

[PHUSE EU Connect 2023 – SD02]

Be future minded while designing your Next generation SCE

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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

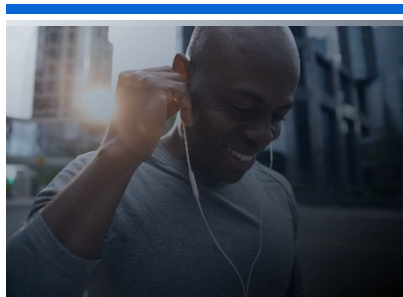
“A more robust clinical trial ecosystem that is capable of producing reliable evidence more efficiently may support more informed decision-making in developing medical products to help patients,” said FDA Commissioner Robert M. Califf, M.D. “These draft recommendations propose a major step forward in 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



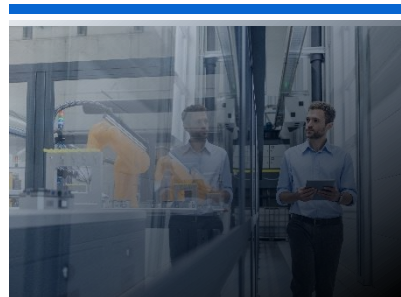
Data

- 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



*TRANSLATED INTO UNMET NEEDS IN
LIFE SCIENCES*

- ✓ 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**

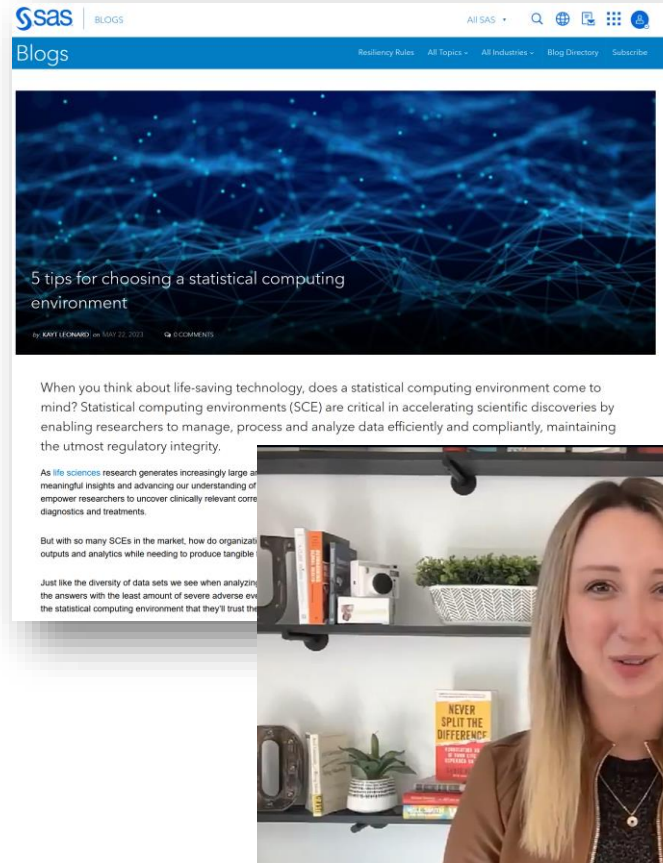
What?



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.



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” ?

