STUDY
Requested by the SANT Committee

Patient-centred health research and innovation in the EU

A preliminary exploratory study

Policy Department for Transformation, Innovation and Health
Directorate-General for Economy, Transformation and Industry
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PE 786.414 - April 2026

EN

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Abstract

This study explores how patient-centredness is understood and applied in research and innovation (R&I) across the European Union. Drawing on case studies from Germany, the Netherlands, and Belgium, and insights from a range of stakeholders, it aims to inform future policy and practice. While patient-centredness is gaining prominence at the EU level, its implementation remains variable across Member States and funding instruments. Overall, the findings highlight both the recognised value of patient involvement in enhancing research relevance and the need for more coherent structures, definitions, and approaches to support its consistent uptake.

This document was provided by the Policy Department for Transformation, Innovation and Health at the request of the Committee on Public Health (SANT).

This document was requested by the European Parliament's Committee on Public Health (SANT).

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VERSION

Original: English
Manuscript completed: April 2026

BIBLIOGRAPHIC REFERENCE FOR THIS PAPER

Lenz, C., Varkonyi, P., Dell'Aquila, M., 2026, Patient-centred health research and innovation in the EU, Brussels: European Parliament, Policy Department for Transformation, Innovation and Health.

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LICENCE

IDENTIFIERS

PE 786.414
ECTI/B/SANT/IC/2025/006
Print ISBN 978-92-848-3595-9 | doi:10.2861/9008254 | QA-01-26-100-EN-C
PDF ISBN 978-92-848-3594-2 | doi:10.2861/8489890 | QA-01-26-100-EN-N

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LIST OF ABBREVIATIONS

AI	Artificial Intelligence
BMFTR	Federal Ministry of Research, Technology and Space, Germany
CHMP	Committee for Medicinal Products for Human Use, European Medicines Agency
CSO	Civil Society Organisation
DDZ	Deutsches Diabetes-Zentrum (German Diabetes Center)
DFG	Deutsche Forschungsgemeinschaft (German Research Foundation)
DKFZ	Deutsches Krebsforschungszentrum (German Cancer Research Center)
DKTK	Deutsches Konsortium für Translationale Krebsforschung (German Cancer Consortium)
DLR	Deutsches Zentrum für Luft- und Raumfahrt (German Aerospace Center)
DZG	Deutschen Zentren der Gesundheitsforschung (German Centers for Health Research)
DZNE	Deutsches Zentrum für Neurodegenerative Erkrankungen (German Center for Neurodegenerative Diseases)
DZPG	Deutsche Zentrum für Psychische Gesundheit (German Center for Mental Health)
EMA	European Medicines Agency
EPF	European Patients’ Forum
ERA	European Research Area
EU	European Union
EUPATI	European Patients' Academy on Therapeutic Innovation
EURORDIS	European Organisation for Rare Diseases
GRIPP2	Guidance for Reporting Involvement of Patients and the Public
HAS	Haute Autorité de Santé (French National Authority for Health)
HIRUZ	Health Innovation and Research Institute, Belgium
HIV	Human Immunodeficiency Virus
HL	Health Literacy
HTA	Health Technology Assessment
IHI	Innovative Health Initiative
IMI	Innovative Medicines Initiative
JCA	Joint Clinical Assessment
JLA	James Lind Alliance
KBF	King Baudouin Foundation
KCE	Belgian Healthcare Knowledge Centre

KPI	Key Performance Indicator
KUL	KU Leuven
LIH	Luxembourg Institute of Health
MFF	Multiannual Financial Framework
MS	Member State
NCD	Non-Communicable Diseases
NCT	National Centre for Tumour Diseases, Germany
NEED	Needs Examination, Evaluation and Dissemination
NIHR	National Institute for Health and Care Research, UK
NHS	National Health Service, UK
NUM	Network of University Medicine, Germany
OECD	Organisation for Economic Co-operation and Development
PAB	Patient Advisory Board
PAC	Patient Advisory Council
PAWO	Patient Advisory Board for Scientific Research. Belgium
PEAK	Patients' Experts Academy for Tumor Diseases
PPI	Patient and Public Involvement
PPP	Public-Private Partnership
PRAC	Pharmacovigilance Risk Assessment Committee, EMA
PREM	Patient-Reported Experience Measure
PROM	Patient-Reported Outcome Measure
PROMIS	Patient-Reported Outcomes Measurement Information System
R&D	Research and Development
R&I	Research and Innovation
RRI	Responsible Research and Innovation
SDM	Shared Decision-making
UCC	University Cancer Center, Hamburg
UZ Gent	Ghent University Hospital
WGBO	Wet geneeskundige behandelingsovereenkomst (Medical Treatment Agreement Act of the Netherlands)
Wkkgz	Wet kwaliteit, klachten en geschillen zorg (the Healthcare Quality, Complaints and Disputes Act of The Netherlands)
Wzd	Wet zorg en dwang (the Care and Coercion Act of The Netherlands)
ZonMW	The Netherlands Organisation for Health Research and Development

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EXECUTIVE SUMMARY

Background

Patient-centredness refers to the deliberate and systematic integration of patients' preferences, perspectives and lived experiences into the research and innovation (R&I) process. Within health R&I, the concept has gained increasing recognition and visibility across the EU. However, its practical implementation remains limited and fragmented.

Aim

This study assesses the added value of patient-centred practices, particularly in decision-making phases; maps the evolving terminological landscape; analyses how the concept is reflected in EU R&I instruments and bodies; and presents three case studies (Germany, the Netherlands and Belgium) to illustrate how patient-centredness has been operationalised and what benefits it offers at national and subnational levels.

Key Findings

Patient-centredness has emerged through a reorientation away from a purely biomedical model, recognising individuals as more than their patient identity. This approach moves beyond the traditional emphasis on scientific evidence alone, placing greater importance on patients' values, preferences, and lived experiences, which is important as they may differ from other decision makers in the health, research, innovation, and care space.

Understandings of patient-centredness vary considerably, reflecting the absence of a standardised definition and resulting in diverse practices. Terms such as "patient-centred", "person-centred", "patient engagement" and "patient involvement" are often used interchangeably, though some stakeholders prefer the latter to emphasise patients' proactive and agentic roles. Patient-centredness can also be conceptualised as a spectrum, ranging from consultation to partnership and co-creation in the design, implementation and dissemination of health R&I.

The literature demonstrates that patient-centred approaches enhance the relevance, legitimacy and real-world applicability of research. Meaningful patient involvement is associated with improved satisfaction, safety, treatment uptake and adherence. Nevertheless, systematic integration across the R&I lifecycle remains fragmented. Contributing factors include limited standardisation, insufficient methodological guidance on measuring impact, and inconsistent uptake of existing EU-funded toolkits and guidance documents designed to support patient-centred practice.

Institutional and policy approaches to patient-centredness differ across Member States (MS). Variation across MS in the legal recognition of patient rights may influence the extent to which patient-centred practices are supported and implemented. At EU level, there are no consolidated data on the share of the approximately €11 billion annual public investment in health R&I that supports patient-centred activities. Investment remains largely project-based and ad hoc. Although EU-funded projects frequently include elements of patient involvement, engagement is often limited in design, governance and leadership phases, despite broad recognition of its strategic value. Operationalisation appears more advanced in certain disease areas, such as cancer and multiple sclerosis, yet funding constraints, limited dedicated calls, and inconsistent recognition and remuneration of patient expertise continue to pose barriers. EU bodies such as the European Medicines Agency (EMA) and the Organisation for Economic Co-operation and Development (OECD) have strengthened patient involvement practices, with growing integration across Horizon Europe, the Innovative Health Initiative (IHI) and EU4Health.

Drawing on the literature, survey findings, interviews and case studies, the study proposes recommendations to strengthen patient-centredness at both EU and MS levels. Identified good practices include the development of formal patient involvement mechanisms; provision of dedicated funding; mandatory patient involvement requirements in R&I processes; patient-driven and needs-based priority setting; capacity-building on patient-centred practices for all relevant stakeholders; and an iterative, learning-oriented implementation approach. The recommendations further outline enabling governance mechanisms, institutional learning platforms and cultural change levers to embed patient-centredness more systematically across EU health R&I.

Table 1: Summary Table of Recommendation

Area	Recommendations
Area 1. Strengthening EU regulatory and governance frameworks to systematically embed patient-centredness across the health R&I lifecycle	Establish patient-centred health R&I strategy and guidance at an EU level
	Establish mandatory patient involvement standards across EU health R&I funding instruments
	Integrate patient-identified and informed unmet needs into EU research priority-setting
	Facilitate meaningful participation in Health Technology Assessment processes
	Streamline minimum standards for effective patient engagement
Area 2. Funding and resource allocation for operationalising, tracking, integrating, and sustaining patient-centred approaches	Create designated systems to capture and track investment in patient-centred R&I in the EU
	Include dedicated budget lines for patient involvement in health R&I grants
	Establish preparatory funding mechanisms for co-design in shaping research
	Provide specified funding for scale up, translation, or continuation of patient-centred deliverables
	Include patient-centred notions in EU funding and domain specific strategies
Area 3. Prioritise and support capacity building for patient-centred practice across stakeholders and promote continuous learning ecosystems	Facilitate patient engagement training for EU-funded researchers and evaluators
	Include provisional skill building activities for patient-centred R&I in relevant projects
	Implement iterative learning mechanisms and feedback loops with accountability mechanisms
Area 4. Knowledge capture, the generation of evidence on impact, and the creation of dedicated spaces to showcase and disseminate best practices	Facilitate integration of patient reported outcomes into health R&I
	Develop and validate standardised frameworks to collect and evaluate patient-centred approaches
	Establish centralised EU platforms to connect stakeholders
	Create an EU-level repository of patient involvement best practices and metrics

Source: Authors' own elaboration.

1. INTRODUCTION

KEY FINDINGS

Patient-centredness refers to the intentional and systematic integration of patient preferences, perspectives, and lived experiences into the research and innovation (R&I) process. It is increasingly recognised as a means of strengthening R&I. However, the operationalisation of such a framework requires a consistent approach across the whole R&I lifecycle, particularly during the design and planning phases. Patient-centred practices remain more commonly oriented towards healthcare delivery, with comparatively less integration into R&I contexts, particularly governance.

Context and Objectives

Across the EU, patient engagement in the design, development, and evaluation of health research, innovations, and interventions is increasingly recognised as essential to improving the relevance, quality, and impact of research.[1] In practice, this has led to growing emphasis on engaging patients in identifying unmet needs, shaping clinical study design and conduct, informing regulatory and assessment processes, and contributing to post-research implementation and monitoring.[2]

Despite this recognition, patient-centred approaches to agenda setting, prioritisation, and decision-making within health R&I remain uneven and limited.[3] [4] Power asymmetries within research systems frequently marginalise patient perspectives, particularly during the early "preparatory" phase, when research questions, strategic priorities, and resource allocations are defined.[5] [6] [7] Decisions made at this stage are critical, as they shape downstream research trajectories, implementation, and evaluation.[8] While patient involvement does occur in some planning processes, substantial gaps remain in understanding what constitutes effective and meaningful participation, especially at these early stages.[9] This gap is further reinforced by the limited availability of evidence on best practices, as much of the existing literature focuses on patient engagement in healthcare delivery rather than in R&I governance.[10]

Collective EU public investment in health R&I reaches around €11 billion annually, comprising approximately €9.7 billion from Member State (MS) governments and about €1.18 billion through the

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[1] Warner, K., See, W., Haerry, D. et al., 2018, *EUPATI Guidance for Patient Involvement in Medicines Research and Development (R&D); Guidance for Pharmaceutical Industry-Led Medicines R&D*, Frontiers in Medicine. https://www.frontiersin.org/articles/10.3389/fmed.2018.00270.

[2] Ibid.

[3] de Wit, M., Cooper, C., Reginster, J.Y., 2019, *Practical guidance for patient-centred health research*, The Lancet, Vol. 3(393), p.1095-1096. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(19)30034-0/fulltext.

[4] Hickmann, E., Richter, P., Schlieter, H., 2022, *All together now - patient engagement, patient empowerment, and associated terms in personal healthcare*, BMC Health Services Research, Vol. 22(1). https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-022-08501-5.

[5] Mitton, C., Smith, N., Peacock, S. et al., 2009, *Public participation in health care priority setting: A scoping review*, Health Policy, Vol. 91(3), p. 219-228. https://www.sciencedirect.com/science/article/abs/pii/S0168851009000232?via%3Dihub.

[6] Manafò, E., Petermann, L., Vandall-Walker, V., Mason-Lai, P., 2018, *Patient and public engagement in priority setting: A systematic rapid review of the literature*, PLoS One, Vol. 13(3). https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0193579.

[7] Gudowsky, N., 2021, *Limits and benefits of participatory agenda setting for research and innovation*, European Journal of Futures Research, Vol. 9(8). https://link.springer.com/article/10.1186/s40309-021-00177-0#ref-CR39.

[8] Manafò, E., Petermann, L., Vandall-Walker, V., Mason-Lai, P., 2018, *Patient and public engagement in priority setting: A systematic rapid review of the literature*, PLoS One, Vol. 13(3). https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0193579.

[9] Ibid.

[10] Ibid.

Horizon Europe programme.[11] Health R&I ultimately aims to improve the lives of end users, including patients. Integrating patient-centred approaches can support this objective, although such contributions are not always systematically reflected in existing budgetary and monitoring frameworks.

There is increasing recognition in conducting and investing in R&I that directly addresses patient needs and broader public health priorities. However, the integration of patient-centred approaches within health R&I remains fragmented and inconsistently operationalised, constraining opportunities for innovation with tangible real-world value.

This study aims to provide a preliminary, illustrative analysis of how patient-centredness is defined, operationalised, and implemented within health R&I across the EU and its MS, with particular attention to decision-making processes and agenda-setting. The period of analysis spans 2022–2025.

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[11] Fernandes, M., Kammerhofer-Schlegel, C., Finauri, G., 2024, *Cost of Non Europe in health policy*, European Parliament Research Service. https://www.europarl.europa.eu/RegData/etudes/STUD/2024/753192/EPRS_STU(2024)753192_EN.pdf.

2. UNDERSTANDING OF PATIENT-CENTREDNESS IN HEALTH R&I

KEY FINDINGS

Understandings of terminology within the patient-centred umbrella vary considerably, reflecting the absence of a standardised definition and resulting in diverse approaches in practice. Although such plurality can facilitate constructive dialogue, the literature notes that limited standardisation constrains comparability. Emerging from a broader shift towards recognising individuals beyond their clinical identity, patient-centred approaches encompass a continuum ranging from consultation and involvement to partnership and co-creation, each denoting differing levels of participation and influence. Interviews with patient and umbrella organisations reflected this definitional diversity, while also revealing broad consensus around core principles. Some interviewees expressed a preference for terms like "patient involvement", perceived as conveying greater proactivity and agency for patients. Survey findings similarly indicated widespread application of patient-centred principles, with 92% of respondents identifying respect for patient values and needs as central to their work.

2.1. Conceptual and terminological interpretations for patient-centred R&I

There is growing evidence and recognition of the importance of patient-centred approaches in R&I. However, variations and inconsistencies remain in the absence of consensus on terminology and scope.[12] Key terms, including patient engagement, involvement, empowerment, and patient-centred care, are inconsistently applied and understood.[13] [14] [15] In the R&I context, distinct from clinical care, patient-centredness remains conceptually ambiguous and is interpreted and operationalised in diverse ways, stemming in part from the lack of a standardised definition.[16] The literature suggests that the form and degree of patient-centredness are context-dependent and often justified on practical grounds, based on their perceived utility.[17]

There is a difference of opinion on whether a standard definition would be beneficial for health R&I. Several interviewed stakeholders expressed their perspective that a lack of consensus is not necessarily problematic, given the breadth and context-dependent nature of the concept. However, they

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[12] Hickmann, E., Richter, P., Schlieter, H., 2022, *All together now - patient engagement, patient empowerment, and associated terms in personal healthcare*, BMC Health Services Research, Vol. 22(1). https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-022-08501-5.

[13] Vat, L.E., Finlay, T., Jan Schuitmaker-Warnaar, T. et al., 2019, *Evaluating the "return on patient engagement initiatives" in medicines research and development: A literature review*, Health Expectations, Vol. 23(1), p. 5-18. https://onlinelibrary.wiley.com/doi/10.1111/hex.12951.

[14] Hickmann, E., Richter, P., Schlieter, H., 2022, *All together now - patient engagement, patient empowerment, and associated terms in personal healthcare*, BMC Health Services Research, Vol. 22(1). https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-022-08501-5.

[15] Pickaert, A.P., 2025, *Patient Involvement in Health Technology Assessments: Lessons for EU Joint Clinical Assessments*, Market Access & Health Policy, Vol. 13(3). https://www.mdpi.com/2001-6689/13/3/38.

[16] Mead, N., Bower, P., 2000, *Patient-centredness: a conceptual framework and review of the empirical literature*, Social Science & Medicine, Vol. 51(7), p. 1087–1110. https://pubmed.ncbi.nlm.nih.gov/11005395/.

[17] Hughes, J.C., Bamford, C., May, C., 2008, *Types of centredness in health care: themes and concepts*, Medicine, Health Care and Philosophy, Vol. 11(4), p.455-463. https://pubmed.ncbi.nlm.nih.gov/18398697/.

emphasised the importance of maintaining open and continuous dialogue, particularly within policy and funding contexts.

The literature does not offer a unified definition of patient-centredness but proposes alternative conceptualisations. The terms patient-centredness and person-centredness are often used interchangeably in the literature, reflecting shared values that position individuals as equal partners in decision-making.[18] [19] However, some authors distinguish between the two, arguing that person-centredness foregrounds the individual as a whole person, while patient-centredness focuses more narrowly on experiences related to illness and care.[20] Others view person-centredness as adding nuance rather than representing a substantive conceptual distinction.[21] [22] Preferences for terminology vary across disciplines; some prefer patient-centredness for its explicit focus on empowerment, autonomy, and engagement, while others treat both as umbrella terms encompassing a range of participatory practices. [23] [24] [25]

Definitions in the literature reflect this diversity of emphasis. One publication co-authored by patient experts and advocates defined patient-centricity as "putting the patient first in an open and sustained engagement of the patient to respectfully and compassionately achieve the best experience and outcome for that person and their family".[26] For other stakeholders, patient-centredness emphasises patients as individuals with resources, capabilities, and expertise, whose inclusion as partners enables lived experience and personal narratives to meaningfully inform and enrich evidence-based research.[27] [28] One umbrella review defines patient-centredness as a philosophy prioritising patients' physical, emotional, and social needs and personal values across the care pathway.[29]

These definitions are primarily rooted in clinical care and do not fully translate to the institutional and governance dimensions of R&I. While patient-centred care has been associated with improved quality

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[18] Moore, L., Britten, N., Lydahl, D. et al., 2016, *Barriers and facilitators to the implementation of person-centred care in different healthcare contexts*, Scandinavian Journal of Caring Sciences, Vol. 31(4), p.662-673. https://pmc.ncbi.nlm.nih.gov/articles/PMC5724704/#scs12376-bib-0007.

[19] Hickmann, E., Richter, P., Schlieter, H. et al., 2025, *Practical Approaches to patient-centred care in Europe: mixed methods study developing a conceptual framework for comprehensive cancer care networks*, JMIR Cancer, Vol. 11. https://www.sciencedirect.com/org/science/article/pii/S2369199925000874.

[20] Raman, K., Vijay Kumar, C., 2018, *What is in the name? Understanding terminologies of patient-centred, person-centred, and patient-directed care!*, Journal of Family Medicine and Primary Care, Vol. 7(3), p.487-488. https://journals.lww.com/jfmpc/fulltext/2018/07030/what_is_in_the_name__understanding_terminologies.1.aspx.

[21] Santana, M.J., Manalili, K., Jolley, R.J. et al., 2017, *How to practice person-centred care: A conceptual framework*, Health Expectations, Vol. 21(2), p.429-440. https://pubmed.ncbi.nlm.nih.gov/29151269/.

[22] Hickmann, E., Richter, P., Schlieter, H., 2022, *All together now - patient engagement, patient empowerment, and associated terms in personal healthcare*, BMC Health Services Research, Vol. 22(1). https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-022-08501-5.

[23] Holmström, I., Röing, M., 2010, *The relation between patient-centeredness and patient empowerment: A discussion on concepts*, Patient Education and Counseling, Vol. 79(2), p.167-172. https://www.sciencedirect.com/science/article/abs/pii/S0738399109004005.

[24] Hickmann, E., Richter, P., Schlieter, H., 2022, *All together now - patient engagement, patient empowerment, and associated terms in personal healthcare*, BMC Health Services Research, Vol. 22(1). https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-022-08501-5.

[25] Gorli, M., Barello, S., 2021, *Patient Centredness, Values, Equity and Sustainability: Professional, Organizational and Institutional Implications*, Sustainability, Vol. 13(23). https://www.mdpi.com/2071-1050/13/23/13217.

[26] Yeoman, G., Furlong, P., Seres, M. et al., 2017, *Defining patient centricity with patients for patients and caregivers: a collaborative endeavour*, BMJ Innovations, Vol. 3(2), p. 76-83. https://pmc.ncbi.nlm.nih.gov/articles/PMC5468520/.

[27] Ekman, I., Swedberg, K., Taft, C. et al., 2011, *Person-centered care-ready for prime time*, European Journal of Cardiovascular Nursing, Vol. 10(4), p.248-251. https://pubmed.ncbi.nlm.nih.gov/21764386/.

[28] Rosengren, K., Brannefors, P., Carström, E., 2021, *Adoption of the concept of person-centred care into discourse in Europe: a systematic literature review*, Journal of Health Organization and Management, Vol. 35(9), p.265-280. https://pmc.ncbi.nlm.nih.gov/articles/PMC9136870/#ref010.

[29] Hickmann, E., Richter, P., Schlieter, H. et al., 2025, *Practical Approaches to patient-centred care in Europe: mixed methods study developing a conceptual framework for comprehensive cancer care networks*, JMIR Cancer, Vol. 11. https://www.sciencedirect.com/org/science/article/pii/S2369199925000874.

and outcomes, patient-centred R&I operates within different structural constraints and faces similar challenges to those identified in care settings, including inconsistent definitions, heterogeneous practices, and a lack of standardised outcome measures.[30] These limitations hinder comparability, learning, and scale-up, prompting calls for greater terminological clarity and standardisation.[31]

The World Health Organization (WHO) characterises person-centred approaches as those that explicitly value individuals' preferences, needs, and perspectives.[32] Historically, patient-centredness emerged in the 1960s as part of a broader effort to reorient medical practice away from a narrow disease-focused model towards recognition of the patient as a whole person embedded within a social and lived context. [33] While this conceptual origin lies in care delivery, its application to R&I introduces distinct implications for governance, participation, and decision-making.

More broadly, patient-centred approaches encompass a spectrum of practices, ranging from consultation and involvement to partnership and co-creation, each reflecting different levels of influence and participation (Figure 1). Engagement is increasingly recognised as a flexible and evolving concept, which should be tailored to specific R&I contexts rather than applied uniformly. [34]

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[30] Burgers, J.S., van der Weijden, T., Bischoff, E.W.M.A., 2021, *Challenges of Research on Person-Centered Care in General Practice: A Scoping Review*, Frontiers in Medicine, Vol. 8. https://www.frontiersin.org/journals/medicine/articles/10.3389/fmed.2021.669491/full.

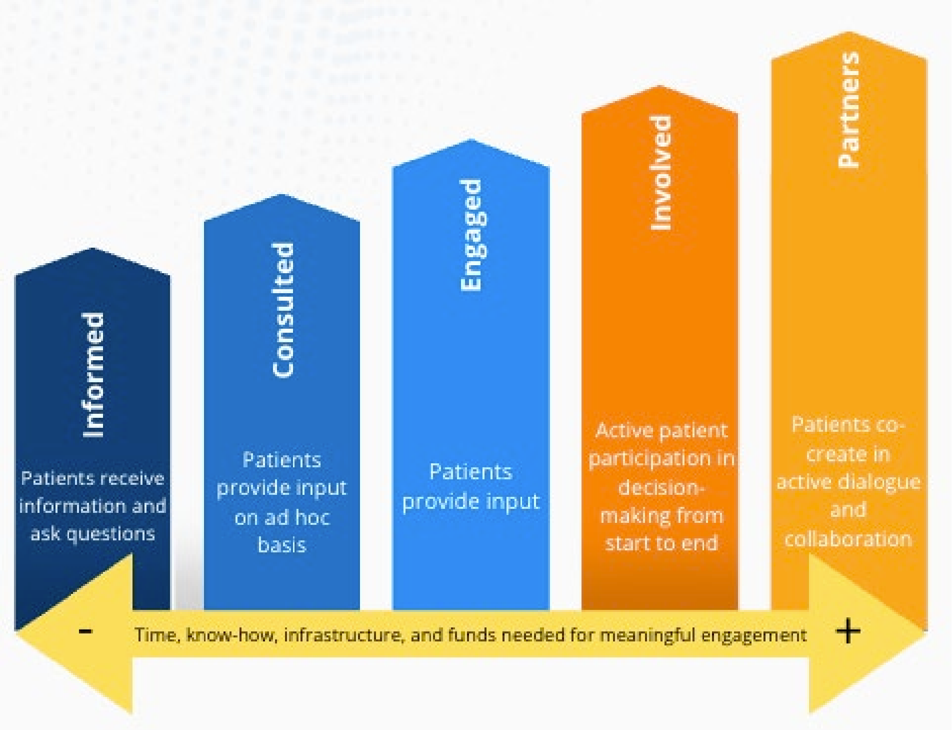
[31] Hickmann, E., Richter, P., Schlieter, H., 2022, *All together now - patient engagement, patient empowerment, and associated terms in personal healthcare*, BMC Health Services Research, Vol. 22(1). https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-022-08501-5.

