

FDA CFR 21 Part 11 Validation Statement: Advarra eRegulatory Management System

This statement refers to Yale Center for Clinical Investigation's customer validation efforts for its use of the Advarra eRegulatory Management System and services to meet the applicable requirements under FDA 21 CFR Part 11.

CFR 21, Part 11, Section 11.1(a) states clearly that electronic records in compliance with Part 11 criteria shall be considered by the agency to be "trustworthy, reliable, and generally equivalent to paper records".

(a) The regulations in this part set forth the criteria under which the agency considers electronic records, electronic signatures, and handwritten signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

Further, CFR 21, Part 11, Section 11.1(d) states clearly that electronic records meeting the requirements "may be used in lieu of paper records":

(d) Electronic records that meet the requirements of this part may be used in lieu of paper records, in accordance with 11.2, unless paper records are specifically required.

Yale Center for Clinical Investigation affirms that Advarra eRegulatory System v. 2023R1 was validated prior to release for general availability on 23MAY2023 by successfully passing all user acceptance validation testing, mandated by YCCI Standard Operating Procedures for system validation, and Advarra eRegulatory system is fully compliant with the requirements for Electronic Signatures per CFR 21, Part 11 Subpart C - Electronic Signatures.