Improved prediction, detection, and treatment approaches for comprehensive stroke management

Update 04-07-2023: Slides 18 & 19 added for clarification

IHI call 5 – topic 3

Klelia SALPEA, PhD
IHI Scientific Project Officer
28.06.2023

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Before we start…

- All information regarding future IHI call topics is indicative and subject to change. Final information about future IHI calls will be communicated after approval by the IHI Governing Board.
- We are recording this session and it will be published on the IHI website and B2Match platform.
- We will also publish the presentation slides.

Before we start…

Questions

- Please use the **‘Join the discussion’ function** at the bottom right of the screen to ask questions.

Today’s webinar

Will cover:

- Introduction to IHI programme
- IHI Call Topic:
  - Challenge, need for public-private collaborative research
  - Scope, outcomes & impacts, budget
- Proposal preparation tips & participant pitches

Will not cover rules & procedures or financial parts

- These webinars are on the IHI website

Innovative Health Initiative

Public private partnership between:

- the **European Union** represented by the European Commission

&

- **Healthcare industry associations:**
  - **COCIR** (medical imaging, radiotherapy, health ICT and electromedical industries)
  - **EFPIA**, including **Vaccines Europe** (pharmaceutical and vaccine industries)
  - **EuropaBio** (biotechnology industry)
  - **MedTech Europe** (medical technology industry)

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COCIR Advancing Healthcare
efpia
EuropaBio The European Association for Bioindustries
MedTech Europe from diagnosis to cure
Vaccines Europe
Co-funded by the European Union

IHI´s General objectives

Through **cross sectoral, pre-competitive** collaboration:

- Turn health research and innovation into **real benefits for patients and society**
- Deliver safe, effective health innovations that **cover the entire spectrum of care** – from prevention to diagnosis and treatment – particularly in **areas where there is an unmet public health need**
- Make Europe’s health industries **globally competitive.**

