

Modernizing and Transforming the Delivery of Analysis and Results from Clinical Trials through an Interactive and Dynamic Data Visualization Application

Dan Schramek, Director, Clinical Programming Disease Area Head, GSK
daniel.j.Schramek@gsk.com

Neharika Sharma, Programming Leader, GSK
neharika.x.sharma@gsk.com





1. Why? The need for data visualization (DV)
2. GSK's RAPIDO DV vision and implementation
3. RAPIDO DV journey from concept to reality

...INCLUDING SPECIAL CONSIDERATIONS
ORGANIZATIONS NEED TO ADDRESS

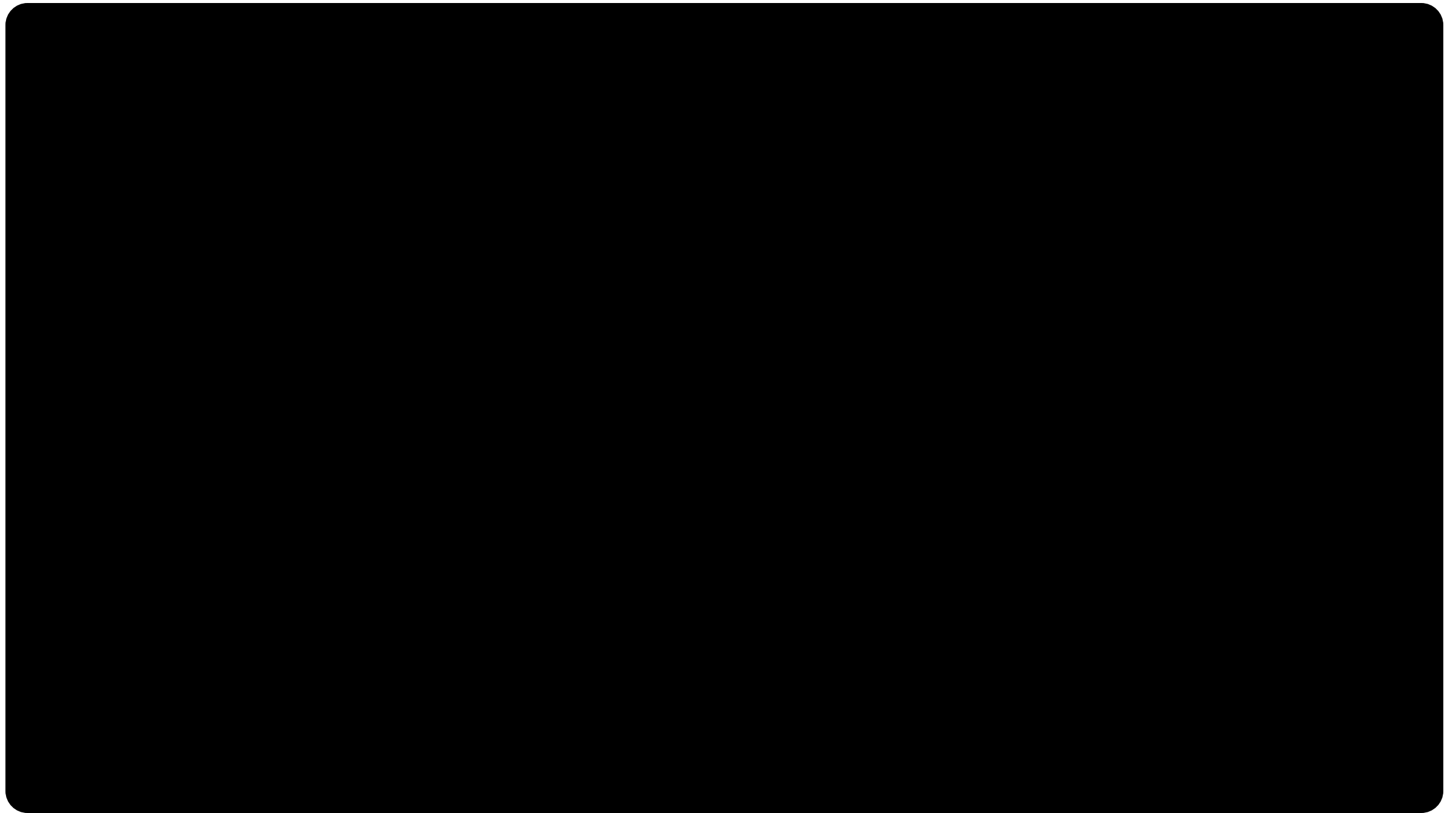


Disclaimer: All data and visualizations in this presentation were created with dummy/fabricated database. There are no data or visualizations from any real GSK products.

Introducing RAPIDO Data Viewer



*Reporting and Analysis Plan Improving Design
and Delivery of Outputs*



Why? The Need for DV



Accelerated decision making precedence and expectations

- self-service dynamic results exploration for subject matter experts
- reduce display production and qc time

Increasing complexity of trials, diseases under study and analyses

- need for enhanced ability to spot trends and differences using technological solutions
