



4th National Clinical Trials Day 2019

Plenary Session Hall of the Senate PCR
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“EHR for clinical research in oncology – center view”

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IRST: the Cancer Institute of Romagna



IRST MISSION	ONCOLOGICAL AND ONCOHEMATOLOGICAL CARE	PUBLIC PRIVATE PARTNERSHIP	SERVICES
	TRANSLATIONAL RESEARCH		
	NETWORK SYNERGY		

RAVENNA SITE
Radiotherapy ward

FORLÌ SITE
Oncological ward

MELDOLA (MAIN) SITE
Department of Clinical & experimental oncoematology
Department of Advanced technologies & procedures

Antonio Branca guest house

CESENA SITE
Oncoematology ward

SERVICES

Inpatients wards
Oncology
Radiometabolic
Immunology

Outpatients wards
Oncology
Hematology
Radiometabolic
Oncodermatology
Cardiology & Oncocardiology
Anesthesia

Radiotherapy & Health physics

Radiology & Nuclear Medicine
Diagnostic
RMN 3T

Laboratory of Biosciences

GMP Radio factory
Robotic oncology pharmacy

IRST (the Romagna Cancer Centre) was born in Romagna, in the middle of Italy, in 2007.

It is a public-private partnership between: the public Regional Health authority, a non-profit private organization, local banking foundations and the University of Bologna.

However, it is fully integrated in the public health system.

In 2012 (twenty twelve) it was recognized by the Ministry of Health as a cancer research institute.

The Institute follows cancer diseases in 4 operational sites, serving a population of about 400.000 citizens.

The main building is in Meldola, where the Specialist Units listed on the right of the slide are located.

Oncological wards are also present at the sites of Forlì and Cesena.

A radiotherapy ward is located in the hospital of Ravenna.

IRST personnel



IT specialists (systems, software, web site, system integration and interoperability, security, ...)



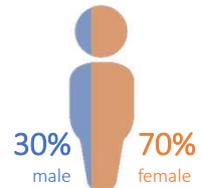
PATHOLOGY groups in IRST:

- Hematology
- Gastroenteric
- Breast
- Neuro-oncology
- Osteoncology and Rare Tumors (CDO-TR)
- Immunotherapy and cell therapy (incl. melanoma)
- Thorax
- Uro-gynecology



with dedicated oncologists, biologists, study coordinator, pharmacist and nurse

about
550 employees



mean age:
40,5 years

HUMAN RESOURCES

We are about 4 hundred and fifty units involved in care, research and support. 2 hundred sixty units of physicians, nurses, pharmacists, technicians, healthcare workers, are mainly dedicated to the assistance. 1 hundred forty four units are mainly involved in research, these are biologists, datamanagers, researchers, statisticians, and so on.

Groups of oncologists are responsible for the assistance and the clinical research activity. There is a division in different specialty teams and each group takes care of a specific oncological disease or to a specific body area with a tumour disease and are coordinated by a supervisor.

In every group, oncologist has the possibility to collaborate with dedicated professionalist as biologists, study coordinators, nurse and pharmacist. The group members work together to define the most appropriate diagnostic-therapeutic procedures and to ensure the best management of cancer patient.

10 IT specialists try to put order in al this mess.

Research activity in IRST

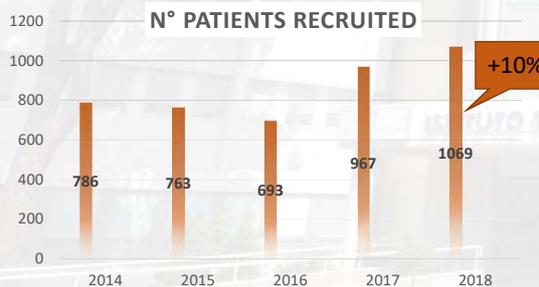
N° CLINICAL TRIALS WITH ACTIVE DRUGS



N° CLINICAL TRIALS PROMOTED BY IRST



N° PATIENTS RECRUITED



SCIENTIFIC PUBLICATIONS



Here we see very quickly a summary of the main research-related activities in our institution: as you can see, all research activities have been increasing for the last 5 years.

In particular, in 2018, we had a 2% increase in the number of clinical trials with drugs, a 10% increase of patients enrolled in clinical trials, a 6% increase of studies promoted by our institute and a 21% increase of scientific publications.

The IRST informatization level/degree is very high.

All informations on patient pathway, business management and research procedures are web based accessible from all IRST sites.

