Data Exchange: A CMC Application Using Structured Data and a Cloud-based Ecosystem

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Innovation in Quality & Technology Beyond the Pandemic

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Accumulus Synergy Background

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

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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
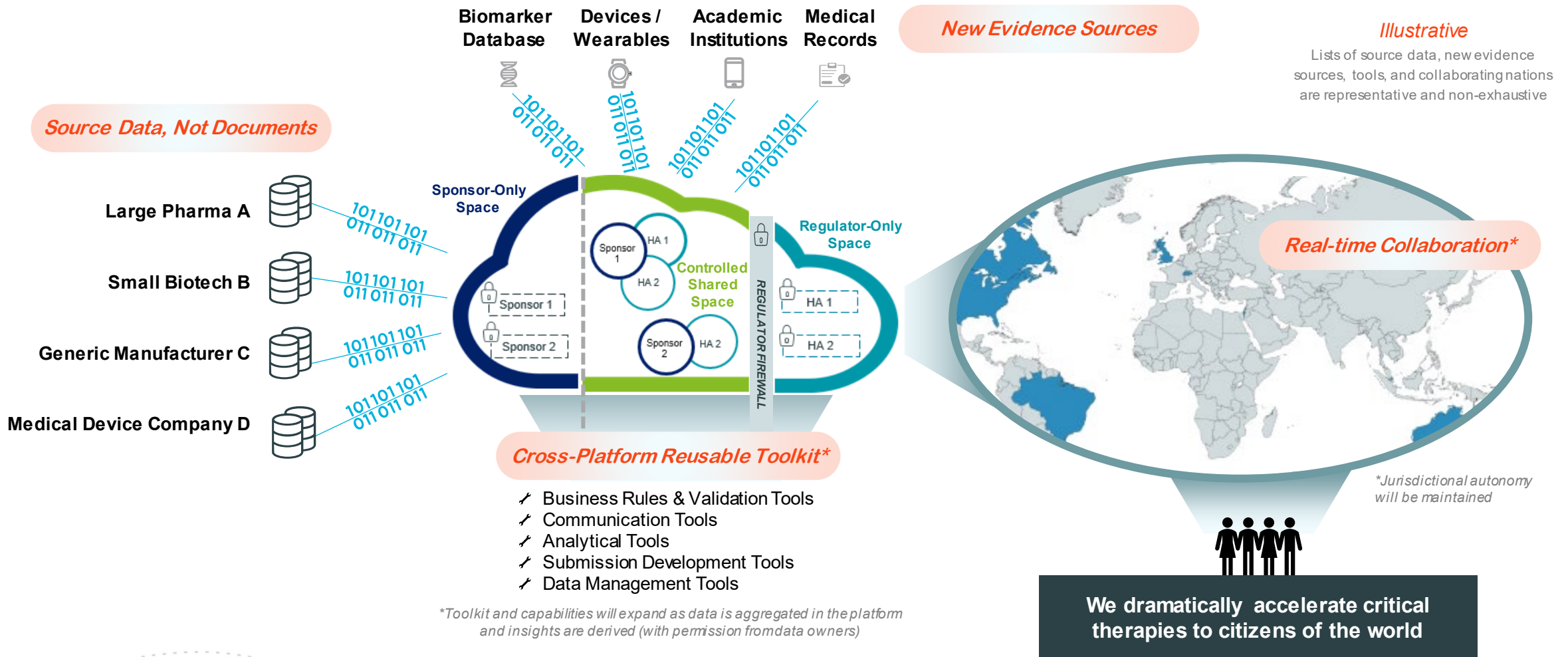
Locked datasets and manual processes

Event-driven interactions

Company- or health regulator-specific solutions

Reliance on narrative and textual elements

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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


New Evidence Sources

Source Data, Not Documents

Real-time Collaboration*

Illustrative
Lists of source data, new evidence sources, tools, and collaborating nations are representative and non-exhaustive

Biomarker Database

Devices / Wearables

Academic Institutions

Medical Records

Large Pharma A

Small Biotech B

Generic Manufacturer C

Medical Device Company D

Sponsor-Only Space

Regulator-Only Space

Controlled Shared Space

REGULATOR FIREWALL

Jurisdictional autonomy will be maintained

Cross-Platform Reusable Toolkit*

- Business Rules & Validation Tools
- Communication Tools
- Analytical Tools
- Submission Development Tools
- Data Management Tools

Toolkit and capabilities will expand as data is aggregated in the platform and insights are derived (with permission from data owners)

