



Health Science, Clinical Research

Visualized Patient Profiles!

Enhanced Timelines for Quick Decision-Making

DV03

Health Inspired, Quality Driven.

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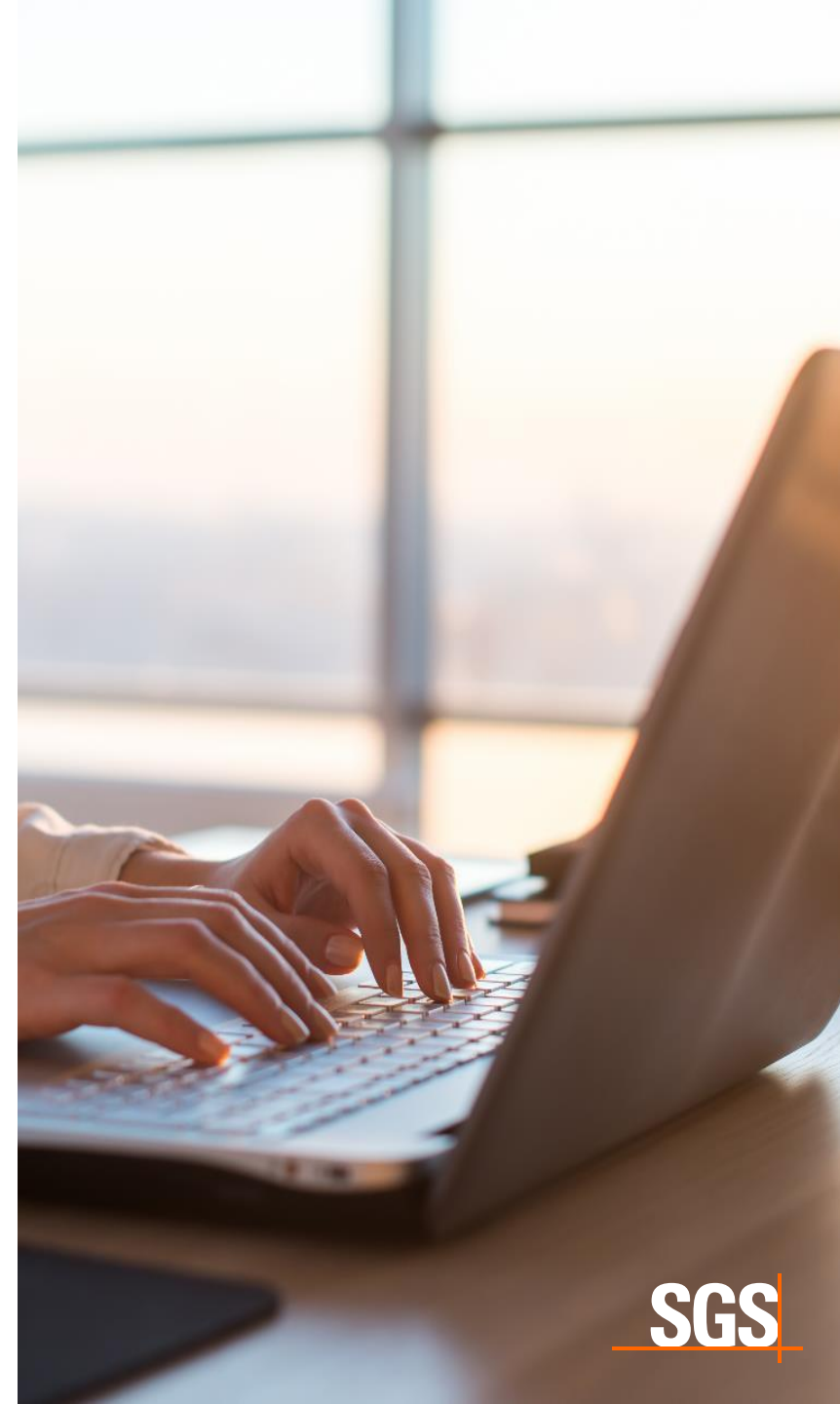


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Overview

- Patient Profile
- From Data to Dashboard
 - Study Flow
 - Conversion
- Reusable dashboard templates
- Validation
- Demonstration
- Challenges & Roadmap
- Conclusion



Patient Profile – What, Why & How

- Display collected data of individual subject participating in clinical trial
- Focus on core safety data to review the subject safety during study
- Contain a lot of data: Adverse Events, Concomitant Medications, Medical History, Procedures (VS, ECG,...), Dosings, Study Visits, Randomization (cohorts, groups,...), Laboratory data,...
- Format depends on scope for which they are used
 - For data cleaning, medical safety review / safety meetings, medical monitoring or patient narratives,...



