CTR: Member State preparedness and national aspects

Independant Ethics committees in France

Pierre-Henri Bertoye, CNRIPH
Commission Nationale des Recherches Impliquant la Personne Humaine

<dgs-cnriph-president@sante.gouv.fr>

10 March 2021

Human research Ethics Committes in France: BRIEF DESCRIPTION OF THE SYSTEM


17 juin 2016 JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE Texte 19 sur 147

Décrets, arrêtés, circulaires

TEXTES GÉNÉRAUX

MINISTÈRE DES AFFAIRES SOCIALES ET DE LA SANTÉ

Ordonnance n° 2016-800 du 16 juin 2016
relative aux recherches impliquant la personne humaine

NOR : AFSP1608692R

1. Law: Public Health Regulation modified in June 2016

"Ordonnance no 2016-800 du 16 juin 2016 relative aux recherches impliquant la personne humaine »

- **3 categories of trials** (interventional, low intervention, "non significant" intervention, with proportional provisions)
- **Trials with and without health products**

- **Art. 8** provides for the **changeover to the European regulation (UE) no 536/2014**
- **Art. 4** describes **Parts from National legislation not covered by the regulation or supplemented by national provisions, remaining applicable**
  - Participant compensation, insurance, financial contribution (L. 1121-10 and 11)
  - Site authorization for FIM trials (L. 1121-13)
  - Healthy Volunteers registry (L.1121-16)
  - Criminal provisions (L.1126-1 to 1126-12)
  - Safety reporting for Healthy Volunteers (L.1123-10)
  - Medicinal products (L.5121-1-1, L. 5125-1, L. 5126-1)
  - French Data protection law (consistent with GDPR)

Clarification guidance for sponsors and Ethics committees

Human research Ethics Committes in France: BRIEF DESCRIPTION OF THE SYSTEM

2. Ethics committee (IEC) organisation and operation

❑ **39 Ethics Committees** in France, called “Comités de Protection des Personnes” (CPP)

- Officially approved by Ministry of Health
- Members appointed by DG of the Regional Health Agency where the EC is located
- 14 titular members distributed into 2 colleges (Scientific and Ethical); 14 alternates
- National competency (1 single opinion covering all the trial related activities in France)
- Scope : . 3 categories of trials on Human persons
  . Trials with and without health products

❑ **Coordinating Unit at the MOH**

- Administrative support
- Information System (I.T.) development, implementation and evolution
- Regulatory support
- Harmonisation (guidances…)
- Training

2. Ethics committee (IEC) organisation and operation

❑ Dossiers randomly assigned to Ethics Committees

- Improvement of the regulation in Oct. 2018: Dossier submitted to a Committee randomly designated from **among the committees** **available and having the necessary competence** to examine the project (…)

❑ Review of the dossiers by EC

2.1. Multidiciplinarity and collegial decision

- Require exchanges between members (meeting „seance"); physical or videoconference
- 1 (or 2 for some committees) meeting / month x 11 months; ad-hoc meetings for Covid

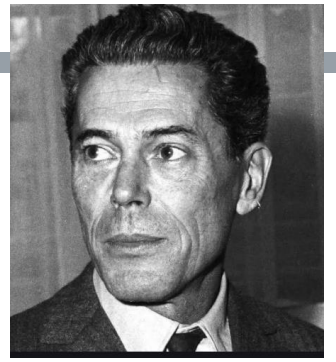
2.2. Independancy

- Independancy from the sponsor, Inv, any other influence
- Application independently assessed by EC and NCA

2.3. Members volunteers, with little or no compensation

Ref: Helsinki declaration Art. 23, WHO/CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects, Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research ('Oviedo') Chapt. III, CTR Art. 2 (11) and Art. 9

