[PHUSE EU Connect 2023 – AD04]

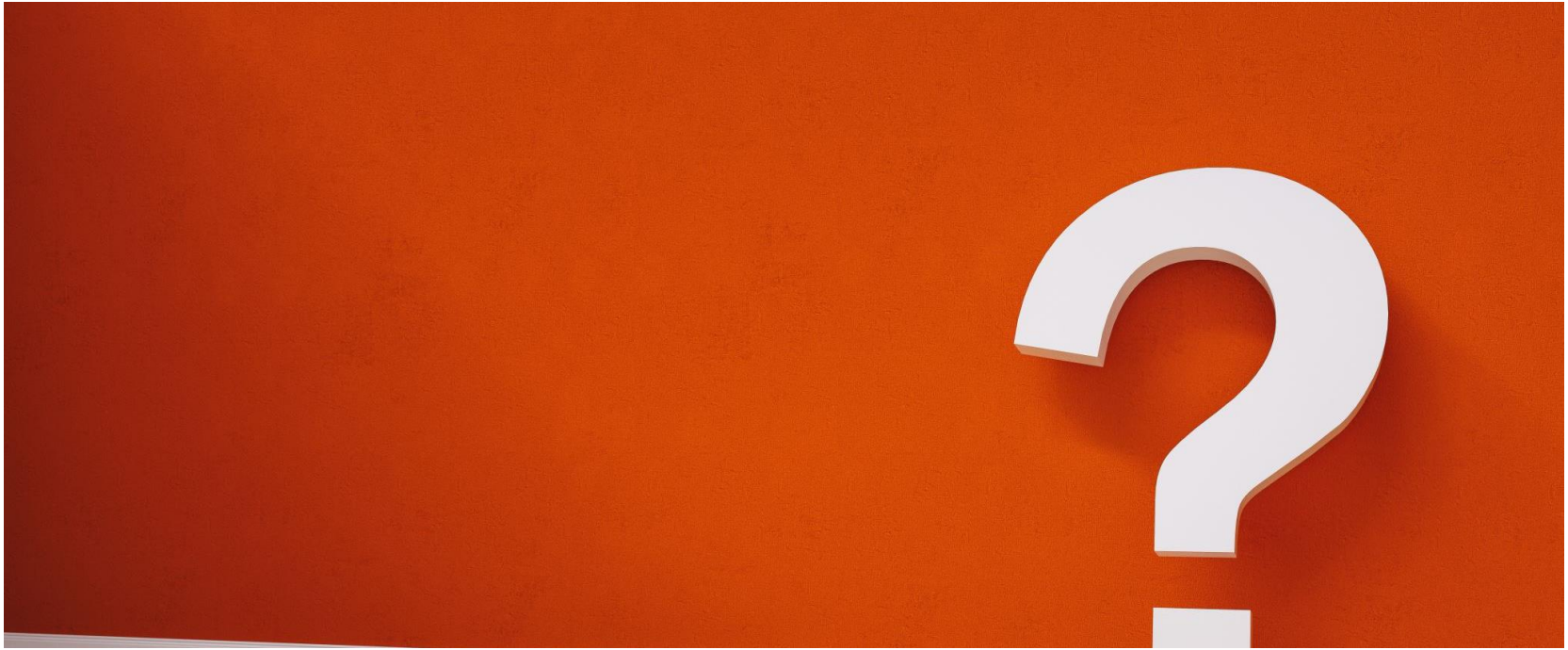
Be future minded while designing your Next generation SCE

Susanne Andersen
Senior Industry Advisor, EMEA & AP Health and Life Sciences CxP, SAS

Olivier Bouchard
Principal Business Solution Manager, EMEA & AP Health and Life Sciences CxP, SAS

SAS Corporate

Why?



