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CLINICAL SITES DIGITALIZATION IN A COMPREHENSIVE ITALIAN MAP

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BACKGROUND

In a context of significant technological and scientific changes, resulting from the past experience of the COVID-19 pandemic emergency, digitalization plays an important role in the evolution of the conduct of clinical trials in Italy. The digital transformation of healthcare represents an impressive opportunity to address the challenges in the field of clinical research and can enhance Italy's competitiveness in the field. The level of digitalization of medical records, that refers to the degree to which a healthcare facility has transitioned from using paper-based records to electronic health records (EHRs) or digital systems, in experimental sites (sites) is one of the key indicators requiring an in-depth investigation. In clinical research, a high level of digitalization enables more efficient and compliant management of the source documents (SDs), facilitating audits, monitoring activities, and regulatory inspections.
The aim of the study was to evaluate the level of digitalization among sites involved in clinical trials in Italy using a comprehensive questionnaire.

METHODOLOGY

This survey was delivered by Working Group Clinical Trial Center of Italian Association of Contract Research Organizations (AICRO) between January 2024 and December 2024. The Working Group includes members from both Contract Research Organizations (CROs) and Clinical Trial Centers (CTCs) of clinical sites. A web-based N-item questionnaire was developed, using REDCap as a factorial design survey (FDS) platform.

RESULTS

The survey was sent to 66 sites, obtaining a response rate of 59.0%(39). Among the responders, a total of 27 (69.2%) facilities are located in the North, 5 (12.8%) in the Center, 7 (18.0%) in the South (Figure 1). Additionally, 19 facilities (48.7%) are classified as Scientific Institute for Research, Hospitalization and Healthcare (IRCCS), (Figure 2).
The roles of responders are: Clinical Research Coordinator/Data Manager (21, 53.8%), Investigator (5, 12.8%), QA Manager, (4, 10.2%), IT Manager, (6, 15.4%) and other roles (3, 7.8%) (Data Scientist, General Manager, and Pharmacist).
Of the sites 33 (84.6%) report having mixed SDs while 2 (5.1%) use completely paper-based SDs and only 4 (10.3%) use completely electronic SDs (Figure 3).
Among the sites with mixed and completely paper-based SDs, 25 (78.3%) of them are currently reorganizing their processes to address the digitalization of medical records within the next 1-5 years. Considering sites with mixed and completely electronic SDs, 18 (48.7%) of them have clinical diaries that require a digital signature, of which 83.3% are validated. Most electronic medical records (28, 75.7%) allow the entry of structured data in addition to free text (Figure 4).
In sites with mixed SDs, some SDs are still managed in paper format, with a variety of documents such as ECGs (16, 48.5%), pharmacy documentation (13, 39.4%), and vital signs monitoring forms (12, 36.4%) that have not yet been fully digitalized. Currently, only 4 sites allow Remote Source Data Verification with direct access to the electronic medical record. In 40% of the sites, the electronic medical record has been evaluated during audits/inspections.

CONCLUSION

In conclusion, the level of digitalization of clinical research sites in Italy remains relatively low (Figure 3), posing challenges in data integration, source document management, and regulatory compliance, however it represents a pivotal step towards enhancing healthcare delivery and improving patient outcomes. The comprehensive mapping of digitalization levels and the utilization of informatic systems highlights both the progress made and the challenges that remain. As Italy continues to embrace innovative technologies, understanding these dynamics will be crucial for policymakers and stakeholders to ensure that all sites can leverage digital solutions effectively.

Figure 1

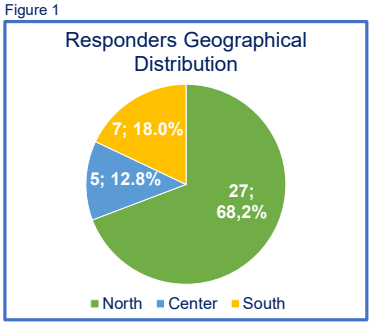


Figure 2

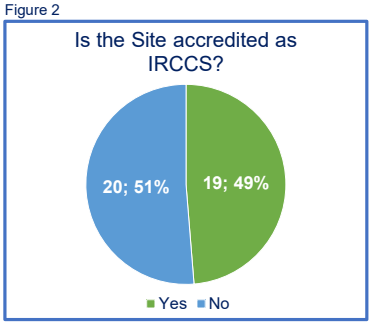


Figure 3

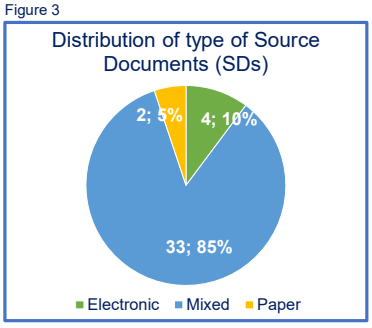
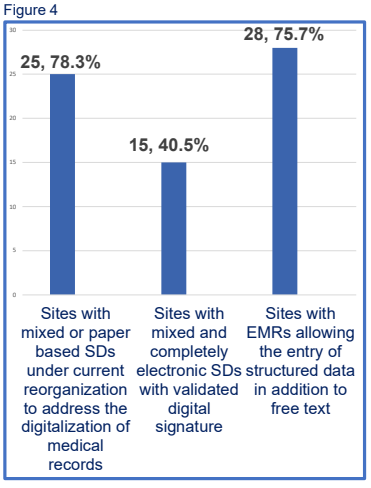


Figure 4



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