2nd International Conference on

Human Genetics

September 21-22, 2026 | **Budapest, Hungary**



ACTIVE CITIZENSHIP NETWORK

CITTADINANZATTIVA

Reframing Access to Advanced Therapy Medicinal Products (ATMPs) in Europe: A Patient-Centered Call to Action for Policy and Systemic Reform

Mariano Votta
Cittadinanzattiva / Active Citizenship Network

Cittadinanzattiva/Active Citizenship Network: a short introduction

Cittadinanzattiva

- Italian NGO founded in Italy in 1978.
- More than 30.000 members, 250 local assemblies and 84 Citizen Advisory Centres.
- Mission: promote active participation of citizens and protection of their rights.


MINISTERO DELLA SALUTE

Cittadinanzattiva
Tribunale per i diritti del Malato

La medaglia d'oro
Al Merito della Sanità Pubblica

Active Citizenship Network

- The European branch of Cittadinanzattiva, established in 2001.
- One of the most widespread & informal network, able to involve in its initiatives 206 civic, patient & user organizations coming from 34 Countries, plus 22 European/Global networks/umbrella organizations.
- Promote the point of view of European citizens in all public policies areas, focusing on healthcare, consumers and corporate social responsibility issues.

www.cittadinanzattiva.it

www.activecitizenship.net

ACTIVE CITIZENSHIP NETWORK
CITTADINANZATTIVA

How we advocate at the national level (I)

Tribunal for Patients' Rights (+250 local point across the entire territory, including Hospitals and Territorial Services & 10,000 volunteers)



84 PIT-Citizen Advisory Centres, front line & back office at the national level.
Each year, all claims & requests of information (average 25,000/year) are included in a National Report submitted to the authorities.

National Coalition of Associations for Patients suffering Chronic Diseases (CnAMC), crosscutting alliance of 130 PAGs and more that work together to strength the success of their actions. From 2000, it publishes a National Annual Report on chronic policies (XX Edition edited on Dec. 2022) and manages a dedicated website.

How we advocate at the national level (II)

Protection:

25.000 complaints = main citizens problems – Annual Report (cfr. 2022 - Edition XXV)

Political actions from real cases















Civic information: communication campaigns sectorial studies, public consultations, editorials, on line and on the spot information, podcast, civic recommendations, opinions etc..





Monitor availability & Civic Audit

Specific methodology to evaluating public health care organizations. Read more



..and at the EU level (I)

Cittadinanzattiva/Active Citizenship Network is official member of:

- *Since 2010:* Member of "Health Policy Forum", later called "Health Policy Platform", the EU platform dealing with health and patients' rights (DG Sante)
- *Since 2014:* Member of "Active Citizenship Structured Dialogue Group", the EU platform dealing with civic participation (DG Home)
- *2016/2019:* Member of the European Consumer Consultative Group, a consultative group entrusted to represent the interests of consumers (DG Justice and Consumers)
- *Since 2018:* official stakeholder and collaborating partner to the European Joint Action on Vaccination (EU-JAV)
- *Since 2019:* a collaborating stakeholder to the EU Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections (EU-JAMRAI)
- *Since 2019:* associated member of the Coalition for Vaccination
- *Since 2022:* Member of the HERA Civil Society Forum (DG HERA)

List of Institutional and non-institutional working groups in which we are involved

Our priorities & download our Action Plan at the EU level

..and at the EU level (II)

Our milestones:

- European Charter of Patients' Rights (2002)
- European Patients' Rights Day (since 2007) celebrated every year on April 18th with local, national and EU events across Europe
- MEPs Interest Group "European Patients' Rights and Cross-border Healthcare" (since 2015)
- MEPs Inter-Institutional Group "SDGs for well-being and consumers' protection" (since 2021)



European Patients' Rights & Cross-Border Healthcare

Member of the European Parliament Interest Group

Inter-Institutional Group
SDGs for well-being and consumers' protection



1. Established in 2002 by Cittadinanzattiva-Active Citizenship Network, together with organizations from 15 EU countries;

2. It lists states 14 that should be guarantee to everyone, everywhere.

3. The rights stated in the European Charter of Patients Rights have as the main starting point the European Charter of Fundamental Rights and several international declarations and recommendations.

