Periplo

# Il ruolo delle reti in tema di innovazione e ricerca

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23 MAGGIO 2017
ROMA

PALAZZO MONTECITORIO
SALA DELLA LUPA, PIAZZA DI MONTECITORIO

# Healthcare innovation

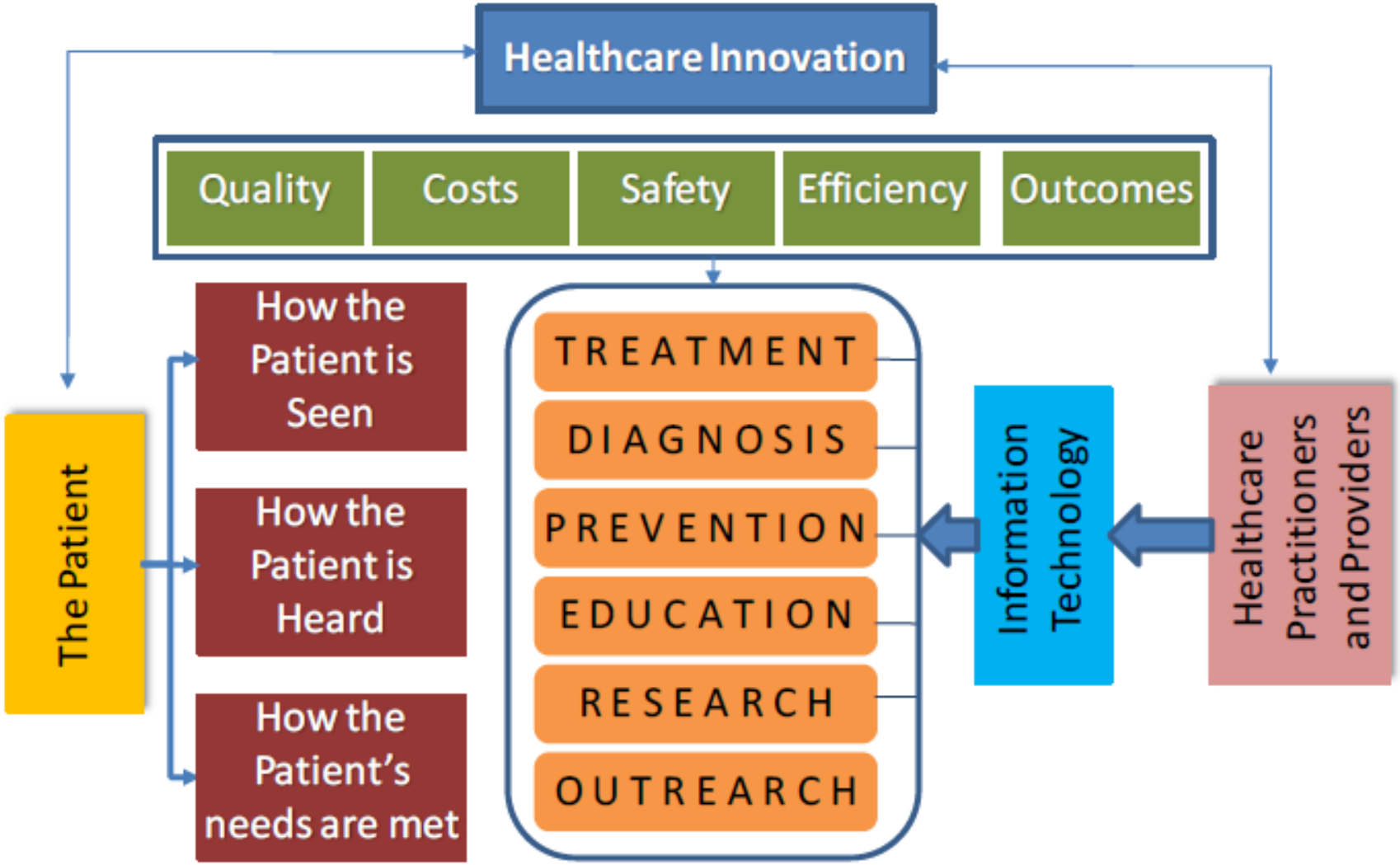
Healthcare innovation can be defined as the introduction of a new concept, idea, service, process, or product aimed at improving treatment, diagnosis, education, outreach, prevention and research, and with the long term goals of improving quality, safety, outcomes, efficiency and costs.

