



Accumulus Synergy: Data Exchange within a Cloud-Based Ecosystem

Michael Abernathy, Accumulus Data Exchange Product Owner

CASSS WCBP 2022 – “One World One Submission”

January 27, 2022

Accumulus Synergy is a non-profit organization dedicated to creating innovative solutions that can reduce regulatory review times and transform global data exchange

Our Vision

**We dramatically
accelerate critical
therapies to citizens of
the world**



Current Focus

- Accumulus is concentrated on driving more **efficient stakeholder collaboration** and improving **data exchange and data management** (with CMC data as the pilot domain)
- Platform and **application development** (Submission Review and Collaboration) **are currently underway** with **Google**

Current Stakeholders

Sponsors



Health Authorities



Regulators and Industry Recognize that Existing Ways of Working and Information Exchange are Ripe for Innovative Maturity

Innovation Challenges



Keeping Pace with Medical Innovation



Escalating Development Costs



Increasing Complexity of Data and Evidence



Enabling Global Collaboration



Addressing Access and Availability Constraints

Today's information exchange creates unnecessary complexity and inefficiencies

Locked datasets and manual processes

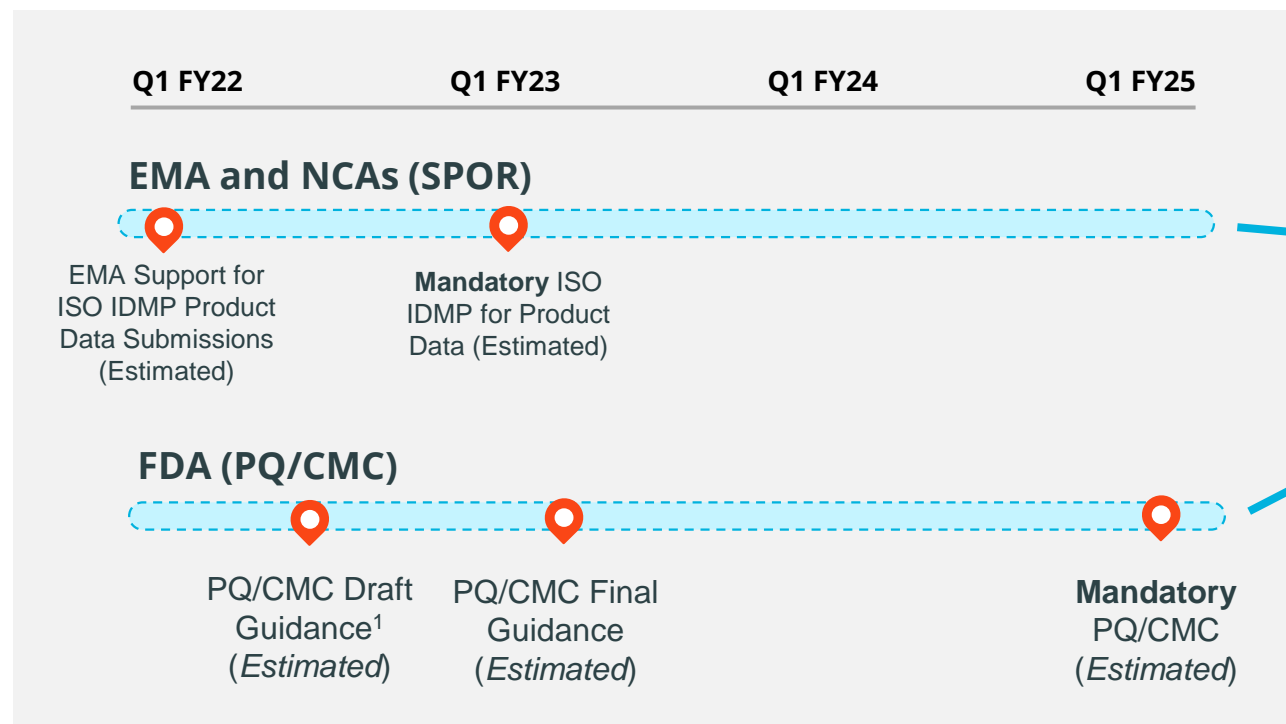
Event-driven interactions

Company- or health regulator-specific solutions

Reliance on narrative and textual elements

Regulators recognize the need for the industry to move towards interoperable, structured data exchange, and are taking initial steps towards implementation

