eSource Symposium: Resolving a Weak Link in the Learning Health Cycle

(Three Seminars: 20, 25, 27 August 2020)

20 August 2020 Agenda: Current Perspectives on eSource, RWD, and Regulations

- **Welcome, Opening Remarks, and Context-setting – Josh Rubin, Kaci Sykora, Rebecca Kush**
- **TransCelerate's eSource Initiative**
  - Rakesh Maniar, Novartis
- **EMA Perspective on eSource, RWD, and Opinion on eSource/DDC**
  - Lisbeth Bregnhøj, DKMA (Good Clinical Practices Inspector)
- **FDA Guidance, Standards, and Strategy on eSource and RWE**
  - Mary Ann Slack, FDA
- **Personalized Medicine and True eSource**
  - Jesper Kjær, DKMA (Data Analytics Center Director)
- **The Common Data Model Harmonization Project**
  - Mitra Rocca, FDA
- **Real World Experience With RWD in Community Practices**
  - Michael Ibara, Elligo Health Research