*The Innovation Journal: The Public Sector Innovation Journal*, Volume 15(1), 2010, Article 2.

# The dichotomy at the basis of the problem

- Too slow adoption  of many innovations, technological advances, and proven new treatments by doctors, hospitals, health administrators, and health care facilities

- Too quick diffusion of other innovations and new treatments, despite insufficient scientific evidence of their clinical utility


Healthcare Innovation
Quality
Costs
Safety
Efficiency
Outcomes
The Patient
How the Patient is Seen
How the Patient is Heard
How the Patient's needs are met
TREATMENT
DIAGNOSIS
PREVENTION
EDUCATION
RESEARCH
OUTREARCH
Information Technology
Healthcare Practitioners and Providers

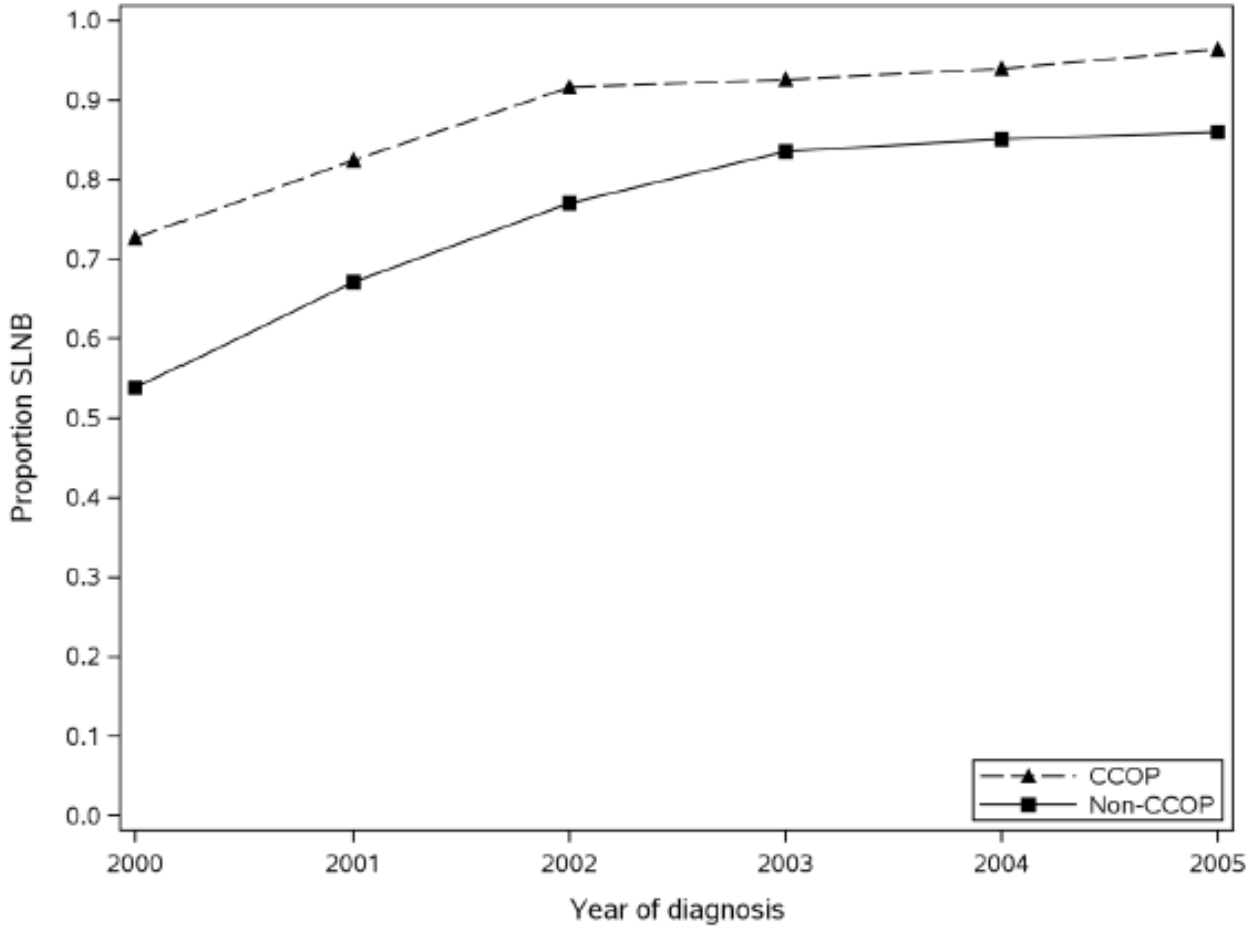
# Role of cancer networks

- To develop a focused health research program