France : Challenges for Ethics Committees in the CTR context

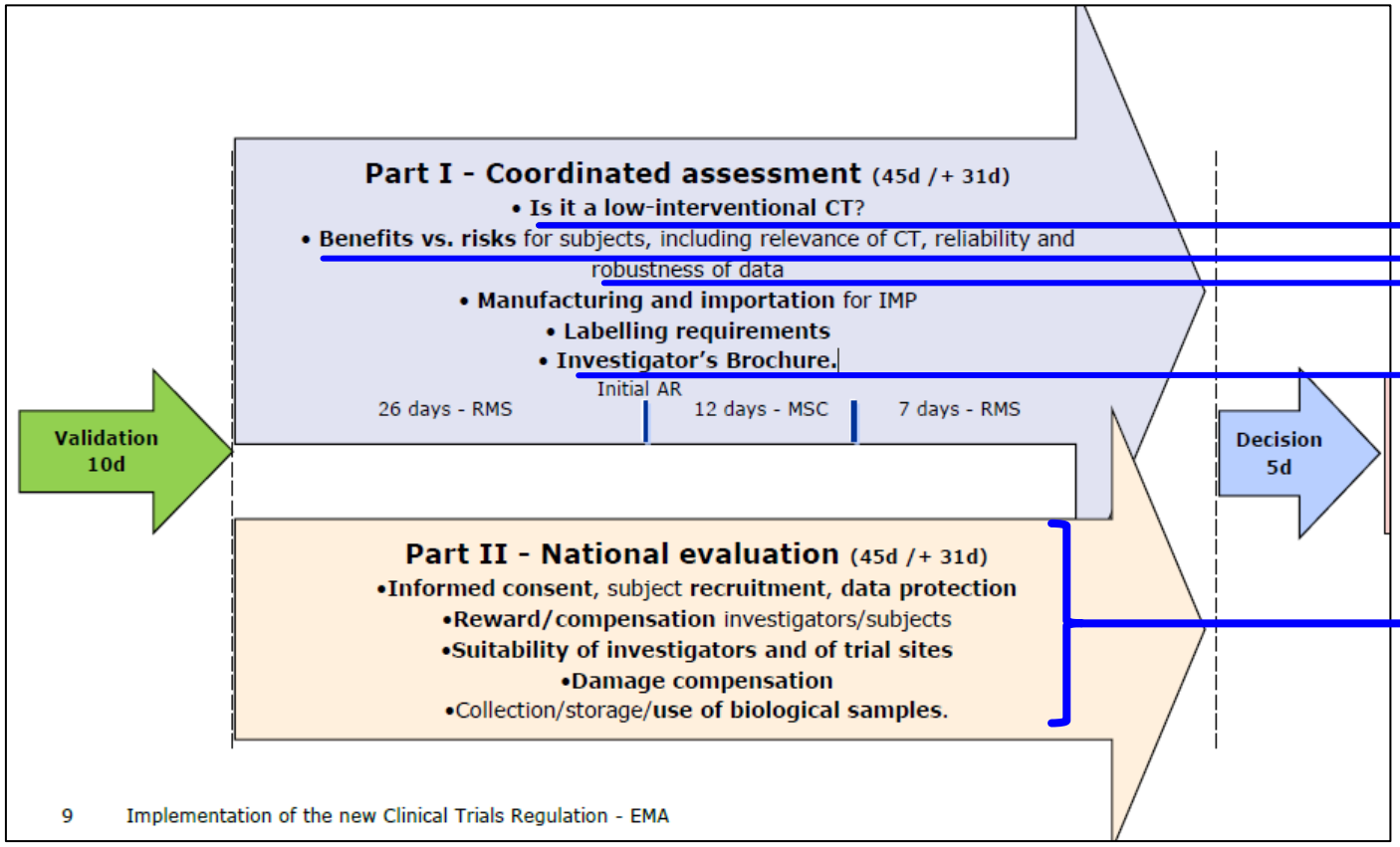


1. Scope of the assessment

« Ce qui n'est pas scientifique, n'est pas éthique »

"what is not scientific, is not ethical" Ja*cques Monod (1910 – 1976)*

"Ethics and knowledge are inevitably linked in and through action"



