

Automation and Central Repository

Are we achieving our aim?

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History? Is Automation not a new idea?

- “Just press the button” was already present 25 years ago



- We developed macros that generated new SAS code
- There were central repositories used by the programmers
- Automation was to give us more free time!

What are the aims of automation?

- To generate more output with less resource – be honest



- Implement standards
- Standardise output across studies
- Maintain standards worldwide
- Reduce recreating the wheel
- Acknowledge reality – requirement is similar but not the same

Aims and Experiences may vary by organisation

- Pharma
 - Implement standards across projects
 - Produce programs that can be sent to regulatory
 - Produce programs that are easy to maintain over time
- CRO
 - Efficient distribution of resource
 - Automation working across clients
 - Consistent looking quality programs produced quickly

Different Automation Approaches in Implementation

Automation by Excel

- Excel is often the go-to software for automation
 - Program names, output titles, filenames, etc. are specified
 - Macro names and parameter values are defined
 - Often space is allocated to perform some pre/post processing
- Avoid black box feeling with complex macros
- Programmers should get opportunity to work on actual programs
- + SAS has a good record with Excel in terms of usability
- + Excel is often used for tracking status, so this is the next step

Central Repository – macros

- Company standard macros are great for standardisation
 - Utility macros
 - Therapeutic area standards offers more exact output
 - Have clear and simple naming convention
 - User manual should be for users!
- Avoid complex macros and too many parameters
 - Resist offering too many options!
 - + Provides standardisation across studies
 - + Easy for programmers to maintain over time



Central Repository – template programs

- For complex output this approach can avoid the black box feeling
 - Programs developed at study level can be elevated
 - Can be used for complex calculations
 - Following GPP is critical
 - Offer search option
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- Complex code and not following GPP
 - If too many, then difficult to find what you are looking for
 - + Not black box, users can adapt to their requirement
 - + Great learning tool for those less experienced

Our experiences tackling the automation challenge

What are we doing?

- A combination of all 3
- Automation – using in-house application – Metalytics
 - Allows us to generate consistent quality output across clients
 - Programs follow GPP and are easy to read and follow by clients
 - Driven by meta-data
 - Searchable, traceable, automatic validation logs and oversight
- Macros – company and client standards
 - Macro development team – quality and documentation
- Template programs
 - Complex tables and ADaM derivations

Why use a multi-pronged approach?

- Automation helps us to auto-generate >60% of programs
 - Search helps programmers to find programs produced by others
 - Oversight and project management time is significantly reduced
 - Automatic validation log is always correct and ready
- Macros:
 - Easy to use macros are key for both automation and quality
- Template programs:
 - These are great for statistical analysis tables and figures where each client want something slightly different

Top tips for automation success

Remember!

- Pharma and CROs have different aims
- Do not let perfect be the enemy of the good
- Everything is always changing
 - Automation and macros should be designed for long term
 - Have an overall concept of an integrated system across dept.
but implement in small steps, agile approach
- Always keep an eye on the benefit
 - What was the aim? Its usually not the process
 - Are you producing more with less?

Questions or Comments?



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