[32] World Health Organization (WHO), 2015, *WHO global strategy on people-centred and integrated health services: interim report*. https://iris.who.int/handle/10665/155002.

[33] Håkansson Eklund, J., Holmström, I.K., Kumlin, T. et al., 2019, *"Same same or different?" A review of reviews of person-centered and patient-centered care*, Patient Education and Counseling, Vol. 102(1), p. 3-11. https://www.sciencedirect.com/science/article/abs/pii/S0738399118306232.

[34] de Wit, M., Cooper, C., Reginster, J.Y., 2019, *Practical guidance for patient-centred health research*, The Lancet, Vol. 3(393), p. 1095-1096. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(19)30034-0/fulltext.

Figure 1: The spectrum of patient-centred approaches



Source: Authors' own elaboration adapted from the following sources. 35 36 Manafò, E., Petermann, L., Vandall-Walker, V., and Mason-Lai, P., 2018, Patient and public engagement in priority setting: A systematic rapid review of the literature, PLoS One. Vol.13(3). https://doi.org/10.1371/journal.pone.0193579; Warner, K., See, W., Haerry, D. et al., 2018, EUPATI Guidance for Patient Involvement in Medicines Research and Development (R&D); Guidance for Pharmaceutical Industry-Led Medicines R&D, Frontiers in Medicine. Vol. 5. https://www.frontiersin.org/articles/10.3389/fmed.2018.00270.

Note: There is a broad spectrum of patient-centred approaches ranging from the lowest end of patients being informed up to the highest where patients are considered partners and partake in co-creation.

Granting patient organisations actual decision-making power, rather than limiting their role to consultation, is essential to operationalising patient-centredness in R&I. This represents a fundamental shift from **engagement** - where patients are asked for input - to **involvement**, in which patients actively participate in decisions. In this context, the European Patient Academy on Therapeutic Innovation (EUPATI), a non-profit, multi-stakeholder public–private partnership originating from an EU-funded initiative, focuses on supporting education and training for patients and patient representatives to strengthen their understanding and capacity in medicines research and development (R&D). EUPATI provides a leading EU-level resource for operationalising patient-centredness through a free online training programme.[37] It has published four guiding principles designed to enable meaningful patient participation across the entire medicines R&D lifecycle, including interactions with regulatory agencies, ethics committees, health technology assessment (HTA) bodies, and the pharmaceutical industry.[38]

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[35] Manafò, E., Petermann, L., Vandall-Walker, V., Mason-Lai, P., 2018, *Patient and public engagement in priority setting: A systematic rapid review of the literature*, PLoS One, Vol. 13(3). https://doi.org/10.1371/journal.pone.0193579.

[36] Warner, K., See, W., Haerry, D. et al., 2018, *EUPATI Guidance for Patient Involvement in Medicines Research and Development (R&D); Guidance for Pharmaceutical Industry-Led Medicines R&D*, Frontiers in Medicine. Vol. 5. https://www.frontiersin.org/articles/10.3389/fmed.2018.00270.

[37] EUPATI, *Patient Expert Training Programme*. https://learning.eupati.eu/admin/tool/custompage/view.php?id=3.

[38] EUPATI, *What is Meaningful Patient Involvement?*. https://toolbox.eupati.eu/resources-guidance/guidance/.

2.2. Stakeholder perceptions on patient-centred definitions and principles in the EU

Central among the ways in which patient-centredness in R&I is understood in practice across the EU is the active involvement of patients. This involvement can be as experts or representatives, from the earliest stages of research, positioning them as genuine co-creators rather than passive consultees. Respondents consulted for this study emphasised the importance of patient empowerment and education as prerequisites for meaningful participation, alongside the principle of "nothing about us without us". Patient-centredness was also framed as a matter of rights, with engagement seen as essential to ensuring that unmet needs and patient priorities are reflected in R&I processes and outcomes.

Most respondents reported relying on internal definitions or applying patient-centred principles pragmatically in their work, rather than adhering to a single external framework. Some highlighted the influence of established resources such as the EUPATI framework.[39] Organisational values and principles were predominantly shaped by institutional strategies, missions, and patient input, alongside external influences including EU and national regulatory frameworks on patient involvement in clinical research, Horizon Europe and Innovative Medicines Initiative (IMI)/IHI programme expectations, the EU HTA regulation, and European Medicines Agency (EMA) requirements. Best practices developed by international organisations and EU-funded initiatives (e.g. EUPATI, EURORDIS, patient and public involvement in EU projects, and European research infrastructures) were also cited as important reference points.

Interviews with patient and umbrella organisations echoed the diversity of definitions but also highlighted broad consensus around the following core principles: partnership with patients from the outset of research, involvement in shaping research design, and recognition of patients' preferences and values in decision-making. The notion of patient-centricity was invoked, referring to approaches that place patients at the centre of R&I decisions rather than treating engagement as peripheral or consultative. A study on biotech companies in Italy showed that they interpret patient-centricity largely as patient engagement, whereby patient knowledge and expertise are central in the R&D process, shifting away from the disease-centred model.[40]

However, interviews with other prominent patient-focused organisations indicated a preference for the term patient involvement over patient-centred or patient-centric. This preference was attributed to perceptions that the latter concepts imply passivity or a lack of patient agency. Some patients report that patient-centredness or patient-centricity puts them, the patient, at the centre of research or care or treatment, but can feel like although they are central to what decisions are made, the decisions are made around them rather than with them, thus limiting their active participation in the decision-making process.

Stakeholders at the Member State level in Germany reiterated the view that the term patient-centredness is quite expansive in its scope and can be complex to understand and apply. In their case, what is beneficial is applying a more narrative approach, prioritising patient preferences and perceptions in their health and healthcare experience and integrating this into decision-making iteratively.

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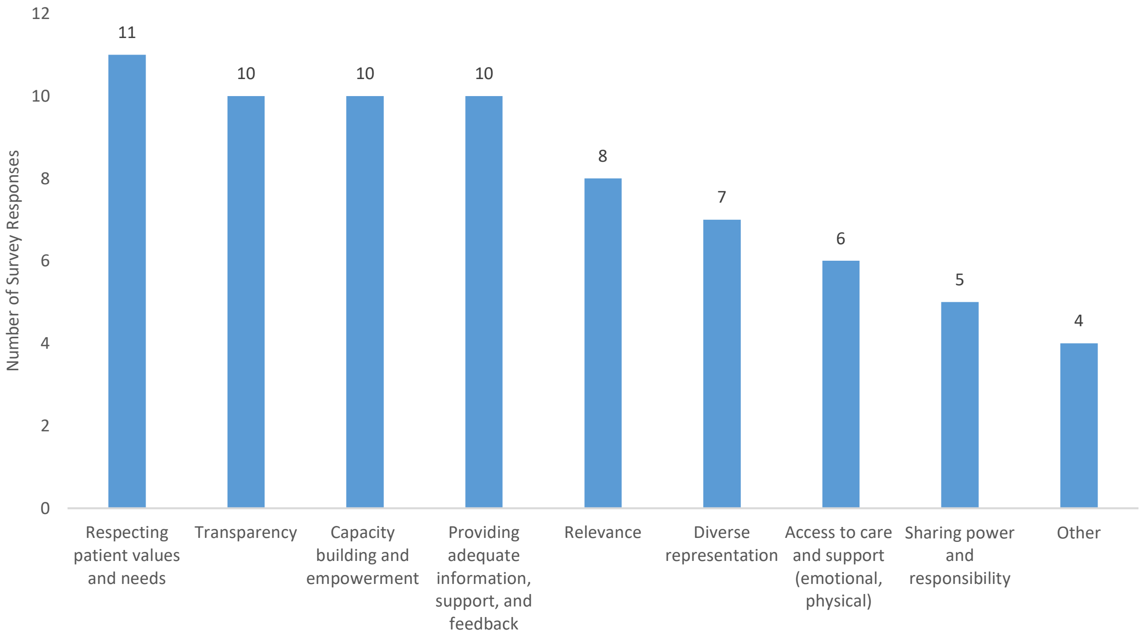
[39] EUPATI, *Guidance for patient involvement in industry-led medicines R&D.* https://toolbox.eupati.eu/resources/patient-toolbox/guidance-for-patient-involvement-in-industry-led-medicines-rd/.

[40] Moretti, S., Sacchetti, F., 2025, *Patient Engagement in Research and Development Processes of Biotech Firms*, Athens Journal of Social Sciences, Vol. 12(2), p.75-86. https://www.athensjournals.gr/social/2025-12-2-1-Moretti.pdf.

Despite this variability, commonly cited principles of patient-centredness show considerable convergence.[41] These include beneficence, autonomy, fairness, transparency, accountability, relevance, equity, and capacity-building.[42] [43] [44] Such principles provide normative guidance but are by themselves insufficient to ensure consistent implementation.

The 12 survey responses received from patient and umbrella organisations active in promoting and implementing patient-centred approaches at both EU and MS levels offer useful insights into how key principles and values are applied in practice. Notably, respect for patient values and needs was reported by 11 out of 12 respondents as a guiding principle in their work (Figure 2). Transparency, capacity building, and provision of adequate information and support followed as the second-highest reported operationalised principles.

Figure 2. The patient-centredness principles and values reportedly applied by the study survey respondents in their work



Source: Authors' own elaboration based on n=12 study survey responses.

Note: The patient-centredness principles and values reportedly applied by the study survey respondents in their work are majorly focused on respect, transparency, empowerment, and ensuring provision of adequate information. The 'other' category included responses comprising of clear and unchanging goals, co-development with patients, meaningful representation and the implementation of logistically feasible projects patients can join and complete including in decision making.

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[41] Pratt, H., Middleton, R., Molloy, L., Moroney, T., 2023, *Connectivity: Person-Centred Research Principles to Inform Constructivist Grounded Theory*, International Journal of Qualitative Methods, Vol. 22. https://journals.sagepub.com/doi/10.1177/16094069231205788.

[42] Warner, K., See, W., Haerry, D. et al., 2018, *EUPATI Guidance for Patient Involvement in Medicines Research and Development (R&D); Guidance for Pharmaceutical Industry-Led Medicines R&D*, Frontiers in Medicine, Vol. 5. https://www.frontiersin.org/journals/medicine/articles/10.3389/fmed.2018.00270/full.

[43] Vat, L.E., Finlay, T., Jan Schuitmaker-Warnaar, T. et al., 2019, *Evaluating the "return on patient engagement initiatives" in medicines research and development: A literature review*, Health Expectations, Vol. 23(1), p.5-18. https://onlinelibrary.wiley.com/doi/10.1111/hex.12951#hex12951-bib-0004.

[44] Hickmann, E., Richter, P., Schlieter, H. et al., 2025, *Practical Approaches to Patient-Centred Care in Europe: Mixed Methods Study Developing a Conceptual Framework for Comprehensive Cancer Care Networks*, JMIR Cancer, Vol. 11. https://www.sciencedirect.com/org/science/article/pii/S2369199925000874.

3. THE VALUE OF PATIENT-CENTREDNESS IN HEALTH R&I

KEY FINDINGS

Patient-centredness reflects a move beyond a purely biomedical approach, placing greater emphasis on patient values alongside scientific evidence. Patient-centred approaches in health R&I enhance relevance, credibility, and alignment with real-world patient needs, and are associated with improved satisfaction, safety, treatment adherence, and, in some cases, reduced healthcare costs. However, their integration across the R&I lifecycle remains limited and fragmented. This reflects a lack of consensus on the added value of adopting these approaches, and how to measure it. Limited evidence of return on investment or engagement, the absence of a standardised definition and frameworks, or validated impact assessment tools contribute to this challenge. Although various toolkits and guidance documents developed through EU-funded projects have sought to address these gaps, they are typically created as ad hoc project outputs and applied

Patient-centredness carries inherent ethical value. As those affected by research outcomes, patients have a right to contribute to shaping them.[45] [46] Evidence shows that patient-centred approaches can bridge the gap between research and practice, helping identify relevant priorities, guide resource allocation, and support credible funding decisions.[47] [48] Their involvement has been described as "a key tool to drive innovation within the European research landscape."[49]

Box 1: Common arguments for embedding patient-centred approaches in R&I highlight three motivations

1. **Experiential expertise**: patients provide first-hand insight into living with a condition and undergoing interventions.
2. **Moral justification**: those affected by research outcomes should have a voice in shaping them.
3. **Pragmatic value**: early and ongoing patient involvement increases the likelihood of successful, impactful research.

Source: Authors' own elaboration based on available literature.

Patient-centredness represents a shift away from a purely biomedical model that prioritises scientific evidence over patient values.[50] [51] Patients bring a unique form of expertise; they are end-users,

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[45] Schölvinck, A.M., Pittens, C., Broerse, J.E., 2020, *Patient involvement in agenda-setting processes in health research policy: A boundary work perspective*, Science and Public Policy, Vol. 47(2), p. 246-255. https://academic.oup.com/spp/article/47/2/246/5766086.

[46] Schölvinck, A.F.M., 2018, *Towards meaningful and sustainable patient involvement in health research decision-making*, Vrije Universiteit Amsterdam, PhD Thesis. https://research.vu.nl/en/publications/towards-meaningful-and-sustainable-patient-involvement-in-health-.

[47] K. Warner, W. See, D. Haerry, et al., 'EUPATI Guidance for Patient Involvement in Medicines Research and Development (R&D); Guidance for Pharmaceutical Industry-Led Medicines R&D', Front Med, Vol.5, 2018. https://www.frontiersin.org/journals/medicine/articles/10.3389/fmed.2018.00270/full#B1.

[48] Vat, L.E., Finlay, T., Jan Schuitmaker-Warnaar, T. et al., 2019, *Evaluating the "return on patient engagement initiatives" in medicines research and development: A literature review*, Health Expectations, Vol. 23(1), p. 5-18. https://onlinelibrary.wiley.com/doi/10.1111/hex.12951.

[49] Ludwig Boltzmann Gesellschaft Open Innovation in Science Center, 2020, *PPIE Implementation Program*, https://ois.lbg.ac.at/wp-content/uploads/sites/24/2022/01/PPIE-Pilot-Call-2020_EN.pdf.

[50] Bombard, Y., Baker, G.R., Orlando, E. et al., 2018, *Engaging patients to improve quality of care: a systematic review*, Implementation Science, Vol. 13(1), p. 98. https://link.springer.com/article/10.1186/s13012-018-0784-z.

[51] Schölvinck, A.M., Pittens, C., Broerse, J.E., 2020, *Patient involvement in agenda-setting processes in health research policy: A boundary work perspective*, Science and Public Policy, Vol. 47(2), p. 246-255. https://academic.oup.com/spp/article/47/2/246/5766086.

consumers, and experts in living with their conditions.[52] Their lived experience provides insights unmatched by any other stakeholder group. Integrating these perspectives into research priority-setting and implementation enhances the legitimacy, relevance, and potential impact of research.[53] This shift is also evident in the updated regulation practice of authorities such as the EMA that explicitly require the incorporation of patient perspectives in the medicine review process to ensure the inclusion of data that goes beyond the scientific outcomes.[54]

When integrated into agenda setting and early decision-making, patient-centred approaches improve the quality, legitimacy, and practical relevance of research.[55] [56] The involvement of patients and patient-centred decisions strengthens the discovery, development, and evaluation of new medicines by jointly identifying unmet needs, refining study designs and outcome measures, and improving endpoint development.[57] Collaboration also fosters greater transparency, trust, and mutual respect among stakeholders. [58]

Evidence increasingly shows that engaging with patients leads to studies better aligned with patient needs and improved efficiency and quality.[59] [60] [61] [62] Conversely, research that does not incorporate patient perspectives risks generating innovations that fail to address real-world needs or limited findings.[63] [64] Indeed, from the patient perspective, there is no innovation if it does not reach patients, either due to being unaffordable or inaccessible to patients. In HIV research, for example, patient involvement has been critical in shaping clinical trial design, with patients informing researchers on participation burdens in ways that ultimately improved the quality and relevance of trial outcomes.[65]

Placing patients at the centre of health R&I, including in early strategic decisions, is associated with improved patient satisfaction, safety, adherence to treatment, and in some cases, lower healthcare

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[52] Ibid.

[53] Duffett, L., 2017, *Patient engagement: What partnering with patient in research is all about*, Thrombosis Research, Vol. 150, p. 113-120. https://pubmed.ncbi.nlm.nih.gov/27817863/.

[54] European Medicines Agency (EMA), 2025, *A path to include patients' perspectives in the regulation of medicines*. https://www.ema.europa.eu/en/news/path-better-include-patients-perspectives-regulation-medicines.

[55] Caron-Flinterman, J.F., Broerse, J.E.W., Teerling, J. et al., 2006, *Stakeholder participation in health research agenda setting: the case of asthma and COPD research in the Netherlands*, Science and Public Policy, Vol. 33(4), p. 291-304. https://academic.oup.com/spp/article-abstract/33/4/291/1614353.

[56] Gudowsky, N., 2021, *Limits and benefits of participatory agenda setting for research and innovation*, European Journal of Futures Research, Vol. 9(8). https://link.springer.com/article/10.1186/s40309-021-00177-0#ref-CR39.

[57] Algorri, M., Cauchon, N.S., Christian, T. et al., 2023, *Patient-Centric Product Development: A Summary of Select Regulatory CMC and Device Considerations*, Journal of Pharmaceutical Sciences, Vol. 114(4), p. 922-936. https://www.sciencedirect.com/science/article/pii/S0022354923000515.

Warner, K., See, W., Haerry, D. et al., 2018, *EUPATI Guidance for Patient Involvement in Medicines Research and Development (R&D); Guidance for Pharmaceutical Industry-Led Medicines R&D*, Frontiers in Medicine, Vol. 5. https://www.frontiersin.org/journals/medicine/articles/10.3389/fmed.2018.00270/full#B1.

[59] Hickmann, E., Richter, P., Schlieter, H. et al., 2025, *Practical Approaches to Patient-Centered Care in Europe: Mixed Methods Study Developing a Conceptual Framework for Comprehensive Cancer Care Networks*, JMIR Cancer, Vol. 11. https://www.sciencedirect.com/org/science/article/pii/S2369199925000874.

[60] Esmail, L., Moore, E., Rein, A., 2015, *Evaluating patient and stakeholder engagement in research: moving from theory to practice*, Journal of Comparative Effectiveness Research, Vol. 4(2), p. 133-145. https://doi.org/10.2217/cer.14.79.

[61] Price, A., Albarqouni, L., Kirkpatrick, J. et al., 2018, *Patient and public involvement in the design of clinical trials: An overview of systematic reviews*, Journal of Evaluation in Clinical Practice, Vol. 24(1), p. 240-253. https://onlinelibrary.wiley.com/doi/10.1111/jep.12805.

[62] Crocker, J.C., Ricci-Cabello, I., Parker, A. et al., 2018, *Impact of patient and public involvement on enrolment and retention in clinical trials: systematic review and meta-analysis*, BMJ, Vol. 363. https://www.bmj.com/content/363/bmj.k4738.

[63] Saesen, R., Lejeune, S., Quaglio, G. et al., 2020, *Views of European Drug Development Stakeholders on Treatment Optimization and Its Potential for Use in Decision-Making*, Frontiers in Pharmacology, Vol. 11, p. 43. https://www.frontiersin.org/journals/pharmacology/articles/10.3389/fphar.2020.00043/full.

[64] Schölvinck, A.F.M., 2018, *Towards meaningful and sustainable patient involvement in health research decision-making*, Vrije Universiteit Amsterdam, PhD Thesis. https://research.vu.nl/en/publications/towards-meaningful-and-sustainable-patient-involvement-in-health-.

[65] European Medicines Agency, 2025, *Reflection paper on patient experience data*. https://www.ema.europa.eu/en/documents/scientific-guideline/reflection-paper-patient-experience-data_en.pdf.

costs.[66] Yet despite growing support, integration of patients remains low.[67] [68] For example, in the case of rare diseases, where research crucially depends on close interaction with the few patients affected by a particular disease at hand, only 18% of people affected by a rare disease have participated in research supporting the development of therapeutics or diagnostics.[69]

Integrating and standardising patient engagement within organisational decision-making continues to be challenging, partly due to the absence of consensus on its value or how to measure it. [70] A persistent tension exists between viewing patient engagement as intrinsically valuable, grounded in fairness, transparency, and accountability ("nothing about us without us"), and viewing it instrumentally, as a means of improving research quality.[71] Research outcomes are stronger and more meaningful when patients are involved from the outset, before key decisions are made.[72]

Interviewees, including regional organisations, national research institutions, and national ministerial stakeholders, emphasised the intrinsic value of meaningful patient engagement in health R&I, particularly at the early stages of agenda-setting and study design. At the same time, stakeholders stressed that patient involvement should add substantive value in R&I activities, rather than being implemented for the sake of implementation. They also noted that patient-centred approaches may not be appropriate or necessary in all areas of research.

A major barrier in substantiating this added value is the lack of robust data demonstrating return on investment or return on engagement for patient-centred approaches, compounded by the absence of a standardised conceptualisation of patient-centredness.[73] [74] Much of the evidence in this space is qualitative and anecdotal, making it difficult to capture "the complexity and mechanisms of change".[75] [76] [77] The effects of patient engagement, which is one aspect of patient-centredness, including its value, associated costs, and possible limitations, are not well understood.[78] However, scientific literature that assessed the value of patient and public involvement (PPI) through quantitative modelling reported

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[66] Hickmann, E., Richter, P., Schlieter, H. et al., 2025, *Practical Approaches to Patient-Centered Care in Europe: Mixed Methods Study Developing a Conceptual Framework for Comprehensive Cancer Care Networks*, JMIR Cancer, Vol. 11. https://www.sciencedirect.com/org/science/article/pii/S2369199925000874.

[67] Vat, L.E., Finlay, T., Schuitmaker-Warnaar, T.J. et al., 2020, *Evaluating the "return on patient engagement initiatives" in medicines research and development: A literature review*, Health Expectations, Vol. 23(1), p. 5-18. https://onlinelibrary.wiley.com/doi/10.1111/hex.12951.

[68] de Wit, M., Cooper, C., Reginster, J.Y., 2019, *Practical guidance for patient-centred health research*, The Lancet, Vol. 3(393), p.1095-1096. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(19)30034-0/fulltext.

[69] Rare 2030, 2021, *Recommendations from the Rare 2030 foresight study the future of rare diseases starts today.* https://download2.eurordis.org/rare2030/Rare2030_recommendations.pdf.

[70] Esmail, L., Moore, E., Rein, A., 2015, *Evaluating patient and stakeholder engagement in research: moving from theory to practice*, Journal of Comparative Effectiveness Research, Vol. 4(2), p. 133-145. https://doi.org/10.2217/cer.14.79.

[71] Vat, L.E., Finlay, T., Schuitmaker-Warnaar, T.J. et al., 2020, *Evaluating the "return on patient engagement initiatives" in medicines research and development: A literature review*, Health Expectations, Vol. 23(1), p. 5-18. https://onlinelibrary.wiley.com/doi/10.1111/hex.12951.

[72] BMFTR, 2021, *Principles of successful patient involvement in cancer research*. https://www.bmftr.bund.de/SharedDocs/Downloads/EN/2021/210907-unite-against-cancer.pdf?__blob=publicationFile&v=4.

[73] Esmail, L., Moore, E., Rein, A., 2015, *Evaluating patient and stakeholder engagement in research: moving from theory to practice*, Journal of Comparative Effectiveness Research, Vol. 4(2), p. 133-145. https://doi.org/10.2217/cer.14.79.

[74] Stergiopoulos, S., Michaels, D.L., Kunz, B.L. et al., 2020, *Measuring the Impact of Patient Engagement and Patient Centricity in Clinical Research and Development*, Therapeutic Innovation & Regulatory Science, Vol. 54, p. 103-116. https://link.springer.com/article/10.1007/s43441-019-00034-0#citeas.

[75] Jagosh, J., Macaulay, A.C., Pluye, P. et al., 2012, *Uncovering the benefits of participatory research: implications of a realist review for health research and practice*, Milbank Quarterly, Vol. 90(2), p.311-346. https://pubmed.ncbi.nlm.nih.gov/22709390/.

[76] Staley, K., 2015, *'Is it worth doing?' Measuring the impact of patient and public involvement in research*, Research Involvement and Engagement, Vol. 1, p. 6. https://pubmed.ncbi.nlm.nih.gov/29062495/.

[77] Vat, L.E., Finlay, T., Schuitmaker-Warnaar, T.J. et al., 2020, *Evaluating the "return on patient engagement initiatives" in medicines research and development: A literature review*, Health Expectations, Vol. 23(1), p. 5-18. https://onlinelibrary.wiley.com/doi/10.1111/hex.12951.

