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Single Day Event

REACTing to Clinical Study Data: Enhancing Insights and Decision-Making

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Agenda

- Data Visualization Tools and REACT
- Why REACT?
- Overview
- Where it fits?
- Process
- Views

Data Visualization Tools

- Informed Decision-Making: Data visualization empowers researchers and clinicians to make informed decisions based on clear, visual insights.
- Trend Identification: Visualization tools aid in identifying trends, patterns, and outliers within clinical data, enabling better decision-making.
- Timely Issue Detection: Real-time data visualization helps detect and address issues promptly, optimizing trial protocols.
- Safety Monitoring: Visualization supports continuous patient safety monitoring and adverse event detection.
- Patient-Centric Approach: Data visualization facilitates the inclusion of patient-reported outcomes, promoting a patient-centric approach to healthcare.
- Streamlined Reporting: Data visualization simplifies the preparation of reports for regulatory submissions and publications.

REACT

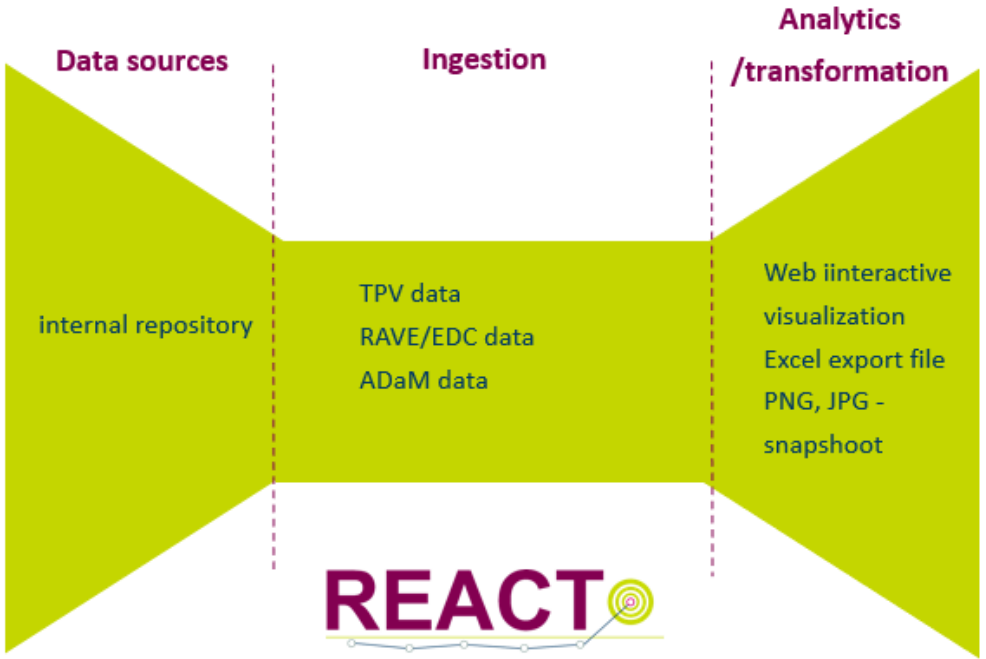
- ✓ REal time Analytics for Clinical Trials or REACT is a web-based application developed at AstraZeneca
- ✓ It enables interactive visualization of clinical study data - available on an ongoing basis and at specific points in time like BDR or end of study reporting data.
- ✓ REACT draws it's data from external EDC, TPV data and etc.
- ✓ Used to populate graphs and tables which allow us to visualize the data like AE, CM, ECG, Lab measurements etc., for individual patients, cohorts or across entire study population.
- ✓ The data seen in REACT are linked so you can use REACT to not only view the data but the relationship between them.
- ✓ Designed to be used by clinical study teams including patient safety, medical scientists, programmers, statisticians and other key stakeholders.

Why REACT?

- Utilizing REACT brings statistical programmers closer to study data, enhancing traditional statistical programming deliverables.
- It improves their ways of working and positively impacts clinical programs.
- Instantly available summaries in REACT enable faster response to ad hoc requests.
- Facilitates more thorough review of deliverables.
- Enhances the efficiency of observing emerging data.
- Allows statistical programmers to focus on more complex summaries and profiles.
- Contributes to decision-making processes.

