

SIGMA

Digitalizing the Analysis & Reporting Space



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Surprise!!

Threading the needles of value

Journey from “Stats Computing Environment” to “Smart Informatics & Analytics Ecosystem”

Where AI will be imbedded in workflow delivering Stats results & insights

How AI will be applied ... what it will deliver for us

Status, next steps, etc.

Pop Quiz ...

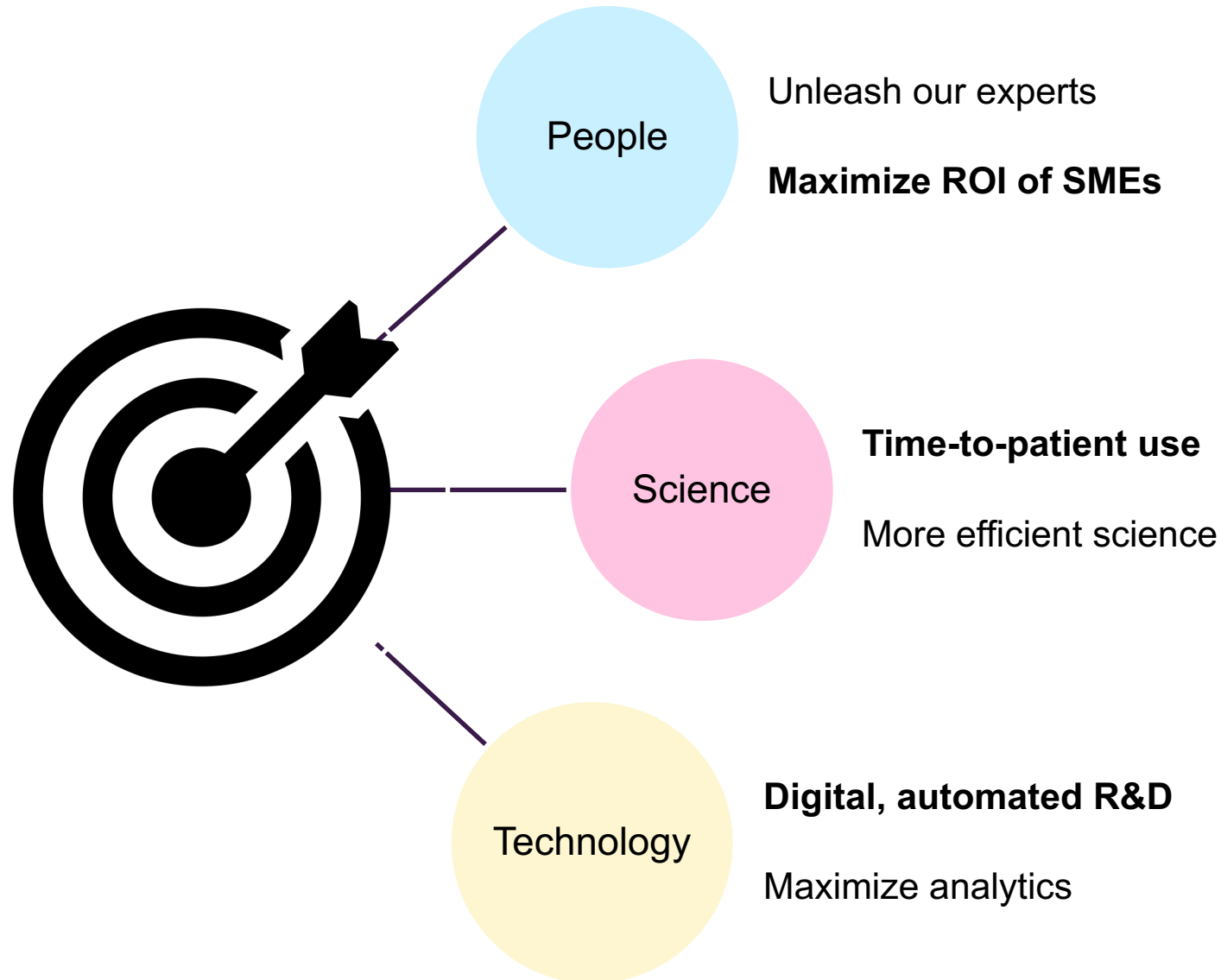
From analog form **to** digital form, without
changes to the process itself ...
think **from** vinyl **to** mp3

**Computable
Processes**

What is the **key** Δ between “**digitizing**” & “**digitalizing**?”

