The MSP Advisory Group and stakeholders' feedback

Industry EU trades perspective

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The ACT EU MSP AG: positive steps and opportunities

The MSP AG promotes communication and convergence across stakeholders

- Provides open and transparent communication and collaboration between its key players
- Identifies stakeholder priorities and areas for action
- Key positive steps in ACT EU: SA pilots, transparency rule revision, MedEthicsEU and CTR Collaborate

Opportunities looking forward:

Achieve CTR full potential	Leverage full potential of MSP AG	Start planning the future now	Think beyond CTR
Many challenges do not need legislative change Find common solutions to identified priorities and challenges, assign timelines and clear accountabilities across stakeholders	Create focused and recurrent discussion groups (e.g. MSP AG focus groups) to address key 2-3 individual priorities and test solutions in pilots Leverage MSP for masterplan development	Design the future of the EU clinical trial ecosystem: Agree across MSP what system we want, what fundamental changes are needed and conduct thorough impact assessment	Identify opportunities (e.g. integration into clinical practice, citizen awareness, high quality EHRs) Integrate missing pieces into workplan to achieve ACT EU vision Mobilize needed political commitment

Key challenges have been identified and initiatives have started, urgency is key to put solutions in place

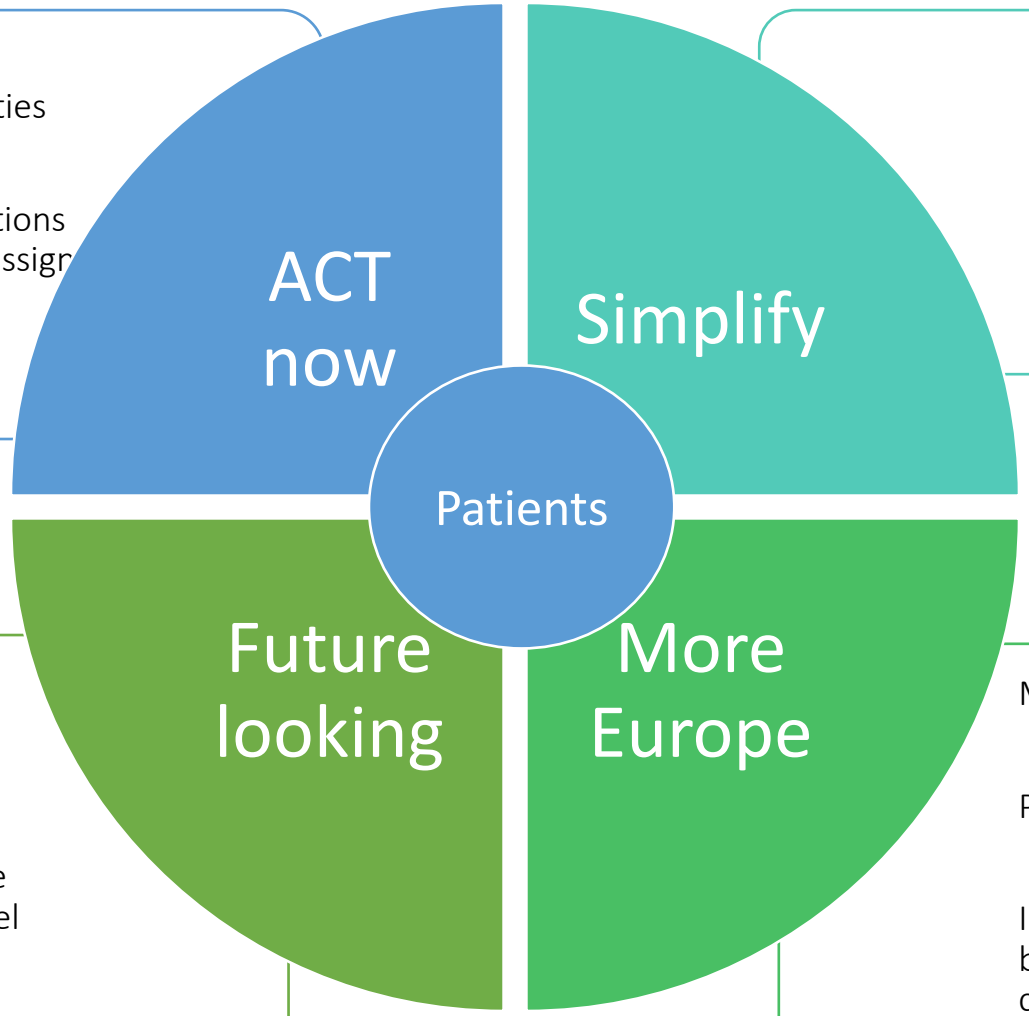
Coordination and Harmonisation among NCAs and EC	COLLABORATE and MedEthicsEU
Resolve current blocking challenges: e.g. modifications	ACT EU MSP, PA2 and Collaborate
Simplified IT system that enables flexibility and communication	CTIS simplification
Resolving the interface between different regulations	COMBINE
Faster and Simplified Approval Process (incl risk-based approach)	Review of CTR
Improved Environment (including sites and information)	ACT EU 11 Priority actions + opportunities

Urgent action is still needed to put in place concrete solutions

Our common goal: a thriving European Clinical Trial Ecosystem that is attractive and competitive and places patients at the center

Make CTR work now by urgently implementing solutions to the key priorities (non-legislative changes)

Focus on the urgent ones, identify the actions needed by each stakeholder group and assign timelines and resources



Move from mapping the current complexity to focus on opportunities for:

- ✓ Simplification,
- ✓ Clear accountability and
- ✓ Increasing trust and convergence

What system is right for Europe and will bring it back to the forefront globally?

How can we be more efficient?

Opportunity to become the region where using fit for purpose novel methods, novel technologies and collecting novel data sources is easy and encouraged

More resources in the ecosystem needed to achieve the aim of CTR and ACT EU

Political commitment to turn Letta and Draghi recommendations into action

Identify and drive key ecosystem aspects beyond CTR: e.g. better integration into clinical practice