

# 2021 Global Conference on Regulatory Science

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CONFERENCE PROCEEDINGS

October 12-13, 2021

Hosted by the Harvard-MIT Center for Regulatory Science



## **ABOUT THE HARVARD-MIT CENTER FOR REGULATORY SCIENCE**

The Harvard-MIT Center for Regulatory Science was established in 2018 to advance research and education in regulatory science. The Center serves the broad community of biomedical research scientists and physicians in academia, industry, and regulatory agencies who seek to improve the development and evaluation of medical products. The primary principle underpinning these activities is the understanding that scientific discoveries will most benefit patients if accompanied by an efficient, rigorous, and adaptable approach to evaluating the many rapidly emerging biotechnologies. The Center aims to be a platform to foster interdisciplinary and multi-stakeholder discussions on scientific and infrastructure needs. The Center supports a Regulatory Science Fellowship, local and international conferences, and a portfolio of research collaborations with regulatory agencies, industry, and other academic institutions.

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## I. INTRODUCTION

### What is Regulatory Science?

Rapidly evolving areas of science are promising new approaches to improving health while demanding new tools, standards, and approaches to evaluate the safety, efficacy, quality, and performance of innovative products. Regulatory science comprises a range of scientific disciplines that are applied to the quality, safety and efficacy assessment of medicinal products and that inform regulatory decision-making throughout the lifecycle of a medicine. Effective regulatory science requires dialogue and collaboration between academic investigators active in the field, and the government and industry groups for whom the evaluation, regulation and marketing of medical products is a central concern.

### Conference Description

Hosted by Harvard-MIT Center for Regulatory Science (CRS), the 2021 [Global Conference on Regulatory Science](#) was held virtually over 2 days, October 12-13, 2021. The event series convenes academic scientists, international regulators and industry experts to explore emerging topics at the intersection of regulatory science and therapeutic development. This year's theme was [Digital Health and Medical Devices](#), and conference participants discussed the challenges and opportunities for harnessing digitally enabled technologies in support of optimal patient health outcomes.

These Proceedings summarize the invited speakers' presentations, panel discussions, and related Question and Answer sessions. The conference also included four working groups, reported separately.

#### *Conference topics included*

- Approaches to accelerate digital health technology adoption
- Digital health regulation and adoption in Europe
- Digital therapeutics for mental and behavioral health
- National device surveillance and registry networks
- Decentralized clinical trials

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*comprises a range of scientific disciplines that are applied to the quality, safety and efficacy assessment of medicinal products and that inform regulatory decision-making throughout the lifecycle of a medicine.*

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## Conference Context and Focus

Opening remarks by  
Florence Bourgeois, Co-  
Director of the Harvard-  
MIT CRS

Bourgeois noted that the Conference was occurring in the context of the ongoing COVID-19 pandemic which has further catalyzed the already rapid acceleration in the development of digital health tools in recent years. In parallel, a number of new regulatory pathways have been implemented to keep pace with innovation. In the past 18 months, **an**

**entirely new environment has emerged where traditional clinic appointments have been replaced with telehealth visits and where disease monitoring has shifted to patient-driven remote**

**measurement.** Meanwhile, the United States Food and Drug Administration (FDA) recognized that digital therapeutics could be a valuable adjunct to traditional mental health products during the pandemic and waived certain regulatory requirements and approvals for digital health devices used to treat psychiatric disorders.

Digital tools encompass a broad range of new technologies influencing how care is delivered, how we diagnose and treat disease, and how we design and conduct clinical studies. They include:

- Mobile health apps and wearable sensors which can provide new flexibility and options to complement traditional disease monitoring. Under current FDA policies, many digital health apps are considered low-risk general wellness products and can therefore be marketed to the public without regulatory review or approval.
- Digital therapeutics (also termed software as a medical device), many of which have indications for mental health conditions and behavior modification. These do require a marketing authorization if they aim to treat, cure, or diagnose disease. Globally, approximately 25 digital therapeutics have been approved by regulatory agencies to date. In addition to impacting clinical care, these products are also driving new mechanisms for reimbursement as sponsors generate efficacy data for submission to regulatory agencies and payers.
- Technologies that can change how we design and conduct clinical trials, enabling a change from traditional approaches centered on clinic visits and in-person data collection to more decentralized workflows that incorporate home visits and leverage remote monitoring to support more patient-centered approaches to study conduct and data collection.

