AUTHORS

Philippe Mortier, Hospital del Mar Research Institute, Barcelona, Spain; CIBER en Epidemiología Y Salud Pública (CIBERESP), Madrid, Spain

Jordi Alonso, Hospital del Mar Research Institute, Barcelona, Spain; CIBER en Epidemiología Y Salud Pública (CIBERESP), Madrid, Spain; Universitat Pompeu Fabra, Barcelona, Spain

Franco Amigo, Hospital del Mar Research Institute, Barcelona, Spain; CIBER en Epidemiología Y Salud Pública (CIBERESP), Madrid, Spain

Montserrat Ferrer, Hospital del Mar Research Institute, Barcelona, Spain; CIBER en Epidemiología Y Salud Pública (CIBERESP), Madrid, Spain; Universitat Pompeu Fabra, Barcelona, Spain

Oskar Flygare, Department of Clinical Neuroscience, Karolinska Institutet, Stockholm, Sweden

Angela Leis, Hospital del Mar Research Institute, Department of Medicine and Life Sciences (MELIS), Universitat Pompeu Fabra, Barcelona, Spain.

Miguel A. Mayer, Hospital del Mar Research Institute, Department of Medicine and Life Sciences (MELIS), Universitat Pompeu Fabra, Barcelona, Spain.

Víctor Pérez Sola, Parc de Salut Mar, Barcelona, Spain; CIBER Salud Mental (CIBERSAM), Madrid, Spain; Universitat Autònoma de Barcelona (UAB), Barcelona, Spain.

Juan Manuel Ramírez-Anguita, Hospital del Mar Research Institute, Department of Medicine and Life Sciences (MELIS), Universitat Pompeu Fabra, Barcelona, Spain.

Ferran Sanz, Hospital del Mar Medical Institute, Dept. of Medicine and Life Sciences (MELIS), Universitat Pompeu Fabra, Barcelona, Spain

Gemma Vilagut, Hospital del Mar Research Institute, Barcelona, Spain; CIBER en Epidemiología Y Salud Pública (CIBERESP), Madrid, Spain

Ella Arensman, School of Public Health & National Suicide Research Foundation, University College Cork, Ireland

Johan Bjureberg, Department of Clinical Neuroscience, Karolinska Institutet, Stockholm, Sweden

Lars Mehlum, National Centre for Suicide Research and Prevention (NSSF), Institute of Clinical Medicine, University of Oslo, Oslo, Norway

Manuel Pastor, Hospital del Mar Research Institute, Dept. of Medicine and Life Sciences (MELIS), Universitat Pompeu Fabra, Barcelona, Spain

Ping Qin, National Centre for Suicide Research and Prevention (NSSF), Institute of Clinical Medicine, University of Oslo, Oslo, Norway

TITLE: PERMANENS – Development of a Clinical Decision Support System Software to enable the Personalized Evaluation and Management of Self-Harm at the Emergency Department

