A COHESIVE VISION
for a Single Global CMC Dossier

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A single global digital chemistry, manufacturing, and controls (CMC) dossier is rapidly transitioning from a bold vision to a practical reality. However, realizing the full potential of these innovations requires significant coordination to harmonize and align across initiatives.

Biopharmaceutical manufacturers and health authorities are increasingly invested in modernizing regulatory authoring and reviewing processes to accelerate timelines and increase efficiency to better serve patients. Over the past several years, notable progress has been made toward data standardization, regulatory collaboration and reliance, and cloud-based data exchange. As the landscape of initiatives and technologies continues to expand, harmonization across jurisdictions must be prioritized as a key outcome to mitigate the risk of introducing further divergence in regulatory expectations and requirements. This article presents an overview and proposal for next steps to enable a single digital dossier as well as a call to action for industry and regulators to further progress toward this vision. Establishing one global quality dossier as an actionable path forward directly fosters patient centricity by supporting the timely availability of critical therapeutics for patients in need.

INTRODUCTION

Biopharmaceutical manufacturers and health authorities bear responsibility for progressing toward a shared goal of bringing safe and effective therapeutics to market for patients in need around the world. Although there have been numerous landmark advancements in drug discovery and development over the past decade, the speed at which novel medicines can be made available to patients remains an ongoing challenge.

Regulatory submissions are required to numerous health authorities to gain individual approvals and to make therapeutics globally available to patients. Across regions, the product being registered has the same quality attributes, but the regulations in place differ, necessitating the creation of region-specific dossiers that contain CMC and quality information in varying levels of detail. These variances result in differences in registered details that must be sustained throughout the lifetime of the product, placing significant burden on sponsors to maintain. In addition, current authoring, reviewing, and submission processes for most biopharmaceutical organizations and health authorities are manual, requiring months to years of hands-on work and subject matter expertise. The overall process results in significant inefficiencies and delays that can span multiple years, contributing to slow approvals, increased costs, and diminished global patient access to critical therapies [1, 2].

In 2020, Janet Woodcock, former acting US Food and Drug Administration (FDA) Director for the Center for Drug Evaluation and Research (CDER), advocated for the need for one global quality dossier in the cloud as a means to accelerate submission and review processes [3]. Toward this aspiration, there have been multiple modernization endeavors in recent years, including cloud-based submission platforms, data standardization, reliance pathways, and global collaboration pilots. Though it is encouraging to see active development in innovation, harmonization must remain central to the overall future-state vision. In the absence of convergence, there is a risk of perpetuating current issues with new technologies, rather than using these advancements as intermediaries for a unified solution.

Accordingly, industry and health authorities must take action to avoid creating a fragmented environment in which multiple overlapping initiatives contribute to an increase in global complexity due to diverging standards, practices, and platforms. This article proposes a roadmap for making a single, structured, standardized global quality dossier a practical reality.

