

WESTFÄLISCHE  
WILHELMS-UNIVERSITÄT  
MÜNSTER

# KIS-basierte Unterstützung der Patientenrekrutierung in klinischen Studien

wissen.leben  
WWU Münster

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# Übersicht

- Patientenrekrutierung: Verbesserungspotenziale durch IT
- BMBF-/TMF-Projekt "KISREK"
- Internationale Sicht: IMI-Projekt "EHR4CR"
- Was können KIS-Softwarehersteller,  
Studienleiter und Studienärzte tun?

Patientenrekrutierung in klinischen Studien

# **VERBESSERUNGSPOTENZIALE DURCH IT**

## Lasagna's law (1979)

In clinical research the prevalence of any disease falls to about 10% of what you thought it was the day you start to look for cases for your study

[Lasagna L, Clin Pharmacol Ther. 1979; 25(5 Pt 2):751-3]

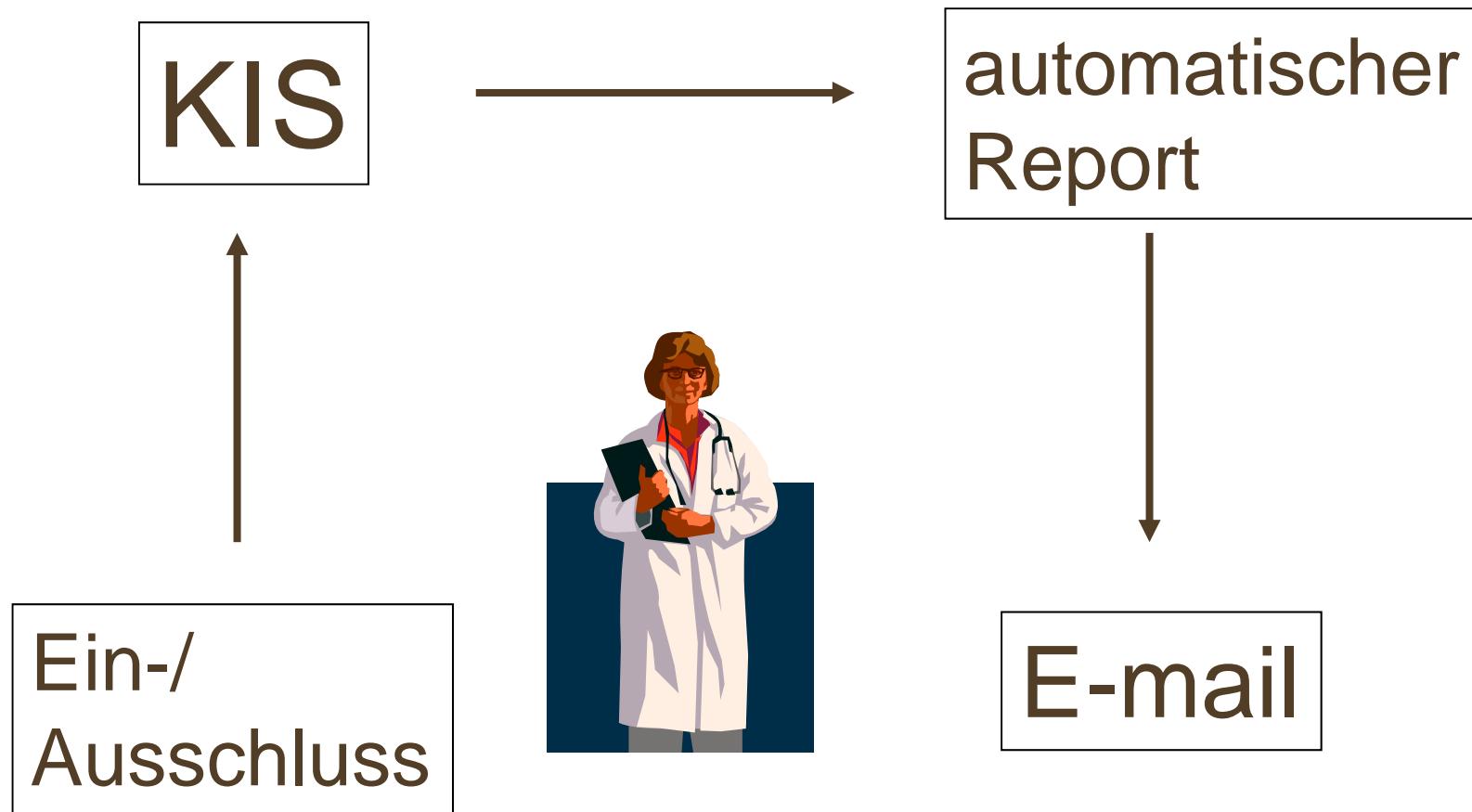


[van der Wouden JC, Blankenstein AH, Huibers MJ, van der Windt DA, Stalman WA, Verhagen AP. Survey among 78 studies showed that Lasagna's law holds in Dutch primary care research. J Clin Epidemiol. 2007;60(8):819-249]

