



# Transforming Global Data Exchange

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# There is industry and regulator recognition that existing methods of 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

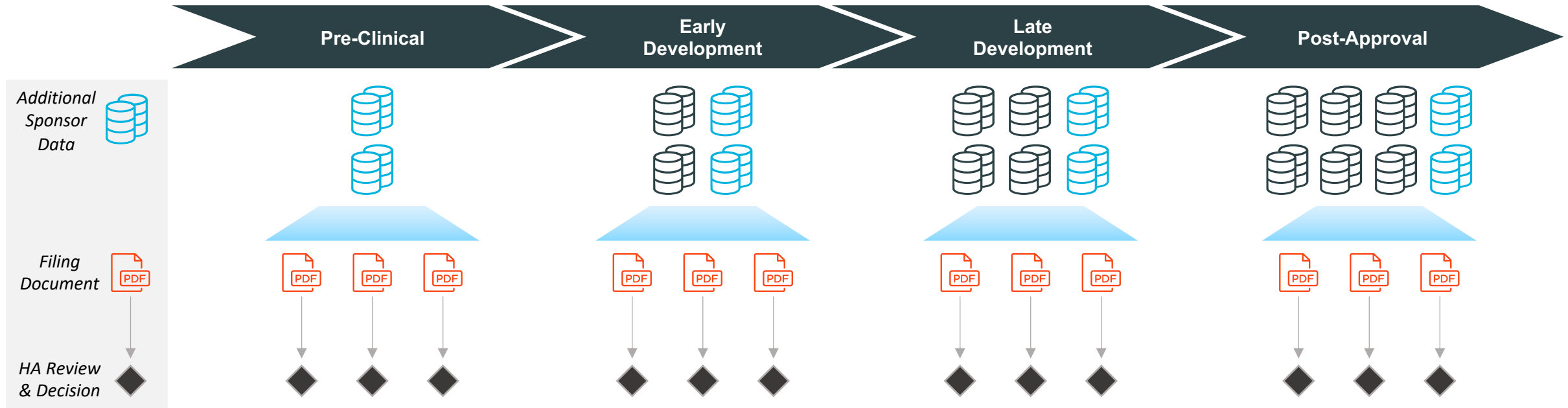
Company- or health regulator-specific solutions

Reliance on narrative and textual elements

# Current State: Submission-Focused and Document-Led Transactions

While data grows throughout product lifecycle, today's submissions continue to be isolated events that lock content in static documents and require customization across jurisdictions