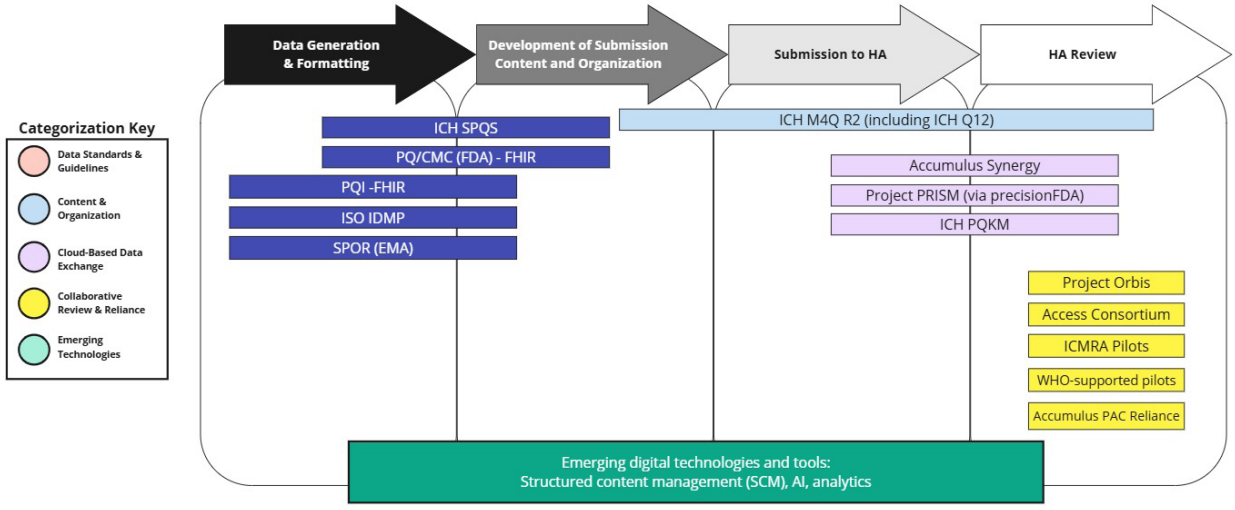
KEY INITIATIVES FOR DIGITAL TRANSFORMATION AND HARMONIZATION

There are multiple ongoing policy, standards, and technology initiatives that seek to advance and optimize regulatory authoring, review, and submission processes. In most cases, these efforts are being orchestrated by different parties and organizations, which have the same general vision but may have diverging objectives and approaches on implementation. A brief summary of the major current initiatives is discussed in this section and depicted in Figure 1.

Content and Data Standardization

In principle, the following efforts are complementary—each addresses a different aspect and scope within the overall CMC

Figure 1: Current landscape of initiative overlap and divergence. Major external industry and health authority initiatives are summarized and organized based on their relevance to the regulatory authoring, submission, and review life cycle.



data continuum. There is ongoing work across standards (PQ/CMC, ISO IDMP, PQI) to ensure continuity and alignment. However, the risk of divergence increases if new region-specific standards emerge and if each region implements a different standard without harmonized specifications. When taken together, the ongoing IDMP revisions, in addition to ICH M4Q(R2) and ICH SPQS, could enable a framework for an integrated CMC standard or set of synergistic data standards.

US FDA Pharmaceutical Quality/Chemistry, Manufacturing, and Controls (PQ/CMC)

The US FDA's PQ/CMC project establishes a fast healthcare interoperability (FHIR)-based data standard to enable structured CMC regulatory information exchange [4].

ISO Identification of Medicinal Products (IDMP)

ISO IDMP aims to standardize medicinal product information—substances, products, organizations, referentials (SPOR)—on a global scale to improve drug monitoring and pharmacovigilance [5]. Although it is not specifically a CMC standard, it incorporates product attributes that are relevant to CMC and is currently undergoing revisions to include a broader CMC scope.

Pharmaceutical Quality Industry (PQI)

PQI is an industry-focused global FHIR data standard that enables structured data exchange between sponsors and their collaborators (contract manufacturing organizations, partners, etc.). PQI is inclusive of 14 domains that span core CMC concepts such as manufacturing process, organizations, specification, and batch information [6]. PQI also provides a framework for sponsors to begin organizing their internal CMC data.

International Council for Harmonisation (ICH) M4Q(R2) and ICH Structured Product Quality Submissions (SPQS)

Revisions to ICH M4Q provide an opportunity to modernize and optimize the Module 3 Common Technical Document structure to prepare for digitally enabled submissions. If effectively designed and implemented, ICH M4Q(R2) could establish a framework that enables a harmonized structured dossier [7]. ICH SPQS takes this further by endorsing a standardized, data-centric approach to Module 3 [8]. Although these developments are promising, implementation will be slow and limited to ICH members, who are anticipated to have different requirement timelines and expectations. Engaging non-ICH members early in the process would help prevent a two-tier system where smaller agencies remain reliant on static documents.

Reliance Pathways and Collaborative Review

Global reliance and collaboration models represent valuable stepping stones toward regulatory convergence. By allowing regulators to share assessment reports and rely on each other's approvals, these initiatives can substantially reduce duplicative work for industry as well as health authorities. Similarly, reliance mechanisms allow for negotiation with health authorities that may permit submission of a single core quality dossier to all regions. However, the use of unstructured documents will remain a rate-limiter for efficiency. The exchange of structured datasets rather than narrative-based documents helps ensure interoperability, standardization, and accessibility in near real time across participating agencies, as well as the use of advanced data analytics technology.

