

Piloting the Clinical Data Specialist Role within Regulatory Review

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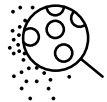
February 27, 2019

The Clinical Reviewer

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



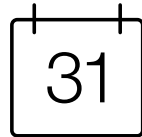
Pursue certifications and training, discover new research trends, and complete organizational tasks

Challenges

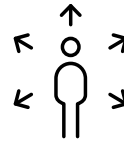
- Reviewers face many obstacles throughout the review process



Submission
size



Review
deadlines



Application
variability



CDISC
standards



Analytic
tools

- 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?

Acknowledgements

Dr. Peter Stein FDA

Dr. Jingzhong Liu FDA

Dr. Lilliam Rosario FDA

Dr. Eileen Navarro Almarino FDA

CDS Team Member:

Joy Li FDA

Peter Glass IBM