Ethics Committee

1. **participates in Part I Coordinated assessment**

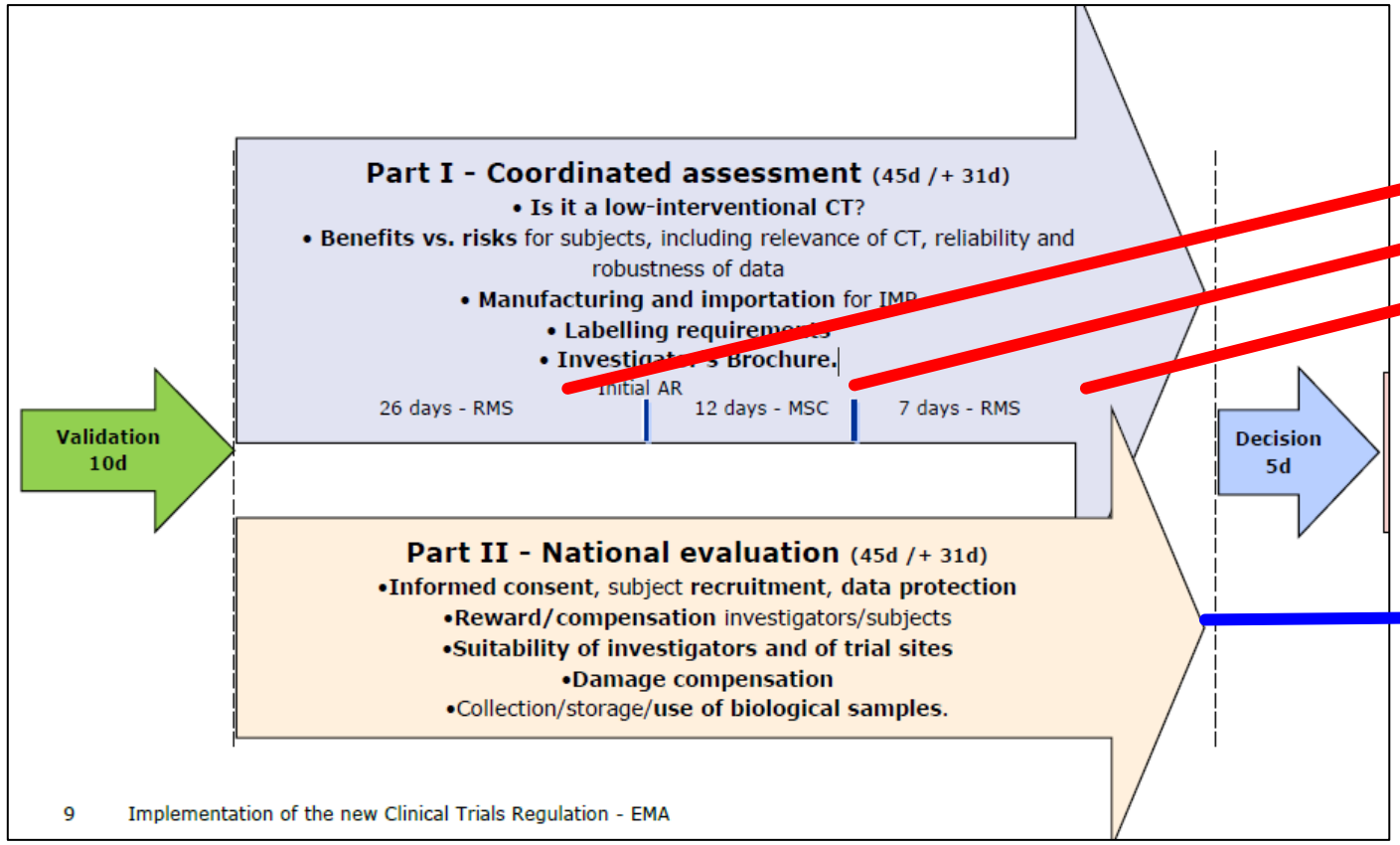
French Law: Art.4 L. 1124-1, I: "Competency for Part I assessment is ANSM (CA)"

1. **Is in charge of 'National' Part II assessment**

French Law: Art.4 L. 1124-1,II: "Competency for Part II assessment is EC"

France : Challenges for Ethics Committees in the CTR context

2. Participation in part I assessment : practical consequences



I. E. C. Level
Gap analysis

- **Coordination between NCA and EC**
  . ***Timelines RMS Assessment report***
  < [10+26] D (initial assessment)
  < (+[12-19 D]) (consolidated review)
  . ***Language of the preliminary report***
  English

- **Timetable, 55D:** consistent / system
- **Part I, II:** 2 Time sequential assessment?