We dramatically accelerate critical therapies to citizens of the world

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Two Prioritized Use Cases Will Activate Core Capabilities and Deliver Near-Term Value to Biopharma Sponsors and Global Health Regulators

Submission Review and Collaboration

Enable concurrent, collaborative review of submissions among global health regulators or within agency committees / divisions

HA	Sponsor	Expected Value
✓	✓	**Facilitate earlier access to medicines and reduce lag across geographies** by streamlining submission review
✓		**Support scientific review and improve efficiency** by facilitating global HA collaboration
✓	✓	**Enable more consistent and consolidated HA feedback** by improving sponsor-HA communication

Accumulus Synergy Core Platform Capabilities

Building Blocks
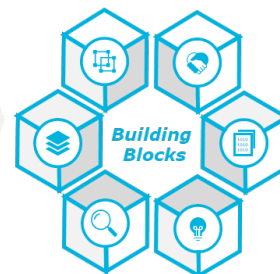
Data Exchange

Structure stability data in a content management repository to enhance submission, review, and post-approval change mgmt.

Expected Value	HA	Sponsor
Alleviate sponsor and HA resource burden in the manual, repetitive process of developing and reviewing submissions	✓	✓
Minimize data errors resulting from manual transcription and validation	✓	✓
Automate and optimize product lifecycle maintenance (e.g., post-approval changes)		✓

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# Submission Review and Collaboration: Transforming How We Collaborate

Real-Time Status Dashboards

The features enabled by Submission Review and Collaboration will be fundamental features of the platform for all subsequent use cases

Cross-HA Review and Commenting
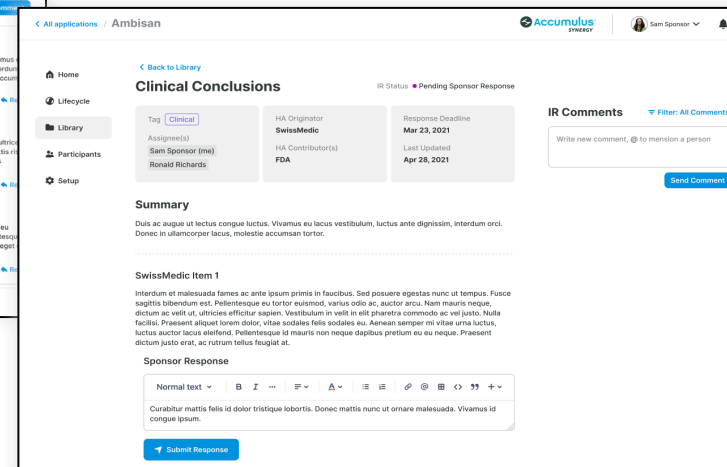
Live Sponsor – HA Information Requests
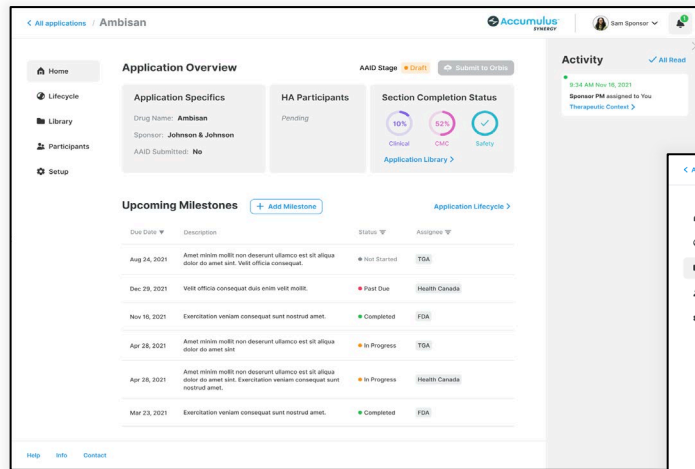
Shows **application details**, participating health authorities, and **progress metrics relevant to individual users**
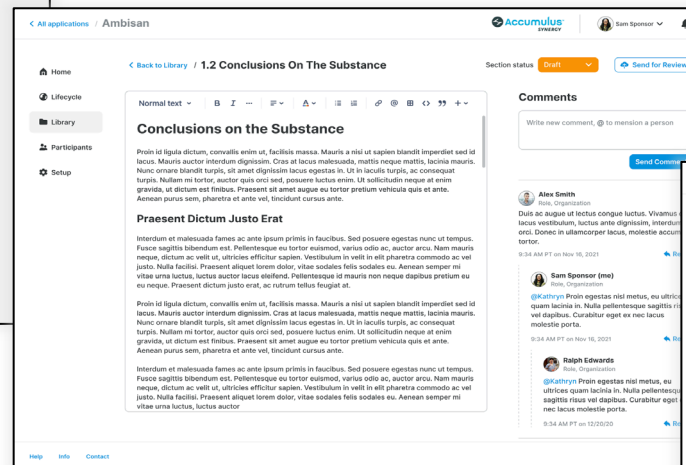
Reviewers can **annotate and comment for inter-and intra-organization discussion**, all within a secure shared space

