4th National Clinical Trials Day 2019

Plenary Session Hall of the Senate PCR
Prague, 14 May 2019

"EHR for clinical research in oncology – center view"

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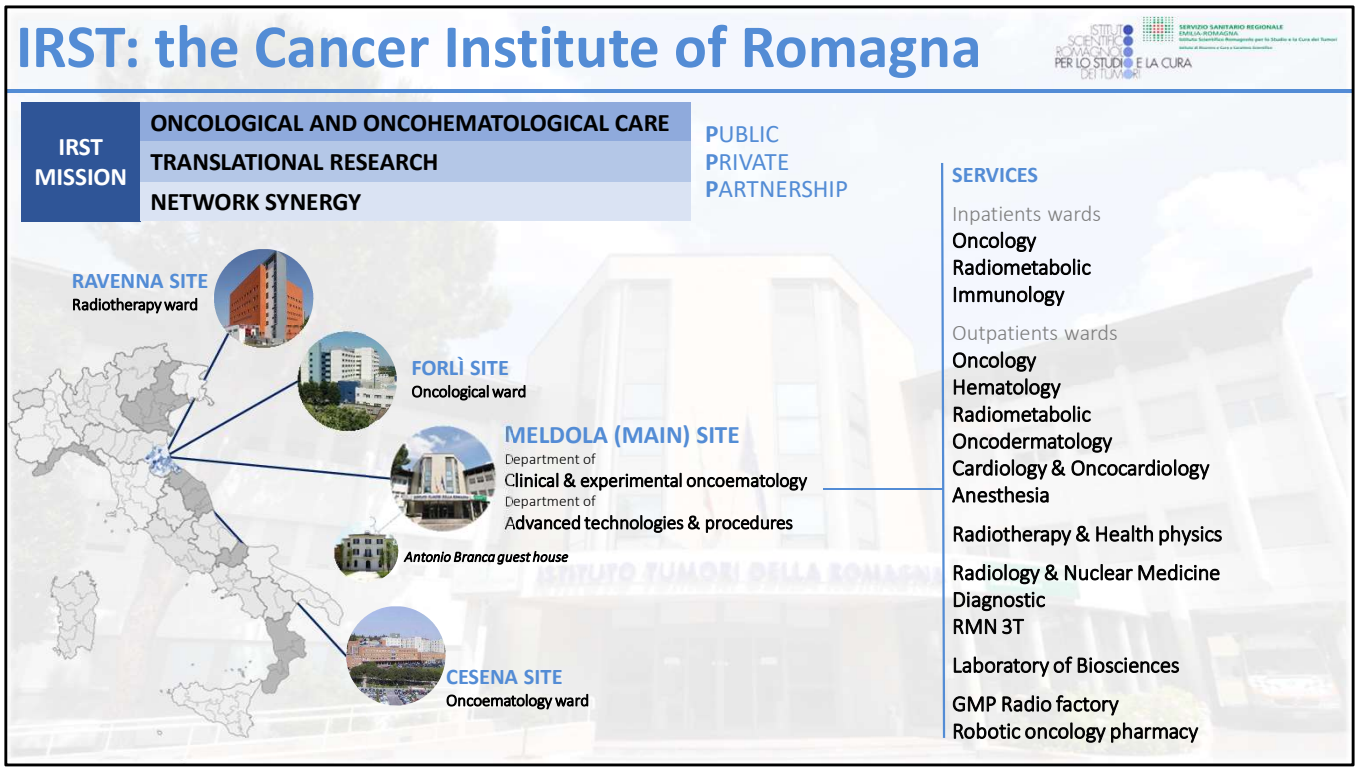


