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A CERTARA COMPANY

Avoiding Policy 0070 Pitfalls

CASE STUDY: "The Bear, the Alligator, and the Sloth"

Background

The European Medicines Agency (EMA) Policy 0070 guidance was initially issued in 2016 and since then has undergone several iterations. The evolving guidance adds complexities to the Marketing Authorisation Application submission process, challenging organizations to be agile with their teams and processes as they establish best practices and stay current with policy changes. Although Policy 0070 continues to be expanded for openness and greater data utility, many aspects of the disclosure process remain undefined, leaving sponsors to work through complex issues on their own. Further updates are expected as the EMA incorporates additional requirements such as advanced anonymization techniques and dataset de-identification. Avoiding pitfalls, ensuring compliance, and keeping teams engaged within the changing paradigm is challenging but critical to success.

"The Bear"

Challenge

Specialized core team hyper-focused on methodology lost track of the big picture, resulting in substantial loss of time and effort.

The Bear, a top-10 pharmaceutical company, identified a small team of medical writers and statisticians as responsible for the submission. The team had no prior EMA Policy 0070 experience and was eager to begin preparations early, prior to receiving notice. The small size of the core team and weekly meetings allowed for productive debate and agile decision-making. However, an early deep dive into redaction methodology and development of document-specific rules ensued without the foundation of an appropriate audit of in-scope documentation. Once additional documents were identified many months from the start of the process, methodologies had to be revised to suit the purpose of all in-scope documentation, with much of the initial effort lost. Furthermore, no additional resources were identified for the EMA consultation round, leading to last-minute scrambling to ensure timely filing.

Solution

Timely identification of in-scope documents and appropriate resource planning from start to finish.

The Bear team engaged Synchrogenix to rapidly apply their rule set using our unique artificial intelligence (AI)-enabled technology. Shortly after the engagement began, Synchrogenix identified that 1) additional documents that were in-scope for redaction and 2) the methodology as it stood would have resulted in inconsistencies and contradictions in the Anonymization Report. Synchrogenix led the Bear team to appropriately revise the rule set and rapidly produce required submission documents to meet the timelines.

When the Bear team recognized that it could not successfully address EMA consultation feedback as they planned, Synchrogenix stepped in to guide the Bear and pivot to a timely and successful filling.

A small, functional core team is crucial but must encompass all critical stakeholders to be effective and efficient. A thorough audit of all in-scope documentation must be performed prior to methodology development. Since EMA consultation may result in substantial changes, resource planning has to allow for rapid scaling up. A sophisticated technology-enabled solution is important to ensure consistency and to allow the throughput to catch up with any re-work time that may be needed.

"The Alligator"

Challenge

The Alligator, a top-20 pharmaceutical company, was working on several submissions. A small, experienced, cross-functional team was identified to coordinate efforts for the submissions and predetermine robust methodology rooted in the submission characteristics. Although the work started upon receiving notice (relatively late), this approach was expected to reduce submission timelines due to perceived reduced necessity to knowledge-share with individual clinical team contributors.

Expert core team did not invest in education and buy-in with all process participants, resulting in frustration and pushback, putting submissions at risk.

In practice, individual submission tasks were delegated to staff with little education around Policy 0070 and inexperience with the required scope, including decisions regarding cross-linking studies. Clinical teams felt isolated from the core team, as they scrambled to fulfill unexpected rapid requests beyond their typical mandate. Alignment broke down as the rigor of activities picked up. Rework occurred often, and frustration escalated, with critical deadlines nearly missed due to pushback.

Solution

The Alligator team engaged Synchrogenix to rapidly apply their rule sets using our unique AI-enabled technology. Observing the challenges that the Alligator core team was facing in their ability to engage downstream process participants effectively, Synchrogenix stepped in to educate key stakeholders appropriately and re-establish alignment. Synchrogenix used their knowledge of responsibilities within the cross-functional teams to highlight stretch tasks that would be required from various staff members and advised on the timing and differences of the activities planned for pre- and post-EMA consultation.

Proactive education of all process participants on Policy 0070. Early alignment on expectations, timelines, and regular communications.

Although central determination of methodology is an efficient and effective approach, well-timed and appropriately-targeted education of all process participants on Policy 0070 is critical. Defining responsibilities and expectations before starting the process (and issuing appropriate updates as the process continues) allows all participants to engage in appropriate contingency resource planning.

"The Sloth"

Challenge

The Sloth, a small pharmaceutical company, received EMA notice. The team had no prior EMA Policy 0070 experience, and no responsible team was identified. Tasks were approached in an ad-hoc manner based on available capacity (low in priority for tasked individuals). Natural leadership of the few resulted in the transfer of skills and knowledge to these individuals. With the majority of the workload falling on them in the context of a full complement of other responsibilities, they were unable to complete tasks in the timely manner. Overall submission timeline was at risk.