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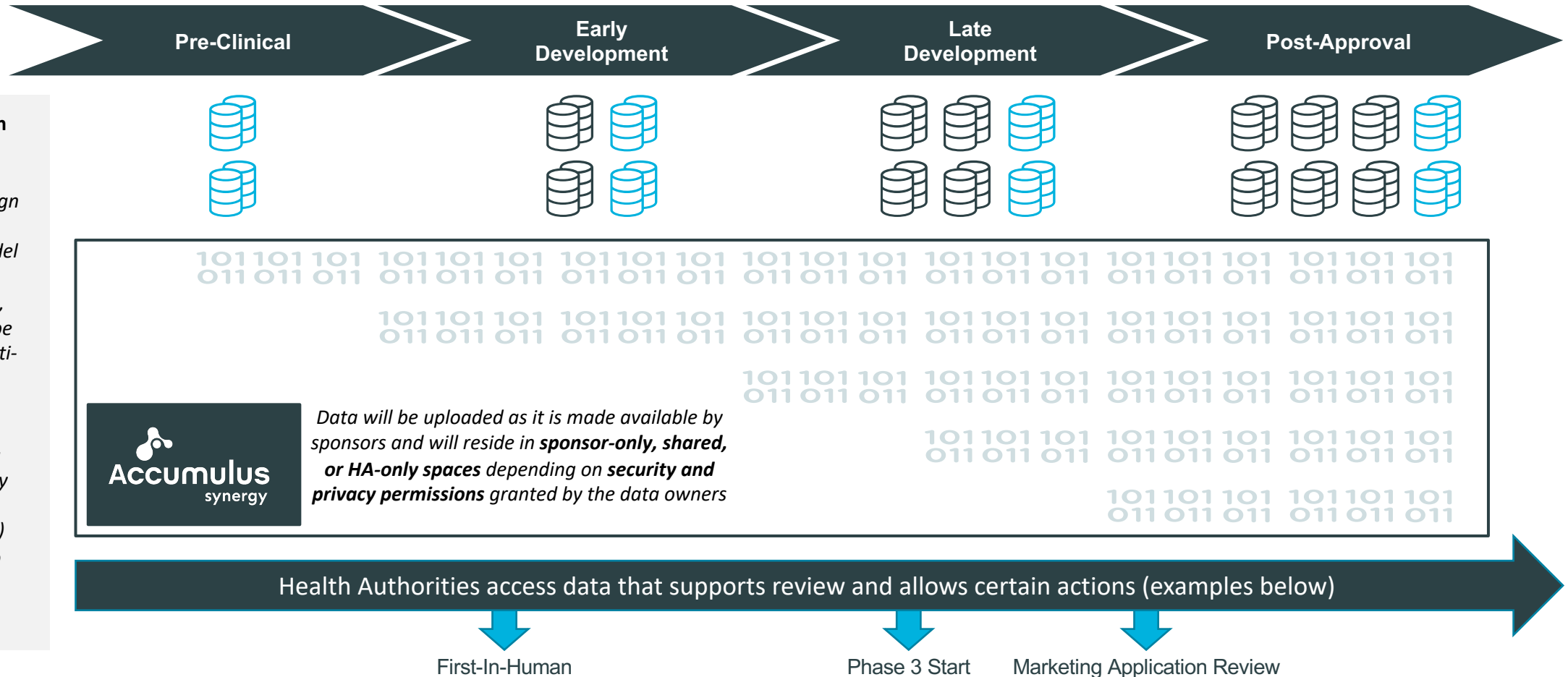
## Key Challenges

- Most content is **shared in PDF format**
- Review is currently **heavily narrative-driven**
- Hard to construct a **regulatory history** for a single product
- Content must **replicated and reformatted** across different jurisdictions
- Content exists in **different systems** across organizations
- Regulatory process revolves around the **submission event**

# Future Direction: Where are we heading? - Data-Centric Reviews

Data submission, review, and assessment will evolve over a multi-year time frame towards a more dynamic interaction that is consistent with how the data is generated

ILLUSTRATIVE



## Future Direction Considerations

*This requires design of a new engagement model and standardization, both which will be a multi-year, multi-stakeholder discussion.*

*Additional data beyond company data (e.g., wearables, EHR) are expected to inform reviews over time*



Data will be uploaded as it is made available by sponsors and will reside in **sponsor-only, shared, or HA-only spaces** depending on **security and privacy permissions** granted by the data owners

Health Authorities access data that supports review and allows certain actions (examples below)