Regulators are starting to give guidance

FDA NEWS RELEASE

FDA Announces Additional Steps to Modernize Clinical Trials

Agency Requesting Feedback on the Draft Recommendations and How They Should Be Applied to Increasingly Diverse Trial Types and Data Sources

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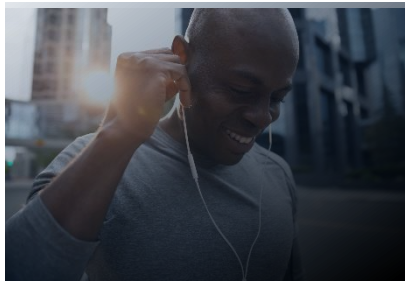
For Immediate Release: June 06, 2023

"A more robust clinical trial ecosystem that is capable of producing reliable evidence more efficiently may support more informed decision-making in developing medical products to help patients," said FDA Commissioner Robert M. Califf, M.D. "These draft recommendations propose a major step forward in this work. Building quality into the design and conduct of trials and encouraging the use of innovative trial designs and health technologies are essential to truly advance clinical trials and generate meaningful results."

To Overcome new business Challenges

Data

- Images, DCTs
- Volume & Modularity (realtime/aggregated)
- Collaboration & Partnerships on Trial
- New Industry Standard (OMOP, FHIR)



