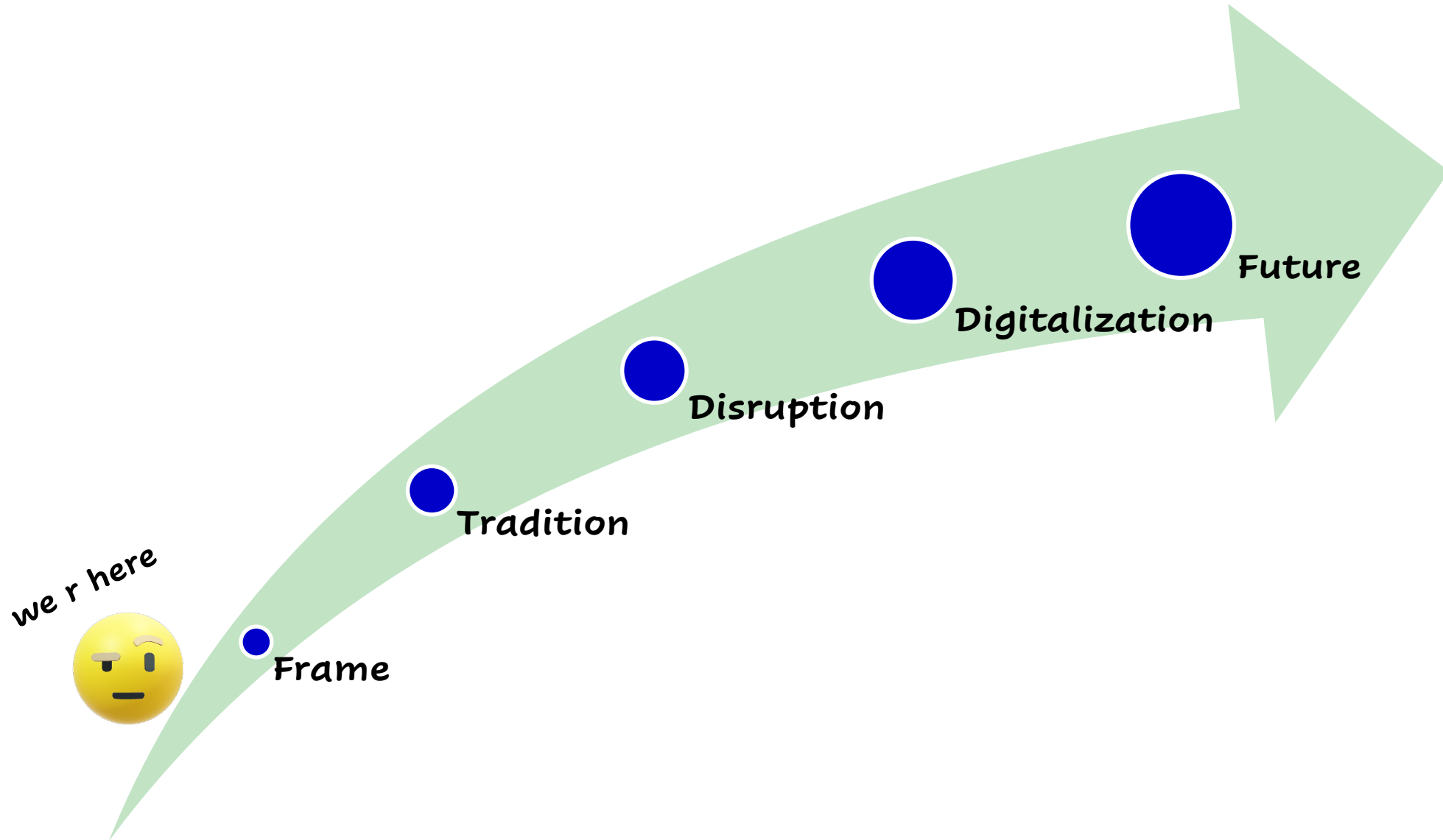


Tipping the scale:
moving from scaling
experts to balancing them
with novel technologies

