



PhUSE SDE Basel

The eRAP tool

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The eRAP tool

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What is the eRAP tool?

A brief introduction

- All Novartis trials require a TFL shells document as part of the Reporting and Analysis Plan (RAP). It shows all the outputs required for a specific reporting event such as a CSR or DMC meeting
- The eRAP is an Excel based tool, used by the Trial Statistician to create the TFL shells document
- Novartis standard outputs are loaded into the tool in the form of a library file. The outputs required for the TFL document are then selected from this library
- Non-standard outputs can also be created by the user

How does the eRAP help us to optimize workflow?

Efficiency

- Commonly required outputs are pre-loaded
- Adding (and removing) output shells is quick and simple
- Excel functionality is much more suited to creating new outputs when compared with using Word
- Review process can be streamlined to allow focus on new & updated outputs

Quality

Consistency

How does the eRAP help us to optimize workflow?

Efficiency

Quality

- Use of controlled library files ensures only approved output shells are used
- Study and Project specific outputs are easily identified for review by the relevant Standards Office
- Export of PDT reduces capacity for errors from the Programming Team

Consistency

How does the eRAP help us to optimize workflow?

Efficiency

Quality

Consistency

- Use of specific eRAP working files for specific deliverables (CSR, DMC etc.) will bring uniformity
- For DMCs, independent Statisticians and Programmers will know which outputs are likely to be required – saves time (& \$\$\$)
- Project specific shells and working files also ensures a standardized end-product

What is the eRAP tool?

A quick demonstration

Next steps

- Milestone specific eRAP templates being developed – CSR and DMC ones already underway
- Requires standardization between different statistics organizations within Novartis

Thank you