4th Incluir Forum

CLINICAL RESEARCH: PARTICIPATE TO TRANSFORM

29th of October 2026

Patient Involvement in Clinical Trial Design

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CTCG project Patient Involvement

- The CTCG is a working group of experts/regulators in the classification, assessment and oversight of clinical trials from National Medicine Agencies from 30 Member States in the EU/EEA.
- The objective of CTCG is to contribute to increasing the attractiveness of the EU/EEA for clinical trials by harmonisation and optimisation of the regulatory environment while assuring the **protection of rights, safety and wellbeing of the trial participants and the generation of robust data**.
- **Patients should have early access to innovative treatments** which will be guaranteed by a flexible regulatory environment for sponsors. CTCG strongly supports interaction with all relevant stakeholders involved in clinical trials.
- **CTCG started a project to foster patient involvement in clinical trial design**

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CTCG Workplan 2024-2025, 2026-2027

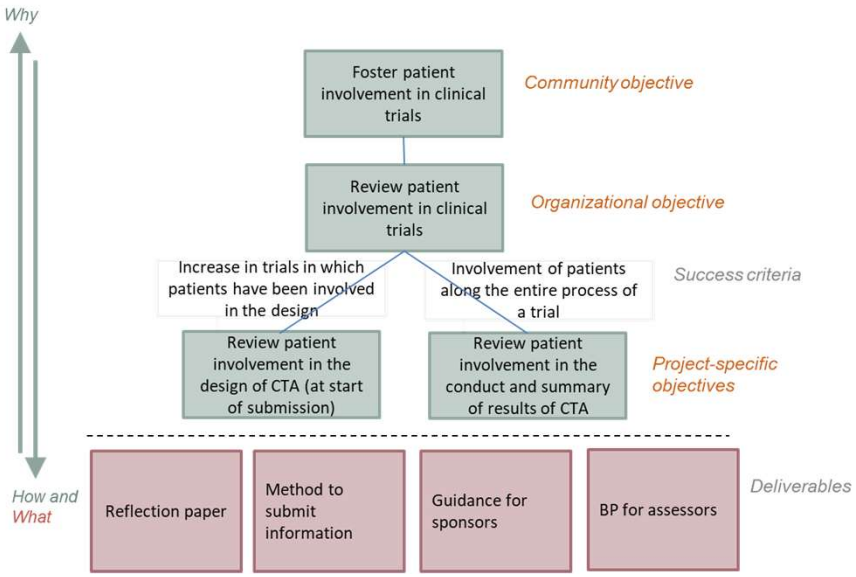
Action plan
1. Promote patient participation by proper implementation of patient involvement in the design and submission of summary of results for laypersons. 2. Create a guidance for sponsors on patient involvement. 3. Create a best practice for assessors to assess patient involvement in clinical trials and update ARs to cover this aspect. 4. Improve equal opportunities for trial participants to access studies by developing a vision on 'fair-inclusion' and achieving greater representation of diverse populations. 5. Strengthen the connection with patients, sponsors, investigators and assessors.

F. Patient/Trial participant centricity and inclusivity

- Position paper to foster patient involvement in design of clinical trials
- Best practice for assessors on how to review patient involvement in CTs

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Project Objectives



- To foster patient involvement by meaningfull review of patient involvement in the design and conduct of clinical trial, including submission of the summary of results for laypersons by regulators and/or ethics committees
- Phase 1: Focus on patient involvement in the design of the clinical trial
- Phase 2: Focus on patient involvement in the conduct and summary of the CTA results.

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Key deliverables and actions

Key deliverable	Action(s)
1. Reflection paper	a. Explore and define format, content, and platform b. Inventarisation of initiatives in MSCs (survey) c. Inventarisation of (European) guidance/information/literature on pt. inv. d. Collect input of stakeholders (on e.g. topics to include in paper, status of such topics and needs/recommendations for the future on pt. inv.) e. Writing/reviewing/publishing
2. Method to include/submit information on patient involvement in CTA	**a. Collect input of stakeholders** b. Align with CTCG c. Develop tools/documents needed for chosen method d. Implementation
3. Guidance for sponsors on patient involvement	a. Connect with sponsors to delineate their needs b. Write guidance c. Reviewing d. Implementation – Organize information sessions/webinar
4. Best practice for assessors	a. Connect with assessors to delineate their needs b. Write best practice c. Reviewing d. Implementation – Organize information sessions/webinar

