



Health Science, Clinical Research

Patient Profiles v2.0

Easy and Quick Clinical Trial Insights in Tableau

DV06

Health Inspired, Quality Driven.

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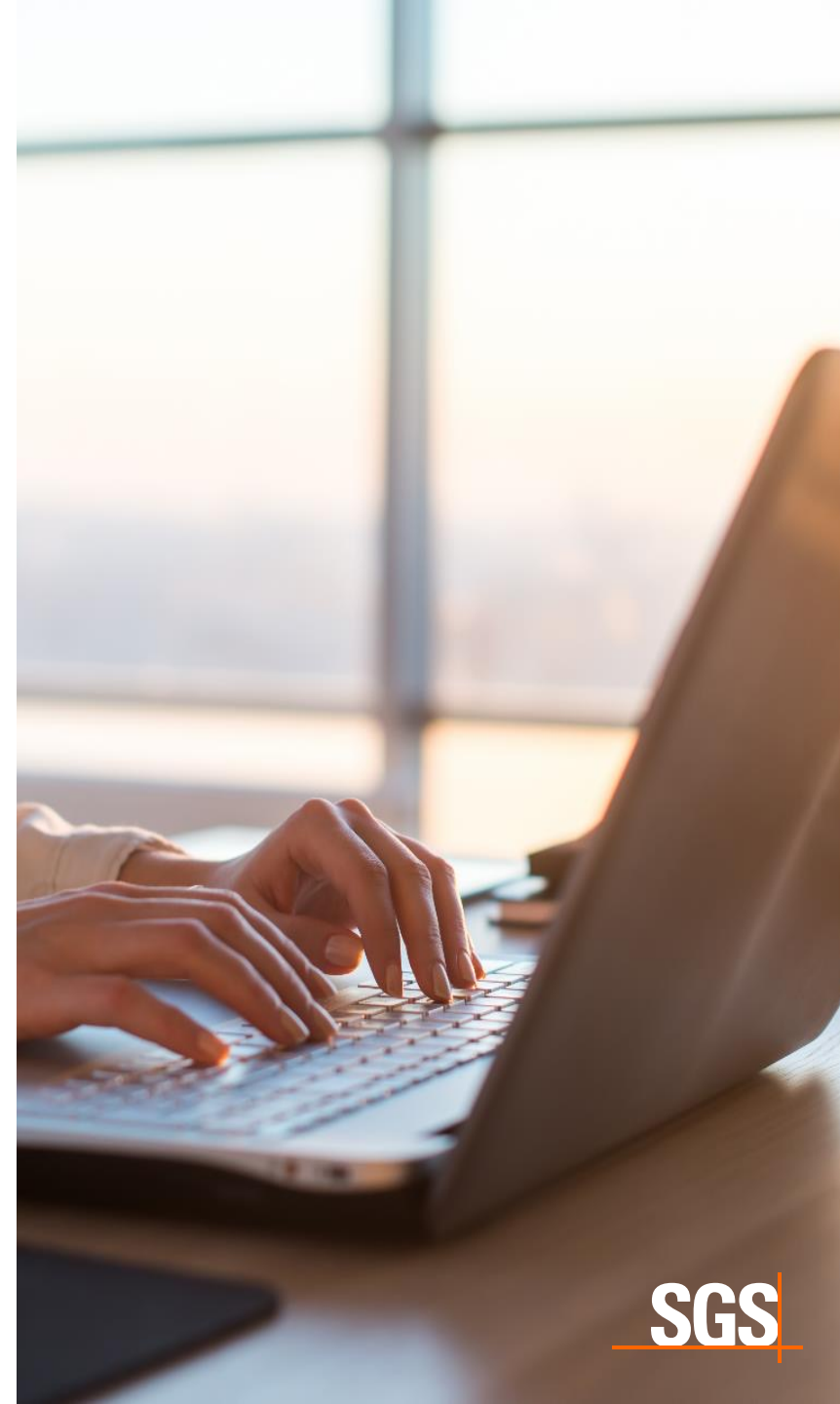


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Overview

- Patient Profile
- Software
- Approach
- Patient Profile v1.0
- Patient Profile v2.0
- Roadmap
- Conclusion