Time

- Faster Execution in a regulated envt
- Automation business processes

People

- Talent Shift
- Hybrid work
- Agility
- Data Driven Decision

Costs

- Industry pressure
- Sustainability & Evt
- Cloud Costs
- New Design on Trials

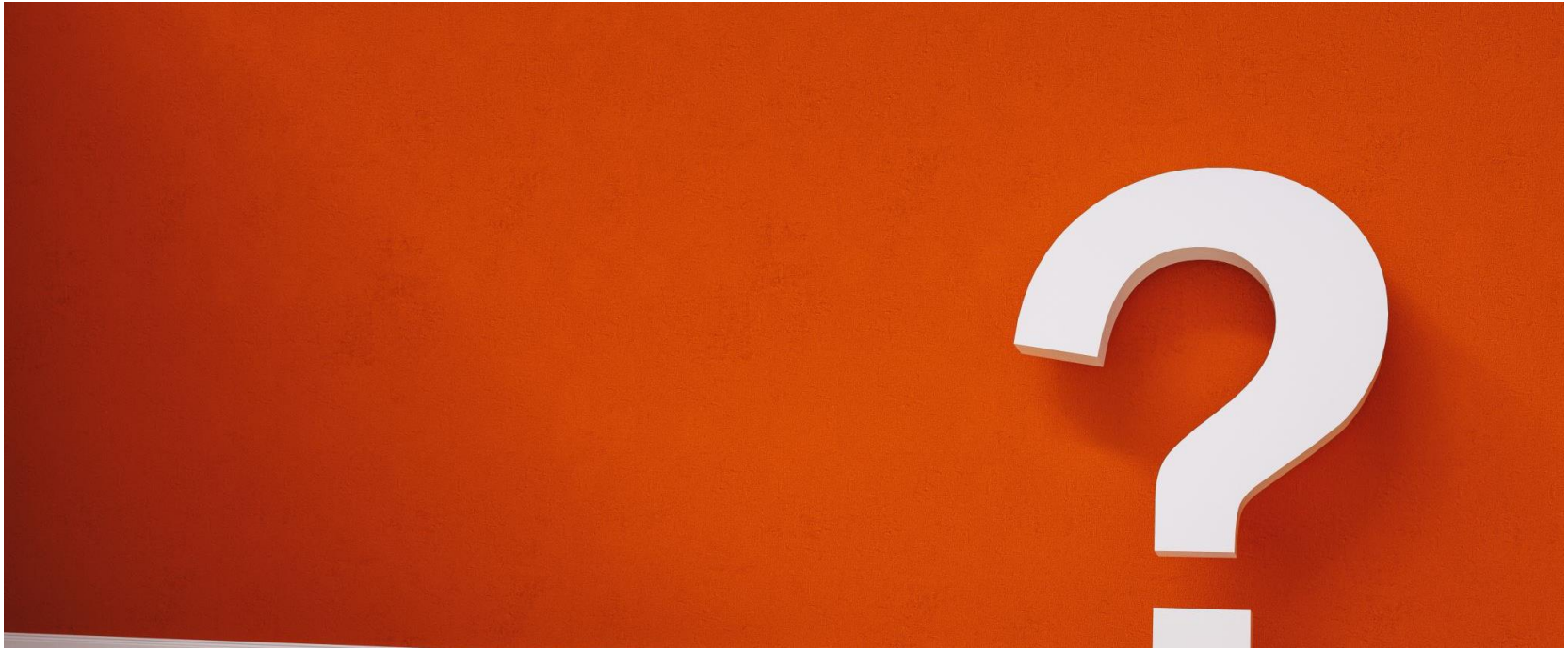
To Address Top Trends in General

And Unmet Needs in Industry

- ✓ Data & AI Governance
- ✓ Synthetic Data
- ✓ Applied Observability
- ✓ Augmented Analytics
- ✓ Data Fabric
- ✓ Trustworthy AI
- ✓ Democratize AI
- ✓ MLOps / ModelOps
- ✓ Decision Intelligence
- ✓ AI Engineering

- ✓ Asset Selection in Drug Discovery
- ✓ Optimize Clinical Development Process and Timelines
- ✓ Optimize the Demand Planning Process in Global Product Supply
- ✓ Smart Manufacturing
- ✓ Integrate RWE* into RCTs**

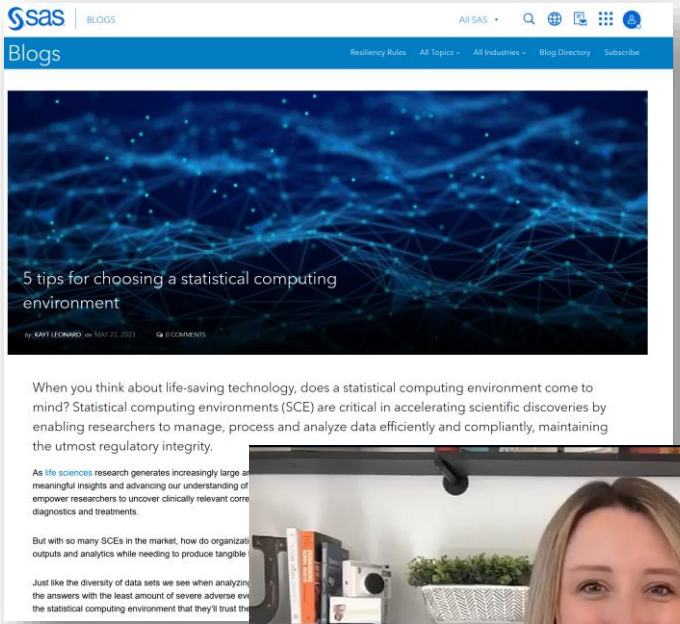
What?



5 tips for choosing a statistical computing environment

1. First things first? It's the about **data security**
2. It's secure, but is it available? **Openness is key.**
3. It worked! But **reproducing** it – and explaining it – is a challenge
4. It's great, but no one can **use it**
5. Pick your statistical computing environment **for now and for the future**

https://blogs.sas.com/content/sascom/2023/05/22/choosing-a-statistical-computing-environment/



Current SCE Deployment Spectrum

Openness is Key

Much more than an opensource stack

1. Bring your own IDE (Phuse Wed. Webinar, November 29th)
2. Use AND COMBINE any language that best suits you
3. API Driven 1st
4. Do not restrict to SASDATASET to all range of file format.

