From: [redacted] SANTE)
Sent: lundi 14 septembre 2020 19:48
To: RYS Andrzej Jan (SANTE); [redacted] (SANTE)
Cc: [redacted] (SANTE)
Subject: Stakeholders meeting about introducing changes to ongoing clinical trials under the Regulation

Dear Andrzej, Dear [redacted],

The main objective of the Clinical Trials Regulation is to make Europe more attractive for clinical trials. Changes occur frequently in clinical trials and it is important that sponsors can introduce changes in timely manner and without hampering the conduct of trials.

SANTE created a working group with key European stakeholders to develop a system for the classification of changes as substantial modifications or non-substantial changes which are relevant for supervision (new concept in the CTR). The overall aim is to increase the flexibility of change submission and management in clinical trials. The group had its first meeting today.

Please find more detail in the meeting summary below. Many thanks to [redacted] and [redacted] for all their help.
Kind regards,
[redacted]

SANTE-Stakeholders discussion on changes to ongoing clinical trials (September 14, 11:00-12:00)

Participants: [redacted] [redacted] (SANTE B4); NL, ES, FI, SE, DE (COM Clinical Trials Expert Group and HMA Clinical Trials Coordination and Facilitation Group); EMA, Quality Working Party, Biologics Working Party, EORTC, ACRO, EFPIA, EUCROF, EuropaBio

Summary:

- The incoming Regulation will ensure a robust and reliable system for the assessment of clinical trials in Europe. This will improve scrutiny, quality and reproducibility. At the same time, it will require a high level of coordination between national regulatory bodies and sponsors as defined by the Regulation. After the authorisation of a clinical trial, the changes that may impact the safety of the trial participant and/or the reliability of the data ("substantial modifications /SM") need to be authorised as well.

- As the result of a long and tedious debate (stakeholder input included), it was agreed that parallel submissions of SM are not allowed under the CTR with the main aim is to ensure the integrity of the trial documentation at any given time during and after authorisation. This is a significant limitation in comparison to the current system where substantial amendments are submitted at national level, with the possibility for several parallel submissions.

- To support the conduct of clinical trials in the EU by providing the necessary flexibility and at the same time remain compliant with the Regulation, DG SANTE proposed to

develop a guidance, in collaboration with all participants (Ethics committees, national competent authorities, EMA, COM, academic and industry sponsors and CROs) about the classification of changes to clinical trials as substantial modifications or non-substantial changes which are relevant for supervision (NSM notification - new concept in the CTR). DG SANTE proposed to use this new category of changes in a broad sense as this would considerably increase the flexibility of the system for the submission of changes and at the same time would be compliant with the Regulation.

- The proposal received strong support from all participants, who have been and will remain actively involved in the development of the guidance. The guidance is aimed to be published as a COM guidance following an endorsement by CTEG.

- SANTE proposal to finalise the first draft of the guidance by the CTEG meeting on 20 November was accepted by the group. To achieve this, a full-day meeting will be organised with this group in October.