[78] de Wit, M., Cooper, C., Reginster, J.Y., 2019, *Practical guidance for patient-centred health research*, The Lancet, Vol. 3(393), p.1095-1096. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(19)30034-0/fulltext.

high return on investment in the inclusion of patient involvement from pre-stages of research, which could allow for important adjustments, including on protocols and recruitment.[79] Although knowledge gaps remain, the literature in this area has grown over the last decade in building the evidence base on the value of integrating patient preferences into health research and development.[80]

A recent review examining the inclusion of patient preferences in medical device development highlighted several key findings regarding the value of incorporating patient perspectives.[81] The review emphasised that patient insights are uniquely shaped by lived experience of both clinical care and daily life with health conditions. Patient priorities and preferences may differ from those of decision-makers, underscoring the importance of engaging patients to identify outcomes and endpoints that are truly meaningful to them. Despite patient preferences not currently being a mandatory part of the medical product lifestyle, the literature points to the need for collaboration between researchers and patients throughout this process, including in industry and regulatory decision making, to facilitate more transparent and accountable product development that better meets patients' needs.[82] [83]

A central challenge is the absence of an agreed-upon framework or validated tools for assessing the impact of patient-centred research and determining which outcomes should be measured.[84] There is currently no standardised methodology for conducting or evaluating patient-centred research, nor a consistent approach to measurement. Instead, researchers are expected to adapt and integrate patient-centred principles across diverse contexts and research designs.[85]

Indicators for tracking outcomes remain fragmented and vary considerably across projects and MS.[86] The literature consistently highlights that the lack of a formalised evaluation framework limits the ability to systematically capture and understand the holistic impacts and benefits of patient engagement in R&I decision-making. [87] Without such a framework, patient-centred and engagement-based approaches risk being undervalued, inconsistently applied, and perceived as lacking legitimacy. [88] Some of the current methods for engaging patients in the research agenda-setting stage are often ineffective and insufficient in capturing and integrating patient inputs and perspectives, which can cross the line

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[79] Levitan, B., Getz, K., Eisenstein, E.L. et al., 2018, *Assessing the Financial Value of Patient Engagement: A Quantitative Approach from CTTI's Patient Groups and Clinical Trials Project*, Therapeutic Innovation & Regulatory Science, Vol. 52(2), p. 220-229. https://pmc.ncbi.nlm.nih.gov/articles/PMC5933599/.

[80] Smith, I.P., DiSantostefano, R.L., de Bekker-Grob, E.W. et al., 2021, *Methodological Priorities for Patient Preferences Research: Stakeholder Input to the PREFER Public-Private Project*, Patient, Vol. 14(5), p. 449-453. https://link.springer.com/article/10.1007/s40271-021-00502-6.

[81] Janssens, R., Huys, I., van Overbeeke, E. et al., 2019, *Opportunities and challenges for the inclusion of patient preferences in the medical product life cycle: a systematic review*, BMC Medical Informatics and Decision Making, Vol. 19(1), p. 189. https://pmc.ncbi.nlm.nih.gov/articles/PMC6778383/.

[82] Whichello, C., Bywall, K.S., Mauer, J. et al., 2020, *An overview of critical decision-points in the medical product lifecycle: Where to include patient preference information in the decision-making process*, Health Policy, Vol. 124(12). https://www.sciencedirect.com/science/article/pii/S0168851020301895.

[83] Mühlbacher, A.C., Juhnke, C., Beyer, A.R., Garner, S., 2016, *Patient-Focused Benefit-Risk Analysis to Inform Regulatory Decisions: The European Union Perspective*, Value in Health, Vol. 19(6), p. 734-740. https://www.sciencedirect.com/science/article/pii/S1098301516304296.

[84] de Wit, M., Cooper, C., Reginster, J.Y., 2019, *Practical guidance for patient-centred health research*, The Lancet, Vol. 3(393), p.1095-1096. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(19)30034-0/fulltext.

[85] Pratt, H., Middleton, R., Molloy, L., Moroney, T., 2023, *Connectivity: Person-Centred Research Principles to Inform Constructivist Grounded Theory*, International Journal of Qualitative Methods, Vol. 22. https://journals.sagepub.com/doi/10.1177/16094069231205788.

[86] Pickaert, A.P., 2025, *Patient Involvement in Health Technology Assessments: Lessons for EU Joint Clinical Assessments*, Market Access & Health Policy, Vol. 13(3). https://www.mdpi.com/2001-6689/13/3/38.

[87] Ibid.

[88] Ibid.

to being tokenistic and used as a box-checking exercise rather than informing the research and outcomes.[89] [90] [91]

Over the past decade, several toolkits and guidance documents, many developed with support from Horizon Europe and the IHI, have sought to address this gap. Initiatives such as PARADIGM, EATRIS+, and EUPATI provide valuable frameworks, guidance, and training curricula to build capacity for engaging patients throughout the R&I process. Existing tools and guidance are typically developed as ad hoc project deliverables and applied in a piecemeal manner, rather than within an endorsed and systematised approach. This contributes to confusion and heterogeneity in practice, further constraining efforts to embed patient-centred research consistently and sustainably.

Box 2: Existing toolkits and guidance documents on patient engagement in R&I developed through EU-funded projects

- PARADIGM:
    - Patient engagement toolbox (source)
    - Patient engagement monitoring and evaluation framework (source)
- EATRIS+:
    - Patient engagement resource centre (source)
- EUPATI:
    - Guidance for patient involvement in industry-led R&D (source)
    - Patient engagement roadmap (source)

Source: Authors' own elaboration based on review of available tools and guidance documents on patient engagement in R&I.

Importantly, legal recognition of patient rights is a critical enabler to patient-centredness.[92] Acknowledging a patient's right to information and choice directly translates into involving them in decisions and leading to greater engagement. Patient rights also reflect and reinforce the broader shift toward patient empowerment, by enabling citizens receiving or seeking medical care to take a more active role in decisions about their treatment and care pathway.[93]

Nonetheless, stakeholders continue to emphasise the need for R&I systems that support more constructive, equitable interactions between science and society, and that embed patient involvement from the earliest stages of decision-making. [94]

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[89] Caron-Flinterman, J.F., Broerse, J.E.W., Teerling, J. et al., 2006, *Stakeholder participation in health research agenda setting: the case of asthma and COPD research in the Netherlands*, Science and Public Policy, Vol. 33(4), p. 291-304. https://academic.oup.com/spp/article-abstract/33/4/291/1614353.

[90] Schölvinck, A.F.M., 2018, *Towards meaningful and sustainable patient involvement in health research decision-making*, Vrije Universiteit Amsterdam, PhD Thesis. https://research.vu.nl/en/publications/towards-meaningful-and-sustainable-patient-involvement-in-health-.

[91] Moore, L., Britten, N., Lydahl, D. et al., 2016, *Barriers and facilitators to the implementation of person-centred care in different healthcare contexts*, Scandinavian Journal of Caring Sciences, Vol. 31(4), p. 662-673. https://pmc.ncbi.nlm.nih.gov/articles/PMC5724704/.

[92] European Commission, 2016, *Patients' Rights in the European Union Mapping Exercise*, Publication for the Directorate-General for Health and Food Safety (SANTE). https://www.activecitizenship.net/multimedia/import/files/patients_rights/charter-of-rights/publications-of-the-charter/Patients_Rights_in_the_European_Union.pdf.

[93] Ibid.

[94] Warner, K., See, W., Haerry, D. et al., 2018, *EUPATI Guidance for Patient Involvement in Medicines Research and Development (R&D); Guidance for Pharmaceutical Industry-Led Medicines R&D*, Frontiers in Medicine. https://www.frontiersin.org/articles/10.3389/fmed.2018.00270.

4. STOCKTAKING OF A FRAGMENTED EU LANDSCAPE

KEY FINDINGS

Although patient-centred approaches are increasingly recognised within EU health R&I, their operationalisation remains inconsistent and fragmented. Definitions vary across MS, contributing to a diverse landscape. There are no consolidated data indicating what share of the EU's €11 billion annual public investment in health R&I systematically integrates patient-centred research. Reporting occurs largely ad hoc at a project level. While EU-funded projects often include some patient involvement, engagement is typically limited in design, governance, and leadership phases, despite broad recognition of its value in shaping relevant goals and outcomes. Operationalisation of patient-centred approaches is stronger in certain health areas, such as multiple sclerosis and cancer, but funding constraints, limited dedicated grants, and inconsistent recognition or remuneration of patient expertise hinder progress. EU bodies such as the European Medicines Agency (EMA) and the Organisation for Economic and Co-operation and Development (OECD) have advanced patient involvement. Varying levels of patient-centredness persist across EU programmes such as Horizon Europe, the Innovative Health Initiative and EU4Health in their strategies, work programmes, and monitoring frameworks. The European Commission has increasingly prioritised personalised medicine, for which patient-centredness serves as a core underlying principle.

4.1. Patchwork implementation of patient-centredness in health R&I in the EU

Historically, patients have been more actively involved in specific areas of health R&I, such as participating in clinical trials, compared to more engagement across all R&I phases and domains including priority-setting, product development, and governance.[95] While there has been a noticeable shift in recent years towards greater recognition of patient engagement as one form of patient-centredness, this progress has often been more evident at the level of policy discourse and rhetoric rather than in consistently embedded practice.[96] Consequently, patient engagement as a core element of patient-centred R&I remains fragmented and unevenly implemented across the European landscape.

As health policy is mostly a competence of the EU MS, the definition and implementation of patient-centredness remains primarily in the hands of individual MS, leading to fragmentation at the legal and operational level. At the same time, EU-level instruments such as R&I programmes foster a gradual soft convergence, promoting patient-centred approaches without formally harmonising national health systems.

Currently, variation exists across EU MS in the extent to which patient involvement in health and research is institutionalised through legislation and policy frameworks.[97] In France, for example, patient involvement has been more fully institutionalised, with the concept of *démocratie sanitaire* (health

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[95] European Patients' Forum, 2017, *The Added Value of Patient Organisations*. https://www.eu-patient.eu/globalassets/library/publications/epf_added_value_report_final.pdf.

[96] Ibid.

[97] European Parliament Research Service, 2022, *Fostering coherence in EU health research: Strengthening EU research for better health*. https://www.europarl.europa.eu/RegData/etudes/STUD/2022/737114/EPRS_STU%282022%29737114_EN.pdf.

democracy) emphasising patient participation as a form of shared power in decision-making, rather than purely consultative engagement.[98]

Patient-centredness and patient involvement are sometimes defined in legal or policy instruments that shape their operationalisation across MS. However, in the absence of standardisation, these definitions and approaches vary considerably, as illustrated in Table 2. A common definition agreed upon at an EU-level could be beneficial. The European Commission could therefore consider proposing a definition in the context of the R&I programme.

Table 2: Definitions on patient-centredness in EU Member States

Conceptual definition/framing	Member States (key institutions) applying this definition
Patient and Public Involvement (PPI): research carried out *with* or *by* patients and the public, rather than *to*, *about* or *for* them. PPI is an active partnership across the full research lifecycle, including participation in decision-making on research priorities, design, and dissemination.	**Belgium** – Belgian Health Care Knowledge Centre (KCE)[99] **Sweden** – Karolinksa Institutet[100] **Denmark** – Danish Cancer Society,[101] Aarhus University[102] **Ireland** (HRB)[103] **Germany** – DZG, [104] DDZ,[105] DZPG[106] **Luxembourg** Institute of Health (LIH)[107]
Patient involvement: "active, meaningful, and collaborative interaction between patients and researchers across all stages of the research process, where research decision making is guided by patients' contributions as partners, recognizing their specific experiences, values, and expertise" (Harrington et al.)[108]	**Sweden** – University of Gothenburg[109] **Germany** – DLR[110]

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[98] Belgodère, L., Pougheon Bertrand, D., Jaulent, MC. et al., 2018, *Patient and public involvement in the benefit–risk assessment and decision concerning health products: position of the Scientific Advisory Board of the French National Agency for Medicines and Health Products Safety (ANSM)*, BMJ Global Health, Vol.8(5). https://pmc.ncbi.nlm.nih.gov/articles/PMC10201242/.

[99] KCE, 2019, *Position of KCE on patient involvement in health care policy research.* https://kce.fgov.be/sites/default/files/2021-11/KCE_320_Patient_involvement_health_care_policy_research_Report_2.pdf.

[100] Karolinska Institutet, 2025, *How can engaging patients and the public enrich your research?.* https://staff.ki.se/research-support/patient-and-public-involvement-in-research/how-can-engaging-patients-and-the-public-enrich-your-research.

[101] Danish Cancer Society, *Patient and public involvement in research*. https://www.cancer.dk/.

[102] Aarhus University, *Patient and Public Involvement*. https://ph.au.dk/rescenpi/patient-partners-in-research/patient-and-public-involvement.

[103] Health Research Board, *Public and patient involvement in research*, website. https://www.hrb.ie/funding/responsible-research-assessment/public-and-patient-involvement-in-research/.

[104] German Centers for Health Research, *Patient involvement creates health for all*. https://deutschezentren.de/en/patient-involvement-data-rich-medicine/.

[105] German Diabetes Center, *Patient and public involvement in research*. https://ddz.de/en/research/institute-for-health-services-research-and-health-economics/patient-and-public-involvement-in-research/.

[106] Lipinski, S., Sünkel, U., Totzeck, C. et al., 2024, *Patient and Public Involvement at the German Center for Mental Health: Achievements and Challenges*, Nervenarzt, Vol.95, p.458-466. https://edoc.hu-berlin.de/items/becdf021-12c4-4830-8e2e-ac82450dd3e9.

[107] Luxembourg Institute of Health, *Patient & Public Involvement*. https://www.lih.lu/en/ppi/.

[108] Harrington, R.L., Hanna, M.L., Oehrlein, E.M. et al., 2020, *Defining Patient Engagement in Research: Results of a Systematic Review and Analysis: Report of the ISPOR Patient-Centered Special Interest Group*, Value in Health, Vol.23(6), p.677-688. https://www.valueinhealthjournal.com/article/S1098-3015(20)30141-8/fulltext?_returnURL=https%3A%2F%2Flinkinghub.elsevier.com%2Fretrieve%2Fpii%2FS1098301520301418%3Fshowall%3Dtrue.

[109] Bergholtz, J., *Patient, Family Carer and Public Involvement in Research – What, Why, and How*, University of Gothenburg. https://www.gu.se/en/gpcc/patient-family-carer-and-public-involvement-ppi-in-research-what-why-and-how.

[110] Stakeholder Interview 23 January 2026 - Harrington et al. definition explicitly mentioned as reference point for patient-centredness in R&I.

Conceptual definition/framing	Member States (key institutions) applying this definition
User involvement (and health democracy framing), emphasising collaboration between patients, citizens, and scientific experts in research and healthcare decision contexts.	**France** – National Authority for Health (HAS)[111]
Participation and **citizen science** as a two-way exchange between researchers and citizens, supporting shared knowledge production and societal relevance of research.	**Netherlands** – ZonMw[112]
Public Involvement: an active partnership between patients, carers and members of the public with researchers that influences and shapes research. Graduated models of involvement include consultation, collaboration, co-production, and user control.	**UK – NIHR**[113]

Source: Authors' own elaboration.

The legislative variation contributes to a less coordinated R&I ecosystem and reinforces the so-called 'translation gap' between research discovery and implementation, where patient needs and real-world contexts are insufficiently integrated into innovation processes.[114] Co-creation, meaning engaging patients as partners in decision making and ownership of initiatives, is widely regarded as a means to bridge this gap and support more transformative innovation; however, complex regulatory environments and the challenges of cross-border collaboration often impede its effective implementation, particularly in academic-led and sometimes multi-country EU and MS funded research.[115] Differences in available infrastructure and funding to support patient-centred health R&I across EU MS present significant challenges for the integration and implementation of these approaches in multinational EU R&I projects. Interviewed stakeholders noted that, in such contexts, MS with greater resources and expertise often become the sole partners able to contribute patient-centred elements to consortia, potentially reinforcing existing inequalities in participation and capacity.

Moreover, legislation beyond the clinical or medical domain, such as in research and policy, often makes little or no reference to patient involvement, limiting the operationalisation of patient-centred approaches in R&I governance and decision-making.[116] Addressing this gap would require a more systematic and integrated approach that transcends local, national, and regional boundaries.[117] Such an approach would need to provide clear guidance across the R&I continuum, defining roles, responsibilities, and expectations to support mutually beneficial partnerships between patients and other stakeholders. [118] To date, however, this has not been done and is by no means an easy feat.[119]

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[111] Haute Autorité de Santé, 2022, *Cooperation between the HAS and users: Arrangements for the involvement of health, social and medico-social care system users and their organisations in the work of the HAS.* https://www.hassante.fr/upload/docs/application/pdf/202309/public_and_patient_involvement_at_french_national_authority__for_health_has_1.pdf.

[112] ZonMw, *Participation and Citizen Science*. https://www.zonmw.nl/en.

[113] National Institute for Health and Care Research, *About Public Involvement*. https://www.peopleinresearch.org/public-involvement/.

[114] European Parliament Research Service, 2022, *Fostering coherence in EU health research: Strengthening EU research for better health.* https://www.europarl.europa.eu/RegData/etudes/STUD/2022/737114/EPRS_STU%282022%29737114_EN.pdf.

[115] Ibid.

[116] European Patients' Forum, 2009, *The Value of Patient Involvement in EU Health Related Projects and Policy*. https://www.eu-patient.eu/globalassets/library/conferenceseminarreports/epf-gothenburg-2009-report.pdf

[117] Rosengren, K., Brannefors, P. and Carlstrom, E., 2021*, Adoption of the concept of person-centred care into discourse in Europe: a systematic literature review*, J Health Organ Manag, Vol.35(9), p. 265-280. https://pmc.ncbi.nlm.nih.gov/articles/PMC9136870/.

[118] de Wit, M., Cooper, C., and Reginster, JY., 2019, *Practical guidance for patient-centred health research,* The Lancet, Vol.393(10176), p.1095-1096. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(19)30034-0/fulltext.

[119] Federal Ministry of Education and Research, 2021, *Principles of Successful Patient Involvement in Cancer Research*. https://www.gesundheitsforschung-bmftr.de/files/2021_06_01_Principles_Paper_bf.pdf.

Inequalities persist across MS not only in how patient-centredness is applied but also in how its value is recognised, particularly within decision-making processes.[120] Patient engagement continues to be implemented largely on an ad hoc basis rather than as a systematically embedded component of R&I, though this does vary in some contexts with examples of increasingly operationalised practice such as in Germany.[121] Despite growing acknowledgement of its benefits, integration of patient-centred approaches from the earliest stages of R&I remains limited, partly due to practical constraints and the absence of consensus on how to assess value and impact.[122] There is no single, universally applicable evaluation metric; instead, evaluation often requires tailored approaches suited to specific projects or contexts. [123] Existing indicators remain insufficient to capture broader outcomes, such as cultural change within research systems. [124]

Evidence from EU-funded projects reinforces these challenges. For example, findings from the European Patients' Forum's (EPF) Value+ report on patient involvement in EU-funded health projects indicate that, while some degree of patient involvement was present, engagement was often limited during project development, governance, and leadership phases.[125] Approximately half of the projects reporting data had allocated resources for patient organisations or included them as consortium partners. [126] The report also highlighted inadequate attention to gender and diversity considerations in patient engagement, which were not systematically addressed. [127]

Challenges related to the representativeness of patients involved in health R&I also emerged as a concern during interviews. From an academic perspective, stakeholders emphasised the importance of ensuring that participating patients reflect the diversity of affected populations, while also highlighting practical difficulties in reaching patients, particularly for less prevalent conditions (i.e., rare diseases). From a policy perspective, a MS ministerial-level interviewee underscored broader systemic challenges related to equitable representation, including disparities linked to gender, age, housing status (with people experiencing homelessness being particularly difficult to engage), and language barriers. These factors raise important logistical considerations and point to the need for more inclusive and decentralised approaches to patient engagement.

The literature highlights a few prime examples of EU-funded projects that facilitated patient and public involvement in the implementation of the research.[128] This included the MULTI-ACT project funded by the European Commission, focused on improving the application of research of persons living with brain conditions employing a participatory governance model.[129] The MULTI-ACT project embodied the patient-centred principle in bringing patients into the core team as partners. Utilising this approach, the project implemented innovative structures including the Engagement Coordination Team which

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[120] Federal Ministry of Education and Research, 2021, *Principles of Successful Patient Involvement in Cancer Research. https://www.bmftr.bund.de/SharedDocs/Downloads/EN/2021/210907-unite-against-cancer.pdf?__blob=publicationFile&v=4.*

[121] Gorbenko, O., Cavillon, P., Giles, RH. et al., 2022, *Co-creating with patients an impact framework across the medicine's life cycle: a qualitative study exploring patients' experiences of involvement in and perceptions of impact measures*, BMC Res Involv Engagem, Vol.8(1). https://link.springer.com/article/10.1186/s40900-022-00334-0?fromPaywallRec=true.

[122] Vat, LE., Finlay, T., Robinson, P. et al., 2021, *Evaluation of patient engagement in medicine development: A multi-stakeholder framework with metrics*, Health Expect, Vol.24(2), p.491-506. https://onlinelibrary.wiley.com/doi/10.1111/hex.13191.

[123] PARADIGM, *Patient Engagement Monitoring and Evaluation Framework*. https://imi-paradigm.eu/petoolbox/monitoring-evaluation/.

[124] Vat, LE., Finlay, T., Robinson, P. et al., 2021, *Evaluation of patient engagement in medicine development: A multi-stakeholder framework with metrics*, Health Expect, Vol.24(2), p.491-506. https://onlinelibrary.wiley.com/doi/10.1111/hex.13191.

[125] European Patients' Forum, 2009, *The Value of Patient Involvement in EU Health Related Projects and Policy.* https://www.eu-patient.eu/globalassets/library/conferenceseminarreports/epf-gothenburg-2009-report.pdf.

[126] Ibid.

[127] Ibid.

[128] Gray, E., Amjad, A., Robertson, J. et al., 2023, *Enhancing involvement of people with multiple sclerosis in clinical trial design*, Mult Scler, Vol.29(9), p.1162-1173. https://pmc.ncbi.nlm.nih.gov/articles/PMC10413782/.

[129] Zaratin, P., Berorello, D., Guglielmino R. et al., 2022, *The MULTI-ACT model: the path forward for participatory and anticipatory governance in health research and care*, Health Res Policy Syst, Vol.20(1). https://pmc.ncbi.nlm.nih.gov/articles/PMC8853400/.

took ownership of meaningful patient engagement and training initiative to build capacity for patients to engage in research processes.[130]

Umbrella organisations advocate for systematic patient involvement across the healthcare system, spanning R&D, regulatory decision-making, and HTAs. To date, however, these efforts have largely been project-based initiatives. At the EU level, for example, the EPF contributes to research governance through patient advisory boards, notably within the IHI, and to some extent Horizon Europe projects. EPF's engagement primarily focuses on research projects, where it supports the development of frameworks and practices for patient participation. Patient advisory boards embedded within specific work packages provide guidance on research methodologies and outputs. This work is more about creating and refining the concept of patient involvement itself, developing models and approaches that can be applied across contexts. By contrast, at the national level, patient involvement tends to be more concrete and operational, particularly in domains such as clinical trials.

Sustaining patient engagement in R&I remains particularly challenging. Engagement is frequently characterised by one-off activities or described as 'window dressing', whereby patient contributions have minimal influence on decisions or outcomes.[131] [132] The current structure of health research systems is not designed to routinely embed patient-centred approaches, placing the onus on individual researchers and institutions to drive engagement efforts. This contributes to inconsistency in practice and limits scalability.[133]

4.2. Implementation experiences in patient-centred health R&I

Drawing on survey responses and interviews with umbrella organisations, patient organisations, and other EU and MS stakeholders, respondents emphasised that patient contributions are essential to defining relevant goals and outcomes that reflect patients as the ultimate beneficiaries of R&I.

Respondents pointed to a limited recognition of the value of patient engagement as was also documented in the literature, a perception that is also reinforced by a lack of explicit demand from funders. Several survey participants noted a continued preference for physician and clinical expertise over patient experience. Consequently, patient engagement within R&I is often treated as secondary to dominant priorities such as scientific novelty, cost efficiency, and speed of delivery, undermining efforts to embed patient-centred approaches in a systematic and sustained manner.

Stakeholders broadly agree on the importance of championing and implementing patient-centred approaches. However, despite growing recognition of the meaningful role patients can play in R&I, including in decision-making, practice remains inconsistent and often insufficient. Survey respondents noted stronger and more structured engagement in certain areas, such as rare diseases and IHI projects. In these contexts, respondents described how patient involvement has contributed to improved recruitment, retention, and protocol feasibility, positively influencing research processes and outcomes.

While patient-centred approaches are increasingly referenced as formal requirements in R&I, stakeholders highlighted that their application is far from universal across research and decision-making contexts, including clinical trials, funding allocation, and regulatory approval. For example, patient-centredness in HTA processes is perceived as more substantive, whereas under the proposed

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[130] Spindler,P. and Lima, BS., 2018, *Editorial: The European Patients Academy on Therapeutic Innovation (EUPATI) Guidelines on Patient Involvement in Research and Development,* Front Med, Vol.5. https://pmc.ncbi.nlm.nih.gov/articles/PMC6236003/.

[131] Schölvinck, A.F.M., 2018, *Towards meaningful and sustainable patient involvement in health research decision-making,* Vrije Universiteit Amsterdam, PhD-Thesis. https://research.vu.nl/ws/portalfiles/portal/69435796/complete%20dissertation.pdf.

[132] Beresford, P., 2007, *User involvement, research and health inequalities: developing new directions*, Health Soc Care Community, Vol.15(4), p.306-312. https://pubmed.ncbi.nlm.nih.gov/17578391/.

[133] Schölvinck, A.F.M., 2018, *Towards meaningful and sustainable patient involvement in health research decision-making,* Vrije Universiteit Amsterdam, PhD-Thesis. https://research.vu.nl/ws/portalfiles/portal/69435796/complete%20dissertation.pdf.

Critical Medicines Act was perceived by a few survey respondents as more arbitrary and implemented as a box-ticking exercise.

Stakeholders further described how the impact of patient engagement in R&I decision-making varies widely. This variation depends on both the methods used to engage patients and the actors involved. Superficial approaches, such as tokenistic consultations or simple feedback forms, were seen as having limited influence on shaping R&I priorities or outcomes. Moreover, the value of engaging patients will differ based on the perspectives of stakeholders and their respective interests and priorities.[134] In line with findings from the literature, another prominent challenge is the lack of robust mechanisms to assess and document meaningful patient engagement. Although some actors demonstrate good practice, these experiences are rarely systematically evaluated or captured, limiting institutional learning and the broader evidence base. Several examples of knowledge exchange initiatives in patient-centred health research were identified by national institutions and organisations; however, these activities are often confined to national contexts. At the same time, most stakeholders across multiple MS highlighted the importance of informal cross-national exchanges, particularly with countries perceived to be more advanced in this area, such as the United Kingdom (UK), in supporting know-how for implementing patient-centred approaches.

