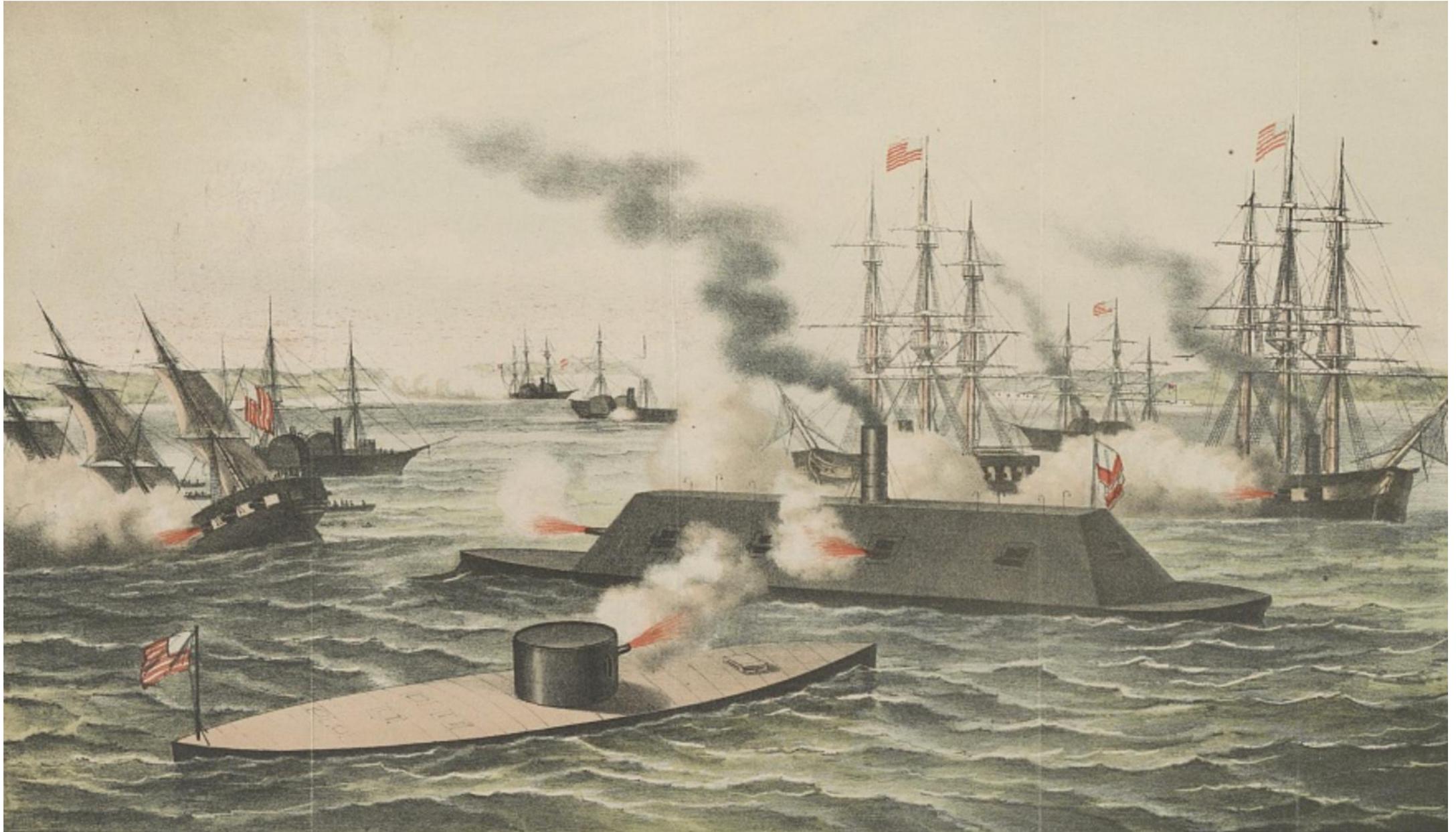


No AI Without Architecture: FHIR as the Data Foundation

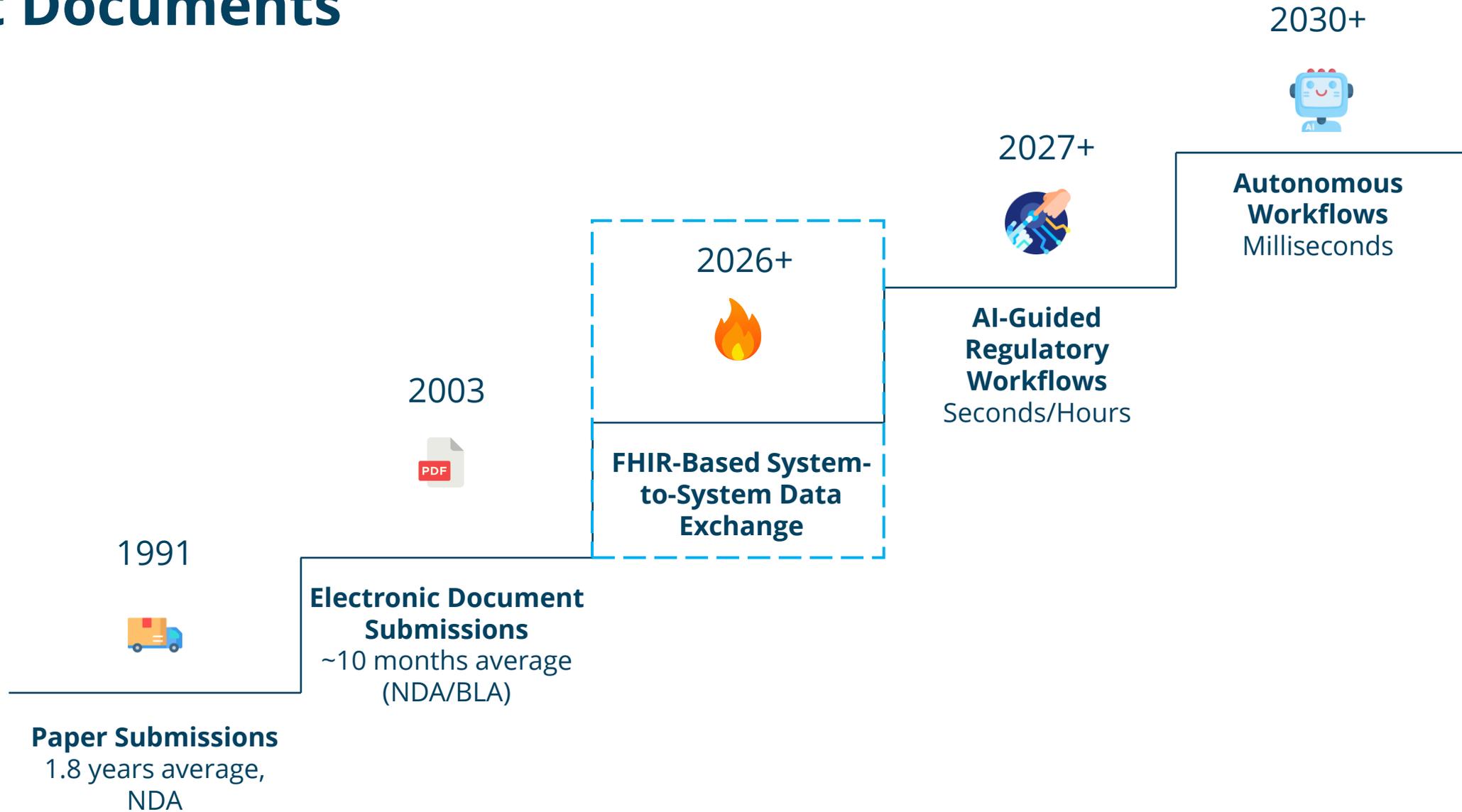
Kåre Hyttel
Director, NNIT

