Break-out session 3

Fostering Innovation in Clinical Trials

Presented by Jane Bryant on 11 Sep 2024
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Introduction

What are the gaps?

What is burdensome for innovative clinical trial design?

Expansion of Fast track CT

Accelerated CT review critical, maintain competitiveness, discuss vision of HMA for facilitating fast track evaluations

Initiative of accelerated CT review in terms of worldwide emergencies, expand scope?

Timeline of contracts etc very important

Example: vaccine development, fast approval process needed. Some NCA have fast track approaches in place for mononational trials. Broader representation or agreement between other MSC to harmonise on approach for fast-track process.

Discussion of vaccine trials valid for next year

Fast Track (2)

IMP that are well known through pivotal studies- only RMS do assessment for efficiency?

Scientific advice already taken and liaised with authorities (type of scientific advice important here) EC involved in SA- not as much as NCA currently

Oncology products: Very important for innovation, high unmet medical need. Criteria for medical need for accelerated approval timings? Eg breakthrough designation in US. Could be in EU? EU timelines longer than other jurisdictions, makes a difference to Sponsors. Other Phases of studies to also be considered for acceleration? Potential for an oncology trial platform with guidance for preparing a CT application, for example what is required and what is already available.

Harmonisation on documentation

eConsent (as part of DCT): Study documents, surveys on what EC should see of in terms of harmonisation. Low consistency between EC across countries and within countries. Recommendation put forward in terms of what should be reported in 9 different study documents (eConsent, harmonisation of terminology, what NCA/EC see for review) Broaden for further information. Impact on timelines for review following guidelines and recommendations?

Academic studies

Harmonisation on EU level for academic studies for requirements on documentation etc, pre-CTA SA very important for this. Can pilot be extended?

Fees for academic studies scientific advice, limited resources but support for innovative trial design in terms of fee reduction across EU

Complex Trials

Platform trials, parallel submission of SM not possible- all trials limited to 4 SM in a trial per year, can this limit be removed? Issue if a complex trial contains more than 4 IMP

Approach for enabling SM submission more easily. Workaround to submit treatment arms as multiple trials using same master protocol. Difficulty in assessment of SM when subsequent updates come very quickly together.

Challenge for non-complex trials also- can change also be enabled here?

Horizon scanning/future endeavours

EU Competitiveness, concerns from Draghi report, some recommendations related to Pharma/trials:

Streamline the set-up and management of multi-country trials in the EU.

Establish rules to address challenges for studies which combine medicines with medical devices and the application of AI. This could follow the recent example of proposals made for reviewed rules on the use of genetically modified organisms (GMOs) in human clinical trials.

Introduce reinforced coordination mechanisms between national ethics committees and a binding EU-level decision-making committee for the authorisation of multinational clinical trials. This would facilitate the starting phase of new clinical studies.

Discussion: need to recover flexibility in the system for all stakeholders, and reinforce harmonisation between EC, with MedEthicsEU an advantage here.

IVDR

Very important for oncology, innovative trials. Interplay between CT/IVDR/MD. Challenging to achieve reasonable timelines for combination studies- measures in place to achieve this? COMBINE project, still in discussion for solutions to these issues.

Proposal to not require the full IVDR for CT applications? What is really needed?

Approval coordinated with CTR applications, rather than in parallel (sequential RFI on both sides, etc) (priority for COMBINE- https://health.ec.europa.eu/medical-devices-topics-interest/combined-studies_en https://health.ec.europa.eu/document/download/77e1409a-f4c0-45db-bff1-4873c7a0e7ae_en?filename=md_combined-analysis-phase-report_0.pdf

BP for combined studies across MSC, shared learning on internal processes.