

About the Presenters



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With nearly 30 years in the pharmaceutical industry, Bill has led large-scale digital transformations, optimizing R&D and IT operations to streamline clinical and biometrics functions. He has worked with nearly all the top 50 pharmaceutical companies and CROs, driving measurable business impact. His expertise lies in innovation, operational efficiency, and leveraging technology to maximize value across the drug development lifecycle.



**Sanyogeeta H.
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Experienced Business Analysis leader with 15 years in healthcare informatics and clinical research. Skilled in managing cross-functional teams, translating complex needs into solutions, and driving process improvements.





SPA MDR CDR SCE

RE02

FHIR for RWD Submissions: Why a U.S. Regulation Signals a Global Shift—and What You Need to Do Now

NOV 2025



The Clinical Data
Science Conference

EU 2025

16–19 November
CCH – Congress Center Hamburg



Agenda

Why Now?

The urgency behind FDA's FHIR direction and what it signals globally

The Global Shift

How connected data flows are driving aligned regulatory expectations

Decoding FHIR

What FHIR really means for RWD submissions: mapping, provenance, reproducibility

Readiness & Risk

How to assess where you stand and avoid falling behind

The 12-Month Plan

Practical steps to pilot, prepare, and align leadership

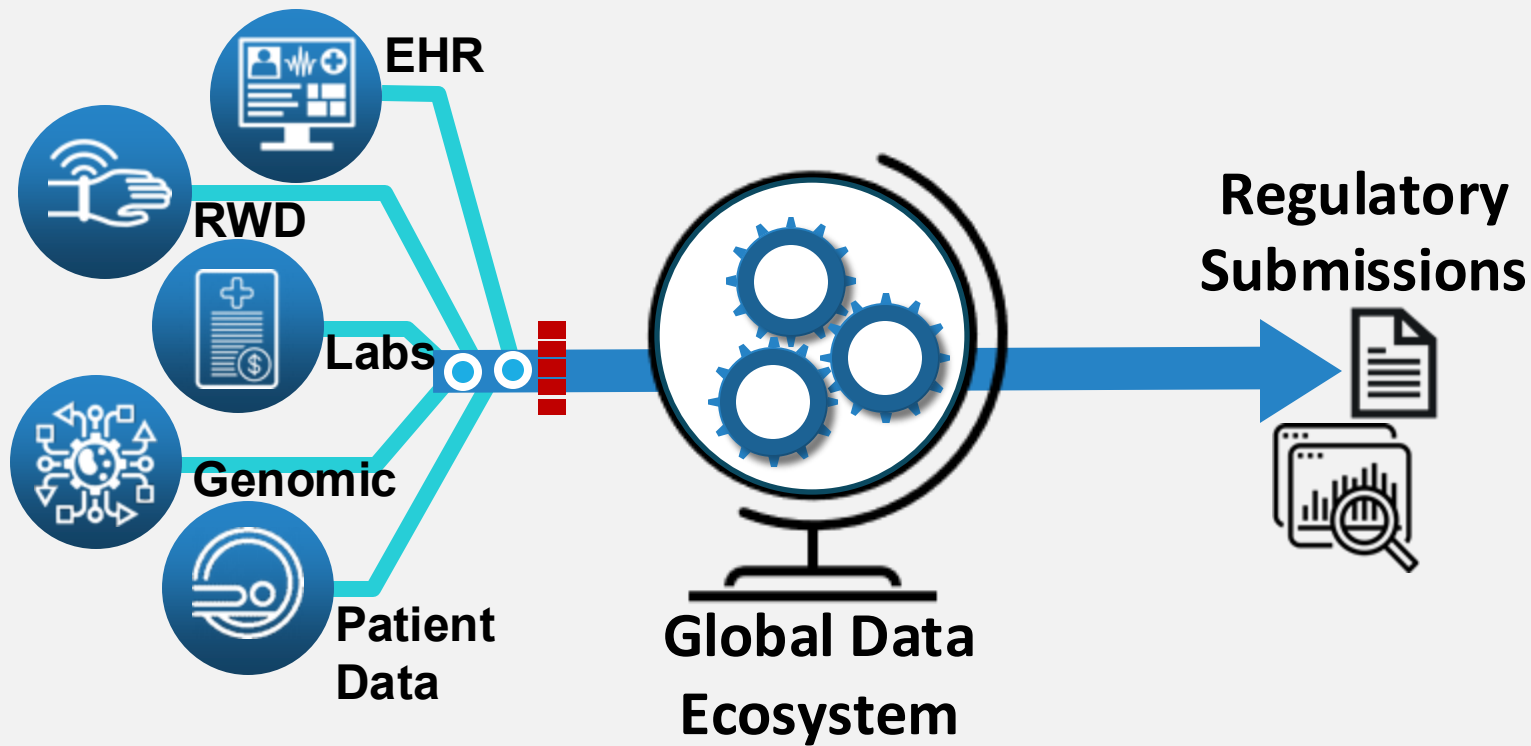
The Call to Lead

Turning compliance into a competitive advantage



Why Now?

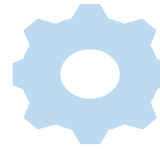
Data Flows Globally - Regulations Will Too



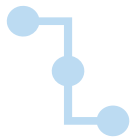
FHIR In Action - Real-World Impact Across Healthcare



Empowering Patients: Apple Health Records uses FHIR APIs so patients can view labs and medications from multiple hospitals — all in one place.



Smarter Workflows: SMART on FHIR apps deliver real-time sepsis alerts and dose calculators directly inside EHRs.



System Connectivity: Epic and Oracle Health use FHIR APIs to enable secure, seamless data exchange across platforms.



Public Health & Research: During COVID-19, FHIR powered real-time reporting and faster patient pre-screening for clinical trials.



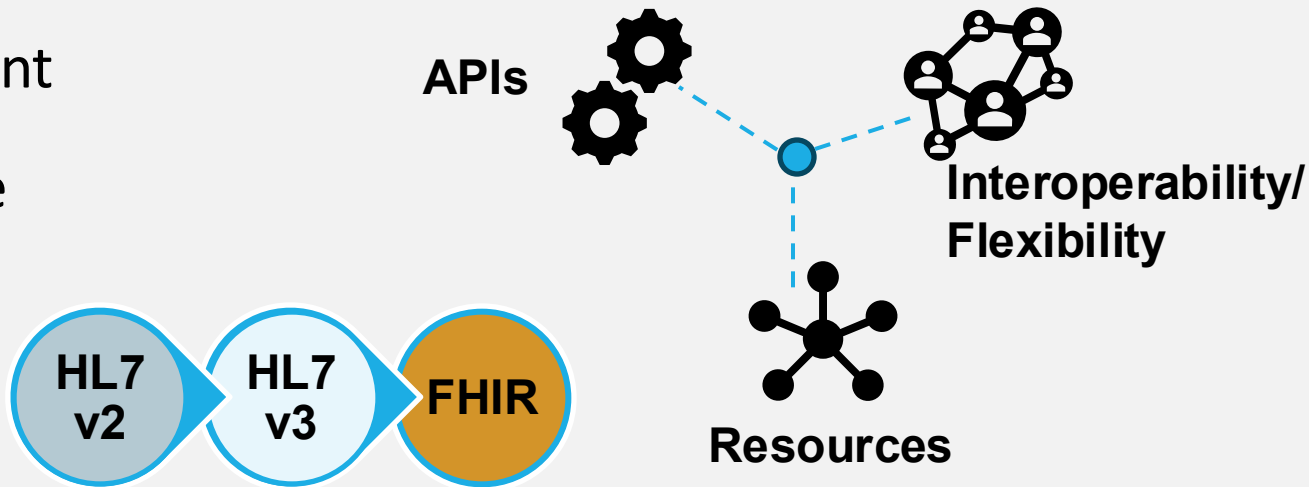
Payer & Provider Efficiency: HL7 Da Vinci and CMS rules use FHIR to streamline prior authorization and open access to claims data.



