Friday, October 16, 2020

7:00 pm (EDT)
Welcome, from the McCreadie Group

7:15 – 9:15 pm (EDT)
Implementation of Innovation: Setting Your Site Up for Success
UAN: 0107-0000-20-218-L04-P · UAN: 0107-0000-20-218-L04-T | 0.2ceu/2.0 hours

Adoption and implementation of best practices in investigational drug activity is critical to improve patient safety, enhance efficiency, and provide the justification necessary to support innovation. This session will gather best practices and drive innovation at your site through dialogue with experts and your peers.

Upon successful completion of this knowledge-based course Pharmacists and Pharmacy Technicians should be able to:

- Review best practices for the operation of investigational drug services within both pediatric and adult environments.
- Describe approaches to developing and utilizing Standard Operating Procedures (SOPS) to ensure a successful service.
- Develop a standardized approach to documentation that includes strategies for paperless or paper-light operations.
- Discuss common barriers and uncover evidence-based strategies for implementation of new ideas.

(Pediatric)
Meghan Tolan Wagner, PharmD, MBA
Manager, IDS
Children’s National Hospital
Washington, DC

(Adult)
Elyse Macdonald, PharmD, MS, BCPS
Pharmacy Manager, IDS
University of Utah Health
Park City, UT

9:15 – 10:00 pm (EDT)
Virtual Cocktail Hour/Networking

Network with your peers virtually by joining an informal meeting room.
Saturday, October 17, 2020

10:00 - 11:00 am (EDT)

Let Me Show You Love: Building Strong Sponsor Relationships
UAN: 0107-0000-20-220-L04-P · UAN: 0107-0000-20-220-L04-T | 0.1 CEU/1.0 hour

This session will provide perspectives from both sponsor and IDS perspectives. Presenters representing both perspectives will discuss challenges relative to competing interests between protocol requirements and institutional practice standards, best practices for effective communication between IDS personnel and sponsors, and strategies for managing expectations from all of the various stakeholders relative to a particular study or project.

Upon successful completion of this knowledge-based course Pharmacists and Pharmacy Technicians should be able to:

- Discuss common obstacles and barriers between sponsors and sites.
- Identify methods for effectively communicating with sponsors.
- Explore approaches to managing expectations from various stakeholders to ensure clinical trial success.
- Discuss key attributes of a strong sponsor and site relationship.

Fae Gwen Wooding, Pharm D
Director, Clinical Research Pharmacy
Pfizer, Inc.
Marlborough, MA

Sapna Amin, PharmD, BCOP
Manager
MD Anderson Cancer Center
Houston, TX

11:00 am - 12:00 pm (EDT)

Adapting Investigational Drug Services in a Pandemic: Lessons Learned and Future Opportunities
UAN: 0107-0000-20-219-L04-P · UAN: 0107-0000-20-219-L04-T | 0.1 CEU/1.0 hour

No one could have anticipated that 2020 would teach us so many lessons about pandemics and public health emergencies. This session will look back at the learnings from COVID-19 and explore the implications investigational drug services (IDS) face moving forward.

Upon successful completion of this knowledge-based course Pharmacists and Pharmacy Technicians should be able to:

- Identify resources to stay abreast of quickly emerging evidence and rapidly changing guidelines to respond effectively in a pandemic or health emergency.
- Discuss strategies for navigating staffing reductions, scheduling, and transitioning to a remote workforce in response to a pandemic or other emergency.
- Describe potential changes needed in process and protocols when planning for an emergency.
- Review opportunities to evolve current IDS pharmacy services for future preparedness.
Heidi Finnes, PharmD, BCOP, FHOPA  
Senior Manager Cancer Research  
Mayo Clinic  
Rochester, MN

12:00 - 12:30 pm (EDT)  
Break

12:30 pm - 1:30 pm (EDT) - Concurrent Round Table Sessions  
Round Table 1: USP 800 Challenges and Successes  
UAN: 0107-0000-20-223-L07-P · UAN: 0107-0000-20-223-L07-T | 0.1 CEU/1.0 hour

USP 800 highlights the importance of evaluating and classifying investigational drugs. This session will provide an overview of USP 800 requirements as they apply to investigational drug service (IDS) activities and provide opportunity for discussion among attendees to share best practices in the development of infrastructure, processes, and policies needed to ensure USP 800 compliance in your IDS activities.

Upon successful completion of this application-based course Pharmacists and Pharmacy Technicians should be able to:
- Review USP800 requirements and their relevance for investigational drug services.
- Develop infrastructure, processes, and policies to comply with USP800.

