Clinical Trials Patient Experience Summit

How Connected Patient-Driven Initiatives are Improving Clinical Trial Productivity

April 7-8, 2016
Sheraton Palo Alto – Palo Alto, CA

Day One, April 7th

8:00 – 8:50 am  Conference Registration Open (Cypress Ballroom Foyer)

9:00 – 9:10 am  Opening Remarks from Conference Chairman
Victor Morrison, Next IT

9:10 – 9:50 am  KEYNOTE PANEL
Clinical Trials & the Patient Experience

At no other time have we had greater access to our own personal health data. Big data, the cloud, and eventual interoperability will enable us to gather, store and connect data in new ways. So what does it mean for the pharmaceutical and clinical trial industry – how can that lead to an improved experience for patients?

Kathy Vandebelt, Global Head, Clinical Innovation, Lilly
Alicyn Campbell, Global Head, Patient-Centric Outcomes Research for Oncology, Genentech
Drew Schiller, Co-Founder, CTO, Validic

9:50 – 10:20 am  Game of Trials: Prepare for the End of CROs when you Least Expected it

Today, the digital connection between market research and bringing therapies to market is missing. Deep understanding and experience with digitally enhanced therapies or digital therapeutics is absent at many clinical research organizations. Digital Outcomes Research (DOR) and the Internet of Things (IoT) are poised to break these adoption barriers. Many CROs will not survive the transition. The potential to accelerate both speed and cost of clinical trials will require collaboration between academic institutions, pharmaceutical companies, medical device and sensor companies, payers and providers to reach new heights. Such collaboration is only possible if study models that focus on what works for patients are embraced.

Ahmed Albaiti, CEO, Medullan
10:20 – 10:55 am LILLY CASE STUDY: Crafting a New Clinical Research Ecosystem around the Most Important Human – The Patient

- How does the industry need to change?
- What should drug developers consider when making the commitment to patient-centricity?
- Where is Lilly actively working to digitize the clinical development ecosystem?
- What does this mean for patients and healthcare providers?

*Kathy Vandebelt, Global Head, Clinical Innovation, Lilly*

10:55 – 11:15 am Networking Break in Exhibition / Networking Area (Cypress Ballroom)

11:15 – 11:45 pm GENENTECH CASE STUDY: Advancing Development and Use of Patient-Reported Outcomes in Drug Development

- How to utilize patient feedback for making existing PRO tools as user-friendly as possible
- Near term opportunities for Genentech to engage patients on their terms
- What’s next?

*Alicyn Campbell, Global Head, Patient-Centric Outcomes, Genentech*

11:45 – 12:15 pm Bridging the Communication Gap: Helping HCPs Help Patients

HCPs and patients recognize an effective doctor-patient communication as essential to high quality medical care. Learn how providing specialized virtual health assistants deliver a competitive advantage by enabling 24/7 information sharing with customers to efficiently improve adherence and unify care.

*Victor Morrison, SVP, NextIT Healthcare*

12:15 – 12:45 pm FDA CASE STUDY: How Patient-Centered Drug Development Initiatives are being put at the forefront of guidelines

The FDA’s Patient-Focused Drug Development initiative is a commitment under the fifth authorization of the Prescription Drug User Fee Act (PDUFA V) that aims to more systematically gather patients’ perspectives on their condition and available therapies to treat their condition.
• How these collaborations will enhance the “voice of the patient” in all aspects of the clinical development process
• Learn about how the FDA aims to better understand patients’ experience with symptoms, impacts on daily living, and available therapies

_Pujita Vaidya, Patient-Focused Drug Development Analyst, FDA_

12:45 – 2:00 pm  
Executive Networking Luncheon – Cypress Ballroom

2:00 – 2:30 pm  
ABBOTT CASE STUDY: Successfully Recruiting for Inpatient Studies

• Recruitment for clinical studies can be very challenging. This presentation will explore various recruitment strategies based on a 3 year oral nutritional supplement inpatient study conducted at 119 sites across the US and PR
• Hear a case study from Abbott Nutrition; what worked? What didn’t work?

_Sonja Acosta, Sr. Clinical Research Associate, Abbott Laboratories_

2:30 – 3:00 pm  
Generating Clinical Evidence for mHealth Solutions with Digitally-Enabled Health Outcomes Studies

Patient receptivity to medical interventions is driven by both biological and behavioral factors. With the advent of digital tools such as wearables, connected devices, and smartphone apps, we are able to collect new types of behavioral data and characterize patient’s behavioral patterns. Understanding how these behavioral patterns tie to health outcomes is critical to optimizing patient outcomes. At Evidation Health, we have analyzed a large dataset that includes both medical claims data and patient behavior data to uncover these relationships. We’ll present some representative findings and discuss how they can be utilized by pharmaceutical companies in research and commercial efforts.

_Jesse Juusola – Head of Outcomes Research – Evidation Health_

3:00 – 3:30 pm  
CTTI CASE STUDY: Effective Engagement with Patient Groups around Clinical Trials

With the increasing commitment to Patient-Focused Drug Development (PFDD) by FDA and patient engagement in translational research, there is a significant opportunity to improve the clinical trials enterprise and enhance participation by patient groups in the work of trial sponsors. PFDD and patient engagement in research should be considered an effort to extend
the benefits of incorporating patient insight and experiences, as well as desires and preferences, from bench to bedside and back.

