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Riunione Annuale
Le sfide della ricerca sul carcinoma mammario

24 - 25 SETTEMBRE 2019

TRIESTE
Savoia Excelsior Palace Trieste - Starhotels Collezione
Riva del Mandracchio, 4

Ph. Courtesy Andrea Carloni
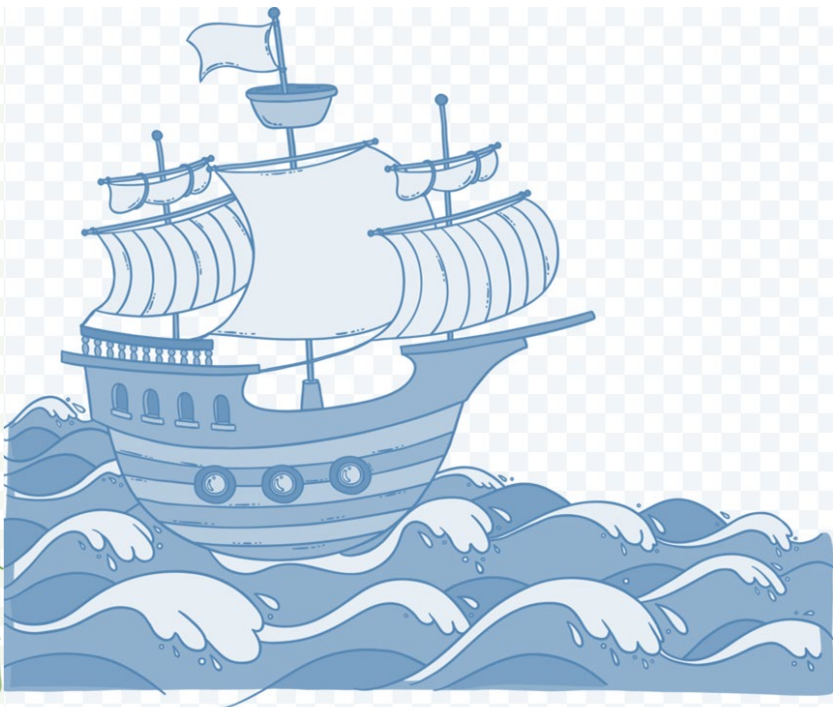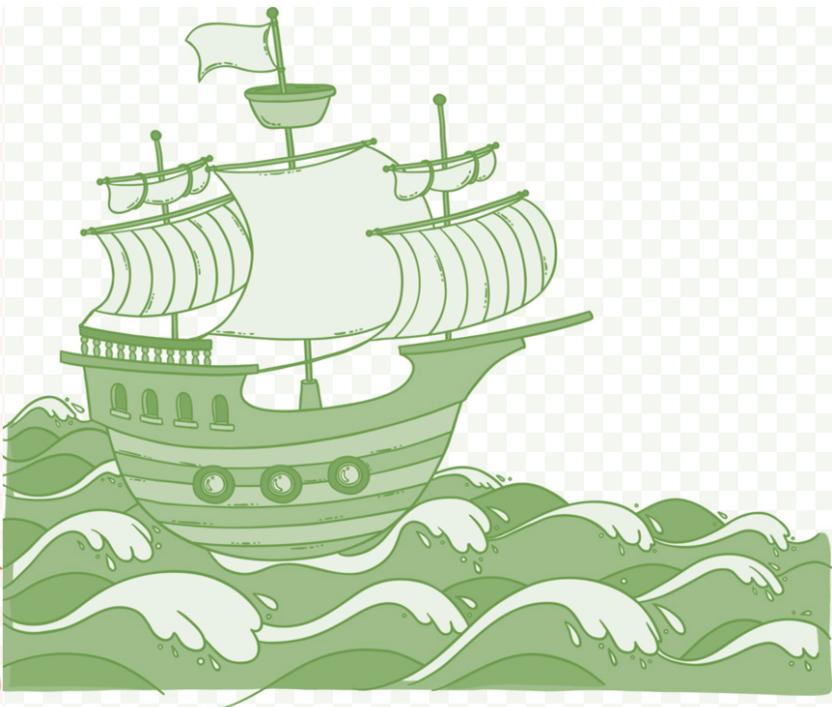
**GIRO DI BOA
REGISTRI E STUDI OSSERVAZIONALI**