Patient Profile – What, Why & How

- Timing and frequency of availability depends on scope
- To date most review of patient profile data
 - In eCRF system, lab reports (laboratory portals)
 - Via programmed listings or tables and figures
 - Excel files, word files or pdf output files
 - Static output
 - High programming effort – long TAT timelines



Patient Profile – The ideal situation ?

- All data in one view
- Contains real-time, up to date, data
- Always accessible for user (ad hoc available)
- Easy to adapt, filter, select your preferred data
- Easy to understand and navigate by users; drug safety physicians, medical monitors, project managers,...
- Ready to use but still flexible for user
- Limit programming efforts for set-up
- Programming by non-technical employees – drag & drop
- Available from the beginning of the trial
- Extract data / save data and visuals

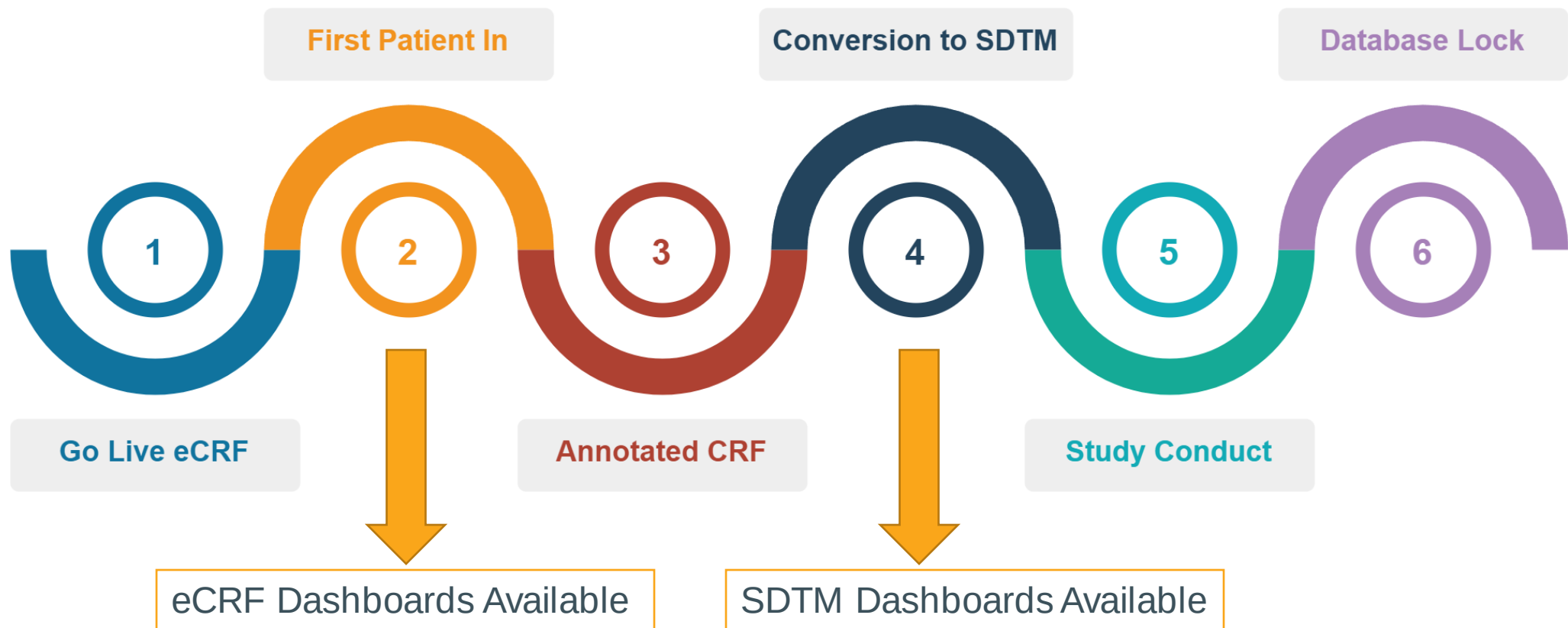




— Patient Profile – New SGS Approach

- Develop Patient Profiles in a data visualization environment
- **Tableau** – analytics software solution – cloud based
 - R Shiny, Spotfire, Power BI
- Develop a standardized approach - Quick deployment
- New patient profile
 - One interactive visual overview on a convenient timeline
 - Supported by other DV dashboards to further drill down into what the data means for full medical safety review