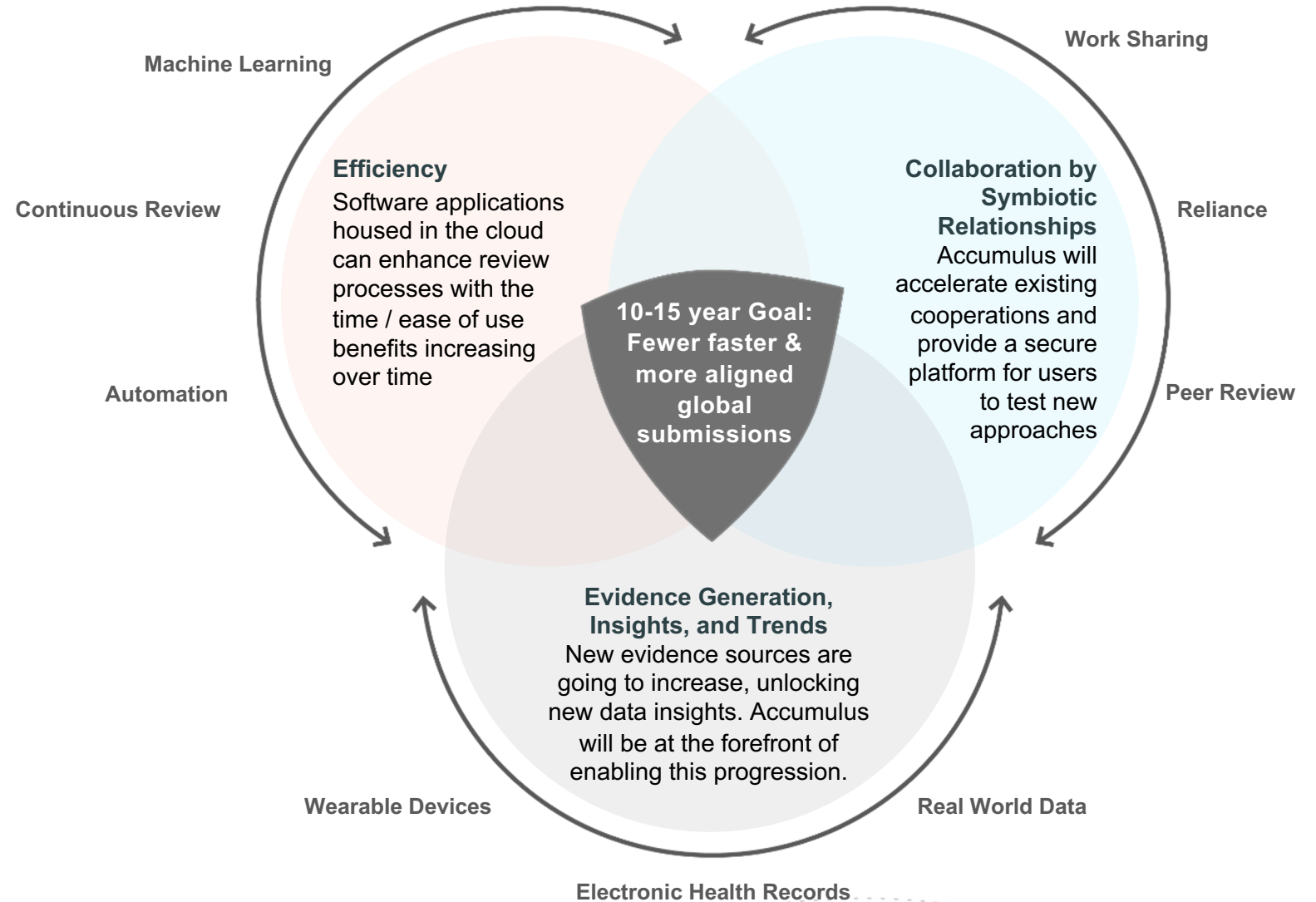
First-In-Human

Phase 3 Start

Marketing Application Review

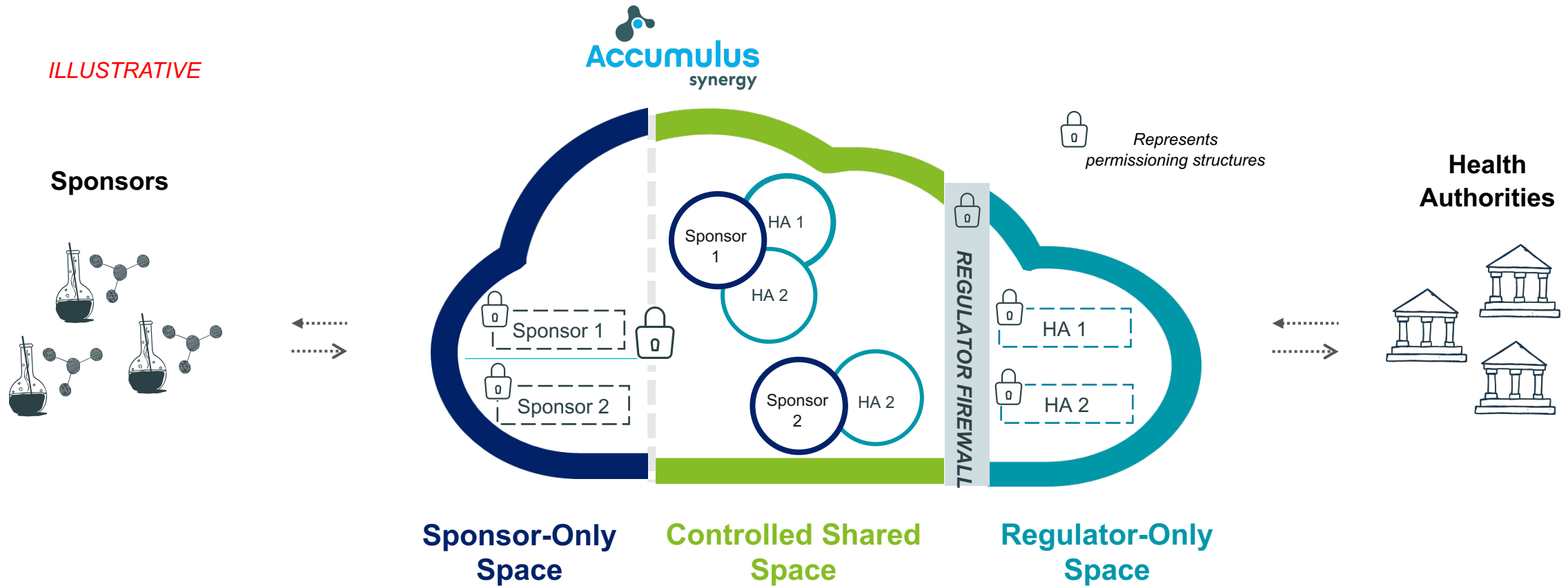
**Accumulus Synergy will embark upon three regulatory policy journeys that will help Accumulus achieve its vision:**

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



