Developing a medication adherence technologies repository: proposed structure and protocol for an online real-time Delphi study

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ABSTRACT

Introduction An online interactive repository of available medication adherence technologies may facilitate their selection and adoption by different stakeholders. Developing a repository is among the main objectives of the European Network to Advance Best practices and technology on medication adherence (ENABLE) COST Action (CA19132). However, meeting the needs of diverse stakeholders requires careful consideration of the repository structure.

Methods and analysis A real-time online Delphi study by stakeholders from 39 countries with research, practice, policy, patient representation and technology development backgrounds will be conducted. Eleven ENABLE members from 9 European countries formed an interdisciplinary steering committee to develop the repository structure, prepare study protocol and perform it. Definitions of medication adherence technologies and their attributes were developed iteratively through literature review, discussions within the steering committee and ENABLE Action members, following ontology development recommendations. Three domains (product and provider information, medication adherence descriptors and evaluation and implementation) branching in 13 attribute groups are proposed: product and provider information, target use scenarios, target health conditions, medication regimen, medication adherence management components, monitoring/measurement methods and targets, intervention modes of delivery, target behaviour determinants, behaviour change techniques, intervention providers, intervention settings, quality indicators and implementation indicators. Stakeholders will evaluate the proposed definition and attributes’ relevance, clarity and completeness and have multiple opportunities to reconsider their evaluations based on aggregated feedback in real-time. Data collection will stop when the predetermined response rate will be achieved. We will quantify agreement and perform analyses of process indicators on the whole sample and per stakeholder group.

Strengths and limitations of this study

- The diverse expertise and geographical spread of the European Network to Advance Best practices and technology on medication adherence COST Action members (39 European countries) and their wider professional network represents a unique and timely opportunity to develop a repository of medication adherence technologies that meets the needs of a diverse audience.
- The scope and content of the Delphi survey represent the work of extensive literature review combined with multidisciplinary expertise of the steering committee.
- The real-time Delphi approach provides improved efficiency of the process, shortens the time of study completion and is particularly suitable for managing larger groups and including people from different geographic locations.
- The Delphi study will use state-of-the-art methodology to measure agreement and predetermine agreement/consensus criteria as well as stability of responses.
- The real-time approach requires specialised software, which limits the range of possible survey configurations and raw data availability for detailed process analyses and requires relatively elaborate instructions for participants, which may increase participation burden.

INTRODUCTION

Taking medication as prescribed often proves difficult for people when managing their...
health, particularly in the long term. Medication adherence is suboptimal in numerous chronic conditions and has a negative impact on chronic disease management, patient’s general health status, quality of life, working ability and healthcare costs. Research on medication adherence has expanded and contributed to raised awareness of the prevalence of suboptimal adherence and how it affects health outcomes. Digital technologies have increasingly gained interest as new interventions for supporting medication adherence have been developed. A diversity of technologies has been proposed, from electronic monitoring devices to mobile applications, to support medication adherence measurements and empower patients with their disease management. However, the rapidly expanding offering of medication adherence technologies (MATech) makes it increasingly difficult to access, evaluate and compare different technologies to make informed decisions and select appropriate tools for specific clinical or research needs. In a 2018 review by Ahmed et al, 5881 medication adherence apps were identified on Google Play and Apple App Stores. However, most of them lacked evidence of effectiveness and did not involve healthcare professionals (HCPs) during their development. Lack of collaboration between stakeholders results in a limited number of developed MATech actually being implemented into the healthcare systems and used daily by HCPs and/or patients. Furthermore, due to differences in healthcare systems across countries, healthcare organisations and reimbursement processes, harmonisation of implementation strategies are lagging behind, which further delays adoption of best practices across countries.

The ENABLE COST Action (‘European Network to Advance Best practices and technoloLogy on medication adherencE’, CA19132) was initiated by experts in medication adherence and digital technologies to fill these gaps regarding evidence and implementation of MATech within healthcare systems. ENABLE aims to raise awareness of available technologies, expand multidisciplinary knowledge on medication adherence at multiple levels, accelerate knowledge translation to clinical practice and collaborate towards economically viable implementation of best practices and technologies across European healthcare systems. These objectives are being pursued within a 4-year period (2020–2023), by three distinct and inter-related working groups (WGs) that map best practices available (WG1), identify and showcase adherence technologies (WG2) and identify suitable reimbursement strategies for implementation in healthcare systems (WG3), supported transversally by a WG4 coordinating communication and dissemination. At present, the ENABLE Action includes a large interdisciplinary network of experts in medication adherence from 39 European countries.

Effective implementation of technology-supported healthcare has been facilitated by centralisation of information in public repositories or ‘solution showrooms’, where users can search for technologies that meet their specific requirements. Several such repositories already exist in the field of digital health, including medication adherence (eg., NHS app Library, MyHealthApps, InterventieNet, GGD AppStore, DIGA, Weisse Liste), but are limited to single countries or types of technology and none represents a comprehensive resource to facilitate adoption of appropriate MATech across health systems. Therefore, ENABLE sets out to develop and maintain a public online repository of MATech where patients, HCPs, researchers and healthcare managers would be able to access and select technologies for adoption in their adherence management activities. For example, a patient may be interested more in the practical benefits of using a MATech in their daily lives, while a researcher may be keen to examine in detail the methodology theory and evidence base behind the MATech development. To meet this goal, the ENABLE repository would need to represent a flexible knowledge management system that would include information relevant to the needs of different stakeholders in a user-friendly format. In medical informatics, knowledge management relies on standardised terminologies, classifications and ontologies to record, share and use data on healthcare research and practice. These standards specify the types of information to encode in the form of distinct ‘entities’ representing objects or phenomena in the real world and their properties (‘attributes’), thus enabling knowledge generation through inference and learning. Adoption of evidence-based health innovations is also facilitated by these common standards, as new technologies need to interact with existing ecosystems in terms of both data interoperability and communicating with potential users in appropriate domain-specific language.

The field of medication adherence is highly interdisciplinary, therefore a useful repository would cross multiple knowledge domains and align with several standards, whether medical (eg., WHO International Classification of Disease), behavioural (eg., the Behaviour Change Intervention Ontology (BCIO) or technical (eg., WHO Classification of Digital Health Interventions). Stakeholder involvement would need to be at the core of this development process, to ensure its content is relevant, clear and complete, and meets community needs. The diverse and geographically spread ENABLE membership and their wider professional network represents a unique and timely opportunity to conduct this work. Considering these quality standards and following methodological recommendations the initial version of the repository structure was prepared. A stakeholder consultation process is proposed to explore their views and level of agreement on the relevance, clarity and completeness of the initial version. The resulting improved version would represent the structure of the ENABLE repository, which will be tested and populated in subsequent steps with users and developers of available technologies.

The present manuscript describes two elements: 1. The proposed structure for the repository.
2. The protocol of the real-time Delphi study to explore stakeholder views on this structure.

METHODS AND ANALYSIS

Steering committee

A steering committee (SC) was established within the COST ENABLE WG2 to coordinate and perform the work. The committee includes 11 ENABLE members from 9 countries in the following areas of expertise: adherence research and education, clinical practice, policy making and technology development. Members are responsible for: (i) determination of the repository scope and framework of attributes defining repository structure, (ii) preparation of the Delphi protocol, (iii) configuration and piloting of the Delphi survey, (iv) selection and invitation of stakeholders to participate in the study, (v) moderating study performance via the online tool and (vi) analysis and interpretation of results.

Determining the repository scope and framework of attributes defining its structure

The determination of scope and development of the attributes’ labels with definitions aimed to align with ontology development procedures as described by Wright et al. and follow a stakeholder engagement methodology as described by Norris et al. and Khodyakov et al. The principles of ontology development, actions taken when generating the framework of attributes and examples of how these principles are applied in the ENABLE project are presented in Table 1. The stakeholder engagement is primarily achieved through the proposed real-time Delphi study, which is described in more detail in the next sections.

Scope and definition of MATech

Four established definitions were used to define the scope of repository and set the framework of attributes: (i) WHO definition of health technologies; (ii) the ABC definition of medication adherence; (iii) the WHO definition of adherence to long-term therapies to highlight the importance of shared decision-making between the patient and the healthcare team and (iv) the definition of best practice in healthcare proposed by the European Commission to guide improvements in European health systems. The information in this definition denotes evidence on safety, efficacy, effectiveness, cost-effectiveness, appropriateness, social and ethical values and quality of the healthcare interventions.

Therefore, we propose to define MATech as devices, procedures or systems developed based on evidence to support patients to take their medications as agreed with healthcare providers (ie, to initiate, implement and persist with the medication regimen).

- Devices, procedures or systems emphasise the inclusion of all technologies, irrespective of their mode of delivery (whether based on electronic or printed supports, delivered through human interaction or a combination of these), with the aim to construct a comprehensive repository in which users can identify diverse technologies to fit their potentially diverse needs.
- Developed based on evidence encompass the requirement of evidence/research that supports at least a potential contribution to either measurement or intervention on medication adherence (eg, validation or pilot studies). Thus, technologies that are not (yet) supported by evidence (eg., development and testing stages), or clinical practice protocols without an evidence base on at least one aspect (safety, efficacy, effectiveness, cost-effectiveness, appropriateness, social and ethical values or quality), will not be (yet) included in the repository until such evidence is produced and reported.
- Support patients to take their medications as agreed with the healthcare providers (ie, to initiate, implement and persist with the medication regimen) encompass the contribution of the technology to medication adherence management—either directly in patients’ self-management, or by supporting professionals to offer such services to patients through all phases of medication adherence.

