VIRTUAL CLINICAL TRIALS IN DRUG DEVELOPMENT CONFERENCE

May 22-23, 2019

The Inn at Penn – Philadelphia, PA

DYNAMIC GLOBAL EVENTS

Day One: Wednesday, May 22, 2019

8:00 AM – 9:00 AM - Registration & Breakfast

9:00 AM – 9:15 AM - Chairperson's Opening Remarks

9:15 AM – 10:00 AM - Keynote Address: Re-Imagining the Clinical Trial Process; Explore the Benefits of Virtual Clinical Trials

- The movement from traditional clinical trials to full virtual and hybrid trials
- What technologies are making the switch easier?
- Addressing challenges that are making the adoption of virtual trials difficult for large pharma
- Obstacles to gathering an incorporating mobile data into clinical trials

Craig Lipset, *Head of Clinical Innovation*
PFIZER

10:00 AM – 10:30 AM - Networking & Refreshment Break

10:30 AM – 11:15 AM - Going Back to the Beginning: Re-Structuring and Designing Internal Processes for Virtual Trials

- Building a framework internally to help virtual trials become more successful
- Fundamental process questions to answer before buying a technology
- Correctly implementing new processes within your organization
- Understanding the skillsets required to capture and utilize data

11:15 AM – 12:15 AM - Panel: Preparing Your Team for the Transition from Brick-and-Mortar to Virtual Clinical Trials and Building Partnerships to Work in Parallel and Share Data-Driven Insights

- Discuss the organizational shift that sponsors need to make to support virtual clinical trials
  - New processes and infrastructure that need to be put into place
  - What skills sets that employees must have?
- Discover how sites are preparing for the shift
  - Examine how coordinators and recruiters must think differently
  - Help PIs become comfortable consenting someone through a computer system and making their diagnosis based upon lab results and telemedicine
- How CROs are preparing internally as innovation in technology continue to advance
  - Becoming more knowledgeable on how virtual trials are conducted and what data is most important to collect
  - Training employees on new topics and technologies

Moderator:

Joseph Kim, BS, MBA, *Senior Advisor, Patient Experience and Design Innovation, Design Hubs Foundations*
ELI LILLY AND COMPANY

Site Perspective:

Jeff Kingsley, DO, MBA, CPI, FACRP, *Chief Executive Officer*
IACT HEALTH

CRO Perspective: TBD
Sponsor Perspective: TBD

12:15 PM – 1:15 PM - Networking Lunch

1:15 PM – 2:15 PM - Let's Talk About Options: Fully-Virtual Clinical Trial, Hybrid Trial, Location-Flexible Trials

- Debate the pros and cons of the fully-virtual trial, hybrid trial and flexible location trials
- What's the difference between hybrid and location flexible trials?
- Examine the barriers to going fully-virtual without geographic constraint
- Requirements within the industry or your organization to make virtual a reality
- Discuss when it's appropriate to replace a clinic visit
- Understanding the benefits of going virtual across all stakeholders

2:15 PM – 3:00 PM – Roundtable Sessions

Roundtable One: Direct-to-Patient Shipping
- Understanding regulations surrounding DTP
- Chain of custody
- Document control

Roundtable Two: Payment/Workflow Solutions in a Flexible Trial
- Paying subcontractors
- Business technologies prepared for virtual
- Discuss workflow challenges

Roundtable Three: Regulatory Challenges
- State licensing
- Interactions with the FDA
- Regulatory responsibilities of the PI

3:00 PM – 3:30 PM - Networking & Refreshment Break

3:30 PM – 4:15 PM - Launching a Virtual Trial: Direct to Patient IMPs
- Ensuring the supply chain is managed and transparent when shipping and tracking trial kits
- Working through and strategizing around unclear regulations
- Keeping up to date with HIPPA & GDPR when capturing patient data
- Tackling product stability concerns, ensuring the product is not compromised during transportation

4:15 PM – 5:00 PM - Discuss How Organizations are Managing the Complexities of Virtual Trials
- Manage the responsibilities of a variety of people that are not involved in traditional trials
- Building a workflow that is conducive with location-flexible trials
- Discuss workflow challenges when using complex models, beyond in-home nurses and telemedicine

5:00 PM – 5:15 PM - Day One Closing Remarks

Day Two: Thursday, May 23, 2019

8:00 AM – 9:00 AM - Networking & Breakfast

9:00 AM – 9:15 AM - Chairperson's Recap of Day One

9:15 AM – 10:00 AM - Panel: Working Together to Improve Patient Engagement Initiatives: Are Virtual Clinical Trials Taking Patient Centricity to the Next Level?
- Debate the pros and cons of the fully virtual trial, hybrid trial and flexible location trials
- What does data privacy mean to pharma vs. patients?
- Explore the ease of using apps and devices in everyday life
- Examine why the patient perspective is important in virtual trial design

Moderator:
Joseph Kim, BS, MBA, *Senior Advisor, Patient Experience and Design Innovation, Design Hubs Foundations*
ELI LILLY

Panelists:
MarlaJan Wexler BSN, RN, CPN
Patient Advocacy & Education

Additional Panelists TBA

10:00 AM – 10:45 AM - Case Study: Lessons Learned

10:45 AM – 11:15 AM - Networking & Refreshment Break

11:15 AM – 12:00 PM - Improve Utilization of Electronic Data Capture in Clinical Trials

- Cloud migration - Why you should consider moving to cloud-based technologies
- Addressing the need for high level R&D and clinical talent
- Using robotic process automation to improve clinical trial productivity

12:00 PM – 1:00 PM - Networking Lunch

1:00 PM – 2:00 PM - Navigating FDA Guidelines and Interactions with Regulators

- Understanding policies and standards surrounding virtual clinical trials
- Examine how RWE can be utilized within a virtual clinical
- Discuss regulatory challenges surrounding data security and reliability generated by mobile technology
- Discuss what regulatory barriers may delay a more widespread use of virtual clinical trials

2:00 PM – 2:30 PM - Networking & Refreshment Break

2:30 PM – 3:15 PM - Discovering What Tools and Devices are Best for Your Specific Needs

- Discuss how to harness digital technology to allow clinical trials to be carried out at a patient's home or local physician's office
- Choosing what platform if best for your organization's needs

3:15 PM – 4:00 PM - FIRESIDE CHAT

During the conclusion of the conference, we will invite comments, insights and questions from those around the room. Have your questions ready for an informal conversation with industry experts

- Where do we see ourselves in 2025?
- Discuss whether we can push virtual trials into Phase 2
- Explore the shifts needed within the industry to achieve success in virtual trials

4:00 PM – 4:15 PM Chairperson's Closing Remarks

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Venue

The Inn at Penn, a Hilton Hotel
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