

# Envisioning Data in Clinical Trials

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Pharma industry is being disrupted from a drug - centric approach to a patient - centric approach leveraging new & transformational technologies, which includes but not limited to

- **Genomics and Personalized Medicine** will redefine existing therapy, practices, and markets
- **Clinical Wearables** combined With Health ecosystems enabling **Virtual & Decentralized trials**
- **Digitally Empowered Patients** will bypass existing processes
- **Metadata** driven automated transformation initiatives
- Therapeutically Minded **AI, NLP & Cognitive Computing** will Improve Science & Health Outcomes
- **Pharma IoT** will breathe dynamic capabilities into static systems
- Virtual **PAs & Helpdesks** becoming smarter and help Investigators and Patients

With the above trends we see tsunami of data getting generated and since Clinical Trial data is at the heart of clinical operations; reviewing it, analyzing it and delivering it to regulatory bodies for approval is essential. However, the data is often difficult to access in real time, not readily available in convenient formats and personnel/processes are often silo'ed in separate departments, which makes managing handoffs challenging, in an evolving landscape fragmented data and overly complex analytics and business processes creates significant compliance, efficiency and execution challenges

To overcome challenges and to become data driven organization with a desired vision of integrated solution where enterprise data and real work evidence data is predominantly used to generate, evaluate, and manage highly reliable insights, given below are few considerations which can help organization to overcome data related challenges and move towards data driven organization

a) **Access to data**–

- Provision to collect and segregation of huge amount of data collected during trials
- Storing of unstructured data
- Provisioning common enterprise level repository at global level.

b) **Managing and integrating the data** –

- Integrating multiple sources in an efficient and timely manner, with vision to have single source of truth
- Data Quality and Data Standards
- Leverage RPA, AI, ML technology for real time integrations

c) **Analyzing data to obtain valuable insights**

- Increase transparency to enable informed decisions
- Advance real time analytics
- Seamless access to information

With the above considerations Pharma Industry is trending towards building or adopting next generation Clinical Data Environment that can enable centralized storage, aggregation, and processing of the clinical data and metadata to enable clinical analytics, data cleaning, data governance and standardization of data to CDISC SDTM standards.

Data driven organizations are anticipating the business needs and working proactively on renovating and reinvesting in modernizing the data architecture which is a data environment that is a living, breathing organism that detects and responds to changes, continuously learns, and adapts, and provides governed and tailored access to every stakeholder within Clinical organization.