

Management of experimental health products in hospital pharmacies: a national survey

E. Delavoipière(1), C. Bouglé(2), M. Daouphars(3), N. Donnadiou(4), L. Bernard(5), R. Morello(1), J. Montreuil(1), F. Divanon(6), 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) Centre de Lutte contre le Cancer (CLCC) Henri Becquerel – Rouen – France, (4) CHU de Rouen Normandie – Rouen – France, (5) CHU de Clermont-Ferrand – Clermont-Ferrand – France, (6) CLCC François Baclesse – Caen – France

Background and importance

- ▶ **Management of investigational health products (IHPs)** = major part of conducting **clinical trials (CTs)**
- ▶ **Specific risks** all along the circuit, with data integrity and patient safety issues
- ▶ But **few standardised tools** available and no national inventory has been conducted in hospital pharmacies

Aim and objectives

- ▶ Make an **inventory** of the current situation in **French hospital pharmacies** → prioritise risk reduction **standardised tools** to develop

Materials and methods

Regional working group:

- ▶ 4 clinical research pharmacists
- ▶ 1 pharmacist of the regional drug observatory
- ▶ 1 pharmacy resident



76 questions

- ▶ Quality approach
- ▶ Proposal of new tools



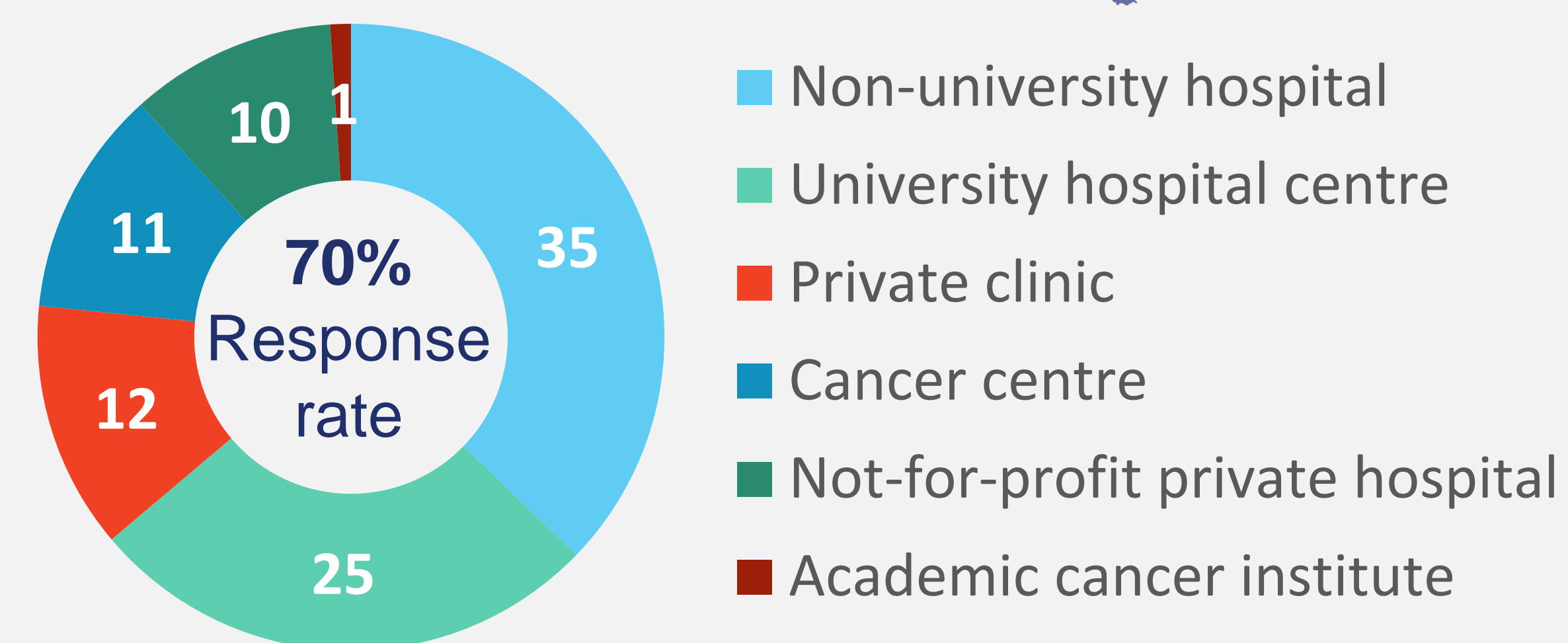
Dissemination

- ▶ Online anonymous survey
- ▶ Emailed to clinical research pharmacists in health facilities
- ▶ Activated from 11 December 2019 to 31 January 2020

