# LIVING EVIDENCE

TO INFORM HEALTH DECISIONS



PROTOCOL SUMMARY

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### 1. Introduction

Despite constant advances in the appropriation of scientific knowledge and technological developments, there is still a gap between health professionals to produce and use more up-to-date evidence in decision-making. Every day in the world, important healthcare decisions are still made with incomplete or outdated information about the effects (benefits and harms) of the different health care interventions available.

In the most recent years, a new methodological approach known as "*Living evidence*" (LE) has emerged (1). LE refers to an efficient -as well as rigorous- evidence synthesis that is continually updating, supported by technological tools that identify and classify all new emerging evidence on a topic of particular interest. This approach, when applied to the resolution of relevant and rapidly changing clinical questions, is optimal to ensure a rapid update of SRs that informs on the effects of controversial health interventions and/or CPG recommendations where there are uncertainties. Besides, along with these initiatives, new user-friendly electronic formats for transferring information have also been proposed to ensure greater usability and impact of the information (2,3).

Nevertheless, integrating the processes to generate and maintain living evidence in the knowledge transfer products (KT-products) used to inform health decisions, such as clinical practice guidelines (CPG), health technology assessment reports (HTA), and structured evidence summaries for health policies (institutional or public), is one of the biggest challenges facing organizations now days.

*"Living Evidence to inform health decisions*" aims to address this need, developing and evaluating a strategy to provide support for producing and incorporating Living Evidence synthesis in different KT-products. It is expected that, through a cooperative institutional effort, the project allows for the construction of an innovative strategy (*Living Evidence to inform health decisions* framework) that facilitates all types of healthcare decisions (including clinical decisions, decisions for clinical recommendations, for public health and coverage decisions) to be based on the most current evidence as it is constantly updated when new studies become available.

The framework will be based on previous developments as those proposed by the Cochrane Living Systematic Review Network (4, 5, 6, 7), the methodological approach for conducting overviews (panoramic reviews of the same topic)(8); the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach (9); the Epistemonikos Evidence Synthesis Project [Epistemonikos-ESP] and its Living Overview of Evidence (L.OVE) platform (10,11).

Our aim is that the framework will be applicable to any country or region, increasing the impact of health research, reducing the costs and time consuming related to KT-products updating processes.

### 2. Objectives

To evaluate and validate a framework for the incorporation of living evidence synthesis in the development of KT products, aimed at problems in which the evidence evolves rapidly or constantly.

To assess the effectiveness and usability of the L.OVE platform as a tool to keep the living evidence.

As a capacity-building research project, our main objective is:

To obtain, improve, and retain new skills, knowledge, and use of validated technological tools needed to develop and use "Living evidence" synthesis to inform health decisions among the health care community and to evaluate the efficacy of the strategies used for building that capacity.

