

INTEGRATION OF CLINICAL TRIALS MANAGEMENT INTO A SAFE AND FULLY-AUTOMATED ONCO-HAEMATOLOGY WORKFLOW

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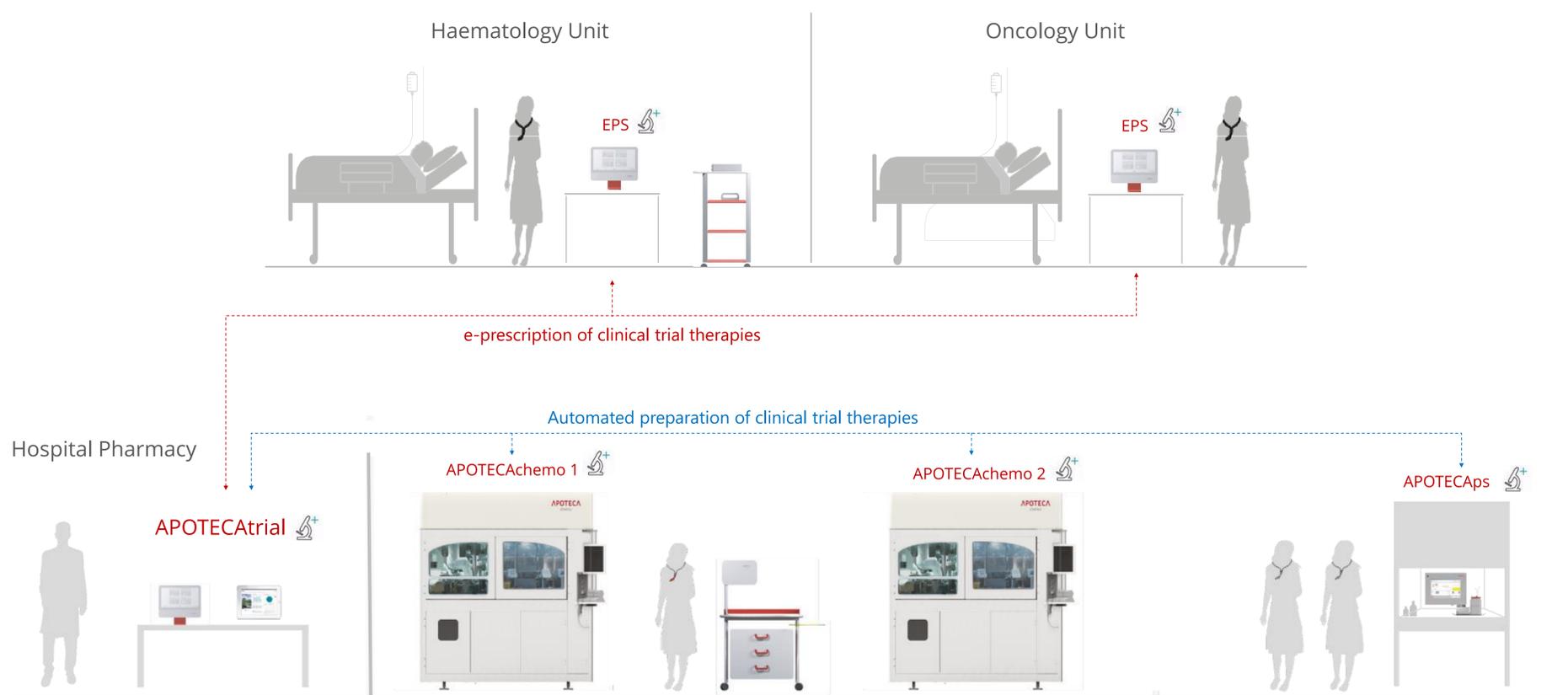
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WHAT WAS DONE?

In 2018, a clinical trial (CT) managing system (APOTECAtrial) was integrated into the existing fully-automated workflow of the chemotherapy production unit. APOTECAtrial was developed to enable real-time visualization of CT-related data and trace the processing of investigational (IMP) and non-investigational (NIMP) medical products, such as delivery, assignment, preparation, return, and disposal.

WHY WAS DONE?

The management of CT requires thorough documentary evidence and well-organized reporting system in compliance with the Good Clinical Practice. Since 2009, the entire onco-haematology workflow is fully-controlled by information technology devices and robotic systems to prevent medication errors and guarantee data integrity. The implementation of APOTECAtrial was aimed to extend the same level of control to CTs.



WHAT HAS BEEN ACHIEVED?

Since 2018, the following results were obtained:

- 95 clinical trials managed
- 81 IMPs/NIMPs and 135 patients entered into the system
- 2,740 injectable therapies prepared
- 690 oral medications and 60 pre-filled syringes delivered

Additional major objectives achieved were:

- automated inventory accounting and stock management
- reduced manual time-consuming activities (i.e. documentation)
- standardized reports in digital not-editable format
- full traceability of all operations

In addition, audit trail tool tracks all user edits and changes performed at any stages of the CTs management by electronically recording user's name, date, and time.

APOTECAtrial was evaluated by clinical research associates (CRA), clinical research organizations (CRO) and CTs sponsors and approved for use in the daily clinical practice.

HOW WAS DONE?

A team of hospital pharmacists, physicians, clinical data managers, and IT specialists analysed the CT workflow and defined the system specifications. Data related to IMP/NIMPs (both for parenteral and oral administration), patients enrolled, and investigator/sponsor affiliations were entered into APOTECAtrial and sorted by CT. The onco-haematology unit's electronic prescribing system (EPS) was bidirectionally interfaced with APOTECAtrial. Aseptic preparation of patient-specific injectable therapies was implemented in the supporting device for manual preparation (APOTECAs) that checks dosage accuracy and identity by photographic and barcode recognition.

WHAT NEXT?

The project represents a good example of multidisciplinary collaboration focused on improving the quality of the processes in healthcare settings. The implementation of information technology and automation ensures improved data integrity, safety, and working efficiency, which are key determinants for managing CTs in hospital pharmacies.