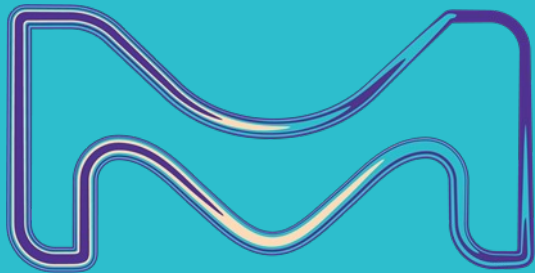


Interactive Data Visualization for Faster and Improved Data Insights

EU Connect PHUSE 2022 / Belfast

Markus Niederstrasser, Jörg Müller, Sihem Merah, Silke Hochstädter
Merck KGaA



MERCK

Agenda

1. Interactive Data visualizations vs. programmed TLF's
2. Why with TIBCO Spotfire?
3. A sneak peak at a Merck example on Clinical Safety Monitoring
4. Demonstrations
5. Data flow
6. Conclusions and Questions & Answers



01

Interactive Data visualizations vs. programmed TLF's

Interactive Data visualizations vs. Programmed TLF's



SELF-SERVICE

Interactive Data visualizations vs. Programmed TLF's



SELF-SERVICE



COLLABORATION

Interactive Data visualizations vs. Programmed TLF's



SELF-SERVICE



COLLABORATION



DRILL-DOWN

Interactive Data visualizations vs. Programmed TLF's



SELF-SERVICE



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DRILL-DOWN



EFFICIENCY



02