sas

Reproducibility is Key

Reconstructing the data points during the development history of the drug

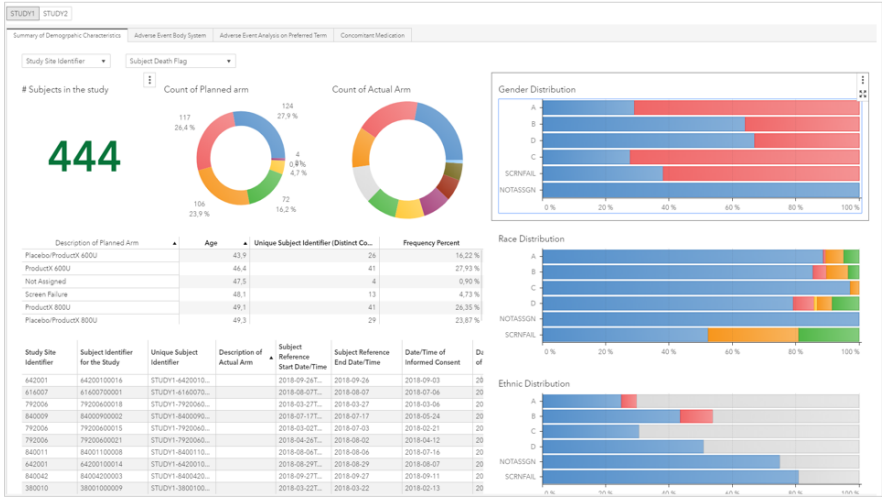
1. Traceability : records are traceable
   - Everything back to the source
   - Reverse Engineer every single steps

2. Accountability
   - Governance & Timestamp on any individual contribution to the data processing & analysis

3. Data Integrity
   - Reliable
   - Trust the outcome

Do not forget to Vizualize the data

Is Industry moving towards “Interactive Submission” ?

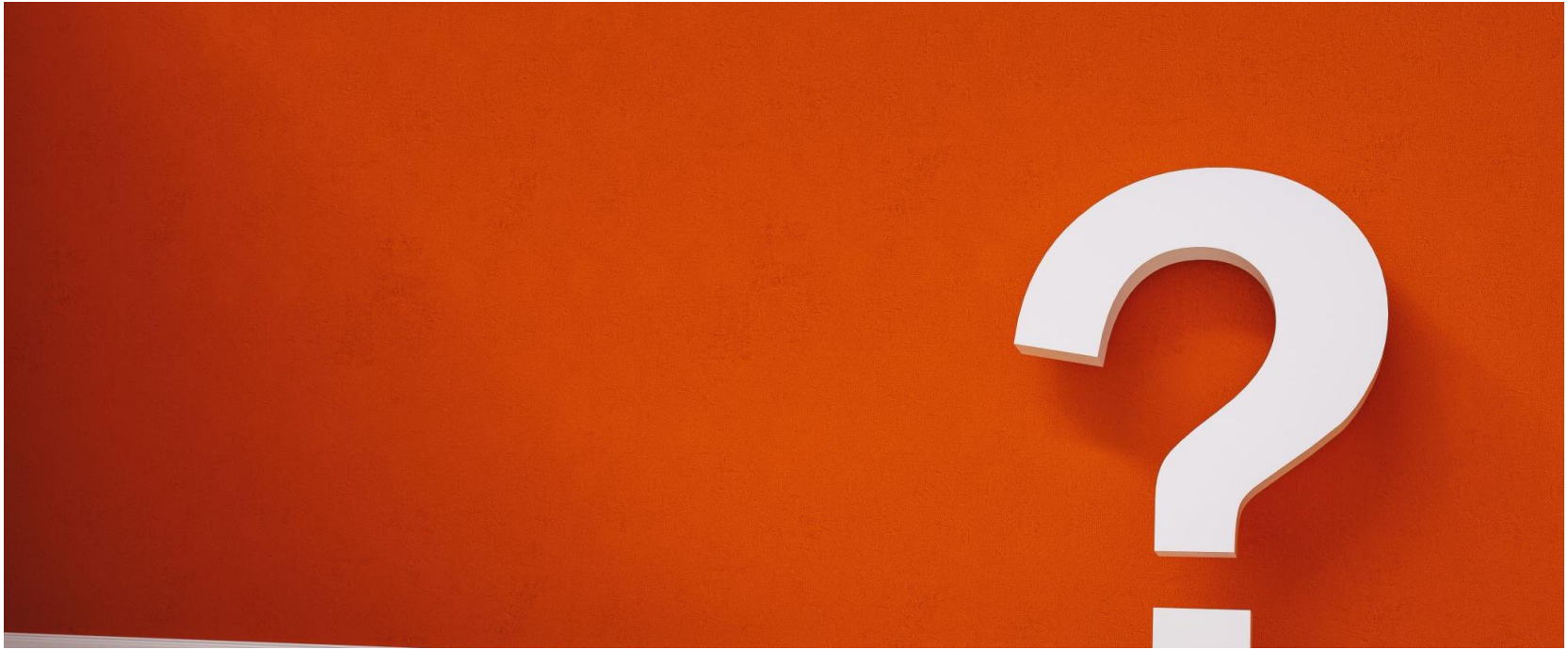


1. Put the data at the center
   - For any user involved in Clinical Trial
   - Minimize the time to decision
   - Efficiency

