



## 4<sup>th</sup> 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 Cancer Institute of Romagna

## IRST MISSION

**ONCOLOGICAL AND ONCOHEMATOLOGICAL CARE**  
**TRANSLATIONAL RESEARCH**  
**NETWORK SYNERGY**

**PUBLIC  
PRIVATE  
PARTNERSHIP**

## 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

### 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





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



## **PATHOLOGY groups in IRST:**

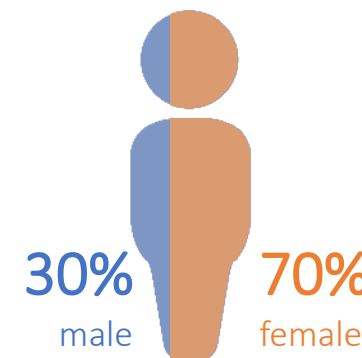
- Hematology
- Gastroenteric
- Breast
- Neuro-oncology
- Osteoncology and Rare Tumors (CDO-TR)
- Immunotherapy and cell therapy (incl. melanoma)
- Thorax
- Uro-gynecology



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

about

**550** employees



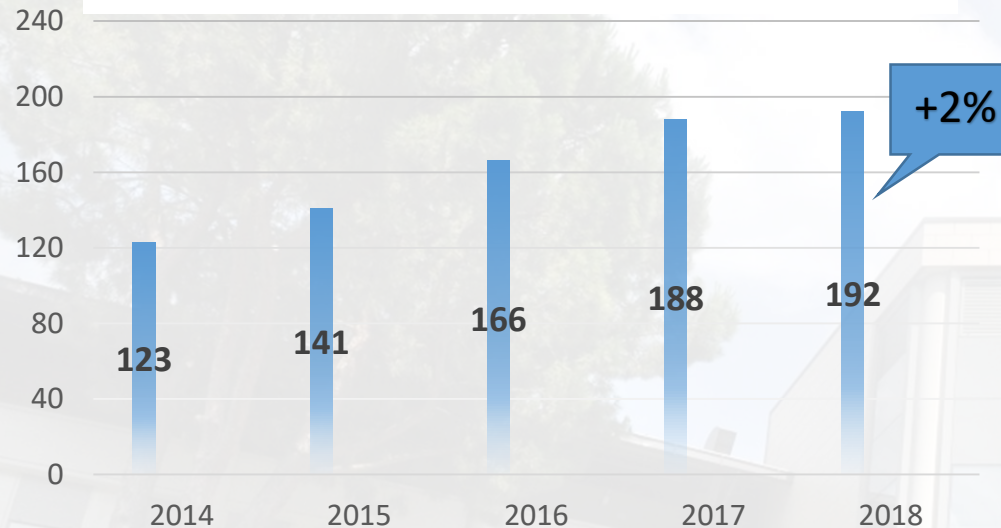
mean age:

**40,5** years

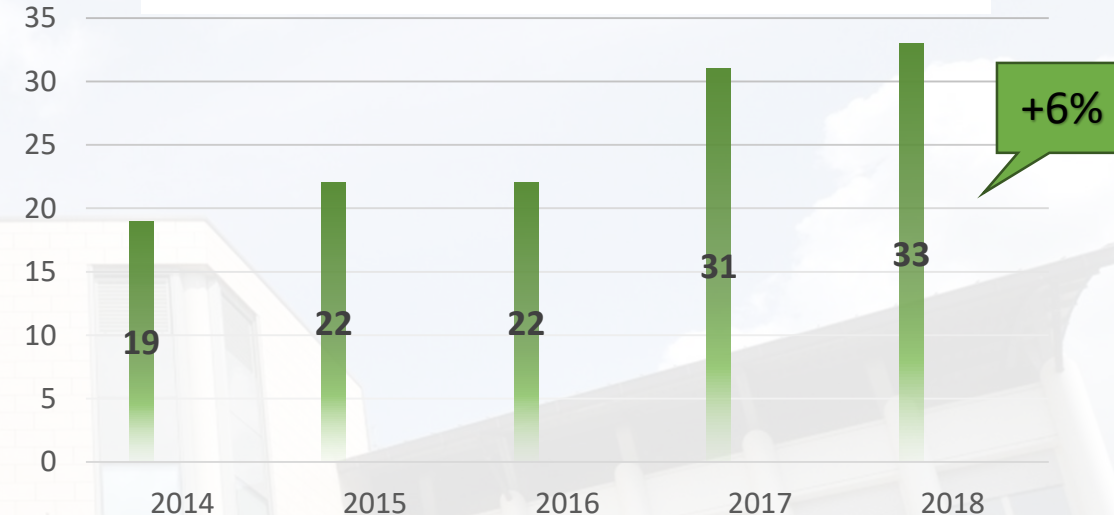
**HUMAN RESOURCES**

# Research activity in IRST

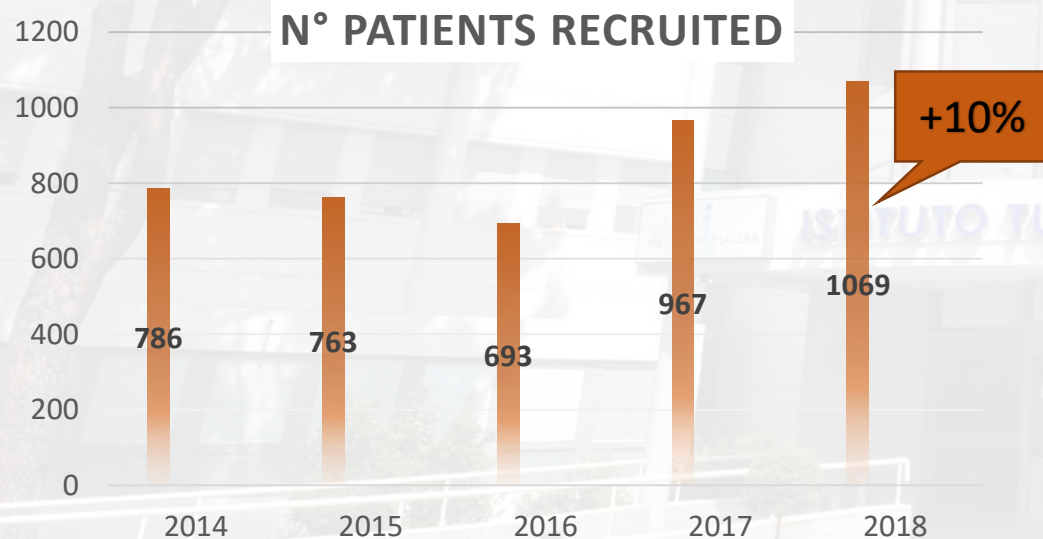
## N° CLINICAL TRIALS WITH ACTIVE DRUGS



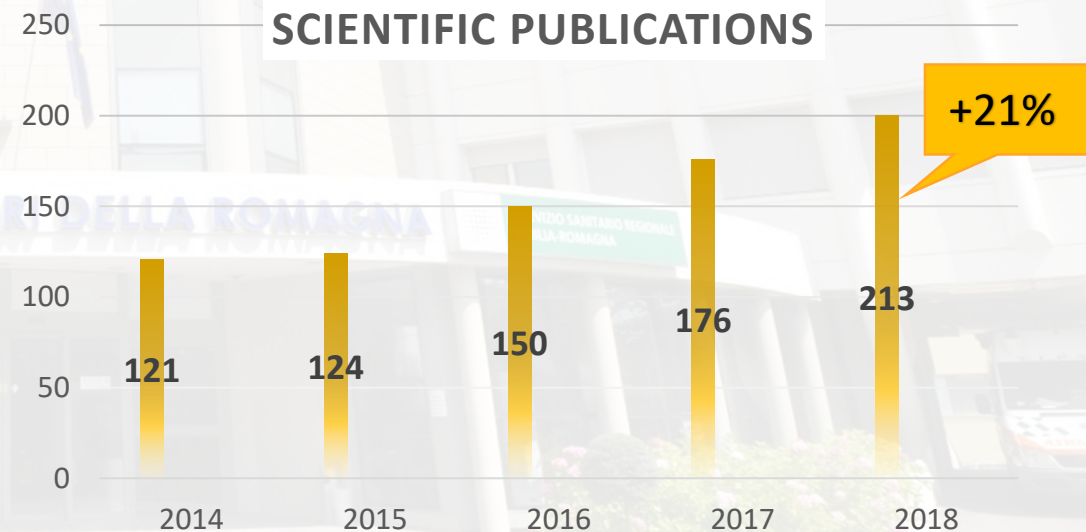
## N° CLINICAL TRIALS PROMOTED BY IRST



## N° PATIENTS RECRUITED



## SCIENTIFIC PUBLICATIONS





## IRST EHR



Web based EHR  
accessible from any IRST sites



Property of LOG80 & IRST



Development led by  
interdisciplinary commission



Online data input



Quality improvement monitoring  
& budget-driven process

New Tab x Settings x +

← → ↻ Start Search Something

SERVIZIO SANITARIO REGIONALE  
EMILIA-ROMAGNA  
Istituto Scientifico Romagnolo per lo Studio e la Cura dei Tumori  
Istituto di Ricovero e Cura a Carattere Scientifico