https://www.ihi.europa.eu/about-ihi/research-and-innovation-agenda

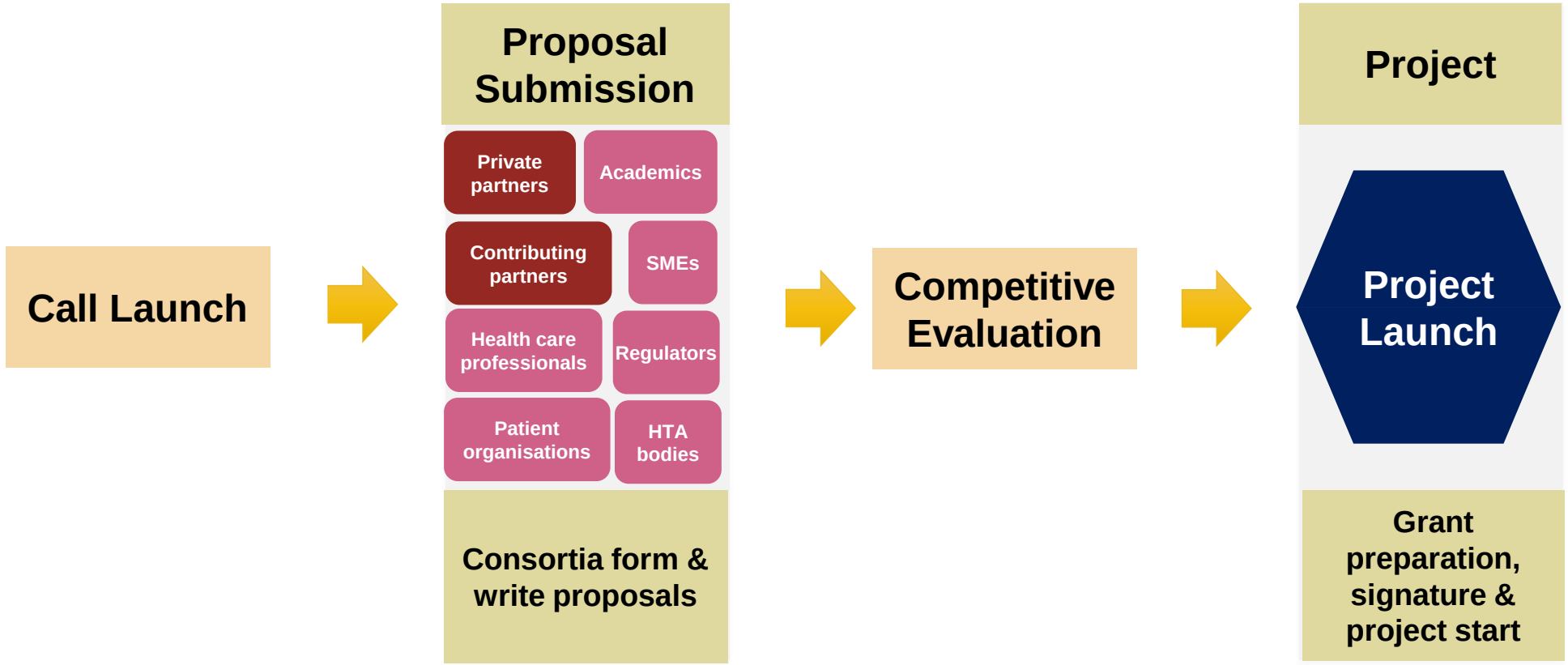
IHI Funding model

As a **public private partnership,** IHI's projects are funded by:

- **EU cash contributions**
  - Primarily supporting universities, research organisations, patient organisations, small and medium-sized enterprises (SMEs), and mid-sized companies.*
- **IHI industry associations' members** and **contributing partners**
  - Must **provide at least 45% of total project eligible costs (**usually via researchers participating in the project)

* Large companies can also receive EU funds

How IHI works: Single-stage procedure



Improved prediction, detection, and treatment approaches for comprehensive stroke management

IHI call 5 – topic 3

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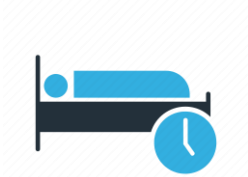
The challenge

Globally, stroke is the second leading cause of death and the third leading cause of disability.



Effective, personalised and rapid care is critical and can make a substantial difference between full recovery and possible permanent impairment or death.

Lack of efficient and comprehensive pathways along the whole continuum of the disease, while several effective treatment approaches are available.

Better communication, sharing and integration of data along the whole stroke care pathway has the potential to be a game changer for stroke patients and for the health care professionals as well as payers.

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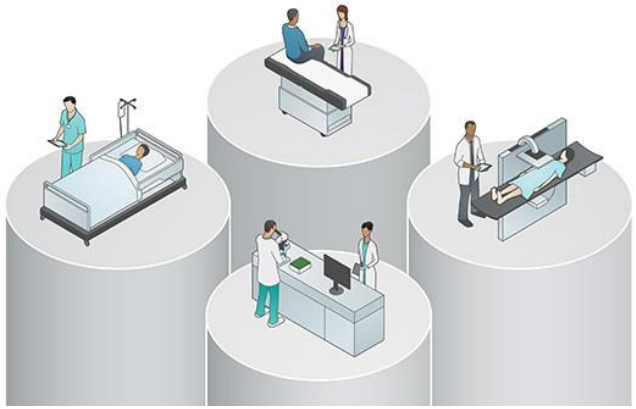
Need for public-private, cross-sector collaboration



Breaking silos in healthcare

Bring the necessary diverse expertise together

Combine different types of resources

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Scope of the topic (A)

Deliver an efficient and comprehensive stroke management pathway focused on patients' needs

Develop approaches to integrate health data along the whole care pathway.
focus on patients at higher risk

Develop next-generation systems:
- promote interoperability
- provide better access to data
- Support better clinical-decision making

Develop innovative tools (AI/ML):
- appropriate risk stratification
- timely prediction of stroke and stroke recurrence
- faster diagnosis and treatment

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Scope of the topic (B)

Deliver an efficient and comprehensive stroke management pathway focused on patients' needs

Propose innovative approaches:

- to improve diagnostic and treatment decisions
- streamline operations
- guide patients in the continuum of stroke care
- improve implementation and scale-up of treatment in Europe
- enhance precision of care delivery
- improve stroke patients' experience and quality of life

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Expected outcomes

Patients: early and rapid diagnosis of stroke, more integrated and precise interventions, and treatment strategies with the patient in the centre

Healthcare professionals:

- Better access to integrated patients' health data
- Efficient coordination among and within stages of care and clinical specialties.