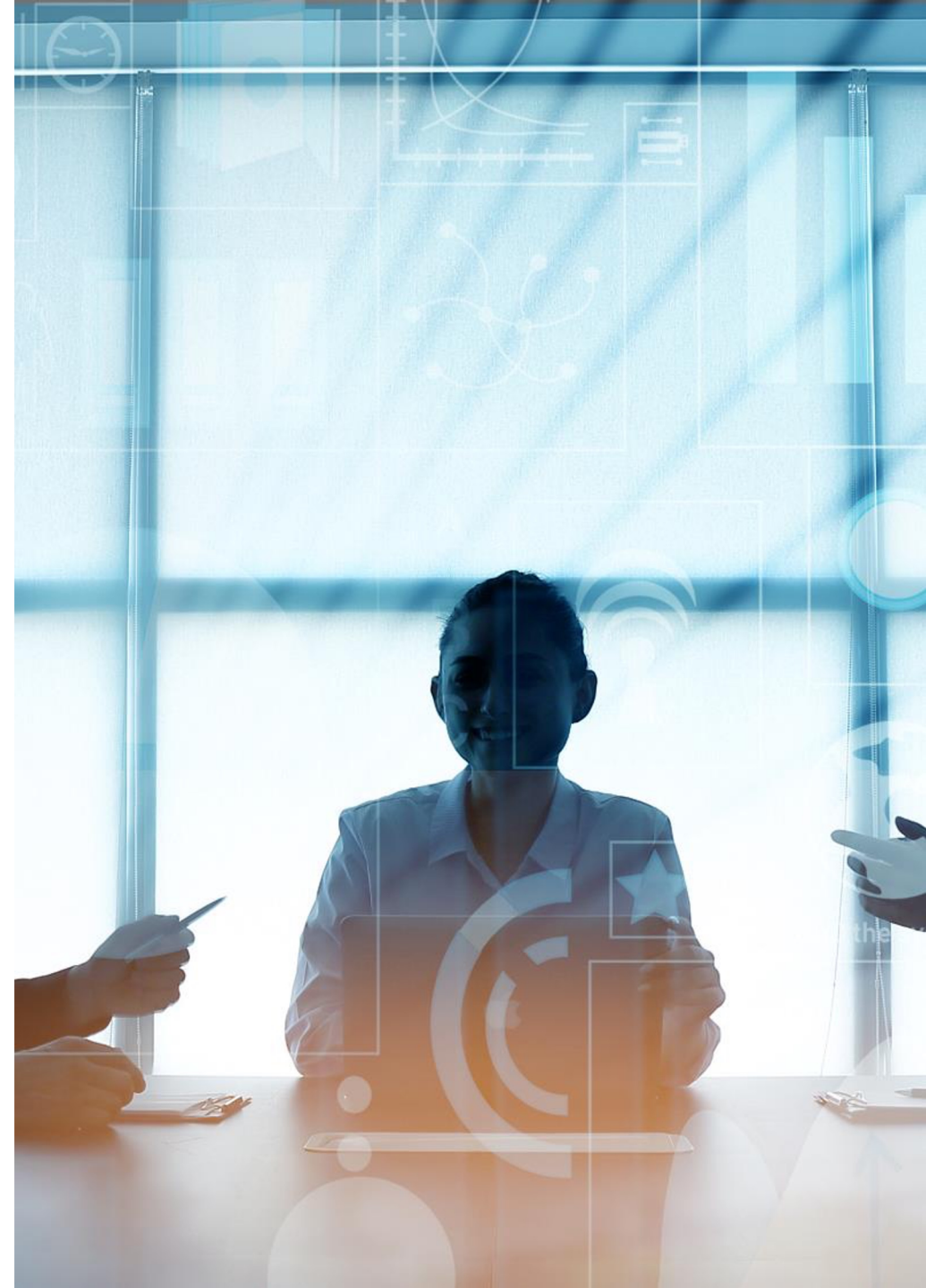
Patient Profile – What, Why & How

- 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



—
Let's play a data review game !

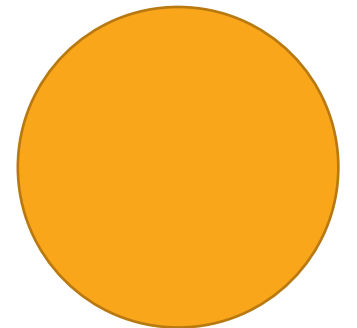
Can you spot the outlier in a laboratory dataset?

You have 5 seconds...

Spot the outlier

You have five seconds, can you find the outlier in the laboratory dataset?

Usubjid	Lbseq	Lbtest	Lbcat	Lborres	Lborresu	Lbdtc	VISIT
SGS-DRG01-001-001-0114	214	Aspartate-Aminotransferase	CHEMISTRY	12	U/L	06/11/2019	DAY1
SGS-DRG01-001-001-0114	214	Bilirubin	CHEMISTRY	60	umol/L	06/11/2019	DAY1
SGS-DRG01-001-001-0115	215	Aspartate-Aminotransferase	CHEMISTRY	17	U/L	19/11/2019	DAY15
SGS-DRG01-001-001-0115	215	Bilirubin	CHEMISTRY	70	umol/L	19/11/2019	DAY15
SGS-DRG01-001-001-0116	216	Aspartate-Aminotransferase	CHEMISTRY	15	U/L	26/11/2019	DAY22
SGS-DRG01-001-001-0116	216	Bilirubin	CHEMISTRY	65	umol/L	26/11/2019	DAY22
SGS-DRG01-001-001-0117	217	Aspartate-Aminotransferase	CHEMISTRY	13	U/L	02/12/2019	DAY29
SGS-DRG01-001-001-0117	217	Bilirubin	CHEMISTRY	63	umol/L	02/12/2019	DAY29
SGS-DRG01-001-001-0118	218	Aspartate-Aminotransferase	CHEMISTRY	14	U/L	10/12/2019	DAY36
SGS-DRG01-001-001-0118	218	Bilirubin	CHEMISTRY	71	umol/L	10/12/2019	DAY36
SGS-DRG01-001-001-0119	219	Aspartate-Aminotransferase	CHEMISTRY	12	U/L	18/12/2019	DAY43
SGS-DRG01-001-001-0119	219	Bilirubin	CHEMISTRY	67	umol/L	18/12/2019	DAY43
SGS-DRG01-001-001-0120	220	Aspartate-Aminotransferase	CHEMISTRY	11	U/L	03/01/2020	DAY57
SGS-DRG01-001-001-0120	220	Bilirubin	CHEMISTRY	66	umol/L	03/01/2020	DAY57
SGS-DRG01-001-001-0121	221	Aspartate-Aminotransferase	CHEMISTRY	58	U/L	28/01/2020	DAY65
SGS-DRG01-001-001-0121	221	Bilirubin	CHEMISTRY	61	umol/L	28/01/2020	DAY65
SGS-DRG01-001-001-0122	222	Aspartate-Aminotransferase	CHEMISTRY	12	U/L	29/01/2020	DAY66
SGS-DRG01-001-001-0122	222	Bilirubin	CHEMISTRY	72	umol/L	29/01/2020	DAY66
SGS-DRG01-001-001-0123	223	Aspartate-Aminotransferase	CHEMISTRY	17	U/L	13/02/2020	DAY80
SGS-DRG01-001-001-0123	223	Bilirubin	CHEMISTRY	68	umol/L	13/02/2020	DAY80
SGS-DRG01-001-001-0124	224	Aspartate-Aminotransferase	CHEMISTRY	15	U/L	15/04/2020	FOLLOW-UP1
SGS-DRG01-001-001-0124	224	Bilirubin	CHEMISTRY	67	umol/L	15/04/2020	FOLLOW-UP1
SGS-DRG01-001-001-0125	225	Aspartate-Aminotransferase	CHEMISTRY	17	U/L	16/07/2020	FOLLOW-UP2
SGS-DRG01-001-001-0125	225	Bilirubin	CHEMISTRY	69	umol/L	16/07/2020	FOLLOW-UP2
SGS-DRG01-001-001-0126	226	Aspartate-Aminotransferase	CHEMISTRY	15	U/L	09/08/2020	FOLLOW-UP3
SGS-DRG01-001-001-0126	226	Bilirubin	CHEMISTRY	61	umol/L	09/08/2020	FOLLOW-UP3
SGS-DRG01-001-001-0127	227	Aspartate-Aminotransferase	CHEMISTRY	12	U/L	22/09/2020	FOLLOW-UP4
SGS-DRG01-001-001-0127	227	Bilirubin	CHEMISTRY	62	umol/L	22/09/2020	FOLLOW-UP4



