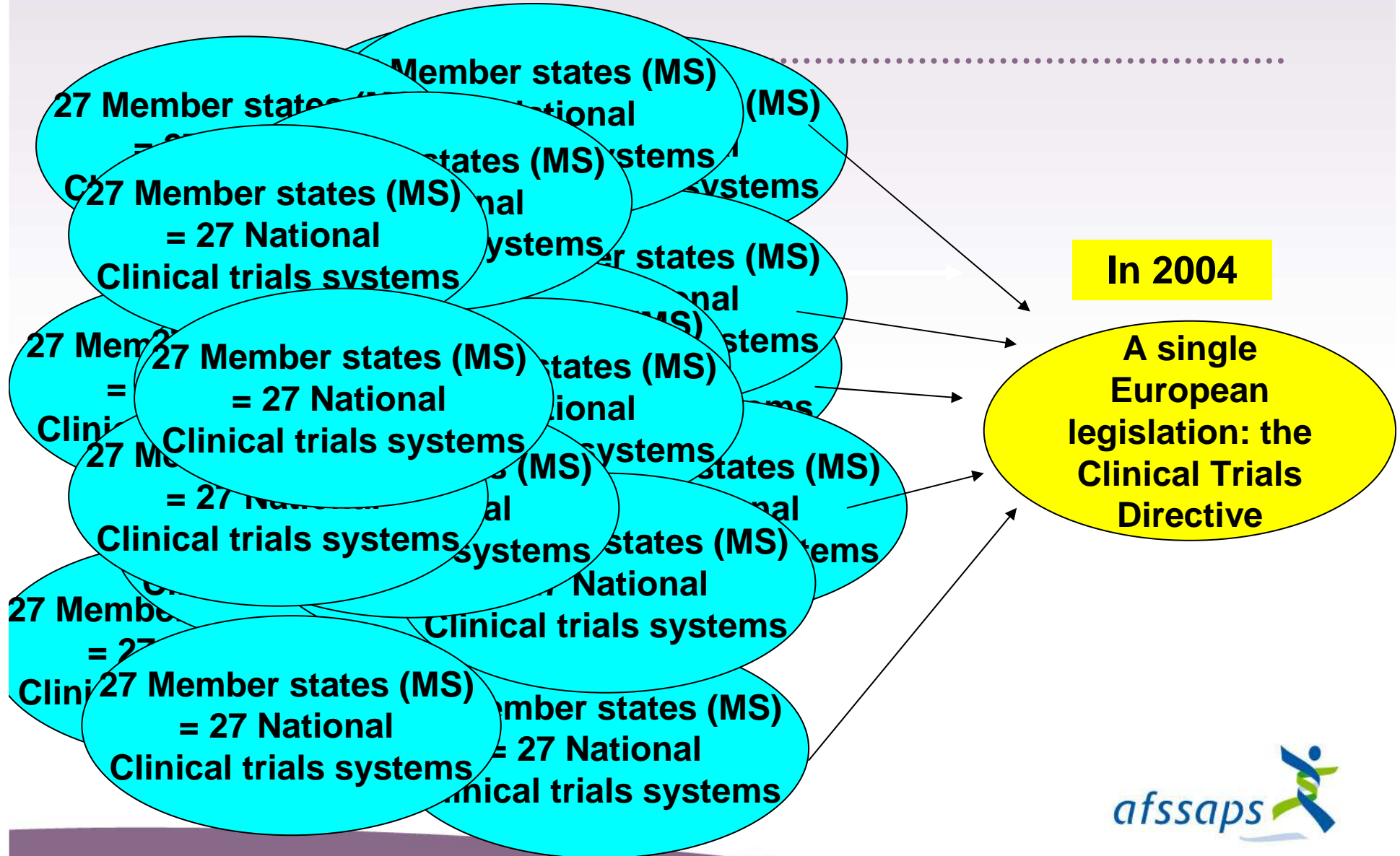


# Strengthening of work-sharing on clinical trials in EU: overview of CTFG activities and perspectives