Results

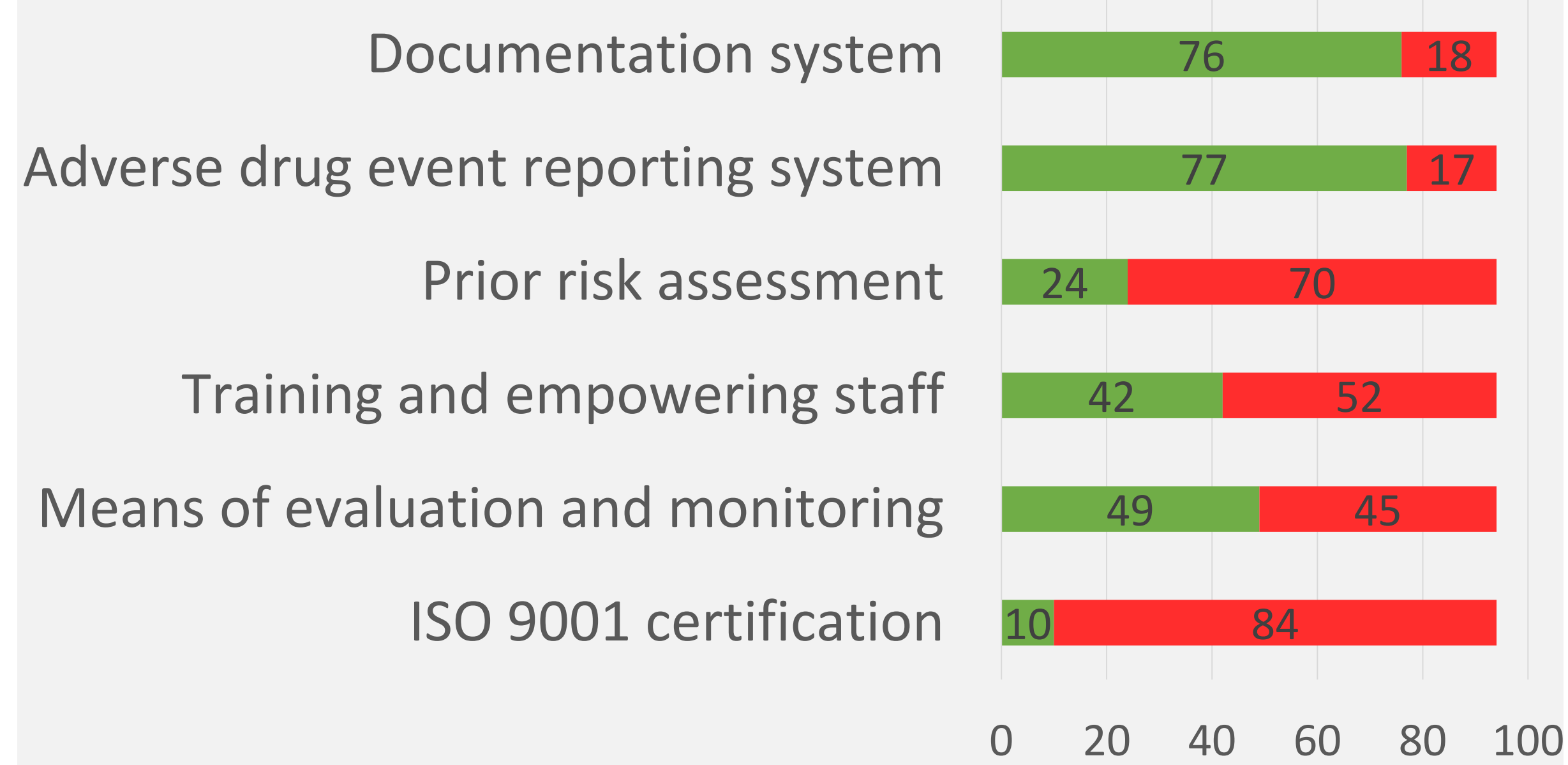
94 participating pharmacists

12 regions



Features of quality approach

