CTR COLLABORATE initiative

ACT EU SG meeting
20 September 2024

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‘CTR collaborate’ Initiative and Initiation

- Increasing work burden for regulators (NCA and Ethics) and sponsors
- Ambition to keep EU/EEA an attractive place to perform CTs
- Perceived need for a coordinated change management process to facilitate EU/EEA collaboration between MSs (NCAs and Ethics)

- CTCG organised workshops for Ethics Committees and NCAs to understand the needs and visions (March and April 2023)
- Broad participation 40 participants (14 MS Ethics – 14 MS NCAs)
- Break out sessions to gather input organised in OBS

Scope of ‘CTR collaborate’

- In order to meet the vision to:
  - Promote **health through novel therapeutic strategies** with medicinal products
  - Have more CTs in the EU to **facilitate research** and provide new treatment options for patients while ensuring the rights, safety and well-being of trial participants and the generation of robust and reliable data.
  - **Make EU more attractive to conduct and participate in clinical trials**

- The project will have the following objectives:
  - Ensure **safe and high-quality clinical trials** with high-quality CT application/dossier
  - Ensuring **appropriate assessment within the legal timelines by harmonisation of procedures within and across MSs** while upholding ethical and regulatory standards
  - **Facilitate NCA and Ethic alignment** within and across MSs by **building trust and common understanding** of CTR and Q&A within the system and ensuring an effective collaboration within and across MSs.
  - **Suitable IT systems** to support and facilitate the submission, assessment and registration of CT applications and notifications during the life-cycle of a clinical trial.

Collaboration between NCAs and Ethic Committees: 4 focus areas

1 Support sponsors/CROs

Collect **feedback** from external stakeholders

Provide sponsor, CRO and investigator **training**

Keep external **guidance** updated and create new guidance (BPs, Q&As, templates)

Mapping of differences between MSCs (Part I, part II)

(pre-CTA) Advice on clinical trial application dossier involving ECs

2 Effective procedures

Alignment of assessment of **part I and part II**

Joined update of **best practices** part I/general

Optimisation of work procedures

Support **communication NCA/EC/sponsor**

Suggest **procedural improvement**

Harmonised templates

Mapping of landscape of part I assessment **NCA/Ethics**

Roundtables/WSs to support harmonisation and BPs

3 Training and information sharing

(Common EMRN) **Platform for** internal **document sharing** NCA/Ethics (/GCP/other groups..)

Communication tool/ platform

Regulator **training** program for both ethics and NCA on principles and BPs – onsite. Also to harmonise on BPs, Q&As.

4 European Forum for Ethics Committees

Support **creation of a European Forum for EC** alignment under CTR/IVDR/MDR

Promote more resources for permanent secretariats of ECs

To be defined..

Brainstorm – deliverables to be refined and decided by project board and project group

ACT EU anchoring and decision for Project Management

- ‘CTCG project’ with lean governance structure – anchored to ACT EU (PA01)
- PA1/PA2/PA10/PA11 - matrix activity to ensure coordination with other activities
- Ensure broad awareness and coordination with other activities e.g. PA11 that targets some same deliverables but for public health emergency only. Ensure problems are addressed in general.
- Problems in scope identified by COM surveys can be addressed within the project to help solve them.
- Contribute to successful implementation of the CTR.