Information requests can be presented **as they arise**, with responses **shared across HAs and documented in a single location** for future reference

Automated Intelligence and Machine Learning will derive productivity and efficiency insights for Sponsors and Health Authorities as information on the platform grows

ILLUSTRATIVE

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The Vision for Data Exchange

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We will bring safe and effective medicines to patients faster and more efficiently by reimaging 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**

Key Value Propositions

Sponsors

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

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

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Data Exchange
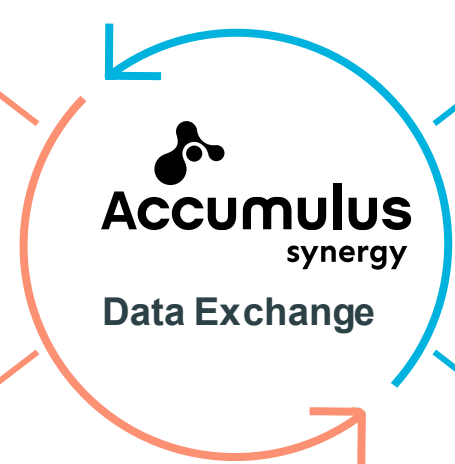
Health Authorities

3 Increase review efficiency and throughput through a **reduction in manual data transcription** into agency databases and review tools
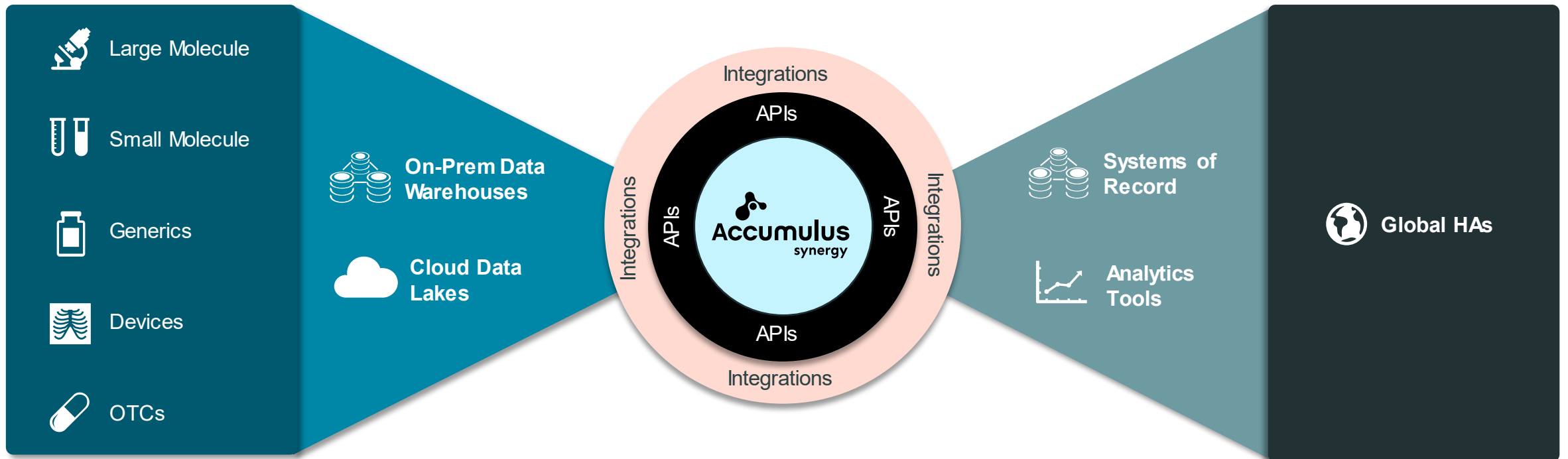
4 For agencies without advanced analytical tools, **reduce the barrier to quantitative data analysis** through a simple download of structured data in Excel format

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With Data Exchange, Information can Flexibly Flow between Sponsors and Health Authority Systems through a Variety of Platform Interaction Paradigms