nnit





Regulatory Success Is Now Measured in Time, Not Documents



Technical Submission Errors Create Strategic Delays

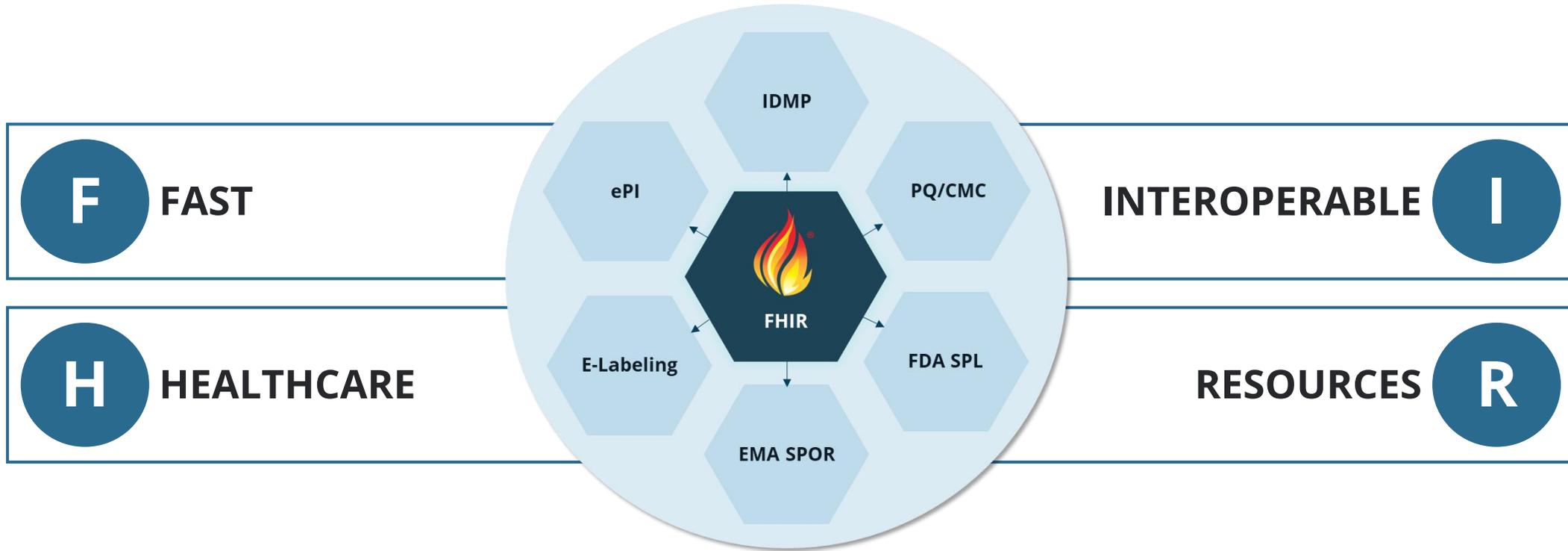
“21.6% of FDA submissions fail due to technical errors – resulting in costly delays. For rejected applications, the median approval delay is 435 days.” (FDA, 2019 | PubMed, 2014)