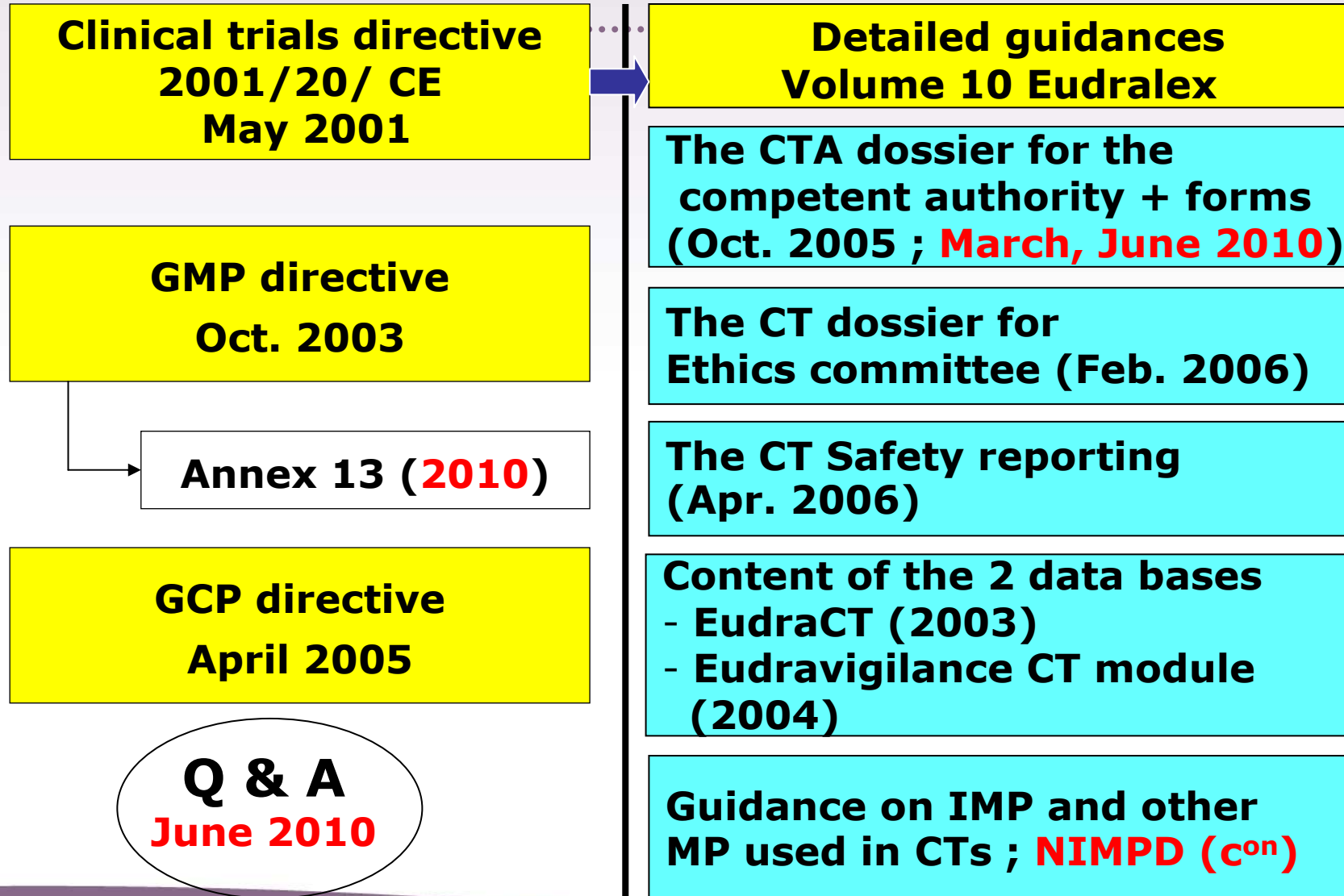
Dr Chantal Bélorgey  
Head, Department of Clinical Trials and special status products  
Chair CTFG