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Principles of ontology development after Wright et al. and actions taken in the ENABLE project</th>
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<tr>
<td>Principles</td>
<td>How they have been applied in the ENABLE project</td>
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<tr>
<td>Have specified scope and scientifically sound and relevant content</td>
<td>Selection of established definitions for delimiting the scope, consultation of stakeholders, piloting for data input and platform search.</td>
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<tr>
<td>Meet the needs of community of users</td>
<td>Consultation of stakeholders, steering committee and Action members sampled from the user community and including diverse areas of expertise.</td>
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<td>Enabling users to understand the meaning of entities</td>
<td>Naming examples of existing ontologies, piloting Delphi survey, technology description form, user form and platform use.</td>
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<tr>
<td>Be logically consistent</td>
<td>Using the methodology recommended for attribute description, checking consistency via Ontology Web Language.</td>
</tr>
<tr>
<td>Be interoperable with existing ontologies</td>
<td>Adopting attributes and labels available in existing ontologies and classifications, expert input on additional attributes and recommendations for interoperability.</td>
</tr>
<tr>
<td>Reflect changes in scientific consensus and remain accurate over time</td>
<td>Repository in open access, sustainability plan developed with Action members and stakeholders.</td>
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ENABLE, European Network to Advance Best practices and technology on medication adherence.
Thus, technologies that focus on other medication management goals, but do not target adherence specifically would be out of scope for this repository. Furthermore, the technologies included would need to be described in terms of their technical characteristics and validation, their behaviour change content, format and context, as well as the characteristics facilitating appropriate implementation in care processes. Hence, evidence from behaviour, implementation and computer sciences informed the initial scope and attributes framework to ensure key features, such as user-centeredness, trustworthiness/credibility, accuracy and relevance of the presented information, tailoring to the needs of different users and interoperability with existing evidence and other sources of information on healthcare technologies.

Framework of attributes

An initial list of attributes was developed based on a literature review and knowledge from the ENABLE members activities such as (i) an ongoing systematic review of e-health interventions on medication adherence for chronic conditions; (ii) a checklist of e-health quality criteria under development; (iii) Interventienet.nl—platform showcasing evidence-based medication adherence interventions in the Netherlands; and (iv) the ABC taxonomy—consensus-based terminology and definitions of medication adherence.

The initial list was presented to the SC and discussed via several videoconferences to generate a more detailed list of attributes grouped on several themes. Each theme was further elaborated by a subgroup of two SC members following a standard format including labels and adherence-related definitions. We adopted the approach from BCIO, where related attributes were searched in topic relevant ontologies/taxonomies/classifications and original definitions and codes were added. The reasons for the choice of certain attributes and labels were detailed for each attribute group. The proposed framework of attributes is graphically presented in figure 1 and online supplemental file 1, while rationale and sources used to define the labels for the MATech repository are presented in table 2 and online supplemental file 2.

The final proposed framework consists of three domains: (i) product and provider information (D1), (ii) medication adherence descriptors (D2) and (iii) evaluation and implementation (D3) aligning with the three elements of the Donabedian healthcare model (i) structure, (ii) process and (iii) outcomes. The domains branch in 13 attributes groups, which then branch further to up to four sublevels of attributes. Each attribute is described with a label and related definition.

Choice and description of the study design

We will perform an online real-time Delphi (RT-Delphi) survey to explore the level of agreement on the MATech definition and relevance, clarity and completeness of the proposed framework of attributes defining the repository structure and gain a deeper insight into stakeholders’ distinct needs and requirements. The Delphi process is a flexible iterative process to consult and/or reach consensus among a group of people on a particular topic. The key characteristics of a Delphi study are anonymity, iteration, controlled feedback and statistical description of group response. The RT-Delphi approach was developed by Gordon and Pease to improve efficiency of the process and shorten the time of performance.

Since then, several online tools have been developed to facilitate the RT-Delphi design and literature describing the use of RT-Delphi and comparison with the traditional multi-round Delphi approach is growing. In contrast to the traditional Delphi, the real-time approach is round-less and offers a constant iteration by providing immediate (real-time) individual and aggregated feedback. Based on new information participants can rethink and modify their answers, which could lead to reconciliation of opinions and eventually to consensus. Participants are encouraged to revisit and engage in the survey several times during the study period. In comparison with the traditional approach, the real-time approach encompasses all key Delphi features and is similar from all key perspectives. Furthermore, the real-time approach is particularly suitable for managing larger groups, decreases moderators’ workload, simplifies inclusion of people from different geographic locations and can be leaner in costs. On the other hand, the approach...
Table 2 The proposed framework of attributes used in the MAtech repository

<table>
<thead>
<tr>
<th>Domain and attribute group</th>
<th>Core question</th>
<th>Rationale</th>
<th>Existing ontology/taxonomy/classification used and adapted</th>
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<tr>
<td>D1 (D1.1) Product and provider information</td>
<td>What product does the entry refer to, to who provides it, who entered its description in the repository and when?</td>
<td>Each entry in the ENABLE repository will refer to a unique product, which will be identified with a unique ID, provided by a unique organisation (manufacturer, developer) with its own unique ID and related metadata (eg, date of entry, verification process, etc) to present the identity of the described MAtech and its provider.</td>
<td>Ontology for medical technology innovation in healthcare centres byITEMAS—only concepts referring to products and their providers were used and adapted.</td>
</tr>
<tr>
<td>D2.1 Target use scenario</td>
<td>What use scenarios and types of users is the technology intended for?</td>
<td>We can distinguish two general categories of users and their characteristics that might influence the choice of technology: (i) self-management use (patients and caregivers)—labels describing patients’ characteristics or their condition (age, functional status, health literacy, etc); (ii) adherence support use by healthcare or social care providers and health system managers, who can initiate a search for MAtech to integrate in their practice. The provider and the setting are also the focus of separate attribute groups.</td>
<td>Systematised Nomenclature of Medicine, Clinical Terms (SNOMED-CT). WHO International Classification of Functioning, Disability and Health. The WHO DHI. ABC Taxonomy.</td>
</tr>
<tr>
<td>D2.2 Target health conditions</td>
<td>Which health conditions could the technology be used for as part of adherence support?</td>
<td>MAtech are usually developed and validated to be used in one or several clinical domains and potential users may search for technologies applicable to the health condition(s) they aim to manage. Since our stakeholders also include lay individuals, special focus was put on using simplified language to avoid misunderstandings and knowledge gaps.</td>
<td>The International Classification of Disease 11th revision. The Health Research Classification System from the UK clinical research association.</td>
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<td>D2.3 Medication regimen</td>
<td>What type of medication regimen(s) is the technology intended for?</td>
<td>Medication regimen can take different schematic forms and be of varying complexity, which may influence the complexity and extent of medication adherence. MAtech may be developed for medications with different characteristics, hence the repository users should be able to indicate the type of regimen to find a MAtech that fits its specific characteristics.</td>
<td>SNOMED-CT. National Cancer Institute Thesaurus. Medical Subject Headings.</td>
</tr>
<tr>
<td>D2.4 Medication adherence management components</td>
<td>What adherence management types and phases does the technology target?</td>
<td>Management of adherence entails two management types, for example, monitoring/ measurement (D2.4.2.A) and support/intervention (D2.4.2.B) by any stakeholder, including the patient himself. Both elements may require different approaches depending on the targeted phase of adherence (D2.4.1).</td>
<td>ABC Taxonomy. SNOMED-CT. Extensive existing literature and own (steering committee’s) methodological know-how. Train4Health (T4H) behaviour change competency framework. BCIO.</td>
</tr>
<tr>
<td>D2.4.2 Measurement/ Measurement methods and targets</td>
<td>If measurement is a component, what measurement methods does the technology use and what do they measure?</td>
<td>A broad range of measurement methods for adherence are available. In addition to adherence behaviours, measurement can also target adherence determinants, other self-management behaviours and outcome measures (eg, HRQoL). Therefore, we have selected a range of measurement models as well as a selection of self-management Behaviours to offer the possibility to describe technologies from a measurement perspective.</td>
<td>SNOMED-CT. Extensive existing literature and own (steering committee’s) methodological know-how. Train4Health (T4H) behaviour change competency framework. BCIO.</td>
</tr>
<tr>
<td>D2.4.2.B.1 Intervention modes of delivery</td>
<td>If intervention is a component, how is it delivered to its users?</td>
<td>Mode of delivery is “physical or informational medium through which a given behaviour change intervention is provided”, can affect intervention effectiveness. Although digitalisation has entered in all aspects of everyday life, the analogue mode is still very relevant. This is especially true within the elderly, who on one hand require more support in medication adherence and are on the other hand less digitally literate. Hence, the repository should encompass all modes.</td>
<td>BCIO. Specifically a taxonomy of modes of delivery of BCI.</td>
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<td>D2.4.2.B.2 Target behaviour determinants</td>
<td>If intervention is a component, what reasons for non-adherence can the technology help address?</td>
<td>The MAtech can address different reasons for non-adherence, defined as determinants of behaviour, which can be non-modifiable or modifiable. Individual-level and modifiable determinants are encompassed as capability (psychological and physical), opportunity (social and physical) and motivation (reflective and automatic), also known as the COM-B model. Theoretical Domains Framework. BCIO. The Mechanisms of Action Ontology. International Classification of Health Interventions.</td>
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<tr>
<td>D2.4.2.B.3 Behaviour change techniques</td>
<td>If intervention is a component, what are the ‘active ingredients’ present in the technology that may trigger change in the reasons for non-adherence targeted?</td>
<td>To trigger/support change in a health behaviour, interventions act by generating change in determinants of the targeted behaviour. The ‘active ingredients’ in these interventions are labelled BCTs. We included only user-level BCTs (ie, BCTs that provide support to medication users) and mapped them according to the COM-B model and across domains. If considered relevant, HCPs level or system-level BCT can be included in the future.</td>
<td>BCT taxonomy. T4H behaviour change competency framework. Cards for Change.</td>
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<td>Domain and attribute group</td>
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<td><strong>D2.4.2.B.4 Intervention providers</strong></td>
<td>If intervention is a component, who delivers the intervention to users?</td>
<td>The provider of intervention is a role played by a person, population or organisation that provides/delivers an intervention. This includes their occupational role and type of relatedness. In medication adherence, the provider is often HCP, hence the quality of the HCP-patient relationships (communication skills, collaborative decision-making, trust in the HCP, HCPs' cultural competences) correlate with patients' adherence.</td>
<td>▶ BCIO, specifically Intervention Source Ontology. ▶ Gender, Sex and Sexual Orientation ontology.</td>
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<tr>
<td><strong>D2.4.2.B.5 Intervention settings</strong></td>
<td>If intervention is a component, where is the service for improving adherence delivered?</td>
<td>Setting is the social and physical environment in which the technology is used to manage medication adherence. Implementation and behavioural science emphasise the importance of understanding and describing the environment in which a certain intervention is delivered as it can significantly influence its outcomes. In addition, not every intervention is applicable or transferable to every setting. We can distinguish between physical and virtual settings as well as the possibility of applying the intervention in any setting.</td>
<td>▶ BCIO, specifically Intervention Setting Ontology. ▶ Consolidated framework for advancing implementation research (CFIR).</td>
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<td><strong>D3.1 Quality indicators</strong></td>
<td>How does the technology meet key quality indicators from different perspectives?</td>
<td>QIs are standardised, evidence-based and measurable items for monitoring and evaluating the quality of healthcare performance. They describe the structure, process and outcomes of care and based on them the standards and review criteria are developed. The target audience of the repository is very diverse and with specific individual needs related to MATech. Thus, we decided to group quality indicators according to their different purposes of use (eg, general, research, decision making, use).</td>
<td>▶ A checklist of e-health quality criteria (under development). ▶ Mobile Application Rating Scale. ▶ Consori-EHEALTH guideline. ▶ Health Technology Assessment Core Model, V3.0. ▶ O'Rourke et al.</td>
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<tr>
<td><strong>D3.2 Implementation outcomes and strategies</strong></td>
<td>What implementation outcomes and strategies are needed and available for adopting this technology in the intended setting?</td>
<td>Implementation sciences provide knowledge on how to facilitate the adoption and use of technologies in real-world settings. The development of MATech often starts without considering the actual use in real-world settings, which prevents successful adoption and scaling up into clinical care. Three implementation outcomes were selected for ENABLE repository: acceptability, feasibility and sustainability to target early, mid and late implementation phases. In addition, eight implementation strategies were selected and adapted to present information on training users for working with MATech, availability of education materials, expertise needed to use the MATech previous implementation experiences, financial, accreditation and other legal aspects of the use.</td>
<td>▶ Proctor et al. ▶ CFIR. ▶ The Expert Recommendations for Implementing Change. ▶ Interventienet.nl.</td>
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</table>

