Accumulus™ synergy

WHITE PAPER

Pharmaceutical Quality (Industry) Data Standard Publication

AN OVERVIEW

Background

The regulatory ecosystem is undergoing a profound digital transformation, driven by the increasing adoption of technology and the growing volume of data within regulatory processes.

Regulatory agencies worldwide are forgoing the traditional paper-based, manual, and siloed processes in favor of embracing digital solutions to streamline workflows, improve data management, and enhance regulatory oversight.

STANDARDIZED DATA EXCHANGE:

Central to the success of this transformation is the creation of standardized data exchange protocols and supporting frameworks. Standardized data exchange offers several key benefits:

IMPROVED TRANSPARENCY

Standardized data exchange promotes transparency and data integrity by establishing clear data definitions, formats, and traceability, enabling regulators to access accurate, timely, and consistent data across systems and jurisdictions.

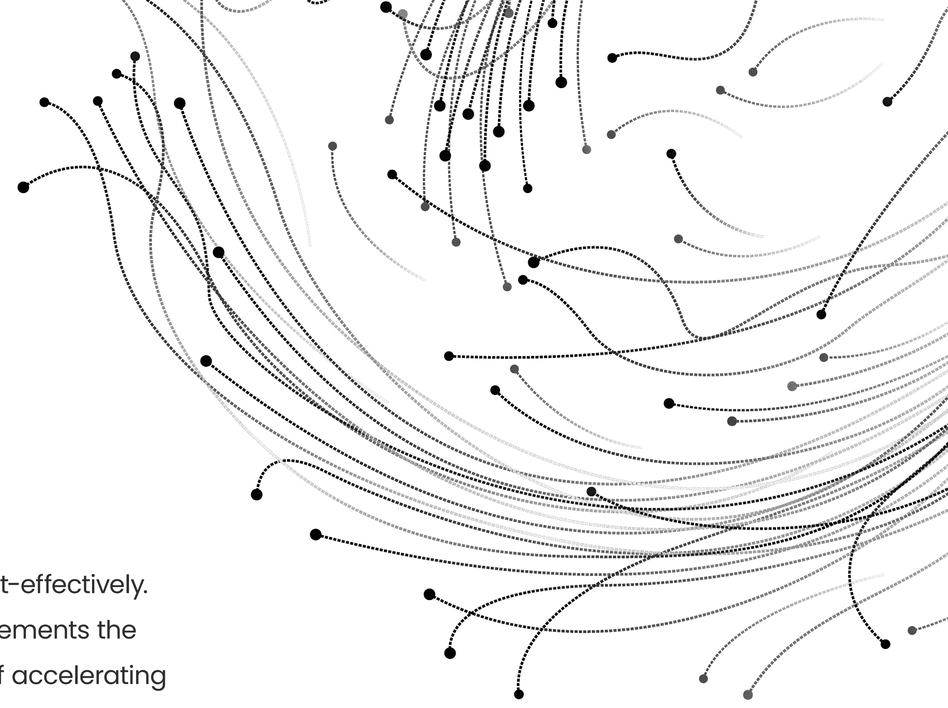
ENHANCED EFFICIENCY

By standardizing data formats, protocols, and communication, regulatory processes become more efficient, reducing manual intervention, data entry errors, and processing time.

FACILITATED COLLABORATION

Standardization fosters collaboration and interoperability among regulators, industry stakeholders, and technology providers, enabling parties to align on common data standards and protocol to exchange information seamlessly.

PHARMACEUTICAL QUALITY (INDUSTRY) DATA:



Pharmaceutical Quality (PQ) (Industry) data refers to the information generated and collected throughout the manufacturing, testing, and distribution processes of pharmaceutical products.

PQ data accounts for the majority of all data exchange interactions within the drug development process, making standardizing its exchange even more critical.

Despite the majority of PQ content being sourced from internal systems in a structured data format, these data sets are often converted to unstructured content (Microsoft Word or PDF documents) when preparing global regulatory filings.

In an effort to enhance both collaboration and information exchange, Accumulus Synergy ("Accumulus") sponsored an initiative with leading biopharmaceutical experts to develop the international standard for PQ (Industry) data, leveraging Health Level Seven International's (HL7) next generation exchange standard, Fast Healthcare Interoperability Resource (FHIR). After undergoing rigorous testing and balloting, the FHIR-based standard was officially approved by HL7 in April 2024 and made publicly available for adoption.

As noted in the PQ (Industry) Implementation Guide, the objective of the PQ standard is ultimately to bring quality medicinal products to market more quickly and cost-effectively. (This objective complements the Accumulus mission of accelerating critical therapies to citizens of the world, making Accumulus a natural sponsor of this initiative.) Furthermore, the adoption of this standard is expected to create more robust manufacturing processes and more manageable global supply chains. Combined, these benefits will help to reduce manufacturing down time and the risk of supply shortages, while increasing product quality and data compliance.