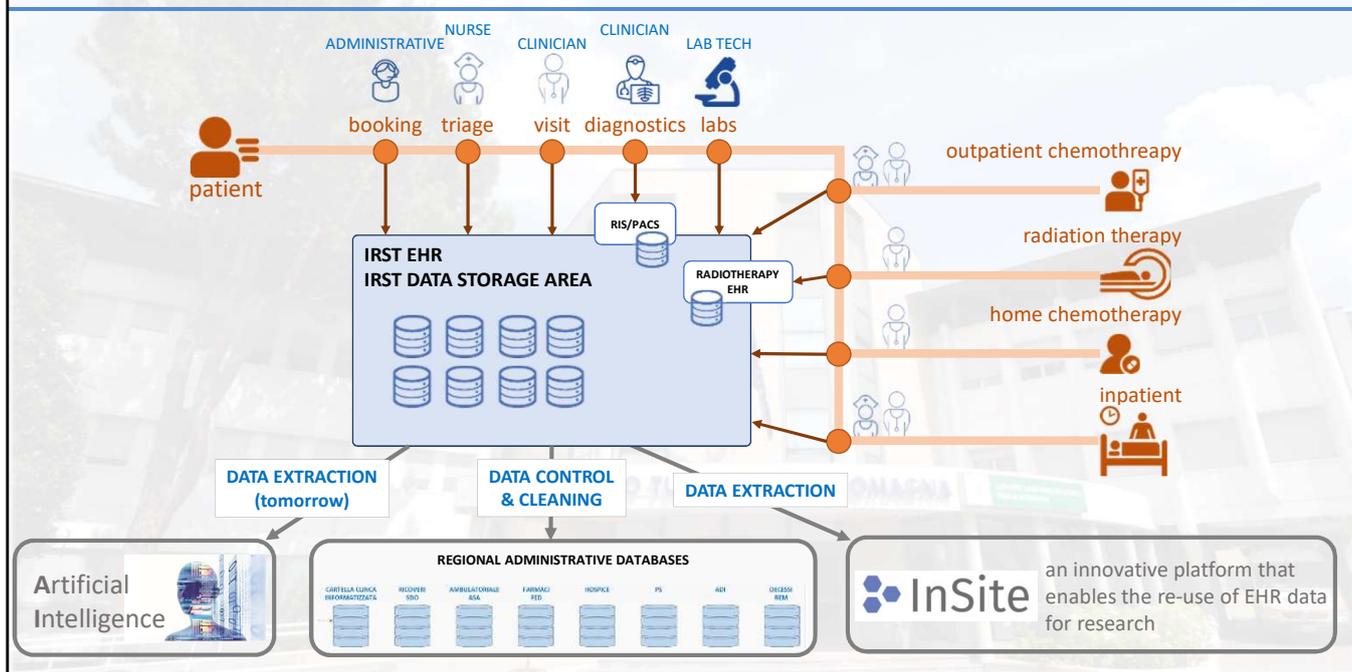
The electronic health record is a property of IRST and his technological partner: log80 (log eighty).

The development is governed by an interdisciplinary commission in IRST

Each IRST operator uses the Electronic Health Record (EHR) according to specific access profile and

data quality is improved by a permanent and continuous monitoring in a badget driven process.

