# Modernizing Global Data Access and Exchange

## Reimagining Regulatory Information Exchange for the Digital Age

### ROUNDTABLE REPORT AND PRIORITY AREAS FOR ACTION

August 2026

Accumulus synergy

Google

# About This Report

Accumulus Synergy is a non-profit organization established to advance a modern, cloud-based ecosystem for the exchange of regulatory information among biopharmaceutical companies and health authorities. Working with regulators, industry, and technology partners, Accumulus Synergy supports the development of shared standards, interoperable platforms, and collaborative approaches that aim to improve the efficiency, transparency, and reach of global regulatory review while preserving the rigor of independent decision-making.

On May 14, 2026, Accumulus Synergy, in collaboration with Google, convened an invitation-only Roundtable that brought together global regulators, biopharmaceutical industry leaders, technology developers, and academic experts. This report summarizes the discussion and presents the priority areas for action that emerged. The views and examples summarized in this report reflect the Roundtable discussion and do not necessarily represent the views or endorsement of Accumulus Synergy, any individual participant, participating organization, or meeting supporter.

## Support for the Meeting

Accumulus Synergy, in collaboration with Google, provided support for this meeting.

# Contents

# Executive Summary

On May 14, 2026, Accumulus Synergy, in collaboration with Google, convened an invitation-only Roundtable that brought together global regulators, biopharmaceutical industry leaders, technology developers, and academic experts. Participants examined the barriers that limit the efficiency of multiregional clinical trials (MRCTs) and the cross-border use of real-world data (RWD) for regulatory submissions. The discussion focused on practical obstacles to data sharing, including fragmented legal bases and transfer mechanisms, inconsistent data governance, and the difficulty of navigating jurisdiction-specific requirements. Participants also highlighted two parallel paths for modernization: using technology to improve the efficiency of existing regulatory processes and using technology to enable more fundamental, data-centric approaches to regulatory information exchange. While near-term efforts often focus on streamlining current document-based workflows, participants emphasized the broader opportunity to reduce reliance on document-centric processes and enable regulators to access data and decision-relevant information more directly.

## Where Modernization Stands

Participants recognized the substantial work already underway across industry, regulatory agencies, and technology providers to modernize regulatory data exchange. While advances in cloud technologies, collaborative review models, and pilot programs have produced meaningful efficiency gains, participants agreed that significant challenges remain in policy alignment, governance, data standards, privacy, consent, and regulatory interoperability. There was broad agreement that scalable, sustainable transformation will require coordinated cross-sector leadership to define a shared vision, establish common frameworks, and advance globally harmonized approaches to submission, review, and data reuse. Participants emphasized pursuing near-term opportunities that can be executed within existing statutory boundaries, such as operational adjustments, pre-competitive standards for cloud-based submissions, clear incentives, and collaborative review mechanisms, alongside longer-term efforts to modernize the underlying policy and legal foundations. The priority areas for action in this report are focused on near-term actions that can begin within roughly one to three years.

KEY OBSERVATION

**"Digital paper"**

Moving from paper to PDFs has changed the format more than the operating model.

**The opportunity is to move toward direct access to structured, decision-relevant information.**

## The Question Shaping the Future State

A central observation framed the discussion: while scientific and technological innovation across the life sciences is advancing rapidly, the mechanisms for regulatory submission and review remain anchored in a document-heavy paradigm, limiting the ability of regulatory processes to fully leverage modern digital capabilities. Participants observed that moving from paper to PDFs has largely produced "digital paper," capturing the appearance of modernization without delivering the efficiencies of cloud-native data networks. At the same time, participants noted that immense organizational resources are increasingly devoted to using artificial intelligence to generate narratives and text summaries that often duplicate information already contained in underlying datasets. Some participants acknowledged that narrative context continues to serve important functions in communicating study findings, supporting interpretation, and documenting regulatory rationale, even as emerging technologies create opportunities to reduce reliance on traditional document-centric approaches. However, the discussion did not reach a consensus on whether a purely data-centric model would be feasible, desirable, or sufficient. Rather, participants identified this as a central question for future regulatory modernization efforts, recognizing that the answer could significantly influence the design of next-generation regulatory information exchange frameworks.

## Future State

Participants envisioned a future regulatory ecosystem that moves beyond static, point-in-time exchanges of information toward a more connected and data-enabled model of evidence generation and regulatory decision-making. Advances in cloud computing, interoperability, and artificial intelligence are creating opportunities for data to be reused, updated, and analyzed throughout the product lifecycle rather than being repeatedly recreated for each submission, review, or research purpose. Some participants emphasized, however, that modernization should not be understood as a shift toward continuous streams of information flowing to regulators. Instead, the goal is to enable trusted access to fit-for-purpose evidence at the right time, supported by appropriate governance, transparency, data quality controls, and regulatory oversight.

This report is organized around three interconnected topics discussed during the Roundtable: sponsor-to-regulator data sharing, regulator-to-regulator collaboration, and data reuse. Each section describes the substantive challenges raised, the perspectives participants brought to them, the initiatives already in progress, and the solutions identified. Discussion across all three converged on a shared goal: faster, more reliable, and more equitable access to safe and effective therapies for patients worldwide. The intent of this Roundtable and resulting report is to establish a foundation for continued cross-sector dialogue, inform future policy and technical development efforts, and advance focused activities toward a more modern, collaborative, and patient-centered regulatory ecosystem.

## Summary of Priority Areas for Action and Further Development

Twelve priority areas for action emerged from the discussion, spanning near-term actions and the foundations for longer-term structural change.

| # | Priority Area | Focus |
|---|---|---|
| **Sponsor-to-Regulator Data Sharing** | | |
| 1 | Establish a Unified Industry Vision and Value Proposition for Regulatory Modernization | Align stakeholders around a common vision and strategic objectives for regulatory modernization, ensuring a shared understanding of the benefits, opportunities, and desired future state. |
| 2 | Modernize Processes from Documents to Structured Data | Transition from document-centric submissions to structured, machine-readable, reusable data. |
| 3 | Extend Modernization to Clinical Trial Sites and the Data Pipeline | Bring trial sites and upstream data generation into the modernization agenda. |
| **Regulator-to-Regulator Collaboration** | | |
| 4 | Advance Collaborative Review Through Targeted Pilots that Define and Demonstrate Value | Use focused pilot programs to demonstrate collaborative review in practice. |
| 5 | Develop a Collaboration Framework Supporting Capacity Building | Define collaboration that also strengthens less-resourced authorities. |
| 6 | Promote Federated Data Access Models | Enable analysis where data resides to preserve data sovereignty. |
| **Data Reuse** | | |
| 7 | Create Harmonized Frameworks for Consent, Reuse, and Transparency | Align consent, data-reuse, and transparency expectations across jurisdictions. |
| 8 | Establish Shared AI Terminology and Require Transparency into AI | Adopt a common AI vocabulary and require transparency into regulatory AI architecture. |

| # | Priority Area | Focus |
|---|---|---|
| 9 | Create Incentives and Design Data for Reuse from Inception | Reward reusable data and design it for reuse from the point of collection. |
| **Cross-Cutting** | | |
| 10 | Establish a Multi-Stakeholder Governance Structure | Create durable governance to coordinate long-term change across industry, regulators, and technology partners. |
| 11 | Establish a Global Evidence Base | Build shared metrics and evidence that demonstrate the value and impact of modernization. |
| 12 | Amplify Patient-Centered Messaging and Convene Expanded Stakeholders | Communicate value in patient terms and broaden participation. |

