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Protection of personal data and commercially confidential information for data submitted to the Clinical Trials Information System in line with Regulation (EU) No 536/2014

Use of deferrals in CTIS
Feedback from Member States

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Application dossier = structured data and documents!

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MSC Objective: Fulfil legal requirements of CTR, and where applicable, national legislation

- **Member States need to be fully informed** (including commercially confidential information and necessary personal data) about the clinical trial in line with CTR and, where applicable, national legislation (see e.g. CTR Articles 6-8, Annex I-II)
- **Non-redacted versions** are the basis for the assessment of and decision on the application
- **Redaction should be restricted** to the legal reasons listed in the CTR i.e. commercially confidential information and personal data
- Redaction of documents is **at present not assessed by Member States** since this is not understood to be our legal obligation

Deferral of publication is based on selected trial category

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- Disclosure rules are laid down in **EMA/228383/2015**
- **Sponsor proposes** deferral of publication at time of initial application
- **Member States (MSCs) review the proposal and decide on deferral** (RMS for Part I RMS, each MSC for Part II) - case-by-case decision
- Focus of MSCs:*"Is the deferral category chosen by the sponsor acceptable?"*
- Publication of MSC documents and data then **usually adapted to the trial deferral category**
- **MSCs need to adapt input to EU Portal** not to include CCI or personal data e.g. in consideration texts in the RFI or decision letter

Deferral vs. Redaction

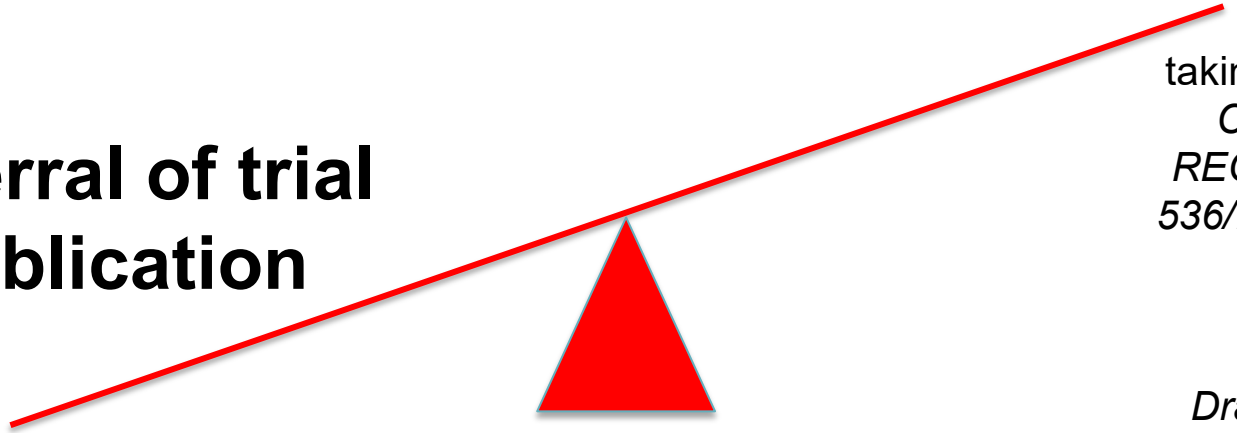
- Application dossier includes structured data and documents (non-redacted and redacted)
- Only documents are possible to redact

Document redaction

taking into consideration
CLINICAL TRIALS REGULATION (EU) NO 536/2014 QUESTIONS & ANSWERS VERSION 6.1
And
Draft Guidance under development EMA/212507/2021

Deferral of trial publication

taking into consideration
EMA MB disclosure rules
EMA/228383/2015



Particular legal aspects to consider for trial category choice

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- **Clinical trials where subject population includes:**
  - **Paediatric subject** (in line with the Paediatric Regulation)
  - **Subjects in emergency situations** (first trial-specific intervention before informed consent)
- **Trials in a public health emergency** (in line with Crisis Preparedness Regulation)
- **Combination aspects:**
  - **Integrated trial phases** = follow higher category → earlier publication!
  - **Several IMPs** = follow category for IMP earlier in development → later publication!
  - **Two different trials with same IMP but not the same phase or population** → different categories apply!

Regulation (EU) No 536/2014 Emergency situation trials

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- First trial-specific intervention before informed consent
- **Always Category 2 or 3 (=therapeutic)** since Article 35 requires scientific grounds for individual clinically relevant benefit for subjects

Article 35

Clinical trials in emergency situations

1. By way of derogation from points (b) and (c) of Article 28(1), from points (a) and (b) of Article 31(1) and from points (a) and (b) of Article 32(1), informed consent to participate in a clinical trial may be obtained, and information on the clinical trial may be given, after the decision to include the subject in the clinical trial, provided that this decision is taken at the time of the first intervention on the subject, in accordance with the protocol for that clinical trial" and that all of the following conditions are fulfilled:

(a) due to the urgency of the situation, caused by a sudden life-threatening or other sudden serious medical condition, the subject is unable to provide prior informed consent and to receive prior information on the clinical trial;

(b) there are scientific grounds to expect that participation of the subject in the clinical trial will have the potential to produce a direct clinically relevant benefit for the subject resulting in a measurable health-related improvement alleviating the suffering and/or improving the health of the subject, or in the diagnosis of its condition;

Regulation (EU) 2022/122
Trials in public health emergency

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- Article 17 requires publication of the protocol at the start of the trial
- Interpreted as "time of trial decision" according to EMA/228383/2015
- **Technical solution = Category 3**

Article 17

Public information regarding clinical trials and marketing authorisation decisions

1. For the duration of a public health emergency, the sponsors of clinical trials conducted in the Union shall, in particular, make the following information publicly available through the EU portal and EU database established respectively by Articles 80 and 81 of Regulation (EU) No 536/2014:

(a) the clinical trial protocol, at the start of each trial for all trials authorised under Regulation (EU) No 536/2014 that examine medicinal products which have the potential to address the public health emergency;

(b) the summary of the results, within a timeline set by the Agency that is shorter than the timeline laid down in Article 37 of Regulation (EU) No 536/2014.

CTR - a new 'legal environment' for Member States and Sponsors

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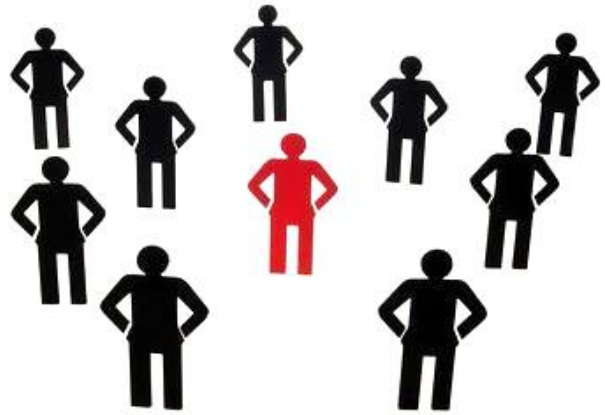

- Aim is to reach harmonisation between Member States.
- Practical experience will clarify
  - what is acceptable and
  - what general principles should apply in our daily work.
- With experience, outcome will be more predictable and consistent.

Questions welcome!