

Clinical trials in Europe.

Introductory remarks

Dr Chantal Bélorgey
Head, CTs Department, Afssaps, France
Chair of CTFG

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agenda

- **Overview of the CTA framework in EU**
- **Authorities and ECs perspectives on CTA**
- **Regulatory requirements for initial CTA**
- **A SME experience in initiating CT**
- **GMP, GCP and safety monitoring**

Figures

- **4 to 5000 CTs per year in EU**
- **In 2009 :**
 - 4513 CTs
 - 57% commercial, 43% non commercial
 - Phase 1 : 33%
 - Phase 2 : 30%
 - Phase 3 : 20%
 - Phase 4 : 17%
- **25 % are multinational (≥ 2 MS)**

The sponsor

- Takes the responsibility for initiation, management and/or financing the CT
- Must be established in the EU community
- Or have a legal representative in EU
- Responsibilities / duties described in the CT directive and detailed guidances : quality of IMPs, quality of CT, choice of investigators, insurance, safety management, ...

The investigator

- **Responsible for the conduct of the CT at the trial site**
- **Applies GCP**
- **Follows the protocol**
- **Notifies safety information to sponsor**

The CT subjects

- Informed consent
- Prior information (nature, objectives, implication, risks of the CT)

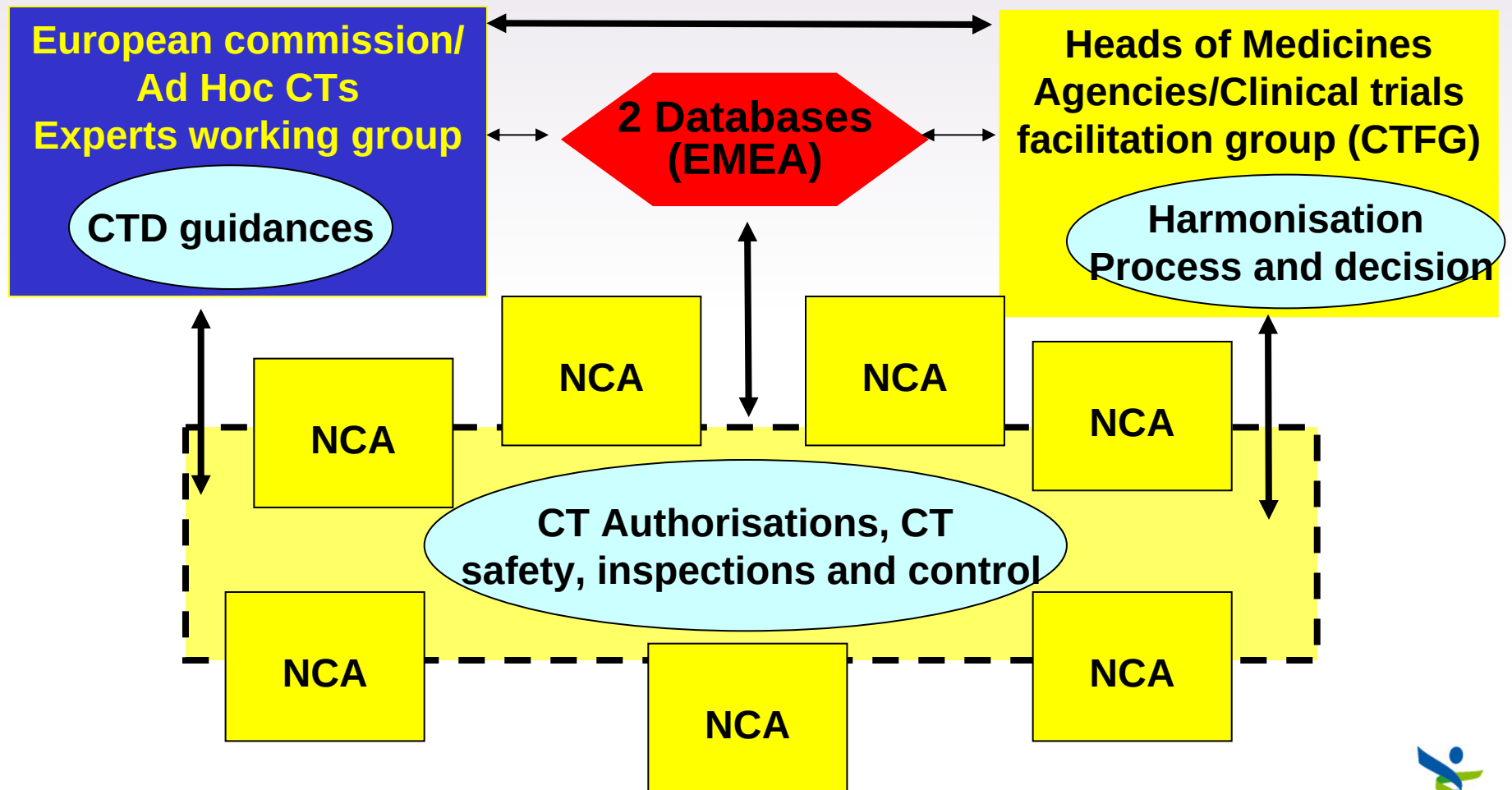
Ethics committees

- **ECs to be established by MS**
 - **Independant body whose responsability is to protect**
 - Rights
 - Safety
 - Wellbeing
- } of the CT subjects

National Competent Authorities (NCAs)

- **generally Medicines Agencies**
- **responsabilities in ensuring Public Health**

NCA – CTFG – EU Commission - EMA



The Clinical Trials Facilitation Group (CTFG)

- Operational group
- Established by Heads of Medicines Agencies (HMA)
- Since 2004
- Representation
 - all National Competent Authorities (NCAs), European Commission, European Medicines Agency
 - Chaired by France, co chaired by Germany
- Terms of Reference
 - Improve interactions between the NCAs, more coordination
 - Promote harmonisation of decisions on CTs, avoid divergent decisions
 - Get a common interpretation of regulatory aspects.