Christopher Colangelo
Pfizer Pharmaceuticals
Global Product Development - Biometrics

Introduction & Topics



Setting the Scene

Key Inputs

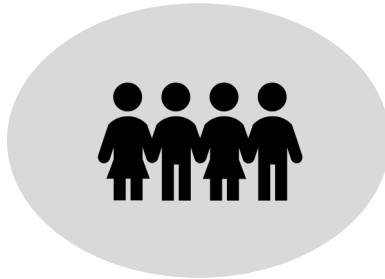


Selected Interim Deliverables

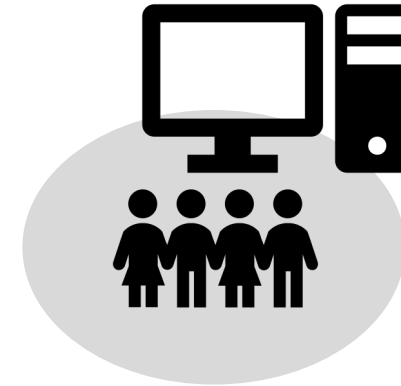


Final Outputs

Study Protocol
Study SAP
Data standards
Integrated SAP
Domain SME



Re-use code & description
LOT + Data Specs + A&R specs
Study code: re-use; tweak; custom
Validate data & analyses
eSub documentation



Study SDTM/ADaM
Pooled/Integrated data
Statistical Results & TFLs
Data for downstream re-use
Submission data & docs

Mentally combine all inputs
Manually re-use info & draft
Manually review & send feedback
Manually assess impact asses & fix
Manually notify downstream

Manually Configure SCE
Manually find + ensure valid code
Manually schedule/launch jobs
Manually QC outputs
Manually publish datasets

Historically ...

Process flows are hyper-dependent on SMEs

If SMEs unavailable → progress halts

If increase in work volume → scale SMEs

Even technologies & data flows were dependent upon SMEs

Popular technologies evolved from calculators ...

- Not tackling burdensome upstream & downstream tasks
- Adding manual steps to “imbed” in broader workflows
- Creating new logistical burdens on SMEs
- Speeding processing times ... not helping delivery times

PHYSICAL BURDEN ON SMES ALMOST ALWAYS INCREASED
MENTAL BURDEN ON SMES ALMOST ALWAYS INCREASED

Helpful to accelerating results ... submitting sooner ... easing burden ...?

Where to “Digitally Intervene”

