

IMPLEMENTATION OF AN INTEGRATED SOFTWARE FOR CLINICAL TRIALS MANAGEMENT AND AUTOMATED PREPARATION OF INVESTIGATIONAL DRUGS IN HOSPITAL PHARMACY

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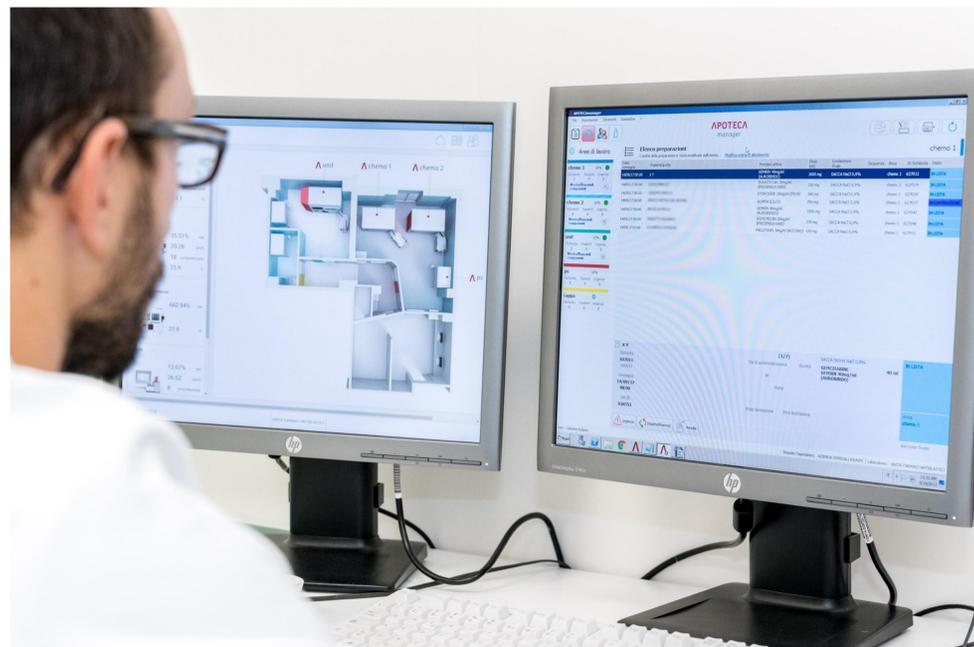
BACKGROUND

In conducting clinical trials (CT), the hospital pharmacy is responsible for receiving, handling, and dispensing investigational drugs, while ensuring high level of quality.

All CT-related data have to be documented and reported in compliance with the CT protocol and Good Clinical Practice (ICH-GCP); thereby encouraging the implementation of an information technology system to support and improve the CT management.

PURPOSE

This pilot study was aimed at evaluating the effectiveness of a software specifically designed to manage cancer CT in hospital pharmacy and fully integrated into the APOTECA platform (Loccioni, Italy) for the automated preparation of injectable drugs.



MATERIAL AND METHODS

The software was installed in the pharmacy-based CT unit in July 2018. The ongoing cancer CT protocols, the investigational drugs, the individual patient data, the sponsor and investigator data were entered in the software database. Detailed reports were recorded including the delivery to the CT site, the inventory at

the CT site, the drug use per patient, the accountability, and the return to the sponsor or alternative disposition of unused investigational drugs.

Any changes to the CT protocol were traced. In addition, through the integration with the APOTECA platform, individually prescribed doses for parenteral

administration were prepared by means of the supporting device for manual preparation APOTECAs (Loccioni, Italy), which verifies dose accuracy by gravimetric control and ensures the drug identification by photographic recognition.

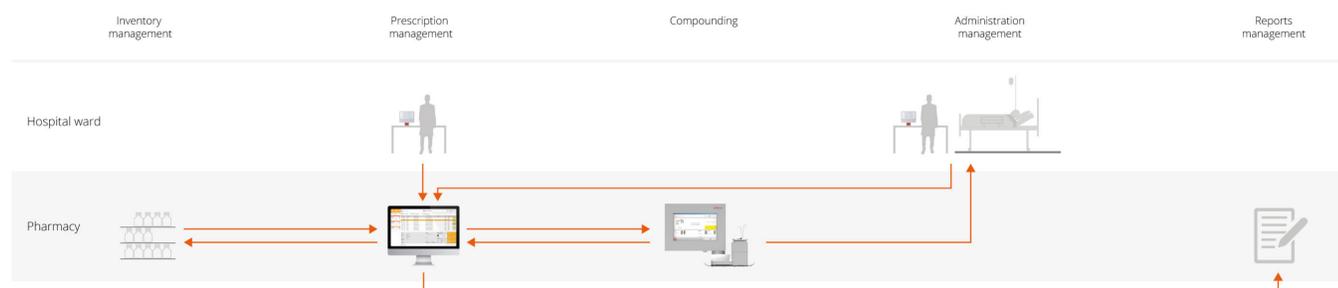
RESULTS

Two months after the installation, about 20% of the 60 ongoing cancer CT were managed through the software, involving overall 25 patients. In total, 10 investigational drugs were entered, of which four for oral administration and six injectable drugs.

Overall, 39 individually prescribed doses were manually prepared by using APOTECAs. The average dose error amounted to 1.56% ranging from 0.13% to 4.29%.

The automated data handling and record keeping were ensured thus improving

quality in the preparation process and reports traceability. The centralized management of all documents reduced the data-entry activity of the pharmacy staff and minimized human errors.



CONCLUSION

The software for managing cancer CT in hospital pharmacy was successfully implemented, thereby encouraging the insertion of

further CT protocols. The next step is the integration with the Oncology Electronic Health Record.