## 3. Methods

### 3.1. Study population

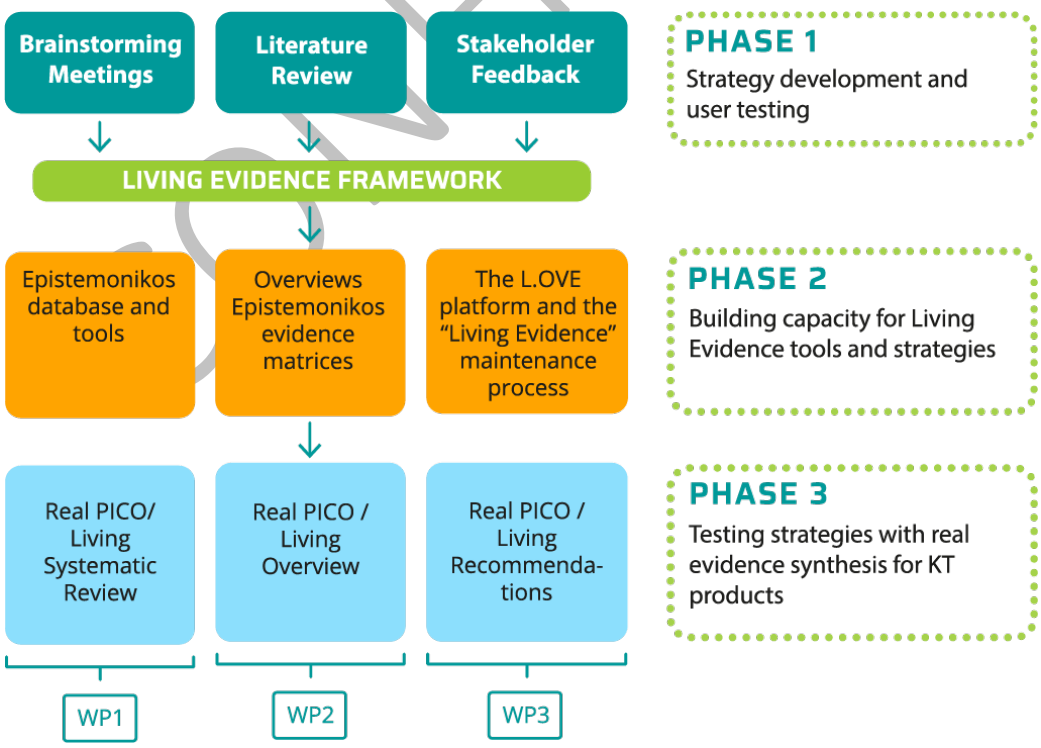
The project is aimed at the professional members of the groups of different organizations in charge of developing knowledge transfer products to inform their own health decisions or to support health decision-makers.

Therefore, our study population will include technical team in charge of developing evidence synthesis and knowledge transfer products in different settings: 1) Scientific Societies; 2) health technology assessment agencies; and 3) Clinical practice Guideline Developers.

### 3.2. Design

*Living Evidence to inform health decisions* is a knowledge translation and capacity building project that involves both the design and evaluation of a strategy to produce and use *living evidence* in the development of knowledge transfer products, such as CPGs, health technology assessment reports, and evidence summaries for decision makers. The project includes three complementary phases (see figure 1)

*Figure 1: A project picture*



### 3.2.1. Phase 1: Strategy development

An initial living evidence framework (LE-framework) will be developed from a detailed and extensive revision of the literature, which will aim to identify not only the methodologies that support the identification, selection, and synthesis of living evidence but also the strategies for incorporating the new relevant evidence in the KT-products (i.e. CPG, HTA, and structured evidence summaries for health policies). For this purpose, the following actions will be carried out: i) review of the methodological articles generated on the subject; ii) a systematic review of the literature of published living systematic reviews; iii) a consultation with expert methodologists working in different groups internationally recognized for their contributions to the live evidence strategy.

The LE-framework will guide groups to use appropriate criteria for defining which clinical problems (structured into clinical questions) benefit from a constant review of the new evidence, the frequency with which these processes should be carried out, and whether to incorporate the new evidence synthesis and conclusions to the KT-products already developed. For this end, the LE-framework will include a list of possible actions (pathway) to guide the incorporation of the new relevant evidence in the CPG's recommendations, the HTA reports, or the structured evidence summaries for institutional or public policies. It will also present alternatives for updating existing publications and for alerting readers and the audience about the updates and relevant points that may imply changes in clinical practice.

The preliminary LE-framework will be reviewed by peers—such members of Cochrane Living Systematic Review network, GRADE working group, the Guideline international network (G-I-N) and the National Institute of Clinical Excellence (NICE) among others working in the field. The comments and contributions from expert peer reviewers will be integrated into the framework to generate a final version that will be applied to diverse examples in the next phases of the project.

### 3.2.2. Phase 2: Building capacity in Living Evidence tools and strategies

For this project, the Epistemonikos L.OVE platform will be the tool used as part of the strategy to keep the living evidence (i.e. for generating and maintaining the living evidence process). L.OVE is a digital tool that combines a series of technological advances (including artificial intelligence algorithms) with the effort of a network of experts, to obtain and organize health evidence as soon as it is produced. With the L.OVE platform https://iloveevidence.com/), the developers have created a comprehensive map of questions relevant for health decision-making, using the PICO format (Population, Intervention, Comparisons, and Outcomes). A L.OVE is created for each health topic or condition (i.e., COPD) and the questions are organized by specific subtopics, such as prevention, diagnosis, therapy, or prognosis. The platform gathers information from 10 sources that are routinely examined in the Epistemonikos Database and can be programmed for searching other databases relevant for the specific topic. Once the PICO question is defined, and search strategies are included in the L.OVE platform, the results are obtained very quickly (between 1 minute to a couple of hours) Information from saved questions is constantly updated as new evidence appears. The screening and selection of evidence processes can be shorter than usual thanks to artificial intelligence.

