

***Il Incontro Nazionale FICOG
I GRUPPI COOPERATIVI IN ONCOLOGIA
LE NUOVE SFIDE DELLA RICERCA INDIPENDENTE***

Reti Oncologiche e Ricerca Clinica

Roma, 5 maggio 2022

P Pronzato

Disclosure

- **Compensations for lectures (last two years)**
 - **AMGEN**
 - **CELGENE**
 - **LILLY**
 - **NOVARTIS**
 - **ROCHE**
- **Compensations for participation in advisory boards (last two years)**
 - **AMGEN**
 - **LILLY**
 - **NOVARTIS**
 - **PIERRE FABRE**
 - **PFIZER**
 - **ROCHE**

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RICERCA DI RETE

- **4. RICERCA DI RETE**
 - **4.1. Ricerca organizzativa**
 - **4.2. Ricerca traslazionale ed europea**
 - **4.3. Ricerca qualitativa**
 - **4.4. Sperimentazioni cliniche**

RICERCA DI RETE

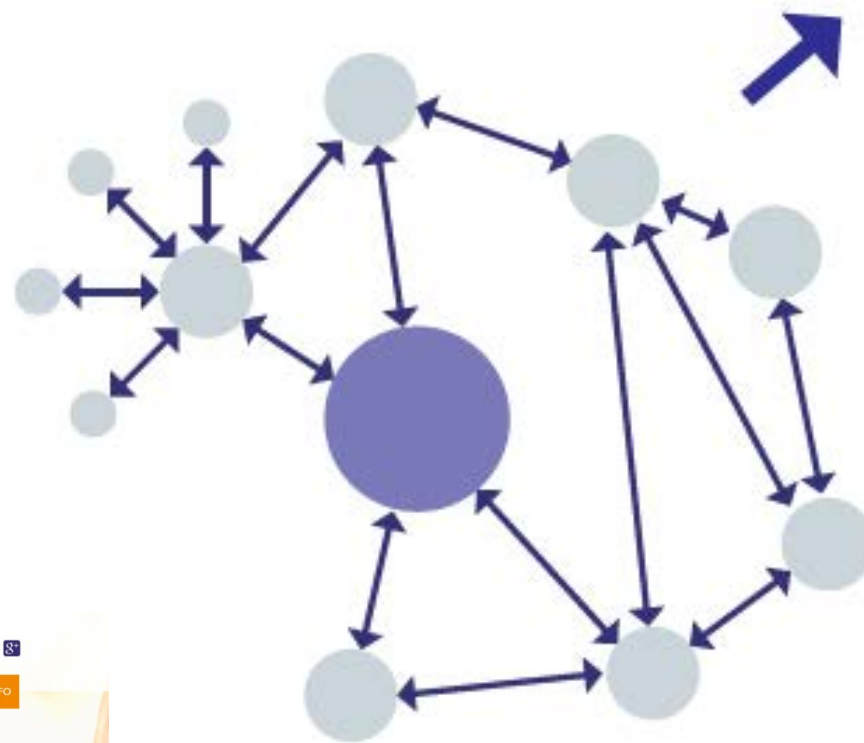
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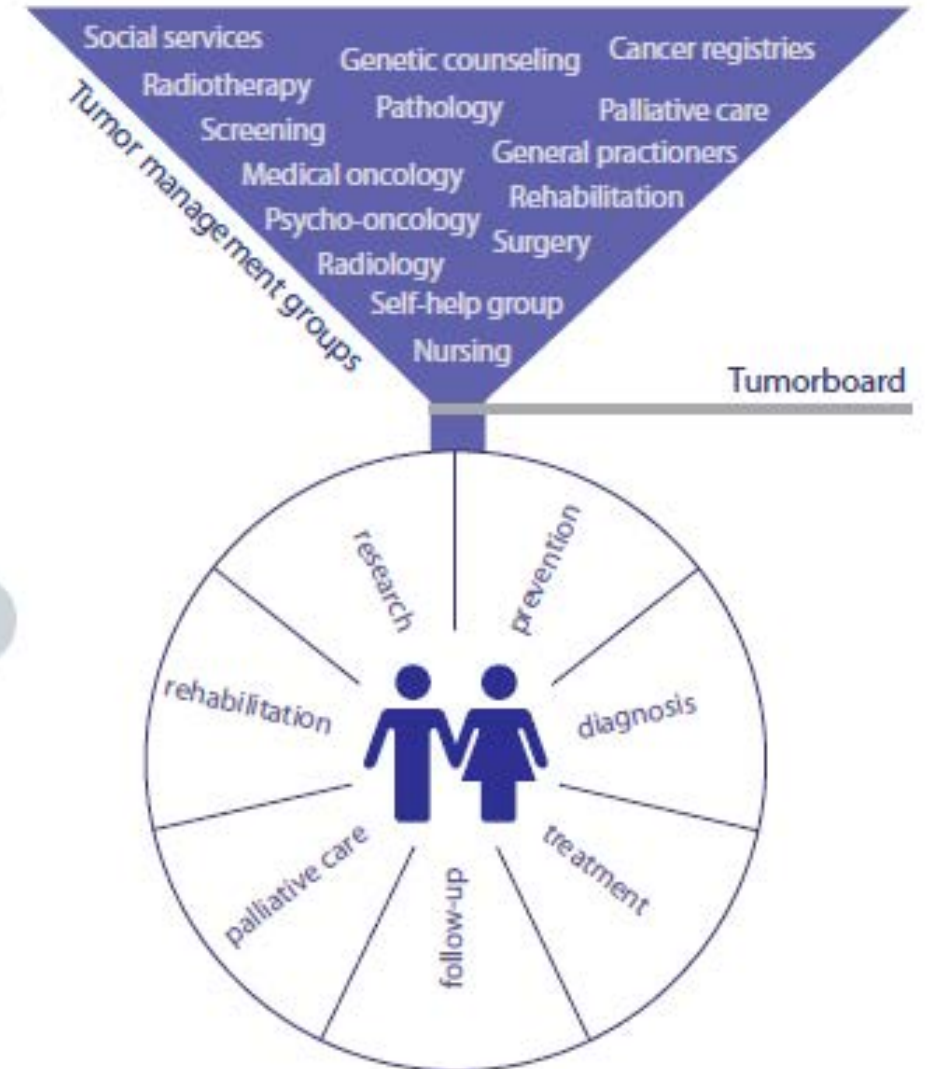
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L'Organizzazione per Gruppi Multidisciplinari e Reti