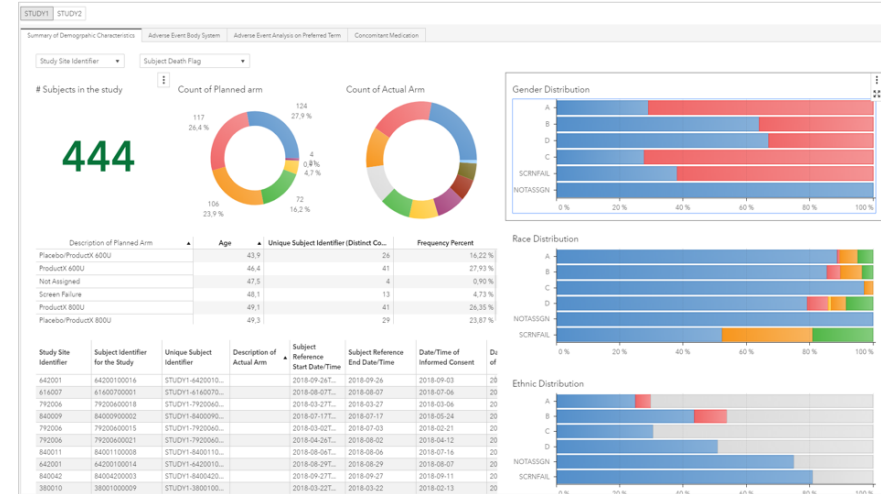
1. Put the data at the center

- For any user involved in Clinical Trial
- Minimize the time to decision
- Efficiency

2. Automation at Maximum

3. Continuum from Exploratory to Regulatory

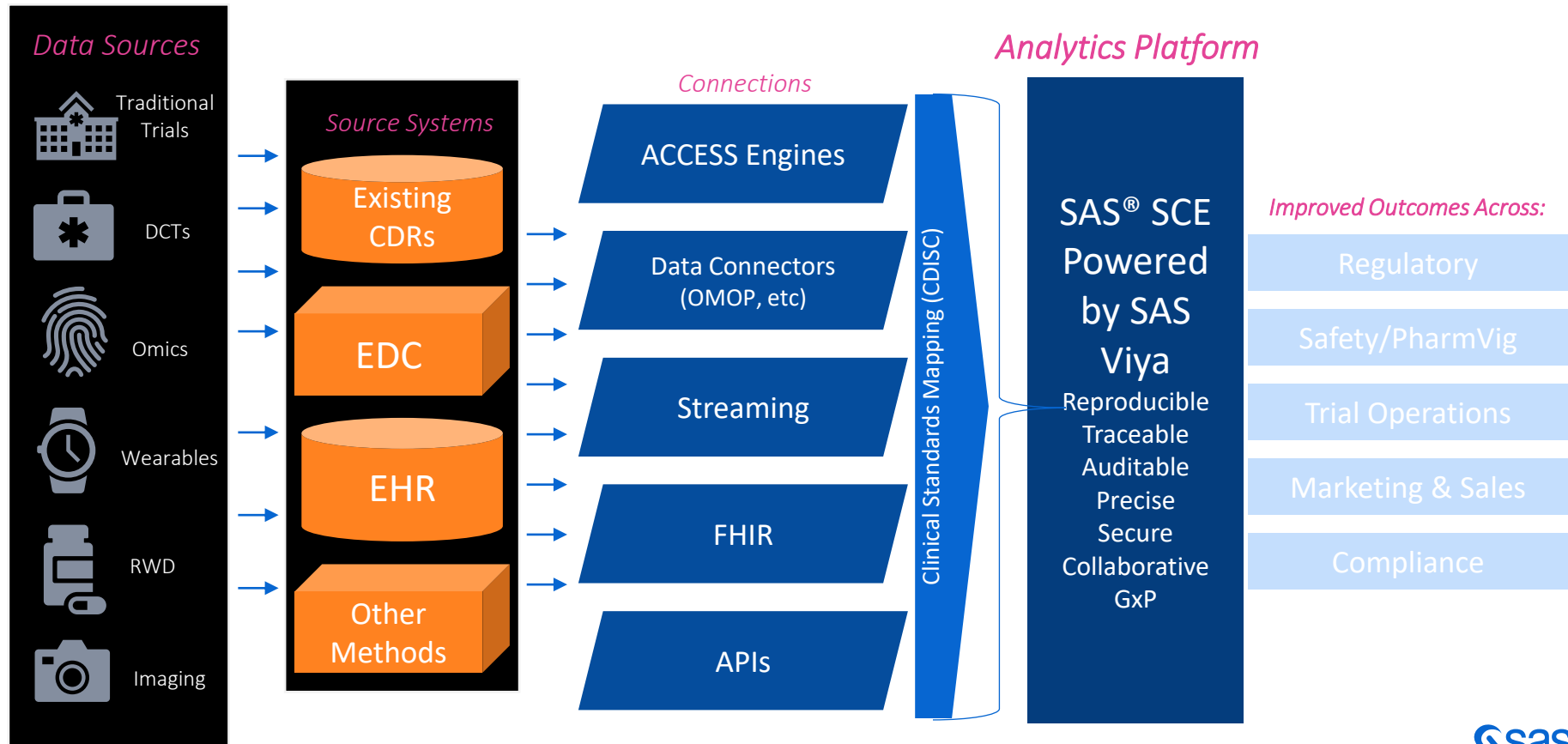
- Any insights from exploratory work should be easily reproducible for the regulatory processes