Project Orbis

Project Orbis is a concurrent submission and review program established by US FDA's Oncology Center of Excellence. The

program includes seven partnering countries: Australia, Brazil, Canada, Israel, Singapore, Switzerland, and the United Kingdom. Each country conducts an independent review that results in the agency's own regulatory decision, but partnering health authorities collaborate on evaluating the application and issuing information requests [15].

Access Consortium

The Access Consortium is a regulatory collaboration and work-sharing initiative between Australia, Canada, Singapore, Switzerland, and the United Kingdom. The initiative aims to reduce duplicative reviewing efforts and to foster regulatory agility through resource and knowledge sharing [16].

International Coalition of Medicines Regulatory Authorities (ICMRA) Product Quality Knowledge Management System pilot

ICMRA launched a collaborative assessment pilot for CMC post-approval changes in response to the COVID-19 pandemic, which has since expanded to include other medically significant products. Several pilots have been conducted to date, with a varying list of health authority participants and observers, including the European Medicines Agency (EMA), Medicines and Healthcare products Regulatory Agency (MHRA), US FDA, Swissmedic, Health Canada, Brazilian Health Regulatory Agency (Anvisa), Health Sciences Authority (HAS), and Pharmaceuticals and Medical Devices Agency (PMDA) [17].

Accumulus Post Approval Change (PAC) Reliance

As described in previously published articles, the platform has supported several companies in conducting cloud-enabled PAC reliance pilots [10–14, 18].

The World Health Organization (WHO)

The WHO is supportive of the development of a regulatory reliance framework and has assisted in the orchestration of several pilots. One notable example is Sanofi's PAC reliance pilot, in which 21 national regulatory authorities participated [19]. Additionally, the WHO's Coalition of Interested Parties network was established in 2021 to leverage regulatory collaboration and harmonization as strategic enablers for strengthening regional regulatory systems [20].

THE EVOLVING LANDSCAPE: OPPORTUNITIES AND RISKS

As previously described, regulatory agencies worldwide are examining the potential to adopt transformational efforts to modernize the submission, review, and approval process for pharmaceutical products. Though these efforts show great promise, the proliferation of new technology initiatives raises questions about convergence versus divergence.

For instance, the US FDA's PQ/CMC data standard was created to standardize CMC regulatory data exchange specifically in the United States. If other health authorities proceed in a similar direction and develop their own region-specific standards, this conflicts with the greater goal of standardization. Similarly, multiple cloud platform providers are currently being explored, including precisionFDA and Accumulus. There are also several different perspectives and practical developments within the realm of reliance mechanisms, with key variations across pilots and separate negotiations needed each time a pilot is conducted. Because there is no consistent standard or framework for reliance, this creates additional logistical and administrative burdens each time a pilot is conducted.

There must be broad global alignment toward a cohesive future vision, or each initiative will individually fail to reach their goal of enhancing efficiency, reducing timelines, and enabling collaboration. Without active coordination, the logistical differences across initiatives will persist and amplify the "submit in multiple formats" paradigm that has long plagued the pharmaceutical industry.

THE COSTS OF FRAGMENTATION

If the current path of partial harmonization and an uncertain technology landscape is continued, this will impose direct and indirect costs to industry and health authorities. Directly, industry will shoulder added overhead to maintain multiple dossier versions, perform region-specific data transformations, and manage divergent filing timelines and requirements as product pipelines continue to expand. Health authorities will similarly face their own challenges with increased application volume, compressed timelines, and variability in workforce size. Indirectly, fragmentation divides and dilutes the impact of limited skilled resources and valuable expertise that could be used to build a harmonized future state.

Although regulations are traditionally viewed as barriers to innovation, there is, at present, a unique opportunity to leverage regulation as a key transformation driver. By making modernization and harmonization mandatory, there is no other option but to adapt. More critically, patients worldwide are directly and personally impacted when products are delayed due to local regulatory hurdles. If a given digital data exchange solution or reliance mechanism is recognized by some agencies but not others, or if a product requires additional studies or documentation to meet a region-specific requirement, patients in some jurisdictions will wait significantly longer for access. For patients, delays are not trivial, and the speed of an approval could be the difference between life and death.