# Background

**A growing body of published literature documents the operational and governance challenges that limit efficient global data sharing in clinical research and regulatory review.** Regulatory and institutional differences, including variability in data governance requirements, inconsistent data quality frameworks, and divergent interpretations of consent and secondary use, have all been identified as barriers to harmonized data exchange and reuse across jurisdictions. Systematic reviews of clinical trial data sharing find that technical, legal, and ethical obstacles, including a lack of standardization and disparate regulatory environments, continue to constrain cross-border collaboration, particularly when multiple national frameworks apply to the same dataset.[1] The complexity of integrating diverse real-world data sources, which often vary in structure, completeness, and provenance, similarly challenges both the generation of robust evidence and its interoperability and acceptability across regulatory authorities.[2]

Pilots and demonstration projects have begun to show how collaborative approaches can address these bottlenecks. Federated data analysis pipelines and common data models have supported multi-institutional RWD integration without moving data across borders, illustrating one path that preserves privacy while enabling scale.[3] Parallel efforts in clinical trial data sharing have shown comparable progress. The Cochrane Repository for Individual Patient Data pilot, for example, sought to facilitate sharing of harmonized individual patient datasets from multiple trials under a safeguarded access model, demonstrating both the feasibility and the difficulty of the approach, with governance and legal agreements proving more time-consuming and complex than anticipated.[4] Surveys of industry participants in regulatory work-sharing initiatives, such as the ACCESS Consortium, suggest that while these frameworks can enhance efficiency, they also reveal practical barriers around predictability, transparency, and process complexity, underscoring the importance of structured guidance, harmonized procedures, and clear communication.[5]

**Regulatory authorities have increasingly pursued collaborative models to coordinate across countries and accelerate access to innovative therapies.** The U.S. Food and Drug Administration's (FDA) Project Orbis enables concurrent submission and review of oncology products across international partners,[6] while the ACCESS Consortium supports work sharing and joint assessments among participating agencies.[7] **These initiatives improve efficiency, reduce duplication, and promote alignment, but they do not eliminate administrative burden, because sponsors must still prepare and submit applications and data to each participating authority and address country-specific requirements.**

Beyond the published literature, several authoritative reports and initiatives bear directly on these themes. International guidance on regulatory reliance establishes that a relying authority retains independence and accountability while giving weight to another authority's assessment.[8] A landmark National Academies study commissioned by the FDA examined mutual-recognition and reliance among medicines regulators amid increasingly globalized drug development and supply chains, concluding that no authority can oversee that enterprise alone and recommending a substantial expansion of reliance to cut duplication and make the most of limited regulatory resources.[9] A joint regulator statement has also called for wider access to clinical data and for assessment information to be shared more openly in the public interest.[10] In parallel, the European Medicines Agency's (EMA) DARWIN EU—a federated network of public and private data partners across Europe (hospitals, primary care, health insurers, disease registries, and biobanks) coordinated by the Erasmus University Medical Center Rotterdam, serving EMA and the national competent authorities of the EU Member States—now generates evidence for regulatory decisions by querying data where it resides rather than moving it across borders, demonstrating the feasibility of the data-sovereignty-preserving models discussed in this report.[11]

Several U.S. statutes and regulations frame the challenges discussed here. The 21st Century Cures Act and the resulting real-world evidence framework direct the evaluation of real-world evidence to support certain regulatory decisions.[12] An abbreviated approval pathway permitting reliance in part on data not developed by the applicant reflects a longstanding mechanism for data reuse.[13] Federal requirements for electronic records and signatures govern the integrity, provenance, and retention of digital submissions.[14] Protections for trade secrets and confidential commercial information constrain the sharing of unredacted assessments among agencies.[15] Federal health-privacy protections, including the de-identification standard, shape what data may be reused and the risk that anonymized data could be re-identified.[16] More recently, draft

FDA guidance addresses the use of artificial intelligence to support regulatory decision-making.[17] Together, these authorities define both the opportunities and the boundaries for modernization. They also illustrate why many of the challenges discussed throughout this report persist. Existing legal and regulatory frameworks were largely developed around discrete submissions, document-based records, and jurisdiction-specific review processes. As stakeholders seek to advance more collaborative, cloud-enabled, and data-centric approaches, important questions remain regarding how regulatory records are created, maintained, versioned, shared, and retained across organizations and jurisdictions. Greater clarity will be needed regarding how existing frameworks apply to emerging models of data exchange, collaborative review, and evidence generation. For example, cloud-based review environments and iterative data exchange raise questions about what constitutes the official regulatory record, how version control audit trails should be maintained, and how records should be retained when information is accessed dynamically rather than submitted as a static dossier. Given these scientific, regulatory, and operational realities, continued collaboration among regulators, sponsors, researchers, technology developers, and patients will be essential to translate current efforts into durable solutions that improve the efficiency of global regulatory decision-making while preserving appropriate safeguards for privacy, consent, and regulatory rigor.

# Framing the Discussion

The roundtable opened with presentations highlighting recent advances in cloud technologies, regulatory collaboration models, and emerging proof-of-concept initiatives. Collectively, these examples demonstrated that many of the technical capabilities required to support more dynamic, collaborative approaches to regulatory information exchange already exist or are actively being tested. While important technical challenges remain, participants generally viewed technical feasibility as less of a limiting factor than organizational, legal, governance, interpretation, and implementation considerations. Against this backdrop, the discussion focused on the barriers and opportunities associated with broader adoption, which centered on the three major themes of sponsor-to-regulator data sharing, regulator-to-regulator collaboration, and data reuse.