ABSTRACT

BACKGROUND: People with self-harm are at elevated risk for not receiving mental health treatment and for death by suicide and other causes. To address this, emergency departments (ED) are key healthcare settings, as they often represent the first medical contact after self-harm, and can offer specialized risk assessment and referral to psychiatric intervention. Unassisted clinician assessments as well as the use of standardized assessment scales are insufficient to accurately identify patients at highest risk for repeated self-harm and suicide. This highlights the need for introducing a personalized medicine approach in self-harm management, including machine learning-based techniques and evidence-based algorithms. OBJECTIVES: The PERMANENS project aims to develop a Clinical Decision Support System (CDSS) software prototype that assists clinicians in the assessment and management of patients with self-harm at the ED. Trained on evidence accumulated in clinical settings and based on the patient's particular clinical history and socioeconomic background, the CDSS will provide the clinician with personalized risk profiles for relevant adverse outcomes, including self-harm, method escalation, death by suicide and other causes, and not following up with proposed treatment. The CDSS will provide an overview of the most important risk factors, and propose an evidence-based treatment plan, tailored to the patient's specific risk profile. METHODOLOGY: User-advisory groups will be held using a co-design framework to obtain the essential user-input throughout the project. Focus groups and web-based surveys will assess currently unmet needs in self-harm management for the CDSS to address. Population-representative registry data from three countries (Ireland, Norway and Sweden) and one region (Catalonia, Spain) will be used to develop the CDSS risk prediction models. The OMOP Common Data Model will ensure data interoperability across sites, and a federated analysis approach will eliminate the need for remote access to individual-level data. Data preparation for predictive modelling will include the development of case validation algorithms, the delineation of adverse healthcare trajectories post-discharge, and the creation of a series of clinically relevant predictor variables. Machine learning-based algorithms will be used to develop clinically interpretable prediction models, including state-of-the-art techniques to deal with class imbalance, feature selection, and prediction bias. Assignment by the CDSS of the most indicated intervention according to the patient's personal risk profile will be expert-based, and guided by a review of randomized controlled trials and published clinical guidelines. The CDSS output and personalized treatment plan will be offered in the format of a digitally transferrable healthcare record in order to improve continuity of care. Small-scale usability testing of the CDSS prototype will be conducted by clinician-patient dyads outside of routine clinical healthcare. A CDSS training manual will be developed. EXPECTED IMPACT: The proposed CDSS will enable structured professional judgement, standardization of care, increased patient satisfaction, and higher treatment compliance among patients with self-harm. Future routine implementation of CDSS for self-harm management at the ED has a high potential for effectively reducing suicide mortality in the population. FUNDING: AC22/00045 (Instituto de Salud Carlos III, under the frame of ERA PerMed); PI22/00107 (Instituto de Salud Carlos III; co-funded by the European Union); Fundación la Marató de TV3 202220-30-31; AGAUR 2021 SGR 00624; ISCIII-FSE CP21/00078.

LEARNING OBJECTIVE: This presentation will explain in detail how a Clinical Decision Support System for the personalized management of self-harm will be developed.

ERA PerMed

PERMANENS

PERMANENS – Development of a Clinical Decision Support System Software to enable the Personalized Evaluation and Management of Self-Harm at the Emergency Department

Philippe Mortier, Jordi Alonso, Franco Amigo, Paul Corcoran, Marie Dahlin, Montserrat Ferrer, Oskar Flygare, Busenur Kizilaslan, Angela Leis, Miguel A. Mayer, Madhav Bhargav, Víctor Pérez Sola, Juan Manuel Ramírez-Anguita, Bo Runeson, Ferran Sanz, Gemma Vilagut, Ella Arensman, Johan Bjureberg, Lars Mehlum, Manuel Pastor, Ping Qin

Karolinska Institutet

GRIB RESEARCH PROGRAMME ON BIOMEDICAL INFORMATICS

National Suicide Research Foundation

NSSF National Centre for Suicide Research and Prevention

Hospital del Mar Research Institute Barcelona

upf. Universitat Pompeu Fabra Barcelona

UCC University College Cork, Ireland Coláiste na hOllscoile Corcaigh

UNIVERSITY OF OSLO

NO CONFLICTS OF INTEREST TO DECLARE

FUNDING: AC22/00045 (Instituto de Salud Carlos III, under the frame of ERA PerMed); PI22/00107 (Instituto de Salud Carlos III; co-funded by the European Union); Fundación la Marató de TV3 202220-30-31; AGAUR 2021 SGR 00624; ISCIII-FSE CP21/00078.

- H2020 ERA-NET Cofund grant (ERAPERMED 2022-091)
- 3-year project (start 01/03/2023) – 1.2M€ total budget
- 5 partners from 4 countries:
  - Karolinska Institute, Sweden
  - Oslo University, Norway
  - National Suicide Research Foundation & School of Public Health, UCC Cork, Ireland
  - Research Program on Biomedical Informatics, Universitat Pompeu Fabra, Spain
  - Hospital del Mar Research Institute, Spain (coordinator)

