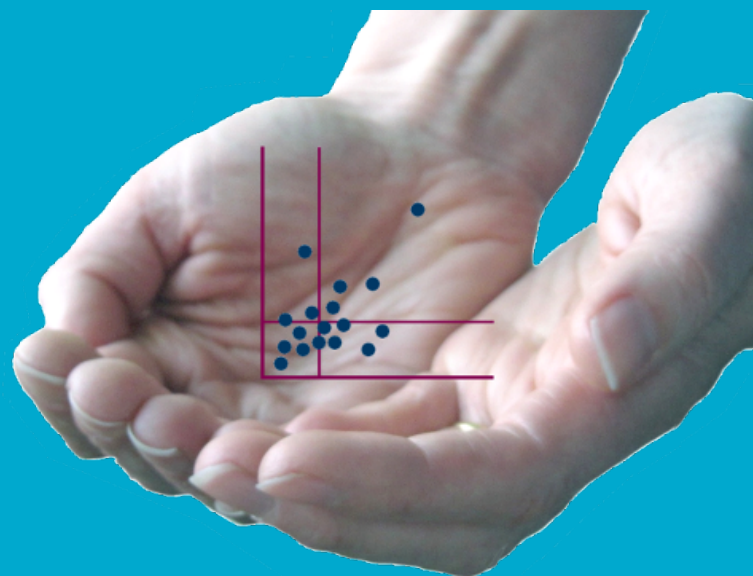


REACTing to data: The Use of Data Visualisation within Early Clinical Statistical Programming at AstraZeneca



Shyamprasad Perisetla & Suzanne Tautz – AstraZeneca, UK

Phuse Annual Conference – Edinburgh, 9th October 2017

Agenda

What is REACT?

Data visualisation and early phase clinical trials

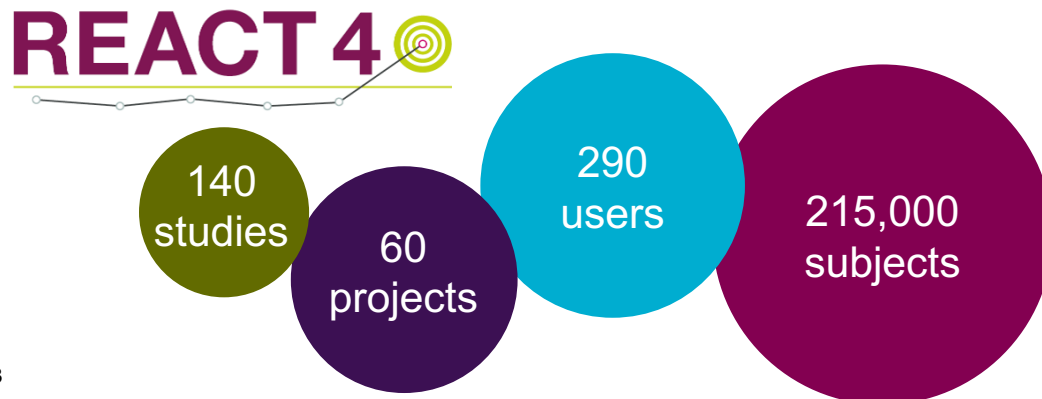
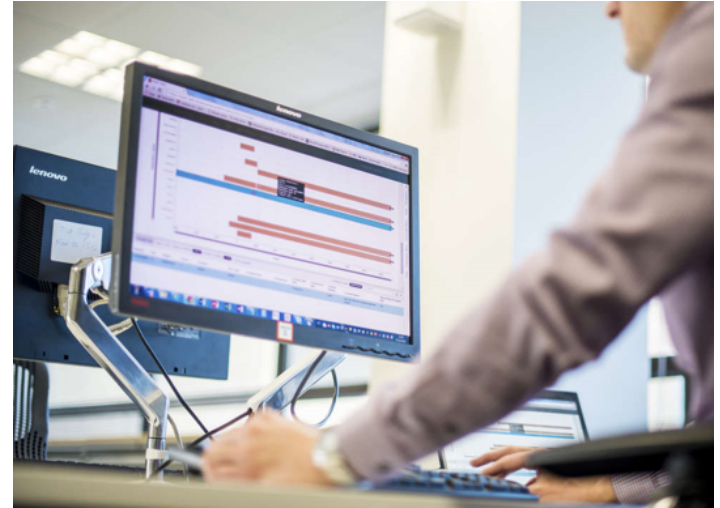
Benefits to ECD statistical programmers

Benefits to vendors

Future & conclusion

REACT (REal time Analytics for Clinical Trials)

- REACT is...
 - a user friendly data visualization tool, designed by AstraZeneca for clinical trials
 - a web application that enables you to view and interact with clinical data
 - easy-to-interpret graphical charts and tables, which can be drilled-down to individual patient level data
 - used by all members of the study team