TOPIC ONE

# Sponsor-to-Regulator Data Sharing

KEY DISCUSSION THEME

### Moving Beyond the "Digital Paper" Paradigm

Participants agreed that, despite the widespread adoption of electronic submission systems, the current regulatory environment, including policy requirements, review processes, technical infrastructure, and organizational practices, remains anchored in a document-centric model best described as "digital paper." Submissions continue to be built around large PDF dossiers, extensive narrative generation, and fragmented, jurisdiction-specific requirements. Electronic submission improved paper-based processes, but participants noted that the underlying operating model has changed little. Sponsors still prepare multiple versions of essentially the same package to satisfy varying requirements across jurisdictions, creating substantial administrative burden, duplicative effort, and delays in achieving simultaneous global approvals. Several participants observed that these inefficiencies are increasingly difficult to justify given the pace of advances in digital technology and growing expectations for more agile, collaborative review. Participants suggested that emerging automation and AI-enabled tools may create opportunities to generate jurisdiction-specific submission documents from a common source of regulatory content and to better align study design with country-specific requirements.

**A central theme was the need to move beyond incremental optimization of legacy systems toward a more modern, platform-based model of exchange.** Participants were emphatic that the objective is not to change the scientific, clinical, or regulatory data being submitted, but to enable the same information to be exchanged, reviewed, and updated through more efficient, interoperable mechanisms. Several cautioned against using emerging technologies, including artificial intelligence, simply to recreate document-based workflows in digital form. Instead, they urged a future-

state vision centered on harmonized review and direct access to structured information. However, participants recognized that AI-driven generation of regulatory documents could provide meaningful near-term efficiencies as an interim step toward this longer-term vision. Participants raised practical questions about whether future platforms could allow regulators to directly access, download, or transfer records while preserving the regulatory controls, audit trails, and record-retention requirements that current frameworks demand.

Participants grounded these themes in concrete experience, pointing to evidence that cloud-based exchange already delivers measurable gains. In the chemistry, manufacturing, and controls (CMC) post-approval space, they cited numerous proof points and a substantial reduction in regulatory questions as agencies reviewed one another's work collaboratively, supported by active regional reliance clusters rather than dependence on a single reference agency.[19] Participants questioned why so many duplicative CMC supplements are required for the same manufacturing standard worldwide, and suggested that the single-review model emerging in the CMC space could be extended into the clinical space as well.

**The most striking illustration came from the speed of the technology itself.**

The most striking illustration came from the speed of the technology itself. Participants highlighted examples of how modern tools may significantly accelerate regulatory processes. One attendee noted example (presented as a participant observation and not independently verified for this report) that AI-enabled approaches have the potential to compress the U.S. Food and Drug Administration (FDA) filing-review step for a new drug application, historically a process that can take approximately 60 days, to as little as one hour in certain contexts. The attendee cautioned that as discovery accelerates, the regulatory system risks being overwhelmed unless its operating model evolves, not merely its file formats. Current submission processes remain anchored in electronic-records frameworks built around document production rather than data exchange.[14,20]

**Cloud-based technologies were recognized as a key enabler of standardization in submission formatting, review workflows, and information exchange, and participants noted that cloud-based approaches are increasingly driving convergence in how dossiers are submitted and reviewed.** Looking to the future state, participants discussed a modular submission model in which shared components are prepared once and reused across jurisdictions while jurisdiction-specific elements are added as needed. Several likened the concept to a U.S. college application system, in which a common core is supplemented by institution-specific materials, reducing duplicative preparation of nearly identical dossiers while preserving each authority's ability to require locally mandated content.

There was broad agreement, however, that technology alone is insufficient. Participants emphasized that fragmentation across regulatory systems is not primarily a technical problem but a structural one, reflecting differences in policy frameworks, consent requirements, anonymization standards, institutional risk tolerance, and regulatory practice. Expectations for anonymization and privacy protection continue to vary significantly across jurisdictions, complicating efforts to establish common approaches. While collaborative work-sharing and reliance models demonstrate that greater alignment is achievable, participants noted that their broader impact remains limited by the absence of globally harmonized standards and consistent legal mechanisms for sharing assessments and content across agencies. Several observed that legislative action and broader policy advocacy, including direct engagement with lawmakers and government stakeholders, may ultimately be necessary to create a durable foundation for modernization, since sponsors today cannot submit a single uniform data package across all jurisdictions.

Participants also stressed the importance of clearly articulating the value proposition. While there was broad support for platform-based exchange, participants noted that sponsors are more likely to invest if benefits can be quantified and communicated as long-term strategic advantages rather than short-term operational improvements. Benefits discussed included reduced duplication, more efficient interactions, accelerated review timelines, better resource utilization, and faster patient access. Participants also identified additional staffing and full-time-equivalent support within regulatory agencies as an important factor in realizing the benefits of modernized review and emphasized the need to establish shared stakeholder objectives and measurable outcomes that demonstrate value to sponsors, regulators, and patients alike.

**Participants agreed that meaningful progress will depend on stronger cross-sector coordination and sustained leadership, and expressed interest in establishing a multi-stakeholder think tank to define a shared**

**vision, scope, and long-term objectives for sponsor-to-regulator data sharing.** Such a forum could bring together industry leaders, regulators, technology experts, and patient-advocacy co-leads to identify priority use cases, align on goals, and develop implementation recommendations. Participants were clear that pilots should not be isolated demonstrations of technology but learning vehicles that inform broader future-state operating models, and several urged industry leaders to step forward to champion change, including by publishing successful case studies and lessons learned, in major academic or business journals.

Engagement with international standard-setting bodies, particularly the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), was identified as essential to developing globally recognized standards for cloud-based submissions and interoperable review. Participants noted that ICH already maintains the technical standards that structure today's submissions, such as the electronic Common Technical Document (eCTD), and could play a central role in defining comparable standards for cloud-based, data-centric exchange. However, they noted that while ICH continues to explore new use cases and expand its guidelines, many existing standards remain fundamentally document-centric. They suggested that industry work with ICH to define new standards for cloud-enabled platforms, structured data exchange, and common technical and security requirements, and proposed that ICH could lead an analysis defining the requirements for future global platform models.[18]

Participants emphasized that, although industry must champion modernization, durable change ultimately requires regulators to lead harmonization, and industry to advance a clear mandate for action may be needed to overcome institutional inertia. Several observed that despite substantial industry investment in technology, regulators frequently continue to rely on manual, paper-based processes, creating a bottleneck that delays patient access. To build the case for change, participants suggested engaging external advisory expertise to operationalize platform-based models and quantify their value.