Why with TIBCO Spotfire?

Why TIBCO Spotfire?

Handles **large datasets** (10 mil+) and provides wide import and export functionalities

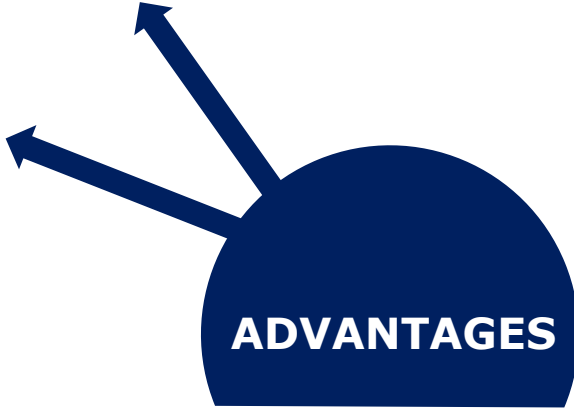


ADVANTAGES

Why TIBCO Spotfire?

The perfect detective kit with **drilldown** and **interactive visuals** to detect **outliers, trends** and **patterns**.

Handles **large datasets** (10 mil+) and provides wide import and export functionalities



ADVANTAGES

Why TIBCO Spotfire?

Modularization approach
for easier and faster
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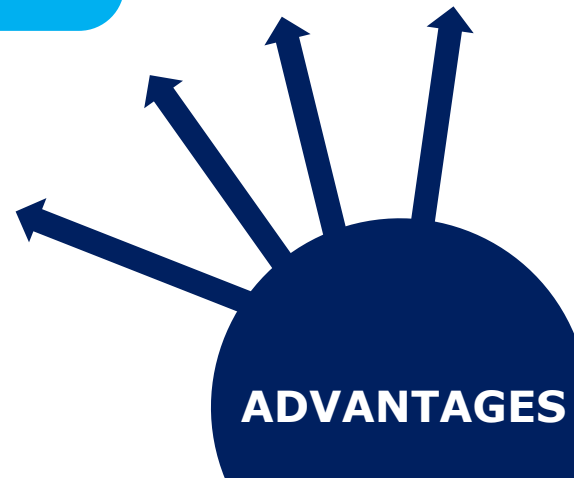
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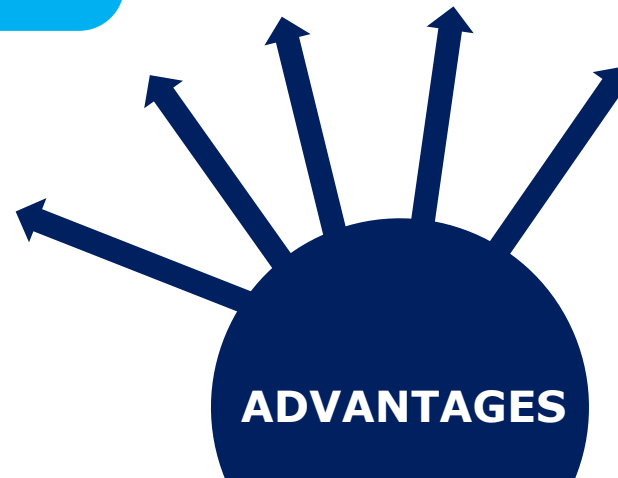
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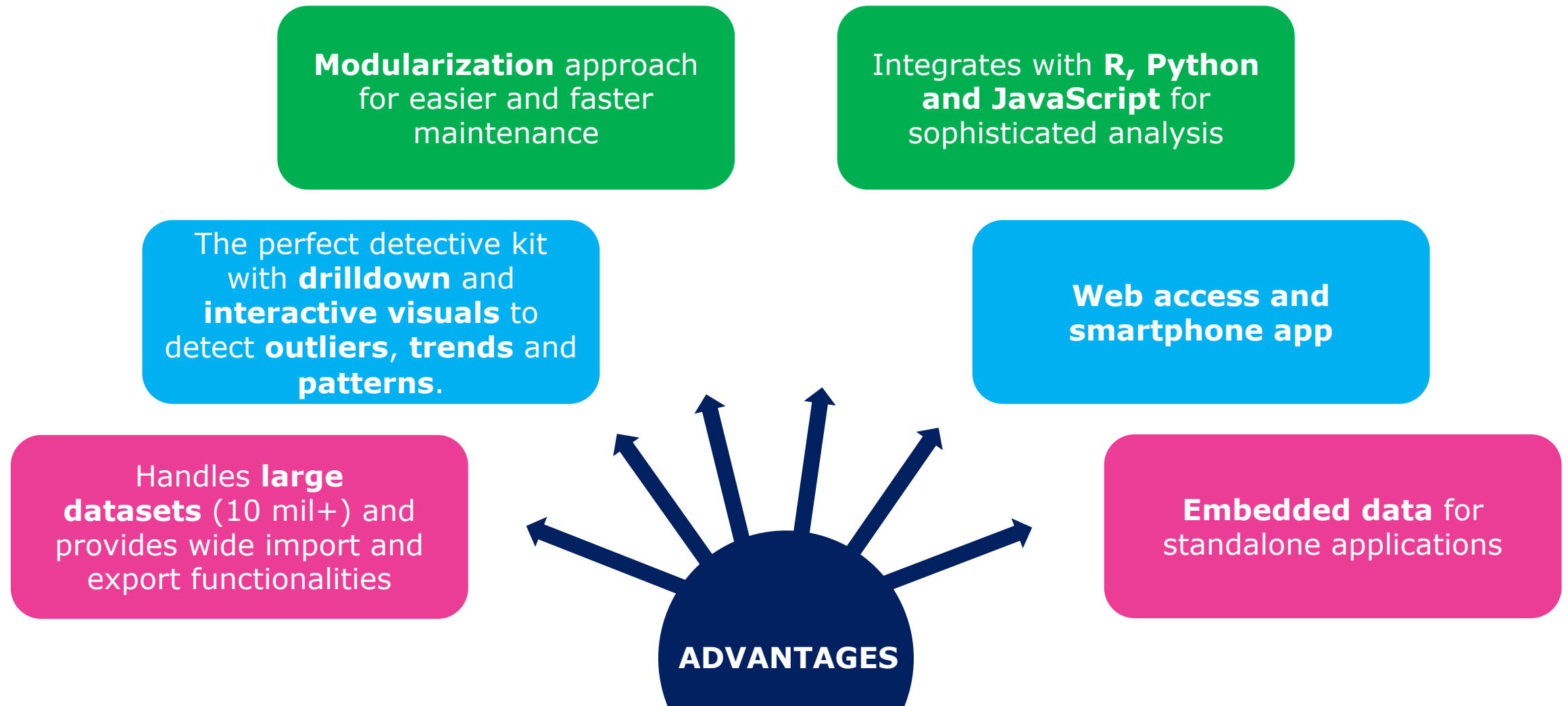
The perfect detective kit
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interactive visuals to
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patterns.

