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ASSOCIATION OF CLINICAL RESEARCH ORGANIZATIONS

December 20, 2023

Lauren K. Roth
Associate Commissioner for Policy
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993–0002

RE: ACRO comment submission:
Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities Guidance for Industry
[FDA-2023-D-4416]

Dear Ms. Roth,

The Association of Clinical Research Organizations (ACRO) represents the world's leading clinical research and clinical technology organizations. Our member companies provide a wide range of specialized services across the entire spectrum of development for new drugs, biologics and medical devices, from pre-clinical, proof of concept and first-in-human studies through post-approval, pharmacovigilance and health data research. ACRO member companies manage or otherwise support a majority of all biopharmaceutical sponsored clinical investigations worldwide and advance clinical outsourcing to improve the quality, efficiency and safety of biomedical research.

ACRO thanks the Agency for releasing the draft Guidance for Industry on Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities. ACRO is pleased to provide the following feedback.

General Comments and Recommendations:

ACRO thanks the agency for the flexibility and expansion of FDA tools to enable evaluation of facilities during the COVID-19 pandemic.

ACRO notes the voluntary nature of remote interactive evaluations (RIEs) and that RIEs may be requested by FDA in a variety of situations. The guidance provides certain expectations -- for example, on conduct and provision of documents. The guidance also encourages responses to observations within a certain timeframe. ACRO would welcome further details on any specific expectations from FDA regarding how RIEs are integrated into company and facility Quality Management Systems

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Section-specific comments:

Section III A. Selecting and Notifying the Facility
The guidance indicates that an RIE would be voluntary. ACRO notes that the FDA will make a request for confirmation of the facility's willingness and ability to participate in an RIE.

A key part of the decision of a facility to be able to take part in an RIE will depend on technical capability and the ability of facilities to meet FDA requirements as listed in Section IV A.
Each request for an RIE will require the facility to review their capability and confirm they can meet FDA requirements in relation to that specific RIE request. In order to enable facilities to conduct a thorough assessment of their ability to take part in an RIE, ACRO recommends the following:

- Provision of as much information on the specific technical expectations of the RIE (currently listed in Section III B.) at the time of the request, in order to enable the facility to accurately and comprehensively evaluate their capability.
- Allowance of adequate time for facilities to carry out the feasibility assessment.

ACRO thanks the Agency for this opportunity to comment on the Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities Guidance for Industry.

Please do not hesitate to contact ACRO if we can provide further details or answer any questions (knoonan@acrohealth.org).

Respectfully submitted,

Karen Noonan
Senior Vice President, Global Regulatory Policy