

ABSTRACT

A lot has changed in the statistical programming paradigm in recent years. We have seen a shift from 'SAS only' programming & analytics to a 'blended' approach which includes SAS® software in combination with R, Python, Java etc. The key driving forces behind this are: new and advanced study design and conduct, data collection using sensor and mobile apps, increased volume of study data, quicker turnaround time for trials and the introduction of Data Science & Artificial Intelligence (AI). AstraZeneca is a forward-looking company and is investing in developing next generation programming teams that are future proof. To adapt to these challenges of managing multiple trials, submissions, and supporting work (Payer, regulatory responses etc.), a central team called 'Data Automation' has been formed to partner with Biometrics Programming & Statistics, Data Management (DM) and DS & AI through standardised automation solutions to drive efficiencies and allow them to focus on the management of clinical trial delivery. This will allow optimisation of DM and Analysis & Reporting (A&R) deliverables by reducing manual activities.

Introduction

The Data Automation team leads the delivery of innovative automation solutions and core centralised activities, bringing standardisation, simplification and efficiencies to clinical data. The team drives best practice, process and solutions to R&D. We are a team of specialist statistical programmers, and technology leaders with an expertise in biometrics programming using a diverse range of software, process and tools.

Strategy

The team is organised with portfolio leads who partner with relevant stakeholders to drive automation solutions. The two main solution delivery methods used are: Holistic (for complex automation projects that require long term development) and Rapid (for quick win projects and MVPs that usually require <3 months development time).

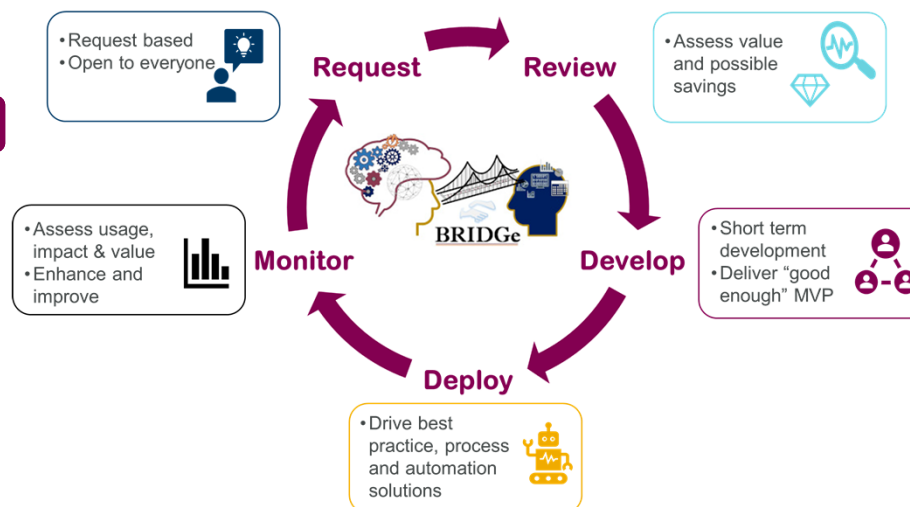
- Up-skilling of SAS programmers to new technologies (e.g. R, Python, etc.) and behaviours (acting as Data Stewards)
- Introduction of Machine learning, predictive analytics and robotic process automation
- End-to-end automation solutions replacing manual and repetitive work
- Incorporate a fit-for-purpose process and infrastructure framework
- Develop automation solutions, which are more Data Science & AI and predictive analytics based, directly communicate with source systems.
- Holistic and scalable automation solutions, which are aligned between Biometrics Programming and Data Management
- Balance in-house vs. outsource strategy for automation tools development
- Align with IT strategy and vision

Showcased Automation Tools and Portfolio

- Metadata-driven automation tool for TFL generation and A&R delivery
→ *Better adherence to TFL standards*
- Clinical Data Standards Change Requests tool that enhances standards development and improves standards governance
→ *A single change management system/process*
- System to automate data collection for new clinical trials based on trial protocol and project standards.
→ *Significant reduction in study start up time*
- Safety reporting and narrative tools
→ *Better consistency and efficiency in regulatory reporting*
- System to auto populate SDTM data within the sample management system
→ *Single solution for sample tracking and regulatory inspection readiness*

How we work within Agile framework

A Rapid Data Automation Development Framework



Skills & Expertise

The team offers a diverse and broad skillset to deliver end-to-end automation.

Programming, Statistical A&R
 SAS, R, CDISC & Data Standards, Robotic Process Framework etc.

Software Development
 .NET (C#, VB), Java, Structured Data (Oracle, SQL Server, MySQL), Unstructured Data (NoSQL), XML, SnapLogic etc.

Data Science, AI, Visualisation
 Python, Teradata, Bourne, Korn, Tableau, Spotfire, Bootstrap etc.

Business Project and Process Management
 Project Management, Process Engineering, Business Analysis etc.

The Next Steps...

