2nd Annual

Virtual Clinical Trials Conference

Explore the Shift to Decentralized Clinical Trials and Navigate the Broad Spectrum of Models Available in 2020

MAY 19-20, 2020

Sheraton Philadelphia University City Hotel

Conference Chair

Craig Lipset, Founder, Clinical Innovation Partners

Speaker Snapshot

Josh Rose, VP, IQVIA R&D Solutions Strategy and Global Head, IQVIA Virtual Trials

Wendi Lau, Vice President, Operational Improvement & Reporting Excellence, Astellas Pharma

Kelly McKee, Head, Patient Recruitment and Patient-Centric Innovations, Vertex Pharmaceuticals

Shelly Barnes, Patient Experience and Implementation Lead, UCB

Amir Lahav, Healthcare Intelligence Consultant, Mitsubishi Tanabe Pharma America

Kyle Faget, Special Counsel, Foley & Lardner, LLP

Jim Kremidas, Executive Director at Association of Clinical Research Professionals

Alka Shaunik, MD, Senior Medical Director, Global Medical Affairs, Sanofi

Learning Objectives

- Discuss how the industry is combining conventional strategies with virtual trials
- Explore trial selection and discover the best options for virtual studies
- Restructuring internal processes to implement a virtual trial
- Understanding the benefits of going virtual across all stakeholders
- Discuss how to improve equity in access and participation through virtual clinical trials

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2nd Annual
Virtual Clinical Trials
Conference

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Why Attend?

With growing pricing demands, increased regulatory scrutiny, patent expirations, and generic competition, it's crucial that R&D departments are able to utilize digital technologies to ensure high-quality clinical trials. The industry is excited about virtual clinical trials, but the adoption curve is still light. As your organization prepares to apply novel technologies to clinical trials, whether they are fully-virtual or hybrid, it's important to take into consideration how operational activities will perform when the trial is conducted virtually as opposed to a standard brick-and-mortar model.

Conceptualizing virtual trials not simply as a standard study, but as a way of doing things differently, is essential to a successful outcome. Join us to examine how the industry is navigating different models of remote trials and gain best practices for preparing or improving internal infrastructure to support a decentralized study.

Who Should Attend

- Virtual Trials
- Decentralized Trials
- Remote Monitoring
- Clinical Innovation
- Patient Experience
- Patient Recruitment
- Trial Design Innovation
- Clinical Projects
- Clinical Operations
- R&D
- Clinical Supply Chain
- Clinical Scientific Affairs
- Outsourcing
- Clinical Regulatory Affairs
- Clinical Data Management
- Clinical Safety
- Medical Advisors

Venue

Sheraton Philadelphia University City Hotel

3549 Chestnut St.Philadelphia, PA 19104

215-387-8000

dmclernan@sheruniv.com

AGENDA DAY ONE
TUESDAY, MAY 19

8:00 REGISTRATION & BREAKFAST

9:00 CHAIRPERSONS OPENING REMARKS
Craig Lipset, Founder, Clinical Innovation Partners

9:15 KEYNOTE: TBD
TBD
- TBD

Josh Rose, VP, IQVIA R&D Solutions Strategy and Global Head, IQVIA Virtual Trials

PANEL

10:00 STRENGTHENING THE IMPLEMENTATION OF VIRTUAL CLINICAL TRIALS

As we move through 2020, the industry will continue to incorporate digital health technologies into clinical study design. Leveraging technologies can improve recruitment, retention and give patients a choice of participating from home or site. Creating a more patient-friendly system is a process the industry is still attempting to solve. This session will discuss opportunities for improvements to virtual studies and examine how organizations are beginning to execute virtual designs.

- Discuss how the industry is combining conventional strategies with virtual trials
- Discuss when it can be more cost-effective to run a virtual clinical trial
- Restructuring internal processes in order to implement a virtual trial
- Investigate the digital health tools that can be utilized to move a virtual trial forward

Moderator: IQVIA
Josh Rose, VP, IQVIA R&D Solutions Strategy and Global Head, IQVIA Virtual Trials

Panelists:
Kelly McKee, Head, Patient Recruitment and Patient-Centric Innovations, Vertex Pharmaceuticals

Additional panelists TBD

11:00 NETWORKING BREAK

11:15 THE PATIENT PERSPECTIVE; WHAT CAN INDUSTRY DO BETTER?