- empowering the study team to gain a greater understanding of the study results

Opportunity for efficiencies and cost savings

- eliminate all subject-level listings*
- remove sub-group analyses and nice-to-have displays

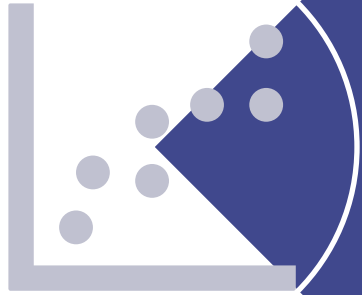
AND...Technology (finally!) and data standards are enablers

*Except for a small number of listings required by regulatory agencies in static form

*Why is there a
need for data
visualization ???*

Data
Visualization ↔
Technology ↔
Efficiency

The RAPIDO DV goal is to modernise and transform data exploration



RAPIDO DV is an interactive data visualisation tool which will allow clinical teams to explore analysis results dynamically



RAPIDO DV will achieve this by enabling dynamic result exploration and self-service data analysis with information that allows them to draw better analytical insights



*Reporting and Analysis Plan Improving
Design and Delivery of Outputs*

Users:

1. Programmers & Statisticians (within Biostats)
2. Medical Writers, Publishing Team
3. Clinical Scientists, Medical Monitors/ Physicians/ Safety Scientists
4. Biomarkers, PK Kineticists, etc.