A – NETWORK



B – FUNCTIONALITY



WHO WE ARE GUIDE HOW WE WORK NEWS & EVENTS TOOLS CONTACT INFO

**CANCON HAS ENDED
THANK YOU ALL**
THE GUIDE IS OUT.

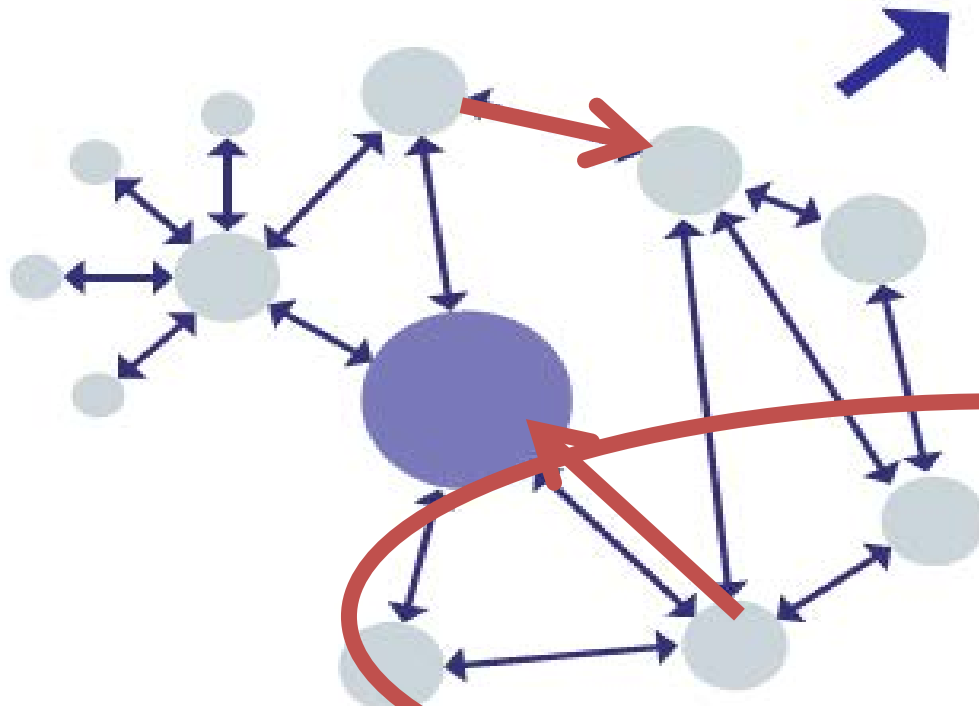
Cancon Guide is the result of three years' work by top cancer experts in 25 countries and 126 organisations. The quality improvement of cancer care is at the heart of Guide. Take control. Read more!

Drivers of Oncology 2020s

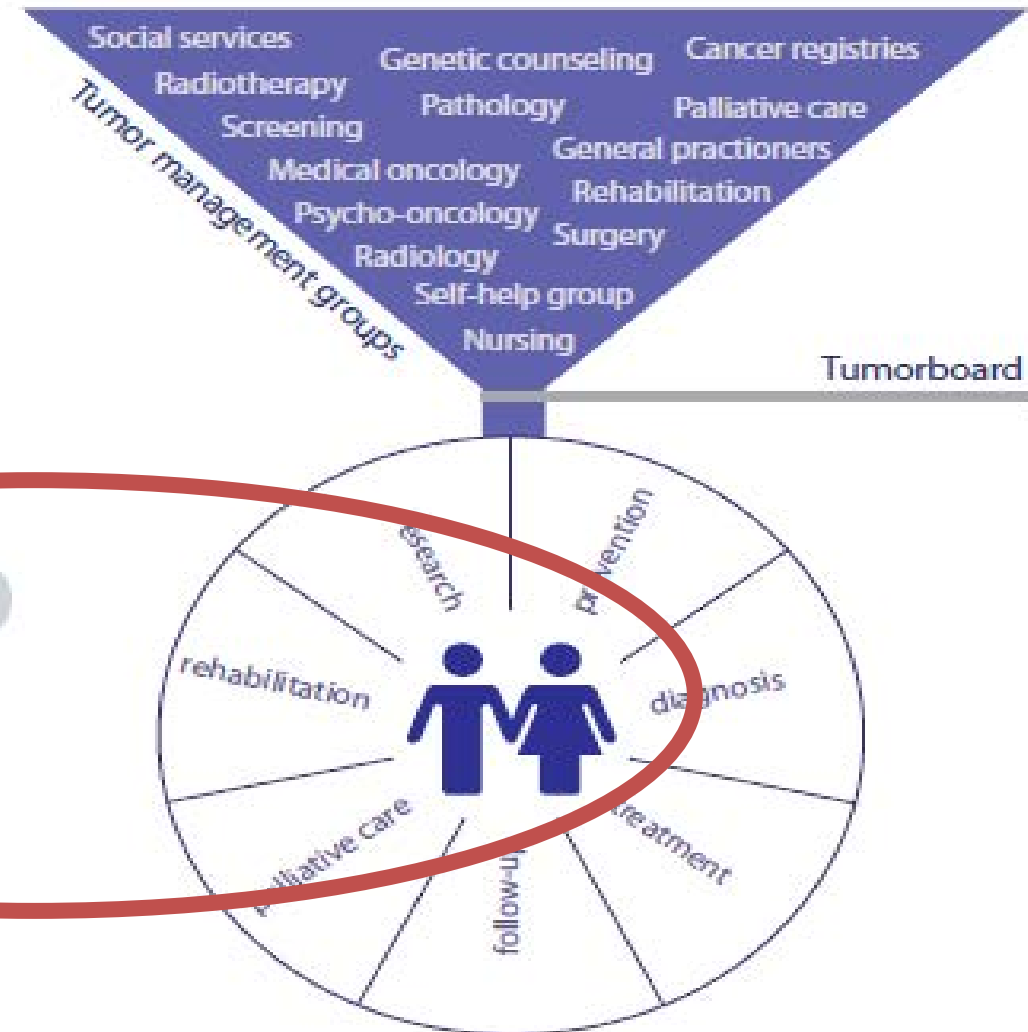
- **Advanced and High Quality Molecular Characterization more frequently Needed**
- **Multiplicity and Diversity of New Drugs**
- **Rare Tumors Emerging**
- **Hubs for a limited number of cases**
- **New Needs (Palliation, Hospitalization, Emergency, etc)**
- **Cancer as Chronic Disease (Chronic Care Model applicable?)**
- **Inequality**
- **Overcoming Bureaucracy**
- **Artificial Intelligence/ Machine Learning/ Big Data/Telemedicine**
- **Patients Empowerment**
- **COVID-19 as a Threat for Cancer Patients**