4. Drafted in 22 languages, it has become a reference for EU citizens' rights in health care and a milestone for other [Charters of rights](#).





2-Right of Access: *Every individual has the right of access to the health services that his or her health needs require. The health services must guarantee equal access to everyone, without discriminating on the basis of financial resources, place of residence, kind of illness or time of access to services.*

3-Right to Information: *Every individual has the right to access to all kind of information regarding their state of health, the health services and how to use them, and all that scientific research and technological innovation makes available.*

7-Right to Respect of Patients' Time: *Eeach individual has the right to receive necessary treatment within a swift and predetermined period of time. This right applies at each phase of the treatment.*

10-Right to Innovation: *Each individual has the right of access to innovative procedures, including diagnostic procedures, according to international standards and independently of economic or financial considerations.*

12-Right to Personalized Treatment: *Each individual has the right to diagnostic or therapeutic programmes tailored as much as possible to his or her personal needs.*

How can these patients' rights be combined on ATMPs?

EU Parliament: Institutional policy dialogue on ATMPs



[24 OCTOBER 2022 | Brussels: “Policy dialogue with Institutions at the EU Parliament on equitable patient access to advanced therapies across Europe”]



[26 April 2023 | The celebration of the 17th European Patients' Rights Day today at the European Parliament: Advanced Therapies in Europe between sustainability, innovation and patients' rights]







Advanced Therapies Medicinal Products revolution & the respect of the patients' right to access to care: a call to action (I)

We call on the European Institutions to:

- Promote a clear, transparent, and adequate regulation regarding ATMPs.
- Reducing health inequalities in access to ATMPs among the Member States also due to financial constraints.
- Promote new health and economic approach: the change in the accounting system to consider the expenses for ATMPs as investments instead of current expenditures. This paradigm shift should be registered by EUROSTAT.
- Support the development of ATMPs centres of excellence across the EU on the model of the European Reference Networks.
- Increase investment in research related to ATMPs.

We call on each EU Member State to:

- Introduce innovative payment models for ATMPs able to capture the "value proposition" of this innovation that guarantee, on the one hand, access to these highly innovative therapies to all potentially eligible patients and, on the other, sustainability for the NHS.
- Reduce health inequalities in access to ATMPs within the Country, with particular attention to the inner/internal areas.
- Ensure greater transparency between regulators, HTA bodies, and payers.
- Promote a multistakeholder approach to ATMPs governance.
- Guarantee civic participation in the ethics committees related to ATMPs.
- Promote wider knowledge about ATMPs among healthcare professionals.
- Increase investment in research related to ATMPs.



Advanced Therapies Medicinal Products revolution & the respect of the patients' right to access to care: a call to action (II)

We call on Local Health Authorities, public & private providers, Health Care Professionals (HCPs), and Patients' Advocacy Groups (PAGs) to better cooperate in the ATMPs field in order to:

- Strengthen patient education programs, communication campaigns and health literacy initiatives, ensuring major confidence among patients and citizens on the opportunities and challanges around the ATMPs.
- Building the public consent around ATMPs sharing best practices and successful case histories.
- Be actively involved in the development of new ATMPs as part of good clinical practice.

We call to citizens to:

- Be aware of the needs of patients with conditions that don't respond to traditional treatment;
- Pay more attention to recognizing the official and renowned source of information related to healthcare.

