PREVIEW

Lorenz
LIFE SCIENCES GROUP

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Dynamic Submission Management: The Future of Health Regulation

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White Paper

1. Executive Summary

PHARMACEUTICAL FILINGS HAVE EVOLVED CONSIDERABLY over the past half century in terms of content, process, and underlying supporting technologies. The industry as a whole has moved globally from primarily paper to mostly electronic submissions, and from almost entirely free-form text to an increasing amount of structured data for advanced internal analysis. Meanwhile, the size and overall complexity of these submissions continues to increase.

This paper discusses this background along with current events and trends impacting the industry today. These include changes to processes, such as the various expedited review processes used recently to address the COVID pandemic vaccine approvals, the increasing interest of agencies in shared reviews, and the broad desire to reduce the time and costs of the submission review process. It also includes changes in content, such as the structured content which is becoming increasingly common. All of this is supported by changes in technology, whether via data format standards such as CDISC or IDMP, or cloud-based deployments which can challenge old cost and security paradigms.

Back in the 90's, LORENZ introduced the term Electronic Submission to the industry. Now, based on the trends described below, we see industry is moving towards what we describe as Dynamic Submission Management (DSM). This is not a specific software or technology product. Rather, DSM represents the next stage in the evolution of pharmaceutical regulation, providing flexibility to the world of filed submissions to meet the challenges of the future.

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DSM provides many opportunities in terms of efficiency, risk-reduction and accessibility. The efficiency is provided by increased shared content, common automated processes, and faster reviews as discussed above. This in turn leads to the possibility of faster overall time-to-market and potentially lower regulatory costs.

The risk-reduction opportunity comes from broader content usage, data transparency, joint reviews and the use of advanced data management tools (e.g., AI and rules-based analysis). This will hopefully maintain or improve public confidence in the regulatory process as drugs move from relatively simple chemistry to advanced genome-based therapies aimed at small population subsets.

The accessibility aspect is exemplified by the use of cloud-based technologies and shared review procedures. While some agencies already work together to share resources, these changes will reduce the barriers further and increase this trend.

This evolution will take some time to be realized globally, and there will be inevitable challenges including the burdens on agencies to adapt their processes to a more dynamic approach. However, we are confident that DSM aspects will develop over time and lead to a better overall regulatory environment for everyone.

