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Role of Associate Director of Biomedical Informatics in Clinical Review at the FDA

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ABSTRACT

The way that Medical Officers review New Drug Applications (NDAs) at the Food and Drug Administration (FDA) has evolved with the digital age. Moreover, FDA requirements for safe and effective drugs has led to larger and more complex clinical trials, contributing to the large amounts of electronic data submitted to the FDA. The large amounts of data present a need to analyze and review clinical trial data efficiently to make regulatory decisions about safety and efficacy. Recently, the position of Associate Director of Biomedical Informatics (ADBMI) was formed at the FDA and filled by clinical reviewers who are leaders in biomedical informatics at the FDA. This presentation highlights how ADBMIs work in their divisions, how they affect the NDA review process, and how the ADBMI perspective has impacted clinical review, including evaluating novel ways to improve the efficiency of regulatory review and leveraging available data to answer scientific and regulatory questions.

INTRODUCTION

With the vast amounts of data from complex clinical trials and evolution of data standards, the Office of New Drugs (OND) at the FDA created the Associate Director of Biomedical Informatics (ADBMI) position in 2017. The ADBMIs are clinical reviewers who are subject matter experts in safety data analysis and analytical review tools at the FDA. They play an integral role in transforming the new drug review process by their work with internal working groups at FDA, and they work to advance biomedical informatics by both their internal and external collaborations. In addition to these working groups and collaborations, the ADBMI are integral part of the review process in their clinical division. This presentation will highlight how the ADBMIs work in their therapeutic area to affect the New Drug Application (NDA) review process.

ADBMI ROLE IN DIVISION

One responsibility of the ADBMI is to support the needs of their clinical division. Table 1 shows the ADBMIs in OND and the clinical divisions that they support.

Table 1. Associate Directors of Biomedical Informatics in the Office of New Drugs

Name	Division / Products	Acronym
Vaishali Popat, MD, MPH	Office of New Drugs	OND
Nhi Beasley, PharmD	Cardiovascular and Renal	DCaRP
Stacy Chin, MD	Pulmonary, Allergy, and Rheumatology	DPARP
Sarah Connelly, MD	Antiviral	DAVP
Joe Tonning, MD, MPH, RPh	Bone and Reproductive	DBRUP
Doug Warfield, PhD	Psychiatry	DPP

Although the needs of each division vary based on the review experience of the medical staff and the number of applications in the division, common needs in the divisions include reviewer mentoring, advocating for the division's best review practices in OND-wide initiatives, and active participation in the NDA reviews. Reviewer mentoring ranges from analyzing the safety data or performing exploratory analyses for the clinical reviewer to being the safety reviewer and working alongside the clinical reviewer during an application review. The ADBMI has an active role in determining the data quality of an application. They are also the division resident expert for questions about reviewer tools or applications, and spend time teaching specific tools and applications to the clinical staff. In addition

to NDA work, the ADBMIs are involved in pre-NDA meetings where we advise sponsors on data standard and data format issues.

CONCLUSION

The ADBMIs play an important role in their divisions, often filling an unmet need. This presentation will highlight how they work in their division.

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