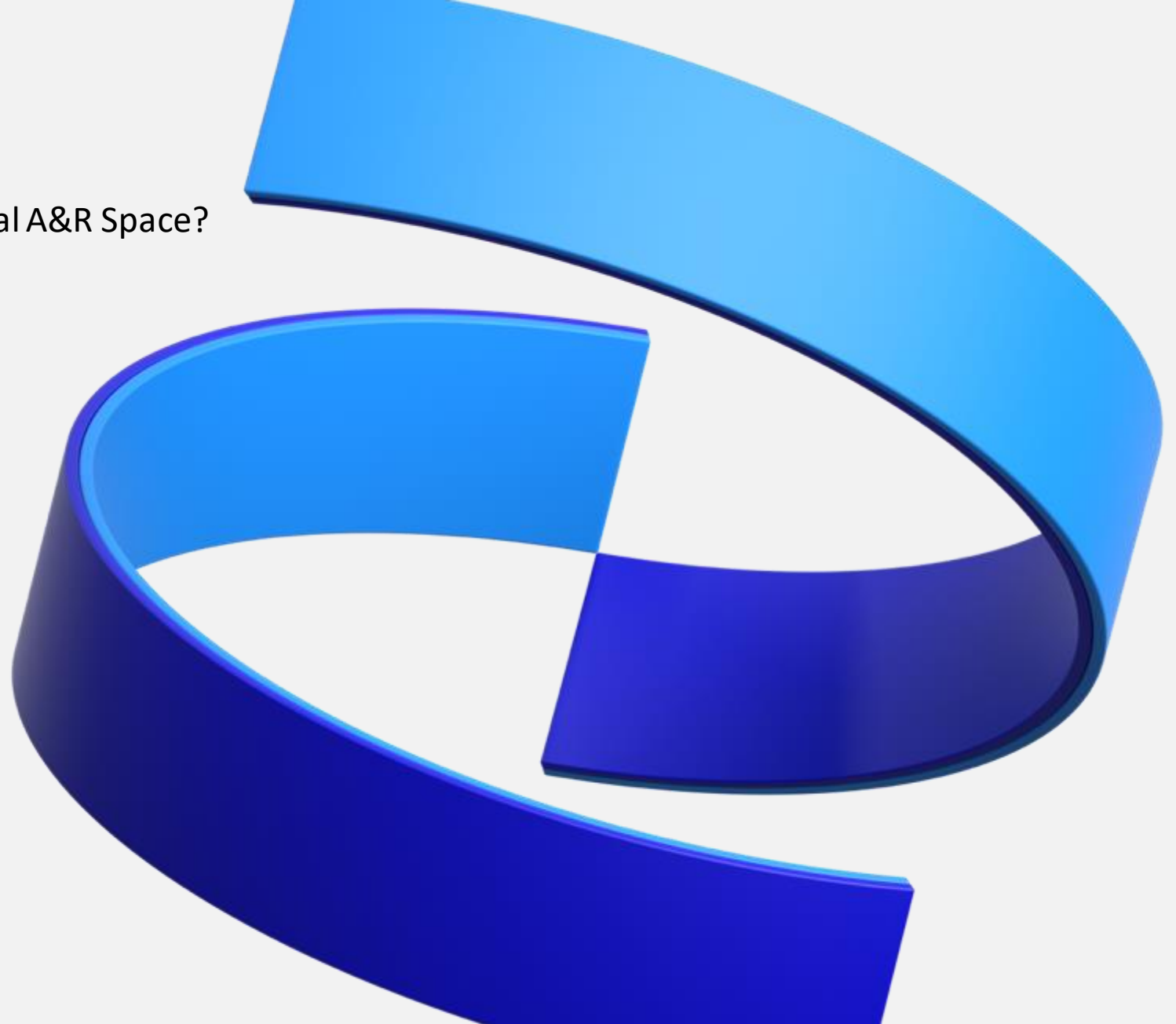


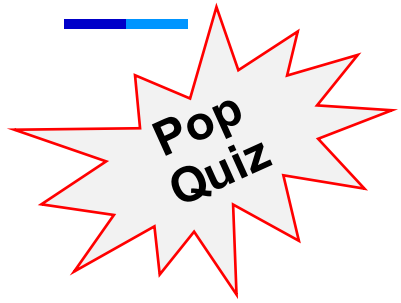


SIGMA:

What is the **Sum** of its Impact on Pfizer's Statistical A&R Space?