Ad-hoc, inexperienced team unprepared for EMA notice. The lack of dedicated resources and planning put submission at risk.

Solution

The Sloth team engaged Synchrogenix to take over the development of the redaction methodology and rapidly apply the rule set using our unique AI-enabled technology. Synchrogenix identified that the team was burned out, with little accomplished and critical deadlines looming.

Synchrogenix led the Sloth team to create an appropriate rule set and rapidly produce required submission documents to meet the timelines with minimal key input from the critical stakeholders.

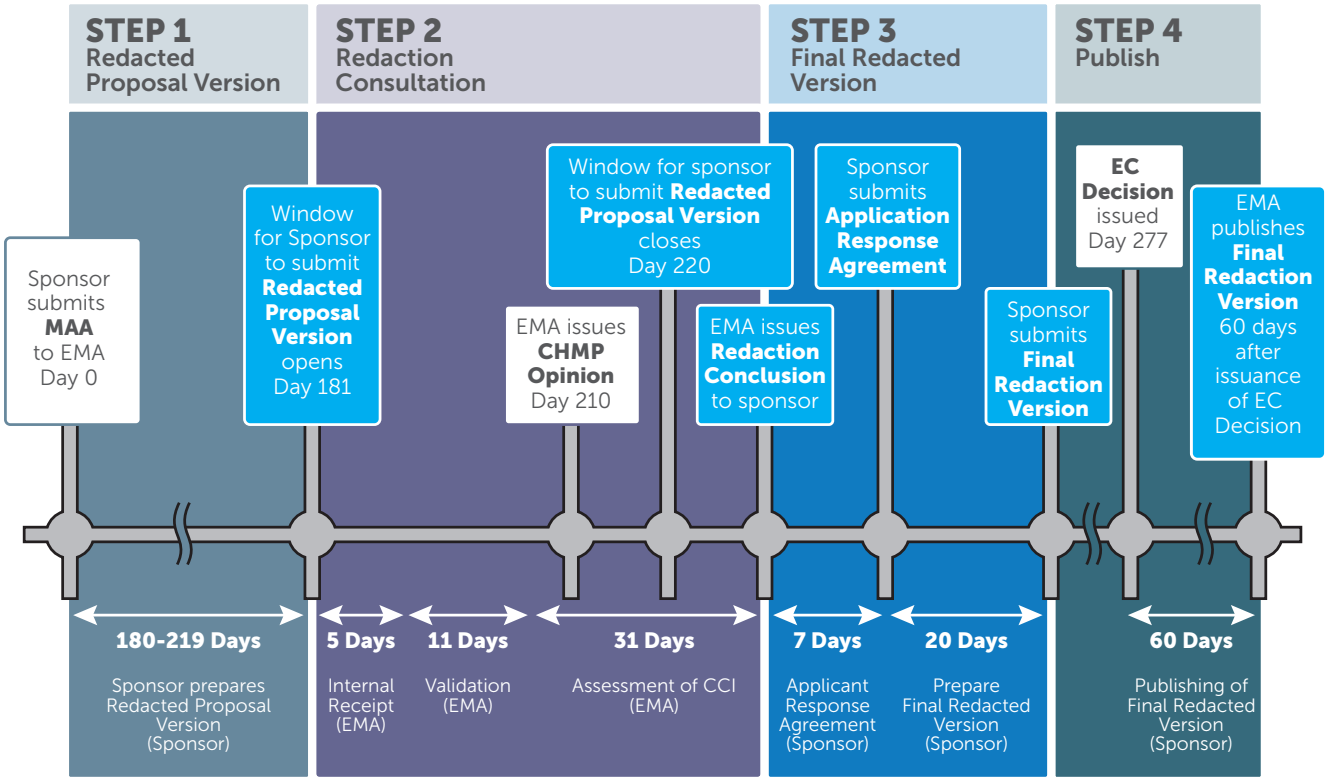
Resource and process planning should begin prior to EMA notice. Early alignment on expectations, roles, and responsibilities is critical.

A dedicated core team is critical and must encompass all relevant stakeholders in order to be effective and efficient. Alignment on responsibilities and expectations before starting the process (and provision of appropriate updates as the process continues) allows all participants to engage in appropriate contingency resource planning.

Impact of Synchrogenix Transparency and Disclosure Services

Synchrogenix has become the market leader for its expert knowledge of transparency guidelines, rule set establishment, best practices for sponsor implementation, and the industry's only AI technology platform ensuring consistent and compliant redaction packages.

Through its extensive experience across sponsor situations, Synchrogenix is able to navigate complexities of the EMA Policy 0070 process (see figure below), proactively identify pitfalls and opportunities, and find the most effective and efficient approach to mitigate risk for meeting data transparency requirements.



EMA Policy 0070 Timeline and Process