12 September 2025

European Medicines Agency

Highlights – 1st EMA-ACRO bilateral meeting

Chaired by Juan Garcia Burgos, Head of Public and Stakeholder Engagement Department

1. Welcome and introduction

The chair welcomed the ACRO delegation to the first bilateral meeting acknowledging the importance of having such exchanges alongside ACRO's ongoing contribution through other groups, including the ACT EU multi-stakeholder platform and its advisory group (MSP AG).

The unique insights that ACRO brings on the field of clinical research were highlighted as a valuable resource for early identification of issues and exploring innovative solutions in the area of clinical trials.

The shared commitment of fostering a robust, efficient, and patient-centred clinical trials environment across Europe was acknowledged.

2. Introduction to ACRO, ACRO's vision for engaging with EMA

ACRO presented an overview of the association, its members and the activities of its working committees highlighting the broad representation of Clinical Research Organisations (CROs) and clinical technology companies.

3. Improving the attractiveness of the EU clinical trials

The positive impact of the changes brought by the Clinical Trial Regulation (CTRs) were discussed noting the need to further emphasise the initiatives introduced so far, that are leading to an increase of applications submitted. These initiatives include the Trial Map, the consolidated advice pilots, the redesigned CTIS sponsor handbook, etc. It was also highlighted that a correct application of regulation provisions will also help reducing delays, inflexibilities and overcoming challenges. Suggestions for improvement were made in terms of further reducing timelines, enhancing alignment and efficiency.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

ACRO was informed of the upcoming publication by EMA of the key performance indicators (KPIs) related to attractiveness (number of multi-national trials) and speed (recruit process). KPIS will be critical in future monitoring of CTs in the EU and ACRO was invited to refer to such KPIs in their future analyses.

ACRO was invited to further share their proposals with other relevant authorities, with the ACT EU MSP AG and other relevant groups, as appropriate.

The importance in engaging in a dialogue with the European Commission on the Biotech ACT proposal was stressed.

4. AI/ML in clinical research and medical product development: harmonising an evolving regulatory landscape

ACRO welcomed the EMA reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle noting its current relevance. Points for clarifications were discussed.

The Agency encouraged ACRO to participate to the HMA/EMA multi-stakeholder workshop on artificial intelligence (20-21 November 2025) and confirmed plans for additional guidance development.

Also in this case, further discussions with the MSP AG on specific proposals was proposed.

5. Conclusions and next steps

The bilateral was an opportunity to learn more about ACRO unique perspectives and proposals and was considered as a complementary engagement channel alongside the association's active participation in the ACT EU MSP AG and other relevant initiatives.