ACT EU - Feedback from kick-off meeting of Multi-Stakeholder Platform

PCWP/HCPWP joint meeting, 28 June 2023

Presented by Peter Arlett, Data Analytics and Methods Task Force

ACT EU 2023 focus

- Reinforced focus on successful **implementation of the Clinical Trials Regulation**, including use of Clinical Trials Information System (CTIS): change management including stakeholder engagement, surveys, training, communication.
- Launch a scheme to **support academic sponsors** conducting large multi-national clinical trials.
- **Creation of the Multi-stakeholder platform**
  - A sustainable platform that enables all stakeholders to collaborate for better clinical trials
  - Kick-off meeting: **22-23 June 2023**
- **Revised workplan** informed by learnings and Network needs and priorities (CTR)
  - Incorporate actions to enable CTs in public health emergencies

Successful MSP kick-off workshop 22-23 June

Recording to be made available here

Objectives:

- **understand different stakeholder perspectives** on how to transform the EU environment for clinical trials
- present and discuss feedback form the **MSP public consultation**
- initiate discussion on the **priority areas** identified in the consultation
- present and discuss a proposed **model** for the establishment of a multi-stakeholder platform for ACT EU

Patients and HCP representatives in each of the 7 panel discussions

Panellists

Panel	Patients/consumers	Healthcare Professionals
Setting the scene	Julian Isla (European Dravet Syndrome Federation)	Sara Badreh (European Hematology Association)
Implementation of CTR	Julian Isla (European Dravet Syndrome Federation)	Rosa Giuliani (HCPWP co-chair)
Role of Ethics *1 PC, 3 MREC, 1 academia, 1 industry panel representative*	Fiona Greenhalgh (European Aids Treatment Group)	
Transparency of CTs	Rosa Castro (European Public Health Alliance	Rosa Giuliani (HCPWP co-chair)
Supporting non-commercial CTs	Mencia de Lemus (SMA Europe)	Denis Lacombe (EORTC)
Scientific Advice	Elizabeth Vroom (World Duchenne Organization)	Denis Lacombe (EORTC)
Multi-stakeholder platform	Michal Rataj (European Patients Federation)	Rosa Giuliani (HCPWP co-chair)

Feedback on session 1: Setting the Scene

Speaker presentations:

- ACT EU initiative;
- Outcome of the public consultation

Panel discussion, followed by Slido engagement for a wordcloud.

- Key outcomes include the need for **data, transparency**, **reduction of bureaucracy**, reduction of **excessive** reporting (e.g. of non serious adverse events), reduction of **complex**, technical jargon in consent forms, more **training** to increase understanding of CTR, **simplification** of guidelines, **collaboration** and **harmonization**, IVDRs, integration with clinical practice, participation effort to be proportional to the trial, **fit for purpose** infrastructure.

Session 2: Priority areas – CTR Implementation

Key outcomes:

- CTR = positive development.
- **Transition** of ongoing clinical trials is critical issue.
- Flexible interpretation of **low-intervention clinical trials** is needed.
- Interplay between **IVDR/MDR/CTR** needs addressing.
- In addition:
  - **PROMs are crucial,** the source is the patient
  - Returning CT **data to patients** and helping them manage registries
  - **Reducing administrative burden**
  - helping **smaller healthcare centers** join in CTs; **decentralisation** of CTs
  - **Simplification** of documentation
  - **Platform for knowledge sharing** needed

Session 2: The role of ethics in clinical trials

Key outcomes:

- Need for **EU platform for ethics** agreed unanimously by stakeholders.
- Scientific Advice may need more MREC participation.
- MRECs should ensure there has been meaningful engagement and inclusion of patient/community in protocol development.
- **Training** and **(regulatory) harmonization** is needed.
- Need for common understanding of ethical review standards.
- Need for MRECs flexibility proportional to risk e.g. for repurposing.

Session 2: Transparency of clinical trials

Key outcomes:

- **Purposeful transparency** better than complete transparency.
- Transparency to be a tool which serves better outcomes.
- Timely transparency is critical (opinions against deferrals).
- **Patient trust needed for patient enrolment** – underpinned by transparency.
- Transparency with publication of negative trials needed.
- Balance between transparency and commercial confidentiality.