Spot the outlier

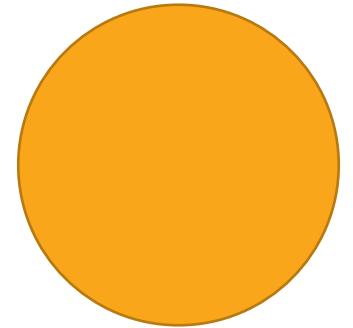
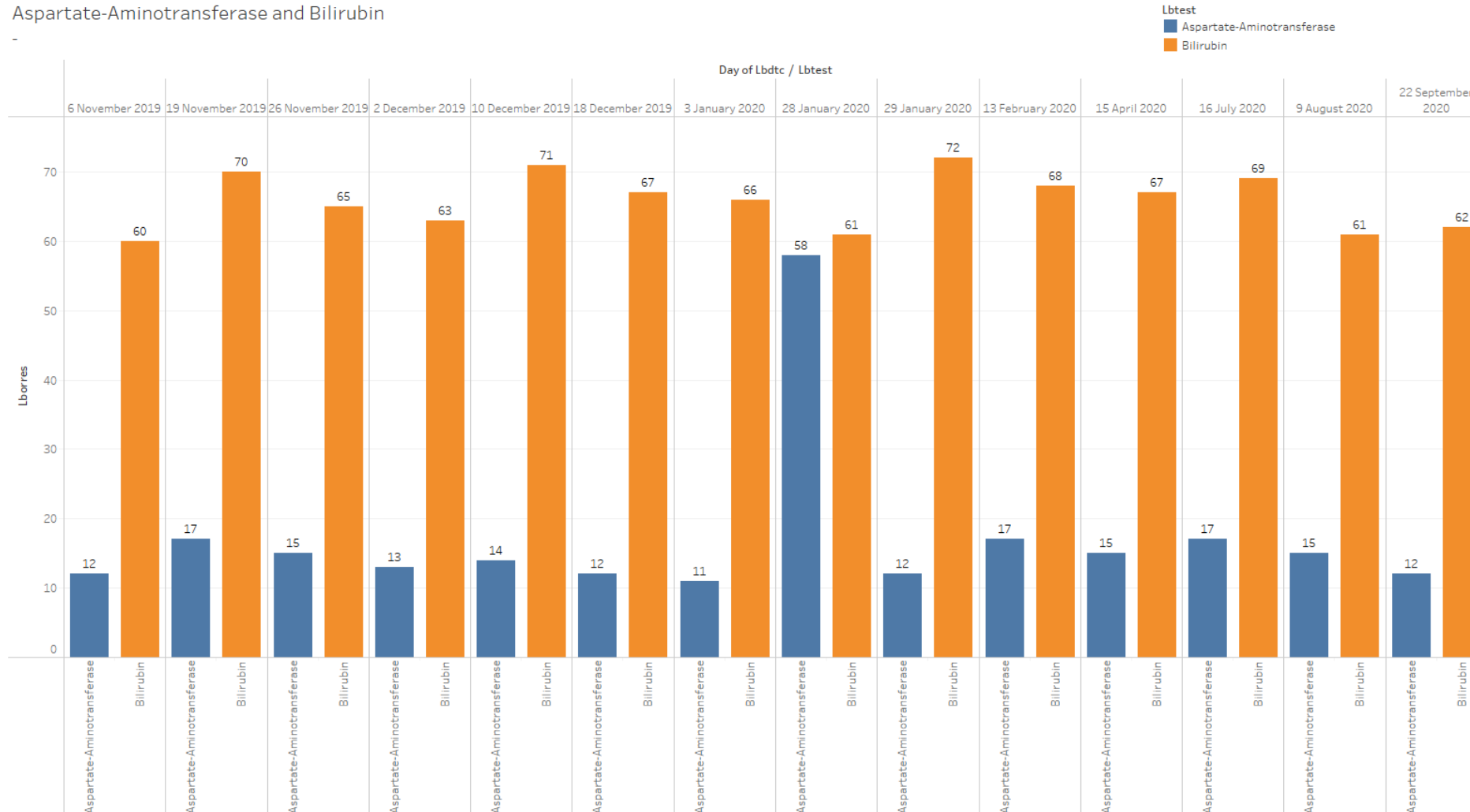
Did you spot the outlier?