Illustrative \$500M/Year Product



FHIR Is Not the Goal – It Is the Control Layer

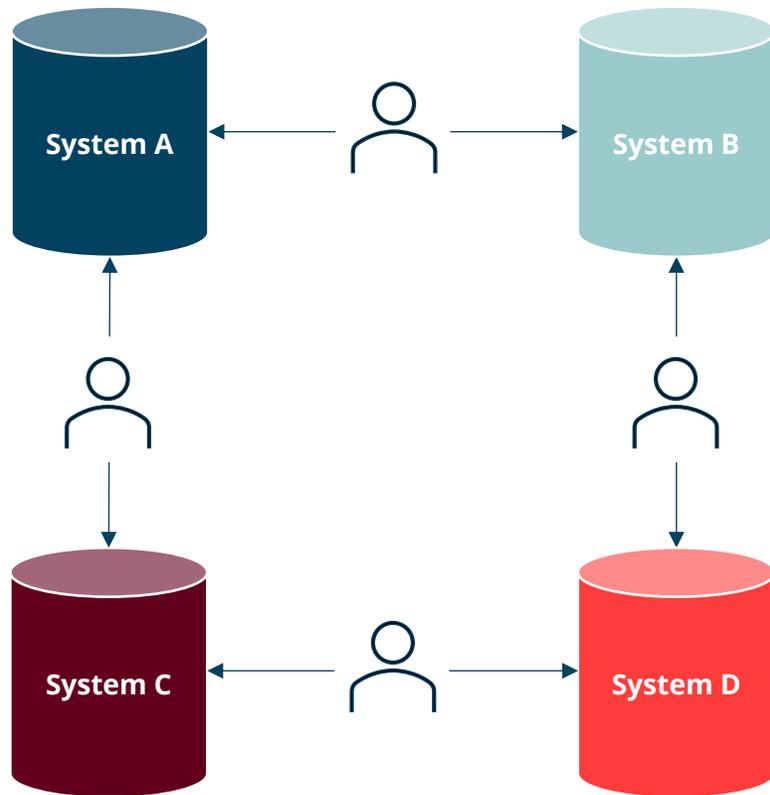
A shared semantic foundation that governs CMC data across systems



Document-Centric Processes Fail at Scale

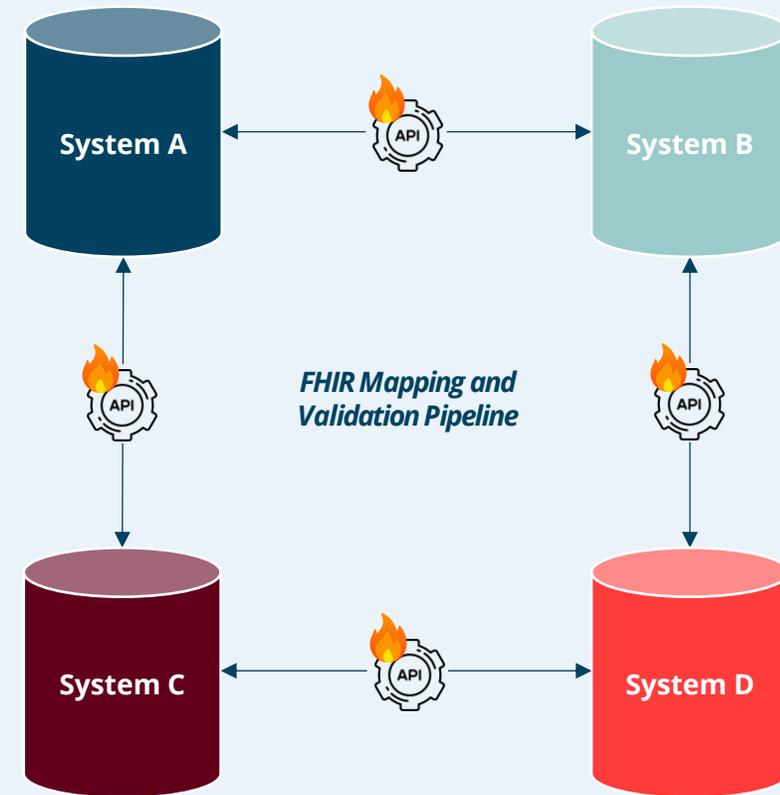
Document-Centric Workflow – Current Challenge

Each system operates independently, forcing humans to manually reconcile data across systems.



FHIR-Semantic Contract

Data moves system-to-system. Validation replaces reconciliation. Each update is trusted by design.



