



## OPENING REMARKS

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Good afternoon and welcome to all of you. First of all, allow me to thank the Italian MEP, Brando Benifei, for his sensitivity in choosing to host the European celebrations of the European Patients' Rights Day again this year.

This nineteenth edition, realized in the framework of the European Year of Digital Citizenship Education, is particularly important for my association.

- 1) First of all, the chosen topic: the crucial role of health data sharing for patients, healthcare systems and medical research, is extremely on time (just think that in March 2025, the Regulation on the European Health Data Space entered into force, marking the start of the transition phase towards full implementation<sup>1</sup>). It is a topic that naturally recalls the importance of the European Patients' Rights Day, which we have been celebrating since 2007. The whole framework of the European Health Data Space (EHDS) cannot stand without a solid foundation of patients' rights protection. This has also been clearly highlighted in the recent training and awareness webinars organised by the European Commission, which I would like to thank not only for accepting our invitation to participate today, but also for promoting these important and timely initiatives.
- 2) Secondly, we are in the middle of the Polish Presidency of the Council of the European Union, to which we extend our sincere thanks for the high political value of their decision to include the

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<sup>1</sup> "European Health Data Space Regulation (EHDS)". EU Commission. [https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds\\_en](https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds_en)

issue of patients' rights in its six-month programme, thus placing it at the centre of the European political agenda. As highlighted in the recently published [White Paper 'Healthcare Policy Recommendations'](#), the willingness to work towards the **official recognition of the European Charter of Patients' Rights** is an important step that has been awaited for years. I am proud to recall that the European Charter of Patients' Rights, which is at the heart of today's celebrations, was **drafted in 2002 by Active Citizenship Network**, together with many civil and patients' organisations from different European countries. Since its inception, it has been a benchmark for the protection of patients' rights in Europe, and today, more than ever, its value is also recognised at the institutional level. The Polish Presidency's decision is more necessary than ever, because **without a common framework for patients' rights, the European Health Union will never be truly complete**: it will always be missing its "leg of rights". This also applies to the full implementation of the European Health Data Space, which directly involves core rights established in the [Charter: access, innovation, privacy, consent, safety, and personalisation of care](#)". We are proud that, after almost 25 years, work is finally underway to **formally recognise these rights in the *acquis communautaire***. And, of course, we reiterate our full support to achieve this goal. A representative of the Polish institutions, which we thank for 2 patronages received, is here today to talk about the above-mentioned commitment.

- 3) Today also marks the presentation of the Interest Group 'European Patients' Rights & Cross-Border Healthcare', which has been already working for several months and is now in its third term, thanks to the sensitivity and vision of many MEPs who have recognised this political initiative as a contribution from civil society to better represent the health needs of European citizens and to strengthen the focus of the European institutions on public health.

The Interest Group's activities are fully in line with both the recommendations of the Conference for the Future of Europe, which stressed the urgent need for greater European involvement in public health issues, and the recent decision of the European Parliament to set up the *ad hoc* standing committee SANT following urgent requests from civil society organisations - indeed, the official document emphasises "responding to citizens' expectations".

On behalf of the Interest Group Secretariat, we would like to thank MEPs Brando Benifei and Tomislav Sokol for agreeing to serve as co-chairs once again.

Now that I have made this necessary preamble, it is time to introduce some useful elements for today's conference:

- The digitisation of healthcare systems has radically changed the way healthcare data is processed, which has become a fundamental resource for disease planning, prevention and treatment<sup>2</sup>. In this regard, we echo the message that emerged on the occasion of the G7 held in Italy on October 2024: *“Making data available, standardized and harmonized is not simple due to technical and cultural challenges related to governance, accountability, data literacy, trust, compliance with data protection rules and security issues; all these aspects are crucial for the protection of patient rights as well as patient acceptance of new technologies. We also acknowledge the high opportunity costs patients have to bear if the potential of their health data is left untapped. We, therefore, commit to actively working on harmonizing data policies and regulations where feasible, including by building on efforts at regional and international level”*<sup>3</sup>.
- On this issue, we are committed at the national and European level to being recognised as a partner that collaborates to promote rights-based digital health technology regulation, policy and practices<sup>4</sup>, in line with our history and the recent civil initiative “Digital Rights and Health Alliance”<sup>5</sup>.
  - In Italy, for example, Cittadinanzattiva has been increasingly involved in recent years in setting guidelines for observational studies and in ethics committees at the national and regional levels<sup>6</sup>.

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<sup>2</sup> ‘The SIMM proposal for the revision of privacy legislation in healthcare: the consensus document’ [www.medicimanager.it/progetto/open-privacy/](http://www.medicimanager.it/progetto/open-privacy/). ‘OPEN PRIVACY’ project: Proposal for the revision of healthcare privacy legislation promoted by SIMM: [www.anmdo.org/wp-content/uploads/2024/05/anmdonews\\_4\\_24\\_def.pdf-del-7-maggio-2024.pdf](http://www.anmdo.org/wp-content/uploads/2024/05/anmdonews_4_24_def.pdf-del-7-maggio-2024.pdf)

<sup>3</sup> “G7 Policy brief on Artificial Intelligence: opportunities and challenges for the Health Sector”: [www.g7italy.it/wp-content/uploads/G7-Policy-brief-on-Artificial-Intelligence.pdf](http://www.g7italy.it/wp-content/uploads/G7-Policy-brief-on-Artificial-Intelligence.pdf)

<sup>4</sup> “Digital rights and Health Alliance. Manifesto to guide rights-based regulation of new technologies for health”. <https://epha.org/wp-content/uploads/2024/12/manifesto-digital-rights-and-health-alliance-2024-november-2024.pdf>

<sup>5</sup> “Introducing the Digital Rights and Health Alliance”: <https://haiweb.org/introducing-the-digital-rights-and-health-alliance/>