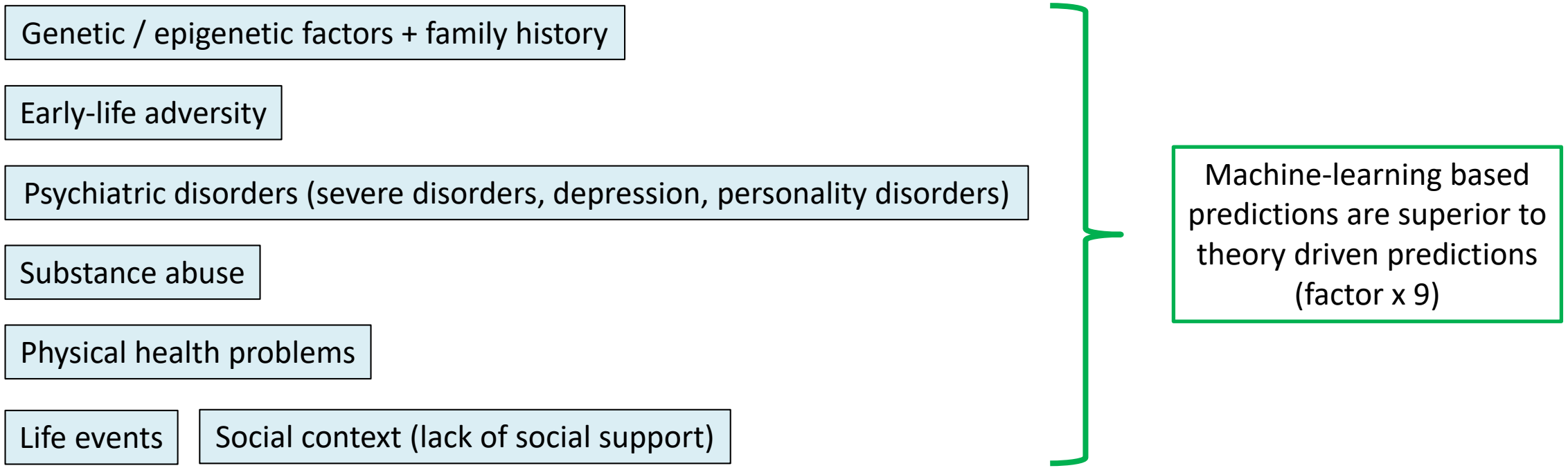
PERMANENS - rationale

- **Suicide** is an important cause of **premature death**, especially among **young** people, causing **immense grief and societal costs**.[1-2]
- **People with self-harm** are at **high suicide risk** and often **lack adequate mental healthcare** and **continuation of care**.[3]
- **Emergency departments**, often the **first** medical contact after self-harm, play a **vital** role in suicide prevention[4], as they can offer **specialized risk assessments and psychiatric referrals**.
- But suicide is **difficult-to-predict highly complex behavior**, and current guidelines, often **one-size-fits-all**, recommend screening methods with **limited accuracy**.[5]
- This emphasizes the need for a **precision medicine approach**, including machine-learning[6] and evidence-based methodologies and techniques.

[1] Naghavi et al. (2019). [2] Fazel & Runeson (2020). [3] Qin et al. (2022). [4] Boudreaux et al. (2016). [5] Carter et al. (2017). [6] Bernert et al. (2020).

Suicide as a complex difficult-to-predict behavioral outcome

Accuracy of **unassisted clinician predictions / clinical instrument predictions** of future self-harm is **insufficient**



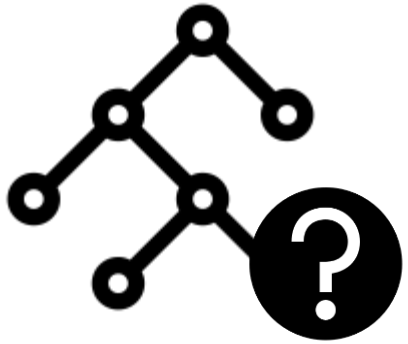
Fazel & Runeson (2020). *New England Journal of Medicine*, *382*(3), 266–274; **Woodford** et al. (2019). *Suicide and Life-Threatening Behavior*, *49*(1), 23–40; **Carter et al. (2017)**. *British Journal of Psychiatry*, *210*(6), 387–395; **Larkin** et al. (2014). PLoS ONE, 9(1), e84282. **Schafer et al. (2021)**. *PLOS ONE*, *16*(4), e0249833.

