

## Accumulus Synergy Learning Health Symposium

September 8, 2021





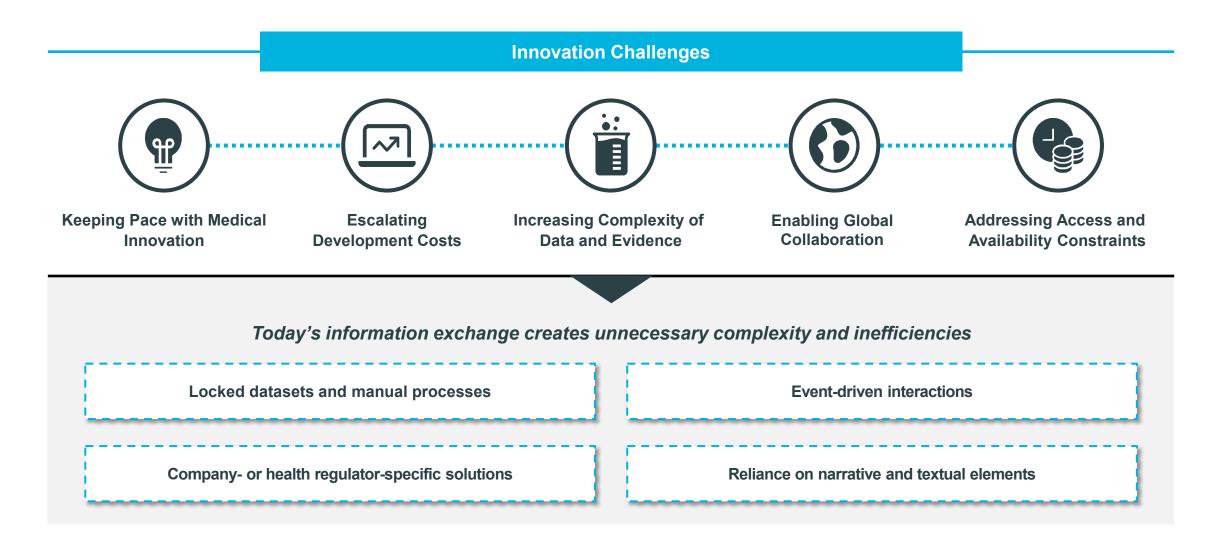
Francisco Nogueira Chief Executive Officer Accumulus Synergy

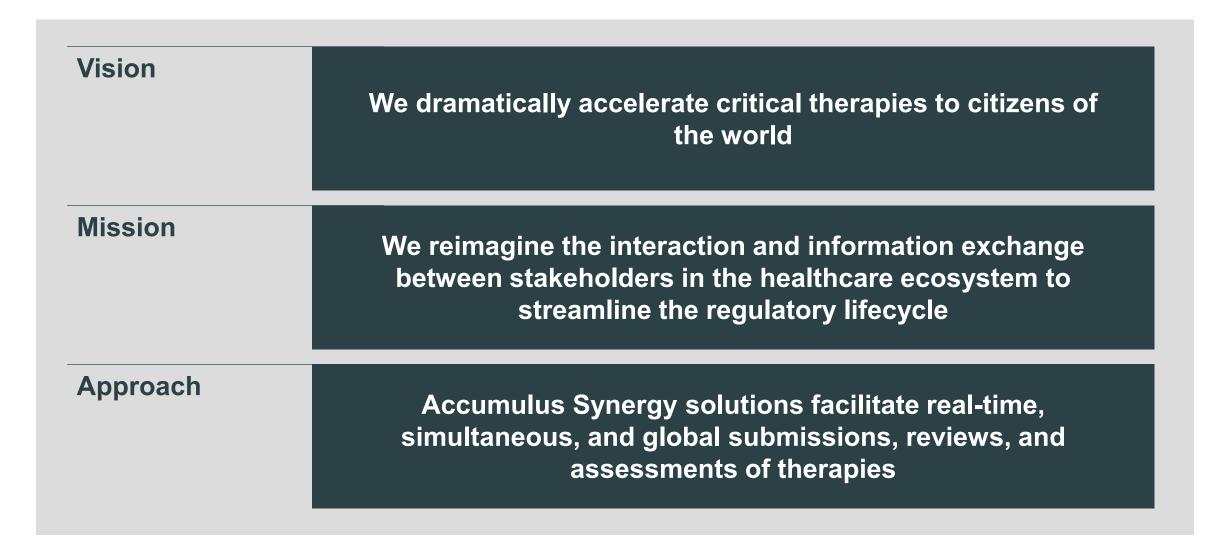


Karen Jones Head of Product Accumulus Synergy

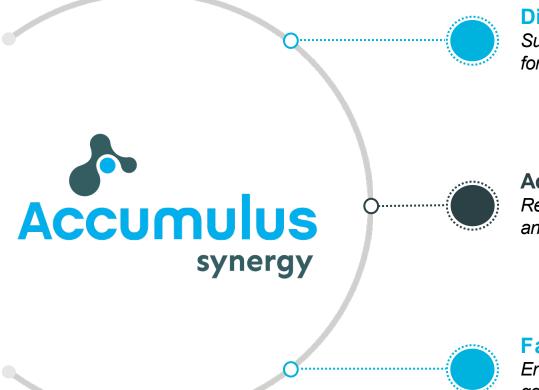
There is industry and regulator recognition that existing ways of working and information exchange are ripe for improvement











