

Single Day Event

Evolving Oncology Therapeutic area, its
future developments & impact on Clinical
Data Analysis

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Abstract

- Selective therapeutic area trials by their virtue demands complex designs (umbrella or adaptive) requiring a collection of huge, varied, complex data with smarter analytics. Oncology is experiencing significant advancements, especially in fields of immunotherapy, targeted therapy, personalized medicine, oncolytic virotherapy, cancer stem cell therapy, artificial intelligence (AI) & machine learning (ML) based analytics. Research focuses on computational Genomics, Epigenome analysis, Metagenomics, Image Analytics & Digital Health etc.
- A deeper incorporation of AI/ML will help in emphasizing combination therapies & biomarkers for diagnosis, treatment monitoring and genomics data. This can potentially address the unmet needs in clinical data analytics of oncology trials.
- Availability of unified platforms to digitally capture data from varied sources (lab data, wearables, ePROs etc.) has led to real time data collection. Effective handling, standardization, reconciliation, and analysis of such voluminous data with technology driven clinical operation, data management, interpretation & analysis is the need of hour.



AGENDA

- 1 Advancements in Oncology
- 2 Current challenges
- 3 Challenges & Solutions for Oncology Data Management
- 4 Data Analysis & Validation using Gen AI
- 5 Addressing the unmet needs with technology.

Immunotherapy

- Harnessing the power of immune system
- Immune system activation/Suppression (T cells & natural killer cells)
- Examples: Nivolumab, Atezolizumab etc

Targeted therapy

- Target specific proteins that supports tumour growth
- Tyrosine Kinase inhibitors (lapatinib, crizotinib, Sorafenib etc)



Cancer stem cell therapy

- Stem cells are transplanted into the patient through intravenous (IV) infusion.

Personalized medicine:

- Drug is guided by the specific biology of each patient's cancer – EGFR, HER2 inhibitors
- Trastuzumab, Imatinib, Vemurafenib

Oncolytic virotherapy

- Virus genomes are engineered to enhance their anti-tumor specificity–RNA virus
- Coxsackie virus, Maraba virus, measles virus (MV), etc

Complex Trial Designs

- Umbrella, adaptive trials
- Biomarker selections
- Statistical Complexity
- High volume of data collection
- varied, complex data collection
- Need for Robust data management



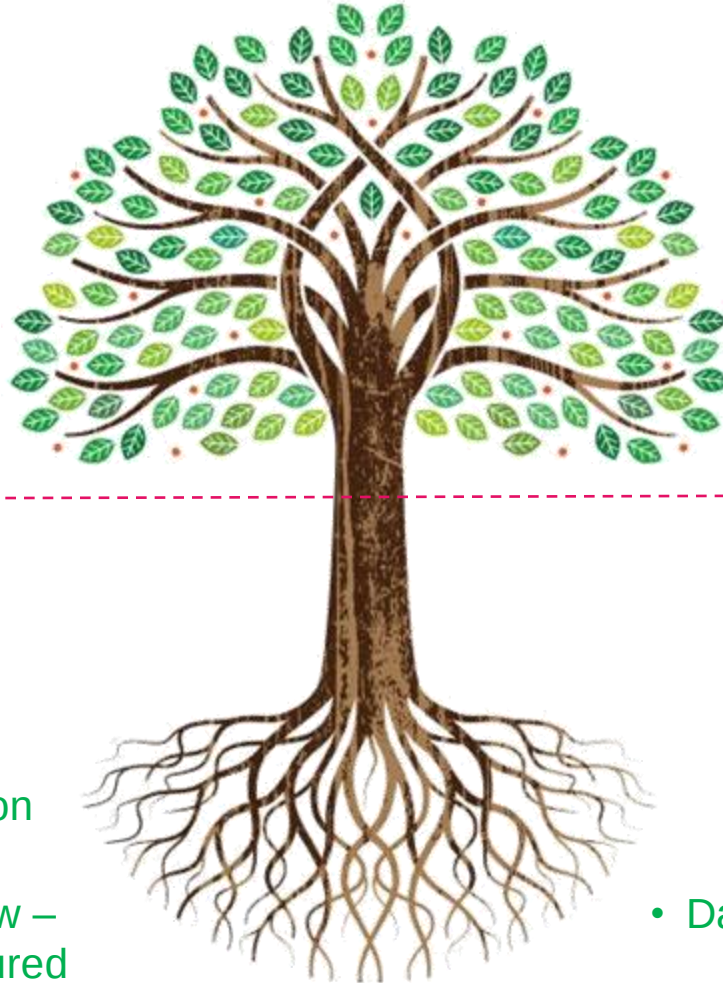
Data Acquisition

- Quality & Integration
- Fragmented or incomplete Data
- Difficult to integrate and analyze
- Lack of Standardization.
- Missing/incomplete data
- Data Silos
- Multi-dimensional data
- Complex data relationships (genomics, imaging, TLFs)
- Large datasets

Data Analytics

- | | |
|--|--|
| • Lack of real-time analytics | • Personalization: Focus on population level and NOT patient level |
| • Limited use of data visualization tools | • Interpretation, and analysis: |
| • Limited predictive modeling | • Time-consuming analysis |
| • Complex Analytics & difficult interpretation | |

Problem: How do we Approach?