PERMANENS: main objectives

To create a **medical software prototype** that **assists** healthcare professionals in **delivering personalized assessments and care** to patients at the **emergency department** with **self-harm.**

To guarantee the **usability, feasibility, and acceptability** of the medical software among **all end-users**, encompassing both **patients and clinicians.**

CLINICIAN



CDSS software prototype

back-end (computation engine)

front-end (user-interface)

PATIENT

Structured Professional Judgement:

- risk scores (0-100%) and visualization
- overview most important predictors
- risk factors in need for assessment
- …

→ **a personalized treatment plan**

DATA-DRIVEN

federated analysis on transnationally harmonized health record datasets (OMOP)

machine-learning based classification models for key adverse clinical events

CDSS software prototype

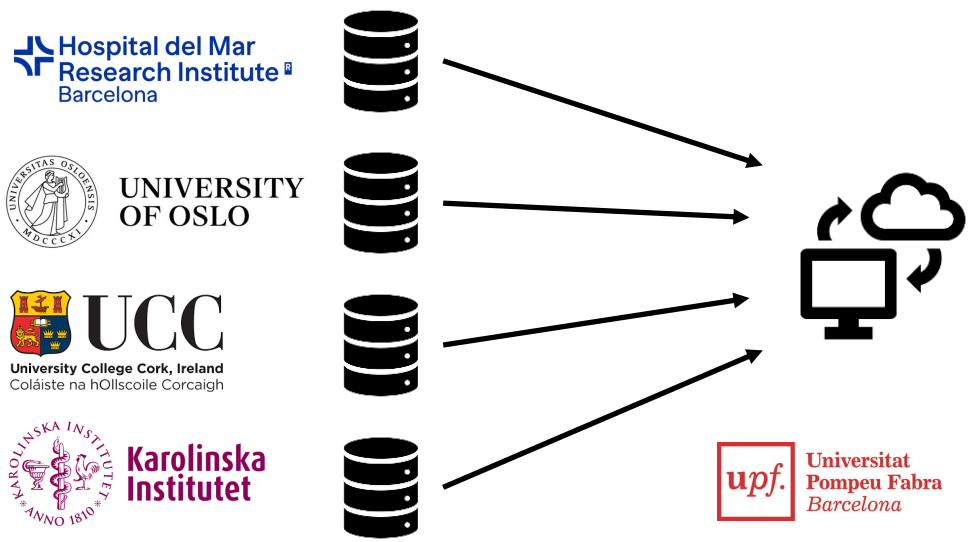
back-end (computation engine)
(link risk & intervention = expert-based)

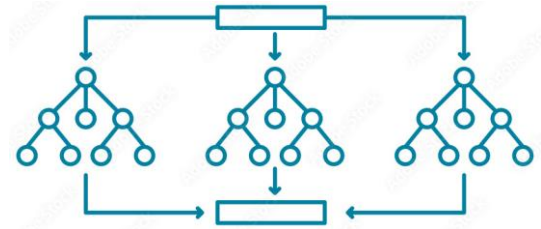
front-end (user-interface)

Structured Professional Judgement:

- risk scores (0-100%) and visualization
- overview most important predictors
- risk factors in need for assessment
- …

→ **a personalized treatment plan**





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Registry data:
- population-representative
- Catalonia, Ireland, Norway, Sweden

Types:
1. mortality data
2. routine electronic healthcare data
3. drug use data
4. administrative data

