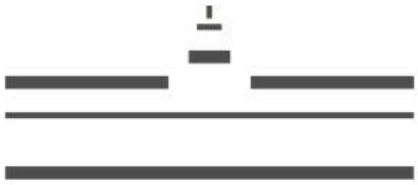


Westfälische
Wilhelms-Universität
Münster

KIS-basierte Unterstützung der Patientenrekrutierung in klinischen Studien

wissen.leben
WWU Münster

Prof. Dr. Martin Dugas

Institut für Medizinische Informatik

Übersicht

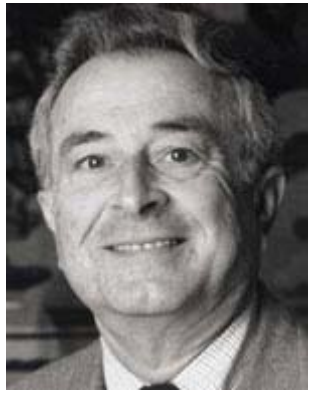
- Patientenrekrutierung: Verbesserungspotenziale durch IT
- BMBF-/TMF-Projekt "KISREK"
- Internationale Sicht: IMI-Projekt "EHR4CR"
- Was können KIS-Softwarehersteller,
  Studienleiter und Studienärzte tun?

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



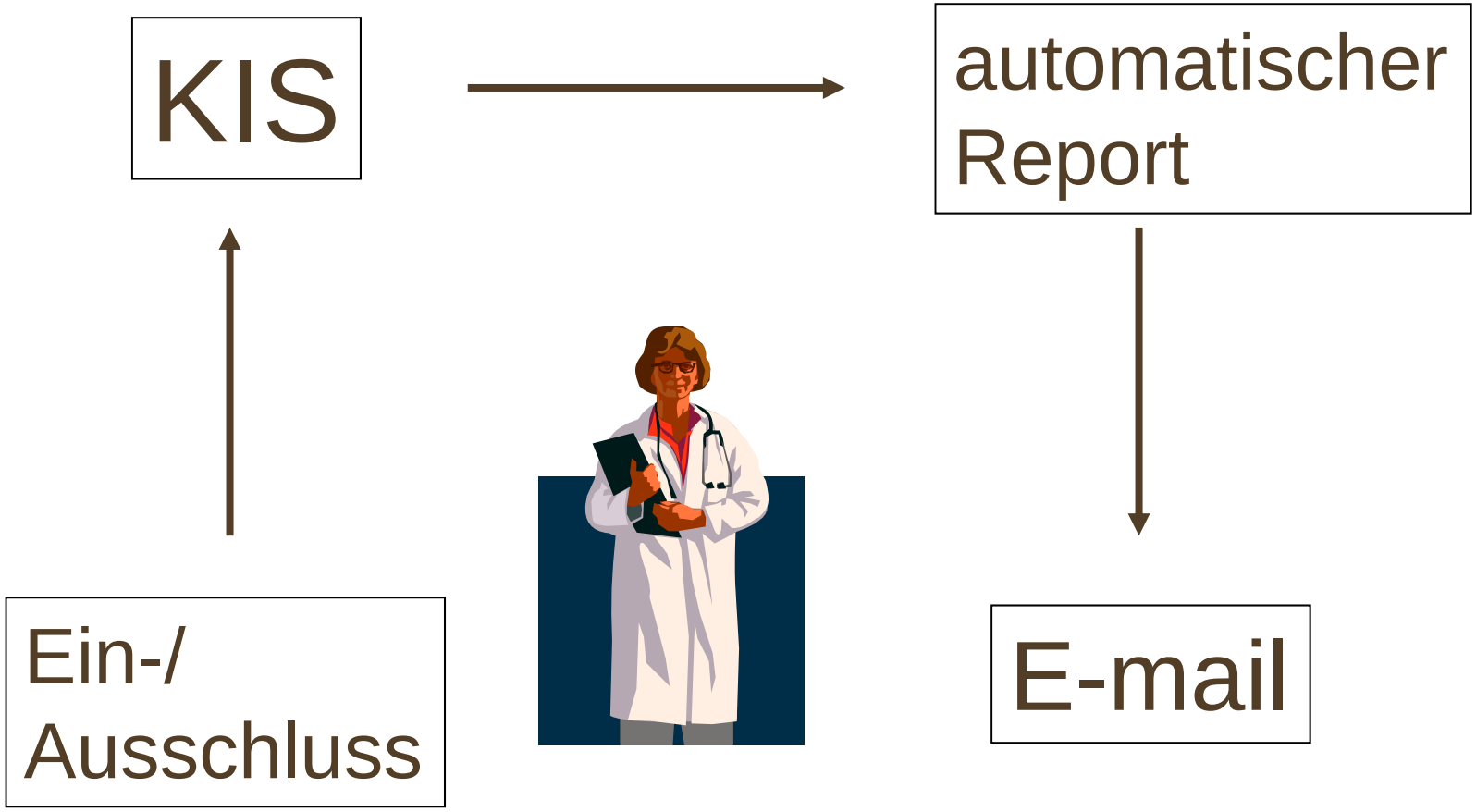
[Lasagna L, Clin Pharmacol Ther. 1979; 25(5 Pt 2):751-3]

