CTR Collaborate and CTCG action on patient involvement

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Presented by Marianne Lunzer on 22-10-2024
ACT EU MSP Annual Meeting

‘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 ECs

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

Anchoring to ACT EU

‘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.

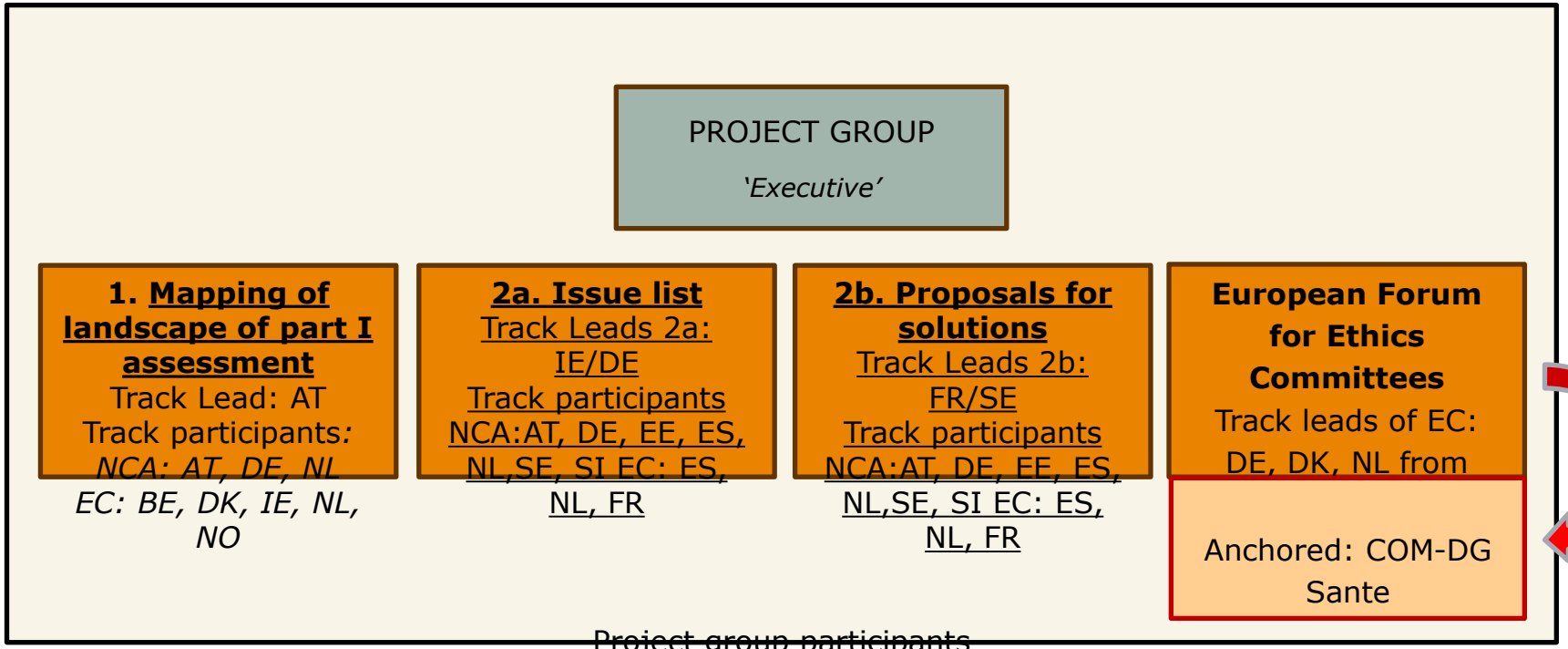
Project management resources – provided by EMA

CTR COLLABORATE - 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

270 stakeholders followed the meeting

Issues raised in the break out sessions have been collected and grouped

Additional input has been received via slido (65 unique topics with 244 votes)

The video recording and materials are available on the event page:

Clinical Trials Regulation (CTR) Collaborate Stakeholder meeting, supported by ACT EU | European Medicines Agency (EMA) (europa.eu)

The meeting outputs will be analysed together with feedback from other ACT EU activities to agree on follow-up actions.

