

## 22nd Advanced Summit on Life Sciences Patents

### Balancing Innovation and Data Privacy: Navigating Global Regulatory Frontiers in Digital Health and Therapeutics

Fairfield Inn & Suites Manhattan Times Square South, New York, NY

05.29.2024 | 4:00-5:00 PM

Event Sponsor: American Conference Institute

In this panel discussion, speakers will dive deep into the evolving landscape surrounding digital health data privacy, a central pillar in the journey from concept to regulatory approval for digital health technologies and digital therapies. The speakers will dissect recent global data updates that attendees cannot afford to overlook and provide strategies for navigating the complex intersection of digital health, data, and IP rights.

- Exploring the regulatory landscape in the United States and the EU on digital health
  - Compiling FDA digital health guidance
  - Digital Health Policy Navigator
- Understanding the regulatory landscape for medical devices
  - Unpacking the FDA's final CDS guidance
  - Understanding the FDA's new medical device cybersecurity guidelines
  - Utilizing FDA's list of devices that incorporate AI/ML
- Appreciating the essential role drug delivery plays in personalized medicine
  - Considering technological advancements that allow for more user-friendly and accurate devices: the integration of microelectromechanical systems (MEMS) and smart devices and the integration of IoT into drug delivery devices (e.g., smart pills, smart auto injectors)
- Exploring the benefits and challenges of AI/ML technologies in medical diagnostics
  - Reflecting on the gaps identified by the Center for Devices and Radiological Health's update on its AI Program
  - Considering the US Government Accountability Office's 2022 report
  - Considering the EU-AI Act, and the UK's MHRA roadmap on software and AI as a medical device
- Getting ahead of the complex intersection of digital health technologies and data privacy and protection
  - The UK's Information Commissioner's Office guidance on the relationship between AI and data protection

#### Speakers:

- Sara Shanti, Partner, Sheppard Mullin

- Abeba Habtemariam, Partner, Arnold & Porter Kaye Scholer LLP
- Ksenia Takhistova, Chief Legal Officer, LCM Biosensor Technologies LLC
- Erin Geygan, Senior Privacy Counsel, Data Protection Legal, Johnson & Johnson

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## Attorneys

Sara Helene Shanti

## Practice Areas

Healthcare

Intellectual Property

Privacy and Cybersecurity

## Industries

Artificial Intelligence