Key Inputs

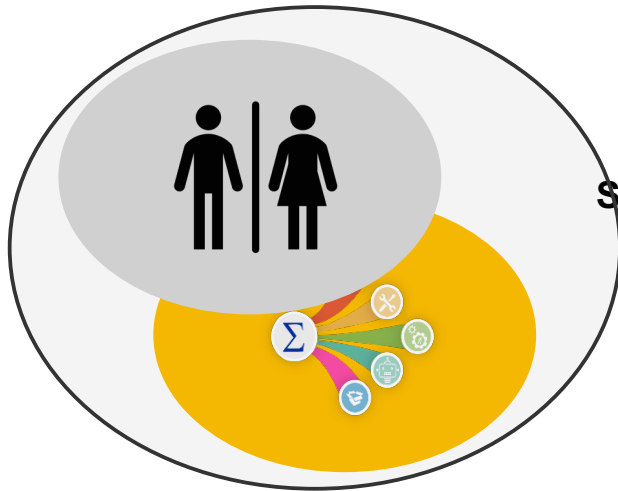


Select Interim Deliverables

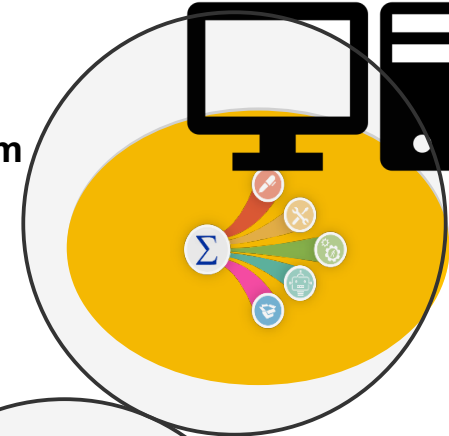


Key Outputs

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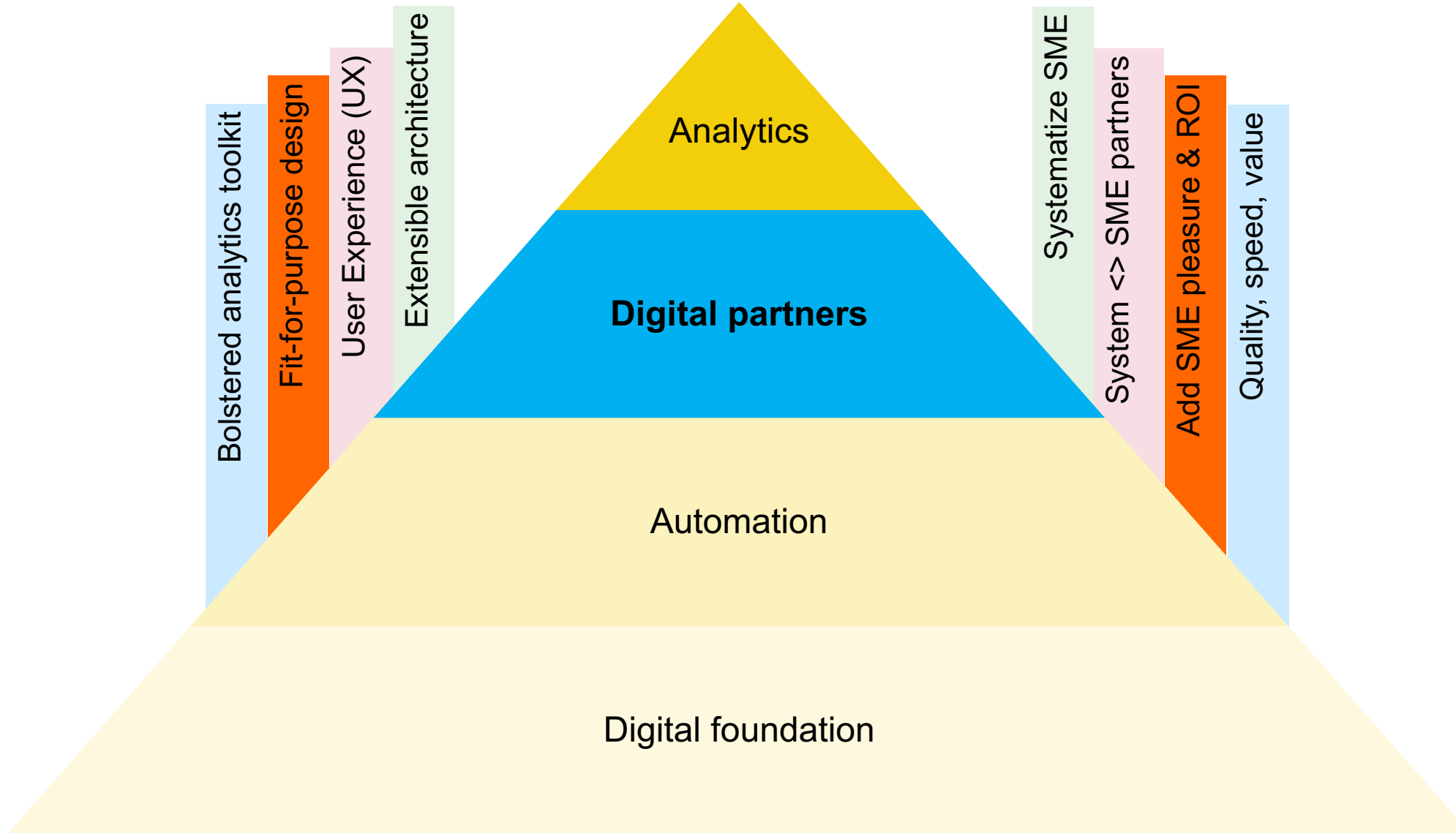
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Pooled/Integrated data
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Data for downstream re-use
Submission data & docs

