

Adoption and Challenges of Electronic Clinical Outcome Assessments and Patient-Reported Outcomes in China: Insights from a Survey of Healthcare Professionals and Industry Stakeholders

RWD188

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BACKGROUND

- The role and advantages of patient experience data including clinical outcome assessments (COA) data in clinical trials and real-world studies have been emphasized in the guidance from FDA¹ and CDE².
- As data collection tools transition from paper-based to electronic implementation, the concept of "patient-centered" has been reinforced^{1,3}.

OBJECTIVES

- To assess the current utilization, challenges, and potential solutions for eCOA/ePRO in China.
- To provide suggestions for enhancing the future implementation of eCOA/ePRO tools and promote the development of patient-focused clinical care.

METHODS

- Study design:** Cross-sectional electronic survey (Sep 24 – Dec 24, 2024).
- Participants:** There are **1,146** participants in total, including 8.8% from hospitals, 7.5% from sponsors, 6.7% from medical technology companies, and 76.6% from Contract Research Organizations/Site Management Organizations (CRO/SMO), among which 70.7% are Clinical Research Coordinators (CRC) and 5.9% are others.
- Sampling:** Snowball sampling based on an on-line questionnaire.
- Questionnaire Domains:** 1) Basic information; 2) eCOA/ePRO usage; 3) User experience; 4) Difficulties and challenges; 5) Future trends and plans.
- Statistical analysis:** Descriptive statistics and subgroup analyses.

RESULTS

Main values of COA/PRO

- Besides **evaluating treatment efficacy and quantifying patient feeling** as the most prominent value (Figure 1), COA/PRO is also considered valuable for **providing timely treatment feedback**, especially for hospital stakeholders.

