

# eHealth Summit 2014, Bern

## 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 2<sup>nd</sup> 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:

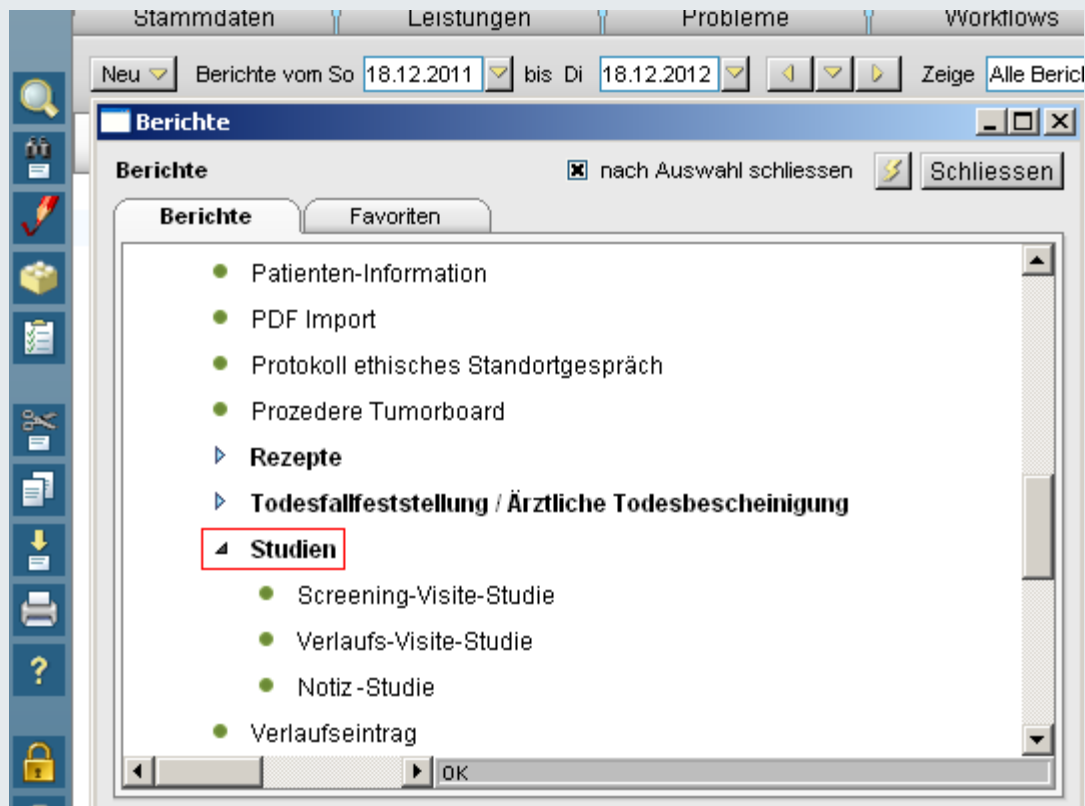
- a **trial registry** for documenting metadata on the clinical trials conducted at the hospital,
- a **patient-trial-assignment-tool** to tag patients in the electronic medical charts as participants of specific trials,
- **medical record templates** for the documentation of study visits and trial related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

Screening-Visite-  vom

Studienname:

Kurztitel:  KEK-Nummer:

Studienbeginn:  Studienende:

Kontaktperson:

Principal Investigator:

Cave/Hinweise:

Einschlusskriterien

Ausschlusskriterien

Abweichungen zum Studienprotokoll

Der Patient wurde vollumfänglich über die Studie aufgeklärt.

Der Patient hat die Einverständniserklärung unterzeichnet.

Anamnese

Medikamente

Externe Laborwerte

Status

Schwangerschaft  Ja  Nein  n.a.