From Data to Dashboard - Study Flow



From Data to Dashboard - Conversion

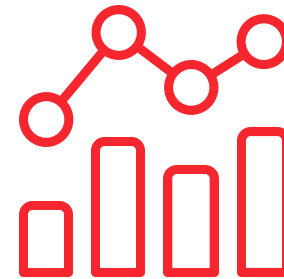
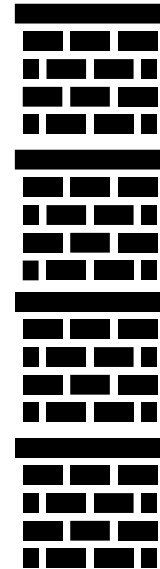
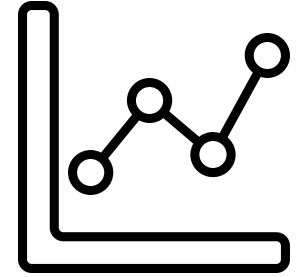
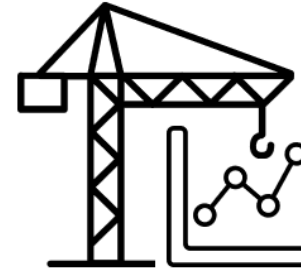


- As part of the standard SGS DM data conversion process
 - New SDTM Data is made available automatically
- A new conversion step activates the DataVis processes
 - The locations of input data and linked dashboards are preconfigured once
 - PowerShell scripts look for updated datasets
 - Those are uploaded to the Tableau server
 - Only relevant dashboards are refreshed, by using the Tableau REST API
- Automated system knows what data go where
 - No manual intervention



Reusable dashboard templates

- A software development methodology
- Templates can be deployed:
 - Internally in a study to quickly go from a quality control environment to production
 - Between different studies of a **same** client
 - Over trials from **different** clients!