PhUSE US Connect 2023
Christopher Colangelo – Pfizer



“An approximate answer to the **right question**
is **WORTH FAR MORE** than a **precise answer** to the wrong one.”

Who originally claimed this?
John Tukey
... yes, a Statistician



“An approximate answer to the **right question**
is **WORTH FAR MORE** than a **precise answer** to the wrong one.”

My claim ...

precise answers to the wrong questions is the biggest reason many “innovative technologies”

- are unattractive to users
- don't meet biz objectives

https://www.brainyquote.com/quotes/john_tukey_205208

“An approximate answer to the **right question**
is **WORTH FAR MORE** than a **precise answer** to the wrong one.”

Common **Business** Objectives:

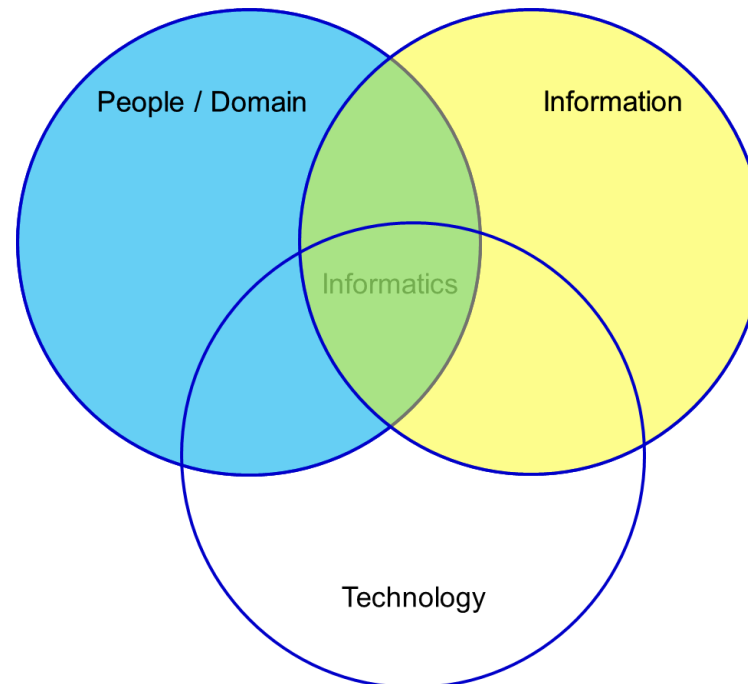
1. Increase process efficiency
2. Decrease Ops spend for A&R
3. Reduce cycle-backs
4. Enhance inspection readiness
5. Accelerate task completion

Which is the **right question** to help achieve those objectives?

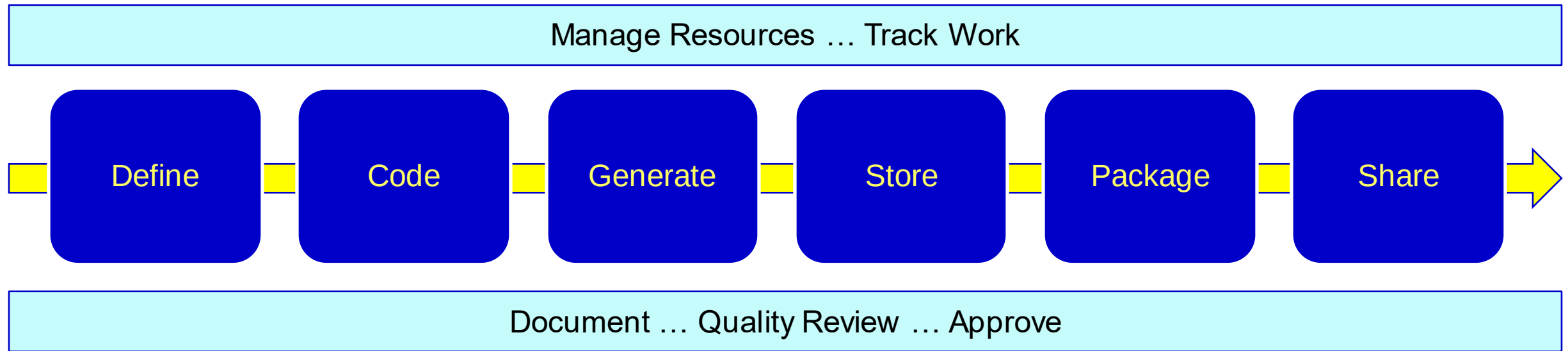
1. Which cloud infrastructure is best for stat computing?
2. How can we increase compute speed by 2x?
3. Best way to transition to R: TFLs & data? Only TFLs?
4. How do we digitalize **info & operations** across A&R?