Regulatory Roadmap for FHIR-Based Submissions



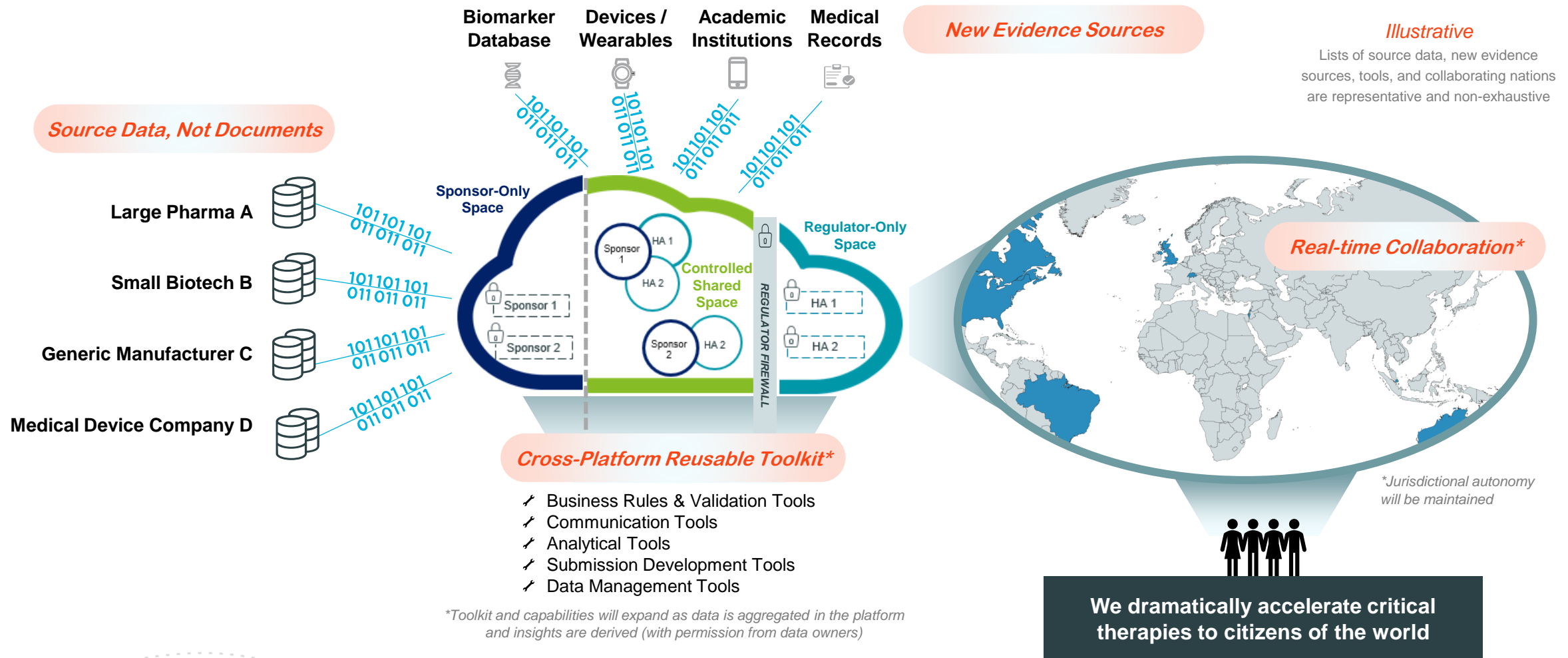
Accumulus Global Footprint



¹ <https://www.fda.gov/media/147696/download>

Our Collective Future State Platform Vision

A reimagined information exchange between stakeholders in the healthcare ecosystem can streamline the regulatory lifecycle and facilitate real-time, simultaneous, and global submissions, reviews, and assessments of therapies



