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[REDACTED]
Cc: [REDACTED] (SANTE); [REDACTED] (SANTE); [REDACTED] (EMA); [REDACTED] (EMA); [REDACTED] (EMA); [REDACTED] fagg-afmps.be;
Subject: Follow-up: Complex clinical trials call -- slides with the scenarios
Attachments: CCT scenarios -- examples.pptx

Dear All,

Many thanks for today's discussion please find attached the scenarios that have been selected for further development (case description+ problem statement).

We ask you to be as specific as possible for the moment in your descriptions/problem statements, on the basis of the received input it should be possible to generalise for higher level recommendations at a later stage.

We will ask suggestions also from experts in CTEG.

I am happy to set up the next call for this group as soon as there is enough material to support the discussion.

Kind regards,

[REDACTED]

From: [REDACTED] (SANTE)
Sent: Tuesday, November 10, 2020 12:47 PM
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Cc: [REDACTED] (SANTE) <[REDACTED]@ec.europa.eu>; [REDACTED] (SANTE) <[REDACTED]@ec.europa.eu>; [REDACTED] (EMA) <[REDACTED]@ema.europa.eu>; [REDACTED] (EMA) <[REDACTED]@ema.europa.eu>; [REDACTED] (EMA) <[REDACTED]@ema.europa.eu>; [REDACTED]@bfarm.de>;

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Subject: Complex clinical trials call -- agenda and

Dear Colleagues,

Following the review and discussion of the stakeholders' paper (as signed by EFPIA, ACRO, EUCOPE and EuropaBio) on Complex clinical trials; EMA, CTFG and SANTE colleagues agreed that in order to be able to set out concrete actions we first need to identify common, critical issues specific to the different complex trial designs.

Therefore, instead of trying to find common solutions for problems related to a highly diverse group covering all sorts of trials with non-conventional designs, we propose to describe common scenarios with prioritised typical/unique problems related to the particularities of the complex trial design.

To start the discussion, we outlined a few scenarios as examples, see them below. This is a non-exhaustive list, the aim is to illustrate the proposed approach. We will ask you to develop additional scenarios or modify the ones below, covering the typical cases and in a way that each scenario illustrates one challenge or related challenges so that they can be understood and solved one by one. Some of these challenges could be addressed in the CTFG consolidated opinion pilot.

Example 1:

Single sponsor randomised CT where e.g. 3 treatment arms involve two different doses of the test product, one arm is a reference product and all these are given during the trial, but a fourth arm is either **a historical data set from other CTs** e.g. placebo, or it is **real world evidence data** on a particular medicine already authorised and used in clinics.

Example 2:

A trial design using **adaptive methodology** in an e.g. an umbrella trial.

Example 3

A trial designed as a **platform trial**

Example 4:

"Subprotocols" are submitted as **separate, but linked CTA** with different CTA/EudraCT numbers in the regulator system

Example 5:

Umbrella trial with a screening platform with **several IMPS and sponsors**, same disease, different subgroups (with different biomarker profile), sharing control arm

Example 5:

Umbrella trial linked to a screening platform **one sponsor, several IMPS**, different subgroups, same disease

Example 6:

Basket trial, several diseases with **different biology** (progression, survival), same biomarker profile, separate, randomized arms, same treatment, **different comparators**

Example 7:

Complex trial with screening platform (one sponsor, one disease, subgroups, multiple treatments) in **multi-country set-up** in the EU/EEA

Example 8:

Complex trial with screening platform (one sponsor, one disease, subgroups, multiple treatments) in **mono-national** set-up in the EU/EEA

Accordingly, the [agenda](#) for this meeting:

- Introduction (all, 5')
 - Typical (regulatory) challenges related to different types of complex trial designs and scenarios (sponsor organisations, 10')
- CTFG and EMA activities in support of CCTs (5-5-')
- Discussion of the proposed example scenarios and approach (25')
- Next steps (10')

Let me know if you would like to raise additional topics on Friday. Thank you for sharing further this message to relevant colleagues in your organisation in case they are not in cc on this message.

On behalf of the CTFG/EMA/SANTE team,

Kind regards,

[Redacted]

[Redacted]



European Commission

Directorate-General for Health and Food Safety
Unit B4- Medical products: quality, safety, innovation
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Sent: Tuesday, November 3, 2020 10:36 AM

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Subject: Joint Industry associations Final paper on CCTs- challenges, case examples and solutions for webinar November 13

Dear [REDACTED]

Please find attached the final paper initiated by EFPIA including the input of other industry associations (ACRO, EUCOPE and EuropaBio) for your consideration and further dissemination with stakeholders in preparation for the webinar on November 13.

The paper includes challenges (see table embedded in the document). The table lists the main challenges industry and academia sponsors are facing when developing and conducting CCTs in Europe. They have been grouped into three different categories: scientific/technical; operational; and regulatory challenges. In addition there may be also 'financial' challenges relating to the intrinsic complexities of some of these CCTs, e.g. with master CTs with sub-protocols, the need to pay fees for the submission of any additional clinical trial applications. Some of these challenges are also illustrated further with some supportive examples. The paper also includes proposed solutions that should help support change of mindset and optimise expertise within industry, regulators and other stakeholders to realise the full potential of CCTs.

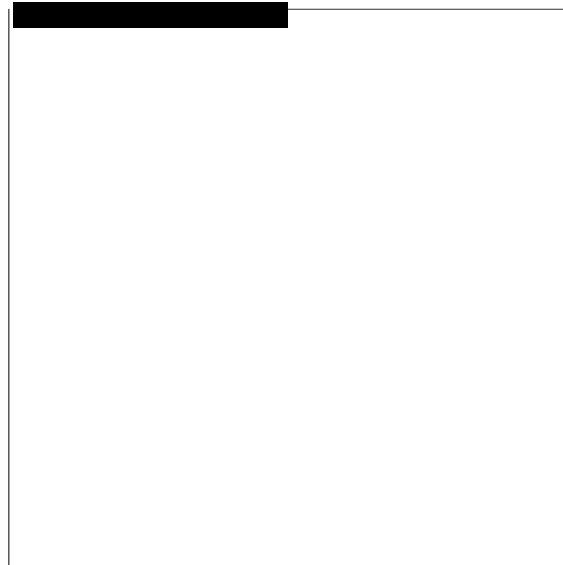
We would also like to understand your plans on how you would like to run this meeting on Nov 13 (3 to 4pm CET time) and whether there is any expectation from the industry associations to present having supportive slides.

With regards,

[REDACTED]

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<https://efpia.eu/news-events/the-efpia-view/statements-press-releases/european-pharmaceutical-industry-response-to-coronavirus/>