**Looking further ahead, participants described a future state in which data are uploaded continuously and iteratively during review, with analysis and response occurring closer to real time rather than only at discrete milestones, moving beyond static document exchanges toward an ongoing dialogue between sponsors and regulators.**

Looking further ahead, participants described a future state in which data are uploaded continuously and iteratively during review, with analysis and response occurring closer to real time rather than only at discrete milestones, moving beyond static document exchanges toward an ongoing dialogue between sponsors and regulators. Some noted that this vision needs to align with the operational realities and regulator needs of regulating agencies. They also emphasized that modernization cannot stop at submission and review. It must extend upstream to clinical trial sites and their technology, which represent the starting point of the data pipeline.[23] Several participants observed that sites are often where inefficiency originates and that bringing them into the conversation is essential to realizing a continuous, data-driven development and review process. Participants also suggested that consideration be given to prioritizing specific countries, regulatory authorities, or use cases best positioned to demonstrate early success and generate broader momentum. Without coordinated industry leadership, a clearly defined long-term vision, and sustained advocacy across regulatory and policy communities, participants cautioned, modernization efforts risk remaining confined to pilots rather than evolving into scalable, system-wide change.

TOPIC TWO

# Regulator-to-Regulator Collaboration

KEY DISCUSSION THEME

## Trust, Governance, and Incentives for Regulatory Collaboration

Participants agreed that regulator-to-regulator data sharing has significant potential to improve regulatory efficiency, consistency, and collaboration, but that implementation remains constrained by a complex set of geopolitical, legal, organizational, and operational challenges. The discussion repeatedly returned to a single insight: the barriers to cross-border collaboration less technical than institutional, reflecting differences in national priorities, regulatory capacity, legal authorities, confidentiality frameworks, and resource models. Participants noted that agencies are ultimately accountable to their domestic mandates, which can create tension between local priorities and the increasingly global nature of pharmaceutical development. Geopolitical considerations, including growing regionalization, data sovereignty requirements, and divergent technology infrastructures, were cited as important factors shaping agencies' willingness and ability to participate in broader data-sharing initiatives.

**A central theme was the need for trusted frameworks that allow regulators to share information while preserving confidentiality and agency autonomy.**

Participants identified geopolitical dynamics as among the most significant barriers, including tensions among major economies that create hesitancy and push countries to prioritize sharing in line with their own strategic interests. Local mandates compound the problem; requirements to use local cloud providers, for example, constrain the technical environments available for cross-border collaboration. A recurring operational concern was that requiring more than one platform burdens agencies that have already invested in their own systems and workflows, and that regulators asked to adopt an additional platform may see reduced rather than improved efficiency if integration is not carefully managed.

Participants emphasized that broader adoption of collaborative review models will depend on establishing a clear and compelling value proposition for regulatory authorities. While many agencies have successfully implemented work-sharing, reliance arrangements, and concurrent review activities through existing processes, there was recognition that regulators may be unable to dedicate additional time, resources, or funding to new approaches unless the benefits are clearly demonstrated. Participants noted that potential value drivers include improved resource utilization, reduced duplication of effort, increased review consistency, strengthened regulatory capacity, enhanced access to specialized expertise, and the ability to accelerate patient access to therapies through more coordinated review activities. Several participants observed that demonstrating these benefits through targeted pilots and measurable outcomes will be critical to securing broader regulatory engagement.

A central theme was the need for trusted frameworks that allow regulators to share information while preserving confidentiality and agency autonomy. Participants noted that existing mechanisms, including confidentiality commitments, bilateral agreements, and memoranda of understanding, provide important foundations but are often limited in scope and slow to establish. One participant described the Swissmedic experience, in which a bilateral confidentiality agreement and a memorandum of understanding were required simply to share a review, not even the underlying data, a process that demanded considerable time and effort with no shortcut available. Differences in national security requirements, legal authorities, and confidentiality obligations continue to create variability in how and when information can be shared, and participants asked whether future technical environments could manage confidentiality obligations within the platform itself where a sponsor's agreement to share already exists.

Underlying these examples was a distinction participants drew repeatedly: technical interoperability is now viewed as largely solved, while legal and confidentiality frameworks remain the binding constraint. Advances in cloud technologies, common data standards, and interoperable systems have reduced many of the historical barriers to information exchange, and existing

collaborative review efforts already demonstrate that multiple regulators can access common environments, review shared materials, and observe one another's questions and comments. Differences in country-specific security controls, however, can prevent one agency from sharing with another absent an applicable confidentiality commitment.[15]

Several participants observed that many regulators remain reluctant or unable to share unredacted assessment reports, in some cases even with the sponsor of the submission, reflecting confidentiality obligations governing trade-secret and confidential commercial information.[15] It is equally true that some sponsors of submissions insist that their intellectual property and trade secrets are protected. Participants observed that agencies must balance opportunities for collaboration against statutory responsibilities, confidentiality obligations, resource limitations, and varying institutional approaches to risk management. Reframing the conversation, several noted that the term "reliance" can carry a negative connotation implying an inability to conduct an independent review and suggested recasting it as a collaborative process that builds trust and capacity while preserving each authority's sovereignty over its own decisions.

Looking ahead, participants described a future state in which regulators collaborate within secure shared environments, access common datasets, review information simultaneously, and exchange comments in real time, shifting away from static summaries toward direct interaction with underlying data while improving transparency and consistency. They cautioned, however, that technology alone will not guarantee success. Multiple jurisdictions continue to pursue independent technology strategies and local infrastructure requirements, and introducing additional platforms can create operational burdens for agencies with established systems. Successful implementation will therefore require careful attention to user adoption, integration with existing processes, and the practical realities facing organizations with varying levels of resources and technical capability.

**Participants emphasized the importance of trust, regulatory readiness, and shared objectives in determining where collaboration can succeed first. Existing collaborative review models, reliance frameworks, and international partnerships were cited as evidence that meaningful cooperation is possible when strong governance and trusted relationships are in place.** Participants discussed how international organizations and regulatory maturity frameworks, such as the World Health Organization's maturity-level classification, can build the foundation for collaboration, noting that regulators may initially be more comfortable sharing among agencies of similar experience and capability. While beginning among well-resourced agencies may accelerate early implementation, participants noted that adoption may be influenced by factors beyond available resources. Regulatory authorities of varying sizes may see value in collaborative approaches that reduce duplication and improve access to information and expertise. Participants stressed the importance of creating pathways for regulatory systems with varying levels of capacity, experience, and capability to participate over time. They pointed to newly established, fully digitalized regulatory systems as models that could enable a single dossier submission, a single inspection, and broader regional access, illustrating how emerging environments may leapfrog legacy approaches by adopting modern infrastructure from the outset. Participants noted that internationally recognized frameworks, such as the World Health Organization's Global Benchmarking Tool (GBT), can provide a structured basis for assessing and strengthening regulatory system capabilities and fostering trust among collaborating authorities. Progression through recognized capability levels was discussed as a positive incentive, as it can encourage investment in regulatory capacity and support participation in trusted information-sharing arrangements. Participants also acknowledged a risk that regulators with greater experience in collaborative review and work-sharing models could advance arrangements that initially exclude authorities with more limited experience or resources and emphasized the need for starter kits, capacity-building efforts, and structured pathways to support broader participation over time.