NEW
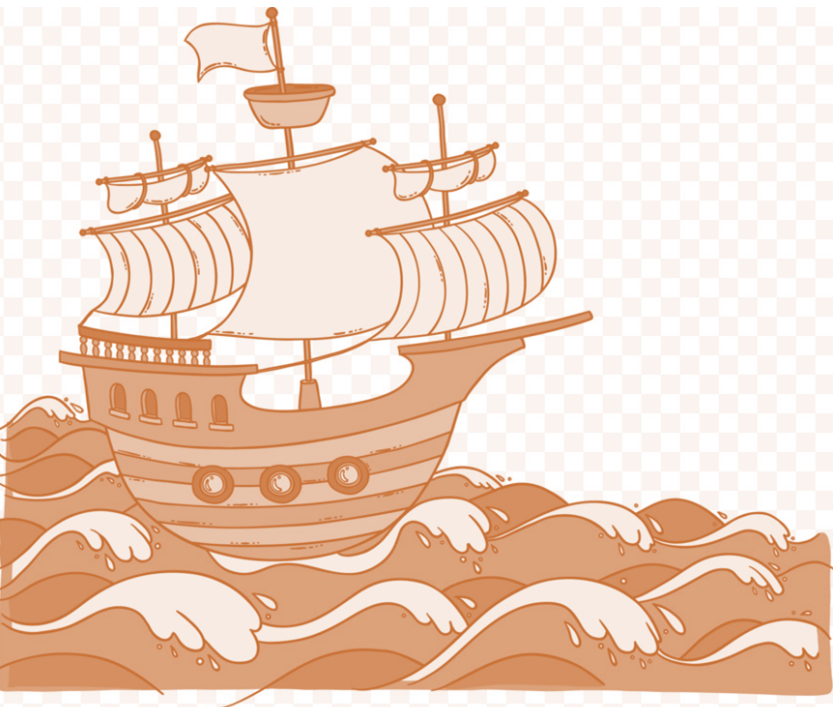
Le nuove proposte

MARTA BONOTTO   Udine

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NEW

Le tre nuove proposte

Perché "imbarcarsi"?

Niente di meglio di uno studio osservazionale ...


Descrizione di fenomeni sanitari

Valutazione di bisogni sanitari

Generazione di ipotesi

Valutazioni di appropriatezza

Abitudini di vita (es. fumo)

Esposizioni ambientali (es. inquinamento)

Sistemi organizzativi

Procedure cliniche entrate nella pratica senza validazione formale

NEW

Progetto:

ASSOCIATION AMONG OBESITY, INFLAMMATION AND OUTCOME IN PATIENTS WITH ADVANCED LUMINAL BREAST CANCER TREATED WITH CDK 4/6 INHIBITORS

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NEW
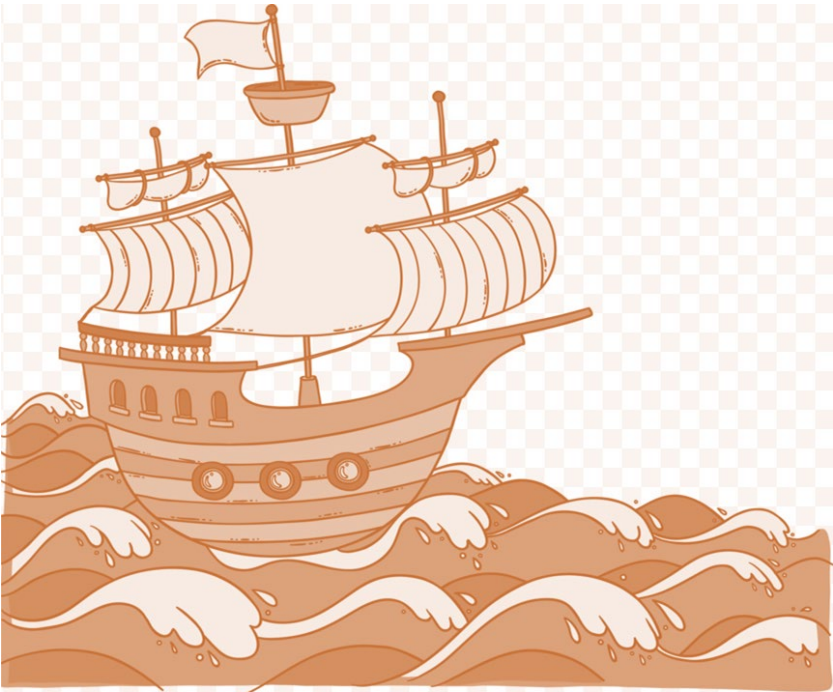
Association among obesity, inflammation and outcome in patients with advanced luminal breast cancer treated with CDK 4/6 inhibitors.
PROPONENTE

Dr. EMANUELA ROMAGNOLI

UOC Oncologia AV3 Macerata

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Association among obesity, inflammation and outcome in patients with advanced luminal breast cancer treated with CDK 4/6 inhibitors.

QUESITO E OBIETTIVI

Primary objectives:

to evaluate the association between **neutrophil-to-lymphocyte ratio (NLR) and systemic immune inflammation index (SII = P × N/L)** and **outcome** in patients with breast cancer in treatment with a CDK 4/6 Inhibitors.

Secondary objectives:

to describe the **variations of NLR and SII** during treatment with a CDK 4/6 Inhibitors.

to analyze the association between **BMI** in patients with breast cancer and in treatment with a CDK 4/6 Inhibitors.

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Association among obesity, inflammation and outcome in patients with advanced luminal breast cancer treated with CDK 4/6 inhibitors.

QUESITO E OBIETTIVI

The study aim to analyze two cohorts of patients:

Cohort A
Patients with advanced luminal BC treated with CDK 4/6 inhibitors as first line

Cohort B
Patients with advanced luminal BC treated with CDK 4/6 inhibitors as second line

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Association among obesity, inflammation and outcome in patients with advanced luminal breast cancer treated with CDK 4/6 inhibitors.

