LIVING EVIDENCE

TO INFORM HEALTH DECISIONS

This document presents the research project
*"Living Evidence to inform Health Decisions"*

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## Content

## Presentation of the project

"*Living Evidence to inform health decisions*" is a knowledge transfer and capacity building research project involving the design and evaluation of a model strategy to generate, use, and apply innovative tools to support health decisions to be based on the most recent evidence.

The project is part of a research program led by María Ximena Rojas as the principal investigator, who currently holds an independent fellowship H2020 Marie Curie Action (MSCA-IF-EF-ST #894990), together with a group of researchers with extensive experience in synthesis processes, knowledge transfer and implementation. This group includes Pablo Alonso, Gerard Urrutia, Gabriel Rada, and David Rigau. It is being executed at the Institut d'Investigació Biomèdica Sant Pau (IIB Sant Pau) in Barcelona, in collaboration with the Epistemonikos Foundation.

### Background

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 Every day in the world, important healthcare decisions are still made with incomplete or outdated information about the effects (benefits and harms) of the different health care interventions available.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 an innovative strategy 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 model 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 model will be constructed on the basis of previous developments as those proposed by the Cochrane Living Systematic Review network (4,5,6,7), the methodological approach

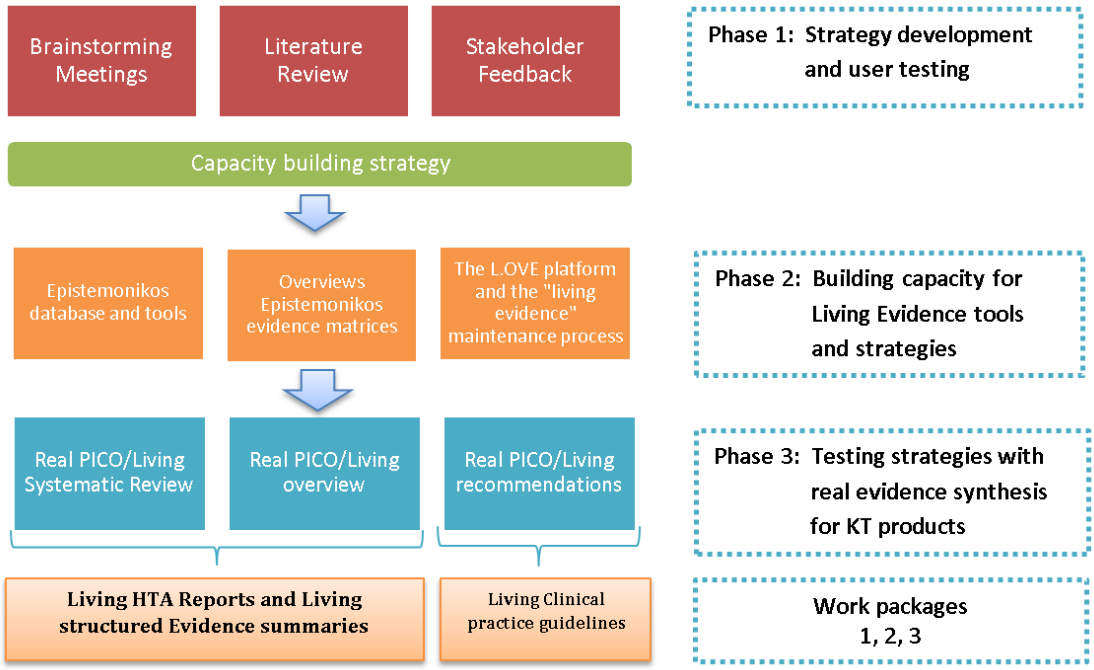
for conducting overviews (panoramic reviews of the same topic)(8); the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach (9); the Epistemonikos Evidence Synthesis Project [Epistemonikos-ESP] and its Living Overview of Evidence (L.OVE) platform (10,11).

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

## Methodological approach

The project includes three complementary phases (see figure 1)

*Figure 1: A project picture*




### *Phase 1: Strategy development and user testing*

An initial living evidence model (LE-model) 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).

We expect the LE-model 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 to the recommendations and conclusions of the KT-products already developed. For this end, the LE-model will include a list of actions (pathway) to guide the incorporation of the new relevant evidence in the CPG's recommendations, the HTA reports, or the structured evidence summaries. 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.

