UNIFIED

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

MEDIZINISCHE UNIVERSITÄT WIEN

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Integrating patient-reported outcomes, preferences and digital measures A landscape analysis across UNIFIED use cases

Baseline resources, shared outcome domains and opportunities for alignment

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ABSTRACT

BACKGROUND Differences in resources, data practices and digital maturity complicate joint use of patient-reported outcomes, preferences and digital measures across conditions.

OBJECTIVES Inventory site resources, identify feasible shared domains and establish a baseline for tracking development during UNIFIED.

METHODS Multidisciplinary teams completed structured templates for five clinical settings. A separate JIA preference study was added to the comparison. The synthesis mapped care pathways, measures, digital systems and research capacity.

RESULTS The clinical settings report multidisciplinary care and overlapping domains in symptoms, function, fatigue or sleep, psychosocial burden and quality of life. Instruments and digital deployment vary. JIA contributes preferences about trial outcomes and methods of collection.

CONCLUSION Shared domains support further alignment and staged evaluation. Measure equivalence, implementation capacity and interoperability need site-level confirmation.

OBJECTIVES AND SCOPE

The assessment maps current resources, identifies compatible outcome domains and gaps, and establishes a baseline for tracking changes throughout UNIFIED.

The inventory covers five clinical settings and one nonclinical preference study.

Centre or study	Population and setting
Helsinki University Hospital, Finland	Parkinson’s disease
Princess Máxima, Netherlands	Childhood cancer survivorship
Uniwersytet Jagielloński Krakowie, Poland	Chronic disease and metabolic risk
Fondazione Policlinico Gemelli, Italy	Paediatric radiotherapy
Istituto Europeo di Oncologia, Italy	Lung cancer
University Medical Center Utrecht, Netherlands	Young people and parents, outside clinical care

APPROACH AND METHODS

Multidisciplinary teams completed standardized templates describing services, populations, care pathways, measures, digital systems, patient involvement and research capacity.

The comparative synthesis mapped clinical outcome assessments, patient preferences and digital measures across settings to identify shared domains and gaps.

Reported practice, planned activity, missing information and non-applicability remain distinct. The landscape was assessed between February and September 2026.

BASELINE AND PLANNED FOLLOW UP

Preserve a validated baseline and repeat the assessment at agreed project milestones. Compare each setting with its own starting point before making cross-site comparisons.

- **Data collection and quality:** Have centres seen change in the completeness, consistency, or availability of clinical data, PROMs, and PREMs?
- **Cross-centre alignment:** Have differences in definitions, measures, and collection schedules narrowed?
- **Staff capacity and collaboration:** Has participation strengthened research skills, multidisciplinary working, or patient involvement?
- **Feasibility and sustainability:** Which project processes can continue in routine practice, and what resources would this require?



RESULTS FROM BASELINE

Clinical settings report multidisciplinary, patient-centred care. Recurring domains include symptoms, function, fatigue or sleep, psychological burden, health-related quality of life and patient experience. Tools and coverage vary.

Alignment is strongest at the domain and care-process level. Shared concepts do not establish interchangeable scores.

Reported measures and digital activities

Entry	Measures and patient information	Digital activities
Parkinson’s	15D, PDQ-39, BDI and motor assessments Satisfaction and preference research	Wearables, video tasks and remote DBS programming
Childhood cancer survivorship	PedsQL generic and fatigue scales Risk-based clinical follow-up and experience questionnaire	No dedicated DHT reported
Obesity	Lifestyle and history questionnaires BMI, blood pressure and laboratory measures	Online questionnaires CGM in some patients
Pediatric radiotherapy	PedsQL, distress, pain and anxiety tools Satisfaction and wearable feasibility	Smartwatch measures of heart rate, respiration and movement
Lung cancer	EQ-5D and EORTC tools Symptom, adherence and satisfaction reports	Cureety and wearable rings Linkage under exploration
JIA	Planned adult and youth EQ-5D forms Preferences for trial outcomes and collection methods	DHT is a preference topic No DHT-derived measures

The assessment supports alignment of selected domains while retaining condition-specific measures. Variation in instruments, digital deployment and research suggests limited feasibility of alignment at the tool-specific level.

CONCLUSIONS AND APPLICATIONS

Common outcome domains and care models support a staged, cross-condition implementation study. Repeating the baseline can identify changes in outcome collection, digital monitoring and study capacity over time.

The project agreed to implement an EQ-5D measure across use cases to strengthen alignment while leveraging currently collected measures. Findings from the landscape assessment also informed a list of required elements for protocols and informed consent forms.

NEXT STEPS

A follow-up landscape assessment at the same centres would help show what changed during the project, which capabilities were sustained, and which barriers remain. Even though the studies are observational and non-interventional, participating centres may develop new ways of collecting outcomes, managing data, engaging patients, and coordinating research.

Priority for longitudinal evaluation
Document what changes, why it changes and how patients influence those decisions. Missing capacity and quality indicators require confirmation before comparisons.

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