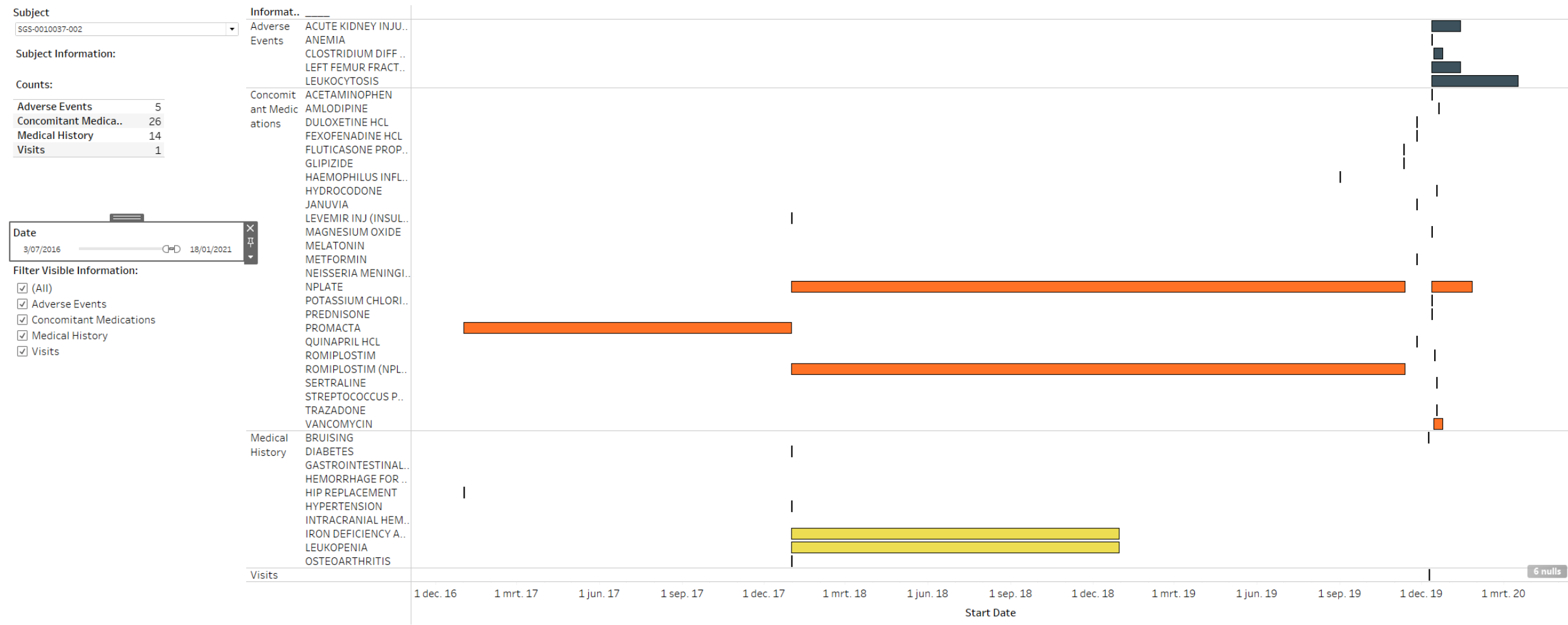


Validation

- The source for Data Visualization is already validated SDTM by a different QC process
- Dashboards exist in 3 different environments for **development**, **testing** and **production**
- **Creation** and **validation** defined by SOP
- Entering of test data in eCRF (UAT)
- Comparison of QC source vs dashboard output
- Re-use of validated dashboards for other projects requires no re-validation!
 - Same data structure (no dashboard updates)

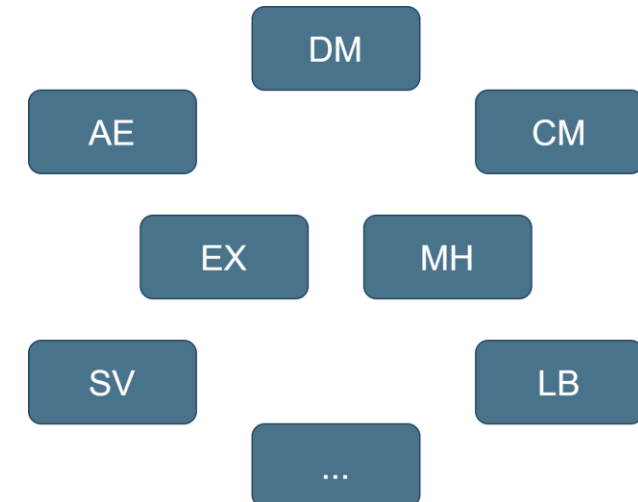
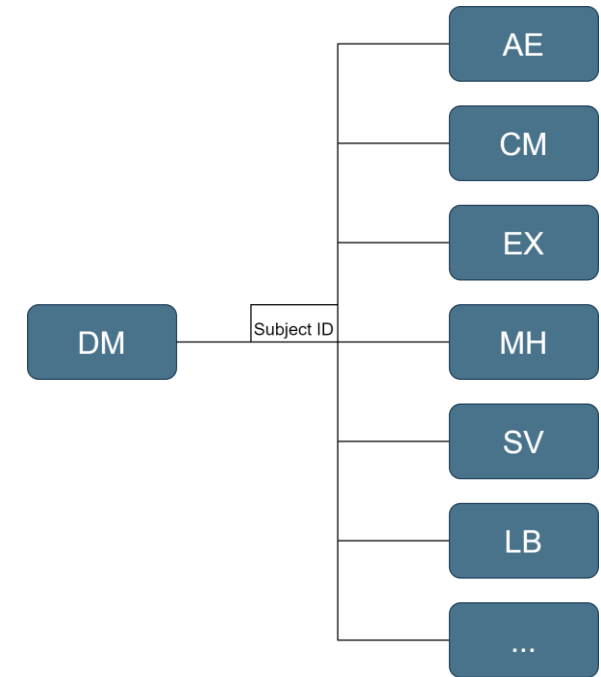


Demo Video: Patient Profile Dashboard



Challenges & roadmap

- Displaying and linking a large amount of data in a single dashboard
- Adding Findings domains (LB, VS, EG)
- Different approach of gathering datasets → use of individual sheets for more control in the dashboard
- Advantage – practical linking to different, domain-specific dashboards
 - While keeping active filters (patient & term/testcd/...)