At the core of this model is the Epistemonikos L.OVE platform, 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. Information FROM saved questions is constantly updated as new evidence appears. The platform gathers information from 10 sources that are routinely examined in the Epistemonikos Database as well as from the other databases relevant for the specific topic. The effectiveness of the platform has been proven by different institutions. Chile's Ministry of Health used L·OVE to update the body of evidence of 150 questions from 22 CPGs in only 6 months. Currently, the L.OVE of COVID-19 is being used by the WHO and other groups to support the generation and synthesis of living evidence necessary to face the COVID-19 pandemic (12,13,14).

The preliminary LE-model will be evaluated 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). The comments and contributions from peer reviewers will be integrated into the model to generate a final version that will be applied to user testing and later applied to diverse examples in the next phases of the project.

### *Phase 2: Building capacity in Living Evidence strategies*

This phase seeks two main objectives: 1) develop the capacity among members of the participant`s organizations to produce living evidence syntheses supported by the L.OVE platform and, 2) 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. The anticipated workshops are as follows:

- Searching and use of Epistemonikos database
- Generating evidence matrices and overview production
- The L.OVE platform and generation of Living Evidence process
- Structured and friendly evidence summaries based on Epistemonikos tools

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.

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

This phase seeks to apply the LE-model 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.

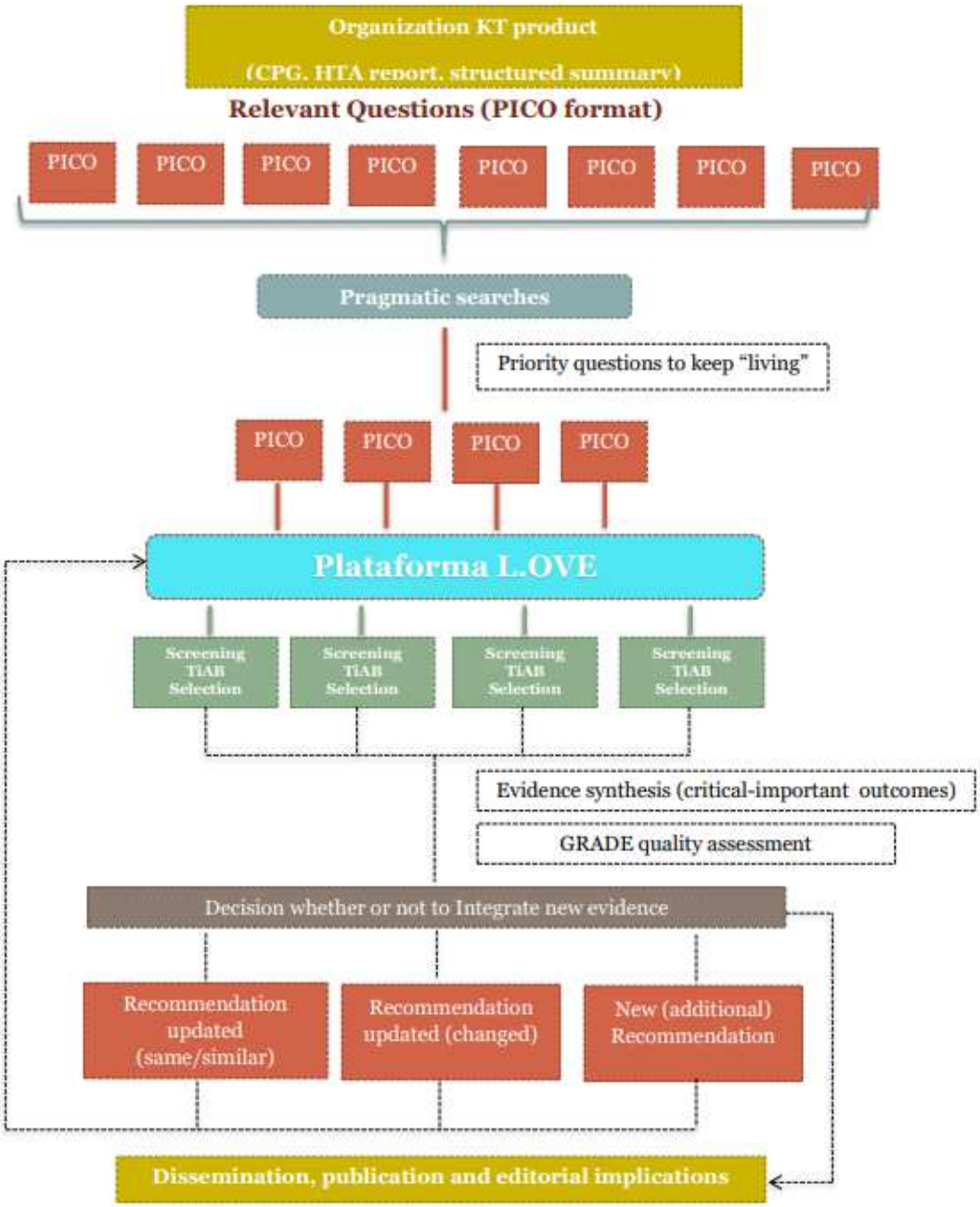
Following the principle of "learning by doing"(15), we expect members from the participant organizations to generate at least two evidence syntheses (i.e. two PICOs) to develop their own KT-products following the LE-model. In this way, the participant's skill development will be strengthened through the experience while we evaluate the LE-model performance.

