350 Hudson Street
New York, NY 10014
United States
medidata.com

March 16, 2023

Medidata acknowledges the release of the European Medicines Agency Good Clinical Practice Inspectors Working Group 'Guideline on computerised systems and electronic data in clinical trials' (EMA/INS/GCP/112288/2023), on March 7th 2023, to come into effect six months after publication. This guideline replaces the 'Reflection paper on expectations for electronic source data and data transcribed to electronic data collection tools in clinical trials' (EMA/INS/GCP/454280/2010). Medidata was actively engaged in the public consultation on the draft version of the guideline in 2021, where the document was carefully reviewed, and expert opinions were provided directly to the EMA, as well as in collaboration with industry consortia. We are analysing the issued guideline with a focus on its applicability to Medidata services. We encourage our clients and the research community to review this publication as well. Medidata will issue further position statements on the guideline in the near future.

Medidata further acknowledges the US Food and Drug Administration's updated draft guidance for industry: Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations Questions and Answers (Revision 1- March 2023) published in the Federal Register on March 16, 2023. As with the EMA Draft 2021 Guideline, Medidata provided extensive feedback to the US Food and Drug Administration on the prior 2017 draft and looks forward to reviewing the updated revision and will provide feedback in the public comment period.