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Single Day Event

Gen AI: Concept beyond SDTM and ADaM

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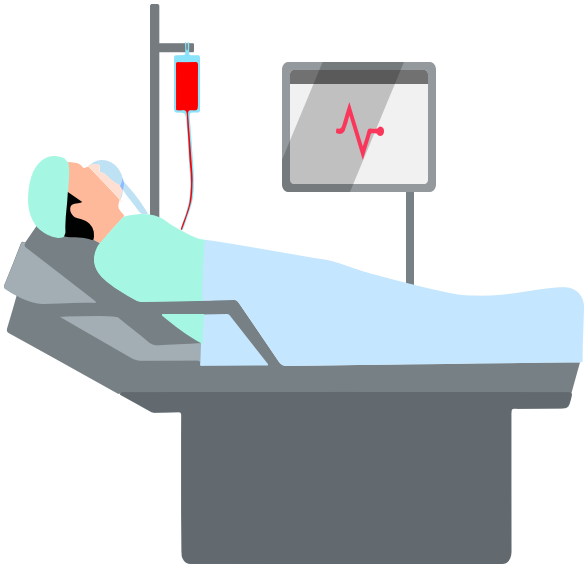
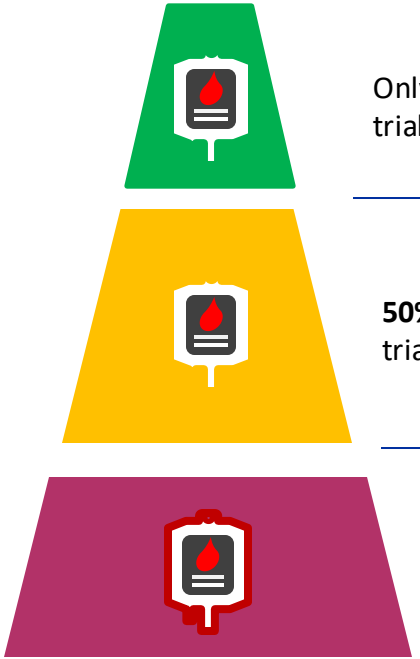
Biggest challenge in clinical trials: Subjects





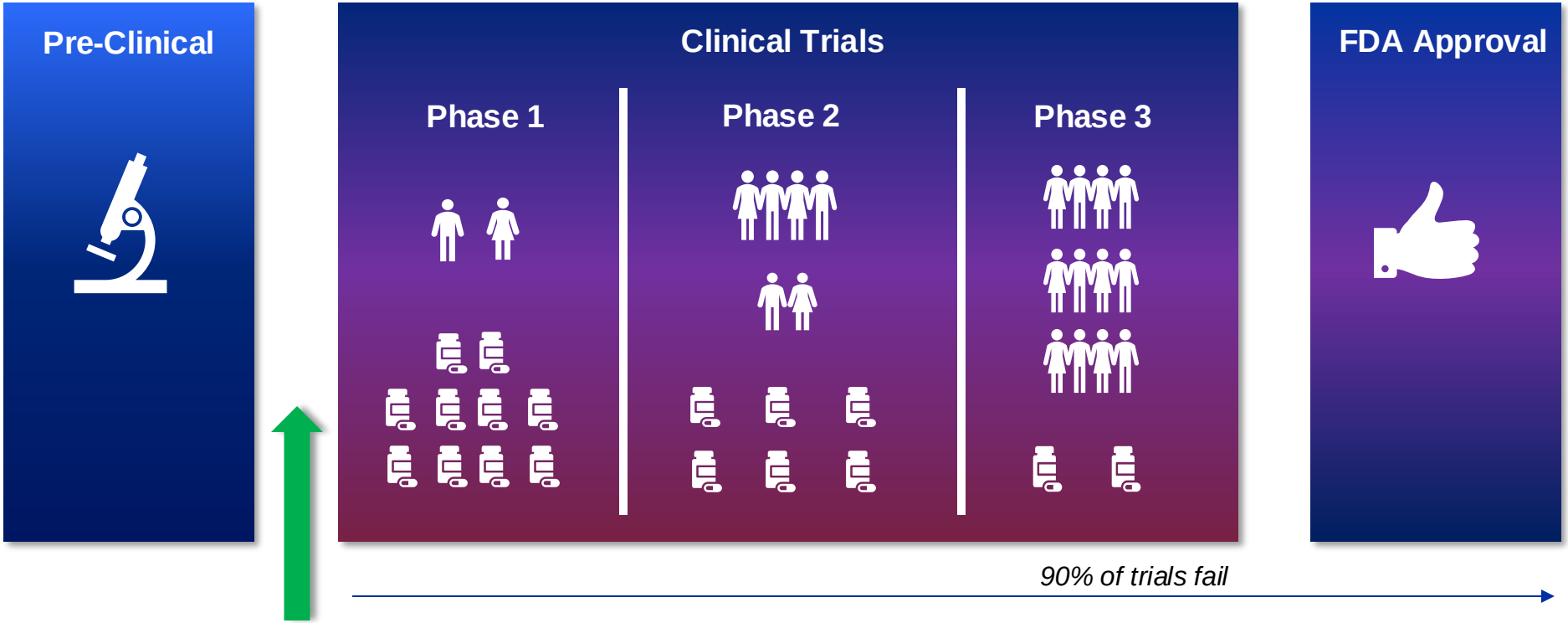
Only **5-15%** are aware of clinical trials