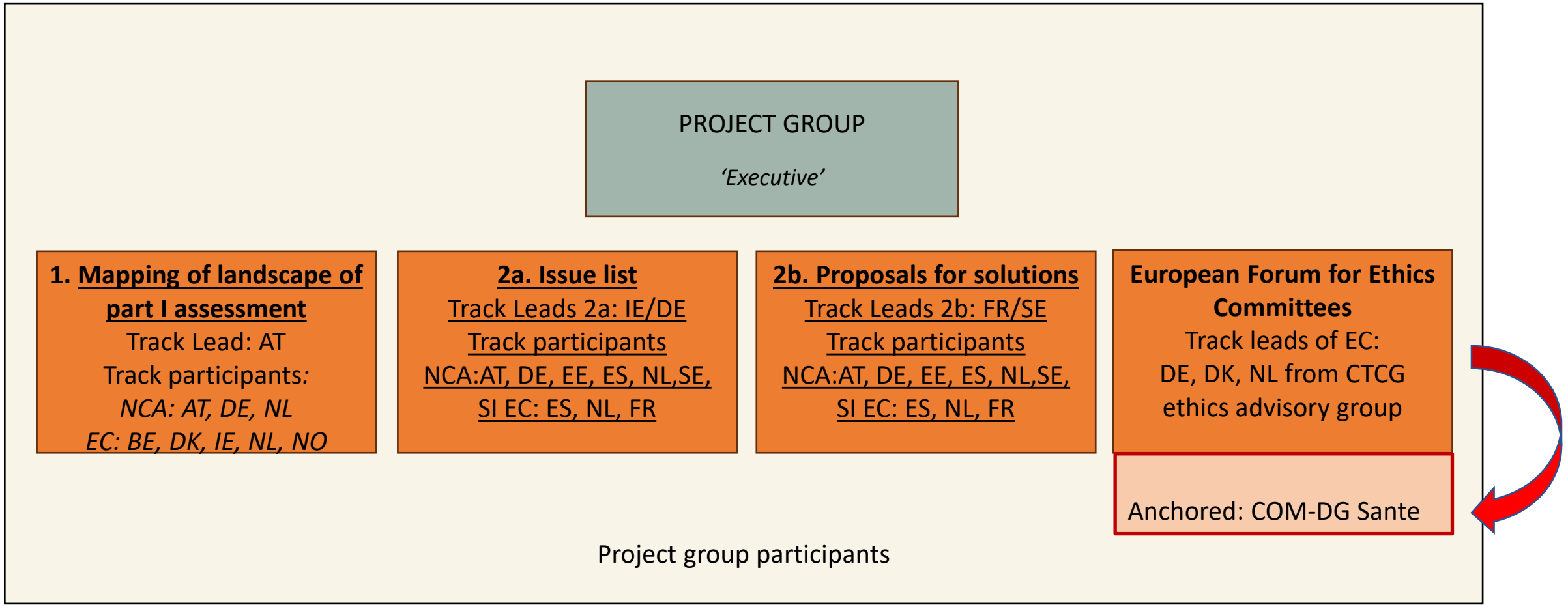
- Project management resources – provided by EMA

CTR COLLABORATE project - deliverables

1. Mapping of landscape of part I assessment NCA/Ethics (survey)
2. Issues requiring optimisation of work procedures: Issue list and proposal for solutions
    a) Issue list (requirements and templates, Part I and II alignment, RFI optimisation, strengthening the role of the RMS, risk adaption)
    b) Proposal for solutions for the issues listed
3. Joint (NCA and Ethics) update of best practices
4. Implementation of best practices via CTCG roundtables/workshops to support harmonisation and collaboration.
5. Communication NCA/Ethics/Sponsor

Working in smaller parallel track teams

- Track teams develop lists/survey/documents
- Track leads facilitate/draft
- Project group reviews and gives input



Stakeholder event 11 September 2024

- MSs (Ethics and NCAs) have given broad input via workshops and next steps
- Sponsor input has been taken from different sources (e.g. CTIS fora), might not be exhaustive
- The scope of the workshop is to understand if the issues identified so far are reflecting the sponsor perspective sufficiently and the MSs input correctly
  - Complete list of issues?
  - Proposed solutions adequate?
- Pre-meeting package sent in advance of the event to understand the activities so far
- Via 4 breakout sessions and slido (open until 2 weeks after the event)
  - Collect additional relevant topics not yet identified
  - Validate the proposed solutions

CTR Collaborate next steps

- Input has been collected from Assessors, Ethics Committee members and sponsors with the ambition to reach out to the people who are doing the daily work
- Issues collected via workshops and stakeholder event beyond the scope of the Collaborate initiative will have to be channelled to ACT EU/CTAG/CTCG/MedEthicsEU/… following discussion on responsibilities
- Collaborate core activities: Change management
  - Collaboration within and across member states
  - Joint development of best practices
  - Implementation of best practices (e.g. best practice on considerations,…)
  - Strengthening the role of the reporting member state
  - Discussing cases at assessors round table for mutual learning to achieve the objectives of CTR collaborate

Thank you for your attention!