



From: [REDACTED] (SANTE)
Sent: vendredi 18 septembre 2020 13:00
To: [REDACTED] (EMA); [REDACTED] (EMA);
[REDACTED] (EMA); [REDACTED];
[REDACTED]; [REDACTED]; [REDACTED]; [REDACTED];
Cc: RYS Andrzej Jan (SANTE); [REDACTED] (SANTE);
[REDACTED] (SANTE); [REDACTED] (SANTE);
[REDACTED] (SANTE); [REDACTED] (SANTE); [REDACTED] (SANTE);
[REDACTED] (SANTE)
Subject: RE: Complex clinical trials meeting with stakeholders September 16
-- presentations

Dear Colleagues,

Thank you for your participation at the meeting on 16 September. Please find below the summary of this meeting by our team. Thank you for letting me know any comments or suggestions you may have.

Summary of the webex call with European regulators and organisations about the conduct of complex clinical trials under the incoming Clinical Trials Regulation

Medical research in Europe is facing an increasing competition from all around the world. The conduct of more innovative trials would increase clinical research efficiency and thus improve competitiveness. Innovative trials is a vague definition for a broad range of different trials designs (adaptive or complex). In addition to the complexity of innovative trial designs themselves, regulatory and financial hurdles are also main factors to hinder their conduct.

EFPIA made a presentation including also examples from concrete cases. Insufficient alignment between regulators was pointed out repeatedly as a major hurdle. In addition, COM was requested to take into account complex trials during the implementation of the Regulation. ACRO's focus was more on the complexity of the CTR and the Clinical Trials Information System, EORTC stressed the importance of having an holistic discussion with all the actors (e.g. participants to clinical trials) preferably for concrete actions. EMA explained that different work-streams need to be identified as best way to approach this complex topic. CTFG explained that national competent authorities have been active on the field and will continue to provide support with this work. Ongoing efforts for guidance through ICH documents have repeatedly been acknowledged.

SANTE explained that the main priority for the COM is the complete and timely implementation of the incoming Clinical Trials Regulation. As COM Pharma strategy explains, developments in trial design will be taken into account during this process. The COM is already working closely with all stakeholders on a guidance for the submission and classification of changes in clinical trials. This will be particularly relevant for complex trials as they are subject to high number of changes and updates. COM requested participants to identify any additional concrete hurdles for complex trials which need to be resolved before the Regulation becomes applicable. It was reinforced that the CTR as such does not contain the concept "complex trial". Flexibility should be found in the existing rules and requirements.

EFPIA and EORTC agreed to submit a draft proposal with concrete problems and proposals. EMA, CTFG and COM are committed to continue the discussions on the basis of this proposal.

Kind regards,

[Redacted]

From: [Redacted] (SANTE)
Sent: Friday, September 11, 2020 4:06 PM
To: [Redacted] (EMA) <[Redacted]@ema.europa.eu>; [Redacted] <[Redacted]@ema.europa.eu>; [Redacted] <[Redacted]@lakemedelsverket.se>; [Redacted] <[Redacted]@bfarm.de>; [Redacted] (EMA) <[Redacted]@ema.europa.eu>; [Redacted] <[Redacted]@efpia.eu>; [Redacted] <[Redacted]@gsk.com>; [Redacted] <[Redacted]@astrazeneca.com>; [Redacted] <[Redacted]@merckgroup.com>; [Redacted] <[Redacted]@acrohealth.org>; [Redacted] <[Redacted]@syneoshealth.com>; [Redacted] <[Redacted]@eortc.org>; [Redacted] <[Redacted]@eortc.org>
Cc: RYS Andrzej Jan (SANTE) <Andrzej.RYS@ec.europa.eu>; [Redacted] (SANTE) <[Redacted]@ec.europa.eu>; [Redacted] (SANTE) <[Redacted]@ec.europa.eu>; [Redacted] (SANTE) <[Redacted]@ec.europa.eu>; [Redacted] (SANTE) <[Redacted]@ec.europa.eu>; [Redacted] (SANTE) <[Redacted]@ec.europa.eu>; [Redacted] (SANTE) <[Redacted]@ec.europa.eu>
Subject: Complex clinical trials meeting with stakeholders September 16 -- presentations

Dear Colleagues,

In preparation for the meeting next week on 16 September about Complex Clinical Trials, EFPIA has prepared the 20 min presentation (attached). As Silvia (EFPIA) explained, "in the midst of the presentation there are Case examples received by EFPIA member companies (slides 7-10). The presentation also includes key challenges and solutions to accelerate and advance the use of CCTs based on case study experiences (slide 11). Additionally, some questions for discussion with stakeholders are included (slides 12 to 13)."

Please let me know by **Monday noon** if you plan to submit a 1-2 slides with additional points to discuss or in response to the questions in the presentation. (The actual slides could be submitted later by end of day, Tuesday). I should be able to send you a draft agenda Monday evening.

Thank you for letting me know if you have not yet received the link to the webex.

Kind regards,

[Redacted]

[Redacted]

Policy Officer - Pharmaceuticals



European Commission

Directorate-General for Health and Food Safety

Unit B4- Medical products: quality, safety, innovation

