

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
DISTRICT ADDRESS AND PHONE NUMBER 10903 New Hampshire Avenue Building 51 Silver Spring, MD 20993 (301) 796-3150 Fax: (301) 594-1204	DATE(S) OF INSPECTION 02/24/2025-02/27/2025 FEI NUMBER 3032745961	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Joyce (NMI) Suhy, EVP, Medical Imaging and Specialty Solutions		
FIRM NAME Bioclinica Inc. / Clario (eResearch Technology, Inc.)	STREET ADDRESS 11th Floor No.3, Lane 227 Dongyu Road, China	
CITY, STATE, ZIP CODE, COUNTRY Shanghai, Shanghai China	TYPE ESTABLISHMENT INSPECTED Contract Research Organization (CRO)	
This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.		
DURING AN INSPECTION OF YOUR FIRM I OBSERVED: The following observations relate to conduct of Contract Research Organization (CRO) for: Protocol Number and Study ID: Study (b)(4) Title: A Randomized, Double-blind, International Multicenter, Parallel-controlled Phase III Clinical Study to Evaluate (b)(4) (b)(4)		
DURING AN INSPECTION OF YOUR FIRM I OBSERVED: OBSERVATION 1 Transfer of obligations to a contract research organization. Specifically, 1. Your firm failed to validate computer systems used to process, manage, and report electronic data from clinical investigations to ensure accuracy, reliability, and consistent intended performance. For example: A) Your firm used unvalidated software applications (b)(4) and (b)(4) (b)(4) to analyze clinical study bone mineral density data despite your June 2023 COTS assessments acknowledging Part 11 requirements. Critical data integrity gaps existed, as		
SEE REVERSE OF THIS PAGE	See page 2 for esignature	DATE ISSUED 02/27/2025
FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS		

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edits/modifications, reassessments, and deletions could be made in these systems with no audit trail before transfer to (b)(4) B) Your validation approach failed to address critical upstream data processing activities, creating risk to data reliability. The absence of validation for these systems resulted in inability to generate complete audit trails, identify users making changes, document reasons for changes, prevent unauthorized modifications, and produce accurate and complete copies of records throughout the entire data lifecycle. 2. Your firm failed to establish and follow adequate procedures to ensure the integrity, accuracy, and reliability of clinical trial data for study (b)(4) Specifically, your firm did not implement effective validation controls, or adequate corrective and preventive actions. For Example: A) Quality Event DEV-06296 documents that correction factors were not properly applied to data in the final data transfer on June 26, 2024, affecting 31 subjects. "There was an IQC correction in prior transfer. In the Final/End of Study transfer, the prior IQC corrections were overwritten with the new data, instead of appended to the prior corrections which is our standard process (IM-SS-W027)." B) Quality Event DEV-06317 documents that hip data for three specific cases (b)(4) (b)(6) were improperly excluded from the data transfer file, despite being required for analysis.		
 Digitally signed by Scott N. Lim -S Date: 2025.02.27 13:52:20 +08'00'		
SEE REVERSE OF THIS PAGE	See page 2 for esignature	DATE ISSUED 02/27/2025
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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."