Each group is presented with the core question it is addressing, rationale and sources used to create labels within the group. A detailed description of all attribute groups with labels and definitions is also available in the online supplemental file 2. BCIO, Behaviour Change Intervention Ontology; BCT, Behaviour Change Techniques; COM-B, Capability, Opportunity, Motivation and Behaviour; HCP, Healthcare Professional; HRQoL, Health-related Quality of Life; MATech, Medication Adherence Technologies; QI, Quality Indicator; WHO DHI, WHO Classification of Digital Health Intervention.
requires specific software, which can sometimes be rigid in terms of survey configuration and analysis, contributes to increases study costs and requires specific instructions for participants. Acknowledging the potential challenges, the advantages of the approach outweighed them and supported a decision to adopt the real-time approach for our Delphi study.

**Sampling and sample size**
We aim to include stakeholders from all 39 countries, participating in the COST ENABLE, covering five different backgrounds per country: (i) adherence and eHealth research (measurement, intervention development, implementation science, health economics), (ii) clinical care (specialist and primary care practitioners providing medication adherence support), (iii) patient representation (age >18 years, active representative in patient associations or healthcare facilities), (iv) policy making and (v) technology development. Hence, the targeted sample size is at least 195 panellists to be invited in the study (39 countries×5 stakeholders).

Purposive sampling will be applied to identify potential panellists. First, requests will be sent through the ENABLE Cost Action membership list to representatives of all 39 countries, requesting them to identify suitable panellists from all five backgrounds. ENABLE members will provide the SC the name, background and email for every potential panellist. Participants’ emails will be entered in the online platform (eDelphi.org—Delphi method software), which will enable anonymity in further steps, that is, individual’s activity and or/answers will not be linked to personal data. All communication with the panellists (invitation, reminders, etc) will be performed through the platform. If more candidates from the same background and country will be suggested, we will invite all candidates to increase the likelihood of achieving the planned sample size. If the expressed interest exceeds the planned sample size, purposeful sampling will be performed to ensure variation in expertise, country and balance other characteristics (eg, years of expertise, gender). To reach simple size and variation in sample characteristics, key international organisations from the field (eg, The International Society for Medication Adherence (ESPACOMP), Pharmaceutical Care Network Europe (PCNE), European Medicines Agency (EMA), European Patient Forum (EPF), etc.) will be contacted to fill any missing gaps, if needed.

**Patient and public involvement**
The goal of this Delphi consultation is to involve stakeholders (patient representatives among them) in decisions regarding the development of ENABLE repository and is part of the broader approach to patient and public involvement followed in the ENABLE Action. Results will be communicated to all stakeholders, and they will be listed and acknowledged among ENABLE collaborators.

**Data collection**
We will use an online platform, eDelphi.org (Metodix, Helsinki, Finland) for data collection. All survey activities—distribution, reminders, communication with and between the panellists and interim analysis of the process will be performed through the tool. The survey will be conducted from 1 October 2021 to 15 January 2022 in three stages:

1. **Pilot stage.** at least 10 members of the COST ENABLE Action, specifically members of the WG2, will be asked to test the survey (including instructions for participants) and to provide feedback on face validity as well as user experience.
2. **First stage phase.** invitation of 20 purposefully selected stakeholders (aiming for variation in expertise, geographical location and gender) to create initial aggregated feedback of the RT-Delphi.
3. **Full-scale RT-Delphi.** all remaining stakeholders will be invited to participate in the study.

Stakeholders will receive an email invitation via the eDelphi platform with a personalised link to the survey. Detailed instructions describing survey aims, rules of engagement and how to use the platform will be available on the platform.

At the beginning of the survey, participants will be encouraged to think of a hypothetical situation in which they would search for MATech applicable to their own setting/role and to assess the proposed attributes from this perspective throughout the survey. First, panellists will be asked to familiarise with the proposed structure and provide general feedback on the completeness. Furthermore, they will be asked to rate agreement with and clarity of the MATech definition and relevance and clarity of each proposed attribute group on a 9-point Likert scale, where 1 represents extremely irrelevant/unclear and 9 represents extremely relevant/clear. We will use the Live 2D format, where each outcome represents one of the two dimensions, that is, the x-axis stands for relevance and the y-axis stands for clarity. Additionally, an open-text field will be provided for panellists to comment on completeness of each attribute group, that is, proposing additional attributes or revising definitions. We will moderate the discussion in the following ways: (i) address technical issues with the platform by responding to the comment when the issues will be solved or provide instructions how to manage the issue and (ii) outline the progress of the study and the most commented questions in bulletins send through the platform once a week. We considered these strategies to encourage panellists to participate, taking into account the length of the survey and the complexity of the concepts they are rating. Delphi survey materials (online supplemental file 3, online supplemental file 4 and online supplemental file 5), including all attributes labels and definitions (online supplemental file 1 and online supplemental file 2) as well as participant instructions (online supplemental file 6), are shown in the online supplemental materials.
For sample description purposes, participants will be requested to provide information on their expertise (profession, years of experience, relevant professional experiences) and demographic characteristics (age, gender, country of practice). This information will also be used to examine differences in participants’ ratings and comments depending on their background and location. These data will be presented in aggregated form and not linked to the individual’s activity or answers. Revisiting and rerating will be encouraged by weekly reminders.

Data collection will be stopped on reaching adequate sample size and characteristics to achieve sufficient representability and generalisability of the opinions gathered. Therefore, we propose stopping the Delphi when three criteria will be met: (i) the total response rate to the survey is ≥30% (number of participants completing the survey, of the total number of stakeholders invited); (ii) a minimum of 10 panellists in each stakeholder group completed the survey; (iii) a minimum of two stakeholders from at least 2/3 of the COST ENABLE countries has completed the survey. We will operationalise survey completion as providing background data and answering at least 75% of the repository structure questions.

Data analysis

Descriptive statistics will be used to characterise the sample of panellists and each stakeholder subgroup regarding profession, years of experience, age, gender and country.

Several measures can be used to determine when consensus is reached, with the percentage of agreement being the most common. Prespecification of the consensus measure and criteria for consensus increases trustworthiness of findings.

Level of agreement on relevance, clarity and completeness

Stakeholder agreement on the proposed definition and attributes will guide decisions on the repository structure. Therefore, we selected a set of criteria representing different levels of agreement and consequently carrying different weights in these decisions. The level of agreement on every attribute for both outcomes (eg., relevance and clarity) will be quantified using the interpercentile range adjusted for symmetry (IPRAS) analysis technique from the RAND/UCLA Appropriateness Method (RAM).