We're At A Tipping Point

Regulators are signaling that FHIR is the future for real-world data submissions.

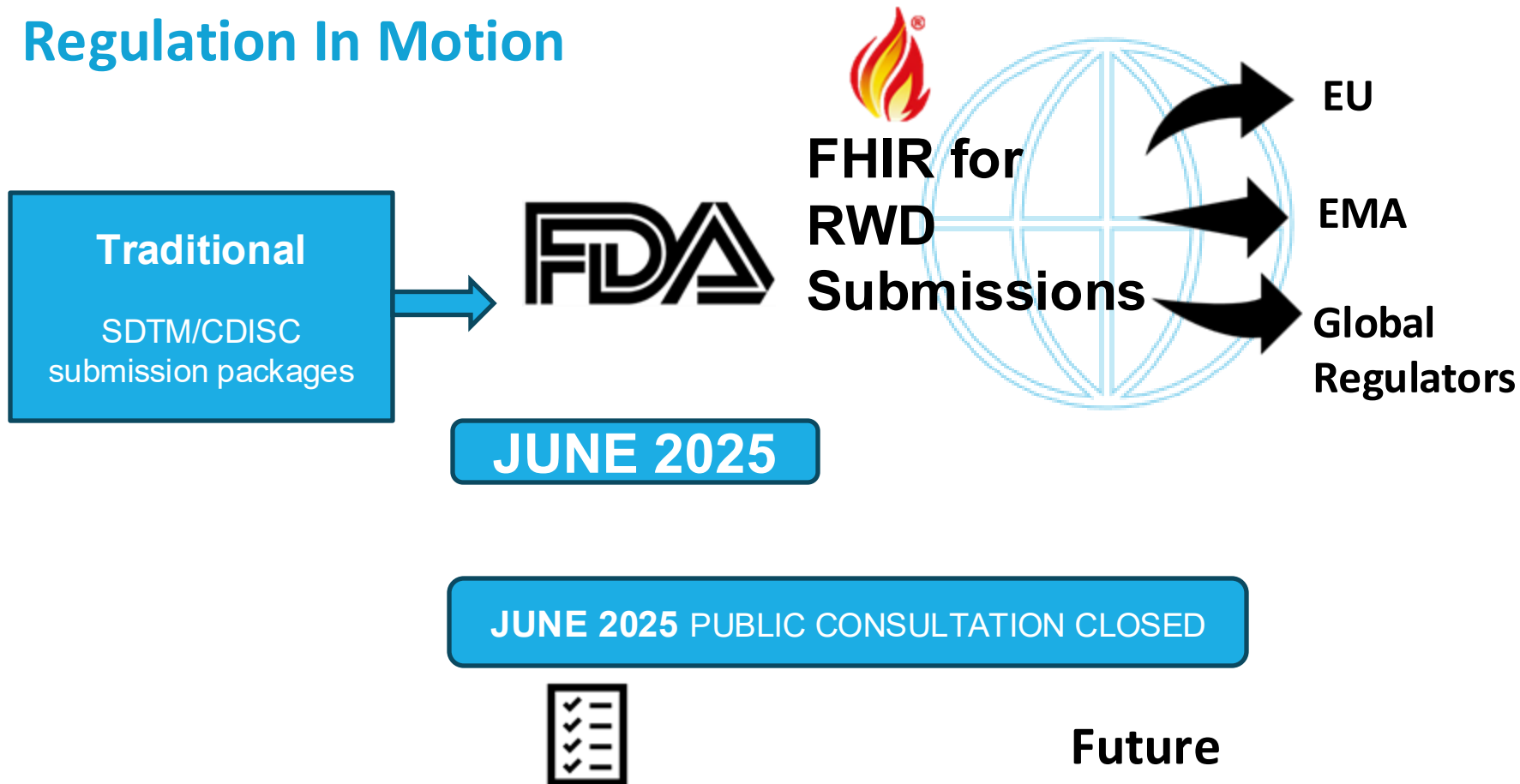
-  Fast to implement
-  Fast to integrate
-  Fast to scale



Early adopters aren't waiting – they are defining the playbook!