Session 3: Supporting non-commercial CTs

Key outcomes:

- Need for **signposting** / regulatory **helpdesk.**
- **Multi-national infrastructures need** to be developed.
- **Fractured funding** needs addressing.
- **Timing** of funding not in line with CT timelines.
- Methodological **guidance**, to address **operational barriers** and to incorporate **CTs in clinical work.**
- **Availability of trial data** to guide research.
- **Harmonization** between countries and regulations needed.
- Need to build on existing information/**data sharing.**
- **Site agreements.**

Session 3: coordination between SA and CT approval

Key outcomes:

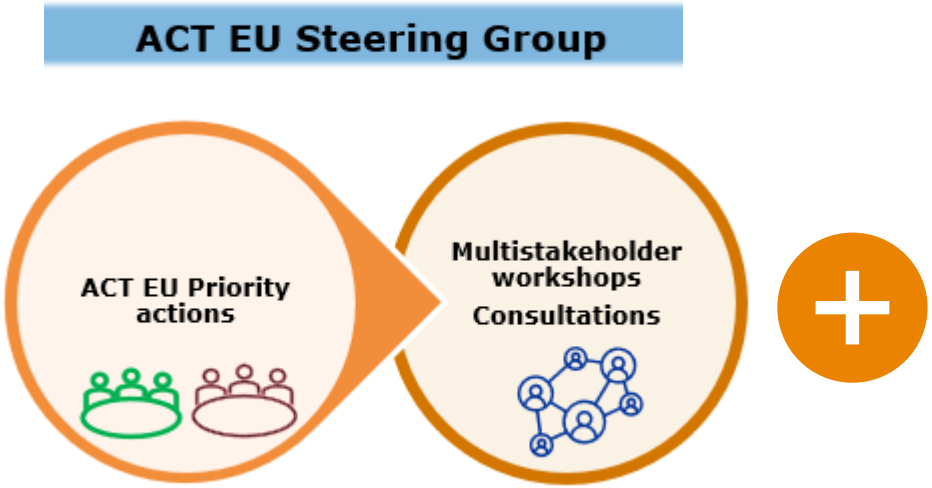
- **PROMs** are important: patient-relevant data to be **validated by patients.**
- Path needed to bring in data collected by patient organisations.
- **Patient involvement at all stages.**
- **Harmonization** of procedures.
- **Joint advice** needed, including HTA in SNSA, and ethics in SNSA.
- **Training** needed on how to reach regulators and understand processes.
- SA 'navigator' needed (**signposting**).

Session 4: Building a multi-stakeholder platform for Europe

Key outcomes:

- **Broad stakeholder involvement** – consider funders.
- Broad agreement to form an **advisory group** and build on ACT EU structure.
- **Shared leadership** among stakeholders with an equal voice.
- Should be **patient-centric ->** research with patients vs on patients.
- **Transparent** and clear, with ability to **engage** on diverse topics.
- Clear **KPIs** to monitor goals of the MSP.
- Call to consider role of ad hoc groups and pilots.
- Platform for **sharing and collaboration.**

Integrate MSP (elements) with existing programme structure



- **Advisory group** linking to **stakeholder communities** AND **priority actions.**
- Advisory group **annual event.**
- **Business processes** underpinning activity.
- **Events** & topic specific workshops.

ACT EU connected with stakeholder community

Advisory group

- Will contribute strategically to the ACT EU programme.
- Will include representation from all identified stakeholder groups & ACT EU enabling bidirectional exchange.
- Will identify stakeholder priorities.
- Will facilitate creation of topic specific workshops (technical discussions) and review groups for PAs (if needed).
- Will advise on stakeholder engagement and communication.

Key conclusions

- Listening to the stakeholders, high interest in: Harmonisation, simplification, patient-centricity.
- the need to focus on developing impactful CTs that are context-appropriate.
- Purposeful transparency.
- Going faster and further, together.
- Agreement on the need for a European platform for ethics committees.
- Agreement on the need for an MSP starting from a strategic advisory group working with ACT EU and multistakeholder workshops on specific topics.

Next steps

- MSP kick-off workshop highlights to be published and recording made available.
- Review stakeholder feedback and discuss priorities with ACT EU governance.
- Platform: drafting selection criteria and mandate for Advisory Group.
- Consultation on the transparency of CTIS is **open until 28 June midnight** (link)
- Upcoming ACT EU events
  - PA4 Multi-stakeholder Workshop on ICH E6 R3 - Public Consultation 13-14 July
  - PA5 Data analytics workshop (3 Oct tbc)
  - PA8 Methodologies workshop in Q4 (November)

Any questions?

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