> “...coupled with the recent launch of our collaboration and data exchange platform, **we’re pushing the boundaries of what’s possible.**”
>
> – Frank Nogueira | CEO

NEXT STEPS

Accumulus remains committed to supporting the expansion and adoption of the PQ (Industry) standard as a means of advancing the regulatory ecosystem, and encourages organizations to unite around this structured, standardized approach for information exchange.

Commenting on this achievement, Frank Nogueira, Accumulus Chief Executive Officer said, “Our sponsorship of the PQ (Industry) data standard is an example of our active partnership within the regulatory ecosystem to help shape policy and raise awareness to positively impact public health. As an industry association, we have both an opportunity and a responsibility to help shape data standardization and harmonization; ultimately propelling the industry toward a fully data-driven global dossier in the cloud. Coupled with the recent launch of our collaboration and data exchange platform, we’re pushing the boundaries of what’s possible.”

For additional information on the PQ (Industry) data standard or ways to get involved with Accumulus, email us at info@accumulus.org.

Frequently Asked Questions

WHY DID ACCUMULUS CHOOSE TO SPONSOR THE CREATION OF THIS DATA STANDARD?

As a nonprofit industry association, Accumulus is a change agent in its work to develop a first-of-its-kind Data and Information Exchange Platform and to engage with regulatory ecosystem partners to propel the industry toward a fully data-driven global dossier in the cloud. As submissions continue to grow in volume and complexity with frequent updates, the traditional reliance on unstructured formats is becoming increasingly less viable. Moving towards a standardized approach to data management will enhance the accuracy, consistency, and reusability of pharmaceutical quality information across the drug development lifecycle.

DOES ACCUMULUS INTEND TO BE A STANDARDS ORGANIZATION?

No. Accumulus Synergy is a nonprofit industry association and an active partner within the regulatory ecosystem. Our work supports and accelerates our delivery of innovative technology—and vice versa. We're uniquely positioned, sitting between regulators and industry, and unlocking effective collaboration and unparalleled efficiency. Through the Accumulus platform, our organization will help the regulatory ecosystem adopt data standards as they relate to regulatory collaboration and information exchange.

WHAT IS HL7?

HL7, or Health Level Seven International, is a globally-recognized standard-setting organization in the healthcare domain. Founded in 1987, HL7 develops standards for the exchange, integration, sharing, and retrieval of electronic health information. These standards facilitate interoperability between various healthcare IT systems and applications. HL7 standards are developed collaboratively by HL7's international community of healthcare professionals, IT experts, vendors, and stakeholders. These standards undergo rigorous testing, validation, and refinement processes to ensure accuracy, usability, and compatibility across different healthcare environments. Read more about HL7 here.

WHAT IS FHIR?

FHIR is an internet-based standard developed by HL7 to address the growing need for fast, flexible, and interoperable data exchange in healthcare. It defines how information can be shared between systems, and provides a standardized framework for structuring healthcare data, using modern web technologies like JSON and XML. This standardized structure ensures consistency and compatibility across different healthcare systems and applications, making it easier to exchange data seamlessly. The standard was developed in the 2010s and is widely used in the clinical/healthcare settings to securely share information with authorized users to support patient care. Read more about FHIR here.

WHY CHOOSE THIS EXCHANGE STANDARD?

FHIR uses building blocks (FHIR Resources) based on domain-specific data standards and leverages exchange technologies (Restful API, XML, JSON) to transmit structured data between systems. Given the flexibility and scalability of this framework, standards organizations have found value in adopting FHIR with the following efforts completed or underway: electronic Medicinal Product Information, Clinical Research Information (CDISC standards), and more. There is great value in having quality data exchange in the same manner.

WHAT IS THE RELATIONSHIP BETWEEN PQ (INDUSTRY) AND PQ/CMC DATA STANDARDS?

The PQ (Industry) standard complements the efforts of the US Food and Drug Administration's PQ/CMC data standard by closing gaps in quality data standardization outside of regulatory scope (quality data submission to regulators). Visit this HL7 confluence page to learn more about the similarities and differences between the two standards.

WHO IS THE TARGET AUDIENCE FOR THE PQ (INDUSTRY) IMPLEMENTATION GUIDE?

The Implementation Guide is preliminarily intended for developers of regulatory systems (such as structured content authoring solutions, regulatory collaboration/information exchange solutions, and manufacturers that produce quality data). In the post-market space, this implementation guide could be used to enable processes that support traceability and data linkage between adverse events or complaints, and the corresponding products, batches, or manufacturing sites.

HOW WILL THE PQ (INDUSTRY) STANDARD BE MAINTAINED AND EXPANDED?

Accumulus remains committed to working with stakeholders to enhance the current data standard as international consensus is achieved. This includes partnering with industry associations, data standards organizations, and international consortia to ensure a diverse voice of representatives are contributing to subsequent versions of the FHIR resources and Implementation Guide.

HOW CAN I ADOPT THE FHIR STANDARD FOR PQ (INDUSTRY)?

The PQ (Industry) Implementation Guide is an organization's first step to adopting the FHIR standard to exchange quality data. This resource is intended to help organizations map their existing data to FHIR resources to support exchange and utilization within systems. In the future, additional resources or events may be convened to help stakeholders incorporate the standard.