From Locked Documents to a Governed, Semantic Contract

Document-Centric Workflow

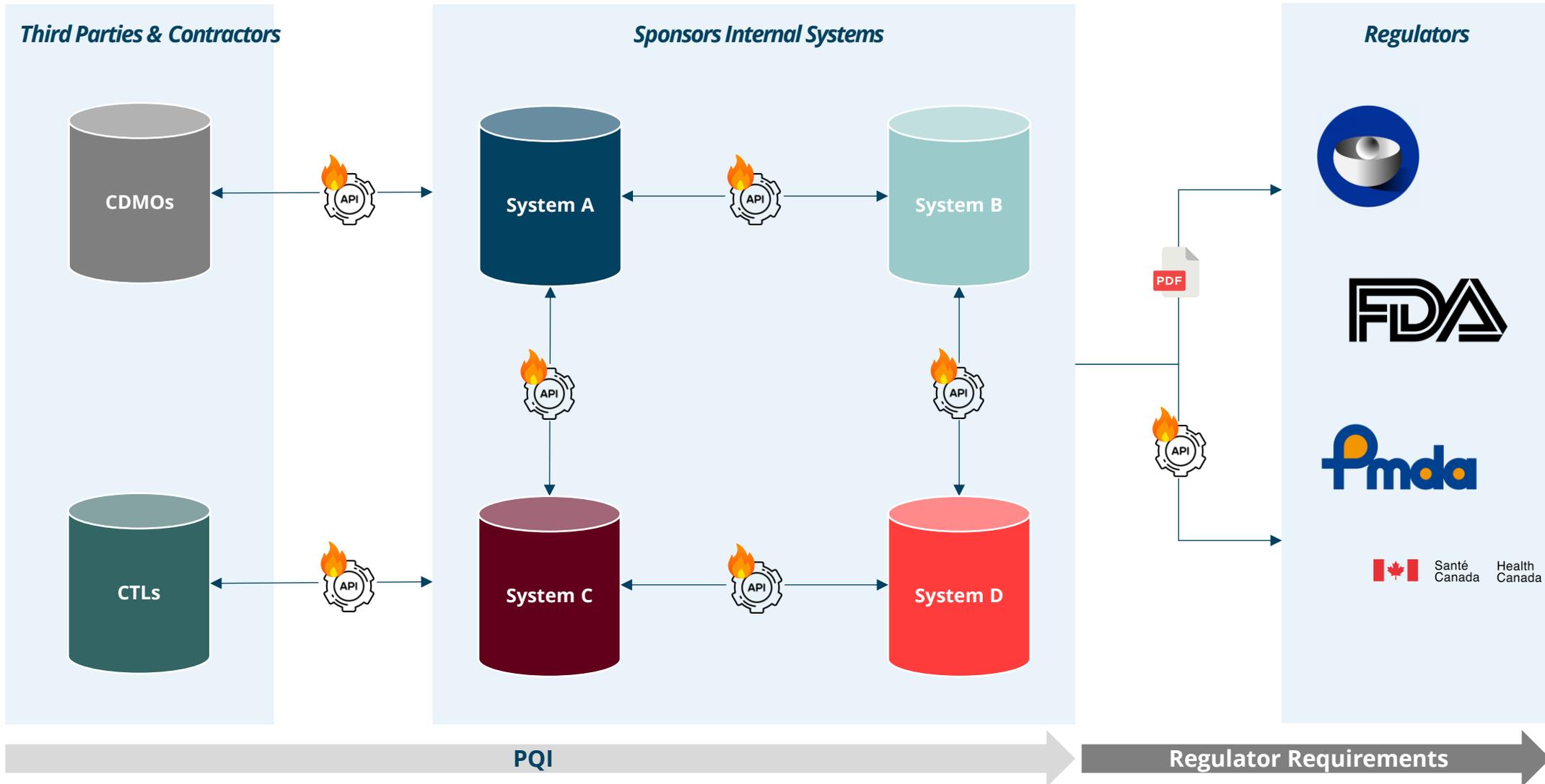
Structure	Unstructured narrative documents
Validation	Late-stage, manual review
Traceability	Manual, document-level reconciliation
Compliance	Manual, retrospective QA

FHIR-semantic Contract

Structure	Machine-Readable Resources
Validation	Point-of-creation automated validation
Traceability	System-to-system, continuous lineage
Compliance	Automated, cryptographically verifiable audit