# A transformation of the submission process can enable a dynamic approach that shifts the focus from documents to data

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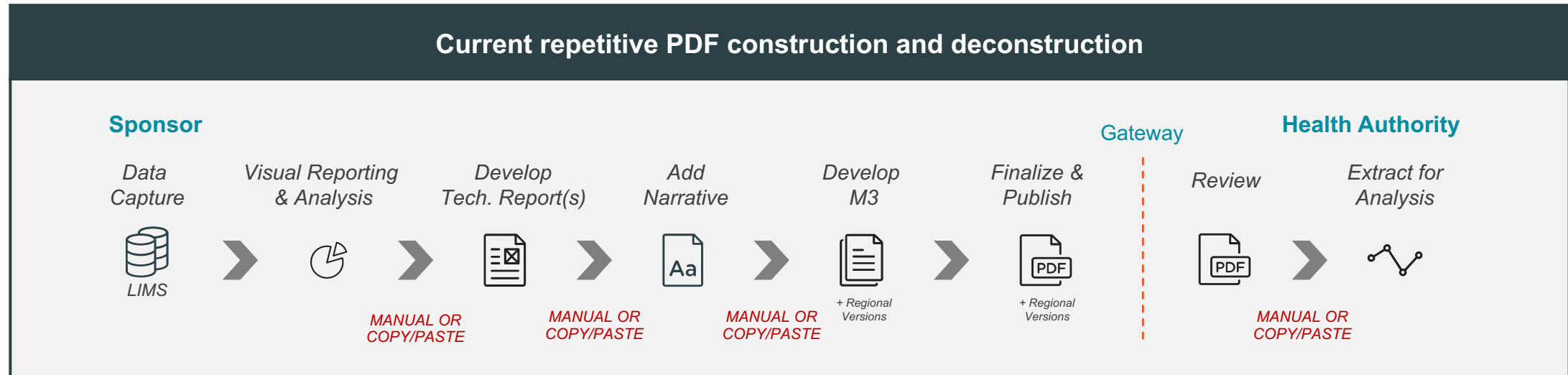


An underpinning prerequisite is the security, privacy, and protection of patient/subject information and company confidential information