**Web access and
smartphone app**

Handles **large
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provides wide import and
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Why TIBCO Spotfire?





03

A sneak peak at a Merck example
on Clinical Safety Monitoring

A sneak peak at a real Merck example on Clinical Safety Monitoring

OVERVIEW OF ALL COMPOUND DATA

Supports **summary and perioding safety data review** within a compounds (pooling) and allows to drill down to single studies.

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Uses safety-relevant data from **the integrated clinical safety database**

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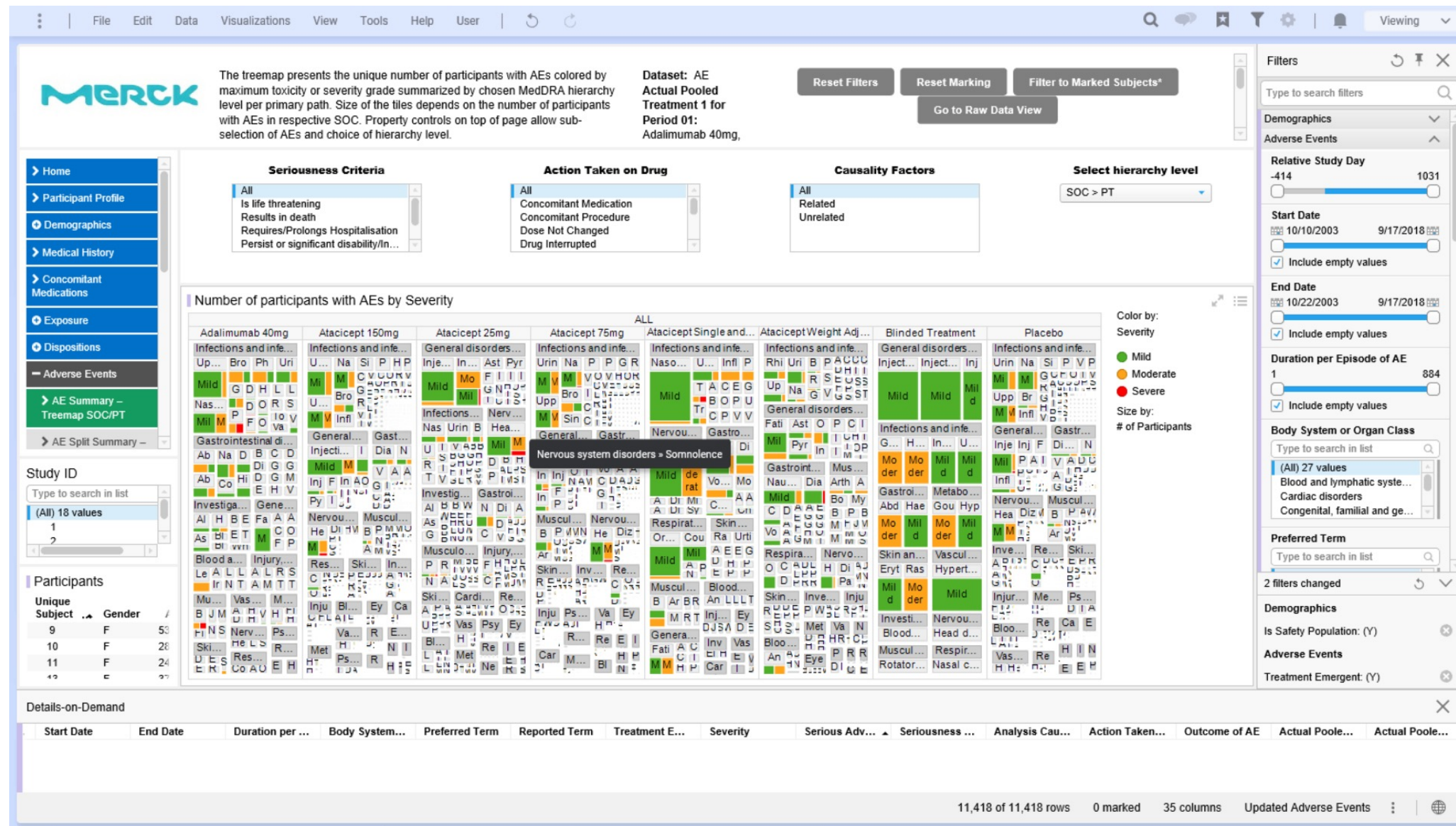
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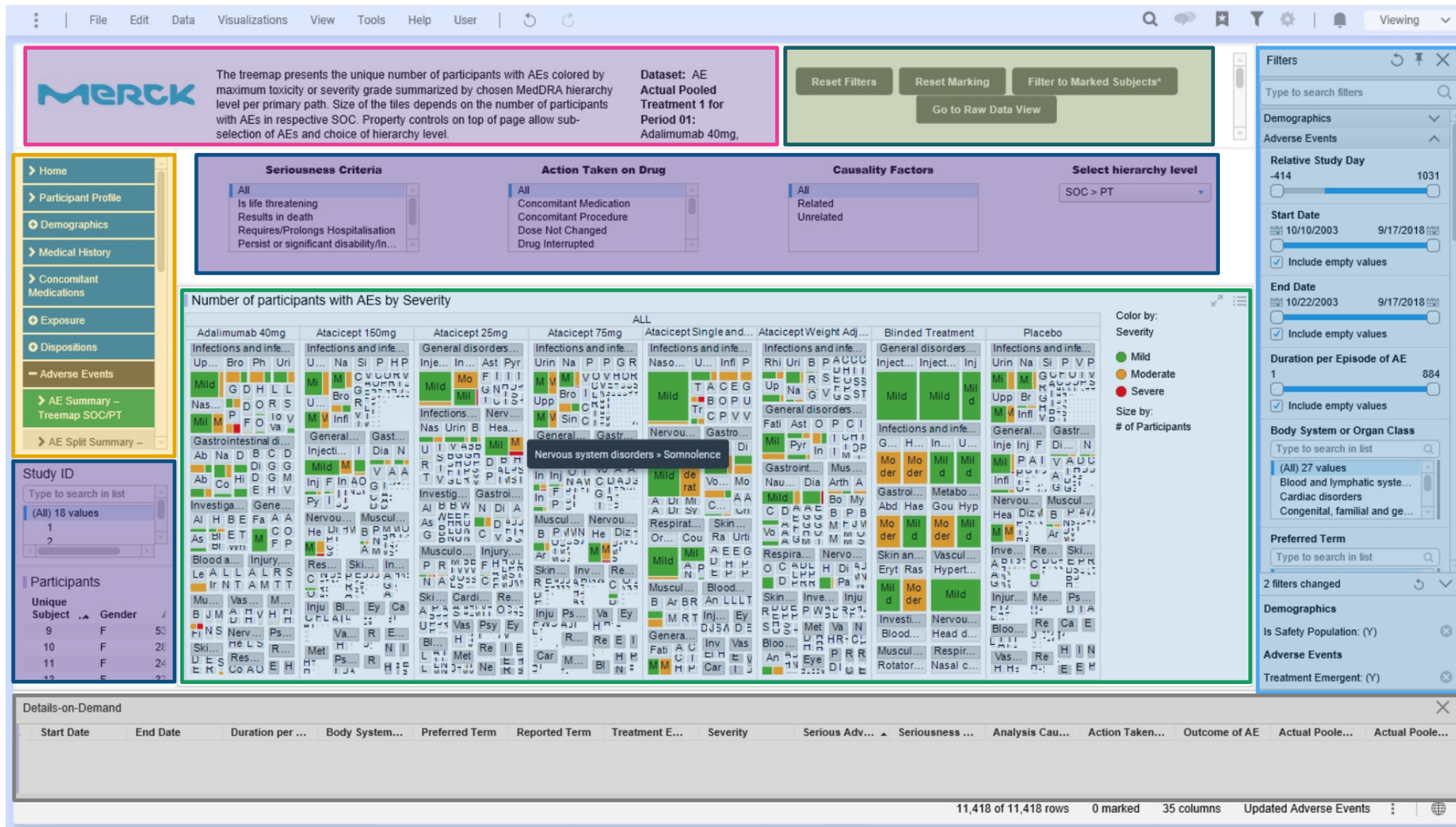
27 LIVE DASHBOARDS

- ✓ 27 pre-defined dashboards
- ✓ a listing generator
- ✓ a patient profile generator
- ✓ and a PDF export tool

