compounded non-sterile products (CNSP). It will also discuss the most commonly used CNSP dosage forms used in clinical trials, including specific considerations and applicable regulations for each form. Lastly, strategies will be reviewed for supporting local investigators in their regulatory submissions for studies involving CNSPs.

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

- Describe regulations that apply to non-sterile compounding programs
- Recall compounded non-sterile preparation (CNSP) dosage forms commonly utilized in clinical trials
- Understand the pharmaceutical monograph, certificate of analysis, preparation instructions, and FDA chemistry, manufacturing & control (CMC) related requirements of an IND application

SPEAKER

Kevin Zinchuk, PharmD, CCRP
Manager, Investigational Drug Service
Brigham and Women's Hospital

3:00 pm - 4:15 pm (ET) **Concurrent Session**

Expanding Research Horizons: Considerations When Growing Your Research Pharmacy to Regional Sites

0.1 CEU/1.0 hours

Research pharmacy professionals are well-positioned to ensure regulatory and protocol compliance and consistency across multiple regional sites, provided they are prepared to adapt to the unique characteristics of each site. Establishing a new research site is nuanced and requires specialized knowledge and planning. This presentation aims to equip attendees with the insights needed to navigate regulatory pitfalls and to recognize what is myth and what is reality, so they can grow their research services safely and effectively.

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

- Discuss why adding regional sites may be important to recruitment and reach
- Identify regulatory distinctions between control sites, satellite sites, and more
- Recognize important barriers and facilitators of regional site expansion
- Provide real world examples of regional research site successes and setbacks
- Discuss the importance of work force capacity, site champions, and other considerations

SPEAKER

Doug Parr, PharmD
Supervisor, Investigational Research Drug Services
Dartmouth-Hitchcock Medical Center

4:15 pm - 5:15 pm (ET)

Sharing Solutions: RPS Moderated Discussions

Join a virtual group discussion and share your ideas, experience, and solutions. Each discussion is focused on a central question and will be led by an experienced moderator.

5:15 pm - 6:30 pm (ET)

Toss it! Lightening the IDS Load by Transitioning to a Paperless System

0.1 CEU/1.0 hours

Communication necessary for initiating and sustaining trials, such as shipping invoices, temperature records, expiration notices, certificates of analysis, and correspondence related to investigational products and research subjects, has historically been documented in physical study binders. However, in the post-COVID virtual landscape, relying on paper-based Investigational Drug Service (IDS) records proves inefficient for monitor visits and audits. Transitioning to electronic record-keeping offers efficiency and enables seamless access to information.

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

- Create an SOP and workflow for electronic recordkeeping
- Develop a training tool for staff and assess staff competency
- Determine and execute go-live transition

SPEAKER

Anu Pradhan, RPh, PhD, BCOP
Investigational Drug Services Manager
Moffitt Cancer Center

Friday, September 13, 2024

11:00-12:15 (ET)

Work Hard, Report Smart: Using the IDS Complexity Scoring Tool to Assess Effort in Clinical Trials

0.1 CEU/1.0 hours

Managing investigational products in research pharmacies requires varying levels of effort, especially as clinical trials continue to grow more complex. This presentation introduces a validated complexity scoring tool, developed by the Vizient Pharmacy Research Committee Investigational Drug Services (IDS) Subcommittee, to assign a complexity score for pharmacy work in study initiation and maintenance. The session will cover the need for this tool and provide guidance on its applications to advance IDS pharmacy practices.

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

- Identify factors that affect the amount of effort required to manage IP for study initiation and maintenance
- Explain how to use the complexity scoring tool for clinical trials at individual sites
- Explore how the complexity scoring tool can be used to assess the workload involved with managing IP in clinical trials

SPEAKERS

Rachel McLuckie, PharmD, BCPS
Clinical Research Pharmacist
The University of Toledo Medical Center

Kangwon (Christina) Song, PharmD
Clinical Research Pharmacist
AU Medical Center at Augusta University

Michelle Yu, PharmD, BCPS
Manager, Investigational Drug Services Pharmacy
University of Chicago Medicine

12:15 pm – 1:30 pm (ET)

Pixels & Prescriptions: Navigating the Digital Landscape in Research Pharmacy

0.1 CEU/1.0 hours

Panel Discussion featuring four IDS Pharmacists from a variety of clinical practices on Optimizing IDS operational efficiency with technology integrations.

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

- Describe initiatives and rollout processes for incorporating technology platforms into IDS operations; specifically, electronic order sets and treatment plans, IV workflow solutions, and clinical trial management systems
- Plan and employ collaboration tactics with IT and other departments to prepare for success
- Recall achievements and challenges to optimize future success and continued maintenance

SPEAKERS

Megan Leiser, PharmD
Investigational Drug Services Pharmacy Supervisor
Advent Health Orlando

Cara Morton, PharmD
Clinical Research Pharmacist
Highlands Oncology

Jennifer Vyskocil, PharmD, MPH
Clinical Pharmacy Specialist
Michigan Medicine

Vy Bui, PharmD, BCPS
Investigational Drug Service Pharmacist
Indiana University, Simon Cancer Center

1:30 pm - 2:15 pm (ET)

RPS Award Ceremony

Non-CE Session

Celebration of the winner of the 2024 Research Pharmacy Summit Award for Excellence and Innovation.