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*It has been estimated that in 2020 alone, more than 90,000 new digital health apps were made available.*

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**Digital tools are beginning to fundamentally change how we approach disease management and clinical study design.** Therefore, the 2021 Global Conference aimed to explore some of the key emerging regulatory issues related to medical devices and digital therapeutics, including the trajectory of these innovations, the clinical evidence supporting their use, the regulatory frameworks underpinning their approval and commercialization, and their adoption in the clinical health care system and trial enterprise.

## II. KEYNOTE ADDRESS: ACCELERATING SCIENCE-BASED DIGITAL HEALTH TECHNOLOGY ADOPTION

*Keynote Speaker:*

**Bakul Patel**, Director,  
Digital Health Center of  
Excellence, Center for  
Devices and Radiological  
Health, FDA

Frequently asked “What is digital health?”, Dr. Patel responds it is not one thing but rather **a convergence of connectivity, data, and computing power for health care across the life of an individual**. The FDA views digital health technology (DHT) across a spectrum that includes mobile apps, implantables, wearables and immersive technologies like artificial reality. However, laws also bound FDA’s regulatory authority to those DHTs that become a medical product.

FDA has been preparing for a digital health future, most recently with the launch of the Digital Health Center of Excellence.<sup>1</sup> The Center aims to innovate regulatory approaches that can be aligned with the goal of empowering multi-stakeholder responsible innovation. Early areas of focus include artificial intelligence/machine learning (AIML), Software as a Medical Device, interoperability, and wireless connectivity. Patel summarized regulatory science questions they are considering including:

- How do we use DHT for decentralized clinical investigations?
- What challenges are generated by information that is provided by a patient without the supervision of a clinician or the investigator, and what methodologic standards do we need to trust such patient-generated data?
- How do we use DHT to do longitudinal research and science that addresses long-term benefits and gives a long-term view into the patient’s life?
- What does validation and verification look like for consumer-grade sensors?
- What are the downstream effects of how data will be used, and therefore what should privacy, security and governance look like?

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*“We don’t want innovation for the sake of innovation. We want innovation that’s responsible, that’s very thoughtful, and that considers patients, and we can do that together by connecting and building partnerships, sharing knowledge across boundaries, and reducing some of the duplication that potentially happens.”*

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### CHALLENGES FOR AIML-BASED SOFTWARE IN MEDICAL DEVICES

1. **Availability of well-curated data sets.** Particularly when thinking about public health and the next potential pandemic, well-curated trusted data sets are crucial.
2. **Transparency** so that users understand the algorithms, how the model makes its decisions, and the frequency of algorithm changes over time.
3. **Assessment of robustness** of whether models sustain their performance or actually get better over time.
4. **The need for harmonization** at all levels, including globally, and **creation of standards and best practices.**

FDA is applying several [regulatory science tools](#), [medical device development tools](#), and frameworks to digital technologies. Guidance and discussion papers have also proven useful to generate comment and discussion within and outside of the medical device community.

Patel concluded with a call for partnerships across broad areas where excellence already exists. The [Collaborative Communities](#) program is one such effort to bring public and private-sector stakeholders together to work on medical device challenges to achieve common objectives and outcomes.

### III. REGULATION AND EVALUATION OF DIGITAL HEALTH APPS

## Impact of the New European Union Medical Device Regulations on Digital Health Companies

*Speaker:*

**Christian Johner,**  
CEO, Johner Institute

Johner highlighted some of the changes introduced by the new EU Medical Device Regulation (MDR) implemented in May 2021. For example, *Qualification and Classification* definitions will require more medical devices to be subject to conformity assessment by a notified body. However, these bodies are unable to meet the review demand and bottlenecks threaten the availability of novel devices. New information security requirements instruct device companies to take specific features of mobile platforms (e.g., size and contrast ratio of the screen) into account. The rationale for emphasis on mobile platforms – and not others such as cloud platforms, robotics or AI – is unclear. A post-market surveillance system must collect and review experiences gained from devices placed on the market and channel the information to the manufacturer, which in turn must analyze the data and take necessary internal (e.g., improving processes) or external (e.g., recalling products) measures.

