



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 September 2023
EMA/INS/GCP/155774/2022
Good Clinical Practice Inspectors Working Group (GCP IWG)

ANNEX III TO PROCEDURE FOR CONDUCTING GCP INSPECTIONS REQUESTED BY THE CHMP: COMPUTER SYSTEMS

Adopted by GCP Inspectors Working Group (GCP IWG)	19 September 2023
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Keywords	<i>GCP inspections, computer systems</i>
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Reference is made to the adopted Guideline on computerised systems and electronic data in clinical trials (EMA/INS/GCP/112288/2023):
[Guideline on computerised systems and electronic data in clinical trials \(europa.eu\)](#).

This guideline was adopted by the GCP IWG on 7 March 2023 and entered into effect on 10 September 2023.