Therefore, this phase seeks two main objectives: i)To build the capacity among professionals of different organizations (i.e. scientific societies, hospital institutions working for evidence based decisions and practice, guideline developing groups and health technology assessment agencies) to produce living evidence synthesis integrated into the Epistemonikos-L.OVE platform and, ii) evaluate the strategies used for building this capacity. A set of training workshops will be carried out, aimed at the participants designated by each participating organization. Training will be focused on the processes inherent to generating living evidence based on the Epistemonikos L.OVE platform. Complimentary workshops for supporting the evidence synthesis process and the evaluation of certainty of updated evidence, according to the GRADE approach, will be provided depending on the degree of experience and previous training of the participants.

#### 3.2.3. Phase 3. Developing living evidence synthesis for KT-products

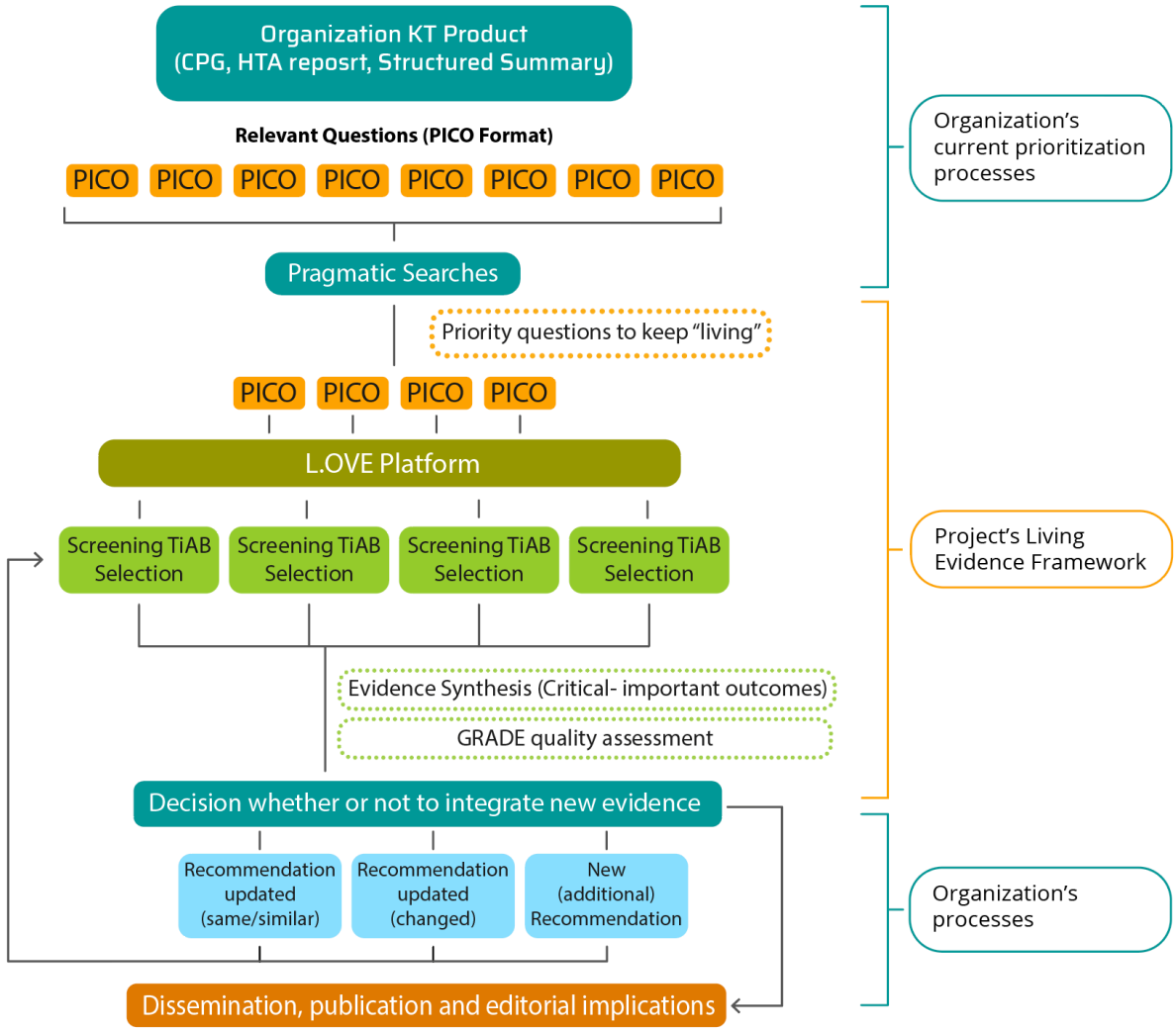
This phase seeks to apply the LE-framework to real life, diverse situations. According to the particular interest of an organization, the KT products to be worked could be: i) structured evidence summaries for institutional and/or public health policies; ii) health technology assessment reports, and iii) evidence-based recommendations for a CPG.

