

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

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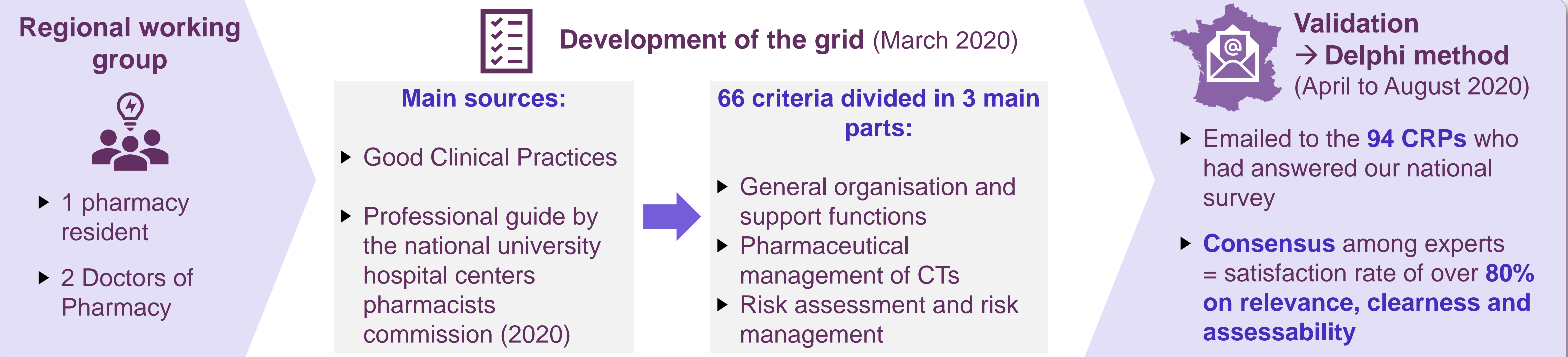
Background and importance

- ▶ 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 st round (15 April to 15 May 2020)	2 nd 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	
I. Organisation générale et fonctions supports	72%
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%
II. Gestion pharmaceutique des essais cliniques	69%
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%
III. Evaluation et gestion des risques	33%
A. Evaluation du circuit	64%
B. Gestion des risques a posteriori	45%
C. Gestion des risques a priori	13%
D. Actions d'amélioration	10%
Pourcentage de conformité globale :	58%