Survey responses identified the lack of standards and organisational structures as a significant barrier to the implementation of patient-centred approaches, noting that this absence limits the ability to implement such approaches with fidelity. Insufficient human and financial resources to support meaningful patient engagement throughout the R&I process were among the most frequently cited challenges. Effective patient-centred implementation requires sustained time and financial resources to enable continuous and meaningful engagement across all stages of R&I, including in the initial design and development phases. However, funding remains a persistent constraint, as dedicated grants are limited and the time, expertise, and contributions of patients are not consistently recognised or remunerated.

Certain funding programmes, such as EU4Health, were identified as particularly challenging due to their preference for engaging large, established patient organisations, which can narrow and bias opportunities for engagement. The pool of potential participants is further constrained in specific contexts where patient populations are small and the number of individuals who are willing, able, and adequately supported to engage is even more limited, for example in the rare disease space.

Several interviewees highlighted the importance of distinguishing between patient experts, individuals with lived experience, and patient organisations, noting that each offers distinct forms of input and representation within R&I processes.

The timing of patient and patient-organisation engagement was also reported as inconsistent. Respondents frequently indicated that they were invited to contribute late in the process, often after key decisions had already been made, and that feedback timelines were often unreasonably short, limiting the quality and depth of contributions and resulting in tokenistic rather than meaningful engagement. Language presents another significant barrier to meaningful patient engagement, both in terms of the languages in which materials are produced and the use of technical or specialist jargon within those materials, rendering it difficult to understand and respond to, as reported by survey respondents, and reflected in the existing literature.[135]

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[134] Staniszewska, S., Abebajo, A., Barber, R. et al., 2011, *Developing the evidence base of patient and public involvement in health and social care research: the case for measuring impact*, International Journal of Consumer Studies, Vol.35(6), p.628-632. https://onlinelibrary.wiley.com/doi/10.1111/j.1470-6431.2011.01020.x.

[135] European Patients' Forum, 2009, *The Value of Patient Involvement in EU Health Related Projects and Policy.* https://www.eu-patient.eu/globalassets/library/conferenceseminarreports/epf-gothenburg-2009-report.pdf.

Additionally, some methodologies employed are not patient-friendly, meaning they are too technical or complex, making it difficult for patients to provide their input and perspectives.[136] In the UK, the National Health Service conducted a research project in 2022 to better understand the challenges of patient-centred research from the perspectives of researchers and patients.[137] Their findings highlighted that research was inaccessible from the patient perspective in terms of understanding, awareness, and complexity of how information was presented. From the researcher perspective, major barriers included limited capacity, little know-how to conduct patient-centred research, and challenges to conduct this within their respective systems. More broadly, a culture of patient-centred research remains underdeveloped, with minimal conditions to facilitate this approach, both in terms of knowledge generation and translation into practice.

4.3. Disease-specific initiatives in advancing patient-centred health R&I in the EU

Variation across disease-specific initiatives further contributes to the fragmented nature of patient-centred R&I. Certain health areas, including cancer, HIV, multiple sclerosis, rare diseases, and Alzheimer's disease, have made substantial progress in advancing patient-centred approaches, supported by stronger advocacy, clearer frameworks, and dedicated infrastructure. These areas offer valuable lessons for broader application across the health R&I ecosystem.

Disease-specific initiatives and research activities across the EU provide important benchmarks and data with monitoring tools such as rare disease and dementia barometers yielding insights into progress and persistent gaps.[138] [139] [140] However, their findings are inherently context-dependent and cannot always be generalised across conditions.

4.3.1. Multiple Sclerosis

The most recent multiple sclerosis barometer (2020) highlights substantial variation in the participation of people living with multiple sclerosis in policymaking and research across the EU.[141] These disparities translate into unequal opportunities for individuals with multiple sclerosis to represent and advocate for their preferences and needs. The report underscores the importance of involving patients and patient organisations more systematically in shaping multiple sclerosis research agendas, both to address existing knowledge gaps in care and disease management and to ensure that research priorities align with patient-identified needs.[142] At the same time, it emphasises the role of national governments in strengthening incentives and structures to operationalise these priorities and support meaningful patient engagement in research.[143]

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[136] European Medicines Agency, *Patient Preference Research: Presentation by K. Morgan*. https://www.ema.europa.eu/en/documents/presentation/presentation-patient-preference-research-k-morgan-mpe_en.pdf.

[137] National Health Service, 2024, *Addressing the barriers to people-centred clinical research.* https://s3.eu-west-2.amazonaws.com/www.hra.nhs.uk/media/documents/People-Centred_Clinical_Research_project_-_final_report.pdf.

[138] European Patient' Forum, 2017, *The Added Value of Patient Organisations.* https://www.eu-patient.eu/globalassets/library/publications/epf_added_value_report_final.pdf.

[139] Alzheimer Europe, 2017, *European Dementia Monitor 2017: Report on Dementia Policies and Services in Europe*. https://www.alzheimer-europe.org/sites/default/files/alzheimer_europe_2017_european_dementia_monitor.pdf.

[140] EURORDIS, 2021, *Rare disease patients' opinion on the future of rare diseases. https://www.eurordis.org/publications/rb_future_rd_report/.*

[141] European Multiple Sclerosis Platform, 2021, *MS Barometer 2020: Full Report*. https://emsp.org/wp-content/uploads/2021/03/MS-Barometer2020-Final-Full-Report-Web.pdf.

[142] Ibid.

[143] Ibid.

Empirical data illustrates these challenges. For example, a study conducted in Denmark reported that only 36% of individuals living with multiple sclerosis participated in research activities.[144] Respondents who were involved expressed positive perceptions of their contribution, noting that their engagement enabled them to provide relevant input and introduce new ideas into research efforts.[145] This finding highlights the perceived value of patient involvement when opportunities for engagement are made available.

A rapid review looking at PPI in multiple sclerosis research identified 43 studies for inclusion, eight of which were clinical trials that included PPI in their design.[146] The majority of these trials were conducted in the United States, with two based in Europe (the UK and Norway). Trials that meaningfully engaged patients were predominantly funded by donors who either prioritised PPI or required it through formal mandates.

In the UK, the OCTOPUS trial represents a leading example of genuine patient partnership in multiple sclerosis research.[147] People living with multiple sclerosis were involved from the earliest stages of the research, actively shaping the study design and implementation through formal governance structures and working groups. Patient input was instrumental in broadening outcome measures to include social participation, alongside clinical endpoints. It also prompted changes to recruitment strategies after concerns emerged that individuals with progressive multiple sclerosis might be excluded due to participation barriers. In response, the research team established funded recruitment hubs across the UK, supported by dedicated infrastructure, to enhance geographical reach and ensure more inclusive participation among people affected by multiple sclerosis.

In the Netherlands, the Dutch Multiple Sclerosis Study exemplifies a patient-centred longitudinal approach, tracking long-term changes in disability and quality of life through patient-reported outcomes rather than relying solely on clinician-reported data.[148] This approach is particularly significant given the subjective nature of disability and its associated challenges, underscoring the value of incorporating patients' lived experiences into both research and care.[149]

4.3.2. Cancer

Cancer represents one of the disease areas where patient-centredness in R&I has received sustained political attention at EU level, supported by strong advocacy networks, dedicated funding, and coordinated policy frameworks.[150] [151] Dedicated organisations such as the European Cancer Organisation and Cancer Patients Europe provide existing infrastructure and systems to advance patient-centred approaches in cancer R&I. This increased attention reflects both the scale of the

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[144] Schjødtz Hansen, J., Vestergaard Rasmussen, P., Brix Finnerup, N. and Bacher Svendsen, K., 2025, *Patient's and researcher's perspectives on patient involvement in research in multiple sclerosis*, Danish Medical Journal, Vol.72(12). https://ugeskriftet.dk/dmj/patients-and-researchers-perspectives-patient-involvement-research-multiple-sclerosis.

[145] Ibid.

[146] Gray, E., Amjad, A., Robertson, J. et al., 2023, *Enhancing involvement of people with multiple sclerosis in clinical trial design*, Mult Scler, Vol.29(9), p.1162-1173. https://pmc.ncbi.nlm.nih.gov/articles/PMC10413782/.

[147] Ibid.

[148] Jongen, PJ., Heerings, M., Lemmens, WA. et al., 2015, *A prospective web-based patient-centred interactive study of long-term disabilities, disabilities perception and health-related quality of life in patients with multiple sclerosis in The Netherlands: the Dutch Multiple Sclerosis Study protocol*, BMC Neurol, Vol.15, 2015. https://pubmed.ncbi.nlm.nih.gov/26238866/.

[149] Ibid.

[150] Casali, P.G., Antoine-Poirel, H., Berrocoso, S. et al., 2025, *Health networking on cancer in the European Union: a 'green paper' by the EU Joint Action on Networks of Expertise (JANE)*, ESMO Open, Vol.10(2). https://www.esmoopen.com/article/S2059-7029(24)01897-0/fulltext.

[151] European Commission, *Working Together: Implementation of the Mission on Cancer*. https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/eu-missions-horizon-europe/eu-mission-cancer/implementation-page/working-together_en.

disease burden and the recognition that patient needs in oncology extend beyond clinical outcomes to include quality of life, survivorship, and equitable access to innovation.[152]

Yet practical integration of patient perspectives across the full cancer R&I lifecycle remains uneven, with meaningful involvement often concentrated in the initial research stage. A recent systematic review of PPI in cancer research exemplifies this pattern: while the majority of studies (20 out of 27) engaged patients at only a single research stage, most often to support the prioritisation of research questions, very few extended this involvement into data generation, analysis, or dissemination.[153] This concentration of engagement at the front end of the research process, which is not unique to cancer research, underscores that patient involvement requires further development to achieve sustained impact.

At the EU level, the Mission on Cancer under Horizon Europe provides a strong framework for advancing patient-centred approaches in R&I. The Mission explicitly recognises patients, cancer survivors, and citizens as active contributors to R&I, with co-creation and engagement as cross-cutting principles across its implementation.[154] It emphasises patient and citizen involvement in priority-setting, research design, and the uptake of results, including through Mission Platforms and structured stakeholder engagement.[155] Its objectives extend beyond biomedical innovation to include prevention, early diagnosis, and long-term survivorship, signalling a broader and more patient-centred understanding of value in cancer R&I.

National and regional initiatives illustrate how EU-level ambitions can be translated into concrete governance arrangements. For instance, the Basque Country Comprehensive Cancer Plan 2025–2030 explicitly identifies patient-centredness as a guiding principle across cancer prevention, care, and research policies.[156] R&I is a distinct priority area within the Plan, with specific actions to institutionalise patient participation.[157] Action 7.4.1 commits to defining and implementing a model for patient and citizen participation in R&I, while Action 7.6.1 identifies the need to create an accessible and centralised clinical trials platform providing transparent information for both professionals and patients.[158] Together, these actions aim to reduce informational barriers to participation and embed patient involvement more systematically within regional cancer research.

Germany's experience with the National Decade Against Cancer similarly demonstrates how sustained political commitment combined with dedicated funding can create enabling conditions for meaningful patient engagement. Stakeholders from the German Centres of Health Research (DZG) noted that cancer researchers are at the forefront of mainstreaming patient-centredness in R&I, having established patient advisory boards across all National Cancer Centres that routinely review clinical trials and have a high level of patient engagement. This advancement reflects the advocacy capacity of cancer patient communities, as well as the systematic integration of patient perspectives into funding requirements from the outset. However, even within this relatively advanced domain area, challenges remain around compensation for patient advocates, standardisation of selection criteria and training

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[152] European Commission, 2021, *Cancer Implementation Plan*. https://research-and-innovation.ec.europa.eu/system/files/2021-09/cancer_implementation_plan_for_publication_final_v2.pdf.

[153] Pii, K.H., Schou, L.H.,Piil, K. and Jarden, M., 2018, *Current trends in patient and public involvement in cancer research: A systematic review*, Health Expect, Vol.22(1), p.3-20. https://pmc.ncbi.nlm.nih.gov/articles/PMC6351419/.

[154] European Commission, *Working Together: Implementation of the Mission on Cancer*. https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/eu-missions-horizon-europe/eu-mission-cancer/implementation-page/working-together_en.

[155] European Commission, 2021, *Cancer Implementation Plan*. https://research-and-innovation.ec.europa.eu/system/files/2021-09/cancer_implementation_plan_for_publication_final_v2.pdf.

[156] Basque Government Department of Health, 2025, *Basque Country Comprehensive Cancer Plan 2025-2030*. https://www.euskadi.eus/basque-country-comprehensive-cancer-plan-2025-2030/web01-s2osa/en/.

[157] Ibid.

[158] Ibid.

for advisory board members, and the formalisation of pathways through which patient input influences research agenda-setting and resource allocation.

4.4. Patient-Centredness in EU Health R&I Infrastructure

The EU is increasingly recognising patient-generated evidence as a way to accelerate innovation including through patient-reported measures and through the updated EU framework for the HTA.[159] [160] The use of patient-generated evidence has been associated with enabling more rapid market entry for developed innovations, identifying cost-effective solutions, and facilitating higher return on investment.[161] [162] The generation of patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs), for example, has expanded considerably, yet these data remain fragmented across MS and within healthcare ecosystems. A lack of standardised frameworks continues to limit systematic integration of patient-generated evidence into R&I decision-making processes, from regulatory evaluation and HTA to the design of core outcome sets and treatment pathways.[163]

The EU health R&I landscape comprises a wide range of institutions and bodies performing distinct but interconnected roles. At the EU level, the European Commission primarily advances patient-centred health R&I through its major funding instruments, notably Horizon Europe and under it, the IHI. In recent years, the European Commission has demonstrated growing interest in personalised medicine, within which patient-centred approaches are foundational.[164] This includes increased attention to PROMs and PREMs as tools to capture patients' perspectives and lived experiences.[165] [166] For example, initiatives engaging people with multiple sclerosis in the provision of PROMs reflect efforts to operationalise personalised approaches while generating mutually beneficial monitoring indicators. [167] In addition, patient preference information is increasingly recognised within Horizon Europe research calls as a relevant criterion for project evaluation.[168] The use of PROMs and PREMs has been widely recognised as an important mechanism for embedding patient-centredness in both research and care contexts. [169]

International bodies also promote the integration of patient-centred indicators within evaluation frameworks, including in the context of health-related research and performance assessment. The Organisation for Economic Co-operation and Development (OECD), for example, has incorporated patient-centredness as a core dimension within its updated framework for health system performance

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[159] European Commission, 2022, *Patient generated evidence to improve outcomes, support decision making, and accelerate innovation*. https://www.ihi.europa.eu/sites/default/files/uploads/Documents/Calls/FutureTopics/DraftTopic_PatientGeneratedEvidence.pdf.

[160] European Commission, 2025, *New EU rules on Health Technology Assessment open up a new era for patient access to innovation*. https://ec.europa.eu/commission/presscorner/detail/en/ip_25_226.

[161] Ibid.

[162] Folkvord, F., Carlson, J.I., Ottaviano, M. et al. 2024, *Using patient-generated health data more efficient and effectively to facilitate the implementation of value-based healthcare in the EU - Innovation report*, Comput Struct Biotechnol J, Vol.24, p.672–678. https://doi.org/10.1016/j.csbj.2024.10.026.

[163] European Commission, 2022, *Patient generated evidence to improve outcomes, support decision making, and accelerate innovation*. https://www.ihi.europa.eu/sites/default/files/uploads/Documents/Calls/FutureTopics/DraftTopic_PatientGeneratedEvidence.pdf.

[164] Casaca, P., Schäfer, W., Nunes, AB. and Sousa, P., 2023, *Using patient-reported outcome measures and patient-reported experience measures to elevate the quality of healthcare*, Int J Qual Health Care, Vol.35(4). https://pmc.ncbi.nlm.nih.gov/articles/PMC10750971/.

[165] Ibid.

[166] Zaratin, P., Samadzadeh, S., Seferoğlu, M. et al., 2024, *The global patient-reported outcomes for multiple sclerosis initiative: bridging the gap between clinical research and care – updates at the 2023 plenary event*, Front Neurol, Vol.15. https://pmc.ncbi.nlm.nih.gov/articles/PMC11225898/#:~:text=To%20fulfill%20its%20mission%20PROMS's,this%20transformative%20approach%20in%20healthcare.

[167] Ibid.

[168] European Commission, 2022, *Patient generated evidence to improve outcomes, support decision making, and accelerate innovation*. https://www.ihi.europa.eu/sites/default/files/uploads/Documents/Calls/FutureTopics/DraftTopic_PatientGeneratedEvidence.pdf.

[169] Casaca, P., Schäfer, W., Nunes, AB. and Sousa, P., 2023, *Using patient-reported outcome measures and patient-reported experience measures to elevate the quality of healthcare*, Int J Qual Health Care, Vol.35(4). https://pmc.ncbi.nlm.nih.gov/articles/PMC10750971/.

evaluation.[170] [171] The indicators promoted by the OECD emphasise the inclusion of patient perspectives as part of monitoring and assessment processes. However, these measures remain primarily oriented towards evaluating the quality of healthcare delivery and system performance, rather than being explicitly designed to assess patient-centredness within health R&I activities. [172]

Beyond the European Commission, other EU bodies play a significant role in advancing patient involvement, most notably the EMA, which has championed patient and public involvement for several decades.[173] The EMA's Regulatory Science Strategy 2020–2025 identifies advancing patient-centred access to medicines and prioritising patient relevance in evidence generation as core objectives.[174] This includes structured patient engagement across EMA activities, such as participation in scientific committees and the Committee for Orphan Medicinal Products.[175] Existing mechanisms already enable patient involvement in regulatory processes, including membership of the Pharmacovigilance Risk Assessment Committee (PRAC), where patients contribute to safety monitoring and risk assessment.[176]

Patient experience data are increasingly recognised as integral to assessing the safety and effectiveness of medicines across the product lifecycle, including in the design and conduct of clinical trials. The EMA has signalled a growing interest in expanding the use of real-world evidence that incorporates patient-reported outcomes and patient preferences, with the aim of strengthening regulatory decision-making and post-marketing surveillance.[177] Such data also hold significant potential value for downstream decision-makers, including HTA bodies. [178]

Despite this recognition, considerable uncertainty remains regarding how patient experience data should be systematically collected, interpreted, and applied, resulting in variability in practice and limiting consistent integration into regulatory and research processes.[179] A recently published EMA reflection paper highlights that patient experience data are not yet embedded systematically across research and development, and argues for their inclusion from the earliest stages of both clinical and

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[170] Cardinali, F., Carzaniga, S., Duranti, G., et al., 2015, *A nationwide participatory programme to measure person-centred hospital care in Italy: Results and implications for continuous improvement*, Health Expect, Vol.24(4), p.1145-1157. https://pmc.ncbi.nlm.nih.gov/articles/PMC8369125/#hex13231-bib-0021.

[171] Carinci, F., Van Gool, K., Mainz, J. et al., 2015, *Towards actionable international comparisons of health system performance: expert revision of the OECD framework and quality indicators*, Int J Qual Health Care, Vol.27(2), p.137-146. https://pubmed.ncbi.nlm.nih.gov/25758443/.

[172] Kendir, C. et al., 2022, *International assessment of the use and results of patient-reported outcome measures for hip and knee replacement surgery: Findings of the OECD Patient-Reported Indicator Surveys (PaRIS) working group on hip and knee replacement surgery*, Publication for the OECD. https://www.oecd.org/en/publications/international-assessment-of-the-use-and-results-of-patient-reported-outcome-measures-for-hip-and-knee-replacement-surgery_6da7f06b-en.html.

[173] Sessa, C., Schmid, C., Tolotti, A. et al., 2021, *The Role of EUPATI CH in Promoting Patient Involvement in Clinical Research: A Multi-Stakeholder Research Project*, Front Med, Vol.8. https://www.frontiersin.org/journals/medicine/articles/10.3389/fmed.2021.795659/full.

[174] European Medicines Agency, 2020, *EMA recommendations from the Regulatory Science Strategy to 2025: Implications for patients and healthcare professionals.* https://www.ema.europa.eu/en/documents/presentation/presentation-11-ema-recommendations-regulatory-science-strategy-2025-implications-patients-and-healthcare-professionals-t-humphreys_en.pdf.

[175] Sessa, C., Schmid, C., Tolotti, A. et al., 2021, *The Role of EUPATI CH in Promoting Patient Involvement in Clinical Research: A Multi-Stakeholder Research Project*, Front Med, Vol.8. https://www.frontiersin.org/journals/medicine/articles/10.3389/fmed.2021.795659/full.

[176] European Medicines Agency, 2022, *How patients contribute to the safety monitoring of medicines*. https://www.ema.europa.eu/en/documents/presentation/presentation-how-patients-can-contribute-safety-monitoring-medicines-s-strauss-meprac_en.pdf-0.

[177] Ibid.

[178] European Medicines Agency, 2022, *Patient experience data in decision making and future guidance*. https://www.ema.europa.eu/en/documents/presentation/presentation-patient-experience-data-decision-making-and-future-guidance-s-bhatti-efpia_en.pdf.

[179] Ibid.

non-clinical research.[180] The paper also acknowledges substantial barriers to operationalisation, notably the absence of comprehensive guidance. [181]

Key challenges identified include concerns regarding data quality, potential biases in interpretation and use, the representativeness of patient populations, and methodological limitations that constrain the types of data generated. [182] Patient preference studies represent a further important source of patient experience data, offering insights into unmet medical needs, priority preferences, and the selection of relevant endpoints. While the EMA recognises the value of such studies, their use remains inconsistent and has yet to be systematically integrated into routine regulatory and research practice. [183]

Recent developments in EU pharmaceutical legislation raise concerns regarding the future of patient influence within regulatory decision-making. The European Commission's original proposal to grant patient representatives voting rights on the Committee for Medicinal Products for Human Use (CHMP) and the PRAC has been weakened in the Council of the EU's negotiating position adopted on 4 June 2025. The potential removal of these voting rights risks reducing patient representatives to a largely observational role, thereby diminishing the substantive influence of patient expertise in decisions that directly affect health outcomes and quality of life.[184] While negotiations are ongoing and no final agreement has been reached, patient advocates emphasise the importance of preserving and strengthening these participatory mechanisms, in continuation of the EMA's long-standing commitment to patient involvement, including in the innovation pipeline. [185]

Broader policy discussions further underscore the role of EU legislation in embedding patient-centred approaches across the health and innovation system. At the 2025 EuropaBio Patient BioForum, participants highlighted the importance of incorporating explicit provisions for patient participation in forthcoming EU initiatives, including the EU Biotech Act, the Critical Medicines Act, the General Pharmaceutical Legislation, and the Life Sciences Strategy. Such measures were identified as critical to ensure that patient perspectives meaningfully inform research, innovation, regulatory decision-making, and, ultimately, healthcare delivery.[186]

In relation to the EU Pharmaceutical Package, initially launched in 2020, formally proposed in 2023, and politically agreed in 2025, one particular issue has been widely identified as a potential constraint on patient engagement and, more broadly, on patient-centredness in innovation and care: the definition of unmet medical need.[187] [188] Under the revised legislation, unmet medical need is more narrowly defined, with direct implications for patient involvement, regulatory decision-making, and market incentives.

The negotiated definition focuses on conditions for which no satisfactory treatment options exist or where a new intervention is expected to deliver a 'significant clinical benefit' over the current standard

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[180] European Medicines Agency, 2025, *Reflection paper on patient experience data*. https://www.ema.europa.eu/en/documents/scientific-guideline/reflection-paper-patient-experience-data_en.pdf.

[181] Ibid.

[182] Ibid.

[183] Ibid.

[184] EURORDIS, *Patient organisations warn against EU rollback on patient involvement in medicines regulation*. https://www.eurordis.org/epf-eurordis-joint-statement-patient-involvement/.

[185] EURORDIS, *Patient organisations call for guarantee of voting rights and meaningful involvement at the EMA*. https://www.eurordis.org/patient-organisations-call-for-guarantee-of-voting-rights-meaningful-involvement/.

[186] EuropaBio, 2025, *Annual Report*. https://www.europabio.org/wp-content/uploads/2025/07/FINAL-EuropaBio-Annual-Report-2025.pdf.

[187] Politico, 2025, *Patient-centered innovation: Can Europe lead the way?*. https://www.politico.eu/sponsored-content/patient-centered-innovation-can-europe-lead-the-way/.

[188] European Parliament, *Deal on comprehensive reform of EU pharmaceutical legislation*. https://www.europarl.europa.eu/news/en/press-room/20251209IPR32110/deal-on-comprehensive-reform-of-eu-pharmaceutical-legislation.

of care.[189] [190] This approach prioritises clinical endpoints, such as morbidity and mortality, while giving limited systematic consideration to patient-defined outcomes, including quality of life, treatment burden, and functional impact.[191] As a result, patient experience and preferences are not consistently embedded in determining what constitutes an unmet medical need.

Patient organisations and advocacy groups have criticised this approach, arguing that a restrictive, clinically driven definition risks marginalising patient perspectives in research and innovation priority-setting.[192] By failing to adequately capture patient-centred dimensions of need, the framework may constrain opportunities for meaningful patient input and reduce the alignment of innovation incentives with real-world patient priorities.