Drivers of Oncology 2020s

A – NETWORK



B – FUNCTIONALITY



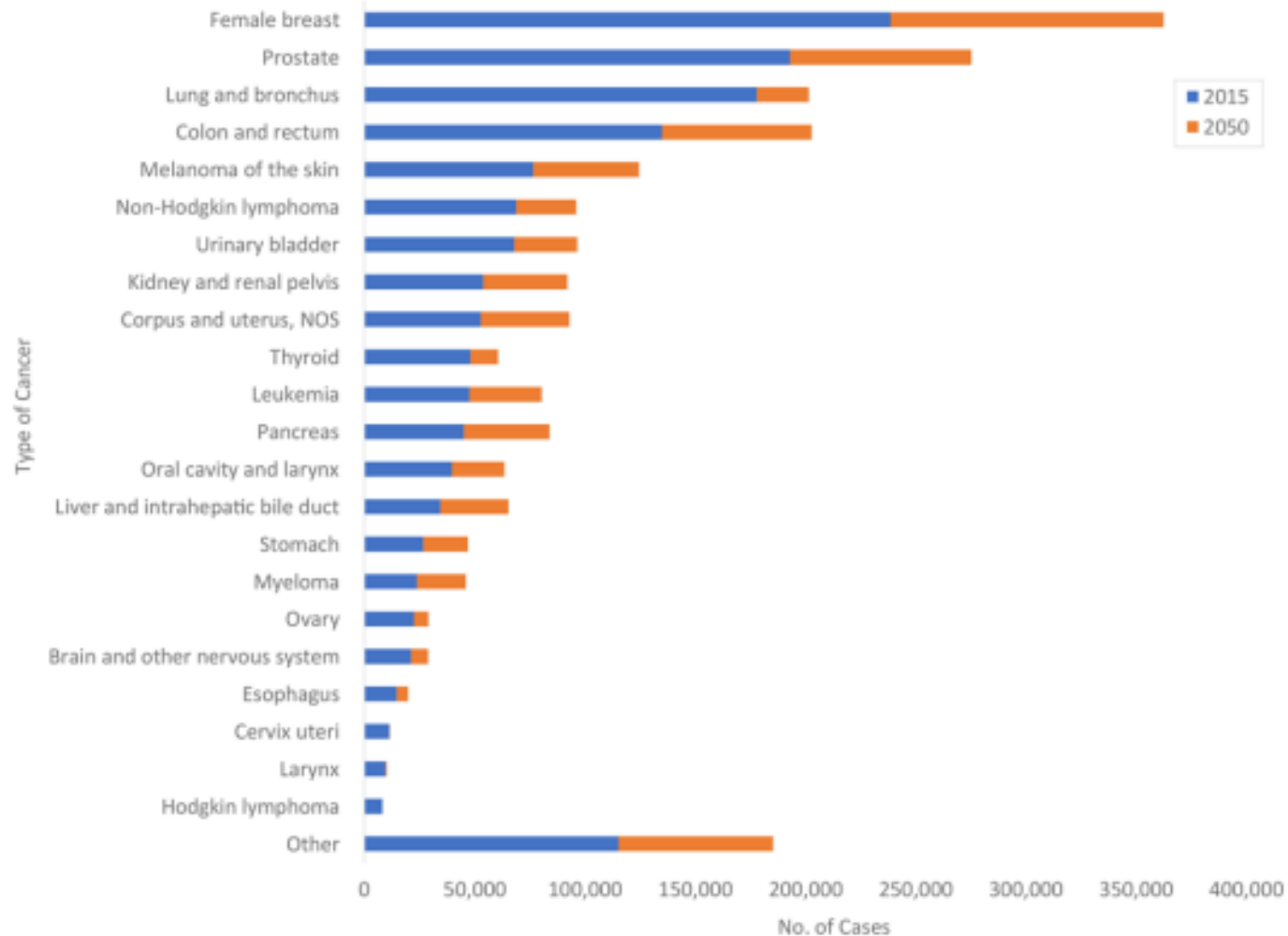


Figure 2. Estimated (2015) cancer cases and projected additional cases (2050) by cancer site, United States. Numbers may not sum to total because of rounding. Abbreviation: NOS, not otherwise specified.

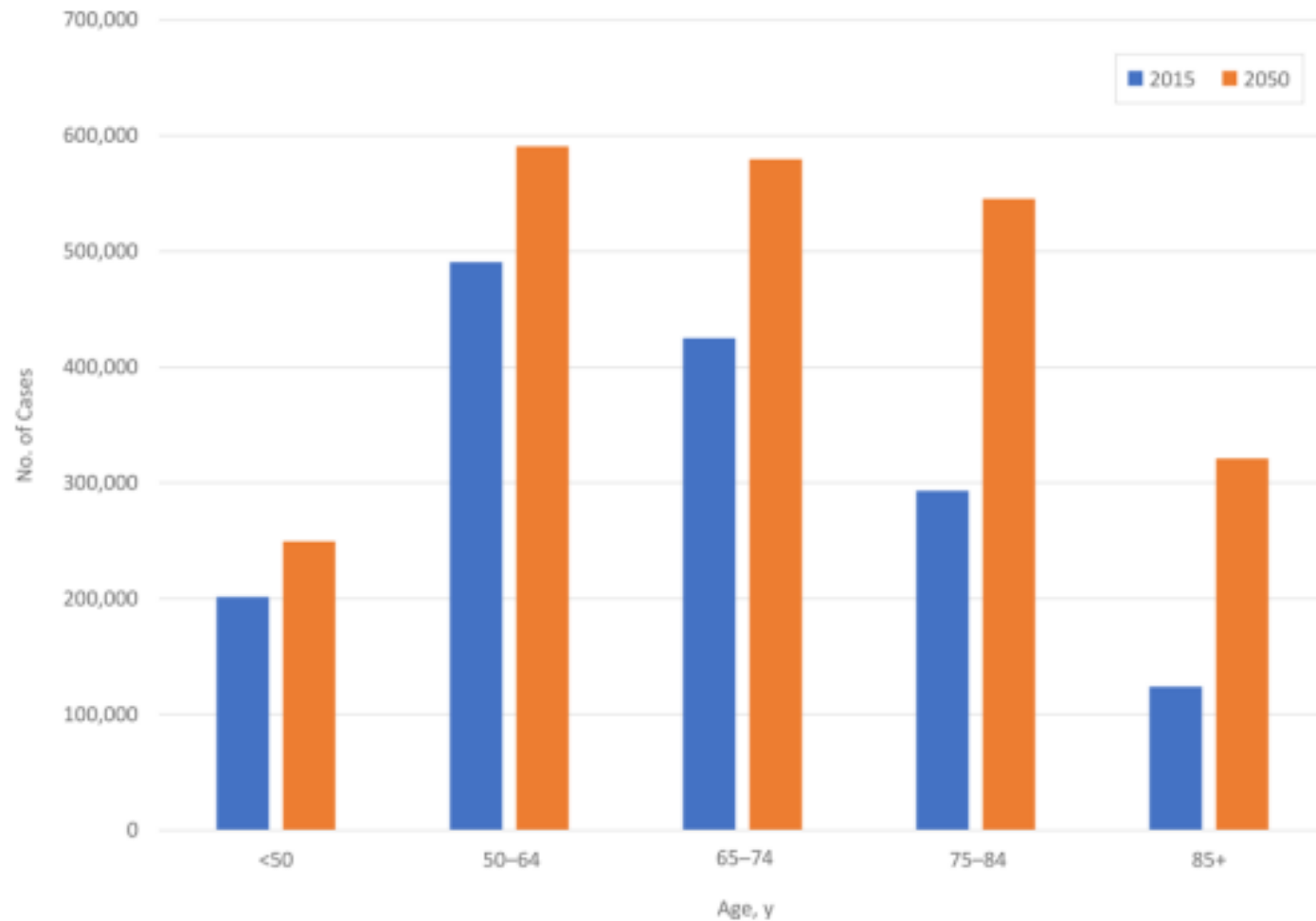


Figure 1. Distribution of estimated 2015 and projected 2050 average annual cancer cases (all sites combined), by age group, United States. Numbers may not sum to total because of rounding.

