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Tools in a Clinical Information System Supporting Clinical Trials at a Swiss University Hospital

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Background

- Issues concerning inadequate source data of clinical trials rank 2nd 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 (1)

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:

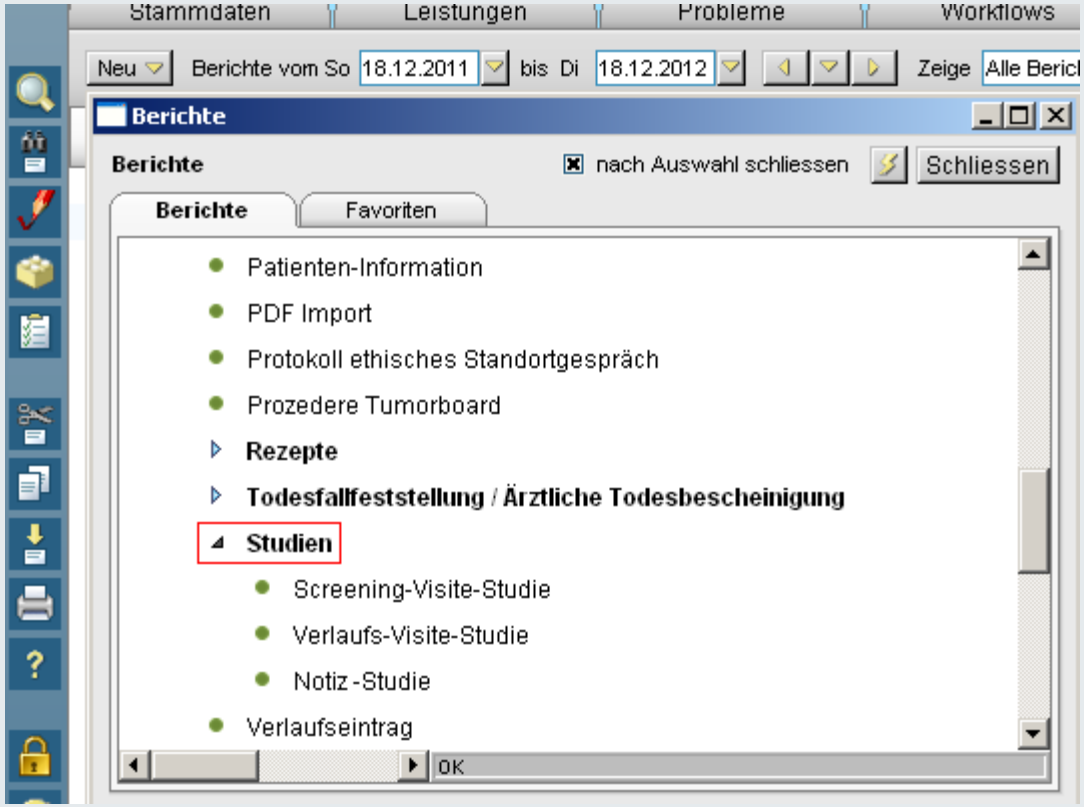
- a **trial registry** for documenting metadata on the clinical trials conducted at the hospital,
- a **patient-trial-assignment-tool** to tag patients in the electronic medical charts as participants of specific trials,
- **medical record templates** for the documentation of study visits and trial related procedures,
- online **queries on trials** and trial participants,

Methods (2)

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:

- **access** to the electronic medical records **for clinical monitors**,
- an **alerting** tool to notify of **hospital admissions** of trial participants,
- queries to **identify potentially eligible patients** in the planning phase as **trial feasibility checks** and during the trial as recruitment support, and
- predefined **sets of orders** for vital signs, laboratory analyses, drug prescriptions and treatments to facilitate the complete and accurate performance of study visit procedures.

