

EUROPEAN COUNTRIES CONSULTATION:

Anchoring EUCCC Certification
in National Realities

WP5 – Inclusion, Certification and
Adherence to EUCCC Certification

ITALY COUNTRY PROFILE



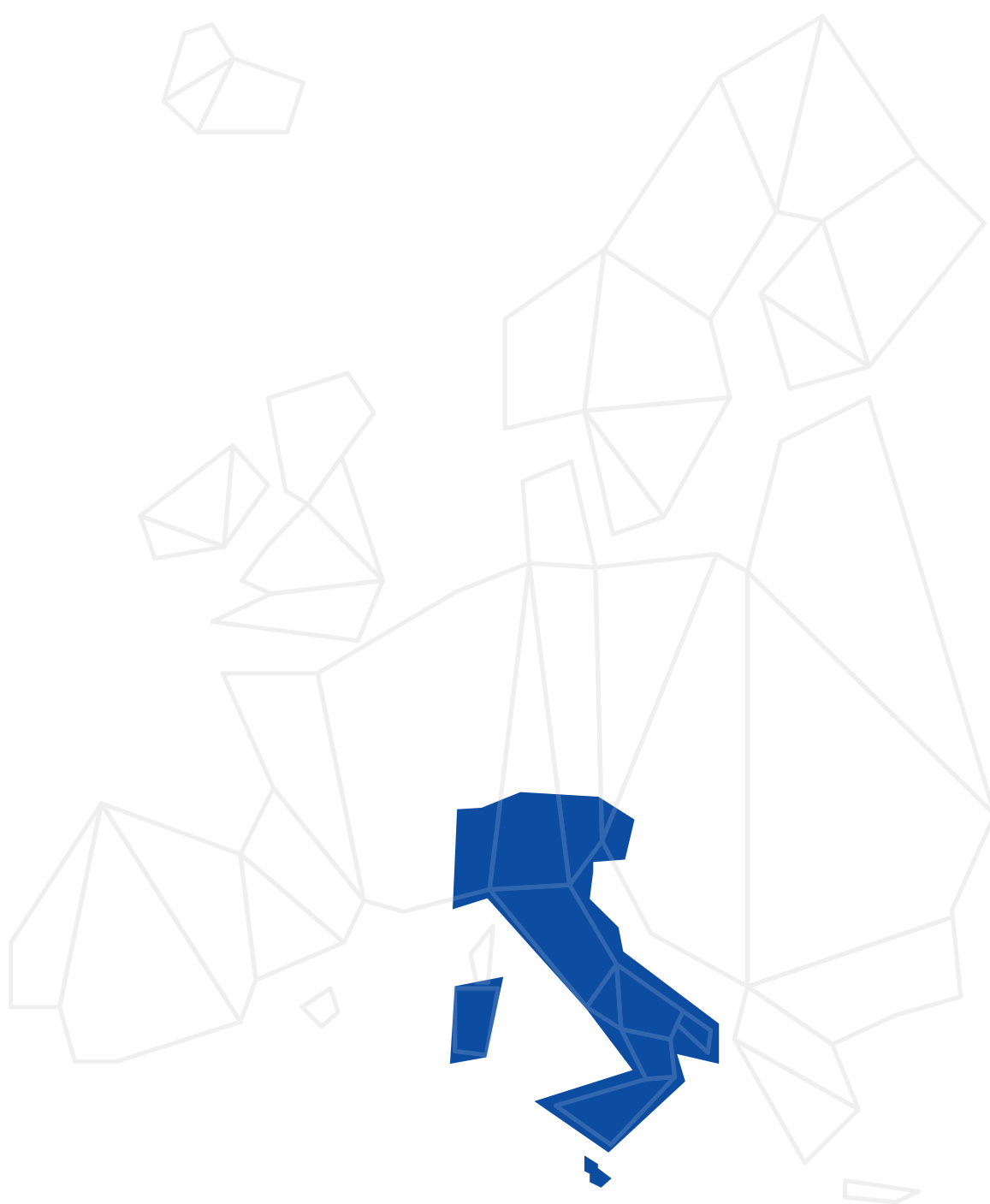
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THE EUROPEAN COMPREHENSIVE CANCER CENTRE NETWORK



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Context: existing certification systems and organization of cancer care

Regional certification of safety and quality of care is mandatory for all acute care providers in order to have the authorization to undergo clinical activity

In Italy, since 1992, certification (*accreditamento*) is mandatory for all hospitals, in order to be eligible for funding from the public system. Their main focus is on minimum requirements for patient safety and quality¹.

Since 2001, the organization of healthcare is the responsibility of regions, therefore certification systems are managed by regions. 21 certification models have been developed in Italy across regions with varying levels of sophistication.

However, to guarantee equity in health service delivery and to ensure a homogeneous level of quality across the country, regions must define their own models and standards based on national guidelines. Indeed, it is necessary that regional certification processes follow some general principles to guarantee that all health care facilities operate according to common quality criteria.