Sponsors

Health Authorities

- Large Molecule
- Small Molecule
- Generics
- Devices
- OTCs

On-Prem Data Warehouses

Cloud Data Lakes

Integrations

APIs

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Integrations

APIs

APIs

Integrations

APIs

Integrations

Systems of Record

Analytics Tools

Global HAs

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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
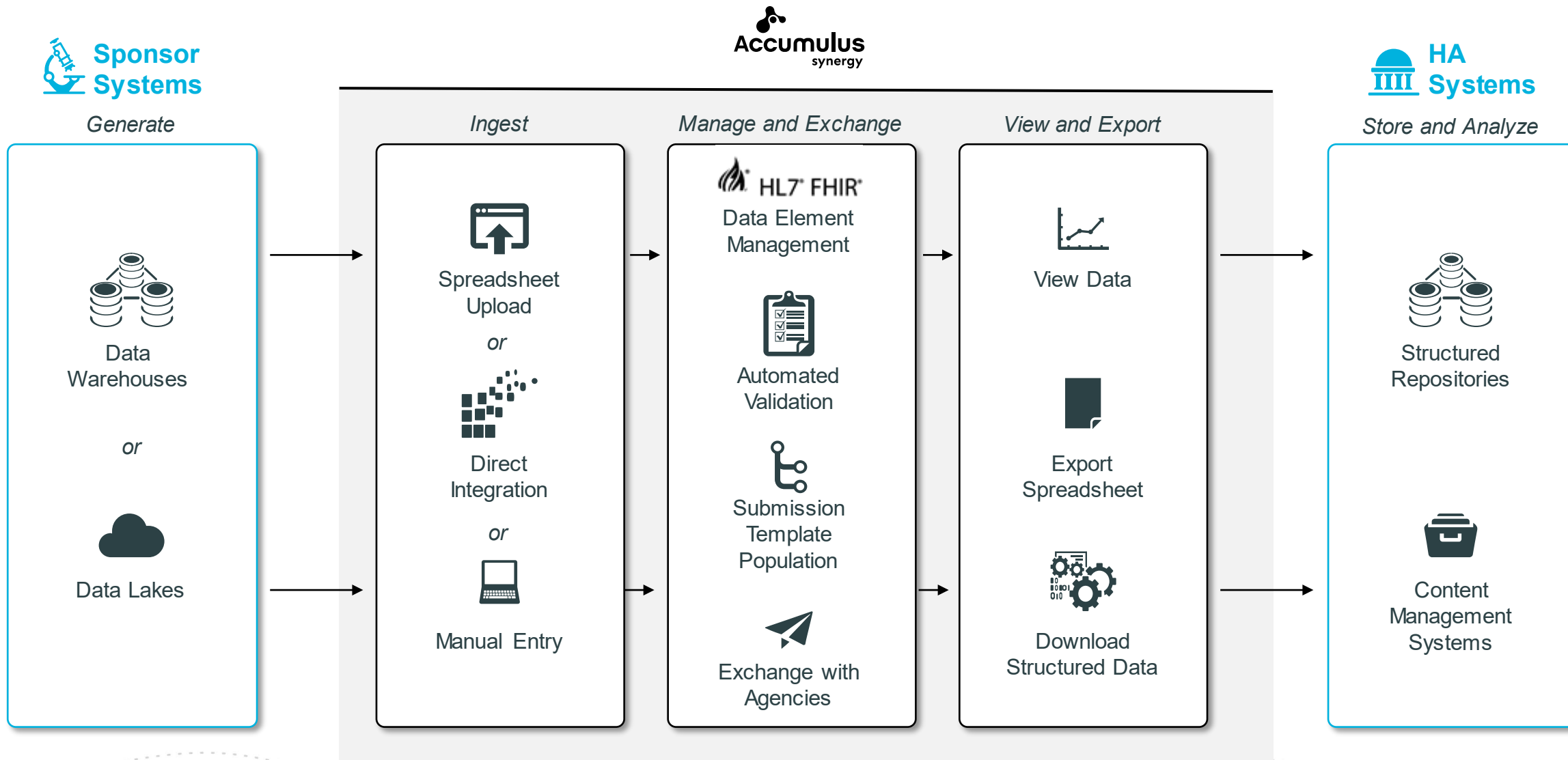
Cross-Functional Application and Scalability

CMC **Clinical** **Pre-clinical** **Safety**

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Ingestion, Exchange, and Export Capabilities are Enabled through the Storage of Validated Common Data Elements