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Position paper on Patients Involvement

- Scope: limited to the opportunities and challenges on how to implement a description of patient involvement in clinical trial applications
- Current status: despite several initiatives, **patient involvement in the regulatory activities is not yet established as standard practice**. The CTR provide some indication on how to involve the patient in the CT design/assessment.
- Strategy: To find out what the **most important barriers are and how implementation could be enhanced**, different stakeholder groups and representatives, including **patient representatives**, MRECs, commercial and non-commercials sponsors, **were asked for their experiences with patient involvement and recommendations for implementation** via a survey and in stakeholder sessions

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Stakeholder Feedback

- Strong stakeholder support for advancing early and meaningful patient involvement, recognizing that cultural change and continuous collaboration are needed to embed patient perspectives in clinical research.
- Added value for clinical trial assessment: **patient input helps assessors better understand benefits, risks, burdens, and relevant endpoints, supporting more informed benefit-risk decisions and more patient-centered trial designs**.
- Implementation challenges remain: **patient involvement is encouraged but not mandatory under the CTR**, requiring flexible and proportionate approaches. A harmonized review framework is being developed to ensure consistent, transparent, and meaningful integration of patient perspectives across clinical trials

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Final Steps

- Drafting group activity concluded
- Draft position paper shared with stakeholder group
- Stakeholder meeting with project team in July
- Adapt paper after input stakeholders
- Finalise paper for endorsement CTCG
- Implementation and communication plan

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ACT EU Activities



Accelerating Clinical Trials in the EU (ACT EU)

- A joint initiative by the European Commission, Heads of Medicines Agencies and EMA, established in 2022
- Building on the momentum of the implementation of the Clinical Trials Regulation (CTR)
- Our vision is to have **better, faster and smarter clinical trials in the EU**, creating a favourable environment for clinical research

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Bringing patient experience at the centre of clinical research

- Testing the approach: a proposed pilot under ACT EU and Patients and Consumers Working Party
- Identify one or two disease areas Based on proposals from patient organisations and analysis of product development pipelines
- Bring together relevant perspectives Patients, carers and clinicians, as applicable Interaction with commercial and non-commercial sponsors
- Develop disease-level, non-product-specific insights Focus on needs and considerations that may be relevant across multiple clinical trials for the disease

Listen

To patients, carers and clinicians

Understand

- Disease burden
- Patient priorities
- Practical considerations for trial design

Inform

Transparent disease-level insights that could support multiple clinical trial procedures