  - Cancer clinical care pathway implementation research
  - Access to care and sustainability
  - Decreasing unjustifiable variances in the quality of care
  - Patient-oriented and patient-led research
- To create and disseminate new cancer knowledge and information
- To translate it into measurably improved health and health care

# Cancer networks: building cancer research capacity

- Provide a venue for targeted collaboration in strategic areas
- Provide access to research resources
- Provide access to funding opportunities

# NCI Community Clinical Oncology Program: Cancer-Focused research network




*Med Care*. 2013 September ; 51(9): 812–818. doi:10.1097/MLR.0b013e31829c8ca4.

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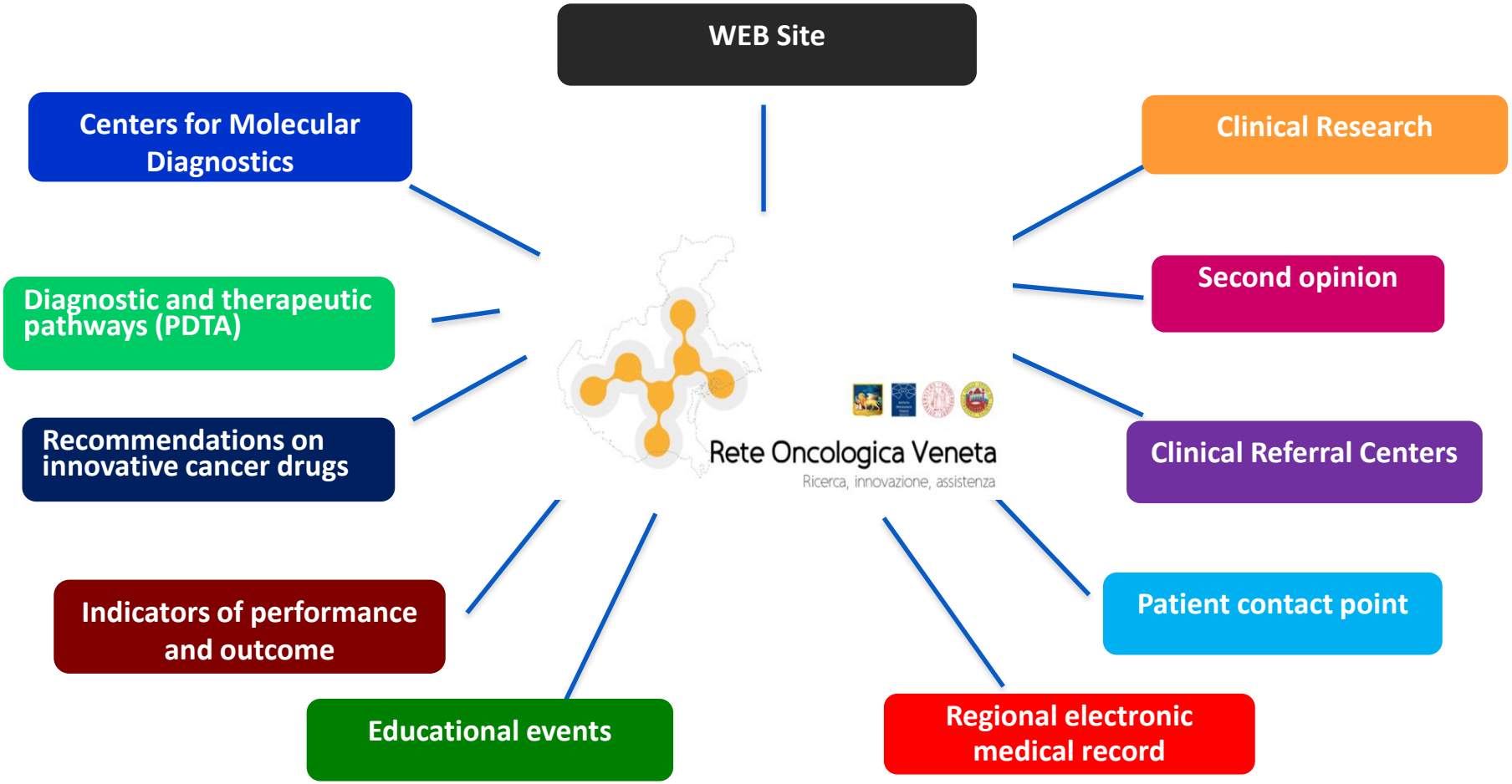
# ROV: Aims and Working Groups