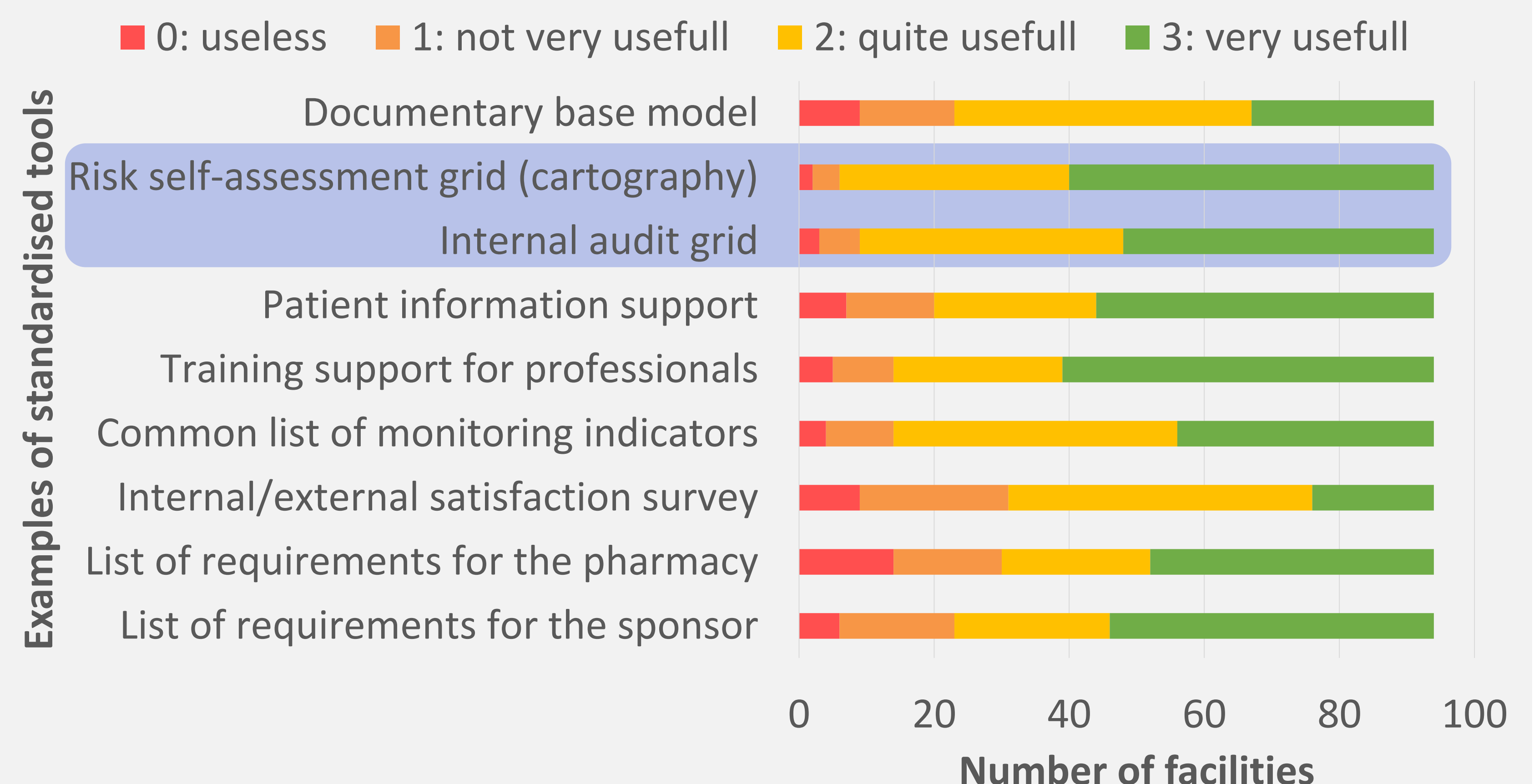
Yes No



Overall results of the 94 participating hospital pharmacies on the components investigated by the survey

