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## Cinema Grade Pro V1.1.3 (486)

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drug exposure and response. The integrated PK/PD model presented in this paper allowed for development and application of PK/PD principles to an NDA approval process that accommodated potentially new endpoints for clinical trials. The fundamental underlying principles of QSP were applied to a previously developed NDA model that has been adapted to the approval process for ribavirin. The model was applied to the development of a single ascending dose (SAD) trial for the drug under two development paths, including one in which a second-generation drug developed for another indication was repurposed. The modelling exercise had significant impact in both trial planning and design, and supports the value of QSP applied to regulatory development in drug applications. Properdin deficiency causes markedly reduced function in young but





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obvious that color grading has been revolutionized by computer technology.

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