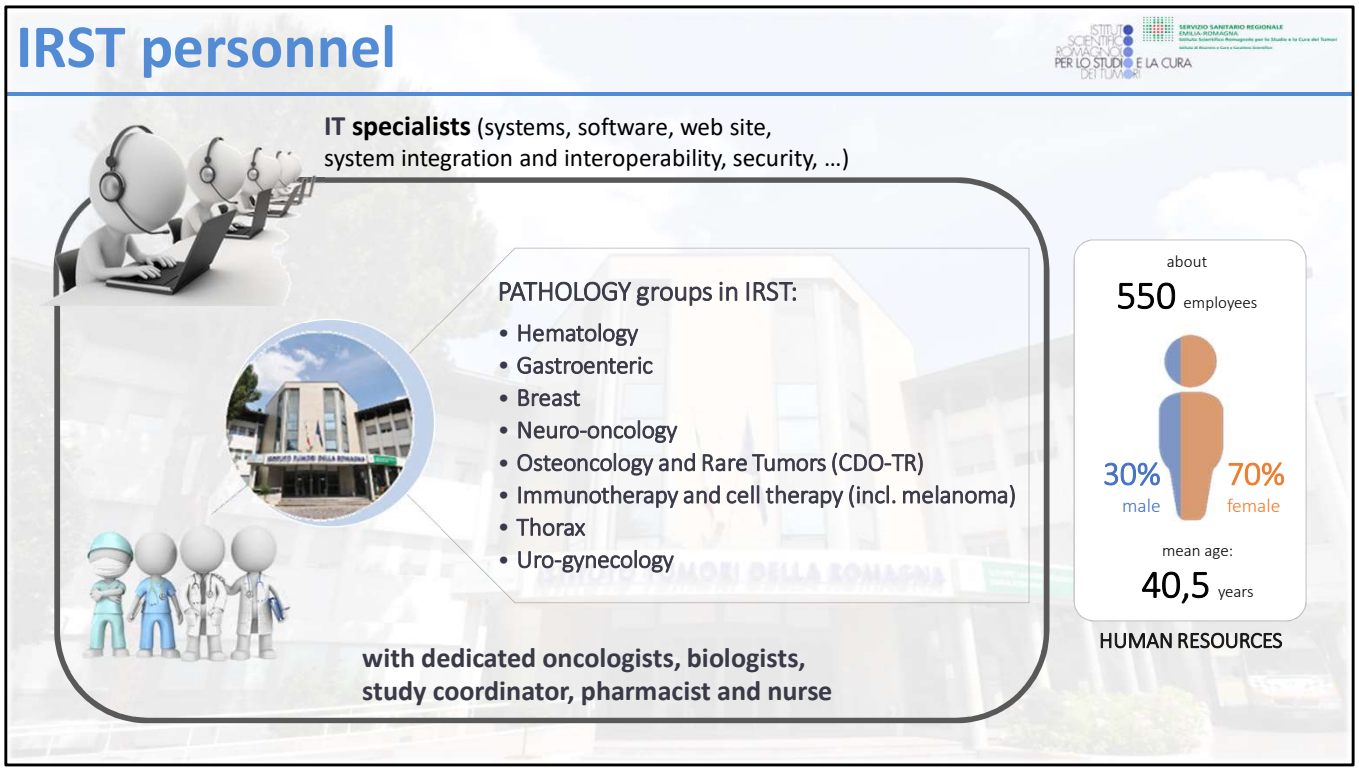
IRST (the Romagna Cancer Centre) was born in Romagna, in the middle of Italy, in 2007.
It is a public-private partnership between: the public Regional Health authority, a non-profit private organization, local banking foundations and the University of Bologna.
However, it is fully integrated in the public health system.

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

The Insitute follow 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.



