

Build vs Buy for the SCE: Considerations for the Future of the Statistical Computing Environment



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Meet the Speaker

Nathan Johnson

Vice President, Digital Innovation
eClinical Solutions

- 20 years experience in clinical research as a SAS programmer and innovator.
- expertise in statistical analysis and reporting, standards development, and data management.
- passionate about reshaping clinical trials through digital transformation, intelligent technology, and increased automation.
- degree in biostatistics from Case Western Reserve University.



SCF FIGHTER

PUSH START BUTTON

BUILD OR BUY

2023 PROUSE US

CREDIT

Statistical Computing Environment

Evolving understanding as Clinical Trials change...

2010

“An SCE is a system that provides a foundation for documenting rigor in the analysis and reporting of clinical trial results while increasing productivity.”

WHAT

New needs
New technologies

WHO

Expanded user base

WHY

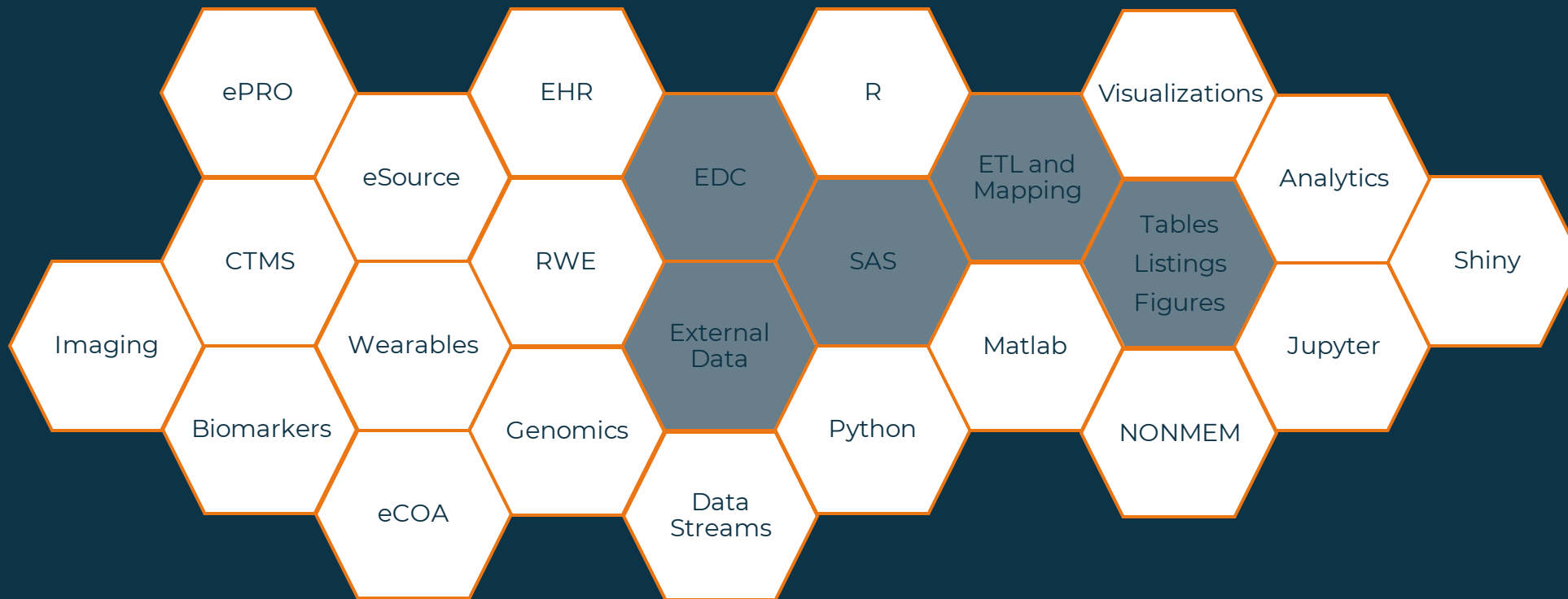
New use cases
New priorities

Hopkins, Duke, Dubman, “Statistical Computing Environments and the Practice of Statistics in the Biopharmaceutical Industry,” *Drug Information Journal*, Vol. 44, pp. 29–42, 2010