RAPIDO Journey

Concept to reality



Special considerations



Development
and testing
strategy



Roll-out and
ramp-up
strategy



**Change
management**



Support
strategy



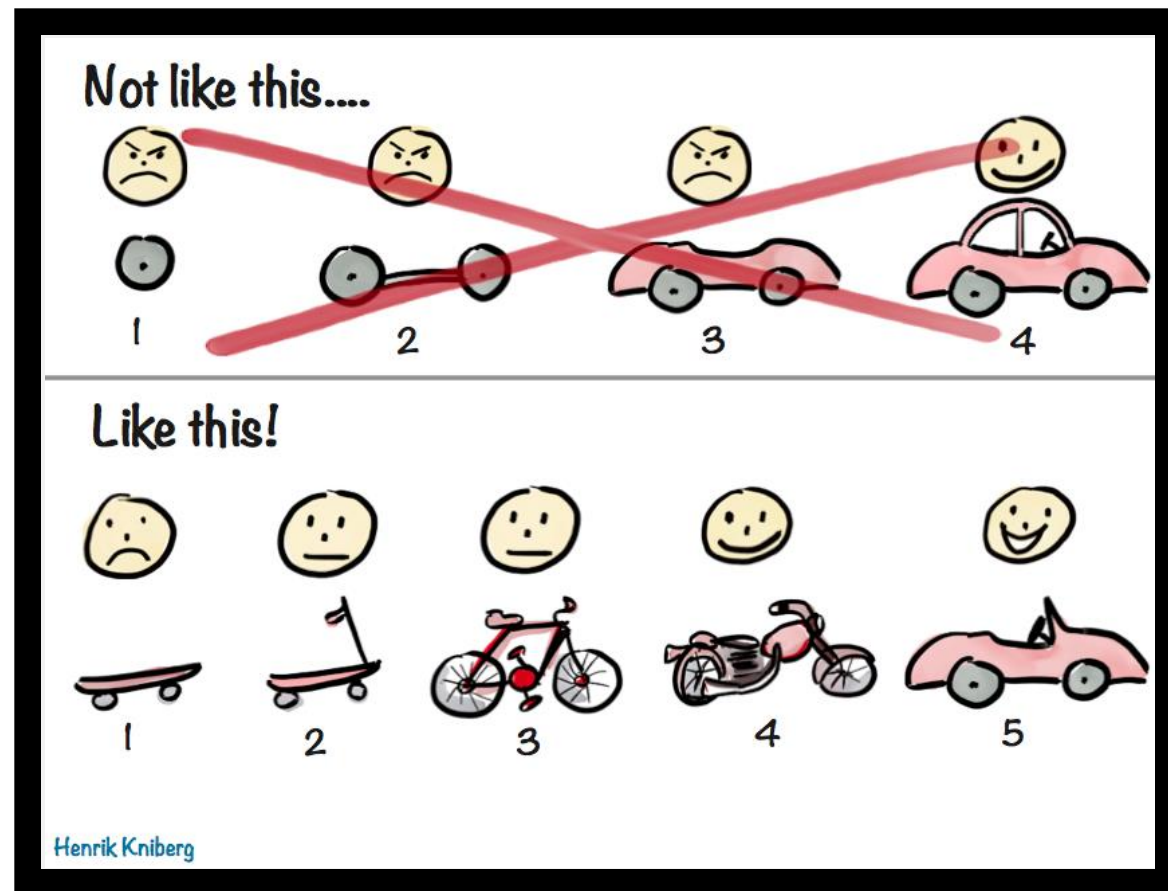
RAPIDO Journey

Development and Testing Strategy

- Off the shelf vs. bespoke development
 - Decision depends on level of customization and control
- GSK chose bespoke Agile development /delivery
- Vendors with key skills GSK Biostatistics does not have (R/Shiny/Java Script)
- Close collaboration between GSK Tech and Business (S&P)
- Validation 21CFR P11 (MVP – Only subject-level listings are validated)

MVP = Minimum Viable Product

What is agile delivery?



RAPIDO Journey

Adoption roll-out and ramp-up strategy



June 2021

Minimum Viable Product

- Pilot Studies

September 2022

All CDISC Studies

March 2022

Access all Subject-Level Data

- First Adopters
- Concierge-level support

December 2022

Automated Onboarding

- Business as usual

Expectations for first adopter study teams and feedback solicitation

First adopter studies



Removal / elimination of most static listings to be replaced by the tool



Embrace and champion RAPIDO DV



Provide feedback – both positive and negative – to help shape future development of the tool



Engage with self-service training suite

SPACE - RAPIDO DV - Early Adoption Survey

Thank you for your participation in this short (approx. 8 minute) survey, which will provide any valuable information to the RAPIDO DV team.

The survey is anonymous and we welcome your open feedback. Survey feedback will be reviewed and used to further shape the RAPIDO DV platform and the RAPIDO DV adoption onboarding and change support for the future. It is a tool to help us better understand your experience and needs.