Beschreibung der Visite:

Einschluss in Studie  Ja  Nein

Beilagen

*Fügen Sie ein Objekt hinzu, indem Sie es mit der Maus in dieses Feld ziehen!*

# Hospital admission alert

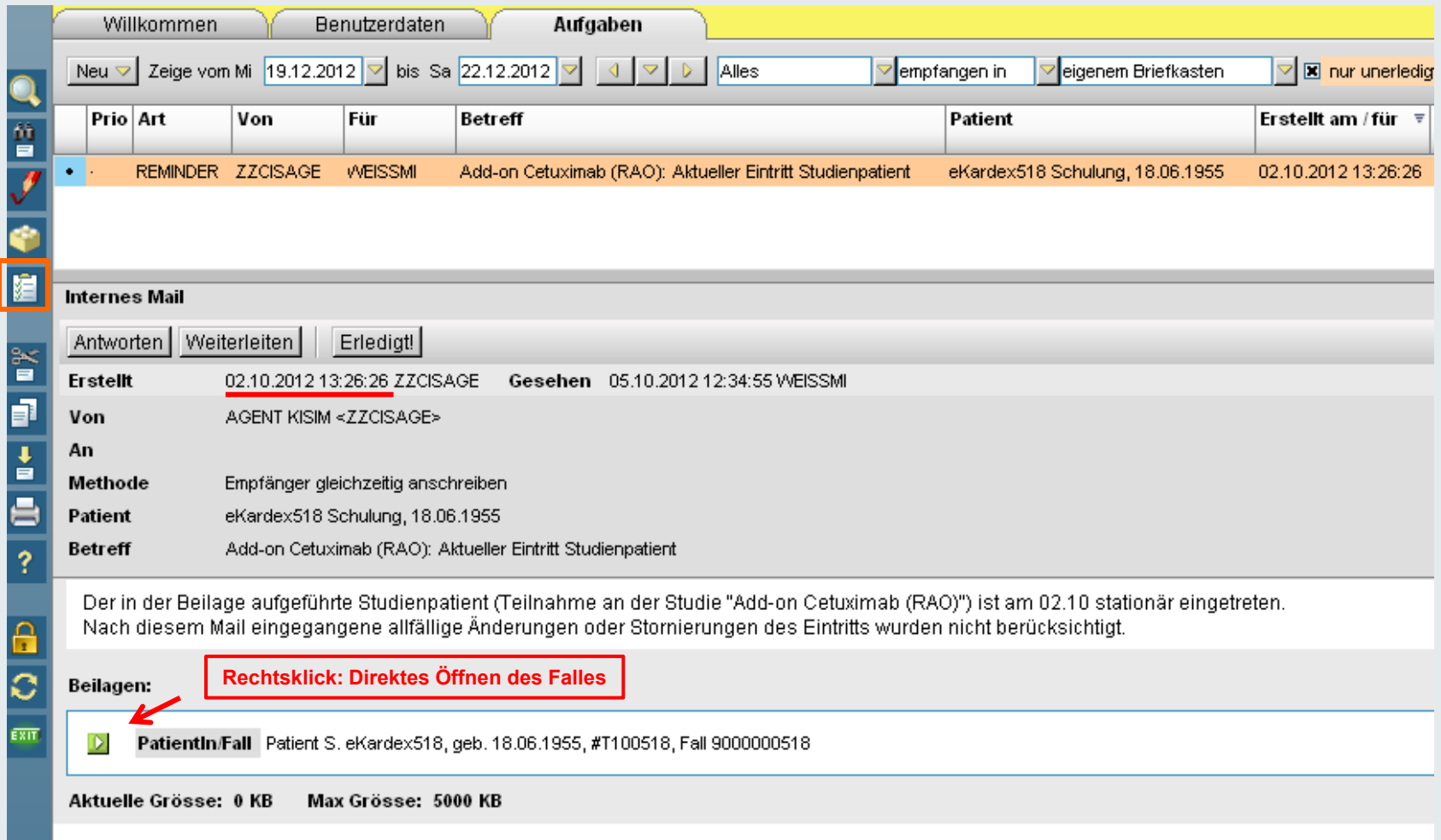
= optional alert feature in the CIS to the Principal Investigator/Study Team Member about hospital admissions of trial participants



