

Speeding up submissions

Assessing the business value, feasibility and risks of new and emerging approaches

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The Saama logo features a blue stylized 'S' icon followed by the word 'saama' in a lowercase, sans-serif font.The Phuse logo consists of the word 'phuse' in a lowercase, sans-serif font, enclosed within a teal circular graphic.

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Overview



In this presentation, we explore and assess types of approaches to optimize and accelerate Biometrics workflows and their impact on speeding up submissions

- Regulatory Submissions are the final major “pre-approval” milestones in clinical development
- Statistical Programming and Biostatistics (Biometrics) constitute the bulk of the “last mile” activities leading up to this milestone
- Though submissions happen in the Closeout phase of the trial, the approaches may involve activities throughout the **Startup**, **Conduct** or **Closeout** phases of the trial





Areas of Automation

**Services Reconfiguration
and Outsourcing**

**Standards Based
Automation**

Metadata-Driven Automation

**Machine Learning and AI-
Driven Automation**



Services Reconfiguration and Outsourcing



Outsourcing services using external specialized entities and cloud based solutions are common ways for pharma companies seeking economies of scale in biometrics

Example applications

- CROs generating submission deliverables such as SDTM artifacts as a service
- Cloud-based solutions for supporting -
 - database design
 - scalable data storage and access
 - interim analysis and database lock



Outsourcing simply shifts the effort



Most applications are already established best practice



Limited incremental advantages for timeline acceleration

Assessment:

This is the status quo baseline - some advantages of scale, but limited incremental value



Effort savings



Future Innovation



Timeline Acceleration

2 Standards Based Automation



Most biometrics teams have built a robust set of internal standards and elaborate macro driven processes to automate specific processes

Example applications

- **Startup phase:** Standardizing specification formats, statistical analysis plans and coding practices
- **Conduct phase:** Standard code and libraries can be used to generate and execute programs
- **Closeout phase:** Standard checklists and procedures can be used to streamline the validation process and finalize the datasets



Standardization can significantly increase reuse and reduce effort



Most larger companies are already utilizing standards-based automation



Automation is often company specific and there are additional opportunities to collaborate across industry for incremental gains

Assessment:

Standards based automation can reduce the effort to write the protocol and CRF, as well as the complexity of programming and validation.



Effort savings



Future Innovation



Timeline Acceleration

Metadata-driven Automation



Metadata-driven approaches have been a promising avenue for innovation and capture of rich information as a source of automation over the past decade.

Example applications

- **Startup phase:** Metadata can streamline and standardize data collection, analysis, and reporting, as well as data integration and sharing across platforms
- **Conduct phase:** Metadata can streamline the creation and modification of analysis datasets and TLFs, as well as data integration and reuse across studies
- **Closeout phase:** Metadata standards and rules can be used to ensure the consistency and quality of reports based on the protocol, CRF, and metadata specifications



Metadata driven automation requires increased effort in data collection to drive automation downstream



Better metadata is often a pre-condition to drive innovation and data-driven transformation



Automation approaches require initial investment for re-tooling of processes, but can thereafter generate significant time savings

Assessment:

Metadata driven automation, if carefully planned, should avoid removing effort from the downstream processes and adding it back in upstream processes



Effort savings



Future Innovation



Timeline Acceleration



Recent improvements in AI-research are likely to drive significant transformations in biometrics automations over the next decade

Example applications

- **Startup phase:** AI can help to speed up and simplify database design and deployment, as well as improve the reliability of the data validation and quality checks.
- **Conduct phase:** Generative-AI for initial code generation (driven from digitized specifications) which can improve program development efficiency and expedite the data validation and cleaning tasks
- **Closeout phase:** AI models and algorithms can be used to automate report generation and archiving processes



AI-driven approaches in biometrics are likely to change the nature of programming tasks and effort



Innovation in Generative-AI for statistical code generation is a promising avenue for future innovation to take place



Early indications are that statistical programming tasks will be significantly more efficient by enabling programmers to harness data science techniques

Assessment:

AI application in Biometrics and Submissions is in its infancy. There is likely to be significant innovation before before these techniques gain wide acceptance.



Effort savings



Future Innovation



Timeline Acceleration



Areas of Automation

1 Services Reconfiguration and Outsourcing



2 Standards Based Automation



3 Metadata-Driven Automation



4 Machine Learning and AI-Driven Automation





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