A Whitepaper from DDi

Automation of Regulatory: Benefits, Pitfalls, Getting Started

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Automation and cognitive intelligence technologies can significantly improve business processes by streamlining activities that are labor-intensive and time-consuming enabling BioPharma organizations to complete hundreds/thousands of hours of manual regulatory reporting work in just hours/minutes with less or no human involvement.

Overview

Automation solutions tend to focus on highly manual tasks that are routine, repeatable, and time consuming. In contrast, cognitive intelligence solutions generally focus on higher skill tasks that require significant knowledge, judgment, insight, and expertise.

In BioPharma and in particular Regulatory areas, automation is used to some to automate workflow and decision-making for a variety of rules-based core processes. As the technologies mature, many firms are expanding their use of automation and cognitive intelligence to drive efficiency, effectiveness, and productivity throughout the Regulatory functions across Regulatory Affairs, Regulatory Operations, CMC ad Labeling.

One area that can benefit greatly from these innovative technologies is regulatory reporting. In the future, the entire regulatory reporting process will likely be automated end-to-end, from source system data to report mapping and business rule automation to report generation. However, reaching that point will likely be a challenging undertaking that canbe done in phases to complete.

Rather than wait for full transformation, BioPharma should capitalize on the significant improvement opportunities available today by focusing on key parts of the regulatory reporting process that are primed for automation and cognitive intelligence. By embracing regulatory reporting's complexity and leveraging these technologies, organizations can lead in existing processes and a same time aim a bit in small parts disrupt the status quo. This paper is to highlight key opportunities, and offers practical considerations to help firms avoid potential pitfalls.

Where to focus

To maximize the savings and other benefits from Automation it's important to focus on the areas within report preparation that can provide the biggest return on investment. These may include:

- Optimization of data extraction from origination systems, systems of record, data warehouses, and other systems that are being performed manually by various data providers
- Standardization of data aggregation and development of reporting templates
- Enhancing regulatory reporting capabilities for both management oversight and report review processes, including reconciliation, variance analysis, review process, etc.
- Streamlining and enhancing of reporting data quality and data lineage documentation should also be considered for automation given the focus on data integrity, documentation, and overall report accuracy
- Development of regulatory report review and analysis packages using technology such as Natural Language Generation ("NLG")

Business benefits

Applying automation to the realm of regulatory reporting can improve efficiency, effectiveness, and productivity. These benefits may include:

- Execution of currently manual tasks on a 24x7 schedule with minimal human supervision
- Redeployment of skilled resources to more value-add tasks

- Enhancements in quality of the data, documentation and overall report accuracy
- Ability to further streamline the process with every cycle by enhancing the bots with additional logic based on new requirements and errors identified during any submission cycle

Getting started

Automation is not a one-size-fits-all silver bullet for the end-to-end regulatory reporting landscape. Complete automation would require a complex, multi-year implementation and a transformation in the mind-set and culture of the organization. However, organizations do not need to wait for complete automation and can target improvements in the short term by using automation in areas that typically emphasize efficiency, productivity, and process enhancement an approach that requires a relatively small investment and a short implementation timeframe.

- *Quick wins:* These initiatives can generally be completed in less than two to three months, enabling a firm to validate concepts and demonstrate benefits before scaling up. An example is automating the data extraction and data cleansing activities, or automating a set of testing activities that have high frequency and volume.
- *Intermediate opportunities:* These are medium-term (3-6 moths) initiatives around process optimization, standardization efforts that can accelerate strategic solutions.
- *Strategic solutions:* These initiatives have a more ambitious scale and impact and typically generate greater savings but in most cases can still be completed in 6-18 months.

Firms should consider pursuing a two-pronged strategy focusing on activities where automation can deliver tangible benefits in the short time-frame. Starting with quick wins helps build momentum and support, making it easier for people to embrace innovation and overcome resistance to change and fear of the unknown. Any benefits achieved in terms of resources and time can be realigned with other strategic initiatives. The early successes can then be expanded or extended to other parts of the regulatory reporting process with the ability to provide greater benefits with reduced risk in the long run. With continued uncertainty surrounding the timing and effect of meaningful legislative regulatory reform, insurers who may well already have grown accustomed to uncertainty since the fiscal crisis may be forced to continue to navigate an unsettled regulatory climate.

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