

Info session : Clinical Trial Regulation

Future Strategy : points of interest

23 th September 2021

Greet Musch

1: First priorities :

- Smooth transition from Directive towards Regulation
- **Forecast CTR mono – and multinational ?**
- **Role of Belgium as Reference Member State ?**
- *Preparing for the implementing act on safety : go live 31 Jan 2022*
- *Preparing for the Union controls at MS level*

2: Additional projects

- Innovative complex clinical trial designs
 - Joint CTFG-EMA-COM WG on Q&A
 - EFPIA Workshop 5 – 6 October

- Decentralised trials
 - Joint CTFG-EMA-COM recommendation paper

- EU 4 Health projects
 - Expedited assessment for COVID 19 therapeutics
 - Coordinated Safety assesment



3: Future CTR info session(s) : topics

- 25 th November 2021 : CTIS (sandbox availability)

Your ideas ??



Contact

**Agence fédérale des médicaments et
des produits de santé – AFMPS**

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A large, stylized graphic of a human eye in the background. The eye is composed of a light blue iris with a white pupil, and a grey arc above and below it representing the eyelids. The entire graphic is semi-transparent.

**Vos médicaments et produits de santé,
notre préoccupation**

**Uw geneesmiddelen en
gezondheidsproducten, onze zorg**