What is **SIGMA** anyway?

SIGMA is Pfizer's custom informatics platform enabling our digital transformation of Clinical Statistical Analysis & Reporting

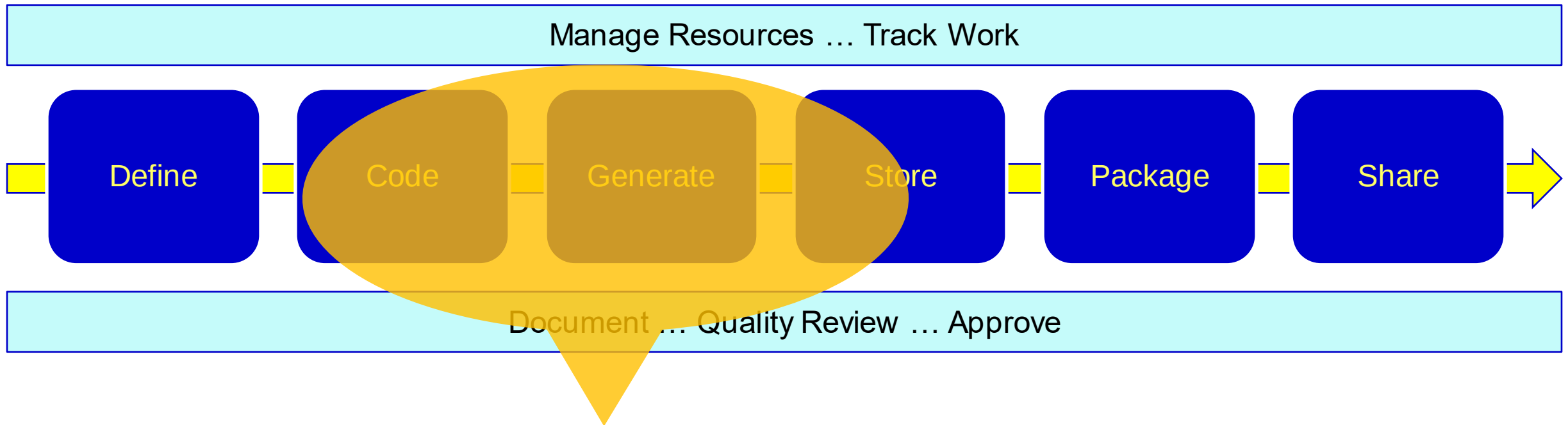


Business Architecture: Key ~~Actions~~ Capabilities in A&R



Business Architecture: Key ~~Actions~~ Capabilities in A&R

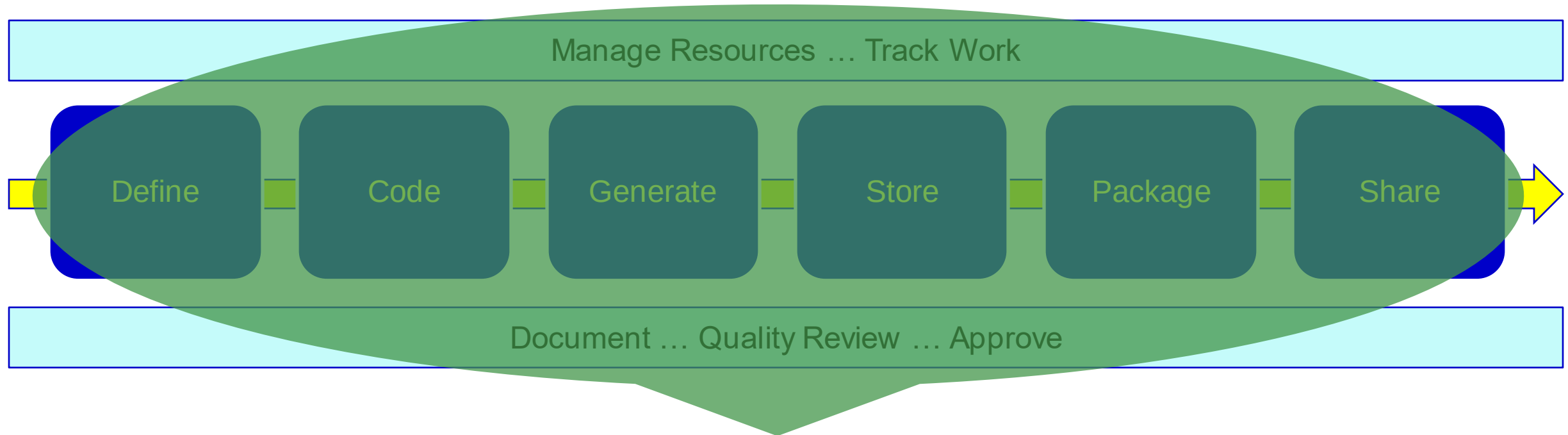
Typical scope & key capabilities in COTS SCEs