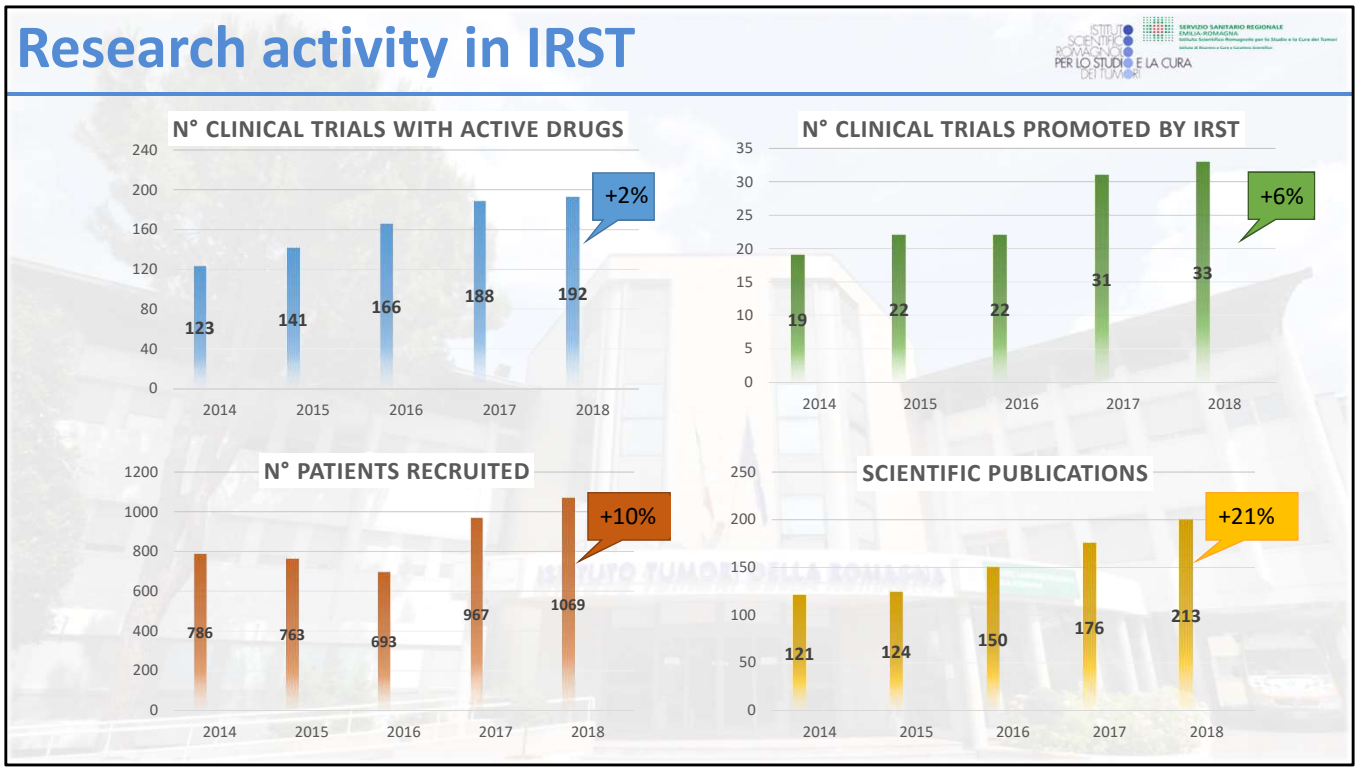
We are about 4 hundred and fifty units involved in care, research and support.
2 hundred sixty units of physicians, nurses, pharmacists, technicians, healthcare workers, are mainly dedicated to the assistance.
1 hundred forty four units are mainly involved in research, these are biologists, datamanagers,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