The Global Shift

Regulation In Motion

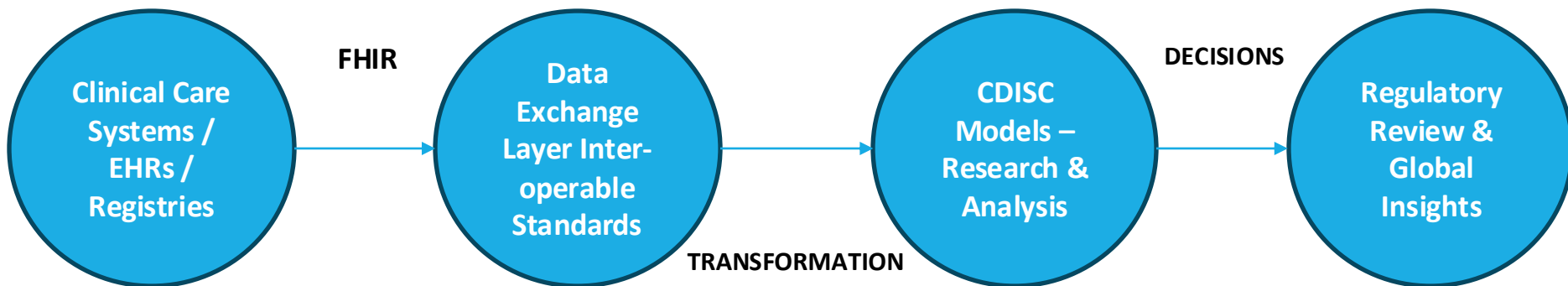


Collaboration In Action

[About](#)[Standards](#)[Tools](#)[Partnerships](#)[Education](#)[Events](#)[Membership](#)

[Home](#) / [Newsroom](#) / New Study Demonstrates Strong Alignment Between CDISC Standards and Alzheimer's Disease Research Data, Highlights Complementarity with HL7® FHIR®

New Study Demonstrates Strong Alignment Between CDISC Standards and Alzheimer's Disease Research Data, Highlights Complementarity with HL7® FHIR®



The Global Ripple Effect – Key Players



Defines the what: the scientific and regulatory requirements for RWD collection and evidence generation. (M11 (CeSHarP); RWE Guidance)



Defines the how (research): the target format for RWD after it has been curated for regulatory submission. (SDTM/ADAM; FHIR to CDISC Mapping)



Defines the how (care): the primary standard for extracting RWD from source EHR systems. (FHIR; Vulcan Accelerator)



Provides the foundational layer of trust, quality, and security that underpins the entire health data ecosystem. (TC 215 (Health Informatics), ISO 8000 (Data Quality))



What's Latest: HL7 Europe Base and Core FHIR Implementation Guide (Draft)

- To make FHIR work smoothly across countries, HL7 Europe has drafted the **Base and Core Implementation Guide** — think of it as Europe's playbook for FHIR.
- It takes a **layered approach** — starting with shared European foundations, then allowing each country or project to build its own specific rules on top.
- The goal is **consistency and reuse** — so instead of every country reinventing the wheel, everyone works from a common FHIR base.
- This means data exchanged in Germany, France, or Spain can follow the same structure — making **cross-border interoperability** much easier.
- Ultimately, this guide is about **building coherence** — one European FHIR language that supports both national flexibility and continental alignment.