CTFG Paris 11 June 2010

# The regulatory context for CTs in EU



# European legislation



## Other European texts

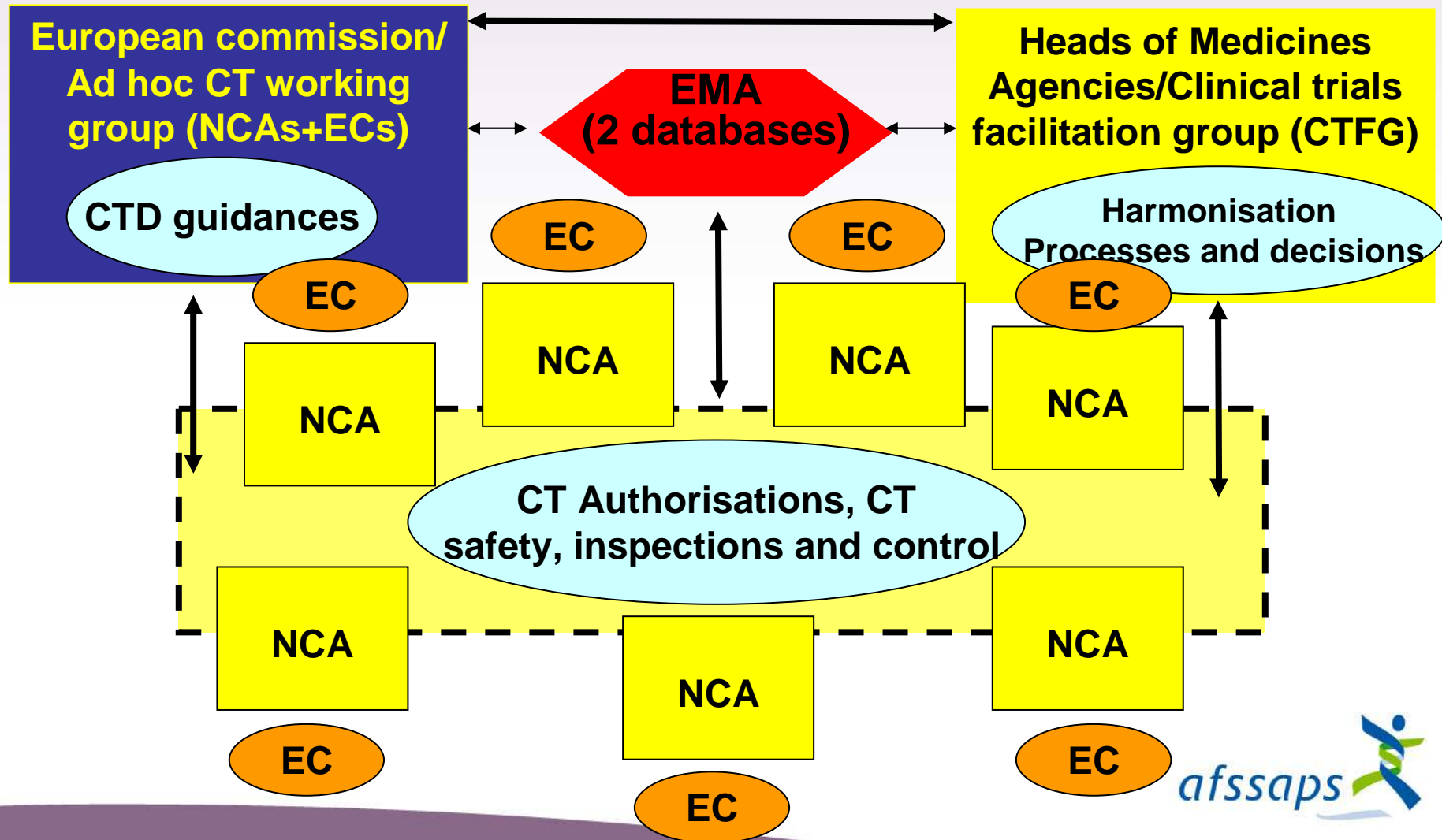
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### **ICH guidelines (all)**

#### **EMA Guidelines**

- Quality of IMPs :
  - Requirements to chemical and pharmaceutical quality documentation (2006)
  - For biologicals (public consultation)
- First in human CTs (July 2007)
- Other guidelines on MP development
- Guideline on virus safety evaluation of biotechnological IMPs (2008)
- Ethical considerations for Cts in children (2008)
- ...