* Required

1. I believe that the RAPIDO DV platform (and products) will improve the efficiency of my work. Rate on a scale of 1-5 with 1 indicating you strongly agree and 5 indicating you strongly disagree with the statement.*

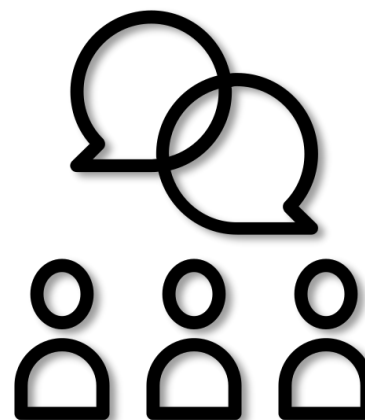
1 2 3 4 5

2. Do you have any comments on your choice of rating for question 1. Option to add comment here.

Enter your answer

3. I believe the RAPIDO DV platform (and products) will improve the efficiency of my work. Rate on a scale of 1-5 with 1 indicating you strongly agree and 5 indicating you strongly disagree with the statement.*

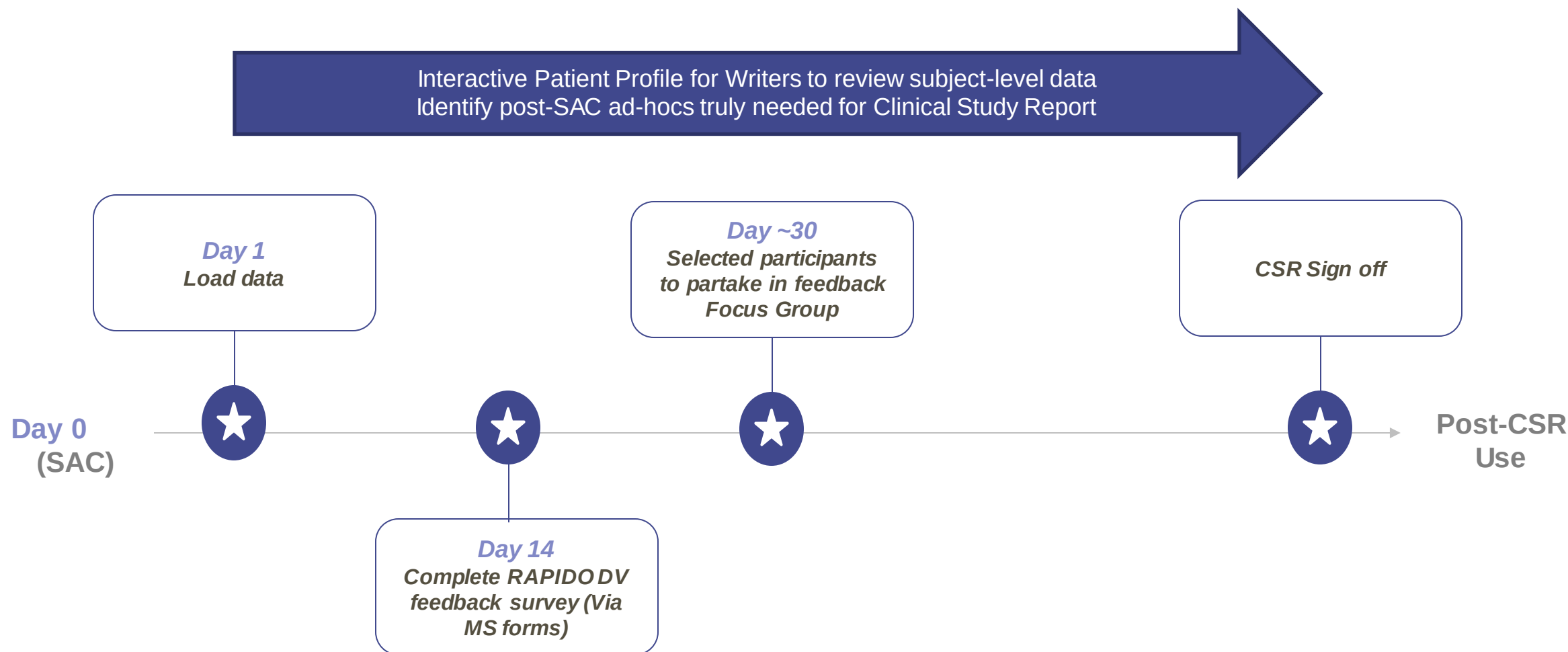
6-8 minute survey sent after the study trial