50% of trials fail to achieve clinical trial enrollment target

20% of subjects drop out after enrolling to a study

Managing rapidly increasing voluminous data in trials will not a be a problem in the future. It is the source(Subject) for generating the scientific data would be a biggest problem

Current approach – What is going to change



Key changes in future for clinical trial advancements

Computer aided drug trials (CADD)

Computational tools and algorithms to study compounds virtually before they are tested in a lab.

In Silico drug trials

Computer-based simulations of how a drug or disease impacts physiological and clinical outcomes.
Help improve and shorten conventional in-person trials, by testing hypotheses and answering key trial design questions prior to actual patient recruitment.

Build future for human less trials

In ~4 months

Build

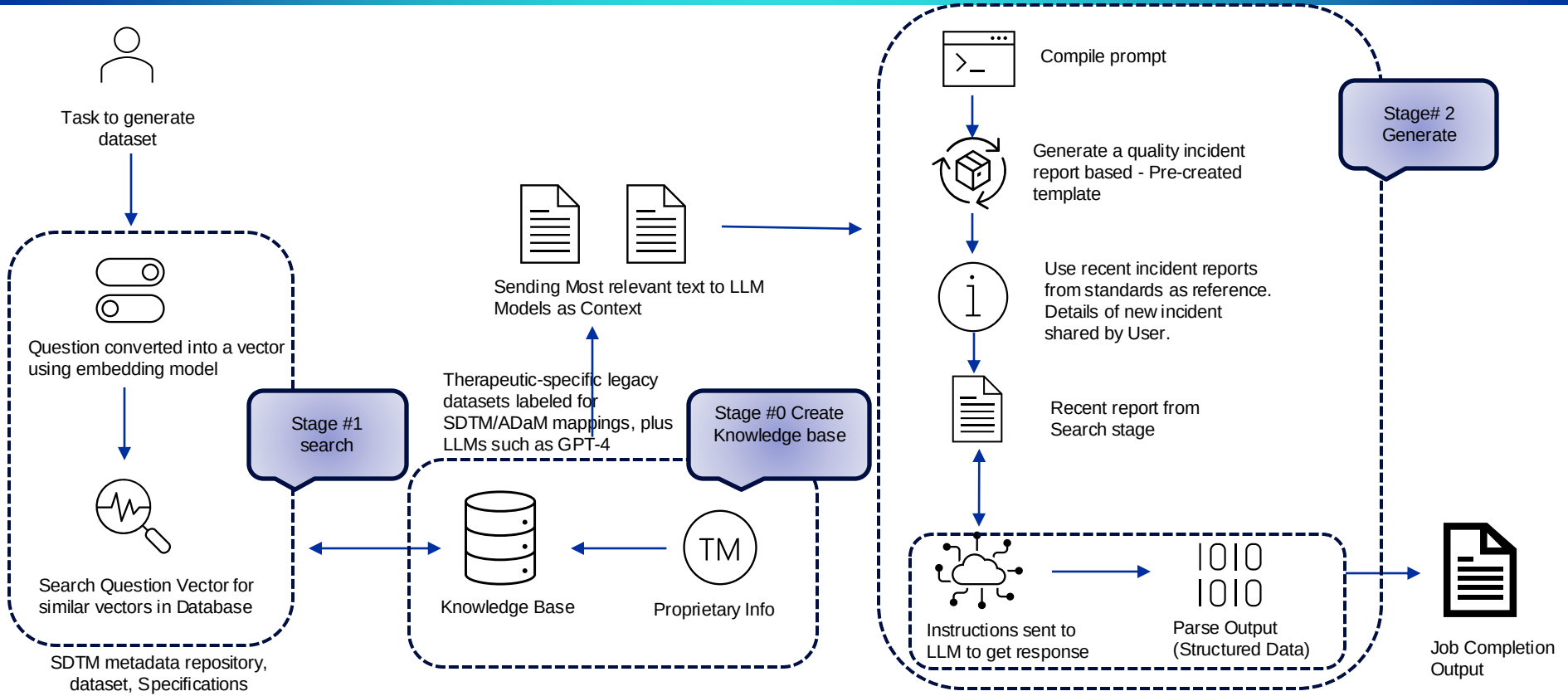
Future

Use Gen AI to develop simulated trials and create TLFs

Submission level data simulated with standards. Eliminate wastes and save time

Generate submission quality data before even human trials

Implementing Gen AI in Automating SDTM and ADaM Dataset Generation



Benefits of Using Gen AI in Generating SDTM and ADaM Datasets

01 Enhanced Error Detection and Mapping Validation for Statistical Programmers

02 Automated Creation of Patient and Safety Profiles

03 Automated Data Issue Detection and Profiling for Preliminary Analysis

04 Faster Access to Actionable Insights, Making Trials Safer and More Efficient

05 Can build interactive Dashboards

06 Futuristic: Build simulation model

Challenges of Implementing GenAI in Automating SDTM and ADaM Datasets

- Initial Investment for Fine-Tuning LLMs
- Long-Term Patience for Results – Solving errors
- Cost of implementation and maintenance
- Regulatory barriers for Gen AI Technology

Thank you

Gen AI is going to change everything what we do today….

Appendix

The Global Healthcare Data Science Community

Contact Channels
UK +44 1843 609600
office@phuse.global
phuse.global

Social Media
@phusetwitta
/phusebook
/phusetube
/company/phuse

Introduction to SDTM and ADaM Standards in Clinical Development

Why SDTM and ADaM Standards are Necessary

- ✓ Consistency in Data Submission
- ✓ Data Traceability
- ✓ Efficiency in Data Review
- ✓ Global Compliance

How SDTM and ADaM Standards Support FDA

- ✓ Standardized Data Flow
- ✓ Facilitates Regulatory Decision-Making
- ✓ Risk Mitigation
- ✓ Support for Advanced Analytics