# EU regulatory framework: stakeholders



# The CTFG

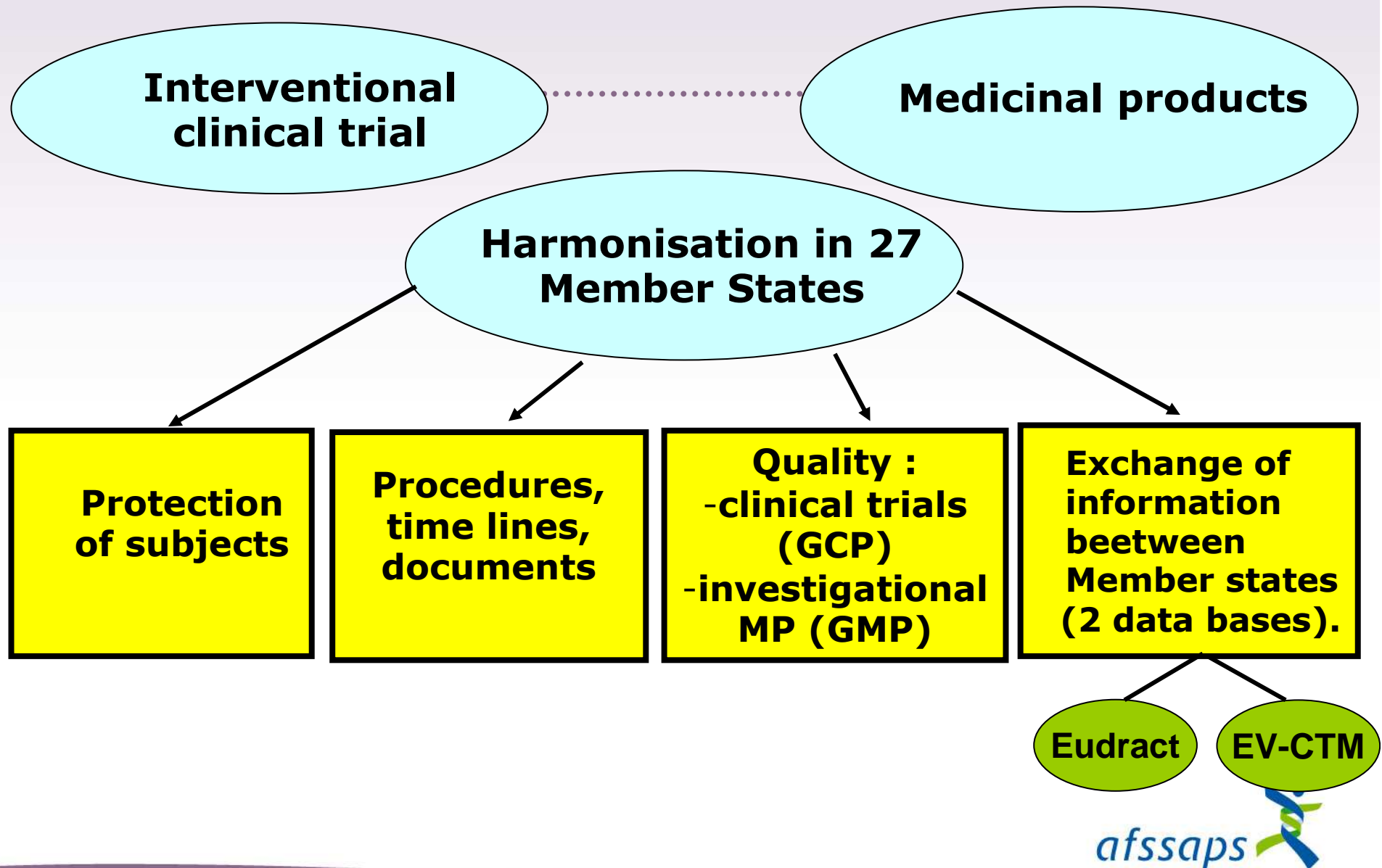
- **Operational group of HMA**
- **Established in 2004**
- **Representation**
  - Heads CT unit/dpt of the National Competent Authorities (NCAs), European Commission, EMA
  - Chaired by France (Afssaps), co chaired by Germany (PEI)
  - Meets 5 to 6 times per year + teleconferences
- **Terms of Reference**
  - Improve interactions between the NCAs, more coordination
  - Promote harmonisation of decisions on CTs, avoid divergent decisions
  - Get a common interpretation of regulatory aspects