Wolfgang Witzel
President, LORENZ Life Sciences Group

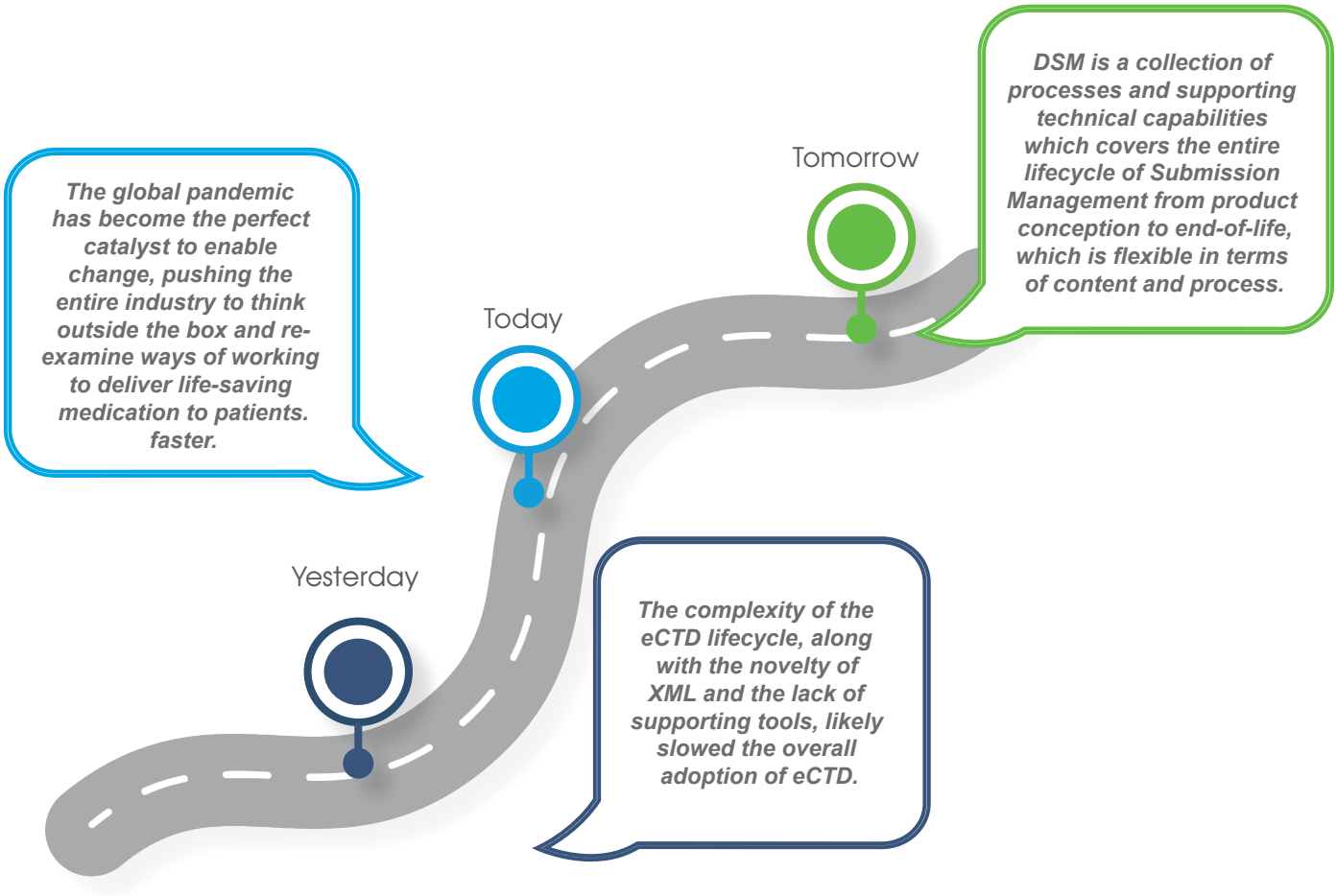
2. Introduction

2.1 Objectives

This document gives an overview of historical submission practices in the regulated life sciences industry and combines this with a review of current trends to project a future vision of submissions.

2.2 Intended Audience

This document is intended for thought leaders in the regulated life sciences agencies and industry as well as the many organizations supporting them. While some technical knowledge may be useful, it is not required and key concepts are explained to the degree required to support the discussion. We have provided links to additional information about many of the topics discussed in the the full version of the paper.



We have discussed this paper and our DSM perspectives with some industry thought leaders to get their views. Some selected comments are included below.

> *LORENZ continues to share their thought leadership by reviewing the past 20 years to set the context for the near and longer term future as submission management transitions from a static to dynamic model. They intertwine the regulatory shift from documents to data, growing product development collaboration, and health authority evolution to rolling submissions and data standards which requires advanced data management. A must read for Regulatory and IT professionals.*
>
> ***Steve Gens, GENS & Associates Inc.***

> *The paper provides an excellent overview of the evolution of submissions and introduces the ambitious dynamic submission management; a future that includes 'structured data for advanced internal analysis,' projected by the industry and by (and between) Health Authorities. The paper focuses on the next steps after 'electronic paper eCTDs' with an excellent overview of structured content process, evolving submission procedures, recognizing that 'current approaches are typically fragmented.'*
>
> *As per the paper, COVID-19 has propelled an exciting revolution in collaboration for a global regulatory framework that necessarily opens doors for dynamic submission management. I believe the speed of change/evolution is directly proportional to the demands of Health Authorities, patients, and sponsor companies. We have seen an amazing acceleration in working differently induced by the recent pandemic for speed of medicines reaching patients. We could go backwards, or events may propel us to better deliver on patient expectations for data exchange, transparency and delivery in unexpected and revolutionary ways.*
>
> ***David Ross, AstraZeneca***

> *In the past, communication and collaboration was always time-consuming, resource-intensive, and slow. Today, we are moving towards centralized solutions and European regulations for the benefit of research, patients, and healthcare professionals. The new Clinical Trials and Veterinary Regulations are examples of the way forward: centralized cloud-based systems covering the entire lifecycle of a medicinal product which supports innovation and research as well as collaboration between regulators and industry partners/sponsors.*
>
> *The Covid-19 pandemic has shown us the advantages of using cloud services within the regulatory environment. This shift allows us to go back to our roots: Scientists can focus on their work, and a fast and intense collaboration between all parties – including regulators, academia, and industry – is easier than ever thanks to the advantages of using cloud services.*
>
> ***Harald von Aschen, BfArM***

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LORENZ Life Sciences Group

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