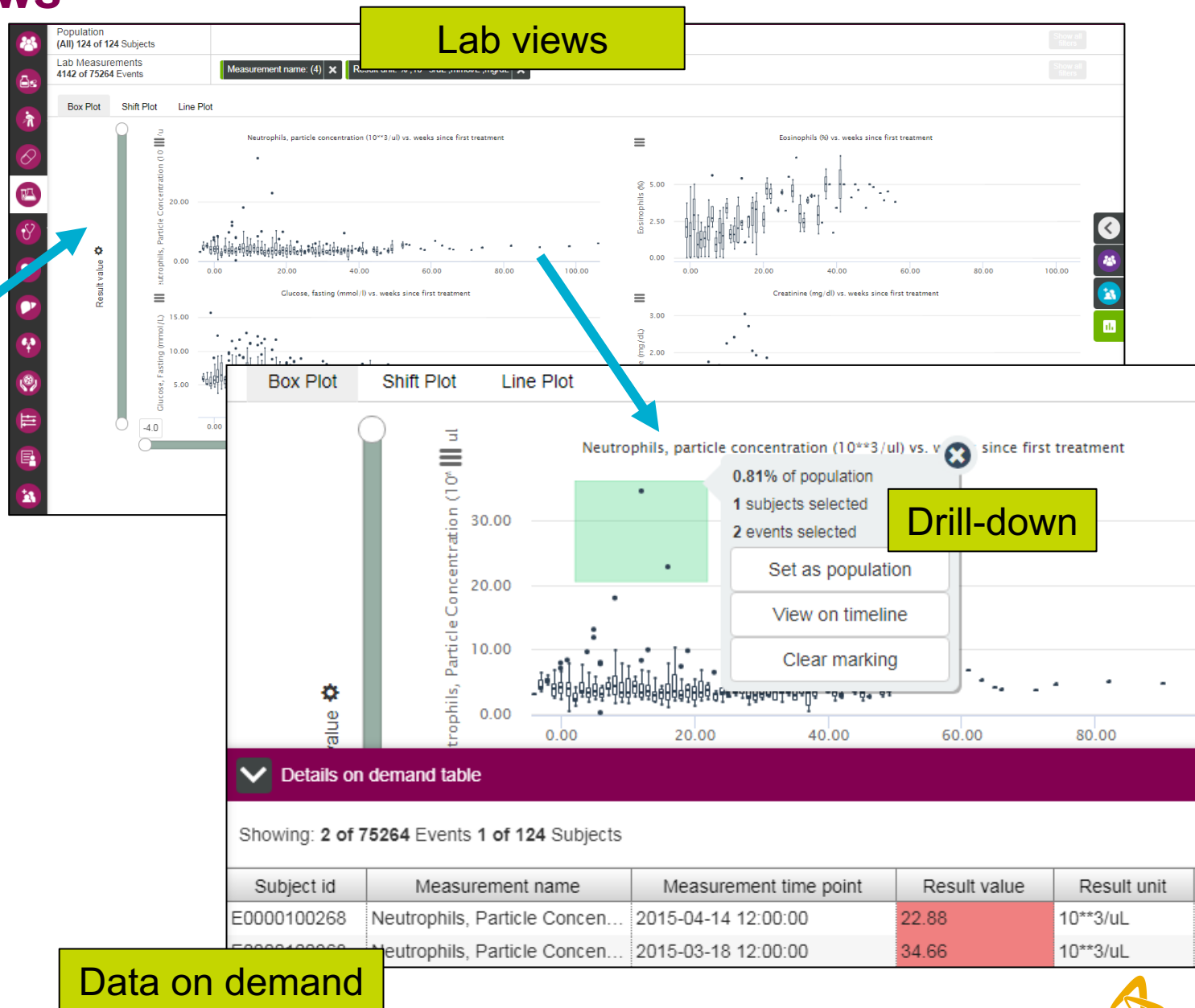


- REACT is not...
 - GxP validated
 - providing derivations of endpoints – it summarises the data as is



REACT Views

- Population Summary
- Dosing & Exposure
- Adverse Events
- Conmeds
- Labs
- Vital Signs
- Cardiac Function
- Liver Function
- Renal Function
- Tumour Response
- Timeline
- Single Subject



REACT Views

- Population Summary
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- Status summ...
- Adverse events
- Conmeds
- Dose

