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Piloting the Clinical Data Specialist Role within Regulatory Review

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ABSTRACT

CDER's Office of Computational Science (OCS) piloted an analytic support service for safety clinical reviewers in the Office of New Drugs (OND). A Clinical Data Specialist (CDS) assists reviewers by evaluating data quality and completeness, and developing analytic approaches to address safety issues identified by the clinical reviewer. The CDS pilot offers OCS an opportunity to develop reusable analysis and code focused on specific therapeutic areas and/or clinical outcomes of interest to improve the efficiency of clinical safety review.

INTRODUCTION

In the spring of 2018, OND collaborated with the Office of Computational Science (OCS) to pilot the Clinical Data Specialist (CDS). As envisioned, a CDS is a clinical data and programming expert supporting a clinical safety reviewer throughout the review process. Taking direction from the reviewer, the CDS performs extensive data fitness activities during the early stages of a review. CDS assesses data composition, quality, and analysis options so reviewers better understand the data to make informed decisions regarding drug submissions. If data-related questions arise, the CDS helps create information requests to applicants and reviews responses for clarity and completion. Additionally, the CDS consults with the clinical reviewer in preparation for Early Filing and Safety Scope meetings to ensure accurate background material is provided. Once initial data fitness activities are complete, the clinical reviewer directs the CDS to provide core safety analyses and conduct appropriate follow-up analyses as needed. The CDS uses analytical tools at the FDA, including multiple programming languages, and can provide multiple variations of an analysis to meet the reviewer's needs. When key findings are determined, the CDS helps the reviewer prepare a safety review information package for each milestone meeting in the review timeline. Finally, during the later stages of a review, the CDS supports the reviewer by building final listings, tables, and figures for inclusion into the draft review document. Ultimately, the support the CDS provides allows the reviewer to focus on more value-added tasks, like generating hypotheses and determining the significance of safety signals.

THE CDS PILOT

The CDS role was piloted on several submissions during 2018. By design, these submissions represented separate therapeutic areas and timelines, so data, tasks, and challenges were varied. Generally, the CDS and clinical reviewer met once a week to discuss tasks and review analysis outputs. Open lines of communication between the clinical reviewer and the CDS were established which was critical to the success of the pilot. From an administrative perspective, tasks completed, effort expended, and 'lessons learned' were tracked to make future modifications to the pilot if needed. Additionally, the CDS supporting each submission collaborated to ensure a high standard-of-work was maintained and similar tools/methods were used. This was accomplished through the establishment of a quality control system. This collaboration also allowed for the sharing of code to reduce workload of an individual CDS and created the foundation for a code repository that could be called upon as needed by future CDS resources.

WHAT WE LEARNED

Almost immediately upon starting the pilot, the intended benefits of the pilot emerged. With an additional resource supporting the review, the clinical reviewers had more time to review findings, determine clinical significance, and create review documents. With a CDS available, time consuming data quality assessment activities now required



minimal input from the reviewer. Analyses that may have taken the reviewers days, or even weeks, to finish were passed off to the CDS who could complete them in a much shorter timeframe due to their greater tool expertise. An additional benefit of utilizing a CDS was the depth at which work could be completed. With a clinical data and programming background, the CDS was able to provide a level of analysis that would be difficult for a reviewer to replicate. Because of this, many of the analyses that were provided generated more questions and new paths of analysis for the review. With the CDS, reviewers were able to spend more time forming and responding to new hypotheses.

By regularly interacting with a CDS, reviewers were consistently exposed to data that was critical to their review, and they had the opportunity to ask questions if they did not understand a certain topic. Clinical reviewers understood data and analysis concepts better with a CDS and were able to drill down further to provide more meaningful insights. This led to improved conversations about data standards, data fitness, and how analyses could be constructed. Over time, the reviewers were able to give more detailed requirements regarding what data should be included in the submission.

WHERE DO WE GO FROM HERE

The opportunity to work alongside a clinical reviewer throughout the entire course of their review resulted in many lessons learned for OCS which point to further opportunities for the CDS role in the future. These lessons are primarily associated with how the CDS role can be multiplied to new people, expanded into new responsibilities, and better supported through tools and infrastructure.

The experience gathered from the CDS pilot has established a foundation for training that can be developed to quickly bring new analysts up to speed. This experience is focused on the capability of current review tools as well as best practices for custom analysis. For custom analysis, often the best solution is to develop new code in a statistical programming language such as R or SAS. The code, frameworks, and practices used within the pilot can be leveraged to train new analysts. Additionally, the lessons learned from gathering and implementing technical requirements can be further developed into a repeatable methodology. As the support provided by a CDS becomes more codified, a repeatable process can be established which doubles as foundational training.

The role of the CDS can be expanded to include additional responsibility as experience within and across review divisions is gathered. CDS resources should be the key personnel to drive consistency in data requirements and analysis. By working with multiple reviewers on multiple submissions within a review division, the CDS can develop analyses that are standard enough to be reused, but specific enough to be of deep value to a division. As standard analyses are codified within review divisions, CDS resources can collaborate across review divisions to identify and develop analyses that should be consistent. By developing consistent data and analysis requirements at the ground level, the CDS role can significantly improve the efficiency and depth of clinical review.

The success of the pilot shows that the CDS role provides significant value and should be invested in. With more CDS resources, expanded responsibilities, and better support, the CDS role can have a significant impact on the way drug applications are reviewed at the FDA.

ACKNOWLEDGMENTS (HEADER 1)

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