From: [redacted] (SANTE)
Sent: mercredi 9 décembre 2020 15:38
To: [redacted] (SANTE); [redacted] @lakemedelsverket.se; [redacted] @ansm.sante.fr; [redacted] @dkma.dk; [redacted] (EMA); [redacted] (EMA); [redacted] (EMA); [redacted] (EMA); [redacted] (SANTE)
Subject: Summary and action points: EFPIA survey assessing the Impact of the EU Covid 19 Clinical Trials Guidance

Dear Colleagues,

Please find below the summary and action points for our discussion this morning.

EFPIA survey assessing the Impact of the EU Covid 19 Clinical Trials Guidance
Participants: [redacted] (SANTE B4), [redacted] (CTFG), [redacted] (GCP-IWG), [redacted] (EMA), [redacted] (EFPIA)

Summary:

- EFPIA launched a survey within its membership in September 2020 including questions on the usefulness of the COVID19 CT guidance on clinical research in the EU. Main findings (n=24 responders): COVID19 had a major negative impact on clinical research, most importantly on recruitment, trial start, remote monitoring/change to monitoring schedule and on direct to patient IMP supply. The regulatory flexibilities helped to mitigate them (incl. trials with GMO). Most important aspects where additional support/guidance would be needed as identified in the survey are rSDV and better alignment between MS. EFPIA explained that this was a first, high-level analysis, producing a more detailed assessment should be possible.
- Regarding:
    - direct to patient IMP delivery: GCP-IWG expressed need for more information regarding site accessibility and consequent protocol deviations, perhaps through a targeted questionnaire. Since this issue was not identified as a "leading issue" in the survey, SANTE asked if the guidance was sufficient to mitigate possible disruptions of IMP delivery to patients. More detail on the experience with direct to patient delivery would be very welcome.
    - rSDV: GCP-IWG circulated a questionnaire about rSDV with EFPIA and the main message from EFPIA to this was the need for additional clarity and guidance. In parallel, GCP-IWG is leading an action with SANTE CTEG to collect more information from national DPAs about the position of the different MS to rSDV in the context of GDPR and data protection, but it probably will take some time to collect the necessary information to decide on next steps. EMA explained that feedback about industry experience regarding the best working approaches to perform rSDV including from outside EU/EEA would be helpful.
    - Dis-harmonisation between MS: EFPIA identified that dis-harmonisation is most frequent regarding the requirements for risk-assessment and classification/notification/submission of changes as SM/USM/NSM. CTFG explained that application through VHP would facilitate harmonisation and sponsors are encouraged to

use this route. SANTE added that the use of VHP is not covered in the survey. EFPIA will reinforce the possibility of using VHP to its membership. CTFG asked for specific examples where dis-harmonisation has the biggest negative impact.

Actions:

- EFPIA: provides more data (breaking down data for COVID-19 developers vs. all responders) most importantly regarding direct to patient drug delivery (issues related to site accessibility and consequent protocol deviations); use (including best approaches also outside EU/EEA) and hurdles of rSDV, use of VHP, concrete examples for recurrent issues stemming from dis-harmonisation. Some additional data will be available next week.
- EFPIA shares its response to the survey on rSDV
- EFPIA: feeds-back to its network that VHP is the encouraged route for better harmonisation (also in the C19 guidance)
- GCP-IWG agrees on next steps for collecting information on rSDV from DPAs. SANTE supports GCP-IWG with this task through CTEG.
- Post-meeting: follow-up discussion with this group can be planned for early 2021

Thank you for the open discussion today. Let me know if you have any comments regarding the summary and list of actions.
Kind regards,

European Commission
Directorate-General for Health and Food Safety
Unit B4- Medical products: quality, safety, innovation