SCE: What

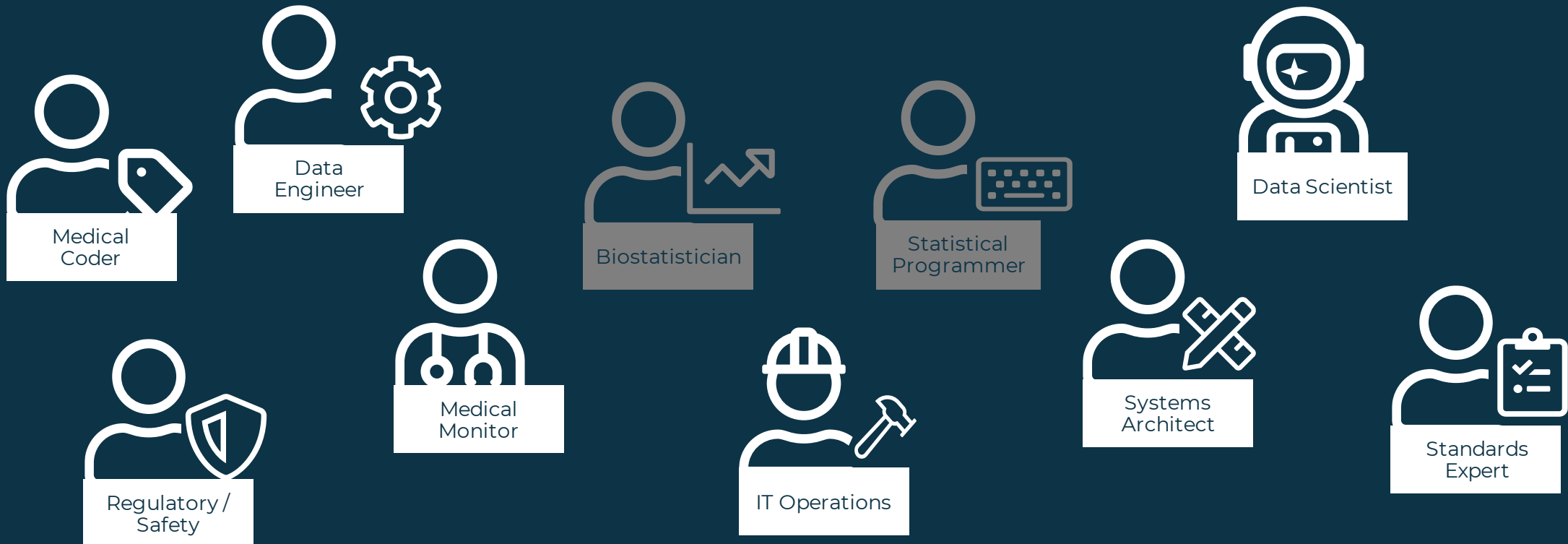
Digital Transformation of Clinical Trials bringing new challenges



... changing the nature of WHAT we want to build or buy.

SCE: Who

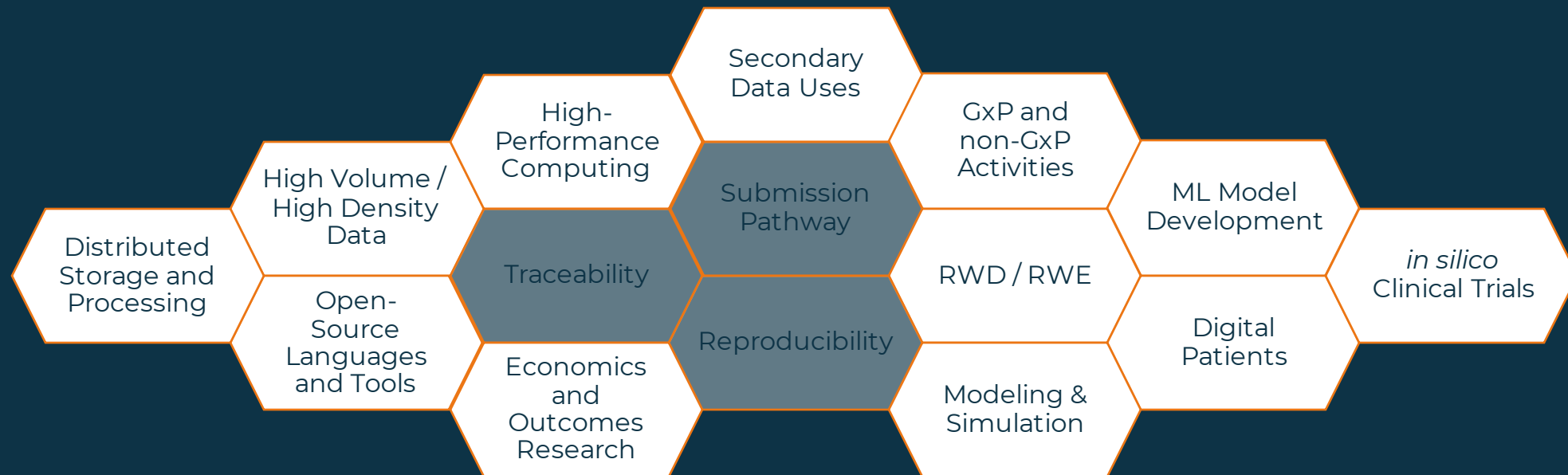
Analytics and computing needs are expanding beyond Statisticians