Health care systems: More effective organisation of stroke management and personalisation of care delivery.

Researchers: New innovative modelling-based tools, and a more patient-centred definition of clinical outcomes after stroke.

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Expected impacts

Accelerated access to the healthcare system and holistic management of stroke that will lead to better health outcomes.

Integrated, advanced solutions for prevention, diagnosis, and treatment of stroke, that facilitate clinical decision-making

Better implementation and scale up of existing effective treatments, ensuring wide coverage of the right treatment options for patients at the right time.

Contribution to the ‘European Health Data Space’ (EHDS).

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Dissemination, exploitation & communication

- **Reserve budget** for effective Dissemination, exploitation & communication
- **Describe the dissemination, exploitation and communication measures** that are planned, and the target group(s) addressed, in particular:
    - Encourage the uptake of the results of the project through a strong communication and outreach plan
    - Allocating appropriate resources to explore synergies with other relevant initiatives and projects
    - If applicable, elements in line with the Availability, Accessibility and Affordability (3A) provisions

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Budget

IHI financial contribution:
~10 - 13M EUR

Industry & CPs Contribution:
~10 - 13M EUR*

Project Budget 20-26M EUR

*at least 45% of the project budget must be covered by contributions from project participants

Total available IHI budget for this topic: 40M EUR

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Simplified budget example

Single-stage call proposals

Type of participant	Total eligible costs + IKAA	Funding rate	Reimbursed eligible costs	Contributions (IKOP,FC,IKAA)
'Public partners' (Universities, hospitals, SMEs, patient orgs, regulators..)	15 million	100%	15 million	0
Private members & contributing partners (requested funding = 0)	15 million	100%	0	15 million
Private members & contributing partners ('Hybrid')	10 million	100%	5 million	5 million
Total	**40 million**	**100%**	**20 million (50%)** Public funds	**20 million (50%)** Private funds

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Simplified budget example

<u>Two-stage</u> call Full proposal

<u>Not eligible for funding</u> : pre-identified private members and contributing partners
Large companies with annual turnover > 500 M

Type of participant	Total eligible costs + IKAA	Funding rate	Reimbursed eligible costs	Contributions (IKOP,FC,IKAA)
'Public partners' (Universities, hospitals, SMEs, patient orgs, regulators..)	20 million	100%	20 million	0
Pre-identified Private members and Contributing partners (not eligible for funding)	20 million	100%	0	20 million
Total	**40 million**	**100%**	**20 million (50%)** Public funds	**20 million (50%)** Private funds

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Proposal Submission & Evaluation

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Proposal Template: Parts A, B & Annexes

- **Part A** is **administrative & researcher data** that is entered in webforms.

- **Part B** is the **narrative part** that includes three sections:
  - Excellence
  - Impact
  - Quality and efficiency of the implementation
- **Read instructions** in proposal template **very carefully**

- **Annexes:**
  - Participant type
  - Budget details
  - Coordinator declaration
  - If relevant, IKAA
  - Clinical studies template*

*If no clinical studies included in the proposal, please upload a statement to confirm that no clinical studies is foreseen.

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Evaluation Criteria (1/2)

- **Excellence**
  - Clarity and pertinence of the project's objectives, and the extent to which the proposed work is ambitious, and goes beyond the state of the art.
  - Soundness of the proposed methodology, including the underlying concepts, models, assumptions, interdisciplinary approaches, appropriate consideration of the gender dimension in research and innovation content, and the quality of open science practices, including sharing and management of research outputs and engagement of citizens, civil society and end users where appropriate.
- **Impact**
  - Credibility of the pathways to achieve the expected outcomes and impacts specified in the work programme, and the likely scale and significance of the contributions due to the project.
  - Suitability and quality of the measures to maximise expected outcomes and impacts, as set out in the dissemination and exploitation plan, including communication activities.

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Evaluation Criteria (2/2)

- **Quality and efficiency of the implementation**
  - Quality and effectiveness of the work plan, assessment of risks, and appropriateness of the effort assigned to work packages, and the resources overall
  - Capacity and role of each participant, and extent to which the consortium as a whole brings together the necessary expertise.