Empirical research examining stakeholder perspectives on the definition of unmet medical need further underscores this challenge.[193] While some areas of convergence exist across industry, academia, and civil society, significant ambiguity and divergence remain regarding priorities and criteria. [194] These findings suggest that the balance between incentivising innovation and ensuring that research and development address patient-centred needs remains unresolved, and warrants continued dialogue.[195]

4.5. EU health R&I funding instruments and patient-centredness

The EU's health R&I ecosystem integrates public investment, cross-sectoral partnerships, and mission-oriented initiatives. Horizon Europe serves as the primary research funding mechanism, with its dedicated Health cluster modestly directing resources toward patient-centred objectives across areas including personalised medicine, oncology, and rare diseases.[196] Within this framework, the IHI operates as a public-private partnership (PPP) that pools EU resources, from Horizon Europe's Pillar II, with pharmaceutical, medical technology, and digital health industry contributions to advance inclusive clinical research; it operates through a collaborative governance structure involving the Commission and industry partners.[197] [198] While Horizon Europe's Health cluster supports research across the full innovation spectrum from basic science to health systems implementation, IHI concentrates on pre-competitive translational research requiring large-scale, cross-sector public-private partnerships.[199]

IHI's governance model enables structured risk-sharing and co-investment in areas where coordination between competing industry actors and academic partners has historically been difficult, such as clinical trial infrastructure, data standardisation, and regulatory science.[200] IHI's governance model includes patient organisations as formal contributing partners alongside industry and research institutions. The EPF and disease-specific patient groups participate in strategic agenda-setting, not

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[189] McCann FitzGerald, *EU Agrees Landmark Reform of Pharmaceutical Legislation*. https://www.mccannfitzgerald.com/knowledge/pharma-and-life-sciences/eu-agrees-landmark-reform-of-pharmaceutical-legislation.

[190] European Patients Forum, 2023, *EPF proposal for a patient-centred framework for defining Unmet Medical Needs.* https://www.eu-patient.eu/globalassets/policy/epf-position-paper-unmet-medical-needs2.pdf.

[191] Ibid.

[192] Ibid.

[193] Wens, I., Claessens, Z., Vanneste, A. et al., 2025, *Unmet medical needs definition and incentives: stakeholders perspectives on the reform of the EU pharmaceutical legislation*, Front Med, Vol.11. https://www.frontiersin.org/journals/medicine/articles/10.3389/fmed.2024.1506243/full.

[194] Ibid.

[195] Ibid.

[196] European Commission, 2025, *Horizon Europe - Cluster 1: Health*. https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/cluster-1-health_en.

[197] European Commission, 2026, *Innovative Health Initiative funding model. https://www.ihi.europa.eu/about-ihi/ihi-funding-model.*

[198] European Commission, 2026, *Who we are - Innovative Health Initiative*. https://www.ihi.europa.eu/about-ihi/who-we-are.

[199] de Vrueh, R.L.A., de Vlieger, J.S.B. and Crommelin, D.J.A., 2019, *Editorial: Public-Private Partnerships as Drivers of Innovation in Healthcare*, Front Med, Vol.6. https://www.frontiersin.org/journals/medicine/articles/10.3389/fmed.2019.00114/full.

[200] Ibid.

merely as consultees but as co-decision makers in research prioritisation.[201] At its core, IHI's strategic R&I agenda emphasises people-centric, rather than product- and pathology-centric, goals; patient-centred domains are explicitly prioritised, including patient stratification, personalised approaches, health literacy, shared decision-making, and diversity and inclusion in trials.[202]

Still, the depth of patient-centricity varies. While patient organisations influence strategic direction, the governance structure of IHI still privileges pharmaceutical industry actors in resource allocation decisions. Critics note that "patient involvement" can become procedural/tokenistic rather than transformative, particularly when patient representatives lack resources to engage equally with well-staffed industry and academic partners.[203] While the IHI model represents meaningful institutional innovation compared to traditional research funding, it faces ongoing tensions between patient empowerment rhetoric and the structural power asymmetries inherent in PPPs.

The following section presents a brief analysis of how patient-centredness is reflected within the EU's principal health R&I funding instruments: Horizon Europe, the IHI, and EU4Health. Table 3 provides a high-level overview of the extent to which patient-centredness is embedded in the strategic frameworks, work programmes, and monitoring mechanisms of these three instruments.

Table 3: Patient-centredness in the EU's principal health R&I funding instruments

EU Funding Health R&I Instrument	Strategic plans including patient-centred notions	Work programme and project calls mentioning patient or person-centred research (2022-2025)	Monitoring patient-centred approaches (indicators or evaluation frameworks including patient-centred elements)
Horizon Europe	Minimally in 2021-2024[204] Minimally in 2025-2027[205]	Yes[206]	Yes[207]
IHI	Yes[208]	Yes[209]	Yes[210]
EU4Health	No[211]	Yes[212]	No[213]

Source: Authors' own elaboration.

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[201] Innovative Health Initiative, *Impact on: patients in research*. https://www.ihi.europa.eu/projects-results/health-spotlights/impact-patients-research.

[202] Innovative Health Initiative, 2022, *Strategic Research and Innovation Agenda*. https://www.ihi.europa.eu/sites/default/files/flmngr/IHI_Strategic_Research_and_Innovation_Agenda_3.pdf.

[203] Gorbenko, O., Cavillon, P., Giles, RH. et al., 2022, *Co-creating with patients an impact framework across the medicine's life cycle: a qualitative study exploring patients' experiences of involvement in and perceptions of impact measures*, BMC Res Involv Engagem, Vol.8(1). https://link.springer.com/article/10.1186/s40900-022-00334-0.

[204] European Commission, 2021, *Horizon Europe strategic plan 2021-2024, Publication for the Directorate-General for Research and Innovation*. https://op.europa.eu/en/web/eu-law-and-publications/publication-detail/-/publication/3c6ffd74-8ac3-11eb-b85c-01aa75ed71a1.

[205] Ibid.

[206] Innovative Health Initiative, 2024, *IHI 2025 Work Programme*. https://www.ihi.europa.eu/sites/default/files/uploads/Documents/About/AWP/WorkProgramme2025.pdf.

[207] Ibid.

[208] Innovation Health Initiative, 2022, *Strategic Research and Innovation Agenda The Innovative Health Initiative Joint Undertaking*. https://www.ihi.europa.eu/sites/default/files/uploads/Documents/About/IHI_SRIA_ApprovedJan22.pdf.

[209] Innovative Health Initiative, 2025, *IHI 2025 Amended Work Programme*. https://www.ihi.europa.eu/sites/default/files/uploads/Documents/About/AWP/WorkProgramme2025_Amend1.pdf.

[210] Innovative Health Initiative, 2024, *IHI 2025 Work Programme.* https://www.ihi.europa.eu/sites/default/files/uploads/Documents/About/AWP/WorkProgramme2025.pdf.

[211] European Commission, *EU4Health programme 2021-2027 – a vision for a healthier European Union*. https://health.ec.europa.eu/funding/eu4health-programme-2021-2027-vision-healthier-european-union_en.

[212] European Commission, 2025, *ANNEX Commission Implementing Decision on the financing of the programme for the Union´s action in the field of health ('EU4Health programme') and the adoption of the work programme for 2025*. https://health.ec.europa.eu/document/download/26284fbb-0c7b-4d4d-ae57-f7f2a47e493f_en?filename=funding_c2025_5148_annex_en.pdf.

[213] European Commission, 2024, *Commission staff working document EU4Health Programme Performance Monitoring and Evaluation Framework*. https://health.ec.europa.eu/document/download/ed0ff0b8-08a5-498c-b442-ee5464bc9f52_en?filename=funding_swd_2024_223_en.pdf.

4.5.1. Horizon Europe

Horizon Europe positions societal relevance and public value as central rationales for publicly funded science. While it does not articulate a stand-alone patient involvement strategy, concerns about the limited translation of research into real-world health benefits are addressed through broader commitments to societal impact, Responsible Research and Innovation (RRI)[214], and mission-oriented research.[215]

As part of the European Research Area (ERA), citizen science by way of improved interaction between the research system and society at large became an explicit policy priority in 2022.[216] The ERA Platform provides available guidance on citizen engagement, emphasising that involving citizens and civil society ensures research aligns with the values, needs and expectations of the society at large, improves quality and fosters trust in science, thereby indicating the programme's intention for research to serve societal goals.[217]

Across its strategic plans, Horizon Europe has advanced its framing and prioritisation of research with user and societal needs as integral components to improved uptake, legitimacy, and effectiveness of innovation in health. The 2021-2024 Strategic Plan makes only cursory reference to the role of R&I in mobilising citizens and patients, patients' associates, and acknowledges the potential of R&I to foster innovative solutions through "interaction with patients and patient empowerment"; it does not recognise patient-centredness or its various dimensions as an explicit strategic priority or requirement for R&I funding.[218] Patient engagement is framed primarily as a supportive activity, rather than a core component of research design or governance.

By contrast, the 2025–2027 Strategic Plan underpinning the respective work programme represents a gradual evolution, placing a stronger and more explicit emphasis on citizen and stakeholder engagement, co-creation, and societal relevance as foundational principles for Horizon Europe's implementation, including in health research.[219] The plan foregrounds the need to strengthen trust in science and ensure that research outcomes deliver tangible benefits for people and communities, explicitly positioning citizens and end-users as active contributors to R&I processes rather than passive beneficiaries.

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[214] ERNA Learn, *Governance, Administration & Legal Base*. https://www.era-learn.eu/support-for-partnerships/governance-administration-legal-base/responsible-research-innovation.

[215] European Commission, 2018, *Mission-oriented research and innovation Assessing the impact of a mission-oriented research and innovation approach: final report*, Publication for the Directorate-General for Research and Innovation. https://op.europa.eu/en/publication-detail/-/publication/c24b005f-5334-11e8-be1d-01aa75ed71a1/language-en.

[216] European Commission, *CORDIS, Citizen science: Inspiring examples of societal engagement for Horizon Europe*. https://cordis.europa.eu/article/id/435872-citizen-science-inspiring-examples-of-societal-engagement-for-horizon-europe.

[217] European Commission, *Horizon Europe support for citizen engagement*. https://european-research-area.ec.europa.eu/horizon-europe-support-citizen-engagement.

[218] European Commission, 2021, *Horizon Europe strategic plan 2021-2024, Publication for the Directorate-General for Research and Innovation*. https://op.europa.eu/en/web/eu-law-and-publications/publication-detail/-/publication/3c6ffd74-8ac3-11eb-b85c-01aa75ed71a1.

[219] European Commission, 2024, *Horizon Europe strategic plan 2025-2027*, Publication for the Directorate-General for Research and Innovation. https://op.europa.eu/en/web/eu-law-and-publications/publication-detail/-/publication/6abcc8e7-e685-11ee-8b2b-01aa75ed71a1.

Box 3: Patient-centredness in the 2025-2027 Horizon Europe Strategic Plan

The 2025-2027 HE Strategic Plan emphasises:

1. R&I are needed to develop solutions including for patient empowerment and patient interaction;
2. Development and implementation of novel health technologies will need to take into account the end user including patients;
3. Focus on patient safety;
4. Support design and development of health products and services to improve patient outcomes;
5. Development of human centred health technologies to enhance personalised medicine and address patient safety.

Source: Authors' own elaboration based on the 2025-2027 Horizon Europe Strategic Plan.

This commitment to citizen and stakeholder engagement is most clearly institutionalised through the EU Missions, such as the aforementioned Cancer Mission, which integrate mechanisms for engaging patients, carers, and the wider public in agenda-setting, priority identification, and feedback loops.[220] Still, explicit engagement requirements are not universal across the programme and no clear criteria or key performance indicators (KPI) exist to incorporate engagement expectations. Reporting requirements also encourage a retrospective approach rather than intentional patient and citizen engagement from the outset to shape project design in a systematic, programme-wide way.[221]

Empirical surveys illustrate the tension between intention and explicit prospective requirements for public involvement. Within the context of the EU Missions, many citizens have expressed a strong desire to participate in mission-related activities yet often lack clear channels or institutional support to make their voices effectively heard, pointing to persistent barriers in access to decision-making processes.[222] While structured opportunities for engagement have expanded, meaningful participation remains uneven and dependent on the specific mechanisms, resources, and structures available within particular calls, projects, or mission frameworks.

Across its work programmes from 2021 to 2027, Horizon Europe explicitly states under various destinations and project calls that a patient-centred approach should be adopted, one which empowers patients, promotes dialogue, encourages shared decision-making, and furthers the evidence base for effective engagement and improved quality of life. Yet none of the work programmes specifies how this is to be achieved or evaluated, rendering it more as an aspiration than an enforceable commitment with meaningful implementation and monitoring mechanism.

An examination of Horizon Europe-funded projects using filters for patient-centred dimensions in R&I using the Cordis database identified 32 active projects during 2022-2025, with varying degrees of patient-centredness across the projects. A selection of projects funded under Horizon Europe, described in Table 4, illustrates this varying level of integration of patient-centredness in R&I, and the requirements for funding allocation.

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[220] European Commission, *EU Mission: Cancer*. https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/eu-missions-horizon-europe/eu-mission-cancer_en;

[221] NCP Flanders, *Citizen Science in Horizon Europe*. https://ncpflanders.be/infosheets/citizen-science-in-horizon-europe;

[222] Horizon Europe NCP Portal, 2025, Citizens' Engagement in Social Challenges: New Report. https://horizoneuropencpportal.eu/news/european-citizens-engagement-social-challenges-new-report.

Table 4: Selected Horizon Europe spotlight projects and their patient-centred dimensions

Project	Patient-centred dimension	Period	EU funding amount
GEREMY: *Gene Therapy for treatment of rare inherited Arrhythmogenic Cardiomyopathy*	EUPATI and KUL ethics partner regularly engaged to ensure the project continuously aligns with patient needs and ethical perspectives.	May 2023 – April 2027	€ 7 774 104
BE-SAFE: *Implementing a patient-centred and evidence-based intervention to reduce BEnzodiazepine and sedative-hypnotic use to improve patient SAFEty and quality of care*	Emphasis on patient involvement by establishing Patient Partnership Advisory Councils[223] with patients, informal carers and patient organisations, which advise on all aspects of the project. Survey among patients and other stakeholders identify barriers and enablers to sleep medicine reduction, and inform guideline development, implementation recommendations, and patient-centred materials to support self-management.	September 2022 – August 2027	€ 4 883 232
UNIFIED: *Unifying Framework for Patient-centred Clinical-study Endpoints derived from Digital Health Technologies*	Project aims to generate a framework to obtain a robust view of a health intervention's full benefits to patients via (i) integrating three key patient-centred data types: patient preference information, clinical outcome assessments, and digital health technology (DHT)-derived measures, and (ii) determining what patients consider minimum clinically important difference.	November 2025 – October 2030	€ 12 599 999
IDEAHL: *Improving Digital Empowerment for Active Healthy Living*	Project maps health literacy (HL) and digital HL research, initiatives and projects in the EU and beyond. Building on this, it launched a large co-creation process, including with patients, to design and plan its EU (d)HL Strategy with the ultimate purpose of empowering citizens.	May 2022 – April 2024	€ 2 791 350

Source: Authors' own elaboration.

4.5.2. Innovative Health Initiative

Within the IHI's Strategic Research and Innovation Agenda, the EU's persistent challenge in translating research outputs into tangible health benefits and real-world solutions is attributed, in part, to the insufficient integration of user and societal needs, including those of patients.[224] In response, the intentional and systematic integration of patient involvement across the research and development lifecycle is identified as a strategic priority to support more meaningful, relevant, and impactful innovation. [225]

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[223] BE-SAFE, *Patient Partnership Advisory Council*. https://besafe-horizon.eu/en/about-be-safe/patient-partnership-advisory-council-pac.

[224] Innovative Health Initiative, 2022, *Strategic Research and Innovation Agenda The Innovative Health Initiative Joint Undertaking.* https://www.ihi.europa.eu/sites/default/files/uploads/Documents/About/IHI_SRIA_ApprovedJan22.pdf .

[225] Ibid.

A core feature of the IHI framework is its explicitly people-centric orientation. The agenda emphasises the need to fully harness partnerships with patients, alongside other relevant stakeholders such as carers, to identify, develop, and implement solutions and technologies that genuinely reflect people's needs, preferences, and lived experiences. To this end, IHI seeks to facilitate patient contributions to R&I through the development of tools, methodologies, and approaches that support the integration of patient preferences and enable genuine cooperation across stakeholder groups.

According to IHI documents, patients play an active role in developing calls contributing to determining the scope or areas of focus.[226] This extends to the example of select patient organisations such as the Breakthrough T1D and the Children's Tumor Foundation becoming Associated Partners in Innovative Medicines Initiative phase 2 (IMI2), the precursor to IHI, which allowed for their input to be included in shaping projects and calls for proposal as well as being an observer in the IMI Governing board.[227]

The IHI strategy further underscores the importance of sustained patient engagement in emerging technological domains, including artificial intelligence (AI).[228] It explicitly recognises that while AI may enhance healthcare delivery and research, it cannot replace the human components of care, reinforcing the need to maintain a patient-centric perspective in the design, deployment, and governance of AI-enabled health innovations. Maintaining a patient-centred approach was highlighted as a key takeaway from a 2024 IHI workshop focused on exploring challenges and opportunities in data, digital health, and AI.[229]

The 2025 IHI work programme places explicit emphasis on patient-centred approaches, encouraging applicants to work in partnership with patients and to consider patient-centred dimensions across research activities, including health technologies and social innovation. [230] IHI guidance for applicants also highlights the inclusion of patient organisations within project consortia. However, this guidance remains relatively high-level and does not provide detailed or operational direction on how patient-centred approaches should be systematically applied throughout the R&I lifecycle.[231] Moreover, the IHI evaluation templates for both single-stage and two-stage Research and Innovation Actions do not explicitly include patient involvement or patient-centredness as assessment criteria, which may limit incentives for applicants to embed these approaches more robustly in proposal design. [232]

IHI is nonetheless distinctive among EU funding instruments in that it incorporates KPIs that reflect patient-centred principles.[233] These include indicators that monitor the involvement of multiple stakeholders, with explicit reference to patient organisations, as well as measures tracking cross-stakeholder collaboration. Additional performance indicators emphasise the development of healthcare solutions that take account of end-user needs, thereby supporting a person-centred approach. In terms of methodological considerations, IHI also includes indicators related to the use of

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[226] Innovative Health Initiative, *Patients as partners – how IHI and IMI engage patients in health research*. https://www.ihi.europa.eu/sites/default/files/uploads/Documents/About/IHI_SRIA_ApprovedJan22.pdf.

[227] Innovative Medicines Initiative Joint Undertaking, *Associated Partners – Get involved in IMI*. https://wayback.archive-it.org/12090/20240425092528/https:/www.imi.europa.eu/get-involved/associated-partners.

[228] Innovative Health Initiative, 2022, *Strategic Research and Innovation Agenda*. https://www.ihi.europa.eu/sites/default/files/uploads/Documents/About/IHI_SRIA_ApprovedJan22.pdf.

[229] Innovative Health Initiative, 2024, *IHI workshop on real-world data, digital health & artificial intelligence.* https://www.ihi.europa.eu/sites/default/files/flmngr/Data%20%26%20Digital%20Report%20PDF_2.pdf.

[230] Innovative Health Initiative, 2024, *IHI 2025 Amended Work Programme*. https://health.ec.europa.eu/document/download/ed0ff0b8-08a5-498c-b442-ee5464bc9f52_en?filename=funding_swd_2024_223_en.pdf.

[231] Innovative Health Initiative Joint Undertaking, 2026, *IHI Guide for Applicants*. https://www.ihi.europa.eu/sites/default/files/IHI_Guide_for_Applicants.pdf.

[232] Innovative Health Initiative Joint Undertaking, 2022, *IHI Evaluation Form for Research and Innovation Actions.* https://www.ihi.europa.eu/sites/default/files/IHI_Evaluation_form_RIA.pdf.

[233] Innovative Health Initiative,2024, *IHI 2025 Work Programme.* https://www.ihi.europa.eu/sites/default/files/uploads/Documents/About/AWP/WorkProgramme2025.pdf.

patient-reported outcomes, signalling recognition of patient experience and preferences as relevant sources of evidence.

An examination of IHI-funded projects using filters for patient involvement in R&D identified five active projects.[234] Applying the same criteria to IMI2, the predecessor of IHI, including projects initiated prior to 2022 but active between 2022 and 2025, yielded eleven projects. Across the five IHI projects identified, patient organisations were included as consortium partners in all cases. The proportion of total project funding allocated to patient organisations ranged from approximately 5% to 26%, as detailed in Table 5. For IMI2 projects identified as involving patients in R&D, all of which included patient organisations as consortium partners, the seven projects for which funding data were available allocated between 0.2% and 19% of total project funding to patient organisations. While patient involvement represents only one dimension of patient-centredness in R&I, these data on partnership structures and funding allocation provide a useful indication of the extent to which patient-centred principles are being operationalised in practice. Though it is difficult to assess how funding decisions were made concerning the allocation of funds for projects.

Table 5: IHI patient engagement and funding for patient organisations

IHI patient engagement in R&D project name	Patient organisations included in consortium	Total funding for patient organisations (Euro)	Percent of total funding
Patient lifestyle and disease data interactium	Parent Project Aps	700 000	26%
Patient-centric blood sampling for improved healthcare (Project-COMFORT)	Patient-Centric Sampling Interest Group Cic	Not listed	-
Research in Europe and diversity inclusion	European Aids Treatment Group Ev; Forum Des Patients Europeens; Irish Platform For Patients' Organisations Science And Industry	1 998 100	6%
Comprehensive methodological and operational approach to clinical trials in rare and ultra-rare diseases	Eurordis - Rare Diseases Europe	505 000	6%
Unifying framework for patient-centred clinical-study endpoints derived from digital health technologies	Association Européenne Pour La Maladie De Parkinson; Childhood Cancer International; Forum Des Patients Européens; The European Coalition For People Living With Obesity Company	618 063	5%

Source: Authors' own elaboration.

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[234] Innovative Health Initiative Joint Undertaking, 2026, *IHI project factsheets – projects and results.* https://www.ihi.europa.eu/projects-results/project-factsheets?keywords=&type=3&status=All&call=All&programmes=All&disease_areas=All&products=All&tools=TR9.

In practice, interviewees from IHI consortia reported that the extent to which patient-centred approaches are integrated into the implementation of IHI projects is highly dependent on consortium leadership. Existing guidelines for operationalising patient-centredness across the project lifecycle lack specificity regarding how such approaches should be implemented, thereby placing considerable discretion in the hands of project leaders. In addition, there is an absence of clear guidance on key parameters essential to meaningful patient engagement, such as capacity building on the concept and implementation of meaningful engagement and the remuneration of patients. As noted in interviews, securing funding for patient remuneration is a persistent challenge, with these costs often among the first to be reduced when project budgets come under pressure. Moreover, there is no standard for the inclusion of capacity building across consortia to ensure all partners share a consistent understanding of what patient involvement means, the value add of it, and how to integrate it meaningfully throughout the project lifecycle.

4.5.3. EU4Health

The EU4Health Programme was established in response to the COVID-19 pandemic to strengthen crisis preparedness across the EU, with the overarching objective of supporting more resilient health systems and healthier populations. Originally endowed with a budget of €5.3 billion for the 2021–2027 period, the programme's financial envelope was subsequently reduced to €4.4 billion following revisions to the Multiannual Financial Framework (MFF).[235]

Although the EU4Health Programme 2021–2027 is not explicitly framed as patient-centred, it maintains the core objectives of protecting people and strengthening healthcare systems.[236] These objectives align with patient-centred approaches through synergistic components, particularly in its emphasis on ensuring access to health data and healthcare services that enhance accessibility for individuals both in routine care settings and during times of crisis.

EU4Health is implemented through annual work programmes. An analysis of the work programmes for 2022–2025 indicates that patient-centredness is explicitly referenced only in the 2024 work programme. In that year, the term appears four times, three of which relate to mental health calls and one to cancer.[237] Nevertheless, broader elements associated with patient-centredness, such as patient and patient organisation engagement, as well as capacity-building support for patient associations, are present across all work programmes. Several calls, particularly in the 2022 and 2024 programmes, emphasise the value of patient engagement on the basis that patients are intended beneficiaries of R&I outcomes, notably in areas including AI, health data, health technologies, and innovative medical devices. [238]

Within the Performance Monitoring and Evaluation Framework, under the "health systems and healthcare workforce" strand, EU4Health is described as supporting actions to improve access to "quality, patient-centred, outcome-focused healthcare and related care services".[239] However, the sole indicator under this strand that explicitly references patients seeks to monitor the number of patient cases, including treatment and management decisions, reviewed by European Reference Networks. While patient-oriented, this indicator relates primarily to care delivery and management rather than patient involvement or engagement in R&I activities.

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[235] European Commission, *EU4Health programme 2021-2027 – a vision for a healthier European Union*. https://health.ec.europa.eu/funding/eu4health-programme-2021-2027-vision-healthier-european-union_en.

[236] Ibid.

[237] European Commission, 2024, *EU4Health 2024 work programme*. https://health.ec.europa.eu/publications/2024-eu4health-work-programme_en.

[238] European Commission, 2022, *EU4Health Work Programme 2022*. https://health.ec.europa.eu/document/download/ee962899-de43-42a0-ab61-caa012b16ebc_en?filename=amended_wp2022_en.pdf.

[239] European Commission, 2024, *EU4Health Work Programme 2024 - Funding and Strategic Document*. https://health.ec.europa.eu/document/download/ed0ff0b8-08a5-498c-b442-ee5464bc9f52_en?filename=funding_swd_2024_223_en.pdf

EU4Health has been subject to several performance assessments, including stakeholder consultations and interim evaluations, which contain limited reference to patient-centred outcomes. The 2024 stakeholder consultation mentioned patient-centredness only in the context of identifying areas where synergies would be most beneficial; approximately half of respondents identified "access to quality, patient-centred healthcare and related care services" as a priority. [240] Although this framing remains largely healthcare-focused rather than R&I-oriented, it signals stakeholder perceptions that patient-centred practices remain insufficient, even in care settings that are themselves informed by R&I.