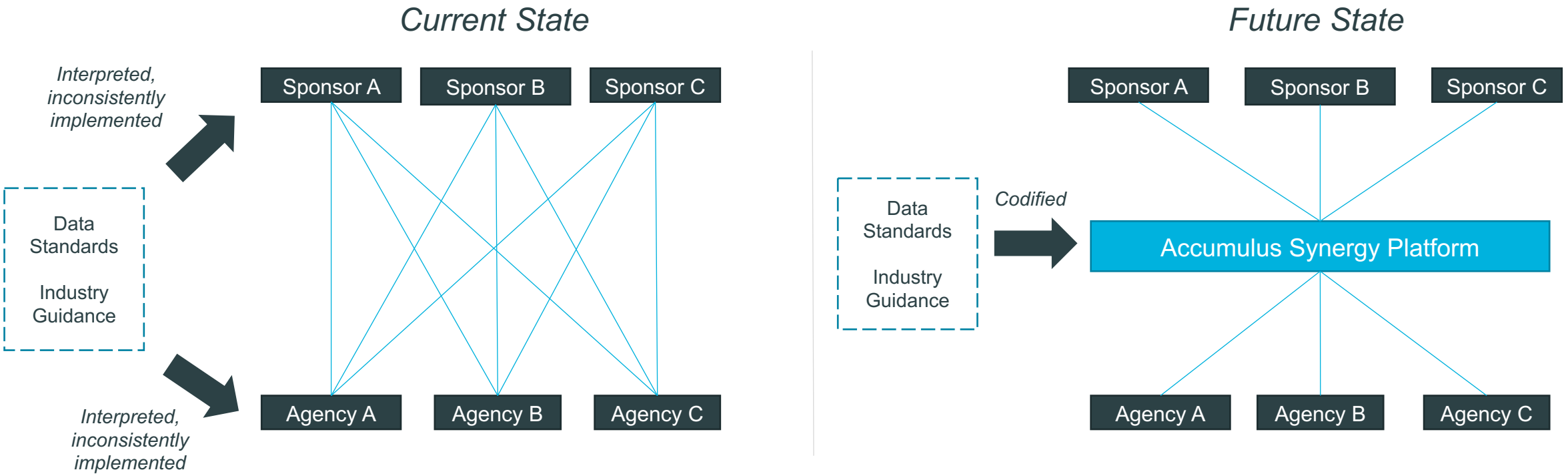
The background features a stylized globe composed of concentric dotted lines. Small, dark blue squares are scattered across the globe, representing data points or nodes. The overall color scheme is a gradient of blue, from a lighter shade at the top to a darker shade at the bottom.

# Accumulus Synergy Approach – Data Exchange in the CMC Space





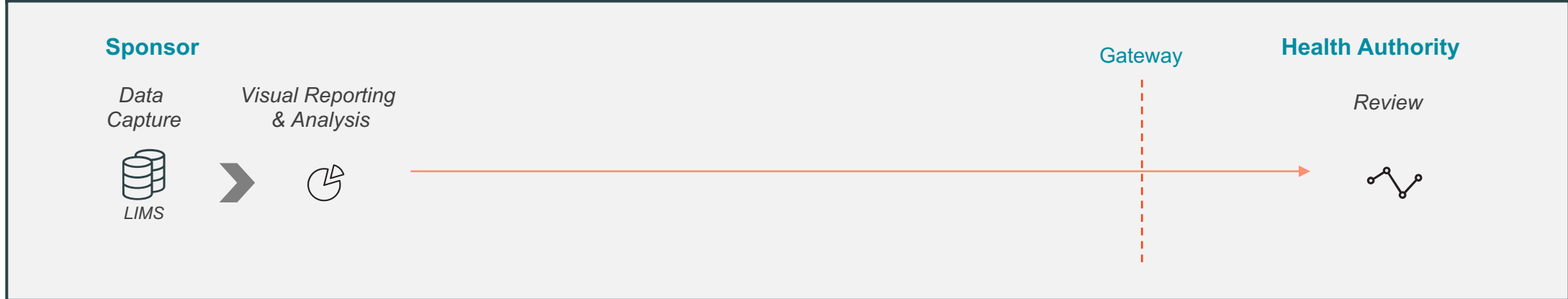
# A Platform Model for Global Information Exchange



Through a standard communication protocol and data model, the Accumulus Platform layer enables industry guidance and global data standards to be strictly defined.

