One Dossier in the Cloud: The Future of Global Dossiers

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The rapid evolution of science and medicine continues to transform the healthcare industry. Real world evidence, personalized medicine, and data analytics allow for the potential to develop life-saving therapies for patients. Technology has been a catalyst for this evolution, improving the way that the regulatory ecosystem can collaborate and exchange information as global product development has come to the forefront of the regulatory ecosystem. Yet despite these advances, alternative review pathways such as reliance, joint assessments, and work-sharing may be seen as pilots, rather than the norm. In a game of tug of war between innovation and traditional regulatory processes, outdated processes are winning.

Region-specific regulations and requirements have the potential to create complex hurdles as the industry attempts to adopt modern review pathways, while adhering to legacy frameworks. Duplicative and siloed work in developing tailored submissions or answering the same questions for multiple National Regulatory Authorities (NRAs) not only results in global drug lag and inequitable access, but increased resource and financial burdens on drug developers, which in turn leads to increased financial burdens on patients. In addition, regulators face resource burdens of their own. If review pathways like reliance and joint assessments are the way of the future, what can the global ecosystem do to break down these barriers?

The Vision of a "Global Dossier in the Cloud"

In the current state, life sciences organizations (LSOs) author and maintain multiple dossier versions to support the global submission and approval of products largely due to company regulatory strategies, intellectual property concerns, and varied country requirements. This results in significant administrative burden and duplication of efforts during the regulatory submission process.

The vision of a "global dossier in the cloud" reflects the concept of a standardized core dossier in a cloud-based platform that will enable streamlined preparation, management, and sharing of regulatory documentation. This concept will allow LSOs and NRAs to interact and collaborate in real-time in a centralized, reputable, and secure online environment. In addition to reducing inefficiencies and duplicative efforts, a "global dossier in the cloud" will enhance transparency and consistency among all stakeholders, ultimately leading to faster submissions and review times.

Achieving this vision will strengthen regulatory collaboration and convergence efforts through facilitating harmonized standards and a shared regulatory operations framework that can be utilized globally.

As a regional use case example, Latin America recognized that variances between country requirements for core technical dossiers were unintentionally inhibiting access to therapies. Nine countries aligned on a technical core dossier compliant with existing regulations. During the first pilot, six countries successfully reviewed a small molecule product, and the sponsor organization confirmed that critical milestones were completed and regulatory decisions made faster than projected (Alvarez et al., 2023). Positive outcomes from a regional reliance pilot such as the Latin America example demonstrate the art of the possible and suggest that broader reliance pilots are feasible as well.

Additionally, a cloud-based platform for dossier sharing can serve as a digital gateway for countries that either lack a regulatory portal entirely or have systems with limitations on the size of dossiers they can receive. For example, immediate value can be gained in low- and middle-income countries (LMICs) where such limitations exist making it difficult to transition from paper-based processes to electronic submissions. To bridge this gap, adopting cloud-based submissions will further accelerate the shift toward digital dossiers for these countries. This approach ensures equitable information distribution, allowing all regulatory authorities (whether low, middle, or high-income countries) to receive the same dossier at the same time, reducing delays and promoting regulatory efficiency.

A single global dossier offers a promising solution, allowing for life science organizations (LSOs) and NRAs to have a harmonized and unified approach to submissions and regulatory requirements. Minimizing the complexity of the global regulatory landscape via a single global dossier could foster the adoption of reliance and convergence practices, ultimately minimizing duplicative efforts, simplifying the submission process, and improving access and quality of therapeutics worldwide.

While a single global dossier offers clear benefits–streamlined processes, reduced costs, and accelerated access to therapies worldwide–there are numerous legal and regulatory challenges that inhibit its widespread adoption and implementation.

National Sovereignty and Regulatory Autonomy

NRAs each set distinct regulations to protect patient welfare and to ensure minimum

quality standards for their citizens. There are also regional differences in terms of priorities, interests, and resources, which could be legal and/or cultural (Kalpana et al., 2022). Regulatory autonomy enables each NRA to interpret dossiers according to their own standards, needs, and decision-making processes. This sovereignty and autonomy is reflected by variations in timing, indications, risk-benefit analysis, or labeling for example. Couple that with inconsistent dossier presentation, clarity, or data completeness, and the result is fragmented decisions and delayed approvals (Institute of Medicine, 2013). A single global dossier would help address differences in things like presentation, clarity, and data completeness. However, it would not address each nation's unique healthcare needs, requirements, or tolerance to risk not to mention differences in the content itself, such as varying manufacturing sites that supply to different regions, different indications, and different product names. To ensure the success of a single global dossier, there must be a legal framework that balances global collaboration and regulatory autonomy.

Privacy and Cross-Border Data Sharing

One of the benefits of a single global dossier is that everyone is seeing the same data and information, leading to greater global transparency and efficiency. However, as with many other legal barriers, different countries have different laws and regulations when it comes to data privacy, and in the case of drug development, patient and clinical trial data. The European Union (EU) General Data Protection Regulation (GDPR) addresses data sharing and privacy and imposes strict requirements on how personal data can be collected, stored, or shared (GDPR, eu, n.d.). In the United States (US), privacy and data sharing laws are fragmented by sector, with the Health Insurance Portability and Accountability Act (HIPAA) at the Federal level and different laws and regulations for other sectors. In addition, privacy and data sharing laws exist at the state-level as well (Welekwe, 2022). While these are just two examples, when considering the global nature of drug development, the landscape becomes even more complex. Developing and adopting a single global dossier while ensuring compliance with a variety of legal frameworks from across the world poses a significant challenge.

