Advancing into the formal quality of informed consent process of clinical trials with medicinal products approved by the ethics committee at a university hospital

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Voluntariness and Ethics

Clear and structured information is essential for voluntary and ethical participation in clinical trials (1).

Study objective

To evaluate the quality of participant information sheets / informed consent formularies (PIS/ICF), identify deficiencies, and propose corrective measures to enhance transparency in clinical trial communication.

Methodology

Document Evaluation

The formal quality of PIS and ICF in 60 clinical trials approved in 2023 was evaluated.

Design

Cross-sectional study with validated checklists (AEMPS) and descriptive statistical analysis (2,3).

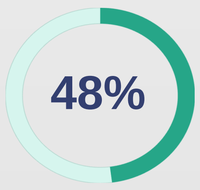
Main Results

92.4%
PIS Compliance
High compliance in Participant Information Sheets.

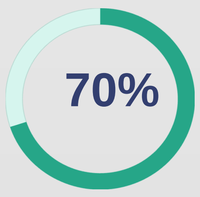
79.9%
ICF Compliance
Level of compliance in Informed Consent Forms.

61-96.4%
Sponsor Variability
Compliance rate between 61% and 96.4%, indicating inconsistencies.

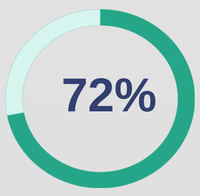
Identified Deficiencies



Incomplete description of study benefits.



Insufficient mention of confidentiality in the use of secondary data.



Omission of detailed visit schedules.

Proposed Improvement Actions

Feedback Protocol

Systematic communication between ethics committees and sponsors to address deficiencies.

Training Program

Comprehensive training in informed consent drafting according to AEMPS guidelines.

Annual Quality Review

Implementation of a review system with updated evaluation checklists.

Conclusions

Standardization of templates and periodic updates of evaluation checklists aligned with current AEMPS guidelines are required to prevent the recurrence of deficiencies and ensure sustained improvement in the formal quality of participant information.

References

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