As a result, the Italian National Agency for Regional Health Services (*Agenzia nazionale per i servizi sanitari regionali*, AGENAS) has developed minimum standards that all regional certification systems must follow.²

Designation for cancer care centers that focus on research: the Scientific Institutes for Recovery and Care (*Istituti di Ricovero e Cura a Carattere Scientifico*), are all OEI certified

27 cancer care institutions that have a strong focus on research receive a label and associated funding (IRCCS). These institutions are grouped under a common umbrella: *Alleanza contro il Cancro* (Alliance Against Cancer)³.

To receive this label and its associated funding, centers must fulfill certain criteria concerning links between research and care and be certified by an internationally recognized body. The criteria for applying include covering minimum catchment areas⁴ and proof of scientific activity such as publication in journals⁵. All IRCCS must have a scientific director, responsible for the research activity component of the center. The research component of IRCCS is funded centrally, while the care component is financed by the regional healthcare system. In most cases, IRCCS cancer institutions are OEI certified. The application process involves documentation reviews and on-site visits, which are published on the Ministry of Health's website. In 2012, the Ministry of Health of Italy supported and financed a program towards OEI accreditation for cancer specific IRCCSs⁶.

ISO is used for laboratories and radiotherapy departments, and **JACIE** for cellular therapies.

Organization of cancer care: main features

The Italian healthcare system is **strongly regionalized**: the central government provides general rules, while the effective organization of healthcare is the full responsibility of the regions.

In the field of cancer, stand-alone cancers coexist alongside general hospitals. Originally, cancer IRCCS were stand-alone hospitals exclusively, but this status has also been given to general hospitals.

The delivery of cancer care in Italy is organised into **Regional Oncological Networks (Reti Oncologiche Regionali)** – organizational units that aim to improve the quality and efficiency of cancer care services at the regional level by implementing standardised guidelines and ensuring consistent coordination between hospitals, clinics, research institutions and multidisciplinary teams of health professionals.

Cancer regional networks are organized by the regions according to principles set nationally but different models exist according to regions: from one region to another, the coordinator (hub) is either a university hospital, a regional hospital, or the regional administration itself. The focus of networks is mainly on care, but there has been recently some focus on clinical trials. A coordination group gathers those responsible for each network in the country.

Networks activities include setting up pathways and volume thresholds and organizing local prevention projects. Very recently, a law has defined the organization of molecular tumor boards, representatives of which are also part of the regional oncology networks. Networks also have a key role in deciding the number and location of high-cost equipment (linear accelerators, for example). They therefore have a crucial role in local planning of cancer infrastructure.

In January 2023, Italy adopted the National Oncology Plan 202327 (NOP), an ambitious strategic framework developed by the Ministry of Health with input from all major stakeholders. Its core involves:

- fully activating Regional Oncology Networks (RONs)
- operationalising diagnostic-therapeutic-care pathways in all regions.
- formalization of molecular tumor boards
- more energetic prevention efforts

Identified barriers towards the implementation of EUCCC certification in Italy

The challenge of heterogeneity in sizes and models of organization of cancer care between regions

The very different sizes between regions represents a challenge in setting CCCs in Italy. Lombardia has 10 million people while Aosta 143 000 inhabitants). A unique CCC model is not possible in Italy considering the size heterogeneity in the country.

Patients' migration from South to North

Historically, Southern Italy is less endowed with infrastructure and resources than the North. There therefore tends to be patient migration movements from South to North (this problem is particularly acute for pediatric cancer care). However, this situation is improving. For example, the Naples National Cancer Institute – IRCCS “G. Pascale Foundation” has made drastic improvements in capacity in the South, as it is now part of WP9 of the EUnetCCC project, considered a best practice to be followed by other cancer centers.

No clear added value of EUCCC certification against OECI

For reasons exposed above, OECI is very present in Italy. Therefore, **the question of the added value of EUCCC certification against OECI** is particularly acute. It will indeed be difficult to convince the centers who are satisfied with OECI certification to shift towards EUCCC. Moreover, the numerous uncertainties surrounding the EUCCC certification process (timeline, procedures, characteristics of EUCCCs...) currently hinder its adoption by cancer centers.

This issue is reinforced by the absence of a clear financial incentive towards EUCCC certification. The issue of financial sustainability also concerns the future network of EUCCC (WP7).

Identified enablers towards the implementation of EUCCC certification in Italy

Strong regional oncology networks

In 2022, more than two thirds of cancer surgery patients received treatment within the regional oncology network of their region of residence, while the remaining patients travelled outside their local area. While nearly 90% of cancer patients were treated within their local RON in the northern and central regions of Tuscany, Friuli-Venezia Giulia, Emilia-Romagna and Piedmont, fewer than 50% were treated within their local RON in the southern regions of Abruzzo, Calabria and Molise.^{7,8}

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A comprehensive system of monitoring and publicly benchmarking the performance of hospital providers

Italy has developed a **sophisticated and comprehensive system of monitoring and publicly benchmarking the performance of hospital providers**⁹, managed by Agenas (National Agency for Regional Health Services). This quality monitoring and benchmarking culture is an enabler towards setting EUCCCs in the country.

