Clinical trials: a standardised selfassessment 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 – 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

Regional working group



- ► 1 pharmacy resident
- ► 2 Doctors of Pharmacy



Development of the grid (March 2020)

Main sources:

- Good Clinical Practices
- Professional guide by the national university hospital centers pharmacists commission (2020)



66 criteria divided in 3 main parts:



- General organisation and support functions
- Pharmaceutical management of CTs
- Risk assessment and risk management



Validation → Delphi method (April to August 2020)

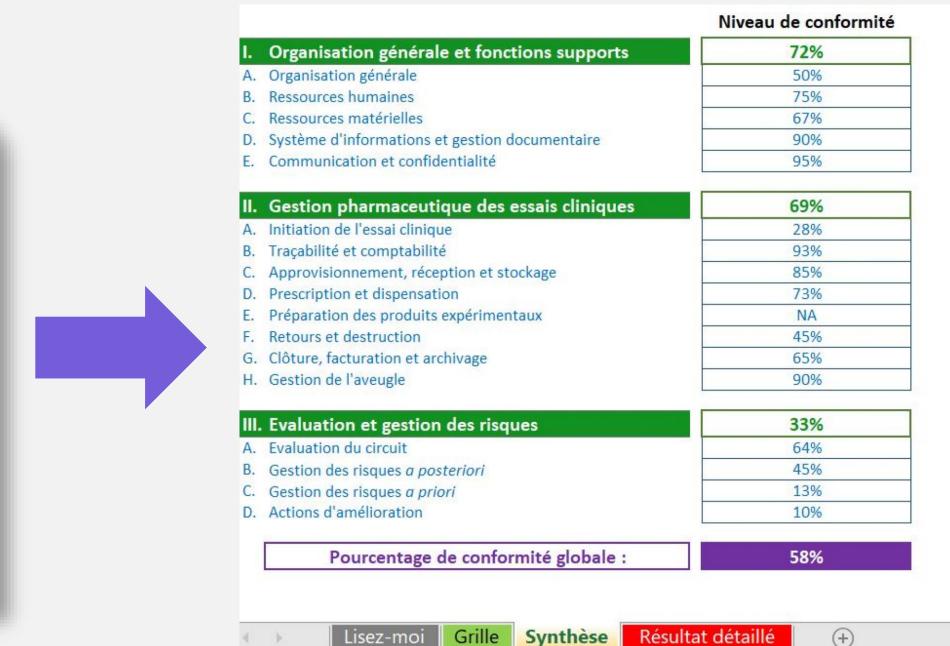
- ► Emailed to the 94 CRPs who had answered our national survey
- Consensus among experts = satisfaction rate of over 80% on relevance, clearness and assessability

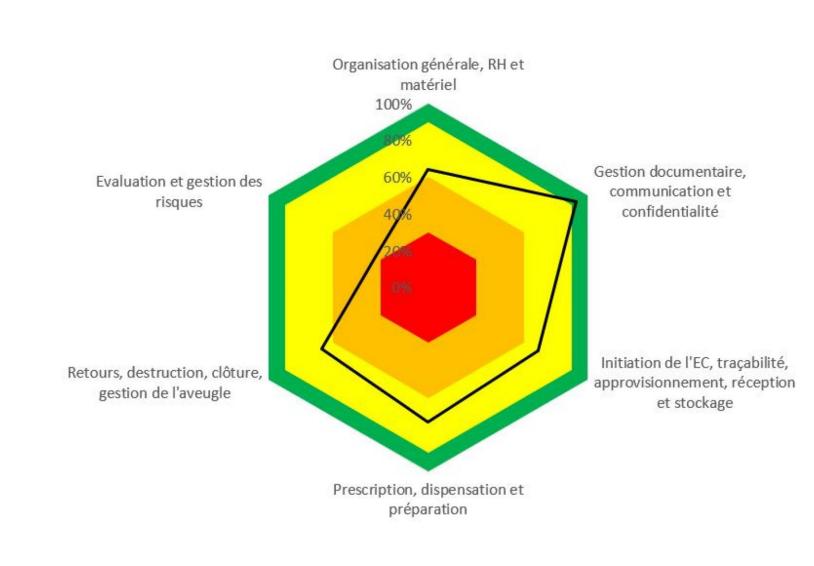
Results

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







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