## Background

- **Reporting duty:** it is legally required by the „Humanforschungsgesetz“ HFG that serious adverse events (SAEs) occurred in *clinical trials and non-clinical research projects* have to be reported in tight timelines 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



Willkommen Benutzerdaten **Aufgaben**

Neu Zeige vom Mi 19.12.2012 bis Sa 22.12.2012 Alles empfangen in eigenem Briefkasten  nur unerledigt

Prio	Art	Von	Für	Betreff	Patient	Erstellt am / für
	REMINDER	ZZCISAGE	WEISSMI	Add-on Cetuximab (RAO): Aktueller Eintritt Studienpatient	eKardex518 Schulung, 18.06.1955	02.10.2012 13:26:26

**Internes Mail**

Antworten Weiterleiten Erledigt!

**Erstellt** 02.10.2012 13:26:26 ZZCISAGE **Gesehen** 05.10.2012 12:34:55 WEISSMI

**Von** AGENT KISIM <ZZCISAGE>

**An**


**Methode** Empfänger gleichzeitig anschreiben

**Patient** eKardex518 Schulung, 18.06.1955

**Betreff** Add-on Cetuximab (RAO): Aktueller Eintritt Studienpatient

Der in der Beilage aufgeführte Studienpatient (Teilnahme an der Studie "Add-on Cetuximab (RAO)") ist am 02.10 stationär eingetreten. Nach diesem Mail eingegangene allfällige Änderungen oder Stornierungen des Eintritts wurden nicht berücksichtigt.

**Beilagen:** Rechtsklick: Direktes Öffnen des Falles

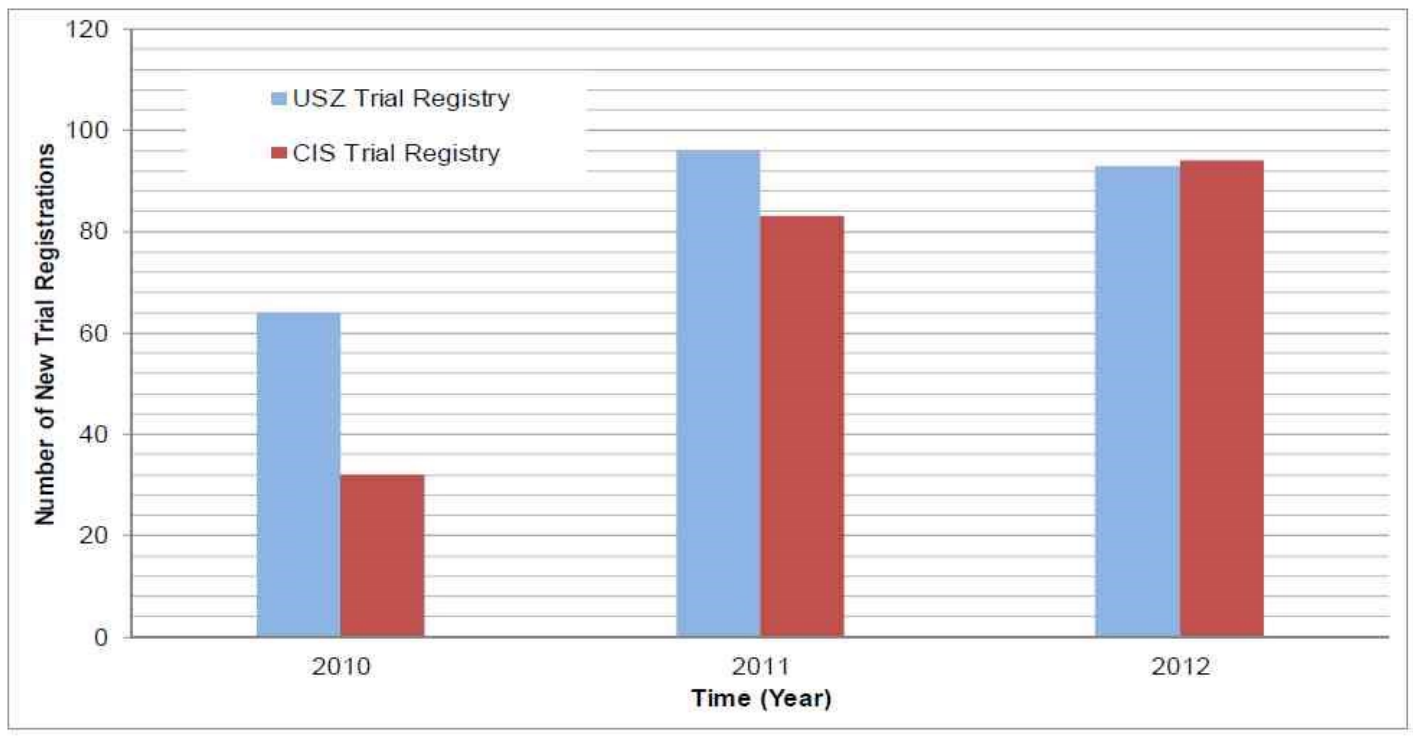
 **PatientIn/Fall** Patient S. eKardex518, geb. 18.06.1955, #T100518, Fall 9000000518