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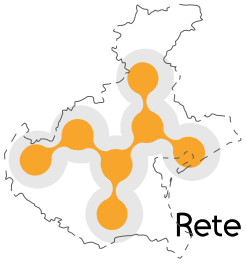
# Clinical Research

- Interaction with pharma representatives for the coordination of clinical trials
- Dedicated Clinical Research Coordinators to support sites in data management
- Educational fostering of the inter-University Master Degree in “Clinical Trials in Oncology: clinical, management and operative aspects”
- Sponsor real-life no profit trials



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# Research Website

- Information on ongoing clinical trials in Veneto Region

- Email notification when a new trial starts

- Meetings to present active trials and promote enrolment

- Patient referral to investigational sites

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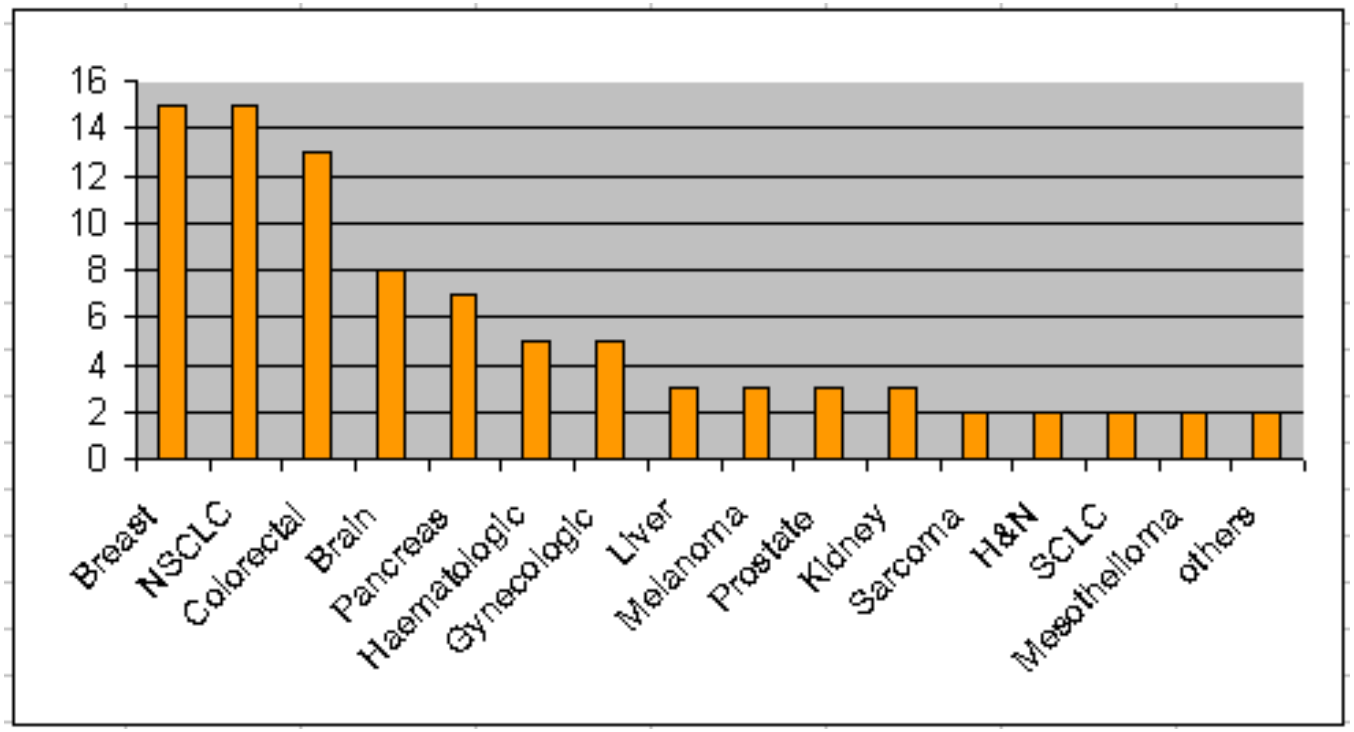
# Research website