There was broad agreement that success will require clearly articulated, high-value use cases that align with regulatory priorities and demonstrate tangible benefits. Some participants discussed beginning with the assessment report itself (a regulator's own scientific review of a marketing application) sharing reviews voluntarily among willing authorities, as a practical first step, since sharing assessments is a lower hurdle than sharing underlying data. Rare and ultra-rare diseases were identified as particularly suitable initial use cases, given the strong shared interest in accelerating access, the smaller volumes of data involved, and the existing reliance on registry data.[22] Participants also highlighted opportunities for regulators to share assessments, questions, analytical approaches, and review experiences in ways that strengthen capacity and promote consistency. They stressed, however, the importance of clearly defining the purpose of collaboration and

distinguishing among knowledge-sharing, collaborative review, and joint decision-making. Even where regulators benefit from shared analyses and common environments, individual agencies will continue to hold responsibility for their own decisions and statutory obligations.

The discussion also highlighted provenance, transparency, records management, and inspection readiness as critical design requirements for any future collaborative environment. Participants noted that regulators must be able to understand precisely what information was reviewed, what analyses were conducted, and what evidence supported a given decision. Evidence shared across jurisdictions should be demonstrably fit-for-purpose and supported by appropriate data-quality controls, traceability, validation, auditability, and inspection access. They pointed to cloud-based analysis pilots and multi-jurisdiction trusted research environment projects as practical vehicles for clarifying these legal records-keeping requirements.[14] Participants further underscored that different jurisdictions bring different intentions to the same data; an identical package may need to support one authority's regulatory requirements in one setting and combined regulatory, payer, and population-health decisions in another. Future systems must accommodate these varied local expectations rather than assuming a single common purpose.

Participants explored verifiable-record approaches, including ledger-based methods, to establish a trusted record of truth across collaborating agencies, and discussed building compliance automations within a restricted cloud boundary. Benefit-sharing and governance for lower-resource settings were raised as critical and often unresolved questions, with clear governance, data sovereignty protections, and equitable benefit-sharing seen as prerequisites for sustained participation. To keep the discussion tractable, participants narrowed the near-term scope to a small set of mature markets, noting that existing collaborative agreements among them often suffer from inconsistent implementation and that these markets themselves face substantial legacy-infrastructure challenges that warrant focused attention.

Encouragingly, participants noted that the COVID-19 pandemic showed that simultaneous, synchronized regulatory review is achievable when political, legal, and regulatory priorities align, when political and legal will align, including coordinated review of real-world data under a hub-and-spoke model.[23] They cautioned, however, that the pace of global access is shaped not only by regulatory barriers but also by sponsors' own launch-sequencing and commercial strategies, which influence when and where applications are filed. Existing pathways that allow non-member authorities to participate in certain reviews were cited as models that already enable broader participation. Finally, participants identified operational requirements such as Certificates of Pharmaceutical Product as a barrier that relegates some countries to a later wave of access, since these are frequently reliance countries still dependent on paper or document-based submissions; addressing such requirements was viewed as an important step toward more equitable and simultaneous global access. The long-term success of regulator-to-regulator data sharing, participants concluded, will depend on common governance frameworks, trusted environments, and sustainable operating models that accommodate differing objectives while enabling more coordinated global review.

TOPIC THREE

# Data Reuse

KEY DISCUSSION THEME

### Unlocking Value While Preserving Trust

Participants agreed that data reuse has the potential to accelerate evidence generation, improve regulatory decision-making, support AI applications, and enhance patient outcomes, but that implementation remains constrained by a complex set of regulatory, ethical, technical, and organizational challenges. The barriers extend well beyond technology and reflect fragmented regulatory frameworks, inconsistent consent models, varying interpretations of privacy protections, and differing national philosophies about data ownership and use. Participants noted that the absence of a harmonized global vision has produced a fragmented landscape in which sharing practices, governance structures, and incentives vary significantly across organizations and jurisdictions. While participants noted that regional initiatives are beginning to

establish common approaches to data access and reuse, the broader ecosystem lacks globally accepted interoperable data formats and structures. Participants suggested that realizing the full potential of data reuse will require international alignment on foundational technical standards, similar to the role that ICH and the eCTD played in standardizing regulatory submissions.

Participants emphasized that data reuse is a broad term whose risks and permissions vary fundamentally with purpose, making careful scoping a prerequisite to progress. The distinct purposes they identified include reuse for AI training, reuse to inform a specific regulatory decision, reuse of real-world and person-level data for drug repurposing and for applications relying in part on data not developed by the applicant,[13] and reuse of historical data to construct external or synthetic control arms. Because each purpose carries a different risk profile, participants cautioned that a single set of rules cannot govern all of them, and that statutory constraints further shape what is permissible in each case.

A central distinction emerged between learning from aggregate or summary-level data and learning from individual patient-level data. Participants generally regarded learning signals from study-report summary statistics as acceptable, whereas training on individual patient data raises materially higher privacy concerns and depends heavily on the sponsor's risk posture and the specific consent obtained. Building on this, participants emphasized that current consent mechanisms were not designed for many emerging reuse scenarios, particularly those involving artificial intelligence, secondary use, and longitudinal evidence generation. They noted significant regional differences, with some countries offering patient opt-out mechanisms while others hold divergent philosophies regarding data ownership and whether access to one's data is a human right. Rather than attempting to reconcile historical inconsistencies, participants favored defining future-state principles for responsible reuse and aligning around a shared vision of what good looks like, even while acknowledging the fundamental philosophical differences towards privacy between, for example, the United States and the European Union.

AI emerged throughout the discussion as both a driver of and a challenge for data reuse. Participants noted that regulators and sponsors are increasingly exploring AI to support knowledge management, quality control, and review. During the discussion, one participant shared an example (presented as a participant observation and not independently verified for this report) that the U.S. FDA is feeding roughly 15,000 investigational new drug applications into an internal AI tool to build knowledge management and assist with regulatory inquiries. At the same time, participants raised concerns about the appropriate use of individual versus aggregate data for model development, the potential for re-identification of anonymized information, and the risk of unintended disclosure of proprietary data through AI-enabled systems.