QUESITO E OBIETTIVI

Paziente (iniziali)	Data di nascita	Kg	cm	BMI	Data diagnosi cito/istologica	Tipo istologico (1 duttale 2 lobulare 3 altro)	Grading	Stadio all'esordio	T	N	ER	PgR	Mib-1	Her 2	Adiuv 1=si 2=no

schema I linea	Data inizio prima linea	Data fine prima linea	Progressione (1=Si 0=no)	Data Progressione	N (prima di iniziare)	L (prima di iniziare)	P (prima di iniziare)	N (prima della TC a 3 mesi)	L (prima della TC a 3 mesi)	P (prima della TC a 3 mesi)	Data ultimo follow-up o morte

schema II linea	Data inizio II linea	Data fine II linea	Progressione (1=Si 0=no)	Data Progressione	N (prima di iniziare)	L (prima di iniziare)	P (prima di iniziare)	N (prima della TC a 3 mesi)	L (prima della TC a 3 mesi)	P (prima della TC a 3 mesi)

Data ultimo follow-up o morte	Successivi trattamenti si(1) no(2)	Decesso (1) si (2) no

NEW

Progetto:

The IDENTITY Study

InheriteD brEast caNcer iTalian regIsTrY:
A RETROSPECTIVE-PROSPECTIVE
OBSERVATIONAL COHORT STUDY TO
EVALUATE CANCER PREVENTION
STRATEGIES IN WOMEN WITH A
DELETERIOUS MUTATION IN BRCA1-2

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The IDENTITY Study: InheriteD brEast caNcer iTalian regIsTrY:
PROPONENTE

Dr. GIACOMO PELIZZARI
Prof. FABIO PUGLISI

Department of Medicine (DAME) – University of Udine
Department of Clinical Oncology – CRO Aviano IRCCS

Email: giacomo.pelizzari.med@gmail.com

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The IDENTITY Study: InheriteD brEast caNcer iTalian regIsTrY:
QUESITO E OBIETTIVI

Primary objectives:

- **To obtain and centralize data about cancer prevention strategies in women with a germline deleterious mutation in BRCA1-2 with or without a history of breast cancer in Italy**

Secondary objectives:

- To **evaluate clinico-radiological follow-up** (type and frequency) of women with a germline deleterious mutation in BRCA1-2 with or without a history of early breast cancer
- To **evaluate treatment** of early and/or advanced breast cancer in women with a germline deleterious mutation in BRCA1-2
- To **evaluate disease-free survival and/or progression-free survival and overall survival** of women with a germline deleterious mutation in BRCA1-2 treated for early and/or advanced breast cancer

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QUESITO E OBIETTIVI

The study is composed of a retrospective cohort (A) and a prospective cohort (B):

Cohort A (Retrospective):
- all consecutive women with a germline deleterious mutation in BRCA1-2 admitted to the participant Center since 1st of January 2010 until site activation will be enrolled.

Cohort B (Prospective):
- all consecutive women with a germline deleterious mutation in BRCA1-2 admitted to the participant Center since site activation until September 2025 will be enrolled.

The observation period will last 10 years since enrollment.

It is expected to enroll approximately 800 – 1000 patients.