ISTITUT  
SCIENTIFIC  
ROMAGNOLI  
PER LO STUDIO  
DEI TUMORI

Sign in

### CCE LOG80 2.6




Login

Login

Password

Password

Login

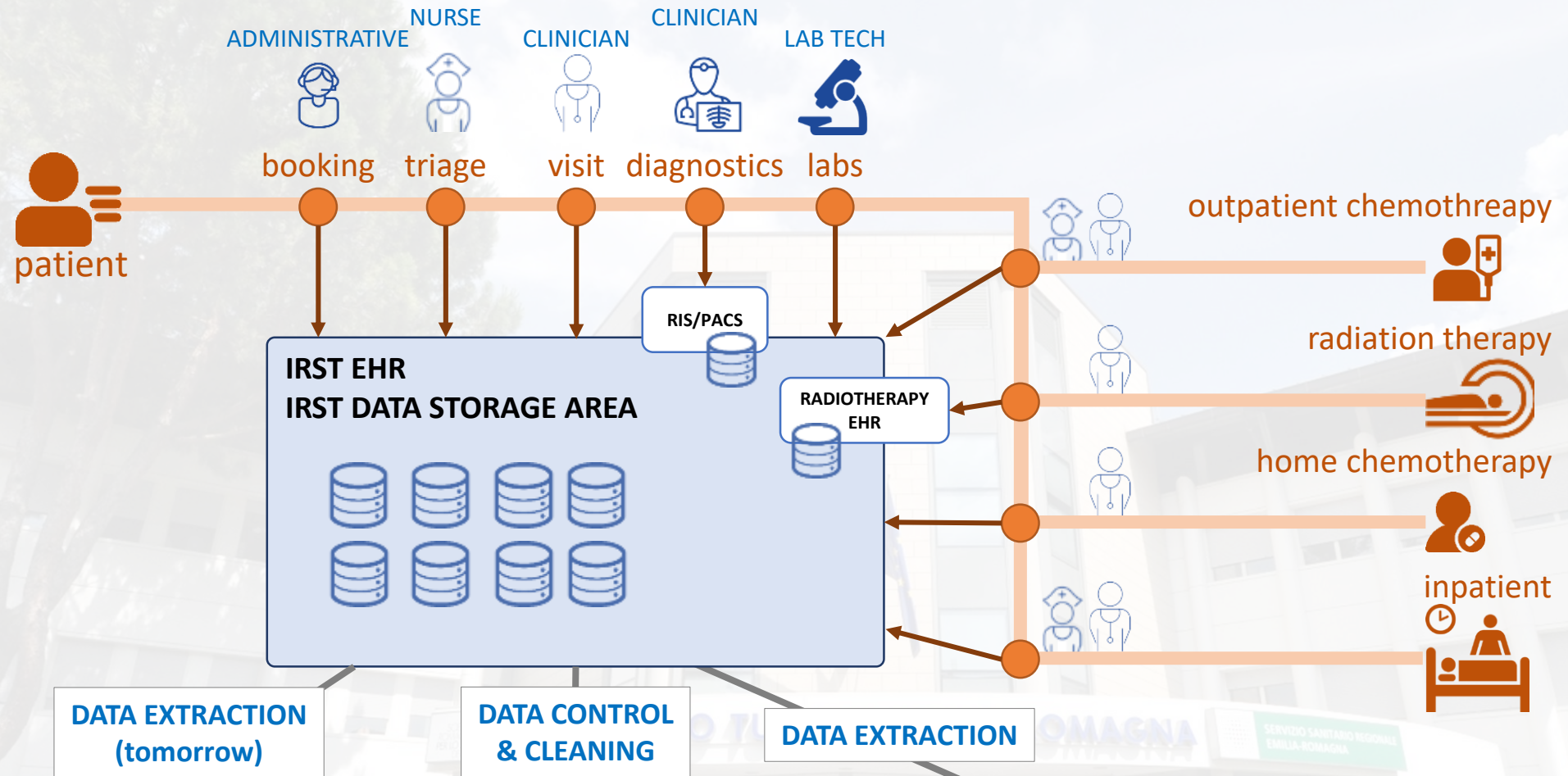


Orario assistenza tecnica: dal Lunedì al Venerdì dalle 08.30 alle 13.30 e dalle 14:30 alle 17:30 il Sabato dalle 09.00 alle 13.00  
N. Esterno: 0543 722595 - N. Fax: 0543 541566 - E-mail: assistenza@log80.it

[Scarica Modulo per Attivazione Nuovo Account](#)  
[Scarica Modulo per Richiesta Cancellazione Account](#)  
[Scarica Modulo per Attivazione Programmi su Account Esistente](#)  
**ATTENZIONE: le richieste incomplete non verranno considerate**