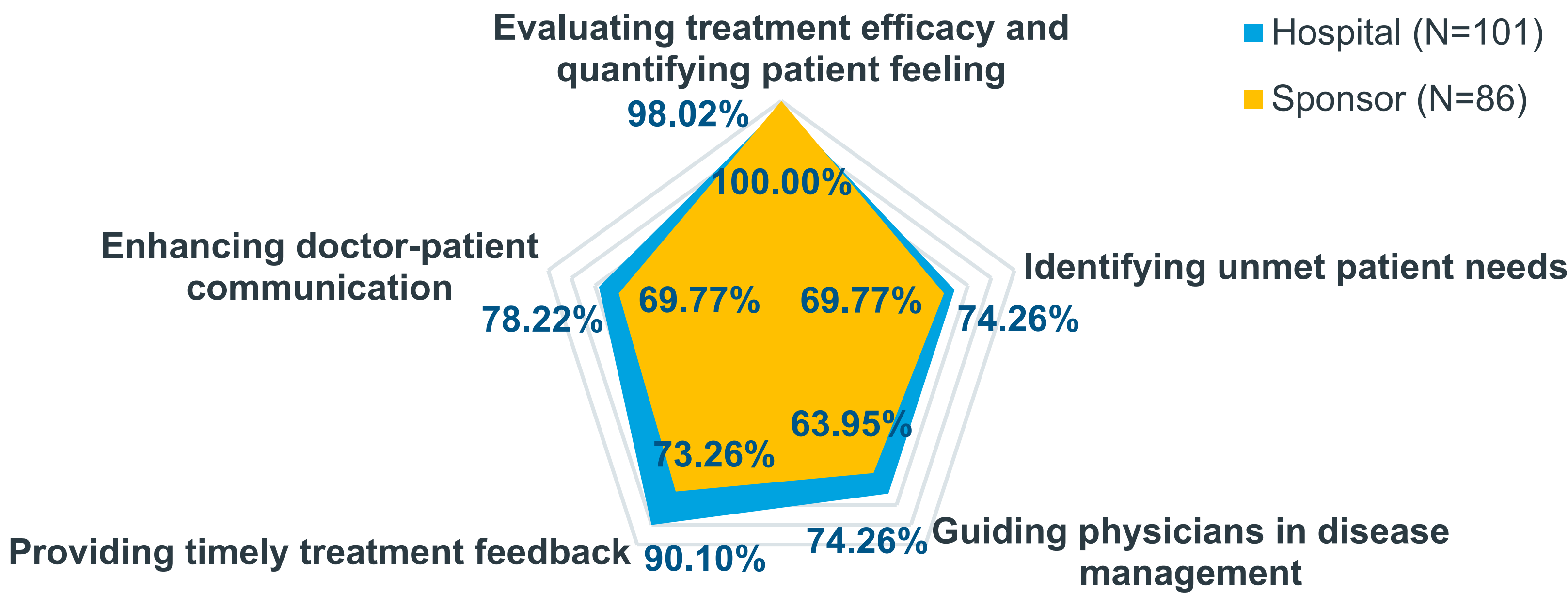


Figure 1. Main values of COA/PRO

User satisfaction & Future trends and plans

- Among the users of eCOA/ePRO from hospitals and sponsors, **68%** and **66%** are satisfied with the eCOA/ePRO tools, respectively.

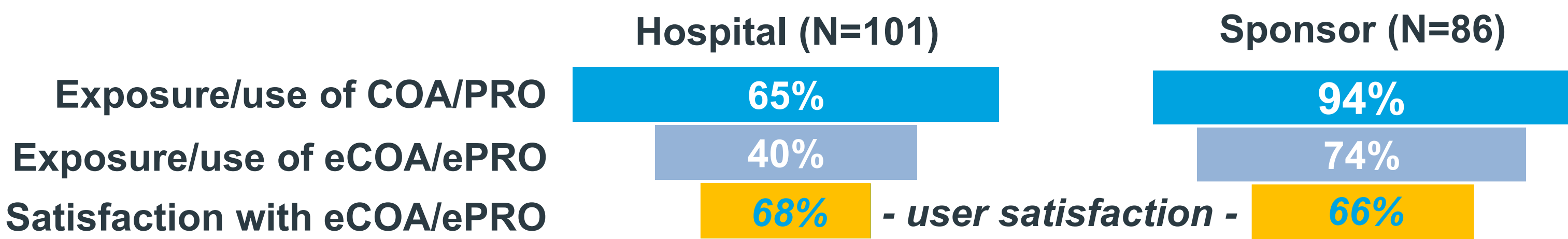
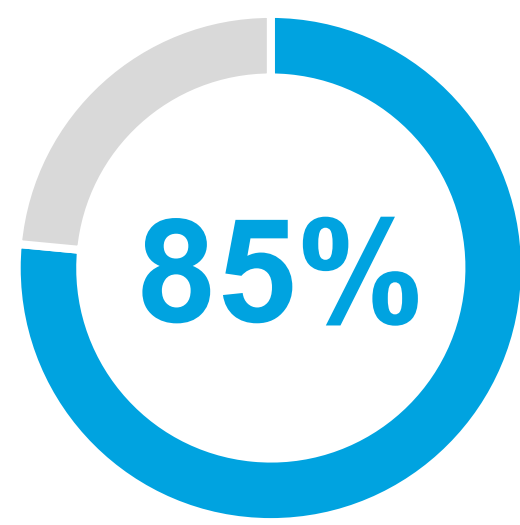


Figure 2. User satisfaction



- Among participants from hospitals and sponsors (N=187), **85%** expect to use eCOA/ePRO in the future.