Focus group session for some study adopters (note: not an expectation for all adopters to take part)

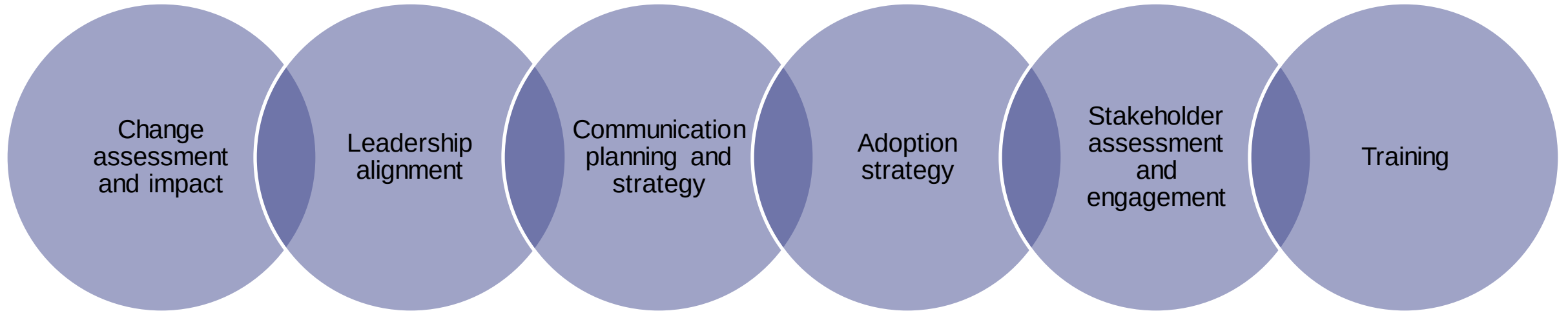
Adoption study timeline for first adopters

Core activities for the duration of your participation in the adoption trial



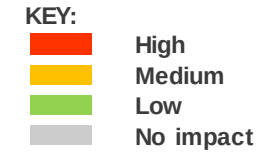
Change Management

Factors critical to successful deployment



RAPIDO DV Change Impact Assessment (CIA)

CIA detail per impact type



PEOPLE	PROCESS	TECHNOLOGY
Summary: Impacted stakeholders will need to complete new tasks and develop new skills which are in line with existing responsibilities. No fundamental changes to job description or role.	Summary: The fundamental process of analysing study results remains, but the way in which this is delivered to stakeholders is changing. Some standard operating procedures will change.	Summary: Introducing a completely new system with new functionality (interactive, dynamic reports) for multiple groups.
• Biostatistics (Programmers and Statisticians) has a role to play in influencing and championing the new RAPIDO DV technology and influencing smaller SACs. • Et cetera	• Teams are used to reviewing static report results in PDF format. RAPIDO DV introduces new, exploratory ways for results analysis which, will enable better insights by study team members outside of biostats. This is both a cultural and process change as teams need to be supported and encouraged to explore results independently. • Et cetera	• All impacted groups need to be trained in new RAPIDO DV technology and understand the benefits the new technology will bring to their ways of working. • Et cetera



Change Management

Leadership alignment, communication strategy, training



RAPIDO DV

Overall impact of change

Based on Change Impact Assessments

How does that break down by impact type?

People & Skills

No change to job descriptions, but users of RAPIDO DV need to complete new tasks and develop new skills requiring training and continued practice. Mindset shift.

Process

Changes to the way study analysis results and listings are delivered to stakeholders. Some changes to standard operating procedures.

Technology

Introduction of a new system with new functionality (interactive and dynamic reports)

2022 for RAPIDO DV is about bringing the Data Visualisation strategy to life, to transform how results are delivered to teams

Business Owners: Suhas Kirani Ravindra, Dan Schramek

Key messages for leadership?