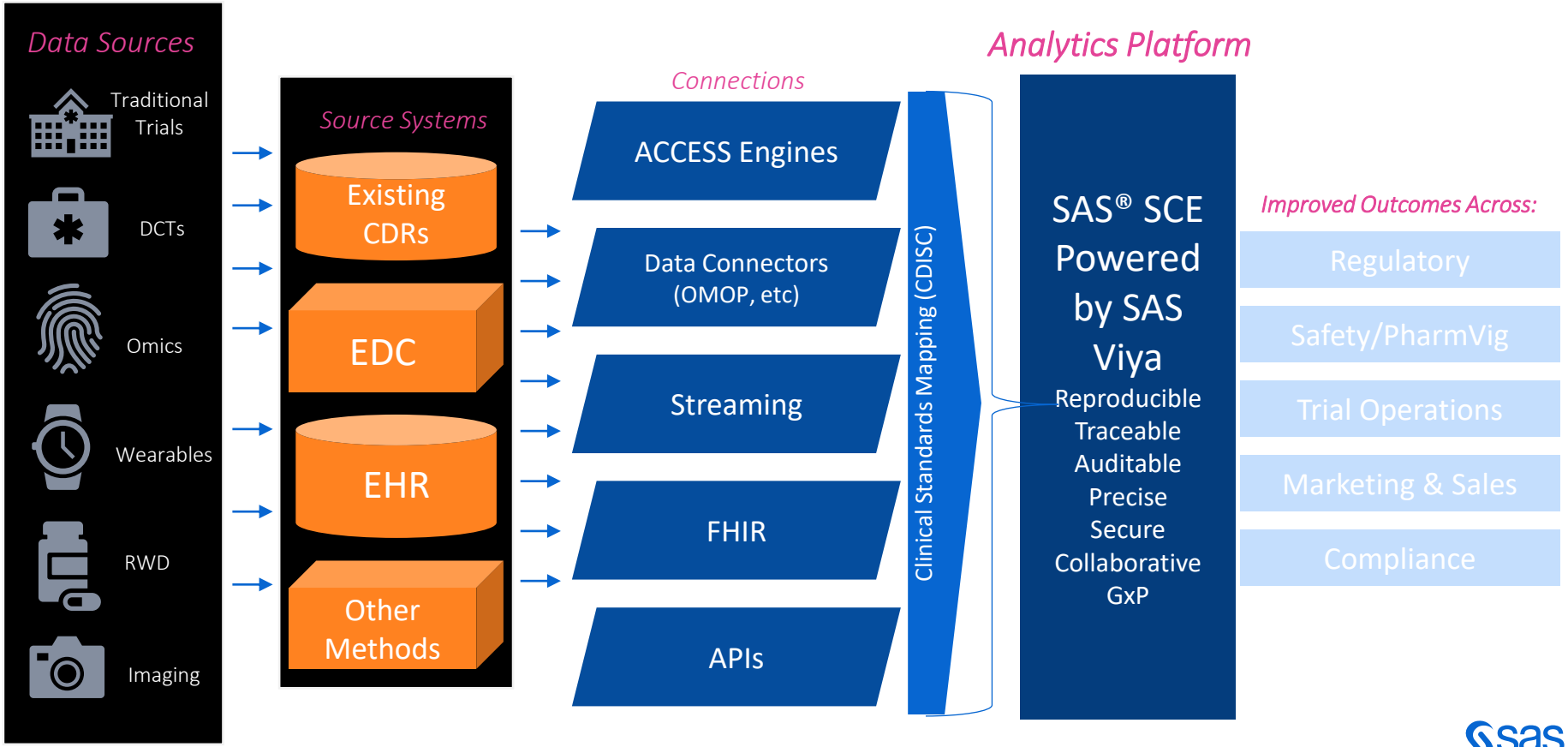
2. Automation at Maximum

3. Continuum from Exploratory to Regulatory
   - Any insights from exploratory work should be easily reproducible for the regulatory processes