REACT Overview

High-level data flow



Current applications

- Review of aggregated data and Single Subject views
- Review of ongoing study data: **AEs** eg. incorrect CTCAE grade, **Labs** eg. abnormal laboratory data, Liver (Hy's-Law), Renal, **VS**
- Timeline view, Detailed summary for patient level data
- Identify trends, data issues and outliers, safety review, speeding up process of writing patient narratives by medical writers
- Identify sites that are source of data issues
- BDR programs quality check (lack of flag applied can be identified)
- Data issues noted (missing unit, improper naming conventions in lab tests)
- Early/late phases – reduction in the number of Tables, Listings, and Figures (TLFs)

Key capabilities

- Web based application, data driven, no dataflow to other systems, read only, 24-hrs data refresh
- Filtering data, numbers of hard-coded filters + customized filters
- Exporting to Excel, Detailed Patient View to Excel, Word, etc.
- Visualization snapshots and exporting to PNG, JPG
- Custom blinding configuration e.g., exclusion criteria, default values

REACT packages - ongoing

Base	• Population (Randomisation dates, Withdrawal/Completion, Patient group information – Cohorts, Dosing, Dose discontinuation, Demography, Countries, Death, Ethnic group) • Adverse Events (Subject counts, AE over time, AE summaries, AE burden) • Concomitant Medications • Laboratory measurements including Liver and Renal Function • Vital Signs • Cardiac Function (ECG, LVEF) • Single Subject View (SSV) only: ➢ Medical history ➢ Surgical history ➢ Substance use (Nicotine, Alcohol) ➢ Overdose ➢ Pregnancy ➢ Liver diagnostic investigation ➢ Liver signs and symptoms ➢ Liver risk factor ➢ Medication Error • Population filters for medical monitoring (derived from Vital Signs, dECG)
Additional dosing and exposure details	• Detailed 'Dose Subject Counts' Plot • Exposure (PK concentration, PK model parameters, PK model parameter vs. AE occurrence, PK model parameter vs. RECIST response, Subject PK profile)
Oncology	• Disease lesion information • RECIST1 (Target and non-target lesions) • RECIST2 • Radiotherapy • Chemotherapy • Foundation Medicine Gene Variant Summary • Single Subject View (SSV) only: ➢ Disease Extent ➢ Pathology
Respiratory	• Exacerbations (classification rules can be customized) • Lung function • e-Diary • Medication of interest • ACQ-6 asthma questionnaire
CV (available in AEs view)	• Cardiac Ischemic events • Cerebrovascular events • Additional Suspected CVOT endpoints
Other	• Biomarkers

RAW data source examples:

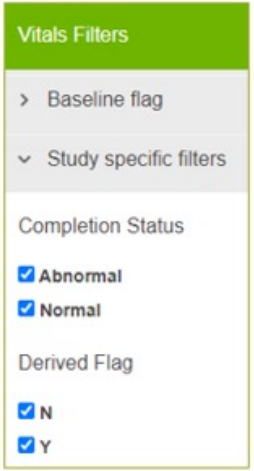
dm.sas7bdat	ex.sas7bdat	vs.sas7bdat	eg.sas7bdat
visit.sas7bdat	ae.sas7bdat	dosdisc.sas7bdat	mer.sas7bdat
ie.sas7bdat	cm.sas7bdat	group.sas7bdat	hiss.sas7bdat

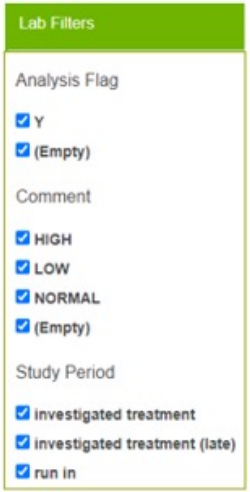
exaca.sas7bdat	diary.sas7bdat
copdex.sas7bdat	diaryre.sas7bdat

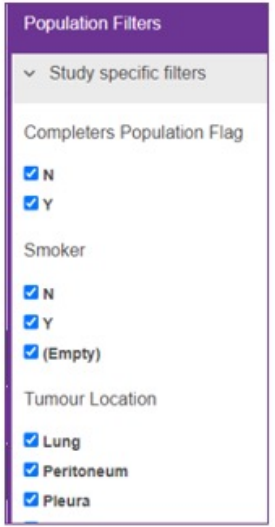
REACT packages - static

Base	• Population (Randomisation dates, Withdrawal/Completion, Patient group information – Cohorts, Study Specific Filters, Dosing, Dose discontinuation, Demography, Countries, Death, Ethnic group, Medical histories) • Adverse Events • Concomitant Medications • Laboratory measurements including Liver and Renal Function • Vital Signs • Cardiac Function (ECG, LVEF)
Additional dosing and exposure details	• Detailed 'Dose Subject Counts' Plot
Respiratory	• Exacerbations (classification rules can be customized) • Lung function

