



Accelerating Trial Startup: Automated Central Monitoring Visualizations and Safety Package Management

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Agenda



- Background and introduction
- Current solution
- Test data to real data
- New solution
- Preparations
- Automation in trial set-up
- Expanding
- Conclusion

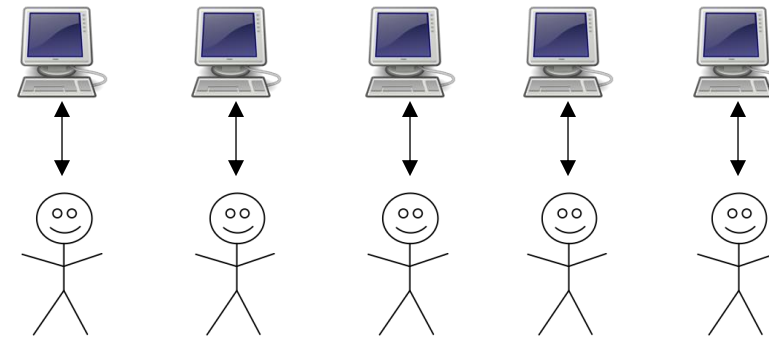
Introduction

Background

- At Ferring we aim to have systems ready for central monitoring and Safety packages at FPFV

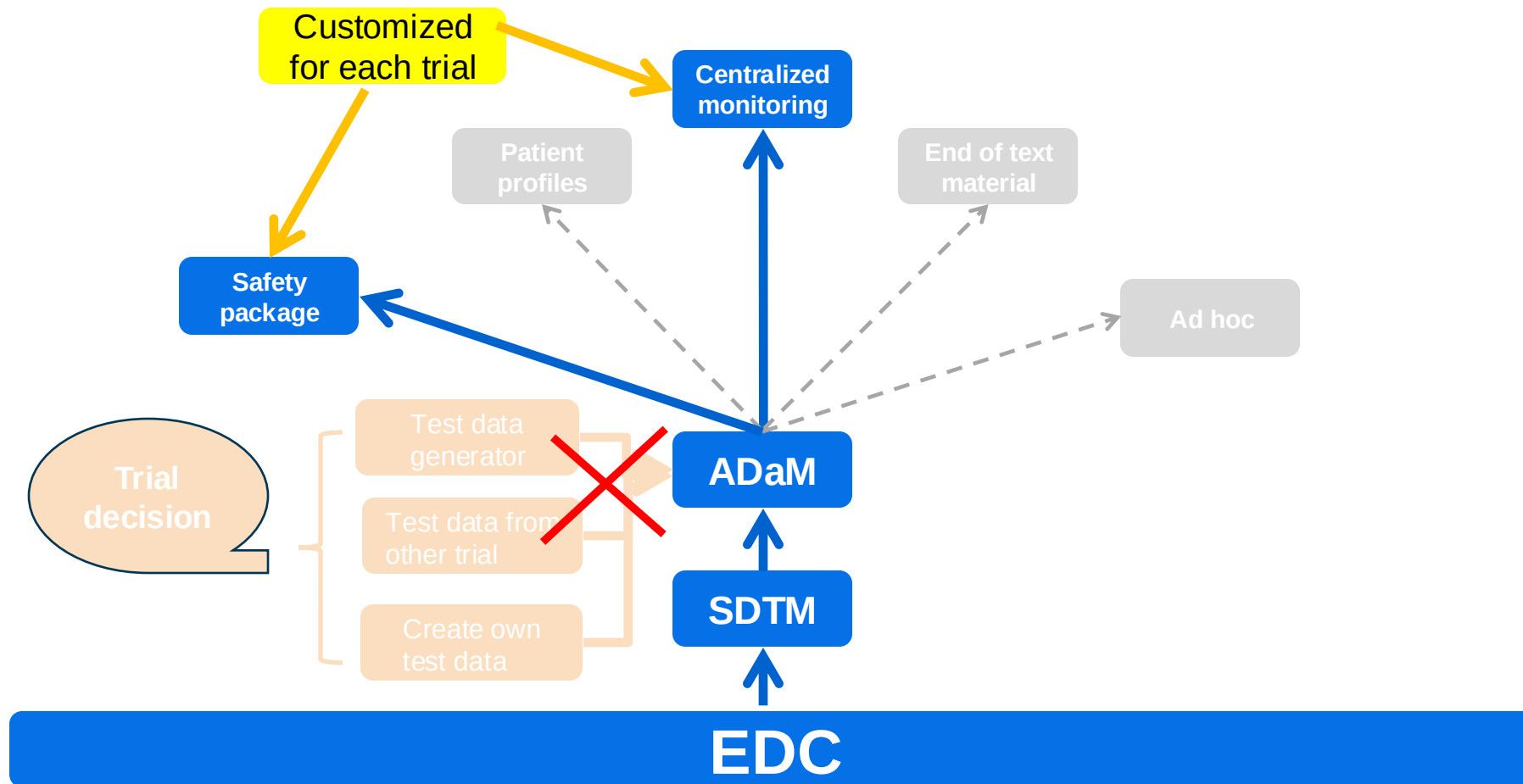
Current solution for trial set-up

- Trial specific solutions
- Manual processes are included