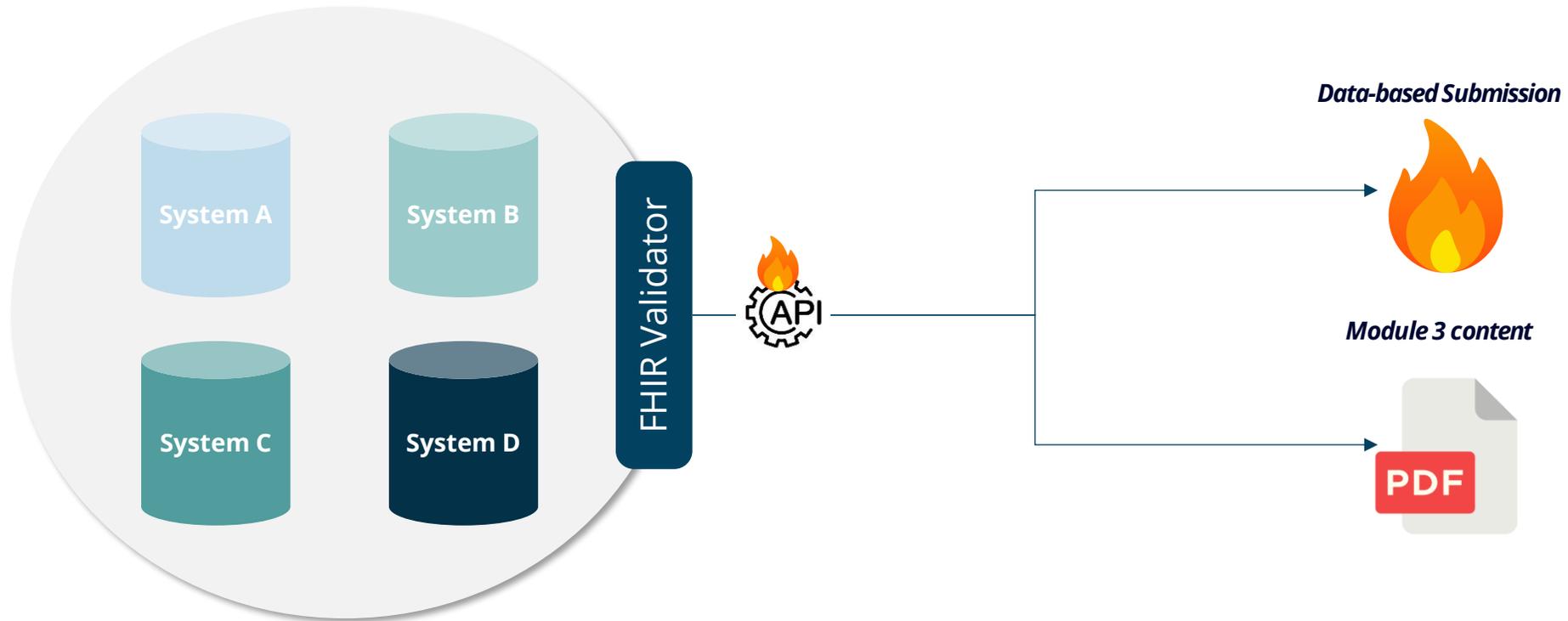
PQI: The Operational Semantic Model for CMC Data

