NEST 2.0 Discussion

- **Problem Statements**

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NEST 2.0 – Problem Statement 1

Title	Improving Follow-Up (FU) Data Collection for Patient Safety
Problem Statement	In the pharmaceutical industry, Pharmacovigilance plays a 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-up attempts 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.

NEST 2.0 – Problem Statement 2

Title	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.

NEST 2.0 – Problem Statement 3

Title	Mass Balance Calculation Methods Evaluation in Analytical Forced Degradation Studies
Problem Statement	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 🧠Track 1: Literature-Based Formula Optimization 🧪 Track 2: Experimental Validation of MB Methods

Thank you