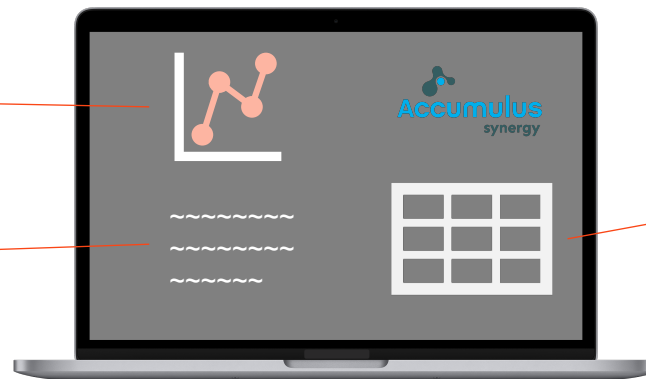
# Transforming How We Exchange Data

Accumulus Synergy will provide raw data, visualized data, and supporting narrative in a “single pane of glass” for reviewers, bypassing the need for PDF construction and deconstruction



**Graphs and Charts** that Sponsors generate and can reuse across filings

**Text narrative** that is autogenerated based on historical filings

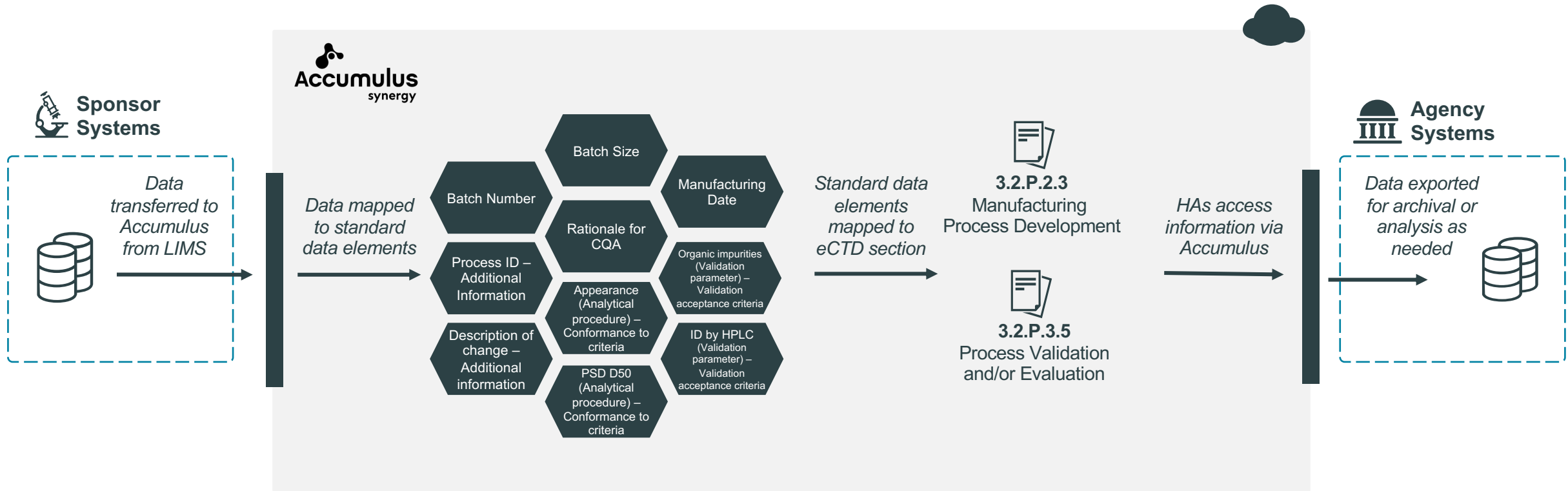


**Raw Data** that can be updated on request for HAs to easily conduct their own analysis

**This technical capability can scale to other clinical and non-clinical data types**

# Process model for standard data element mapping via Accumulus

Through cloud-based technology and standard interfaces, the platform will allow for the exchange of raw data elements that can be referenced across eCTD modules.



## OUR VISION

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

**For more information, please visit <https://www.accumulus.org/>**



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