Track selection

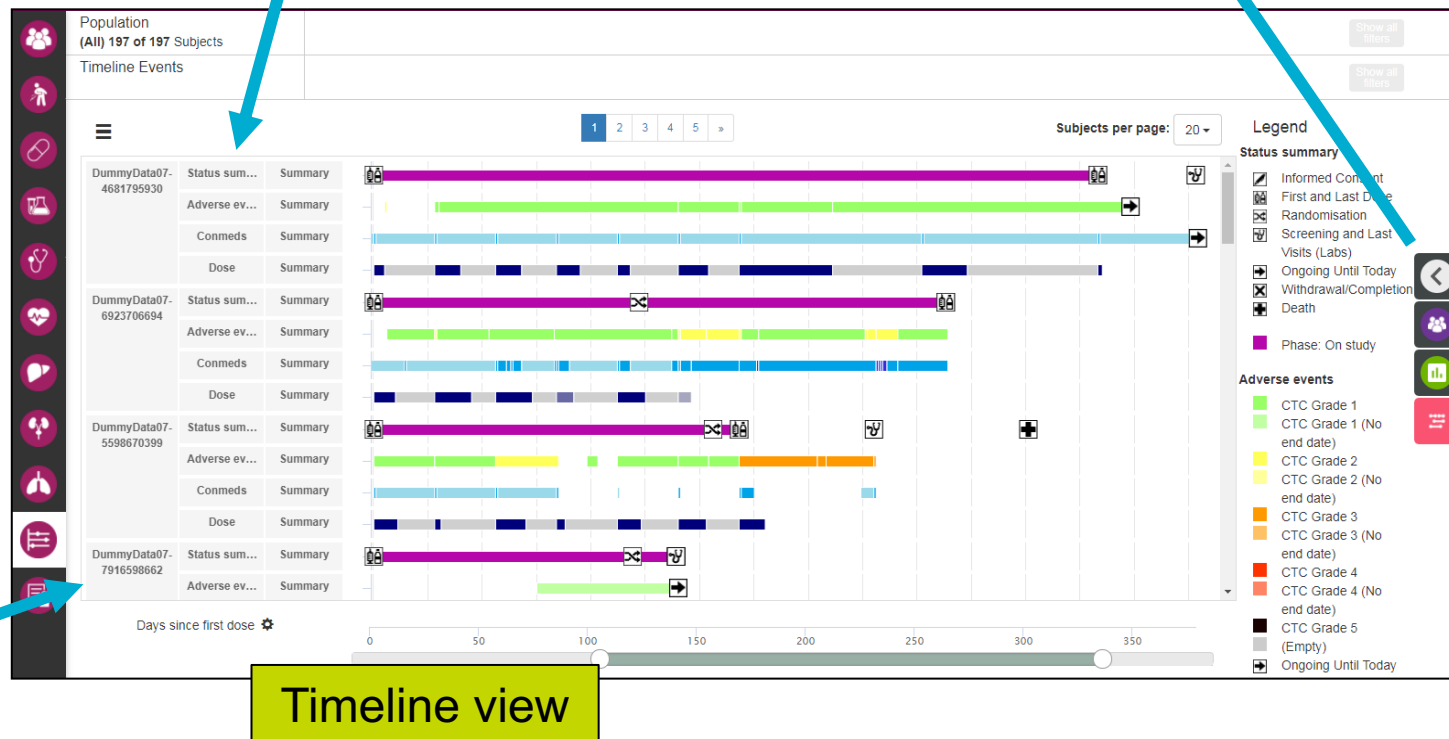
Data filters

Population
62 of 124 Subjects

Sex: Female X

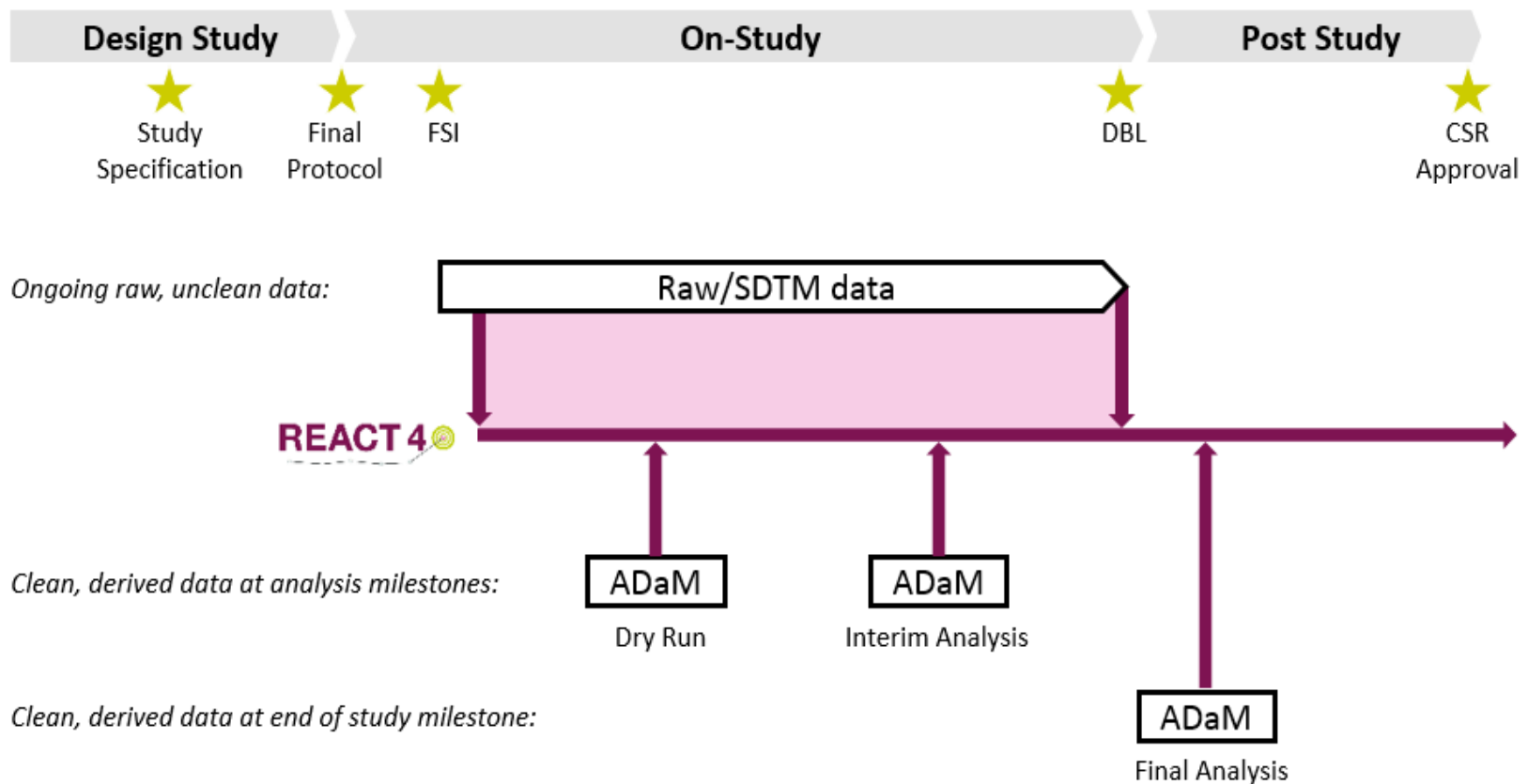
Adverse Events
97 of 2057 Events

Max. severity: (4) X



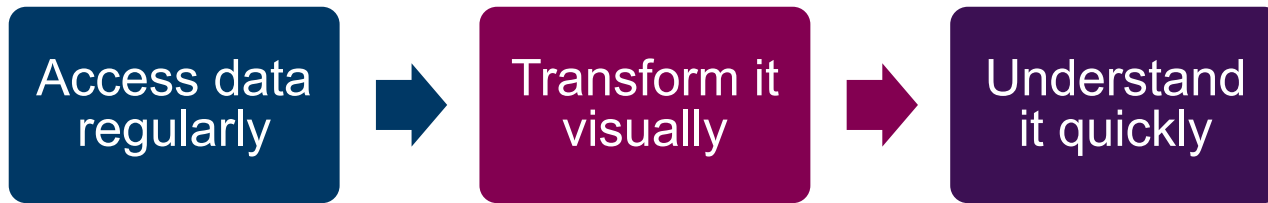
REACT Data

- Raw, SDTM and/or ADaM datasets can be read into REACT, on an ongoing basis or at specified data cut points including end of study

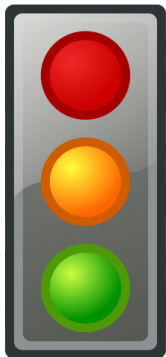


Data Visualisation in Early Phase Clinical Trials

- Data Visualisation tools can be particularly impactful for early phase studies



- The early phase trials at AstraZeneca are conducted by ECD (Early Clinical Development) organisation

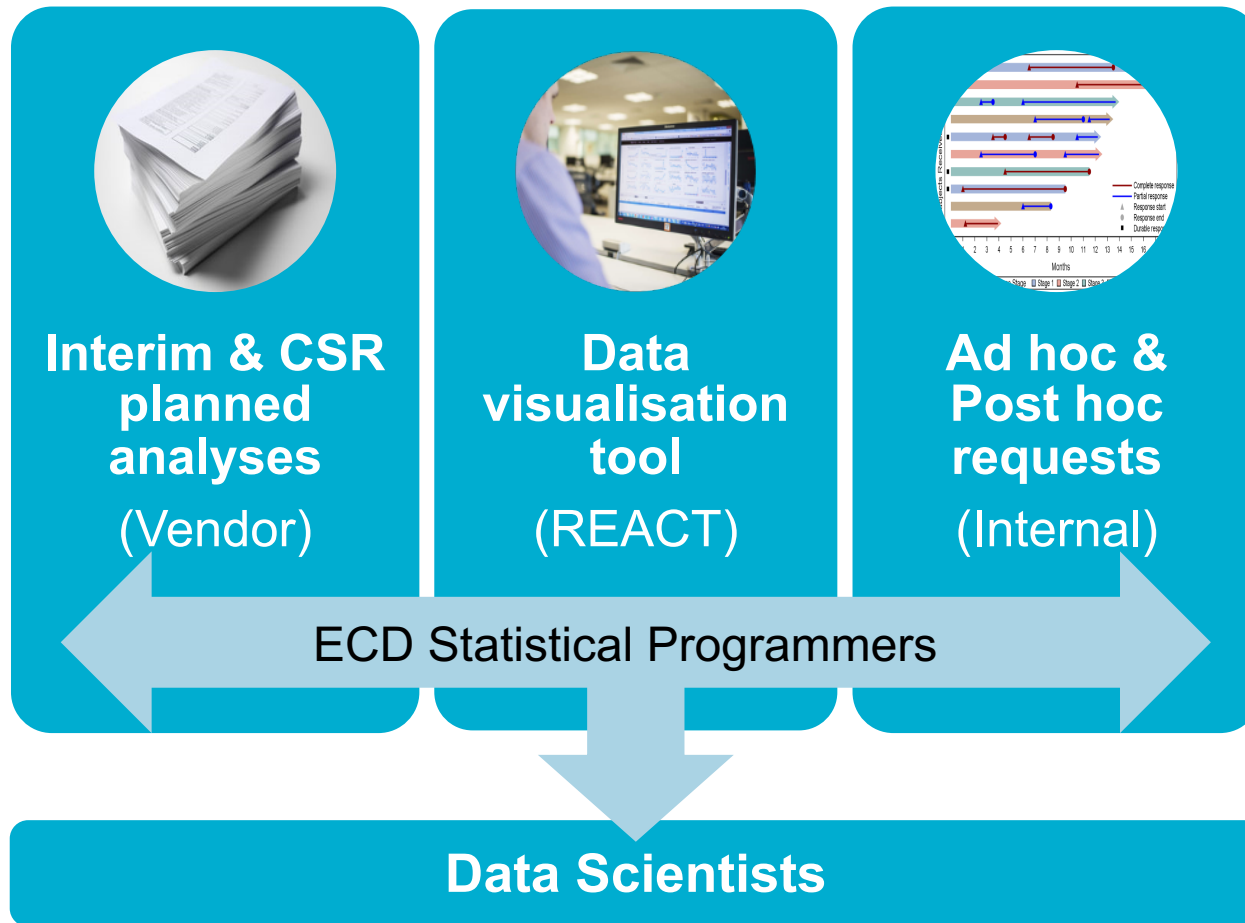


- ECD are focussed on understanding emerging study data
 - **Make an early decision to stop study**
 - **Adapt to signals**
 - **To advance the program**
- Go/No Go decisions



ECD Statistical Programmers

- Within ECD, regular intensive analysis is performed



REACT Benefits ECD



REACT benefits Study Teams

- Investigate a benefit/risk profile of a treatment
- Respond to and prevent the escalation of data issues
- Support making decisions on dosing
- Monitor the safety of patients in clinical trials