To assess potential impact of the new regulations on digital health companies, Johner and colleagues studied 1000+ companies. Companies claimed there will be a negative impact on innovation and on the number of new products placed on the market. **Most companies plan to withdraw some existing products, and they expect an increase in prices.**

The potential implications for regulatory science and regulatory scientists are considerable. Johner posits that there is no evidence that the new regulations will improve the safety, performance, and clinical benefit of medical devices, nor is it clear what problem they were trying to solve. He suggests that regulatory science should:

- **Help manufacturers in the short term to survive in the existing system.** Automation could be applied to increase efficiency (e.g., in monitoring regulatory changes, conducting post-market surveillance)
- **Generate scientific evidence for risk-based regulation** that does not require inflexible, linear and burdensome approval processes. Align regulatory processes between the U.S. and Europe.
- **Develop concepts to increase selectivity of enforcement** where the few ‘bad guys’ are eliminated and the majority of ‘good guys’ are not unnecessarily burdened
- Identify ways to **support innovation and innovators**



## Panel: Regulating Digital Health Apps: An International Overview and Country Case Studies

Essen summarized findings of a comparison of national approaches to health app policy in 9 countries with well-developed health care systems and regulatory apparatuses. All of them find existing processes for health technology assessment insufficient for apps,

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*The health app space is a bit like the Wild West. It's bewildering. We all see this potential but we don't really know what to choose or what to recommend.*

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particularly regarding data privacy and security, information quality, and transparency. Reliance on published evidence doesn't fit the rapid development cycle of apps. And existing procedures don't cover wellness apps or answer whether an app should be reimbursed.

Therefore, all the countries are developing frameworks and processes to provide more guidance, although they are at different stages of development, with Germany and Belgium considered the pioneers. Most countries are focusing on apps qualifying as medical device products; typically, several regulatory bodies are engaged although one has primary authority. There is a convergence in the criteria used to evaluate health apps (e.g., transparency, usability) but substantial challenges remain to operationalize, implement, and enforce acceptable levels. *Most countries are in a stage of experimentation and learning and no one really has the answer to what design is the best.*

### GERMANY: DIGITAL HEALTH APPLICATIONS (DiGA) FAST TRACK

Matthies characterized DiGA Fast Track, an early example of regulating the digital therapeutics space, as a structured way for digital health applications to access standard care. Applying to Class I and IIa MDR medical products, it encompasses a clear set of requirements, a path to reimbursement, pricing parameters, and a preliminary approval option to be listed for 12 months while additional evidence is collected. Listed apps are simply prescribed by a physician and must focus on the daily life of patients.

### INITIATIVES OF THE U.S. FDA DIGITAL HEALTH CENTER OF EXCELLENCE

Recent digital health authorizations include those for diagnosing diabetic retinopathy and a digital therapeutic for children with ADHD. Twelve digital health guidance documents have been published since FY2018, and a report will be issued later this year on learnings from the Digital Health Software Precertification pilot program. Work is also ongoing with the International Medical Device Regulators Forum to create an internationally harmonized framework. Finally, a regulatory framework for Artificial Intelligence/Machine Learning-based Software as a Medical Device is under development.

### MHEALTH BELGIUM: A JOINT GOVERNMENT AND INDUSTRY INITIATIVE FOR DIGITAL HEALTH

MHealthBelgium has created a process and [online portal](#) to validate online medical device apps. Three levels with associated criteria are represented in a 'validation pyramid'. Level 1 requires CE declaration

#### Panelists:

**Ariel Stern**, Associate Professor, Harvard Business School (Moderator)

**Anna Essen**, Associate Professor, House of Innovation, Stockholm School of Economics, Sweden

**Henrik Matthies**, Managing Director, Health Innovation Hub, Federal Ministry of Health, Germany

**Anindita Saha**, Assistant Director, Digital Health Center of Excellence, CDRH, FDA

**Steven Vandeput**, Coordinator, mHealthBelgium

as a medical device to the Federal Agency for Medicine and Health Products and compliance with EU GDPR regulations. Level 2 encompasses interoperability and safe connectivity requirements. Level 3 (M3) is reserved for apps for which social-economic added value has been demonstrated. These M3 apps are eligible for financing on the national level by the national payer authority.

#### **DATA PRIVACY AND SECURITY AND EVIDENCE GENERATION**

Panelists discussed key issues in data privacy and security, agreeing that the patient needs to be in control of their own data. However, data access is important for scientific purposes, for value creation, for new research and development, and for policymaking. Patients are often excited to share their data with researchers and new policies are therefore needed to facilitate and maximize reuse of data.

