Towards Better Health Data
Key Success Factors for Good Looking Data

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Cancer Institute of Romagna (IRST)
IRST: THE CANCER INSTITUTE OF ROMAGNA

PUBLIC
PRIVATE
PARTNERSHIP

Dpt. Clinical & experimental oncoematology
Inpatient wards
Oncology
Radiometabolic
Immunology
Outpatient wards
Oncology
Hematology
Oncodermatology
Cardiology & Oncocardiology
Anesthesia

Dpt. Advanced technologies & procedures
Radiometabolic
Radiotherapy & Health physics
Radiology & Nuclear Medicine Diagnostic
RMN 3T

Laboratory of Biosciences
Cancer Registry of Romagna and Epidemiology
GMP Radio factory
Robotic oncology pharmacy

RAVENNA SITE
Radiotherapy ward

FORLÌ SITE
Oncological ward

MELDOLA (MAIN) SITE
Dpt. Clinical & experimental oncoematology
Dpt. Advanced technologies & procedures

Antonio Branca guest house

CESENA SITE
Oncoematology ward

OVER 21,000 REFERRED PATIENTS/YEAR
- 6,700 NEW PATIENTS/YEAR
- 2,086 PATIENTS WITH DRUG ADMINISTRATION

HUMAN RESOURCES
380 FTE
29% male
71% female
mean age 40,5 yrs

TUMOR SITE DISTRIBUTION

Hematology: 30%
Breast: 25%
Gastroenteric: 15%
Urogynecology: 14%
Osteoncology & rare tumors: 6%
Lung: 10%
**BIOSTATISTICS & CLINICAL TRIAL UNIT**

### Tasks

- Study coordinator activity of oncological clinical trials (phase I-IV)
- Methodological support for protocol and scientific work writing
- Clinical Trial Quality Team for IRST-promoted studies
- Technical support to non-cancerous research in the Romagna area
- Biostatistics
- Real world/Outcome/organizational research
- Training activity
- Clinical research support and monitoring support for the Bugando Medical Center (Tanzania)

### Human resources-roles

<table>
<thead>
<tr>
<th>Role</th>
<th>N.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Head</td>
<td>1</td>
</tr>
<tr>
<td>Outcome research</td>
<td>1</td>
</tr>
<tr>
<td>Training</td>
<td>1</td>
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<tr>
<td>Biostatistics</td>
<td>4</td>
</tr>
<tr>
<td>CTQT (IRST promoted studies)</td>
<td>4</td>
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<tr>
<td>Study coordinators</td>
<td>24</td>
</tr>
<tr>
<td><strong>Totale</strong></td>
<td>31</td>
</tr>
</tbody>
</table>

### Clinical Research 2016

- **CTs active in IRST**: 166
- **CTs company promoted**: 55%
- **CTs promoted by IRST**: 20%
- **Pts recruited Dept Onco**: 362
- **Recruited/new Dept Onco patients**: 13%
- **Pts recruited in IRST**: 731
- **Pts recruited Romagna Network**: 952
- **Sponsored activity value (€)**: 2.500.000

**PATHOLOGY GROUP MATRIX**

<table>
<thead>
<tr>
<th>IRST</th>
<th>Ravenna</th>
<th>Lugo / Faenza</th>
<th>Rimini</th>
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<tbody>
<tr>
<td>Urology</td>
<td>Thoracic pathology</td>
<td>Haematology</td>
<td>Gastroenteric</td>
</tr>
<tr>
<td>Breast</td>
<td>Thoracic pathology</td>
<td>Haematology</td>
<td>Gastroenteric</td>
</tr>
<tr>
<td>Osteoncology and rare tumors</td>
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<td>Haematology</td>
<td>Gastroenteric</td>
</tr>
<tr>
<td>Thoracic pathology</td>
<td>Thoracic pathology</td>
<td>Haematology</td>
<td>Gastroenteric</td>
</tr>
<tr>
<td>Radiometabolic medicine</td>
<td>Thoracic pathology</td>
<td>Haematology</td>
<td>Gastroenteric</td>
</tr>
<tr>
<td>Neuro oncology</td>
<td>Thoracic pathology</td>
<td>Haematology</td>
<td>Gastroenteric</td>
</tr>
<tr>
<td>Palliative care</td>
<td>Thoracic pathology</td>
<td>Haematology</td>
<td>Gastroenteric</td>
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</tbody>
</table>