Sponsor Systems

Generate

Data Warehouses

or

Data Lakes

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Ingest

Spreadsheet Upload

or

Direct Integration

or

Manual Entry

Manage and Exchange

HL7 FHIR

Data Element Management

Automated Validation

Submission Template Population

Exchange with Agencies

View and Export

View Data

Export Spreadsheet

Download Structured Data

HA Systems

Store and Analyze

Structured Repositories

Content Management Systems

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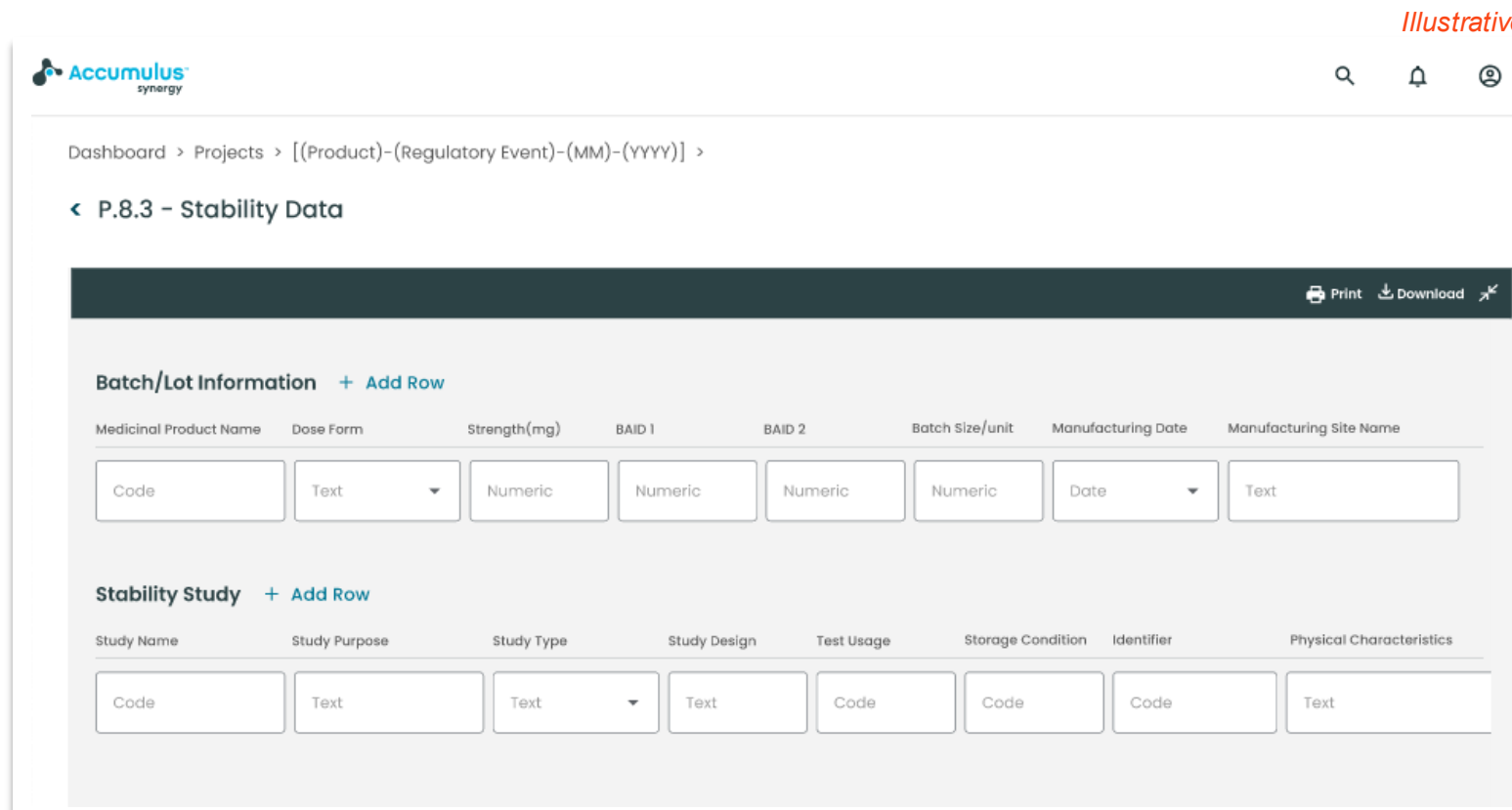
Illustrative

Sponsor

Manual Entry

or

Excel Upload

or

Direct Integration

Import data

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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