[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]

GEFÖRDERT VOM
Bundesministerium
für Bildung
und Forschung

Patientenrekrutierung in klinischen Studien

BMBF-/TMF-PROJEKT "KISREK"

BMBF-/TMF-Projekt "KISREK"

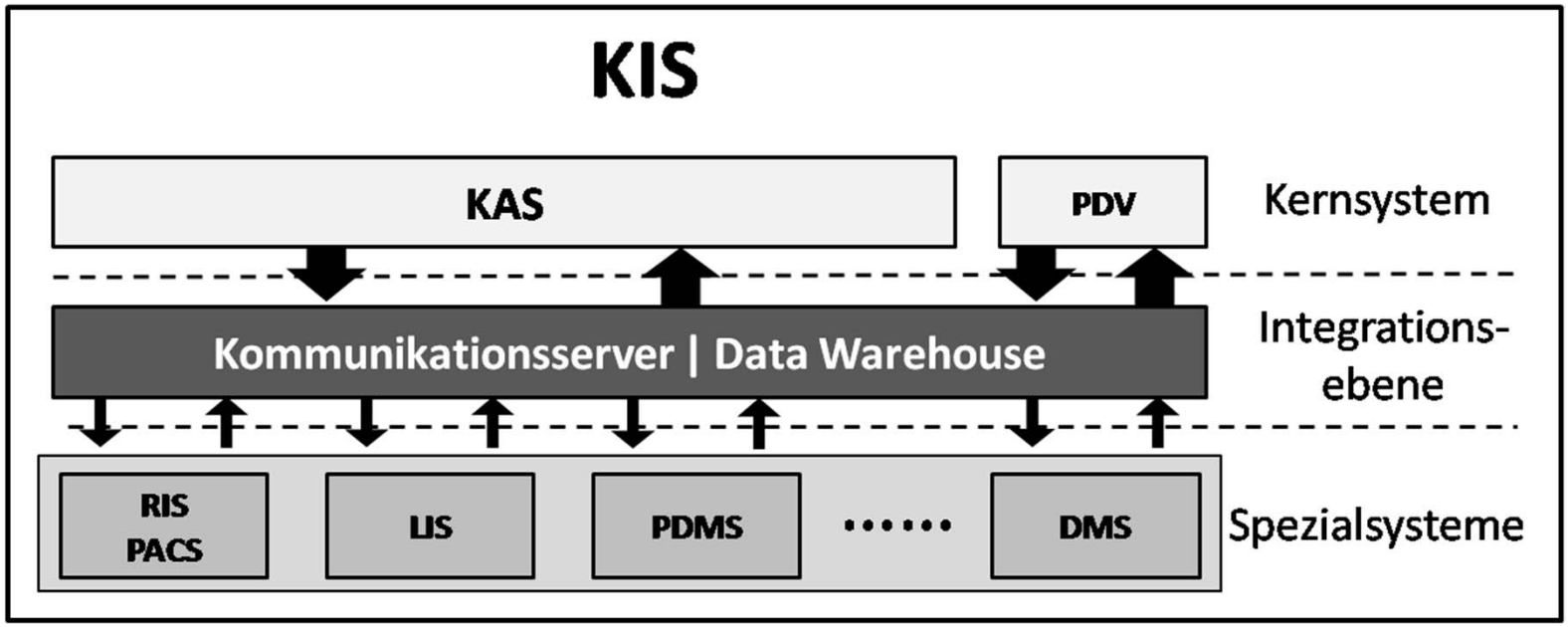
- Münster Orbis
- Erlangen Soarian + DWH
- Düsseldorf medico
- Heidelberg ISH*med
- Gießen KAOS + KomServ

