Establishing an Interoperable Clinical Trial Information System within MIRACUM

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STC EFMI 2019 Hannover
MIRACUM is . . .

- 10 University Hospitals and Universities
- 2 Universities of Applied Sciences
- one Industry partner (Averbis GmbH)
- . . . in seven Counties
MIRACUM UC 1: Support for Patient Recruitment

- IT-solution integrated in the local HIS for the support of patient recruitment
Vision of UC 1 ⇒ multi-centric implementation

Study registry

Screening list

Study candidates

Study physician/management

Patient data

Query module

Study characteristics

Query

Result

Notification

MIRACUM UC 1: Objectives

- Hospital-wide trial registries at all partner sites
- Analysis of in-/exclusion criteria of 50 trials conducted in MIRACUM
- Comparison of criteria with data elements of the EPR
- Evaluation of data quantity and completeness of selected data elements
- *IT*-solution *integrated in the local HIS for the support of patient recruitment*
- Evaluation of the solution
Local hospital-wide trial registry: requirements

- Single point of entry, multiple usage
- Hospital-wide access for all staff
- Integration with the HIS
- Exports and key indicators (e.g. for proposals)
- Extensible and configurable for local requirements: e.g. CCC, OncoBox, DKTK
Integration with national and international registries

- No universal interface format
- Individual implemention
- Definition of workflows
Local, consortial and public access to trial registries

- Hospital-wide trial registry
- Central trial registry
- Internal views
- External views

• User specific views
• Searches for active studies throughout MIRACUM
Consortium-wide synchronization of trial characteristics

- Core data set with 14 parameter
- Still open: formalization of in-/exclusion criteria
## Analysis of existing clinical trial registries

<table>
<thead>
<tr>
<th>Site</th>
<th>IT-solution</th>
<th>Applied in</th>
<th>Export formats</th>
<th>No of trials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site 1</td>
<td>SecuTrial®</td>
<td>Hospital wide</td>
<td>SAS</td>
<td>Approx. 500</td>
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<tr>
<td>Site 2</td>
<td>IHD / SecuTrial®</td>
<td>Oncology</td>
<td>XML</td>
<td>800-900</td>
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<td>Site 3</td>
<td>IHD: JAVA-based web application</td>
<td>Hospital wide</td>
<td>CSV, PDF</td>
<td>Approx. 2700</td>
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<tr>
<td>Site 4</td>
<td>Redmine®</td>
<td>Anaesthesia dept.</td>
<td></td>
<td>20</td>
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<tr>
<td>Site 5</td>
<td>Excel®</td>
<td>Oncology</td>
<td></td>
<td>n/a</td>
</tr>
<tr>
<td>Site 6</td>
<td>Desemo®</td>
<td></td>
<td></td>
<td>n/a</td>
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<td></td>
<td></td>
<td>n/a</td>
</tr>
<tr>
<td>Site 8</td>
<td>not yet established</td>
<td></td>
<td></td>
<td>Approx. 200</td>
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<tr>
<td>Site 9</td>
<td>not yet established</td>
<td></td>
<td></td>
<td>Approx. 180</td>
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<tr>
<td>Site 10</td>
<td>centraXX®: currently being established</td>
<td>Neurology, Cardiology, hospital wide planned</td>
<td>SAS, STATA, XML, CSV</td>
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</table>
Core parameters for MIRACUM-wide exchange of trial information

- Primary Registry and Trial Identifying Number (WHO item 1)
- Secondary Identifying Numbers (WHO item 3)
- Contact for Scientific Queries (Principal Investigator) (WHO item 8)
- Scientific Title (WHO item 10)
- Health Condition(s) or Problem(s) Studied including ICD-code (WHO item 12)
- Key Inclusion and Exclusion Criteria (incl. gender, age) (WHO item 14)

- Study Type (WHO item 15)
- Recruitment Status (WHO item 18)
- participating institutions and departments,
- information about the last import and
- the date of the last changes.
Implementation of a local clinical trial registry software