# CTFG mandate

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- **2008**
- **Within the current legal framework :**
  - **Coordinate or share scientific assessment of multinational CTs**
  - **Harmonise processes and practices**
  - **Develop data sharing and information systems**
  - **Communicate**
- **with the aim to set up best practices between MS**
- **and to propose changes or clarification of guidelines and legislation.**

# The clinical trial directive and guidances



# Room for improvement for MNCTs

## What is required to NCAs by sponsors?

### 1 . Improve harmonisation of the administrative process

- **Avoid :**

- National CTA and safety requirements
- National divergent decisions
- National approaches to SA
- Bureaucratic burden

### 2. Facilitate the administrative process

- Same dossier
- Single repository
- Electronic submission
- Applications in English

### 3. Improve the scientific review outcomes by NCAs

- Better definition of the objectives of the review process
- Coordinated scientific decision on the same CT

## There are also difficulties for NCAs!

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- Different roles of NCAs and Ethics committees in each MS
- Different scopes of assessment
- Different experiences on scientific assessment
- Different resources

## Objectives of CTFG

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- Consider the results of the CTD impact analysis by the Commission (30/03/2010)
  - Facilitate conduct of CTs in EU.
  - Reduce workloads (sponsors, NCAs)
  - Use resources effectively
  - Prepare to new CT legislation (October 2011)
- Use the transitory period to improve the system.

# What CTFG offers to sponsors

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***In order to accelerate CTA and improve CT safety for multi national CTs (MNCTs)***

- ***Voluntary NCAs cooperation (current legal framework)***
- ***Simplification of processes***
- ***Harmonisation of CT assessment by NCAs***
- ***How?***
  - ***Networking and coordination***
  - ***Improved IT systems***
  - ***Common procedures***

# CTFG 2008-2009: Coordination of MN CTs scientific assessment by NCAs

- Build common assessment criteria and same approach
- Same objectives of the review process: subjects safety, IMP quality and safety, best time-frames

## 2008

- **A forum for scientific discussion**
  - CTA assessors networks
  - Regular scientific exchanges
  - Scientific meetings dedicated to specific technical issues (Q,NC,C)
  - Data sharing :
    - EU databases
    - CTFG mail box
    - Vitero system

## 2009

- **A standardised procedure for coordination of multinational CTA assessment**
  - The voluntary harmonisation procedure (VHP)
- **A simple administrative process**
  - Same application dossier, single repository, electronic submission, English mandatory

## CTFG 2008-2009: improvement of processes

---

- Reflexions on
  - CTA dossier
  - CTA process
  - Substantial amendments
  - NIMP dossier content
- The new CT1 guidance
- Improvement of EudraCT
  - Electronic alerts
  - Standard reports
  - EU-CT public registry (2010)

## CTFG 2008-2009 : CT safety monitoring

---

- Progress relating to electronic population of EV-CTM
- Reports from EV-data analysis system
- Provisions for IMP dictionary
- ASR move to DSUR

## Priorities 2010-11

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- **Improve MS participation** in work-sharing assessment;
- Enlarge and improve the **VHP (→ version 2)**;
- Implement **work-sharing of CTs safety** information;
- Explore the simplification of processes and assessment using a **risk based approach**;
- **Reduce specific national requirements** as much as possible;
- Assist the European Commission in the **simplification** of the EU legislation;
- **Interact** with other European working groups ;
- Improve transparency and **communication**.

## Action : Coordination/simplification of CTA assessment

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- Implement the VHP **version 2**
- Develop **more flexibility** in the internal process of assessment

with the objective to use **VHP to all MN CTs.**

## Action : coordination of assessment of CT safety information

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- Work share Annual Safety Reports assessment
- Harmonise the interpretation of DSUR.
- Improve SUSARs assessment
  - How to improve harmonisation of SUSARs reporting by sponsors
  - Define what NCAs need to make EVCTM the primary safety database for CTs in EU

## Action: improvement of information systems to facilitate work-sharing and simplify processes

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- EV-CTM:
  - NCAs needs to be defined and implemented
  - Simplify trainings
  - Link EudraCT and EV-CTM
- A securised electronic CTFG repository for internal use and for external dossiers

## Action: Input in the development of EU legislation and harmonised interpretation

---

- Assist the European Commission in **developing future legislation** and improve with the Commission the related **guidances**.
- Develop a **forum for a common interpretation of legislation and guidances**
  - The new CTA guidance (May 2010)
  - The next DSUR
  - IMP/NIMP definitions
  - Interventional/ non interventional...