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

- 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

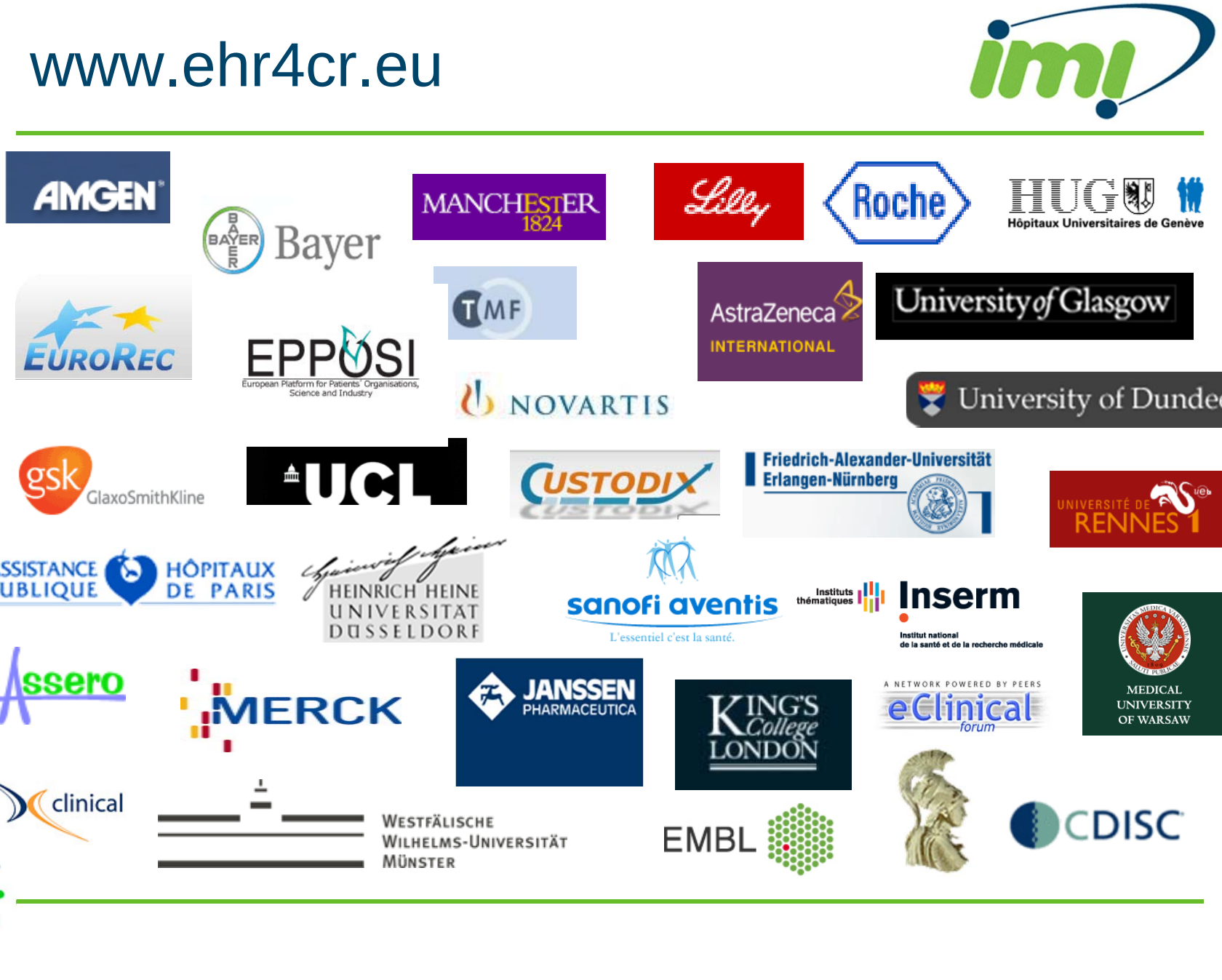
- Relativ hoher Aufwand für Aufbereitung der E/A-Kriterien
- Vollständigkeit abhängig von der Merkmalsgruppe
- Rechtzeitigkeit meist nicht für Live-Rekrutierung geeignet
- Vergleichbare Datenlage in universitärem und nicht-universitärem Krankenhaus