The Vision for Data Exchange



We will bring safe and effective medicines to patients faster and more efficiently by reimagining regulatory information exchange

To achieve our vision, we will focus on delivering a cloud platform that allows for exchange of structured data in alignment with changing regulatory needs. The platform will allow customers to:

- **Store validated regulatory data in a common format**
- **Automatically map terminology across jurisdictions**
- **Construct templated filings from common data**
- **Exchange structured filings with global regulators**
- **Flexibly import/export data through key integrations**



The First Offering for Data Exchange Looks to Provide Value to Both Sides of the Regulatory Information Exchange Paradigm through a Common Data Platform

Key Value Propositions



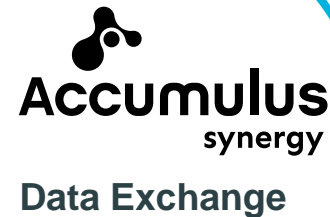
Sponsors

Enable Health Authorities to **accelerate post-approval submission reviews** through exchange of standard, structured data to support life cycle management activities

Prepare for forthcoming **PQ/CMC** & SPOR (ISO IDMP) data standardization requirements through **step-by-step data upload, data element mapping, and controlled terminology validation**

1

2



Health Authorities

Increase review efficiency and throughput through a **reduction in manual data transcription** into agency databases and review tools

For agencies without advanced analytical tools, **reduce the barrier to quantitative data analysis** through a simple download of structured data in Excel format

3

4

Data Exchange provides a unified platform for flexible, standardized data exchange to enhance regulatory agility and efficiency



