ABSTRACT: BioCelerate, a subsidiary of TransCelerate BioPharma, Inc., is a nonclinical industry consortium driving initiatives to increase efficiency and productivity in early-stage R&D. Our objective in developing common templates for nonclinical studies is to drive efficiencies in toxicology-study management across the spectrum of Biopharma and Contract Research Organizations (CROs). Our initial project resulted in a protocol template for FIH-enabling repeat-dose toxicology studies.

The process to develop the initial protocol template utilized the OECD/FDA GLPs as a starting point and excluded process instructions where large variations in preferences existed. Advantages to using a common template include (1) decreasing the time it takes to develop a protocol and thus start a study, (2) improvement of overall study quality by decreasing errors due to unfamiliarity with protocol formatting, (3) optimization of time in managing multiple studies, and (4) optimizing time spent on subsequent report/SEND preparation and review. Two 2019 webinars introduced the initiative and were used to collect stakeholder feedback. Responses to poll questions indicated that a majority of stakeholders used multiple repeat-dose toxicology protocol templates, and experienced problems associated with protocol inconsistency including process/time inefficiencies and reduced quality of study execution. There was a mixed response regarding the inclusion of SEND information in the protocol.

Building on these and earlier discussions, BioCelerate collaborated with CROs, health authorities, and BioPharma to develop a common protocol template for FIH-enabling repeat-dose toxicology studies. Version 1.0 of the protocol was released publicly in 4Q19 for voluntary adoption. The template and supporting implementation materials can be downloaded from the BioCelerate website.

BioCelerate provides reports on the uptake/use of the common protocol template and shares critical feedback from early adopters on the gaps as well as the usefulness of the template. BioCelerate will continue to work with collaborators and stakeholders in evaluating options and recommendations for content and structural improvements. Input from all stakeholders will help us develop the next generation protocol template as well as shaping our next-steps.
for subsequent common templates (e.g. Common Report Template). These activities will further support BioCelerate’s goal of improving toxicology study operational efficiency and quality.