

## USE CASE 1 –

# STUDIENREGISTER UND PATIENTENREKRUTIERUNG

**Prof. Dr. Hans-Ulrich Prokosch**

23.02.2018

MIRACUM Symposium

- In vielen Universitätskliniken liegt kein aktueller Überblick über aktuell laufenden / rekrutierende Studien vor
  - oft verteilt auf einzelne Kliniken oder ein CCC
- Studien leiden unter Rekrutierungsproblemen

Dilts and Sandler:

“... of 218 trials analyzed, 20.6% of the trials opened, resulted in no actual accruals and **53.7% had fewer than five patients accrued.**”

Campbell und Kollegen:

“A review of 114 trials between 1994 and 2003 by the Medical Research Council and Health Technology Assessment Programmes found that **less than one-third met their target recruitment** within the time originally specified.“

[1] Dilts DM, Sandler AB. Invisible barriers to clinical trials: the impact of structural, infrastructural, and procedural barriers to opening oncology clinical trials. *J Clin Oncol* 2006; 24: 4545–52.

[2] Campbell MK, Snowdon C, Francis D, et al. Recruitment to randomised trials: strategies for trial enrollment and participation study. The STEPS study. *Health Technol Assess* 2007; 11: iii, ix–105.

# Viele Pilotprojekte keine nachhaltigen Infrastrukturen



- **2011:**



International Journal of Medical Informatics

Volume 80, Issue 6, June 2011, Pages 371-388



## Comparing semi-automatic systems for recruitment of patients to clinical trials

Marc Cuggia <sup>a</sup> , Paolo Besana <sup>a</sup>, David Glasspool <sup>b</sup>

- **2014:**

JOURNAL OF MEDICAL INTERNET RESEARCH

Köpcke & Prokosch

Review

## Employing Computers for the Recruitment into Clinical Trials: A Comprehensive Systematic Review

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<sup>2</sup>Department for Medical Informatics, Friedrich-Alexander University Erlangen-Nuremberg, Erlangen, Germany

[1] Cuggia M, Besana P, Glasspool D. Comparing semi-automatic systems for recruitment of patients to clinical trials. Int J Med Inform 2011

[2] Köpcke F, Prokosch HU. Employing computers for the recruitment into clinical trials A comprehensive systematic review. Med Internet Res 2014;16(7):e161

# bisherige Projekte



- **KISREK:**  
KIS-unterstützte Patientenrekrutierung



- **EHR4CR:**  
Electronic Health Records for Clinical Research

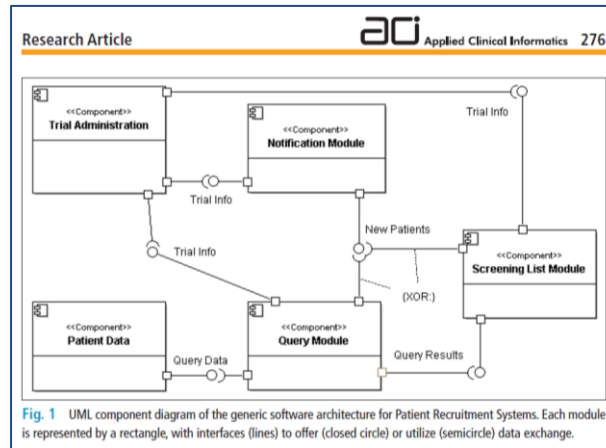


- 10 Pharmaceutical Companies (members of EFPIA)
- 24 Public Partners (Academia, Hospitals and SMEs)
- 2 Subcontractors



# bisherige Ergebnisse

- **KISREK:**



- Studienregister
- Query Modul
- Patientendaten
- Notification Modul
- Screening Modul

- **EHR4CR:**

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Digital Healthcare Empowering Europeans  
R. Cornet et al. (Eds.)

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A European inventory of data elements for  
patient recruitment

Research Article

## User Satisfaction Evaluation of the EHR4CR Query Builder: A Multisite Patient Count Cohort System

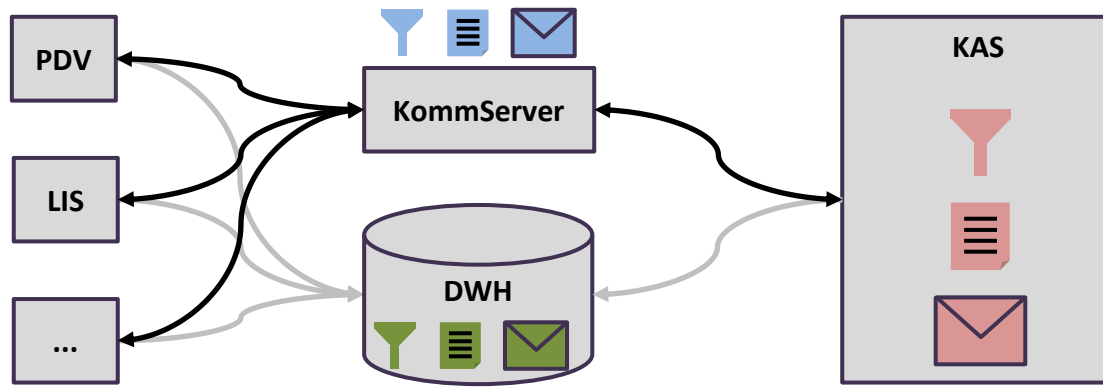
Iñaki Soto-Rey,<sup>1</sup> Aurèle N'Dja,<sup>2</sup> James Cunningham,<sup>3</sup> Axel Newe,<sup>4</sup> Benjamin Trinczek,<sup>1</sup>  
Caroline Lafitte,<sup>2</sup> Brita Sedlmayr,<sup>4</sup> and Fleur Fritz<sup>1</sup>

[1] Trinczek B, Köpcke F, Leusch T, Majeed RW, Schreiweis B, Wenk J, Bergh B, Ohmann C, Röhrig R, Prokosch HU, Dugas M. Design and multicentric implementation of a generic software architecture for patient recruitment systems re-using existing HIS tools and routine patient data. Appl Clin Inform. 2014 Mar 19;5(1):264-83.