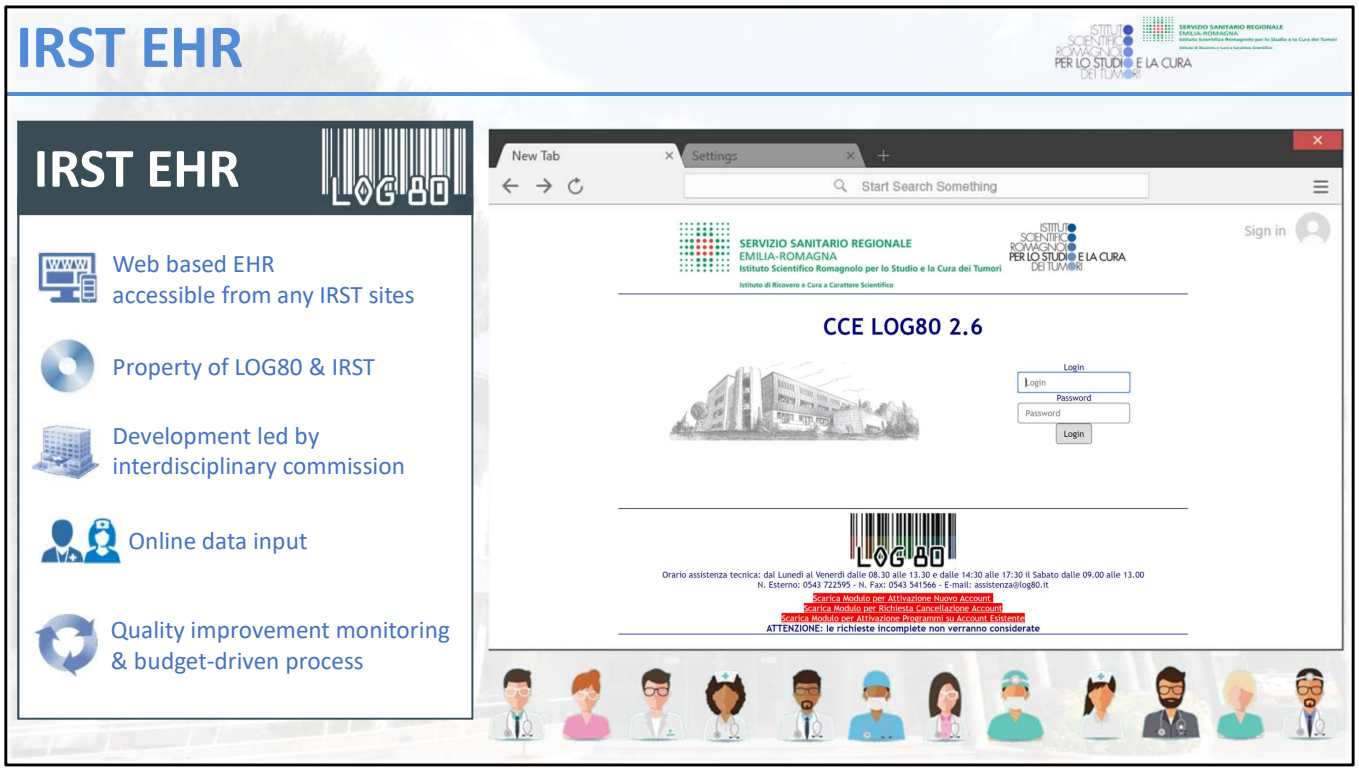
10 IT specialists try to put order in al this mess.

Research activity in IRST



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.

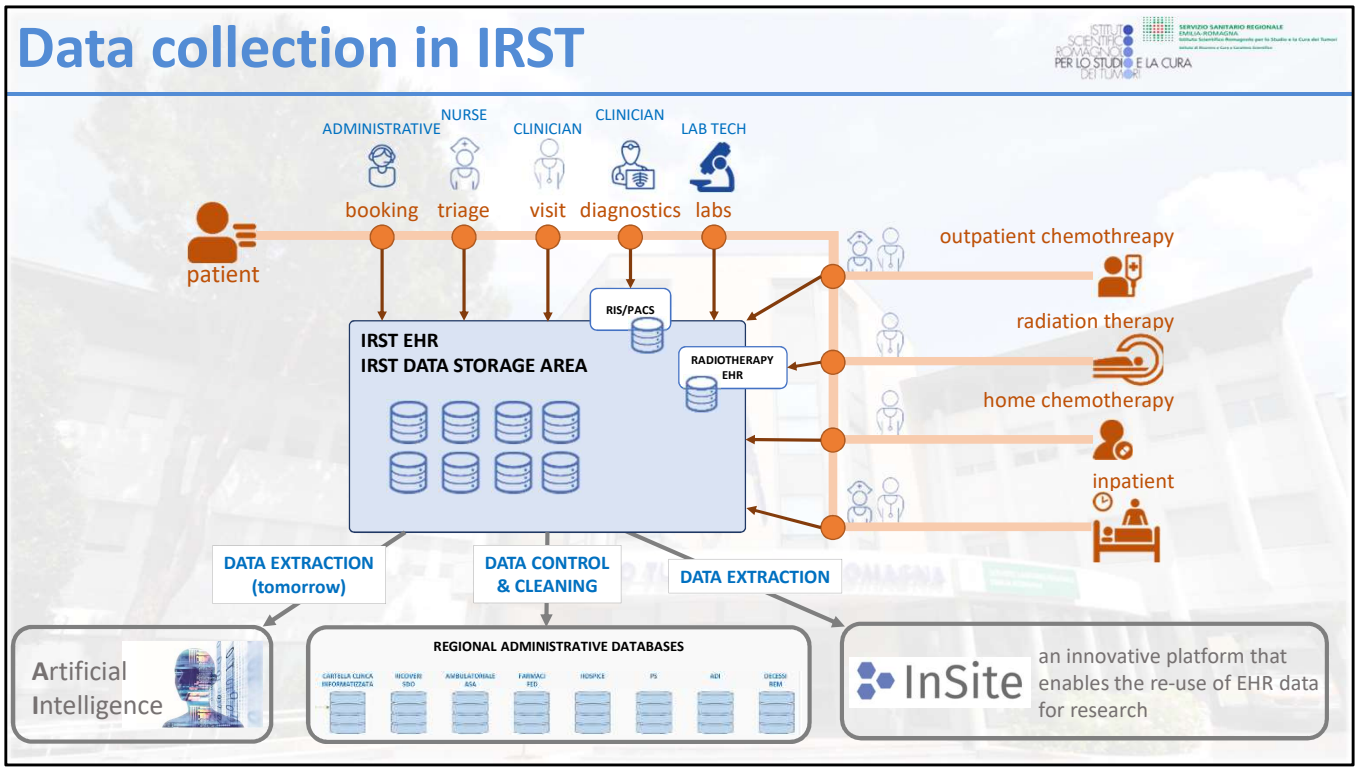
In particular, in 2018, we had a 2% increase in the number of clinical trials with drugs, a 10% increase of patients enrolled in clinical trials, a 6% increase of studies promoted by our institute and a 21% increase of scientific publications.