Innovative Medicines Initiative

Internationale Sicht

ELECTRONIC HEALTH RECORDS FOR CLINICAL RESEARCH

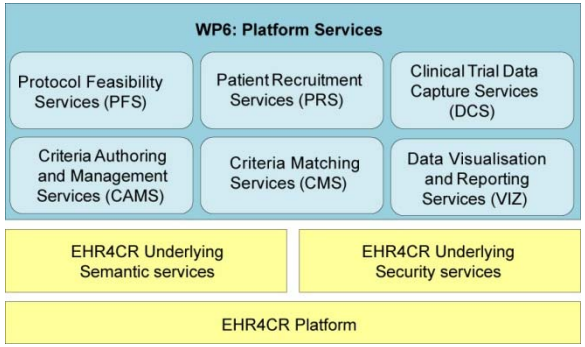
www.ehr4cr.eu

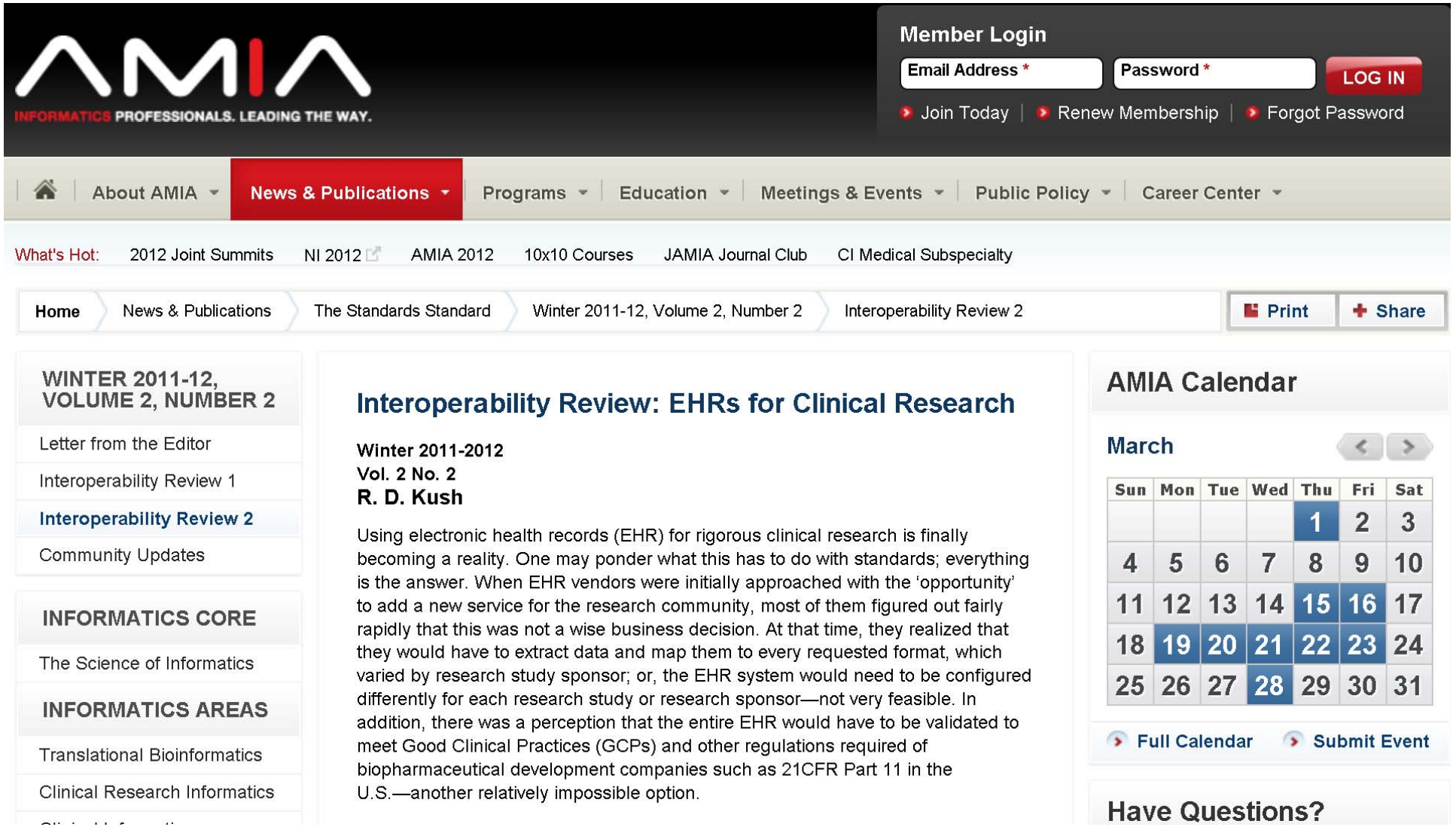


EHR4CR Technical Platform

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.





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

About IMIA
Contact Us
Members
Governance
Working Groups and Special Interest Groups
Taskforces
IMIA Yearbook
IMIA Endorsed Documents
IMIA Award of Excellence
Strategic Plan

2012 European Summit on Trustworthy Reuse of Health Data

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