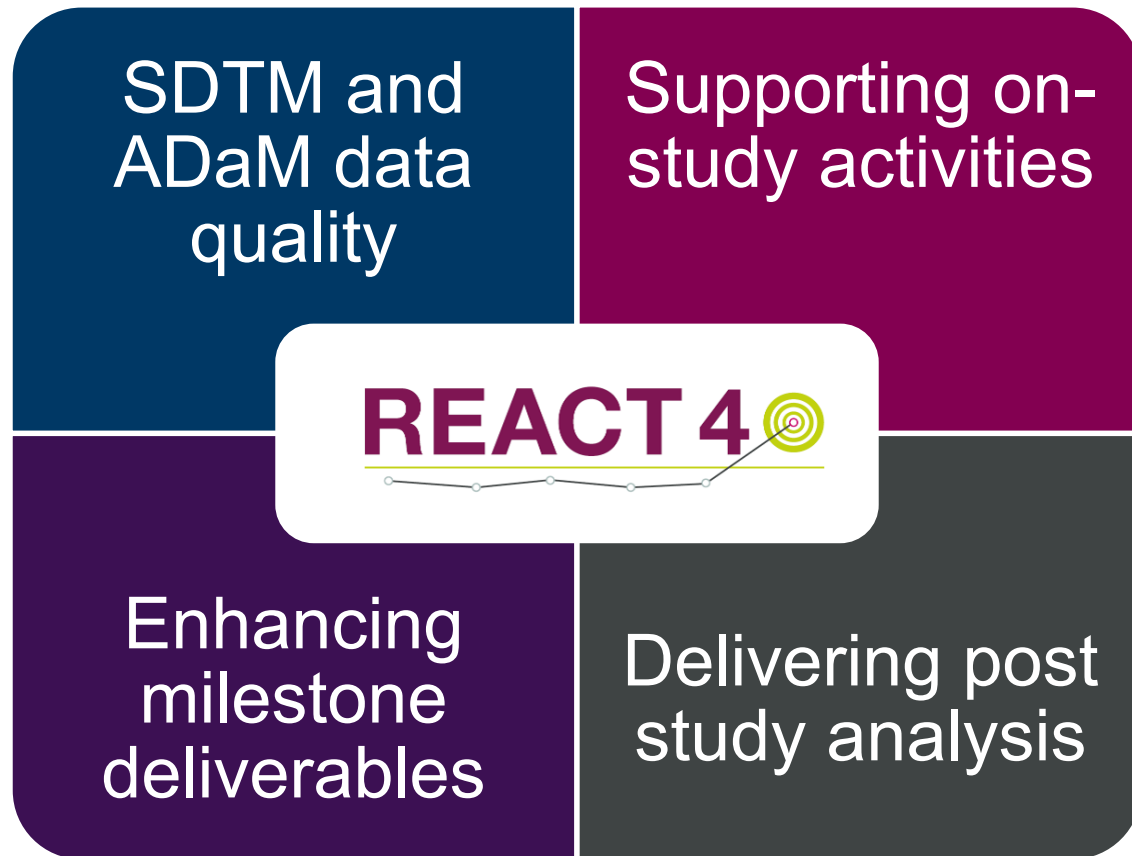
REACT benefits Statistical Programmers

- Respond to ad hoc requests more quickly
- Review vendor deliverables more thoroughly
- Observe emerging data more efficiently

The purpose of this presentation is to describe the benefits realised by ECD statistical programmers through having REACT in their analytical toolkit.

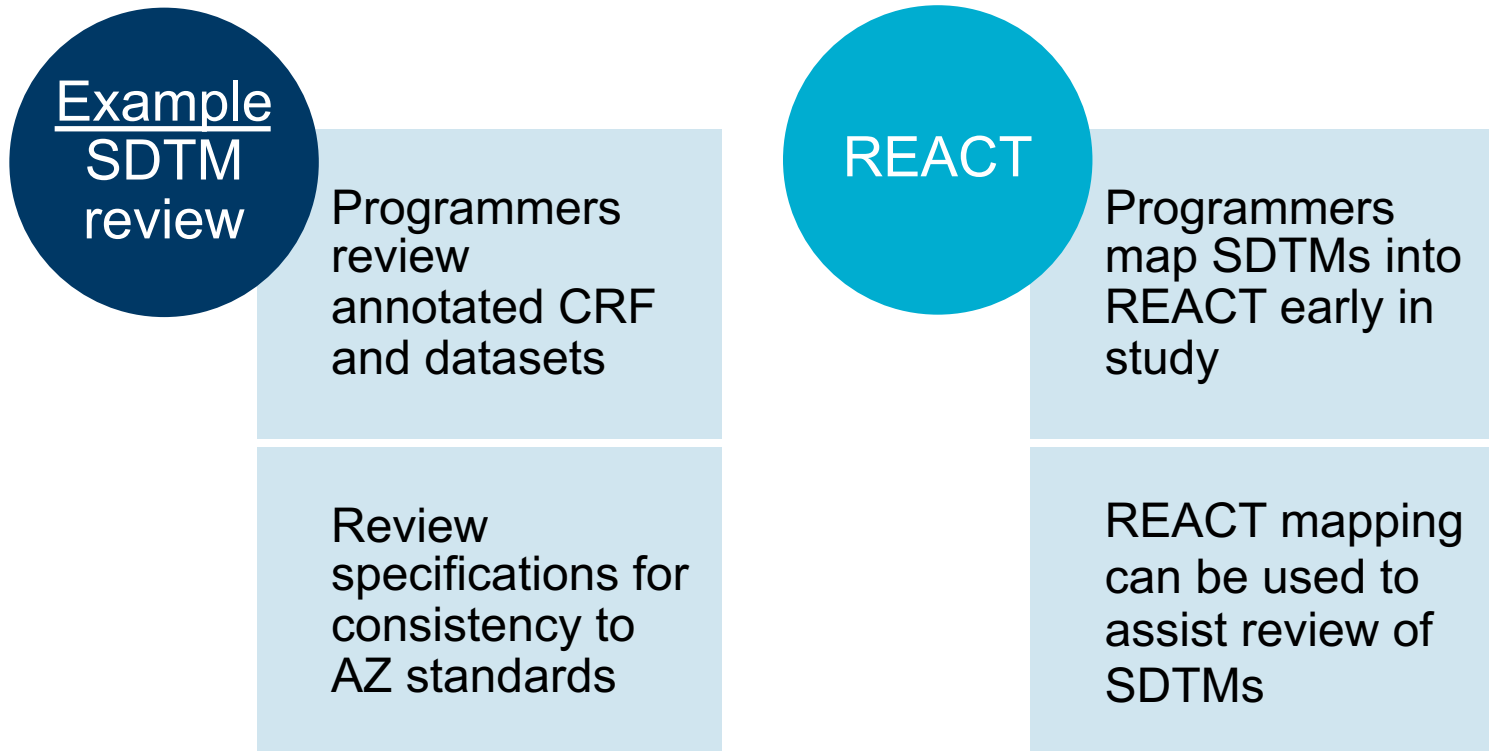


Benefits of REACT to ECD Statistical Programmers



SDTM and ADaM Data Quality

- SDTM and ADaM data are provided by vendor
- REACT allows programmers to get closer to this data