<sup>6</sup> In Italy Cittadinanzattiva is a member of several ethics committees, both national and regional. In particular, [Anna Lisa Mandorino, Secretary General at Cittadinanzattiva, is member of the Comitato Etico Nazionale per le sperimentazioni cliniche relative alle terapie avanzate \(“ATMP”\)](#). Cittadinanzattiva is on the [“Comitato Etico Nazionale per le Sperimentazioni Cliniche degli Enti Pubblici di Ricerca \(EPR\) e altri Enti Pubblici a Carattere Nazionale”](#) managed by l’Istituto Superiore di Sanità. In addition, at the territorial level (for example): [Maria Platter, Cittadinanzattiva-Toscana, is member of the “Centro di coordinamento nazionale dei comitati etici territoriali”/ “National coordination center of territorial ethics committees”](#). [Lorenzo Latella, Cittadinanzattiva-Campania, is member of the “Comitato Etico Campania 1”](#) [Elio Rosati, Cittadinanzattiva-Lazio, is member of the “Comitato Etico Territoriale LAZIO AREA 1”](#)

- At the European level, we are involved in several EU-funded projects, such as FACILITATE (FrAmework for CLinical trIal participants' daTA reutilization for a fully Transparent and Ethical Ecosystem) which, as we will see shortly, aims to develop an ethical, legal and regulatory framework to enable the return of clinical trial data to trial participants and other healthcare professionals involved in their care.

The participation of citizen and patient associations in these initiatives ensures that the views of those who will ultimately be involved in the process can be expressed.

That said, we know that most citizens are poorly informed and unaware of the potential and positive effects that could result from the use of health data, both for themselves and for public health, and this is why greater investment and collaboration are needed. The European Health Data Space has introduced a very important principle for citizens: 'data altruism'<sup>7</sup>. We are working to develop this further, to move from 'data altruism' to 'data solidarity', to ensure data serves the public good while respecting patients' rights.

- However, the potential of the European Health Data Space to improve patient autonomy over health data faces a number of challenges, including the insufficient digital literacy of the EU population. Recent data shows that only 55.6% of the EU population has at least basic digital skills<sup>8</sup> (and in Italy the situation is even worse, with only 45.7%, ranking my country among the five worst in the EU).

This suggests that despite improved access to health data, people with low digital literacy may find it difficult to navigate electronic health records (EHRs), understand the information they contain, or fully exercise their rights to restrict access and request rectification of inaccurate or incomplete data. Similarly, patients and citizens may not understand the implications of using health data for secondary purposes or be able to exercise their right to opt out of data sharing<sup>9</sup>.

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<sup>7</sup> 'Review of pharma legislation: balancing innovation and access' [www.farmacista33.it/politica-sanitaria/30299/revisione-della-pharma-legislation-equilibrio-tra-innovazione-e-accesso.html](http://www.farmacista33.it/politica-sanitaria/30299/revisione-della-pharma-legislation-equilibrio-tra-innovazione-e-accesso.html)

<sup>8</sup> "Shaping Europe's digital future". DESI 2024 report on digital literacy among EU citizens: [https://digital-decade-desi.digital-strategy.ec.europa.eu/datasets/desi/charts/desi-indicators?period=desi\\_2024&indicator=desi\\_dsk\\_bab&breakdown=ind\\_total&unit=pc\\_ind&country=AT,BE,BG,HR,CY,CZ,DK,EE,EU,FI,FR,DE,EL,HU,IE,IT,LV,LT,LU,MT,NL,PL,PT,RO,SK,SI,ES,SE](https://digital-decade-desi.digital-strategy.ec.europa.eu/datasets/desi/charts/desi-indicators?period=desi_2024&indicator=desi_dsk_bab&breakdown=ind_total&unit=pc_ind&country=AT,BE,BG,HR,CY,CZ,DK,EE,EU,FI,FR,DE,EL,HU,IE,IT,LV,LT,LU,MT,NL,PL,PT,RO,SK,SI,ES,SE)

<sup>9</sup> "Embracing democracy in healthcare – Creating an inclusive and trustworthy European Health Data Space" (17 September 2024): <https://eurohealthobservatory.who.int/publications/i/embracing-democracy-in-healthcare-creating-an-inclusive-and-trustworthy-european-health-data-space>

- In conclusion, the effective use of health data and public awareness to support decision-making is a key issue. The experience of the Covid-19 pandemic has led to important developments in a relatively short period. In this context, organisations such as my own, which has been working for years on citizens' rights in the field of health, are committed to exploring the boundaries between citizens' right to privacy and the promotion of health as a fundamental human right. New strategies should be identified to protect individuals and their dignity, without hindering the use of data to support their care and public health policies.

The relationship between health and privacy is a key issue because it involves two of the fundamental rights that are most exposed to the development of technology and innovation<sup>10</sup>.

- Institutions, experts and experiences promoted by public and private actors will help us today to better understand where we are heading and the crucial role that Civil Society Organisations (CSOs) and Patients' Advocacy Groups (PAGs) can play. For a more comprehensive and transparent process, for building trust, and ensuring that the needs and perspectives of patients are taken into account<sup>11</sup>.

I thank you for your attention and wish you a fruitful event.

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<sup>10</sup> 'Privacy and healthcare data management' by Isabella Mori, Head of Protection and Transparency Policies at Cittadinanzattiva. <https://www.recentiproggressi.it/archivio/4042/articoli/40222/>

<sup>11</sup> "Embracing democracy in healthcare – Creating an inclusive and trustworthy European Health Data Space" (17 September 2024): <https://eurohealthobservatory.who.int/publications/i/embracing-democracy-in-healthcare-creating-an-inclusive-and-trustworthy-european-health-data-space>