... changing for WHOM we are building or buying.

SCE: Why

Today's clinical trials are also bringing new analytic needs

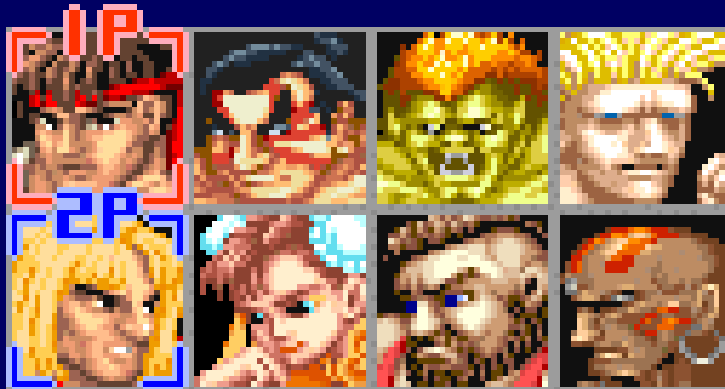


... changing the underlying WHY behind build or buy.

SCE: How

Despite these changes, you still have a choice to build or buy.

PLAYER SELECT



Multi-faceted Decision



1P

PAUSE US

2P

SCE

BUILD

23

BUY

FIGHT!



Features



BUILD



- + Satisfy unique user requirements and specialized workflows
- + Solve immediate problems



- Limited vision
- Tool to accomplish existing processes better

BUY



- + Broader industry perspective reflecting best practices
- + Future-looking, seeking digital transformation



- Unfamiliar paradigms, interface, UX, or workflows
- May not fully address current perceived problems

Key Question:



Are our internal use cases truly unique, or would we benefit from lessons learned from across the industry?

Accountability & Ownership



BUILD



- + Maintain full control and internal accountability
- + Ability to drastically adjust workflows



- Develop new SOPs for software development
- Long-term support resourcing

BUY



- + Leverage vendor validation and processes
- + Offload maintenance burden



- Loss of internal control; difficult to change solutions
- No control over prioritization of feature requests



Key Question:



Do we have the internal resources / commitment not only to develop but to maintain and enhance the new solution?

Cost



BUILD



- + Spread out expenses over longer period of time
- + No ongoing license fees



- Hidden costs of maintenance and future innovation
- Risk of project overages

BUY



- + Lower Total Cost of Ownership (TCO)
- + Cost estimates more reliable based on set contracts



- Higher upfront investment
- Hidden costs of vendor selection process

Key Question:



How do we demonstrate ROI, and how confident are we that costs can be accurately estimated and controlled?

Expertise



BUILD



- + Leverage existing institutional insights
- + Smoother knowledge transfer



- Skill set outside of core competencies
- Diverting resources from organizational core mission

BUY



- + Software development expertise with latest tools
- + Leading innovation



- Not designed to specific internal processes
- May lack specialized subject-matter expertise

Key Question:



What are we best at, and would developing an SCE cater to and best utilize those strengths?

Time



BUILD



- + Integration could be built into development process
- + Custom solution could shorten adoption time



- Long lead time for development, iterations
- Additional time for validation, documentation

BUY



- + Faster time to deliver value to end users
- + Established documentation and training materials



- If extensive customization is needed, longer time to value
- Full implementation timeline (migration, training)

Key Question:



What is our overall anticipated timeline, including full implementation and user adoption?

1P

PAUSE US

2P

SCE

BUILD

23

BUY

CONCLUSIONS



Conclusions

- Fully understand WHAT, WHO, and WHY before investigating the HOW.
- Is it always BUILD vs BUY?
 - **BUY + BUILD**
(off the shelf with extensive customization)
 - **BUY to BUILD**
(development partnership with vendor)

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1P

PAUSE US

2P

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K.O.



Thank you!

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