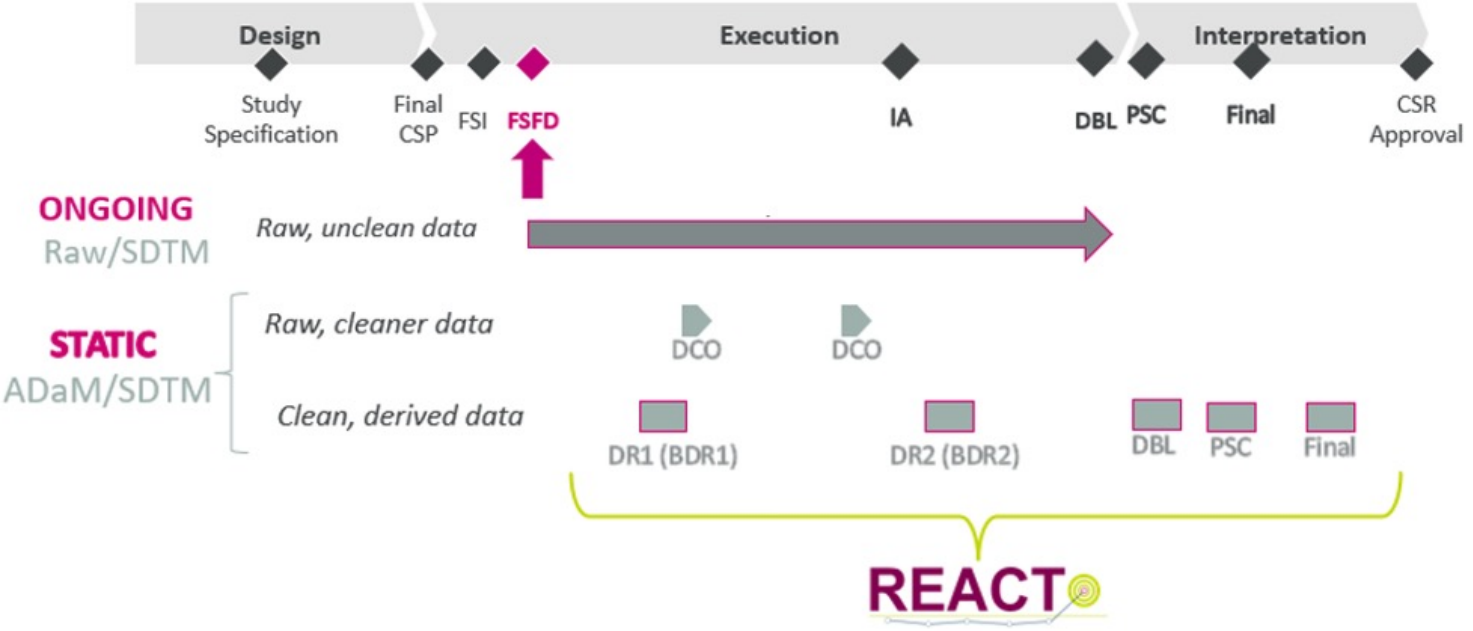
Analysis Flags can be incorporated into available views (eg. taken from ADSL, ADAE, ADLB, ADVS etc.)