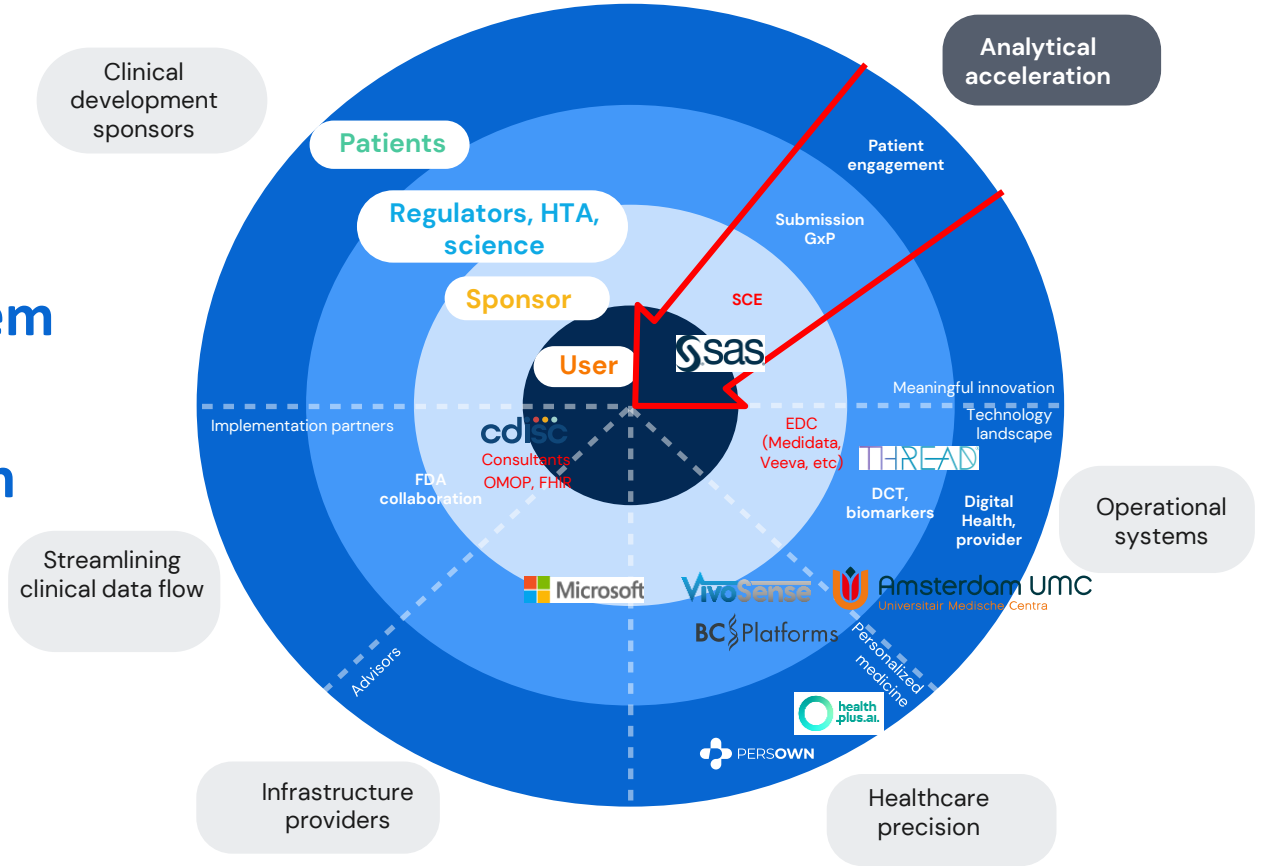
The SAS Perspective



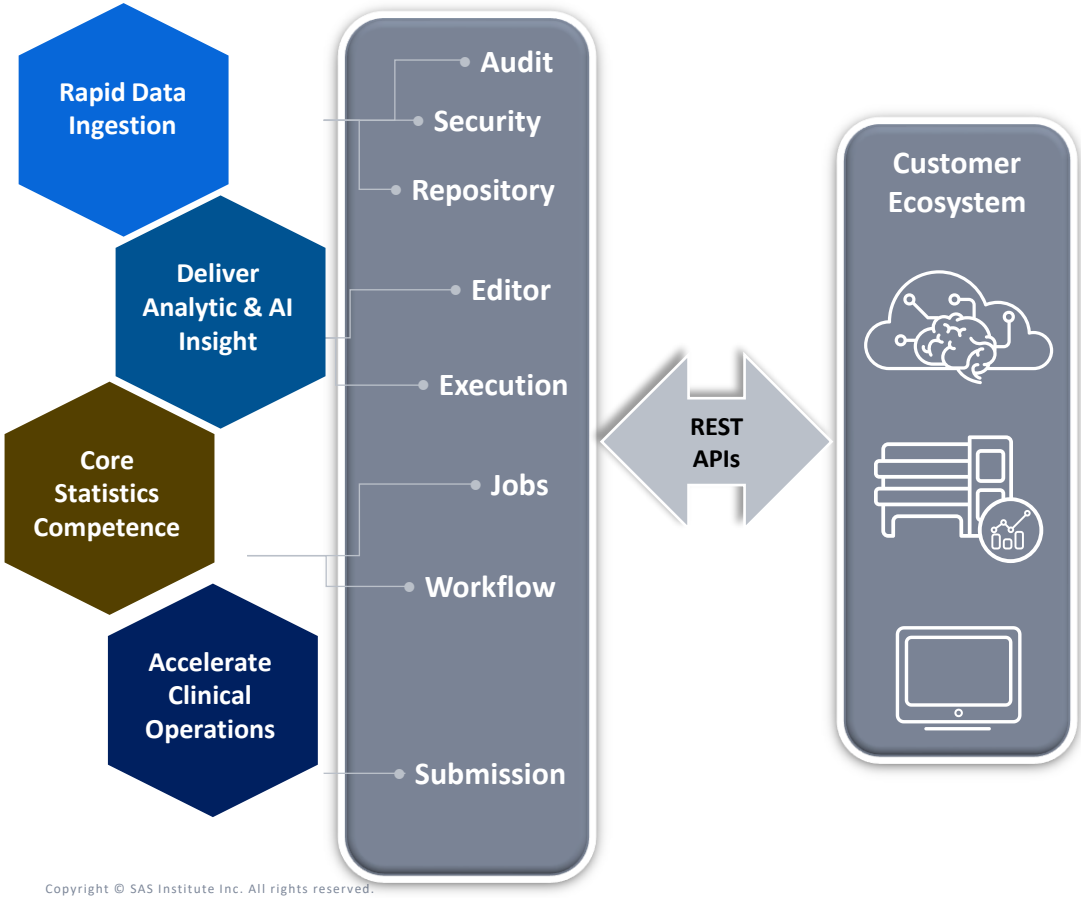
The Future of Efficient, Data-Driven Clinical Trials



Partner clinical ecosystem & Collaboration between industry leaders

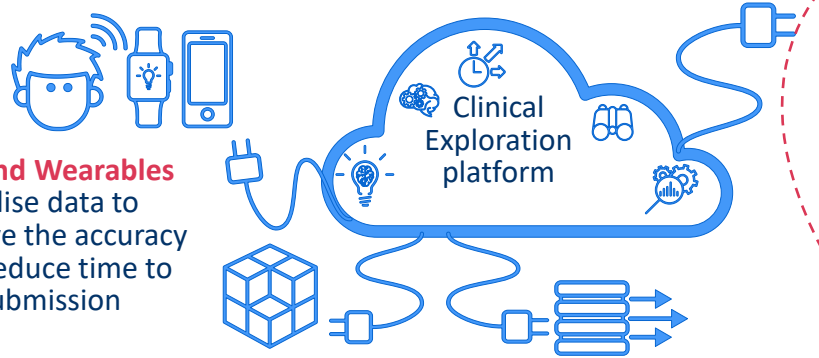


The New SCE of the Future : Modular and Open Design



- Modularized to meet your needs
- Open architecture for integration and orchestration
- Regulatory compliant
- Scalability with Viya

