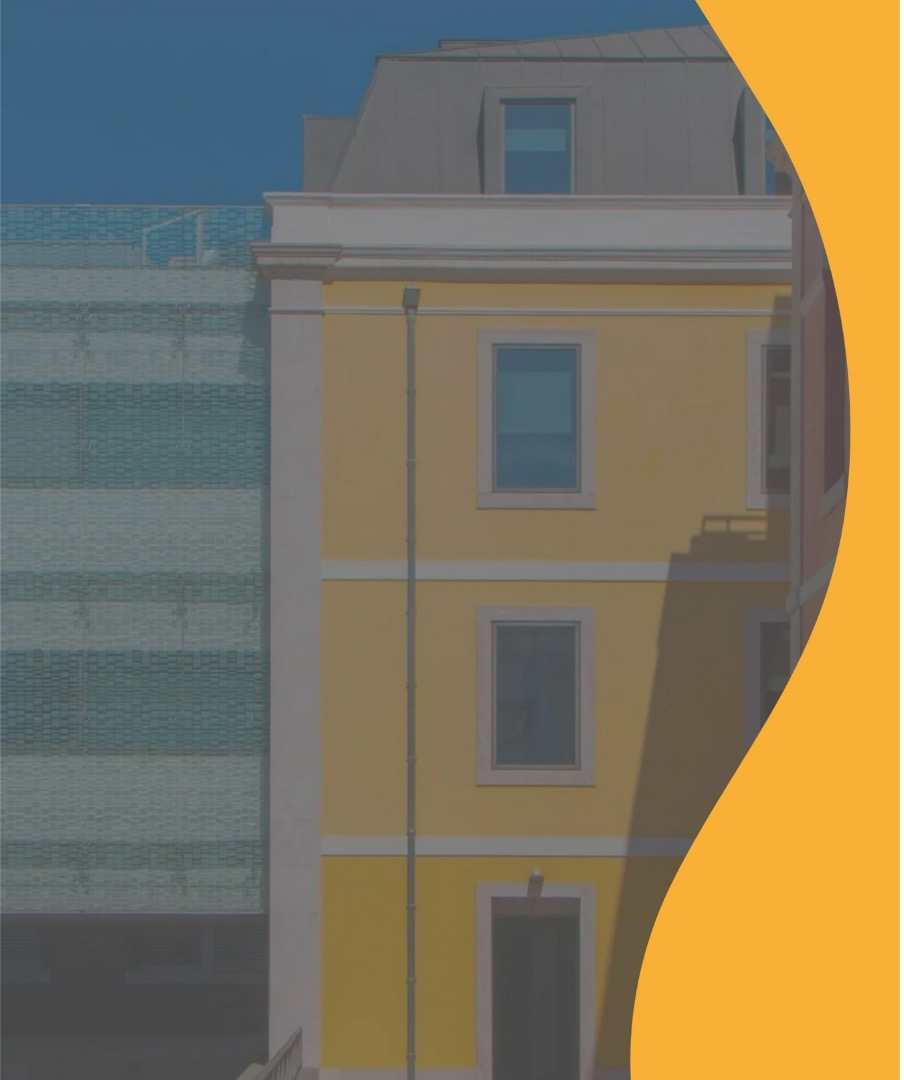

Colégio de Especialidade Assuntos Regulamentares

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Academic Research

Clinical Trials and Clinical Investigation with Medical Devices

Lúcia Domingues, PhD

Coordinator of NOVA Clinical Research Unit (**NOVA CRU)**

Coordinator of the Master's Degree in Clinical Research Management (**MEGIC)**

2024

