ACRO
ASSOCIATION OF CLINICAL RESEARCH ORGANIZATIONS

10 June 2022

To: Nathalie Macle, Public and Stakeholders Engagement Department
European Medicines Agency
Domenico Scarlattilaan 6 | 1083 HS Amsterdam | The Netherlands

From: Karen Noonan
Senior Vice President, Global Regulatory Policy
ACRO (Association of Clinical Research Organizations)

RE: **Response from the Association of Clinical Research Organizations (ACRO) to a Public Consultation Concerning the Physical Attendance and The Location Of Personal Residency of The Qualified Person (EMA/INS/169000/2022, 11 May 2022)**

Introduction

The Association of Clinical Research Organizations (ACRO) represents the world's leading clinical research and 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-man studies through post-approval and pharmacovigilance research. ACRO member companies manage or otherwise support a majority of all clinical investigations worldwide. The member companies of ACRO advance clinical outsourcing to improve the quality, efficacy, and safety of biomedical research.

ACRO thanks the European Medicines Agency for this opportunity to comment on the proposed Questions & Answers Concerning the Physical Attendance And The Location Of Personal Residency Of The Qualified Person.

Comments

1. ACRO welcomes the recognition by the GMDP Inspectors Working Group that the experience with remote QP batch certification, introduced as an emergency measure of regulatory flexibility during the COVID-19 pandemic, was successfully implemented to the extent that this practice may now be considered on a routine basis as the pandemic recedes. ACRO fully supports this initiative and the process described in the proposed Question and Answer document.

2. ACRO welcomes the clear statement in the proposed document that the principle of remote QP batch certification applies to both Investigational Medicinal Products (IMPs) and products authorized for marketing.

3. As this is an EU-level guidance, the statements in several of the draft answers that some Member States/national competent authorities may have specific national requirements are not helpful. It is often difficult for clinical trial sponsors and marketing authorization holders to obtain the necessary information on specific national requirements and so we recommend that the document is accompanied by an annex that sets out the specific requirements of the individual Member States.

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4. ACRO is pleased to note that A. 2 confirms that "It is the responsibility of the MIA holder to guarantee that . . . c) an appropriate system for electronic signatures is in place." In a number of situations, ACRO members have reported a lack of harmonization between Member States with regard to requirements for electronic signature systems. In relation to QP batch release for all EU member states, it is important that the e-signature is accepted by all Member States. We therefore recommend the addition to A.2 of the statement "The electronic signature system should meet the requirements of the Member State in which the QP is located."

5. Finally, we would like to note that remote certification during a crisis or occasionally during periods of travel, etc. is somewhat different from being a totally remote QP with limited first-hand knowledge of the site he/she supports. Clear guidance will be necessary concerning the circumstances needed to permit remote QP certification and to ensure the QP has the necessary background for appropriate compliance.

Thank you for this comment opportunity.
Please contact ACRO (knoonan@acrohealth.org) if we can provide additional details or answer any questions.

Respectfully submitted

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