Test data to real data

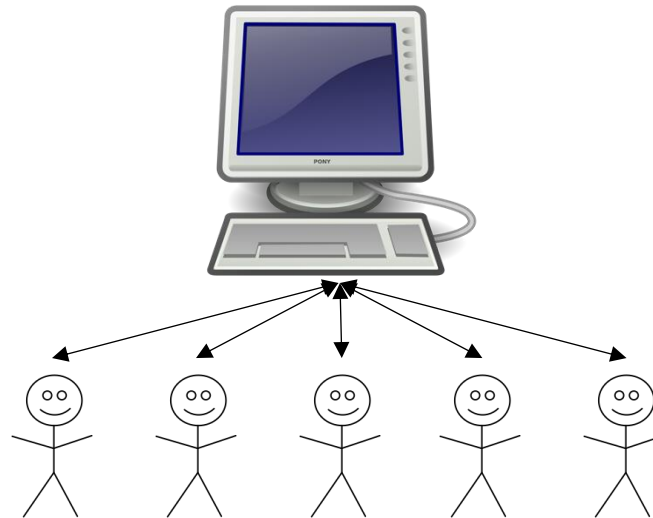
Current solution



Introduction

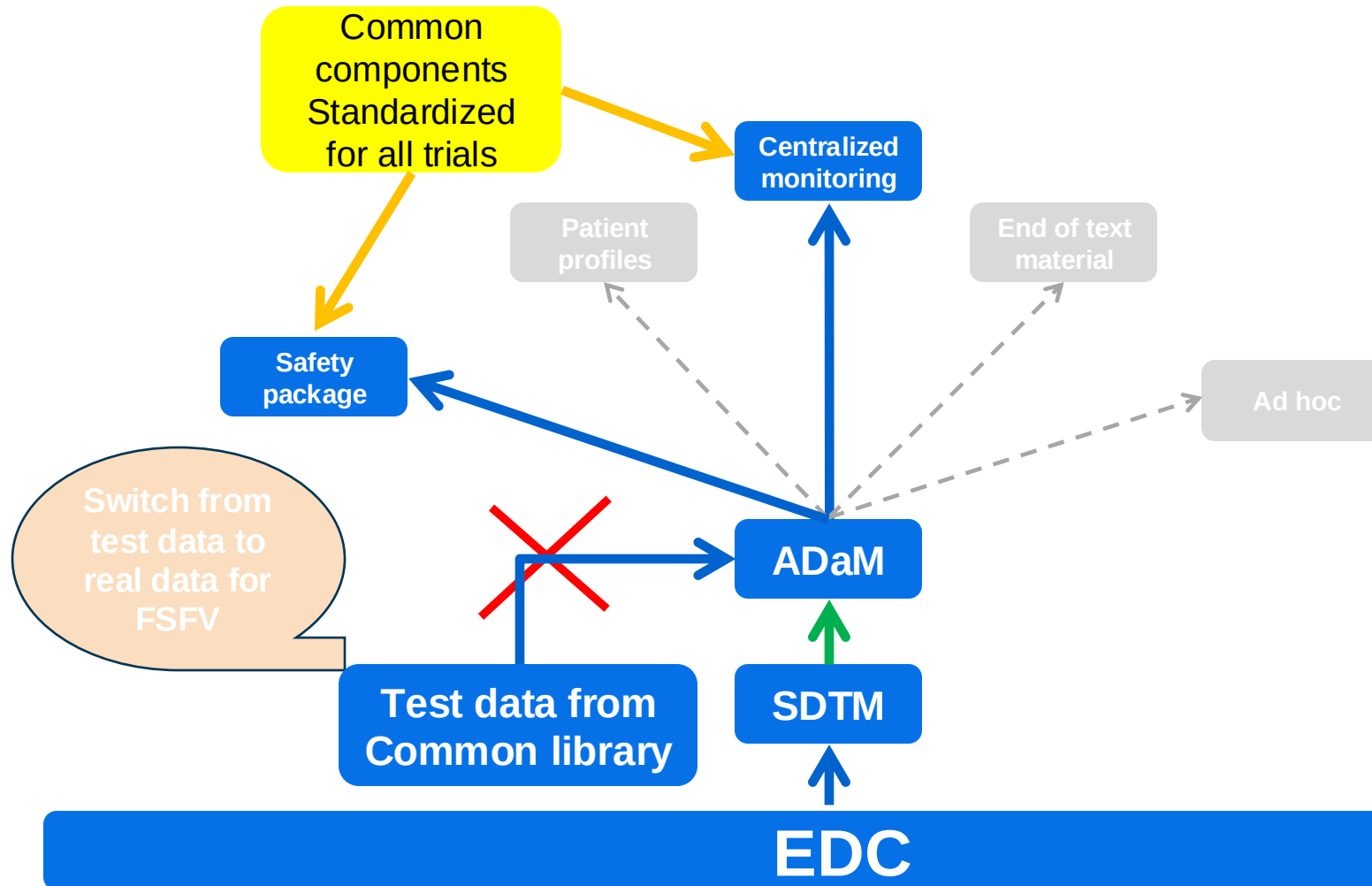
Room for improvement

- Streamline and have a more efficient process for the trial set-up
- Reduce manual workload
- A more efficient resource allocation