Institutional endorsement at the national and at the EU level

European Patients' Rights & Cross-Border Healthcare
Member of the European Parliament Interest Group

European Alliance for Transformative Therapies



"ATMPs give hope to patients where therapeutic options are currently lacking or non-existent and they must be able to reach patients sooner. Our priority is always to put patients' interest first". Watch the video message of the EU Health Commissioner Stella Kyriakides at the #EPRD23



**FARMACI: SCHILLACI, 'NUOVO QUADRO NORMATIVO PER RIMBORSO TERAPIE INNOVATIVE'* = 'Con un apposito tavolo'. Roma, 17 gen 2023. (Adnkronos Salute) - Il tema delle terapie avanzate "da un lato presenta costi assoluti estremamente elevati e dall'altro la capacità di incidere in modo decisivo e in tempo rapidissimi sulla storia naturale di patologie ad elevata mortalità e di impatto sulla salute evitando cure prolungate nel tempo. Questi aspetti rendono i costi di queste terapie più un investimento, una spesa in conto capitale che una spesa corrente. Si tratta quindi di definire un nuovo quadro normativo specifico per il rimborso di queste terapie da parte del Ssn che preveda da un lato la possibilità di un periodo di ammortamento del costo e dall'altra uno schema a rimborso a risultato 'pay for performance'». Lo ha annunciato il ministro della Salute, Orazio Schillaci, nel suo intervento in Commissione Sanità e Lavoro al Senato nel seguito delle comunicazioni sulle politiche del suo dicastero.*

Articles & video interviews on ATMPs



The value of investing in **Advanced Therapy Medicinal Products**: combining sustainability, innovation and **respect** for **patients' rights**

MARIANO VOTTA
Director Cittadinanzattiva-Active Citizenship Network

To move towards the European Health Union, we probably also need to go beyond the current narrative concerning the European pharmaceutical legislation review which - in synthesis - seems to be limited to the following statement: "the fate of the pharmaceutical sector is at stake as well as the future of national health systems". Talking about the future scenarios of the Advanced Therapy Medicinal Products (ATMPs) that the review might outline, what about the justified expectations of patients? What is holding us back from including and considering in the debate also the point of view of the so-called 'final users' of the health service, the ultimate recipients of the decisions whose effects will be experienced in practice? Travelling at different speeds. How can innovation and access be combined? To try to answer these questions, Cittadinanzattiva - through its EU branch Active Citizenship Network – has recently presented a proposal at the European Parliament, endorsed by 48 Patient Advocacy Groups (PAGs) from 12 Member States, to try to make up ground on the patients' right to access advanced therapies, calling for a change in institutional mentality to classify spending on ATMPs as an investment and not as a cost.

All potential, eligible patients have the right to access Advanced Therapy Medicinal Products, and national health budget constraints cannot be an obstacle. Nowadays, traditional reimbursement and budgeting schemes are unable to amortise the value of ATMPs, whose costs and benefits are not aligned. These types of therapies need new and different payment and accounting methods which consider the high initial costs and the large and lasting benefits over time, both for patients and for national health systems. It is time to change the institutional mindset to classify the expenditure on Advanced Therapy Medicinal Products as an investment and not as a cost, which is possible if a decision is made to review - from Eurostat downwards – the current economic and financial classifications of healthcare expenditure. The cost of these therapies could be amortised over the years in relation to the savings generated over time. In particular, they could be entered in the state budget over several years and not all in the year of expenditure. This would significantly increase the financial sustainability of these costs by the public sector over time and promote greater and more equitable use of ATMPs in the population, without putting public finances at risk.

This proposal - realised with the unconditional support of VITA (Value and Innovation for Advanced Therapies coalition) - also received an encouraging endorsement from Italy's new Health Minister during an official hearing at the Senate of the Italian Republic in January 2023 while, at the European level, the European Health Commissioner Stella Kyriakides, on the occasion of the 'European Patients' Rights Day' held in April 2023 emphasised that "ATMPs give hope to patients where therapeutic options are currently lacking or non-existent and they must be able to reach patients sooner. Our [European Commission's] priority is always to put patients' interest first".

Above all, we believe that the two aspects can only be better combined and find a point of connection with each other if, in the field of ATMPs, we also succeed in strengthening and guaranteeing spaces for the participation of citizens and PAGs in the decision-making process. This is also why, in Italy, we warmly welcomed the invitation of national institutions to join the National Ethics Committee for clinical trials on advanced therapies ('ATMPs'), set up in February 2022 at the Italian Medicines Agency, as the only actor to represent the civic and patient point of view on the issue. For the same reason, we urge to overcome the extreme polarisation of the public/private debate that is accompanying the pharma legislation review which, despite its inevitable complexity, needs to be integrated from a civic and patient perspective.