AI/ML combine all inputs
AI/ML generate drafts/suggestions
AI/ML + Manually review & send feedback
Auto assess impact & suggest fix
Auto notify downstream

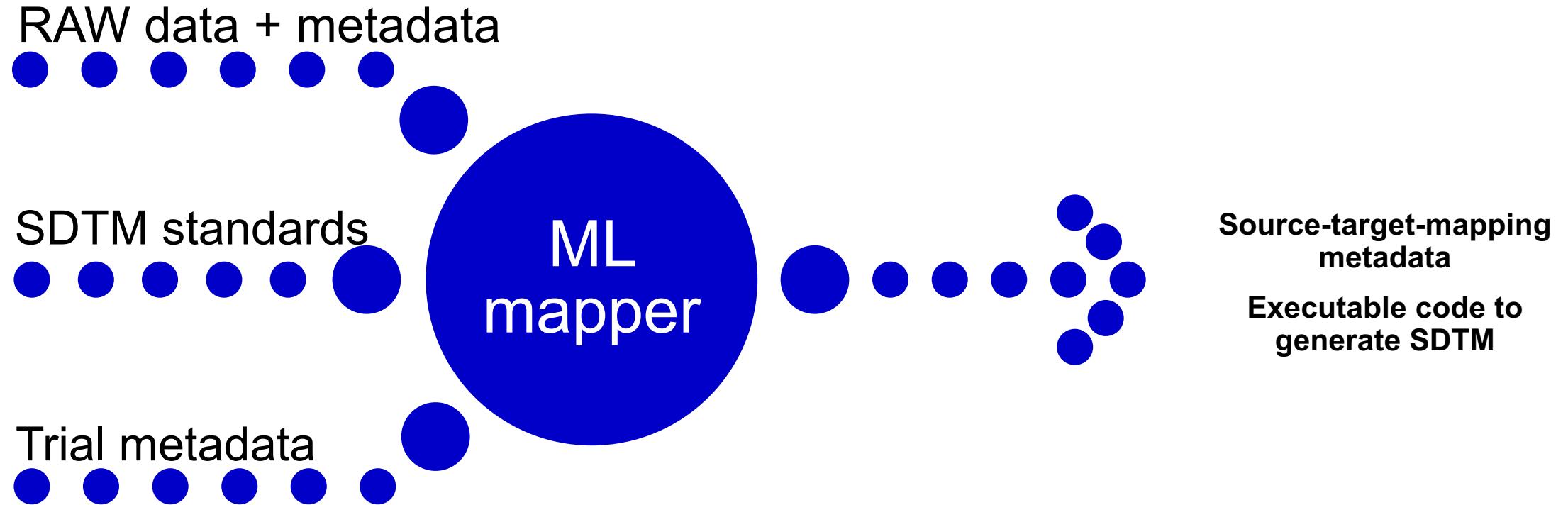
Auto Configure **SIGMA**
AI/ML find + **Manually** ensure valid code
Auto schedule/launch jobs
AI/ML QC outputs
Auto publish datasets

Breakthroughs that
change patients' lives

How to “Digitally Intervene”