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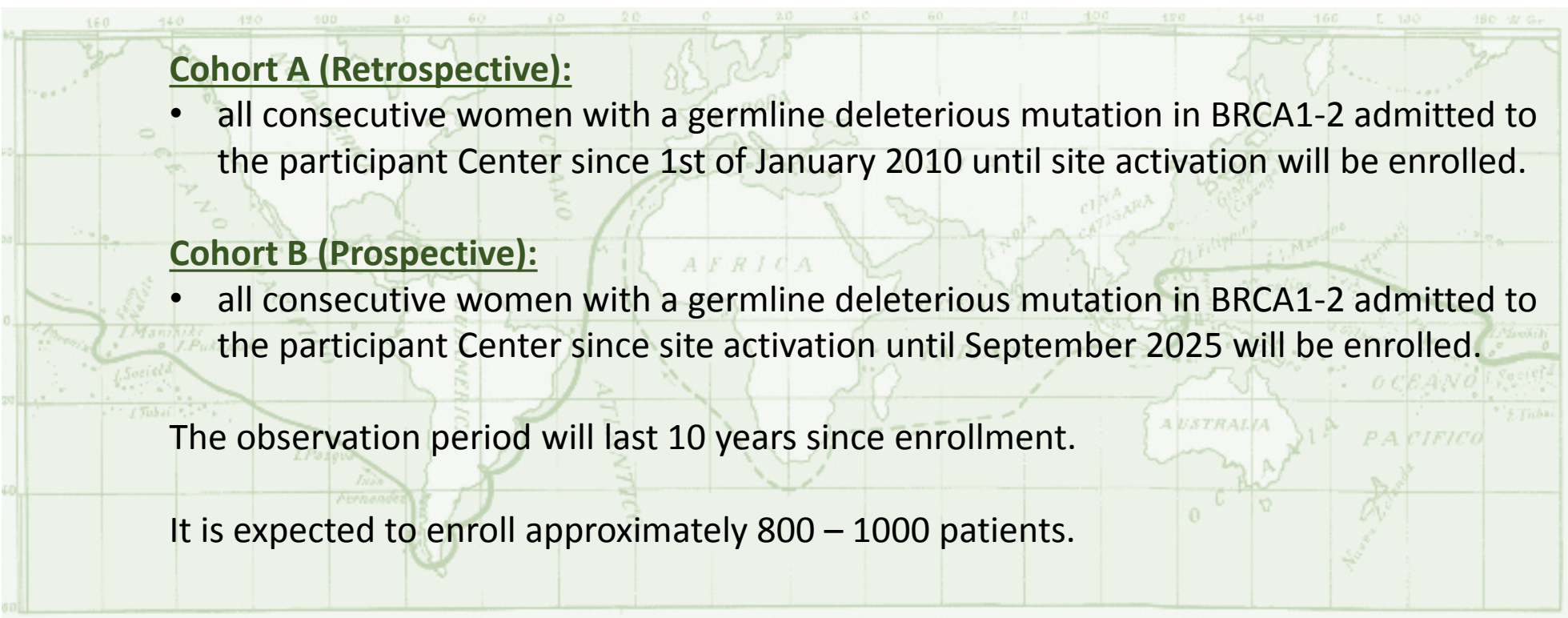
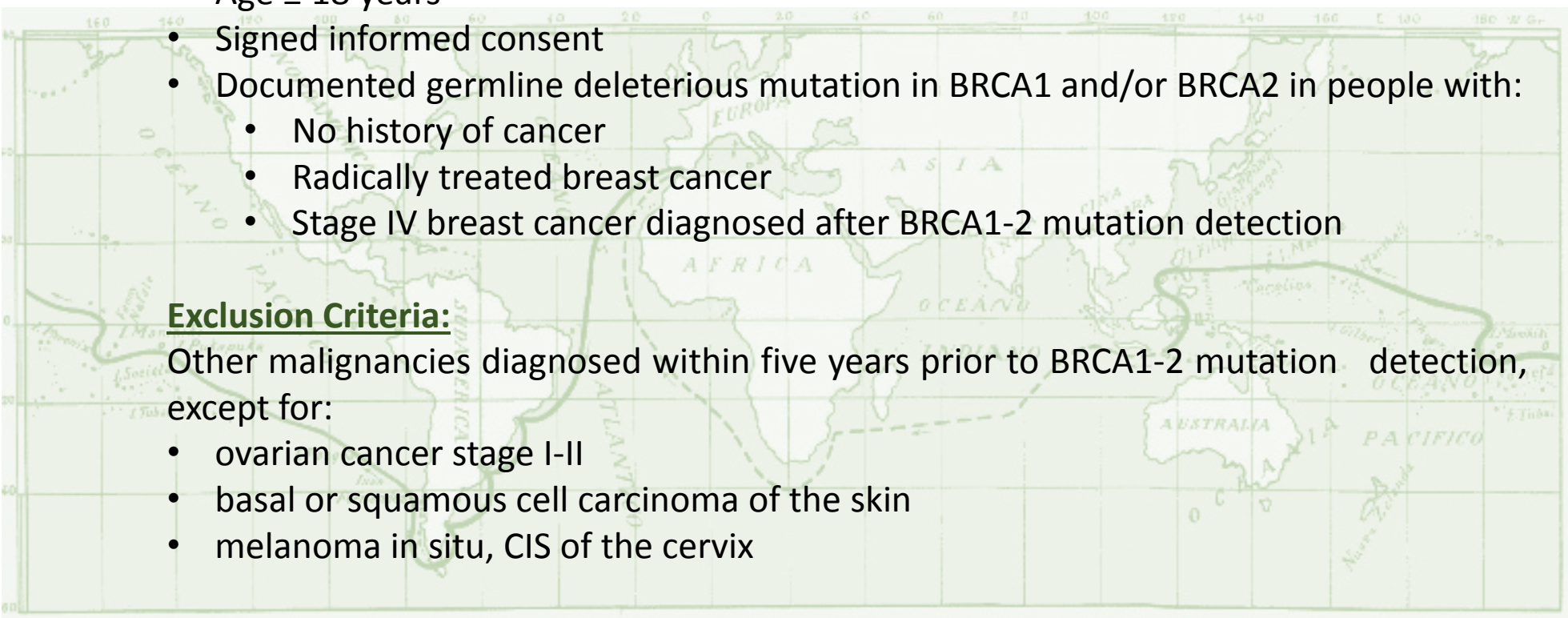# The IDENTITY Study: InheriteD brEast caNcer iTalian regIsTrY:
QUESITO E OBIETTIVI

Inclusion Criteria:
- Female sex
- Age ≥ 18 years
- Signed informed consent
- Documented germline deleterious mutation in BRCA1 and/or BRCA2 in people with:
  - No history of cancer
  - Radically treated breast cancer
  - Stage IV breast cancer diagnosed after BRCA1-2 mutation detection

Exclusion Criteria:
Other malignancies diagnosed within five years prior to BRCA1-2 mutation   detection, except for:
- ovarian cancer stage I-II
- basal or squamous cell carcinoma of the skin
- melanoma in situ, CIS of the cervix

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# The IDENTITY Study: InheriteD brEast caNcer iTalian regIsTrY:
QUESITO E OBIETTIVI

| Timeline |
|---|
| • Ethical committee evaluation 27.08.19 |
| • Starting accrual September/October 2019 |

Centers – Partial
Adamo – Messina
Arpino – Napoli
Bologna – Reggio Emilia
Cannita – L'Aquila
Collovà – ASST Ovest Milanese
Cortesi – Modena
De Laurentis – Napoli
Del Mastro - Genova
Gamucci – Roma
Minisini – Udine
Sini – Roma
[…]