Now with Data Visualisation...

Spot the outlier

And now?

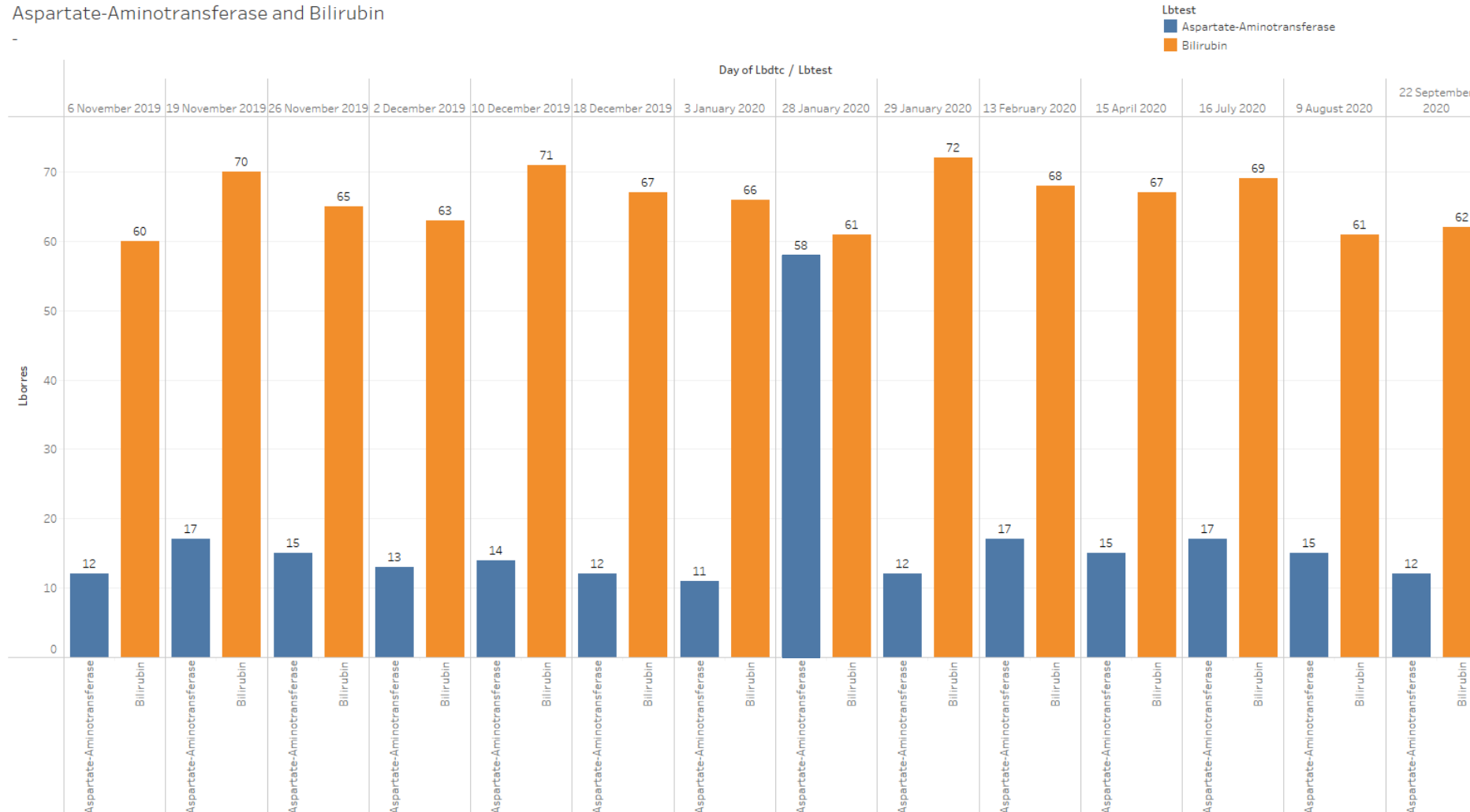
Aspartate-Aminotransferase and Bilirubin



Spot the outlier

And now?

Aspartate-Aminotransferase and Bilirubin



Patient Profile – The ideal situation ?

- All data in one view
- Always accessible & available from beginning of the trial
- “Real-time” data
- Extract & save the data and visuals
- Easy to understand and navigate by end users; drug safety physicians, medical monitors, project managers,...
- Easy to adapt, filter, select your preferred data
- Ready to use but still flexible for end user
- Programming by non-technical employees
- A fast set-up with limited programming efforts – short TAT





— Patient Profile – The Right Tool for the Job

- Patient Profiles in a data visualization environment
- **Tableau** – analytics software solution – cloud based
 - Spotfire, Microsoft Power BI, Qlik
 - R Shiny, Python, SAS
- **Rapid prototyping**: drag-and-drop interface
- **Interactivity**: filters, tooltips, and drill-down capabilities
- **Data Connections**: various data sources including databases, spreadsheets cloud-based platforms and SAS datasets
- **Supports** and easily **integrates** Python and R

