Accumulus Synergy: Data Exchange within a Cloud-Based Ecosystem

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CASSS WCBP 2022 – “One World One Submission”
January 27, 2022
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

- Roche
- Jazz
- SANOFI
- Pfizer
- Lilly
- Bristol Myers Squibb
- basilea
- Takeda
- psk
- AMGEN
- FDA
- Health Canada
- Asta
- MHRA
- EMA
- USA
- Australian Government
- TGA
- Synmedic
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

<table>
<thead>
<tr>
<th>Q1 FY22</th>
<th>Q1 FY23</th>
<th>Q1 FY24</th>
<th>Q1 FY25</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EMA and NCAs (SPOR)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EMA Support for ISO IDMP Product Data Submissions (Estimated)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mandatory ISO IDMP for Product Data (Estimated)</td>
<td></td>
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<tr>
<td><strong>FDA (PQ/CMC)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PQ/CMC Draft Guidance(^1) (Estimated)</td>
<td>PQ/CMC Final Guidance (Estimated)</td>
<td></td>
<td>Mandatory PQ/CMC (Estimated)</td>
</tr>
</tbody>
</table>

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1 [https://www.fda.gov/media/147696/download](https://www.fda.gov/media/147696/download)

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Accumulus Global Footprint
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

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
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 Platform Vision

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


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

<table>
<thead>
<tr>
<th>PQ/CMC Data Element(s) Name</th>
<th>Data Element Definition</th>
<th>Data Element Definition Source</th>
<th>Data Type</th>
<th>Controlled Terminology/ Vocabulary</th>
<th>Valid Values</th>
<th>FHIR Artifacts</th>
<th>ICH Q12 EC?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Batch or Lot Information</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product proprietary name, product non-proprietary name, strength, numeric numerator, strength numeric numerator UOM, dosage form, route of administration</td>
<td>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</td>
<td>Adapted from NCI EVS C53294</td>
<td>Text, numeric, code</td>
<td>ISO IDMP: Medicinal Product Name, Manufactured Item Dose Form, Reference Strength</td>
<td>NCI concept code for pharmaceutical dosage form: C42636; SPOR Referential List for basic dosage form</td>
<td>MedicinalProduct.name, MedicinalProduct.combinedPharmaceuticalDoseForm</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Manufacturing Process Information</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Equipment class and subclass, working capacity</td>
<td>Equipment is categorized by class (operating principle) and subclass (design characteristic)</td>
<td>SUPAC Manufacturing Equipment Addendum</td>
<td>Text, numeric</td>
<td>ISO IDMP: ISO11615/ISO11238 – Out of scope; ASTM E1705-15; ASTM E2363-14; SUPAC Addendum</td>
<td>SUPAC Manufacturing Equipment Addendum, ASTM standards</td>
<td>PharmQualitySpecification Extension: AdditionalInformation</td>
<td>Yes</td>
</tr>
</tbody>
</table>

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.

### Manual Entry
- Import data

### Excel Upload
- Excel upload

### Direct Integration

<table>
<thead>
<tr>
<th>Batch/Lot Information</th>
<th>Add Row</th>
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</thead>
<tbody>
<tr>
<td><strong>Import data</strong></td>
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</table>

<table>
<thead>
<tr>
<th>Stability Study</th>
<th>Add Row</th>
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</thead>
<tbody>
<tr>
<td><strong>Export shared data in alignment with regulatory requirements</strong></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Excel Export</th>
<th>Integrate with systems of record</th>
</tr>
</thead>
</table>

Illustrative Manual Entry Excel Upload Direct Integration
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

**DataX Data Element Repository**
Through integrations with Accumulus APIs, data is ingested and stored in standard data elements within the platform

**Filing Template Assembly**
Flexible templates are used to assemble data elements for sharing with agencies

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

**Structured Repositories**

**Heterogenous Data**

**Validated, Standard Data Elements**

**Assembled Elements**

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

Figure 2. Chromatogram of degradation products of bromazepam obtained during the kinetic study of acid hydrolysis after 30 (a), 60 (b), 90 (c), 120 (d), and 150 (e) minutes.
The Data Exchange Solution will Support CMC Data as it’s First Data Domain, with a Strong Roadmap to Add Additional Data Sources

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

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

Where available, data can be structured in accordance with international standards. In domains without international standards, Accumulus will attempt to influence or generate standards.

Represented appropriate permission, access rights, security, and privacy requirements.

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