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NEW
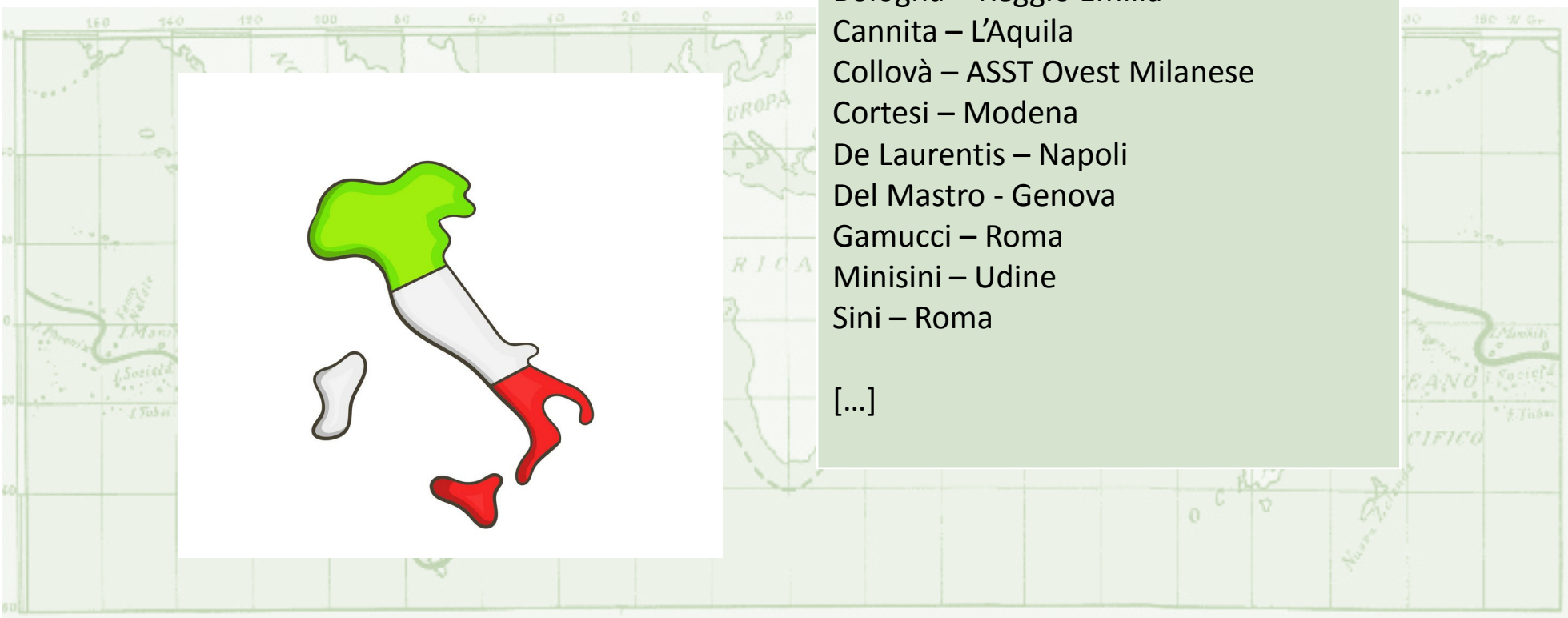
Progetto:

AN AUTOMATED I2B2-BASED REGISTER FOR A NETWORK DATA-SHARING AND DEVELOPMENT OF OUTCOMES RESEARCH STUDIES

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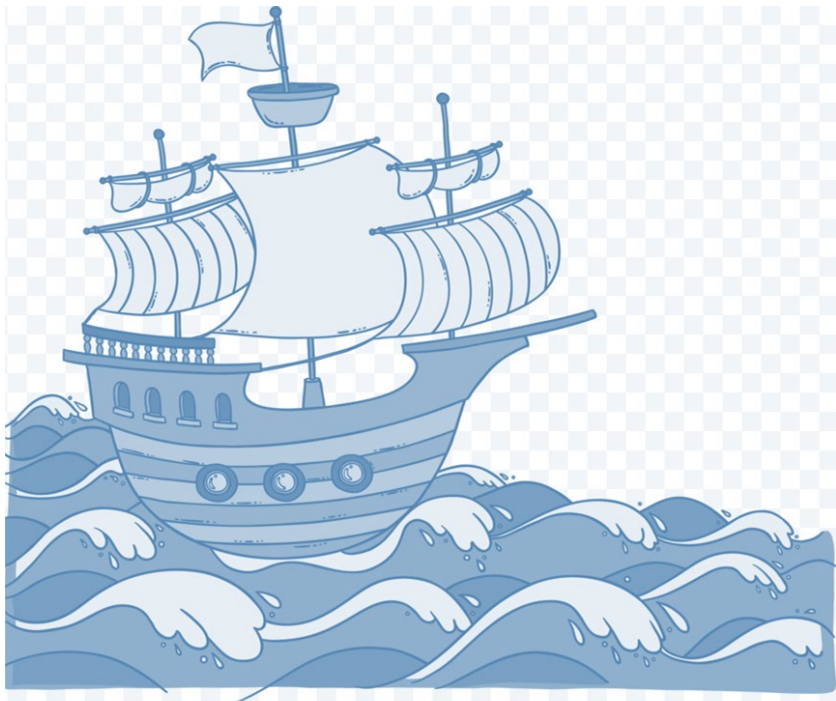
NEW

An automated I2B2-based register for a network data-sharing and development of outcomes research studies

PROPONENTE

Dr. ALBERTO ZAMBELLI

Hospital "ASST Papa Giovanni XXIII", Bergamo

Email: **alberto.zambelli@asst-pg23.it**

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QUESITO E OBIETTIVI

Objectives:

The implementation of i2b2 platform at different GIM-sites to contribute to an i2b2-GIM network, that paves the way for innovative programs of data-sharing and multiple outcomes research studies.