[2] Soto-Rey I, N'Dja A, Cunningham J, Newe A, Trinczek B, Lafitte C, Sedlmayr B, Fritz F. User Satisfaction Evaluation of the EHR4CR Query Builder: A Multisite Patient Count Cohort System. Biomed Res Int. 2015;2015:801436.

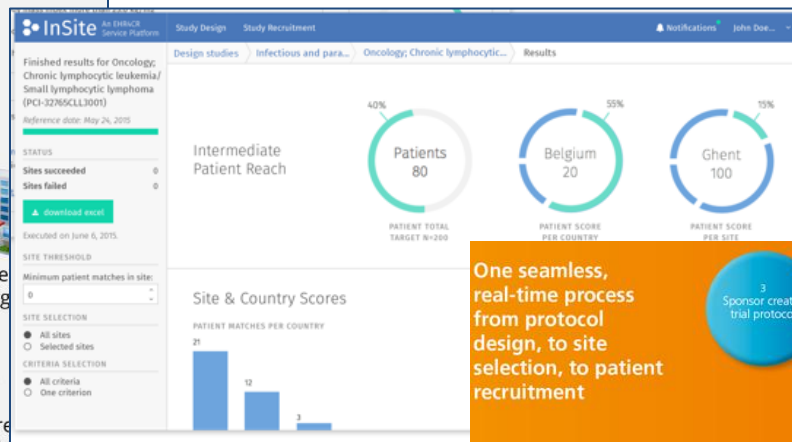
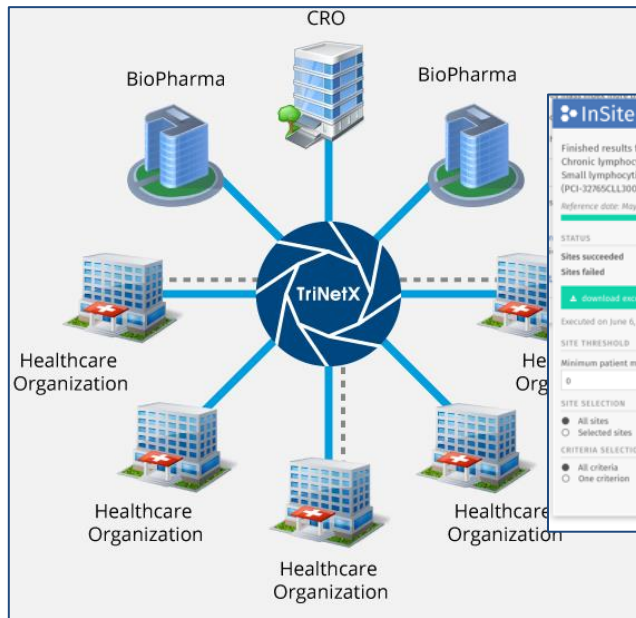
[3] Doods J, Lafitte C, Ulliac-Sagnes N, Proeve J, Botteri F, Walls R, Sykes A, Dugas M, Fritz F. A European inventory of data elements for patient recruitment. Stud Health Technol Inform. 2015;210:506-10.

# UC1 und KIS/KAS Integration Rekrutierungsoptionen

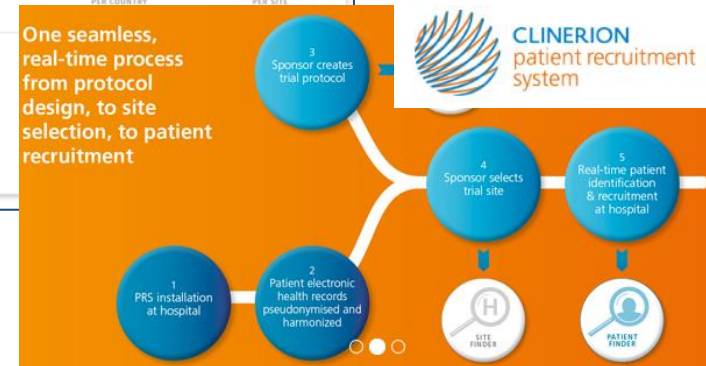


- **Aufbau klinikumsweiter Studienregister an allen Standorten**
- **Analyse der Ein-/Ausschlusskrit. von 50 „MIRACUM-Studien“**
- **Abgleich mit Datenelementen der Elektronischen Krankenakten**
- **Evaluation der Datenvollständigkeit und Datenqualität**
- **Etablierung einer in das lokale KIS integrierten IT-Lösung zur Unterstützung der Patientenrekrutierung**
- **Evaluation des Impacts der IT-Lösung**

- Etablierung einer in das lokale KIS integrierten IT-Lösung zur Unterstützung der Patientenrekrutierung
- Option zur Anbindung an Pharma-initiierte Feasibility- und Rekrutierungsnetzwerke



One seamless, real-time process from protocol design, to site selection, to patient recruitment





# Vielen Dank für Ihre Aufmerksamkeit



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