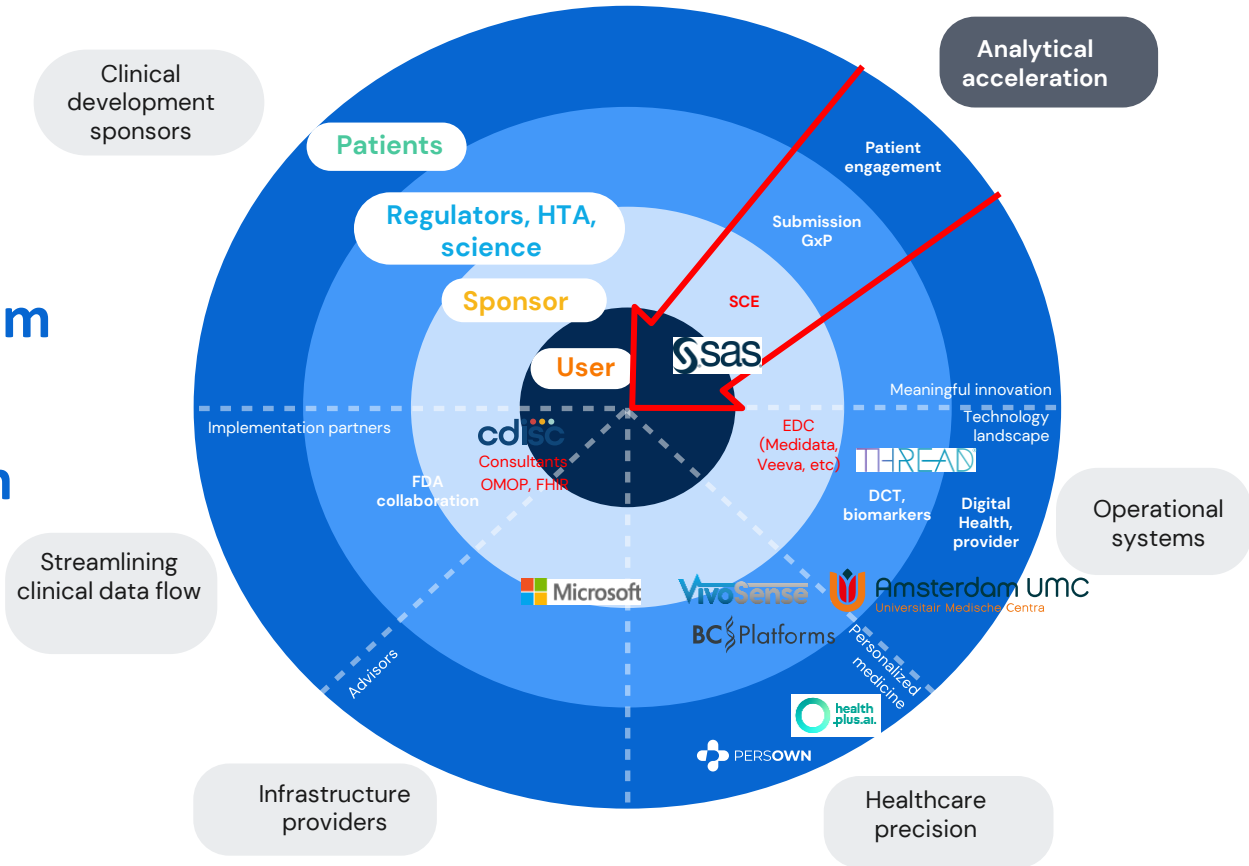
The SAS Perspective



