

Integration of clinical study data to support trial simulation activities

Raj Bandaru

Sanofi Pharmaceuticals, USA

Like much of the pharmaceutical industries, we at Sanofi are also experiencing a shift in clinical development strategies to adopt more digital technologies and analytics placing greater emphasis on data and model driven approaches. We have set up a strong integrated capability across quantitative systems models, disease progression models and empirical models driving a rigorous clinical trial simulation process to inform design and key decisions in our clinical research. To this end, access to historical clinical trial data has been central. However, using clinical study data for broader clinical research use has several limitations and challenges. We are implementing several processes and intelligent informatics solutions to enable easier access to clinical study results and conducting integrated analytics using state of the art methods and tools. Here we describe some of the informatics solutions we are developing and how these could eventually be applied to support trial submission activities. One example is in the use of a machine learning methods to index data and make it searchable without compromising data security or patient privacy. We are also applying intelligent approaches to data de-identification and harmonization across multiple studies to support meta-analysis. A pilot effort using a learning based approach to data harmonization has shown significant promise and we are exploring other applications including management of metadata and terminologies using machine learning approaches. Some challenges however still exist primarily in the governance of data access and patient privacy issues. We are working on developing clear rules and guidelines that will eventually also help with automating data governance activities. Another challenging area will be in handling genomic and digital health data and we foresee an opportunity for automated machine learning algorithms to help in not only managing the data, but to also discover patterns and associations to clinical outcomes.

Biography

Raj Bandaru heads a data analytics and knowledge management function in Translational Informatics at Sanofi Pasteur. He is championing the adoption of cloud and big data analytics at Sanofi, bringing advances in clinical research together with big data and digital technologies. Over the past two decades, he has led data management and analysis across research and clinical development at various pharmacy and biotech companies and most recently led a data and analytics consulting practice. He has an MBA from Babson College, with a focus on clinical informatics and operations research and also holds graduate degrees in statistics and genetics.

raj.bandaru@sanofi.com

Notes: