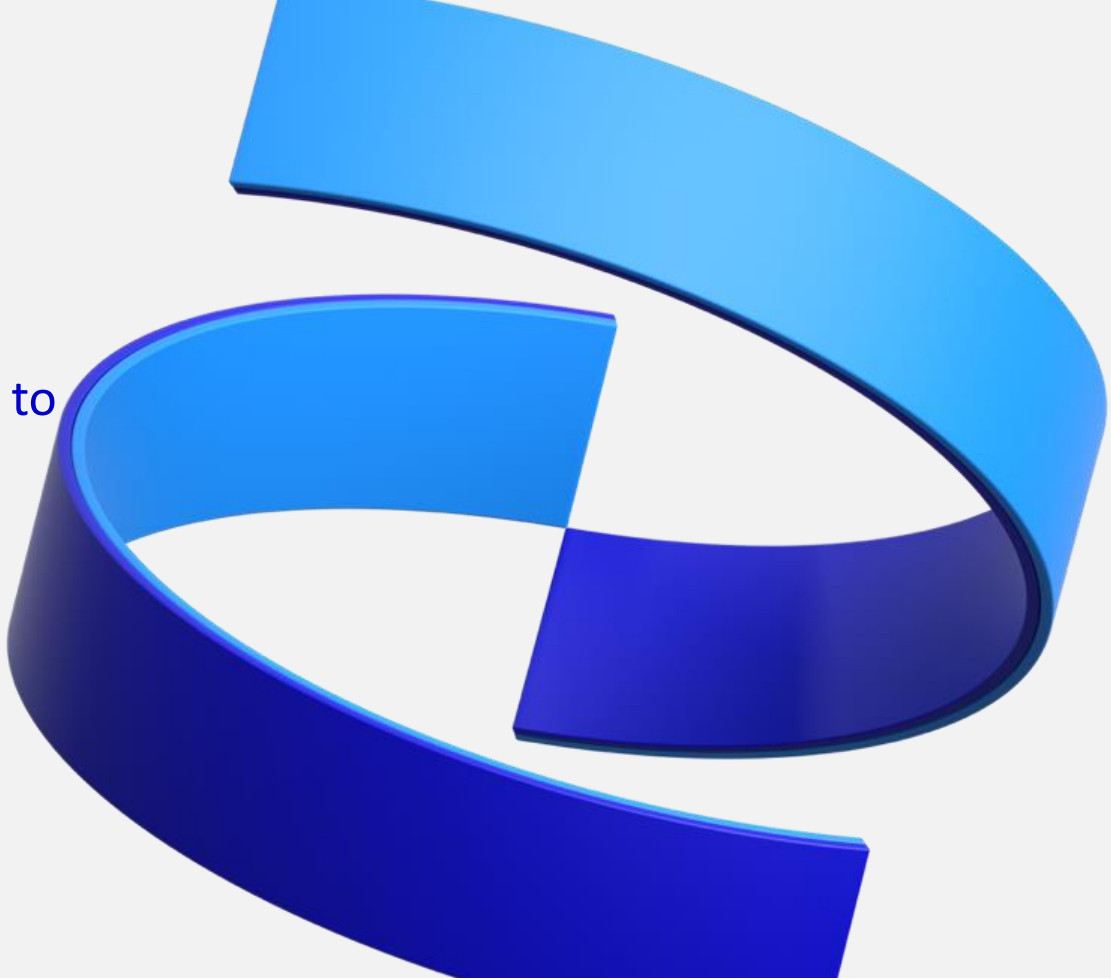
Joint HMA / EMA Workshop on AI

Company Experience of Using AI to Aid Drug Development

April 2021



Speakers and Topics

Introduction

Boris Braylyan, Vice President
Pfizer, Global Product Development,
Operations Center of Excellence,
Information Management

Automation in Data Reconciliation

Prasanna Rao

Automation in Regulatory Portfolio Planning

Pooja Diwale

Automation in Pharmacovigilance

Ana Aymes

Automation on Statistical Table Quality Control

Dan Tortora

Automation in Data Reconciliation

Problem

Pfizer explored **Machine Learning (ML)** based data reconciliation due to:

- Increased data complexity
- High volume of data (in millions)
- Reduction in cycle time targets

While ensuring Data Integrity, Quality and Fit-for-Purpose Data

Challenges

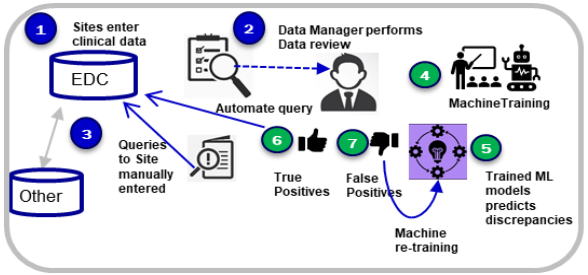
- **Variability** across studies need sophisticated ML algorithms to generalize
- Minimize or eliminate **False Negatives**
- **Interpretability** of ML
- Data entered in free text format need **Natural Language Processing (NLP)**
- **Change Management**/adoption of ML with other data reconciliation tools

Approach

❶-❸: Current manual reconciliation

❹-❺: Subject matter experts training ML, semi-supervised

❻-❼: Human-in-the-loop feedback



Lessons Learned

- Start with **one therapeutic area**
- **Progressively add** capabilities as models mature
- **Automation** focused implementation
- Emphasis on **User experience** and adoption
- **Educate Stakeholders** on Accuracy improvement thru continued human-in-the-loop feedback

Value

- **50% Reduction** in time between data capture and query issue
- Improvement in data quality and **near real-time predictions**

Automation in Regulatory Portfolio Planning

Problem

Pfizer faces an increasing workload due to increased complexity and number of global regulatory submissions.

- *30K+ product licenses in 170+ HAs*
- *45K+ dossier submission per year; 3K active at any one time*
- *Double-digit volume increase*
- *Greater complexity, especially in emerging markets*
- *Submissions take longer and more expertise for approval*

Can we use technology to pull information from multiple different sources, and produce and maintain predictive regulatory filing plans compliant with Market and Health Authority (HA) requirements?

Approach

Transparency of Data — Consolidate data into one platform

Rules-Driven Planning Model — Incorporate complex business rules and regulatory requirements

Technology-Enabled Portfolio Management — Light-touch human review of automated filing forecasts

Lessons Learned

- Establish **standardization of using AI & ML terminology**
- Early establishment of **data quality being part of the business ownership culture**, not viewed as a "cleanup activity"
- Emphasis on **User experience**, Adoption and Change Management

Value

- **Scalability**: From <1K→35K+ submissions, 11→51 markets per year
- **Cost Savings**: Saving 43K hours/year; 40% efficiency gains
- **Agility**: Industry-first predictive modelling-based regulatory planning platform
- **Certainty**: Enabling greater predictability for stakeholders (e.g. drug supply)

Automation in Pharmacovigilance

Problem

Manual processing of ICSRs will not be sustainable. Volume of Adverse Events (AEs) are in the millions and growing.

Approach

- Optimizing business process through a **single, global intake tool** lays the foundation for a comprehensive automation program
- **Source agnostic automation** enables processing of structured & unstructured data by reducing the time it takes to get information into the Safety system and enhances automation agility

Lessons Learned

- **Frequent quality training** data cycles for optimization is necessary. Must account for data scarcity events too.
- **Continuous performance monitoring** is key to minimize non-conformance
- Robust documented **validation system** is essential
- Balanced integration of automation with a **human in the loop**
- **Be cautious** at beginning with defined short-term wins coupled with a long-term vision and strategy for sustainable success

Value

- **Scalability**: Capability of auto-processing large volume of AE's
- **Innovation**: Move beyond current paradigm of rule-based approaches to future natural language processing & machine learning

Automation of Statistical Table Quality Control

Problem

- Statisticians currently perform **manual QC** Review of Clinical Study Tables & Listings which is time and resource intensive. In addition, double-programming is often required as part of the QC Review Process.
- Issues with Clinical Study Tables & Listings are often discovered late in the process resulting in **re-work and re-generation** of the tables and listings which often delays key study milestones.

Challenges

- **Gaining "trust"** of statisticians in results of the AI-based QC Review.
- **Limited Health Authority guidance** around use and validation of AI-based systems.

Approach

Partner with clinical data analytics software company on developing intelligent QC checks using NLP and Machine Learning to automate the QC Review of Clinical Study Tables & Listings.

Lessons Learned

- **Conformity to company defined standards** around study tables & listings can improve the performance of AI checks.
- **Volume of historical tables required** for successful algorithm training was higher than expected.

Value

- **Accelerate issue detection** upstream in the Clinical Study process.
- **Reduces** process steps, effort, & time to remediate issues.
- Debugged tables when starting cross-org content review **increases confidence** across organizations
- **Reduce calendar time** between data

Thank You!

Questions?