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

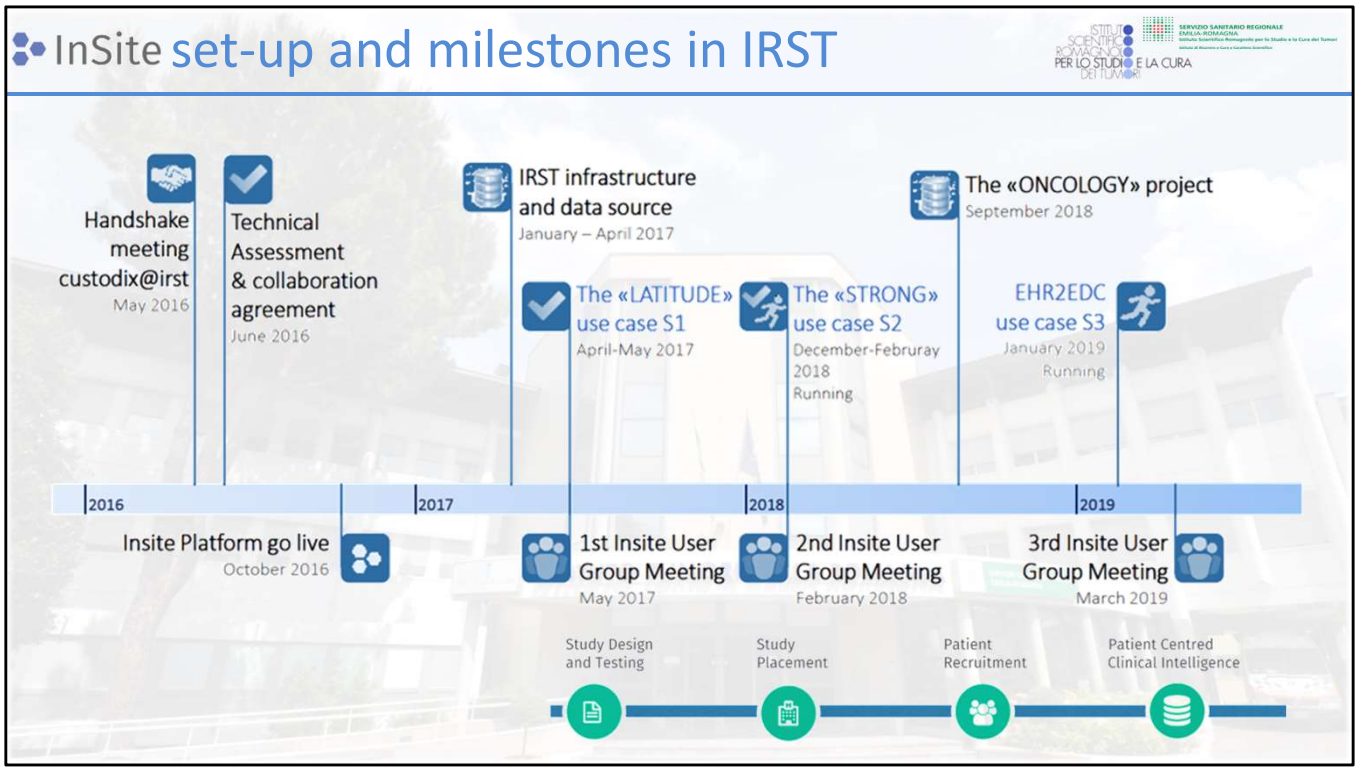
Each IRST operator uses the Electronic Health Record (EHR) according to specific access profile and
data quality is improved by a permanent and continuous monitoring in a badget driven process.