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Tips for applicants

Tips for applicants

- **Read all the call-relevant material, especially the topic text**

https://www.ihi.europa.eu/apply-funding/future-opportunities

- **Watch the “Rules and Procedures” and “preparing the financial part of the proposal” webinars**

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Tips for applicants

- Form your consortium **early**
  - Always think “**public-private partnership**“
  - Include partners bringing **in-kind contributions**

- Ensure that **all information requested in the call text and proposal template** is provided to allow the evaluation experts to easily assess your proposal against the evaluation criteria

- Consider & plan for the potential **regulatory impact** of results

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Key points

Proposals

- **Read the call text** very carefully
- Follow all the guidance in the **proposal template**
- Reserve dedicated **funding for communication & sustainability**

Finding consortium partners

- Be proactive
- **Start working now!**

Finding project partners

You'll need to build or join a consortium!

- Network with **your contacts & IHI Call days participants:**
- https://ihi-call-days.ihi.b2match.io/
- Use EU Funding & Tenders portal **partner search tool:**
  - https://europa.eu/!QU87Nx
- Get in touch with your **IHI national contact point**:
  - https://europa.eu/!D7jyMy
- Network on social media:
  - www.twitter.com/IHIEurope
  - be.linkedin.com/company/innovative-health-initiative

How to book your meetings via the B2Match platform

Book your meetings in 4 easy steps

1. Make yourself available
2. Look for partner on the participants or organisation tab
3. Select date, time, attendees (up to eight per meeting), add message
4. Send the meeting request and wait for the reply

Step by Step guide on how to book meetings: https://europa.eu/!FkjV9n

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Thank you for your attention

ihi.europa.eu

COCIR Advancing Healthcare

efpia

EuropaBio The European Association for Bioindustries

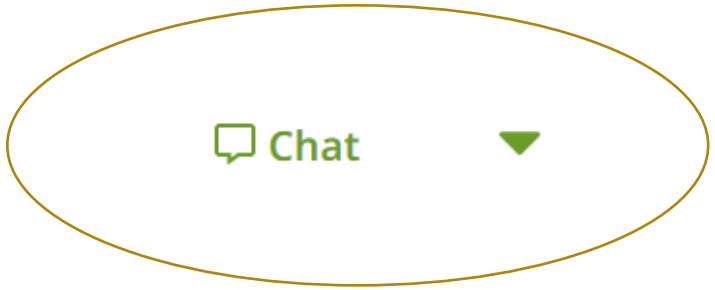
MedTech Europe from diagnosis to cure

Vaccines Europe

Co-funded by the European Union

Questions time

If you want to ask a question please use the chat function on the right corner of your screen



#IHICallDays

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Call 5

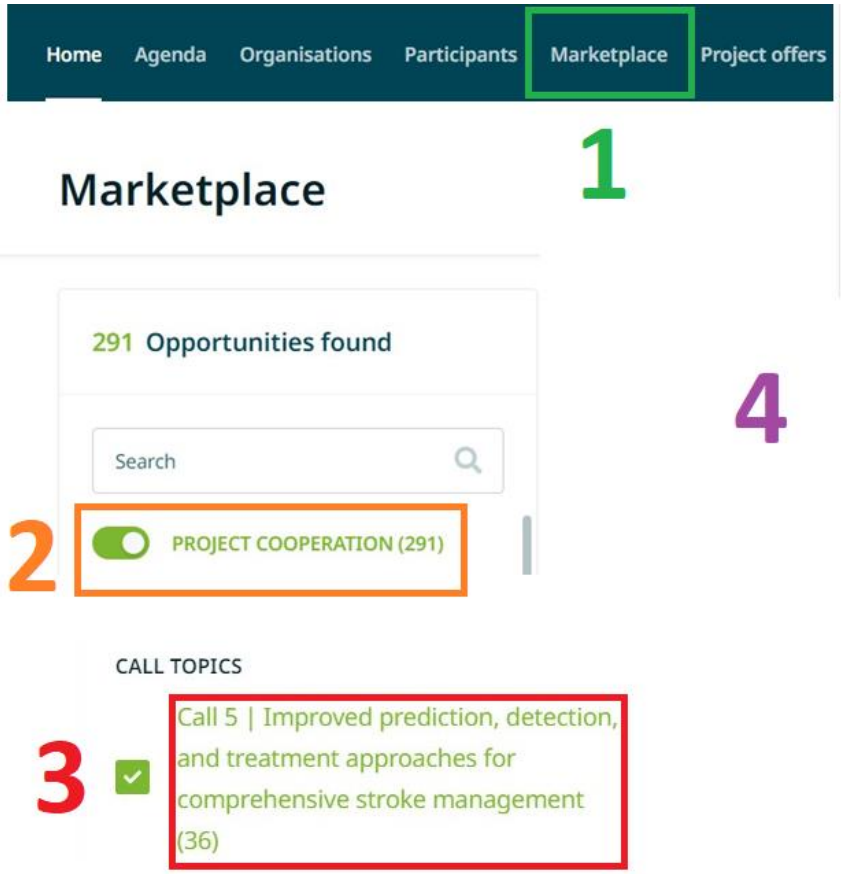
26 June	15:00-16:30	IHI rules & procedures
27 June	10:00-12:10	Non-animal approaches for health technologies
27 June	14:00-16:10	Theranostics solutions
28 June	14:00-16:10	Stroke management
29 June	10:00-12:10	Synthetic data generation
29 June	14:00-15:30	The financial part of the proposal