First, the disagreement index (DI) will be calculated as a ratio between the interpercentile range (IPR) and IPRAS. A DI >1 (ie, IPR >IPRAS) indicates disagreement exists. IPR is calculated using the 30th–70th percentile. IPRAS for the 9-point Likert scale is calculated according to the formula presented in the RAM User Manual.

Second, the median and DI will define different levels of agreement and steer the decisions about the repository structure. For the relevance:

i. items with the median of 7–9 and no disagreement will be considered relevant and mandatory;
ii. items with the median of 4–6 or disagreement will be considered optional;
iii. items with the median of 1–3 and no disagreement will be considered not relevant and candidates for exclusion.

For an even number of participants, median ratings of, for example, 6.5 or 3.5 will be assigned to the higher level. Stakeholders’ responses per question will be summarised using descriptive statistics. For clarity ratings, the above criteria will be applied as (i) sufficiently clear to remain unchanged; (ii) optional changes and (iii) candidates for rephrasing.

Panellist comments in the open-text fields will be analysed qualitatively, using content analysis. Findings will be used to rephrase and improve clarity of certain attributes or to add additional attributes proposed by stakeholders.

Subgroup analysis

Following the primary analysis on the whole sample, a subgroup analysis per stakeholder group will be conducted to examine variation in opinions and potential differences among subgroups. The same agreement criteria will be applied and descriptive statistics will be stratified by stakeholder group. In addition, we will determine the reliability of ratings per question within stakeholder group by calculating the intraclass correlation coefficient (ICC). The ICC calculation is based on the two-way random model, considering type (average measures) and definition of relationship (consistency) and is presented in Equation 1. ICC >0.70 will indicate moderate-to-good reliability.

Equation 1. Calculation of the ICC expressed in %. MSr stands for mean square for rows and MSg stands for mean square for error.

\[
\text{ICC} = \frac{\text{MS}_r - \text{MS}_g}{\text{MS}_r} \times 100 \quad [\%]
\]

Analysis of process indicators

By analysing process data from the online tool, we will describe in more detail how stakeholders’ responses evolved through iterations and how consensus or certain level of agreement has formed.

Stability of response presents the consistency of responses within the study period and between respondent group stability, which is considered a necessary precondition for determining the level of agreement or if consensus was achieved. Different measures of dispersion (eg., median, IQR) and statistical approaches (eg., descriptive, inferential) can be used to measure stability, which can be calculated between rounds (traditional Delphi) or at the end of the study (RT-Delphi).

We will use the coefficient of quartile variation (CQV) as a descriptive measure of response stability. CQV will be calculated over all participants (CQV_total) and within the same stakeholder group (CQV_sub) to account for expected higher variation in response between different stakeholder groups. A CQV_total <30% and CQV_sub <15% will be considered as stable response. CQV calculation is shown in Equation 2.
Equation 2. Calculation of the CQV, expressed in %. Q3 stands for value of the third quartile and Q1 for first quartile.

\[ \text{CQV} = \frac{Q3 - Q1}{Q3 + Q1} \times 100 \% \]

Final repository structure
After conducting the analyses described above (planned to be finalised at the end of April 2022), results suggesting modifications to the proposed structure will be considered for adoption by the SC in a subsequent version, which will represent the final structure of the ENABLE repository implemented on the initial ENABLE repository version. Further work will be considered to address results that might suggest ongoing debates in the field about certain attribute groups or the need for more in-depth consultation and evidence generation. This work will accompany the iterative improvement of the repository during the ENABLE Action.

ETHICS AND DISSEMINATION
Ethical considerations and consent to publish
The study is designed to ensure participants’ anonymity and to manage personal data in line with EU regulation. Before starting the survey, every participant will provide an informed consent electronically on the study entry page. Participants will be asked to carefully read through the statement regarding the study aim and nature as well as the data handling procedures and to mark their understanding and agreement. The results will only be published in an aggregated form and no personal details will be revealed.

An ethical approval for the activities of the COST ENABLE Action, including this Delphi study, was granted by the Malaga Regional Research Ethics Committee (‘Comité de Ética de la Investigacion Provincial de Malaga’) on 29 April 2021 (online supplemental file 7). In addition, a data protection assessment was carried out by the Data Protection Officer at the University of Basel. According to this instance, the Delphi study protocol was determined as compliant regarding data protection and security (online supplemental file 8).

Future implications and challenges
The proposed scope and framework of attributes together with findings from this Delphi study will represent the first steps on the pathway to create an evidence-based, interoperable and user-friendly MATech repository. Following the Delphi consultation and integration of the repository module on the ENABLE website,57 providers of MATech (public or private) would be invited to upload information on their products via a MATech description form based on the final repository structure. The accuracy of the information would be verified by an independent review panel through a procedure yet to be established. Important challenges lay ahead, such as how to select MATech for inclusion in the repository given the broad scope of the definitions proposed, how to ensure accurate information about the technologies included, how to provide the information in other languages than English and in non-technical language accessible for all and how to maintain a representative and varied offer of technologies in the long term. Nevertheless, the ENABLE repository promises to bring together stakeholders from different backgrounds to build a common language which can have an important positive impact on medication adherence research and practice.

Dissemination
The repository will be publicly accessible for interested parties. The use of the repository will be promoted and supported by dissemination meetings, workshops and training schools. The findings of the study will be presented via publications (reports and manuscripts in open access peer-reviewed journals) and oral presentations to different stakeholders in conferences and meetings. The spirit of COST Actions is networking and dissemination of ideas; hence, the action is open for anybody who would wish to join or would like to be informed about its activities.

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Contributors

All authors contributed to the work and formation of this manuscript. The first draft was prepared by UNM, CG, JR, and AD. All other members of the steering committee (PB, FH, MTH, CJ, FMR, DS, and IT) reviewed and upgraded the first version. All steering committee members (CG, JR, PB, FH, MTH, CJ, FMR, DS, and IT) worked on the development of the scope and framework of the attribute groups, UNM and AD coordinated the work. SPG was consulted as the expert in Delphi methodology, specifically the RAND/UCLA Appropriateness Method. The final version of the protocol was prepared by UNM and reviewed by all other authors (CG, JR, PB, SPG, FH, MTH, CJ, FMR, DS, IT, and AD). All authors have read and approved the final version of the manuscript.

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Disclaimer

Funders had no role in the study design, content work and preparation or writing of the manuscript.

Competing interests

SPG is a research team member for ExpertLens (an online platform and methodology for conducting modified-Delphi studies), SPG’s spouse is a salaried employee of, and owns stock in, Eli Lilly and Company.

Patient and public involvement

Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the ‘Methods and analysis’ section for further details.

Patient consent for publication

Not applicable.

Ethics approval

An ethical approval for the activities of the COST ENABLE Action, including this Delphi study, was granted by the MalagaRegional Research Ethics Committee (“Comité de Ética de la Investigación Provincial de Málaga”) on 29th April 2021. In addition, a data protection assessment was carried out by the Data Protection Officer at the University of Basel. According to this instance, the Delphi study protocol was determined as compliant regarding data protection and security.

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ENABLE Repository Delphi survey - study information letter

What is this study about?

Adherence to medication has been found to be suboptimal in numerous chronic conditions and to have a negative impact on chronic disease management, patient’s general health status, quality of life and working abilities as well as health care costs and waste. Numerous technologies exist to support medication adherence, yet few are implemented into practice. An online interactive repository of available technologies may facilitate their selection and adoption by different stakeholders. Developing such repository is among the main tasks of the ENABLE COST Action (CA19132), within the remit of Working Group 2. To meet this challenge the ENABLE Action includes a large interdisciplinary network of experts in medication adherence from 39 European countries and has initiated several activities towards these goals. A definition of medication adherence technologies and a framework of attributes were developed. The framework was structured into three domains (product and provider information, medication adherence descriptors and evaluation and implementation) branching in attribute groups, which branch further into sublevels with related labels and definitions.

What to expect from study participation?

The proposed definition and framework will be evaluated in a real-time online Delphi study by stakeholders from 39 countries with research, practice, policy, patient representation and technology development backgrounds. It is expected that you and other invited stakeholders evaluate the proposed the relevance, clarity and completeness of the definition and repository attributes. All participants have multiple opportunities to reconsider their evaluations based on aggregated feedback updated in real-time.

Participants are invited to rate the degree of relevance and clarity of the proposed definition of medication adherence technologies, and of each attribute group, by placing a dot on a 2D-grid; the position of the dot on the vertical axis indicates clarity (low to high = bottom to top), and its position on the horizontal axis indicates relevance (low to high = left to right). Participants are encouraged to provide their comments and suggestions (anonymously) on the comments section and engage with other participants’ comments.

We will stop the survey when a predefined number of participants will respond, and when stability of responses will be reached. We will summarize the results descriptively and compare evaluations across stakeholder groups and countries. We will quantify agreement among stakeholders on proposed attribute groups using the IPRAS analysis technique from RAND/UCLA Appropriateness Method.
How to participate?

Firstly, by this email we extended our invitation to you and are asking for authorization to use your email within the scope of this study. If after considering this information you agree to participate, please access directly the link provided in the email sent from the eDelphi.org. You will be formally asked about your consent to participate when you will access the survey after a brief introduction, and the questions will appear only once you will consent to this study.

How are data collected and stored?

For this study it is necessary to collect some personal data. This includes your name and email address, as well as your age, gender, field of work/expertise, country, education level and the role of your participation with years of experience in it (researcher/academic; healthcare practitioner; policy/decision maker; patient representation; eHealth/IT specialist). Your name and email address are not linked to other data you provide by answering the survey. The personal data will not be visible to other respondents. The personal data used for conducting this study will be stored until the end of the COST Action ENABLE (October 2024) and then erased.