Began to support certain steps in a workflow to code & generate outputs
Does not support the lifecycle of generating study specs
Minimal to no support for packaging & share data or stat results per consumer needs

Business Architecture: Key ~~Actions~~ Capabilities in A&R

Scope & key capabilities in SIGMA



AI/ML draft study specs ... persisted as a knowledge graph

Metadata integration with "SCE"

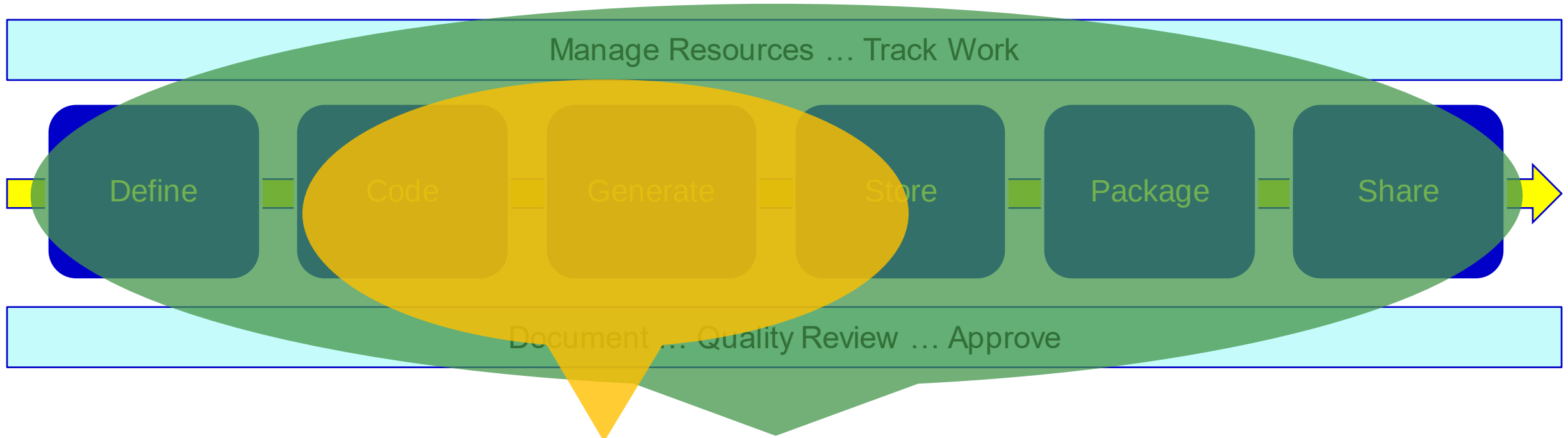
Statistical results persisted as a knowledge graph

WYSIWYG table design

System generation/capture of metadata

Business Architecture: Key ~~Actions~~ Capabilities in A&R

Scope & key transformers in SIGMA



AI/ML draft study specs ... persisted as a knowledge graph

Statistical results persisted as a knowledge graph

WYSIWYG table design

System generation/capture of metadata

Parse results from display

— SIGMA: Key Transformation Levers & Challenges (Solutioning)

Digital transformation of A&R core operations requires:

- **Understanding** of A&R deliverables; processes; skillsets & SME; drug development & regulatory context
- **Knowledge** of modern computer science, information science, & informatics disciplines
- **Strategically combining** them to design custom informatics solutions that drive novel A&R operations

Transformation Levers

AI/ML draft study specs ... persisted as a knowledge graph

Statistical results persisted as a knowledge graph

WYSIWYG table design

System generation/capture of metadata

} Parse results from display

— SIGMA: Key Transformation Levers & Challenges (Adoption)

Transformation Levers

AI/ML draft study specs ... persisted as a knowledge graph

Statistical results persisted as a knowledge graph

WYSIWYG table design

System generation/capture of metadata

} Parse results from display

Changing how workers work

Changing how managers manage

Disrupting the measuring & ensuring quality

Perceived threat to job security

Smashing the glass ceiling of skepticism



Thank you!
**I'm happy to answer
any questions ...**

For further information on this presentation or regarding **SIGMA**, please contact:

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