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.



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.

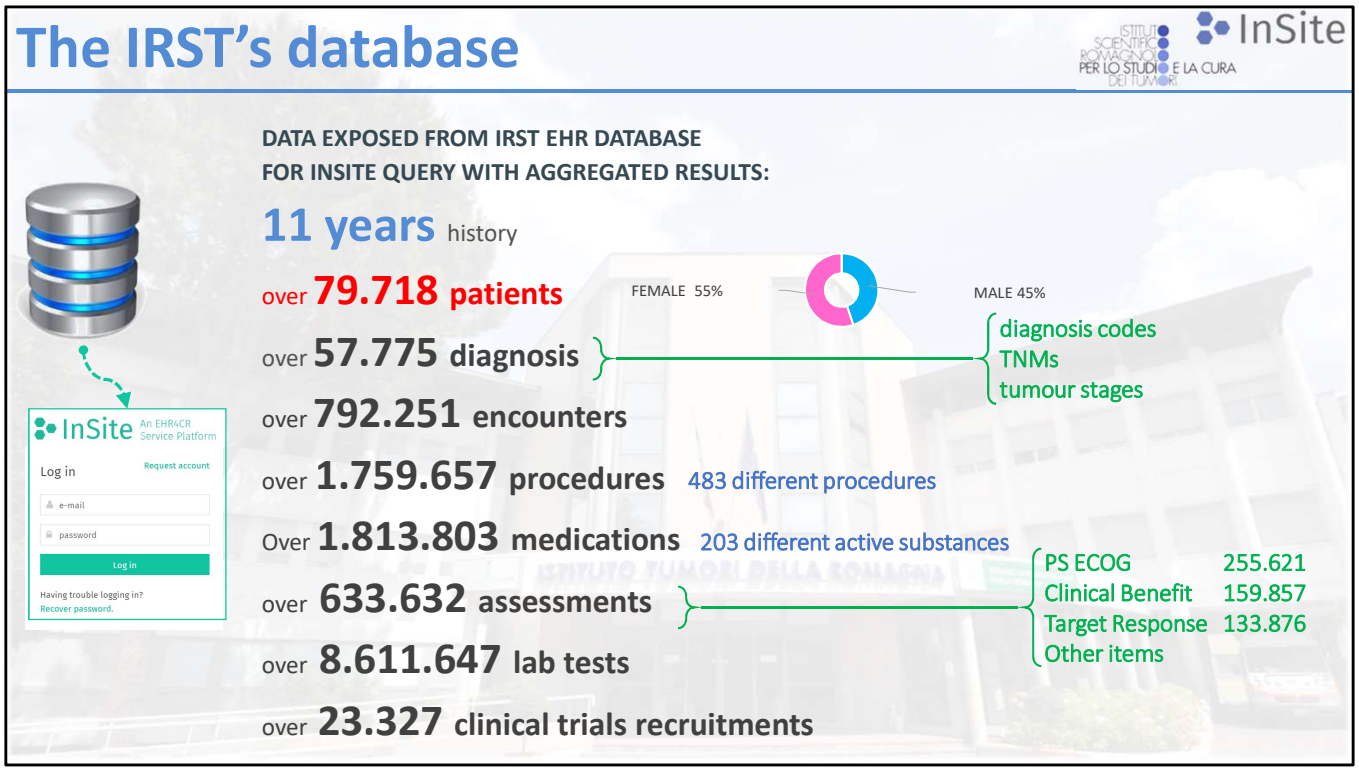
We had the opportunity to work on three use cases:

• 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.

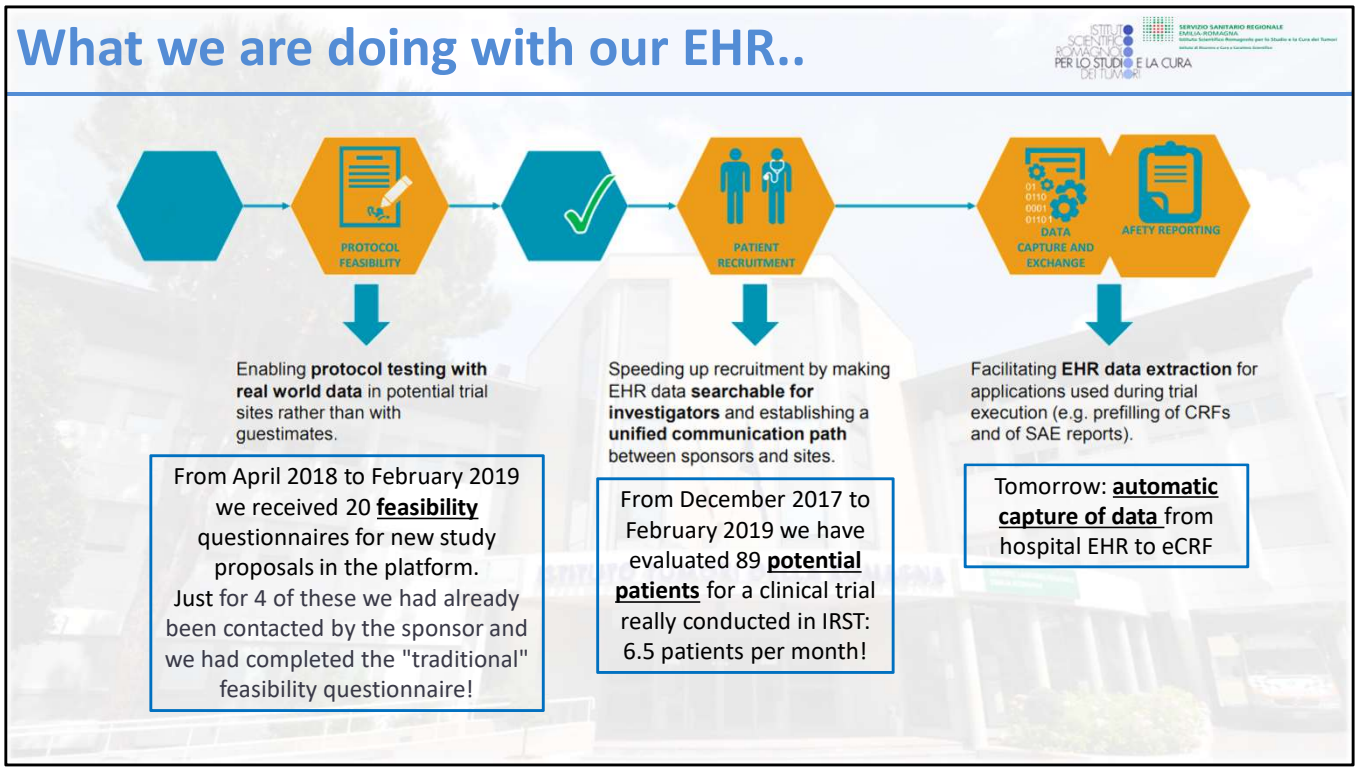
At the same time, in collaboration with Custodix, we have completed in about 4 months a project named “the oncology project” by which we added to our data, specific information about cancer treatment: setting and line, tumor markers and lab tests and also clinical trials enrolment data directly from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