The interim evaluation covering the 2021–2024 period reported that research and academic institutions benefited from EU4Health support for health research focused on patient outcomes, particularly in improving access to innovative treatments, though specific examples were not provided.[241] The evaluation also noted emerging benefits for patients linked to digital health activities, while recognising that many impacts remain nascent and are likely to materialise over the longer term. Consistent with these findings, the EU4Health performance webpage reports that approximately 350 patients completed training to participate in collective HTA activities.[242] Furthermore, it was reported that digital health initiatives advanced across Europe, with around 20 MS receiving support to digitalise their health systems and develop MyHealth@EU services, thereby expanding patient access to their own health data. [243]

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[240] European Commission, 2024, *2024 EU4Health Stakeholders' Consultation*. https://health.ec.europa.eu/document/download/64f28955-a8ff-40a5-b79f-2d90df58813b_en?filename=funding_eu4health_2024-consultation_report_en.pdf.

[241] European Commission, 2025, *Study supporting the interim evaluation of the EU4Health Programme Regulation (EU) No 2021/522*. https://health.ec.europa.eu/document/download/1c3532d2-d0c8-43bd-ae3d-abd3692bce4c_en?filename=funding_eu4Health_2021-2024_interim-evaluation_study_en.pdf.

[242] European Commission, 2025, *EU4Health – programme performance statements*. https://commission.europa.eu/strategy-and-policy/eu-budget/performance-and-reporting/programme-performance-statements/eu4health-performance_en#contribution-to-horizontal-priorities.

[243] European Commission, 2025, *Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the interim evaluation of the EU4Health Programme 2021–2024 (COM(2025)709final).* https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=COM:2025:0709:FIN.

5. EU MEMBER STATE CASE STUDIES

KEY FINDINGS

There is heterogeneity in the implementation of patient-centred health R&I across EU MS with valuable experiences and lessons to glean for potential scale up and adaptation across contexts. The three case studies on Germany, the Netherlands, and Belgium highlight examples of national and subnational activities advancing the practice and institutionalisation of patient-centred R&I.

Germany is increasingly institutionalising patient-centred practices in R&I through formalised policies, funding requirements, and established patient advisory bodies across institutions; though challenges persist concerning a lack of standardisation of definitions, compensation for patient involvement, and sustainability of resources to ensure the continuation of this approach.

The Netherlands is a leader in patient-centred health R&I in the EU, supported by strong government policy and national stakeholders, with patient involvement institutionalised through shared decision-making and formal roles for patient organisations in guideline development, policymaking, and quality initiatives, and increasingly embedded as a requirement in publicly funded research to better align studies with societal and patient needs.

Belgium has developed a range of patient involvement structures and funding requirements that reflect meaningful progress, but implementation remains uneven across institutions and largely dependent on funder mandates rather than embedded in national policy or publicly funded research by default.

Reflecting the fragmented landscape described above, there is substantial heterogeneity across EU MS in the implementation of patient-centred decision-making in health R&I. While some countries have established robust systems to engage and partner with patients throughout the R&I lifecycle, others lack structured mechanisms to support meaningful participation. In such contexts, patient involvement is often limited to consultative, ad hoc, or informal roles, with little influence over research priorities or decision-making processes.

Several MS have introduced formal mechanisms for patient involvement, including patient representation on committees, advisory boards, and governance structures. Examples include France, Germany, Spain, and the Netherlands. Other MS are initiating patient engagement mechanisms, such as Bulgaria where a Patient Council on Patient Rights was recently put into place and where the Association of Research-Based Pharmaceutical Manufactures initiated a skills building programme for patient organisations.[244]

In some cases, patient partnership has been further institutionalised through policy or legal frameworks. France, in particular, has embedded patient participation within its legal system through multiple instruments, including Article L.1111-2 of the French Public Health Code (Code de la santé publique) and the 2016 Law to Modernise the French Healthcare System. Together, these measures

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[244] European Federation of Pharmaceutical Industries and Associations, *Patient engagement: accelerating progress in a spirit of partnership*. https://www.efpia.eu/news-events/the-efpia-view/blog-articles/patient-engagement-accelerating-progress-in-a-spirit-of-partnership/.

reinforce patients' rights to information and participation in health governance and decision-making, contributing to the concept of démocratie en santé (health democracy).[245] [246] [247]

In addition, some MS benefit from strong national patient platforms that support structured and capacity-building approaches to engagement in health R&I. Notably, the EUPATI national platforms play a key role in training and empowering patients to engage meaningfully in research processes. There are currently 24 EUPATI national platforms operating across EU MS and internationally, functioning as independently governed structures that mirror the public–private partnership model at national and local levels. These platforms support patient education, training, and empowerment, while also facilitating locally driven initiatives to strengthen patient-centred capacities. For example, in Switzerland, the national EUPATI network conducted a survey to inform its work programme, identifying lack of resources as the primary barrier to patient involvement, followed by limited access to information and uncertainty around pathways to becoming a patient advocate. [248]

The absence of standardised approaches to patient-centred R&I across the EU creates challenges for harmonisation, particularly in the context of multinational studies, and contributes to regional variation in practice.[249] [250] There is also no formal exchange between MS to share experiences, know-how, and implementation lessons. Systematic documentation of best practices and structured learning from MS with more formalised engagement mechanisms could help identify transferable approaches and opportunities for adaptation in other contexts.

To this end, three MS were selected as case studies to enable an in-depth examination of national experiences and lessons learned. Case studies have also been flagged as a potential avenue for learning in developing best practices for the EU and its MS.[251] These case studies were not intended to rank or compare best and worst performers; rather, they were selected based on survey responses highlighting them as informative examples and on recent efforts to institutionalise patient-centred approaches in R&I. The selected countries (Germany, the Netherlands, and Belgium) offer diverse institutional models from which other MS may draw relevant insights.

5.1. Germany

Germany operates a universal health system based on mandatory insurance, delivered through a multi-payer structure with statutory and substitutive private health insurance plans. Germany has one of the highest levels of health expenditure in the EU, with per capita spending of approximately €5.414 in 2023, the majority of which is publicly financed.[252] The country also benefits from a highly developed

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[245] Devillier, N., 2017, *Chapter 6. The law on the modernization of our health system: the provisions regarding health data*, Journal International de Bioéthique et d'Éthique des Sciences, Vol. 28(3), p. 57-61. https://pubmed.ncbi.nlm.nih.gov/29561100/.

[246] Caniard, E., 2015, *Involvement of patient and user organizations in public health institution: the case of the Haute Autorité de Santé (HAS) in France*, OpenEdition Books, p. 189-220. https://books.openedition.org/pressesmines/1577?format=toc.

[247] Thiveaud, D., Orlikowski, D., Ollé, F. et al., 2023, *Why and how can we improve patient and caregiver information for the proper use of their medical devices throughout the care pathway?*, Thérapies, Vol. 78(1), p. 53-65. https://www.sciencedirect.com/science/article/abs/pii/S0040595722002414.

[248] Sessa, C., Schmid, C., Tolotti, A. et al., 2021, *The Role of EUPATI CH in Promoting Patient Involvement in Clinical Research: A Multi-Stakeholder Research Project*, Frontiers in Medicine, Vol. 8. https://pmc.ncbi.nlm.nih.gov/articles/PMC8733300/.

[249] NIVEL, 2021, *Variation between EU countries in implementing EU privacy legislation makes joint actions in health care and research more difficult*. https://www.nivel.nl/en/nieuws/variation-between-eu-countries-implementing-eu-privacy-legislation-makes-joint-actions#:~:text=22-02-2021-,Variation%20between%20EU%20countries%20in%20implementing%20EU%20privacy%20legislation%20makes,scientific%20research%20purposes%20and%20statistics.

[250] Pickaert, A.P., 2025, *Patient Involvement in Health Technology Assessments: Lessons for EU Joint Clinical Assessments*, Journal of Market Access & Health Policy, Vol. 13(3). https://www.mdpi.com/2001-6689/13/3/38.

[251] European Medicines Agency, 2022, *Patient experience data in decision making and future guidance.* https://www.ema.europa.eu/en/documents/presentation/presentation-patient-experience-data-decision-making-and-future-guidance-s-bhatti-efpia_en.pdf.

[252] European Observatory on Health Systems and Policies, OECD, 2025, *Germany: Country Health Profile 2025*. https://eurohealthobservatory.who.int/publications/m/germany-country-health-profile-2025.

R&I ecosystem, hosting Europe's largest pharmaceutical sector. [253] In 2022, Germany's per capita investment in research and development reached €59, nearly double the EU average and that of France, although lower than levels observed in Belgium and Slovenia.[254] This strong funding and institutional landscape provide a conducive environment for advancing patient-centred approaches in health R&I.

Description of patient-centred applications in health R&I in Germany

Patient involvement in health-related decision-making and health R&I is not a novel concept in Germany. While patient engagement has a longer tradition within the healthcare system in Germany, structured and institutionalised patient involvement in research governance is a more recent development. Legislative provisions enabling patient engagement in healthcare governance date back to 1976, and patients have long held advisory roles within federal committees, albeit largely without voting rights.[255] Citizen councils and participatory fora also exist at regional and institutional levels.[256]

Interviewees highlighted that the term "patient-centredness" is not always explicitly used in Germany; instead, the emphasis is often placed on "active patient participation" or "patient involvement", reflecting the evolving and context-dependent nature of the concept in practice. Other interviewees spoke to the importance of distinguishing between patients 'taking part' in research and true 'involvement' which they define as co-creation between patients and researchers. The topic has developed rapidly recently, but a systematic definition, approach, documentation, and evaluation, as well as comprehensive structural integration of the topic, still need to be addressed.[257]

Policy and funding frameworks

In recent years, patient-centred approaches have gained increasing prominence within health R&I. Federal funding bodies, particularly the Federal Ministry of Research, Technology and Space (BMFTR), have institutionalised patient engagement within funding requirements.[258] Expert discussions during the process of developing new funding guidelines and evaluations to review research proposals for funding are also carried out with the participation of patient representatives. Calls for proposals increasingly mandate explicit plans for patient participation across the research cycle, from agenda-setting to dissemination. Where participation is not feasible, applicants must provide justification.

This institutionalisation has contributed to what interviewees described as a 'cascading effect', encouraging uptake across smaller funding bodies, including the Innovation Fund of the Federal Joint Committee and German Cancer Aid.[259] Dedicated funding streams have also emerged to support participatory research. For example, the Berlin Institute of Health's QUEST Centre funded projects that demonstrate active patient involvement in research design and implementation.[260] This funding stipulates research that shows patients having an active role and voice in the research planning, implementation and/or dissemination. For example, one funded study investigated the efficacy of app-

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[253] Ibid.

[254] Ibid.

[255] Federal Ministry of Justice and Consumer Protection, *Ordinance on the Participation of Residents in Matters of Home Operation (Heimmitwirkungsverordnung - HeimmwV)*. https://www.gesetze-im-internet.de/heimmitwirkungsv/BJNR018190976.html.

[256] Engler, J., Kuschick, D., Tillman, J. et al., 2022, *Aktive Patient*innen- und Bürger*innen-Beteiligung in der allgemeinmedizinischen Forschung*, Zeitschrift für Allgemeinmedizin, Vol. 98, p. 178-183. https://link.springer.com/article/10.53180/zfa.2022.0178-0183.

[257] Forum Gesundheitsforschung, 2023, *Declaration of the Forum Gesundheitsforschung on the Active Involvement of Patients in Health Research.* https://projekttraeger.dlr.de/media/gesundheit/GF/Forum-GF_Erkl%C3%A4rung-Patientenbeteiligung_27-03-2023.pdf.

[258] Ibid.

[259] Oster, L., Hell, A., Moegling, I. and Brütt, AL., 2026, *Patient participation in health research in Germany: current status and future prospects*, Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz, Vol.69(2), p.182-188. https://pmc.ncbi.nlm.nih.gov/articles/PMC12852197/.

[260] Berlin Institute of Health, *QUEST Fund for Patient & Stakeholder Engagement*. https://www.bihealth.org/en/translation/innovation-enabler/quest-center/calls-and-awards/quest-fonds-fuer-patient-stakeholder-engagement.

based self-acupressure from women who experience menstrual pain whereby young women who experience this pain were involved in the planning and design of the study.[261]

It is also important to recognise the reciprocal dynamic between institutional practice and policy development. Early institutional initiatives in structured patient involvement, particularly at major research institutions, contributed to visibility and helped inform subsequent policy and funding frameworks. The development has therefore been shaped by both top down and bottom-up dynamics.

Stakeholders emphasised that financial support and formal requirements have been critical enablers; without explicit funding provisions, participatory practices would likely have remained limited. Participatory activities in BMFTR-funded projects are now eligible for financial support, and certain funding lines require or enable joint development of research questions by scientific experts and patient representatives (e.g. funding line "practice-changing clinical trials for the prevention, diagnosis and treatment of cancer" or "clinical trials with high relevance for patient care").

In parallel, interviewees recognise the need to evaluate participatory approaches systematically, acknowledging that cultural change and structural adaptation take time. Nevertheless, there is a lack of structured approaches for determining the quality and impact of participatory approaches stemming in part from the often inadequate and unstructured documentation of participation activities.

At a national level, health research priorities are guided by the Federal Health Research Framework Programme, an iterative strategy designed to reflect societal needs.[262] Participatory processes, including workshops with patients and citizens, have informed its development to more accurately reflect current research needs and priorities. Core principles such as "People at the Centre" and "Personalisation and Digitalisation as Key Enablers" inform strategic priorities and funding decisions.[263]

In 2023, the BMFTR published a national strategy for participation in research to improve the conditions for public involvement in research and research policy. For instance, the Ministry has been funding the participation conference PartWiss (*Partizipation in der Wissenschaft*, participation in science) since 2022 to support networking between the various participatory approaches such as participatory health research.[264]

The project management agency responsible for implementing funding measures for health research on behalf of the BMFTR published a practical guidance for patient involvement in clinical research.[265] [266] [267] Interviewees emphasised the importance of continuous exchange between policymakers and the research community to ensure alignment between political priorities and research agendas.

The Health Research Forum, established in 2015, further supports coordination across research organisations, industry, academia, healthcare providers and patient representatives. It functions as a strategic dialogue and advisory platform. In 2023, it has published a Declaration on Active Involvement of Patients in Health Research including commitments of the academic institutions represented in the

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[261] Blödt, S., Daniel, P., von Eisenhart-Rothe, S. et al., 2018, E*ffectiveness of app-based self-acupressure for women with menstrual pain compared to usual care: a randomized pragmatic trial*, American Journal of Obstetrics and Gynecology, Vol.218(2), p.227. https://www.sciencedirect.com/science/article/pii/S0002937817323359?via%3Dihub.

[262] Federal Ministry of Research, Technology and Space (BMFTR), *Health Research*. https://www.bmftr.bund.de/EN/Research/Health/health_node.html.

[263] Ibid.

[264] *PartWiss*, website: https://www.partizipation-wissenschaft.de/project-description/.

[265] A. Schütt, E. Müller-Fries and S. Weschke, 2023, *Aktive Beteiligung von Patientinnen und Patienten in der Gesundheitsforschung. Eine Heranführung', DLR Projektträger*,. https://zenodo.org/records/7908077.

[266] Federal Ministry of Research, Technology and Space, *Public Participation – Research, Society and Social Innovations.* https://www.bmftr.bund.de/EN/Research/Society/SocialInnovations/PublicParticipation/publicparticipation.html.

[267] P. Schrögel, 2025, *Ein Leitfaden für Partizipation in der Forschung*. PartWiss, https://zenodo.org/records/14786253.

Health Research Forum on how they will create favourable conditions in their respective spheres of activity and support corresponding activities and processes.[268]

Implementation across research in Germany

Implementation of patient participation remains uneven across health research domains. Disease areas such as cancer and mental health are more advanced, supported by long-standing infrastructure and targeted national initiatives. For instance, the National Decade Against Cancer, initiated by the BMFTR, has integrated patient perspectives into funding considerations from its inception, supported by dedicated resources.[269] In clinical research, patient involvement is particularly well embedded: interviewees estimated that for the BMFTR as funder in recent years all clinical trial review boards include patient representatives. These representatives primarily assess relevance, feasibility, and patient burden, while scientific and technical merit continues to weigh more heavily in funding decisions, particularly in international calls. In the EU research program ERA-NET NEURON, German partners have made important contributions to including the perspective of patients and carers into the funding process. [270]

Across the German Centres of Health Research (*Deutsche Zentren der Gesundheitsforschung*, DZG), patient advisory mechanisms have become increasingly common. Nearly all centres have established Patient Advisory Boards (PABs) or advisory bodies, supported by a cross-centre working group that facilitates exchange and dissemination of best practices. The German Centre for Mental Health, although more recently established, has similarly embedded patient perspectives from the outset, including through a large-scale public survey, to inform its research agenda, an approach cited by interviewees as a national best practice in participatory agenda-setting.

Institutions active in cancer research in Germany have developed sustainable participatory structures and are widely regarded as national leaders in this area. Different research institutions, like the German Centre for Neurodegenerative Diseases (DZNE) and the German Cancer Research Centre (DKFZ), established a Patient Advisory Council (PAC) to integrate patient perspectives into strategic decision-making. Interviewees at the German Cancer Research Centre (DKFZ) described this development as strongly enabled by leadership-level prioritisation, which facilitated institutional buy-in and fostered a broader cultural shift towards patient involvement as standard practice. Established in 2018, the PAC draws on lessons from US NIH and UK models. It comprises 12-13 patients who advise across cancer areas rather than on specific tumour types, as well on other relevant topics such as data protection, data sharing, and gender-sensitive research. The Councils recommendations are formally addressed to the DKFZ Management Board and fed into strategic decision-making processes. Patient representatives are also included in the DKFZ Board of Trustees and participate in structured exchanges with the National Centre for Tumour Diseases (NCT), the German Consortium for Translational Cancer Research (DKTK), and a wider network of approximately 70 patient advocates, who are organised in Patient Research Councils embedded in the governance structure of the NCT.

Patient representatives have been an integral part of the NCT from the very beginning. The systematic integration of the patient perspective into all research activities and decision-making processes ensures that all activities of the NCT are aligned with the needs of patients. Furthermore, the Patients' Experts Academy for Tumor Diseases (PEAK) of the NCT provides all interested individuals with the

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[268] Forum Gesundheitsforschung, 2023, *Declaration of the Forum Gesundheitsforschung on the Active Involvement of Patients in Health Research.* https://projekttraeger.dlr.de/media/gesundheit/GF/Forum-GF_Erkl%C3%A4rung-Patientenbeteiligung_27-03-2023.pdf.

[269] Federal Ministry of Education and Research, *National Decade Against Cancer.* https://www.dekade-gegen-krebs.de/en/home/home_node.html.

[270] Lichtenberg, H., Müller, C., Lindeman, H. et al., 2025, *How to integrate patient and carer perspectives, methodological rigor, and ethics into biomedical research funding*, PLoS Biology, Vol. 23(12). https://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.3003551.

necessary knowledge, through practice-oriented courses and online seminars, to actively contribute to cancer research. In this way, patient representatives receive continuous and structured training.

Innovative participation methods have been developed in partnership with patients, including in the German Cancer Consortium (DKTK), which include digital tools such as *fragdiepatienten.de* that enable patient input from the earliest stages of research design. [271] The NCT also hosts an annual conference, "Patients as Partners in Cancer Research", fostering exchange and learning across institutions.

Other cancer research institutions have similarly developed robust participatory structures. The University Cancer Centre (UCC) Hamburg has operated a Patient Advisory Board for Research since 2020, advising on research direction and patient relevance.[272] Since 2022, UCC Hamburg and Schleswig-Holstein have offered training programmes to prepare patients to become patient ambassadors, enabling them to contribute effectively to research design and implementation.[273] [274]

At a national level, the National Decade Against Cancer has formalised its commitment to meaningful engagement through the Alliance for Patient Participation in Cancer Research, aimed at establishing new standards of practice. A complementary document, which was co-created with 130 contributors, most of them patient advocates, outlines principles for successful patient involvement in cancer research synthesises approaches related to ethics, resources, communication, and timing, emphasising that effective engagement enhances the relevance and impact of research. [275]

The German Research Foundation (DFG) also actively supports patient participation. Its Clinical Trials Programme requires projects to be patient-oriented and allows funding to be used for compensating patients involved in research activities.[276] Projects are encouraged to prioritise early and continuous patient participation, including during the planning phase, to increase the likelihood that outcomes reflect patient-relevant priorities. Finally, interviewees noted examples of patient-driven innovation. In one case, advocacy by the Type 1 diabetes community identified the need for a diabetes pump not yet available on the market, prompting research and development that directly improved patient quality of life.[277]

Interviewees identified several key enablers of effective participation: institutional commitment at senior leadership level, explicit funder requirements, dedicated funding, and specialised patient involvement coordinators. These coordinators play a critical role in mediating between researchers, management and patients, while supporting the administrative and logistical demands of engagement. Funding for preparatory phases, often up to 18 months, was also highlighted as best practice, enabling co-creation of study designs prior to submission of grants and formal project approval. The Network of University Medicine (NUM), established during the COVID-19 pandemic, was cited as an additional

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[271] DFKZ, *Patient Involvement in Cancer Research*. https://www.dkfz.de/en/patient-involvement.

[272] Oster, L., Hell, A., Moegling, I., Brütt, A.L., 2026, *Patient participation in health research in Germany: current status and future prospects*, Bundesgesundheitsblatt – Gesundheitsforschung – Gesundheitsschutz, Vol. 69(2), p. 182–188. https://pmc.ncbi.nlm.nih.gov/articles/PMC12852197/.

[273] Ibid.

[274] University Cancer Center Hamburg, *ONCOlleg*. https://www.uke.de/english/departments-institutes/centers/ucc-hamburg/patients/involvement-engagement/oncolleg.html.

[275] Federal Ministry of Education and Research, 2021, *Principles of Successful Patient Involvement in Cancer Research*. https://www.bmftr.bund.de/SharedDocs/Downloads/EN/2021/210907-unite-against-cancer.pdf?__blob=publicationFile&v=4#:~:text=1.3.,potential%20for%20all%20over%20time.

[276] German Research Foundation, *Clinical Trials Programme*. https://www.dfg.de/en/research-funding/funding-opportunities/programmes/individual/clinical-trials.

[277] Weinberger, N., Pobiruchin, M., Fritsche, A., Woll, M.A.S., 2023, *Do-it-yourself-Therapie für Menschen mit Typ-1-Diabetes*, Diabetologie, Vol. 19, p. 136-143. https://link.springer.com/article/10.1007/s11428-022-00970-w.

enabling structure, providing shared infrastructure and standardised approaches to patient-reported outcomes. [278]

Despite this progress, challenges remain. Stakeholders consistently highlighted difficulties related to patient recruitment and selection, training for both patients and researchers, limited operational guidance, and insufficient resources, particularly for activities not tied to individual projects. Researchers reported risks of being overburdened by regulatory and methodological requirements, leading in some cases to minimal or tokenistic approaches to patient engagement. A lack of shared definitions and mutual understanding of patient involvement further complicates implementation. Moreover, patient advocates are often inadequately compensated for their time and expertise, posing ethical and practical concerns, and limiting sustainability.

There are now formalised expense allowances and travel support for in-person meetings. For some institutions like DKFZ this reimbursement has been included from the start, while other financial compensations models are increasingly adopted such as in the NCT. Though, as described by interviewees, there are certain considerations that need to be made including tax and benefit implications that differ on an individual basis informing the amount they are willing to accept.

Interviewees highlighted several priorities for strengthening patient-centred health research and innovation in Germany. These include clearer incentives and funding structures, reimbursement for patient participation, expanded training and guidance, and greater use of digital tools to link research, healthcare systems, and patients. Early and consistent patient involvement in research decision-making and resource allocation, alongside recognition of time commitments and fair compensation, was seen as essential.

There was also strong support for greater European-level coordination and standardisation, such as establishing a European PROMIS centre to facilitate the translation and uptake of patient-reported outcome measures. More broadly, interviewees and available national-level documents emphasised the need for a cultural shift towards systematic patient engagement across the R&I lifecycle, supported by structural funding, practical guidance, and clearer funder requirements to help normalise these practices. [279]

Overall, Germany demonstrates growing institutionalisation of patient participation in health R&I, supported by strong political commitment and funding capacity. Further investment in enabling structures, incentives, and evaluation mechanisms can facilitate continued embedding of patient-centred approaches across research domains and decision-making processes.

5.2. The Netherlands

The Netherlands has a universal healthcare system, ruled by four health-care related acts, that blends public regulation with mandatory private insurance. All residents are legally required to purchase basic health insurance from private insurers, who must accept everyone and offer a government-defined benefits package covering essential care such as GP visits, hospital treatment, and prescriptions.[280] The Dutch primary care model is characterised by strong general practice, continuity of care, and a holistic, generalist approach to patient management.

In the Netherlands, patients' rights are ruled by different regulations: the Medical Treatment Agreement Act (WGBO), the Care and Coercion Act (Wzd), and the Healthcare Quality, Complaints

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[278] Network of University Medicine, *Connecting Research. Improving Health.* https://www.netzwerk-universitaetsmedizin.de/en.

[279] Forum Gesundheitsforschung, 2023, *Declaration of the Forum Gesundheitsforschung on the Active Involvement of Patients in Health Research*. https://projekttraeger.dlr.de/media/gesundheit/GF/Forum-GF_Erklärung-Patientenbeteiligung_27-03-2023.pdf.