Participants identified a persistent communication gap between the pharmaceutical and technology sectors around the term "AI training," and stressed the need to distinguish creating a frontier model, fine-tuning, retrieval-augmented generation, benchmarking, and agentic applications, as these approaches use, retain, and expose data in fundamentally different ways. Participants noted that concerns about data use are often shaped by early experiences with consumer-facing AI chat services and uncertainty regarding how data are incorporated into models, managed within enterprise environments, and protected from unauthorized access. They emphasized the importance of improved shared understanding of these distinctions to support informed risk assessment and governance. Additionally, asking regulators specific questions about architecture, data flows, and handling was viewed as essential to productive dialogue. Participants described a future in which sponsor and regulator systems could exchange information securely through a cloud intermediary, which would require clear accountability for ensuring the right data are used, validated, and spot-checked.

Transparency and trust were recurring themes. Participants raised data-integrity and confidentiality concerns, including past instances of regulator correspondence reaching the wrong recipient and the risk that proprietary information from one sponsor could be exposed through shared systems. While participants acknowledged that these challenges are not unique to digital environments, they noted that modern technologies can increase both the speed and scale at which errors may occur, reinforcing the need for appropriate safeguards and oversight. They called for greater regulator transparency into technical architecture, including how the FDA's Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research manage their data, and whether internal systems share a common semantic layer and interoperate, so that stakeholders can align on shared terminology. Looking ahead, participants described a future state in which sponsors and regulators interact through secure cloud-based environments and interoperable AI systems, while recognizing that realizing it will require clear governance, validated analytical tools, and agreed-upon standards for data access, quality, and performance.

Participants cautioned that significant practical barriers continue to limit adoption and identified the absence of clear incentives as the most immediate. Without a tangible reward, such as a meaningful reduction in review or approval timelines, sponsors are unlikely to absorb the substantial cost of curating reusable data, and individuals within organizations need a clear return on investment to justify the effort internally. Participants noted that clinical data are often treated as a competitive advantage and that internal silos frequently prevent teams from sharing knowledge about reusability across an organization. They also cautioned that stakeholders cannot simultaneously advocate for open sharing while withholding their own proprietary data.

**A related theme was that reusability must be designed into data collection from the outset rather than retrofitted, since making one-off datasets reusable later is expensive.** Achieving it requires forward-looking consent, metadata and provenance captured at the source, and parallel statistical and regulatory innovation.[21] Participants characterized current reuse as uneven and inconsistent, a consequence of limited investment and of data management not planned from the inception of clinical trials. They pointed to emerging models that demonstrate its value: research-foundation registries that turn natural-history data into a reusable comparator for regulatory review, reducing the need to recreate that evidence for each program, and cloud-based environments that allow digital health endpoints to be pooled and reused across studies.[22] Such uses remain the exception rather than the norm, largely because historical data were not captured with reuse in mind and because the scientific context of each dataset must be matched carefully to each new purpose.

**Participants articulated a longer-term vision of shifting evidence generation from discrete, sequential trials toward a continuum, including seamless designs that add and drop arms and approaches that link patient records to enable longitudinal reuse.**

Participants articulated a longer-term vision of shifting evidence generation from discrete, sequential trials toward a continuum, including seamless designs that add and drop arms and approaches that link patient records to enable longitudinal reuse. They cautioned that record-linkage and tokenization techniques are not uniformly recognized across countries, are used primarily in the United States, and raise key-management and re-identification challenges that grow as more data are linked. Participants discussed the legal frameworks that shape reuse, including patient opt-out rights that require mechanisms for withdrawing data and the diminishing reliability of anonymization given concerns about re-identification.[16] They noted that U.S. law permits the use of real-world evidence to support certain regulatory decisions while its application to pre-market submissions remains limited,[12] and suggested that data permissions be categorized as contractual, patient-granted, or policy-based to determine when each element may be reused.

Participants also explored emerging technical approaches that may enable more secure and scalable reuse, including trusted execution environments, tokenization strategies, and privacy-preserving architectures, while recognizing that these introduce their own governance and international implementation challenges. They noted that while the European Health Data Space is an interesting development, the active frontier increasingly involves integrating multimodal data, such as genomic and other omics datasets, through trusted and secure processing environments. Particular attention was given to the need for robust security controls, threat modeling, and continuous risk assessment to ensure that AI systems and data-sharing environments cannot be manipulated to expose sensitive information. Participants identified quality control as a near-term, lower-risk application of AI, noting that both sponsors and regulators are exploring its use to confirm that submissions are complete and ready before substantive review begins.

Participants concluded that realizing the full value of data reuse will require coordinated action across regulators, industry, technology providers, and patient communities. Success will depend on establishing a harmonized vision, creating clear incentives for participation, improving transparency around technology and governance, and developing trusted environments for secure and responsible sharing. Without sustained leadership and cross-sector alignment, participants cautioned that efforts may remain fragmented and unable to capitalize on the potential of data reuse to advance regulatory science, clinical development, and patient care.

# Priority Areas for Action

The priority areas for action below reflect the themes, insights, and proposed directions that emerged from the Roundtable dialogue. They are framed as near-term actions that could be pursued within existing legal and operational frameworks while laying the foundation for longer-term transformation. They are grouped below by the discussion topic they address, with recommendations that cut across topics presented last under Cross-Cutting. The order in which they are presented is intended for organizational purposes only and does not reflect a ranking or prioritization of importance. While these recommendations reflect areas of broad interest and discussion among participants, they are not intended to represent formal consensus positions or endorsements by any individual participant or organization. Rather, they are offered as potential directions for future action to stimulate continued dialogue and cross-sector collaboration.

## Sponsor-to-Regulator Data Sharing

### Priority Area 1. Establish a Unified Industry Vision and Value Proposition for Regulatory Modernization

Progress toward a more modern regulatory ecosystem requires a clearly articulated and widely understood vision and value proposition that defines the limitations of today's document-centric paradigm and aligns stakeholders around a common vision for the future. Industry has an important role to play in championing this effort by working with regulators and other stakeholders to develop fit-for-purpose value propositions that show how modernized approaches can deliver greater efficiency, stronger collaboration, and more timely access to innovative therapies. The case for change must be simple and compelling, and stakeholders such as patients must be able to understand the problem if the vision is to attract broad support.