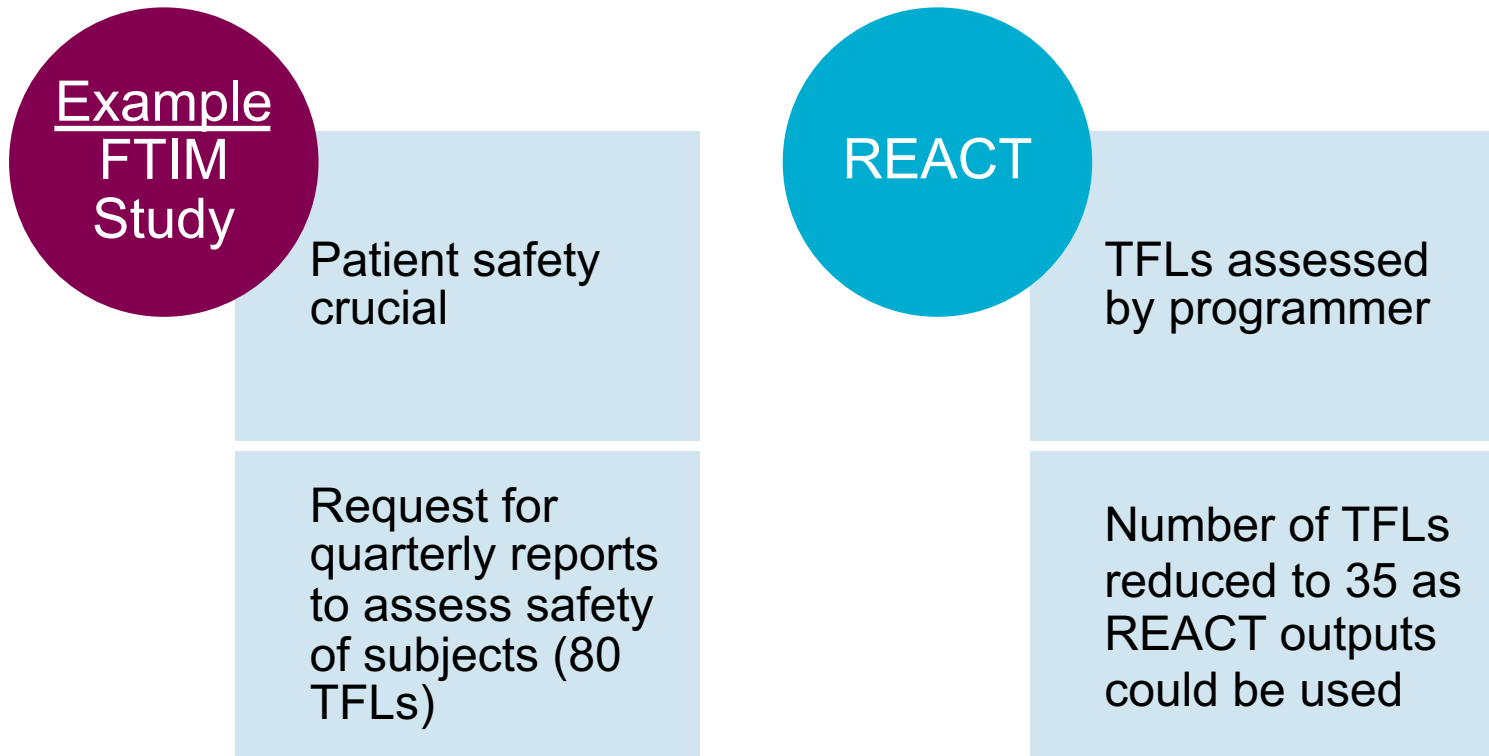


Quality of SDTMs are addressed proactively and at an early stage in the study avoiding an impact at future milestones



Supporting On-study Activities

- On-study analysis is ad hoc, unplanned and data driven
- REACT allows programmers to continually support study teams



More time to program complex targeted analyses, further deep-dives, or programmatically confirm the REACT results



