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

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

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:

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

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