Data Harmonization

Data harmonization at the international level is essential to a single global dossier. Reputable consortia like the International Council for Harmonization Technical Requirements of Pharmaceuticals for Human Use (ICH), the International Pharmaceutical Regulators Programme (IPRP), and the World Health Organization (WHO), among

others, are leading policy efforts to define and harmonize key data standards to ensure reliable and consistent data exchange (ICH Official Website, n.d.; IPRP Official Website, n.d.; WHO Official Website, n.d.). Despite the efforts of these organizations, many of these standards have not been adopted into regulatory processes, limiting the ability to utilize a single global dossier due to inconsistencies in data format, regulatory compliance issues, and/or difficulties related to data analysis. Only 23 members and 38 observers participate in ICH amongst 195 countries globally (ICH Official Website, n.d.). Accordingly, it can be difficult to envision how the global community would embrace a global standard that only 31% had a hand in developing. There is also a need for data harmonization across various use cases that rely on similar or identical data sources to combat inconsistent and duplicative efforts. Lack of data harmonization can also lead to slower decision-making and increased costs, as multiple submissions require significant time and resources to reformat or reconcile submissions.

Regulatory Harmonization

Although the principles are similar to data harmonization, regulatory processes vary significantly between jurisdictions. As LSOs face the challenge of obtaining approvals from multiple regulatory bodies, the regulatory ecosystem must consider the convergence of regulatory policies and regulations. Whether through alignment of approval requirements or clear pathways for sharing confidential information among regulators, regulatory harmonization is imperative to the success of a single global dossier. This level of collaboration and alignment requires participation from all global stakeholders (FDA Website, 2023).

Varying Uses of eCTD

The Electronic Common Technical Document, also known as eCTD, is the standard format for submitting applications, amendments, supplements, and reports to NRAs (FDA Website, 2024). eCTD contains specifications on how a submission is organized and structured, allowing for the harmonized electronic submission of dossiers to NRAs. Many NRAs have been able to move away from paper-based submissions, and eCTD is currently the only globally approved and ICH-recommended standard (EFPIA, 2021). However, eCTD also allows for regional specifications and requirements, requiring LSOs to tailor portions of their submissions for each region, leading to delays and increased costs in the submission process. In some cases, eCTD is not utilized at all, which could make the transition to a single global dossier challenging for NRAs with

varying organizational maturity levels. As of 2021, only 16 countries have adopted eCTD (EFPIA, 2021).

Given these challenges, achieving a single global dossier is complex and will require time and global collaboration. A clear pathway with incremental steps will be essential. eCTD has provided a standardized format when it comes to the structure and organization of a submission, but there is still variation with regard to content harmonization. One foundational step would be the creation of a master dossier to enable a standardized, globally applicable document that contains common data and navigation structure, which can serve as the basis for submissions across multiple regions. This master dossier can then be tailored to meet specific regional requirements, reducing duplication while maintaining flexibility. Additionally, by utilizing a master dossier, an LSO could create as many dossiers as needed for submissions across multiple regions (Alvarez et al., 2023). There have been successful use cases when it comes to the achievable success of a master dossier, such as the Roche post-approval change reliance pilot, where the same variation dossier was submitted to all 48 of the participating health authorities simultaneously (Mangia et al., 2024). In February 2025, Amgen submitted the first-ever, digitally generated Chemistry, Manufacturing, and Controls (CMC) post-approval change dossier to nearly two dozen participating reliance countries simultaneously, allowing for the Reliance Reference Country and all participating regulators to review the dossier at the same time. (Accumulus Synergy, 2025). As previously mentioned, the pilot in Latin America also successfully piloted a master dossier for a new molecular entity (NME) with nine markets that spanned large, medium, and small populations, resulting in accelerated submissions and evaluation schedules (Alvarez et al., 2023). While these groundbreaking pilots show what is attainable, the regulatory ecosystem needs to continue to move the needle when it comes to harmonized global standards, frameworks, regulations, and processes that can support its implementation and adoption, and conduct more pilots to include more regions and submission types in order to build trust and confidence. As an industry, we need to move from pilots to practice to enable real change and real benefit to patients worldwide.

The implementation of a master dossier not only paves the way for a single global dossier, but for real-time data exchange as well. This would allow for seamless sharing of content, whether it be structured or narrative, between LSOs, NRAs, and other stakeholders without delays, wasted resources, or inefficiencies. As a result, the ecosystem would be able to benefit from faster regulatory decisions, improved data quality, and continuous lifecycle management. From there, digital

transformation can achieve its full potential; collaborative cloud technology, AI, automation, and advanced analytics could revolutionize the analysis of regulatory insights and clinical data.

Industry-wide collaboration will be essential to harmonize and implement a single global dossier. Harmonization, collaboration, core dossiers and finally a single global dossier are incremental yet crucial steps that will transform and redefine how global dossiers are managed and exchanged in an increasingly connected regulatory ecosystem. By working together to prioritize common standards, aligned processes, and innovative technology, the ecosystem can not only streamline regulatory submissions but also enable real-time data exchange, improve data quality, and accelerate equitable access to life-saving treatments. Achieving a single global dossier will foster greater consistency, transparency, efficiency and innovation across the regulatory landscape, ultimately benefiting regulators, industry, and patients. Future efforts should be made to further define tangible steps to achieve the ultimate vision.

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