2. National collective level: system for Ethics Committees

France : Adaptive measures for Ethics Committees in the CTR context

Very short notice and workload: adaptation of EC organisation and operation

1. **Implementation of a <u>nationally coordinated system</u>:**
2. **<u>Assignment of the dossiers</u> to Ethics Committees i) available, ii) competent**
3. **<u>Review</u> of the dossier by the E.C.**
4. **<u>Supervision, preparation and trainings</u>**

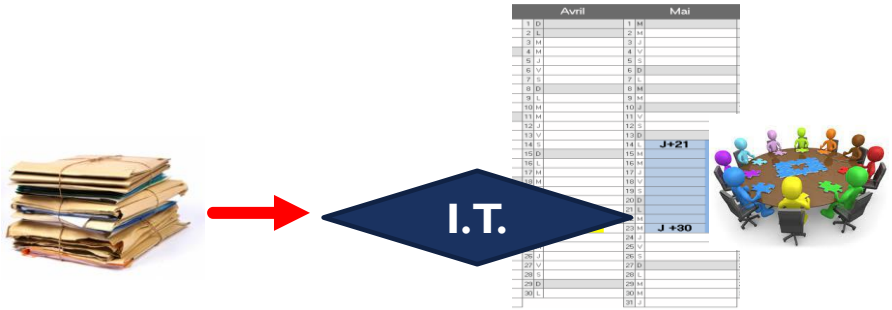
1. Implementation of a <u>nationally coordinated system</u>:

- Coordinated calendar between IECs (to cover each week of the year)
- Duty continuity by each IEC (the IEC system will have to operate year-round, including summer)
- Implementation of a 40th Ethics Committee

France : Adaptive measures for Ethics Committees in the CTR context

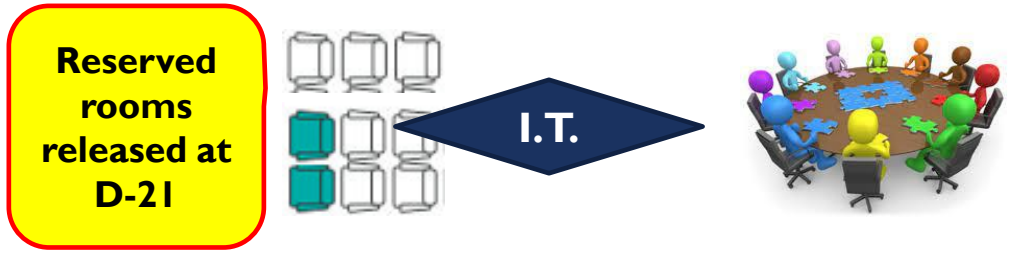
2. Assignment of the dossiers to Ethics Committees: I.T. adaptation

➢ Availability of the EC



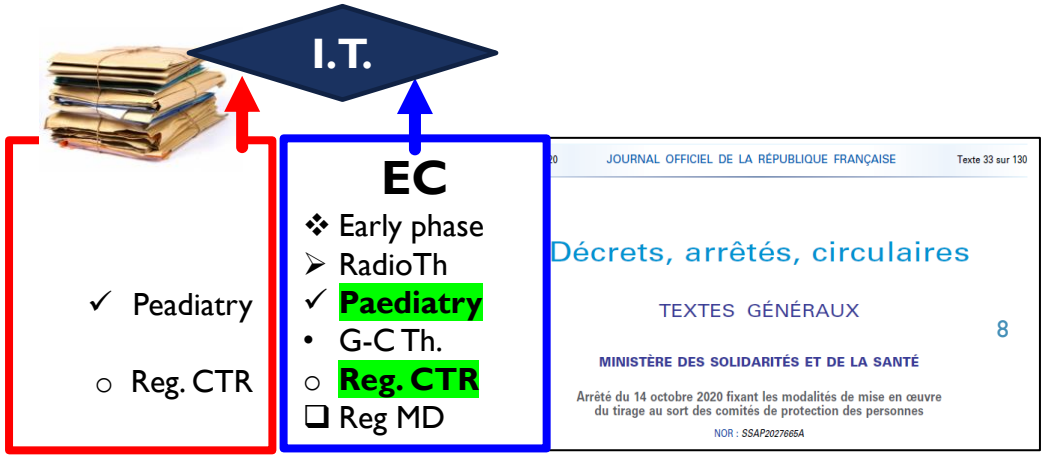
Selection of the Ethics committee with the soonest meeting