Page 10 of 10

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SGS-0010037-001

SEX	Race	AGE	Armcd
F	WHITE	47	Null

Adverse Events	11
Concomitant Medications	18
Study Dosings	24
Lab Results	979

IFC Date ▼

stop Date _____

Show Marker

Mark specific date

(All) ▼

(All) ▼

1

(All) ▼

ADVERSE EVENT ▼

■ ADVERSE EVENT

BLINDED ▼

(Multiple values) ▼

(All) ▼

(All)

■ HIGH

- Contusion
- Ecchymosis
- Headache
- Heavy menstrual bleed.
- Leukocytosis
- Musculoskeletal chest ..
- Nausea

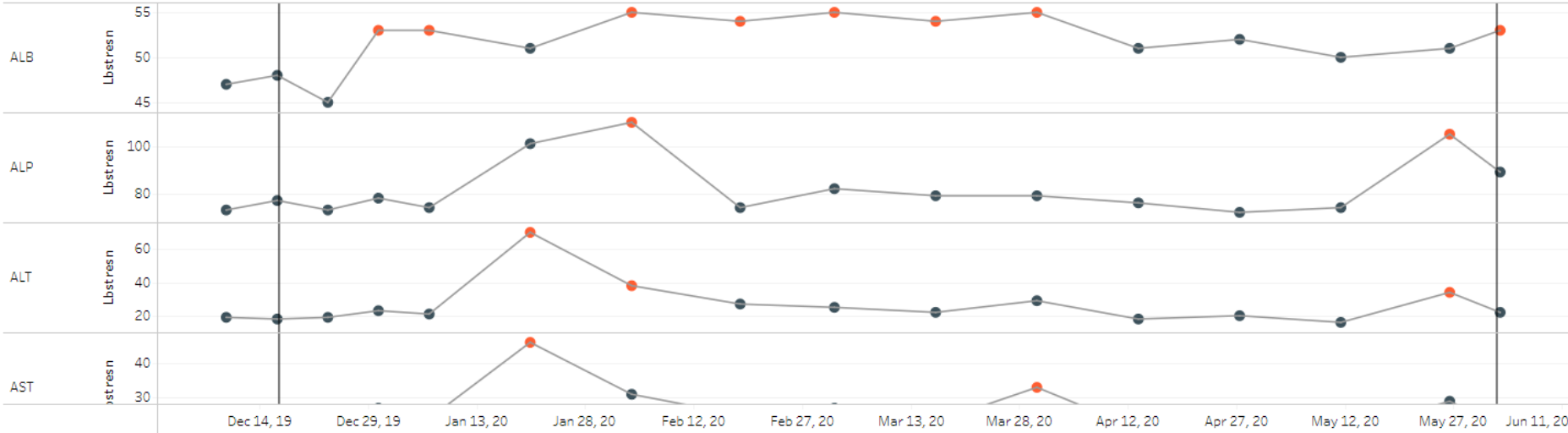
PARACETAMOL
PROCHLORPERAZINE ..