Aktuelle Grösse: 0 KB Max Grösse: 5000 KB



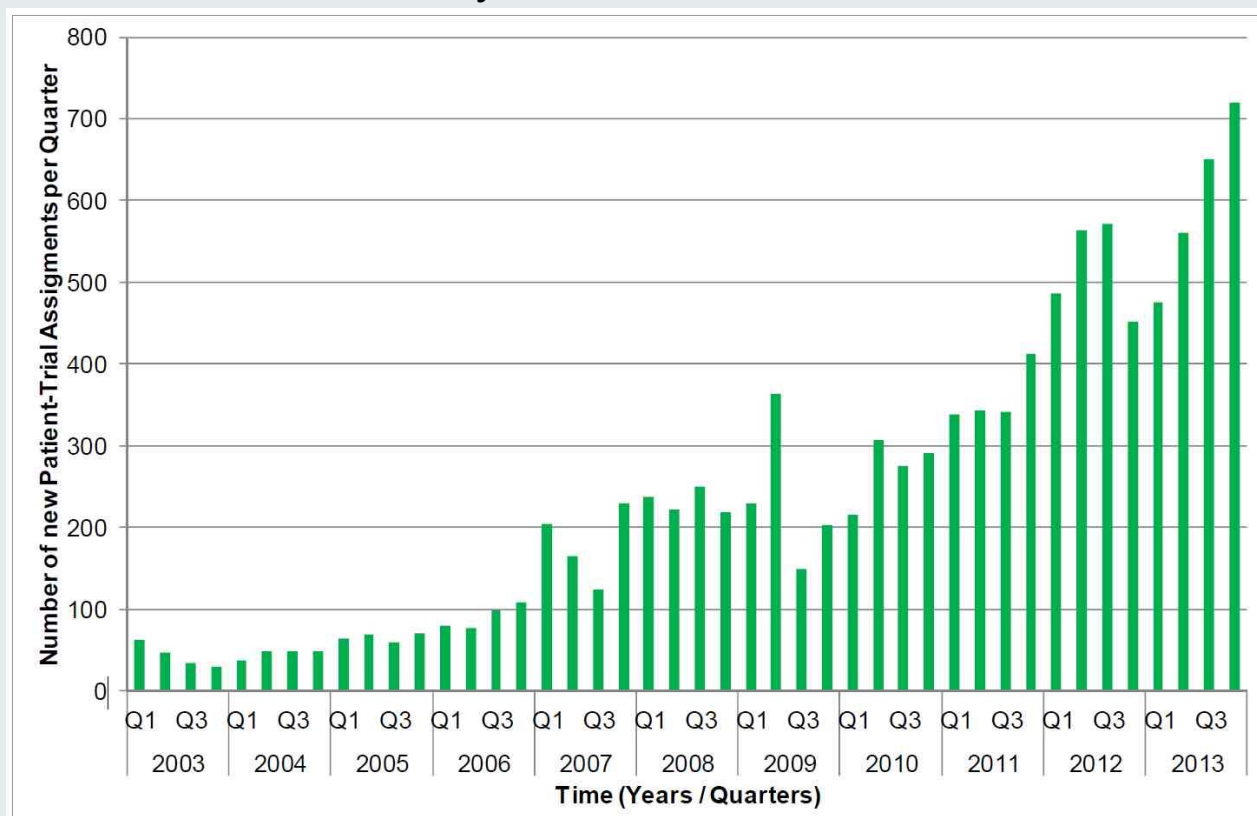
# Results

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