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QUESITO E OBIETTIVI

I2b2 is an effective, exportable, academic, open-source data-warehouse system

I2b2 allows to share data from different archives and different institutions

I2b2 provides an automated temporal electronic phenotyping (clinical pathway) and supports processes of learning intellegence for research and treatment
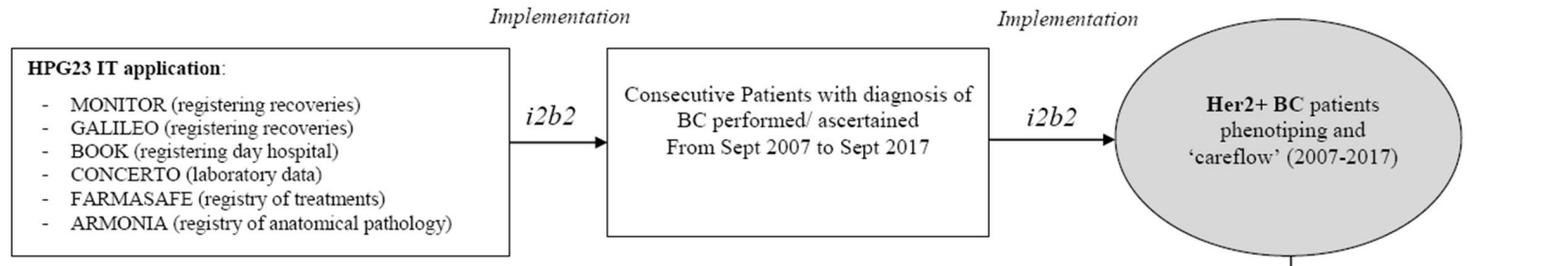
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AN EXEMPLE OF THE POTENTIAL OF I2B2 ON ARCHIVE ELECTRONIC DATASET (10YR-HER2+BCS SURVEY)
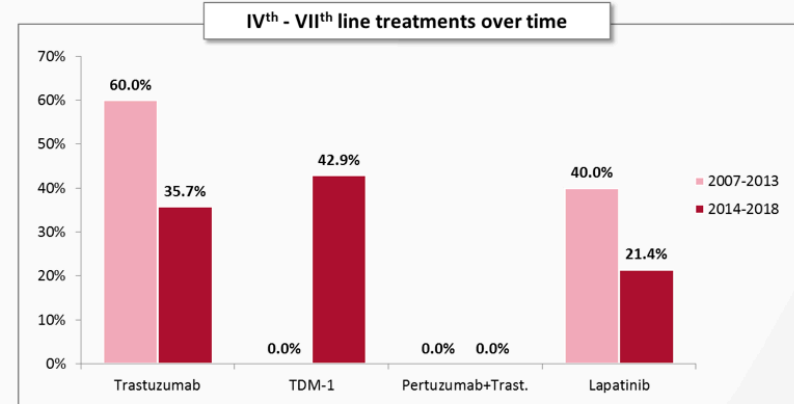
AN EXEMPLE OF THE POTENTIAL OF I2B2 ON ARCHIVE ELECTRONIC DATASET (10YR-HER2+BCS SURVEY)

