

# Clinical trials: a standardised self-assessment tool to reduce the multiple risks of the pharmaceutical circuit

E. Delavoipière(1), C. Bouglé(2), L. Bernard(3), R. Chevrier(4), B. Lortal(5), F. Peyron(6), F. Renon-Carron(7), B. Thielemans(8), A. Thole(9), F. Divanon(10), A. Alix(1)

(1) Centre Hospitalier Universitaire (CHU) de Caen Normandie – Caen – France, (2) Observatoire du Médicament, des Dispositifs médicaux et de l'Innovation Thérapeutique de Normandie – Caen – France, (3) CHU de Clermont-Ferrand – Clermont-Ferrand – France, (4) CLCC d'Auvergne Jean Perrin – Clermont-Ferrand – France, (5) CLCC Institut Bergonié – Bordeaux – France, (6) Assistance Publique Hôpitaux de Marseille Hôpital Nord – Marseille – France, (7) CHU de Limoges – Limoges – France, (8) CHU de Lille – Lille – France, (9) CLCC Eugène Marquis – Rennes – France, (10) CLCC François Baclesse – Caen – France

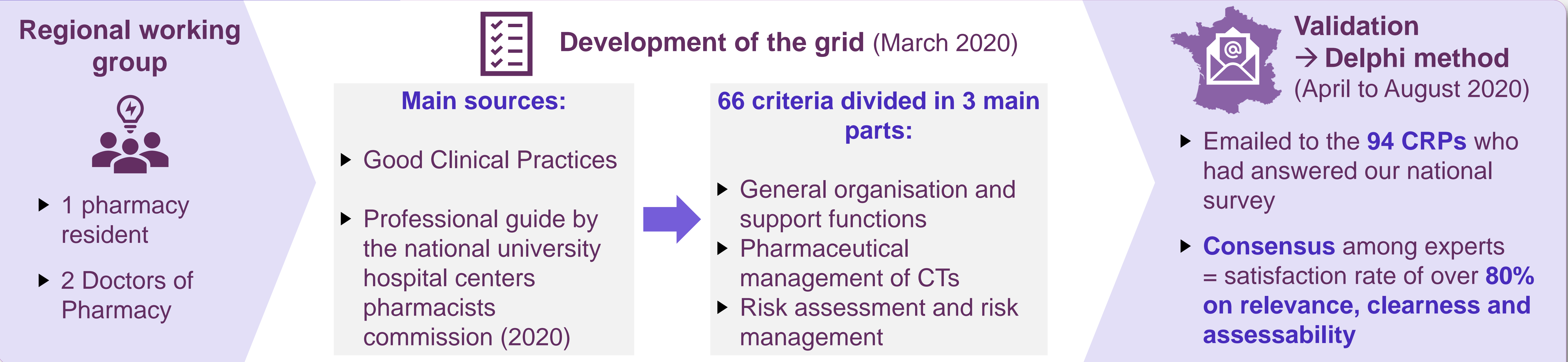
## Background and importance

- ▶ Despite a strict regulatory framework of **clinical trials (CTs)**, **few standardised tools** are available
- ▶ According to our national survey conducted in 2020:
  - ▶ **Quality approach** → initiated by all **clinical research pharmacists (CRPs)**, but very **heterogeneous** and **more implemented** in the university hospital centers and cancer centers, with a **high activity level**
  - ▶ 88/94 CRPs are interested by **new standardised tools** for the **investigational health products (IHPs) circuit**
  - ▶ The most **useful** tool is the **self-assessment grid**, according to 94% of CRPs
- We developed such a tool to **manage specific risks of IHPs** (complex protocols, assignment of treatment numbers, confusing labelling...)

## Aim and objectives

- ▶ Create a **standardised self-assessment grid** to manage the **specific risks of IHPs**

## Materials and methods



## Results

2 rounds of proofreading:	1 <sup>st</sup> round (15 April to 15 May 2020)	2 <sup>nd</sup> round (18 June to 14 August 2020)
Number of criteria	66	64
Number of proofreaders (per type of facilities)	16 (7 Cancer centers + 4 University hospital centers + 3 Non-university hospitals + 2 Not-for-profit private hospitals)	8 (5 Cancer centers + 3 University hospital centers)
Participation rate	17% (16/94)	50% (8/16)
Rate of consensual criteria on relevance, clearness and assessability	85% (56/66)	89% (57/64)
Consensus rate on deletion of criteria	Not applicable	75% (3/4)
Number of revised criteria	36 modifications, 4 deletions, 2 additions	18 modifications, 2 deletions, 0 addition

→ Validation of the **final version** of the grid, including **62 criteria**

## Conclusion and relevance

- ▶ This **interactive tool** will be distributed in a free public online **“CTs” toolbox**
- ▶ It will provide a **conformity score per process**, allowing specific risks to be identified across the circuit of IHPs, by pharmacies in any health care facility, whatever the level of activity

Niveau de conformité	
<b>I. Organisation générale et fonctions supports</b>	<b>72%</b>
A. Organisation générale	50%
B. Ressources humaines	75%
C. Ressources matérielles	67%
D. Système d'Informations et gestion documentaire	90%
E. Communication et confidentialité	95%
<b>II. Gestion pharmaceutique des essais cliniques</b>	<b>69%</b>
A. Initiation de l'essai clinique	28%
B. Traçabilité et comptabilité	93%
C. Approvisionnement, réception et stockage	85%
D. Prescription et dispensation	73%
E. Préparation des produits expérimentaux	NA
F. Retours et destruction	45%
G. Clôture, facturation et archivage	65%
H. Gestion de l'aveugle	90%
<b>III. Evaluation et gestion des risques</b>	<b>33%</b>
A. Evaluation du circuit	64%
B. Gestion des risques a posteriori	45%
C. Gestion des risques a priori	13%
D. Actions d'amélioration	10%
<b>Pourcentage de conformité globale :</b>	<b>58%</b>