INTEGRATING THE PATIENT PERSPECTIVE

The pharmaceutical industry should make every effort to commit to a patient-first mindset. Accordingly, the driving force behind all these harmonization efforts should be the patient's needs. Divergent requirements and duplicative reviews create delays in product availability, especially in low- and middle-income markets. Moreover, patient confidence in the quality and safety of medicines depends on a consistent global standard—if certain regions allow for different specifications or extended testing protocols, questions may arise about uniform safety and efficacy. Additionally, there is

increasing interest from industry in using patient-centric quality standards and product development approaches that reflect patient interests [21]. These developments should be reflected in attempts to harmonize across regions.

By embracing one global quality standard and one harmonized CMC dossier, industry can increase submission preparation efficiencies and coordinate responses to health authority information requests, thereby resulting in faster approvals. Patients worldwide would benefit through simultaneous global launch strategies, improved supply chain robustness, and a greater availability of lifesaving or life-enhancing therapies.

ADDRESSING LEGISLATIVE AND REGIONAL BARRIERS

Several current challenges introduce ambiguity in the feasibility of adopting a global cloud-based platform. Specifically, local data privacy, residency, and cybersecurity regulations differ across regions. Countries have varied (and sometimes conflicting) rules about where data may be stored, who may access it, and how it must be secured. Though these regulations serve legitimate public interest, they can pose significant technical and legal challenges. In the long term, a global framework—possibly championed by the WHO or another supranational body—could set out guidelines that balance sovereign regulatory concerns with the need for seamless data sharing.

Despite these barriers, the industry must avoid focusing on obstacles. Rather than insisting on a one-size-fits-all cloud platform, an interim solution could feature multiple regional clouds, united by an interoperable data standard that ensures any submission data can be transferred seamlessly between them. In essence, this is a "network of networks" concept, wherein local solutions remain in place while adhering to universal interoperability frameworks.

Moreover, collaboration with smaller agencies—particularly those in emerging markets—is critical. These agencies often have limited resources and may be overlooked when large agencies (e.g., US FDA, EMA) chart new digital strategies. Nevertheless, broad global alignment cannot be achieved if many regulators remain dependent on paper-based or PDF-based reviews in different formats. A potential solution is for global consortia or industry organizations to offer standardized cloud templates or capacity-building programs, thereby integrating smaller regulatory authorities into a broader harmonized ecosystem.

PRACTICAL NEXT STEPS

Define Core Pillars of a Single Digital Dossier

To arrive at a harmonized future state for one global digital dossier, a three-pronged approach encompassing policy, technology, and change management can be considered.



Policy

Achieving a harmonized global digital dossier requires supportive policy and legislation as a foundational priority. The desired future-state vision is not attainable in the absence of a regulatory framework that enables both technological innovation as well as reliance pathways that fit a variety of use cases and scenarios (postapproval changes, marketing applications, and more). Although there are ICH initiatives that aim to address some of the logistical challenges with advancing modernization goals, such as ICH PQKM [22], ICH guidelines develop slowly and may benefit from support from other consortia and forums.

Technology

In the ideal state, a single cloud-based solution will be deployed, hosted by a neutral party, and accepted for global access and use. However, due to legislative and regional barriers, discussed earlier, it can be envisioned that even if multiple cloud solutions are developed, there should be an opportunity for integration and interoperability that allows systems to "talk" to one another. Thus, even if separate regional systems persist, adopting interoperable standards for data models, controlled vocabularies, and application programming interfaces (APIs) can ensure that the same CMC dossier can be sent to multiple parties without the need for manual reformatting.

Change management

Successful adoption of new paradigms depends on the willingness of both regulators and industry to adapt. Transitioning from an unstructured, document-centric format to a modular, data-driven, structured submission will present technical hurdles and challenges. Companies must upskill their workforce and design internal systems for data generation, formatting, and governance to align with structured data submission requirements. Regulators, in turn, must enhance their review processes and develop standard procedures for international collaboration, invest in IT infrastructure, and train staff to evaluate structured data.