- Pace of adoption is increasing: **all studies with SACs from late September onwards are expected to onboard to RAPIDO DV** (aligned with the 2022 Biostats objectives).
- Study teams are expected to **reduce their total number of outputs (from 250 to 220)** and **remove static listings**. ADaM datasets still need to be created for the dynamic listings capability of RAPIDO DV
- Post SAC review & exploration** of results should be **done in RAPIDO DV first**. If interesting results are identified, team should request that the S&P team produce the summaries & figures needed for study reports / publications
- The RAPIDO DV **test environment** is available for all
- We continue to gather **feedback** regularly from adopters re what works well and what doesn't; if your teams have challenges or ideas please encourage them to share with us
- Users must take the necessary **training on Keep Growing Campus**, please support and allow time for this. There are also optional drop in sessions, focus groups, Q&As and demos to support users.
- MW & study report QC reviewers** to use RAPIDO DV for **participant-level details** in the study report and **not from static listings**.

+ Shifts in how we work

Dynamic decision making Focus on what really matters Mindset to do things differently

Benefits for our teams?

From reviewing static PDF reports, to independently producing dynamic, exploratory analysis and results

Better understanding of data by all study team members (from being able to explore data on their own)

When teams are embedded in the new tech & processes, RAPIDO DV automations will reduce study setup and submission timelines

What does RAPIDO DV mean for our people?

New system in RAPIDO DV Additional training and adoption support New dynamic method to display & explore data

Training

[Home](#)
[Before starting](#)
[Getting started](#)
[Using RAPIDO Data Viewer](#)
[FAQ, help, support](#)

The RAPIDO Process

What training should I take?

There are 3 core training modules to be taken to use the RAPIDO DV tool. Everyone must take the 'Use of RAPIDO DV' module and will find necessary supplementary training on the *Before Getting Started* page of this KGC. To see where you should go next, view the table to the right!

Topic:	For everyone	For SLPs only	For statisticians, Medical Writers and Other End-users
Core Training:	RAD - L - VQD - WI -021096 - Use of RAPIDO Data Viewer	RAD - CDV - 9693 - SPACE Authorisation Tool	
Supplementary Training:	- <i>Before Getting Started</i> KGC Page - <i>Getting Started</i> KGC Page	- <i>Getting Started</i> KGC Page - <i>Using RAPIDO DV</i> KGC Page	<i>Using RAPIDO DV</i> KGC Page

Approach	Intent	Who	Methods
Top-down	- Foster advocacy - Strengthen S&P partnership - Counter resistance	Engagement with senior leaders, TA & functional heads	- LT meetings 1 x 1s
General awareness	- Foster curiosity & build excitement - Share practical details ("To Know, To Do")	- S&P Community - Study partner roles (e.g. Medical Writers, Study Leaders)	- Broad communication via Workplace, email cascade, etc. - Opportunities at forums, town halls, etc.
Targeted	Embedding new ways of working with teams at key events during development cycle	- Teams beginning Study planning - Teams approaching CSR Review	- Facilitated by study lead statisticians & programmers at key events (Protocol Review Forum) - DV Tool first adopter teams