CRO: Contract Research Organization **CRC:** Clinical Research Coordinator **PRO:** Patient-Reported Outcome
SMO: Site Management Organization **COA:** Clinical Outcome Assessment **eCOA:** Electronic Clinical Outcome Assessment
ePRO: Electronic Patient-Reported Outcome

Challenges in eCOA/ePRO utilization

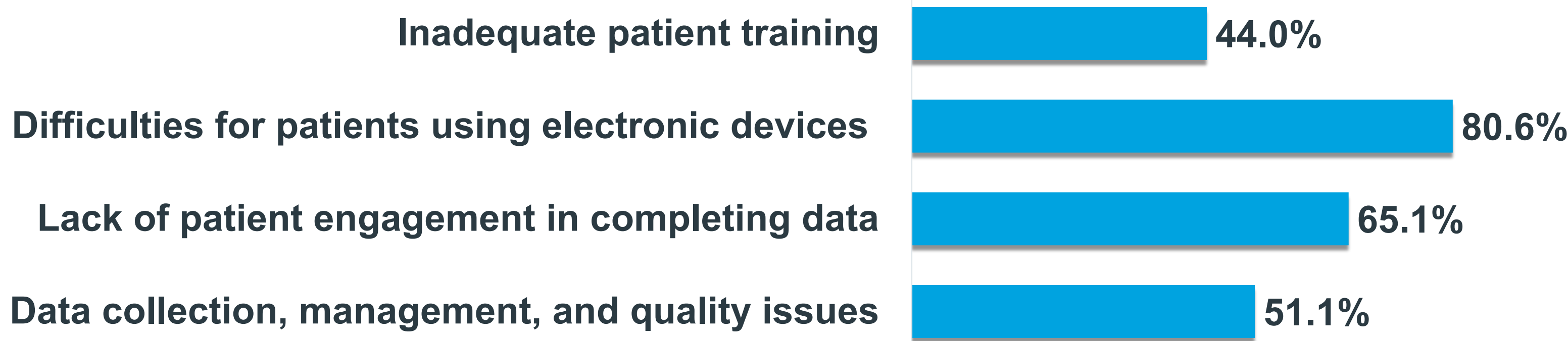


Figure 3. Challenges in eCOA/ePRO utilization (N=1146)

- Major challenges for sponsors:** data collection, management, and quality issues.
- Major challenges for hospitals:** patient engagement in data completion, patients' difficulties in using electronic devices, and inadequate patient training.

Aspects of eCOA/ePRO tools needing improvement

- For eCOA/ePRO tool improvements, sponsors demand **better localization** and **user interface** more, while hospitals need **stronger technical support** and **platform compatibility** more.