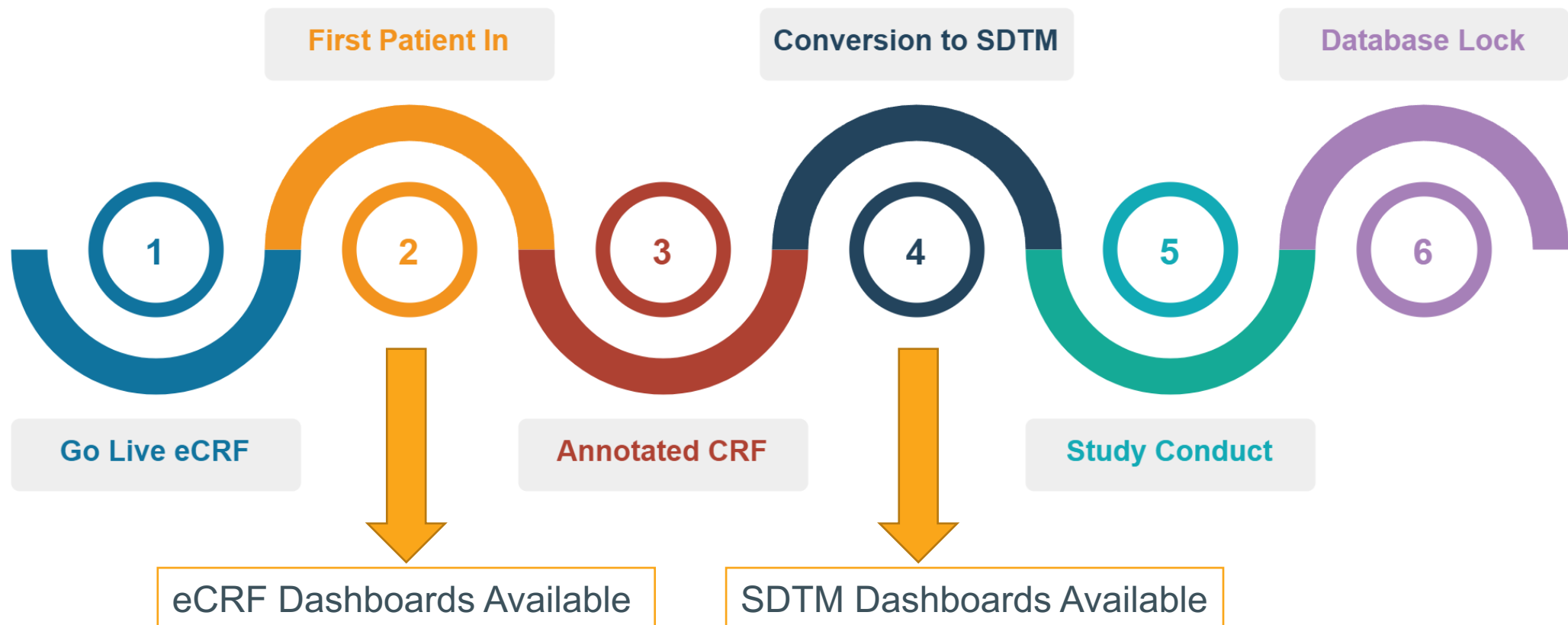


Patient Profile – SGS Approach

- Develop a standardized approach - Quick deployment
 - Foundation: integration and preparation of diverse data sources → SDTM
- **Software Development Life Cycle** approach & SOP
- **Validation:** DEV, TEST & PROD
 - Standard dashboard – no/limited re-validation
- **Security:** strictly separated environments per client = sites
 - Own URL
 - Own set of users and dashboards

