FUTURE OF CLINICAL TRIALS

The Future of Clinical Trials Summit

7-8 December, 2021 | Virtual

Confirmed Speakers Include:

- **Chair Day One: Deborah Collyar,** *Founder & President,* **Patient Advocates in Research**
- **Chair Day Two: Rob Scott,** *Former Chief Medical Officer,* **AbbVie**
- **Kristen Wheeden,** *CPAG Committee Chair,* **RDCRN-CPAG** *and Executive Director,* **American Porphyria Foundation**
- **Alan J. Balch, PhD,** *Chief Executive Officer,* **NPAF**
- **Jen Horonjeff,** *Founder & CEO,* **Savvy Coop**
- **Katie Baca-Motes,** *Co-Founder Scripps Digital Trial Center,* **Scripps**
- **Dan Paulson,** *Global Vice President, Clinical Development,* **Bayer Global**
- **Johan Baeck,** *Senior Vice President, Clinical Development & Med Affairs, Biostats & Programming,* **Jounce Therapeutics**
- **Michele Rhee,** *Vice President, Patient Affairs & Advocacy,* **X4 Pharma**
- **Steven Wiviott,** *Vice President, Clinical Trials Research & Administration,* **Mass General Brigham**
- **Veronica Suarez,** *Executive Director of R&D Portfolio and Program Management,* **Seqirus**
- **Michelle Shogren,** *Senior Director of Innovation - Pharma R&D Clinical Operations,* **Bayer**
- **Michael Benecky,** *Senior Director, Regulatory Affairs,* **UCB**
- **Laurie Myers,** *Director, Global Health Literacy & Oncology Health Equity,* **Merck**
- **Peter Schaeffer,** *Projects, Clinical Platforms and Sciences TPR Analytics Director,* **GSK**
- **Meghan McKenzie,** *Principal, Inclusion Strategy & Partnering, Chief Diversity Office,* **Genentech**
- **Angel Soubhie,** *Medical Director & Head Clinical Trial Scientists,* **Bayer Pharmaceuticals**
- **Sarah Bilali,** *Director, Global Regulatory Affairs, Devices,* **UCB**
- **David Morin,** *Director of Research,* **Holston Medical Group**
- **Michelle Tarver,** *Deputy Director, Office of Strategic Partnerships and Technology Innovation and Program Director for Patient Science,* **Digital Health Center of Excellence, CDRH, FDA**
- **Lorena Kuri,** *Head, Diversity Strategy,* **Bristol Myers Squibb**
- **Lauren Bataille,** *Head, Digital Medical Capabilities,* **Novartis**
- **Samantha Reyes,** *Patient Engagement Lead,* **Amgen**
- **Ed Ramos,** *Director of Digital Clinical Trials,* **Scripps**
- **Veronica Moore,** *Senior Manager, Patient Advocacy,* **Horizon Therapeutics**
- **Bray Patrick-Lake,** *Scientific Advisor,* **DiMe**
- **Shalome Sine,** *Project Manager,* **CISCRP**
- **Ting Pun**, *Patient Advocate & Family Partner*, **Stanford Healthcare**

Day One: Tuesday, 7th December 2021	
A PATIENT-CENTRIC APPROACH: BLENDING DIGITAL BEST PRACTICE AND INNOVATIVE TECHNOLOGIES TO IMPROVE TRIAL ACCESS, DIVERSITY, INCLUSION, ENGAGEMENT AND RESPONSIVENESS	
10:15	**Event welcome**
10:20	**Chair's opening remarks and setting the scene** **Deborah Collyar,** *Founder & President,* **Patient Advocates in Research**
10:30	**Innovation, R&D and decentralization: Accepting change, risk and a "fail-fast" attitude** Fostering a true culture of innovation is not a straightforward process. It requires a vision, technological capabilities, adaptability and a willingness to accept risk. Whilst most of us are confident in our purpose, direction and technologies, risk is often seen as the 'elephant in the room'. However, this shift to decentralized trials is arguably the biggest change this industry has faced in 40 years, forcing us to embrace change and overcome traditional barriers. But what does this mean in reality and how does this relate to both the patients and the business? ● What have been the short and long-term impacts of the industry leveraging remote and virtual strategies? ● How can we accurately assess the impact on centricity, productivity and pace through digital innovation? ● Are virtual and decentralized trials as patient-centric as we're led to believe and have we fully proven the value proposition to the patients? ● How confident are we that we're maximizing its potential, and what do we see as the 'end goal' for decentralized trials ● What do we consider to be the unintended consequences and biggest lessons learned to date? **Michelle Shogren,** *Senior Director of Innovation - Pharma R&D Clinical Operations,* **Bayer**
11:00	**Panel Discussion: Digital Tech: Relieving old burdens or creating new ones?** The role of digital tools in clinical trials can have many benefits - it can improve recruitment, eligibility, access, feedback, data collection and ultimately the patient experience. However, exploring virtual clinical trial platforms requires an arguably greater onus on the participant, especially with regards to an understanding of how to maintain a controlled environment, use the technology or systems correctly and ensure efficacy and transparency at all times. So, with all this, can we really claim to be