Following the principle of "learning by doing" (12), we expect members from the participant organizations to generate at least one evidence syntheses (i.e. one PICO) needed to develop their own KT-products following the LE-framework. In this way, the participant's skill development will be strengthened through the experience while we evaluate the LE-framework performance. This process is illustrated in Figure 2.

Each evidence synthesis will be worked as an independent project, with an assigned working group that will involve content experts (physicians) and methodological experts from the participating organization (i.e., HTA agencies, guideline development groups, scientific organizations, research consortiums, hospital institutions) and a member of the research team (i.e. IIB Sant Pau and Epistemonikos Fundation).

Information necessary to evaluate the LE-framework, and the use of the L.OVE platform as the tool for keeping the evidence "living", will be collected through the whole process. The results of these evaluations will allow the framework to be redefined as a tool to incorporate and maintain living evidence in the KT-products that the participating organizations regularly produce.

*Figure 1: The evidence synthesis process*




## 4. Results

This project will generate different types of results;

- those related to the design and evaluation of the framework and the use of the LOVE platform as a tool to keep the evidence alive

- those related to capacity building to use and apply living evidence in the evidence syntheses that organizations regularly carry out

- those directly related to the evidence syntheses completed by the project participants

- the generation of structured summaries on priority topics for decision-making as a useful and practical transfer tool for clinicians and decision-makers.

We will generate publications on the construction of the LE-framework, the results of its evaluation as a tool to incorporate living evidence in the KT-products, as well as the usefulness of the L.OVE platform for this purpose.

The results of the evidence syntheses (i.e. LSR or overviews) will be published in national and international indexed scientific journals, according with the agreement made with the participating organizations. The KT-products from which they are derived will be disseminated through the usual channels used by the participating organizations.

Evidence summaries will be published initially on the project website in English and Spanish and will be freely accessible to clinicians and other health personnel. An example of the summaries is available in the project annexes.

## 5. Ethical Issues

This project has been evaluated by the Hospital de la Santa Creu i San Pau Ethical Committee with the fundamental ethical principles and approved by the European Commission for research actions.

An informed consent will be requested prior to the inclusion of the professionals from the different participating organizations, and they will have the option to voluntarily retire from the project at any time. Special attention will be paid to guarantee the principle of autonomy and avoid coercion by the employing organizations.

Both the participating organizations and their members will directly benefit from the results of this investigation.

Transparency will be guaranteed in the training and evaluation processes both for the participants and for the organization to which they belong.

## 6. Funding

The project is sponsored by the co-executing institutions: Fundació Institut de Recerca del Hospital de la Santa Creu i Sant Pau (IIB-Sant Pau http://www.recercasantpau.cat/es/) and the Epistemónikos Foundation (https://www.epistemonikos.cl/), which provide the infrastructure for its development, as well as the time of its researchers participants. There is a Marie Curie for Individual Researchers grant from the European Commission (EC https://cordis.europa.eu/project/id/894990/es) that protects the time of the principal investigator.



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