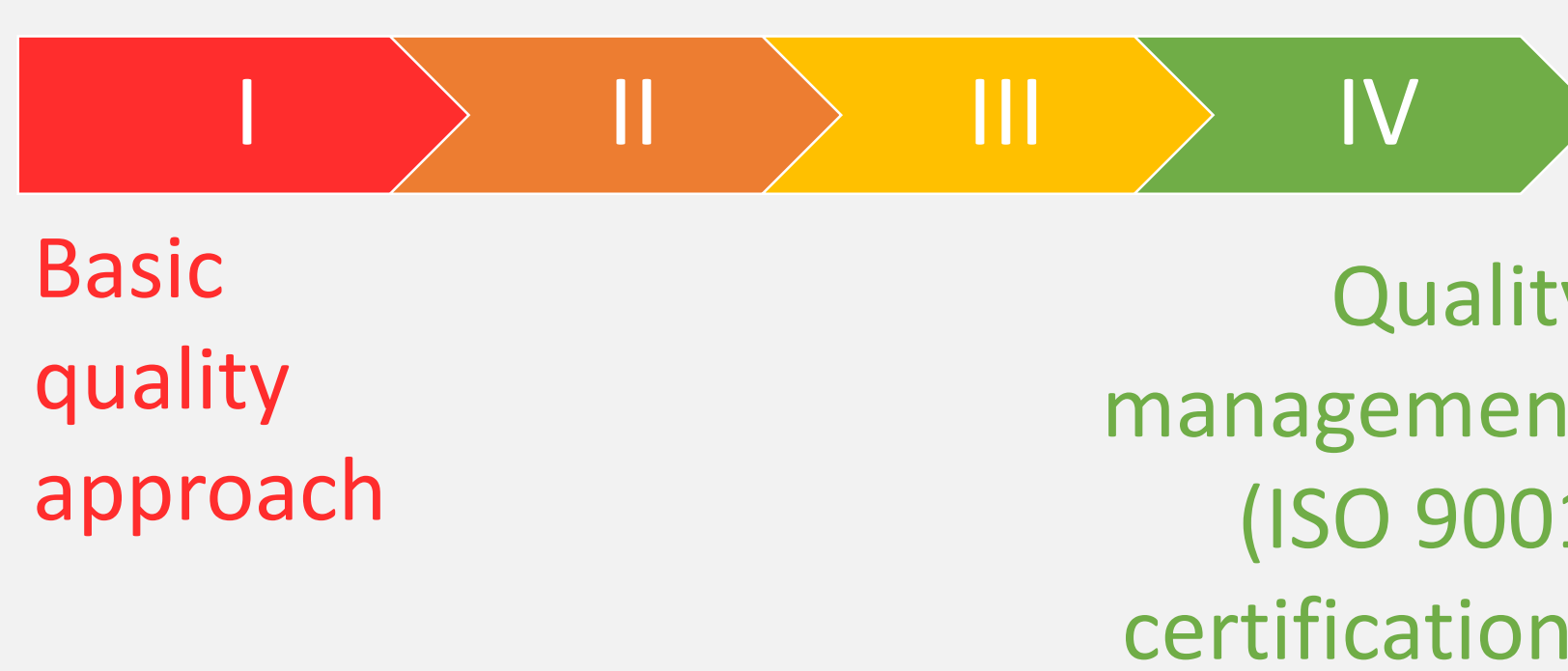
Tools: expectations and needs

88/94 pharmacists interested



Distribution of the utility scores attributed by the 94 pharmacists to each standardised tool proposed

Overall score of quality approach



- ▶ **Score II** is the **most frequent** (38/94)
- ▶ The score:
 - ▶ depends on the **type of health facility** ($p < 0,0005$)
 - ▶ increases with the **number of active CTs** ($p < 0,0005$)

Conclusion and relevance

- ▶ All types of facilities conducting CTs represented + response rate → **overall interest** in this topic of **IHPs' management**
- ▶ **Quality approach = heterogeneous** in hospital pharmacies, more implemented in the university hospital centres and cancer centres, with a high **activity level**
- ▶ Needs identified → **2 tools prioritised** : **self-assessment and traceability audit grids**, soon to be validated and disseminated
- ▶ Such tools will help to **upgrade practices** in hospital pharmacies by identifying the specific risks and improving the IHPs' circuit