[280] National Health Care Institute, 2016, *Health care in the Netherlands.* https://english.zorginstituutnederland.nl/documents/2016/01/31/healthcare-in-the-netherlands.

and Disputes Act (Wkkgz), including full information, informed consent, access to medical records, and shared decision-making (SDM) between patients and clinicians. [281] Notably, in 2020, the Netherlands formalised the SDM approach under the WGBO. [282]

Initiatives targeting this perspective are growing, with broad institutional and patient support, as echoed by one of the interviewed stakeholders from civil society. However, widespread implementation remains difficult as the cultural shift is still underway and the definition of this notion remains heterogeneous.[283] [284]

For example, one interviewee from the medical sector highlighted that, in paediatric care, rather than adhering to a single definition, patient-centredness is described more through a shared decision-making lens through "working together with patients and families to shape treatment decisions, research priorities, and outcome measures", while carefully considering the burden of participation. The interviewee emphasised that meaningful engagement depends on respecting individual preferences, with some patients wishing to take an active role in decision-making, while others prefer professional guidance. Ultimately, those interviewed also recognised how patients should be treated as whole persons, ensuring that broader outcomes such as wellbeing, fatigue, anxiety, and quality of life are considered alongside disease-specific indicators.

There are also examples of bottom-up approaches in the Dutch system such as the Young & Cancer Care Network which engages adolescents and youth in the oncology space in creating tools, systems, and research reflective of their shared inputs and needs.[285]

In the Netherlands, patient organisations have institutionalised roles in formal healthcare decision-making, including involvement in guideline development, policymaking, and research projects. In the country, there are three main umbrella organisations representing patients: the Dutch Patient Federation (Patiëntenfederatie Nederland),[286] MIND Nederland[287] and Ieder(in),[288] each one advocating for different patient groups and diseases areas.[289] They are recognised by the government as key actors within the system, alongside providers and insurers brought into decision making spaces.

Patient engagement however does not happen automatically. In several projects, interviewees spoke to the considerable effort that was made to involve patients. Researchers spoke to facing several challenges around identifying and engaging patients willing and able to participate in research processes, resulting in limited participation.

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[281] Adu-Gallant, C., Toelen, J., Sluiter-Post, J., De Coninck, D., 2024, *Knowledge Gaps and Bridges: The Relationship between the Awareness of General Patient Rights and the Awareness of Minors' Patient Rights in the Netherlands,* Children, Vol.11(1), https://pubmed.ncbi.nlm.nih.gov/38255422/.

[282] Elwyn, G., Joseph-Williams, N.,Edwards, A., 2025, *Implementation of shared decision making in the Netherlands: A case study*, Oxford Textbook of Shared Decision Making in Healthcare, p.127-130. https://academic.oup.com/book/60842/chapter-abstract/529685710?redirectedFrom=fulltext.

[283] van der Weijden, T., van der Kraan, J., Brand, P. L. P., et al., 2022, *Shared decision-making in the Netherlands: Progress is made, but not for all. Time to become inclusive to patients*, Z Evid Fortbild Qual Gesundhwes, Vol.171, p.98-104. https://pubmed.ncbi.nlm.nih.gov/35613990/.

[284] Building on this, Raaijmakers et al. presents patient-centredness as a shift away from single-disease management programmes toward a Person-Centred Integrated Care (PC-IC) approach that prioritises shared decision-making, personal goals, and holistic assessment, particularly for patients with multimorbidity. See: Raaijmakers, L. H. A., Schermer, T. R., Wijnen, M., et at., 2023, Development of a Person-Centred Integrated Care Approach for Chronic Disease Management in Dutch Primary Care: A Mixed-Method Study, Int J Environ Res Public Health, Vol.20(5). https://pubmed.ncbi.nlm.nih.gov/36900842/.

[285] Vandekerckhove, P., Harris,, B.H.L., Koizia, L., et al,, 2025, *Why We Need a Patient-Centered Innovation Renaissance: A Horizontal and Vertical Integration of Knowledge to Transform Care Pathways*, Patient Experience Journal, Vol.12(2), p.9-13. https://pxjournal.org/journal/vol12/iss2/3/.

[286] Dutch Patient Federation, *About Us*. https://www.patientenfederatie.nl/over-ons.

[287] National Platform for Mental Health, *About MIND – Improving Mental Health in the Netherlands*. https://wijzijnmind.nl/over-mind/over-mind.

[288] Ieder(in), *UN Convention on the Rights of Persons with Disabilities as a compass Everyone participates*, https://iederin.nl/.

[289] These three umbrella organisations represent respectively: patients with chronical and rare diseases, patients with mental health diseases and patients with disabilities.

Interviewees emphasised that a key way their organisations acknowledge the value of patient involvement is through providing remuneration for patient participation.[290] This was specifically mentioned as a lesson learned by academic stakeholders in terms of ensuring sufficient budget for remuneration at the point of budget discussions prior to grant submissions. Expecting patients to volunteer their time while other stakeholders are compensated is seen as inequitable and potentially undermining genuine engagement. According to the interviewee, recognising patients' contributions through appropriate payment is a fundamental step towards more sustainable and meaningful involvement and a true sign of operationalising patients as partners.

On the other hand, other interviewees mentioned that compensating patients can sometimes be counterproductive. In some cases, financial compensation may create tax-related issues or even cause patients to lose their social benefits. For this reason, a voluntary support format with a more modest payment is sometimes preferred by both patients and researchers, as it is less likely to affect their benefits. Using an intermediary stakeholder, as patients' federations, with whom a contract can be established is also preferred at times.

Another interviewee highlighted how it is important to allocate sufficient time for interviews and consider budgeting for an independent moderator during group activities, as external facilitation can help balance project interests and create the space needed for patients to meaningfully share their experiences and perspectives.

Finally, even when resources, time, and motivated researchers are available, it is not always easy to find patients willing to take part in project groups. Recruitment efforts may involve asking clinicians to reach out to patients, distributing flyers, or sharing calls for participation through social media. Despite these strategies, participation levels often remain limited. As the stakeholder noted, this may partly reflect the fact that some patients simply prefer "to remain patients rather than becoming actively involved in research activities".

The Dutch system serves as a strong example of how patient participation can meaningfully strengthen research by ensuring that patients' perspectives are genuinely taken into account and that studies reflect real societal needs.[291] For example, in funding programmes of the Netherlands Organisation for Health Research and Development (ZonMW)[292], patient representatives are actively involved in evaluating research proposals and shaping research agendas.

As highlighted by one interviewee, the patient-centred approach is becoming increasingly prominent and more systematically embedded in practice. Involving patients is gradually turning into a formal requirement, particularly when applying for public or project funding. For example, several funding schemes and projects now require applicants to demonstrate how patients are meaningfully involved in projects, for example, by including patient representatives on advisory boards or co-developing research objectives with researchers while also requiring explicit explanation for not including patients if researchers have not included it in their grant. One academic interviewee spoke to this change in grant structure as an important shift in the norms of how researchers think about their work.

This also translates into including diverse patient panels to assess the relevance of research and review broader, non-disease-specific proposals, while ensuring that disease-specific projects are connected to the relevant patient organisations, and that panel members have completed training to help them look beyond their own disease from a wider perspective.

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[290] van de Bovenkamp, H. M., Trappenburg, M. J., & Grit, K. J., 2010, *Patient participation in collective healthcare decision making: the Dutch model*, Health Expect, Vol.13(1), p.73-85. https://pubmed.ncbi.nlm.nih.gov/19719537/.

[291] Ahmed, A., van den Muijsenbergh, M. E. T. C., & Vrijhoef, H. J. M., 2023, *Person-centred care in the Dutch primary care setting: Refinement of middle-range theory by patients and professionals*, PLoS One, Vol.18(3). https://pubmed.ncbi.nlm.nih.gov/36893112/.

[292] The Netherlands Organisation for Health Research and Development (ZonMw), *About ZonMw: Working with knowledge to boost good health for al.* https://www.zonmw.nl/en/about-zonmw.

Applications of patient-centredness in health R&I in the Dutch system

Despite the lack of standardised and institutionalised processes, the Netherlands is at the forefront of patient-centred approaches in health R&I among EU MS, supported by the government and other Dutch authorities and stakeholders, like the previously mentioned ZonMW.

ZonMW is the main public funding body in the country for R&I in healthcare, prevention, and wellbeing. It funds R&I aimed at improving prevention, care, and quality of life, with a strong emphasis on societal impact, implementation in practice, and patient- and citizen-centred approaches. ZonMW works on behalf of the Dutch Ministry of Health, Welfare and Sport and the Netherlands Organisation for Scientific Research.

Even though the organisation has dedicated teams focused on patient involvement and has made it a mandatory component of research, a shared definition of patient-centredness remains largely implicit. In practice, its meaning and operationalisation vary depending on the context, meaning there is no one-size-fits-all approach. Patient involvement is required across all calls, with clear criteria to follow, and even meeting the minimum expectations is already considered valuable. However, participation is not treated as a static requirement; rather, it is designed to be dynamic and meaningful. This is often achieved through structured collaboration with specific patient organisations and strong links to research groups, ensuring that citizens and patients are treated as equal partners throughout the entire research process. A key priority is to ensure that patient participation is well organised and moves beyond tokenistic practices, instead promoting genuine co-creation and active collaboration between patients and researchers.

In order to do that, as highlighted by another stakeholder, having clear criteria is important to guide how and to what extent patients should be involved in the research process. One tool mentioned in this context is the Involvement Matrix developed by Utrecht University through a co-creation process with patients, which helps define different roles that patients can take on during a project. [293]

Interviewed stakeholders underlined the strong importance of embedding and valuing patient-centredness within the Dutch system, which is largely driven by political will. In fact, with government support, patient-centredness is reinforced, and patients' experiential knowledge could become increasingly recognised as legitimate and valuable scientific knowledge, as suggested by one interviewee. On the other hand, stakeholders also underline that this dependence on governance support could lead to the opposite outcome: if the government lessons its support of this approach anymore, public funds may decrease.

Stakeholders from civil society also highlighted how necessary it is to have other actors involved in mainstreaming this approach. This is the case, for example, of different umbrella patient organisations, like the Dutch Patient Federation, which promotes the integration of patient perspectives in the research agenda and in different funding schemes.

Patient-centred approaches in health R&I are also applied in the field of patient preference research, which plays an important role in informing pharmaceutical development and market decision-making at national and regional levels. For example, Erasmus University, a part of the PREFER IHI project, examined patient preferences for available treatment options for conditions such as rheumatoid arthritis and found a clear preference for oral treatments over injections; these insights were subsequently considered in regulatory deliberations at the EMA.[294]

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[293] Smits, D.W., van Meeteren, K., Klem, M. et al., 2020, *Designing a tool to support patient and public involvement in research projects: the Involvement Matrix*, Res Involv Engagem, Vol.6. https://pmc.ncbi.nlm.nih.gov/articles/PMC7296703/.

[294] Innovation health initiative, *PREFER*. https://www.ihi.europa.eu/projects-results/project-factsheets/prefer#:~:text= Where%20there%20are%20a%20variety,treatments%20which%20may%20be%20inconvenient..

At the Amsterdam University Medical Centre, PROMs are increasingly integrated into both standard care and research across hospitals and academic institutions. A recent initiative convened a range of stakeholders, including patients, clinicians and umbrella organisations, for several Delphi rounds to develop a set of generic PROMs, intended to form the basis of a non-disease-specific catalogue applicable across routine care settings.

The Dutch vision in relation to the EU R&I landscape

In relation to the broader EU R&I landscape, stakeholders underline how EU funding criteria for consortia often require the involvement of civil society organisations, but do not explicitly mention patient organisations. it is important to name patient organisations specifically rather than diluting them under the broader category of civil society. In this sense, if patient organisations are only mentioned under the label of "civil society", their role might become optional and unclear, and easily interchangeable with other organisations that do not represent patients' lived experience.

Finally, based on the Dutch model, one interviewee from the medical sector suggested that, at the EU level, a collaborative training programme and knowledge-sharing platform on patient involvement, bringing together experts to develop educational materials and exchange best practices under an EU stamp, could help strengthen capacity and encourage wider sharing of expertise across projects.

5.3. Belgium

Belgium operates a social health insurance system characterised by compulsory coverage and a governance structure that mixes federal and regional competencies in healthcare delivery and financing.[295] Belgium's health expenditure per capita is among the highest in the EU, standing at EUR 4,570 in 2023, almost 20% higher than the EU average, reflecting strong public investment in health services and research infrastructure.[296] [297] It is also home to a dense, internationally integrated research ecosystem and is the EU's leading MS for pharmaceutical R&D investment, with per capita R&D spending in 2022 more than five times greater (EUR 227, PPP adjusted) than the EU average.[298]

Belgium is deeply engaged in EU health R&I programmes such as Horizon Europe and in Joint Action networks, including for cancer expertise under the EU Mission on Cancer–related initiatives.[299] [300] Belgian institutions, including the Belgian Health Care Knowledge Centre (KCE), play an active role in European evidence generation networks such as EUnetHTA and the International Horizon Scanning Initiative, underpinning Belgium's engagement in collaborative R&I governance at the EU level.[301]

Patient-centred applications in health R&I

In Belgium, patient participation and involvement in healthcare decision-making and research have become progressively institutionalised through consultative and advisory mechanisms, albeit mostly

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[295] European Observatory on Health Systems and Policies, 2024, *Belgium: health system summary 2024*. https://iris.who.int/server/api/core/bitstreams/d7c86178-b23e-4bb4-b7c5-d2d8ced89ca6/content.

[296] Eurostat, 2025, *Healthcare expenditure statistics – overview*. https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Healthcare_expenditure_statistics_-_overview.

[297] OECD, 2025, *Health at a Glance 2025: Belgium*. https://www.oecd.org/en/publications/2025/11/health-at-a-glance-2025-country-notes_2f94481e/belgium_41a4cff0.html.

[298] OECD, European Observatory on Health Systems and Policies, 2025, *State of Health in the EU Belgium: Country Health Profile 2025*. https://www.oecd.org/content/dam/oecd/en/publications/reports/2025/12/country-health-profile-2025-country-notes_7e72146d/belgium_88f4fa48/7a3ecbc3-en.pdf.

[299] European Commission, *Horizon Europe Country Profile: Belgium*. https://dashboard.tech.ec.europa.eu/qs_digit_dashboard_mt/public/extensions/RTD_BI_public_HE_Country_Profile/RTD_BI_public_HE_Country_Profile.html?Country=BE.

[300] Sciensano, *JANE - Joint Action on European Networks of Expertise*. https://www.sciensano.be/en/projects/joint-action-european-networks-expertise.

[301] KCE, 2022, *International Collaborations*. https://kce.fgov.be/en/research-programmes/international-collaborations.

without formal decision-making authority.[302] KCE has played a significant role, formally recognising patients as "experts by experience" and has issued methodological guidance to support patient and public involvement across multiple stages of the research process, including topic selection, study design, validation of research tools, and interpretation of findings.[303] [304]

In addition, research-specific patient advisory structures have emerged within academic and hospital settings, reflecting a shift towards more upstream forms of patient involvement in research design. The Patient Advisory Board for Scientific Research (PAWO), established in 2020 at the Health Innovation and Research Institute (HIRUZ) of Ghent University Hospital (UZ Gent), was among the first permanent structures in Belgium dedicated specifically to integrating patient perspectives across scientific research rather than project-specific consultation.[305] [306]

PAWO functions as a standing advisory body supporting researchers across disciplines by mobilising the experiential knowledge of patients, relatives, and caregivers. PAWO members contribute to protocol development, funding applications, and patient-facing materials, and may be involved at any stage of research, including pre-clinical phases, with earlier involvement increasingly encouraged over time. Inspired by research practices in the UK and the Netherlands, the initiative was introduced in Belgium by the former head of HIRUZ. Since then, similar patient advisory structures have been established at UZ Brussels and UZ Antwerp.[307] [308]

The PAWO model illustrates the evolution of patient involvement in Belgium from ad hoc consultation towards more structured, consistent engagement, although remaining advisory in nature. Patient feedback is operationalised through written recommendations, online focus group discussions, and in-person meetings held several times a year, with particular emphasis on assessing feasibility, clarity of communication, patient relevance, and expected added value of research. PAWO does not provide formal training on scientific research to its members, reflecting an explicit choice to preserve the perspective of the "average patient". The PAWO Symposium from December 2025 highlighted that patient involvement through the advisory board increasingly occurs at earlier stages of research, including pre-clinical and protocol development phases.[309]

Patient involvement is a key pillar of research at UZ Gent. Proposals are strongly advised to pass through PAWO review, with an emphasis on demonstrating active engagement that influences research objectives. In this modern framework, genuine collaboration is valued over the traditional submission of letters of support.

Funder-driven requirements and priority-setting

Funding requirements have played a significant role in reinforcing patient-centred practices more broadly. Certain Belgian funders, notably Kom op tegen Kanker (Stand Up to Cancer), require concrete

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[302] KCE, 2012, *Models for Citizen and Patient Involvement in Health Care Policy*. https://kce.fgov.be/sites/default/files/2021-11/KCE_195C_citizen_and_patient_participation.pdf.

[303] Dauvrin, M., Koh, L., Cleemput, I., 2022, *Supporting patient involvement in health service research: development of a methodological guidance*, European Journal of Public Health, Vol.32(3). https://academic.oup.com/eurpub/article/32/Supplement_3/ckac130.162/6766578?login=false#google_vignette.

[304] KCE, 2019, *Position of KCE on Patient Involvement in Health Care Policy Research.* https://kce.fgov.be/sites/default/files/2021-12/KCE_320C_Patient_involvement_health_care_policy_research_Synthesis_0.pdf.

[305] University of Gent, *Patient Advisory Board for Scientific Research*. https://www.uzgent.be/nl/student-en-onderzoeker/patientenadviesraad-voor-wetenschappelijk-onderzoek.

[306] Patient Advisory Council for Scientific Research, University of Gent, 2020, *Annual Report 2020: Patient Advisory Council for Scientific Research*. https://hiruz.be/wp-content/uploads/jaarverslag2020.pdf.

[307] University Hospital Brussels, *Patient participation*. https://www.uzbrussel.be/fr/web/neem-zelf-uw-zorg-in-handen/participation-des-patients.

[308] University Hospital Antwerp, *Research, Innovation and Valorisation*. https://www.uza.be/en/research-innovation-and-valorisation.

[309] University of Gent, *Patients as partners in scientific research*. https://www.uzgent.be/nl/agenda/patienten-als-partners-in-wetenschappelijk-onderzoek.

and documented evidence of patient involvement from the earliest stages of research design, with patient committees accounting for a substantial share of funding decisions.[310] Since 2016, Kom op tegen Kanker has operated a Biomedical Patient Committee that contributes to 30 percent of the funding decision weight, alongside expert scientific review, to ensure patient added value and participation.[311] This represents a marked shift and has contributed to normalising early patient engagement in cancer research in Belgium.

From the private philanthropic funding side, the King Baudouin Foundation (KBF), operating across health and social domains, offers another distinctive vantage point. KBF's approach to patient-centredness is multi-layered, extending beyond participation within individual research projects to encompass the upstream co-design of funding calls and thematic priority-setting exercises. For the latter, KBF draws on the James Lind Alliance (JLA) framework to apply a participatory model, adapted to the conditions of each thematic programme area.[312] It has applied this approach across a range of health domains, most recently through its MIND10 project, where participatory priority-setting was used to inform the mental health research agenda for a new funding call.[313] Reflecting a conscious effort to surface needs least visible in the existing evidence base, recruitment for the priority-setting exercise was deliberately directed toward underrepresented populations, in particular conditions historically marginalised in research, rather than better-organised patient communities in more thoroughly researched disease areas.

KBF adapts the JLA approach to deliberately include researchers and policymakers throughout priority-setting workshops, rather than at the synthesis stage alone. Interviewees stressed that without upstream investment in researcher buy-in, patient-identified priorities risk being ignored or research questions cherry-picked to fit pre-existing agendas. Workshops for vulnerable populations and for researchers were also staged sequentially. Mixed sessions convened only once trust had been established in separate settings, illustrating the sensitivity required to prevent existing power asymmetries from reasserting themselves within participatory processes. KBF is also increasingly embedding patient and stakeholder involvement as a formal eligibility criterion rather than an evaluative preference. In thematic calls such as mental health and cystic fibrosis, the absence of a multi-stakeholder consortium renders a project ineligible at the outset, reflecting a structural shift from incentivising to explicitly requiring patient involvement for funding eligibility.

Challenges of meaningful engagement

Stakeholders raised the concern that the "patient expert" model, under which patients are trained to participate in scientific committees, can inadvertently strip away precisely the experiential perspective that makes patient contribution distinctive. KBF's preferred approach favours transdisciplinary conditions that allow patients and researchers to meet as full persons before the structured logic of a research agenda narrows the space of exchange. This concern about performative versus substantive engagement resonates with observations from the federal research institute level at Sciensano, where passive stakeholder meetings in which patient organisations are present but not genuinely activated, were described as producing the appearance of consultation without meaningfully steering research direction.

Interviewees also raised a broader concern about the lack of public empowerment over collectively generated research resources. Belgium's opt-out system for residual biological material for instance

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[310] Kom op tegen Kanker, *Patient Participation - Research and Project Funding*. https://www.komoptegenkanker.be/wat-we-doen/onderzoek-en-projecten-financieren/patientenparticipatie.

[311] Kom op tegen Kanker, 2025, *Regulations clinical studies Kom op tegen Kanker 2025*. https://www.komoptegenkanker.be/sites/default/files/media/2024-10/Regulations%20clinical%20studies%20Kom%20op%20tegen%20Kanker%202025_English.pdf.

[312] James Lind Alliance, *About Priority Setting Partnerships*. https://www.jla.nihr.ac.uk/about-priority-setting-partnerships.

[313] King Baudouin Foundation, 2025, *Bridging Gaps in Mental Health: 10 Research Priorities*. https://kbs-frb.be/en/bridging-gaps-mental-health-10-research-priorities.

legally protects individual rights but leaves most citizens unaware that leftover clinical samples may be used for non-commercial research. This represents a missed opportunity to build trust and meaningful public voice into how research capabilities are used. The 101 Genomes fund,[314] a patient-family-initiated dynamic consent model developed for Marfan syndrome, demonstrates what is possible when patients and their families have both information and agency. Yet this kind of initiative remains difficult to scale without dedicated resources and institutional support.

Operationalising needs-driven research

The NEED (Needs Examination, Evaluation and Dissemination) project, coordinated and implemented by KCE and Sciensano in partnership with other public bodies, exemplifies an ambitious national initiative to operationalise patient-centredness in health R&I through structured unmet needs assessment.[315] Launched in 2023, the project aims to compile patient and societal unmet health-related needs into a shared evidence base to inform needs-driven policy and innovation decision-making.[316] This aligns with emerging EU research priorities emphasising better integration of patient needs into R&I agendas, including through EU-commissioned studies on high-burden under-researched conditions.[317]

The rigorous methodological approach of the project underscores the importance of generating systematic evidence on unmet needs as a prerequisite for shifting from a supply-driven to needs-driven healthcare innovation.[318] This shift is also increasingly recognised as critical in EU R&I discussions, particularly those emphasised during the 2024 Belgian Presidency of the Council of the EU.[319] The NEED project's governance reflects strong policy anchoring, with two Belgian federal cabinet members participating in the project steering committee, underlining its strategic relevance for national priority-setting.[310]

Methodologically, the NEED project gathers both quantitative and qualitative data from multiple sources to assess unmet needs across health conditions. Sciensano draws on existing national datasets, to estimate unmet need indicators across multiple conditions without additional patient burden. These include the National Health Interview Survey, a cross-sectional population survey collecting self-reported data on health status, healthcare use, lifestyle, and socio-demographic characteristics. KCE collects additional quantitative and qualitative data through structured engagement with patients and clinical experts, complemented by literature reviews. All estimates and findings are compiled into the NEED database, where data can be accessed and downloaded for further use. This multi-source design reveals a structural tension: secondary data analysis can scale rapidly across dozens of conditions, while primary data collection through patient and expert engagement is richer in contextual insight but considerably more resource-intensive, particularly for rare diseases. The risk is that time pressures privilege approaches that can deliver faster outputs, inadvertently marginalising the experiential knowledge the project aims to centre.

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[314] 101 Genomes Foundation, *Genomics for rare diseases*. https://f101g.org/en/.

[315] NEED, 2023, *Launch of the NEED project*, https://health-needs.eu/index.php/en/news-en/launch-of-the-need-project.

[316] NEED Collaborators, 2024, *NEED: Needs Examination, Evaluation and Dissemination*. https://healthinformation.sciensano.be/shiny/NEED/.

[317] European Commission, 2023, *Scoping study on evidence to tackle high-burden under-researched medical conditions*, Publication for the Directorate-General of Research and Innovation. https://op.europa.eu/en/publication-detail/-/publication/eae32303-96e3-11ed-b508-01aa75ed71a1/language-en.

[318] KCE, 2022, *Identifying Patient needs: methodological approach and application*. https://kce.fgov.be/en/publications/all-reports/identifying-patient-needs-methodological-approach-and-application.

[319] Belgian presidency, Council of the European Union, *Priorities*. https://wayback.archive-it.org/12710/20241018132616/https:/belgian-presidency.consilium.europa.eu/en/programme/priorities/.

The NEED assessment framework published in 2025 sets out criteria and indicators to systematically assess unmet patient and societal needs for various health conditions.[320] This framework was submitted for consensus to 26 experts from 17 EU Member States, ensuring its relevance and acceptability across diverse European contexts. The resulting core version is designed to facilitate meaningful assessments that can inform policy and innovation prioritisation. The project's outputs include a series of methodological tools and reports, such as the NEED research toolbox and studies identifying and analysing unmet needs for specific health conditions.[321] These publications provide evidence-based inputs that can support both national and EU-level priority-setting and policy decisions.