	reducing the patient burden? ● What do we identify as the greatest burdens participants face when undergoing decentralized clinical trials? ● How can patient centricity be measured objectively, and what exactly should we be measuring? ● Are we ensuring the patient voice is heard throughout the lifecycle of a trial? What impact does this have on delivery? ● Are we offering enough reassurance, support, education and social interaction throughout the trial? <u>Panellists Include:</u> **Johan Baeck,** *Senior Vice President, Clinical Development & Med Affairs, Biostats & Programming,* **Jounce Therapeutics** **Stephen Wiviott,** *Vice President, Clinical Trials Research & Administration,* **Mass General Brigham** **Lauren Bataille,** *Head, Digital Medical Capabilities,* **Novartis** **Ting Pun**, *Patient Advocate & Family Partner*, **Stanford Healthcare**
11:45	**What's the regulatory outlook?** With an influx of digital health initiatives and solutions flooding the market, staying up to date on how to remain compliant, whilst also remaining innovative and patient-centric is hugely taxing, especially when setting policy is a timely process. Join us, as we take a look into how the FDA is helping industry tackle the pace of change and proactively engaging with businesses to stay ahead of the curve ● What can be done to ensure that the patient's voice is heard throughout the lifecycle of a trial to guarantee better engagement and reduce patient burden? ● How can virtual and decentralized trials encourage greater diversity of participation, and be more reflective of the demographic they are aiming to serve? ● What lessons have you learned over the last few years and how is that shaping how you see things changing in the future? **Michelle Tarver,** *Deputy Director, Office of Strategic Partnerships and Technology Innovation and Program Director for Patient Science,* **Digital Health Center of Excellence, CDRH, FDA**
12:15	**Lunch**
13:15	**Elevating the patient voice** From a patient's perspective, the positives of participating in a clinical trial can be clear - more information, support, access and arguably control - but what about their concerns? More tests, data efficacy concerns, potential trust issues and that fear of being a

	"guinea pig" are all very real, and that's if they even know a trial even exists! This is why elevating the patient voice is so crucial to creating effective trials, but in a world obsessed with data, how much are we stopping to listen to personal preferences, perceptions and values? ● How have patient advocates impacted the drug development process? ● What can be done at local, regional and national levels to put patients at the heart of clinical trials? ● Are we seeing improvements in accrual and retention when using patient advocates? If so, how much? ● What's the biggest obstacle preventing greater industry involvement with patient advocacy groups? **Alan J. Balch, PhD,** *Chief Executive Officer,* **NPAF**
13:45	**Panel Discussion: Digital trials from a patient's point of view** Join us as we meet with a series of patient advocates who open up on their experience of digital trials, both good and bad, and how they are now sharing their story with others to influence digital trial design, reduce patient burden and encourage greater diversity and inclusion within digital trials. ● How easy are trials to access, use and complete? ● Do you have the opportunity to share feedback regularly throughout the process? ● Should patients ultimately have greater involvement over trial design? ● In your experience, what were the biggest drawbacks with a purely virtual trial? Panellists Include: **Kristen Wheeden,** *CPAG Committee Chair,* **RDCRN-CPAG** *and Executive Director,* **American Porphyria Foundation** **Deborah Collyar,** *Founder & President,* **Patient Advocates in Research** **Michele Rhee,** *Vice President, Patient Affairs & Advocacy,* **X4 Pharma** **Veronica Moore,** *Senior Manager, Patient Advocacy,* **Horizon Therapeutics**
14:30	**Afternoon extended wellness break**
15:00	**Tackling cultural drivers, prejudice and mistrust in clinical trials** The unparalleled speed at which effective Covid-19 vaccines were created is a shining example of modern day brilliance. However, it also unfortunately served to highlight the growing inequalities and lack of diverse participation, commonplace in clinical trials. It goes without saying that diversity and inclusion is essential to providing safe and effective treatments for all, but equally the