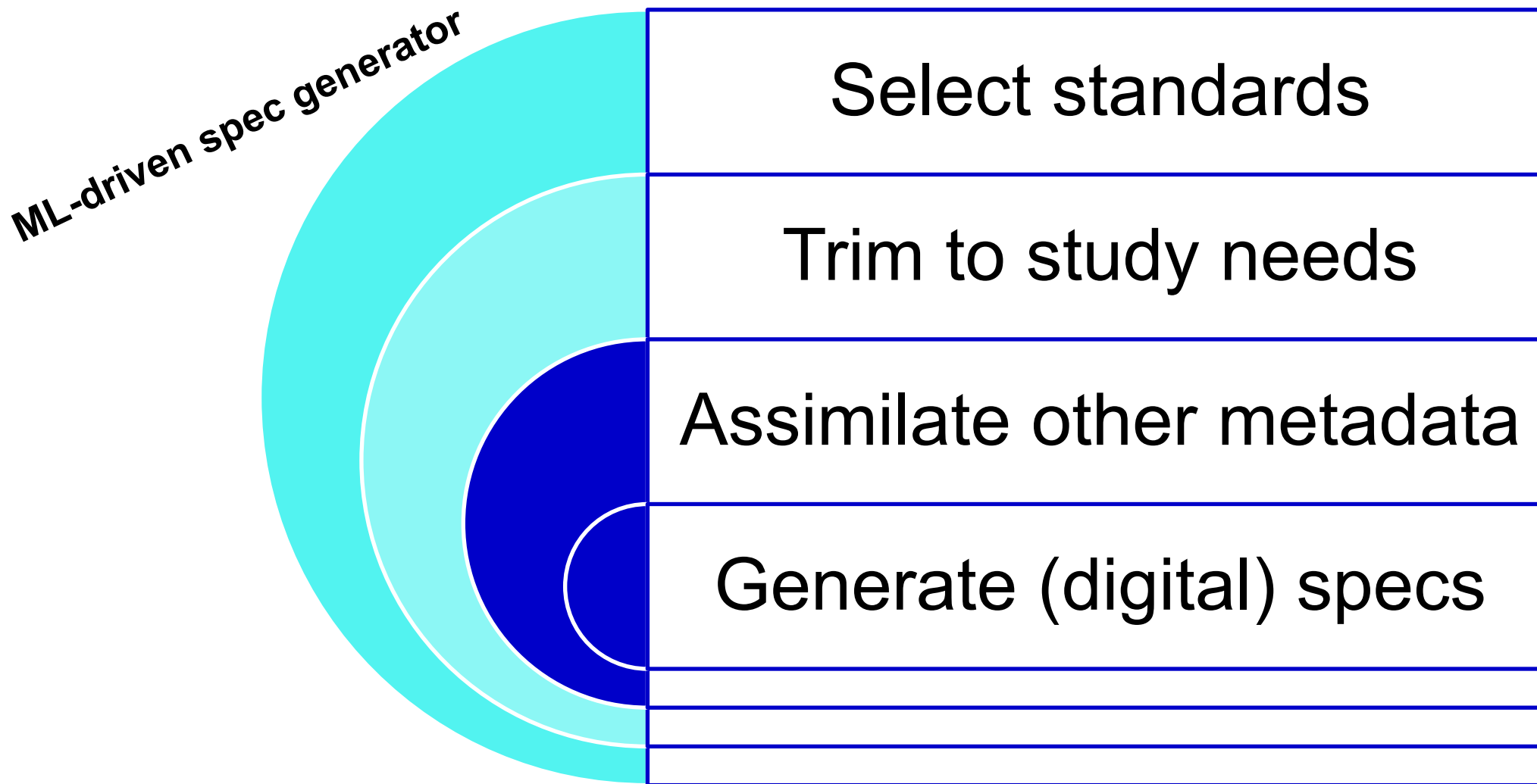


Digital Partner #1 for A&R SMEs





Digital Partner #2 for A&R SMEs



— Digital Partner #3 for A&R SMEs

Unblinded BOT ...