Systemic gaps and pathways forward

The experience of interviewed researchers operating across institutions reveals structural asymmetries that characterise patient involvement in Belgian health R&I more broadly. At Sciensano, patient organisations may be invited to annual stakeholder consultations, but engagement remains largely passive. No institutional guidelines govern what patient involvement should look like, no dedicated support unit exists to assist researchers in designing it, and for work funded through core government allocations, no obligation to pursue it arises unless a specific funder or government mandate demands otherwise. Where no such requirement exists, researchers default to the minimum, such as a letter of support from a patient organisation. As one interviewee noted, even in structured stakeholder meetings at Sciensano, patient involvement leans passive: patient organisations are present, affirming the work being done, and suggesting future directions, but without active facilitation this input rarely substantively steers research priorities or design.

The funder-driven rather than institutionally embedded nature of patient involvement affects consistency and quality in practice. Even where funder requirements exist, there is little mid-project evaluation to verify that stated commitments are being honoured, and no standardised methodology to distinguish genuine engagement from tokenistic compliance. The absence of a coherent national framework means that the quality of patient involvement in any given study depends heavily on the individual researcher's prior experience, institutional affiliation, and access to networks.

Overall, Belgian stakeholders pointed to the need for institutional changes. Meaningful standardisation of patient-centred approaches necessitates legislative or regulatory embedding of patient involvement requirements across national and subnational funding instruments alongside structured guidance for researchers on how to meet those requirements meaningfully. Without an obligation, researchers will continue to find the path of least resistance. In the interim, two demonstrably effective interventions were identified: institutional patient involvement units modelled on PAWO, which create in-house infrastructure and expertise that individual researchers can access; and funder-level requirements that prompt reflection on patient involvement before it becomes an afterthought. Both are modest relative to the scale of the systemic gap, but the Belgian evidence suggests they reliably shift researcher behaviour and offer a replicable template for MS at earlier stages of building patient-centred practice into their research systems.

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[320] KCE, 2025, *NEED assessment framework 2025: EU expert consensus and core version*. https://kce.fgov.be/en/need-assessment-framework-2025-eu-expert-consensus-and-core-version.

[321] NEED, *Publications & research - Needs Examination, Evaluation and Dissemination*. https://health-needs.eu/index.php/en/research/publications-research-en.

6. REFLECTIONS AND RECOMMENDATIONS

KEY FINDINGS

Lessons from the case studies, interviews, the survey, and the literature allow for the compilation of several recommendations to strengthen patient-centredness in the EU and in MS. Best practices from case studies include the institutionalisation of patient involvement structures, ensuring availability of dedicated funding, mandatory patient-involvement requirements in R&I processes, need-driven priority setting that is patient-driven, providing opportunities for building capacities and skills for operationalising patient-centred practices, and having a 'just starting' mentality while keeping a continuous learning attitude. Furthermore, recommendations put forth in this section address enabling mechanisms, institutional learning platforms, and cultural change levers that would allow for stronger patient-centred health R&I in the EU.

6.1. National best practices that could be scaled up at the EU level

Drawing on the literature, document reviews, interviews, and case studies, several best practices can be aggregated concerning the application and operationalisation of patient-centred approaches in heath R&I in the EU and at a national level.

Effective patient-centric health R&I requires institutional infrastructure that goes beyond project-based consultation. Complementary upstream measures are needed to sustainably integrate and scale patient engagement comprising of human and financial resources, systemic enablers, and opportunities for learning and culture change.

Table 6 highlights a series of best practices identified in the included MS case studies. These practices and approaches can provide a beneficial foundation for selection of options to be applied and adapted across the EU and its MS.

Table 6: Selection of best practices and respective examples identified from MS case studies

Institutionalised patient involvement structures *The establishment of permanent and sustainable patient bodies at institutional and ministerial levels, formally integrated into decision-making processes, priority-setting, and embedded as a standard component of health R&I activities.*
• Belgium's Patient Advisory Board for Scientific Research (PAWO) at university hospitals exemplifies structured integration of patient perspectives beyond episodic consultations. Established as permanent bodies rather than project-based structures, these boards operate at an institutional level, thereby enabling ongoing engagement throughout the research lifecycle, as well as organisational learning. This approach also addresses capacity issues by maintaining dedicated patient cohorts across multiple research initiatives, thereby reducing recruitment efforts while building expertise among patient contributors. • The German Cancer Research Centre (DKFZ) initiated the Patient Advisory Council to operate at a strategic level by addressing cross-cutting issues such as data sharing and gender-specific research, rather than as part of individual projects. Patient representatives also participate in multiple advisory capacities, such as within university medicine structures and on the boards of trustees, thereby contributing their perspectives across governance layers. Critical to the success of these patient advisory bodies has been dedicated support infrastructure, in the form of dedicated patient involvement

coordinators and funding to support volunteer patient involvement. This institutionalised approach of permanent participatory structures has yielded notable advancements, such as 80 % of clinical trial review boards now including patient representatives.

- In the Netherlands, institutionalised patient involvement is demonstrated through the formal integration of patient-centred principles into national legislation and governance structures. For example, in 2020 the Netherlands integrated shared decision-making (SDM) within the legal framework of the Medical Treatment Agreement Act (WGBO), creating a clear and stable foundation for patient involvement in healthcare and related research practices.

Dedicated funding and mandatory patient-engagement requirements

The provision of dedicated funding mechanisms to support the operationalisation of patient engagement, including mandatory requirements for patient involvement within the research process and flexible funding streams that enable the co-development of patient-informed research priorities.

- Belgium's *Kom op tegen Kanker* (funding agency for cancer research) demonstrates how funding structures can embed patient involvement. Patient committees review proposals alongside scientific panels, with patient input required from the proposal development stage onwards. This ensures patient perspectives shape research from the outset. Making engagement a donor requirement rather than leaving it to researcher discretion creates normative pressure that drives culture change.
- In Germany, timing and infrastructure constraints are increasingly being addressed to enable meaningful patient involvement. The DLR Projektträger (German project management agency) provides dedicated funding for 18-month preparatory phases, allowing researchers to co-design studies with patients before projects are formally approved. This solves a common problem of the limited flexibility of traditional funding models to adapt to patient input once projects are funded.
- In the Netherlands, ZonMW has established a strong model to provide dedicated funding and internal teams to support patient engagement, making it a mandatory requirement across all research calls. While expectations are clearly defined through standard criteria, patient involvement must be adapted to different research contexts rather than following a single fixed model. Patient engagement is treated as a meaningful and dynamic partnership, supported through structured collaboration with patient organisations and close links to research groups. This ensures patients are involved as equal partners throughout the research process, promoting genuine co-creation and preventing tokenistic participation.

Patient identified needs-driven priority setting

Mechanisms that enable the systematic identification of needs articulated by patients, thereby informing agenda-setting and priority development within health R&I.

- Belgium's NEED project operationalises patient-centredness at the system level by developing systematic frameworks for unmet needs assessment. By generating the evidence base to inform policy prioritisation and funding allocation, the project aligns patient demand with research direction. The methodology's validation through consultation with experts from 17 Member States demonstrates potential for cross-national application while adapting for contextual sensitivities. Such an approach addresses a fundamental limitation of current R&I governance in which systematic mechanisms to incorporate lived experiences into research priorities are currently missing.
- In Germany, the Federal Health Research Framework Programme is a strategy that informs funding and prioritisation of health R&I. This iterative framework is updated around every ten years. The current Programme was developed collectively to ensure it was informed and reflected real world and patient-identified needs in R&I. This was done through participatory based workshops and discussions including with patients to ensure the Framework reflected patient, citizen, and research informed needs.
- In the Netherlands, patient-centredness is a core principle of research priority setting, supported by strong political will and government backing. Patients' experiential knowledge is increasingly recognised

as legitimate and valuable evidence, helping ensure that funded research reflects real societal needs. This model is operationalised through structured involvement of patients' federations and patient participation, including diverse and trained patient panels that assess research relevance beyond single-disease perspectives. Disease-specific proposals are also systematically linked to the appropriate patient organisations.

Opportunities for capacity and skill building

The establishment of enabling training structures to equip patients with the skills and knowledge required for meaningful engagement in research and innovation, alongside capacity-building for researchers and other stakeholders to understand, implement, and mainstream patient-centred approaches.

- The European Patients' Academy on Therapeutic Innovation (EUPATI) addresses a fundamental capacity constraint in patient-centred R&I by equipping patient advocates with expert-level knowledge in medicines development. Launched through the Innovative Medicines Initiative (which became the IHI in 2022) and now operating as an independent foundation, EUPATI has trained over 150 patient experts through its rigorous Patient Expert Training Programme. EUPATI is a multi-layered enabling structure providing an intensive credentialing programme for patient experts capable of serving on ethics committees and advisory boards; an open-access multilingual Toolbox; and National Platforms in 24 MS that deliver locally grounded training while maintaining quality standards. Crucially, EUPATI trains both patients and professionals from academia and industry through co-created programmes, creating a shared language and mutual understanding that enables more meaningful partnership.
- The Network of University Medicine (NUM) in Germany, established during COVID-19, provides shared research infrastructure across 36 academic medical centres, and standardised approaches to patient-reported outcome measures, reducing the burden on individual researchers while ensuring consistency across institutions. Such central/pooled infrastructure enables smaller institutions to mainstream patient-centred research and researchers to benefit from quality-assured, standardised resources.

'Just starting' patient-centred approaches using a continuous learning mindset

Rather than waiting for ideal conditions, patient-centred approaches should be integrated and implemented proactively. This requires a flexible, iterative methodology, grounded in continuous learning and a willingness to adapt practices in response to emerging evidence and contextual realities.

- Several MS-level stakeholders, for example in the Netherlands, emphasised the importance of 'just starting' patient engagement or involvement at any level recognising the continuous learning that is to be applied rather than deferring action until optimal patient and public involvement frameworks are fully developed. An iterative, developmental approach recognises that even within large organisations with varied levels of awareness and interest in patient engagement, foundational work, however imperfect initially, enables subsequent activities to become more meaningful and impactful.
- Conducting any activity for the first time is challenging and requires motivation and commitment, with senior management endorsement proving particularly critical for facilitating buy-in from other staff members.[322] Stakeholders across MS reiterated how support from leadership of an organisation or institute is a critical enabler for implementation, scale up, and uptake.

Source: Authors' own elaboration.

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[322] Jobson, E., Garcia, M., Sharek, D., et al., 2024, *Embedding patient engagement in the R&D process of a life sciences company through co-creation with a patient expert R&D board: a case study*, Res Involv Engagem, Vol.10. https://pmc.ncbi.nlm.nih.gov/articles/PMC11539748/#CR12.

6.2. Recommendations on strengthening patient-centric health R&I in the EU

Strengthening patient-centredness in EU health R&I requires coordinated action across regulatory, funding, and operational domains. These recommendations address structural enablers, procedural mechanisms, and cultural transformation as necessary precursors for sustained change.

The following section outlines a set of macro-level policy recommendations, structured around specific areas to reform. Each overarching recommendation is supported by thematic recommendations and specific actions designed to facilitate their implementation.

a. Area 1 - Strengthening EU regulatory and governance frameworks to systematically embed patient-centredness across the health R&I lifecycle

R1. Establish a patient-centred health R&I strategy and guidance at EU level

- Identify and establish structured guidance on patient-centred notions in health R&I through collective means and build off existing EU-funded and evidence-based work. This could be higher level in facilitating wider applicability to EU frameworks and instruments.
- Create a clear and consistent roadmap for patient involvement across the R&I lifecycle and highlight opportunities for engagement in existing EU bodies, instruments, and mechanisms such as joint clinical assessments (JCAs).
- Collect and maintain an open access EU catalogue of best practices and patient-centred approaches in the health R&I space across the research lifecycle to provide guidance that is practical, applicable, and real world informed.

R2. Establish mandatory patient involvement standards across EU health R&I funding instruments

- All EU health R&I funding programmes and calls should include explicit patient involvement requirements within proposal criteria, accompanied by clear evaluation standards. Where patient-centred approaches are not feasible or appropriate, applicants should be required to provide a justified explanation.
- Evaluation panels should include patient representatives and non-academic experts with voting rights when reviewing R&I proposals. Panel representation should be made more transparent.
- Patient-centredness should be assessed alongside scientific excellence in funding decisions.
- Standardised reporting on patient involvement should be mandatory in both applications and final project deliverables across EU-funded programmes, with MSs encouraged to adopt aligned standards.
- Explicitly mention patient organisations as distinct from civil society organisations (CSOs) when describing requirements for composition of consortia of EU funded projects.

R3. Integrate patient-identified and informed unmet needs into EU research priority-setting

- Transition to mandatory patient inclusion in R&I project call design, to ensure research is consistently aligned with real patient needs, rather than depending on individual researchers' or project choices. If involvement is not feasible (e.g., preliminary cellular level research, etc.), applicants should be required to provide a clear justification and describe alternative ways to safeguard patient relevance.

- The European Commission should establish systematic mechanisms for translating patient needs into research priorities, building on Belgium's NEED methodology.[323] This requires dedicated funding for unmet needs assessments conducted through validated frameworks involving patient communities, complemented by real-world evidence and patient-reported outcomes data.
- Unmet needs assessment findings should inform thematic priorities within Horizon Europe successor programmes, the European Competitiveness Fund, and relevant Joint Undertakings.
- This NEED based methodology could also be scaled at a national level in MS to provide context informed, patient-identified needs across health domains to inform national-level agenda setting. This would also require dedicated public funding or blended funding options to incentivise uptake and sustainable integration.

R4. Facilitate meaningful participation in HTA processes

- Build a clear participation roadmap for HTA processes to facilitate meaningful and harmonised patient involvement across the EU.[324]
- Communicate consistent timelines and expectations for patient involvement opportunities in JCAs and Joint Scientific Consultations early to all stakeholders.
- Ensure availability of oral and written contribution opportunities to align with EMA and leading HTA agency practices, facilitating meaningful participation.
- Create specific teams or identify specific individuals responsible for patient engagement in HTA agencies.[325]

R5. Streamline minimum standards for effective patient engagement

- Offer different ways to participate across all research phases, including priority setting, spanning virtual, digital, and in-person formats, as well as oral and written contributions.
- Clarify and communicate roles and responsibilities for patients, researchers, and other stakeholders from the outset, accompanied by clear information on how patient contributions will be collected, used, and integrated into research priorities and project outputs.
- Develop communication and participatory materials using plain, nontechnical language and translate into multiple languages to ensure accessibility.
- Provide ample time (weeks/months) prior to opening participation opportunities as well as plenty of time (multiple weeks) to fulfil participation tasks
- Make funding available to support travel and volunteer stipends for patients and patient organisations to ensure equitable and representative participation.

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[323] KCE, 2022, *Identifying Patient needs: methodological approach and application.* https://kce.fgov.be/en/publications/all-reports/identifying-patient-needs-methodological-approach-and-application.

[324] Pickaert, A.P., 2025, *Patient Involvement in Health Technology Assessments: Lessons for EU Joint Clinical Assessment*, J. Mark. Access Health Policy, Vol.13(3), 2025. https://www.mdpi.com/2001-6689/13/3/38.

[325] Ibid.

b. Area 2. Funding and resource allocation for operationalising, tracking, integrating and sustaining patient-centred approaches

R6. Create designated systems to capture and track investment in patient-centred R&I in the EU

- Develop a coherent framework to define and document patient-centredness in the context of health R&I to enable standardised capturing of investment across the EU health R&I ecosystem.
- Using this framework, a mapping exercise can be done to document current funding allocations and integration practices across programmes and Member States.
- Monitoring indicators can be created to track investment and outcomes over time.

R7. Include dedicated budget lines for patient involvement in health R&I grants

- Health R&I grants at an EU or MS level should provide clear language on how available funding could be used for patient involvement across the research process.
- Examples of ways a dedicated budget could be allocated to support patient involvement could include compensation for patient time, training for both patients and researchers, accessibility accommodations to ensure diversity of perspectives, and coordination/operational costs for patient organisation involvement.
- Certain budget quotas should be established to incentivise the integration of patient-centred approaches which could be tied to certain evaluation criteria in proposal decision making.

R8. Establish preparatory funding mechanisms for co-design in shaping research

- Make funding available for short-term pre-research that is dedicated to co-creation research proposals prior to submission.

R9. Provide specified funding for scale up, translation, or continuation of patient-centred deliverables

- A recurring weakness across projects is that high-quality patient-centred toolkits, guidelines, and engagement frameworks frequently lose momentum once project funding ends. To address this, the European Commission should introduce dedicated follow-on funding streams specifically designed to scale, operationalise, or integrate validated patient-centred outputs into EU and national systems. This could include:
    - Translation and implementation grants to embed validated toolkits and guidelines into EU agencies, Joint Undertakings, JCA and national research frameworks.
    - Scale up extensions for high-performing projects (12–24 additional months) to transition deliverables from pilot phases to institutional uptake.
    - An EU funded, hosted, and managed repository of developed tools, frameworks, and contacts to facilitate wider dissemination of materials to allow for broader uptake.

R10. Include patient-centred notions in EU funding and domains specific strategies

- Future Horizon Europe strategic plans should formally acknowledge the role of end users including patients, carers and affected communities in shaping research, innovation, and health system reform. This could then in turn be operationalised through mandatory patient engagement criteria in work programme regulations, performance indicators tied to meaningful involvement, and earmarked funding to support patient engagement capacity.

- Forthcoming initiatives like the next EU Non-Communicable Diseases (NCD) Plan should integrate patients in design and governance aspects. Learning from the Europe's Beating Cancer Plan, structured consultation mechanisms, advisory boards with patient representation, and co-creation processes can ensure policies reflect lived experience. For the NCD plan, this should include formalised patient roles in priority-setting, monitoring frameworks and implementation processes.

c. Area 3. Prioritise and support capacity building for patient-centred practice across stakeholders and promote continuous learning ecosystems

R11. Facilitate patient engagement training for EU-funded researchers and evaluators

- Establish standardised competencies on patient-centred health R&I applicable for implementors and consortia.
- Institutionalise training for principal investigators and consortium partners on patient engagement methods as eligibility criteria for EU funding. Training should include components on power sharing, patient empowerment, communication with diverse literacy levels, co-design facilitation techniques, collecting and interpreting PROMs/PREMs, etc.
- Provide training for proposal evaluators on assessing meaningful patient engagement quality to avoid tokenistic box-ticking.

R12. Include provisional skill building activities for patient-centred R&I in relevant projects

- Recognising that meaningful participation requires organisational capacity and understanding, support the inclusion of skill-building activities prior to project implementation. These may take the form of training programmes or mentorship models that equip researchers and coordinators with a clear understanding of what meaningful patient involvement and participation entails. Embedding such preparatory mechanisms is critical to ensuring consistent buy-in and ownership of patient-centred principles across all project phases and among all contributing actors. For instance, this can be included as a mandatory preliminary activity in IHI proposals.
- Support the integration of existing and previously EU-funded projects that have developed structured curricula, training, and tools on patient-centred approaches including patient involvement, engagement, and participation.

R13. Implement iterative learning mechanisms and feedback loops with accountability mechanisms

- The EU should mandate regular evaluation of engagement practices with findings publicly reported. This evaluation should document systematic barriers, facilitators, and modifications across projects and MS, contributing to an evidence base that demonstrates which approaches result in meaningful rather than tokenistic engagement. Public reporting of evaluation findings creates accountability while enabling learning across projects and MS.

d. Area 4. Knowledge capture, the generation of evidence on impact, and the creation of dedicated spaces to showcase and disseminate best practices

R14. Facilitate integration of patient reported outcomes into health R&I

- Establish a regional European PROMIS centre to facilitate the translation and uptake of PROMs. This centre, like that of the United States, can establish a bank of PROMs and offer technical assistance to build capacity and integration of PROMs in research across the EU and MS.[326]

R15. Develop and validate standardised frameworks to collect and evaluate patient-centred approaches

- Build standardised tools for reporting of patient involvement in health R&I leveraging existing frameworks such as the GRIPP2 checklist (Guidance for Reporting Involvement of Patients and the Public) to facilitate broader collection, consistent reporting, and increased interoperable interpretation of patient involvement across the R&I ecosystem.327
- Integrate developed indicators for evaluating patient-centredness into monitoring and evaluations frameworks for EU funding instruments health R&I including Horizon Europe and IHI.
- Fund dedicated research to develop, test, and validate evaluation frameworks applicable across diverse research contexts, ensuring patient-centredness (involvement, engagement, etc.) can be rigorously assessed including its impact.

R16. Establish centralised EU platforms to connect stakeholders

- Create a centralised digital platform to showcase research projects and engagement opportunities for patient organisations, patient representatives, research experts, and other relevant stakeholders.
- Develop and maintain an up-to-date database to enable researchers and managers to identify, search for, and engage with established patient organisations and patient experts across a range of domains.
- Establish an EU-wide working group consisting of active stakeholders and implementors in the field of patient-centred health R&I to allow for proactive learning and sharing that goes beyond MS borders.
- Host, co-host or sponsor an annual conference to showcase learnings and lessons across the EU in patient-centred health R&I across health domains.

R17. Create an EU-level repository of patient involvement best practices & metrics

- Establish a centralised repository for the systematic capture and curation of knowledge and tools, documenting patient engagement and involvement methodologies, case studies, and lessons learned across the EU, MS, and internationally.

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[326] Bingham, C.O. III, Bartlett, S.J., Merkel, P.A., et al., 2016, *Using Patient Reported Outcomes and PROMIS in Research and Clinical Applications: Experiences from the PCORI Pilot Projects*, Qual Life Res, Vol25(8), p.2109-2116. https://pmc.ncbi.nlm.nih.gov/articles/PMC4946989/.

[327] Staniszewska, S., Brett, J., Simera, I., et al., 2017, *GRIPP2 reporting checklists: tools to improve reporting of patient and public involvement in research*, BMJ, Vol.358, https://pmc.ncbi.nlm.nih.gov/articles/PMC5539518/.

  - Ensure this is well maintained and kept up to date with ongoing research, including EU funded research and allow for options of submissions that could be reviewed to be included in the platform.
  - Include points of contact for experts implementing the approaches highlighted on this platform to allow for ease of connectivity.

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ANNEX

Methods

For this study, a mixed-methods design was employed, integrating a survey, document review, literature review, qualitative data collection, and triangulated analysis. The literature review comprised desk-based research drawing on peer-reviewed and grey literature identified through systematic keyword searches across relevant databases. The document review focused on publicly available EU-level materials, including work programmes, strategic documents, and performance and evaluation frameworks.

In addition, a preliminary survey was developed and disseminated to umbrella organisations and patient organisations across the EU, remaining open between November and December 2025. Twelve responses were received from six patient organisations, three umbrella organisations, and three self-reported other organisations from across the EU. 17 semi-structured interviews were also conducted with relevant stakeholders at the EU level and within selected MS to inform in-depth case studies (Table A1). Drafted case studies were shared with interviewees from respective MS for review and additional input prior to finalisation.

Germany, the Netherlands, and Belgium were chosen due to their documented experience in implementing patient-centred approaches in health R&I, offering potentially transferable lessons and best practices for cross-country learning and exchange.

Table 7: Overview of stakeholder organisations interviewed

Patient organisations	European Organisation for Rare Diseases
	European Patient Forum
	European Regional and Local Health Authorities
	The European Patients' Academy
Germany	German Centre for Cardiovascular Research
	DLR Projektträger
	Charite – Universitätsmedizin Berlin
	Federal Ministry of Education and Research
	The German Cancer Research Center
Netherlands	Dutch Patient Federation
	The Netherlands Organisation for Health Research and Development
	Amsterdam Medical Centre
	Erasmus University Rotterdam
Belgium	Belgian Health Care Knowledge Centre
	Health Innovation and Research Institute of Ghent University Hospital
	King Baudouin Foundation
	Sciensano

Source: Authors' own elaboration.

Limitations

The study did not review individual EU-funded projects to assess the extent to which patients were engaged in decision-making processes.

Three case studies were selected based on the availability of accessible and relevant data in these countries and the time available to complete the study. Information presented therefore may not be applicable across all MS, each of which operates within distinct institutional, political, and health system contexts.

Participant recruitment relied on targeted identification of survey respondents and interviewees to ensure relevance to the study's objectives; however, this approach may have excluded additional stakeholders with pertinent insights. Despite efforts to engage several additional stakeholders at a national level, challenges with unavailability and time constraints resulted in the inability to schedule interviews potentially resulting in missed opportunities to gather information. Interviews with EU-level institutional bodies could not be conducted due to scheduling constraints and limited availability, which restricted the ability to capture these perspectives directly.

Finally, the analysis relied predominantly on qualitative data, as relevant quantitative data, particularly financial data related to funding allocations within health R&I, were largely unavailable.

This study explores how patient-centredness is understood and applied in research and innovation (R&I) across the European Union. Drawing on case studies from Germany, the Netherlands, and Belgium, and insights from a range of stakeholders, it aims to inform future policy and practice. While patient-centredness is gaining prominence at the EU level, its implementation remains variable across Member States and funding instruments. Overall, the findings highlight both the recognised value of patient involvement in enhancing research relevance and the need for more coherent structures, definitions, and approaches to support its consistent uptake.

This document was provided by the Policy Department for Transformation, Innovation and Health at the request of the Committee on Public Health (SANT).

PE 786.414
ECTI/B/SANT/IC/2025/006
Print ISBN 978-92-848-3595-9 | doi:10.2861/9008254 | QA-01-26-100-EN-C
PDF ISBN 978-92-848-3594-2 | doi:10.2861/8489890 | QA-01-26-100-EN-N