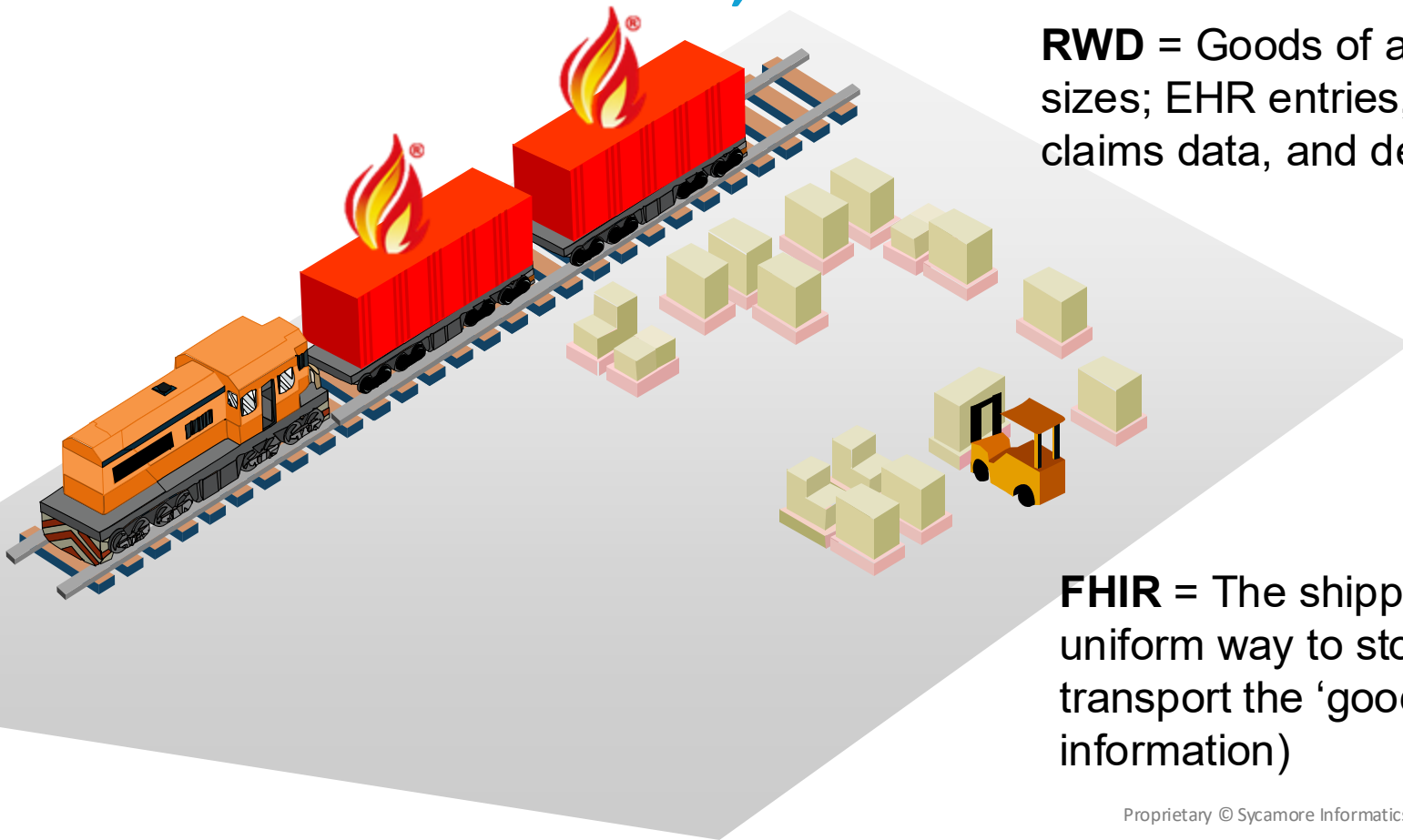


Decoding FHIR

RWD Is The Content, FHIR Is The Container

RWD = Goods of all shapes and sizes; EHR entries, lab results, claims data, and device readings

FHIR = The shipping container; uniform way to store and transport the 'goods' (aka information)



FHIR Is The Container - U.S. Interoperability Is The Transport System



USCDI = The Essential Goods List:

Defining the minimum set of items every container must carry (e.g., demographics, medications, vitals).