Oncological Networks Main Missions

- **ACC**
 - Translational Research
- **Cooperative Groups**
 - Multicenter RCTs and other Trials (with newer design)
- **Regional Oncological Networks & RNTR**
 - Recruitment and Path
 - Organizational Changes Impact
 - Real World Data
 - Quality Assurance

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SPERIMENTAZIONE CLINICA

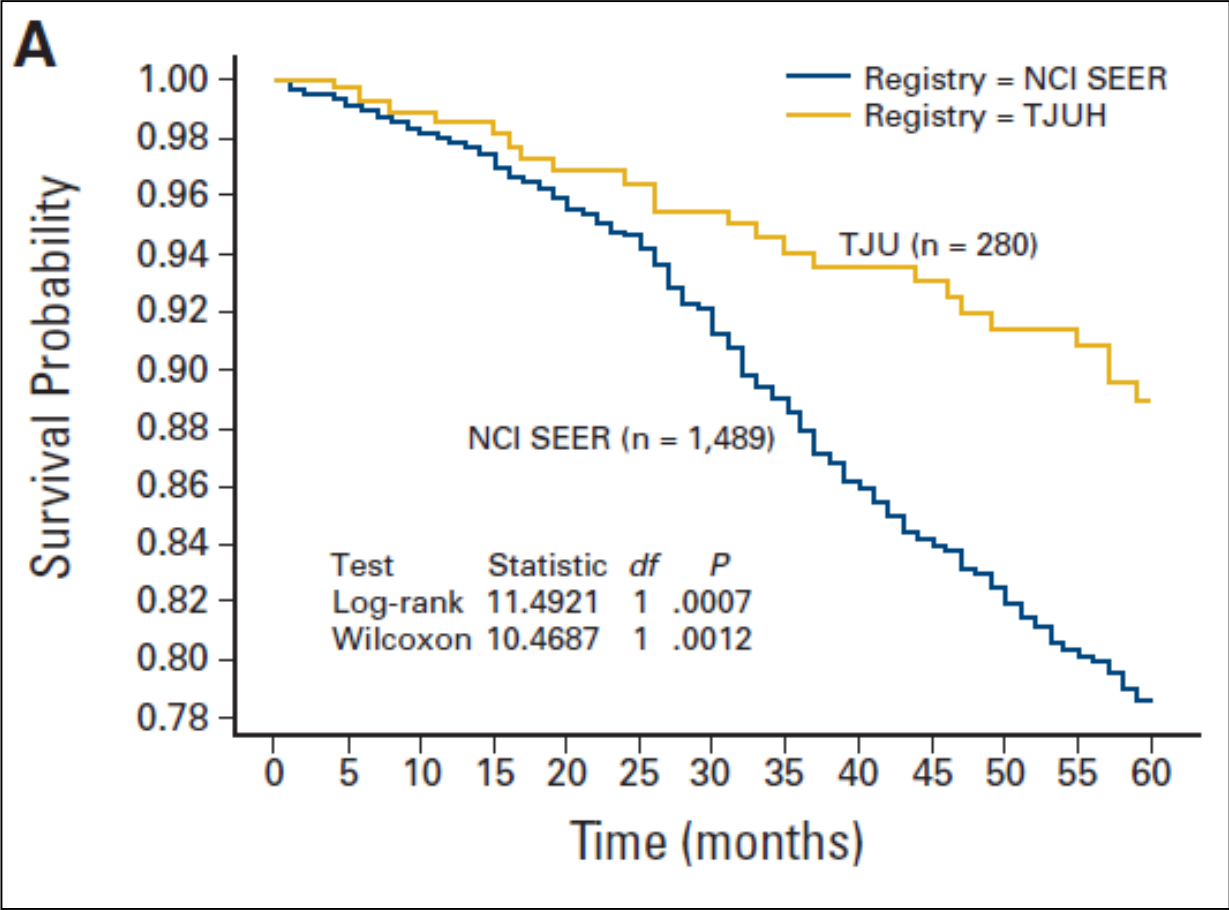
- La ricerca clinica rappresenta un'importante opportunità di accesso precoce alle cure innovative, pertanto, la presenza di *network* in grado di **orientare** i pazienti verso le sperimentazioni cliniche di **nuovi medicinali**, soprattutto quando **rari**, può coniugare innovazione, **equità** di accesso e qualità dell'assistenza.