Test data to real data

New solution

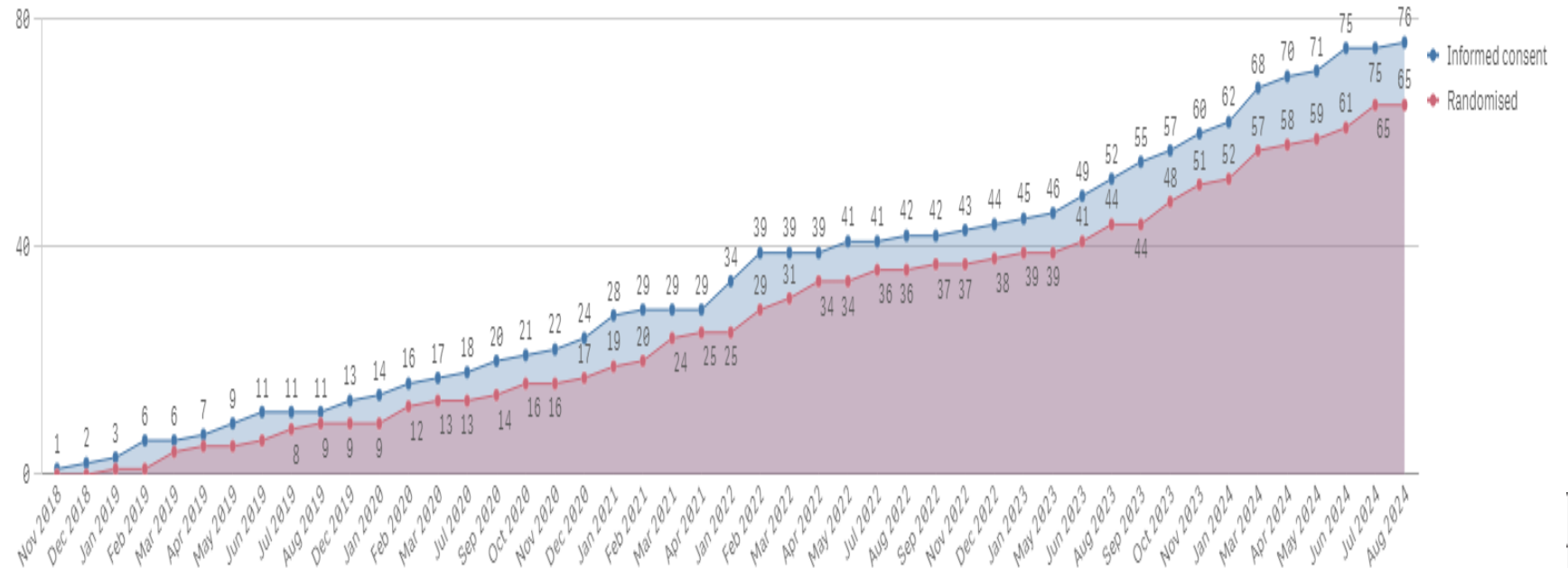


Preparations

Defining elements for trial start up

- Central monitoring and safety packages
- Defining minimal set of key data elements
- ADaM based
- ADS

Recruitment Over Time



Preparations

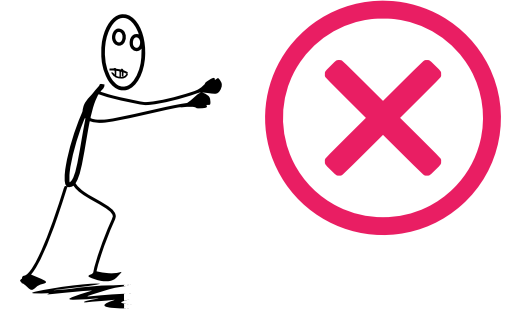
Test data

- Standardized SDTM data for key variables
- Create test data aligned with standardized SDTM
- Place in a common area within our system which is accessible to all users
- Frontload before FPFV

Automation in trial set-up

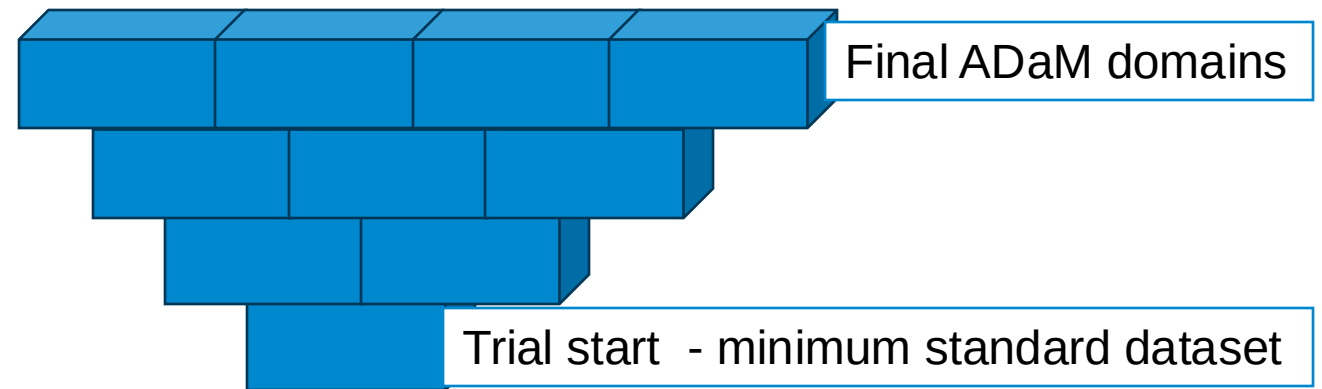
The role of automation in trial start up

- Safety and efficacy
- Minimize errors
- To automate faster visualization of data when data updates
- Reduce manual workload
- Manual process higher risk of inconsistency
- Process more reliable when automated



Expanding

- Expanding ADaMs for Comprehensive Monitoring
- Continue to build ADaM gradually following the trial progress, collection of data
- Modular system
 - More robust
 - More comprehensive



Conclusion

- From manual process to automated process, we will accelerate trial start up and improve data accuracy
- Reduces manual workload and enhances patient safety
- Automation provides an efficient solution for trial management



Thank you!

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