Supporting On-study Activities: Example

Haematology parameters

Demographic characteristics

Race ⚙️

All (N = 124)	
Count of subjects	
Asian	49
Other	38
White	37
Total	124

Subjects (count) ⚙️

Population
(All) 124 of 124 Subjects

Lab Measurements
29797 of 75264 Events

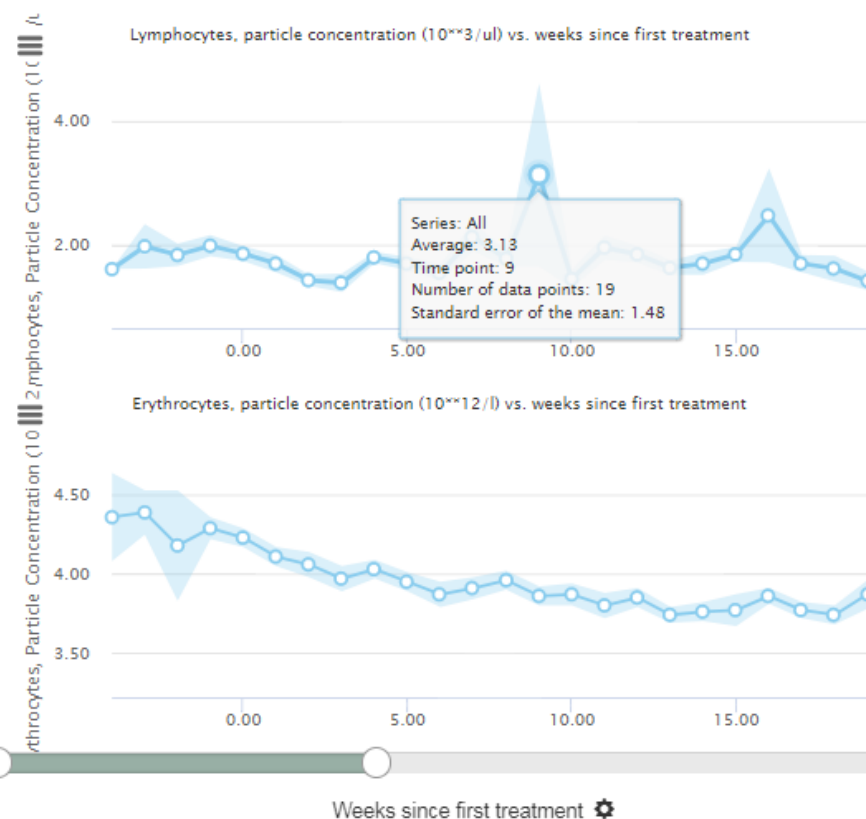
Measurement category: Hematology ✕

Box Plot

Shift Plot

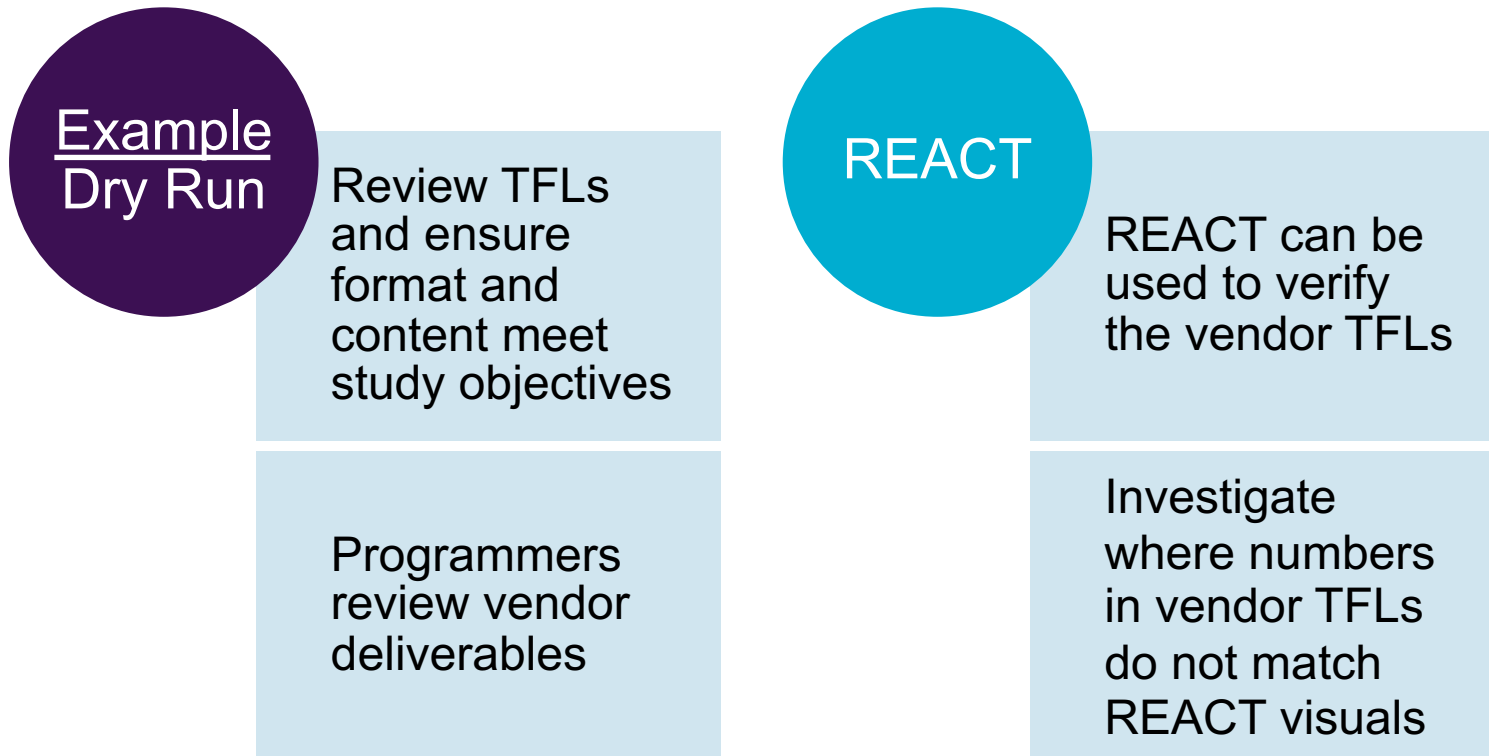
Line Plot

Result value ⚙️



Enhancing Milestone Deliverables

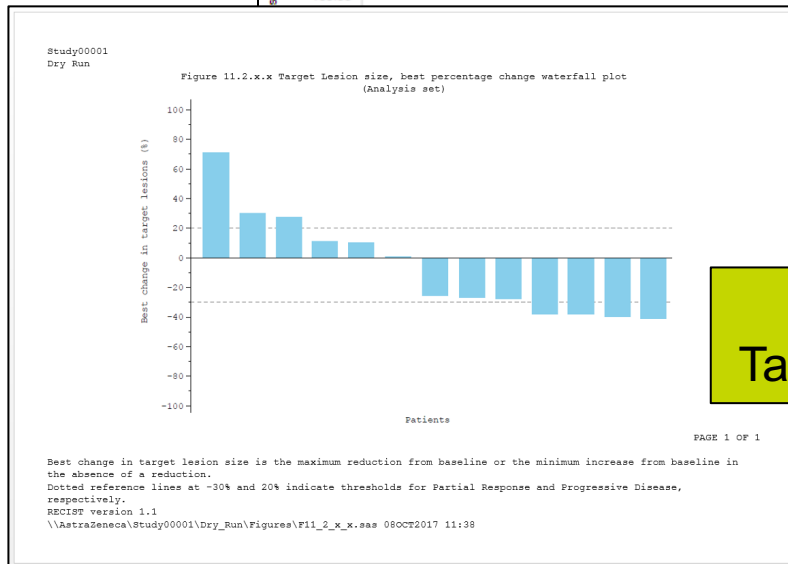
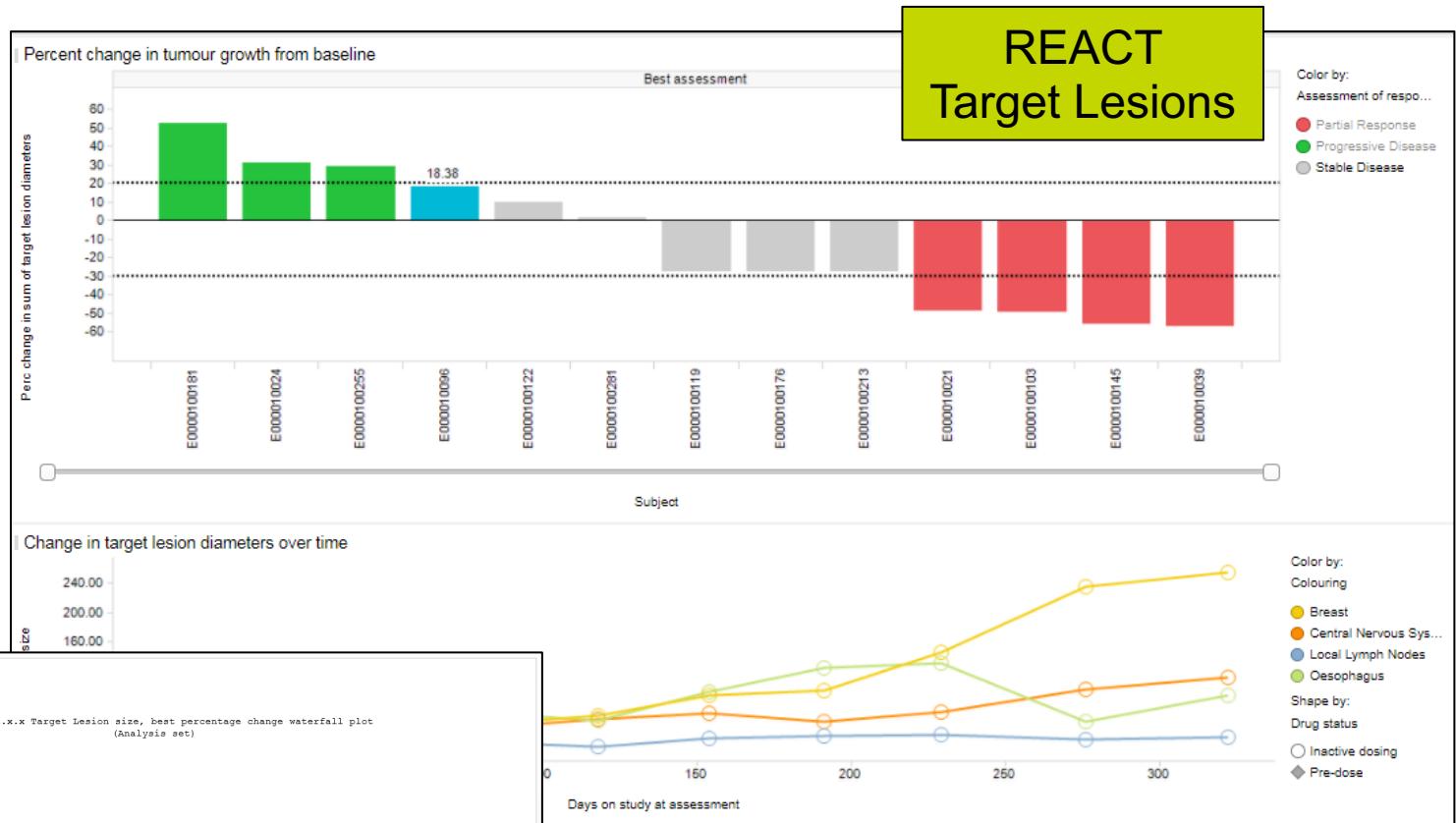
- Milestone (planned) deliverables are provided by vendor
- REACT allows programmers to consistently review the deliveries