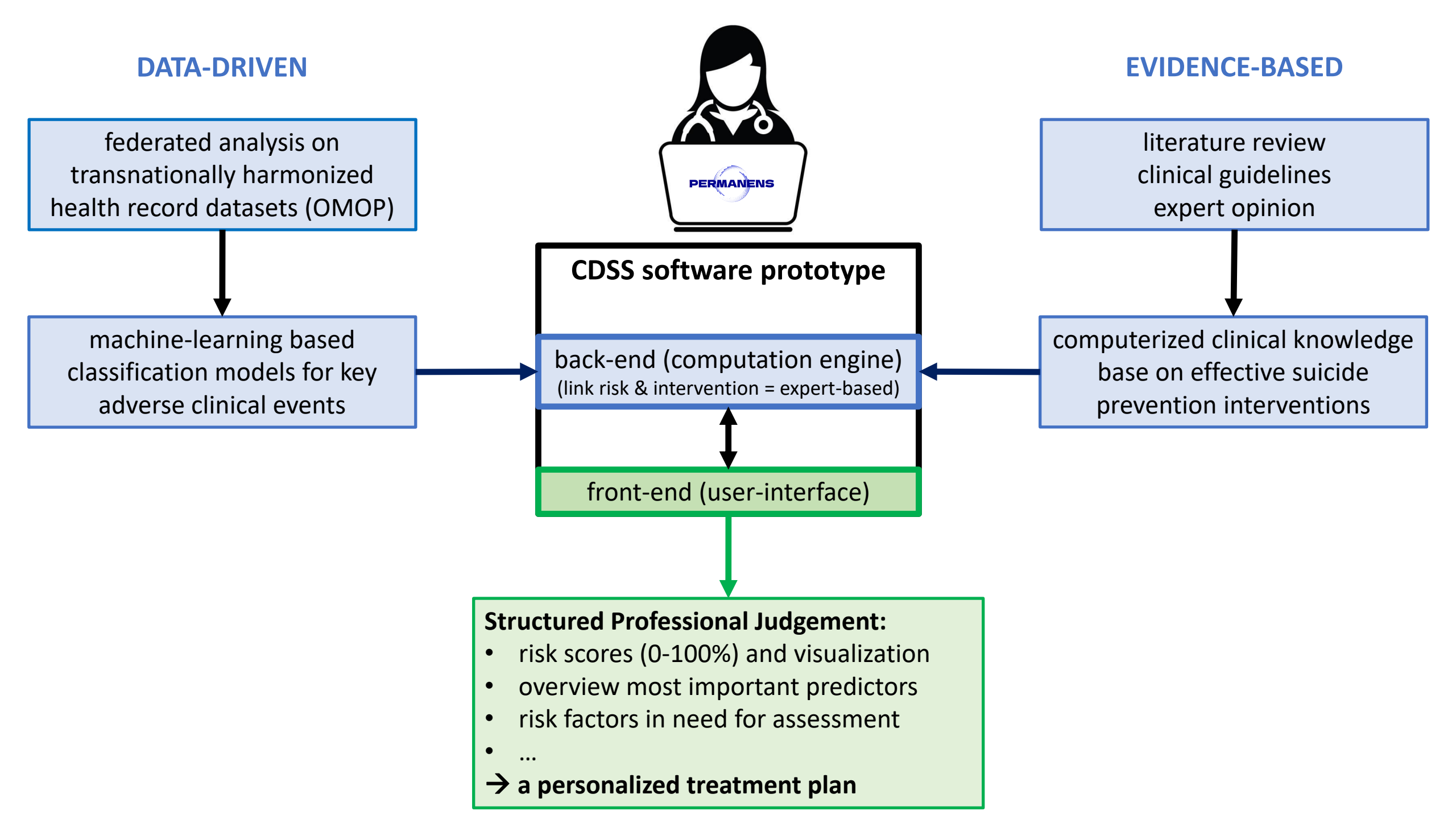
Federated analysis platform:
- centralized analysis without need for individual-level data access
- query objects

Data harmonization:
- OMOP common data model
- ICD/ATC codes

Identification key adverse clinical outcomes:
- self-harm repetition
- suicide
- premature death
- non-adherence Tx

Data preparation for predictive modelling:
- case validation
- feature preparation