Ethical and data protection approvals

This study obtained ethics approval from Malaga Regional Research Ethics Committee in April 2021. In addition, the Delphi protocol was determined as compliant regarding data protection and security by Data Protection Officer from University of Basel.

For more information about your rights on data processing, and further questions about the project please contact the ENABLE-R Delphi at wg2enablecost@gmail.com.

On behalf of the ENABLE WG2 Steering Committee,

Alex Dima and Urska Nabergoj Makovec
Summary of the Delphi survey

Welcome

Instructions for the Delphi survey (2 pages)

Agreement with the GDPR statement

Demographic information (gender, age, country, education, professional field)

Through which perspective are you answering today?

<table>
<thead>
<tr>
<th>Experience</th>
<th>Research/education professional</th>
<th>Healthcare practitioner</th>
<th>Policy/decision makers</th>
<th>Patient perspective</th>
<th>eHealth/IT specialist</th>
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What is a "medication adherence technology"?

For the purpose of this repository, we propose the following definition: "Medication Adherence Technologies (MATech) are devices, procedures or systems developed based on evidence to support patients to take their medications as agreed with the healthcare providers (i.e. to initiate, implement, and persist with the medication regimen)."

1) Please rate your level of agreement with the proposed MATech definition (X axis).
2) Please rate the CLARITY of the MATech definition (Y axis).

Detailed explanation of the definition and repository scope:

- **devices, procedures or systems** emphasize the inclusion of all technologies, irrespective of their mode of delivery (whether based on electronic or printed supports, delivered through human interaction, or a combination of these) with the aim to construct a comprehensive repository in which users can identify diverse technologies to fit their potentially diverse needs.

- **developed based on evidence** encompass the requirement of evidence/research that supports at least a potential contribution to either measurement or intervention on medication adherence (e.g., validation study on measurement of medication adherence, or pilot study with medication adherence among outcomes). Thus, technologies that are not (yet) supported by evidence (e.g., are in earlier stages of development and testing), or clinical practice protocols without an evidence base on at least one aspect (safety, efficacy, effectiveness, cost-effectiveness, appropriateness, social and ethical values or quality), will not be (yet) included in the repository until such evidence is produced and reported.

- **support patients to take their medications as agreed with the healthcare providers (i.e., to initiate, implement, and persist with the medication regimen)** encompass the contribution of the technology to medication adherence management – either directly in patients’ self-management, or by supporting professionals to offer such services to patients through all phases of medication adherence. Thus, technologies that focus on other medication management goals, but do not target adherence specifically would be out of scope for this repository.

The MATech definition and scope of the repository is based on the WHO definition of health technologies, the WHO publication "Adherence to long-term therapies: evidence for action", the ABC taxonomy and the European Commission definition of best practice.

Supplemental material placed on this supplemental material which has been supplied by the author(s).
D1.1 Product and provider information

The product and provider domain entails basic information about the product and provider organization as well as the description of the repository entry and source of information.

1) Please rate the RELEVANCE of this attribute group (X axis).
2) Please rate the CLARITY of this attribute group (Y axis).

Further explanation:
Domain 1 consists of one attribute group and includes the attributes for the description of basic product and manufacturer/developer information, as follows:
1. **Product** is a device, procedure or system, that could be used to manage adherence to medication described by its name, brand, type, release date, ...
2. **Provider organization** is the organization that produces and/or makes the product available for users described by its name, type, domain activity, contact details...
3. **Repository entry** is a description of a health technology by a repository author account (ID, date of entry, update, verification).
4. **Author of the product description** is a person or group of persons who enters information about at least one MATech in the ENABLE-R database (ID, name, date, contact details).

*The definitions of domain 1 are based on the ITEMAS ontology. For a more detailed view of the respective sub-levels with labels and definitions please check the interactive graph or the Excel file under supporting information.*
Table of contents for Domain 2 – medication adherence descriptors

D2.1 Target use scenario

Target use scenario is the type of common adherence management activities that the technology is intended to be used for (i.e., for self-management of adherence or support service use).

1. Please rate the RELEVANCE of this attribute group (X axis).
2. Please rate the CLARITY of this attribute group (Y axis).

Further explanation:
Target use scenario entails:
1. **Adherence self-management** is the scenario in which the technology is used for adherence self-management activities and can be further defined by:
   - Person in the healthcare environment (patient or caregiver)
   - Patient age group (adult, adolescent, child, infant)
   - Patient functional status (mental functions, sensory functions, movement-related functions)
   - Patient literacy (health literacy, including medication literacy)
   - Patient polypharmacy
   - Patient multimorbidity

2. **Adherence support use** is the scenario in which the technology is used for activities supporting taking medication in a health/social care provision setting and can be further specified by the following user types:
   - Professional health and social care provider
   - Health (system) manager

The definitions of target use scenarios are based on several taxonomies -SNOMED-CT, and WHO International Classification of Functioning, Disability and Health (ICF), and Digital Health Interventions (DHI)- and research literature sources. For a more detailed view of the respective sub-levels with labels and definitions please check the interactive graph or the Excel file under supporting information.

D2.2 Target health conditions

Target health conditions are the type of diseases or health problems the technology is intended for.

1. Please rate the RELEVANCE of this attribute group (X axis).
2. Please rate the CLARITY of this attribute group (Y axis).

Further explanation:
Target health conditions entail:
1. Blood
2. Cancer and neoplasms
3. Cardiovascular
4. Congenital disorder
5. Ear
6. Eye
7. Infection
8. Inflammatory and immune system
9. Injuries and accidents
10. Mental health
11. Metabolic and endocrine
12. Musculoskeletal
13. Neurological
14. Oral and gastrointestinal
15. Renal and urogenital
16. Reproductive health and childbirth
17. Respiratory
18. Skin
19. Stroke
20. Generic health relevance

The definitions of target health conditions are based on The International Classification of Disease (ICD-11) and The Health Research Classification System (HRCS) from the UK clinical research association. For a more detailed view of the respective sub-levels with labels and definitions please check the interactive graph or the Excel file under supporting information.

D2.3. Medication regimen

Medication regimen attributes are the prescribed schematic form/therapeutic plan of medication therapy that the technology is intended for.

1. Please rate the RELEVANCE of this attribute group (X axis).
2. Please rate the CLARITY of this attribute group (Y axis).

Further explanation:
Medication regimen attributes entail:
1. Type of intention as the purpose for which the medication is prescribed (e.g., preventive or therapeutic).
2. Duration of treatment presents the intended interval of treatment and relates to the clinical course and disease conditions (e.g., short or long-term).
3. Route of administration is the route in which medications/doses are administered to unfold pharmacological effects (e.g., oral, inhaled, injections/subcutaneous, infusion/parenteral, patches, topical).
4. Number of monitored medications defines how many distinct medications are monitored by the technology, if applicable (e.g., single medication, multiple medication).
5. Prescribed dosing frequency defines the dose-taking patterns recommended for medicines administration, in which doses should be taken at defined time intervals over a defined time period (e.g., once-daily, multiple daily dosing at fixed intervals, once per week dosing, multiple dosing per week in fixed intervals, dose adjustment recommendations).

The definitions of medication regimen attributes are based on several taxonomies: SNOMED-CT; National Cancer Institute Thesaurus (NCIT) and Medical Subject Headings (MeSH). For a more detailed view of the respective sub-levels with labels and definitions please check the interactive graph or the Excel file under supporting information.

D2.4.1. Phase of medication adherence

A medication adherence phase is a time interval between the prescription start and end dates that is behaviourally (i.e., linked with specific determinants and outcomes) and metrically (i.e., requires specific estimation methods) distinct.
1. Please rate the RELEVANCE of this attribute group (X axis).
2. Please rate the CLARITY of this attribute group (Y axis).

Further explanation
Medication adherence phases include

1. **Initiation** is the phase of adherence that covers the start of a prescribed treatment, i.e., the period from when the prescription is issued to the first dose taken (i.e., the initiation event).
2. **Implementation** is the phase of adherence from the initiation until the last dose taken during which one can estimate the extent to which the patient’s dose taking and timing are linked to the prescribed dosing regimen.
3. **Discontinuation (Persistence)** is the phase of adherence that refers to the end of treatment execution and covers the period until last dose is taken, e.g. end of therapy or termination by patient. Persistence is the period between initiation and discontinuation.

*The definitions of adherence management are based on the ABC Taxonomy. For a more detailed view of the respective sub-levels with labels and definitions please check the interactive graph or the Excel file under supporting information.*

**D2.4.2.A Monitoring/measurement type of management**

Medication adherence monitoring, or measurement, is type of adherence management that refers to estimating (repeatedly) medication adherence behaviours, determinants, and/or outcomes.

1. Please rate the RELEVANCE of this attribute group (X axis).
2. Please rate the CLARITY of this attribute group (Y axis).

Further explanation
Medication adherence monitoring/measurement entails:

1. **Measurement method** is a way in which information is gathered and summarized by the technology about the patient’s medication adherence. It is further specified into the following:
   - **Direct observation method** is a measurement method consisting in observing medication intake directly.
   - **Pill count method** is a measurement method consisting in calculating left over pills in containers/blisters at a specific time point.
   - **Self-report method** is a measurement method using data reported by patients or caregivers about themselves (e.g., *diary, questionnaire, interview/consultation*).
   - **Electronic monitoring method** is a measurement method using data from devices that record medication taking events electronically (e.g., *smart packages, smart pill, digital event record system*).
   - **Electronic healthcare database method** is a measurement method using routinely collected data as part of a longitudinal healthcare process (e.g., *electronic medical records, claims/dispensing, record linkage system*).
   - **Laboratory method** is a measurement method based on clinical assessment through invasive procedure (e.g., *measuring drug concentration, biomarker or treatment response in samples from body fluids*).