- 90 Clinical trials
- 18 tumor types
- 9 regional participating sites



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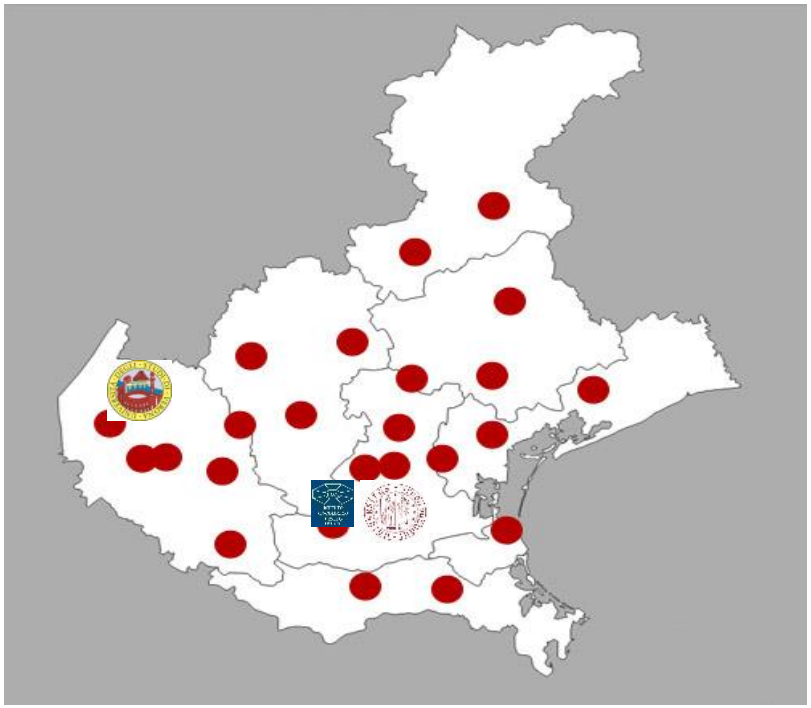
# The Veneto Oncology Network: choice of excellence for every patient



OlympiAD
OLaparib in ADvanced BRCAm breast cancer

***Assessment of the Efficacy and Safety of Olaparib Monotherapy versus Physicians Choice Chemotherapy in the Treatment of Metastatic Breast Cancer Patients With Germline BRCA1/2 Mutations.***

First patient worldwide

**I3Y-MC-JPBL** monarch 2

**A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study of Fulvestrant with or without LY2835219, a CDK4/6 Inhibitor, for Women with Hormone Receptor Positive, HER2 Negative Locally Advanced or Metastatic Breast Cancer**

