

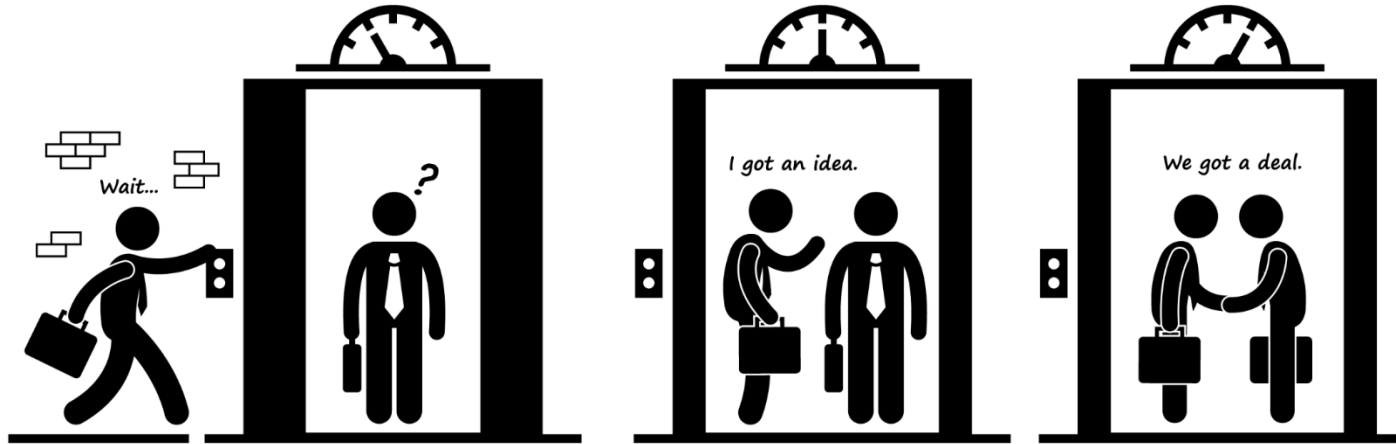
SIGMA

Going Digital in the Analysis & Reporting Space



Information & Analytics To Power the Right Decisions, At The Right Time, For The Right Customers