Creating an experience that is less burdensome for patients is a top priority for the industry. Virtual trials can improve convenience for participants giving them broader options. This session will dive into a patient's experience with a virtual clinical trial, let's discuss the burdens participants are still facing.

- Explore the ease of using apps and devices in everyday life
- Examine why the patient perspective is important in virtual trial design
- Discuss what being monitored continuously is like through the patient perspective
- What does data privacy mean to pharma vs. patients?
- Lack of provider engagement

Patient Panel

12:00 NETWORKING LUNCH

1:00 RECRUITMENT FOR CLINICAL TRIALS & EXPANDING ACCESS

- Discover how virtual clinical trials help bridge the underserved communities
- Using data to better understand patient populations
- How to best relieve patients of trial burdens to retain participants
- Discuss how to improve equity in access and participation through virtual clinical trials

Shelly Barnes, Patient Experience and Implementation Lead, UCB

PANEL

1:45 DETERMINING IF VIRTUAL METHODS ARE A SUITABLE OPTION

Virtual clinical trials are not appropriate for every kind of clinical study. If a study requires complicated health measurements that require a trip to a clinic, a virtual study may not be a good option. How do you determine a good option for a virtual study and what companies are pushing forward with virtual trials? Explore trial selection and discover the best options for virtual studies.

- Explore trial selection and discover the best options for virtual studies
- Discover trials where capturing accurate and timely data through devices has been successful
- Discuss patient needs and how much face-to-face interaction in necessary
- Discuss new study designs (such as basket trials, adaptive trials, etc) and if they are amenable to virtual

Moderator: Craig Lipset, Founder, Clinical Innovation Partners

Panelists:
Alka Shaunik, MD, Senior Medical Director, Global Medical Affairs, Sanofi

Additional panelists TBD

AGENDA DAY ONE
TUESDAY, MAY 19

2:30 NETWORKING BREAK

2:45 WHICH MODEL IS RIGHT FOR YOU? DISCOVER THE BROAD VARIETY OF SOLUTIONS

When it comes to virtual trials, one size does not fit all. Because every trial is unique, it's important to determine the right model for the study. This session will examine the broad variety of options available for exploring.

- Examine if virtual, hybrid, siteless or conventional trials are the best option for your study
- Learn about outsourcing vs. in house management of virtual trials
- Understand how to ease into virtual methods with a more flexible or hybrid approach

COVANCE

3:15 LET'S TALK ABOUT POLICY – DISCUSS HOW THE FDA IS APPROACHING THE SHIFT TO DECENTRALIZED CLINICAL TRIALS

Applying current regulations to new conditions will vary based on the disease area, the type of investigational drug, and the types of trial activities that are decentralized. Policies and regulations will need to consider the integrity of the data that digital technologies produce in a virtual setting. This session will explore the areas of interest for regulators when thinking about policy considerations for virtual clinical trials.

- Examine the challenges and potential solutions to issues surrounding the collection of remote data from patients
- Discuss how to ensure the integrity and accuracy of electronic records from remote measurements
- Learn how investigators should evolve to train personnel on new processes unique to virtual clinical trials
- Ensure that participants are accurately familiarized on how their data will be shared

FDA Representative
Invited

3:45 NAVIGATING THE LEGAL AND REGULATORY CONSIDERATIONS OF A DECENTRAILIZED TRIAL

- Federal and State regulation of technology and the use thereof for the provision of patient services
- PI Licensure
- Establishment of patient relations
- Permitted modalities/technology
- Standards of practice
- Use of technology with patients/PI oversight
- Patient Consent and Data Considerations
- Consent requirements/electronic delivery
- Data capture – use of technology for same
- HIPAA and 21 CFR Part 11 consideration

Monica Chmielewski, Attorney, Foley & Lardner, LLP
Kyle Faget, Special Counsel, Foley & Lardner, LLP

4:30 DISCUSS THE PROCESSES OF EVALUATING NEW WEARABLE SENSORS AND MOBILE TECHNOLOGY FOR DATA GENERATION IN VIRTUAL TRIALS

Implementing new methods and technologies isn't as easy as it sounds, new methods also bring new challenges. This talk will review successful case studies for evaluating new procedures and help bridge the gaps between conventional and virtual trials.

