Real-World Cardio-Respiratory Health Monitoring for Clinical Research and Tele-Cardiology

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ECSEL JU - IMI JU Joint Info session 18 June 10:00 AM - 1:00 PM CEST
CLINICAL TRIAL SERVICES
Profil is a full-service CRO focused on early phase clinical trials in diabetes and obesity.

PROFIL’S RESEARCH FOCUS
Profil focuses on diabetes and obesity research; that focus makes us the best in our field.

DIABETES TREATMENT
Profil Germany is the partner of choice for diabetes treatment clinical studies.

FREE RESEARCH TOOLS
Free online tools for your clinical research.

MEDICAL TECHNOLOGY RESEARCH
Medical device development at Profil.
Profil is a full service CRO performing early phase clinical trials with a strong focus on obesity, (pre)diabetes, and diabetes complications.

- >400 employees
- 2 inhouse CRUs >80 test beds
- Huge recruitment capabilities
- Data Management & Statistics
- Regulatory Affairs
- Pharmacology
- GMP-certified pharmacy
- Medical Technology
- Cardiovascular Research
- Medical device development
- Metabolic ward
www.profil.com

Inhouse development and **proprietary technology** of Profil

CE Mark certified **class IIb** medical device

**Central remote monitoring** of clinical experiments

**Parallel & quantitative assessment** of
- Insulin (analogues) time-action profiles
- Insulin sensitivity
- Beta cell function
- Endogenous glucose production
- CGM systems

https://www.profil.com/services/hyperinsulinemic-euglycemic-clamp
Lack of real-world data problem

Clinical research

low predictive value of clinical trials

- European Commission & OECD: Health at a glance report. November 22, 2018

- Average Costs: 1.5B €
- Average Time: 15 years
- Success rate: 1 in 10
- Failure rate: 50% in phase III
- Post-marketing withdrawal: 462
Lack of real-world data problem

- Emergency hospitalization in Heart Failure $46$ Bio € (US & EU)
- Within 5 years up to **50%** of people with diabetes hospitalized for Heart Failure decompensation **die**
RealWorld4Clinic

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https://www.openaccessgovernment.org/realworld4clinic-clinical-research/81957/

RealWorld4Clinic Kickoff · 10-11 February 2020 · Grenoble, France

EIT Health Funding 2020 – 2022: 3 Mio €
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- Developing a **class III medical sensor** anchored to the fundus of the stomach in immediate proximity to the heart, the lung and the gastric tract to access **multiple parameters**

- Ultimate ambition: making **real-world monitoring** of cardio-respiratory health a **Standard** in **out-patient cardiology care**
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- Smartphone-based communication platform
  - Patient reported outcomes (PROMs) assessment
  - Web-based data presentation dashboards tailored to clinical research and outpatient cardiology care

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https://eithealhealth.eu
Personal data lifecycle management platform

- Seamless connectivity and interoperability
- Secure, patient-centric data vault
- Dynamic, fine-grained consent management
- Complete, privacy-preserving data access

Encryption

Heterogenous sources of personal data

Secure hooks to external algorithms and systems

Access to Audit logs and pre-built compliance services

Data scientists & Researchers

Industry experts & professionals

Authorities and Players

Care givers & relatives
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- Stepping stone approach to market launch: **drug development**
  - secured application environment, clear commercial case
  - generation of user experience
  - demonstration of regulatory and legal compliance
  - generation of evidence, peer-reviewed publications
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https://eithealth.eu

- Stepping stone approach to market launch: cardiology
  - Instruments for outcome prediction (payers) and performance measurement (outpatient cardiology care)
  - Proactive tackling of ethical, legal and social issues
  - Performance-related remuneration model
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Seeking for collaboration in RDCTs

RealWorld4Clinic / RealWorld4Clinic partners interested in

- driving of / participating in an IMI – ECSEL Joint Activity Trials@Home

- interaction with Trials@home e.g. in
  - exploring & implementing sensor-based technologies, platforms for communication & data lifecycle management
  - addressing ethical, legal and social issues
  - designing and running a pan-European pilot
  - contributing to the advancement of RDCTs for improving the efficacy of drug development and the effectiveness of clinical care

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1 Zana Technologies, PrYv and SentinHealth participated in the Trials@Home technology scan
2 Profil has submitted an Expression of Vision on next generation digital technologies for RDCTs in the context of the Call 2020-3 IMI-ECSEL Joint Activity
Thank you very much!