HA

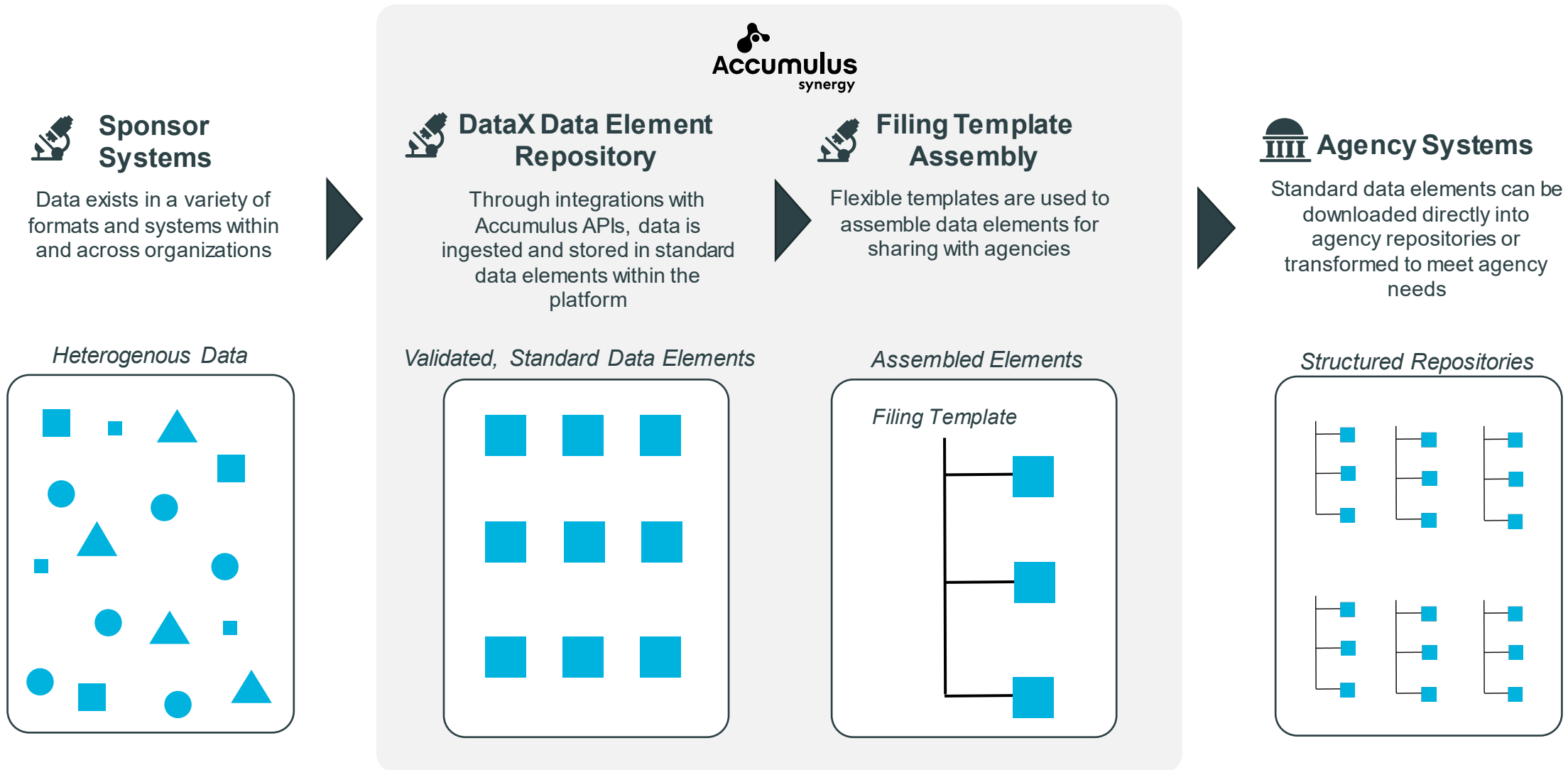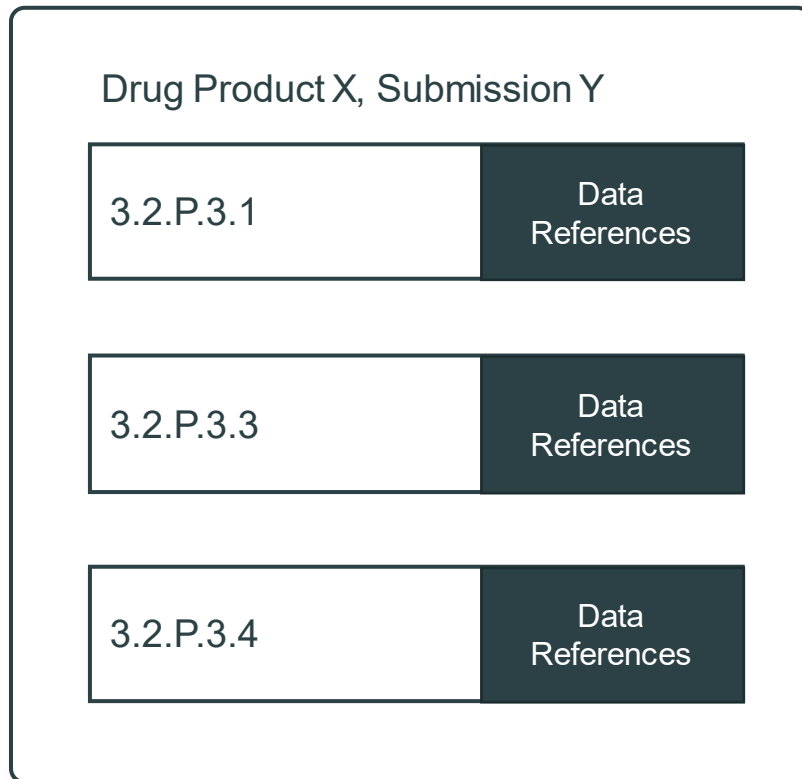▼ *Export shared data in alignment with regulatory requirements*