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 both the participating organizations (i.e. HTA agencies, guideline development groups, scientific organizations, research consortiums, hospital institutions) and the research team (i.e. IIB Sant Pau and Epistemonikos Fundation).

The figure 2 presents the process we will follow for developing the evidence synthesis for KT-products using the *LE-model*.

Information necessary to evaluate the LE-model, 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 model to be redefined as a tool to incorporate and maintain living evidence in the KT-products that the participating organizations regularly produce.

*Figure 2. Process for developing the evidence synthesis for KT-products following the LE-model*




## Expected results and dissemination

The primary result will be a framework that will serve as a model to incorporate living evidence into decision making (LE-model). The LE-model will summarize logically and transparently all the elements for incorporating living evidence in in CPG recommendations, HTA reports, and/or structured evidence summaries for decision makers. It will be available to the different organizations that work on these KT-products to inform decisions, so their decisions can be based on the most recent evidence, which will result in benefits for patients and in reducing costs of update processes.

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

As knowledge transfer and capacity-building project it will also generate other results grouped in three complementary work packages [WP]:

| WP1. Living Systematic Reviews and/or Living Overviews | WP2. Structured and friendly evidence summaries | WP3. Living Guideline recommendations. |
|---|---|---|
| Achieve training of members from the participating organizations in charge of performing evidence synthesis to inform decisions in the production of living evidence synthesis, either RSs or overviews supported by the L.OVE platform. | Achieve training of members from the participating organizations (i.e. scientific organizations, guideline developers, hospital institutions, HTA agencies) in the preparation of structured and friendly evidence summaries to inform decision makers, following the methods proposed by the SUPPORT project (16) and supported by Epistemonikos tools to keep them "living". | Achieve building the capacity among members of the guideline development groups or tasks forces to develop and update guideline recommendations supported by the L.OVE platform, as part of their current developing and updating process. |
| Up to two LSR/overviews produced by each participating organization | One Structured evidence summary for each prioritized question developed. | Up to two evidence based recommendations of selected CPGs from two participating organizations. |

We will present the evaluation results on the relevance and effectiveness of the training strategies used in the project to build capacity in scientific meetings and publications.

The results of the evidence syntheses (i.e. LSR or overviews) will be published in national and international indexed scientific journals, as agreed 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.

## Ethical aspects

This project has been evaluated by the Hospital de la Santa Creu i San Pau Ethical Committee with the fundamental ethical principles. 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.