Programmer reviews milestone delivery efficiently and can perform more detailed assessments of vendor deliverables



Enhancing Milestone Deliverables: Example

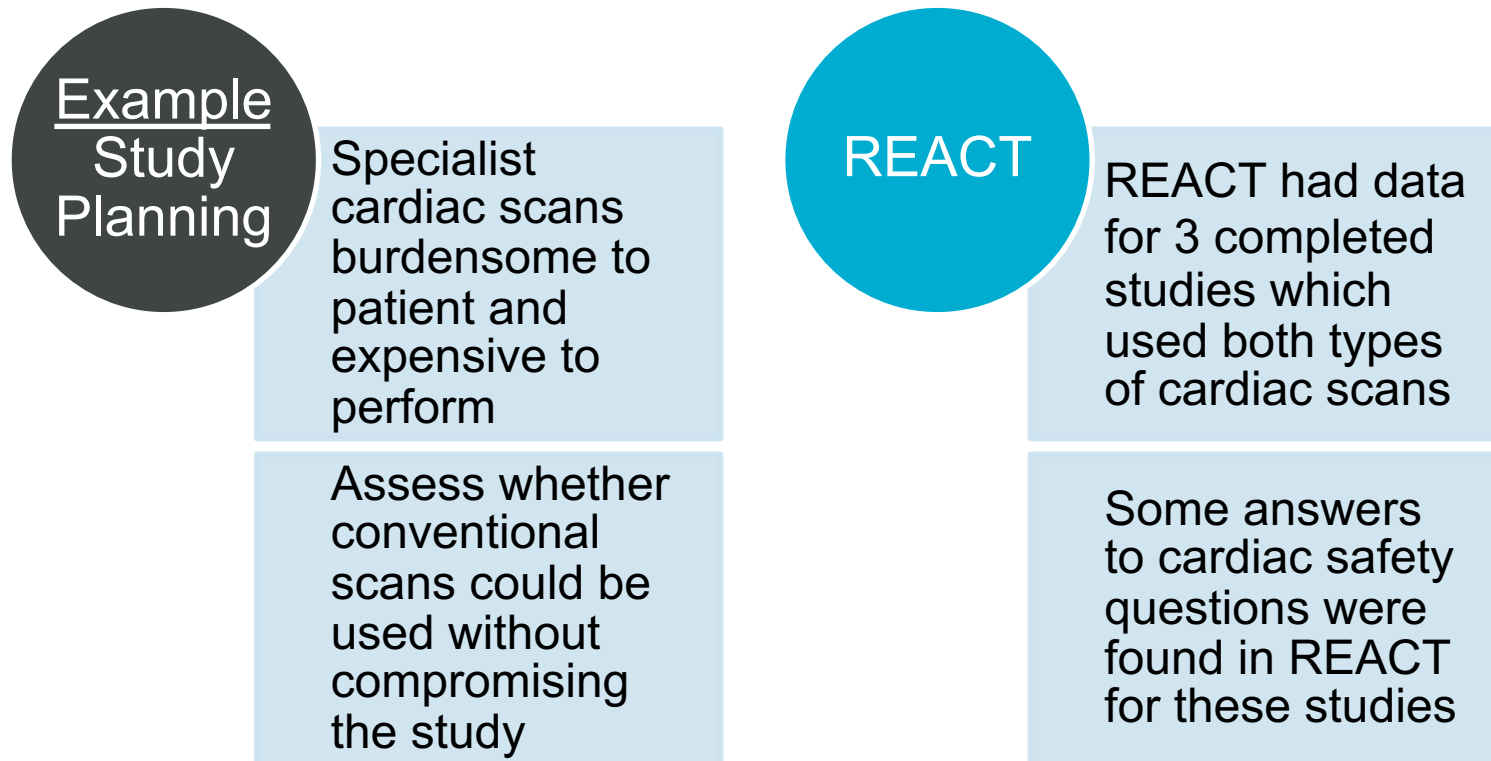


TFL Target Lesions



Delivering Post-study Analysis

- Teams engaged in final data for clinical interpretation post-study
- REACT allows programmers to support post-hoc investigations



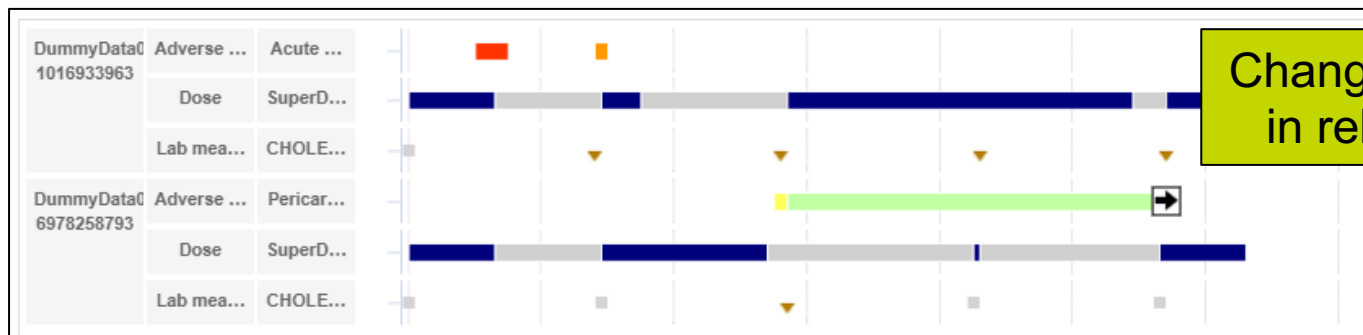
Safety assessment enhanced by combination of REACT views and programmatic outputs to design a better study for future