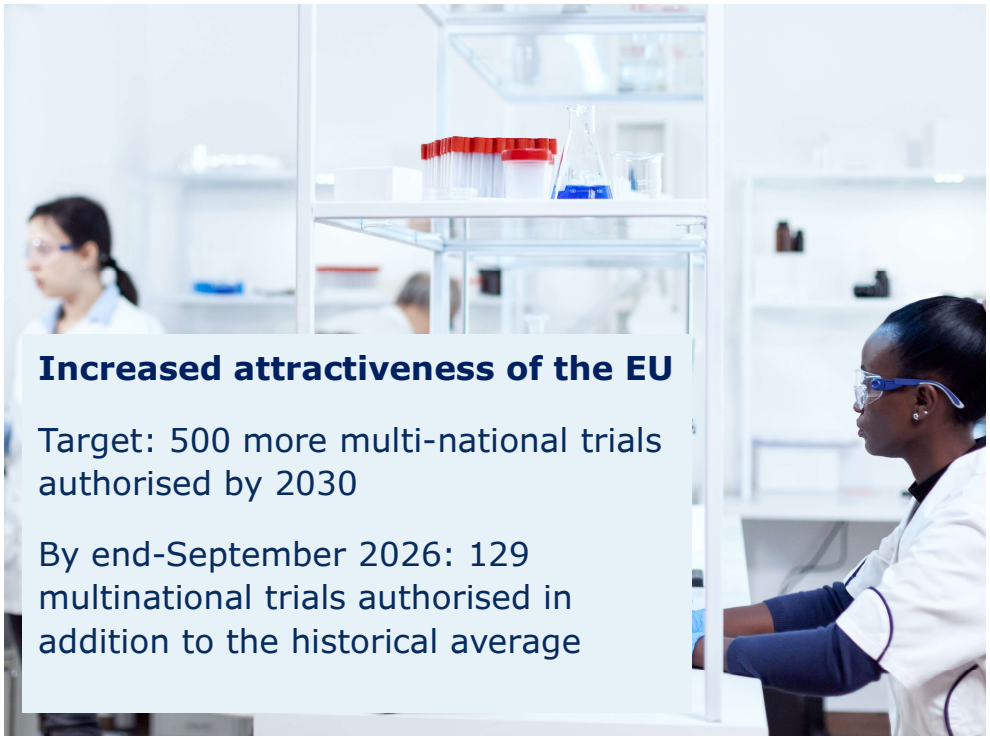


Disease-specific patient panels

European Commission | EMA | HMA Heads of Medicines Agencies

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Progress against 2030 EU clinical trial targets



Increased attractiveness of the EU

Target: 500 more multi-national trials authorised by 2030

By end-September 2026: 129 multinational trials authorised in addition to the historical average



Faster access to treatment

Target: 66% of trials recruit participants within 200 days from application submission by 2030

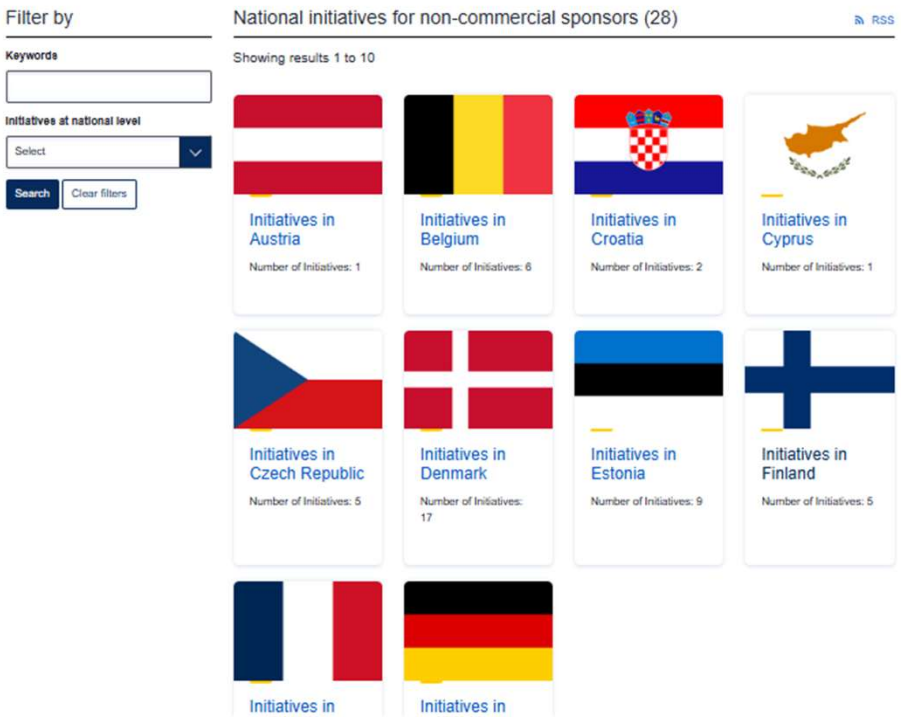
By end-September 2026: 41% of trials meet this timeline