Oncological Networks Main Missions

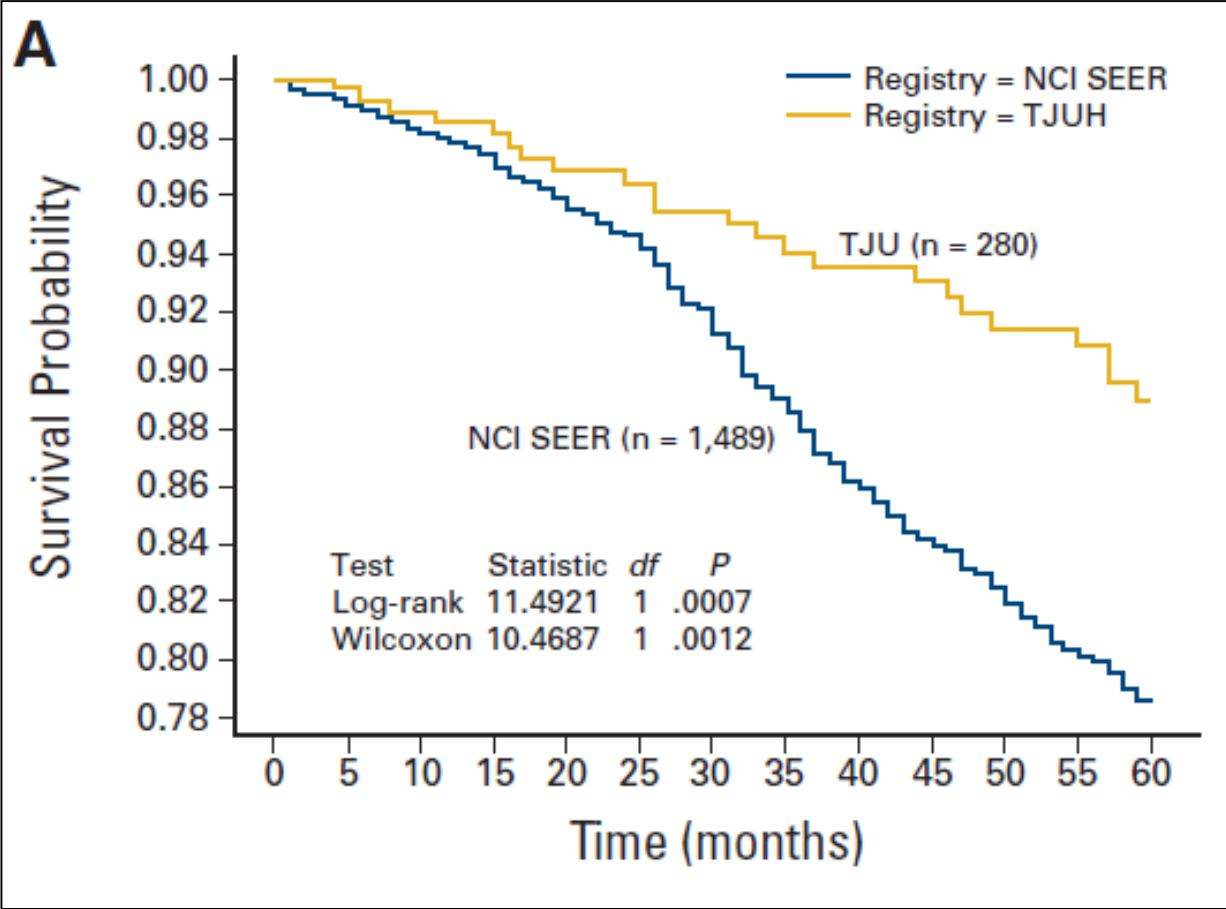
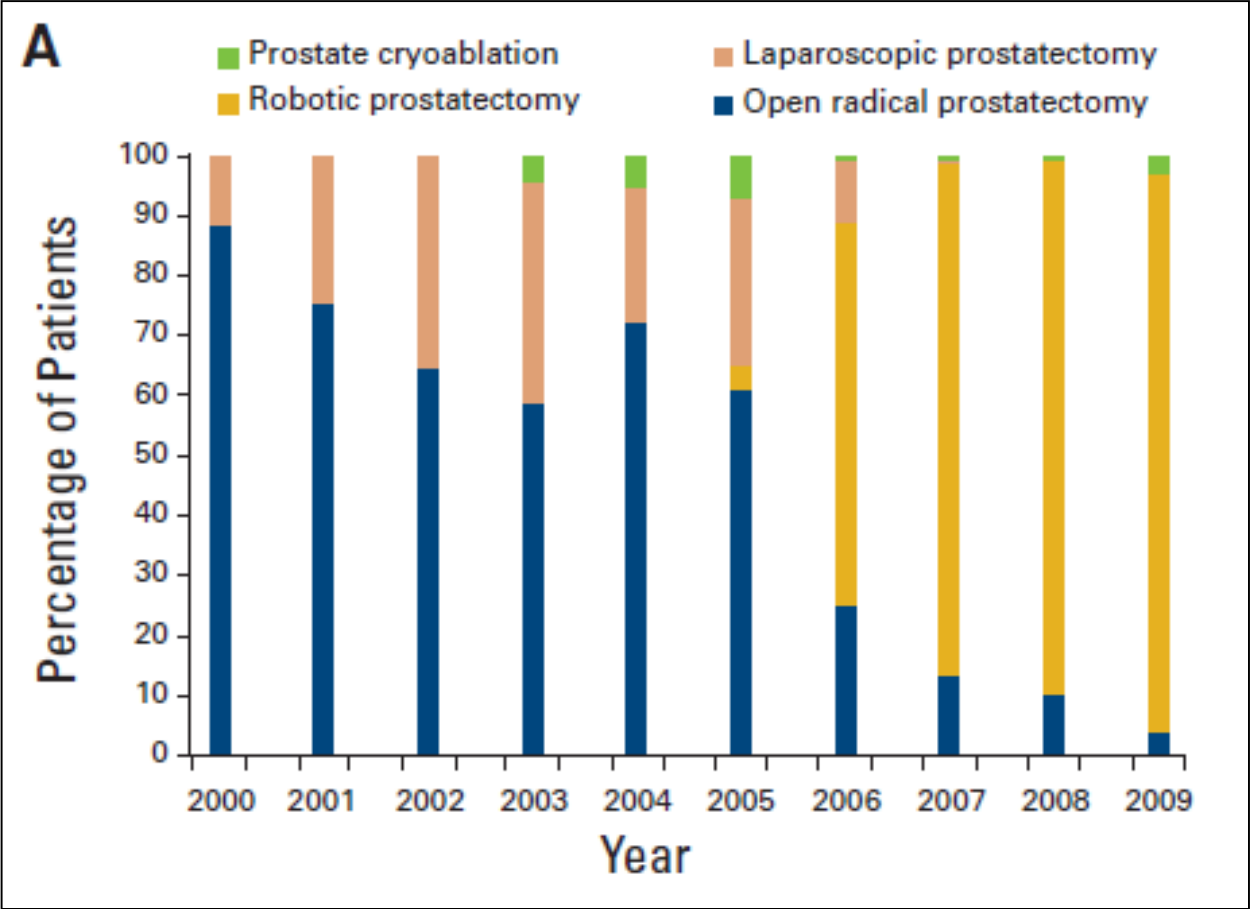
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Organizational Changes Impact

Multidisciplinary Approach & Technology vs DMT



Multidisciplinary Approach & Technology vs DMT



Evaluating Oncology Clinical Pathways Programs (ASCO)

- **Is it Expert Driven?**
- **Does it reflect stakeholder input?**
- **Is it transparent?**
- **Is it evidence-based?**
- **Is it patient focused?**
- **Is it clinically driven?**
- **Is it timely?**
- **Is it comprehensive?**
- **Does it promote participation in clinical trials?**

The AMBORA Trial

Knowledge Generated

This study demonstrated that medication errors and side effects related to the oral antitumor drugs can considerably be reduced by intensified clinical pharmacological/pharmaceutical care. Moreover, patient-reported outcomes are significantly improved.

Relevance

Patients treated with new oral antitumor drugs (eg, kinase inhibitors) experienced a major, clinically relevant benefit from an intensified clinical pharmacological/pharmaceutical care program. Our intervention might serve as a blueprint for medication safety programs at other sites.

REAL LIFE – REAL WORLD
(RWD → RWE?)

What is Real World Data?

[Real-world data] can be defined as data relating to patient health status or the delivery of health care routinely collected from a variety of sources, such as the EHR and administrative data.