SDTM and ADaM as Foundational for AI in Clinical Trials

- ✓ Baseline for AI Training Data
- ✓ Enhancing Automation Opportunities

Resources for Advanced Learning

- ✓ CDISC's SDTM and ADaM Implementation Guides
- ✓ FDA Study Data Technical Conformance Guide
- ✓ PhUSE Working Groups on Data Standards

Conventional SDTM and ADaM Dataset Generation Process

Manual Data Mapping and Transformation

Converting raw clinical trial data into CDISC-compliant SDTM and ADaM formats typically requires labor-intensive mapping and transformation tasks.

Repetitive Coding for Standardization

Programmers often write repetitive code for standard conversions, validations, and formatting, ensuring compliance with CDISC guidelines.

Layered Quality Checks and Validation

Multiple validation layers are required to detect errors, discrepancies, and compliance gaps, adding to project timelines.

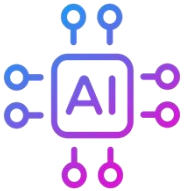
Documentation and Traceability

Detailed documentation is needed to track data flow from source data to analysis datasets, essential for audits and regulatory submissions.

Challenges of Conventional SDTM and ADaM Dataset Generation

Time-Consuming Processes	• High manual workload makes the process time-intensive, slowing down overall clinical study timelines.
High Error Rates and Rework	• Manual coding increases the risk of errors, leading to additional rework and validation cycles.
Resource-Intensive	• The need for specialized programming resources with CDISC knowledge increases project costs and demands significant team bandwidth.
Inflexibility with Complex Study Designs	• Complex or adaptive trial designs often require custom coding, which can complicate standardization and slow the process further.

Introduction to Generative AI in Clinical Development



What is Generative AI?

- GenAI is a type of artificial intelligence that learns from existing data to generate new content, such as text, images, or structured data, that resembles the patterns and structures in the source data.
- **Example:** Tools like ChatGPT demonstrate how GenAI can generate coherent text by learning from massive datasets.

GenAI as a Game-Changer for Clinical Development

- GenAI holds immense potential to handle large volumes of unstructured and structured data, converting them into actionable insights or regulatory-compliant formats, essential for clinical research and development.
- **Impact:** Accelerates processes that are traditionally manual, freeing up resources for higher-level analytical work.

