Accumulus Synergy
Learning Health Symposium

September 8, 2021
Introductions

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*Accumulus Synergy*

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*Accumulus Synergy*
There is industry and regulator recognition that existing ways of working and information exchange are ripe for improvement.

**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
## Accumulus Synergy Vision, Mission, and Approach

<table>
<thead>
<tr>
<th>Vision</th>
<th>We dramatically accelerate critical therapies to citizens of the world</th>
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<tbody>
<tr>
<td>Mission</td>
<td>We reimagine the interaction and information exchange between stakeholders in the healthcare ecosystem to streamline the regulatory lifecycle</td>
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<tr>
<td>Approach</td>
<td>Accumulus Synergy solutions facilitate real-time, simultaneous, and global submissions, reviews, and assessments of therapies</td>
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Accumulus will transform industry ways of working through several key paradigm shifts:

- **Disrupt the document-based review**
  Submission content migration from static documents to Accumulus platform for collaborative review and communication

- **Accelerate continuous data-driven review**
  Real-time data submission through upstream integration with sponsors and ongoing review between health regulators and sponsors

- **Facilitate simultaneous global activity**
  Enable global submission, review, and disposition to reduce lag across geographies and jurisdictions
Patient Value at the Center for Accumulus

Improved productivity and efficiency will generate higher throughput while maintaining quality and safety.

Improved speed-to-market will allow patients around the world to receive critical medicines.

Improved efficiency and speed-to-market will drive revenue opportunities.

Improved data visibility will drive secondary value opportunities in supply chain, clinical trials, etc.

Logos indicate currently engaged health regulators and sponsors.
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.

Our Collective Future State Platform Vision

- **Source Data, Not Documents**
- **Large Pharma A**
- **Small Biotech B**
- **Generic Manufacturer C**
- **Medical Device Company D**

**New Evidence Sources**

- **Biomarker Database**
- **Devices / Wearables**
- **Academic Institutions**
- **Medical Records**

**Parallel Review**

- **Real-time Collaboration**

**Work Sharing**

**Reliance**

**Regressor Firewall**

- **Medical Records**
- **Academic Institutions**
- **Devices / Wearables**
- **Biomarker Database**

**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)

*Jurisdictional autonomy will be maintained

We dramatically accelerate critical therapies to citizens of the world

**Illustrative**

Lists of source data, new evidence sources, tools, and maturity level nations are representative and non-exhaustive.

ML = WHO Maturity Level

ML 1/2

ML 3/4

ML 4
Accumulus Synergy prioritized two use cases to activate core capabilities.

**Demonstrate New Ways of Collaborating:**

- **Parallel Review Shared-Space Use Case**
  
  Enable concurrent, collaborative review of submissions among global health authorities or within agency committees / divisions.

Accumulus will support a live Project Orbis Assessment Aid submission from a sponsor to health authorities with Release 1.0 in 2021.

**Goal**

**Use Case**

**Product Release**

**Demonstrate New Ways of Exchanging Data:**

- **CMC Data-Driven Submissions Use Case**
  
  Structure CMC data in a content management repository to enhance submission, review, and post-approval change management.

Accumulus is currently working with health authorities to identify a CMC filing type with narrative, data, and visuals for Release 2.0.
Thank you for participating in today’s discussion!

For more information, please visit https://www.accumulus.org/
Appendix
How Accumulus Synergy is different

Focus on the regulatory submission process

- Creating the first-ever global cloud-based data exchange platform – leveraging the most sophisticated digital technology in the world
- Changing from the traditional dispatch of static information and documents, to a cloud environment with real-time data and communication

Partnering and Collaborating with Global Health Authorities

- First company to transform engagement and collaboration with global regulatory authorities
- Since inception, Accumulus Synergy has collaborated with several global health authorities to co-create solutions that will ensure regulatory convergence
Global health regulator engagement continues to grow

<table>
<thead>
<tr>
<th>2019</th>
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<th>2021</th>
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<tr>
<td>Agreed to Collaborate</td>
<td>Began Project Orbis Collaboration</td>
<td>Signed PPP</td>
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<td>Apr 2019</td>
<td>June 2020</td>
<td>Dec 2020</td>
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<tr>
<td>Joined Steering Committee</td>
<td>Kicked-off Accumulus EMA Subcommittee</td>
<td>Signed RCA</td>
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<td>Oct 2019</td>
<td>May 2020</td>
<td>Apr 2021</td>
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<tr>
<td>Participated in Working Session</td>
<td>Initiated Discussions</td>
<td>EU NCA Webinar</td>
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<tr>
<td>FDA</td>
<td>EMA</td>
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<tr>
<td>EMA</td>
<td>PMDA</td>
<td>Apr 2021</td>
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<tr>
<td>PMDA</td>
<td>TGA</td>
<td>Re-engaged with the PMDA Team</td>
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- Jun 2020: Began Project Orbis Collaboration
- May 2020: Kicked-off Accumulus EMA Subcommittee
- June 2020: Initiated Discussions
- Jul 2020: Kicked-off Accumulus PMDA Subcommittee
- Sep 2020: Began Engagement via Project Orbis
- Jan 2021: Agreed to Collaborate
- Mar 2021: Held Kick-Off Meeting
- May 2021: Began CMC / PR use case collaboration
- Aug 2021: Product Roadmap Workshop