#### **CONSIDERATIONS FOR EVIDENCE GENERATION IN A WORLD OF DIGITAL HEALTH TOOLS**

- 1. New study designs are needed.** We cannot rely on conservative, 24-month designs which are not adaptable and which do not take into account real-world data. Consider prospective trials and including additional endpoints such as improved quality of care.
- 2. The FDA legislative framework for medical devices, written in 1976, needs updating** to account for assessing real-world performance and technology changes such as dynamic software and push updates to remote devices and remote technologies.
- 3. Test opportunities to provide a “fast track” for innovation,** e.g., allowing an app to be on the market for a certain period of time while collecting larger scale evidence.
- 4. Conduct pilot programs;** it is unlikely there will be a one-size-fits-all answer.

## Approaches to Evaluate Digital Mental Health Risks and Benefits

Mental health and behavioral disorders have been an area of particular interest in the development of digital therapeutics. Torous began by noting the considerable innovation happening in digital health in the mental and behavioral disorders space, especially with smartphone apps. Phones used as wearables can record information to quantify people's lived experience, offer behavioral interventions to support health, and collect real-time responses or assess how people are doing. He acknowledged the need to increase access to care, but cautioned **it is important we don't use new technologies to do so at the price of quality of care.**

*Speaker:*

**John Torous**, Director of Digital Psychiatry, Beth Israel Deaconess Medical Center

Despite potential benefits, patients, especially those with illnesses like schizophrenia, bipolar disorder, or severe depression, may not be ready to use technology and the risk exists to create or exacerbate digital divides. However, his group is learning that it is possible to teach digital literacy. They have also identified that implementing these technologies, particularly in behavioral health, requires offering additional help to clinicians. A new team role – digital navigator – may help.

### A NEED TO BALANCE INNOVATION WITH REGULATION

Digital innovations spawn questions including how digital navigators will be regulated or monitored, and how we will know if an app is safe or trustworthy. The FDA issued an enforcement policy intended to help expand availability of digital health therapeutic devices for psychiatric disorders during the COVID public health emergency.<sup>2</sup> Could this “lower bar” for approval become permanent...and should it? Risks include lower standards of evidence for effectiveness and implied FDA endorsement. The Federal Trade Commission has also weighed in regarding breaches of data in apps that collect sensitive health data.<sup>3</sup> These requirements add complexity to the regulatory landscape and the area of enforcement discretion may be particularly difficult to ascertain in mental health and behavioral disorders. For apps addressing mood, stress, anxiety, or depression, developers may assert “we’re a wellness app” and therefore avoid any FDA regulation.

### FUTURE APPROACHES AND OUTSTANDING ISSUES

The FDA is piloting a Digital Health Software Precertification Program,<sup>4</sup> aimed at streamlining oversight of software-based medical devices for manufacturers committed to post-approval performance monitoring of their products. This is important as many apps claim to be effective at diagnosing a mental health or behavioral disorder condition or treating symptoms but very few cite published evidence.<sup>5</sup> We also need to understand if patients are actually using the apps and at what levels of engagement. Apps also have potential iatrogenic effects, e.g., unguided exposure therapies without a treatment plan can increase symptom severity and many apps lack adequate safety or crisis management plans.<sup>6</sup> **Significant data privacy issues persist across mobile health apps<sup>7</sup>** and are of particular concern for sensitive mental health and behavioral disease diagnoses.

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*The free searchable online database at [MindApps.org](https://www.mindapps.org) characterizes 600 mental and behavioral health apps by 105 objective dimensions (e.g., does it offer peer support?)*

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## IV. INFRASTRUCTURE TO ADVANCE EVIDENCE GENERATION

### Supporting National Device Surveillance: Registry Networks

*Speaker:*

**Ralph Brindis**, Senior  
Medical Officer, External  
Affairs- ACC National  
Cardiovascular Data  
Registry

Reviewing the rationale for using registry networks to support national medical device surveillance, Brindis related that such registries are the only current sources that include granular clinical data needed for risk adjustment (e.g., medical device identifying information needed to capture specific exposure), and that have the potential to leverage global participation. Challenges with registries include their capture of only specific devices and conditions, and limited longitudinal-follow up. The

latter issue has been addressed by merging data sets with Centers for Medicare and Medicaid Strategies (CMS) data, electronic health records, and administrative data. Merged registry datasets are a source of real-world evidence to inform device safety and effectiveness assessments, conduct benefit/risk determinations, serve as the basis for device approvals and post-market surveillance, offer feedback to improve quality of care, and identify new indications or populations for study.