- Review how companies are preparing to explore new digital solutions
- Recognize strengths across different models and learn how teams are building their capabilities to align with new methods
- Developing digital health strategy for using sensor technology in virtual trials
- Understanding the value of incentivized strategies for patient engagement when using wearables and healthcare apps

Amir Lahav, Healthcare Intelligence Consultant, Mitsubishi Tanabe Pharma America

5:00 CLOSING REMARKS

Craig Lipset, Director Former Head of Clinical Innovation, Global Product Development, Pfizer

END OF SESSIONS DAY ONE

IQVIA

5:00 IQVIA HOSTED COCKTAIL RECEPTION

Remarks: Josh Rose, VP, IQVIA R&D Solutions Strategy and Global Head, IQVIA Virtual Trials

IQVIA invites you to join us for a cocktail reception following the conference. Join your peers and make connections with the speaking faculty. We'll provide an open bar with appetizers from 5:00 - 6:00. We hope you'll be able to join us for this fun networking opportunity at this year's Virtual Clinical Trials Conference.

6:00 COCKTAIL RECEPTION CONCLUDES

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AGENDA DAY TWO
TUESDAY, MAY 20

8:00 NETWORKING & BREAKFAST

9:00 CHAIRPERSON'S RECAP OF DAY ONE
Craig Lipset, Founder, Clinical Innovation Partners

9:15 THE BIG CHALLENGES WHEN CONSIDERING A VIRTUAL CLINICAL TRIAL

When faced with tight regulation and balancing the adoption of new technology with patients' best interests, it can be nerve-racking to push forward with virtual trial designs. This session will explore some of the big challenges that arise when considering new technology in clinical studies and how to overcome challenges to ensure the desired outcome.

- Address concerns over data accuracy
- Ensuring technology required works as it should
- Discuss how organizations are being too conservative with their approach to virtual trials
- Examine social and cultural barriers

Wendi Lau, Vice President, Operational Improvement & Reporting Excellence, Astellas Pharma

PANEL

10:00 MISTAKES TO AVOID WHEN COLLECTING DATA THROUGH DIGITAL HEALTH TECHNOLOGIES

- Examine case studies and discuss mistakes that could have been avoided
- Working through technical difficulties with the user interface
- Discuss the risk of sharing sensitive health information online
- Learning the skillsets required to capture and utilize data
- Developing digital health strategy for using wearable technology in virtual trials

Moderator:
Craig Lipset, Founder, Clinical Innovation Partners

Panelists:
Amir Lahav, Healthcare Intelligence Consultant, Mitsubishi Tanabe Pharma America

Additional panelists TBD

11:00 NETWORKING BREAK

11:15 Examine Participation Burden

TBD

- TBD

Yaritza Peña, Research Analyst, Tufts CSDD, Tufts University School of Medicine

12:00 NETWORKING LUNCH

1:00 ACRP PRESENTATION

TBD

- TBD

Jim Kremidas, Executive Director at Association of Clinical Research Professionals

1:45 WHAT ROLE DOES AI PLAY IN VIRTUAL CLINICAL TRIALS?

Will artificial intelligence help streamline the virtual clinical trial process? AI-based models are helping with trial design, patient recruitment, increasing cybersecurity, remote monitoring, EHR processing and more. This session will explore possible applications for AI in decentralized trials and how AI is already changing the clinical landscape in 2020.

- Discuss how organizations are effectively using AI to optimize trial design and performance
- Examine how technology is transforming clinical research
- Identify key challenges when implementing AI into trial design
- Consider whether decisions can be based on RWD analyzed by AI

SPEAKER
TBD

2:15 NEW PROCESSES AND INFRASTRUCTURE REQUIRE NEW SKILLS

- Discuss the organizational shift that sponsors need to make to support virtual clinical trials
- Becoming more knowledgeable on how virtual trials are conducted and what data is most important to collect
- Training employees on new topics and technologies
- What skills sets must employees have?

SPEAKER
TBD

3:00 CLOSING REMARKS
Craig Lipset, Founder, Clinical Innovation Partners

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