



**RESEARCH ARTICLE**



## Europe's beating cancer plan & citizens' engagement – The Manifesto for the right to personalized medicine for cancer patients

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### Abstract

As we advance Personalized Healthcare (PHC) across Europe, also thanks to the EU Commission initiatives, such as the Europe's beating cancer plan and the development of the European Reference Networks (ERNs), it is critical not to lose sight of the patient, and to ensure that PHC is made safe, accessible, and affordable to all: every patient has the right to be treated with the best technology for their specific disease based on their specific situation.

Technological developments, the basis of personalized medicine, have made available for many patients new diagnostic and therapeutic options that have often led to a better therapeutic adherence to treatment and a better quality of life.

In order to allow personalized medicine to develop its full potential in the coming years in Italy and in the rest of the EU, many challenges will have to be faced within the healthcare sector.

From the point of view of civic and patient associations, in the face of changing scenarios, it is essential that citizens are aware of this, know how to assert their rights and are vigilant and the first actors of change. In this context, the "Manifesto for the right to personalized medicine for cancer patients", wants to intervene in support of patients suffering from cancer, providing an in-depth analysis of the opportunities that the approach to personalized medicine today can represent.

Launched in Italy in July 2020 by Cittadinanzattiva, the Manifesto is now brought to the attention of European Institutions, in particular the MEP Interest Group "European Patients' Rights and Cross-Border Healthcare" by Active Citizenship Network, the EU branch of the Italian NGO.

Keywords: Personalized Healthcare, personalized medicine, patients' rights, cancer patients, Cross-Border Healthcare.

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## 1 | INTRODUCTION

**P**ersonalized Medicine means a therapeutic approach that provides “the study of genotypic and phenotypic characteristics (including also the environment, lifestyle, comorbidities, psychosocial state), of each individual, and aims to integrate these information, giving unique characteristics to complex diseases that can thus be diagnosed and treated more effectively, with a clear impact both from a clinical and socio-economic point of view” (1).

It is therefore appropriate to understand personalized oncological medicine, not only as a personalization of diagnosis and therapy (based on the specific molecular characteristics of the tumor, the so-called precision medicine), but as a global vision of personalized care, based on the specificity of the individual person, in a path of treatment that puts the single patient at the center both from the therapeutic point of view and from the point of view of the quality of life. Technological developments, at the basis of personalized medicine, have made available for many patients new diagnostic and therapeutic options that have often led to a better therapeutic adherence to treatment and a better quality of life (2).

In the face of such evolving scenarios, it is essential that citizens are aware of this, know how to assert their rights and be vigilant and the first actors of change. From this point of view, the long-term commitment in the area of oncology by the Italian NGO Cittadinanzattiva is strictly linked with the principles stated in the “European Charter of Patients’ Rights (3)”, a milestone to advocate on health issues at the EU and national level, based on the Charter of Fundamental Rights of the European Union. The “European Charter of Patients’ Rights” has been drafted in 2002 by Active Citizenship Network, the EU branch of Cittadinanzattiva, together with many associations. Even if no one of us were only focused on Personalized Healthcare, the high sensitivity about the respect of the person allowed us to state, among the others, the **Patients’ Right to Personalized Treatment**, as follows: “*Each individual has the right to diagnostic or therapeutic programs tailored as much as possible to his or her*

*personal needs. The health services must guarantee, to this end, flexible programs, oriented as much as possible to the individual, making sure that the criteria of economic sustainability do not prevail over the right to health care”.*

Almost 20 years later, from this principle and the advances in scientific research, the “Manifesto for the right to personalized medicine for cancer patients” was drafted in July 2020. This manuscript aims to illustrate – for the benefit of the international scientific community, institutions and Patients’ advocacy groups (PAGs) – the essential elements of the Manifesto, starting from a careful examination of the following eleven rights: the right to personalized treatment; diagnostic and therapeutic innovation; equity of care; quality of life; information and guidance; timeliness of care; access to appropriate care; participation and choice of care; training; privacy and respect for psychological aspects; humanization.

