Welcome and Introductions – Josh Rubin, Jonathan Chainey, Rebecca Kush

Dr. Christopher Chute, Bloomberg Distinguished Professor of Health Informatics, Professor of Medicine, Public Health, and Nursing at Johns Hopkins University, and Chief Research Information Officer for Johns Hopkins Medicine

The Synergy Between Federated and Centralized Clinical Data Repositories and Its Impact on Data Quality

There has been a convergence of common data models (CDM) used for research, enabling analyses to support the learning health systems. The National COVID Cohort Collaborative (N3C) leveraged four CDMs to generate a large, centralized repository for COVID research. CDMs generated locally have the obvious advantage of local curation and verification against source data. Centralized datasets permit high-throughput benchmarking of data, distributions, units of measure, and relative missingness, to potentially identify outliers. Outliers can be addressed with contributing organizations and reconciled (accepted or corrected); in some cases, such as missing units of measure, data can by “corrected” by matching data distributions to benchmarked distributions. N3C has demonstrated strong synergies across federated and centralized data models, each improving the other.

Frank Nogueira, CEO, Accumulus

Funded by ten leading biopharma companies, the non-profit Accumulus Synergy, Inc. was formed in 2020 to create a cloud-based platform, to transform data sharing between the biopharma industry and global health authorities. The common-platform approach aims to improve efficiencies in the regulatory process by leveraging advanced technology, including data science and AI, as well as tools for data secure exchange to improve patient safety, help reduce the cost of innovation, and ultimately bring patients safe and effective medicines faster. It will work with partner companies, key stakeholders, and global health authorities to build and sustain a platform that meets regulatory, cybersecurity, and privacy requirements spanning clinical, safety, chemistry and manufacturing, and regulatory exchanges and submissions. For more information, please visit www.accumulus.org.