## Patientenrekrutierung heute

"Almost half of all trial delays are caused by participant recruitment problems and the percentage of studies that complete enrolment on time is extremely low across all clinical trial markets: 18% in Europe; 17% in Asia-Pacific, 15% in Latin America; 7% in the USA".

[Kalra et al. iHealth Connections 2011; 1(2):108-113]



[Dugas M, Lange M, Berdel WE, Müller-Tidow C. Trials. 2008;9:2]

# KIS-basierte Patientenrekrutierung

- +100% Patientenrekrutierung bei Studie zu septischem Schock

[Herasevich V, Pieper MS, Pulido J, Gajic O. Enrollment into a time sensitive clinical study in the critical care setting: results from computerized septic shock sniffer implementation. JAMIA 2011;18(5):639-44]

- +100% Patientenrekrutierung bei Diabetes-Mellitus-Studie

[Embi PJ, Jain A, Clark J, Bizjack S, Hornung R, Harris CM. Effect of a clinical trial alert system on physician participation in trial recruitment. Arch Intern Med. 2005;165(19):2272-7]

- +50% Patientenrekrutierung bei Brustkrebsstudie

[Séroussi B, Bouaud J. Using OncoDoc as a computer-based eligibility screening system to improve accrual onto breast cancer clinical trials. Artif Intell Med. 2003;29(1-2):153-67]

- +40% Patientenrekrutierung in 3 von 7 Studien

[Dugas M, Lange M, Müller-Tidow C, Kirchhof P, Prokosch HU. Routine data from hospital information systems can support patient recruitment for clinical studies. Clin Trials. 2010 Apr;7(2):183-9]

- Review von 28 Clinical Trial Recruitment Support Systems (CTRSS)

[Cuggia M, Besana P, Glasspool D. Comparing semi-automatic systems for recruitment of patients to clinical trials. Int J Med Inform. 2011 Jun;80(6):371-88]