The patients' rights to innovation and to access, both stated in the European Charter of Patients' Rights, should be inextricably interlinked in every area of healthcare. Unfortunately, in many contexts this does not happen, and even in the field of ATMPs, where innovation is advancing, there are cases of withdrawal or threatened withdrawal of existing and accessible therapies. So, in the presence of innovative therapeutic solutions, approved by the competent regulatory authorities, available on the market and already being used by eligible patient groups, having already proven their efficacy, we should have the courage to affirm the principle of irreversibility of access to treatment. Those who are already using them cannot be continually exposed to the situation of uncertainty. What is at stake is the credibility of the healthcare system as a whole and of all the actors involved, public and private. But above all, it concerns the medical history of so many patients who see in these innovative treatments a hope that was not even imaginable a few years ago, as well as the dreams of those who live alongside them, and the ultimate essence of ATMPs is that of being 'dream savers'.

HEALTH EUROPA

THE LATEST **EU POLICY**
CLICK HERE TO SUBSCR

More info here

Home › News › Health Policy News › European Patients' Rights Day and ATMPs: Combining sustainability, inno

News | Health Policy News

European Patients' Rights Day and ATMPs: Combining sustainability, innovation and respect for patients' rights

24th April 2023



17th EUROPEAN PATIENTS' RIGHTS DAY - 26 April 2023 - European Parliament, Brussels





---

mercoledì 26 aprile 2023

Federfarma

Cittadinanzattiva

Disponibili in Europa 20 terapie avanzate, 6 contro i tumori Al Parlamento Europeo la Giornata europea dei diritti del malato



Le News di Ansa Salute - ROMA, 26 APR - Da quella per l'emofilia di tipo A a quella per la malattia dei bambini farfalla, oltre 20 terapie avanzate sono entrate in commercio, tra cui sei per la cura di diverse forme di cancro. Allargare la possibilità di accedere a queste cure, spesso molto costose, è il tema al centro della conferenza organizzata a Bruxelles, presso il Parlamento europeo, per la Giornata europea dei diritti del malato. All'evento promosso da Active Citizenship Network, la rete europea di Cittadinanzattiva partecipano rappresentanti di pazienti, Istituzioni europee, Organizzazione Mondiale della Sanità, esperti ed operatori sanitari. Le terapie avanzate costituiscono nuove opportunità per il trattamento di malattie rare e oncologiche perché permettono di modificare funzioni fisiologiche compromesse, anche con la correzione di mutazioni acquisite su base genetica. "Vogliamo che le nuove terapie - dichiara Stella Kyriakides, Commissaria europea per la salute - siano accessibili in maniera rapida e per questo abbiamo sviluppato protocolli che permettono, da un lato, di velocizzare lo sviluppo dei nuovi farmaci di maggiore interesse per la salute dei cittadini, e dall'altro, di renderli rapidamente disponibili ai pazienti". "I vincoli dei bilanci sanitari nazionali - spiega Anna Lisa Mandorino, segretaria generale di Cittadinanzattiva - non possono essere un ostacolo all'accesso dei pazienti alle terapie avanzate. Queste terapie necessitano di nuove e diverse modalità di pagamento e contabilizzazione, che tengano conto degli elevati costi iniziali e dei duraturi benefici nel tempo, sia per i pazienti che per i sistemi sanitari nazionali".