Medical record templates



Medical record templates

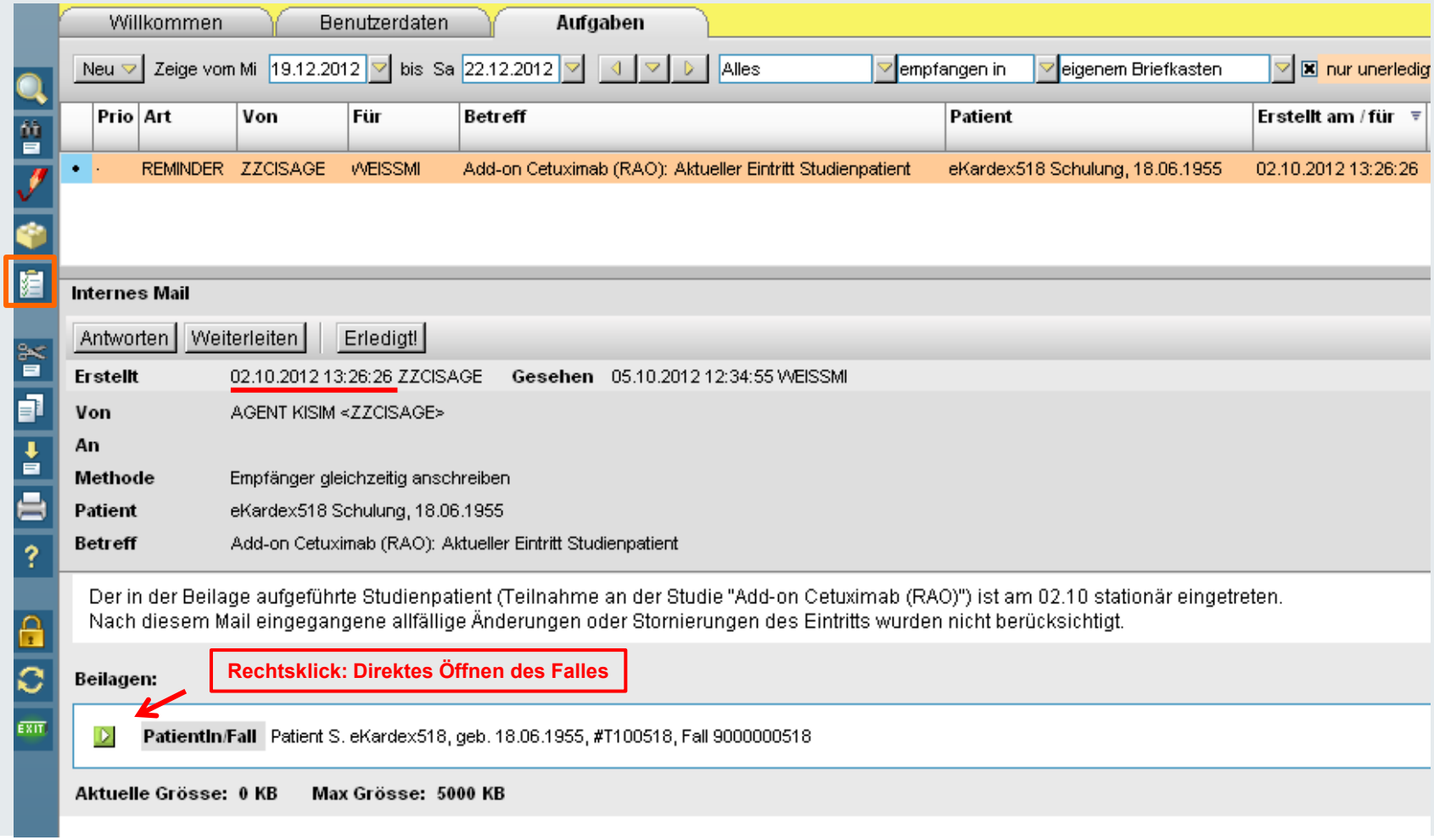
Hospital admission alert

= optional alert feature in the CIS to the Principal Investigator/Study Team Member about hospital admissions of trial participants

