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
  o Rakesh Maniar, Novartis

• EMA Perspective on eSource, RWD, and Opinion on eSource/DDC
  o Lisbeth Bregnhøj, DKMA (Good Clinical Practices Inspector)

• FDA Guidance, Standards, and Strategy on eSource and RWE
  o Mary Ann Slack, FDA

• Personalized Medicine and True eSource
  o Jesper Kjær, DKMA (Data Analytics Center Director)

• The Common Data Model Harmonization Project
  o Mitra Rocca, FDA

• Real World Experience With RWD in Community Practices
  o Michael Ibara, Elligo Health Research