Data collection in IRST

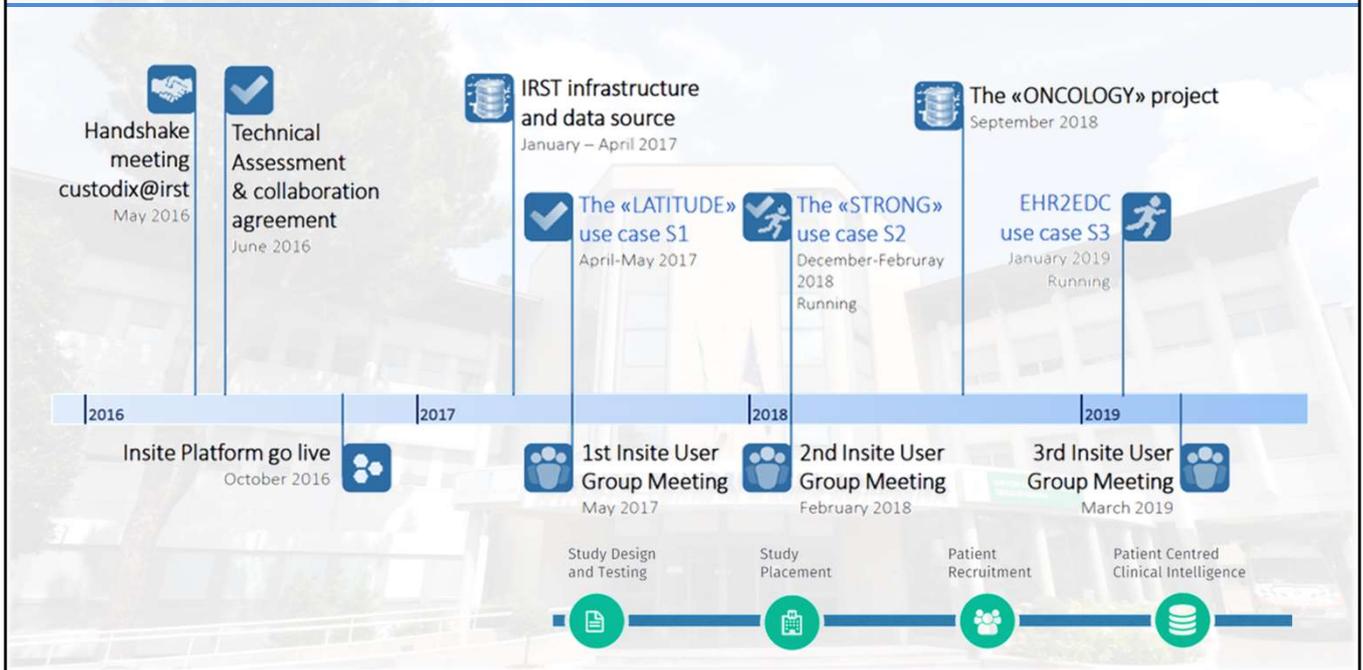


Regarding the collection of the data about the patient in our institute, at each step, dedicated personnel enter the data of interest directly into the EHR: starting from administrative data when the first appointment is created to laboratory results, treatment procedures, clinical data at triage and hospitalization, and so on..

The data entered into EHR are therefore available for administrative analysis regarding data control and cleaning and for research: from artificial intelligence to real world data extraction.

The high level of informatization, the interest in the real world data and the need to simplify the processes due to the ever-increasing number of clinical trials active and in activation at our institution, allowed us to accept the proposal of the InSite Platform about three years ago.

InSite set-up and milestones in IRST



The Custodix-IRST collaboration started 3 years ago, followed by a technical assessment and a shared collaboration agreement. IRST and Custodix involved their own competences to make the data from IRST accessible from the Insite platform.

We had the opportunity to work on three use cases:

- The first use case aimed to investigate the feasibility of this tool: we verify inclusion criteria for a closed clinical trials and we match – by the platform – all the patients really enrolled
- The second one, currently running, is aimed to test the ability of the platform to find eligible patients for the clinical trial directly from our EMR.
- The last one, started a few months ago, has the purpose to verify the data transferability from EHR to EDC by the mean of the InSite Platform.

At the same time, in collaboration with Custodix, we have completed in about 4 months a project named “the oncology project” by which we added to our data, specific information about cancer treatment: setting and line, tumor markers and lab tests and also clinical trials enrolment data directly from our EHR.

The IRST's database

DATA EXPOSED FROM IRST EHR DATABASE FOR INSITE QUERY WITH AGGREGATED RESULTS:



11 years history

over **79.718** patients

FEMALE 55%



MALE 45%

over **57.775** diagnosis

diagnosis codes
TNMs
tumour stages

over **792.251** encounters

over **1.759.657** procedures **483** different procedures

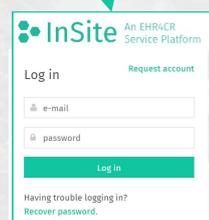
Over **1.813.803** medications **203** different active substances

over **633.632** assessments

PS ECOG 255.621
Clinical Benefit 159.857
Target Response 133.876
Other items

over **8.611.647** lab tests

over **23.327** clinical trials recruitments



Our institute has made available on the Insite platform 11 years of information on more than seventy-one thousand patients and more than one and half million coded drug administrations...

The IRST data mapping

EDC CONCEPT / AREA	IRST EHR			IRST INSITE PLATFORM
	CODED	NON coded	if non coded..	
DEMOGRAPHICS	✓			✓
GENERAL MEDICAL HISTORY		✗	plain text	
COMORBIDITIES AND SYMPTOMS		✗	plain text	
CONCOMITANT MEDICATION		✗	plain text	
PATHOLOGY / HISTORY OF CANCER	✓			✓
TUMOR MOLECULAR CHARACTERIZATIONS	✓			will be added
PRIOR CANCER SURGERY / THERAPY / RADIOTHERAPY	✓			✓
PHYSICAL EXAMINATION		✗	plain text	
VITAL SIGNS	✓			
PERFORMANCE STATUS	✓			✓
LABORATORY EXAMINATIONS	✓			✓
CARDIOLOGIC ASSESSMENT	✓			✓
TUMOR ASSESSMENT (IMAGING)		✗	plain text	
TUMOR ASSESSMENT (RESPONSE)	✓			will be added
STUDY TREATMENT ADMINISTRATION	✓			✓
ADVERSE EVENTS (AE / SAE)		✗	plain text	

What we are doing with our EHR..



Enabling **protocol testing with real world data** in potential trial sites rather than with guestimates.

From April 2018 to February 2019 we received 20 **feasibility** questionnaires for new study proposals in the platform. Just for 4 of these we had already been contacted by the sponsor and we had completed the "traditional" feasibility questionnaire!