Background

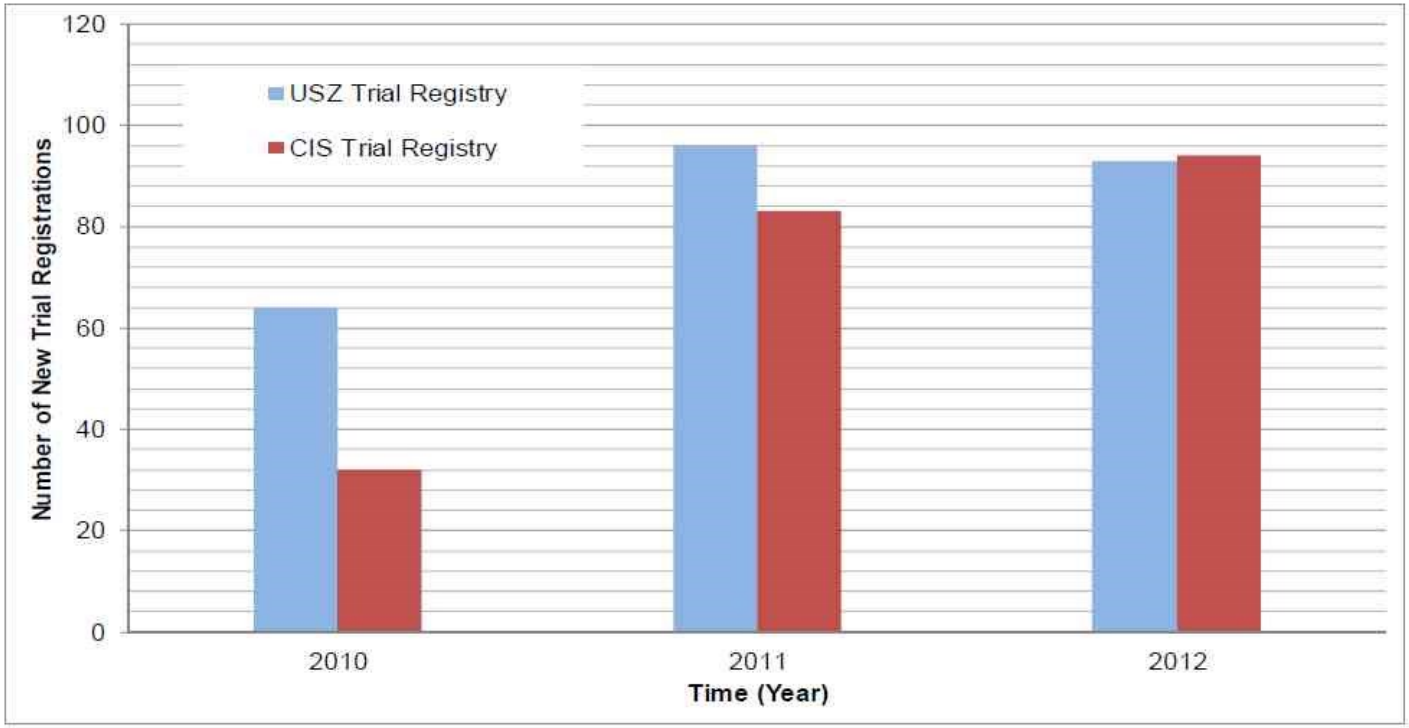
- Reporting duty: it is legally required by the „Humanforschungsgesetz“ HFG that serious adverse events (SAEs) occured in *clinical trials and non-clinical research projects* have to be reported in tight timlines to sponsor/regulatory authorities
- Safety: depending on the study intervention a timely contact between PI and treating physicians can be important in case of emergencies
- Design: Hospitalisations may be an study endpoint (e.g. re-hospitalisation studies) or hospitalisations should trigger study specific procedures (e.g. blood drawings in cohort studies)