# Data collection in IRST



Artificial  
Intelligence



## REGIONAL ADMINISTRATIVE DATABASES

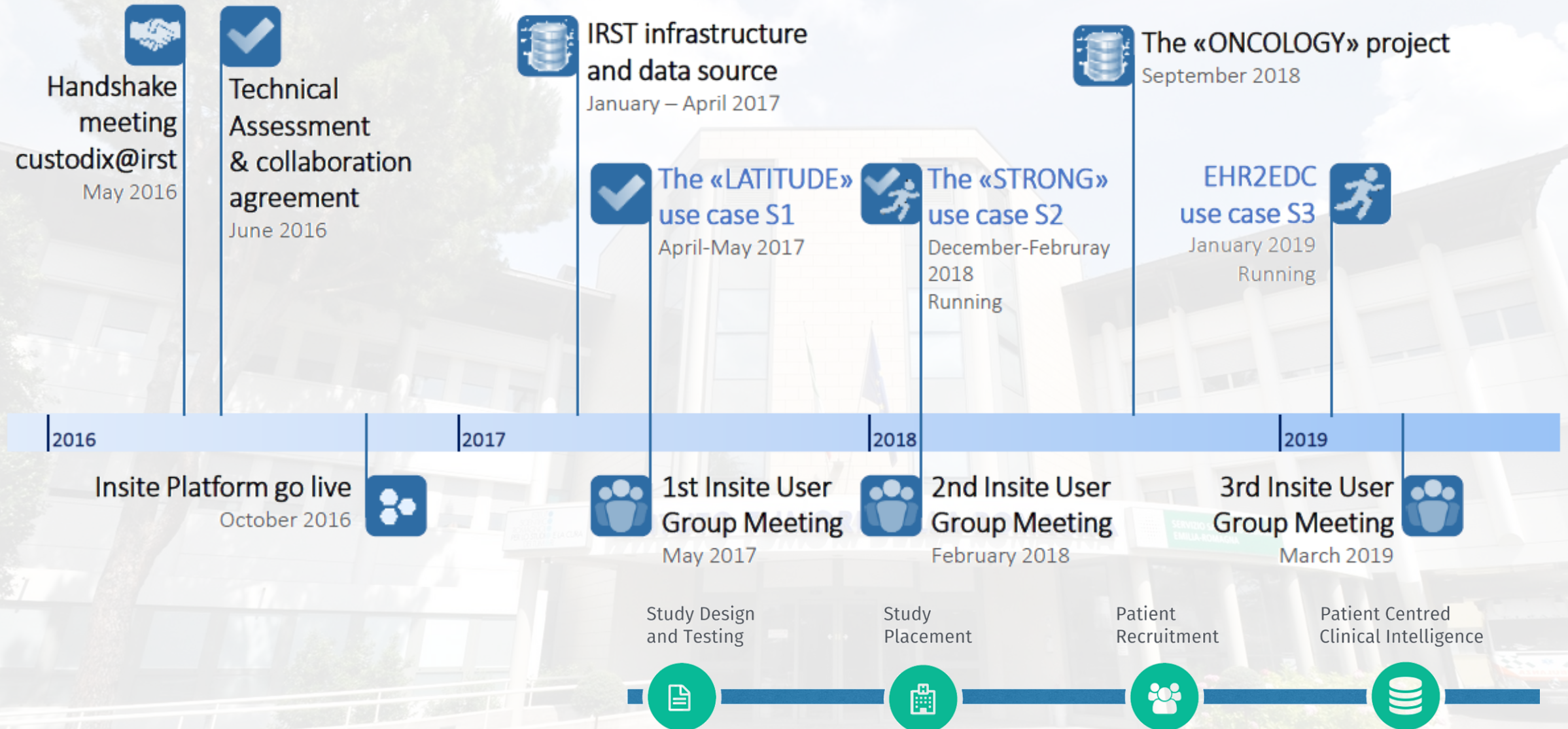


**InSite**

an innovative platform that  
enables the re-use of EHR data  
for research



# InSite set-up and milestones in IRST



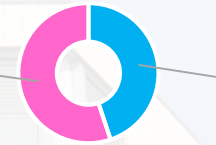
# The IRST's database

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



**InSite** An EHR4CR Service Platform

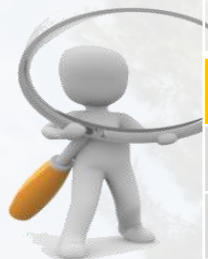
Log in [Request account](#)

[Log in](#)

Having trouble logging in?  
[Recover password.](#)

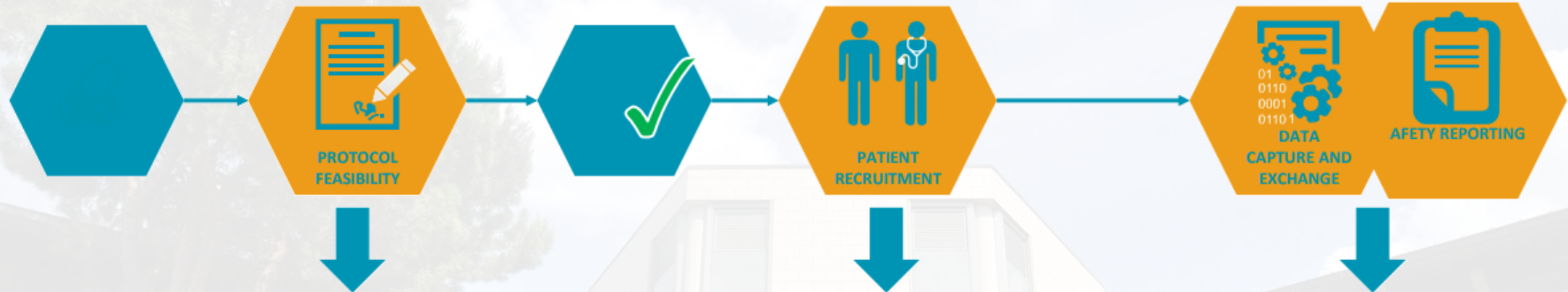


# The IRST data mapping



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



- 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**



# Take home message..

**Data quality  
in EHR**

## HEALTHCARE MANAGEMENT

- Quick access to information
- Data for operational management
- Data for business intelligence and budgeting
- Clinical pathway monitoring
- Precision medicine
- Avoids repeated entries
- Multidisciplinary management

## RESEARCH IMPROVEMENT

- Rapid data extraction from EHR
- Better use of EMR data for clinical trials purpose
- Faster eligible patients identification and more efficient enrolment process
- Data for Outcome Research, Economic Research and Artificial Intelligence
- Hospital network for no-profit study

**GOOD DATA FOR  
GOOD HEALTHCARE  
AND GOOD RESEARCH!**





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**Thanks**