RWD & RWE Papers

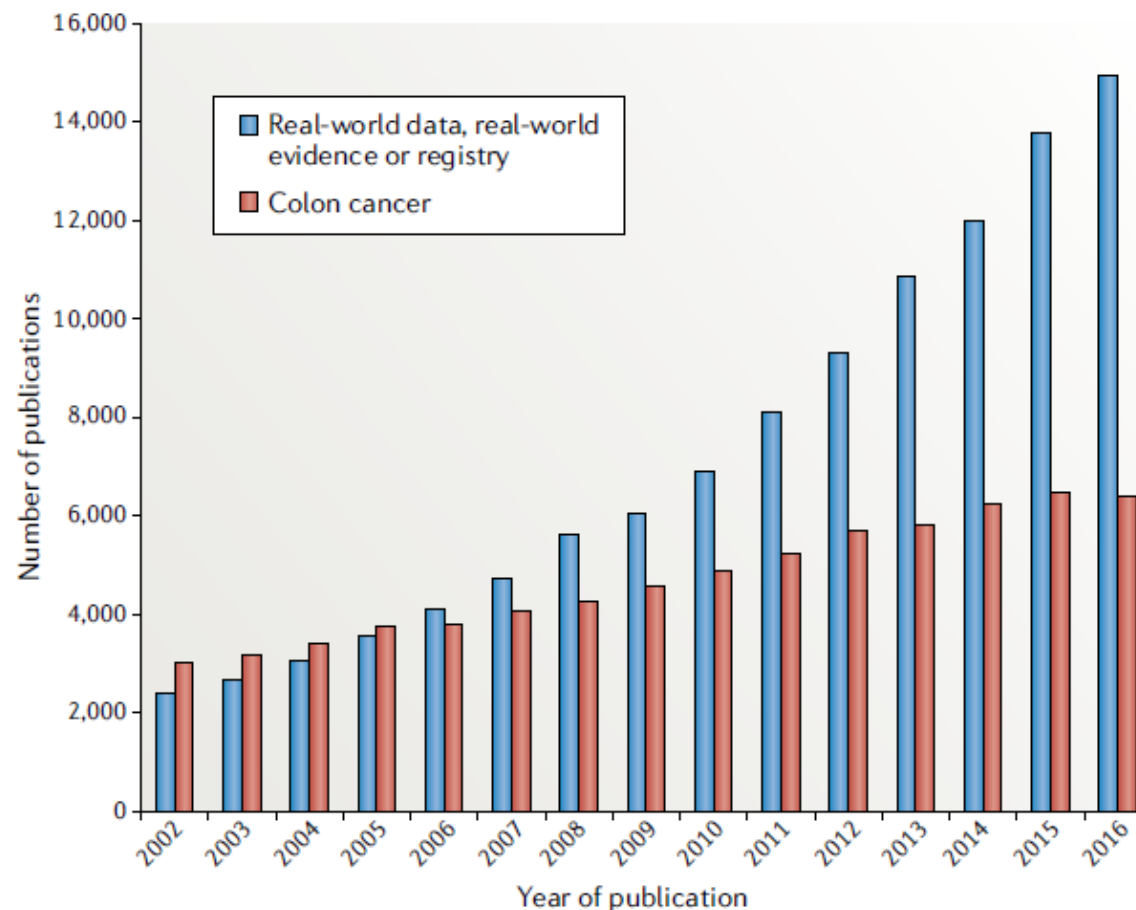


Fig. 1 | **Increased reporting of studies using real-world data.** Temporal trends in publications identified in the PubMed database for each year between 2002 and 2016 using the search terms “real-world data”, “real-world evidence” or “registry” (sum of results) versus “colon cancer” are shown.

Expectations

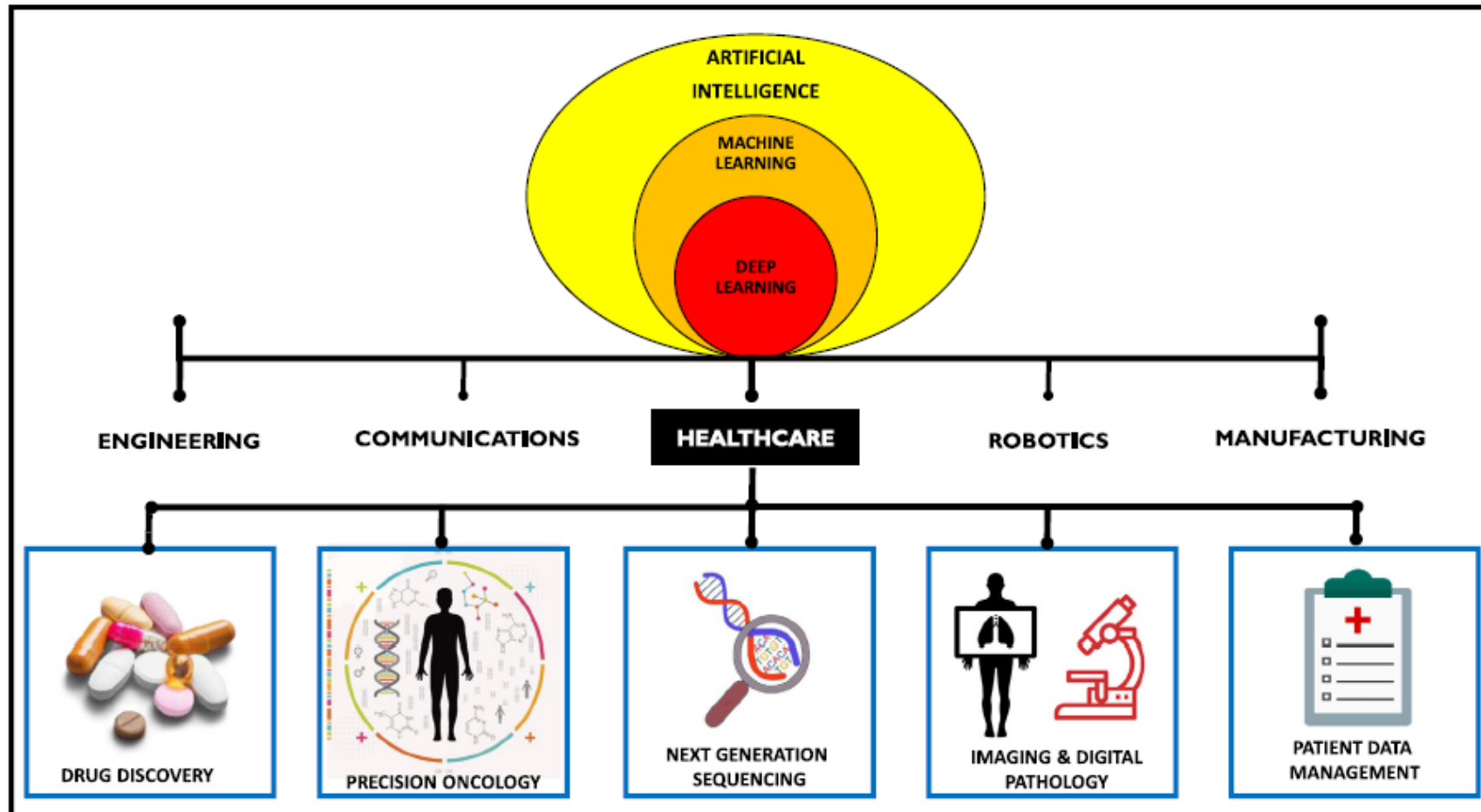


Fig. 1. An overview of the applications of artificial intelligence in some major sectors. Artificial intelligence (AI) and machine learning (ML) have important applications in healthcare and precision oncology. ML is a subset of AI that uses neural networks to solve healthcare problems and predict treatment outcomes by pattern recognition in patient datasets. The accuracy of the data is warranted by implementing deep learning of machines [4–10].

