A Modern Curriculum for Training Scientists in Model-Informed Drug Development: Progress Report on FDA Grant to Train Regulatory Scientists

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Abstract
Under U.S. Food and Drug Administration (FDA) grant (2U18FD005320-06), Critical Path Institute (C-Path) and experienced private sector partners collaborated with global health organizations to create didactic video materials in an e-learning format on model-informed drug development (MIDD) topics relevant to a non-modeling audience. Several multinational pharmaceutical companies contributed case studies illustrating the application of the MIDD approach in practice. Training videos were created and divided into several modules: introducing the MIDD landscape for drug development and regulatory science, a review of various model types used for MIDD, discussions of how models inform drug development and regulatory decisions, future goals of MIDD, and discussions on the interconnectedness of models used for MIDD. Examples and vignettes from stakeholders and thought leaders were included. These educational materials fill a gap between academic and “on the job training” for regulators, academic, and industry scientists, delivering insights and value for those performing modeling and non-modelers reviewing the output of modeling and simulation work. A total of 13 hours of video content is currently available. A small panel of FDA reviewers is currently beta-testing the learning management system (LMS). Future efforts for this MIDD training initiative will include expansion of the content via an expanded and diverse faculty, 1:1 online mentorship sessions, and eventually broader access to this resource consistent with an open science approach and curriculum. The MIDD training LMS can accommodate a diverse learning ecosystem; further development may also accommodate different audiences in the future.

You can read the full publication in its original format here.