.



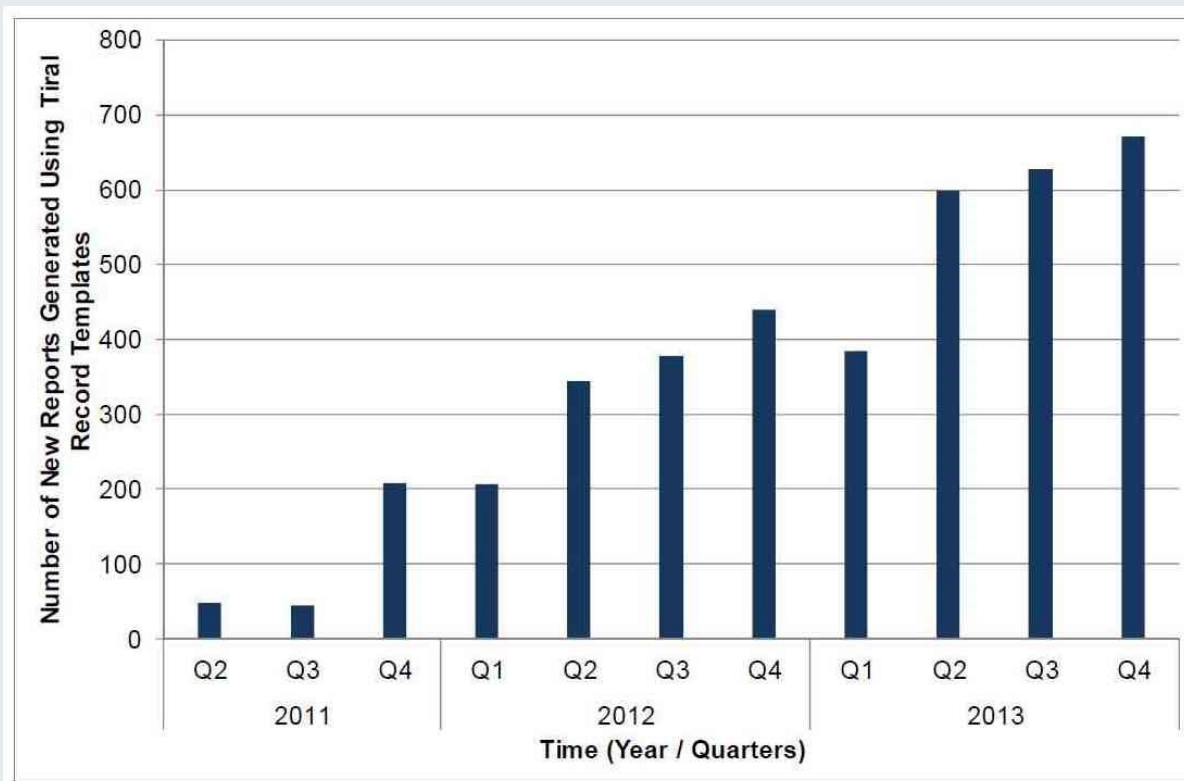
# Results

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.