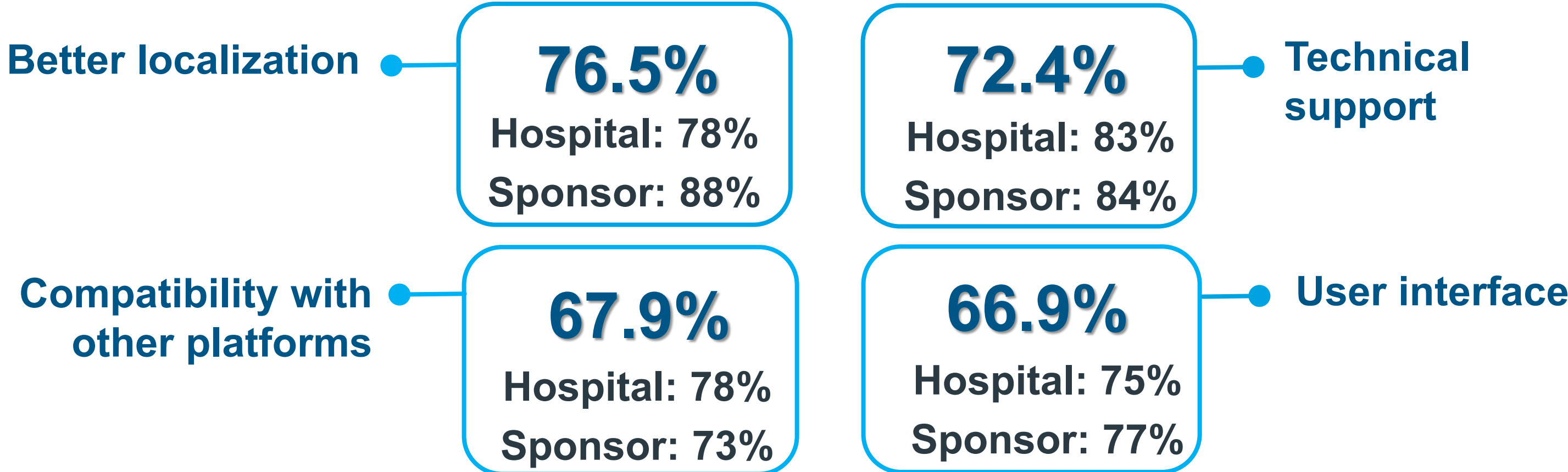


Figure 4. Aspects of eCOA/ePRO tools needing improvement (N=1146)

Industry's focus on ethical/regulatory considerations

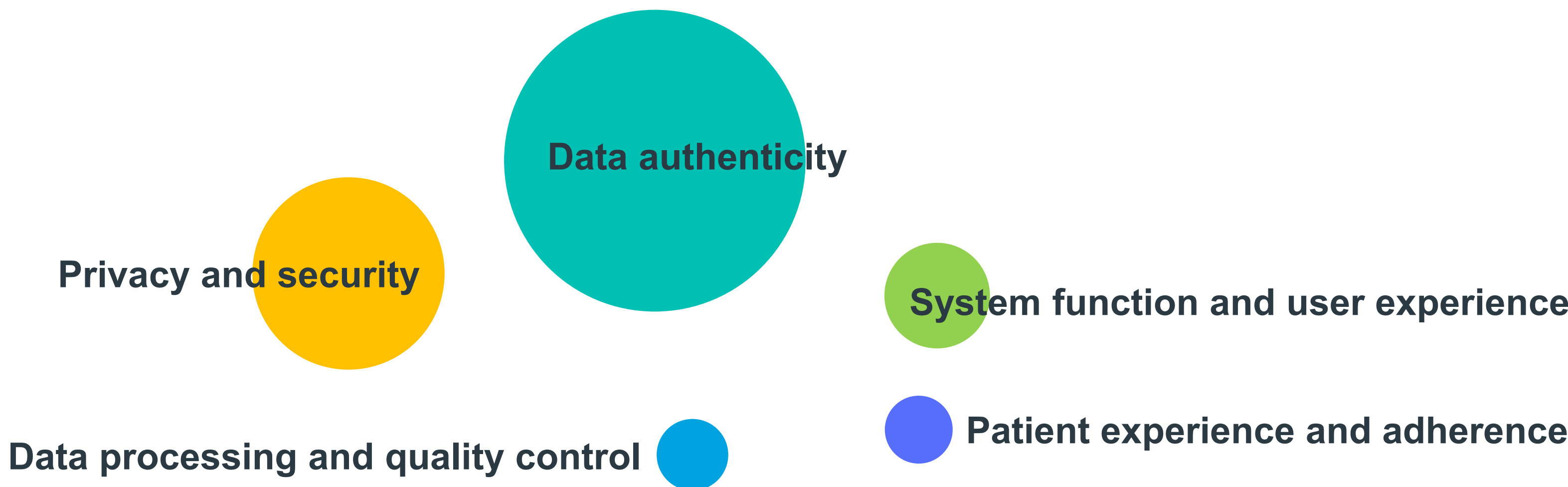


Figure 5. Industry's focus on ethical/regulatory considerations (N=1146)

CONCLUSION

- This study demonstrates widespread recognition of COA/PRO's clinical value and high satisfaction with eCOA/ePRO implementations among Chinese professionals, indicating strong potential for future adoption despite existing challenges.
- The findings highlight the critical need for **enhanced localization, robust technical support, ensured data integrity and safety, and seamless integration with existing systems** to optimize the use of eCOA/ePRO in China, laying the groundwork for patient-centered clinical practices.

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