2. **Measurement target** is a component of the adherence causal (logic) model measured by the technology. It is further defined by:
   - **Determinant measure** is measurement targeting causal influences on the behaviour that can be modifiable (amenable to intervention with a medication adherence technology).
• **Behaviour measure** is measurement targeting a self-management behaviour (e.g., adherence, diet, physical activity, tobacco use, symptom monitoring and management).

• **Outcome measure** is the measurement targeting the effects of the behaviour or change of behaviour on the patient's status (e.g., health outcome, quality of life).

The definition of adherence monitoring/measurement is based on the ABC Taxonomy. The definitions of measurement methods and targets are based on several taxonomies -SNOMED-CT, the Train4Health (T4H) behaviour change competency framework and the behaviour change intervention ontology (BCIO), as well as scientific literature and the methodological expertise of the repository Steering Committee. For a more detailed view of the respective sub-levels with labels and definitions please check the interactive graph or the Excel file under supporting information.

D2.4.2.B Support/intervention type of management

Medication adherence support and/or intervention is a type of adherence management that refers to generating change in medication adherence determinants and thus behaviours and outcomes.

1. Please rate the RELEVANCE of this attribute (X axis).
2. Please rate the CLARITY of this attribute (Y axis).

Attribute groups further describing medication adherence support/intervention type of management are presented for your review in the next pages.

The definitions of adherence management types are based on the ABC Taxonomy.

D2.4.2.B.1 Intervention modes of delivery

Intervention modes of delivery are the ways used to deliver a medication adherence intervention.

1. Please rate the RELEVANCE of this attribute group (X axis).
2. Please rate the CLARITY of this attribute group (Y axis).

Further explanation

Intervention modes of delivery entails:

1. **Printed material** is the mode of delivery involving use of printed material (e.g., brochure or printed media such as poster, newspaper/leaflet)
2. **Human interaction** is the mode of delivery involving a person as intervention source who interacts with an intervention recipient (e.g., face to face consultations or network/patient groups)
3. **Electronic mode** is the mode involving electronic technology in the presentation of information or the mode of motivation to an intervention recipient (e.g., smartphone/tablet, wearable electronic device like smart box, smart inhaler, smart tube, smart button or digital media like internet, social media, broadcast media, billboard).

The definitions of intervention modes of delivery are based on the Behaviour Change Intervention Ontology (BCIO), specifically a taxonomy of mode of delivery of behaviour change interventions (BCI). For a more detailed view of the respective sub-levels with labels and definitions please check the interactive graph or the Excel file under supporting information.
D2.4.2.B.2 Target behaviour determinants

Target behaviour determinants are causal influences on medication adherence that can be modifiable (amenable to intervention with a medication adherence technology).

1. Please rate the RELEVANCE of this attribute group (X axis).
2. Please rate the CLARITY of this attribute group (Y axis).

Further explanation
Target behaviour determinants entails:

1. **Capability** is a group of determinants referring to what an individual can do themselves to take medication as agreed with the healthcare provider (e.g., psychological/cognitive capability or physical capability/skills).
2. **Opportunity** is a group of determinants referring to the conditions in the individual’s external environment that can facilitate medication adherence (e.g., social opportunity/influences or physical opportunity/environmental context and resources).
3. **Motivation** is a group of determinants referring to what extent the individual feels driven/willing/energized to take medication as agreed with the healthcare provider (e.g., reflective motivation or automatic motivation).

The definitions of target behaviour determinants are based on the Capability, Opportunity, Motivation and Behaviour (COM-B) model, the Theoretical Domains Framework (TDF) and the Behaviour Change Intervention Ontology (BCIO), specifically The Mechanisms of Action (MoA) Ontology currently in development. For a more detailed view of the respective sub-levels with labels and definitions please check the interactive graph or the Excel file under supporting information.

D2.4.2.B.3 Behaviour change techniques

Behaviour change techniques (BCTs) are options/activities included in the technology that aim to influence determinants (barriers and facilitators) of medication adherence behaviours.

1. Please rate the RELEVANCE of this attribute group (X axis).
2. Please rate the CLARITY of this attribute group (Y axis).

Further explanation
BCTs entails:

1. **BCTs acting on capability:**
   - **feedback and monitoring** means the technology includes options to record medication intake and its effects and feed this info back to the user (e.g., biofeedback, feedback or self-monitoring on behaviour, feedback or self-monitoring on outcomes).
   - **repetition and substitution** means the technology includes options/activities to perform certain actions repeatedly and systematically in order to enforce medication adherence behaviours and replace other behaviours not beneficial for medication adherence (e.g., habit formation, behavioural practice, graded tasks).
   - **shaping knowledge** means the technology includes options for the user to learn about how to take medication as agreed with the healthcare provider, what they can do themselves to stick to the schedule in difficult situations, and test different ways of doing this.
2. **BCTs acting on opportunity:**
   - **demonstration of behaviour** means the technology includes an observable sample of how to take medication as agreed with the healthcare provider, directly in person or indirectly (video, pictures, drawings).
   - **prompts & cues** means the technology includes ways to prompt medication intake at the agreed time. Restructuring the physical environment & adding objects means the technology includes advice on how to change the environment to make it easier to take medication as agreed with the healthcare provider.
   - **identity** means the technology includes ways of strengthening a positive identity that includes taking medications agreed with the healthcare provider.

3. **BCTs acting on motivation:**
   - **goals and planning** means the technology includes options to encourage setting goals related to adherence and planning to achieve them (e.g., action planning, discrepancy between behaviour and goals, goals setting and reviewing, problem solving).
   - **pros & cons** means the technology includes ways to identify and compare reasons for wanting or not wanting to take medication as agreed with the healthcare provider.
   - **regulation** means the technology includes advice and/or options/activities aiming to keep motivation for medication adherence within a range favourable for performing adherence-related behaviours (e.g., conserving mental resources, reducing negative emotions).
   - **self-belief** means the technology includes ways of increasing the person’s confidence they can take medication as agreed with the healthcare provider.
   - **imaginary reward** means the technology includes advice on how to imagine correct performance of medication intake.

4. **BCTs acting across all three determinant groups:**
   - **social support** means the technology includes options to advise, arrange or provide social support (practical, emotional, other), or praise/reward taking medication as agreed with the healthcare provider. Social reward means the technology includes verbal/non-verbal rewards when the patient shows effort and/or progress in taking medication as agreed with the healthcare provider.
   - **information about consequences** means the technology includes information about consequences (health-related, emotional, social, environmental) of medication adherence (or non-adherence) and emphasize their relevance for the person.

The definitions of behaviour change techniques are based on the Capability, Opportunity, Motivation and Behaviour (COM-B) model, the Theoretical Domains Framework (TDF), the Behaviour Change Techniques (BCT) taxonomy v1, and the Behaviour Change Intervention Ontology (BCIO). For a more detailed view of the respective sub-levels with labels and definitions please check the interactive graph or the Excel file under supporting information.
D2.4.2.B.4 Intervention provider

Intervention provider is a role played by a person who uses the technology to assist the patient in their self-management of medication adherence.

1. Please rate the RELEVANCE of this attribute group (X axis).
2. Please rate the CLARITY of this attribute group (Y axis).

Further explanation

Intervention provider entails:

1. **Health care professional** is an intervention provider that applies scientific knowledge in medicine, nursing, midwifery, pharmacy, dentistry and/or health promotion to support patients in managing their health (e.g., medical doctor, nursing professional, pharmacist, dentist, associated health professional).
2. **Psychosocial care professional** is an intervention provider that applies scientific knowledge in psychology, sociology and other social sciences to support individual and families in a community in their well-being and life goals (e.g., psychologist).
3. **Personal care worker** is an intervention provider that delivers care, supervision and assistance for children, patients and elderly, convalescent or disabled persons in institutional and residential settings.
4. **Personal provider** is an intervention provider that is related to the person to whom the intervention is targeted through aspects of their personal lives (e.g., family member, carer, friend, peer).

The definitions of the intervention provider attributes are based on several taxonomies: BCIO, in particular the Intervention Source Ontology, and Gender, Sex and Sexual Orientation Ontology (GSSO). For a more detailed view of the respective sub-levels with labels and definitions please check the interactive graph or the Excel file under supporting information.

D2.4.2.B.5 Intervention setting

Intervention setting is the social and physical environment in which the technology is or can be used to manage medication adherence.

1. Please rate the RELEVANCE of this attribute group (X axis).
2. Please rate the CLARITY of this attribute group (Y axis).

Further explanation

Intervention setting entails:

**Physical setting** is an intervention setting that consists in a physical environment where the medication adherence technology is used (e.g., residential facility, healthcare facility, educational facility, community facility).

**Virtual setting** is an intervention setting that consists in a virtual environment where the medication adherence technology is used (e.g., telemedicine, telepharmacy).

An intervention can be applied or applicable to one type of settings, or to both.

The definitions of the intervention setting attributes group are based on the BCIO, in particular the Intervention Setting Ontology. For a more detailed view of the respective sub-levels with labels and definitions please check the interactive graph or the Excel file under supporting information.
Table of contents for Domain 3 – evaluation and implementation

D3.1.1.A ISO certification

ISO certification is a general quality indicator referring to whether the MATech has obtained one or more ISO certification labels relevant for its content and purpose.

