General Introduction :

The CTCG is an active partner in the ACT EU initiative and collaborates together with other groups within the European Medicines Regulatory Network (EMRN) , as well as with other groups at the European Commission for the realisation of its workplan .

The CTCG workplan shall be revisited regularly taking into account the ACT EU initiative timelines for the overarching framework and adapting to reality when needed .

1. **Harmonisation and coordination to support the full implementation of the CTR**

Key Objective:

- **To harmonise and coordinate issues relating to the full implementation of CTR**

Deliverables:

- Traffic light report for Member States periodically updated and discussed at CTCG plenaries including the following topics
  i) cooperation within Member States (National Competent Authorities and Ethics Committees),
  ii) experience in Member States on ability of academic sponsors to adapt to the regulation and CTIS,
  iii) technical experience using CTIS,
  iv) regulatory experience applying CTR,
  v) scientific and ethical assessment of applications [periodically updated before CTCG plenaries]
  Starting Q2 2022
- Identification of blocking issues by CTCG, representing the CT assessors community experience on assessments, second could be feedback from sponsors, CTEG and CTAG and propose a solution where possible **Starting Q2 2022**
- Workshop on blocking issues for Clinical Trials in general and multinational trials in particular (structuring hurdles as technical hurdles, regulatory hurdles and areas with scientific divergences) with CTCG, CTEG and CTAG participation with the aim to propose a list of hurdles and proposed solutions to be repeated twice yearly (every 6 months, year 1 and year 2) **Starting Q4 2022**
- Action plan on eliminating hurdles and facilitating clinical trials (ii. above, project managed by a CTCG Best Practice subgroup with the long-term goal to streamline and simplify processes in support of faster and robustly coordinated assessment of trial applications, including risk-based approaches **Starting Q2 2023**
- Report on experience applying expedited assessment timelines in crisis situations [project managed by the EU4Health Joint action CT-CURE updating CTCG and CTEG regularly with final report **First report Q4 2022 ; final report Q 3 2023**

2. **EU/EEA Observatory for clinical trials: (I) Processes and Results**

Key Objective:

- **The development of quantitative and qualitative KPI to monitor CTR performances and monitor the attractiveness for EU/EEA region for clinical trials (cfr Regulation 536/2014 : Art 97)**

- **Initial submission and life cycle CT authorization process**

- **Safety surveillance throughout the CT life cycle**

Deliverables:

- Input to Commission / Act EU based on update of the KPIs proposed by CTFG April 2021; define the baseline (performances before the start of CTR (the last 3-5 years) , foresee the necessary BI tools via CTIS/Others for public and non-public reports: **May 2022**

- Identify KPI for CTCG internal use (Harmonisation and coordination to support the full implementation of the CTR) to be supported by EMA BI reports starting **Q2 2022**

- Yearly periodic reports on the performance of the network analyzing KPIs, identify hurdles and potential measures to be taken, discuss on mitigations in coordination with CTAG to avoid duplication of information : **starting from Q4 2022 (more frequencies)**

- Analyse experiences and making an action plan to promote large multinational trials in academia (link with EU Commission RTD) **2023**

3. EU/EEA Observatory for Clinical Trials: (II) Risk Mitigation and Evolution of Clinical Trials as well as Horizon Scanning

Key Objective:

- **To develop a risk mitigation strategy, for First in Human/early phase trials and relevant critical innovative evolutions in clinical research**

Deliverables:

- Identify / collection of tools how to collect data: **first proposal Q3 2022**

- Reports to CTCG of detected and collected innovations in clinical trials research and development (methodologies, strategies, tools), pro-actively estimating the impact on risks in authorisation/surveillance/conduct of clinical trials

- By feedback of designated observers in most relevant EMRN groups (SAWP – ITF / EU-IN / WP CT Methodology): **starting from S2 2022**

- By feedback of CTCG assessors to identify (*) and discuss specific CT / ScAdv with innovative elements in clinical research via dedicated meetings (dedicated meetings – set up working group and initiate recommendations/guidance): **starting from S2 2022**

- Reports to CTCG analysing retrospectively the safety relevant notifications and amendments of the identified (*) ongoing trial(s), re–evaluating the initial assessment estimating (could this have been prevented) and propose improvements in assessment/recommendations to sponsor's clinical development plans: **starting from S1 2023**

- Initiate recommendations/guidance (set up working group/s) for identified topics **starting gradually from S1 2023**

4. Safety Surveillance

Key Objective

- **To implement Pharmacovigilance in clinical trials based on Implementing Regulation and CTCG's Safety best Practices**

Deliverables:

- Robust oversight and supervision on safety of participants in CTs through efficient workshare via safety assessment Member State (saMS) per investigated active substance **starting Q2 2022**
- Conducting JA on cooperation in safety assessment, , implementing cooperation in safety assessment **starting Q2 2022**
- Evaluation of communication and cooperation with the available IT tools during the first year to inform the need for improved guidance **starting Q2 2022**
- Improvement and update the Best Practice for Pharmacovigilance in CT with experience gained on procedure and assessment : for urgencies starting Q4 2022 and revision **starting in Q2 2023**
- Establishment/maintenance of fast CTCG network for emerging safety issues potentially impacting clinical trials **starting Q2 2022**
- Maintenance/reinforcement of CTCG participation in the EMRN network, e.g. IRN **ongoing**
- Define bidirectional interaction of CTCG with PRAC and CHMP **starting Q2 2022**
- Active participation in EVWG, reporting in both directions **ongoing**