Certain study personnel are firewalled from blinded data prior to breaking the blind

Can postpone some operational activities or create risk for unintentional unblinding

A BOT can execute tasks against blinded data **if it outputs safe info**

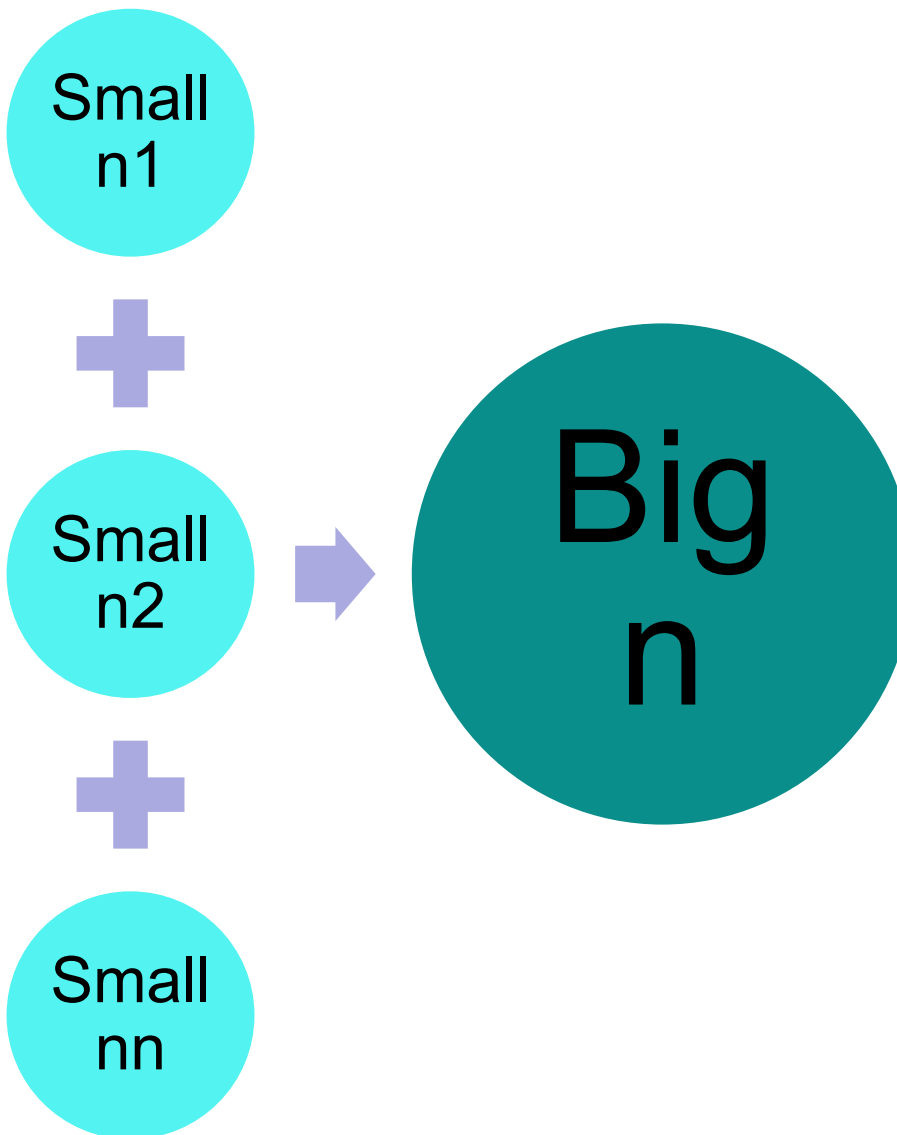
Example use-cases:

- Comparing success of code vs blinded data compared to code performance vs unblinded data
- Performing analytics against blinded data to assess statistical methodology assumptions sooner
- Enable A&R work currently done by a firewalled analysis team ahead of a DMC
- Automate triggering of a DMC based on thresholds defined in the SAP after automating that A&R work
- Enabling AI/ML work on blinded data