Efficiency and Consistency in Data Preparation

- GenAI can automate repetitive tasks like mapping and transforming data into CDISC-compliant formats, ensuring both speed and consistency across datasets.
- Benefit: Reduces time spent on manual data prep, significantly improving data processing efficiency

Introduction to Generative AI in Clinical Development

Potential to Minimize Human Error

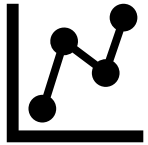
- By reducing manual input, GenAI minimizes the likelihood of coding errors, which are common in conventional dataset preparation processes.
- Benefit: Enhances data accuracy and reliability, which is critical in regulatory submissions.

Automated Data Mapping

- GenAI can learn from past mapping tasks to predict and automate SDTM and ADaM mappings for new datasets.

Error Detection and Correction

- GenAI models can identify inconsistencies or anomalies in datasets, suggesting corrective actions to ensure data integrity.

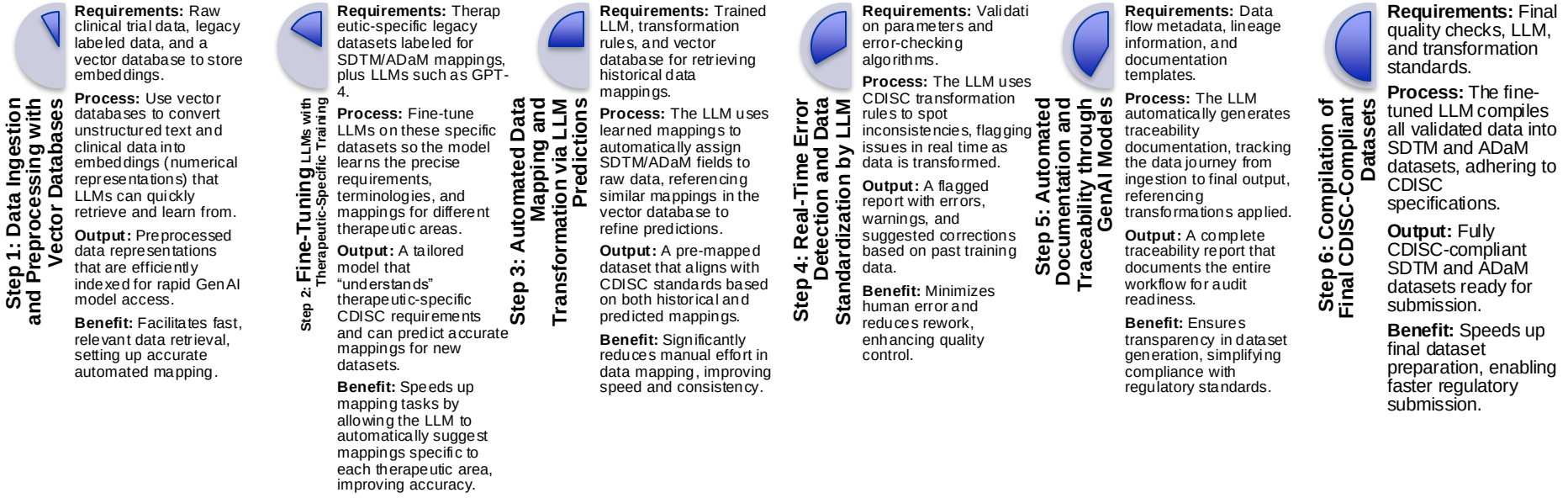


Data Transformation and Standardization

Transforms raw clinical trial data into CDISC formats, aligning with regulatory standards without extensive manual coding.

Implementing GenAI in Automating SDTM and ADaM Dataset Generation

Asked one of my team member to create a flow chart for this… Will replace it



Benefits of Using GenAI in Generating SDTM and ADaM Datasets

Enhanced Error Detection and Mapping Validation for Statistical Programmers

- **Benefit:** GenAI can automatically review SDTM and ADaM mappings, identifying potential mismatches or inaccuracies by comparing with historical mappings and CDISC standards.
- **Outcome:** Early detection of incorrect mappings and data inconsistencies, reducing error rates and the need for time-consuming rework.
- **Reference:** *BMC Medical Informatics and Decision Making* found that AI-driven automation improved data accuracy and reduced errors (BMC Medical Informatics).

Automated Data Issue Detection and Profiling for Preliminary Analysis

- **Benefit:** GenAI models can pre-process data to identify anomalies, missing values, or unusual patterns, helping statistical programmers address data issues before advanced analysis.
- **Outcome:** Enables cleaner, more accurate datasets for downstream analysis, enhancing the reliability of trial results and safety evaluations.
- **Reference:** A recent *Journal of Clinical Data Management* report highlights AI's role in enhancing preliminary data accuracy and issue detection.

