



Approach to consulting academic stakeholders

MSP AG meeting, 27 September 2024

Presented by Ana Zanoletty (EMA)

One of the key principles for ACT EU is to leverage external initiatives including networks, funding mechanisms, communications, etc.

To date, ACT EU has been supported exclusively through matrix working of experts of its founding organisations with some programme management and meeting support from EMA.

To fully realise the potential benefits of ACT EU, external funding will be required for some of the actions.

- Priority areas for possible EU level funding to support the transformation of the European clinical trials environment described in a [paper](#) published in Q3 2023
 - **Supporting academic sponsors conduct of multinational clinical trials**
 - Delivering a clinical trials data analytics research agenda
- Proposal builds on feedback from stakeholders, recommendations from STARS project, mapping for multinational investigator initiated clinical studies conducted by the Research Partnership with EU Member States – ERA4Health.



Development of a Member State Network of national helpdesks

Capability and capacity building project based on twinning to incentivise the expansion of existing support structures within NCAs, leading to the creation of a network of national helpdesks

“Train the trainer” regulatory science training programmes for academia

NCAs support national academia offering training to local organisations which can in turn provide support to local academic researchers

Encouraging clinical research network development and collaboration

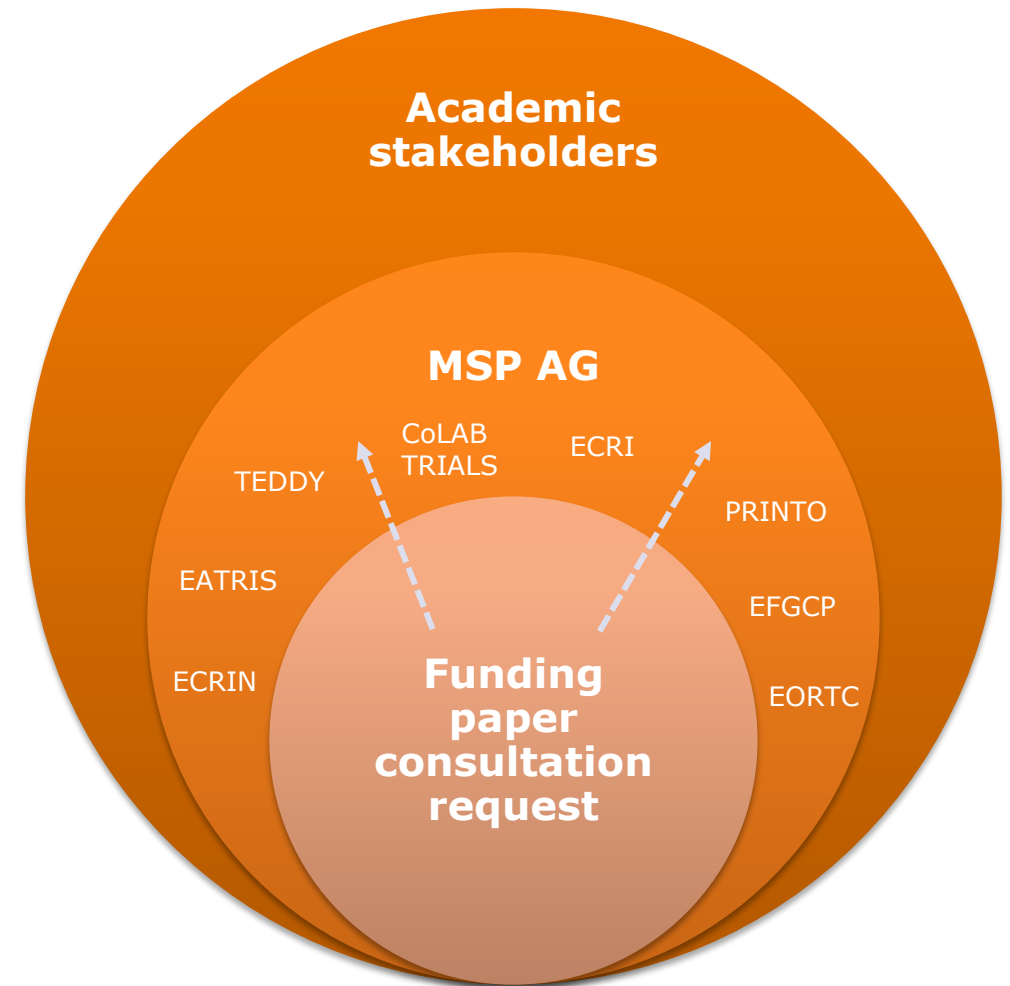
Sustainable, integrated European networks clustered by therapeutic areas or major public health topics for an ever-warm clinical research workforce

Development of a standard site agreement and other templates

Creation of a suite of templates with standard clauses to address diverse contracting requirements such as agreements with commercial sponsors, material transfer agreements, data ownership agreements etc.

Proposal for consultation

- Request from ACT EU SG to consult stakeholders on potential gaps
 - MSP AG vs Academic stakeholders more broadly
- Proposal to consult all MSP AG academic organisations:
 - Leverage group expertise
 - Streamlined process
 - Quick turnaround of feedback
 - Rapid endorsement by ACT EU SG
- Does the MSP AG agree?



Next steps

- Introduce proposal to the MSP AG – July 2024
- Discussion on best approach to consult academic stakeholders – September 2024;
- Consultation with academic stakeholders to identify potential gaps in the recommendations Q4 2024
 - Survey via Slido; 3-week consultation
- Provide paper to ACT EU Steering Group for endorsement Q4 2024;
- Provide final recommendations to the Commission services for further consideration for 2026 funding work programmes – Q1 2025.