- Treatment Selection

- Huge Data Volume

- Complex Analytics & difficult interpretation

- Inefficient Data Collection

- Data Integration & Analysis

- Irrelevant data & Data Cleaning

- Right Data Selection (Protocol – SOA?)

- Use of Right channel/platform

- Data Standardization

- RWE Analysis

- Imaging Analytics & Interpretation

- Predictive Modeling

- Synchronized data flow – unstructured to structured

- Data Tracking Frequency

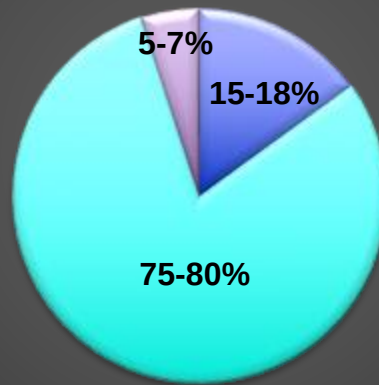
- Efficient Trial Design

- Treatment Optimization



Challenges & Solutions : Oncology CDM

Clinical Data Management Efforts



■ Study Set Up ■ Study Conduct ■ Study Close Out

- Complexity: Medium/Complex; TA: Oncology
- Major Contributors in Conduct are EDC Data review(~40%), External Data management (~20%) & Project Management (~15%),

Challenges:

- Higher study specific eCRF & Complex study designs
- Data entry errors by site due to dynamic visit structure
- Higher amendments
- Higher % of non CRF data & various sources of data
- More Interims and DSMB due to long duration of studies
- Multiple handoff due to long duration....

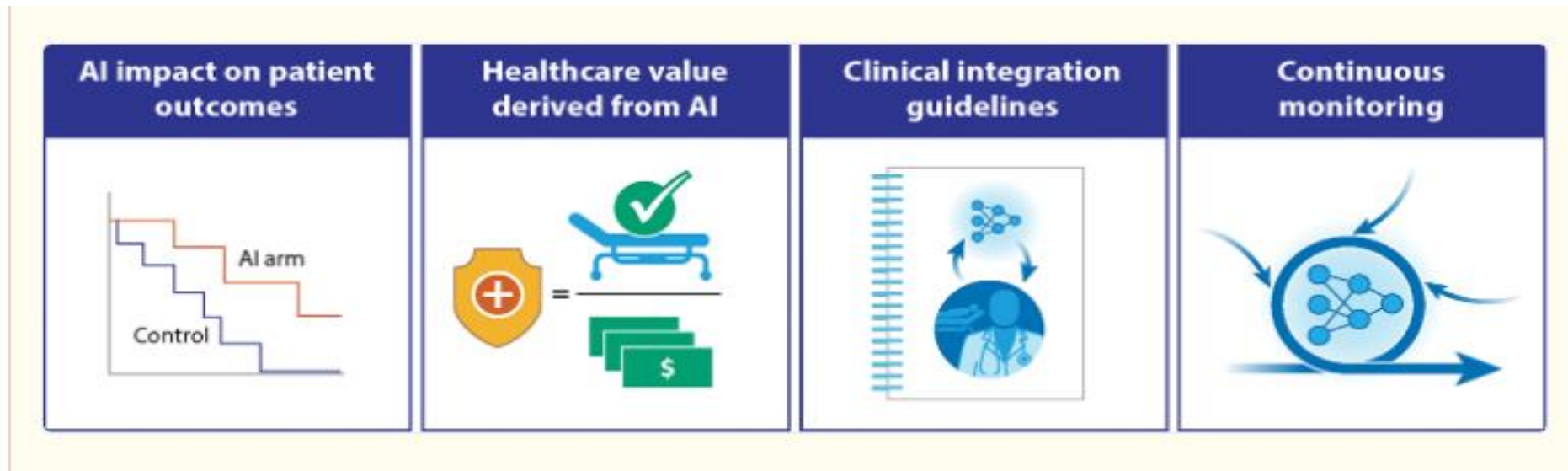
Solution:

- Robust TA specific standard development
- Enhance TA competencies and protocol knowledge for DM
- Data visualization tool and trend analysis helps Query Reduction & Data Quality improvement
- Regular sharing of study health through metrics to manage effective and expedited data cleaning
- Optimization of study build & data review by technology (GenAI/AI/ML) implementation
- Risk based data management approach
- Process improvement with Agile

“Average \$200000 to 250000 cost E2E data management of Oncology medium complex trial. Efficiency gain ~30% feasible with Technology intervention (Gen AI/AI-ML/RPA solutions) & process improvement”

Considerations for AI in Oncology

- Cancer screening (lesion detection), diagnosis (False negative, Benign vs malignant, grades) & treatment (genomic interpretations etc, first line of choice (chemo etc)
- Structured AI applications based on cancer type and clinical domain
- These applications encompass various data modalities, including imaging, genomics, and medical records..