Stakeholder event 11 September 2024

Sponsor input on the topics to be discussed were received before the meeting

Via 4 breakout sessions

- Harmonisation in the EU Clinical Trials Framework
- New strategies for streamlining clinical trial review and approval processes
- Fostering innovation in clinical trials
- Enhancing CTIS functionality and operational efficiency

CTR Collaborate next steps

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

Patient involvement in clinical trial design

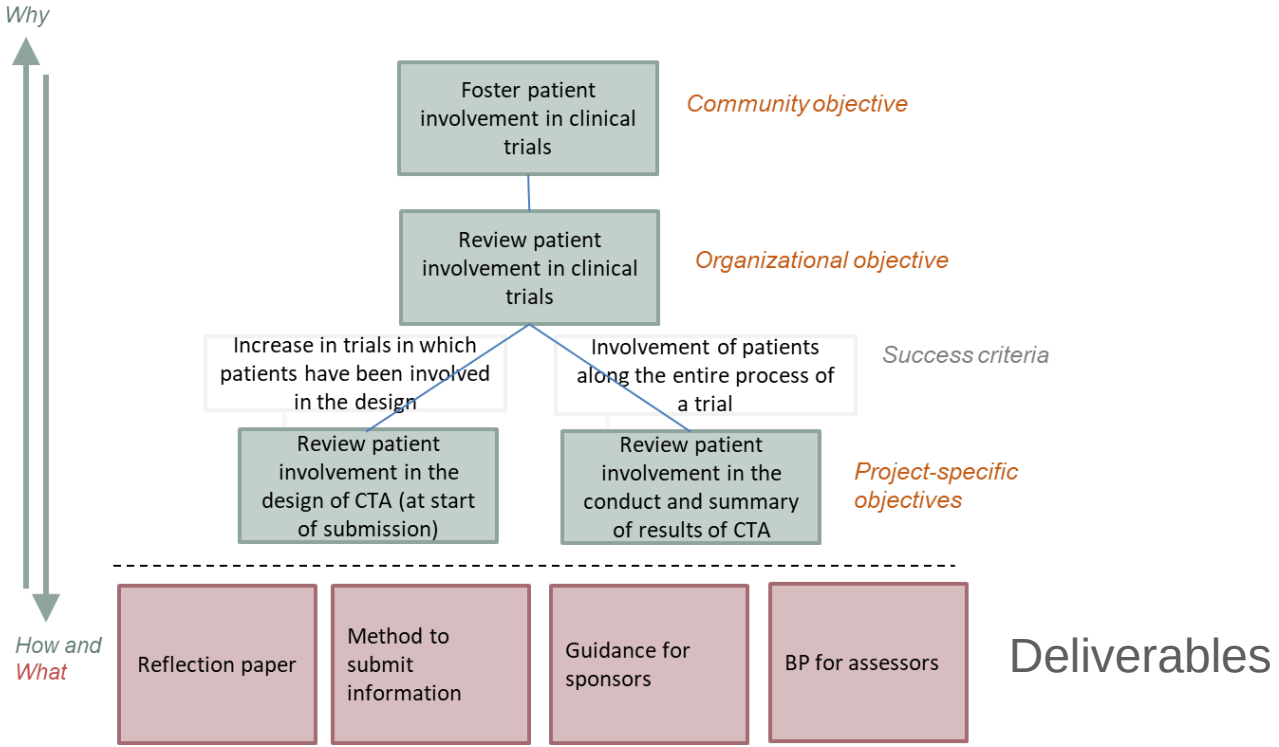
CTR:

- CTR Annex I D 17(e):
  The protocol shall at least include: ... (e) where patients were involved in the design of the clinical trial, a description of their involvement.
- Annex I D 24:
  The protocol shall be accompanied by a synopsis of the protocol. *Q&A: "Sponsors should consider to make the synopsis understandable to a layperson".*
- CTR art. 37.4:
  ... the sponsor shall submit to the EU database a summary of the results of the clinical trial ... accompanied by a **summary written in a manner that is understandable to laypersons**.

WHO BP for conduct of CT

"Key message: Potential participants and/or members of the relevant community provide valuable contributions to the design, execution and interpretation of the results of clinical trials."