## Action: communication with stakeholders to assist them in conducting CTs in EU

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- Public communication
  - Public meetings with stakeholders
    - Bonn April 2010
    - Paris June 2010
    - Brussels November 2010
  - Invite stakeholders for discussion
- CTFG/HMA website



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<b>About HMA</b>
HMA Management Group/PS BPG
Working Groups
<b>Clinical Trials Facilitation Group</b>
Homeopathic Medicinal Products Working Group (HMPWG)
Working Group on PSUR synchronisation
HMA Topics
Stakeholder Information
HMA Calendar
FAQ
Contact form
Contact points
Recruitment

### Clinical Trials Facilitation Group

#### Introduction

EU Heads of Medicines Agency (HMA) agreed in 2004 to establish a clinical trials facilitation group (CTFG) to co ordinate implementation of the EU clinical trials directive 2001/20 EC across the member states.

In relation to clinical trials the CTFG acts as forum for discussion to agree on common principles and processes to be applied throughout the European medicines regulatory network (EMRN).

It also promotes harmonisation of clinical trial assessment decisions and administrative processes across the national competent authorities (NCA).

#### CTFG members and representatives

The CTFG is attended by representatives from the NCA's, European Commission and the European Medicines Agency. CTFG is currently chaired by Dr Chantal Belorgey (AFSSAPS), the co chair is Dr. Hartmut Kraft (PEI) and the secretariat for the group is Kristof Bonnarens (fagg-afmps)

[CTA Assessment in member states](#) (130.37 kb)

[Guidance document for a Voluntary Harmonisation Procedure \(VHP\) for the assessment of multinational Clinical Trial Applications](#) (164.28 kb)

- International CTFG Workshop on the Voluntary Harmonisation Procedure (VHP) for the Assessment of Multinational Clinical Trial Applications,30 April 2010, Bonn [click here](#)

[Official contact points of competent authorities](#) (104.52 kb)

#### CTFG Mandate

CTFG received a new mandate and terms of reference from HMA this was adopted on the 4/1/08.

The main priorities and functions of CTFG will be

- Sharing of scientific assessments
- Harmonise processes and decisions
- Participate in development of information systems
- Communication
- Co operation with other working groups.

[Mandate for HMA Clinical Trials Facilitation Group \(CTFG\)](#) (166.61 kb)

Heads of Medicines Agencies: Clinical Trials Facilitation Group - Microsoft Internet Explorer

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Adresse <http://www.hma.eu/77.html> OK Liens

**Facilitation Group**

Homeopathic Medicinal Products Working Group (HMPWG)

Working Group on PSUR synchronisation

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**CTFG Workplan**

In order to achieve and implement this mandate, CTFG has prepared a [work plan for 2010-2011](#).

The CTFG has the following work plan ambitions and aims for the next 2 years

- Sharing of scientific assessment of multinational clinical trials
- Harmonising processes and practices relating to clinical trials mainly in the fields of clinical trial applications (CTA), clinical trial amendments and safety procedures.
- Developing data sharing and participating in the improvement of information systems
- Developing communication with stakeholders and co-operating with other EU working groups

**CTFG activity report**

 [CTFG activity report 2008 - 2009](#) (31.55 kb)

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## Action: Active participation in EU working groups

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- The European Commission's ad hoc experts group CT legislation and guidances
- Other EU or EMA working groups
  - interactions between CTFG and EMA
    - CHMP (procedure)
    - Eudravigilance WG (CT subgroup)
    - GCP Inspectors WG
    - EudraCT TIG
    - PEDCO

## Where to get information on CTs in EU

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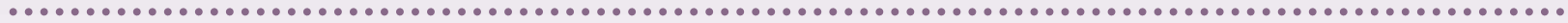
- European Commission website

<http://ec.europa.eu/enterprise/sectors/pharmaceuticals/human-use/clinical-trials/>

- CTFG website :

<http://www.hma-eu/77.html>

and NCAs websites



Thank You