Meeting highlights – ACT EU Multi-stakeholder Platform Advisory Group

18 June 2026, 09:30-13:30 (CEST), Teams meeting

Co-Chairs: Catherine Paugam-Burtz (Regulatory co-chair), François Houÿez (Stakeholder co-chair)

1. Opening of the meeting

The meeting was opened by the regulatory co-chair, who thanked Denis Lacombe, the outgoing stakeholder co-chair, for his leadership and commitment during the first two years of the MSP AG. His work alongside the former regulatory co-chair, Maria Lamas, helped establish the platform as an important forum for exchange and co-creation across the clinical research community. The regulatory co-chair then welcomed François Houÿez, who has been appointed as stakeholder co-chair for a two-year mandate.

François Houÿez thanked the ACT EU governance and MSP AG members and expressed his commitment to build on the group's work. In his farewell remarks the outgoing stakeholder co-chair, Denis Lacombe, wished the group continued success and confirmed his engagement as an EORTC's alternate representative.

Looking ahead, the co-chairs recalled the platform's shared objective of strengthening the European clinical research ecosystem by reflecting stakeholder needs, enhancing the attractiveness and competitiveness of clinical research in Europe, and ultimately improving access to innovative treatments for EU citizens.

2. Update from ACT EU programme manager

The group was updated on the ACT EU workplan adopted in May 2026. Developed together with Member States and the European Commission ACT EU regulatory partners and with stakeholders' input, the workplan sets out priorities for 2026–2027 based on the recently revised seven objectives. These cover stakeholder engagement, innovation, inclusivity, capacity building and other actions supporting better, faster and smarter clinical trials in the EU.
Progress was presented against the programme's two key performance indicators: 500 additional authorised multinational clinical trials by 2030 and 66% of trials recruiting within 200 days of application submission. By March 2026, 19 clinical trials in addition to the historical trend had been authorised and 41% had met the recruitment target. Continued monitoring will help identify where further action is needed (see slide 8).

Updates were also provided on the Programme's activities (see slides 10-20) including

the April webinar on contractual agreements that attracted considerable interest and brought together perspectives at both national and European levels, ongoing work to streamline sponsors serious-breach reporting and consolidated advice in clinical trials that continue to be in place with considerations to move to permanent offering (pre-CTA).
In addition, activities to support non-commercial sponsors recently expanded with dedicated regional webinars planned towards the end of the year and work continue on training needs for academia and SME by making existing resources easier to find on the ACT EU website. Change-management activities are being coordinated to support the uptake of programme deliverables and prepare for developments linked to the Biotech Act.

During the discussion, members welcomed the revised workplan and the activities to measure KPI and how these could impact priorities and deliverables of the Programme. It was highlighted that the monthly clinical trials newsletter can be a helpful tool to keep abreast of latest developments within ACT EU as well as additional tools, e.g. communication campaigns, to inform stakeholders of the existing tools and initiatives. Members were also invited to share any substantive comments on the simplified clinical trial application package developed under the ACT EU priority action on clinical trials in public health emergencies.

Next steps / Action points:

- MSP AG members are invited to share any substantive comments on the simplified clinical trial application package for public health emergencies with the drafting group

3. Legislative, non-legislative and other updates

Update on Biotech Act

The European Commission updated the group on the Biotech Act and the accompanying Commission staff working document published in May 2026 outlining the expected positive impact of the BTA on the economy and public health system. Discussions are progressing in the Council and European Parliament, with trilogues expected to begin in early 2027.

Measures relevant to clinical trials include shorter authorisation timelines, greater reliance on the assessment conducted by the reporting Member State, tailored procedures for public health emergencies, more harmonised data governance, and provisions supporting decentralised elements in clinical trials and the use of artificial intelligence (see slide 4). The measures aim to make the EU more attractive for clinical research, improve inclusivity and reduce costs for sponsors, including small and medium-sized enterprises. The supporting analysis estimates that the package of measured introduced by BTA could increase clinical trial activity in the EU by 10–30%, with wider benefits for innovation, employment and patient access (see slide 5).

Update on EU4Health initiative

Two planned EU4Health joint actions were presented. The first aims towards support for non-commercial sponsors (NCS) and is led by Czechia; the second led by Austria, focuses on implementation of the Clinical Trials Regulation and capacity building. Both are intended to strengthen cooperation between Member States and support more consistent application of efficient procedures (see slide 6).
A proposed EUR 10.9 million call for stakeholders to support one or two multinational clinical trials is also under discussion for 2026 annual work programme.
The call would support innovative approaches, including decentralised elements and artificial intelligence. (see slide 6).