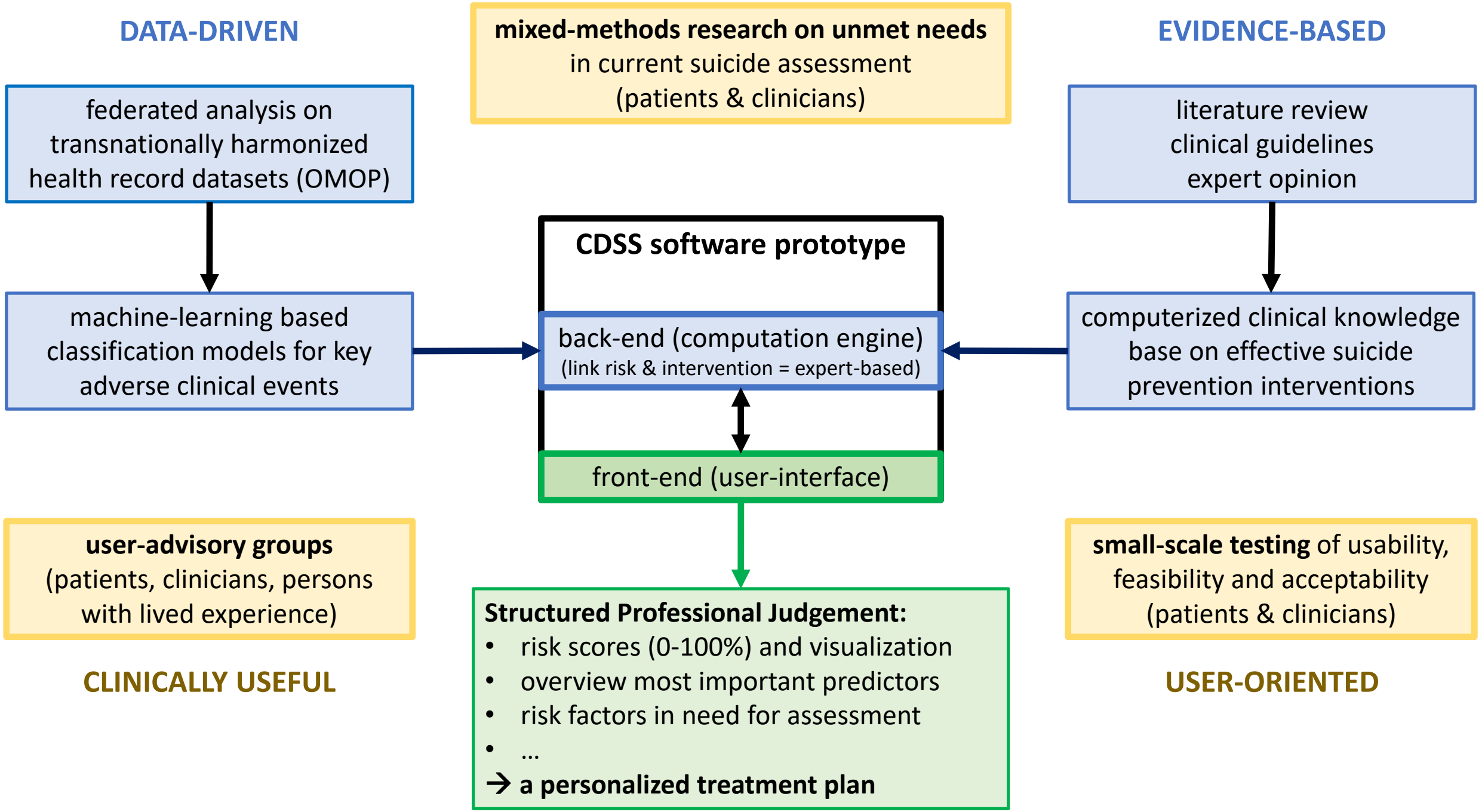
Development prediction models:
- machine learning
- clinically interpretable
- stratified (e.g., sex)
- class imbalance, feature selection, prediction bias, k-fold cross-validation, SHAP-values


DATA-DRIVEN
EVIDENCE-BASED
federated analysis on transnationally harmonized health record datasets (OMOP)
literature review
clinical guidelines
expert opinion
PERMANENS
CDSS software prototype
machine-learning based classification models for key adverse clinical events
back-end (computation engine)
(link risk & intervention = expert-based)
computerized clinical knowledge base on effective suicide prevention interventions
front-end (user-interface)
Structured Professional Judgement:
• risk scores (0-100%) and visualization
• overview most important predictors
• risk factors in need for assessment
• …
→ a personalized treatment plan

Systematic Review of Clinical Practice Guidelines (CPG) in Suicide Prevention

- Led by **Karolinska Institute**
- **Databases:** Ovid MEDLINE, Ovid MEDLINE In-Process & Other Non-Indexed Citations, EMBASE, Web of Science, Cochrane Library, gray literature
- Quality assessment of evidence: **Agree II tool**

- **P**opulation: **adult patients** with **self-injurious thoughts and behaviors**
- **I**ntervention: **any intervention**
- **C**omparators: no comparator; any psychosocial comparator; any pharmaceutical comparator; treatment as usual; waitlist comparator
- **A**ttributes of eligible CPGs: any language, published ≥2008, globally, **explicitly evidence-based**
- **R**ecommendation characteristics: explicitly discuss / compare ≥1 intervention of interest