Sneak peak: General structure of a visualization page



Sneak peak : General structure of a visualization page



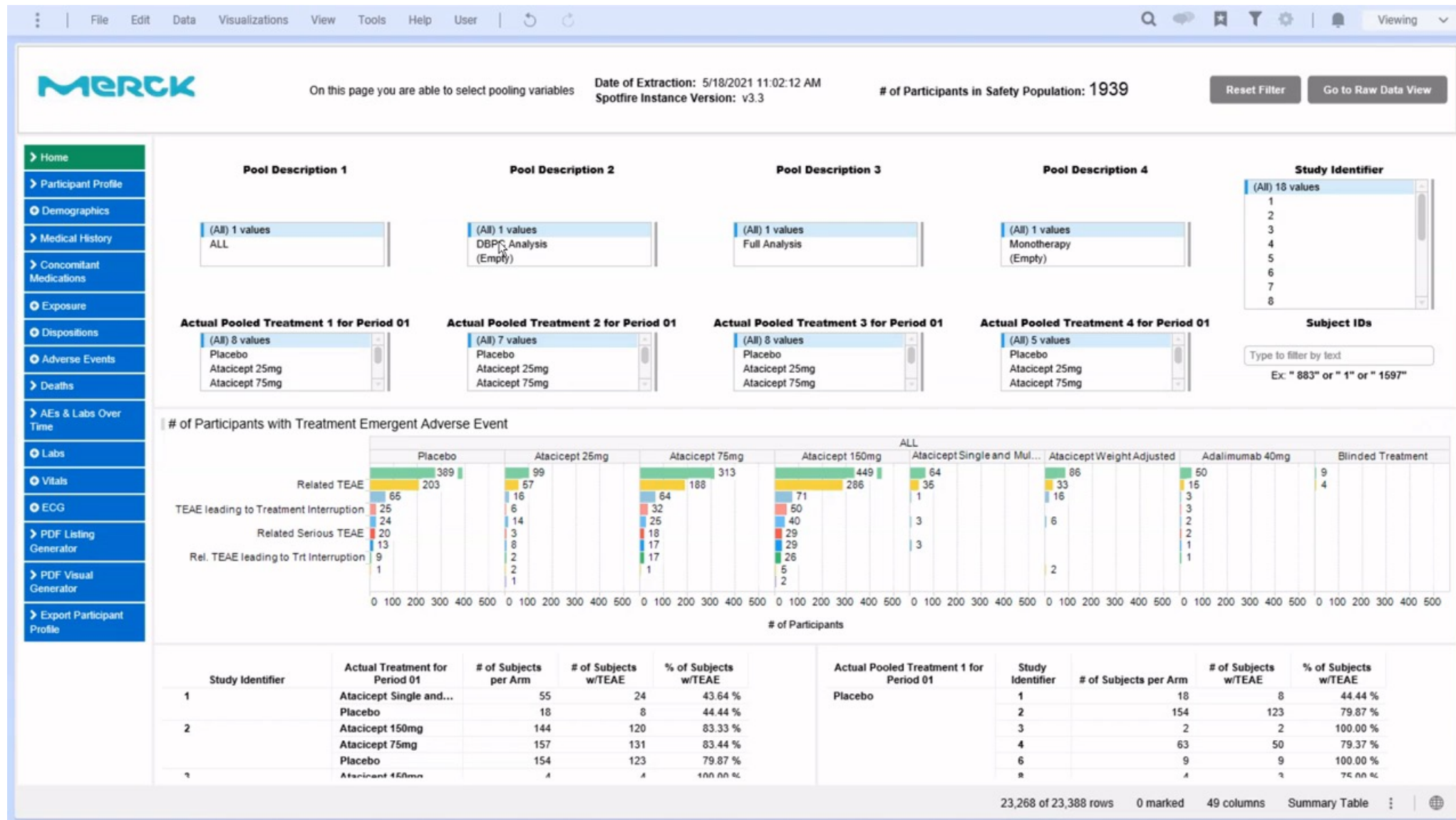


04

Demonstrations

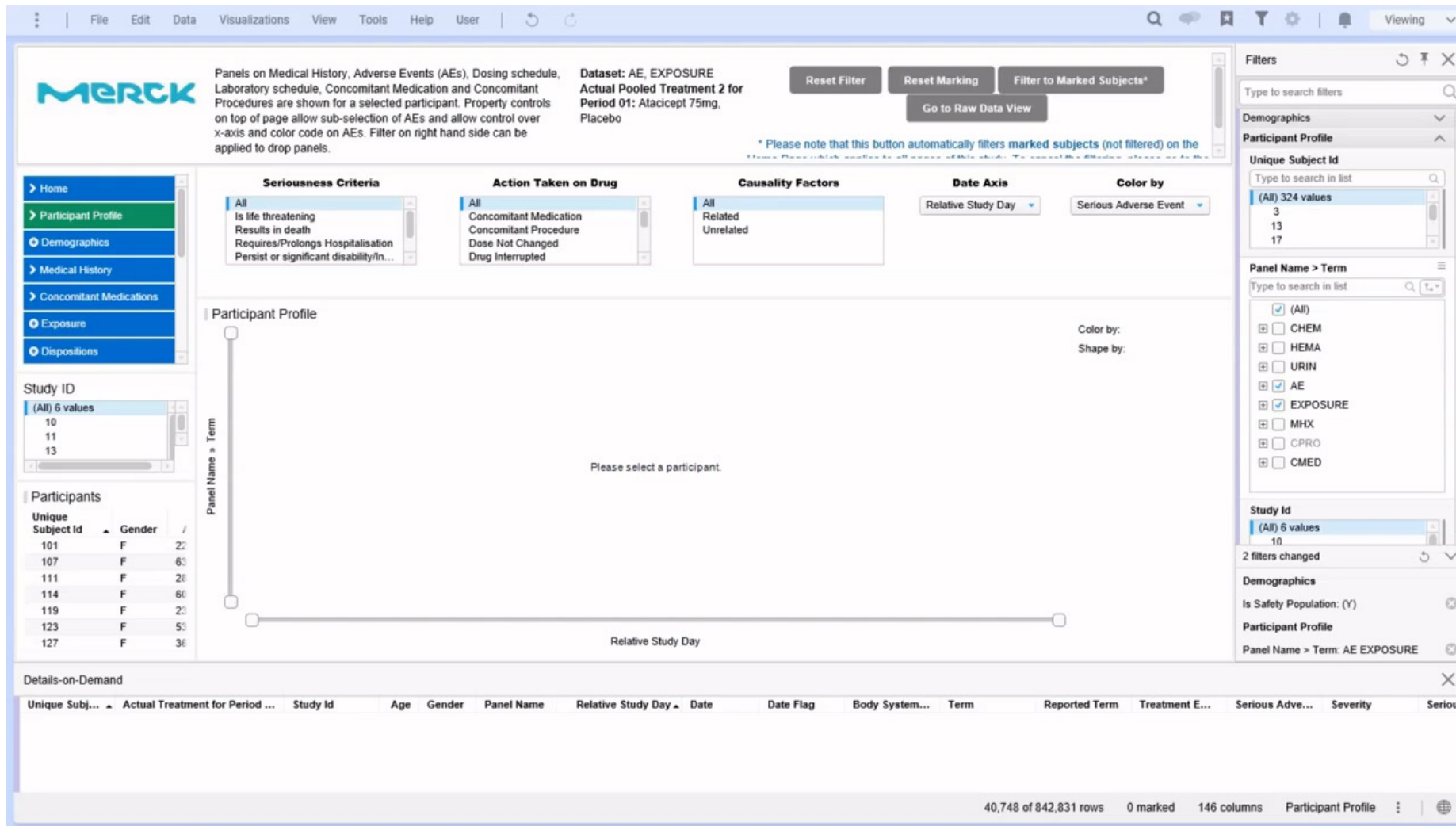
using test data

Sneak peak : Start page & pooling selection



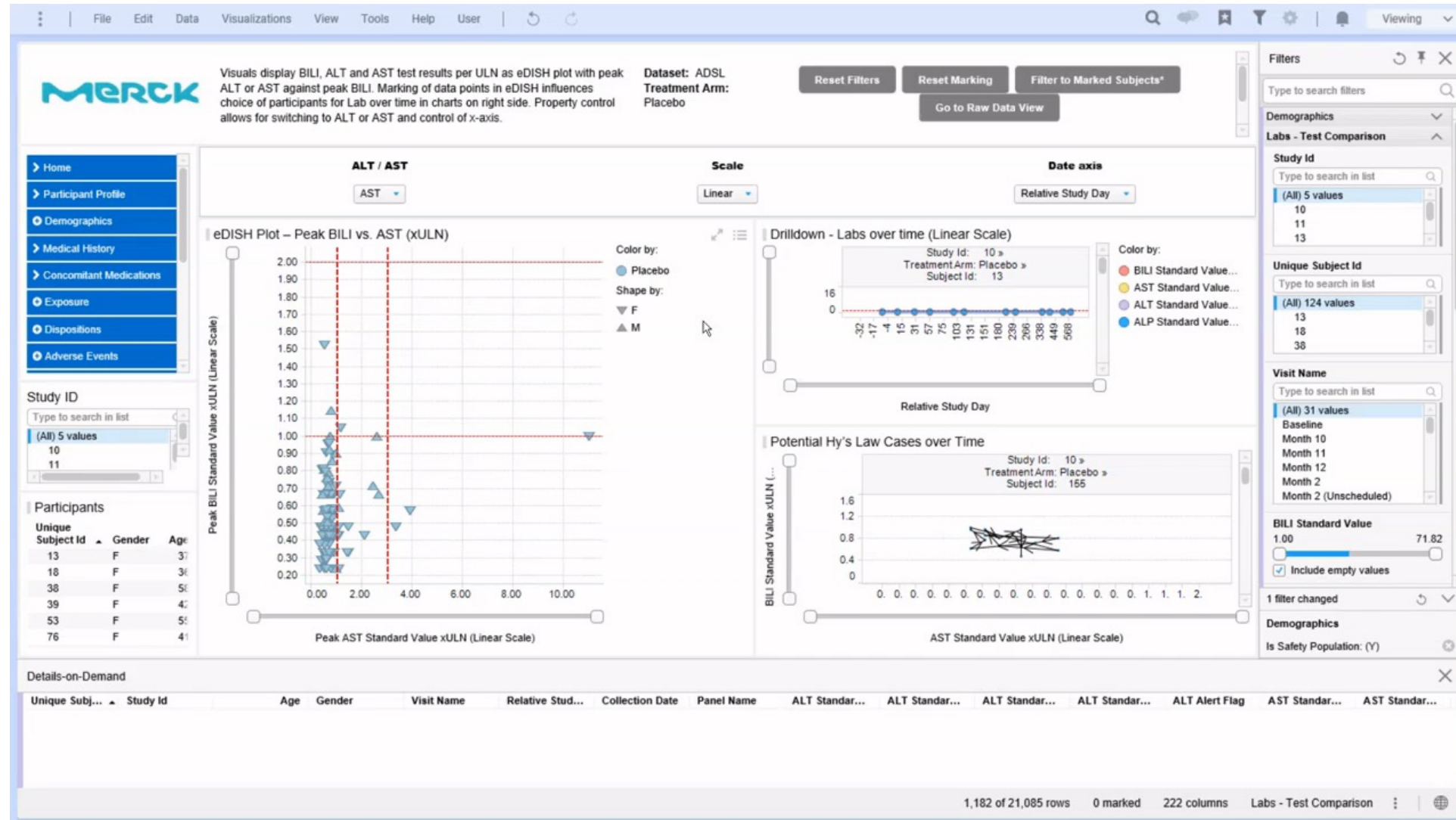
Demo: Participant Profile

ANONYMIZED DATA



Demo: Laboratory - eDISH

ANONYMIZED DATA



Demo: Interactive AE table in combination with R

Merck AE Summary Dashboard

Dataset: AE
Actual Pooled Treatment 2 for Period 01: Atacicept 75mg, Placebo

Reset Filters Reset Marking Filter to Marked Subjects* Go to Raw Data View

* Please note that this button automatically filters marked subjects (not filtered) on the Home Page which applies to all pages of this study. To cancel the filtering, please go to the Home Page.