First patient in Europe

**1 IRCCS**
**2 Universities**
**2 Teaching Hospitals**
**21 Community Hospitals**
**8 Advocacy Groups**

# MOST
# study design

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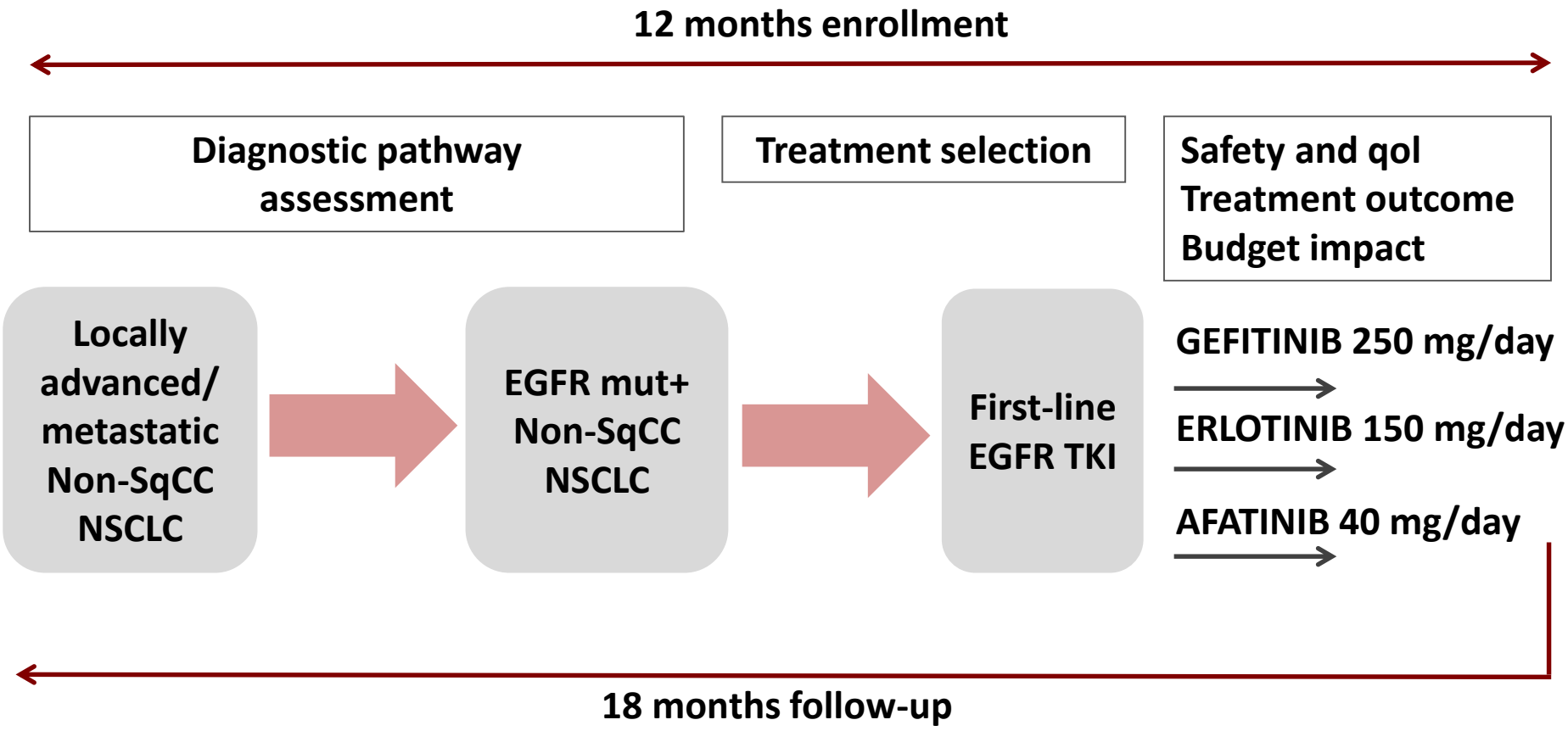


PI G. Pasello

# *MOST study primary endpoints*

***to assess the compliance of the participant centers to the diagnostic-therapeutic pathways and treatment recommendation defined and expressed by the ROV coordination***

**1.Diagnostic pathway**

•Proportion of non-squamous NSCLC with available EGFR mutation test at the diagnosis (automatic test execution after non-sq NSCLC diagnosis)

•Time-frame between diagnostic biopsy and histology report (including EGFR mutation test)