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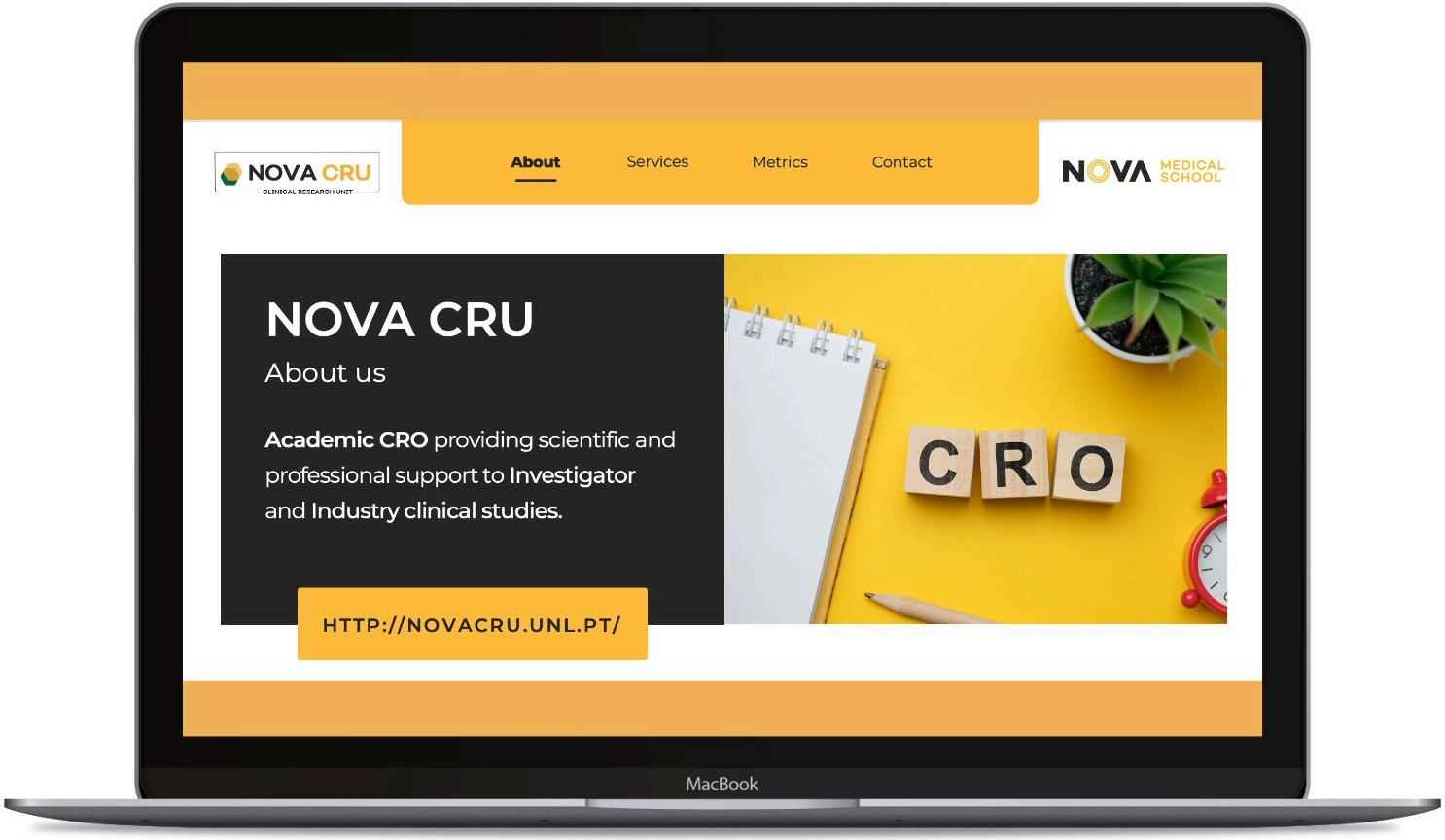

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Academic Research

Systematic Investigation

Academic research involves a structured and methodical process of inquiry to expand knowledge and understanding in a specific field.

Peer Review

The findings of academic research are subjected to scrutiny and validation by other experts in the field through a peer review process.