Sharon Hesterlee, Chief Science Officer, Myotonic Dystrophy Foundation

3:30 – 3:50 pm Networking Break in Pre-Function Foyer

3:50 – 4:10 pm How Innovation at Roche is leading to Better Education for Patients in Clinical Trials

• Hear how Roche/Genentech is dedicating resources around digital experience to improve patient education – and understand why this is important for improving patient relations
• Discover how patient recruitment and retention can be improved with better educational resources in a digital world

Nariman Nasser, Digital Strategist, Operational Innovation, Roche

4:10 – 5:00 pm STARTUP PANEL: Hear from the latest tech companies’ leadership on their challenges in implementation and outreach

• Hear from top innovators who are leading the charge on improving the patient experience
• Understand their concerns and hurdles that they must overcome from FDA and gain support within organizations

Moderated by Shannon Bergstedt, Evidation Health

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<th>Engaging Patients to Gather Medical Record Data</th>
<th>Technology for Early Detection – How can it be applied to Clinical Trials?</th>
<th>The Last Healthcare Frontier – The Patient</th>
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<td>1. Medical record data is so vital to the trial process, but current solutions don’t work.</td>
<td>1. Transferring Wearables From Fitness to Personalized Healthcare Through Individual Breast Cancer Screening</td>
<td>1. P-MAR - Patient Med Adminstration Record</td>
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<td>2. To engage patients, give them something of real value - access to all their records.</td>
<td>2. Innovative, Personal Early Breast Wellness Screening</td>
<td>2. PGHD – Patient-Generated Health Data</td>
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<td>3. Bring consumer tech insights to patient experience.</td>
<td>3. What have we learned?</td>
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<td>4. Applications across the drug development lifecycle.</td>
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<td>Rob Royea, CEO, Cyrcadia</td>
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<td>Noga Leviner, CEO, Picnic Health</td>
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<td>Naveen Khan, CEO, PT Pal</td>
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5:00 – 6:30 pm Networking Drinks Reception in Cypress Hall

6:45 pm End of Day One
Day Two, April 8th

8:00 – 9:00 am  Day Two Registration Open

9:00 – 9:10 am  Chairman’s Day One Recap and Opening Remarks
**Ben Lei, Evidation Health**

9:10 – 9:35 am  GSK CASE STUDY: Voice of the Patient in Safety
- Social media medication discussions; what are patients saying?
- Who is posting on social media about medications?
- What it means for patient safety activities at one global pharmaceutical company

**Michele Thomas, Director of Safety Innovation, GlaxoSmithKline**

9:35 – 10:00 am  The Starting Line - Leveraging Smart Technologies to Help People Become and Stay Healthier

Promoting and sustaining positive behaviors to become lifestyle changes is a serious challenge. We will explore AI, IT, medical devices and other technologies that we can leverage to help people add years to their lives and life to their years.

**Greg Caressi, SVP, Healthcare & Life Sciences, Frost & Sullivan**

10:00 – 10:40 am  KEYNOTE PANEL: Digital Trial & Error: The Evolution of Clinical Trials Recruitment Experience

- Overview of the evolution of clinical trials recruitment and retention – considerations around patient journals, monitoring, site visits, data handling & privacy
- How pharma, CROs and other research organizations are utilizing social media and other strategies to improve their targeting and understanding of recruitment
- How can patient engagement can create a better relationship and improve patient recruitment & retention

**Meghan McKenzie, Sr. Clinical Program Lead, Genentech**
**Sonja Acosta, Sr. Clinical Research Associate, Abbott**
**Rajesh Menon, Sr. Clinical Research Associate, Genentech**
**Moderated by Ben Lei, Evidation Health**

10:40 – 11:00 am  Using Technology to Collect Standardized, Reliable and Clinically Meaningful Patient Data
Leveraging technology to develop effective measurement tools
Empowering patients to self-report quantitative data
Creating efficiencies and improving the consistency of clinical data collection across sites
Navigating the development map for Software as a MedDevice

Drew Schiller, Co-Founder, CTO, Validic

11:00 – 11:20 am Networking Break in Pre-Function Foyer (Cypress Ballroom)

11:20 – 11:50 am MEDABLE – The App and Analytics Platform for Healthcare

Michelle Longmire, CEO, Medable

11:50 – 12:20 pm Revolutionizing Clinical Trials: How Pharma Clinical Trials can become more Patient-Centric

• Patient knowledge is an evolving area and hidden opportunity for clinical development
• How to design a patient-centric study
• Leveraging existing social networks for patient connections and insights; lessons learned
• How do we get to patients earlier than we ever have before?

Meghan McKenzie, Sr. Clinical Program Lead, Genentech

12:20 – 12:40 pm CenterWatch: Helping Patients Connect with Clinical Trials

At CenterWatch, our mission is to be the leading source of clinical trials information for both clinical research professionals and patients. As a pioneer in publishing clinical trials information, CenterWatch was the first Internet site to publish detailed information about active clinical trials that could be accessed by patients and their advocates. Today, we have one of the largest clinical trial databases actively seeking patients on the Internet.

Joan Chambers, COO, CenterWatch

12:40 – 1:15pm Evaluating the Utility of Wearable Technology in Oncology Care

• Cooperative research between FitBit and clinical oncology group program at Cedars-Sinai
• Overview of Study: Activity tracking Oncology Wearables and Reporting System
  o Background & purpose
  o Basic research plan
Discussion – clinical application

- Clinical Perspective – Behavioral Medicine goals for improvement of patient treatment experience, quality of life, treatment adherence, communication with medical team
- Scientific & Business Perspective – timeliness of wearable technology research in healthcare

Arvind Shinde, MD, Oncology Supportive Care, Cedars-Sinai

1:15 – 2:30 pm Executive Networking Luncheon
Cypress Ballroom

3:00 pm End of Conference