**2. Treatment selection**

•Proportion of EGFR mut+ patients receiving first-line EGFR TKI and proportion treated with each EGFR TKI

# MOST study
# *Secondary endpoints*

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***To evaluate and describe in a 'real-life' population of EGFRmut+ advanced NSCLC patients:***

**3. Treatment outcome** (in overall population and according to mut type)
- Time to treatment failure and/or Progression free survival
- Response rate and disease control rate
- Overall survival

**4. Safety**
- treatment-related adverse events of each EGFR TKI
- dose reduction and treatment interruption due to treatment-related adverse events

**5. Pharmaco-economical impact**: estimate of the negotiation agreement effect on the budget impact (average cost/patient)

# MOST study
## *Exploratory endpoints*

- **Selection criteria** adopted by the Medical Oncologist for first-line **treatment choice**
- Assessment of **safety profile** of each EGFR TKI evaluated by the investigator and **by the patient**
- **Quality of life** and patients reported outcomes (PROs)

The **monitoring of the diagnostic-therapeutic pathways** and the comparison with pivotal trials data will be performed through **specific indicators** aiming at evaluating its quality and adequacy

# ENROLLMENT STATUS

## *21 APR 2017*

| Center | Eligible pts | EGFRm+ Completed data |
|---|---|---|
| IOV | 112 | 28 |
| Adria | 3 | 0 |
| Belluno | 10 | 0 |
| Castelfranco | 24 | 3 |
| Mestre | 6 | 2 |
| Legnago | 10 | 2 |
| Mirano | 7 | 3 |
| Negrar | 15 | 3 |
| S. Donà | 2 | 1 |
| Treviso | 6 | 1 |
| Montecchio | 2 | 0 |
| Verona | 5 | 4 |
| | **202** | **47** |

# Breast-DX Italy: Impact of the Oncotype DX® Breast Cancer Assay on Resources Optimization and Treatment Decisions for Women with Estrogen Receptor-Positive, Node-Negative and Node-Positive Breast Carcinoma: a prospective Italian multicenter study.

**PROGRAMMA PER LA RICERCA INNOVAZIONE E HTA (PRIHTA) – REGIONE DEL VENETO**
**Coordinatore:** Istituto Oncologico Veneto IRCCS, Padova **PI:** Prof. PierFranco Conte

- Prospective, multicenter study (ROV)

- To evaluate the impact of Oncotype DX® on the decision making processes of physicians in recommending adjuvant therapy and on resources optimization in an Italian setting