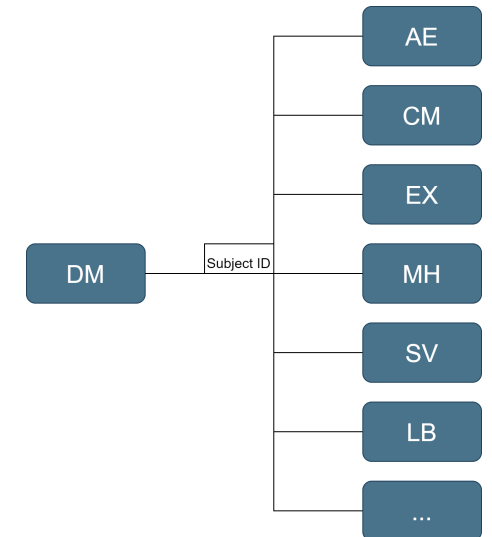


From Data to Dashboard - Study Flow

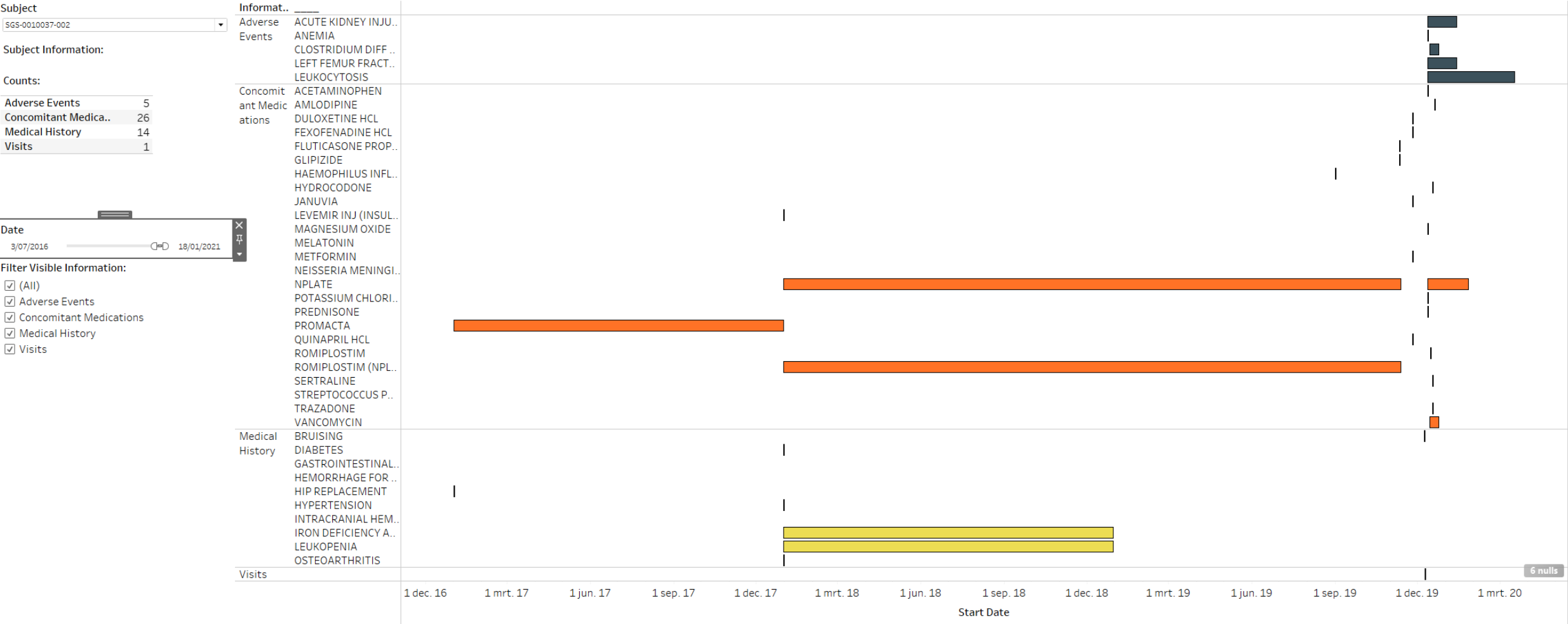


Patient Profile – v1.0

- First version of the patient profile: with the ideal situation in mind
- Served as a valuable tool for safety data review
- Limitations
 - Flexibility
 - Adaptability
 - Scalability
 - Limited user interactivity
 - Domain level interaction



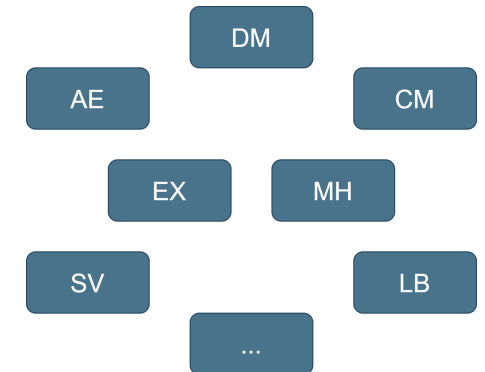
Patient Profile v1.0





— Patient Profile – v2.0

- Enhanced Flexibility
 - Modular architecture – scalability
 - Adding more domains including finding domains with different visualisation needs



- Interactive User Experience
 - Advance per domain interactive features
 - Domain specific customizable views
 - Dynamic filter options



Patient Profile – v2.0

- Improved Performance
 - Remove complexity of data merging
 - Deploying dashboards much quicker
- Improved drill down capabilities
 - Richer / detailed domain tooltip information
 - Targeted drilldown to other more detailed dashboards

