

Biomedical Informatics in the Office of New Drugs, CDER/FDA

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Biomedical Informatics is an emerging and rapidly growing field which integrates medicine, computer science, and information science. The Office of New Drugs has developed a new team of biomedical informaticians to help modernize the regulatory review by developing the toolset, mindset, and skillset necessary to implement best practices for the clinical review. They work with other offices in CDER to provide user perspective in tool development and enhancements, data standards development and help leverage internal information to conduct efficient regulatory reviews. This presentation will talk about professional development activities in this emerging field at the FDA as well as various workgroup activities and projects to incorporate innovative technologies to advance review science.

This presentation will talk about how the grandfathering period in the Clinical Informatics board certification sparked professional development activities in this emerging field at the FDA and various activities in workgroups and projects to incorporate innovative technologies to advance review science. These workgroups are focused on learning new tools to analyze data submitted in the NDA/BLA/IND applications, helping to leverage internal (e.g. meeting minutes) and external data (e.g. distributed health networks) for regulatory drug review, and keeping up to date with new regulations and guidance related to this rapidly expanding area of new technologies. These workgroups provide a collaborative space where staff members with different skillsets across offices can collaborate and share their collective experience.

In this time of data revolution, leveraging this opportunity may help to engage staff in modernization initiatives many organizations are facing. Availability of new professional development pathways is motivating and inspiring hundreds of staff members to develop the necessary skills to function effectively.

CONCLUSION

The Biomedical Informatics is a new and emerging field which integrates medicine, computer science, and information science. The grandfathering period of Clinical Informatics board certification as well as potential AHIC pathways provided unique opportunities, which can be leveraged to help create win-win situation for staff engagement in any health care organization.

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