**Study coordinators**: 24
EHR IRST: LOG80

**IRST EHR**

- Web-based EHR accessible from any IRST site
- Property of LOG80 & IRST
- Development led by interdisciplinary commission
- Online data input
- Quality improvement monitoring & budget-driven process

Clinicians and other operators enter data realtime during their activity with/for patients

LOG80 is our web service

EHR is accessible from our sites across the local area network

**10-year history**

- Over 66,000 patients
- Over 52,000 diagnosis
- Over 657,000 meetings
- Over 1,599,000 drug administrations
- Over 1,383,000 procedures
- Over 528,000 assessment info

DATA INQUIRY FOR:

- Management & benchmark
- Clinical Trials
- Research outcome
ANAMNESIS
- Tumor site
- Performance status
- TNM and Stage
- Biopsy
- Metastasis
- Molecular profiles

THERAPIES
- Active substances
- Settings of therapy lines
- Phase
- Schedule
- Start, stop
- Discontinuation of treatment
- Response

FOLLOW UP
- Specifics disease coding

DICTIONARIES
- ICD
- SNOMED
- ATC
- RECIST criteria
- NCI-CTCAE criteria
- ...

TREATMENT DIARY
- Response
- Performance status
- Disease progression

TOXICITIES
- Effects
- Level

BEST CARE
- Online availability of all clinical data
- Optimal time management
- Reduction in error
- Standardization of procedures
- Appropriateness of prescriptions

BEST RESEARCH
- Outcome research
- Clinical epidemiology studies
- Experimental research

2007
EHR IRST: Clinical Trials

Clinical Trial List
Classified by tumor type

<table>
<thead>
<tr>
<th>#</th>
<th>Acron./Cod./Sede</th>
<th>Sede</th>
<th>Aperti</th>
<th>Aperti+recl. chiuso</th>
<th>Chiusura</th>
<th>N. delibera</th>
<th>Data delibera</th>
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<tr>
<td>30</td>
<td>Caelyx anziante Caelyx anziante - Avanzato (I linea)</td>
<td>Mammella</td>
<td>00/00/0000</td>
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<td></td>
<td></td>
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<tr>
<td>32</td>
<td>Cardiogran, Studio di fase IV per valutare l’attiv 0006 - Mammella</td>
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<td></td>
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<tr>
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<tr>
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<td>Lilly 5096 Allowt H3-EW-5096</td>
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<td>MANTA 2 Manta2 - Mammella</td>
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<tr>
<td>55</td>
<td>MYOCET e XELODA Studio dosifinding 0007 - Mammella</td>
<td>Mammella</td>
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<td>MYOCET, Studio di Fase I-II nel trattamento di priL017 - Avanzato (I linea)</td>
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<td>56</td>
<td>PROTECHTS/02/SELE/01 Italfarmaco - fase III</td>
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Data coded
- Clinical Trial internal code
- Administrative data
- Target patient characteristics
- Enrollment aims
- Treatment schemas
- Active sites

Simplified workflow

Clinical Trial
- Proposal
- Scientific evaluation
- Ethical committee evaluation
- Site activation
- Enrollment, activities and cost evaluation
- Closing

Shared documents
- Synopsis
- Protocol
- Flowchart
- Informed Consent
- QoL Questionnaire
- Letter to GP
- SAE form
- Biological Protocol
- Biological Informed Consent
PATIENT ENROLLMENT IN IRST
CHEMOTHERAPY PRESCRIPTION

EHR suggests all the suitable clinical trials for the patient on the basis of the therapy schema.