FHIR PQI Defines the Operational Data Layer Required for ICH Q12 and SPQS



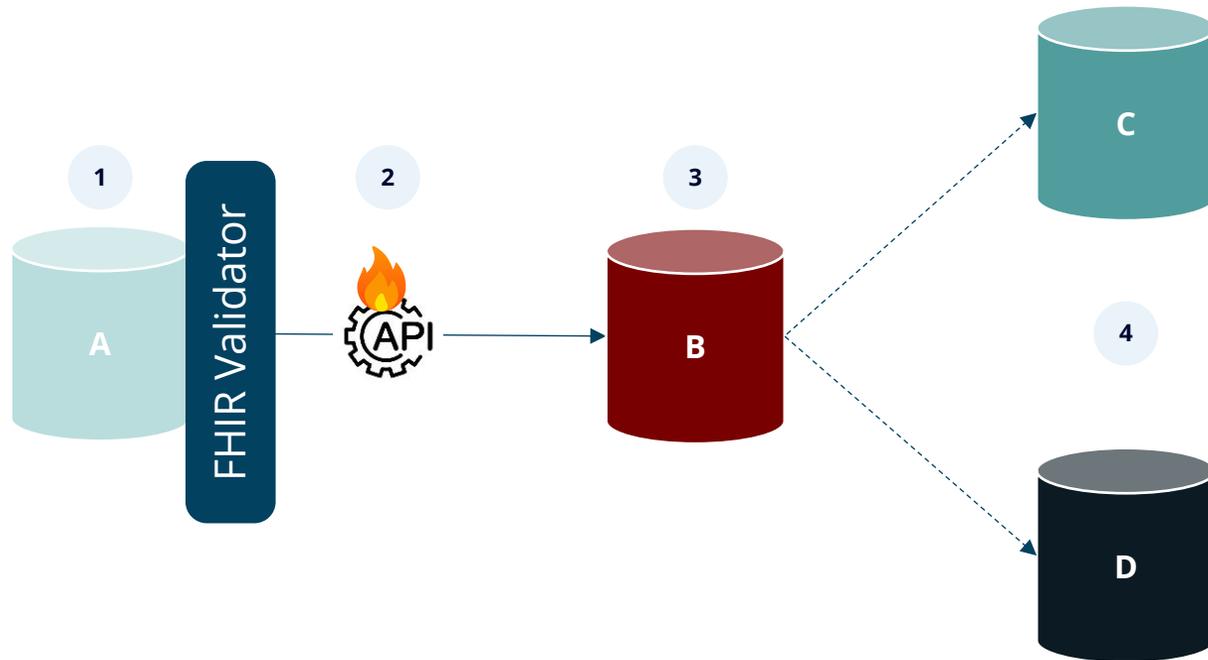
Case Study #2

Submission Content Is Assembled – Not Authored



Case Study #1

When CMC Data Changes, Every System Updates Automatically



- 1 A regulated CMC attribute changes at the source
- 2 The change is validated and normalized into FHIR
- 3 Downstream systems receive the same trusted update in real-time
- 4 The pattern scales across all internal and external systems as needed

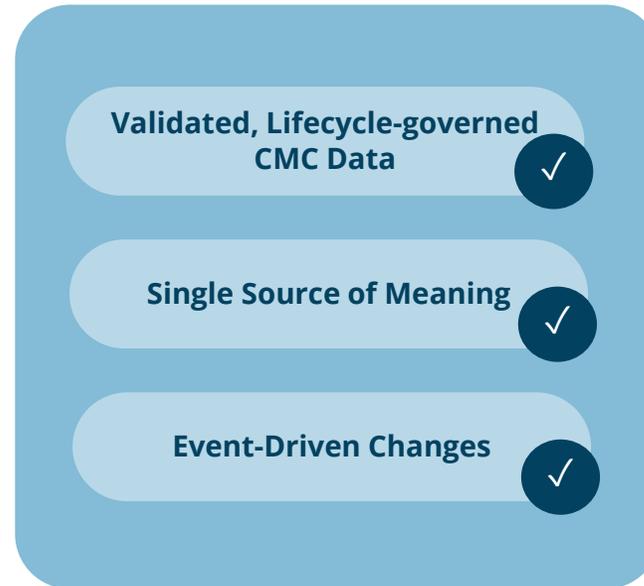
AI Is Safe Only When Architecture and Governance Is Trustworthy

FHIR makes AI inspectable, constrained, and therefore trustworthy – this is what ICH Q12 needs to work in practice – and what SPQS assumes exists before submission.

Governance & Compliance Layer



FHIR Semantic Data Layer



AI Execution Layer



The future is NOT written in narrative...

It is built in data