Improving the Quality and Efficiency of RCTs

SOUNDING BOARD

The Magic of Randomization versus the Myth of Real-World Evidence

Rory Collins, F.R.S., Louise Bowman, M.D., F.R.C.P., Martin Landray, Ph.D., F.R.C.P.,
and Richard Peto, F.R.S.

RWD Studies

- The comparison of outcome of nonrandomized **groups** of pts who have received different treatments in the real world is problematic, primarily because the groups of pts **might differ** with respect to **prognostic features (known or unknown)**

**REAL LIFE – REAL WORLD
QUALITY**

FOCUS ON QUALITY

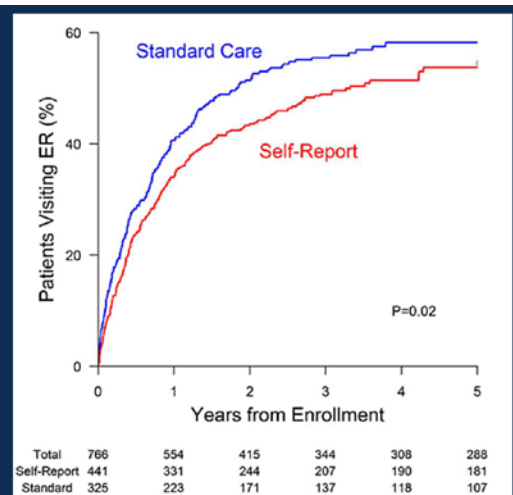
Use of Electronic Administrative Databases to Measure Quality Indicators of Breast Cancer Care: Experience of Five Regional Oncology Networks in Italy

CONCLUSION Despite highlighting some limitations in the use of administrative data to measure health care performance, this study shows that evaluating the quality of BC care at a population level is possible and potentially useful for guiding quality improvement interventions.

PROs and PROMs

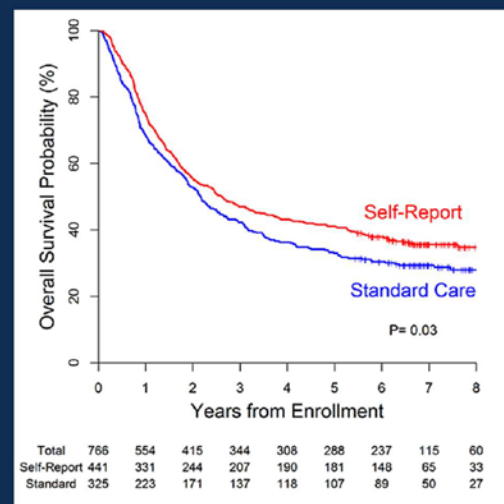
Proportion of Patients Visiting Emergency Room

- Compared to standard care, 7% fewer patients in the self-reporting arm visited the ER, with durable effects throughout the study ($P=0.02$)

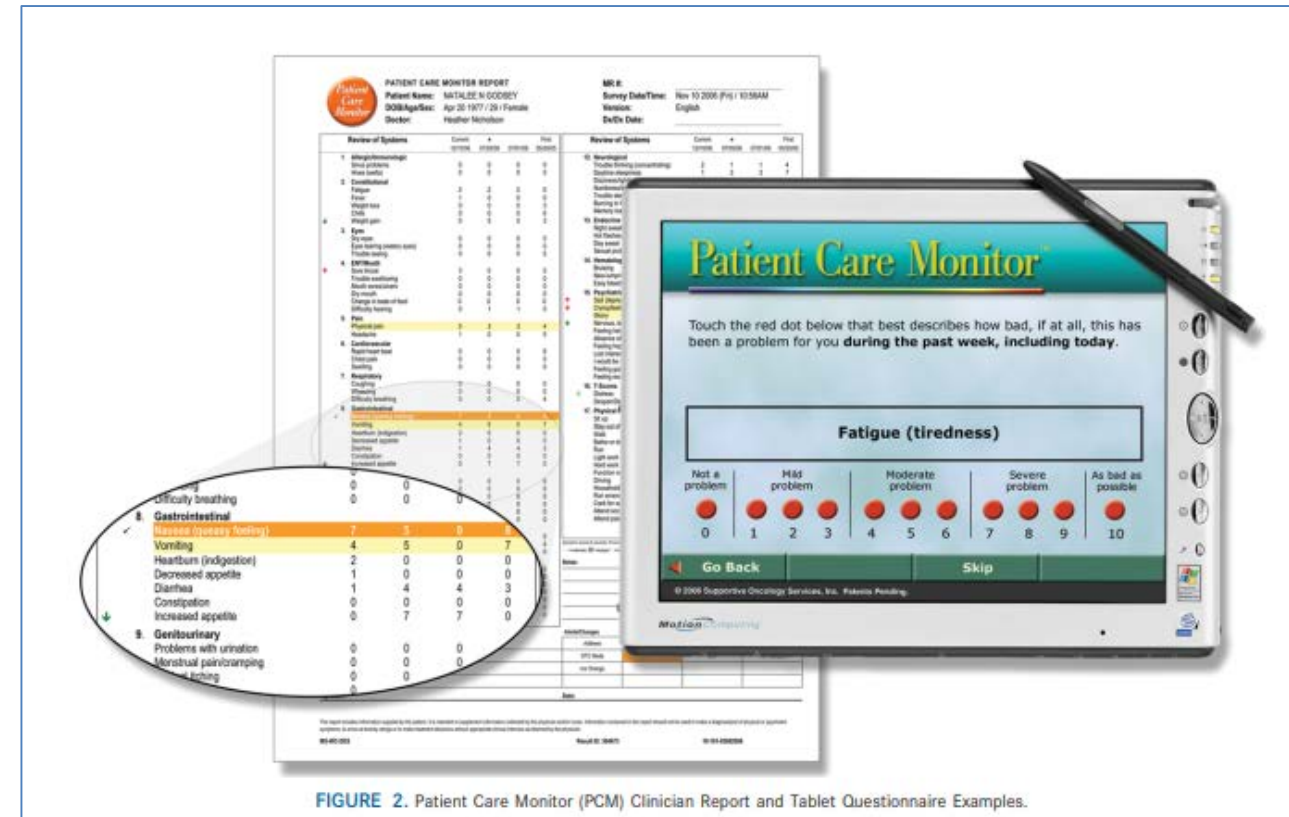


Overall Survival

- Compared to standard care, median survival was 5 months longer among patients in the self-reporting arm (31.2 vs. 26.0 months) ($P=0.03$)
- Remained significant in multivariable analysis: Adjusted hazard ratio 0.832 (95% CI; 0.696, 0.995)