Contribution to Knowledge

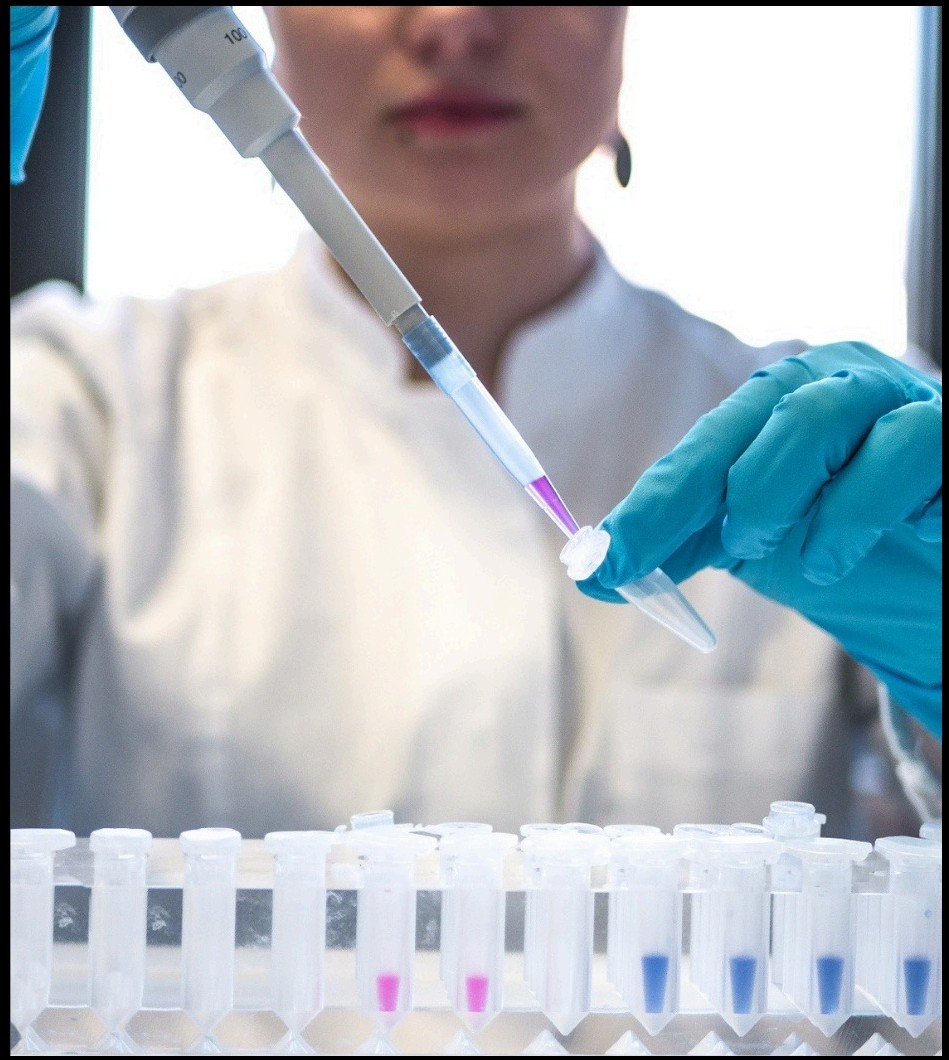
Academic research aims to contribute to the existing body of knowledge, providing new insights or challenging established theories.

Academic research is a rigorous and systematic process that generates new knowledge, challenges existing ideas, and advances understanding in various fields of study.

Academic Research Drivers

Academic research is a rigorous and systematic process that generates new knowledge, challenges existing ideas, and advances understanding in various fields of study.

What are the **challenges** for **academic researchers**?



Academic Research Challenges

Funding Limitations

Securing adequate funding for academic research can be a significant challenge, often requiring extensive grant writing and competition with other institutions.

Reproducibility Issues

Ensuring the reproducibility of research findings is crucial, but can be impacted by complex experimental designs, lack of standardization, and publication bias.

Data Management Challenges

Effectively managing and storing large datasets, ensuring data quality, and maintaining data security and privacy can be complex in academic research settings.