Prioritisation of 'EU' dossiers



➢ Necessary competence of the EC

- Characterictics of the dossier (declared by applicant)
- Competence declared by the EC in the I.T.



France : Adaptive measures for Ethics Committees in the CTR context

3. Review of the dossier by EC : independently by EC and NCA, with cooperation

- EC: . assessment by rapporteur and collegial discussion.
  - All the EC members receive the dossier through the I.T.
  - Videoconference with at least the compulsory Quorum of members
    - 7 members for interventional trials
    - 5 membres for low-intervention trials
  - Perspectives:
    - 2 meetings per month (1 plenary, 1 ‚restricted' meeting)
    - 2 „parallel subcommittees" ?
    - Strengthening the secretariat

- Interaction . with UE CTIS and NCA :

  . Contact points identified

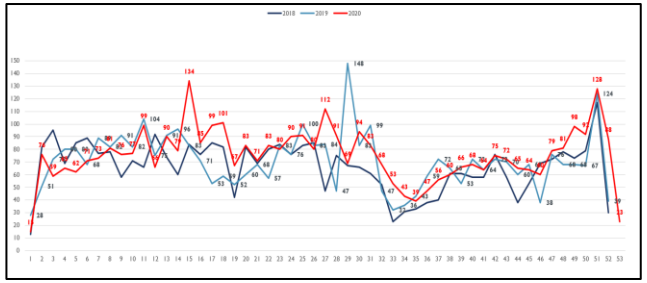
  . EC Contribution in english in the context of the RMS report

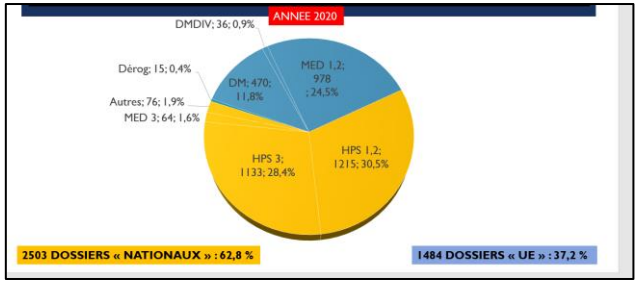
  . Interface and Interoperability between UE CTIS, EC IT and ANSM systems

France : Challenges for Ethics Committees in the CTR context

4. Supervision, preparation and trainings

4.1. Indicators, Follow-up and by the MOH Coordinating Unit





4.2. National Pilot phase

- Set up in **September 2015,** in conjunction with ethics committees (CPP), academic and industrial sponsors https://www.ansm.sante.fr/Activites/Medicaments-et-produits-biologiques/Phase-pilote-application-du-Reglement-UE-N-536-2014-du-Parlement-europeen/(offset)/10
- **Oct 2019**: **Focus on EC - NCA cooperation within [10+26D]**

4.3. Harmonization and Trainings

Member State preparedness and national aspects
Ethics commmittees in France

Thank you for your attention!

Questions ?

Pierre-Henri Bertoye

DOI
https://dpi.sante.gouv.fr/dpi-public-webapp/app/recherche/declarant, Declaration n°88663, 09/06/2020

Acknowledgements
- Ms Claire Bahans, (ChairP CPP Sud-Ouest 4, CNRIPH, VP CNCP)
- Ms Virginie Rage, (VP CPP Sud-Med 4, CNRIPH, ChairP CNCP)
- Ms Marie-Amélie Eudeline (VP CPP Sud-Est 4, CNRIPH)

- The 39 Ethics Committees in France
- Coordination Unit, DGS – PP1, MOH
- ANSM