1. Please rate the RELEVANCE of this attribute (X axis).
2. Please rate the CLARITY of this attribute (Y axis).

The definitions of quality indicators are based on a checklist of e-health quality criteria (under development), Mobile Application Rating Scale (MARS), and the Consort-EHEALTH guideline.

D3.1.1.B Evidence from scientific evaluation

Evidence from scientific evaluation is a group of general quality indicators referring to whether the evaluation of MATech has been performed through the systematic, rigorous, and meticulous application of scientific methods, and the evidence obtained.

1. Please rate the RELEVANCE of this attribute group (X axis).
2. Please rate the CLARITY of this attribute group (Y axis).

Further explanation

The evidence from scientific evaluation entails:

1. **Research on development** means evidence from scientific evaluation is available to support the design of the MATech. This also encompasses the classification of quality of the presented evidence.
2. **Research on effectiveness** means evidence from scientific evaluation is available to support the effectiveness of the MATech (excluding cost-effectiveness, outlined in section D2.1.3 and implementation outcomes, outlined in section D3.2). This also encompasses the classification of quality of the presented evidence.
3. **Ethical and legal aspects** means the MATech research has ethical approval, has considered and addressed any risks for the target population, complies with the current laws on research on humans and data privacy and safety, and has shared information about how it meets these requirements.

The definitions of quality indicators are based on a checklist of e-health quality criteria (under development), the Mobile Application Rating Scale (MARS), and the Consort-EHEALTH guidelines. For a more detailed view of the respective sub-levels with labels and definitions please check the interactive graph or the Excel file under supporting information.

D3.1.1.C Development standards

Development standards are a group of general quality indicators referring to whether the MATech has been developed according to standards established in the development of health technologies.

1. Please rate the RELEVANCE of this attribute group (X axis).
2. Please rate the CLARITY of this attribute group (Y axis).
Further explanation
The development standards entail:

1. Development process means all development activities undertaken with respect to MATech are clearly described, such as activities related to preparation, development and optimization of product components as well as the manufacturing, validation and distribution process of the MATech.

2. User-centred design process means the MATech was developed in an iterative design process in which designers involved the target users and their needs in each phase of the design process. The users' requirements, objectives, and feedback were taken into account during the development process.

3. Conflict of interest means the provider’s conflict of interests are clearly described to assure trust and transparency.

4. Updates of information sources means information sources are periodically verified (proven to still be correct and accurate) and updated (new information added or design changed).

The definitions of quality indicators are based on a checklist of e-health quality criteria (under development), Mobile Application Rating Scale (MARS), Consort-EHEALTH guideline. For a more detailed view of the respective sub-levels with labels and definitions please check the interactive graph or the Excel file under supporting information.

D3.1.1.D Technological standards

Technological standards are a group of general quality indicators referring to whether a MATech corresponds to criteria commonly used to assess the technical functioning of electronic/digital components, if applicable.

1. Please rate the RELEVANCE of this attribute group (X axis).

2. Please rate the CLARITY of this attribute group (Y axis).

Further explanation
The technological standards entail:

1. Performance - the MATech works fast and accurately without bugs or errors (e.g., reliability of the interactive components, design scalability).

2. Data protection - collected data is properly protected to prevent sensible data leakage (e.g., data encryptions, antivirus supported maintenance, data storage place and capacity and protection against theft or physical attacks).

3. System integration - evidence of MATech meeting the technical, privacy and security requirements of health care systems.

4. Inter-devices portability - the MATech can be connected with several devices.

The definitions of quality indicators are based on a checklist of e-health quality criteria (under development), Mobile Application Rating Scale (MARS), Consort-EHEALTH guideline. For a more detailed view of the respective sub-levels with labels and definitions please check the interactive graph or the Excel file under supporting information.

D3.1.2 Research-related quality indicators

Quality indicators that evaluate if the research on the MATech has been performed according to standards established in measurement and intervention research.

1. Please rate the RELEVANCE of this attribute group (X axis).

2. Please rate the CLARITY of this attribute group (Y axis).
Further explanation
The research-related quality indicators entail:

1. **Theory base** means the MATech is developed based on theory, evidence, theoretical framework.
2. **Validity of measurement** means the MATech is valid for certain conditions, populations, etc. (content validity)
3. **Validity of intervention** means the use of BCTs in the MATech is evidence based, i.e., there is scientific evidence that the chosen BCTs are likely to be effective in influencing the chosen behaviour determinants.
4. **Reliability of measurement** means the MATech shows a high test-retest reliability, internal consistency, and inter-rater reliability.

The definitions of quality indicators are based on a checklist of e-health quality criteria (under development), Mobile Application Rating Scale (MARS), Consort-EHEALTH guideline. For a more detailed view of the respective sub-levels with labels and definitions please check the interactive graph or the Excel file under supporting information.

D3.1.3 Policy-related quality indicators
Quality indicators related to Health Technology Assessment (HTA) procedures and concepts that inform decision-making regarding implementation and use of health technologies.

1. Please rate the RELEVANCE of this attribute group (X axis).
2. Please rate the CLARITY of this attribute group (Y axis).

Further explanation
The policy-related quality indicators entail:

1. **Economic and cost evaluation (ECO)** means an economic analysis has been performed to inform value-for-money judgements about the MATech with information about costs, health-related outcomes and economic efficiency. It entails several types of analysis (e.g., cost-effectiveness, cost-utility, cost-benefit, budget impact), which can be country or system specific, thus the repository also needs to specify where these indicators apply.
2. **Current use of technology (CUR)** specifies the regulatory status (authorization and reimbursement) of the technology. These information are country or system specific, thus the repository also needs to specify where these indicators apply.

The definitions of policy-related quality indicators are based on Health Technology Assessment (HTA) Core Model, version 3.0 and O'Rourke et al. (2020). "The new definition of health technology assessment". For a more detailed view of the respective sub-levels with labels and definitions please check the interactive graph or the Excel file under supporting information.

D3.1.4 Use-related quality indicators
Quality indicators that evaluate if the MATech use meets users’ expectations and provides a pleasurable experience of interaction with the technology.

1. Please rate the RELEVANCE of this attribute group (X axis).
2. Please rate the CLARITY of this attribute group (Y axis).
Further explanation
The use-related quality indicators entail:

1. **Usability** means MATech qualities such as simplicity, organization, intuitiveness and reliability. High usability is indicated when MATech is simple, well organized, intuitive and reliable.
2. **Satisfaction** means satisfaction with MATech assessments were performed to control the level of satisfaction of the end user.
3. **Customization** means the MATech or some parts of it can be customized to the needs of the individual user.
4. **Aesthetics** is the perception of the product, which can be described as aesthetic (size, layout, graphic, font size etc.) as this was evaluated in a research project or external review.
5. **Readability** means the ease of understanding or comprehension achieved by the style of writing. The reader must be able to recognize (decode) the words in the medical device patient labelling as well as comprehend the meaning of the text.

*The definitions of quality indicators are based on a checklist of e-health quality criteria (under development), the Mobile Application Rating Scale (MARS), and the Consort-EHEALTH guideline. For a more detailed view of the respective sub-levels with labels and definitions please check the interactive graph or the Excel file under supporting information.*

**D3.2.1 Implementation outcomes**

Implementation outcomes are characteristics of the technology regarding its implementability in clinical practice, as supported by evidence.

1. Please rate the **RELEVANCE** of this attribute group (X axis).
2. Please rate the **CLARITY** of this attribute group (Y axis).

Further explanation
Implementation outcomes entail:
- **Acceptability** means whether stakeholders reported satisfaction with various features of the technology and the experience of using it to support medication adherence
- **Feasibility** means whether stakeholders perceived the technology as practical and fit for use in supporting medication adherence
- **Sustainability** means whether stakeholders perceived the technology as appropriate for routine sustained use in supporting medication adherence

*Definitions of implementation outcomes and strategies are based on Proctor et al. (2011) "Outcomes for Implementation Research: Conceptual Distinctions, Measurement Challenges, and Research Agenda", the Consolidated framework for advancing implementation science (CFIR), the Expert Recommendations for Implementing Change (ERIC) and the Interventionen.nl website. For a more detailed view of the respective sub-levels with labels and definitions please check the interactive graph or the Excel file under supporting information.*

**D3.2.2 Implementation strategies**

Implementation strategies are characteristics of the technology that facilitate implementation and maintenance of the technology in a setting.

1. Please rate the **RELEVANCE** of this attribute group (X axis).
2. Please rate the **CLARITY** of this attribute group (Y axis).
Further explanation
Implementation strategies entail:
1. **Training** are activities to teach stakeholders about the technology and how to use it and integrate in the medication adherence support processes.
2. **Educational materials** are materials stakeholders may consult to learn about the technology and how to use it and integrate in the medication adherence support processes.
3. **Funding** are financial strategies and/or additional costs to facilitate adoption of the technology into medication adherence support practice.
4. **Expertise sharing** are information from previous implementations on what helped adopt the technology into medication adherence support practice.
5. **Technical assistance** are systems to support implementation of the technology into medication support practice.
6. **Consultation** means accessing direct support from experts for the implementation of the technology into medication support practice.
7. **Accreditation & legal approvals** are credentials and/or licensing to acquire or prove to be able to use the technology in a setting in the conditions necessary for optimal safety and effectiveness.
8. **Collaborations** means involving multiple institutions in delivering the medication adherence support solution that uses the technology.
9. **Access to additional resources** means access to data, space, laboratory facilities.

*Definitions of implementation outcomes and strategies are based on Proctor et al. (2011) “Outcomes for Implementation Research: Conceptual Distinctions, Measurement Challenges, and Research Agenda”, the Consolidated framework for advancing implementation science (CFIR), the Expert Recommendations for Implementing Change (ERIC) and the Interventionen.nl website. For a more detailed view of the respective sub-levels with labels and definitions please check the interactive graph or the Excel file under supporting information.*
Thank you and see you soon!