### Priority Area 2. Modernize Regulatory Processes by Transitioning from Documents to Structured Data

Regulatory processes should move beyond PDF-based workflows toward structured, interoperable, and machine-readable data environments. Current systems often replicate paper-based processes in digital form, creating inefficiencies for sponsors and regulators alike. Future efforts should focus on identifying the minimum information necessary to support a decision and on enabling data-driven review that leverages advances in cloud computing and artificial intelligence, while preserving the controls and retention requirements that regulatory frameworks demand.[14] Structured data environments should incorporate mechanisms to ensure fitness-for-purpose, provenance, data quality, traceability, validation, auditability, and inspection readiness so that modernization strengthens, rather than diminishes, confidence in regulatory science.

### Priority Area 3. Extend Modernization to Clinical Trial Sites and the Data-Generation Pipeline

Efforts to modernize submission and review will deliver limited benefit if the upstream data-generation pipeline remains unchanged. Stakeholders should bring clinical trial sites, their technology, and the broader trial ecosystem into the modernization agenda so that data are captured in structured, reusable form at the point of generation. Aligning site-level data practices with downstream submission and review modernization would support a more continuous development and review process and reduce duplicative effort across the lifecycle.[23]

## Regulator-to-Regulator Collaboration

### Priority Area 4. Advance Collaborative Regulatory Review Through Targeted Pilot Programs that Define and Demonstrate Value

Stakeholders should implement focused pilots that test new approaches to collaboration while addressing the associated legal, governance, and infrastructure requirements. These pilots should also help define and demonstrate a clear value proposition for regulatory authorities, recognizing the resource, operational, and legal constraints under which many agencies operate. Rather than attempting large-scale transformation immediately, stakeholders should pursue incremental implementation through clearly defined use cases (e.g., rare and ultra-rare diseases), building on existing models such as collaborative review initiatives and reliance-based frameworks. Sharing the assessment report among willing authorities is a practical, lower-risk first step, since sharing reviews is a smaller hurdle than sharing underlying data. Rare and ultra-rare diseases are particularly suitable initial use cases given the shared global interest in accelerating access, the smaller volumes of data involved, the need to combine data across jurisdictions to generate sufficient evidence, and the existing reliance on registry data. Pilots should be designed not only to test technical feasibility but also to build institutional confidence, demonstrate value, and support the organizational and cultural shifts required for adoption. New tools alone will not drive transformation; sustained leadership engagement, clear incentives, and opportunities to build trust and familiarity will be important to enabling broader implementation.

### Priority Area 5. Develop a Regulatory Collaboration Framework that Supports Capacity Building

Future collaboration models should be designed not only to support joint review but also to strengthen regulatory capacity globally. A structured framework should encompass three distinct functions: collaborative review; capacity building and upskilling; and observational access to regulatory information. Supporting broader participation through shared learning, starter kits, and collaborative review opportunities can promote convergence while preserving national decision-making authority. Modernization initiatives should enable leapfrog adoption among resource-constrained regulators and manufacturers, and new platforms should reduce rather than increase technological barriers by providing shared infrastructure, standardized tools, and opportunities for collaborative participation that build local capability.

### Priority Area 6. Promote Federated Data Access Models that Preserve Data Sovereignty

The future of regulatory collaboration may not require moving data across jurisdictions; the goal can instead be framed as allowing regulators to examine the data where it resides rather than transferring it. Stakeholders should explore federated approaches that let authorized regulators access or analyze data in place while maintaining compliance with local privacy, confidentiality, and sovereignty requirements.[11] Such models may reduce legal barriers, increase confidence, and provide a more scalable foundation for global collaboration, provided that questions of legally compliant access are resolved up front. Federated approaches must be accompanied by clear governance frameworks, legal mechanisms, confidentiality protections, and sustainable operating models.

## Data Reuse

### Priority Area 7. Create Harmonized Frameworks for Consent, Data Reuse, and Transparency

To support responsible data reuse, stakeholders should develop patient-centered consent frameworks through direct patient partnership in consent design, governance, and oversight. Future consent models should support dynamic permission management, reduce participant burden, and keep patients as active partners in decisions about the use and reuse of their data. Technical standards should clearly define how data may be reused across research, regulatory, and public health contexts, and a shared technical template for consent could help align practice across organizations. These efforts should emphasize transparency regarding data governance, provenance, and the use of artificial intelligence, and should be developed with meaningful patient involvement so that confidence in reuse is grounded in clear communication of benefits and robust safeguards.

### Priority Area 8. Establish Shared AI Terminology and Require Transparency into Regulatory AI Architecture

A persistent gap exists between the pharmaceutical and technology sectors in how terms such as "training" are used. Stakeholders should adopt a shared vocabulary distinguishing frontier-model creation, fine-tuning, retrieval-augmented generation, and benchmarking, because each carries a distinct profile for how data are embedded and exposed. Regulators should provide greater transparency into their technical architecture, including whether internal systems share a common semantic layer, and should support threat modeling so that privacy, consent, and data integrity controls are supported by robust security design and threat modeling and can be demonstrated and trusted, consistent with emerging FDA guidance on artificial intelligence. [17]

### Priority Area 9. Create Incentive Structures and Design Data for Reuse from Inception

The absence of clear incentives is the most immediate barrier to data reuse; sponsors are unlikely to absorb the cost of curating reusable data without a tangible return such as reduced review or approval timelines. Stakeholders should define concrete incentives and shift toward designing data for reuse from the inception of collection, with consent that anticipates future uses, supporting metadata and provenance, and complementary statistical and regulatory innovation, building on existing real-world evidence authorities.[12]

## Cross-Cutting

### Priority Area 10. Establish a Multi-Stakeholder Governance Structure to Drive Long-Term Change

Sustained progress will require dedicated leadership beyond individual pilot programs. A multi-stakeholder think tank or coordinating body should be established to develop the strategic vision, build consensus across sectors, coordinate advocacy, and engage international standard-setting organizations such as the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use to advance globally recognized standards.[18] Participants identified the International Coalition of Medicines Regulatory Authorities (ICMRA) as a potential forum through which discussions on governance and regulatory collaboration could be advanced, given its existing role in facilitating cooperation among regulatory authorities. Participants also noted the importance of engaging industry stakeholders, including organizations such as the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), to ensure industry perspectives are incorporated into future discussions. This body should include regulators, industry, patient advocates, technology experts, and global health organizations so that modernization remains aligned with public health objectives and patient needs. Rather than focusing only on digitizing existing document-centric workflows, regulators and industry should establish a shared vision for a data-

centric ecosystem that identifies what information is truly required to support a decision, when it is needed, and how it should be exchanged across the lifecycle. In addition to advancing common standards and governance approaches, stakeholders should identify areas where differences in interpretation and implementation of existing frameworks create unnecessary barriers to collaboration. Structured forums for dialogue, case studies, and operational guidance could help promote greater consistency across organizations and jurisdictions while respecting local legal and regulatory requirements.