	barriers to entry for many are complex, long-standing and without an easy solution. In this session, we'll be exploring critical issues surrounding not only diversity and inclusion, but also access, recruitment and engagement to ensure best-practice is maintained throughout. Key discussion points include: ● What do you consider to be the greatest barriers to entry for those from under-represented communities? ● How does this vary on a regional, national and global scale? ● What role can technology play in improving trust and creating an inclusive environment? ● What are we tracking issues such as recruitment, diversity, engagement and attrition against and how reliable is it? **Veronica Suarez,** *Executive Director of R&D Portfolio and Program Management,* **Seqirus**
15:30	**Inclusive Design: Are your trials reflective of the patient population they aim to serve?** Eligibility, recruitment and diversity is unquestionably a major hurdle with regards clinical trials. However, mounting social pressures, alongside the adoption of digital and decentralized clinical trials, is seen as an opportunity to address concerns over inclusivity and patient engagement. In this session we'll explore co-creation from start to finish, with an emphasis on how to avoid common mistakes and what 'best practice' should look like. ● How can we ensure that as an industry, we are improving the way we match the right patients to the right trials and run them for 'real' patient populations? ● Increasing education and awareness to avoid implicit bias to improve recruitment? What steps should we be taking to overcome this? ● Is this concern a small part of a broader diversity and inclusion issue around health inequalities? ● What other approaches would you recommend to extend the reach of trials to a more diverse set of participants? <u>Panellists Include:</u> **Meghan McKenzie,** *Principal, Inclusion Strategy & Partnering, Chief Diversity Office,* **Genentech** **Lorena Kuri,** *Head, Diversity Strategy,* **Bristol Myers Squibb** **Deborah Collyar,** *Founder & President,* **Patient Advocates in Research**
16:15	**Chairs closing thoughts & Close of day one** **Deborah Collyar,** *Founder & President,* **Patient Advocates in Research**

Day 2: Wednesday, 8th December 2021	
OVERCOMING BARRIERS TO PROGRESS: HOW TO MAXIMIZE THE USE OF DECENTRALIZED TRIALS WITHOUT COMPROMISING ON QUALITY, TRANSPARENCY OR SECURITY	
10:40	**Event welcome**
10:45	**Chair's opening remarks and recap** **Rob Scott,** *Former Chief Medical Officer,* **AbbVie**
11:00	**Health equity and health literacy: Opportunities for pharma to take action** Health equity can be defined as everyone having "a fair and just opportunity to be as healthy as possible", extending far beyond equality and inequality. It seeks to identify and address these inequalities, whilst fixing the system to offer equal access to tools and opportunities. However, social determinants of health often play a critical role in the decision of participants to participate in trials, as does literacy, as depending on the circumstance, anyone may struggle with health information. ● What is health equity and why does it matter? ● How are the social determinants of health and health literacy helping achieve health equity? ● Why does this matter to pharma and to patients - clinical trials, marketing and beyond ● What have we learned to date and what are the next steps? **Laurie Myers,** *Director, Global Health Literacy & Oncology Health Equity,* **Merck**
11:30	**Regulatory considerations during digital clinical innovation** Innovation, R&D and the value derived from patient feedback cannot be understated when it comes to clinical trials, but with "digitals" potential to radically improve trial phases, speed-up time-to-market and expand access to experimental treatments, why are many still struggling to balance this with existing regulation? Throughout a series of use cases we explore exactly how you can deliver industry-leading digital patient experiences whilst remaining compliant, current and relevant. Key points covered include: ● Are regulations inhibiting further innovation within clinical trials? ● How involved are the regulators in digital R&D and how does this vary on a national vs. global level?

	● How do we balance key issues such as safety, effectiveness, patient privacy, data and cybersecurity? ● Do the regulations and principles remain the same, even if the channels don't, or should regulations adapt to a growing use of digital and decentralized trials? **Michael Benecky,** *Senior Director, Regulatory Affairs,* **UCB** **Sarah Bilali,** *Director, Global Regulatory Affairs, Devices,* **UCB**
12:00	**How to use '*The Playbook*' for decentralized trials success at scale** <u>Panellists Include:</u> **Bray Patrick-Lake,** *Scientific Advisor,* **DiMe** **Jen Horonjeff,** *Founder & CEO,* **Savvy Coop** **Katie Baca-Motes,** *Co-Founder Scripps Digital Trial Center,* **Scripps** **Ed Ramos,** *Director of Digital Clinical Trials,* **Scripps**
12:45	**Lunch**
13:45	**Is Remote Monitoring here to stay?** As with many things, Covid-19 has forced us to break out of our traditional silos and rethink how previously rudimental tasks are performed, none-more-so than around site monitoring for clinical studies. However, remote monitoring, although initially seen as a short-term fix, can provide a range of long-term benefits, which is making many reconsider how they'll operate moving forwards. In this session we'll explore critical thinking, including: ● Are virtual site tours comprehensive enough to provide a strong enough case to be used for pre-site selection? ● How can you ensure patient security and safety across all stages of the trial? ● Cost reduction and operational efficiency are often referenced as key reasons to adopt remote monitoring, but what does this look like in general terms? ● Are hybrid solutions not a better long-term option? **David Morin,** *Director of Research,* **Holston Medical Group**
14:15	**Leveraging Critical Insights from Patients and Care Partners in Trial Protocols to Create More Inclusive, Patient-Friendly Studies**