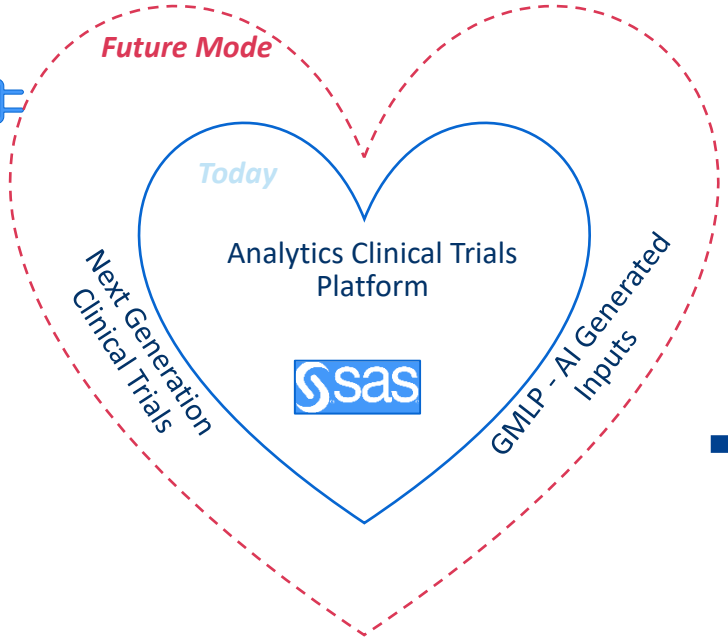
SAS - integral part of your fast growing Innovative Analytical Ecosystem



IOT and Wearables
tilise data to improve the accuracy and reduce time to submission

Open Source
Enable new models & techniques to be developed and industrialised

Control AI Reliability
Turn AI/ML generated outputs into validated RWE and insights



Why SAS?

We enable safe **Innovation** by complying with new FDA requirements

We **Mitigate Project Risk** by providing seamless integration into existing estate

We create **Efficiency** by orchestrating new technologies to shorten R&D time

STREAM ANALYTICS & STATISTICS (SD)

06.11.2023 | 14:00-14:30 | HALL 10B

Driving better health for more people SAS Life Science Analytics

Olivier Bouchard, SAS
William Kuan, SAS

DATA VISUALISATION (DV)

08.11.2023 | 11:00-11:30 | HALL 10A

Data Visualisation: Get The Full Picture With SAS

Andy Bayliss, SAS

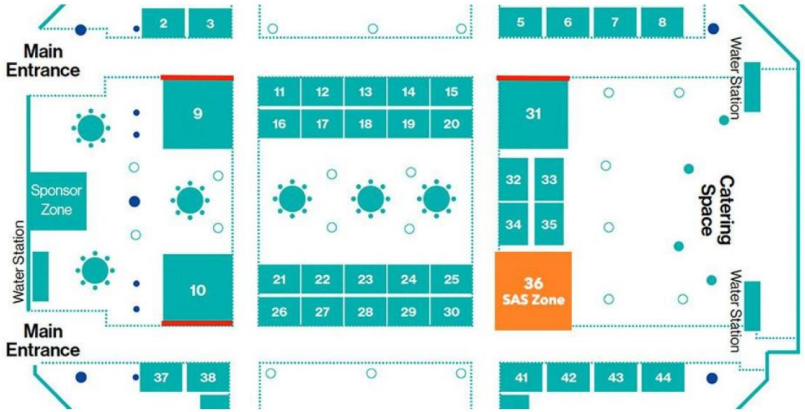
SAS Hands-on workshop

Do you get the Full Picture of your Data? Build you interactive Clinical Data Visualization in a secure & scalable platform to discover hidden insights

By Soundarya Palanisamy and Olivier Bouchard, SAS

Tuesday, 7th of November 2023 | 16:00-17:30 | Hall

You can find us in Hall 3 :



Thank you