### Priority Area 11. Establish a Global Evidence Base for Regulatory Modernization

Broader adoption of cloud-based platforms and collaborative review will depend on demonstrating measurable value. Stakeholders should systematically collect, benchmark, and publish evidence from existing pilots and implementation programs, including effects on review timelines, submission preparation effort, regulator workload, infrastructure costs, question cycles, approval timing, and patient access. Stakeholders should establish a common evaluation framework that defines accountable organizations, pilot-selection criteria, success measures, and decision points for scaling. Near-term deliverables could include a standardized scorecard for modernization initiatives, a common set of pilot evaluation criteria, and periodic public reporting on outcomes. Evaluation should measure both operational efficiency and public health impact to ensure that modernization efforts deliver meaningful value for regulators, sponsors, and patients. Potential metrics include:

- Reduction in duplicative submissions and jurisdiction-specific dossier variations
- Reduction in regulatory question volume and question-cycle times
- Time to first regulatory decision and overall review timelines
- Number of agencies participating in collaborative or shared reviews
- Number of pilots successfully transitioned from demonstration projects to routine operational use
- Time to patient access across regions
- Number of legal, policy, or confidentiality frameworks clarified, aligned, or harmonized
- Regulatory resource utilization, infrastructure costs, and return on investment
- Capacity-building outcomes for participating regulatory authorities

### Priority Area 12. Amplify Patient-Centered Messaging and Convene Expanded Stakeholders

The case for modernization should be translated into patient-centered messaging that families can understand and champion, recognizing that patient organizations are often more credible advocates than industry and that policymakers are focused on competing priorities. Stakeholders should engage patient communities directly in shaping consent and governance, develop tangible messaging grounded in patient access, and sustain momentum through follow-on convenings and a public report that broadens participation to include contract research organizations, patients, and bioethicists.

# Conclusion

The discussions convened through this Roundtable reinforced that the challenges associated with global regulatory information exchange are no longer primarily technological. Advances in cloud computing, interoperability standards, collaborative review models, artificial intelligence, and privacy-preserving architectures have shown that more efficient approaches to data sharing, review, and evidence generation are increasingly achievable. The primary barriers now lie in the alignment of policy, governance, incentives, legal frameworks, organizational readiness, and stakeholder trust. Participants also emphasized that successful modernization would require addressing differences in how existing frameworks are interpreted and implemented, not simply developing new technologies or policies. Organizational incentives, institutional practices, and varying approaches to risk management can create barriers even where legal authorities and technical

capabilities already exist. Progress will therefore depend on leadership, trust-building, and change-management efforts alongside continued work on standards, governance, and technology.

Participants broadly agreed that the existing ecosystem remains constrained by processes and structures designed for an earlier era. Electronic submissions, collaborative review initiatives, and emerging data-sharing platforms have introduced meaningful improvements, yet many underlying workflows still replicate paper-based approaches in digital form. As the volume, complexity, and velocity of biomedical innovation continue to accelerate, these legacy approaches risk becoming increasingly difficult to sustain. Modernizing how information is exchanged, reviewed, and reused will be essential to ensuring that regulatory systems can continue to support timely patient access to safe and effective medical products.

At the same time, participants emphasized that modernization should not be viewed as a purely technical transformation. Future success will depend on establishing a shared vision for what a modern regulatory ecosystem should achieve, defining clear value propositions for all stakeholders, and creating trusted governance structures capable of balancing innovation with privacy, security, transparency, and regulatory rigor. Progress will require collaboration across regulators, industry, technology providers, patients, academia, and policymakers, because no single organization or sector can address these challenges alone.

The priority areas for action presented in this report are intended as practical opportunities for near-term progress within existing legal and operational frameworks while laying the foundation for longer-term transformation. Collectively, they reflect a recognition that meaningful change will require both incremental progress and sustained strategic ambition. Pilot programs, collaborative review initiatives, data-sharing frameworks, and standards development should be viewed not as isolated projects but as building blocks toward a more connected, interoperable, and efficient global regulatory environment.

Ultimately, the path forward is not constrained by a lack of ideas, technology, or pilots. The challenge is one of leadership. Participants consistently noted that many of the foundational components needed to modernize regulatory information exchange already exist; what remains uncertain is who will take responsibility for convening stakeholders around a common vision and driving coordinated action. The future regulatory ecosystem will not emerge through technology alone. It will require organizations and leaders willing to champion change, align interests across sectors, and move the conversation from experimentation to implementation. Across the discussion, participants returned to a single North Star: speed to patient access, achieved through one reusable core dossier, coordinated review, and locally accountable decisions, with the ability to succeed and to fail fast.

# Call to Action

Participants emphasized that meaningful regulatory modernization would require coordinated action across the broader ecosystem. The discussion highlighted the important role of industry as a catalyst for change by articulating a shared vision, identifying practical opportunities, investing in innovative approaches, and demonstrating value through targeted pilots and collaborative initiatives. At the same time, participants recognized that sustainable transformation cannot be achieved by any single stakeholder and will require partnership among regulators, industry, technology providers, patient organizations, academic institutions, and international standards bodies. Regulatory authorities will remain essential partners in shaping future-state approaches, providing regulatory alignment, and enabling adoption of solutions that advance shared goals. Priority areas for action and further development include:

### SPONSOR-TO-REGULATOR

**01** Establish a unified industry vision and value proposition for regulatory modernization

**02** Modernize regulatory processes by transitioning from documents to structured data

**03** Extend modernization to clinical trial sites and the data-generation pipeline

### REGULATOR-TO-REGULATOR

**04** Advance collaborative regulatory review through targeted pilot programs that define and demonstrate value

**05** Develop a regulatory collaboration framework that supports capacity building

**06** Promote federated data access models that preserve data sovereignty

### DATA REUSE

**07** Create harmonized frameworks for consent, data reuse, and transparency

**08** Establish shared AI terminology and require transparency into regulatory AI architecture

**09** Create incentive structures and design data for refuse from inception

### CROSS-CUTTING

**10** Establish a multi-stakeholder governance structure to drive long-term change

**11** Establish a global evidence base for regulatory modernization

**12** Amplify patient-centered messaging and convene expanded stakeholders

## PROGRESS CAN BEGIN NOW

While long-term transformation will require sustained commitment, participants agreed that meaningful progress can begin now through coordinated action, shared learning, and a willingness to challenge legacy approaches. The opportunity exists to move from isolated pilots and fragmented initiatives toward a more connected, interoperable, and patient-centered regulatory ecosystem.

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