From current tasks & methods **to** re-engineered tasks & methods,
uniquely enabled by digital technologies & *digitized info* ...
think **from** schlepping to the record store **to** downloading via iTunes

SIGMA: Corporate Goals (**Bold Moves**) and Our **Strategy**



Database information

Expand information/metadata

Digitalize processes

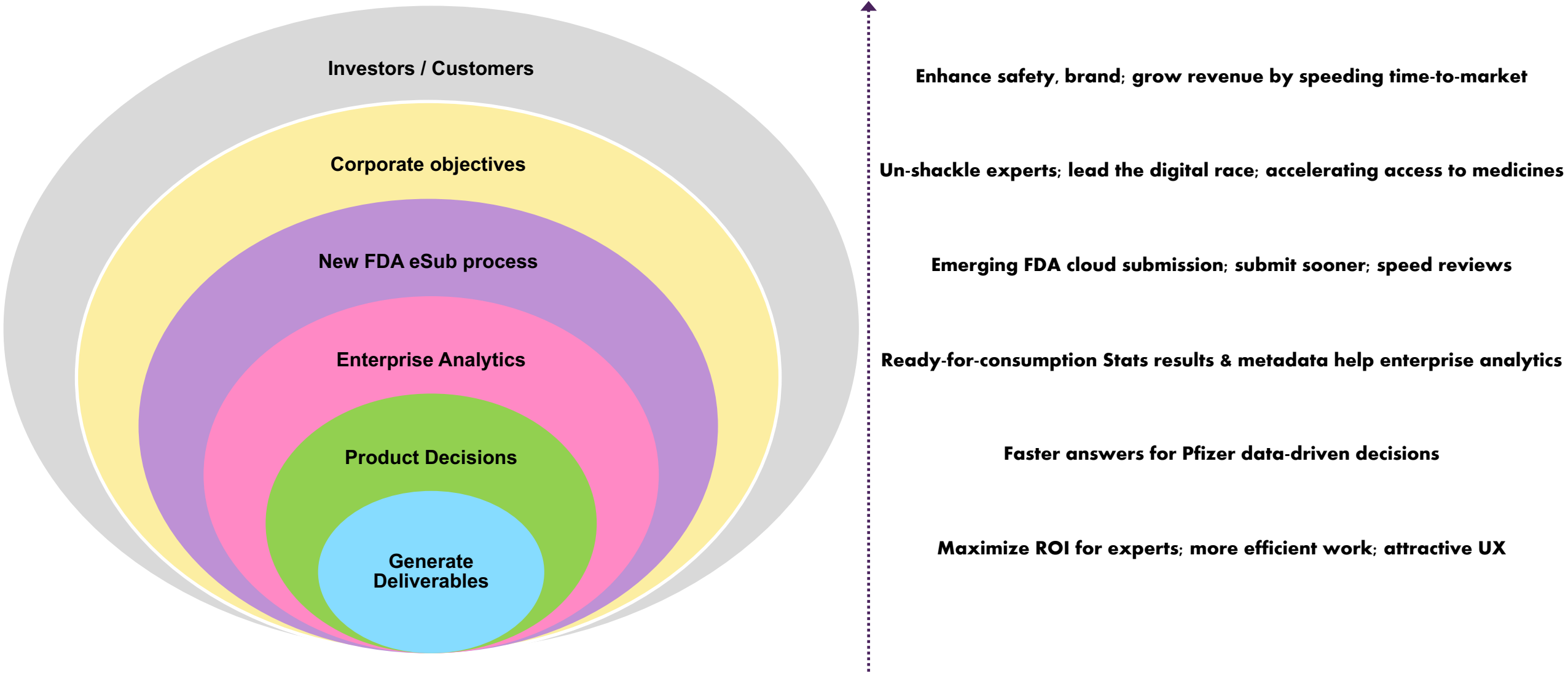
Informatics-based UIs & UX

Technology as hands & feet

Technology as thinker

Technology as memory jogger

SIGMA: Layers Of Impact From Our Strategy



SIGMA: Digitalizing In The Analysis & Reporting Space

Can see / verify data
Can see / verify logic
Can automate job execution
Can directly reproduce outputs
Can integrate into CDF
Can control, persist data
Can control, persist artifacts
Can auto-generate metadata

Can see / verify data
Can see / verify logic
Can automate job execution

Can see / verify data
Can see / verify logic
Can automate job execution
Can directly reproduce outputs
Can integrate into CDF

Can auto-draft specifications
Can see / verify data
Can see / verify logic
Can automate job execution
Can directly reproduce outputs
Can integrate into CDF
Can control, persist data
Can control, persist artifacts
Can auto-generate metadata

Can see / verify data
Can see / verify logic
Can automate job execution
Can directly reproduce outputs
Can integrate into CDF
Can control, persist data
Can control, persist artifacts
Can auto-database stat results
Can AI-select applicable standards
Can AI-draft specifications
Can AI-quality check outputs
Can auto-generate much metadata
Can show lineage / quality
Can auto-build submission info

User-experience

Automation

Automation
+
AI/ML



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SIGMA: Foundational Business Concepts

What to make

Define

How to make

Code it

Do

Generate it

Manage it

Depot

(Re-)Use it

LOTs

SDTM specs

ADaM specs

Analysis specs

Reporting specs (mocks)