# STUDY DESIGN

**1. PROSPECTIVE REGISTRATION OF ALL CONSECUTIVE ER+, HER2-, N0-1 (0 to 3 positive nodes), T1-3 BC PATIENTS**

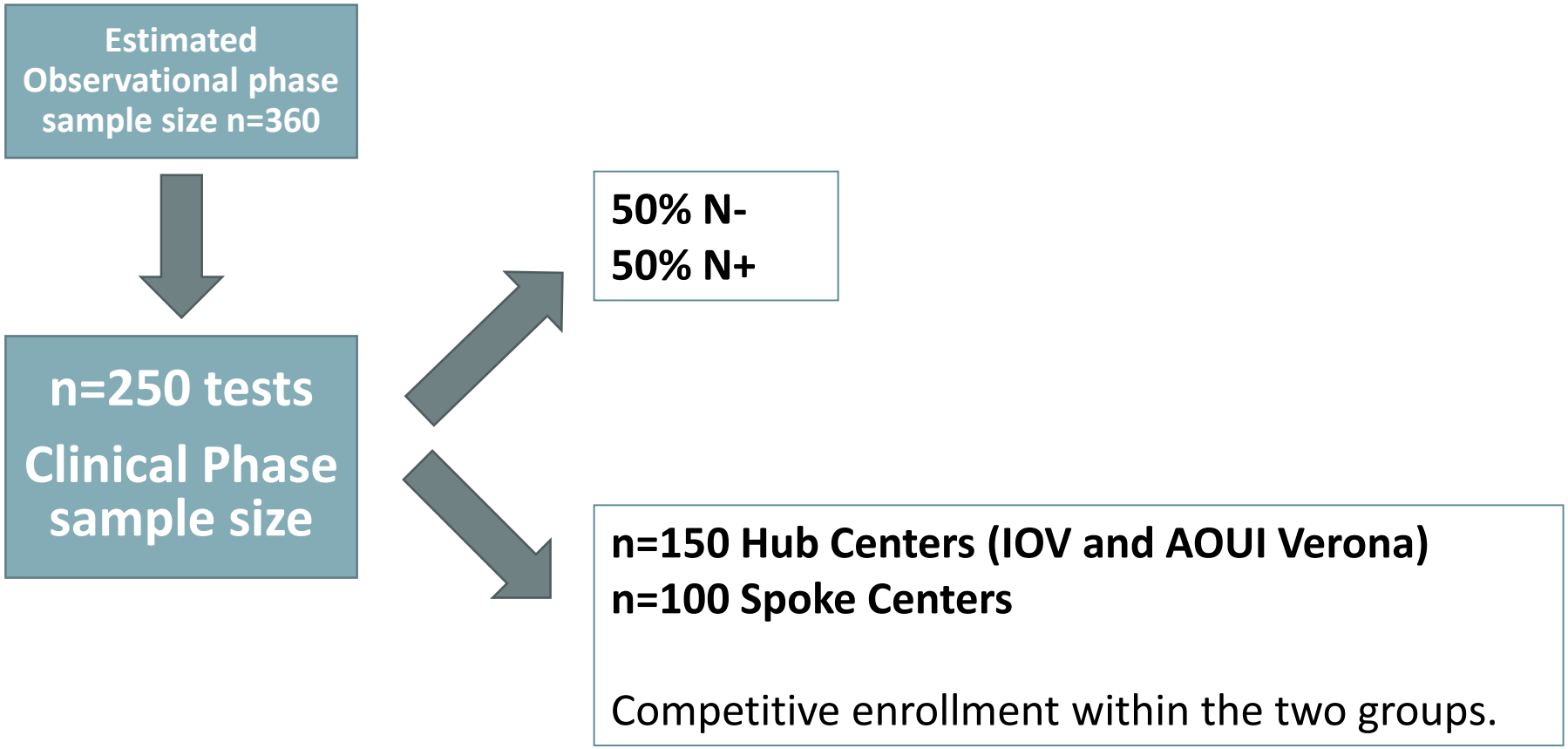
**2. CATEGORIZATION IN RISK GROUPS BASED ON TRADITIONAL PROGNOSTIC FACTORS ACCORDING TO PROTOCOL CRITERIA**

| Low-Risk | Intermediate-Risk | High-Risk |
|---|---|---|
| At least 4 of:<br>G1; T1a-b; Ki67 <15%;<br>N0; ER >80% | Not classified as low or high risk. | At least 4 of :<br>G3; T≥2; Ki67 >30%,<br>N1; ER <30% |

**3. ONCOTYPE DX PROPOSED TO INTERMEDIATE-RISK PATIENTS ONLY**

Data collected: pre-RS treatment recommendation; post-RS treatment recommendation; treatment that was actually started;. post-RS physician's perception of test utility.

# SAMPLE SIZE




**Enrollment completed: December 2014 to August 2016**

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# REGIONAL ONCOLOGY ELECTRONIC HEALTH RECORD (EHR)

- Sharing of diverse layers in a single health record specifically dedicated to cancer patients

- Section Layout:
  - Tumor type
  - Molecular pathology
  - Clinical Management
  - Drug treatment

- Aim:
  - Indices of Oncology Pathways (PDTA)
  - Drug recommendations

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# Formazione ROV (2014-16)

*(DGR n. 2067 del 19.11.2013)*

**N. 12 Convegni Presentazione Proposta PDTA**
2014-2016
partecipanti n. **2.522 – ECM 45**

**N. 3 Convegni aggiornamento PDTA** 2015-2016
partecipanti n. **511 – ECM 10**

**N. 32 Incontri oncologici** 2014- 2016
partecipanti n° **1.280 – ECM 128**

**Partecipanti: 4.313**
**ECM: 183**

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ROL Rete Oncologica Lombarda

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