• Based on open-source components
• Implementation at 5 sites in MIRACUM
• Further development collaborative (might become open-source)
• Informed by experience with long-term development of the DRKS (German registry of clinical trials now at DIMDI)
### Implementation of a clinical trial registry software

<table>
<thead>
<tr>
<th>P-Nummer</th>
<th>Akronym DE</th>
<th>Abteilung</th>
<th>DRSK-ID</th>
<th>Aspekt CCC</th>
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<td>P000012</td>
<td>BERUF1</td>
<td>Testabteilung Dresden</td>
<td>DRKS00003642</td>
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<td>P000011</td>
<td>ATHENA</td>
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<td>DRKS00003654</td>
<td>Akronym DE, Akronym EN, Abteilung</td>
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<td>DRKS00003772</td>
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<td>P000008</td>
<td>EWING 2008</td>
<td>Testabteilung Dresden</td>
<td>DRKS0000132</td>
<td>DRSK-ID, Eudamed</td>
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<td>P000007</td>
<td>CAESAR</td>
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<td>EudraCT, Universal Trial Number, Vorlagennr.</td>
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<td>ISAR-SAFE</td>
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<tr>
<td>P000005</td>
<td>kein Akronym</td>
<td>Testabteilung Freiburg</td>
<td>DRKS00010297</td>
<td>Aspekt CCC, Aspekt DKT</td>
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<tr>
<td>P000004</td>
<td>Testino</td>
<td>Testabteilung Freiburg</td>
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<td>Test2</td>
<td>Testabteilung Freiburg</td>
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<td>EWOG-MDS 98</td>
<td>Testabteilung Freiburg</td>
<td>DRKS00000001</td>
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<tr>
<td>P000001</td>
<td>Freiburger Test</td>
<td>Testabteilung Freiburg</td>
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<td></td>
</tr>
</tbody>
</table>

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Registerstammdaten

**WHO-Akronym:** EWOG-MDS 98

**UKF-Abteilung:** Testabteilung Freiburg

- Aspekt CCC
- DKT-Studie

**Zuletzt durchgeführte Importe:** DRKS (DRKS00000001) am 14.01.2019 16:15
### WHO-Parameter

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Details</th>
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<tbody>
<tr>
<td>Einschluss des ersten Studienteilnehmers:</td>
<td>Tatsächlich 03.07.98</td>
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<tr>
<td>Geplante Studienteilnehmeranzahl gesamt:</td>
<td>850</td>
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<td>Monozentrisch/Multizentrisch:</td>
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<td>National/International:</td>
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<td>Einschlusskriterium Geschlecht:</td>
<td>Beide</td>
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<td>Einschlusskriterium Mindestalter:</td>
<td>Keines</td>
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<tr>
<td>Einschlusskriterium Höchstalter:</td>
<td>18 Jahre</td>
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</table>

#### Einschlusskriterien:


#### Ausschlusskriterien:

- Kinder mit Trisomie 21
- Kinder mit den folgenden zytogenetischen oder molekularen Auffälligkeiten:
  - t(8;21)(q22;q22) [AML1/ETO fusion gene]
  - t(15;17)(q22;q12) [PML/RARα rearrangement]
  - inv(16)(p13q22) [CBFβ/MYH11 rearrangement]

#### Englisch:

All children and adolescents with MDS under the age of 19 diagnosed between July 1998 and June 2002 are registered as study patients.

- Children with Down syndrome
- Children with the following cytogenetic or molecular abnormalities:
  - t(8;21)(q22;q22) [AML1/ETO fusion gene]
  - t(15;17)(q22;q12) [PML/RARα rearrangement]
  - inv(16)(p13q22) [CBFβ/MYH11 rearrangement]
On the way to a MIRACUM-wide clinical trial Information System

- Further development
  - Central registry
  - Synchronization
  - Formalization of in-/exclusion criteria
  - Query component
  - Integration with HIS
MIRACUM UC1 Partner - Thank you
Hospital-wide trial registry

Core data set

Central trial registry

External views

Internal views

EPR

Deutsches Register Klinischer Studien

German Clinical Trials Register

ClinicalTrials.gov

CSV

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