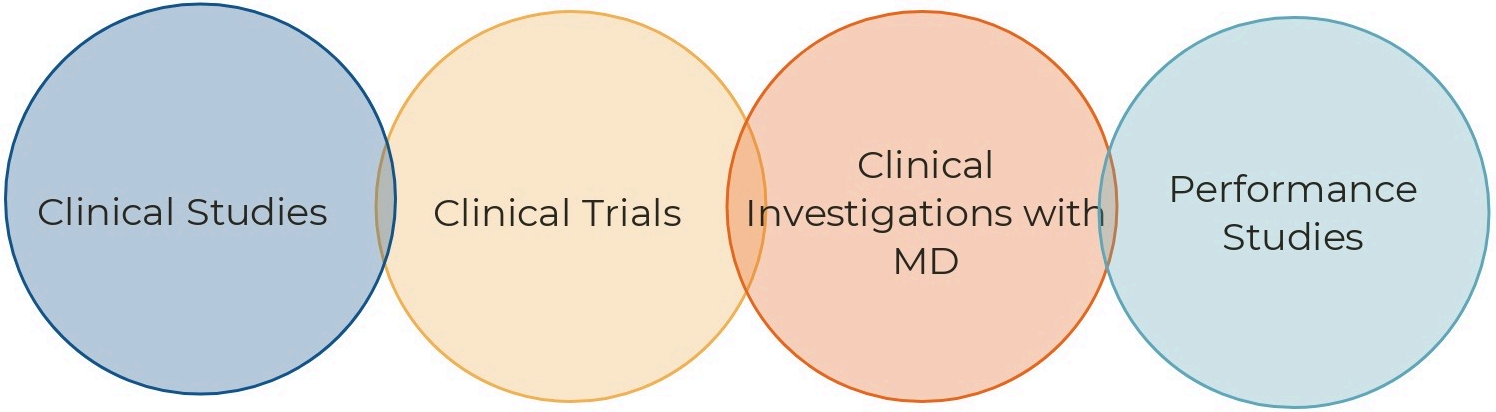
Interdisciplinary Collaboration

Fostering successful collaboration between researchers from different disciplines is important but can be hindered by differences in terminology, methodologies, and institutional cultures.

Addressing these challenges requires innovative strategies, institutional support, and a commitment to continuous improvement in the academic research landscape.

Academic Research Challenges

Clinical Study Terminology



Academic Research Challenges

Submission to Regulatory Authorities

Securing and Managing Funding

- **Underestimation of costs** (eg. monitoring and other operational activities).

Documentation for Regulatory Submission

- Lack of **centralisation of responsibilities** (there isn't one point of contact)
- **Delayed responses** from investigators and clinical site
- Lengthy processes for **contractual and financial decisions** and signatures.

Study Design Development

- Developing a scientifically sound and feasible study design **requires expertise in clinical study methodo**logy and terminology.
- Protocol development, including anticipating potential challenges, is essential and requires experience.

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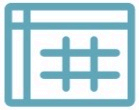
Academic Research Challenges

Clinical Study Operations



Data Collection

- Implementing **robust data collection methods** can be challenging when there is no budget allocated for an electronic software and data manager.

Resource Limitations

- Investigator-initiated studies often have **limited access** to resources like dedicated **study coordinators**, **research nurses**, and **administrative support**.

IP Management

- Handling intellectual property rights, especially if the study leads to patentable inventions or commercially viable products.