SDTM data

ADaM data

Stat analysis results

Stat reports

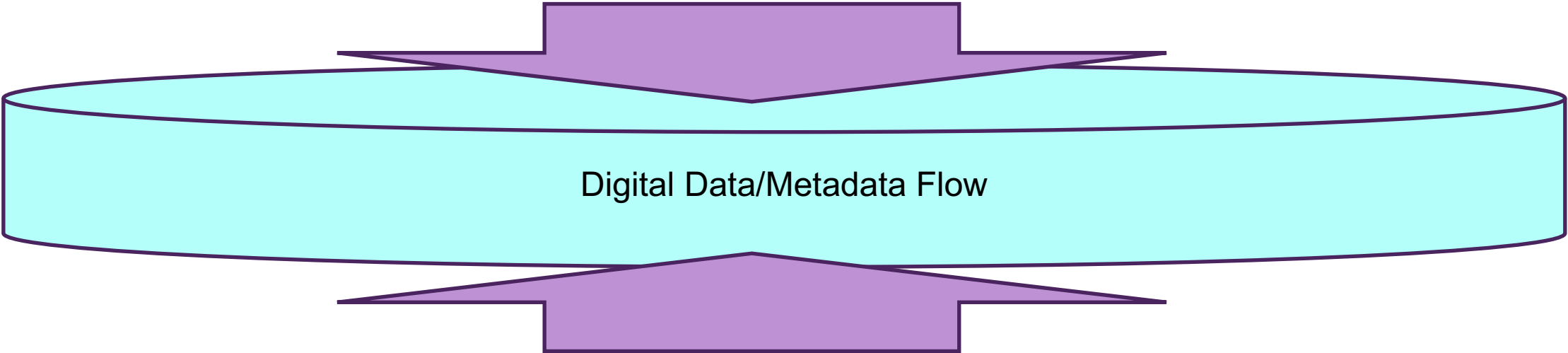


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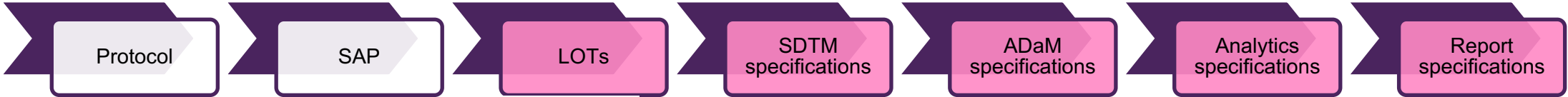
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SIGMA: AI-driven Creation of Key Study Deliverables

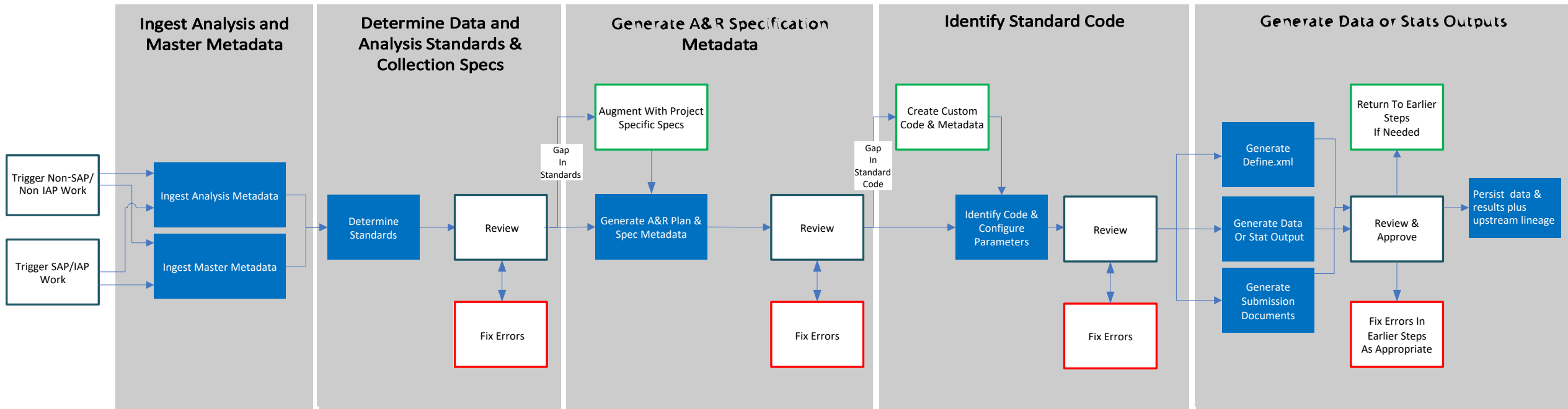
Standards



Specifications



SIGMA-enabled Workflow for A&R Generation



Inherent variability → automation will not – CANNOT – significantly remove demand on SMEs

AI / ML → baseline expertise ... grow over time ... sooner learning starts, sooner it becomes “smarter”

Reality → AI / ML will yield drafts/suggestions ... SMEs will vet ... feedback loop pirates info from QC of outputs

Completed hackathon to AI-identify DM data queries

Completed hackathon to AI-draft study build documentation – including LOTs

Planning hackathon to AI-select standards for a study, configure them to yield specifications

POC databased analysis results

Defining AI apps that leverage our “open architecture” concept

Heading to RFP (05/2020)



AI-generate code

AI-verify specs-through-outputs

AI-identify safety risks ... then generate insights to assess them

AI-identify drug combinations that identify new patents or markets

AI-identify data distributions

AI-assess statistical method assumptions

AI-derive logical mappings by reverse-engineering input data & corresponding results

AI-identified sub-groups or sub-group influencing characteristics