BLINDED

100

ALT

AST



Challenges & roadmap

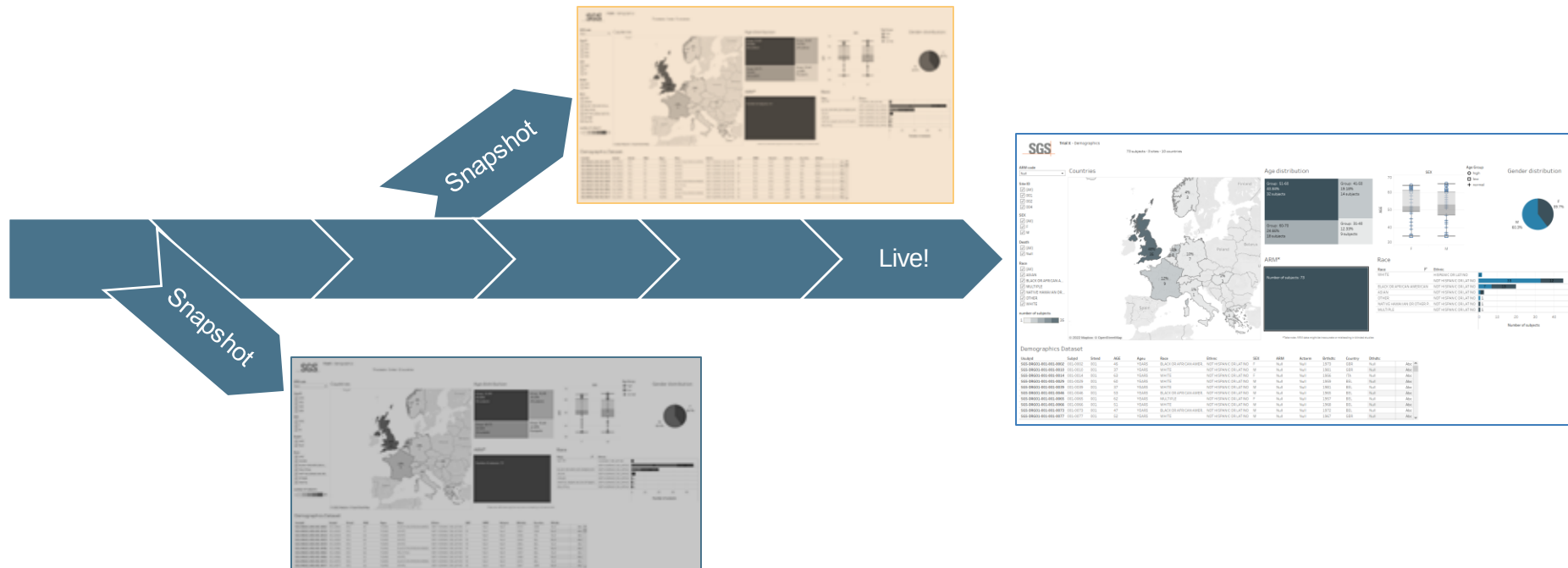
- Using other data sources instead of SDTM for creating standard dashboards
 - eCRF – structural differences per project
 - Requires project-specific programming
 - Horizontal structure of Findings domains → No stable structure per project

	LB_DAT_MM	LB_DAT_DD	LB_TIM	SODIUM	SODIUM_RAW	SODIUM_UN	POTASSIUM	POTASSIUM_RAW	POTASSIUM_UN	CALCIUM	CALCIUM_RAW	CALCIUM_UN	ALB	ALB_RAW	ALB_UN	CREAT	CREAT_F
▶	5	27	8:19	140	140	mmol/L	3.68	3.68	mmol/L	1.22	1.22	mmol/L	43.5	43.5	g/L	64	64
	6	3	8:43	141	141	mmol/L	3.96	3.96	mmol/L	1.06	1.06	mmol/L	46.2	46.2	g/L	67	67
	7	22	7:43	140	140	mmol/L	3.74	3.74	mmol/L	1.29	1.29	mmol/L	46.9	46.9	g/L	63	63
	6	10	8:17	141	141	mmol/L	3.77	3.77	mmol/L	1.32	1.32	mmol/L	46	46	g/L	67	67
	6	24	8:24	142	142	mmol/L	3.99	3.99	mmol/L	1.29	1.29	mmol/L	46.2	46.2	g/L	65	65
	7	8	8:08										46.92	46.92	g/L	67	67
						mmol/L			mmol/L			mmol/L			g/L		
	5	19	08:06	142.2	142.2	mmol/L	4.13	4.13	mmol/L	2.36	2.36	mmol/L	49.8	49.8	g/L	87	87.0
	5	26	08:09	142.8	142.8	mmol/L	4.06	4.06	mmol/L	2.42	2.42	mmol/L	54.3	54.3	g/L	90.4	90.4

- No coding available? Use of internal coding tool or eCRF coding module...
- Availability of external vendor data

Challenges & roadmap

- Daily refreshed dashboards - always up to date BUT
- For specific study timepoints - Safety Review Meetings (DSMB, SRC, IDMC ...) or Interim locks
- Underlying data may not change (cut-off datasets)
- Keep interactivity of dashboards (to be displayed during the review meeting)
- Can “document / save / go back to ” datasets and dashboard outputs of specific timepoint
- Create a separate environment in Tableau (snapshots) with fixed underlying data



Conclusion

- Patient profile dashboard has many advantages:
 - Displays a lot of data in a single accessible view
 - User-interactivity:
 - Filters
 - Drill down to other dashboards
- Tableau data pipeline & standard dashboards leads to early & real time availability for quick decision making





Questions?

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