## 2 | MATERIALS AND METHODS

The “Manifesto for the right to personalized medicine” has been promoted by Cittadinanzattiva, with the unconditional contribution of Roche, and officially presented in July 2020 in Italy via webinar. The Manifesto was drawn up thanks to the joint work with the following scientific societies, doctors, and patient associations:

- AIOM, Associazione Italiana di Oncologia Medica
- Alleanza contro il cancro
- Europa Donna Italia
- FMP, Fondazione per la Medicina Personalizzata

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## EUROPE'S BEATING CANCER PLAN & CITIZENS' ENGAGEMENT – THE MANIFESTO FOR THE RIGHT TO PERSONALIZED MEDICINE FOR CANCER PATIENTS

- FNOMCeO, Federazione Nazionale degli Ordini dei Medici Chirurghi e degli Odontoiatri
- LILT, Lega Italiana per la Lotta contro i Tumori
- Lorusso Domenica, Responsabile ricerca clinica fondazione policlinico gemelli IRCCS
- Normanno Nicola, Cell Biology and Biotherapy Unit INT - Fondazione Pascale
- PERIPLO, Associazione reti oncologiche
- Pruneri Giancarlo, Head, Department of Pathology, Fondazione IRCCS Istituto Nazionale Tumori
- ReS, Fondazione Ricerca e Salute
- SIAPEC, Società Italiana di Anatomia Patologica
- SIF, Società Italiana di Farmacologia
- WALCE onlus - Women Against Lung Cancer In Europe

For the benefit of cancer patients living in Italy, the experts have identified the following 11 principles that must be guaranteed and respected in order to make them eligible for the patients' right to personalized medicine:

**Right to personalized treatment:** Every person has the right to a personalized medical treatment capable of determining the best possible health outcome, which also takes into account and respects all relevant individual characteristics, such as: the genotypical and phenotypical characteristics of the individual, gender, age, the presence of multiple pathologies, taking more medicines, lifestyle and psycho-social conditions, and religious/cultural differences.

**Right to diagnostic and therapeutic innovation:** Every person has the right to access innovative diagnostic therapies and technologies, if deemed appropriate to his/her case, in order to gain a potential advantage over traditional diagnostic therapies and technologies without residence constraints and administrative, bureaucratic and economic obstacles.

**Right to 'fairness of care':** Every person has the right that health is guaranteed fairly throughout the country. Access to innovative diagnostic services and targeted therapies, evaluated according to criteria of appropriateness, must be guaranteed regardless of territorial and economic considerations so as to ensure that every patient has the same opportunities for treatment.

**Right to quality of life:** Every person has the right to have therapies that limit as much as possible adverse events, thus contributing to improve his/her quality of life and that of the people who care for him/her. He/she has the right to access to therapies that are as personalized as possible. He/she has the right to be respected, listened to and to receive useful information about the therapy in progress in a constant and effective doctor-patient communication, based on mutual collaboration in the definition of the best therapeutic path. The patient must be oriented by the clinician on the diet and healthy lifestyle to adopt (rest, exercise, psychophysical well-being) in order to prevent and contain adverse events. The patient should be precisely informed about the various possible adverse events and should obtain timely intervention if they occur. The patient has the task of ensuring timely communication to the doctors who treat him/her of the occurrence of any adverse events.

**Right to information and guidance:** Every person has the right to be informed in a simple, clear and complete way about their pathology, the repercussions on their quality of life, the health treatment they undergo or will have to undergo. He/she must be made aware of the opportunities for diagnosis and treatment that are available for his pathology, even if they are available at other health facilities, other than those where he/she is being treated, and therefore be put in a position to access them.

**Right to timely care:** Every person has the right to receive a precise diagnosis and access to timely care as soon as possible, taking advantage, where necessary, of innovative diagnostic technologies without limitations or delays caused by organizational dysfunctions, bureaucracy, waiting lists and economic considerations that limit access.

