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Customer Case Study: Overview of the CDISC Pilot Project

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ABSTRACT

This talk discusses the goals, the process, and achievements of the CDISC Pilot Project to date. In particular, the talk reviews decisions made and actions taken to achieve the first CDISC Pilot submission to FDA in June 2006. The process for establishing FDA expectations and requirements, and the specifics of the structure of the first submission, is discussed. Subsequent comments on the submission package from FDA participants, and actions then taken to address those comments, are reviewed.

No paper was submitted for publication.

CONTACT INFORMATION

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