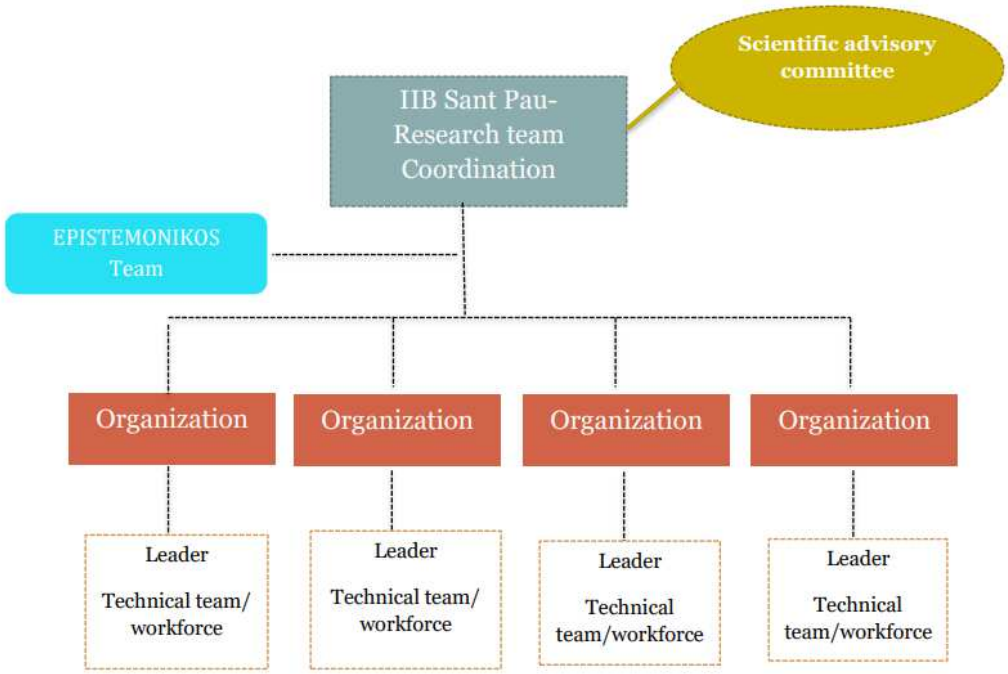
Transparency will be guaranteed in the training and evaluation processes both for the participants and for the organization to which they belong.

## Project Management Structure

The project is being coordinated from the Clinical Epidemiology and Public Health Service of the Hospital de la Santa Creu i Sant Pau (IIB Sat Pau[1]).

A scientific advisor committee is being conformed to members of Cochrane Living Systematic Review network, GRADE wg, the Guideline international network (G-I-N) and the National Institute of Clinical Excellence (NICE).

As participants, we are inviting national and international organizations that develop clinical practice guidelines, health technology assessment reports or summaries for evidence-based informed policies in healthcare institutions. Among these, organizations of which the IIB Sant Pau research group members are part and have successful networking experiences such as: the European Respiratory Society (ERS), the American Thoracic Society, the European Commission Initiative on Breast Cancer's guidelines on screening and diagnosis of breast cancer (ECIBC), the Spanish research group in breast cancer (GEICAM), the institutions of the Consortium of the Spanish Network for Biomedical Research in Epidemiology and Public Health (CIBERESP[2]); health technology assessment agencies (e.g. AQuAS) and secondary and tertiary health care institutions (hospitals) that are part of the MAPAC [3] project in Spain.




*1 http://www.recercasantpau.cat/es/grupo/epidemiologia-clinica-y-servicios-sanitarios/*
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## Why organizations should take part?

The organizations that agree to participate and in particular their members (i.e. task force in charge of developing and updating evidence syntheses for KT-products), will not only have the opportunity to evaluate the model and give their opinion on its final version but also receive training in the technical support required to incorporate the use of living evidence based on innovative technologies, in their current processes.

For example, the incorporation of the LE-model in the guideline development will facilitate the process of updating specific recommendations within a CPG, since it will allow the evidence that supports its recommendations on the most relevant health issues, to be continuously updated, especially those with rapidly evolving evidence.

This process will lead to:

- Quick responses to the release of new evidence
- When new relevant evidence is identified by the living review, an updated recommendation and publication release is expected to occur in few weeks.
- Increase trustworthy by avoiding outdated recommendations
- Increase impact and dissemination of guidelines

The publication of periodic updates of the recommendations that change as new evidence becomes available and probably in advance of the publication of the update of the global CPG, will increase the group's publications on topics of greater interest to clinical practice.

## What does participation imply?

To determine the relevance and suitability of the model, the members of the participant organization will be directly involved in phases 2 and 3. The research group as well as the Epistemonikos team will provide accompaniment and support in each step of the process.

It is expected that enrolled participants take part of:

- Identification and prioritization process of the specific question(s) for which it is desired that *living evidence* be available
- Training courses and workshops planned as part of the project
- Development of the synthesis of evidence following the LE-molde for the questions of interest of his/her organization
- Incorporation of the evidence synthesis carried out into their institution's KT-products (i.e. recommendations in CPGs, HTA reports, etc.)
- Surveys, interviews or assessment activities planned to evaluate the strategies used in each of the aforementioned processes

The organization's participation will have explicit recognition in all the publication and dissemination strategies that are carried out relating to the project and its results.

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