Progress update MedEthicsEU

MedEthicsEU presented progress under its 2025–2026 workplan (see slides 3-6), which focuses on harmonising Part II dossier requirements, operational procedures and ethical review. Recent outputs include a harmonised template for recruitment and informed consent and best-practice documents on drafting considerations (finalised) and conditional approvals (ongoing) both developed together with the Clinical Trials Coordination Group (CTCG).

Q&A session

The discussion addressed the variety of organisation and set up of Ethics Committees at national level and the differences in the resources and capacity available to ethics committees across Member States. The European Commission noted that there are provisions in the Biotech Act to provide Member States with the necessary tools for the assessment of the applications and the forthcoming joint actions are expected to strengthen cooperation for NCA, ethics committees and GCP inspectors. Efficient stakeholder consultation on templates and future guidance documents was also discussed which will be considered in future work.

4. Patient involvement in clinical trial design and conduct

Update on patients' priorities discussion

The group was updated on follow-up to the letter outlining 12 patient priorities. A meeting with the signatory patient organisations was scheduled for 10 July to identify tangible outputs for each priority and align on feasible actions within the ACT EU workplan.

Preparatory work has also started on disease-specific patient panels. The panels would be co-created with patient organisations and other stakeholders, building on existing engagement approaches while avoiding duplication. A pilot is targeted for the first quarter of 2027.

Members supported further discussion on patient experience data and patient involvement in clinical trials, including through a dedicated workshop. This is being considered for the first quarter of 2027, following ongoing consultations and mapping of related initiatives.

Next steps / Action points

- ACT EU plans to provide an update on the progress with the disease-specific patient panels at the September 2026 MSP AG meeting.
- MSP AG members are welcome to share suggestions and questions on patient involvement and the proposed patient panels ahead of the September meeting.

5. Clinical trials in nuclear medicine: Insights on challenges and opportunities

Survey insights on nuclear medicine clinical trials

The European Association of Nuclear Medicine (EANM) presented findings from a survey conducted between October and December 2025 among nuclear medicine professionals across Europe. The survey explored barriers to conduct non-commercial clinical trials and reflected multidisciplinary perspectives from several Member States (see slide 8).

The principal challenges identified were regulatory complexity and fragmented requirements, limited funding, administrative burden, restricted access to novel radiopharmaceuticals, and shortages in infrastructure and specialised staff. Patient participation in the clinical trial may also be affected by limited awareness, travel and other logistical constraints, and restrictive eligibility criteria (see slide 11-14).

Suggested measures included greater regulatory harmonisation, dedicated funding, more centralised approval processes and stronger academic networks (see slide 15-16). Germany's parallel assessment model was highlighted as a useful example for diagnostic studies, while members noted that therapeutic trials present additional regulatory and operational challenges. Emerging research

opportunities include alpha therapies in prostate and breast cancer, glioblastoma and pancreatic cancer. Adequate infrastructure and more harmonised guidance were considered important to support trial participation and evidence generation.

6. MSP organisation updates

MSP AG: group and mandate renewal

The MSP AG Secretariat outlined the process and timeline for renewing the MSP AG mandate and composition, which will involve two separate exercises.

First, a feedback survey will gather the views of permanent, alternate and *ad hoc* representatives on the group's organisation, working dynamics, mandate and rules of procedure. Members will be invited to share both their individual experience and the perspective of their organisations, with a view to identifying opportunities for more effective, constructive and inclusive stakeholder engagement. Preliminary feedback will be considered at the MSP AG meeting on 17 September and discussed further at the annual meeting on 22 October. Members are encouraged to complete the survey by 30 September 2026.

A separate call for expressions of interest, open from 17 September to 29 October 2026, will support the renewal of the group's composition. The feedback and outcomes of both exercises will inform the revised composition, mandate and rules of procedure, which are expected to be finalised by the end of 2026. The renewed MSP AG is due to begin its mandate in March 2027 (see slides 3-5).

Next steps / Action points

- MSP AG members are encouraged to complete the feedback survey, reflecting both individual and organisational perspectives.

Planning ACT EU MSP annual meeting

The ACT EU MSP annual meeting will take place on 22 October 2026 in Amsterdam. It will provide an opportunity to reflect on the first three years of the MSP AG and help shape future priorities.

Next steps / Action points

- Academic and healthcare professional representatives are particularly welcome to put forward nominations for the annual meeting programme committee as currently not represented.

7. Closing remarks

The co-chairs thanked the speakers, members and participants for their presentations, contributions and active engagement throughout the meeting.

Looking ahead, members were encouraged to complete the feedback survey and share any suggestions on patient involvement in the design and conduct of clinical trials, including the proposed patient panel. The co-chairs also highlighted the forthcoming consultations on the simplified clinical trial application package, inviting members to provide timely input once the documents become available.