Anay Moscu, PharmD, BCPS, BCOP  
IDS Manager  
Moffit Cancer Center  
Wesley Chaper, FL

12:30 pm - 1:30 pm (EDT) – Concurrent Round Table Sessions  
Round Table 2: Transducing Gene, Viral, and Vector Studies into the IDS Landscape  
UAN: 0107-0000-20-224-L04-P · UAN: 0107-0000-20-224-L04-T | 0.1 CEU/1.0 hour

There are unique aspects to gene/viral/vector studies that may require changing and adapting different procedures. This discussion-based session will focus on these unique trials and what different approaches need to be taken for storage, handling and dispensing of these therapies.

Upon successful completion of this knowledge-based course Pharmacists and Pharmacy Technicians should be able to:
- Review unique aspects of managing gene/viral/vector studies requiring process modifications or deviations from other procedures.
- Discuss appropriate storage, handling, and dispensing protocols for gene/viral/vector studies.
- Coordinate with the research team to dispense medication to patients.
John Petrich, MS RPh  
IDS Manager  
Cleveland Clinic  
Cleveland, OH

12:30 pm - 1:30 pm (EDT) - Concurrent Round Table Sessions

**Round Table 3: Up Close & Virtual: How Hybrid/Virtual Trial Design Impacts Pharmacy Services**

Virtual and hybrid trials are becoming more and more prevalent, simultaneously presenting great opportunities (and some challenges) for investigational drug services. This discussion-based session will explore opportunities and challenges for pharmacy services relative to these trials. Participants will also engage in conversation around strategies and expectations of stakeholders, including sponsors and regulators.

_Upon successful completion of this knowledge-based course Pharmacists and Pharmacy Technicians should be able to:_

- Discuss the challenges and opportunities associated with virtual and hybrid trials for an investigational drug service (IDS).
- Describe strategies for managing challenges and needed change relative to the use of virtual/hybrid trial structures.
- Explore potential changes in expectations from sponsors and regulators relative to virtual/hybrid trials.

R'Kes Starling, RPh, MBA  
CEO/President  
Reveles Clinical Services  
Southlake, TX

1:30 - 2:30 pm (EDT)

**Get On Track: Measuring and Reporting Metrics**

Utilizing metrics to track productivity is vital to assessing current performance and anticipating future department needs. Many types of internal and external metrics have been identified and used in health-system pharmacy but may not directly apply to an Investigational Drug Services Pharmacy. This course will identify metrics used to track productivity within health-system pharmacies, clinical trial departments, and investigational drug services pharmacies. Strategies will be discussed to help IDS pharmacies generate elective metrics and reporting methods to track and performance and anticipate future department needs.
Upon successful completion of this application-based course Pharmacists and Pharmacy Technicians should be able to:

- Describe metrics used within health-system pharmacy to measure performance.
- Identify data commonly tracked within clinical trial departments.
- Develop metrics that appropriately monitor performance in and IDS pharmacy.
- Generate effective reporting methods to track productivity in an IDS pharmacy.
- Evaluate IDS pharmacy metrics to anticipate future department needs.

Ryan Bender, PharmD
IDS Pharmacy Supervisor
Atrium Health
Charlotte, NC

2:30 - 3:30 pm (EDT)
It’s About the Money: Successful Billing of Self-Sufficient Services
UAN: 0107-0000-20-222-L04-P · UAN: 0107-0000-20-222-L04-T | 0.1 CEU/1.0 hour

This session will examine budget and financial issues that can often create challenges as investigational drug services move toward a self-sufficient model. Best practices in tracking, documenting, and reporting reimbursement funds will be discussed to ensure organizational goals are met.

Upon successful completion of this knowledge-based course Pharmacists and Pharmacy Technicians should be able to:

- Describe the components of a successful billing process model for self-sufficient services.
- Discuss challenges relative to implementing a billing process relative to self-sufficient services and strategies to address them.
- Review best practices for tracking, documenting, and reporting reimbursement funds.
- Identify opportunities to improve the IDS budget and finances.

Susan Rogers, BS Pharmacy
RPh Director, CRP Investigational Drug Services
Emory University School of Medicine
Atlanta, GA
Course Information

Registration Fee

**Early Registration:** $200 good through 9/30/2020

**Registration:** $250 good through 10/16/2020

**Residents and Technicians:** $150 good through 10/16/2020

No refunds will be made for cancellation requests as attendees are able to attend on-demand sessions and receive the CE credits at a later date convenient for the attendee.

Continuing Pharmacy Education (CPE) Information

CEImpact is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Participants will receive CPE codes for the live (virtual) courses they attend and will be required to complete an online exam and evaluation on CEImpact’s LMS by November 15, 2020. Once successfully completed, click the Submit button. The CPE Statement of Credit can then be accessed on CPE Monitor, www.MyCPEMonitor.net.