“Artificial Intelligence (AI) in Oncology: Current Landscape, Challenges, and Future Directions” [Artificial Intelligence \(AI\) in Oncology: Current Landscape, Challenges, and Future Directions - PMC](#)



Data Analysis & Validation using Gen AI

Increased adoption of AI/ML: Content generation

- Efficient Trial Designing
- Treatment Optimization
- Data interpretation using Gen AI solution: Table/Graphs to Text Summarization, Imaging Analytics & Interpretation
- RWE Analysis: Greater emphasis on real-world evidence
- Predictive Modeling: Data tracking frequency (all or mean), trend analysis & forecasting

Data Acquisition: Real time data capture

- Unified platforms
- Wearables data (digital devices)
- ePROs (patient dairies/QoLs)
- Externa data (lab, biomarkers etc)

Data processing & validation

- Gen AI based study build solution (protocol to eCRF spec & edit check spec)
- Smart query management
- Efficient data validation as per trial requirement (objectives/endpoints)

Role evolution

- Medical Writers to Content Scientist: content reuse & standardization, prompt crafting, data driven authoring
- Data Managers to Data Scientist: Use of data analytics & Visualization for real time visibility and risk identification
- Blending the study designer role into data mangers



Addressing the unmet need with Technology

Diagnosis:

Early & right diagnosis (image analytics and lab parameters)

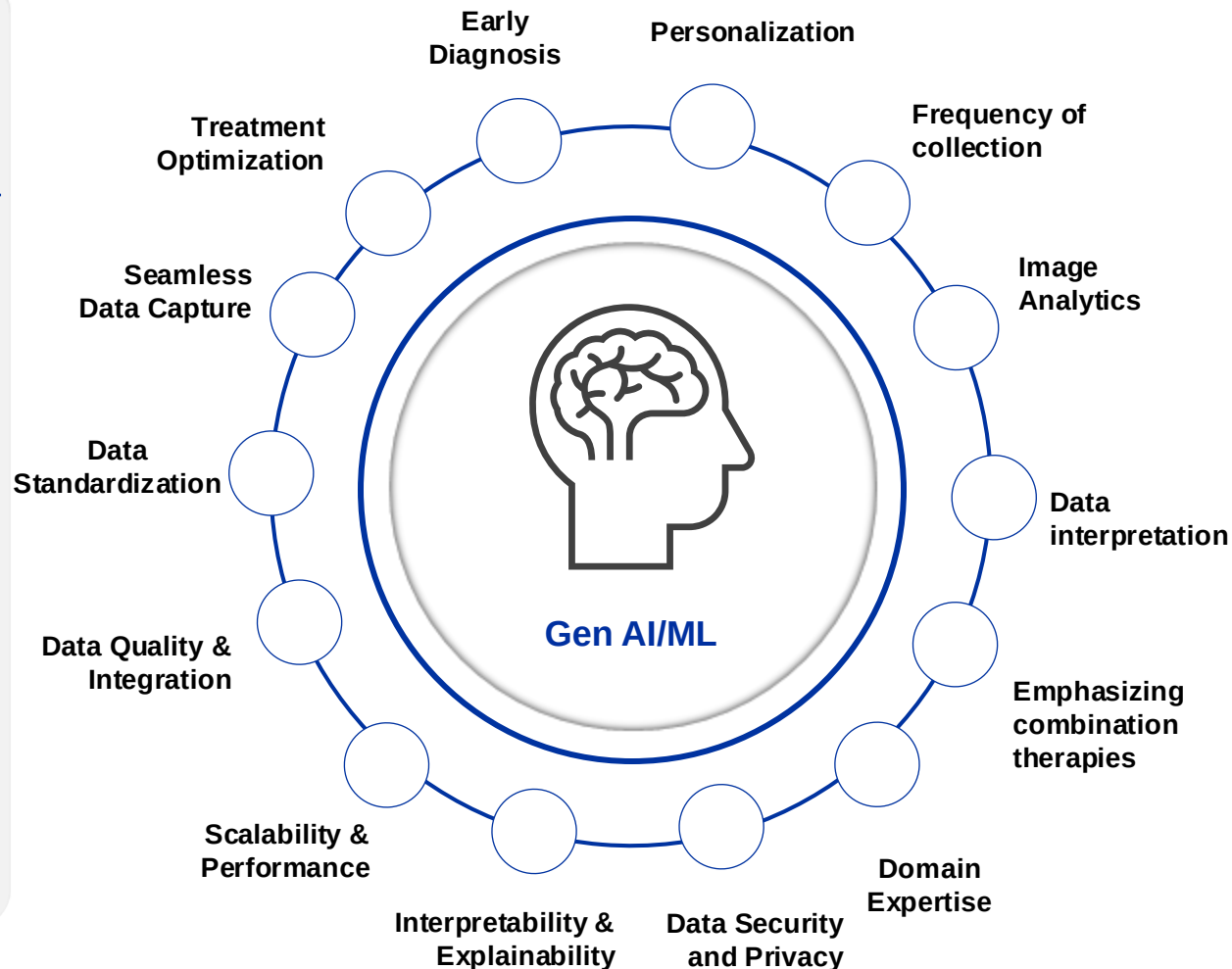
Real-time Insights:

Analyzing data in real-time and providing alerts and notifications.

Data Security and Privacy polices.

Apply advanced encryption and access controls.

Treatment Optimization: Suggest the right combination treatment or biomarkers for diagnosis based on RWE data or Patients



Seamless & real time digital data capture from varied sources (lab data, wearables, ePROs)

Interpretability and Explainability: Provide transparent and understandable models and results.

Data Standardization:

- Standardize as per relevant standards and ontologies.
- Data flow: Synchronization, unstructured to structured - Data to consent

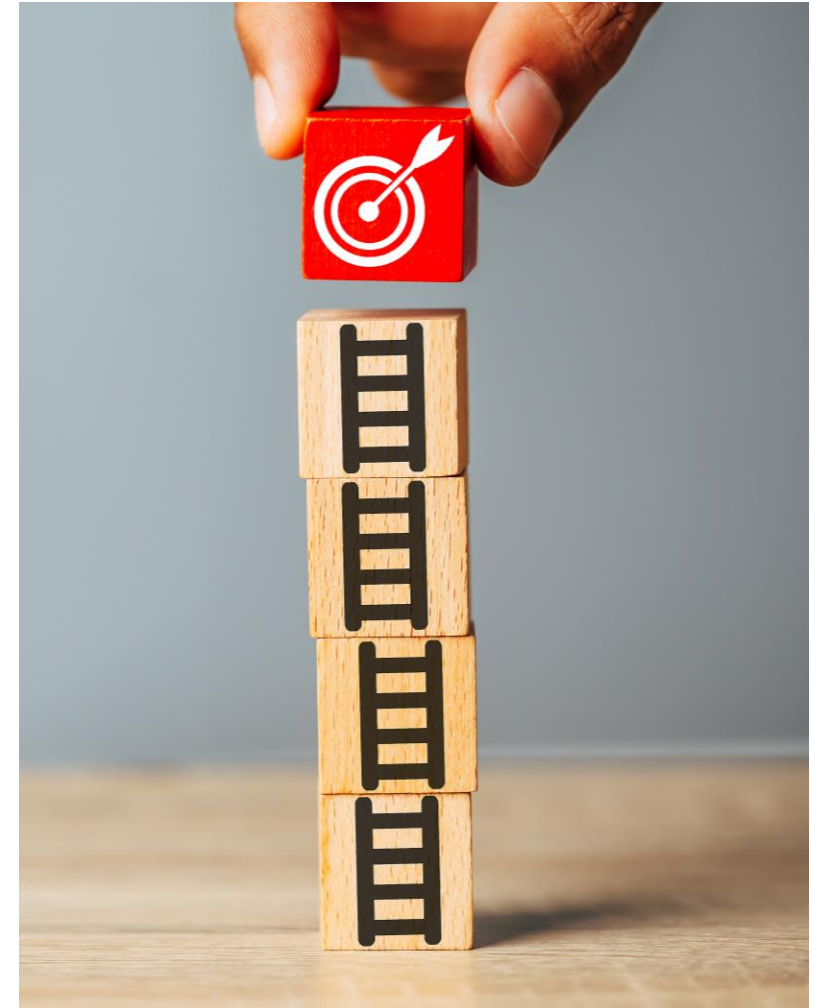
Data Quality and Integration: Identification, correction & seamless integration of Data from multiple sources.

Domain Expertise: leveraging knowledge graphs and ontologies to provide context and understanding.



Conclusion

- Increased adoption of AI/ML across all stages of oncology trials
- Development of more sophisticated unified platforms to enable real-time data collection and analysis
- Greater emphasis on real-world evidence
- Enhanced collaboration and data sharing
- Effective data management and analysis are critical to success
- Acceptance & Readiness for Role Evolution – Domain & technology expertise



Thank you



**The Global Healthcare
Data Science Community**

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