NEW

Automated recognition of antiHER2 lines of treatment
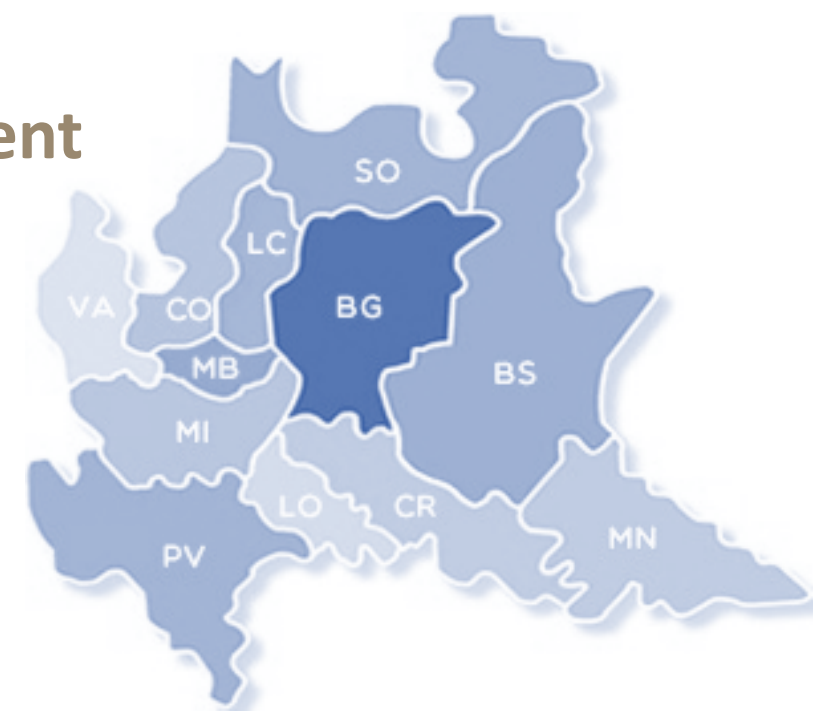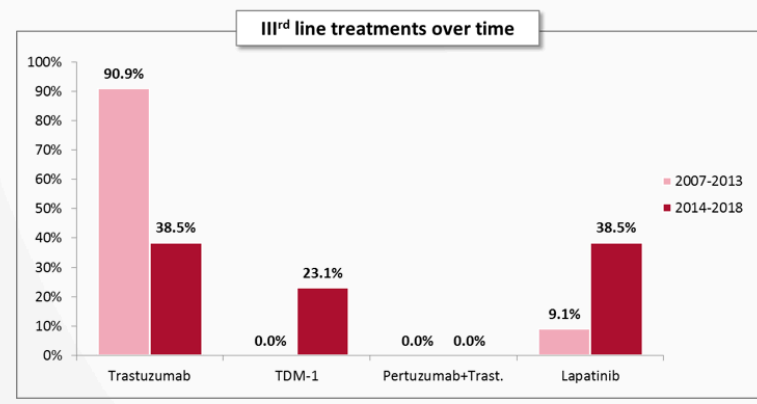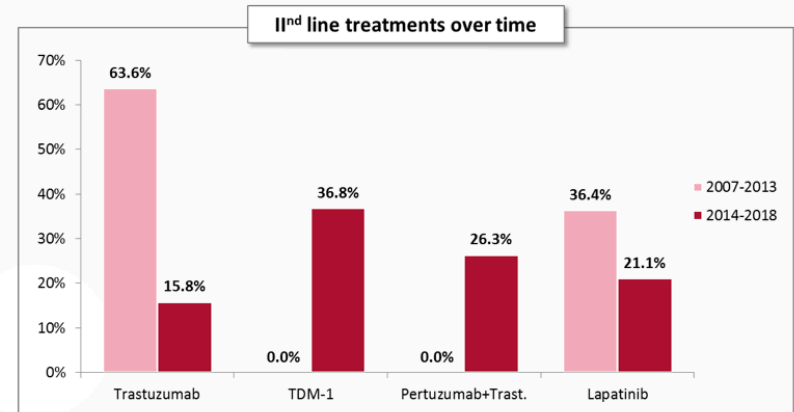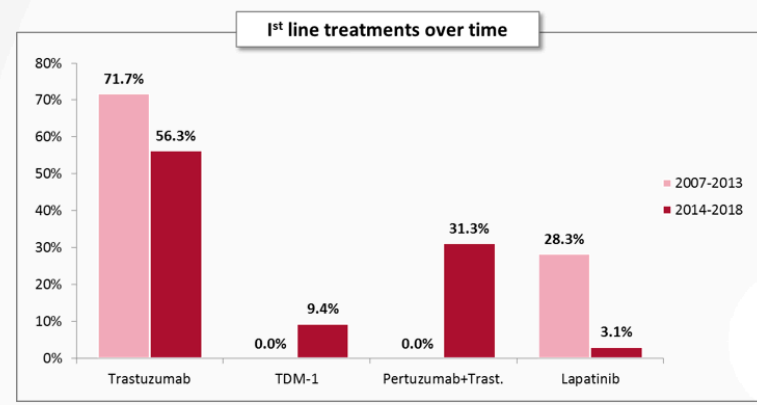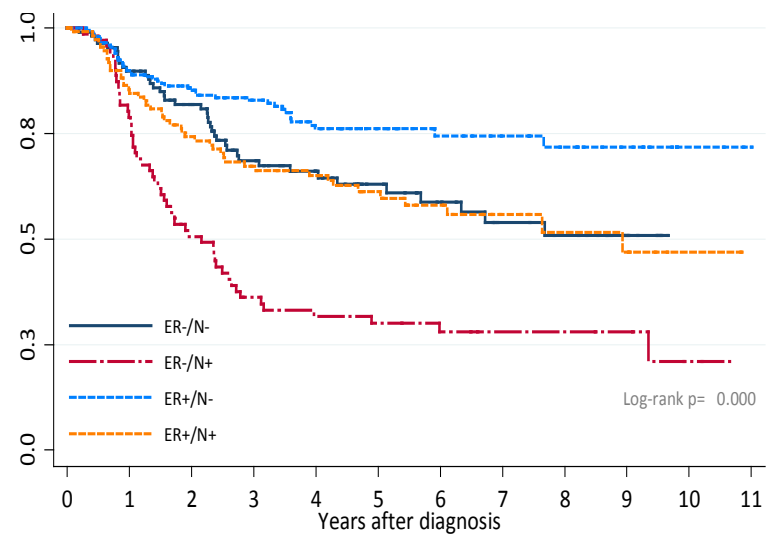
AN EXEMPLE OF THE POTENTIAL OF I2B2 ON ARCHIVE ELECTRONIC DATASET (10YR-HER2+BCS SURVEY)

NEW

EFS/OS automated description

HER2+ eBC: Overall survival by ER/N status

Log-rank p= 0.000

Log-rank p= 0.000

ER-/N-
ER-/N+
ER+/N-
ER+/N+

Years after diagnosis

N (events)