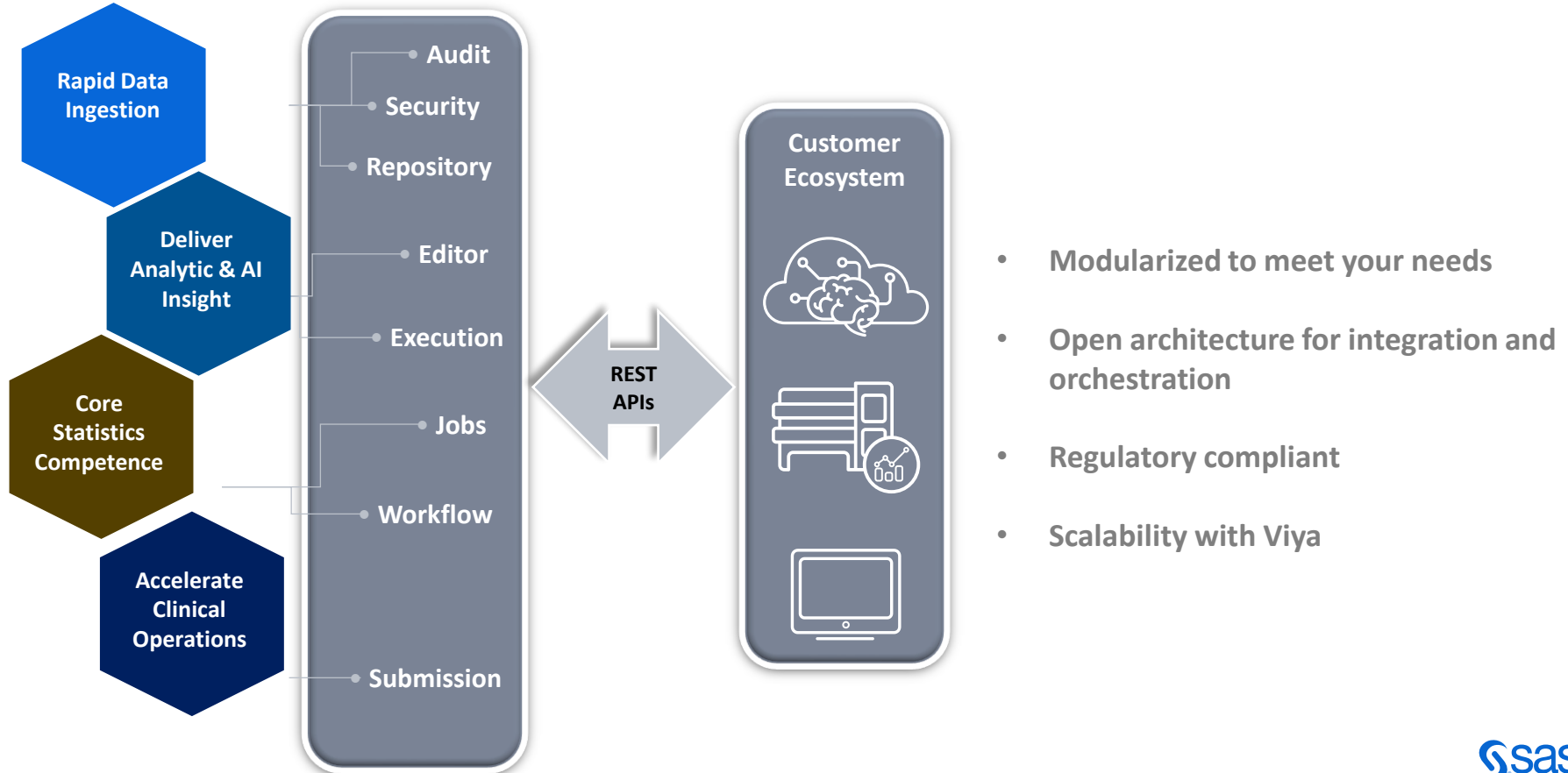
The Future of Efficient, Data-Driven Clinical Trials