Interoperate

*Flexible data import
& export*



Standardize

*Comply with regulatory
data requirements*



Exchange

*Secure managed
data exchange*

Cross-Functional Application and Scalability

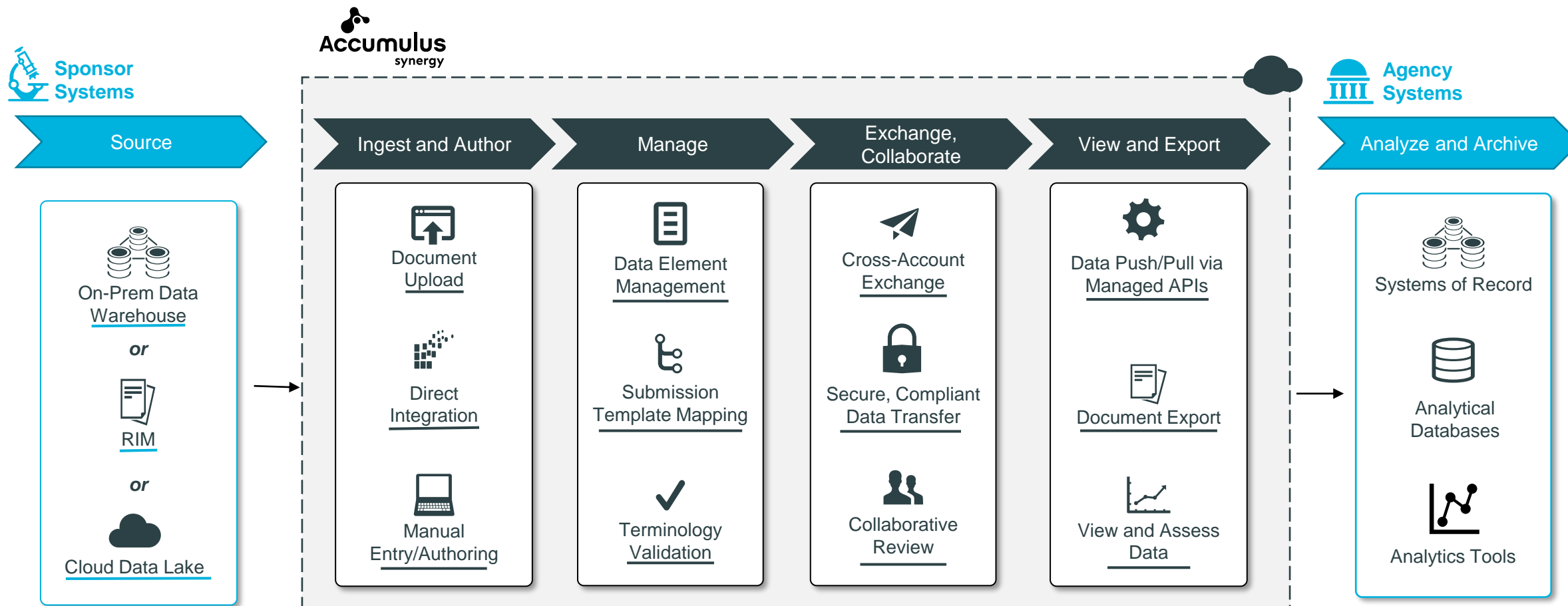
CMC

Clinical

Pre-clinical

Safety

Accumulus provides a managed platform for sponsors and regulators to securely exchange and collaborate on structured regulatory information



Accumulus Will Utilize Module 3 Data Mapping to Provide Structure and Standardization for CMC Data Requirements




1. Use [PQ/CMC data elements](#) for high-level categorization of data
2. Align ISO IDMP ([SPOR API Specification](#)) Controlled Terminology where applicable. For Out-of-Scope elements, Accumulus to propose solution.
3. Valid values to align with Controlled Terminologies, with regional considerations for acceptable terms/formats.
4. Assess whether data component is an EC, based on ICH Q12 guidance and potential risk impact




PQ/CMC Data Element(s) Name	Data Element Definition	Data Element Definition Source	Data Type	Controlled Terminology/ Vocabulary	Valid Values	FHIR Artifacts	ICH Q12 EC?
Batch or Lot Information							
Product proprietary name, product non-proprietary name, strength numericnumerator, strength numericnumerator UOM, dosage form, route of administration	A commonly used name or a systematic name assigned to the chemical or compound; The content of an active ingredient expressed quantitatively per dosage unit, per unit of volume, or per unit of weight, according to the pharmaceutical dosage form. This should be the strength as listed on the label	Adapted from NCI EVS C53294	Text, numeric, code	ISO IDMP: ISO11615 – Medicinal Product Name, Manufactured Item Dose Form, Reference Strength	NCI concept code for pharmaceutical dosage form: C42636 SPOR Referential List for basic dosage form	MedicinalProduct.name MedicinalProduct.combinedPharmaceuticalDoseForm	Yes
Manufacturing Process Information							
Equipment class and subclass, working capacity	Equipment is categorized by class (operating principle) and subclass (design characteristic)	SUPAC Manufacturing Equipment Addendum	Text, numeric	ISO IDMP: ISO11615/ISO11238 – Out of scope ----- ASTM E1705-15; ASTM E2363-14; SUPAC Addendum	SUPAC Manufacturing Equipment Addendum, ASTM standards	PharmQualitySpecification Extension: AdditionalInformation	Yes

Data Element Mapping moves us closer to a structured and standardized filing enabling us to leverage technology and automation


Data is Brought into the System, Assessed to Ensure Quality, and Submitted for Agency Review

Illustrative

 **Sponsor**

 **Manual Entry**
or
 **Excel Upload**
or
 **Direct Integration**

Import data



Dashboard > Projects > [(Product)-(Regulatory Event)-(MM)-(YYYY)] >

< P.8.3 - Stability Data

Print Download

Batch/Lot Information + Add Row

Medicinal Product Name	Dose Form	Strength(mg)	BAID 1	BAID 2	Batch Size/unit	Manufacturing Date	Manufacturing Site Name
Code	Text	Numeric	Numeric	Numeric	Numeric	Date	Text

Stability Study + Add Row

Study Name	Study Purpose	Study Type	Study Design	Test Usage	Storage Condition	Identifier	Physical Characteristics
Code	Text	Text	Text	Code	Code	Code	Text



