



The French Agency for the  
Safety of Health Products

# Regulatory agencies and Quality in Clinical trials

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# 1. Points to consider (1/2)

## 1.1. Global environment for clinical trials

- Life cycle of the product
- Geographic Globalization
- Sponsor characteristics (SME, Big pharma...)
- Multiplication of CROs and Vendors
- Development plans (Early phase, adaptive design, PASS...)
- Technical evolutions (IV/WRS...)

# 1. Points to consider (2/2)

## 1.2. Current European environment for C.T.

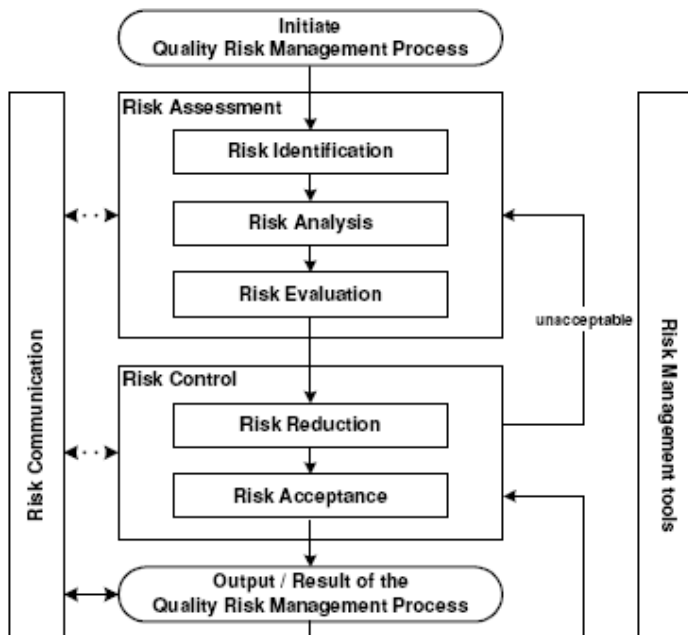
- No IND like process
- Clinical trial authorisation and oversight by National C.A.
- National and European level procedures for Marketing authorisation
- 3 forums for cooperation and harmonisation
  - Group for the Devpt of guidelines for the CT Directive
  - Clinical Trial facilitation group (CTFG): CT assessors
  - GCP Inspector Working Group (GCP IWG): GCP inspectors

# 2. How R.A. can help

## 2.1. Involvement in Risk based approach, Definitions and Tools

### Risk based approach, ICH Q9

Figure 1: Overview of a typical quality risk management



### 1. Acceptable risk / quality:

- Trial patient safety and integrity
- Reliability and accuracy of the Trial results
  - . Primary endpoints
  - . Secondary endpoints

### **Common definition on Acceptable risk / quality**

- With scientific / medical / methodological signification
- For Regulators (CT assessors, MA assessors, GCP inspectors), Sponsors, Investigators, Insurance companies...

## 2. How R.A. can help

### 2.1. Involvement in Risk based approach, Definitions and Tools

#### 2. Risk identification and assessment

- Origin of the risk  
(IMP, Trial design / procedures, capacity of the sites)
- Categorization

### Common Risk assessment Tool ? (Must be simple...)

*Initiatives and discussions : CTTI, MHRA-DRC-DH, EMA GCP IWG – CTFG, Bfarm-Adamon, Afssaps-Optimon, OECD*

## 2. How R.A. can help

### 2.1. Involvement in Risk based approach, Definitions and Tools

#### 2. Risk-adapted approaches

- Trial related activities concerned
  - . Information submitted to the Authority
  - . Product traceability (including labelling)
  - . Monitoring
  - . Safety surveillance and reporting

#### Common approach on Adaptation of Standards ?

- Approaches by
  - . Sponsors
  - . Competent authorities
    - Assessment purpose
    - Inspection purpose

## 2. How R.A. can help

### 2.2. Focus on what matters for Assessment and inspection

- **Assessment of clinical trials and clinical trial results**
    - Authorization and follow-up of clinical trials
    - Clinical trial results in Marketing authorisations
    - **Adequation/adaptation of the requested documentation**
    - **Clear rules for assessment**
      - Definition of the critical elements
- => Clear rules for sponsors

#### ***Initiatives and discussions in European forums :***

- *Group for the Devpt of guidelines for the CT Directive :*
  - *Discussions on requirements adapted to the foreseeable risk ?*
- *CTFG : harmonisation of practice / Voluntary harmonized procedure*

## 2. How R.A. can help

### 2.2. Focus on what matters for Assessment and inspection

- **Inspection of clinical trials**

- . **Understandable inspection process**

- . **Defined criteria for selection of trials, organisations, sites**  
including Risk based approach

- . **Harmonized approach on fields and data inspected**

- . ***Initiatives and discussions in European forums :***

- EMA GCP IWG-CHMP : Triggers for inspection, 2001 (under revision)*

- GCP IWG-CMDh : Points to consider / generic applications, 2004*  
*Triggers for inspections / BE trials, 2011*

- GCP inspection policy, 2006*

- GCP IWG – CTFG : Coordination of inspections outside MA context (Draft)*

- . ***EMA – FDA Initiative on GCP inspections***

## 2. How R.A. can help

### 2.3. Information, Assistance, Education

- **Information**

- **of stakeholders**

- . **Guidances on expectations**

- . **Policies and processes**

- (i.e. MRC/DH/MHRA project on R-B approaches to the mgt of CT (MHRA R-B inspection process, FDA Model for Site selection...)

- . **Feed back of evaluation and inspection,**  
(programs, findings...)

- . **Working groups on Clinical trials**

- Afssaps: 2 groups,**

- . Evaluation

- . GCP

- **exchange between authorities**

- . **Programs, findings, sites of interest (Central lab, BE CROs...)**

## 2. How R.A. can help

### 2.3. Information, Assistance, Education

- **Assistance**

- Scientific advice
- Afssaps: Advice for advanced product developments

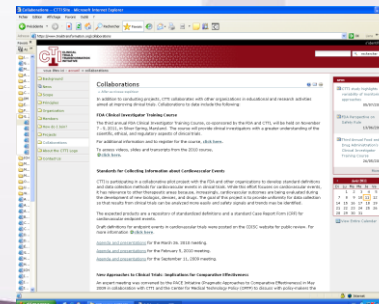
- **Education**

- Afssaps, training of investigators:
  - . 2009 : guidance document for training for investigators

[http://www.afssaps.fr/Activites/Essais-cliniques/Formation-des-investigateurs/\(offset\)/2](http://www.afssaps.fr/Activites/Essais-cliniques/Formation-des-investigateurs/(offset)/2)

. 2011 : initiative with High School of Public Health and Cengeps, in collaboration with representatives from University, Public and Private sponsors, CROs, Investigators, to dispense training courses for trainers.

- CTTI / FDA Training course





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**Thank you for your attention**

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