Page 10 of 10

AEs	Cms
-----	-----

 $\leq$ = CM taken before trial start

Null

SGS-0010037-001

SEX	Race	AGE	Armcd
F	WHITE	47	Null

Adverse Events	18
Concomitant Medications	18
Study Dosings	24
Lab Results	97

IFC Date ▼

stop Date _____

Show Marker

Mark specific date _____

(All) ▼

(All) ▼

1

(All) ▼

ADVERSE EVENT ▼

ADVERSE EVENT

BLINDED ▼

(Multiple values) ▼

(All) ▼

(All) ▼

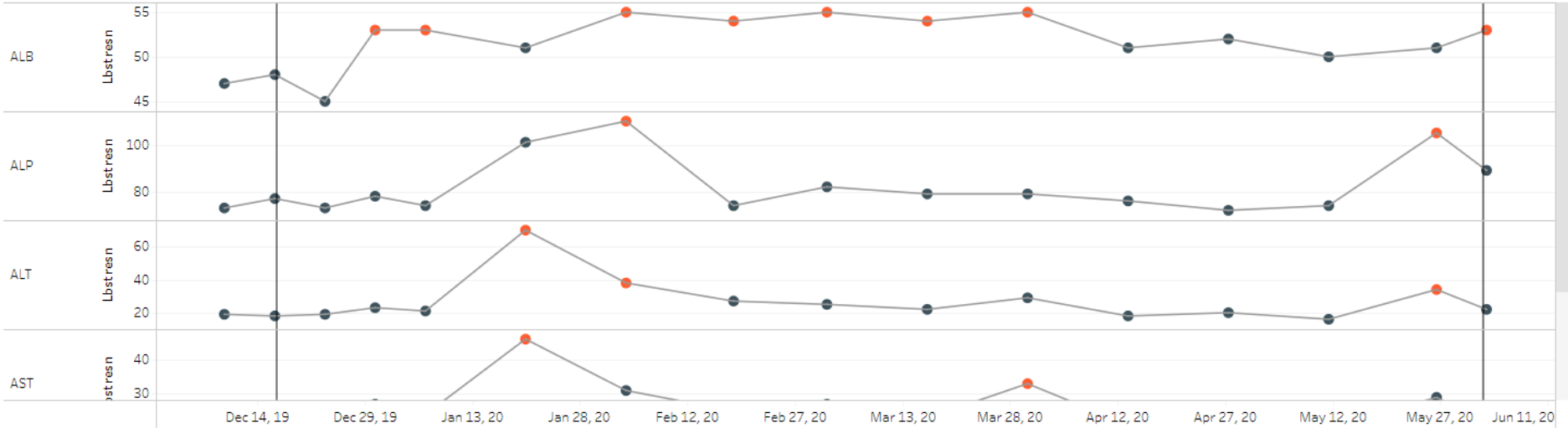
HIGH

Heavy menstrual bleed...

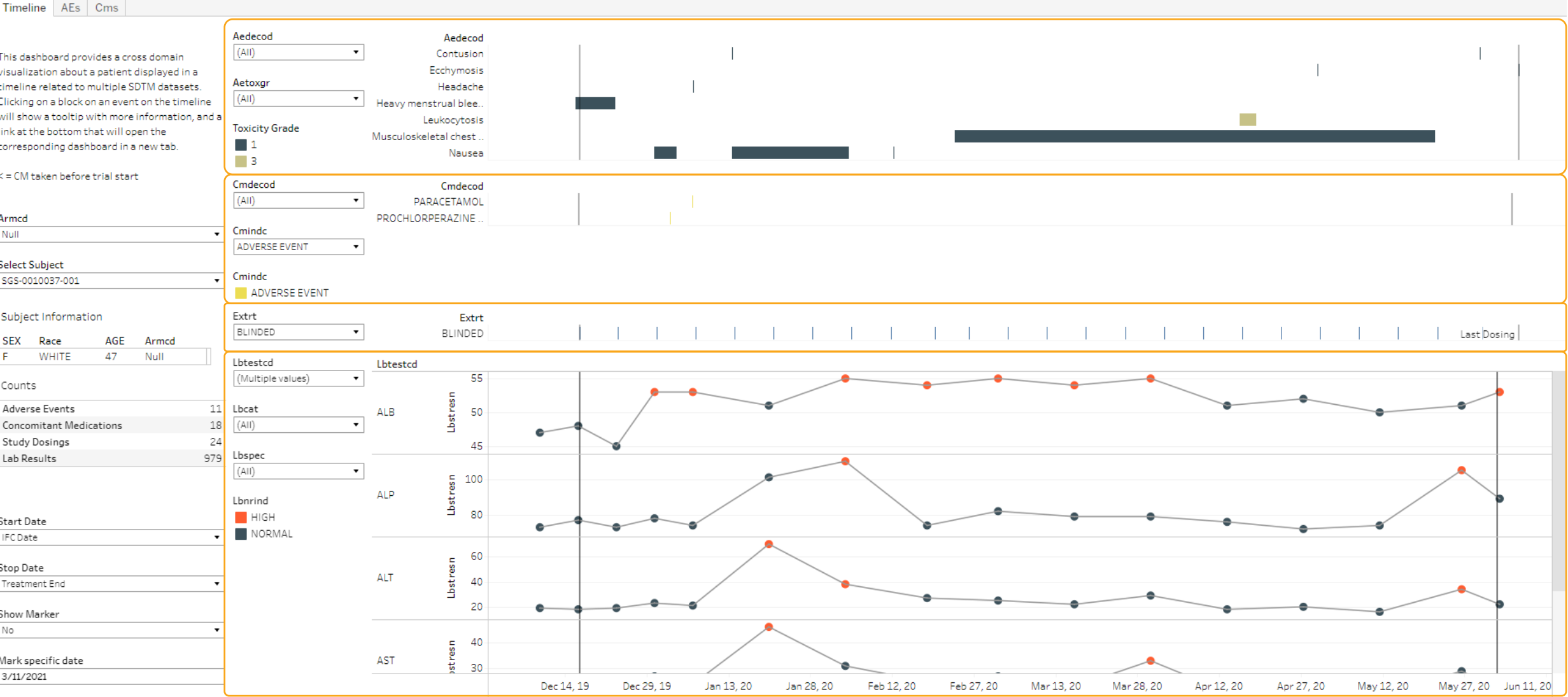
PARACETAMOL

BLINDED

100



Patient Profile – v2.0



AEs	Cms
-----	-----

 $\leq$ CM taken before trial start

Aetoxgr
(All)

Toxicity Grade

- 1
- 3

Cmdecod
(All)