#### **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

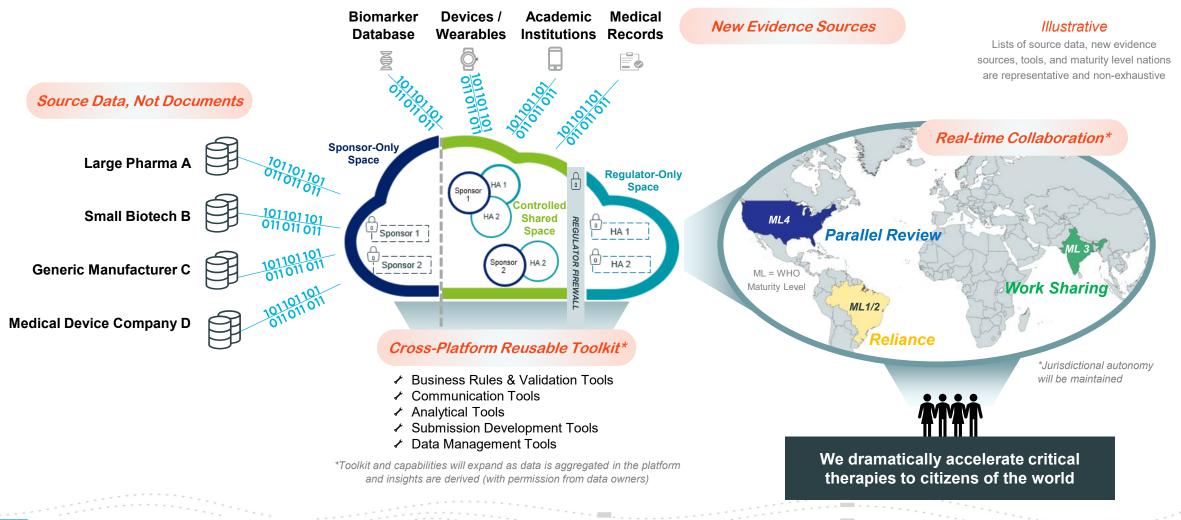




## Our Collective Future State Platform Vision



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





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 Product Release

Goal

Use

Case

**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

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## Thank you for participating in today's discussion!

## For more information, please visit <a href="https://www.accumulus.org/">https://www.accumulus.org/</a>







### Focus on the regulatory submission process

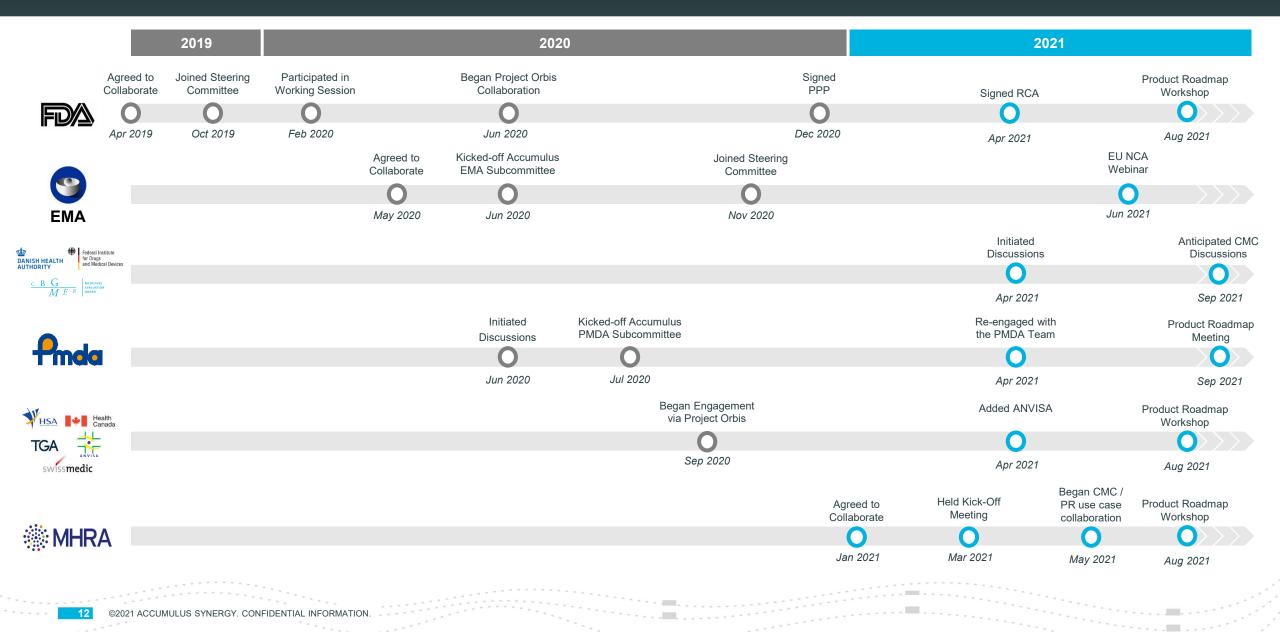
- Creating the first-ever global cloud-based data exchange platform leveraging the most sophisticated digital technology in the world
- Changing from the traditional dispatch of static information and documents, to a cloud environment with real-time data and communication

# 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





12



Accumulus Synergy, Inc. 1534 Plaza Lane / #210 / Burlingame, CA 94010 accumulus.org