## Operational Challenges and Solutions with Implementation of an Adaptive Seamless Phase 2/3 Study

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## Abstract

A wide variety of operational issues were encountered with the planning and implementation of an adaptive, dose-finding, seamless phase 2/3 trial for a diabetes therapeutic. Compared with a conventional design, significant upfront planning was required, as well as earlier, more integrated cross-functional coordination. The existing infrastructure necessitated greater flexibility to meet the needs of the adaptive design. Rapid data acquisition, analysis, and reporting were essential to support the successful implementation of the adaptive algorithm. Drug supply for nine treatment arms had to be carefully managed across many sites worldwide. Details regarding these key operational challenges and others will be discussed along with resolutions taken to enable successful implementation of this adaptive, seamless trial.

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Abbreviations: (DMC) Data Monitoring Committee, (DP) decision point, (dula) dulaglutide, (ERB) ethics review board, (HbA1c) hemoglobin A1c, (IRC) internal review committee, (IT) information technology, (SAC) Statistical Analysis Center, (SAP) statistical analysis plan, (SOP) standard operating procedure

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