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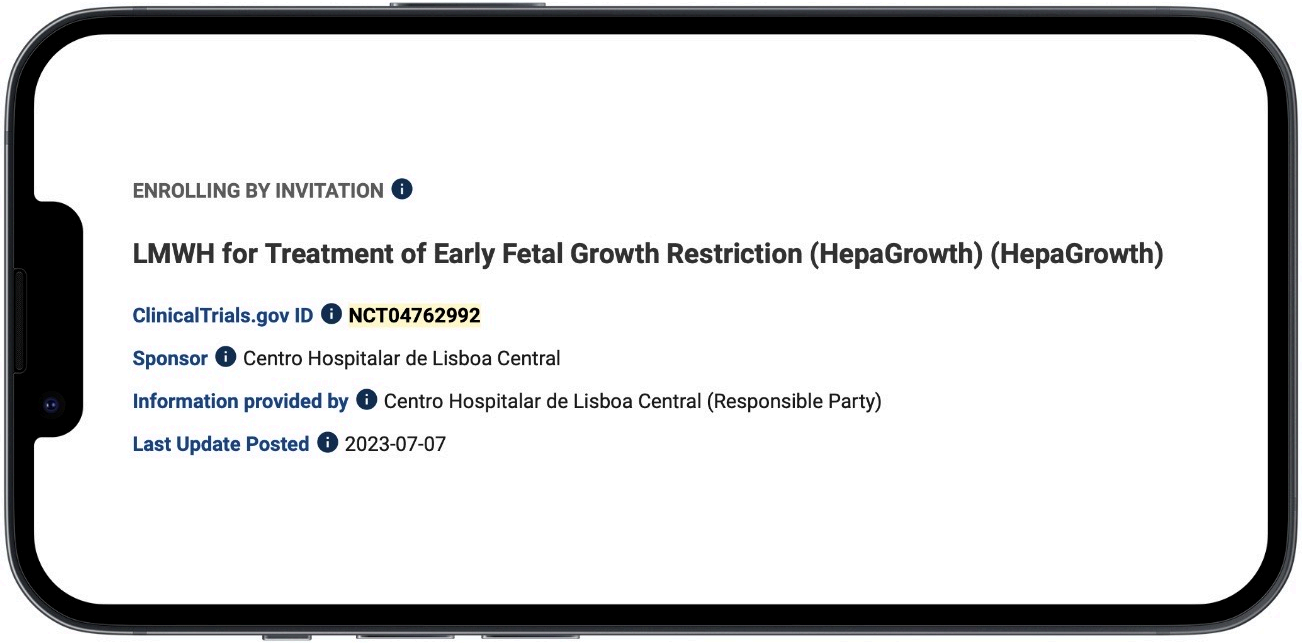
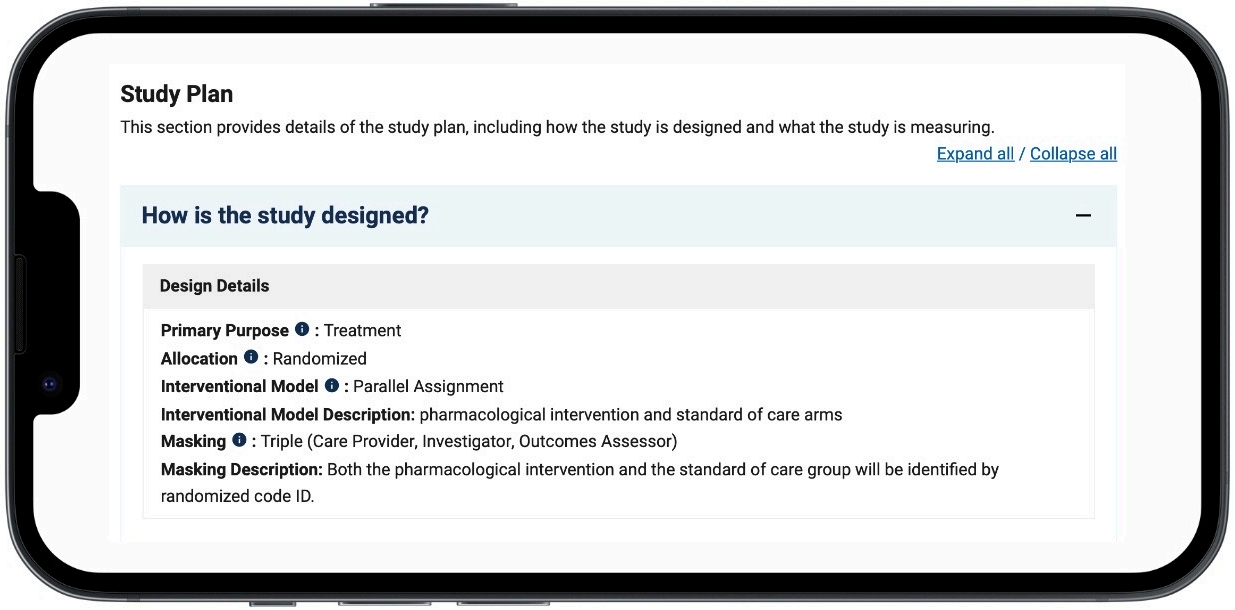
Academic Research Challenges

Regulatory Compliance

Ensuring compliance with local, national, and international regulations can be daunting, particularly for researchers who might not have dedicated regulatory support.

