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

- 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

<table>
<thead>
<tr>
<th>2 rounds of proofreading:</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</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(per type of facilities)</td>
<td>16</td>
<td>8</td>
</tr>
<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

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

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