Automated Creation of Patient and Safety Profiles

- **Benefit:** GenAI can generate comprehensive patient and safety profiles by summarizing critical metrics and data points from SDTM and ADaM datasets, without manual re-coding.
- **Outcome:** Supports real-time, data-driven insights into patient safety trends, helping trial teams conduct preliminary analysis and make proactive decisions faster.
- **Reference:** Studies in *Clinical Pharmacology & Therapeutics* demonstrate AI's effectiveness in generating patient safety profiles from standardized datasets.

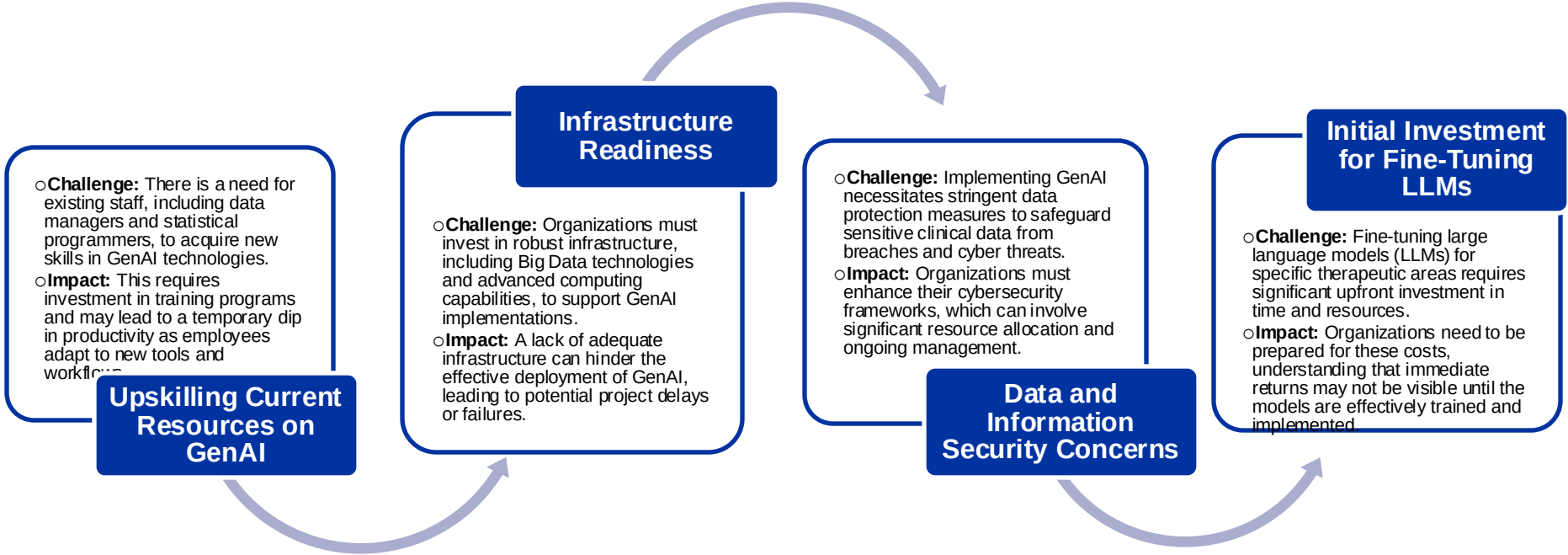
Integration with Business Intelligence (BI) Tools for Interactive Dashboards

- **Benefit:** GenAI-driven SDTM and ADaM datasets are ready for integration into BI platforms, enabling interactive dashboards and action-oriented reports without additional data reformatting.
- **Outcome:** Improves clinical trial oversight and decision-making, providing real-time insights to enhance patient safety and accelerate study timelines.
- **Reference:** A 2023 study in *Applied Clinical Informatics* highlights the use of AI-automated datasets in BI platforms, improving data visualization and decision-making (Applied Clinical Informatics).

Faster Access to Actionable Insights, Making Trials Safer and More Efficient

- **Benefit:** Automated dataset generation and real-time data visualization streamline access to critical safety and efficacy metrics, enabling faster, more informed decision-making.
- **Outcome:** Clinical teams can rapidly identify trends, address patient safety concerns, and adjust trial parameters if necessary, ultimately enhancing patient outcomes.
- **Reference:** The *Journal of Clinical Research* discusses the positive impact of AI on clinical trial safety and efficiency through accelerated data insights.

Challenges of Implementing GenAI in Automating SDTM and ADaM Datasets



Challenges of Implementing GenAI in Automating SDTM and ADaM Datasets