Scope of CTCG Project



Project governance structure

PROJECT BOARD

Marianne Lunzer/Monique Al
CTCG mentor

PROJECT MANAGER

Sevgi Fruytier/Evelyn van der Aa

PROJECT GROUP

CTCG members
MREC member/Patient representative

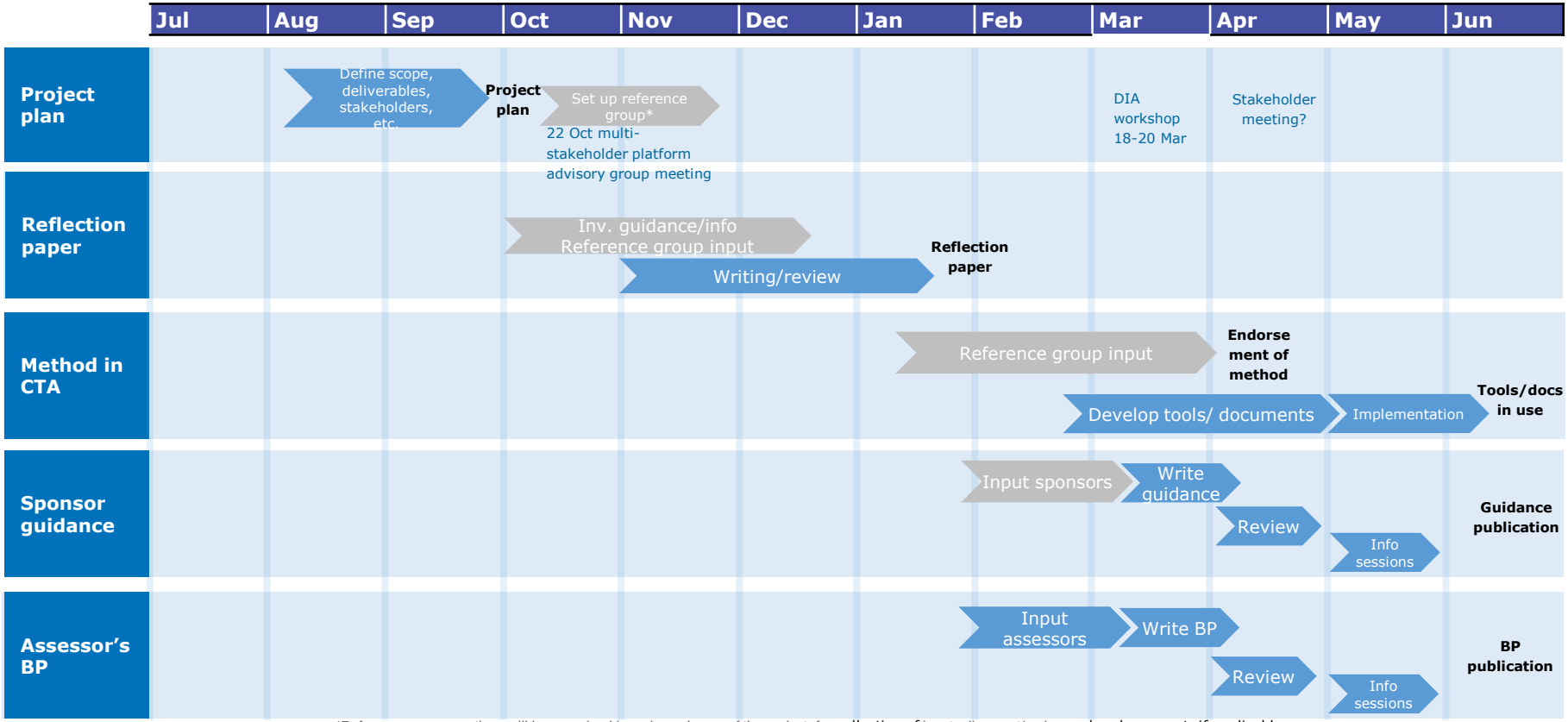
REFERENCE GROUP(S)

Patient(organizations)
Commercial sponsors
Non-commercial sponsors
CROs
Ethics committees
NCAs

Call for reference group members

If you are interested to participate in the reference group or have questions about the project, please contact
Evelyn van der Aa (e.vd.aa@ccmo.nl, ctr@ccmo.nl) and/or Sevgi Fruytier (se.fruytier@ccmo.nl)

Timelines



*Reference group meetings will be organized in various phases of the project, for collection of input, alignment/review and endorsement, if applicable.

Any questions?

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