Clinical Trials


ENROLLING BY INVITATION
LMWH for Treatment of Early Fetal Growth Restriction (HepaGrowth) (HepaGrowth)
ClinicalTrials.gov ID NCT04762992
Sponsor Centro Hospitalar de Lisboa Central
Information provided by Centro Hospitalar de Lisboa Central (Responsible Party)
Last Update Posted 2023-07-07


Study Plan
This section provides details of the study plan, including how the study is designed and what the study is measuring.
Expand all / Collapse all
How is the study designed?
Design Details
Primary Purpose : Treatment
Allocation : Randomized
Interventional Model : Parallel Assignment
Interventional Model Description: pharmacological intervention and standard of care arms
Masking : Triple (Care Provider, Investigator, Outcomes Assessor)
Masking Description: Both the pharmacological intervention and the standard of care group will be identified by randomized code ID.

Clinical Investigation with Medical Device - Diagnosis

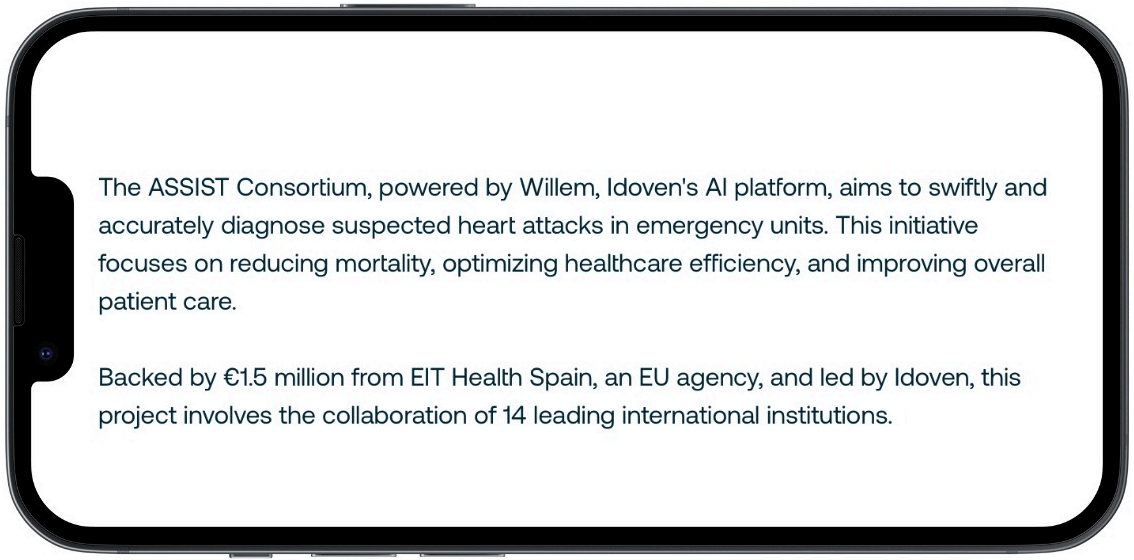
Idoven

AI-powered cloud platform for cardiology that improves arrhythmia detection and enables early detection of cardiovascular diseases. Idoven leverages deep learning algorithms trained on a large ECG dataset to identify 23 cardiac patterns.

https://www.idoven.ai/collaborative-research

ASSIST
AI-Powered Early Diagnosis for Heart Attacks

Building AI-based ECG analysis solution for early and accurate heart attack diagnosis



https://www.idoven.ai/collaborative-research

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Clinical Investigation with Medical Device- Treatment

VA | PREVENTION
DIABETES RESEARCH
MacBook

VA|PREVENTION: Digital Intervention for Diabetes Prevention

Randomized Controlled Trial (RCT)

VA|PREVENTION involves an RCT to evaluate a digital intervention for diabetes prevention in high-risk adults.

Personalized Digital Intervention

The intervention is a person-centered digital solution with a virtual coach using AI to support behavior change for diet and physical activity.

Economic Evaluation

The project includes an economic evaluation to assess the cost-effectiveness of the digital intervention.

Interdisciplinary Research Team

The project has a team of 16 researchers from a consortium of 5 national institutions and research units.

VA|PREVENTION aims to develop and evaluate an innovative digital intervention for type 2 diabetes prevention in high-risk adults, combining RCT, economic evaluation, and an interdisciplinary approach.

Assistente Humano Virtual
Dashboard partilhável com os profissionais de saúde e rede social da pessoa

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