After filtering, click here to recalculate the AE Summary Dashboard

AE Summary Dashboard

Condition	Atacicept 150mg			Atacicept 25mg			Atacicept 75mg			DBPC Analysis			Atacicept Weight Adju...			Blind	
	n	N	%	n	N	%	n	N	%	n	N	%	n	N	%	n	
Any TEAE	449	572	78.50	98	130	75.38	313	384	81.51	64	111	57.66	39	112	34.82	9	
Any related TEAE	286	572	50.00	56	130	43.08	188	384	48.96	35	111	31.53	17	112	15.18	4	
Any related TEAE with max severity Moderate or Severe	137	572	23.95	24	130	18.46	88	384	22.92	12	111	10.81	7	112	6.25	1	
Any serious TEAE	71	572	12.41	15	130	11.54	64	384	16.67	1	111	0.90	1	112	0.89	-	
Any TEAE with max severity Severe	65	572	11.36	10	130	7.69	53	384	13.80	5	111	4.50	-	-	-	-	
Any related serious TEAE	29	572	5.07	3	130	2.31	18	384	4.69	-	-	-	-	-	-	-	
Any related TEAE with max severity Severe	29	572	5.07	2	130	1.54	17	384	4.43	2	111	1.80	-	-	-	-	
Any TEAE leading to death	5	572	0.87	1	130	0.77	1	384	0.26	-	-	-	-	-	-	-	
Any related TEAE leading to death	2	572	0.35	1	130	0.77	-	-	-	-	-	-	-	-	-	-	

AE Summary Dashboard by PT

Mark values in AE Summary Dashboard to see PT distribution here.

AE Details

Select cells from the AE Summary Dashboard.

Participants

Unique Subject	Gender
3	F
13	F
17	F
18	F
19	F
25	F
..	-

Filters

Type to search filters

Demographics

Actual Treatment for Period 01

Type to search in list

Is Safety Population

☐ N ☒ Y

Country

Type to search in list

Unique Subject Id

Age

16 83

☐ ☒ Include empty values

Gender

☒ F ☒ M

2 filters changed

Demographics

Is Safety Population: (Y)

Adverse Events

Treatment Emergent: (Y)

18,981 of 18,981 rows 0 marked 27 columns AE Summary Dashboard

Demo: Output generators & Patient profile generator

The screenshot displays the Merck clinical data visualization tool interface. The top navigation bar includes links for File, Edit, Data, Visualizations, View, Tools, Help, and User. The main content area is titled 'INFORMATION PAGE' and contains the following sections:

- Header:** This page allows you to export a PDF File made of:
 - The Information Visual
 - And the visuals on the selected page.
 Warning: Your PDF can be made of several hundreds or thousands of pages if you do not apply any filtering.
- Left Sidebar:** A list of navigation options including Home, Participant Profile, Demographics, Medical History, Concomitant Medications, Exposure, Dispositions, Adverse Events, Deaths, AEs & Labs Over Time, Labs, Vitals, ECG, PDF Listing Generator, PDF Visual Generator, and Export Participant Profile.
- 1. Refresh INFORMATION PAGE from page:** A dropdown menu currently set to '(None)' with a refresh icon.
- 2. Export to PDF the corresponding visual:** A list of available visualizations for export, including Participant Profile, Medical History, Concomitant Medications, Exposure, AE Summary - Treemap, AE Split Summary, AE Summary - Bar, AE Summary by Grade, AEs Over Time, AE Summary - Time to First Onset, AE Summary Dashboard, Deaths, AEs & Labs Over Time, Lab DUJ, Lab Summary (Baseline v. worst), Lab Summary - Change from Baseline, Lab per Participant, Lab Monitoring, HystLaw Dashboard, Vitals Summary, Vitals Over Time, Vitals Summary Dashboard, ECG Summary and Details, and ECG Over Time.
- Modified filters:**
 - Filtering done on page: Home
 - Summary Table: No Filtering
 - Filtering done on page: Concomitant Medications
 - Demographics: Is Safety Population: (Y)
- Marked Participants IDs in Participant Table on page Concomitant Medications:** None

The bottom status bar shows '133 of 12,229 rows', '0 marked', '297 columns', and 'Adverse Events'. The URL at the bottom is <https://spotfireclinical-val.merckgroup.com/spotfire/wp/render/ySytCQ8vZ7J-4R8Klg/#>.