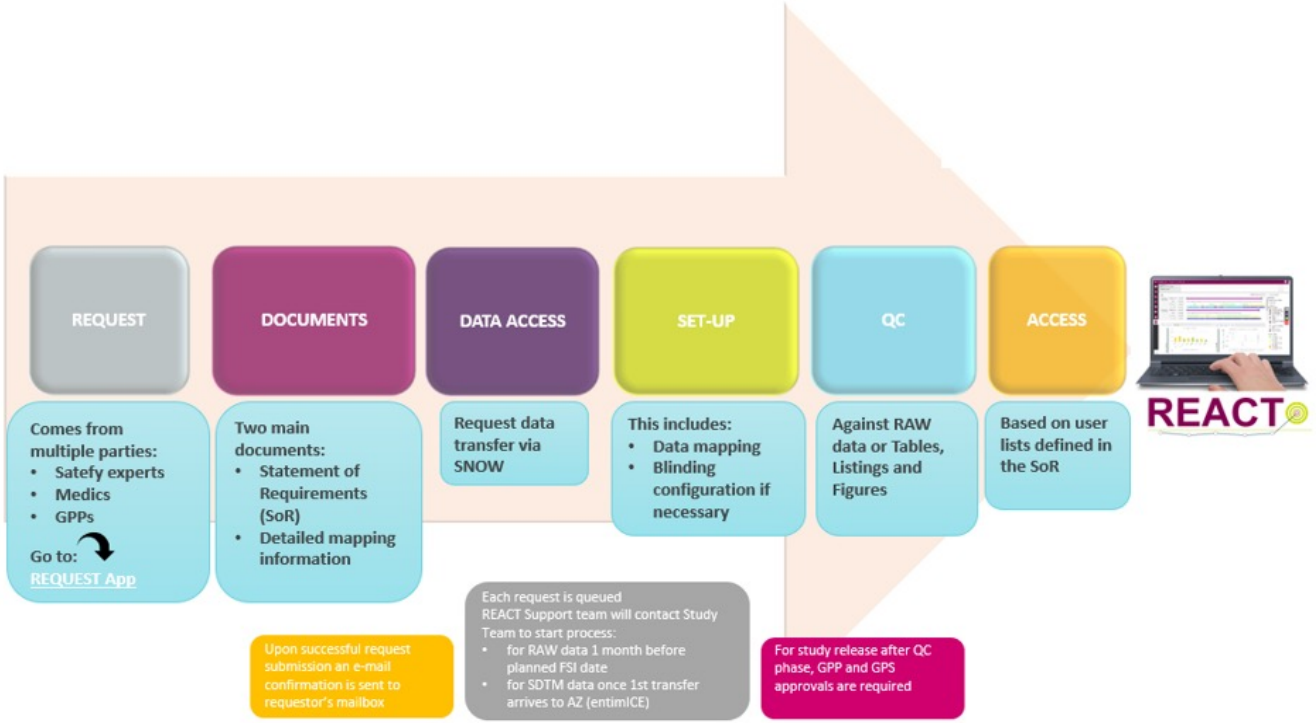




Where REACT fits?