TEFCA = The National Trade Route Agreement:

Creating common pathways so containers can move freely across states and networks without bottlenecks.



Cures Act Rules = The Transportation Regulations:

Ensuring no one hoards containers and that all participants have fair access to the network.



Peeking Inside The Container

FHIR Observation: Simplified JSON snippet

```
{
  "resourceType": "Observation",
  "id": "lab-glucose",
  "status": "final",
  "code": {
    "coding": [
      { "system": "http://loinc.org", "code": "2345-7",
        "display": "Glucose [Mass/volume] in Blood" }
    ]
  },
  "subject": { "reference": "Patient/123" },
  "effectiveDateTime": "2025-09-15T09:30:00Z",
  "valueQuantity": {
    "value": 102,
    "unit": "mg/dL",
    "system": "http://unitsofmeasure.org",
    "code": "mg/dL"
  }
}
```

SDTM LB Domain (tabular view)

STUDYID	USUBJID	LBTEST	LBTESTCD	LBCAT	LBORRES
STUDY01	123	Glucose	GLUC	CHEM	102

LBORRESU	LBOTC	LBSTRESN	LBSTRESU	LBSTAT
mg/dL	2025-09-15T09:30:00	102	mg/dL	

Mapping / Transformation



How Complex Is This?



Provenance & Reproducibility

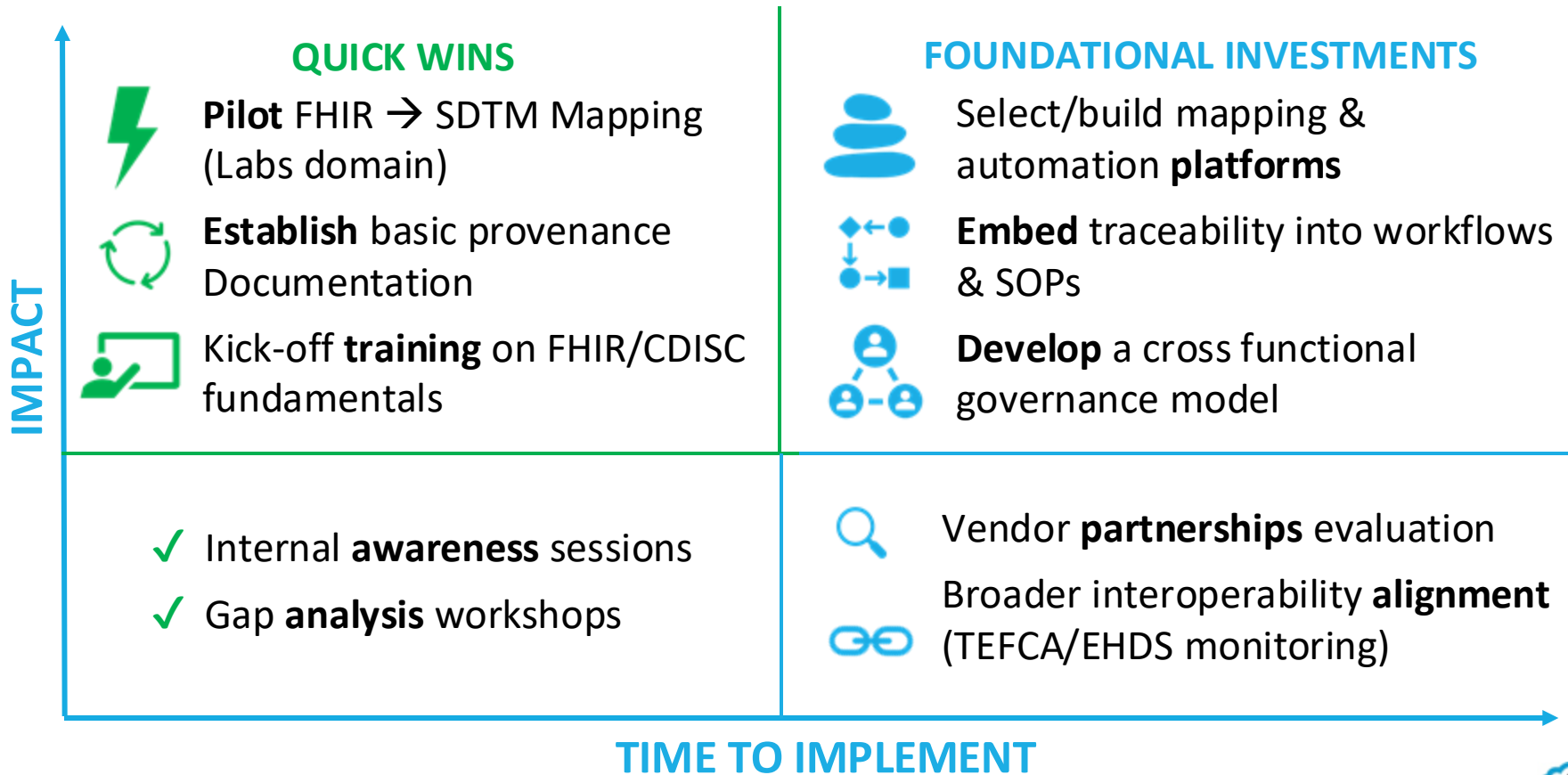
Readiness & Risks

What You Should Know Now?

- **Assess** your current RWD → CDISC conversion capabilities
- **Identify** provenance and process gaps
- **Evaluate** the state of interoperability adoption (FHIR, vocabularies, pipelines)
- Recognize where regulators will **expect** traceability vs. flexibility

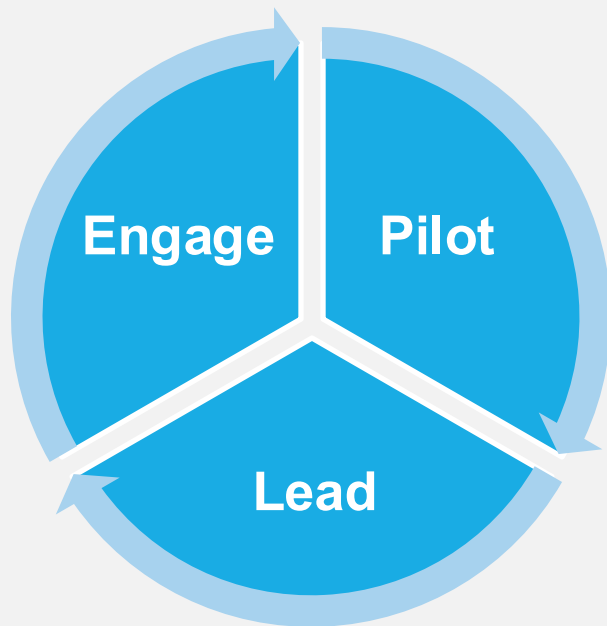


12-Month Action Plan



The Call To Action

Call To Action



- **Join** HL7, Vulcan, PhUSE working groups
- **Give feedback** to regulators (FDA, EMA, etc.)
- **Bring** real-world trial use cases to the table



- **Test** FHIR-to-SDTM transformation
- **Use** real data (EHR/registry/claims)
- **Partner** with tech vendors & data owners



- **Assign** accountable leadership
- **Budget** for data infrastructure & reskilling
- **Align** governance across RWD, regulatory, and IT



The Question Is – Are You Ready?

NOT READY



FUTURE READY



Q & A

Connect with the Presenters!

Bill Qubeck



Sanyogeeta Andhale



Thank you!



SPA  MDR  CDR  SCE 