Quarterly progress reports published on the ACT EU website

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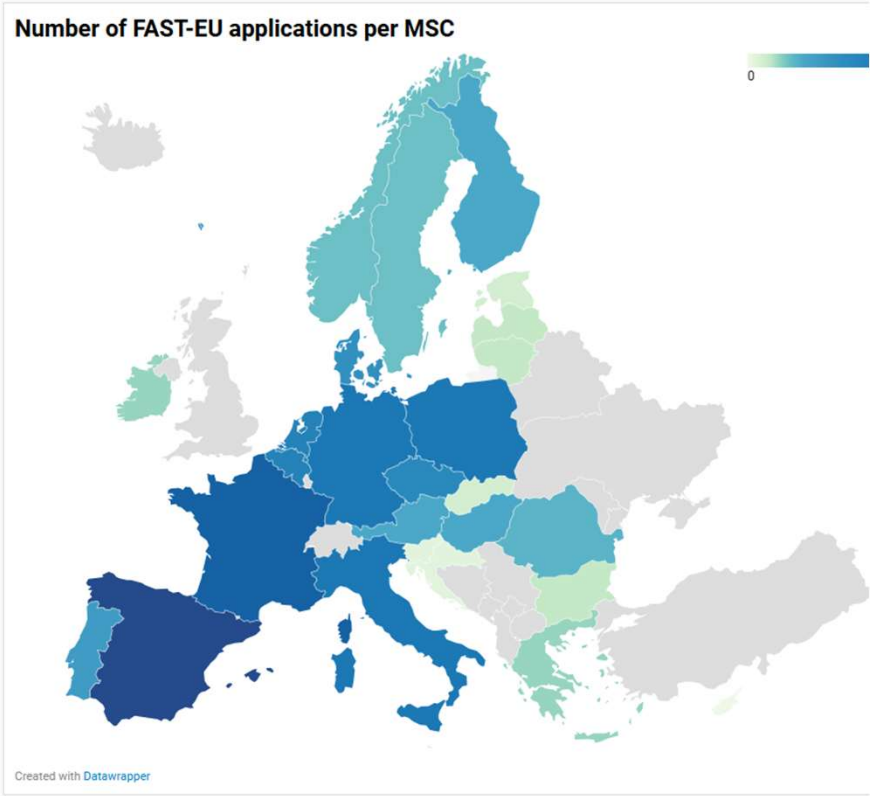
ACT EU Priority action on support for non-commercial sponsors

- Helpdesk for non-commercial sponsors
- Dedicated webpage for non-commercial sponsors:
  Interactive map of national initiative to support non-commercial sponsors
- ‘Regional’ webinars
- Workshop with relevant information (funding, fee waivers,…)



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Facilitating and Accelerating Strategic Clinical Trials in the EU - FAST EU



- Shorter timelines
- Validation and assessment run in parallel.
- Inclusion of all Member States during the whole assessment process.
- Trust in the decision by involvement of national Ethics Committees.

Same scientific and ethical standards. Different choreography.

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Streamlining contractual agreement to speed up trial initiation

- Bringing together national and EU-level experience on clinical site agreements between sponsors and trial sites
- Following a successful webinar on 1 April 2026, a follow-up webinar is planned in December 2026 based on stakeholders' input
- ACT EU is collecting existing models for contractual agreements in consultation with EU Member States, to be signposted on ACT EU website
- **Aim is to speed up the process for patient recruitment**