Patientenrekrutierung in klinischen Studien

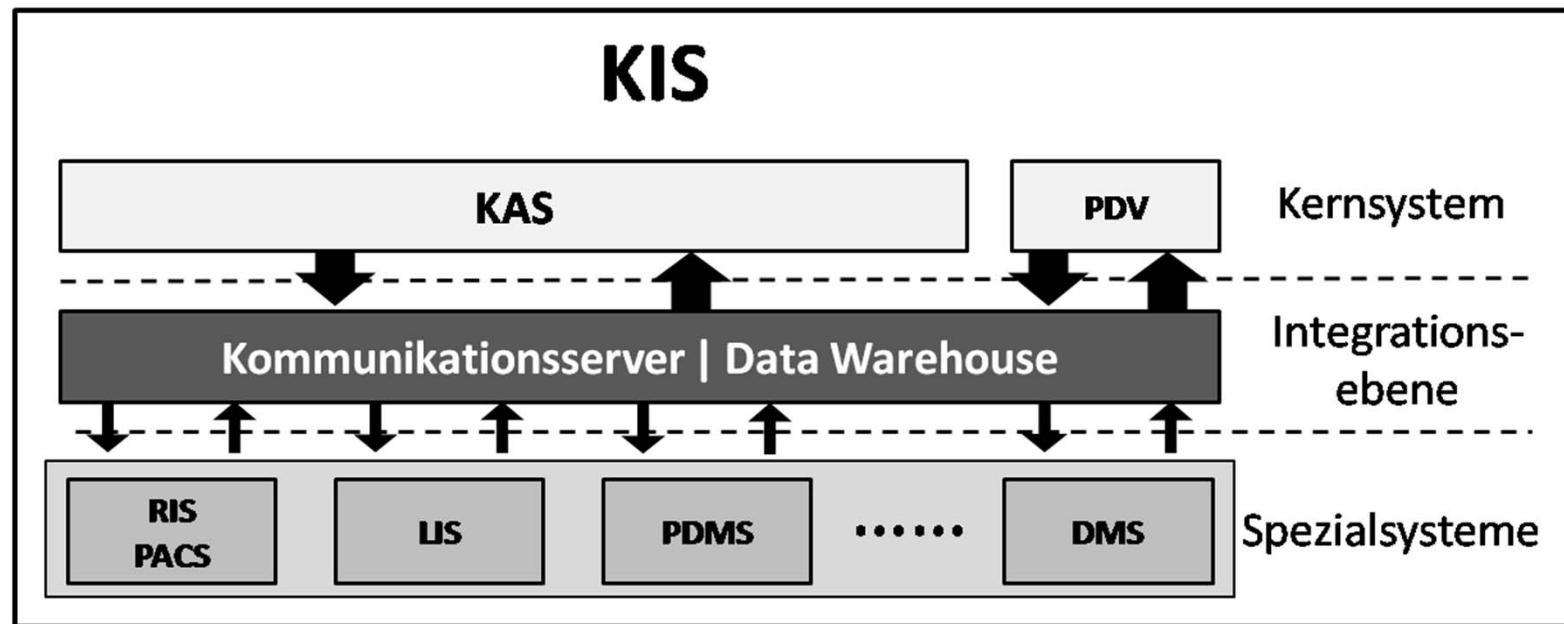
# **BMBF-/TMF-PROJEKT "KISREK"**

## BMBF-/TMF-Projekt "KISREK"

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- Münster           Orbis
  - Erlangen       Soarian + DWH
  - Düsseldorf      medico
  - Heidelberg      ISH\*med
  - Gießen           KAOS + KomServ
- 5 Projektpartner, 5 KIS
- Aufgabe: Entwicklung, prototypische Implementierung und Evaluation einer KIS-Architektur
  - Start: 01.09.2010, 24 Monate Laufzeit

# AP 1: Analyse der KIS-Werkzeuge



## AP 2: Analyse der KIS-Funktionen

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- Analyse der KIS-Funktionen
  - Workflow-Engine
  - Reporting & Queries
  - Benachrichtigung (E-Mail)
  - Arbeitslisten & Formulare
  - Kommentare, Icons, Stationslisten und -grafiken
- Vorhanden, parametrierbar, implementierbar
- Derzeit kaum Austausch möglich
- Standardisierung & Zusammenarbeit mit Herstellern notwendig

## AP 3: Eignung von KIS-Routinedaten

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- Relativ hoher Aufwand für Aufbereitung der E/A-Kriterien
- Vollständigkeit abhängig von der Merkmalsgruppe
- Rechtzeitigkeit meist nicht für Live-Rekrutierung geeignet
- Vergleichbare Datenlage in universitärem und nicht-universitärem Krankenhaus



Innovative Medicines Initiative

Internationale Sicht

# **ELECTRONIC HEALTH RECORDS FOR CLINICAL RESEARCH**

[www.ehr4cr.eu](http://www.ehr4cr.eu)



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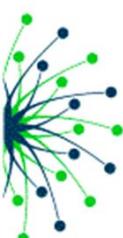
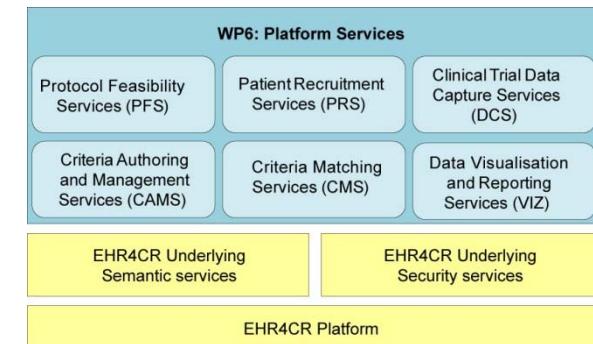


# EHR4CR Technical Platform



## EHR4CR platform will:

- Support the feasibility, exploration, design and execution of clinical studies and long-term surveillance of patient populations;
- Enable trial eligibility and recruitment criteria to be expressed in ways that permit searching for relevant patients across distributed EHR systems, and initiate confidentially participation requests via the patients' authorised clinicians;
- Provide harmonised access to multiple heterogeneous and distributed clinical (EHR) systems and integration with existing clinical trials infrastructure products (e.g. EDC systems);
- Facilitate improvements of data quality to enable routine clinical data to contribute to clinical trials, and importantly vice versa, thereby reducing redundant data capture.