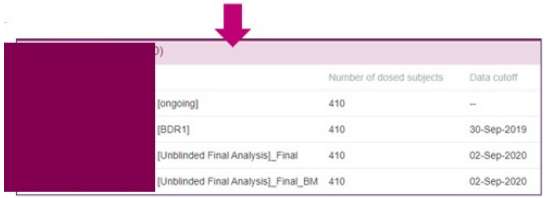


REACT process



REACT views

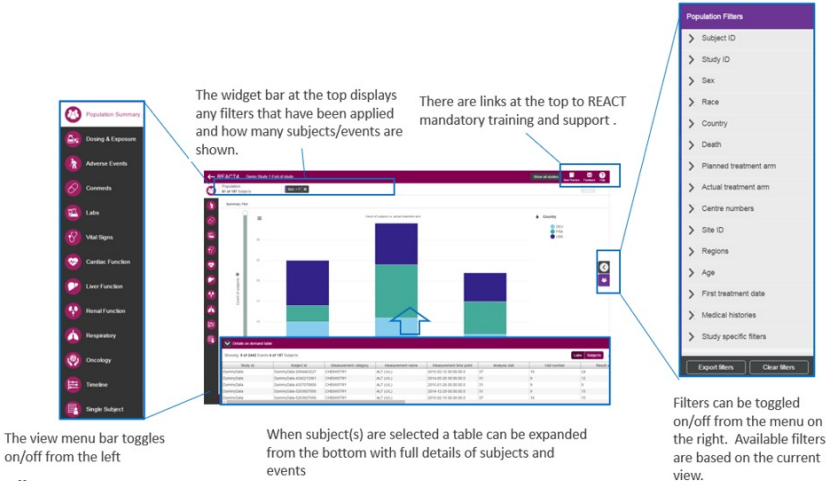
Ongoing & static instances in one place



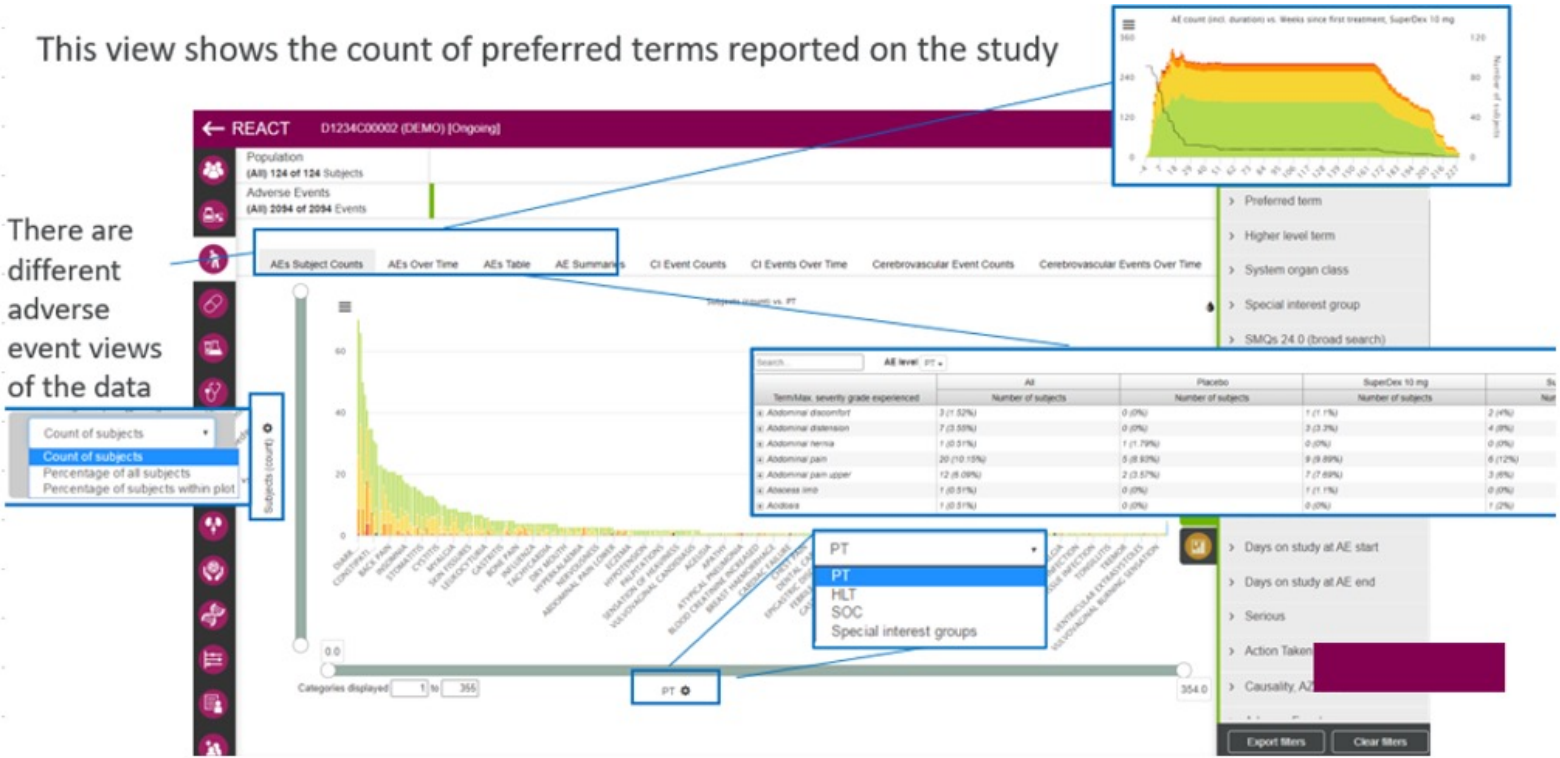
Cross-study review is feasible if the same data format (ie. raw or ADaM)

Available views

- Population Summary
- Dosing & Exposure
- Adverse Events
- Vital Signs
- Conmeds
- Cardiac Function
- Timeline
- Labs
- Respiratory
- Liver Function
- Renal Function