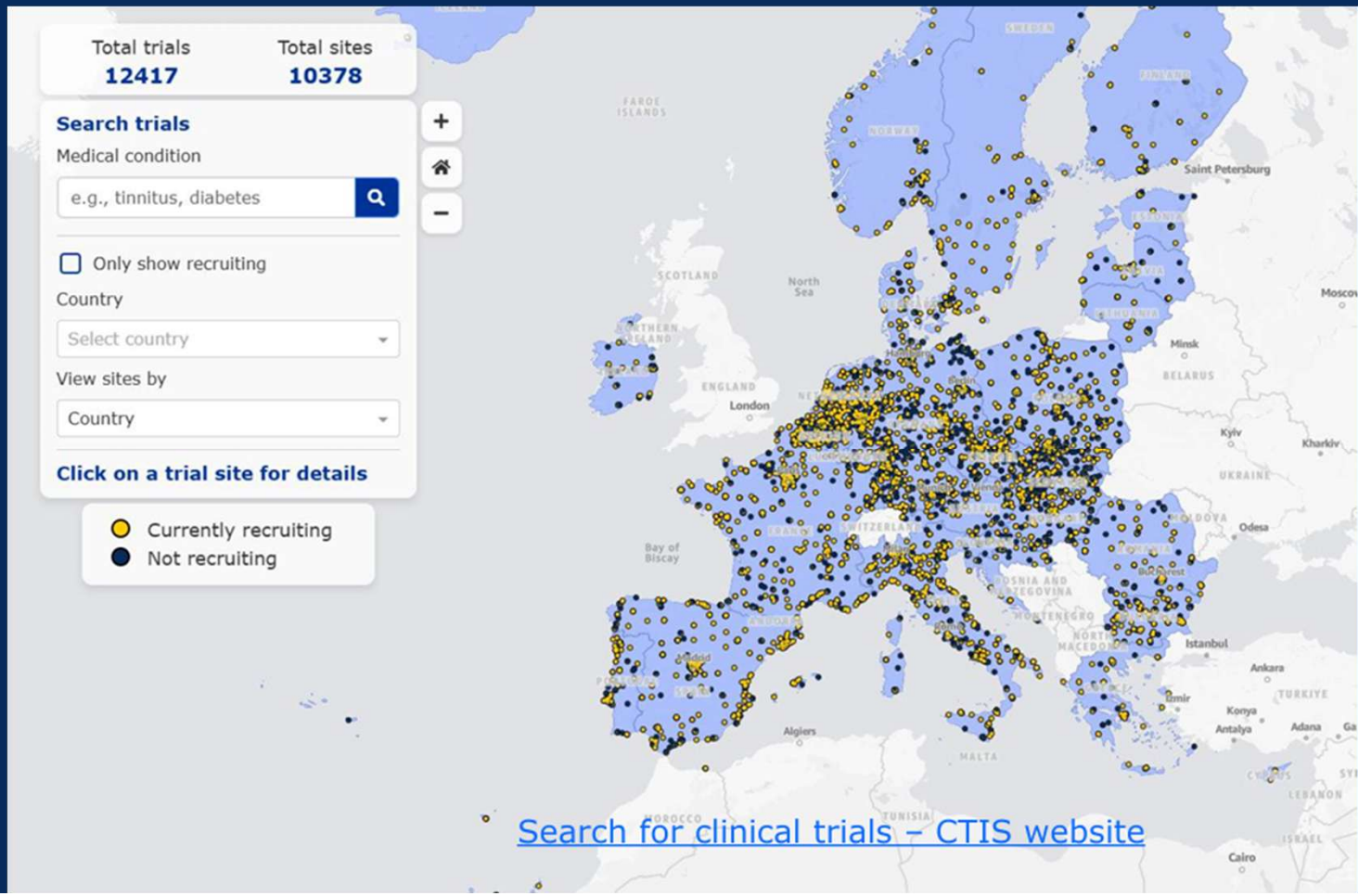
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Finding clinical trials on the Trial Map

- **Trial Map** developed to empower patients and healthcare professionals
- Integrated with CTIS public portal
- Easy access to information on more than 10,000 clinical trials by geographical region and disease area
- Search now available in all official EU/EEA languages

Possible to provide feedback the map

Search for clinical trials – CTIS website



Submission of summary of results

The European Medicines Regulatory Network (EMRN) is taking several actions to increase compliance with clinical trial results reporting requirements for scientific summary of results and layperson summaries:

- CTIS sends automated alerts when results are due for submission in the system. In addition, recent notifications sent directly to the users' e-mail address have been enabled
- A targeted mailing campaign to non-compliant sponsors started in September 2026 to remind non-compliant sponsors of their legal obligations to submit results
- A video is planned to be launched (November 2026) to raise awareness of the importance of submitting high-quality data to CTIS - including clinical trial results - and why this is important for patients
- Member States are also considering taking additional national measures

European Commission | EMA HMA Heads of Medicines Agencies

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Giving a voice to stakeholders: the Multi-stakeholder platform (MSP)

Current composition of the MSP Advisory Group

- 1 Regulator Co-chair & 1 Stakeholder Co-chair
- 20 permanent stakeholder representatives appointed via public call for expression of interest:
- from patients'/consumers' organisations
- from healthcare professionals' organisations
- from academia
- from industry EU trade organisations
- from funders
- Ethics Committee representatives
- Ad hoc participation of other experts

MSP AG - Renewed composition

- Call for expression of interest for new group composition open until 30 October 2026
- Nominations to be submitted by completing the form : EUSurvey- Survey
- Composition of the MSP AG to be enriched and include principal investigators from learned societies, investors, start-ups and funders
- The ACT EU Steering Group will endorse the revised composition of the AG
- The new group will meet in Q1 2027 with a revised mandate

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Thank you for your attention!



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