ER-/N-	109 (11)	95 (8)	79 (12)	56 (2)	44 (2)	33 (2)	26 (2)	19 (1)	16 (0)	8 (0)	0 (0)	0
ER-/N+	72 (15)	56 (20)	35 (10)	24 (3)	21 (1)	18 (1)	14 (0)	9 (0)	7 (0)	5 (1)	2 (0)	0
ER+/N-	202 (20)	178 (8)	152 (5)	128 (9)	93 (0)	68 (1)	40 (0)	32 (1)	27 (0)	17 (0)	6 (0)	0
ER+/N+	113 (17)	93 (11)	77 (7)	65 (2)	56 (3)	39 (2)	28 (1)	17 (1)	11 (1)	10 (0)	4 (0)	0
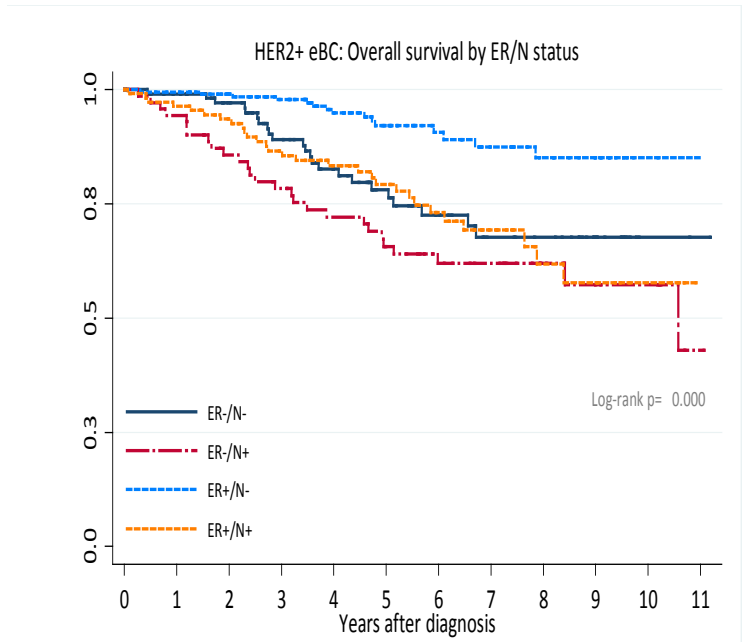
N (deaths)

|																					
ER-/N-	109 (1)	105 (2)	93 (7)	74 (5)	58 (3)	45 (3)	34 (2)	25 (0)	22 (0)	13 (0)	2 (0)	1
ER-/N+	72 (4)	67 (6)	58 (5)	52 (4)	46 (4)	39 (2)	32 (0)	26 (0)	16 (1)	9 (0)	7 (1)	1
ER+/N-	202 (1)	197 (1)	177 (2)	156 (4)	123 (3)	89 (1)	60 (2)	48 (1)	36 (0)	23 (0)	7 (0)	0
ER+/N+	113 (4)	105 (3)	97 (7)	84 (3)	73 (3)	56 (4)	42 (2)	29 (2)	16 (1)	14 (0)	7 (0)	0
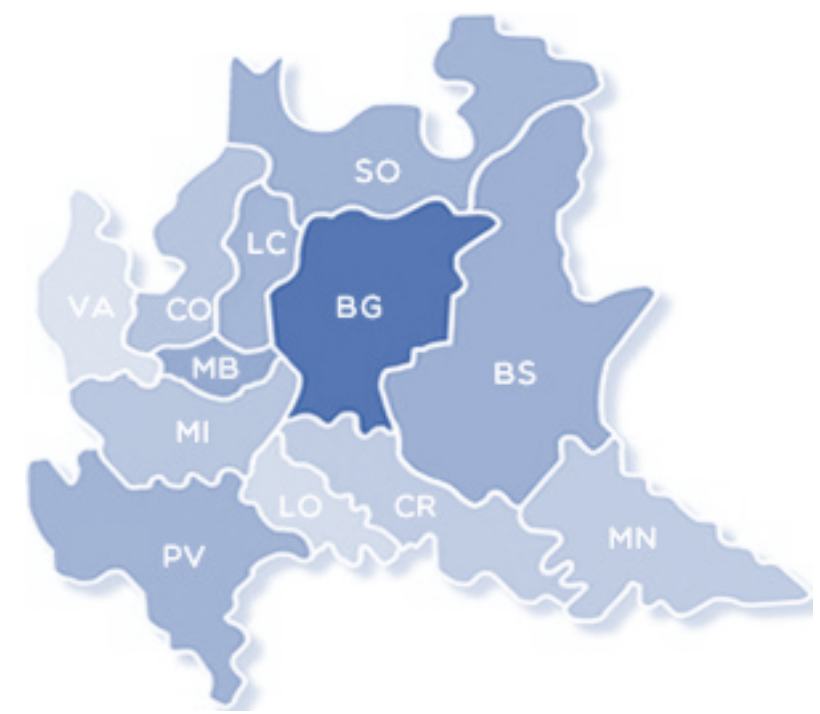
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Le tre nuove proposte

NEW

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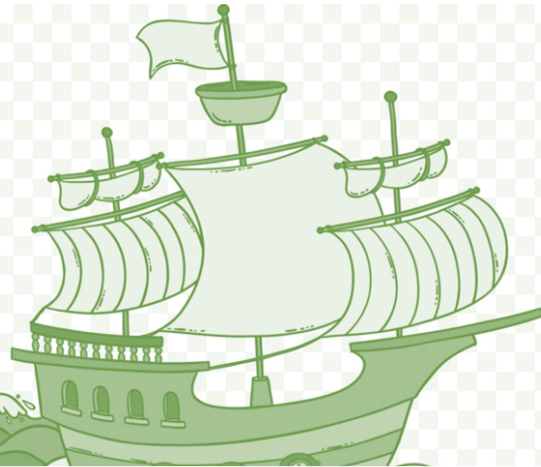
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InheriteD brEast caNcer iTalian regIsTrY:
A RETROSPECTIVE-PROSPECTIVE OBSERVATIONAL COHORT STUDY TO EVALUATE CANCER PREVENTION STRATEGIES IN WOMEN WITH A DELETERIOUS MUTATION IN BRCA1-2

An automated I2B2-based register for a network data-sharing and development of outcomes research studies

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