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

The IRST data mapping

	IRST EHR			
EDC CONCEPT / AREA	**CODED**	**NON coded**	**if non coded..**	**IRST INSITE PLATFORM**
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	



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

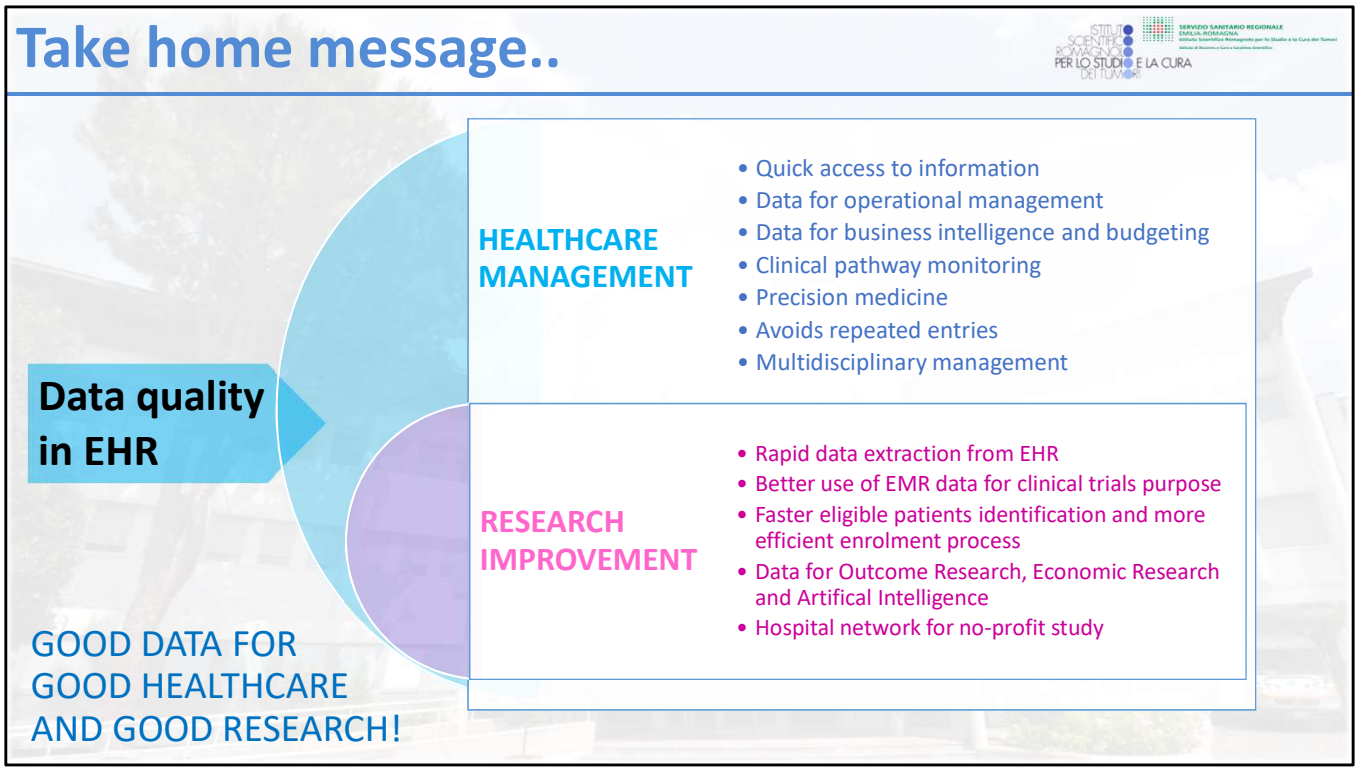
- rapid and simple **data extraction** from our medical records
- **promote** our **non-profit studies** and include other hospitals in Italy and Europe with a sufficient number of patients
- network of hospitals can participate together to **European calls**

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