Introduction

Issues concerning inadequate source data of clinical trials rank second in the most common findings by regulatory authorities. The increasing use of electronic clinical information systems (CIS) by healthcare providers offers an opportunity to facilitate and improve the conduct of clinical trials and the source documentation.

Methods

In 2011/2012 a set of tools was developed and implemented into the CIS of the University Hospital Zurich (USZ) to support clinical research, including;

1: a trial registry for documenting metadata on the clinical trials conducted at the hospital,
2: a patient-trial-assignment-tool to tag patients in the electronic medical charts as participants of specific trials,
3: medical record templates for the documentation of study visits and trial related procedures,
4: online queries on trials and trial participants,
5: access to the electronic medical records for clinical monitors,
6: an alerting tool to notify researchers of hospital admissions of trial participants,
7: queries to identify potentially eligible patients in the planning phase as trial feasibility checks and during the trial as recruitment support, and
8: pre-defined sets of orders for vital signs, laboratory analyses, drug prescriptions and treatments to facilitate the complete and accurate performance of study visit procedures.

Results

The number of approximately 100 new registrations per year in the voluntary CIS trial registry now matches the numbers of the existing mandatory USZ trial registry. Likewise, the yearly numbers of patients tagged as trial participants as well as the use of the standardised trial record templates increased to 2073 documented trial-enrolments and over 200 reports generated/month in the year 2012. Accounts for 32 clinical monitors have been established in the first two years monitoring a total of 49 trials in 16 clinical departments. Within one year, 79 running trials (22% of all active trials registered in the CIS) have activated the hospital admission alert option, generating approximately 85 alerts per month.

Conclusion

The popularity of the presented CIS tools demonstrate their potential to facilitate the conduct of clinical trials. Future studies on monitoring and inspection findings will have to evaluate their impact on quality and safety.

Reference


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