Export shared data in alignment with regulatory requirements

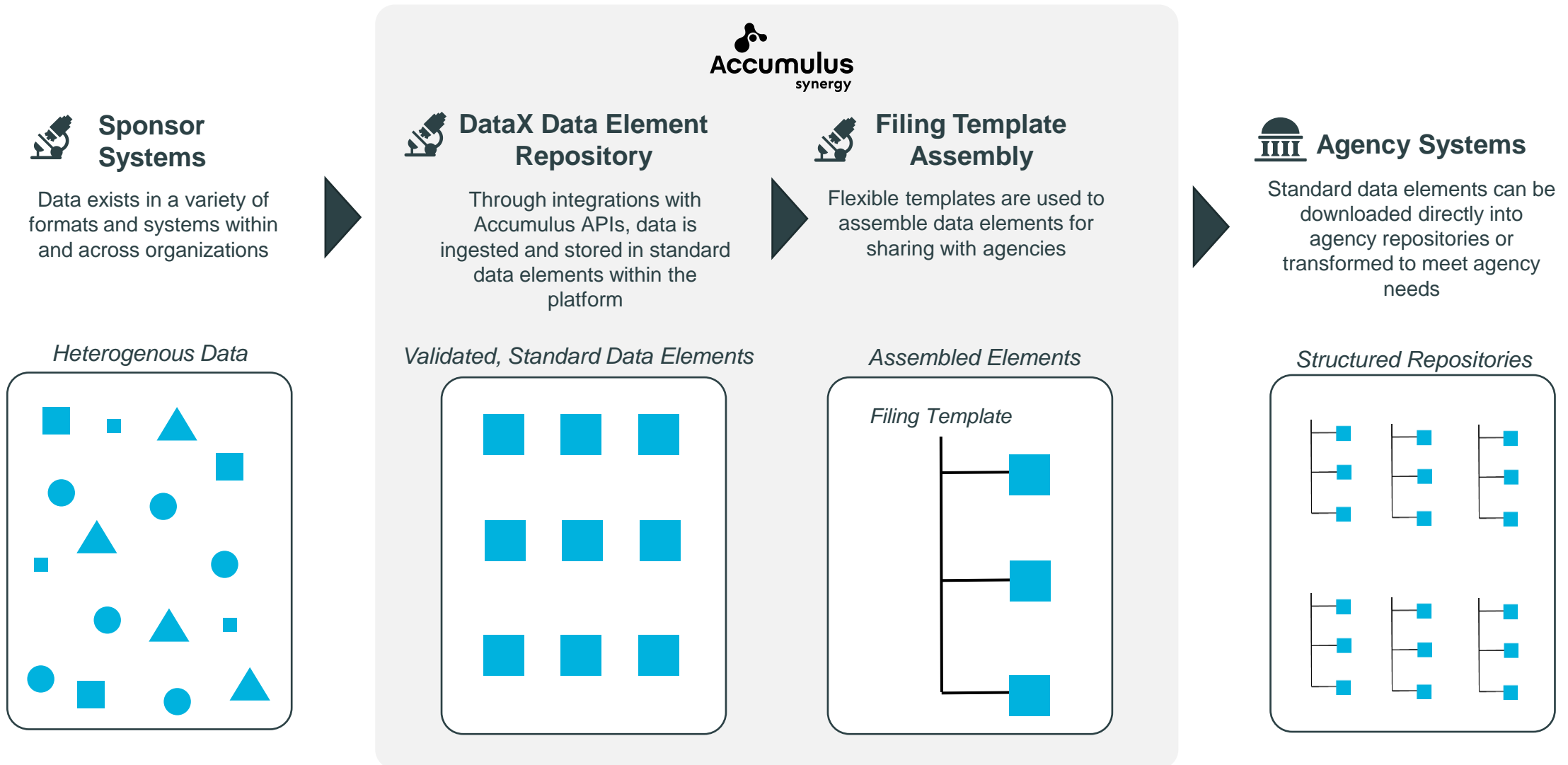


Excel Export

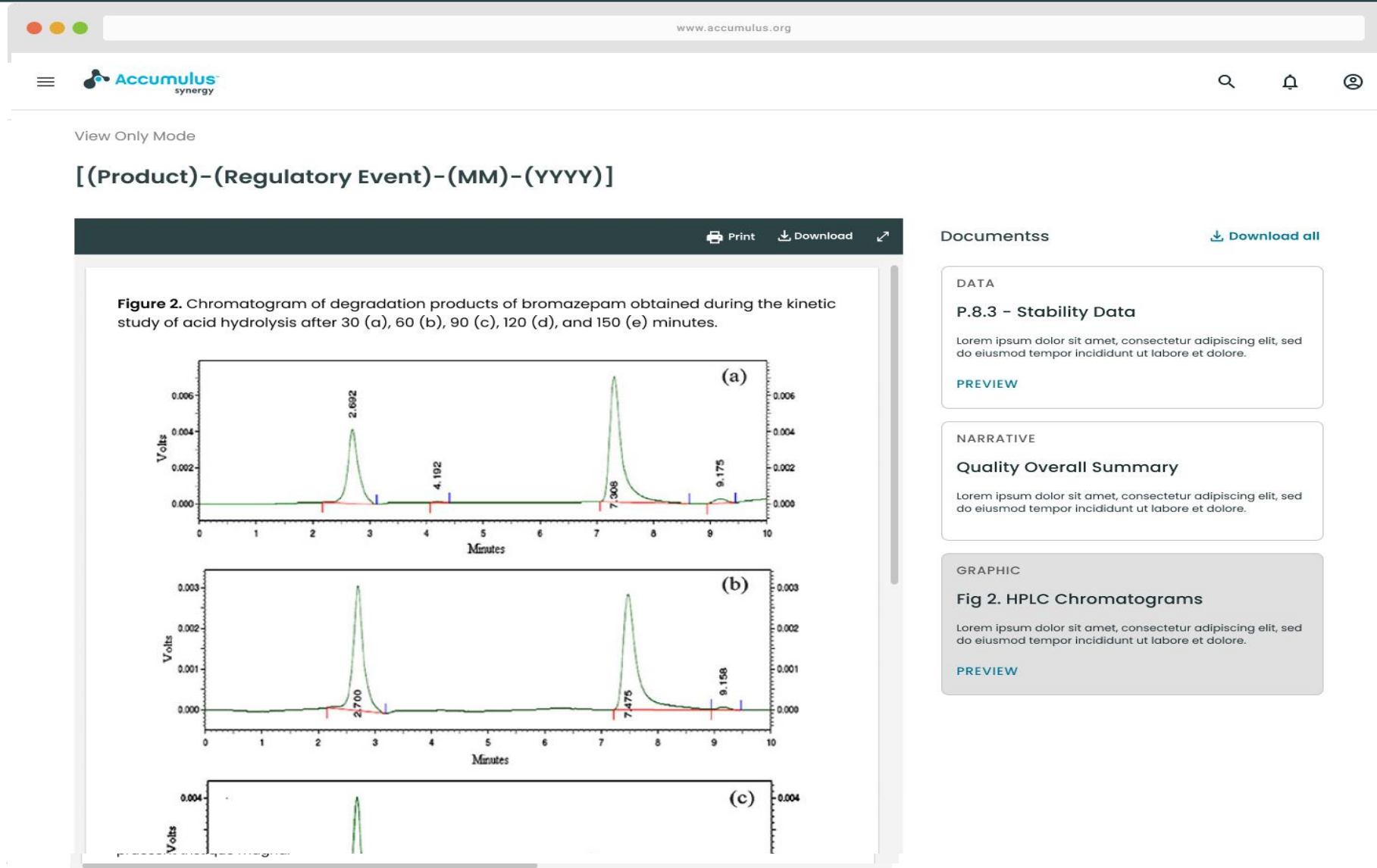


Integrate with systems of record

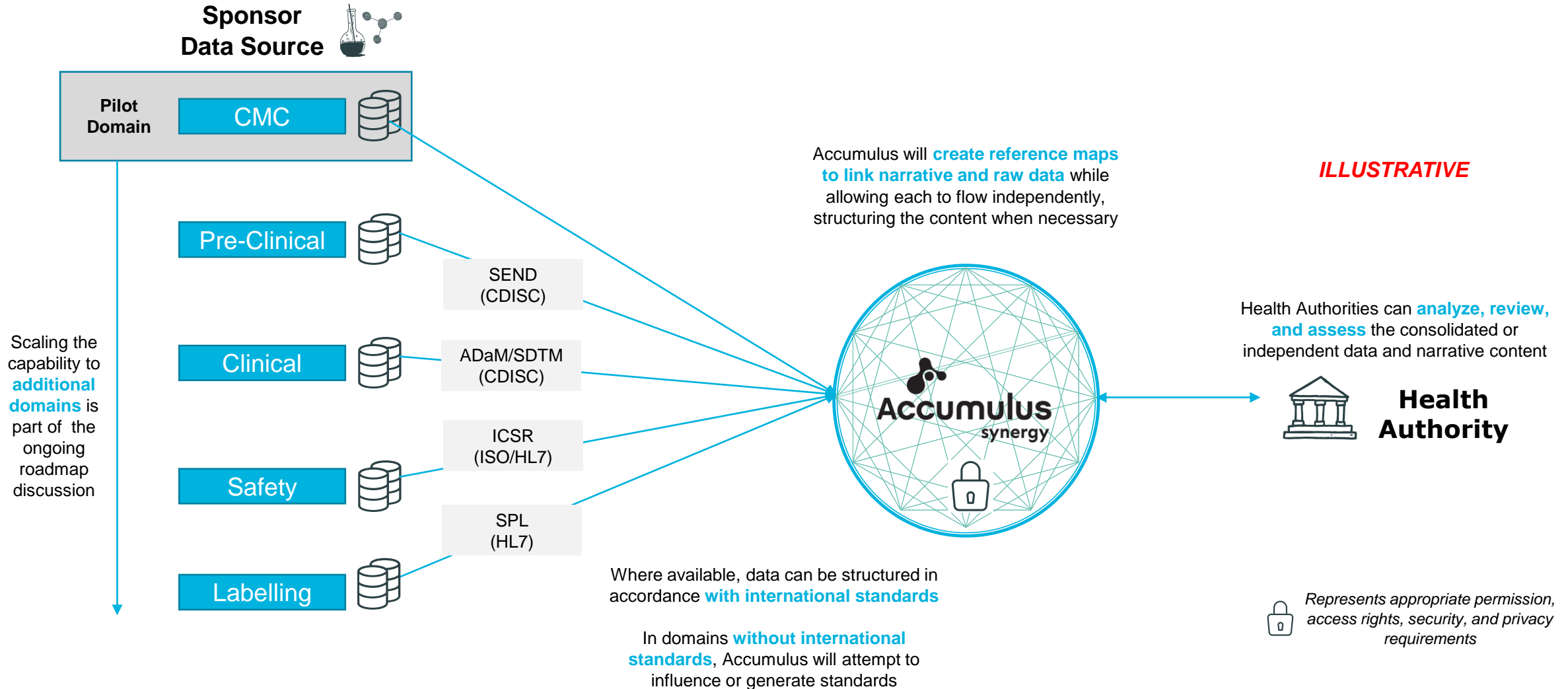
Through Standard Data Structures, the Platform Allows Sponsors and Agencies to Communicate in a Common Language



DataX Supports Visualization of Data, Narrative, and Graphical Content in a “Single Pane of Glass”



The Data Exchange Solution will Support CMC Data as it's First Data Domain, with a Strong Roadmap to Add Additional Data Sources



**Thank you for the opportunity to present at today's conference.
We greatly appreciate your feedback, perspectives and ideas to
advance the Accumulus Synergy mission and vision.**



Accumulus Synergy, Inc.

1534 Plaza Lane / #210 / Burlingame, CA 94010

accumulus.org