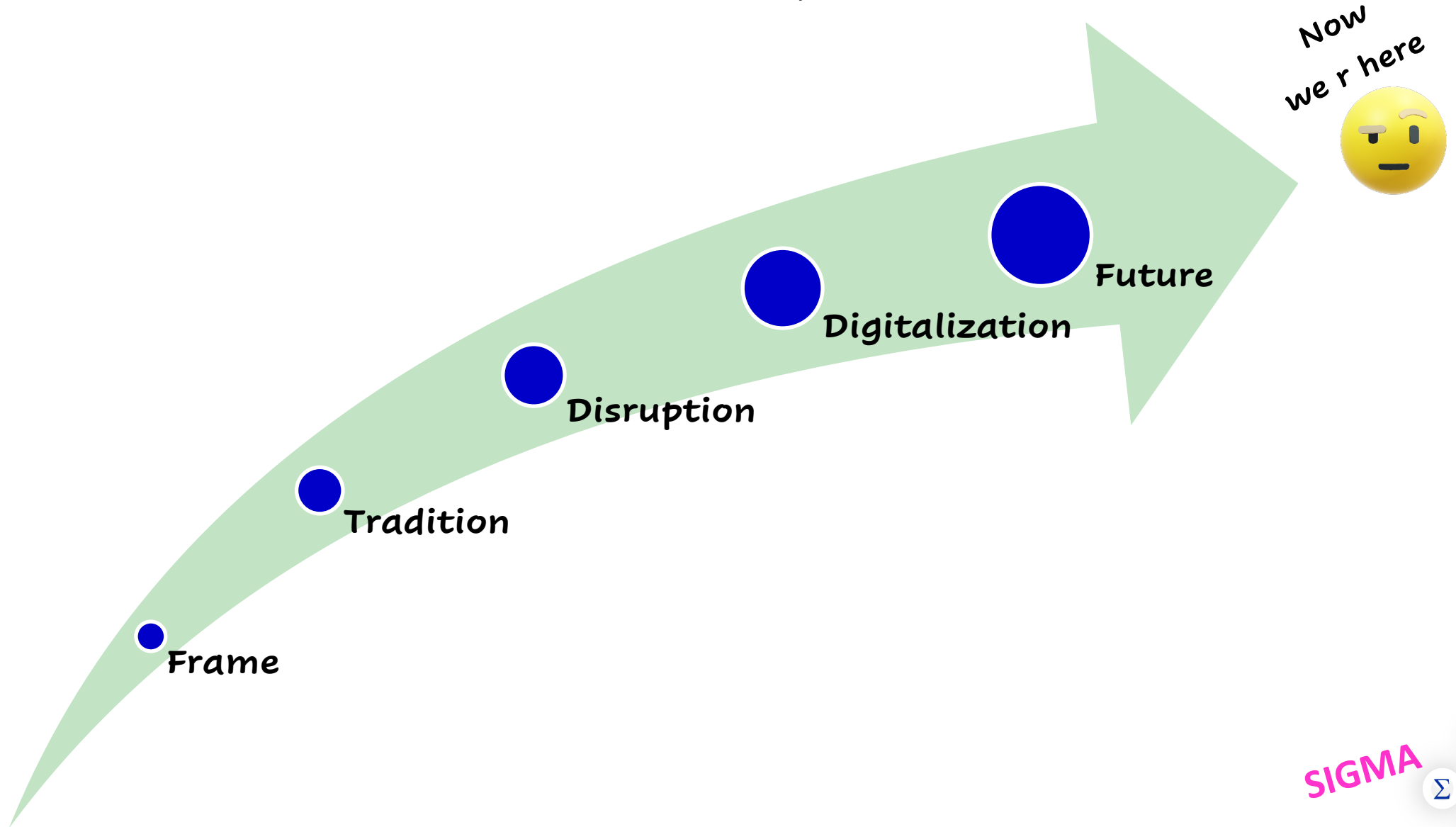


Digital Partner #4 for A&R SMEs

ML-driven Quality checking



Summary



Thank you



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