Delivering Post-study Analysis: Example



Cardiac events by increasing dose



Benefits of REACT to Vendors

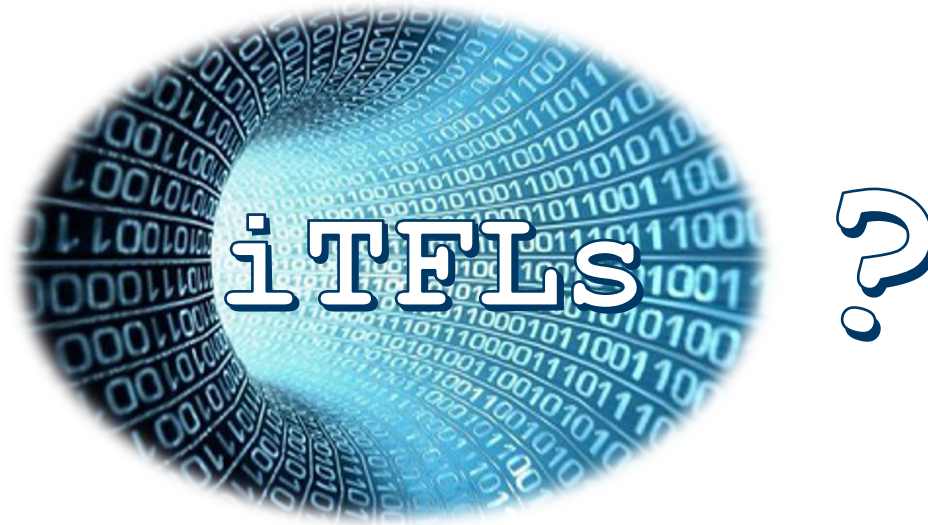
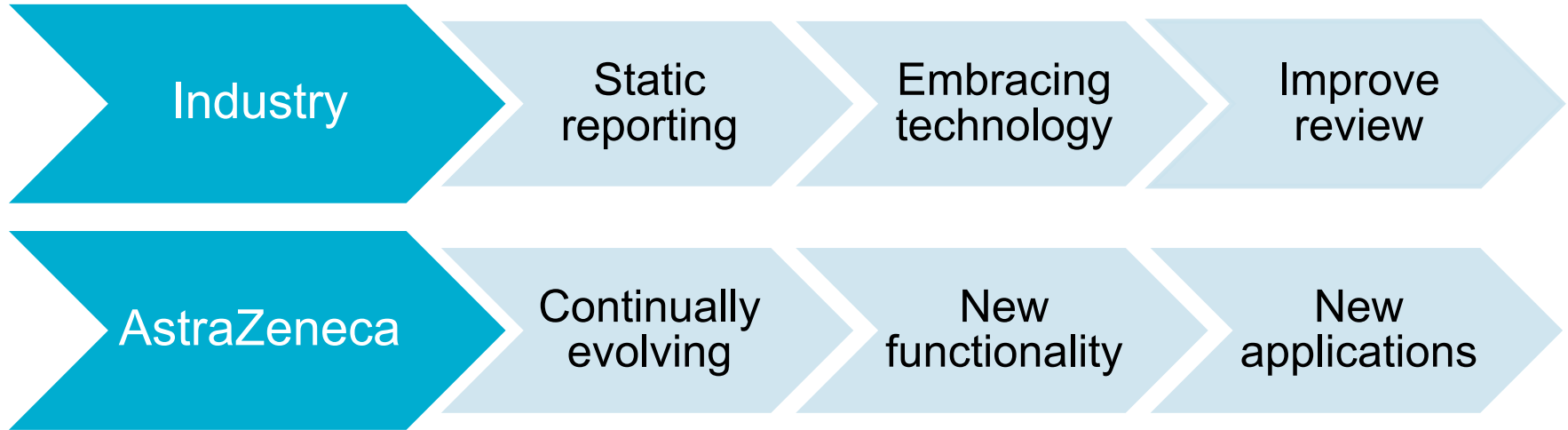


- ECD vendors are part of the clinical study team and able to access REACT
- Internal and external study team members are aligned
- Vendors are able to identify data and quality issues through REACT
- Vendors empowered by REACT views:
 - keep up to date with data entry
 - increase frequency of SDTM transfers

Through using REACT, vendors feel closer to data and study

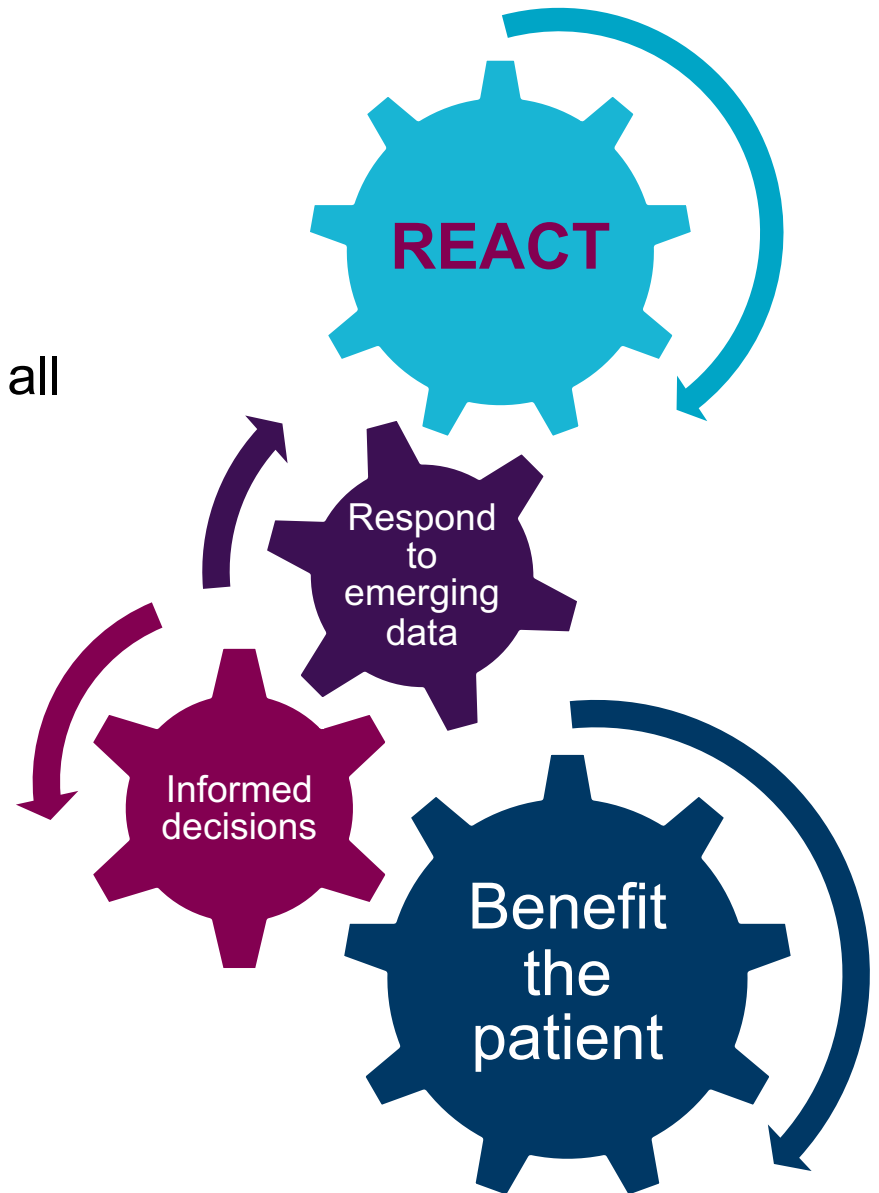


Future



Conclusion

- REACT enhances access to data for all
- ECD statistical programmers are embracing new technologies to:
 - ✓ improve standard deliverables
 - ✓ strengthen support to study teams
 - ✓ evolve as data scientists





Thank you!

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