**Right to access to appropriate care:** Every person has the right to access a treatment that provides a net

benefit and minimizes the risk they may face. He/she has the right to an accurate evaluation of all the relevant information that characterizes him/her (genetic, phenotypic, comorbidity, lifestyle and psychosocial condition) and that contribute to determine appropriate treatment choices.

**Right to participation and choice of treatment:** Every person has the right to participate in therapeutic choices and his or her opinion must be listened to, respected and taken into account in specific moments of discussion identified within the therapeutic plan with multidisciplinary teams. The Health Service must promote itself as an agent of active information towards patients and their families, fostering that awareness and competence useful to involve users in a shared decision-making process with health professionals: a process that in some cases can be particularly difficult and must be approached with due sensitivity and delicacy.

**Right to training:** Every person has the right to be followed by doctors trained in the use of new technologies, able to orient them with respect to new diagnostic and therapeutic opportunities and able to interact in a complementary way with respect to the various skills. At the same time, healthcare personnel have the right to training in order to be put in a position to orient the patient in a precise manner, to opt for appropriate therapeutic choices, to be able to use new technologies.

**Right to privacy and respect for psychological aspects:** Every person has the right to have psychological aspects evaluated and to receive psychological support for himself and the caregiver where necessary. Given the complexity and delicacy of the subject, the person has the right not to be left alone when the test results are returned and that this moment is accompanied and managed by the doctors of reference. He/she has the right to receive support in understanding the possible implications of certain results, with particular regard to the analysis of genes that may be affected by mutations. He/she also has the right to confidentiality of personal information, including information regarding his state of health. The execution of a gene sequencing test, must always be preceded by an informed consent that must explain to the patient, in a clear and detailed way,

the type of test that will be used, its purpose and by whom and how the data will be stored and processed; the patient will also be asked for any consent to the specific use of the data for research purposes and the storage in specific computer databases.

**Right to the humanization of care:** Every person has the right to receive a treatment based on courtesy, availability, dialogue, listening, acceptance and empathy, by all health workers and not. He/she has the right to a humanizing approach to care, also oriented to the involvement and common planning of the care path.

The message of the Manifesto echoes several related concepts such as “patient-centered care” and “patient rights”, critical for an effective and equitable delivery of care.

### 3 | RESULTS AND DISCUSSION

Despite the great progress made in recent years, there is still a long way to go in Europe to achieve the goals of personalized medicine. The challenges that patients, healthcare systems and companies in the sector are facing include issues related to different standards of healthcare across countries, where different pricing systems often exist, and to problems of cross-border access for patients (4). Moreover, at a regional level within Member States, as in the Italian case, alignment is necessary to ensure equal access to all patients regardless of the area in which they live: north, south, east or west of the country (5). For an effective implementation of the Manifesto in Italy, it is necessary to focus decisively on some **concrete actions**:

- **favor the full involvement of the patient in the treatment process**, from diagnosis to follow-up, in order to improve health outcomes;
- **favor the psychophysical well-being not only of the patient but also of those who assist him/her**, In this perspective, it will be necessary to focus on the synergy between patient/caregiver and healthcare worker, implementing channels of communication and dialogue through the greater use of tools such as

telemedicine and teleconsultation when possible in the context of the proposed therapy;

- **include new diagnostic tests on molecular alterations (NGS) in the Essential Levels of Assistance (Lea) and define uniform tariffs for refund to the Regions.** In Italy, there are strong territorial differences that over time have led to and are still today developing great inequalities between citizens in the use of accessible and quality services. In the area of accessibility to gene sequencing tests (NGS), there are few regions that guarantee their provision; in other regions, which have not provided for the inclusion of the tests in the regional Essential Levels of Assistance (LEA), patients cannot actually use them, except through a fee, or are forced to move to regions where they are provided. As a result, access to targeted therapies is also partly compromised. In this respect, **in order to ensure appropriate access to targeted medicines for patients, regulatory developments and changes to the conditions of accessibility foreseen under the current rules are necessary.**
- clearly define, through **specific guidelines**, the criteria of access for patients to the use of gene sequencing methods (NGS) and start **an evaluation of the structures eligible for the use of NGS technology and targeted therapies**, favoring organizational modalities also between regions to guarantee the same treatment opportunities to every citizen;
- promoting **the establishment of groups of experts in different disciplines (Molecular Tumor Board) on the territory** according to precise and shared standards and in close connection with each other, through a network of collaboration and a continuous exchange of information. To this end, it is essential **to implement a unique and transparent information platform that connects the various oncology centers to the Molecular Tumor Boards.**
- promote and ensure **the training of specialized personnel** in particular on: **technical skills for**