The five device-related registries of the National Cardiovascular Data Registry capture the vast majority of implanted cardiovascular devices in the U.S. Benefits for device development and assessment include:

- Considered by stakeholders to be a trusted third party
- Data quality and assurance (training and support, data completeness checks, data accuracy audits)
- Time savings of months or years in device indication approvals vs. using randomized clinical trials<sup>8</sup>
- Longitudinal linkages of claims and administrative data facilitate post-approval studies

The Medical Device Epidemiology Network (MDEpiNet), a global public-private partnership, aims to advance a patient-centered medical device evaluation and surveillance system. With an organizational structure that includes the FDA, a coordinating center at Weill Cornell Medicine, and international chapters, MDEpiNet builds coordinated registry networks (CRNs) and collaborative learning communities in multiple clinical areas (e.g., devices for ischemic stroke, breast implants, and cardiac devices). The coordinating center promotes the use of unique device identifiers, uses a HIVE (high-performance integrated virtual environment) to leverage data to advance post-market surveillance, and conducts comparative outcome studies to inform clinicians and regulatory decision-making.

Going forward, the National Evaluation System for Health Technology (NEST), comprised of multiple stakeholders including MDEpiNet, device registries, CRNs, CMS and the FDA, is adding new networks annually and includes data for over 160 million patients, which is shared via a central cloud and federated data distribution model.

In closing, Brindis shared several examples of [the power of using registry platforms for prospective active surveillance for medical device safety](#).<sup>9</sup> This approach could deliver timely post-approval confirmation of high-risk device safety, supporting FDA initiatives for post-market surveillance.

# Considerations for Implementing Decentralized or Flexible Clinical Trials

Mather and Demanuele shared learnings from their large-scale decentralized clinical trial to build an algorithm for COVID-19 symptom monitoring for future vaccine R&D. Study recruitment, screening, consenting and enrollment happened online, enabled by an app. Subject symptom monitoring occurred daily including voice recordings and answering symptom diary questions.

- **A solely social media-based recruitment strategy is likely ineffective**, especially for meeting diversity goals. Consider adding print or radio ads and targeted approaches for different patient populations.
- FDA e-consenting requirements have been modified during the COVID-19 pandemic, but **it is important that e-consenting tools can capture remote signatures and conducting remote and automated identity verification.**

*Speakers:*

**Charmaine Demanuele**,  
Director, Early Clinical  
Development Biostatistics, Pfizer

**Robert “Joe” Mather**, Executive  
Director, Head of Advanced  
Sciences, Digital Medicine &  
Translational Imaging, Early  
Clinical Development, Pfizer

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*Q&A excerpt:*

## **Data heterogeneity**

*“There’s actually much more heterogeneity than we generally expect in the data and there needs to be a lot of careful analysis of data coming from decentralized BYOD trials.” - Charmaine Demanuele*

While we understood that there would be heterogeneity among the devices, what we weren’t expecting is within a given day and a given participant, they would switch mobile platforms and the types of devices...it was an unexpected outcome. This could introduce unintentional biases that we don’t yet fully understand.

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- **Challenges of a BYOD (bring your own device model) vs. providing participants a phone.** Participants downloaded the study app to multiple devices (e.g., phone, tablet), and also changed phones (e.g., Android to iOS) over the course of the study. Device heterogeneity is considerable; different models have different screen sizes, affecting reading, as well as differing noise profiles, affecting recordings.
- The app is replacing the research assistant or the clinician in a clinical setting. **Clear instructions in audio, visual, and text are needed to help participants perform study tasks correctly.** Incorporate user testing into study design.
- Although a decentralized clinical trial transfers much of the responsibilities for data collection and processing to the participant, it also pushes **more burden onto vendors, technologies and sites to ensure GCP compliance and that data is audible for future regulatory interactions.**
- **All study sites are not created equal;** many lack the scale and staff to support all aspects of a fully decentralized trial. Additional staff may be necessary to interact with site investigators and their staff.

## Panel: Advances in Decentralized Trials and Regulatory Considerations

Chan cited areas where existing ‘analog’ clinical trial processes are antiquated: 1) participant diversity and the generalizability of trial results for diverse populations, 2) ensuring that efficacy derived in an artificial environment translates to real-world treatment effectiveness, and 3) patient agency, participant centrality, and consumer experience.

