UNIFIED

Unifying Framework for Patient-centred Clinical-study Endpoints derived from Digital Health Technologies

PRESS RELEASE

UNIFIED Launches to Put Patient Voices at the Heart of Healthcare Decisions

Rotterdam, 4 November 2025 – Erasmus University Rotterdam and Pfizer lead UNIFIED (Unifying Framework for Patient-Centred Clinical-study Endpoints Derived from Digital Health Technologies), a five-year, €27 million global public-private partnership funded by the Horizon Europe Innovative Health Initiative Joint Undertaking. The project aims to develop a harmonised, internationally aligned approach, integrating patient-centred clinical-study endpoints to support the full benefit of a therapy to patients.

Clinical outcomes that are measured in clinical trials and used to guide regulatory and health technology assessments often fail to represent what truly matters to patients. UNIFIED seeks to close this gap by uniting 40 partner organisations – including leading universities, hospitals, patient organisations, clinical guideline organisations, and industry partners from Europe, Canada, and the United States. The project will build an evidence-based framework and consensus-based recommendations, providing structured guidelines, protocols, and standards to: (i) integrate patient preference information (PPI), clinical outcome assessments (COAs), and/or digital health technology (DHT)-derived measures into healthcare decision-making, and (ii) determine the minimal (clinically) important difference (MCID/MID) in a clinical-study endpoint, based on what is meaningful to patients. By combining these types of patient-centred data, UNIFIED offers a robust view of the full benefits of a health intervention through a truly patient-focused lens.

Why action is needed now

Despite increasing recognition by industry, regulators, and health technology assessment (HTA)/payer bodies of the need to incorporate patient perspectives into decision-making, this is not yet common practice. UNIFIED will tackle this urgent problem thanks to available (i) technological advancements (e.g., Artificial Intelligence, telemedicine); (ii) policy support (e.g., patient-focused drug development and patient engagement requirements); (iii) cultural shifts in healthcare (e.g., growing focus on patient experiences and communication); and (iv) different types of patient-centred information (e.g., patient preferences, patient-reported outcomes, and digital health measures).

"We see this as a breakthrough project. By combining the expertise of public and private institutions, we hope to close the gap that patients, clinicians, industry, academics, and policymakers have long faced. It's ambitious, it's necessary, and it directly addresses what patients have been seeking."

- **Prof. Dr. Esther de Bekker-Grob**, Professor of Health Economics & Health Preferences, Erasmus University Rotterdam

What UNIFIED will deliver

Over the next five years, UNIFIED will take concrete steps to ensure that the evidence used to evaluate health interventions reflects patients' needs, preferences, and priorities. The project will develop a comprehensive, harmonised, and internationally aligned framework to integrate PPI, COAs, and DHT-derived measures. It aims to determine MCID/MID in a patient-centred, DHT-derived clinical-study endpoint, along with consensus-based practical recommendations for using the 'UNIFIED Framework' across research and development, clinical practice, regulatory review, HTA, and reimbursement decision-making.

Medical use cases in five different disease areas – paediatric radiation oncology, lung cancer, Parkinson's disease, obesity, and juvenile idiopathic arthritis – will generate evidence to support the development of the framework. By working across such diverse conditions, UNIFIED will ensure that the framework can capture patient-centred benefits in both rare and common diseases, for children as well as adults.

Collaboration with all stakeholders will be key to the success of UNIFIED. Regulators, HTA bodies, clinicians, and patient organisations will be involved throughout to ensure that the framework and recommendations are both practical and applicable in real-world decision-making. The ambition is clear: by the end of UNIFIED, truly patient-centred measures of clinical benefit should no longer be the exception. They should become an integral part of healthcare decision-making across these stakeholders.

"This project will deliver not only an evidence-based framework but also one that is practical, sustainable, and accessible. For too long, the outcomes that matter most to patients have been overlooked. The European Patients' Forum plays a key role in the project by ensuring that patient perspectives guide every stage of the work and healthcare outcomes mirror patients' daily realities and priorities.''

- **Bianca Pop**, European Patients' Forum Project Officer.

The impact five years from now

The successful completion of UNIFIED will mark a turning point in how healthcare systems define the value of treatments. Today, decisions are driven mainly by clinically objective measures such as disease or symptom severity and clinical progression. In five years, with the UNIFIED Framework in place, decision-making will also be guided by novel measures that capture a more comprehensive range of patient-centred benefits. For patients, this shift means that treatments aligned with their needs and values are more likely to be developed, approved, and reimbursed. For clinicians and health systems, it will offer a fuller picture of how treatments impact what matters to patients and take this into account. For industry, UNIFIED will provide a clearer path to using patient-centred endpoints in clinical studies. For policymakers, it will facilitate more targeted resource allocation toward solutions that best meet patients' needs.

Our Partners

Academic, Clinical, and Public Health Institutions

1. Erasmus University Rotterdam (NL)
2. Medical University of Vienna (AT)
3. University of Amsterdam (NL)
4. Hochschule Neubrandenburg (DE)
5. University of Calgary (CA)
6. University of Twente (NL)
7. Catholic University of Leuven (BE)
8. University of Milan (IT)
9. Jagiellonian University (PL)
10. Princess Máxima Center (NL)
11. University Medical Centre Utrecht (NL)
12. European Institute of Oncology (IT)
13. Helsinki University Hospital (FI)
14. Andalusian Public Foundation Progress and Health (ES)
15. The Hospital for Sick Children (CA)
16. H2O Pan-European Health Outcome Observatory (DK)
17. PanCare (NL)
18. European Academy of Neurology (AT)
19. Fondazione Policlinico Universitario Agostino Gemelli IRCCS (IT)

Patient/Citizen Organisations

20. European Patients' Forum (BE)
21. Cassie and Friends: A Society for Children with Juvenile Arthritis and Other Rheumatic Diseases (CA)
22. Childhood Cancer International Europe (NL)
23. The European Coalition for People living with Obesity (IE)
24. Parkinson's Europe (BE)

Industry and Small & Medium Enterprises

25. Pfizer Inc (US)
26. AbbVie Inc (US)
27. AstraZeneca AB (SE)
28. F. Hoffmann-La Roche AG (CH)
29. Janssen Biologics BV (NL)
30. Mölnlycke Health Care AB (SE)
31. Novartis Pharma AG (CH)
32. Novo Nordisk A/S (DK)
33. Siemens Healthineers AG (DE)
34. UCB Biopharma (BE)
35. IQVIA Solutions Belgium (BE)
36. Amgen (BE)

37. GenAIz (CA)
38. John Snow Labs Inc (US)
39. Collaborate Project Management (DE)
40. Promptly – Software Solutions for Health Measures SA (PT)

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