	World events led to a near-overnight shift towards the broad adoption of decentralized trials. This shift reinforced the importance of patient-centric care with an increased emphasis on individualized experiences. Understanding this, TransCelerate focused on how to develop practical guidance and solutions for industry that enable the future success of decentralized solutions (e.g., telemedicine) in a patient-friendly manner. After collaboratively engaging with major ecosystem partners including regulators, patients, sites, care partners and industry groups, TransCelerate incorporated important feedback into its solutions to help to promote more inclusive and accessible trials for all. In this session, we will speak about the changed ways of working and critical insights gained by deploying patient-facing digital technology and focusing more on patient and care partner voice in decentralized clinical trials. We will address the following: ● Enabling and accelerating the adoption of patient facing digital technologies in clinical trials ● Incorporating virtual and patient considerations into deployment of patient facing digital technologies such as Technology interruptions, Data management and Remote training for patients on technology ● Providing more effective ways to engage with patients and care partners in the design and execution of clinical trials ● Considering best practice for virtual patient engagement ● Considering care partners more proactively in the clinical trial journey ● Ensuring resources are adapted for diverse populations ● Considering how to develop and navigate the path to Health Authority approval to use digital tools for Novel Digital Endpoint development in a clinical trial This session will also address real world examples of deploying patient technology, lessons learned in considering patient and care partner experience in decentralized trials, and challenges and successes for regulators, patients, sites, and industry groups **Peter Schaeffer,** *Projects, Clinical Platforms and Sciences TPR Analytics Director,* **GSK** **Samantha Reyes,** *Patient Engagement Lead,* **Amgen**
14:45	**Panel Discussion: What impact are the likes of wearables, sensors and digital biomarkers having on clinical trials?** The benefits of using wearables in clinical trials are obvious. They can objectively collect data remotely and virtually - reducing the onus on the patient or site to manually keep data records - improve efficiency and reduce costs by minimising, or eradicating clinical site time, and provide real-time enabled insights to help drive the effectiveness of the trial itself. However, they are not without their concerns and with reducing patient burden seen as a major challenge by most, are they the right solution for your trial? ● What are proof-of-concepts teaching us about the feasibility of wearables in trials? ● What effect are they having on data collection endpoints and the flow of data across multiple platforms? ● Are we building solutions that don't just work for data capture and efficacy within clinical trials, but that also work for patients

	too? ● Do we feel the regulations are clear on what is and isn't possible for the use of wearables in clinical trials? <u>Panellists Include:</u> **Dan Paulson,** *Global Vice President, Clinical Development,* **Bayer Global** **Angel Soubhie,** *Medical Director & Head Clinical Trial Scientists,* **Bayer Pharmaceuticals**
15:30	**Flexibility: A Key Patient Engagement Strategy** Patient recruitment and retention are consistent challenges for clinical trial sites, and patients who participate in clinical trials often drop out due to the logistical burdens associated with participation. Recent trends in patient engagement and new clinical trial models are rapidly emerging which provide more flexibility and reduce these burdens on patients. But which of these strategies are most important to patients, and where can clinical trials leverage these strategies to best impact patient experiences? In this session, Shalome Sine, Project Manager at CISCRP explores the importance of flexibility as a key patient engagement strategy, allowing clinical trial participants to take on trial participation requirements as part of their busy lives. The presentation will cover topics such as: ● Clinical trial aspects where patients most desire flexibility (Ex. Expense reimbursement, visit scheduling, online PROs, etc.) ● What does flexibility mean for informed consent, study visits, and follow-up? ● Which new clinical trial models and technologies can provide patients with the flexibility they need? **Shalome Sine,** *Project Manager,* **CISCRP**
16:00	**Chairs closing thoughts** **Rob Scott,** *Former Chief Medical Officer,* **AbbVie**
End of conference	