CTCG role in pre-CTA advice and consolidated opinion

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ACT EU multi-stakeholder platform workshop

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Clinical Trial Coordination Group
CTCG

CTCG Workplan and Scientific Advice

To coordinate with other EMRN relevant groups and integrated with the overall planning process of the European medicines agencies network strategy to 2025, a one-stop-shop where relevant questions related to clinical trials from academic and industry sponsors may be solved without overlapping

Contributing to consolidate a coordinated approach all along the Network whilst avoiding duplication of effort and contradiction

CTCG

Support collaboration for integrated scientific advice covering the entire innovative lifecycle of pharmaceutical products (from early development to post MA life cycle)

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

CTCG – Workplan and Scientific Advice

To contribute as needed to national, multinational or central scientific advice procedures on specific questions concerning the elaboration of clinical development programmes, both on general matters and on those relating to specific clinical trials

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

CTCG

The CTCG is the group of experts that coordinate those aspects related with the procedural aspects of CT, with a focus on potential national points of attention, while contributing with their expertise to the discussions and positions on all the other general or product related aspects

- Enhance intra-network information exchange
- Procedure on how to provide SA/consolidated opinion
- Recommendations to sponsors how to seek SA for trial specific issues and general issues related to CT

CTCG – Workplan and Scientific Advice

CTCG ingredients for an improved scientific advice coordination between clinical trial approval and clinical trial design

To represent a cross-trial clinical trial expert perspective on general and product-related matters including in case of a public health emergency

To develop and support a network of assessors, where relevant including representatives of ethics committees, and establish processes for structured communication in order to provide a contribution to the Network

In case of horizontal matters with critical ethics components, the CTCG may involve the Clinical Trial Expert Group of the European Commission (CTEG) for a joint approach or the CTCG members communicate with national Ethics Committees on the aspects with a view to harmonise processes

CTCG

CTCG SA related activities

Pre-submission meetings as RMS and discussion at the Round Table of Assessors

Participation in the pilot SNSA and sharing of national SA outcomes

Use of common platforms

Mutual observers in SA related groups

Need for general or specific consolidated opinion

Participation in SA activities organised within the remit of ETF, ensuring prompt reporting back and direct involvement on clinical trials in their MS

Consolidated processes will be developed to efficiently manage scientific advice cases and enhance coordination across relevant stakeolders. Pilot phases before delivering the final product, which will ultimately facilitate the development of safe and effective medicines for the benefit of patients. Q1 2023-Q4 2024 to develop a “consolidated SA process”

Thanks for listening.

Questions?