Aedecod
Contusion

Headache

leukocytosis

Nausea

Cmdecod

Null

Select: SGS-0010037-001

SGS-00

Sub

SEX

F

Count

Adv

Concomitant Medications

Study Dosings

Lab Results

Start Date

IEC Date

Stop Date

Treatment End

Show Marker

No

Mark specific date

3/11/2021

Lbnrind

■ HIGH

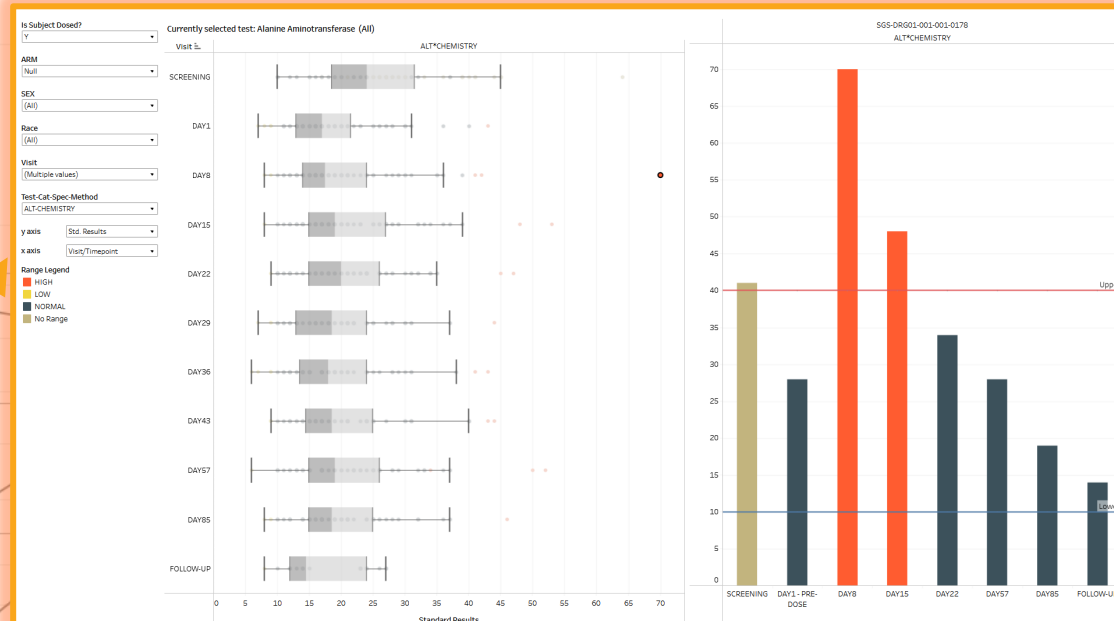
■ HIGH
■ NORMAL

ALP

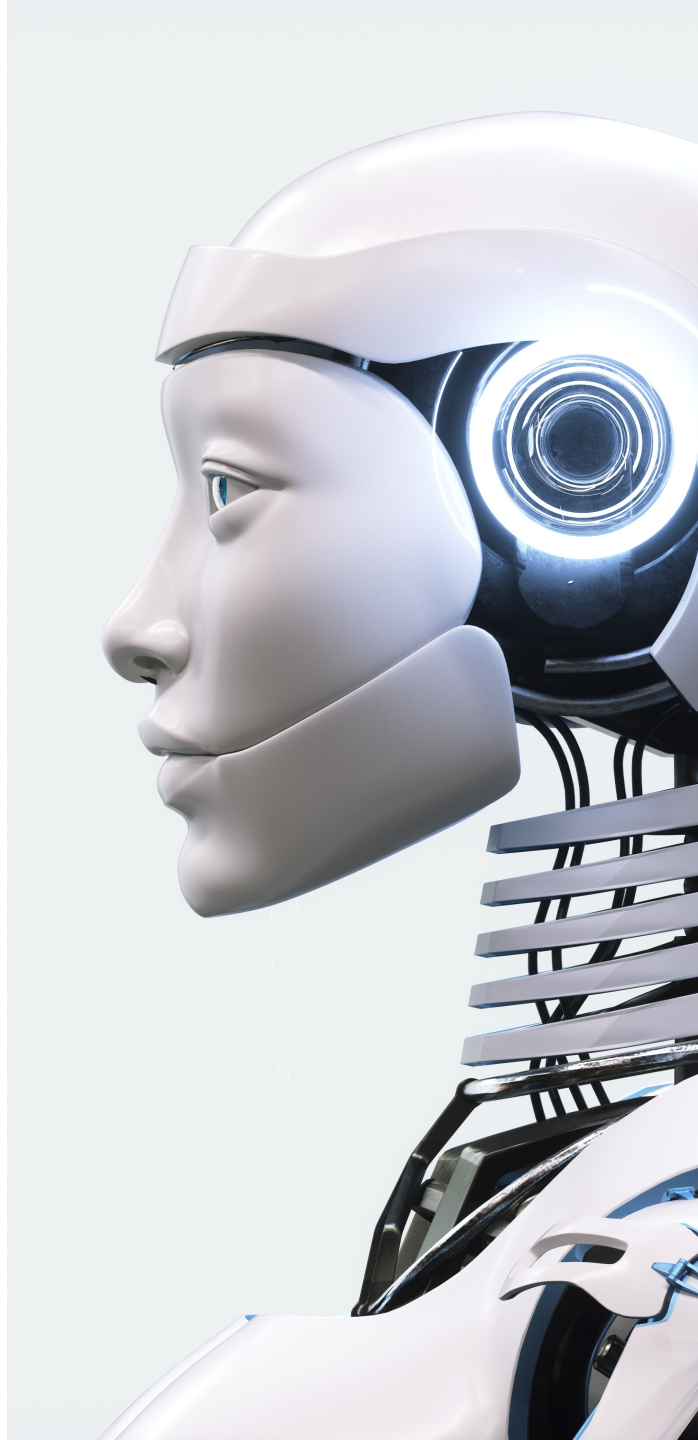
ALT

AST

Last Dosing



Roadmap



Integration with artificial intelligence and machine learning algorithms

Einstein Copilot for Tableau

Tableau Pulse

Conclusion

- Patient profile dashboard improved:
 - Displays a lot of data in a single accessible view and one timeline
 - User-interactivity:
 - Domain Filters and views
 - 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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