DATA-DRIVEN
mixed-methods research on unmet needs
in current suicide assessment
(patients & clinicians)
EVIDENCE-BASED
federated analysis on
transnationally harmonized
health record datasets (OMOP)
literature review
clinical guidelines
expert opinion
CDSS software prototype
machine-learning based
classification models for key
adverse clinical events
back-end (computation engine)
(link risk & intervention = expert-based)
computerized clinical knowledge
base on effective suicide
prevention interventions
front-end (user-interface)
user-advisory groups
(patients, clinicians, persons
with lived experience)
small-scale testing of usability,
feasibility and acceptability
(patients & clinicians)
Structured Professional Judgement:
• risk scores (0-100%) and visualization
• overview most important predictors
• risk factors in need for assessment
• …
→ a personalized treatment plan
CLINICALLY USEFUL
USER-ORIENTED

Implementation research

- Led by UCC Cork
- People with lived experience (PLE) + family / friends / caregivers / colleagues of PLE + representatives of PLE associations + healthcare professionals
- 18 years or older
- Personal invitation and/or snowball sampling

User-advisory groups:

- **Obtain periodic feedback on project's objectives – methodology - results**
- n = ± 8 - minimum 2/year – 1 hour online group meetings – all countries

Focus groups:

- **Evaluate currently unmet needs in self-harm management at the emergency department + perception of use of AI-based tools to improve management**
- n = 4-5 (PLE) + n = 8 (others) – 1.5 hour online focus group – Ireland / Spain

PERMANENS

			FIRST YEAR				SECOND YEAR				THIRD YEAR			
			1-3	4-6	7-9	10-12	13-15	16-18	19-21	22-24	25-27	28-30	31-33	34-36
WP1		Project Coordination Activities	IMIM											
WP2	Task 2.1-5	IRB approvals; DMP; DCDSA; extract local registry data + quality control; maximise transnational data interoperability [OMOP]	IMIM/UPF (all partners)											
	Task 2.6	implement transnational data analysis methodology (federated analysis)		UPF (all partners)										
WP3	Task 3.1-2	identify suicide attempts; identify adverse healthcare trajectories				U OSLO (CORK + IMIM +KAR I)								
	Task 3.3-5	preparing data for predictive modelling: identify high-risk groups + prepare predictor variables + case-control selection						U OSLO (CORK + IMIM + KAR I)						
WP4	Task 4.1-3	predictive modelling: ML-based classification algorithms							UPF					
WP5	Task 5.1-2	create clinical knowledge base effective suicide prevention interventions; create transferable personal healthcare record	KAROLINSKA I (U OSLO)											
WP6	Task 6.1-3	develop software backend & frontend + technical/functional validation								UPF				
WP7	Task 7.1	establish user-advisory groups	NSRF CORK (U OSLO + KAR I + IMIM)											
	Task 7.2	mixed-methods research on unmet needs in suicide risk assessment	NSRF CORK (U OSLO + KAR I + IMIM)											
	Task 7.3	small-scale testing of the CDSS prototype										NSRF CORK (U OSLO + KAR I + IMIM)		
WP8		Knowledge Exchange and Dissemination Activities	U OSLO (all partners)											

Improving clinical care for patients with risk of self-harm and suicide

- Enabling **Structured Professional Judgment**[1], i.e., enhancing the clinician's assessment process in a **standardized and evidenced-based manner**, ensuring that all areas of risk are comprehensively evaluated, without replacing the clinician's judgment
- Offering a **personalized treatment plan** tailored to each patient's unique risk profile, hereby enhancing **continuity of care,** increasing **treatment adherence**, and increasing **overall patient satisfaction**
- **Optimizing resource allocation** within the high-pressure environment of the emergency department by **systematically directing resources to patients with the highest levels of need**

[1] Gray et al. (2021).

Future plans & challenges

- Medical licensing & regulatory pathways
- Real-time integration of the CDSS in healthcare information systems
- Randomized controlled trial of the CDSS to test effectiveness
- Adding additional data sources to improve prediction and risk management (text-mining, EMA)
- Exploring pathways to commercialization

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