Accelerate Standardization Efforts

Data standardization is a powerful lever for harmonization and significantly increases the potential for further automation and digitalization. Industry and regulators should fast-track the harmonization, adoption, and implementation of existing data standards (PQ/CMC, IDMP, PQI). The ongoing IDMP revisions are on track to support this goal, and the development of the ICH SPQS guideline, once initiated, should also be supportive in endorsing a global standardization strategy. These initiatives take time to implement; however, industry can take steps now to prepare for data standardization by ensuring technological readiness to consume and export structured data; de-siloing source data across systems; and leveraging structured authoring solutions.

Expand Reliance and Collaborative Mechanisms

Previous PAC reliance pilots have demonstrated that reliance can increase efficiency and accelerate review timelines [18]. Efforts should expand beyond major regulatory agencies to include medium and smaller agencies, ensuring that the benefits are distributed globally. Additionally, in the current state, reliance pilots have divergent inclusion criteria and logistical nuances, which creates significant effort for all parties to coordinate on a plan each time a reliance filing is pursued. It would be beneficial for regulators, in collaboration with industry, to develop a framework for reliance across scenario types to reduce administrative burden and make reliance more accessible by reducing some of the uncertainty in the approach.

Democratize IT Solutions to Increase Global Availability

Although larger health authorities have made investments in modernizing their IT systems in pursuit of digital innovation, many smaller agencies lack the resources to develop their own robust IT systems. Existing cloud platforms can offer shared infrastructure that can be made broadly available. Though ICH PQKM seeks to solve some of the unknowns on a potential governance and a payor model [9], cloud vendors that hope to participate in this space should keep small and medium-sized markets in mind. Smaller health authorities may even be able to adopt widely available, internet-enabled technologies faster than ICH countries due to greater potential for agility and flexibility. Additionally, solution providers should consider organizing training and capacity-building initiatives for regulatory authorities new to structured data review.

Integrate with Pharma 4.0™ and Automation Initiatives

A single global dossier format would dovetail with broader industry trends toward digitization, digitalization, and the Pharma 4.0™ movement [23]. Real-time data flowing from manufacturing sites to regulatory databases that uses standardized data fields could facilitate advanced review methods such as continuous verification and real-time release. The process would also enable advanced analytics, such as artificial intelligence and machine learning, for automated signal detection and optimization of manufacturing processes—further speeding development, reducing errors, and enhancing product quality.

Maintain a Patient-Centric Perspective

Each step in this harmonization journey should remain grounded in the impact on patients. Sponsors can highlight case studies showing how a unified CMC dossier accelerated market entry for essential medicines and improved global supply chain resilience. Particularly for lifesaving therapies (e.g., oncology, vaccines), consistent global data frameworks can save lives by minimizing review times and ensuring equal access.

CONCLUSION

A single global digital CMC dossier—exchanged via the cloud and accepted by regulators worldwide—is rapidly transitioning from a bold vision to a practical reality as industry and regulators make

significant strides in exploring possibilities for collaboration, structured data exchange, and data standardization. However, realizing the full potential of these innovations requires significant coordination to harmonize and align across initiatives. Divergence in technology platforms, regulatory policy, and legislative environments must be mitigated to achieve the future-state vision. Additionally, industry's willingness to change will be paramount to the success of this transformation.

A unified approach, anchored in shared data standards and guided by reliance frameworks, can enable one product, one filing, and one approval for all patients. Such an approach not only fosters efficiency for sponsors but also hastens patient access, advances pharmaceutical innovation, and reduces regulatory reviewer burden.

The call to action is clear: regulators, industry leaders, consortia, and global health organizations must collaborate with renewed urgency to streamline policy, technology, and change management. By doing so, industry can accelerate the timeline to a "one-click" submission scenario, delivering tangible benefits to patients and catalyzing the next generation of pharmaceutical innovation. If implemented effectively, the single global dossier can stand as a testament to what is possible through shared vision, rigorous standardization, and a resolute commitment to global public health.

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