Excel Export

Integrate with systems of record

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

Sponsor Systems

Data exists in a variety of formats and systems within and across organizations

Heterogenous Data

DataX Data Element Repository

Through integrations with Accumulus APIs, data is ingested and stored in standard data elements within the platform

Validated, Standard Data Elements

Filing Template Assembly

Flexible templates are used to assemble data elements for sharing with agencies

Assembled Elements

Filing Template

Agency Systems

Standard data elements can be downloaded directly into agency repositories or transformed to meet agency needs

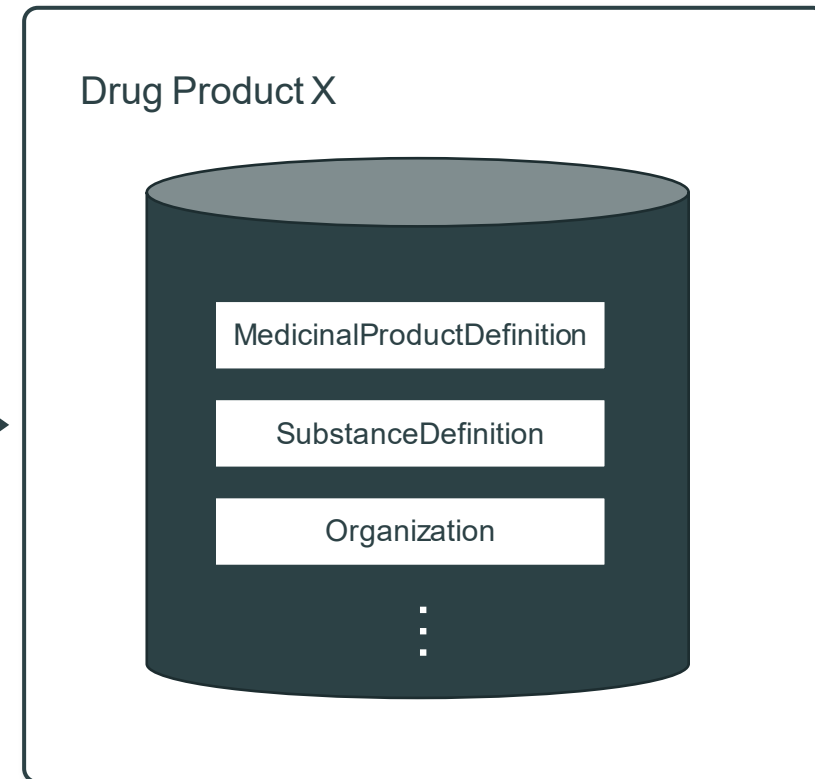*Structured Repositories*

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Common Core Data Elements are Stored and Mapped into Submission Templates to Unlock Re-usability and Enable Standardization