Speeding up recruitment by making EHR data **searchable for investigators** and establishing a **unified communication path** between sponsors and sites.

From December 2017 to February 2019 we have evaluated 89 **potential patients** for a clinical trial really conducted in IRST: 6.5 patients per month!

Facilitating **EHR data extraction** for applications used during trial execution (e.g. prefilling of CRFs and of SAE reports).

Tomorrow: **automatic capture of data** from hospital EHR to eCRF

From April 2018 to February 2019 we received 20 **feasibility** questionnaires for new study proposals in the platform. Just for 4 of these we had already been contacted by the sponsor and we had completed the "traditional" feasibility questionnaire!

With the platform we have also tested the **recruitment** for a trial really conducted in IRST and we have evaluated 89 potential patients from December 2017 to today, and therefore 6.5 patients per month!

Well, if this is the present.. we are expecting much more from the future!

The project about the self-completion of the **eCRF** from the electronic medical record is about to start and it would be an important improvement for our daily work!

IRST academic trials and Cohort Analysis

- rapid and simple **data extraction** from our medical records
- **promote** our **non-profit studies** and include other hospitals in Italy and Europe with a sufficient number of patients
- network of hospitals can participate together to **European calls**

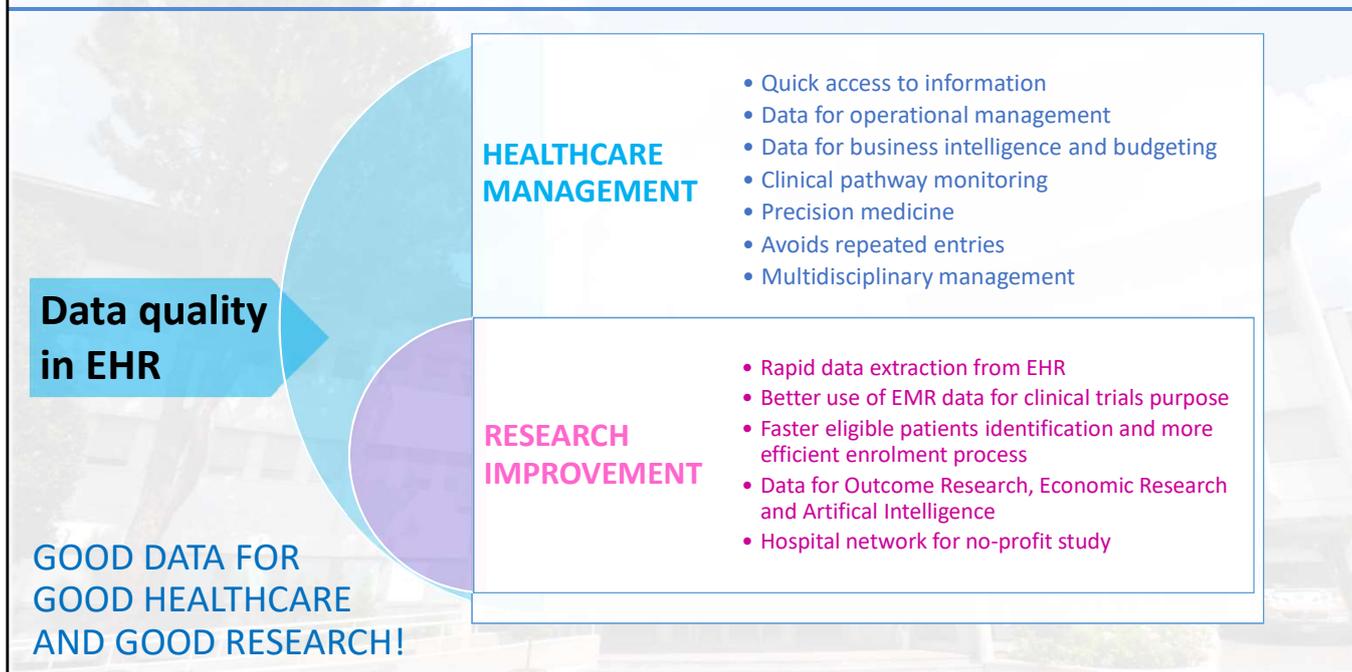


We are using the platform to make queries in our electronic medical records to evaluate the number of patients affected by a specific pathology and or treated with a specific drug.

We will also to use the platform to promote some non-profit studies of which IRST is the promoter, to find other hospitals in Italy and in Europe that will participate in the study and with a sufficient number of potential patients. We have identified one of our studies that we would like to upload into the platform and extend to European centers.

It will also be important to use the network of hospitals in the platform to take part together to European calls.

Take home message..



In conclusion, we can say that **GOOD DATA** are essential **FOR GOOD HEALTHCARE AND GOOD RESEARCH**, because we can have...



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Thanks