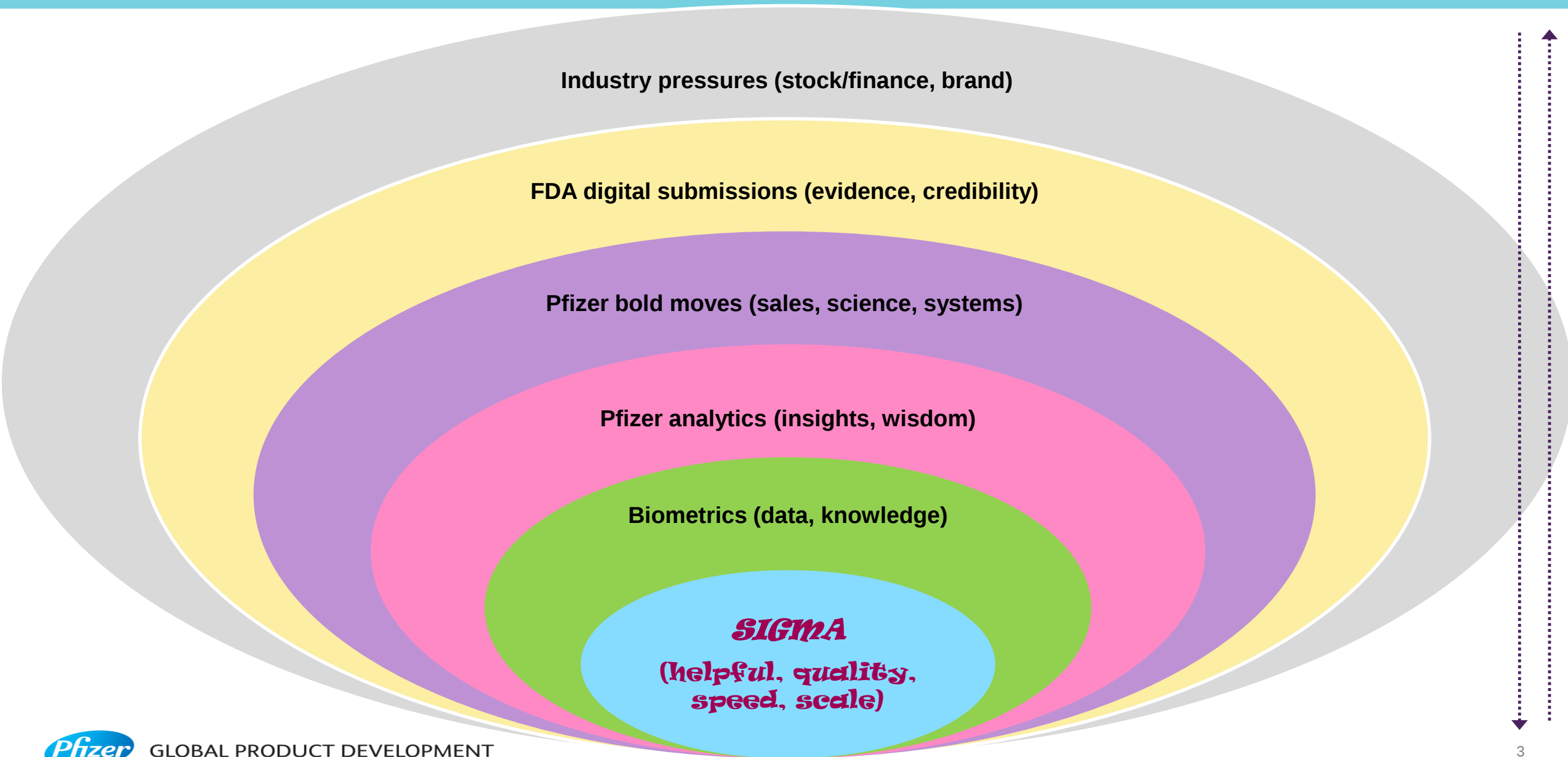
SIGMA Vision ... In An Elevator Speech



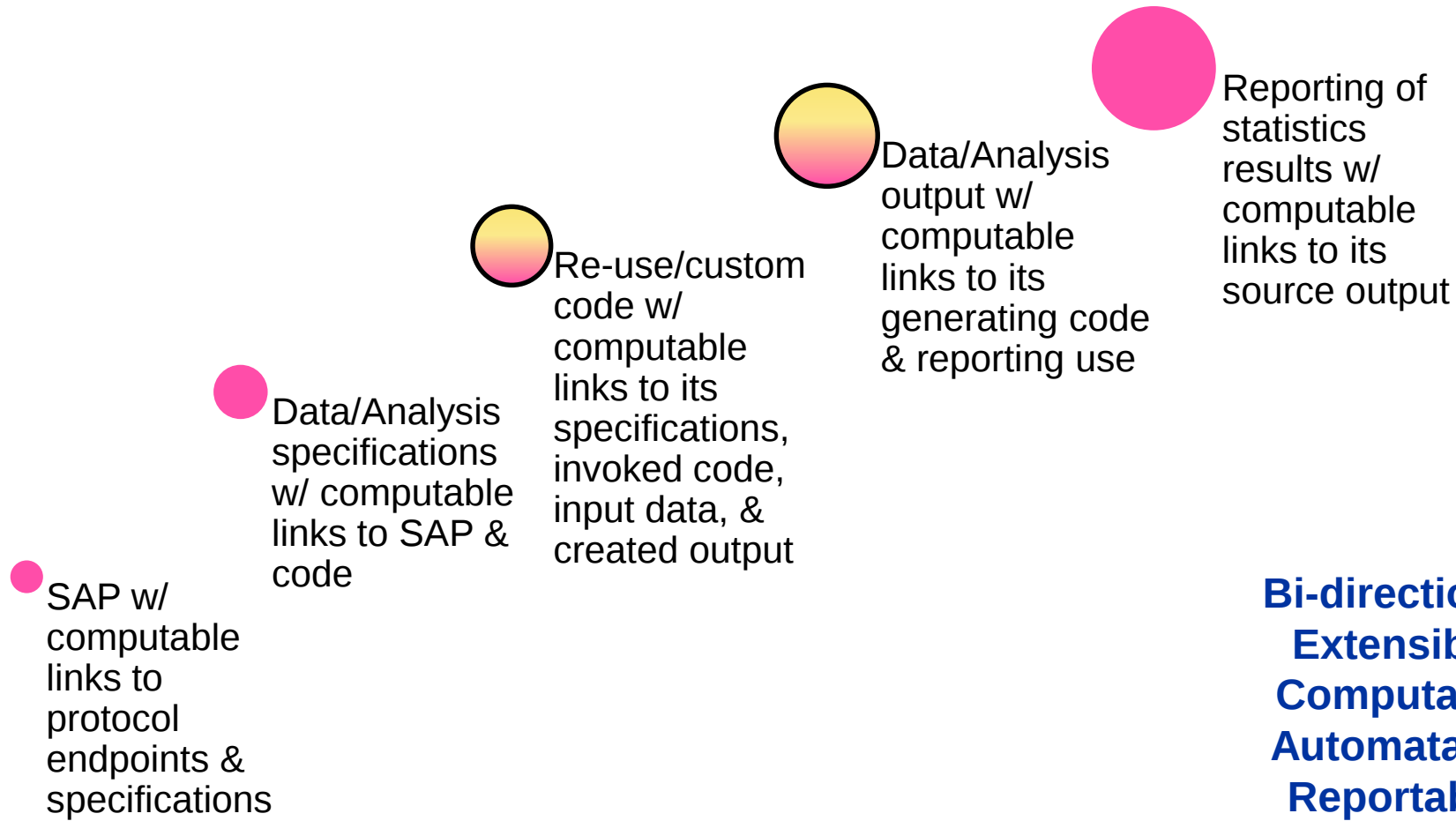
To be Pfizer's *strategic informatics engine* for clinical analysis & reporting—

Digitalize up-stream ... speed results ... accumulate submission evidence

Why **SIGMA**: Let Me Put This In Context



SCE vs. SIGMA: Improve Current Scope, Then Expanded It



**Bi-directional
Extensible
Computable
Automatable
Reportable
Re-usable**

Key Guiding Principles for SIGMA

Maximize ROI of our experts

Re-engineer A&R generation & expand scope of work digitized

System-generate & store linked metadata

Automate & apply AI/ML where able, when able

Modernize architecture & use elastic/cloud technologies

Accumulate metadata prospectively, not harvest / collect them at the end

“Summing-up” The “Legwork” SIGMA Will Take From Me

Today—the SCE-enabled **current-state**—you manually:

enter ... seek, find, fix ... identify ... populate ...

reference ... track ... fill-out & submit ... provide ...

coordinate & enforce ... find & record ... copy & paste

Tomorrow—the SIGMA-enabled **future-state**—you will manually:

approve ... augment ... adjust ... override ... query ...

visualize

Scope/Example deliverables:

protocols ... LOTs ... SAPs ... eCRFs ... SDTM standards & specs ... ADAM standards & specs ... delivered
data sets ... analysis standards & specs ... analysis results ... CSR messaging

Capturing & Making Stat Results Electronically Available

~~Stat output (TFL)~~ = **stat analysis results** + ~~display formatting~~

Current pain:

Most painful part of coding is the display formatting

Least automatable part of coding is the display formatting

Biggest delay to availability of usable results is the display formatting

Future remedy:

Send results to a **results database** to persist

Semantically **link those results, their input data, & corresponding metadata**

Enable direct **access, export to file, render hardcopy**

How Do I Get Displays/Reports For CSRs, Posters, Papers?