Dear panellist,

you have made it to the end of the survey. We appreciate your effort and valuable contribution to development of the ENABLE repository of medication adherence technologies.

Please remember to visit the survey several times during the study period to reconsider your answers based on the aggregated feedback and discussions with the other anonymous panellists. Reminders will be sent every 2 weeks to remind you to log in and participate again.

Please don't hesitate to contact us on wg2costenable@gmail.com in case of any questions.

Best wishes,

The ENABLE WG2 Steering Committee
General data protection statement (GDPR)

By continuing the survey, you declare that you have read, understood and agreed with the following statements:

1. This Delphi survey is performed by the COST Action ENABLE (CA19132) Working group 2 with principal investigators Alexandra Lelia Dima and Urska Nabergoj Makovec.
2. The aim of the study is to explore the level of agreement on the proposed structure for a repository of medication adherence technologies
3. Participation in the survey is voluntary and the study is designed to ensure participants’ anonymity as one of the key features of the Delphi approach.
4. The collected personal data will be used exclusively for conducting the study and analysing and reporting results in an aggregated form.
5. In order to illustrate some study findings, we might quote statements provided by individual respondents in open text fields; however, the Delphi platform ensures that no personal data can linked to such statements.
6. A data protection assessment was carried out by the Data Protection Officer at the University of Basel. According to this instance the Delphi study protocol was determined as compliant with data protection and security standards.
7. The personal data used for conducting this study will be stored until the end of the COST Action ENABLE (October 2024). You can address your rights regarding access to, correction of or limitation of use of your personal data through the email wg2enablecost@gmail.com anytime during that time period.
Welcome to the ENABLE-R real time Delphi survey!

**ENABLE** is a European Cooperation In Science and Technology (COST) project ("CA19132 - European Network to Advance Best practices & technology on medication adherence") that aims to raise awareness of medication adherence technologies and best practices, and to foster and extend multidisciplinary knowledge on medication adherence at patient, treatment and system levels. COST is supported by the EU Framework Programme Horizon 2020. ENABLE currently has members from 39 European countries.

**ENABLE-R** will be an online repository of medication adherence technologies (ENABLE-R), which will describe a wide range of technologies relevant for different potential users: patients, healthcare professionals, managers of healthcare organisations, policy makers, researchers. The aim is to develop a user-friendly repository, where users will be able to search technologies with specific attributes, that would fit their context and needs.

**This Delphi survey aims to explore the level of agreement with the proposed scope and structure of the repository.** A steering committee has been working since October 2020 to define medication adherence technologies and propose a repository structure that considers many aspects of such technologies and their use in different settings. To ensure that the scope and structure is in line with stakeholders’ needs and expectations, we created this Delphi survey to consult with stakeholders across Europe on several key elements of the proposed scope and structure. The study obtained ethical approval and positive data protection assessment. Please consult the survey information letter or contact us at [wg2costenable@gmail.com](mailto:wg2costenable@gmail.com) if you have any questions.

You were recognized as a stakeholder in the area of medication adherence and are invited to participate in this Delphi survey. Thank you for taking time to complete this survey. We value your contribution.
Instruction for the Delphi survey

The content and structure of the survey

The survey includes **23 questions** related to repository structure, each presented on a separate page. Before starting the survey, we request some **basic information** about you and your experience in medication adherence.

- We present the proposed **definition of the medication adherence technologies (MATech)** for your consideration.
- We invite you to take some time **to explore the full framework of attributes**. It consists of **three domains** (D1. Product & provider information; D2. Medication adherence descriptors; D3. Evaluation & implementation) with underlying attribute groups. Each attribute group branches further in sublevels with related labels and definitions and is labeled with domain number and consecutive number according to the level it represents (e.g. D2.1 or D2.1.1). The complete framework is presented in an interactive graph and in a Excel document detailing proposed structure, labels, definitions and justifications; you may open these documents in separate windows so that you can consult them throughout the survey. After familiarizing yourself with the framework, we ask you to provide general comments about **any missing attributes** relevant for a future MATech repository.
- We describe each domain on one page and present each attribute group and respective sublevels for your consideration on separate pages and ask you to rate their **overall relevance and clarity** and provide comments or suggestions for improvement of attribute labels or definitions, and any specific thoughts about any missing attributes in this particular group.

The real time Delphi approach

This survey uses a **real-time approach**, which means that, once you answer a question, you will immediately see other’s responses and comments and aggregated feedback on your screen. The strength of the Delphi approach lies in participants having the opportunity to revisit their answers based on other’s answers and comments. Hence, it is very important that you **visit the survey two or more times during the study period and reconsider your answers based on the aggregated results and discussions in the comments section**. You are also encouraged to engage in the discussion by explaining the reasons for your responses and making suggestions for improvement. These will also appear in real-time and allow (anonymous) exchanges among stakeholders.

We will regulary check the platform, send updates on the study progress and reminders to (re)visit the survey.

Completing the survey

It should take you **45 to 60 minutes** to complete the survey the first time, and approximately **30 to 60 minutes** for revisiting your answers at a later moment (depending on the level of engagement in discussions you prefer).

You can **navigate across pages** in the survey by clicking on the blue arrow above the page number. An index window opens and you can choose which questions you would like to answer. For the first
visit to the survey, we recommend following the order provided. You can log in and out of the survey and upon return continue answering where you stopped the last time.

**Format of the questions**

For each attribute, an interactive 2D grid with two axes (see below) will appear:

- **the horizontal (X) axis** represents **RELEVANCE** of the proposed attribute group for the repository structure on a scale from 1-9 (left-right), where 1 indicates extremely not relevant (far left) and 9 indicates extremely relevant (far right). By relevance, we mean the extent to which these attributes are important in order to make informed choices regarding their adoption and use.
- **the vertical (Y) axis** represents **CLARITY** of the attribute group labels and definitions on a scale from 1-9 (bottom-top), where 1 indicates extremely not clear (bottom) and 9 indicates extremely clear (top). By clarity, we mean the extent to which the labels and definitions of these attributes are easy to understand and apply by repository users.
- after deciding on your rating on both axes, you can mark your answer in the grid and a blinking dot will appear representing both your ratings. **One dot for two ratings: left-right RELEVANCE, bottom-up CLARITY.**
- the scale is continuous, which means you can click anywhere in the grid and thus rate using decimal values (e.g. 4.7)
- after providing your answer, you will be able to see other participants’ ratings represented as dots on the same grid, and aggregated feedback on the right side of the 2D grid.
- You can change your ratings any time during the study period, by moving the blinking dot on the grid. Moreover, you are encouraged to revisit your answers on multiple occasions in light of other participants’ answers.

Each attribute page also contains a **comments section**. Below the 2D grid you can find open text fields to provide comments or suggestions on the attribute and related sublevels. All comments are displayed anonymously. Please provide your comments in the relevant pre-defined category:

- revisions of attribute labels and definitions
- missing attributes in this group

There you can also see other participants’ comments and suggestions and respond to them. Please remember to save your comments before leaving a page so that they can be recorded and displayed.
Servicio Andaluz de Salud
CONSEJERÍA DE SALUD

Dra. Dña. Gloria Luque Fernández, Secretaría del CEI Provincial de Málaga

CERTICA:

Que en la sesión de CEI de fecha: 29/04/2021 ha evaluado la propuesta de D/Dña.: Pilar Barnestein Fonseca, referido a la MS1 del Proyecto de Investigación: "COST Action "European Network to Advance Best practices & technology on medication adherence" (ENABLE) ".

Este Comité lo considera ética y metodológicamente correcto.

La composición del CEI en esta sesión es la siguiente:

Dra. Ana Alonso Torres (UGC Neurociencias)
Dra. Encarnación Blanco Reina (Farmacología Clínica)
Dra. Begoña Jiménez Rodríguez (UGC Oncología)
Dra. Marta Blasco Alonso (Obst. y Ginecología)
Dr. Rafael Carvajal Ponsalé (Anatomía Patológica)
Dª. Ana Díaz Ruíz (Licenciada en Derecho)
Dr. José C. Fernández García (UGC Endocrinología y Nutrición)
Dr. Manuel Herrera Gutiérrez (UGC UCI)
Dra. Mª Victoria de la Torre Prados (UMA)
Dr. José Leiva Fernández (Médico Familia)
Dra. Mª Dolores López Carmona (Medicina Interna)
Dr. Jesús López del Peral (Esp.Protec.Datos)
Dña. Carmen López Gálvez del Postigo (Miembro Lego)
Dª. Inmaculada Doña Díaz (Alergología)
Dra. Gloria Luque Fernández (Investigación)
Dra. Cristobalina Mayorga Mayorga (Laboratorio)
Dra. Mª Angeles Rosado Souvirón (UGC Farmacia)
Dra. Leonor Ruiz Sicilia (UGC Salud Mental)

Lo que firmo en Málaga, a 29 de abril de 2021

Fdo.: Dra. Gloria Luque Fernández
Secretaría del CEI
Basel, 25. Mai 2021

Data Protection Assessment of your project “Developing a medication adherence technologies repository: an online real-time Delphi survey protocol”

Dear Ms. Ribaut

I would like to confirm, that we have reviewed your project with regard to data protection and data security. Based on the documents provided to us, we can confirm that data protection is complied with in your project. In particular, since you collect the survey responses exclusively anonymously and no conclusions can be drawn about individual persons.

Yours sincerely,

Danielle Kaufmann
Data Protection Officer