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**WINTER 2011-12,  
VOLUME 2, NUMBER 2**

Letter from the Editor  
Interoperability Review 1  
**Interoperability Review 2**  
Community Updates

**INFORMATICS CORE**  
The Science of Informatics

**INFORMATICS AREAS**  
Translational Bioinformatics  
Clinical Research Informatics

Interoperability Review: EHRs for Clinical Research

Winter 2011-2012  
Vol. 2 No. 2  
**R. D. Kush**

Using electronic health records (EHR) for rigorous clinical research is finally becoming a reality. One may ponder what this has to do with standards; everything is the answer. When EHR vendors were initially approached with the 'opportunity' to add a new service for the research community, most of them figured out fairly rapidly that this was not a wise business decision. At that time, they realized that they would have to extract data and map them to every requested format, which varied by research study sponsor; or, the EHR system would need to be configured differently for each research study or research sponsor—not very feasible. In addition, there was a perception that the entire EHR would have to be validated to meet Good Clinical Practices (GCPs) and other regulations required of biopharmaceutical development companies such as 21CFR Part 11 in the U.S.—another relatively impossible option.

**AMIA Calendar**

**March**

Sun	Mon	Tue	Wed	Thu	Fri	Sat
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

[Full Calendar](#) [Submit Event](#)

**Have Questions?**

<http://www.amia.org/news-and-publications/volume-2-number-2/interoperability-review-2>



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## 2012 European Summit on Trustworthy Reuse of Health Data



### 2012 European Summit on Trustworthy Reuse of Health Data

May 14-15, 2012 | Brussels, Belgium | <http://euhealthdata2012.imia.info>



IMIA will host the 2012 European Summit on Trustworthy Reuse of Health Data at the Hotel Metropole, Brussels, Belgium on May 14-15, 2012.

The 2012 European Summit on Trustworthy Reuse of Health Data will create a forum for the development of guidelines on Trustworthy Reuse of Health Data by convening a meeting of European healthcare leaders from academia, public health, industry, users, and government. The initiative's ultimate goal is to publish a framework that will continue to encourage the development of the necessary conditions among EU organisations to enable large-scale sharing of data, and methods and expertise in the meaningful reuse of care records for research and healthcare service development.

Key links: [Summit Objectives](#) | [Participation](#) | [Venue](#)

### Mission

To build consensus on the reuse of health data for public health, patient, and commercial benefit across the European Union (EU), to inform relevant policies, and to align with international initiatives.

### Next IMIA GA Meeting

IMIA General Assembly  
2012

Sep 7 2011 - 00:00

The 2012 IMIA General Assembly will be held on 23 October 2012 in Beijing, China. Further details will follow.

### Featured Events



About NI 2012

### Upcoming events

ANIA-CARING Nursing Informatics (Event)  
(16 days)

Rutgers 30th Interdisciplinary

Patientenrekrutierung in klinischen Studien

# **WAS KÖNNEN KIS-SOFTWARE- HERSTELLER, STUDIENLEITER UND STUDIENÄRZTE TUN?**

# KIS-Softwarehersteller: Neue Standardfunktionen

- Abfragemodul:  
Semantische Annotationsmöglichkeit für KIS-Merkmale  
(z.B. UMLS, LOINC, SNOMED-Kodes)
- Benachrichtigungsmodul
- Screeninglistenmodul  
Kennzeichnung von Studienpatienten
- Basale Studienverwaltung

# Studienleiter & Studienärzte

- Bessere Ein-/Ausschlusskriterien für Klinische Studien
    - Präzise Kriterien ("no major disease")
    - Weniger Komplexität (Nachvollziehbarkeit, weniger komplexe zeitliche Bezüge)
    - Weniger Kriterien
- Nur 637 von 1000 E/A-Kriterien informativ  
[Tu SW, Peleg M, Carini S, Bobak M, Ross J, Rubin D, Sim I. A practical method for transforming free-text eligibility criteria into computable criteria. *J Biomed Inform.* 2011;44(2):239-50]
- Bessere klinische Dokumentation
    - Weniger Dokumentation (Redundanz!)
    - Vollständigkeit bei den wichtigen Datenelementen