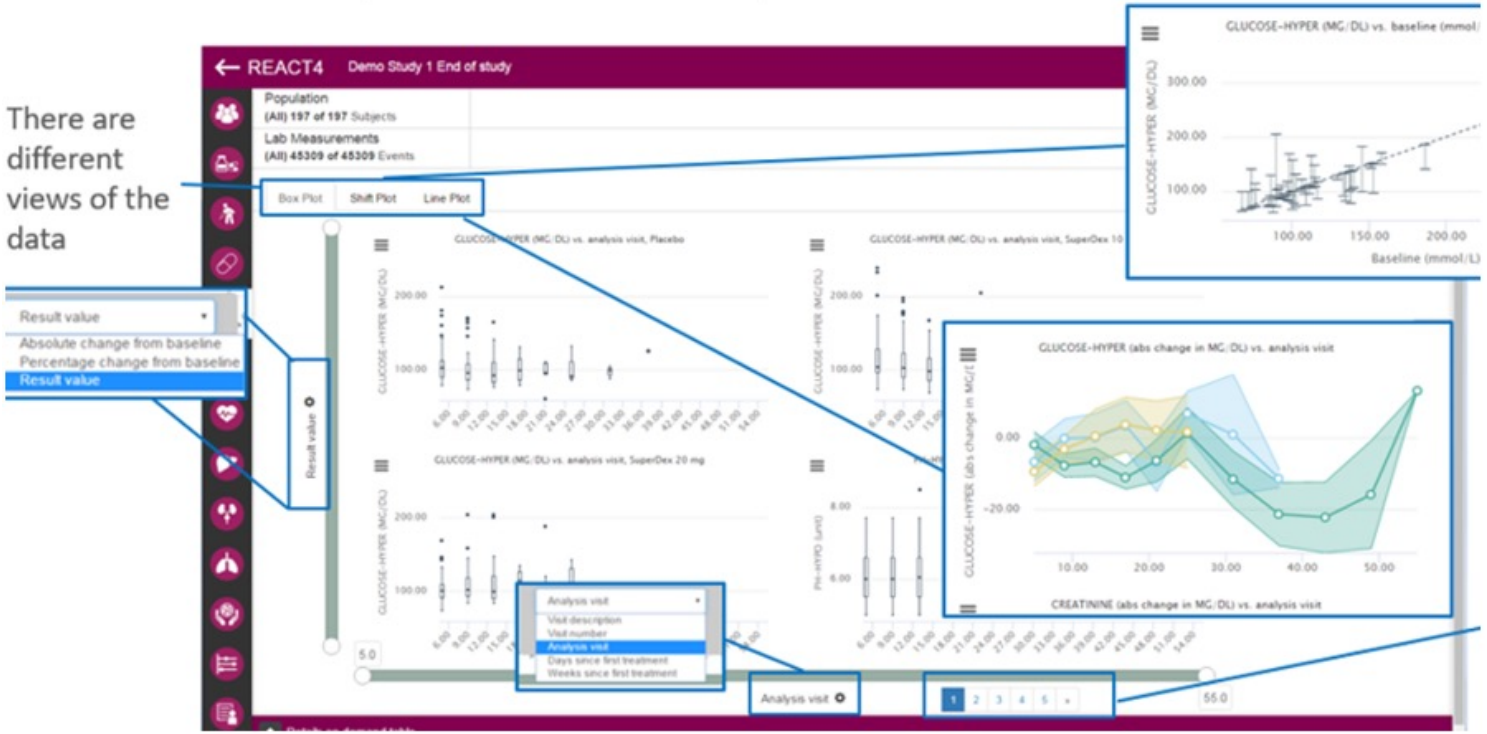
View – Adverse Events



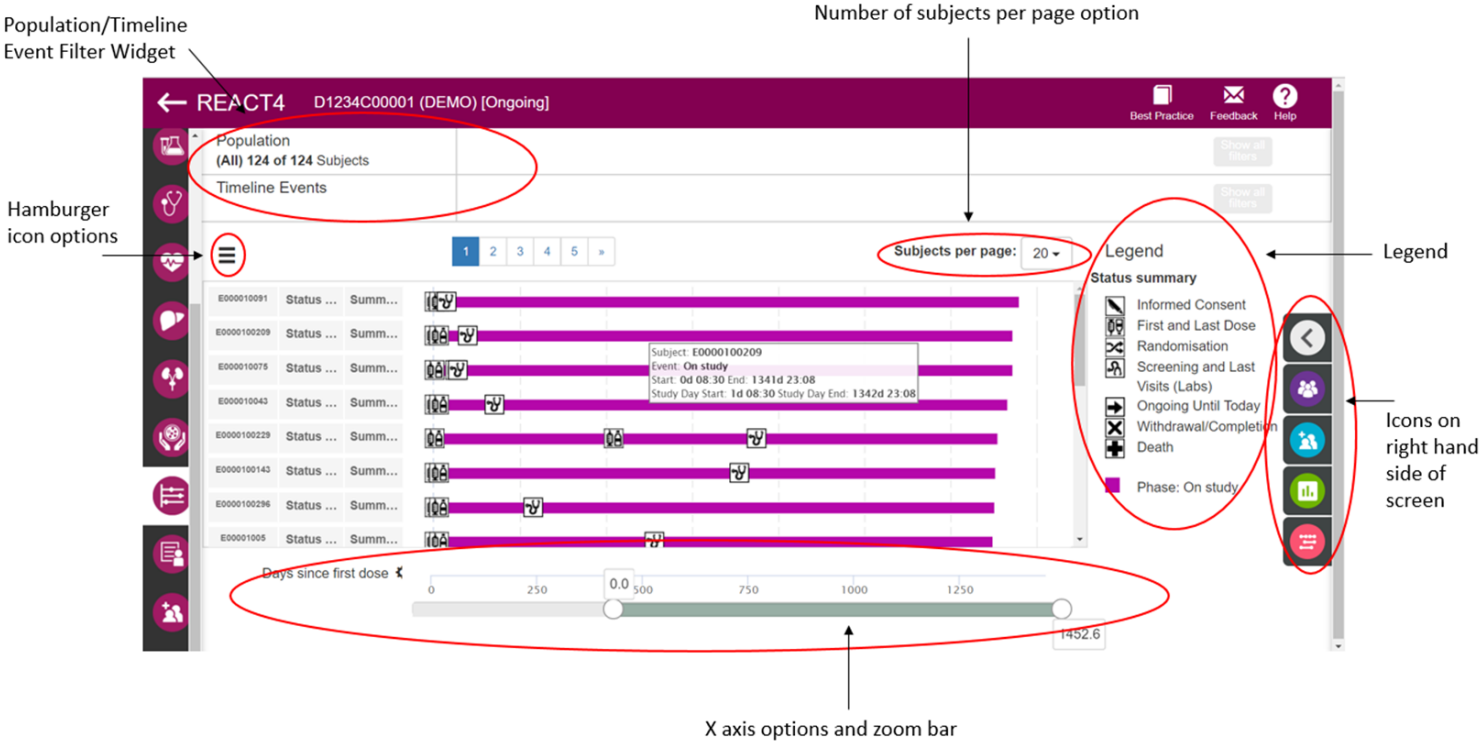
View – Laboratory Measurements

This view shows a box plot of different laboratory measurements over time

There are different views of the data

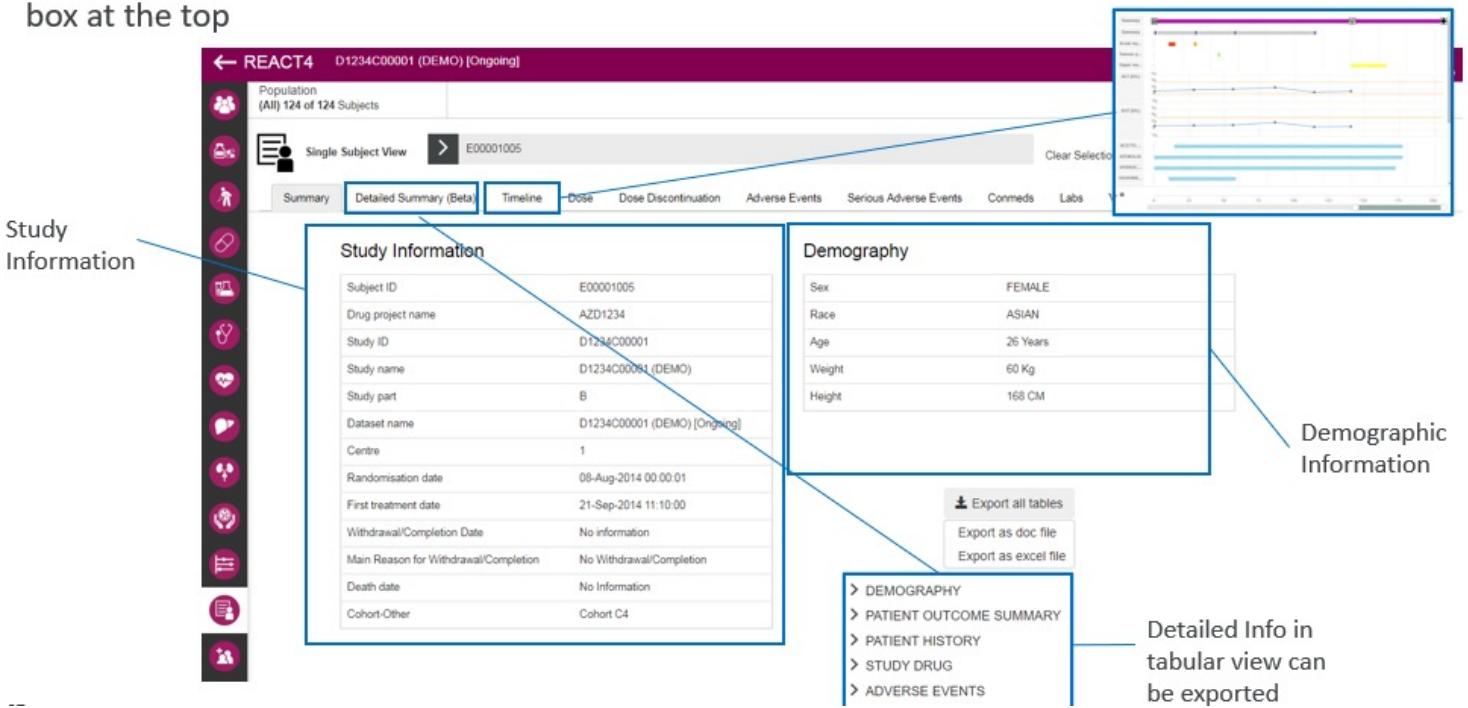


View - Timeline



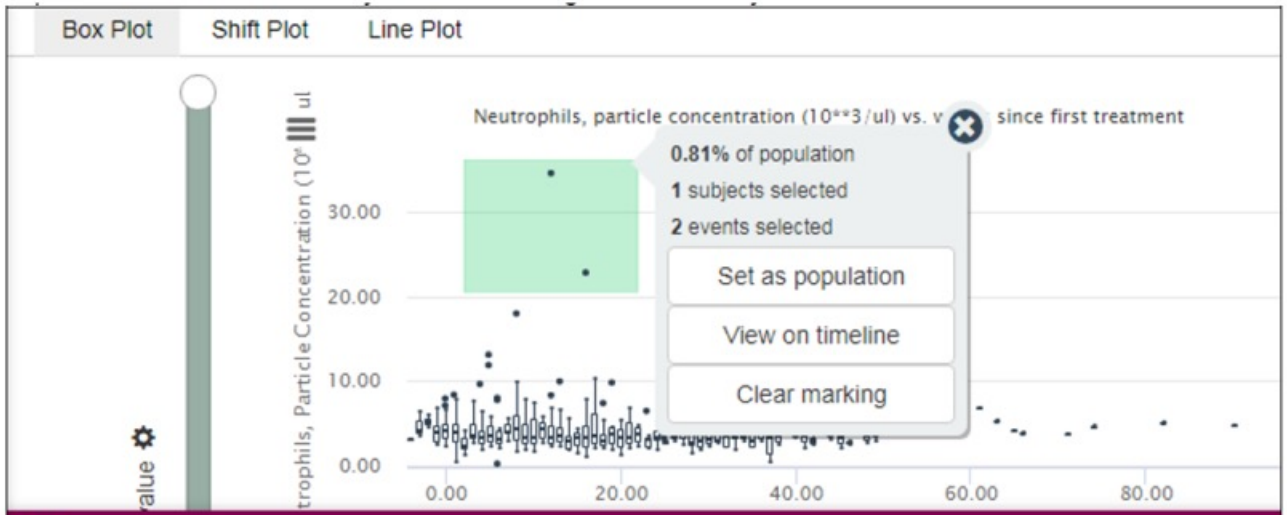
View – Single Subject

This is the view for a single patient, either selected in a different view or selected in the search box at the top



View - Patient profile

Drill-down functionality



Details on demand table

Showing: **2 of 75264** Events **1 of 124** Subjects

Subject id	Measurement name	Measurement time point	Result value	Result unit
E0000100268	Neutrophils, Particle Concen...	2015-04-14 12:00:00	22.88	10**3/uL
E0000100268	Neutrophils, Particle Concen...	2015-03-18 12:00:00	34.66	10**3/uL

View – Ongoing vs Static

Ongoing

- AZ RAW data (CDASH/SDTM)
- Data refreshed every 24-hours
- Study specific filters can be added
- QC done against datasets
- Data is calculated in most of cases, data base logic is quite complex
- Single Subject view, CV and Oncology package are available only in ongoing instance

Static

- ADaM/SDTM data
- One-time data upload
- Study specific filters or flags like 'Treatment emergent flag' can be applied
- QC done against TLFs
- Treatment arms are available
- Most data is taken directly from data source – only analyzed data is shown

Conclusion

- REACT enhances system, process simplification, automation and standardization
- REACT tool is aligned with AZ standards
- REACT visualisation capabilities are data driven, which means that you can only see plots and tables for which you have data in your dataset.
- It’s about visual, almost pictorial view of events
- It’s about the speed, simplicity, of understanding those results. And it’s about collaboration. No trial is run in the exact same way. Trials deviate as we’re going forward.

Thank you!

The Global Healthcare Data Science Community

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