**the future development of NGS tests; consolidation of a culture of privacy** that balances information needs for scientific purposes and the respect and involvement of the person; **relational aspects** that allow professionals to collect information that affects individual susceptibility to the disease and at the same time create a better empathic approach and a better relationship of trust.

#### 4 | CONCLUSIONS

With patients at the core of Personalized Healthcare, tailoring care to the unique characteristics of each individual should be the goal of any well-functioning PHC system.

Every year, 3.5 million people in the EU are diagnosed with cancer, and 1.3 million die from it. Over 40% of cancer cases are preventable. Without reversing current trends, it could become the leading cause of death in the EU.

To date, more than 200 different types of cancer are known, almost half of which fall into the less common or rare categories and for many tumor growth is driven in part by genomic alterations. The need is to have and evaluate more and more evidence that characterize the tumor from a molecular point of view. The Europe's beating cancer plan – which aims to reduce the cancer burden for patients, their families and health systems – may provide the ideal framework for the further development of PHC across Europe. The plan will address cancer related inequalities between and within Member States with actions to support, coordinate and complement Member States' efforts.

This Manifesto aims to intervene in support of patients suffering from cancer, providing an insight into the opportunities that the approach to personalized medicine can represent today. With this work Cittadinanzattiva wants, first of all, to inform patients about their rights and consolidate their central role through conscious and active participation in all decisions concerning their treatment path. Cittadinanzattiva also wants the Manifesto to be at the same time a tool in support of the National Health Service and

of health professionals, indicating paths and strategies useful for the implementation of the model of personalized medicine, the implementation of which will require an important adjustment from the point of view of health governance and the various actors involved.

In addition to a direct impact at national level, we hope that the Manifesto could also have an indirect usefulness at European level: on the one hand, the Manifesto could contribute to better bring the needs of patients and citizens closer to the objectives of the next “Europe’s beating cancer plan”; on the other hand, it could be the starting point for a broad discussion aimed at guaranteeing the necessary rights and protections, still far from being fully guaranteed, even though recognized by the European Directive on cross-border care (6). To this end, a presentation of the Manifesto to the European Parliament in the framework of the Interest Group “European Patients’ Rights and Cross-border Healthcare” (7) is of particular interest as a premise for a sharing of the same, and its adoption in the context of the centers of excellence gathered in the European References Network (8).

#### **Abbreviations:**

PHC: Personalized Healthcare

ERNs: European Reference Networks

PAGs: Patients’ advocacy groups

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7. The idea to encourage a MEPs informal Interest Group focused on patients’ rights follows the widespread request of more than 80 civic and patient organizations sent to the EU Parliament to recognize officially the value of citizens’ initiatives, such as the European Charter of Patients’ Rights, based on the Charter of Fundamental Rights of the European Union, and the European Patients’ Rights Day, which has been organized every year on April 18th since 2007 at local, national and EU level. <http://www.interestgroup.activecitizenship.net/>
8. European Reference Networks are virtual networks involving healthcare providers across Europe. They aim to tackle complex or rare diseases and conditions that require highly specialised treatment and a concentration of knowledge and resources. There are 24 ERNS involving 25 European countries included Norway, over 300 hospitals with over 900 healthcare units and covering all major disease groups. [http://ec.europa.eu/health/ern/policy\\_en](http://ec.europa.eu/health/ern/policy_en)

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