PRESENTED AT: ASCO ANNUAL MEETING '17 #ASCO17 Presented by: Ethan Basch, MD
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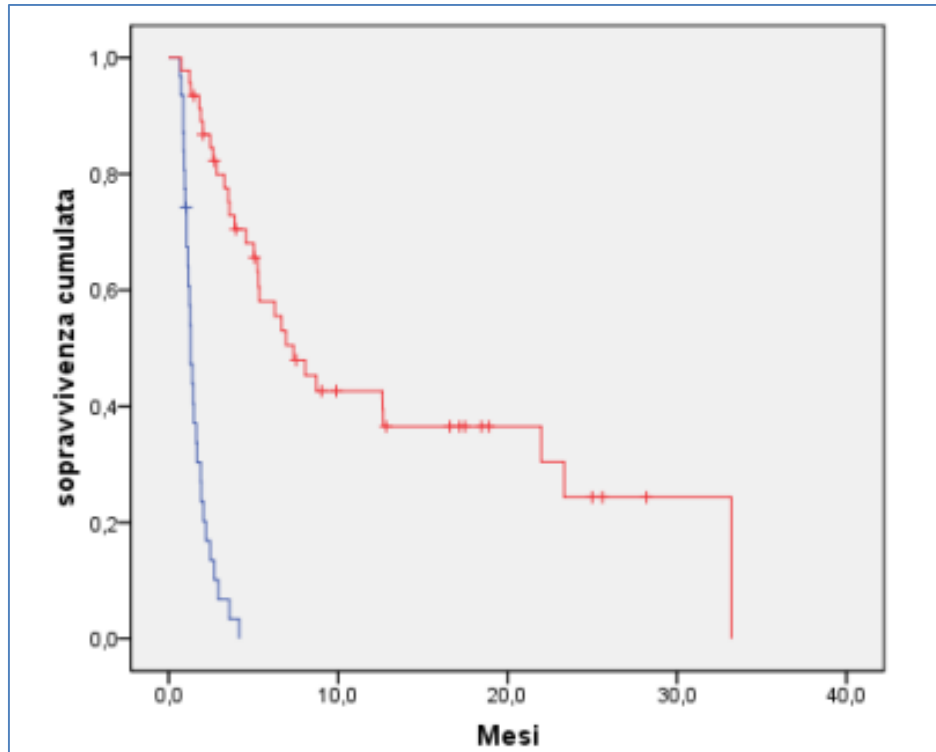
RICERCHE DI RETE
Progetti di Rete MinSal
Ricerca Finalizzata
2016 & 2018

NET 2018

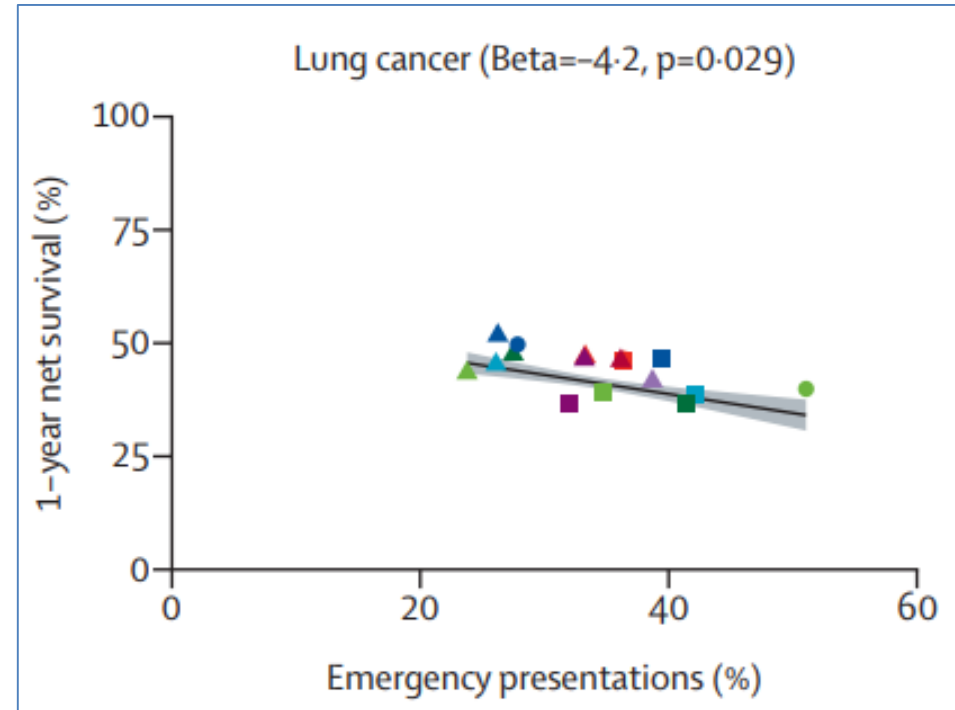
 <p><i>Ministero della Salute</i> Direzione Generale della Ricerca Sanitaria e Biomedica e della Vigilanza sugli Enti</p> <p>BANDO RICERCA FINALIZZATA 2018 esercizio finanziario anni 2016-2017</p>	<p>Project Title:</p> <p>Palliative care needs and prognostic factors assessment for appropriate referral to specialized palliative care services. Impact on quality of care in oncological and non-oncological terminally ill patients.</p>
 <p><i>Ministero della Salute</i> Direzione Generale della Ricerca Sanitaria e Biomedica e della Vigilanza sugli Enti</p> <p>BANDO RICERCA FINALIZZATA 2018 esercizio finanziario anni 2016-2017</p>	<p>Project Title:</p> <p>Organizational innovations and new needs of care for end-of-life cancer patients.</p>
<p>Project Code: NET-2018-12367032-2</p>	<p>Principal Investigator: Pronzato Paolo</p>
<p>Research Type: b) Change-promoting: valutare la sicurezza, efficacia, costo-efficacia, di trattamenti/tecnologie/interventi sanitari per cui sussistano significativi margini di incertezza relativamente agli aspetti menzionati, anche con studi clinici di fase 3 e 4</p>	<p>Applicant Institution: Ospedale Policlinico San Martino</p>
<p>Project Type: WP PROJECT - 2</p>	

- *Il rischio di Ospedalizzazione è alto anche per la Chemioterapia tradizionale*
- *Il rischio di Ospedalizzazione è relativo al contesto organizzativo*
- *Il rischio di Ospedalizzazione è simile in Istituti Tumori e Ospedali Generali*
- *Il rischio di Ospedalizzazione è maggiore nella Real World rispetto ai Trials*
- *La maggioranza dei ricoveri sono unplanned e passano per ED*
- *Impatto dell'età, delle comorbidità e del Performance Status*
- *Ruolo delle Cure Palliative Simultanee/Precoci*

Emergency Presentation



Unpublished Personal Data



S McPhail, Lancet Oncology 2022

CONCLUSIONS

Conclusions

- **Multidisciplinarity & Networks have been Implemented (?)**
- **DMTs and Networks (ROR & RNTR) should be in charge for**
 - **Helping Centers to recruit patients in Trials**
 - **Carrying out Research on**
 - **Impact of Organizational Changes**
 - **RWD as complementary to Evidence built by Clinical Trials**
 - **Quality (incl PROMs)**