~~Stat output (TFL)~~ = ~~stat analysis results~~ + **display formatting**

Design:

CAD/CAM-like **graphical design** enables **WYSIWYG**

Generates & persists needed **metadata** to describe

Display **designs persisted** as “templates,” (re-)used when needed to render

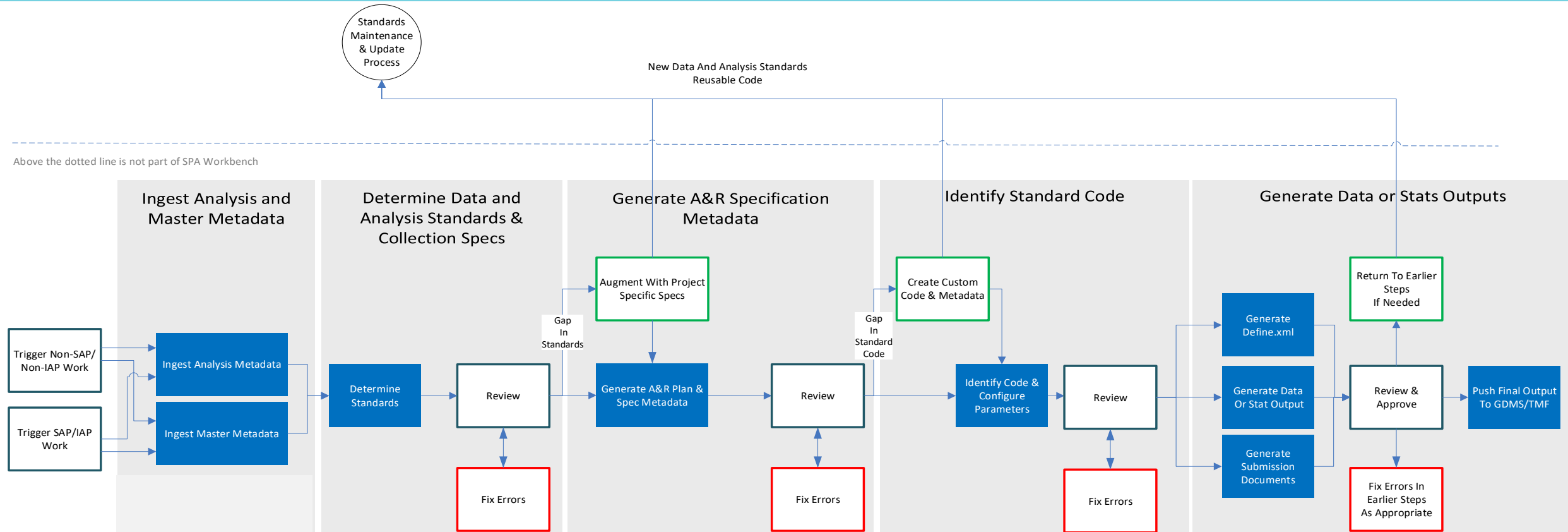
Render:

Reference saved display designs

Generate new ones, as needed

Render to file/hard copy

SIGMA-enabled Workflow for A&R Generation



The more standards, the more standardized, the more automatable, the quicker/quality outcomes

Enables organic growth of standards, standardization, & automation/AI

SIGMA Business Value Overview

Scientific / Operational impacts:

Operational cycle-time reduction & risk mitigation
Availability of scientific information
Automation targets as we “go digital”

Financial impacts:

Reduction in operational spend
Generation of additional revenue

FDA / Submissions impacts:

- Necessary for FDA’s future digital submission process
- Necessary for Pfizer’s future submission timeline targets

