ACRO Innovate Advocate Collaborate

March 26, 2024

Lauren K. Roth,
Associate Commissioner for Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 32,
Silver Spring, MD 20993–0002

RE: ACRO comment submission on:
Conducting Remote Regulatory Assessments—Questions and Answers; Revised Draft Guidance for Industry (2024)
FDA-2022-D-0810-0031

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ACRO thanks the Agency for issuing this Q&A revised draft guidance, which provides helpful clarity on the nature of Remote Regulatory Assessments (RRAs) as part of the FDA's armamentarium of tools for the oversight of FDA-regulated products and establishments. ACRO appreciates the opportunity to provide our industry's thinking and recommendations in response to the revised draft guidance. ACRO would like to offer three recommendations to help strengthen the final version of this Q&A resource.

First, throughout the draft guidance, a distinction is made between mandatory and voluntary RRAs. As the draft guidance notes:

> *Mandatory RRAs are conducted under legal authorities mandating the establishment's participation. Requests for records or other information from establishments subject to section 704(a)(4) of the FD&C Act, and requests for FSVP records under 21 CFR 1.510(b)(3) and 1.512(b)(5)(ii)(C), are included among RRAS that are mandatory. RRAs that are not conducted under statutory or regulatory authorities mandating an establishment's participation are voluntary in that an establishment can decline to participate or withdraw participation during the RRA, in which case the Agency may consider other tools for evaluating compliance with FDA requirements.*

Some site establishments have not fully converted from pen-and-paper approaches to the use of digital, electronic records. Because it would be difficult for sites that still take pen-and-paper approaches to comply with the electronic nature of mandatory RRAs, we believe it is vital for FDA to utilize the final guidance as an opportunity to strongly encourage all research sites to fully convert to the use of electronic records.

Second, Line 291 of the draft guidance states: *"FDA may review electronic systems and source records by screen sharing and livestream/video."* We wish to note that "over the shoulder" access can be a burden for establishments undergoing an RRA. We ask the Agency to consider including the option of obtaining direct access. As long as the accessible data is restricted to what is appropriately in scope, in a read-only scenario, the FDA should have the option to login directly and review records independently.

Finally, we note that in the discussion of *Question 16 – What may occur upon completion of an RRA?,* the draft guidance notes that both close-out meetings and also written reports may not always take place.

Lines 431 to 433 of the draft guidance discuss close-out meetings:

> *Upon completion of an RRA, FDA may have a closeout meeting with the establishment's management. At the closeout meeting, FDA may present a written list of RRA observations, if any, and describe and discuss such observations in sufficient detail to enable understanding and foster an appropriate response.*
> Footnote 38 clarifies:
> *There may be some instances where a closeout meeting may not happen, such as for some requests under section 704(a)(4) of the FD&C Act. In such circumstances, FDA intends to notify the establishment that the RRA is concluded, along with any pertinent information.*

Lines 453 to 458 of the draft guidance discuss final written reports:

> *As part of the RRA process, FDA intends to ordinarily prepare a report consisting of a narrative and supporting documents that communicates the summary of information reviewed, conditions and practices found, and the observations identified. FDA generally expects to provide a written copy of the narrative portion of the RRA report to the establishment, following the determination that the RRA is closed (see 457 21 CFR 20.64(d)(3)). At that time, the report and supporting documents, with any applicable redactions, also become available for public disclosure upon request.*
> Footnote 40 clarifies:
> *There may be some instances where a report may not be written or provided, such as when the requested records under section 704(a)(4) of the FD&C Act were used to prepare for an inspection or for some requests for FSVP records under 21 CFR 1.510(b)(3) and 1.512(b)(5)(ii)(C).*

ACRO believes that verbal feedback and written summaries are important information for the establishment that has undergone an RRA. We ask that the final version of the guidance makes a stronger commitment to the provision of both close-out meetings and final, written reports, to establishments as we believe these kinds of feedback will support the overall success of RRAs as an oversight tool. We ask the Agency to consider take a stronger stand on these kinds of feedback to industry – perhaps by providing a very narrow set of circumstances where this feedback would not be provided and/or giving the establishment an opportunity to request a close-out meeting and/or written report when it is not provided by FDA.

Thank you for the opportunity to provide feedback on this draft guidance on Conducting Remote Regulatory Assessments.

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Respectfully submitted,

Karen Noonan
Senior Vice President, Global Regulatory Policy