Piloting the Clinical Data Specialist Role within Regulatory Review

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At the U.S. Food and Drug Administration (FDA), clinical reviewers are responsible for a variety of mission critical tasks:

- Review the safety and effectiveness of new products through NDAs and BLAs
- Evaluate IND applications ensuring sponsors are qualified to conduct clinical trials
- Conduct post-marketing activities and monitor safety data of previously approved products
- Participate in developing guidances and assisting policy activities
- Pursue certifications and training, discover new research trends, and complete organizational tasks
Challenges

• Reviewers face many obstacles throughout the review process

• Reviewers must be efficient and effective in analyzing clinical data as the analyses provide critical information throughout the review
Solution

• In collaboration with the Office of Computational Science (OCS), FDA’s Office of New Drugs (OND) initiated a pilot to provide analysis and programming support directly to clinical reviewers
• The Clinical Data Specialist (CDS) role was introduced in the spring of 2018
The Clinical Data Specialist

- Clinical data and programming expert
- supporting a clinical safety reviewer throughout the review process
The Clinical Data Specialist (Cont.)

• Review and assess study data composition, quality and usability during the early stages
• Support medical reviewers to prepare information requests (IR) regarding the data issue and review responses for clarity and completion
• Ensure accurate background material is provided for Early Filing and Safety Scope meetings
• Provide core safety analyses and conduct appropriate follow-up analyses as needed
• Provide multiple variations of analyses to meet the reviewer’s needs
• Develop custom analyses and reports using statistical programming languages and enhance FDA analytical tools to efficiently provide outputs of interest
• Support medical reviewers to prepare safety review information package for each milestone meeting
• Build final listings, tables, and figures for inclusion into the draft review document
Realized Benefits

• The support provided by the CDS allowed the reviewer to focus on more value-added tasks, such as...
  – Reviewing critical safety findings
  – Forming and responding to new hypotheses
  – Determining clinical significance and weighing the risk/benefit profile
  – Creating review documents

• The CDS enhanced the reviewer’s understanding of data analysis practices, providing more meaningful insights

• The collaboration led to improved conversations about data standards, data quality, and high-impact analyses
Moving Forward

The experience gained through the CDS pilot has led to new opportunities for the role in the future.

For instance, the CDS role can be...

- Multiplied to new people
- Expanded into new responsibilities
- Better supported through tools and infrastructure
The CDS role can be multiplied to new people

- The CDS pilot provided a foundation for the training and development of additional CDS resources. This can be achieved by:
  - Utilizing the generated statistical programming code and frameworks for future review support
  - Establishing a repeatable methodology for gathering and implementing analysis requirements
  - Instituting a training curriculum based on experience from the pilot
The CDS role can be expanded into new responsibilities

- CDS resources should be key personnel to drive consistency in data requirements and analysis
  - They can develop analyses that are reusable and can be modified to address specific needs
  - They can work across review divisions to identify and create consistent analyses

- By developing consistent data and analysis requirements, the CDS role can improve the efficiency and depth of clinical review
The CDS role can be better supported through tools and infrastructure

• Through the institution of a code repository, experienced CDS resources would be able to easily manage and share code

• Experienced programmers could leverage the code to create stand-alone analytic tools for sufficiently generic analyses

• Document repositories could be implemented to properly store and archive the critical review documents
Conclusion

• 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

• Questions?
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