05

Data flow

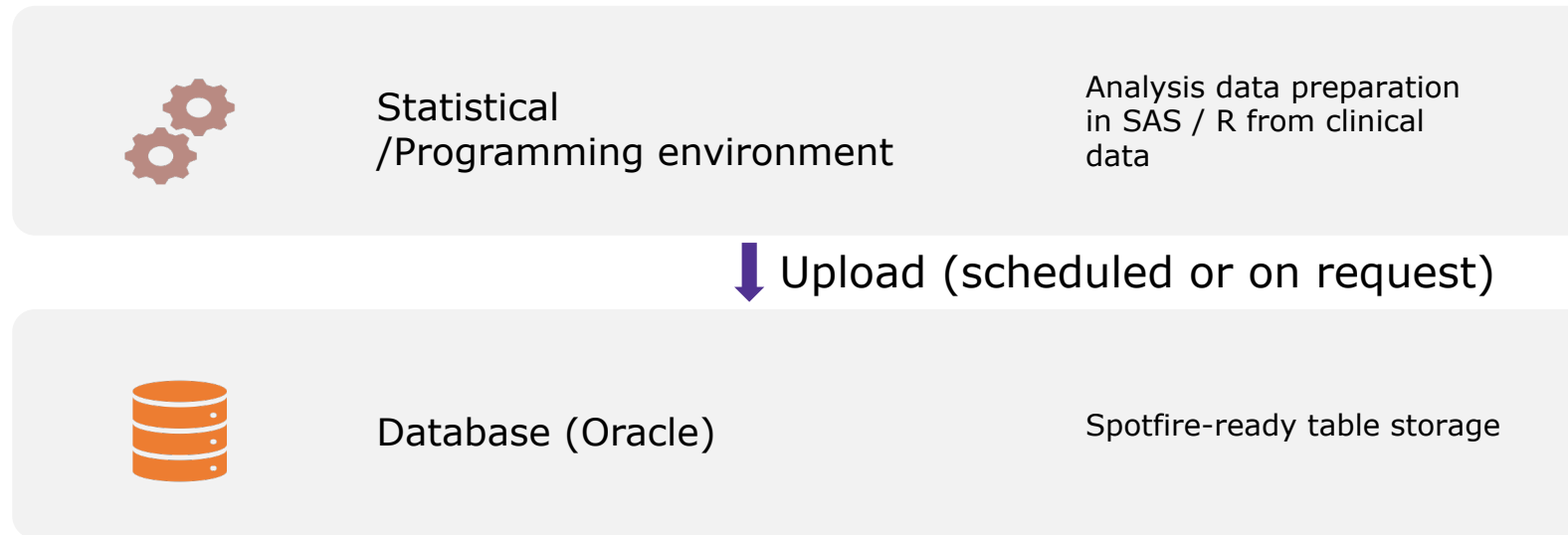
Data flow



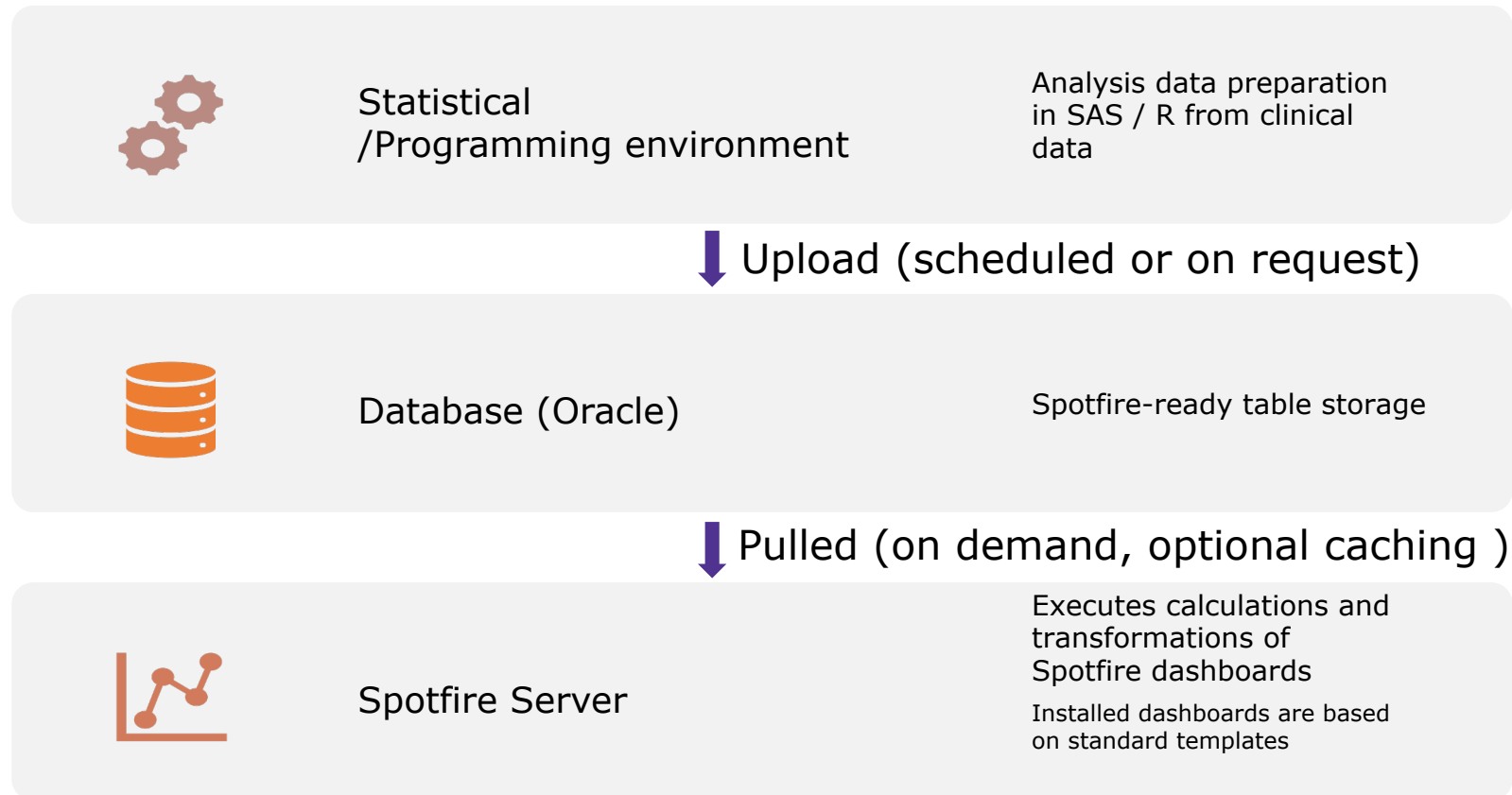
Statistical
/Programming environment

Analysis data preparation
in SAS / R from clinical
data

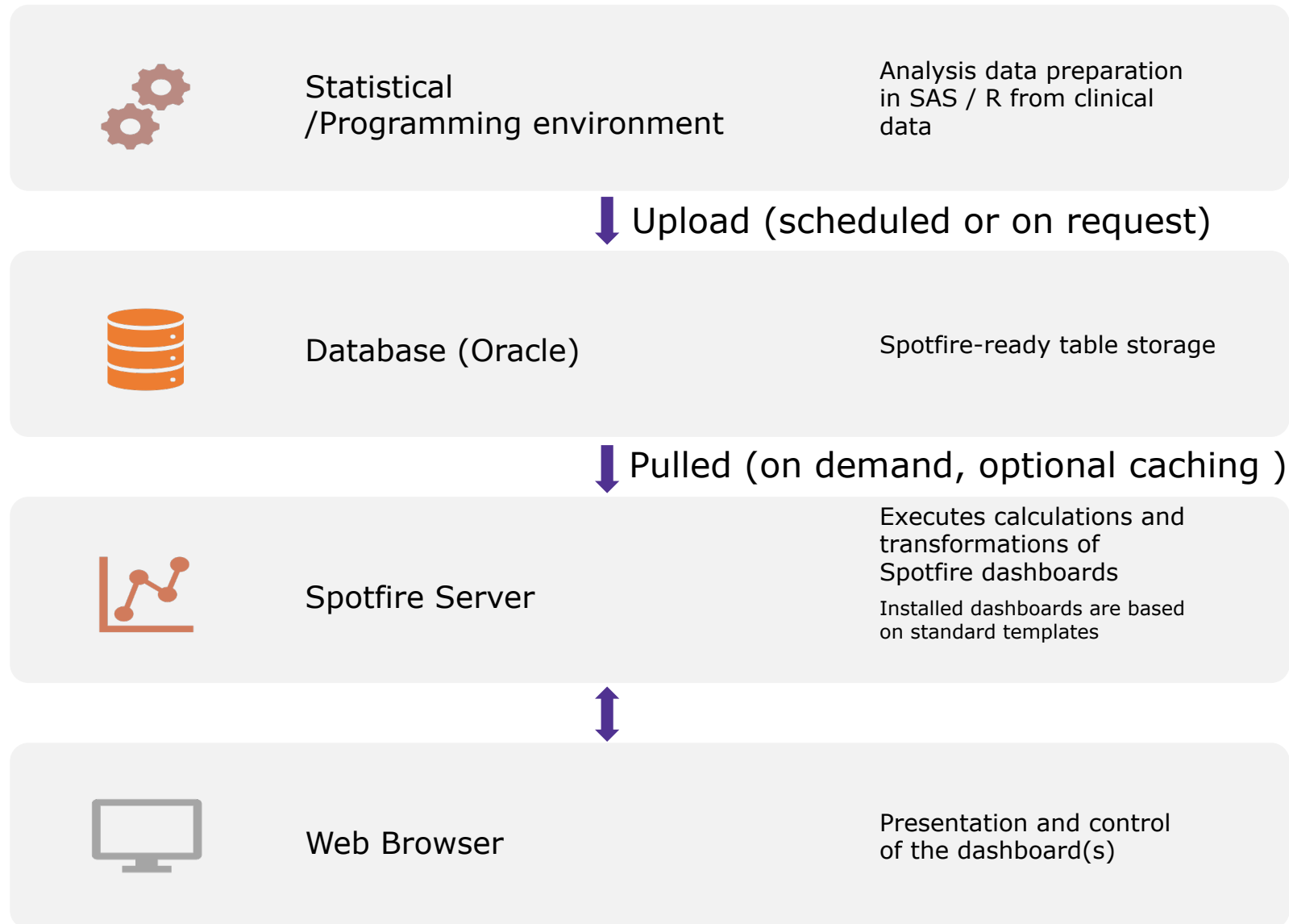
Data flow



Data flow



Data flow





06

Conclusions & Q&A

Conclusion



SHIFT FROM STATIC TLFS TO SELF-SERVICE AND INTERACTIVE VISUALISATIONS

Conclusion



SHIFT FROM STATIC TLFS TO SELF-SERVICE AND INTERACTIVE VISUALISATIONS



FLEXIBILITY AND REUSABILITY OF EXISTING ASSETS THANKS TO INTEGRATION TO R AND SAS

Conclusion



SHIFT FROM STATIC TLFS TO SELF-SERVICE AND INTERACTIVE VISUALISATIONS



FLEXIBILITY AND REUSABILITY OF EXISTING ASSETS THANKS TO INTEGRATION TO R AND SAS



LARGE DATASETS, FAST PROCESSING AND REASONABLE RESPONSE TIME FOR BETTER USER ACCEPTANCE

Conclusion



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NEW FEATURES IMPLEMENTED QUICKLY AND EFFICIENTLY

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NEW FEATURES IMPLEMENTED QUICKLY AND EFFICIENTLY



CHANGE IN WAY OF WORKING FOR END USERS AND PROGRAMMERS AND CLOSER COLLABORATION ACROSS ALL DEPARTMENTS

Questions and Answers



For further question please reach out to Markus.Niederstrasser@merckgroup.com