<table>
<thead>
<tr>
<th>Il paziente è elegibile in uno di questi studi?</th>
<th>Documenti allegati</th>
<th>Conferma</th>
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<tbody>
<tr>
<td>ALIMTA 12 h IC - IOR 100 05</td>
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<td>Amgen 20050136</td>
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<td>EISAI E7389</td>
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<td>FASE I con LBH589</td>
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<tr>
<td>TRABECTIDINA (Yondelis)ET-B-027-06</td>
<td></td>
<td></td>
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<tr>
<td>ZOOM. Studio di fase III</td>
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</table>

Physicians confirm the eligibility for a study or select the non-eligibility reason:

- Not eligible
- No active study available
- Patient refusal
- Physician decision
- Other reasons
Feasibility: real-time query on 10-year data base

Screening log: real-time monitoring

Monitoring observed/expected recruitment plan

<table>
<thead>
<tr>
<th></th>
<th>Jan</th>
<th>Feb</th>
<th>Mar</th>
<th>Apr</th>
<th>May</th>
<th>Jun</th>
<th>Jul</th>
<th>Aug</th>
<th>Sep</th>
<th>2017</th>
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<tr>
<td>Patient enrolled</td>
<td>+2</td>
<td></td>
<td>+7</td>
<td>+1</td>
<td></td>
<td>+1</td>
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<td>+13</td>
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<tr>
<td>Screening failure</td>
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<td>1</td>
<td>1</td>
<td></td>
<td></td>
<td>2</td>
<td></td>
<td>5</td>
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<tr>
<td>Total enrollment</td>
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<td>10</td>
<td>10</td>
<td>11</td>
<td>12</td>
<td>13</td>
<td>14</td>
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Real-time electronic drug accountability

Active monitoring of grant and implementation of active cycle of invoicing system

<table>
<thead>
<tr>
<th>Monitor Session Date</th>
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<th>30/06/2017</th>
<th>Total</th>
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<tr>
<td>Outpatient procedures</td>
<td>€ 3,500</td>
<td>€ 14,100</td>
<td>€ 17,600</td>
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<tr>
<td>Radiological procedures</td>
<td>€ 550</td>
<td>€ 7,518</td>
<td>€ 8,068</td>
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<tr>
<td>Chemotherapy</td>
<td>€ 27,700</td>
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<td>€ 27,700</td>
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</table>
A PLATFORM FOR SHARING RESULTS

the roadmap

Handshake meeting
May 2016

Technical Assessment & collaboration agreement

Go live
October 2016

IRST infrastructure and data source
January – April

A study use case
May 2017

Increased cooperation today

the team

Platform provider

- Healthcare management
- Biostatistics and clinical trials unit
- Outcome research group
- Information Technology
  • System Engineer
  • Data Engineer

- Hospital Engagement and Real World Data Services manager
- Clinical Data Managers
- IT Specialists

- Global Clinical Operations Senior Manager
- Project Manager
- Clinical Research Data Scientist

Transparency, data sharing and public scrutiny of results

Privacy, personal data & patient rights protection

Commercial confidentially & unfair competition

International comparisons of health system performance among OECD countries: Opportunities and data protection challenges

Jillian Odebrecht, Elektra Roczni, Nick Klaarz

Article info

Abstract

Objective: To summarize the data protection framework in the health care sector, focusing on the European Union and the USA. The purpose of this article is to discuss the potential benefits of international comparisons of health system performance among OECD countries, and to highlight some of the challenges and opportunities associated with data protection. The study use case involves increased cooperation today.
INCLUSION
1. newly diagnosed (within 3 months prior to randomization) men with mHNPC on positive bone scan or metastatic lesions on CT or MRI
2. ≥18 years of age
3. ECOG performance grade 0, 1 or 2
4. at least 2 of the following 3 risk factors:
   i. Gleason score ≥8;
   ii. presence of 3 or more lesions on bone scan;
   iii. presence of visceral metastasis

EXCLUSION

Cohort Builder

10 patients recruited in the study

HIT RATIO 100%
each patient included in the clinical trial was found through the filters of the platform cohort builder

10 patients recruited in the study
What would sponsors like to have from sites?

TRUTHFUL DATA
SPEED & UPDATES

What would sites like to have from sponsors?

KNOWLEDGE
SUPPORT