2:15 pm – 3:30 pm (ET) **Concurrent Session**

Navigating USP 800 Compliance in an IDS: Classification, Handling, and Best Practices

0.1 CEU/1.0 hours

Implementing USP 800 poses significant challenges for healthcare institutions. Investigational Drug Services (IDS) encounter an additional layer of complexity due to the unique requirements of investigational agents. In contrast to commercial drugs, investigational agents often lack sufficient data to guide safe handling practices, necessitating careful assessment of their hazards and exposure potential. Beyond USP 800, investigational pharmacies regularly face new challenges at the forefront of new drug and cellular therapy developments. This session will provide strategies to guide IDS pharmacies in the evaluation, classification, and handling of investigational agents and in navigating the integration of institutional standards while simultaneously developing IDS policies and procedures to address gaps that exist.

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

- Define USP 800 standards
- Discuss considerations for handling hazardous drugs
- Select appropriate USP 800 risk assessment strategies for classification of investigational products
- Identify IDS challenges beyond USP 800

SPEAKERS

Kristen Gonzales, CPhT
Certified Pharmacy Technician, Investigational Drug Services Pharmacy
Children's Hospital Colorado

Alison Grimsley, PharmD, MBA, BCPS, BCPPS
Investigational Drug Service Supervisor
Children's Hospital Colorado

2:15 pm – 3:30 pm (ET) **Concurrent Session**

Get in the Fast Lane: An IDS Contribution to Reducing Clinical Trial Activation Timelines

0.1 CEU/1.0 hours

To reduce the clinical trial activation timeline at Froedtert & the Medical College of Wisconsin, the Investigational Drug Service (IDS) contributed to the reduction of the treatment plan review period by over seventy percent. This presentation outlines the site's three-phase overhaul of their previous process, highlighting the creation of a multidisciplinary feasibility committee that assesses study viability and streamlines communication. The session will explore potential process changes and their impact on accelerating the delivery of oncology treatment plans.

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

- Describe the role of IDS in the clinical trial activation process
- Identify three ways that IDS can contribute to the reduction of the clinical trials activation timeline
- Design and implement changes to decrease clinical trials activation based on the described process in this presentation

SPEAKER

Emma Carroll, PharmD, BCOP
Investigational Drug Pharmacist
PGY2 Oncology Pharmacy Residency Program Director
Froedtert Hospital and Medical College of Wisconsin

3:30 pm – 4:30 pm (ET)

Sharing Solutions: RPS Moderated Discussions

Join a virtual group discussion and share your ideas, experience, and solutions. Each discussion is focused on a central question and will be led by an experienced moderator.

4:30 pm – 4:45 pm (ET)

Break

4:45 pm - 6:00 pm (ET)

Raising the Platform: Exploring Pharmacy Impacts of Novel Trial Designs

0.1 CEU/1.0 hours

Cancer therapies are evolving from traditional chemotherapy to innovative treatments such as targeted agents. The novel mechanisms of these pipeline drugs necessitate changes in the landscape of clinical trial design. This presentation will explore model-based, model-assisted, and adaptive trial designs. It will highlight the benefits and drawbacks of these new approaches, while addressing the impacts on investigational drug services.

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

- Recognize the need for new trial designs
- Describe novel phase I and adaptive trial designs
- Examine the drawbacks and benefits of phase I trial designs
- Analyze the impact of trial designs on real-world research pharmacy practice

SPEAKERS

Amanda Sabol, PharmD, MPH, BCPS
Assistant Director of Pharmacy
The Ohio State University Wexner Medical Center

Naomi Digiantonio, PharmD, BCPS, BCOP
Specialty Practice Pharmacist - Clinical Treatment Unit Pharmacist
The James Cancer Hospital at Ohio State University

Course Information

Registration Fee and Discounts

Pharmacists Registration (Early): $225
Residents and Technicians Registration (Early): $175
Early registration ends on August 31st at midnight.

Pharmacists Registration (Begins 9/1/2024): $275
Residents and Technicians Registration (Begins 9/1/2024): $225

Contact McCreadie Group at info@mccreadiegroup.com (prior to registering) for a 25% group discount if 4 or more people from your site will be attending. Cancellations made by the end of the day on Sunday, September 8, 2024 will receive a 90% refund.

Continuing Education

Attendees can earn up to 8 live hours of Continuing Pharmacy Education (CPE) credits.

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 completion of the conference materials, participants must complete an activity evaluation and verification of attendance by November 1, 2024. Participant data will be submitted to The Monitor within fourteen (14) days.