Hospital admission alert



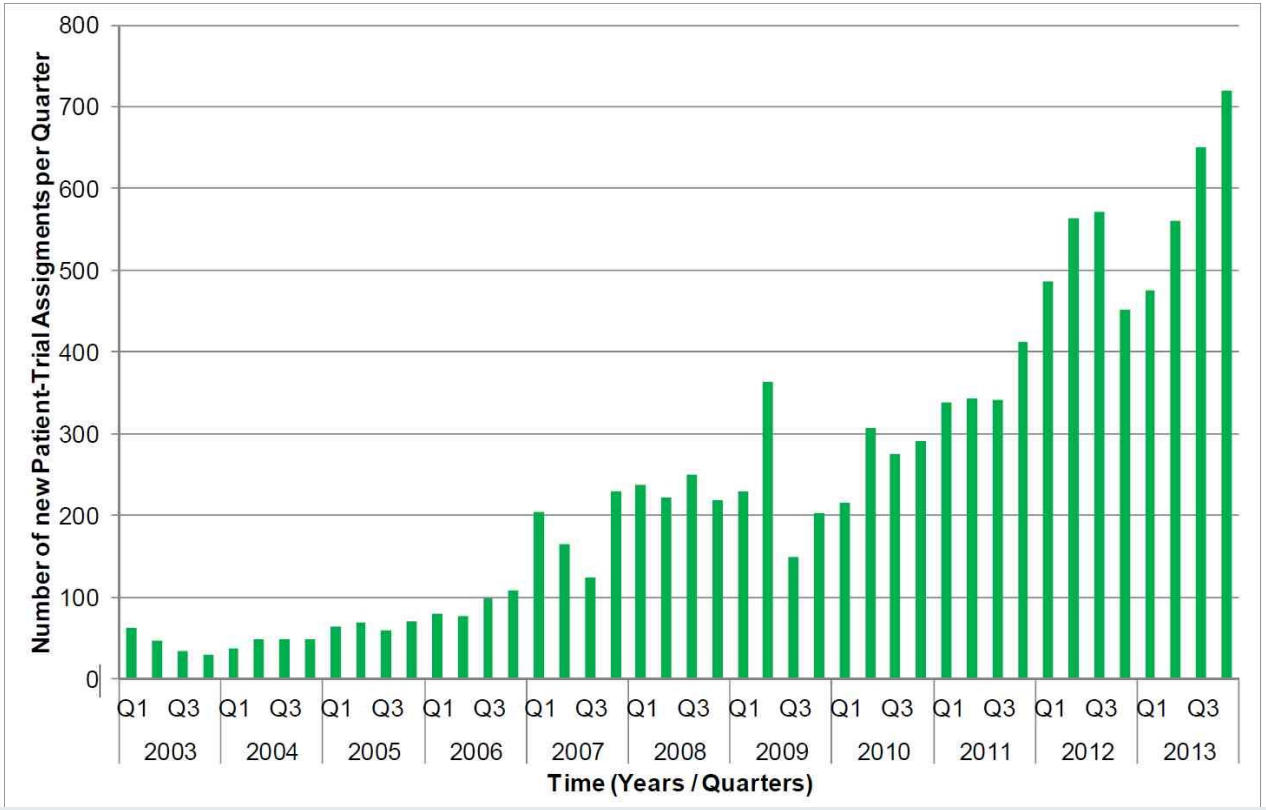
Results

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.



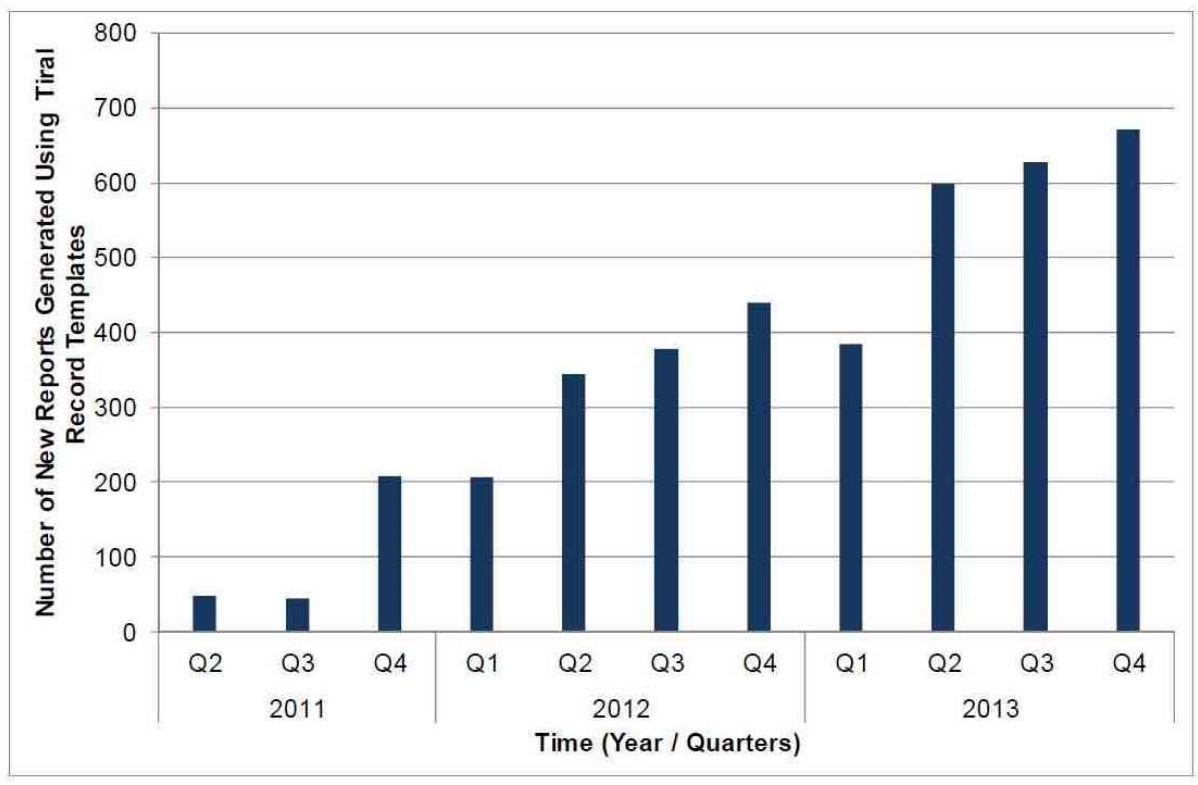
Results

The yearly numbers of **patients tagged as trial participants** increased to 2408 documented trial-enrolments the year 2013.



Results

The use of the **standardized trial record templates** increased to 190 reports generated/month in the year 2013.



Results

Access for clinical monitors:

Accounts for **32 clinical monitors** have been established in the first two years monitoring a total of **49 trials in 16 clinical departments**.

Hospital admission alerts:

Fifteen months after adding the optional feature of hospital admission alerts of trial participants, 107 running trials have activated this option, including **48 out of 97 studies (49.5 %) registered in the year 2013**, generating approximately **85 alerts per month**.

Conclusion

- The popularity of the presented CIS tools illustrates their potential to facilitate the conduct of clinical trials.
- The tools allow for enhanced transparency on trials conducted at the hospital.
- Future studies on monitoring and inspection findings may evaluate their impact on quality and safety.