Conditions for successful EUCCC certification implementation in Italy

It is hoped that the implementation of EUCCCs in Italy will bring the following benefits:

- Develop data-driven decision-making
- Reinforce collaborations between centers
- Develop innovation
- Improving pathways
- Connection research and care
- Developing clinical trials

However, in order for implementation of EUCCC certification to be successful, the following issues should be addressed:

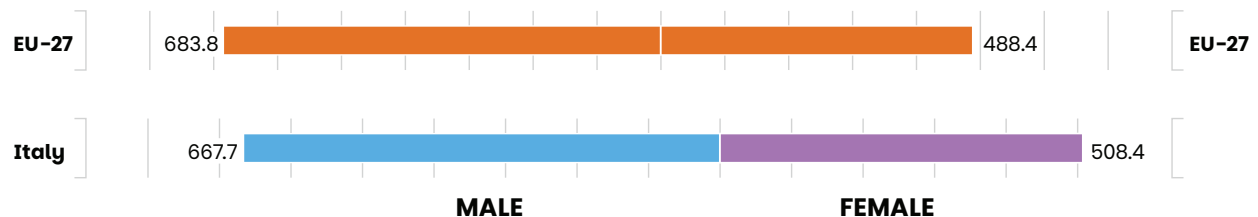
- Addressing the challenge of heterogeneity in sizes and models of organization of cancer care between regions by enabling different EUCCC organizational models to coexist: about half could use a “hub-and-spoke” model (central specialised hub facility connected to local ambulatory spokes), while the remainder could implement an integrated comprehensive cancer care model. For smaller regions, it would make sense to develop consortium-based model with several hospitals.
- Concerning the issue of differences in endowments between the Northern and Southern regions, EUCCCs in Italy should accompany the movement towards further equity in patient care quality within the Italian territory by improving care and research for those centers that are currently less developed in this regard. By design, adherence to the EUnetCCC network should enable smaller and less developed centers to benefit from additional resources.
- Clarifying the added value of EUCCC adherence against OEI is a crucial issue in a country that has overwhelming OEI presence. Centers that are currently OEI certified must see a clear advantage in engaging in EUCCC certification.
- Like most countries, for the moment, the Ministry of Health of Italy has not yet officially recognized EUCCC certification within the framework of the Italian healthcare system. **A key success factor for the sustainable establishment of EUCCC certification in the future organization of cancer care in Italy will be acquiring official recognition from the Italian authorities.**

Number of certified CCCs: 11
Number of EUCCC pilot centers: 2

Epidemiology: incidence, mortality and survival rates

Incidence rate:

Estimated incidence, both sexes, all sites but non-melanoma skin, 2022¹⁰



Mortality rate:

Cancer mortality
ASMR per 100 000 population



Survival rates:

For the selection of cancers:

Colon cancer 5-year survival
% survival for patients diagnosed 2010-2014



Breast cancer 5-year survival
% survival for women diagnosed 2010-2014



Lung cancer 5-year survival
% survival for patients diagnosed 2010-2014



Screening Performance

Breast cancer screening
% of target population



Cervical cancer screening
% of target population



Colorectal cancer screening
% of target population



Risk factors

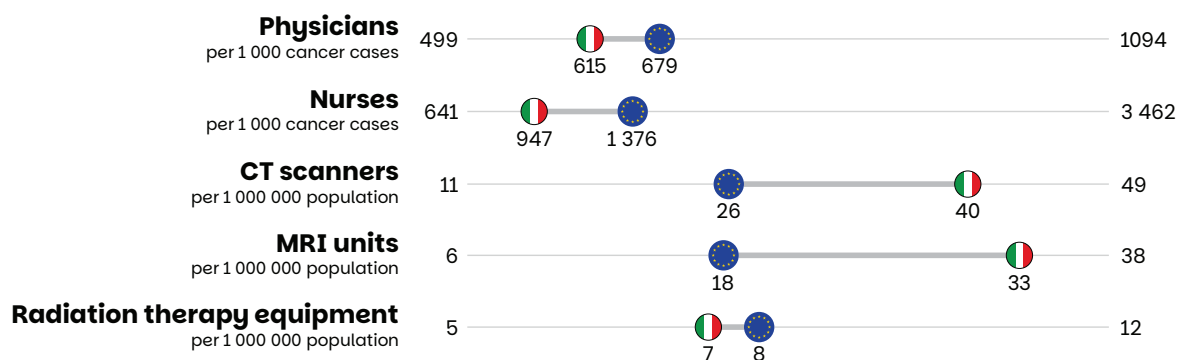
Daily smoking
% of population aged 15+



Alcohol consumption
Litres per capita, population aged 15+



Human resources and infrastructure



Number of clinical trials: 33 386¹¹

Endnotes

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9. <https://pne.agenas.it/ospedaliera/indicatori>
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11. <https://www.who.int/observatories/global-observatory-on-health-research-and-development/monitoring/number-of-clinical-trials-by-year-country-who-region-and-income-group>



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