19 November 2015

To: European Commission
DG Health and Food Safety
Unit D6 "Medicinal products – Quality, Safety and Efficacy"
B-1049 Brussels

From: ACRO (Association of Clinical Research Organizations)

RE: **ACRO Comment and Statement of Support of Consultation document: *Detailed arrangements for clinical trials inspection procedures including the qualifications and training requirements for inspectors, pursuant to Article 78(7) of Regulation (EU) No 536/2014***

The Association of Clinical Research Organizations (ACRO) represents the world's leading, global clinical research organizations (CROs). Our member companies provide a wide range of specialized services across the entire spectrum of development for new drugs, biologics and medical devices – from discovery, pre-clinical, proof of concept and first-in-man studies through post-approval and pharmacovigilance research. With more than 110,000 employees (including 30,000 in Europe) engaged in research activities around the world, ACRO advances clinical outsourcing to improve the quality, efficiency and safety of clinical research. Each year, ACRO member companies conduct more than 9,000 clinical trials involving nearly two million research participants in 142 countries.

ACRO welcomes and strongly supports the consultation document *"Detailed arrangements for clinical trials inspection procedures including the qualifications and training requirements for inspectors, pursuant to Article 78(7) of Regulation (EU) No 536/2014"* and its emphasis on vital components of a robust inspections infrastructure – such as qualification and training requirements for inspectors; procedural rules for inspections; sufficient resources; collaboration; and coordination.

Thank you for the opportunity for ACRO to provide our statement of support for this important consultation document on clinical trial inspections procedures. Should you have any questions or require further information, please do not hesitate to contact ACRO at knoonan@acrohealth.org.

Respectfully submitted,

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