5. Shared Scientific Assessment experience of clinical trial applications

Key Objective

- **To share experience in scientific advice and assessment with the aim of promoting the attractiveness of the EU system by optimising and streamlining the modalities for seeking scientific advice related to clinical trials and clarifying this towards the stakeholders concerned.**

Deliverables:

- Recommendations to sponsors how to seek SA for trial specific issues and general issues related to CT **Q3 2022**
- Procedure on how to provide CTCG SA/consolidated opinion, where applicable **Q4 2022**
- Working together with EMRN on development of the concept for providing optimized and streamlined scientific advice related to clinical trials; ultimately delivering a filtering method for best use of different SA modalities – leading to scientific harmonization **starting from 2023**
- Support collaboration for integrated scientific advice covering the entire innovative lifecycle of pharmaceutical products (early development to post MA life cycle) **starting from 2023**

6. Training

Key Objective:

- **To provide adequate "hands on" and training for NCA colleagues, including the ethics committees**

Deliverables:

- Organisation of regular sessions exchanging experiences on CT applications (authorisation/ safety and surveillance / conduct) for the NCA's and ethics committees: **Starting from Q2 2022**
- A EU NTC curriculum for regulation, assessment and supervision of clinical trials, IR Safety (link with JA CT Cure and JA 12 Safe CT), including ethics and keep training material updated : **Starting from Q4 2022(*)**
- Training for safety cooperation and round tables for regulatory and scientific discussions (EU4Health Joint Action 12 SAFE CT)for a network of safety assessors in pharmacovigilance in CT **starting Q2 2022**
- Support interaction with academics/universities and SMEs, together with EMA (identify needs and offers), aiming for a fruitful bi-directional exchange **S2 2023 (*)**
- Establish the cooperation with EMA in connection with EMA's action plan on Regulatory Science and Research needs and provide input on relevant topics **S2 2023 (*)**

(*) to be fine tuned with ACT EU

7. Participation in Development of Information Systems

Key Objective:

- **To actively participate in maintenance and delivery of CTIS, supporting IT systems and governance meetings**

Deliverables:

- Active participation in IT maintenance/delivery and governance meetings to support in the development of an adequate IT infrastructure including prioritisation of CTIS backlog for IT development (CTIS) **ongoing**
- Reports from CTIS maintenance/delivery and governance meetings to CTCG **ongoing and at least quarterly**
- Check of EMA updates on CTIS implementation and training on EMA webpages **starting Q3 2022, quarterly**
- Request presentation of actual delivery of prioritised issues **ongoing**
- Participation/organisation in/of trainings/stakeholder meetings on CTIS **ongoing**
- Evaluate if IT support for safety fulfills its objectives **Q1-2 2023** and influence the yearly evaluation according to IR and co-decide the business functional specifications for the final Safety IT support **2023**
- Active participation in safety IT maintenance and further development **ongoing**

8. Cooperation with other relevant EMRN and EU groups

Key Objective:

- **Establish cooperation mechanisms with the most relevant EMRN and EU groups**

Deliverables:

- Identify relevant groups and ongoing projects (projects, guidance) within other relevant (global and) EMRN groups.
- Set up rules on cooperation (initiation, CTCG observer/contact person, transparency to chair/vice chair and group)
- Common position paper HMA-Commission , clarifying the roles and responsibilities of CTCG / CTEG and CTAG, identifying common work streams/domains and modes of operation **Q2 2022**
- Meeting report from discussions of Chairs CTCG with Chairs of the main relevant EMRN groups, reporting on exchange work plans (if applicable) and proposed modes of operation: gradually starting from **Q2 2022**
- Reports from nominated CTCG representatives in the EMRN at CTCG : gradually starting from **Q2 2022**

➢ (Pre) - Authorisation:

- EU-IN **Q2 2022**
- EU-INNO (includes HTA) **Q2 2022**
- ETF **Q2 2022**
- PDCO **Q3 2022**
- CHMP **Q3 2022**
- SAWP/ ITF **Q2 2022**
- CT Methodology **WP Q3 2022**
- Data analytics **Q3 2022**
- Big Data **Q3 2022 (Registries)**
- HMA Innovation section (MAWP)
- Ethics **Q1 2022 (advisory group)**
- SWP **Q4 2023**

➢ Safety and surveillance

- PRAC S2 2022
- IRN
- EV EWG

➢ Conduct of clinical trials

- GCP-IWG

➢ Overarching SciCoCoBo

♦ CTCG List of adopted designated observers in the main relevant EMRN groups: **Q3 2022**

♦ Proposal for support the multi stakeholder platform with stakeholders, including patients and ethics, to exchange on hurdles and relevant innovative topics: **starting in S2 2022**

♦ Proposal for support in training academic sponsors: **starting with CTIS Q2 2022**; develop a plan for **S1 2023**

♦ Explore how to integrate patient engagement in the design and conduct clinical trials: **S2 2023**

9. Communication

Key Objective:

♦ **Develop a CTCG communication plan**

Deliverables:

♦ Stakeholders meetings with sponsor associations, academics networks, patient organisations and health care providers autonomously and/or in collaboration with the other relevant EMRN bodies Small communication plan adopted **Q3 2022**

♦ Communications reporting achievements to HMA , interested parties , general public increasing the visibility of the network (*) and the CTCG group. Working methods adopted **Q3 2022**

(*) to be fine tuned with ACT EU

10 : Secretariat