Connecting dots in Biometrics
Clinical data strategies (5 Vs)

Veracity
Data integrity and ALCOA

Velocity
Appropriate data storage at increased volume, speed and frequency

Variety
Integrating both structured and unstructured data from a wide range of sources and transform them into useful information

Volume
A few datapoints per CRF to more than tens of thousands of datapoints generated per patient per week

Value
Maximize the relative value of any one data point in this ocean of data
Creation of Data Lake

- Sensors and wearables
- RWD
- eCOA
- EMR and EHR.
- eCRF, Local labs and CTMS
- Labs, biomarkers and imaging
Benefits of data lake creation

- Democratization
- Enhanced data quality
- Incorporation of varies data structures and formats
- Scalability
- Versatility
- Flexibility
- Advanced Analytics and trending
- Real time data cleaning
Strategizing in study startup

• Usage of technology and streamlining of processes to reduce time between protocol finalization and DB Go Live.
• Metadata driven approach to a clinical data lake to integrate multiple data sources irrespective of the varied structures and formats
• Automation of integration and checks will help us get true insights and trending.
• Creation of structured protocol developer tool to develop eCRF design in collaboration with the global library.
• Creation of DMP through standard templates and collaboration within the tool to manage updates and DMP approvals.
• Standard and flexible libraries accommodating multiple study designs.
• Using streamlined, fit-for-purpose and risk-based approaches to improve the costly and lengthy postproduction eCRF change process
• Targeting edit checks on what matters (i.e., being risk-based and focusing on critical data and processes)
Strategizing in study conduct and lock

- Embracing AI and agile methodology to shorten time from LPLV to DB lock drastically.
- A real time data cleaning technology on the data lake with all data sources integrated.
- Collaboration between EDC and data lake platform to create prompters to give cues to end users.
- Creation of bots to raise queries in EDC platform will ensure high quality data delivery at real time.
- Utilization of AI to understand datasets more deeply, understand data trends to identify new insights.
- Collaborating with vendors to bring in real time data reconciliations and automating the vendor process.
- Collaborating through the data lake platform to highlight protocol deviations, route issues to different stakeholders (including sponsors).
- Creation of user friendly and tailored dashboards, enhanced and real time reporting system.