Leadership engagement

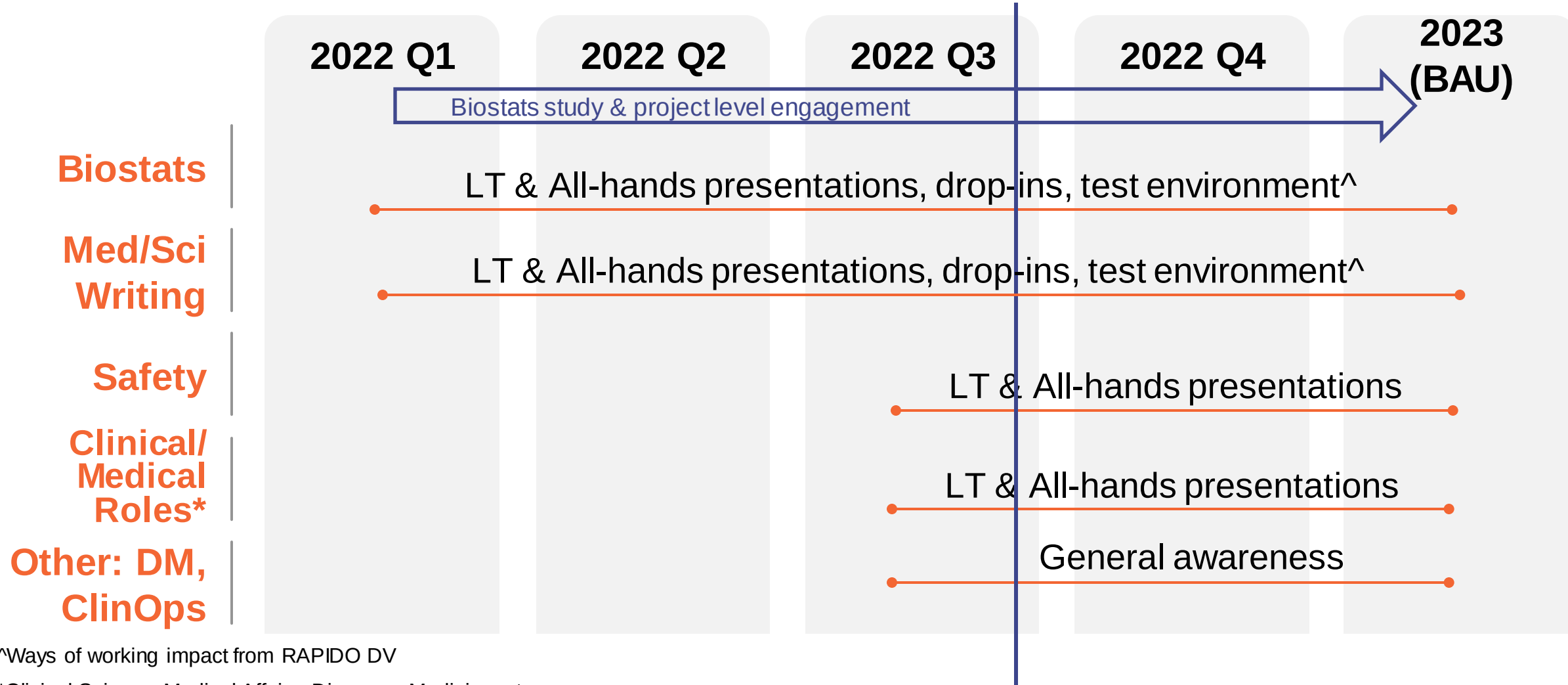
Comm strategy

RAPIDO DV Engagement Plan (2022+)

RAPIDO DV R7



Target largest impacted groups first



^Ways of working impact from RAPIDO DV

*Clinical Science, Medical Affairs, Discovery Medicine, etc.

- Co-author: Neharika Sharma
- GSK RAPIDO DV Leadership Team:
 - BO: Suhas Kirani Ravindra Aug 2021 to Dec 2022
 - PO: Daniel McDonald
 - BSO: Mandeep Sidhu
 - Business Adoption Lead: Namrata Pokhrel
 - Business SME Lead: Alex Carlton
 - SPACE Business Lead: Eileen Ching
 - SPACE Steering Committee: Samantha Warden, Rich Davies
- Change Management: North Highland, led by Louise George
- Special acknowledgment and thanks to Maria Dalton, RAPIDO DV BO from inception of the project through Aug 2021.

Finally...

Thank you to the entire GSK Business SME and R&D Tech development teams that have worked tirelessly to achieve our vision for data visualization!

BO: Business Owner; PO: Product Owner; BSO: Business System Owner, SME: Subject Matter Expert

GSK