### WHAT, EXACTLY, IS A DECENTRALIZED CLINICAL TRIAL (DCT)?

Panelists noted there is no single agreed-upon definition. DCTs may be inclusive of both process changes as well as the use of digital technologies and are characterized by a shift from a dependency on all visits taking place in a conventional research site. A focus is on expanding options for participants, adapting the trial more to the people participating in it than the other way around, increasing diversity in trials, and using technology to help patients more easily identify trials they could potentially participate in. Hybrid models are the most common currently, and a decentralized trial may just mean a conventional trial that was designed to include some new, more accessible methods within the study.

#### Panelists:

**Yvonne Chan**, Executive in Residence and Scientific Steering Committee, Digital Medicine Society (Moderator)

**Craig Lipset**, Co-Chair, Decentralized Trials & Research Alliance

**Derk Arts**, Founder & CEO, Castor  
**Andy Coravos**, Co-Founder & CEO, HumanFirst

**Leonard Sacks**, Associate Director for Clinical Methodology, Office of Medical Policy, CDER, FDA

### MAXIMIZING POTENTIAL BENEFITS AND REGULATORY CONSIDERATIONS: AN FDA PERSPECTIVE

Sacks summarized opportunities of interest to the FDA including telehealth for research visits; video interactive technologies for remote informed consent; the ability for local healthcare services to go to

patient homes to get blood or other tests typically done in a clinical setting; how to get investigational drugs directly to patient homes; and whether sensors and other digital health technologies can be used to get physiological information directly from patients. **The potential benefits of DCTs are accompanied by regulatory concerns.** One is how to ensure supervision of trial activities performed remotely, and how are requirements for investigator responsibilities satisfied, particularly when local healthcare providers are involved. **A fundamental question is what is a ‘research site’ in a decentralized environment.**

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#### Q&A excerpt:

#### Keep the momentum and get involved

*“The future hasn’t been built yet... COVID’s lasting longer than any of us thought it would and for many folks, these trials start getting really hard. And so this is really a critical time for all of us involved in this work to make sure that we keep pushing through, and that we don’t just say, ‘Okay, this was harder than the old versions’.” – Andy Coravos*

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### ARE DIGITAL MEASUREMENTS VALID AND MEANINGFUL?

Considerable discussion considered the need to validate the technologies and determine whether the information they provide is meaningful. Digital health technology adoption has lagged other decentralized trial features in post-pandemic studies, potentially because regulators and sponsors are not

confident about relying on technologies to acquire data that was previously acquired via study staff. The

new FDA Center for Excellence in Digital Health will help expose reviewers to software and hardware engineering and statistical approaches which traditional drug reviews are not familiar with.

#### **OPPORTUNITIES TO ADVANCE DECENTRALIZED CLINICAL TRIALS**

1. **Make changes incrementally**, using measurements that have already been used in clinical practice such as remote glucose, monitoring weight measurements and patient-reported outcomes, in order to build confidence.
2. **Support the Decentralized Trials and Research Alliance** and other collaborative efforts working to reduce regulatory ambiguities and variability from one country to the next.
3. **Identify crowdsourcing opportunities** for developing digital measurement data sources between pharma organizations and research sponsors so that the “heavy lift” does not all fall on the FDA.

## V. SUMMARY

Digital health devices represent considerable, albeit only partially realized, benefits for optimal patient health outcomes. The growth of smartphones is developing a population with unprecedented ease with digital tools, and the potential for adoption and uptake of wearables, digital interventions, and medical apps is tremendous. However, obstacles to further progress include apprehension and lack of confidence in the use of new technologies and in new ways of doing things.

While no “new normal” has yet emerged from the continuing COVID-19 pandemic, technologies are permeating the clinical care environment and will inform their further use in research. Studies showing the comparability between traditional measurements and measurements made using more innovative technologies will be reassuring both to industry and to the FDA and other regulatory bodies. Support from the academic community for new methods of analysis for novel data would also be helpful.

*Recurrent conference topics included:*

- Digital health technology adoption is underway; true innovation will likely be incremental
- Patients and clinicians need resources and tools for choosing among myriad health apps
- An opportunity exists to exploit real-world evidence for clinical management, research, and device development and evaluation
- Decentralized trial models may reach broader populations of patients that have not historically been served in traditional clinical trials

*Closing remarks  
moderated by Peter  
Sorger, Co-Director of  
the Harvard-MIT CRS*

*Panelists: Florence  
Bourgeois, Laura  
Maliszewski, Leonard  
Sacks, Joe Mather,  
Christian Johner*



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