TrendSanità

Home | Pillole | Live | Video Interviste | Ebook | Podcast | Speciali | Across Europe | Health For Dreamers | Newsletter | Accedi

COMUNICAZIONE | FARMACI | SANITÀ DIGITALE | LEGALE | PROCUREMENT | PNRR | DISPOSITIVI MEDICI | Cerca sul sito



ACN | Farmaci | malattie rare | Pazienti | Sostenibilità | Terapie avanzate

Terapie avanzate: è tempo di considerarle un investimento anziché un costo

In occasione della Giornata europea dei diritti del malato, Cittadinanzattiva - Active Citizenship Network ha organizzato una conferenza al Parlamento europeo a Bruxelles per riflettere sulle terapie avanzate

di **Adriana Riccomagno** 3 Maggio 2023 Tempo di lettura: 7 min

International peer-reviewed publications

Family Medicine and Medical Science Research

OPEN ACCESS Freely available online

Research Article

A Civic Audit to Monitor Oncological Facilities across Italy: an Advocacy Tool in Line with the New Ambitious EU4Health Programme

Mariano Votta*, Valeria Fava, Maira Cardillo

Active Citizenship Network, c/o Cittadinanzattiva APS, Rome, Italy

More info here

Journal of Medical Research and Health Sciences

Received 10 Dec 2020 | Revised 10 Feb 2021 | Accepted 25 Feb 2021 | Published Online 10 Mar 2021

DOI: https://doi.org/10.15520/jmrhs.v4i3.325

JMRHS 4 (3), 1199–1203 (2021)

ISSN (O) 2589-9031 | (P) 2589-9023

RESEARCH ARTICLE

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

Mariano Votta [1*] | Valeria Fava [2] | Maira Cardillo [3]

European Journal of Public Health, 1–4

© The Author(s) 2023. Published by Oxford University Press on behalf of the European Public Health Association.
This is an Open Access article distributed under the terms of the Creative Commons Attribution-NonCommercial License (https://creativecommons.org/licenses/by-nc/4.0/), which permits non-commercial re-use, distribution, and reproduction in any medium, provided the original work is properly cited. For commercial re-use, please contact journals.permissions@oup.com

https://doi.org/10.1093/eurpub/ckad189

Public attitudes, knowledge and educational needs toward genetic testing and omics sciences: a pilot survey conducted in Italy

Giovanna Elisa Calabrò [1], Francesco Andrea Causio[1], Denise Pires Marafon[1], Michele Sassano [2], Francesca Moccia[3], Roberta Pastorino[1,4], Stefania Boccia[1,4]

Downloade

Richardson-Parry *et al.*
International Journal for Equity in Health (2023) 22:19
https://doi.org/10.1186/s12939-023-01841-6

International Journal for Equity in Health

RESEARCH Open Access

Interventions to reduce cancer screening inequities: the perspective and role of patients, advocacy groups, and empowerment organizations

Afua Richardson-Parry[1*], Carole Baas[2], Shaantanu Donde[3], Bianca Ferraiolo[4], Maimah Karmo[5], Zorana Maravic[6], Lars Münter[7], Ignacio Ricci-Cabello[8], Mitchell Silva[9], Stacey Tinianov[10], Jose M. Valderas[11], Seth Woodruff[12] and Joris van Vugt[13]

Focus on Medical Sciences Journal Review Article

Feb 2021, Volume 7, Issue 1

ERNs Multi-Stakeholder Forum to Enhance Patients' Rights and to Enhance Cooperation on Cross-border Healthcare

Mariano Votta [1*], Daniela Quaggia [2], Michaela Papavero [3]

Main achievements in Italy

Italy has established a comprehensive ATMP framework:

- ***October 2025* Bill:** A draft law was introduced in the Senate establishing a €250M experimental Fund and multi-year, outcome-based reimbursement models for ATMPs. Read more
- ***April 2026* Financial Shift:** The Senate Health Committee officially redefined advanced and gene therapies as long-term strategic capital investments rather than annual current expenditures. Read more
- ***May 2026* Real-World Application**: This new structural model is already a reality. Italy achieved a historic milestone with the NHS fully reimbursing and administering the first "one-shot" gene therapy for beta-thalassemia and sickle cell disease to a 14-year-old patient (May 19, 2026). Read more

These milestones bridge the gap between financial governance and clinical access, proving that Italy is pioneering sustainable, universal access to life-changing innovations.



Mariano Votta

Responsible EU Affairs at Cittadinanzattiva

Director Active Citizenship Network

m.votta@cittadinanzattiva.it

@marianovotta

https://www.linkedin.com/in/mariano-votta-b854a92a/