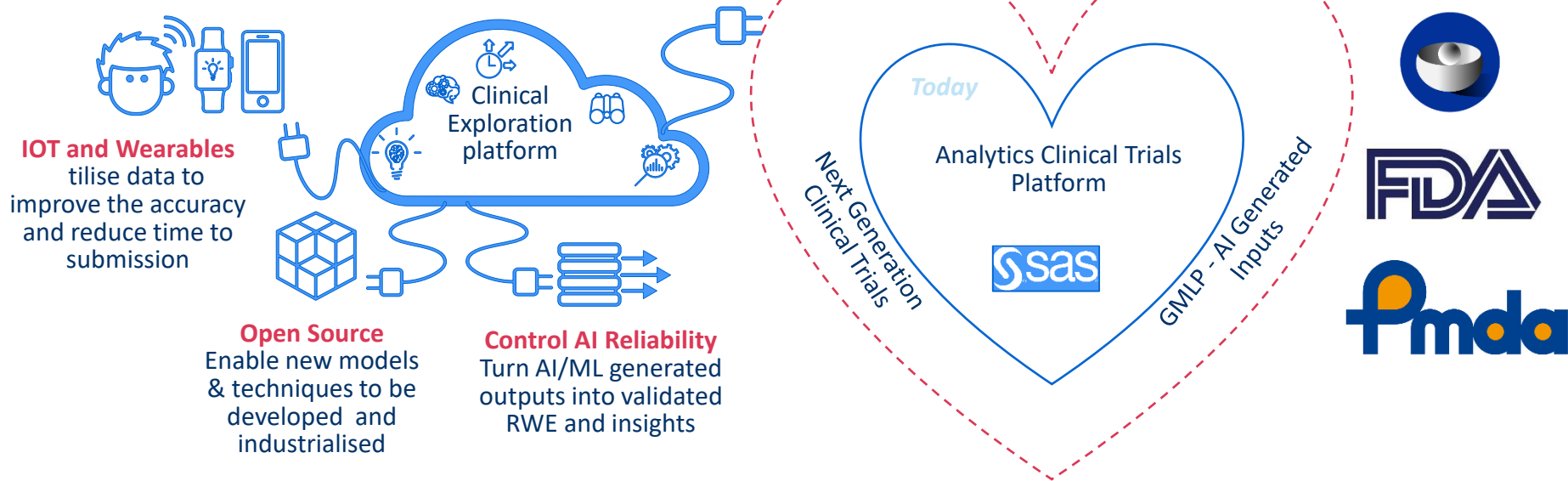
Partner clinical ecosystem & Collaboration between industry leaders



The New SCE of the Future : Modular and Open Design



SAS - integral part of your fast growing Innovative Analytical Ecosystem



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

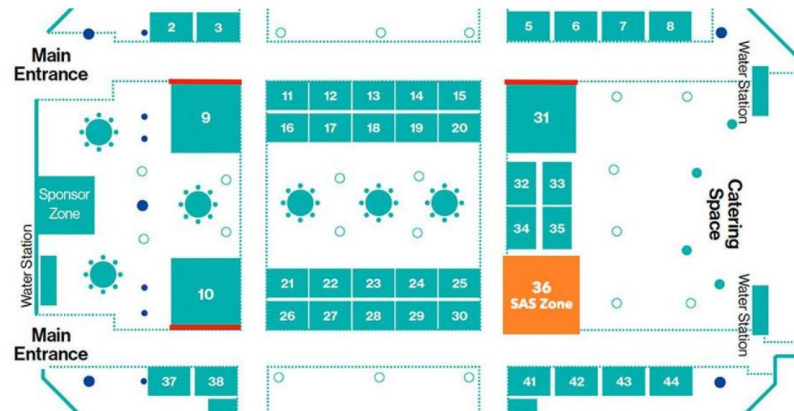
By Soundarya Palanisamy and Olivier Bouchard, SAS



Tuesday, 7th of November 2023 | 16:00-17:30 | Hall 3



You can find us in Hall 3 :



Thank you

