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1. Integrated insight-driven data-flow model

Problem Statement: -

Clinical trials generate vast amounts of heterogeneous data from multiple sources, including electronic data capture (EDC) systems, laboratory reports, site operational metrics, and monitoring logs. However, these data streams often remain siloed, leading to delayed identification of operational bottlenecks, inconsistent data quality, and limited visibility for scientific decision-making. Current processes rely heavily on manual review and fragmented communication between Clinical Trial Teams (CTT), Clinical Research Associates (CRAs), and investigational sites, which increases cycle times and operational risk.

Challenge Statement: -

There is a critical need for an integrated solution that can ingest and harmonize clinical and operational data in near real-time, apply advanced analytics to generate actionable insights, and proactively detect data quality issues and operational inefficiencies. Furthermore, the solution should leverage Generative and Agentic AI capabilities to enable intelligent collaboration, automate routine tasks, and provide context-aware recommendations to stakeholders, thereby accelerating trial execution and improving scientific outcomes."

Please refer to data sets attached.

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2. Problem Statement: Improving Follow-Up (FU) Data Collection for Patient Safety

Section	Key Points
Title	Improving Follow-Up (FU) Data Collection for Patient Safety
The Problem	In the pharmaceutical industry, Pharmacovigilance plays an important part in assessing ongoing safety profile of the product. When a patient experiences an adverse event related to a company's medication, companies must collect adverse event information. Most often the initial report lacks key information, and the company initiates a follow up with reporter for seeking any missing information for a comprehensive assessment and ensure patient safety. However, many follow-ups attempt with patients or their healthcare providers fail because complex and frequent requests overwhelm busy professionals and discourage responses, and growing concerns about scams or fraud make reporters more cautious and less likely to engage. Reasons for Follow-Up Data Collection: - International regulations require companies to collect all necessary information and follow up when initial reports are incomplete or unclear. - Organizations are required to submit aggregate reports/RMPs with comprehensive information. Regulators use these reports to determine whether medicine should remain on the market or require additional warnings. - Companies must comply with worldwide reporting rules. Failure to obtain complete information can create compliance issues and erode trust with regulators.
What We Need	The goal is to develop a practical, globally standardized solution that uses new technology and process improvements to streamline follow-up data collection. The solution should: - Be easy for patients and doctors to use, regardless of location. - Tailor communication for different regions and cultures while ensuring security and privacy. - Use digital tools to automate routine steps and help focus on higher-risk cases. - Ensure that all collected data is accurate.
Ideas for Innovation	- Create secure, user-friendly digital platforms for communication and data entry that can be customized per region. - Implement automation and artificial intelligence to prioritize follow-ups and check for missing or inconsistent information automatically. - Use real-time data validation and multilingual support to reduce manual errors and overcome geographic or language barriers. - Build cross-country teams to share lessons learned and develop best practices for handling follow-ups effectively. - Offer support to healthcare professionals and patients to encourage higher participation in follow-ups.
Why This Matters (Strategic Impact)	- Ensures patient safety through faster risk identification and response. - Maintains compliance with global regulations and builds credibility with authorities and the public. - Increases the quality and reliability of safety data, supporting better informed decisions that improve patient outcomes. - Helps pharmaceutical companies operate more efficiently, avoid costly delays, and maintain a good reputation.

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3. Problem Statement: Mass Balance Calculation Methods Evaluation in Analytical Forced Degradation Studies

Background: Mass balance (MB) calculations play a critical role in forced degradation studies, as they help verify whether all components of a drug substance, both the active pharmaceutical ingredient (API) and its degradants, are properly accounted for during stress testing. This assessment ensures the analytical method is stability-indicating and provides insight into degradation pathways. Regulatory expectations emphasize that MB should be close to 100%, indicating minimal loss due to factors such as volatility, adsorption, or undetected species. When MB values are significantly lower, it signals potential gaps in method sensitivity or incomplete detection of degradants, prompting further investigation. Various calculation approaches, including simple, absolute, and relative mass balance methods, are used to evaluate completeness and detectability, each with its own strengths and limitations depending on the level of degradants and analytical variability.

What is Mass Balance?

Mass Balance is a way to check if all components of a drug substance (API and its degradants) are accounted for during forced degradation studies. It helps confirm:

- Completeness of analytical methods
- Understanding of degradation pathways

Regulatory Expectation:

Regulators expect that forced degradation studies demonstrate:

- A scientifically sound approach to calculate MB
- Reasonable recovery of API and degradation products (usually close to 100%)

Identification of gaps if MB is significantly low

Common MB Calculation Methods

Hypothetical situation:

- Initial sample: API = 98%, Degradants = 0.5%
- Stressed sample: API = 82.5%, Degradants = 4.9%

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1. **Simple Mass Balance (SMB)**
   Formula: MB=API in stressed sample + degradants in stressed sample

   API = 82.5%, Degradants = 4.9%; MB = 87.4%

   Limitation: Does not consider initial API content; can mislead if initial assay ≠ 100%.

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2. **Absolute Mass Balance (AMB)**
   Formula:
   AMB= (API stressed + Degradants stressed) / (API initial + Degradants initial) ×100
   Initial = 98.5%, Stressed = 87.4%; AMB = 88.7%
   Limitation: Acceptable thresholds can mislead when degradation is minimal or undetected.

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3. **Absolute Mass Balance Deficiency (AMBD)**
   Formula: AMBD=100−AMB
   AMBD = 100 - 88.7 = 11.3%
   Use: Indicates how much is missing.

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4. **Relative Mass Balance (RMB)**
   Formula: RMB= (Increase in Degradants / Loss of API) * 100
   Increase in Degradants = 4.4%, Loss of API = 15.5%; RMB = 28.4%
   Insight: Shows detectability of degradation products.

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5. **Relative Mass Balance Deficiency (RMBD)**
   Formula: RMBD=100−RMB

RMBD = 100 – 28.4 = 71.6%
Use: Helpful when degradation is significant.

Which Method to Choose?

Regulatory Perspective:
No single method fits all cases. Choice depends on:

- Drug substance properties
- Level of degradation
- Analytical method sensitivity
- Pathway complexity

Challenge Tracks:

🧠 Track 1: Literature-Based Formula Optimization

- **Goal:** Critically evaluate existing MB formulas using scientific literature and regulatory guidelines.
- **Tasks:**
  - Review and compare. Simple Mass Balance (SMB); Absolute Mass Balance (AMB); Absolute Mass Balance Deficiency (AMBD); Relative Mass Balance (RMB); Relative Mass Balance Deficiency (RMBD)
  - Identify theoretical gaps or limitations
  - Propose a new or improved MB formula with thresholds highlighting the need for mass balance investigations
- **Outcome:** A scientifically justified formula or selection framework for MB calculations.

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🧪 Track 2: Experimental Validation of MB Methods

- **Goal:** Conduct a forced degradation study to empirically test MB methods.
- **Tasks:**
    - Select a model drug and develop a stability-indicating method
    - Apply stress conditions and collect degradation data
    - Calculate MB using all five methods and analyze the performance
- **Outcome:** Data-driven recommendation of the most reliable MB formula and thresholds.

Expected Deliverables:

- Comparative analysis report
- Recommendation matrix
- Draft white paper