Submission Template Library
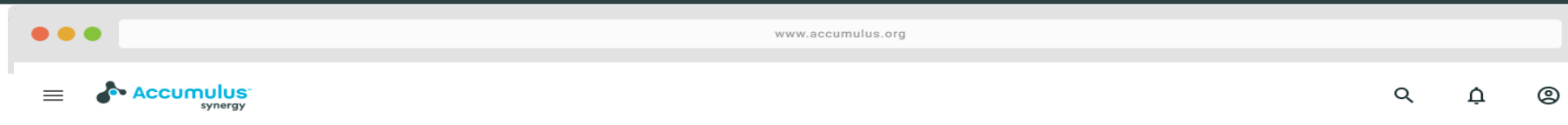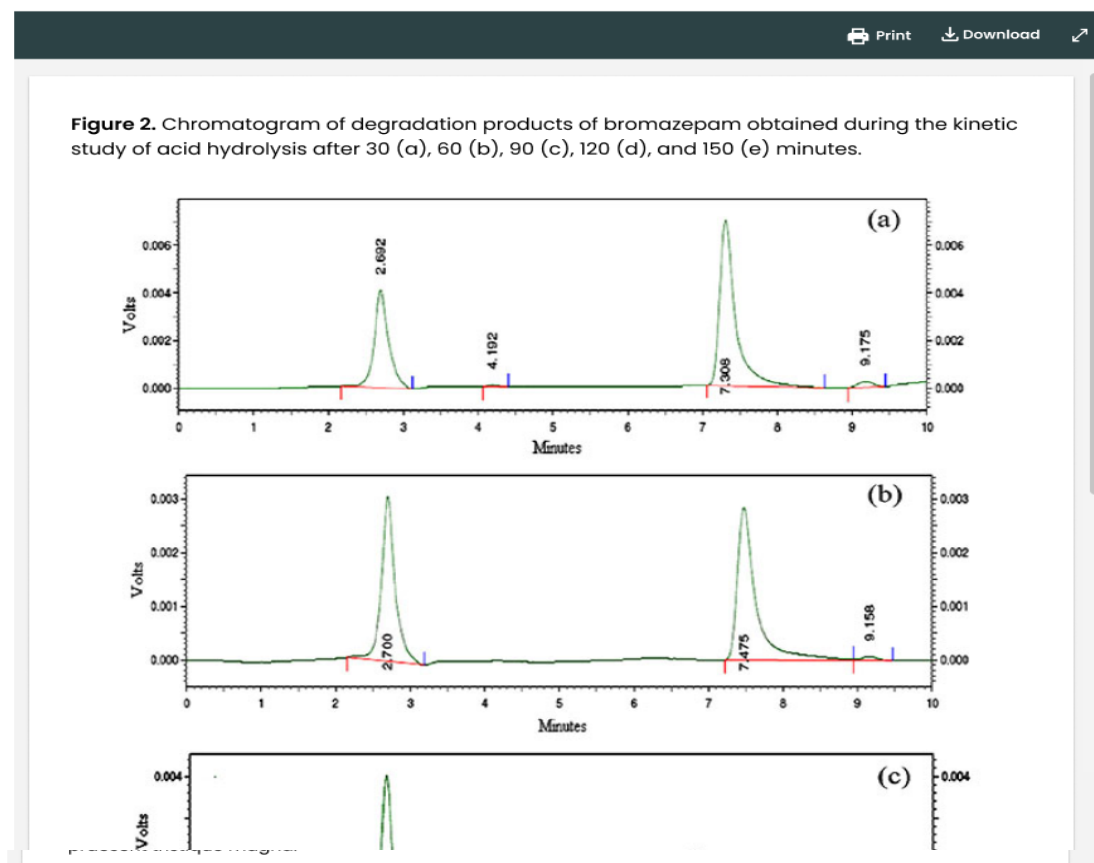
Drug Product X, Submission Y

| 3.2.P.3.1 | Data References |

| 3.2.P.3.3 | Data References |

| 3.2.P.3.4 | Data References |

Supported by FHIR Artifacts

Drug Product X

MedicinalProductDefinition

SubstanceDefinition

Organization

Public

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

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

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Sponsor Data Source

Pilot Domain | CMC

Pre-Clinical

SEND (CDISC)

Clinical

ADaM/SDTM (CDISC)

ICSR (ISO/HL7)

Safety

SPL (HL7)

Labelling

Scaling the capability to **additional domains** is part of the ongoing roadmap discussion

Accumulus will **create reference maps to link narrative and raw data** while allowing each to flow independently, structuring the content when necessary

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Health Authorities can **analyze, review, and assess** the consolidated or independent data and narrative content

Health Authority

Where available, data can be structured in accordance **with international standards**

In domains **without international standards**, Accumulus will attempt to influence or generate standards

Represents appropriate permission, access rights, security, and privacy requirements

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

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