Online event

Register now

COCIR efpia EuropaBio MedTech Europe from diagnosis to cure Vaccines Europe Co-funded by the European Union

Marketplace



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PROJECT COOPERATION — Updated on June 21, 2023

EEG based Triage of Stroke Patients

What type of organisation are you looking for? (Question for consortium/coordinator seeking partners)

What kind of expertise are you looking for? (Question for consortium/coordinator seeking partners)

PROJECT COOPERATION — Updated on June 21, 2023

Medical image analysis and segmentation

We would like to join a consortium and can contribute the following expertise:

Medical image data are used in a variety of ways for diagnosis, treatment planning, monitoring of interventions, observation of condition changes and documentation. Common image modalities range from

PROJECT COOPERATION — Updated on June 21, 2023

Remote vital functions monitoring, evaluation and smart interventions

Our research center focuses on the collection, remote monitoring, and evaluation of vital data.

What do we bring to the consortium?

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Thank you for your attention

ihi.europa.eu

COCIR Advancing Healthcare

efpia

EuropaBio The European Association for Bioindustries

MedTech Europe from diagnosis to cure

Vaccines Europe

Co-funded by the European Union

We are taking now a 5 minutes break

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Pitching Session

Call 5 – topic 3 – Stroke management – 28 June 2023

Number	First Name	Last Name	Job position	Organization	Title of the presentation
1	Debra	Umlauft	Product Director	GE HealthCare	Prevention of Stroke through Early Detection of Afib
2	Maria Fernanda	Scoz Luz	Healthcare and Life Sciences Business Development	DQ Technologies AG (Decentriq)	Compliant and safe data collaborations for comprehensive stroke management
3	Richard	Cimler	Head of Research Center	University of Hradec Kralove	Remote monitoring of vital functions focused on stroke - prediction, detection, and treatment
4	Buse	Bilgin	5G/6G R&D Engineer	Turkcell Technology	Communication Infrastructure for Early Stroke Detection and Efficient Treatment
5	Thierry	Fumeaux	CEO	Acthera Therapeutics	Hard-Shelled Liposomes (HSL) Improved thrombolytic therapy for acute ischemic stroke
6	Robert	Hofsink	PPP Manager	Philips	DISCO: Data driven Integrated solutions for Stroke Care pathway Optimization
7	Harald	Schmidt	Professor	Maastricht University - Pharmacology and Personalised Medicine	SAVEBRAIN+
8	Marc	Serra	CBD	ROBOPEDICS	Rehab after stroke: Robopedics

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POSTED-AFIB

Prevention of Stroke through Early Detection of Afib

Contact person name – Debra Umlauft

Organisation – GE HealthCare

E-mail – debra.umlauft@ge.com

Topic number: Call 5, Topic 3

POSTED-AFib

Challenges and objectives

Vision Statement - Improved prediction, detection and treatment approaches for comprehensive stroke management by early identification of atrial fibrillation in the community.

Objective: By identifying and diagnosing patients who may be at risk, or currently have atrial fibrillation at the point of primary care, the patients can then be directed towards optimal care pathways established in the ESC atrial fibrillation guidelines, thus improving their outcomes towards stroke prevention.

Rationale

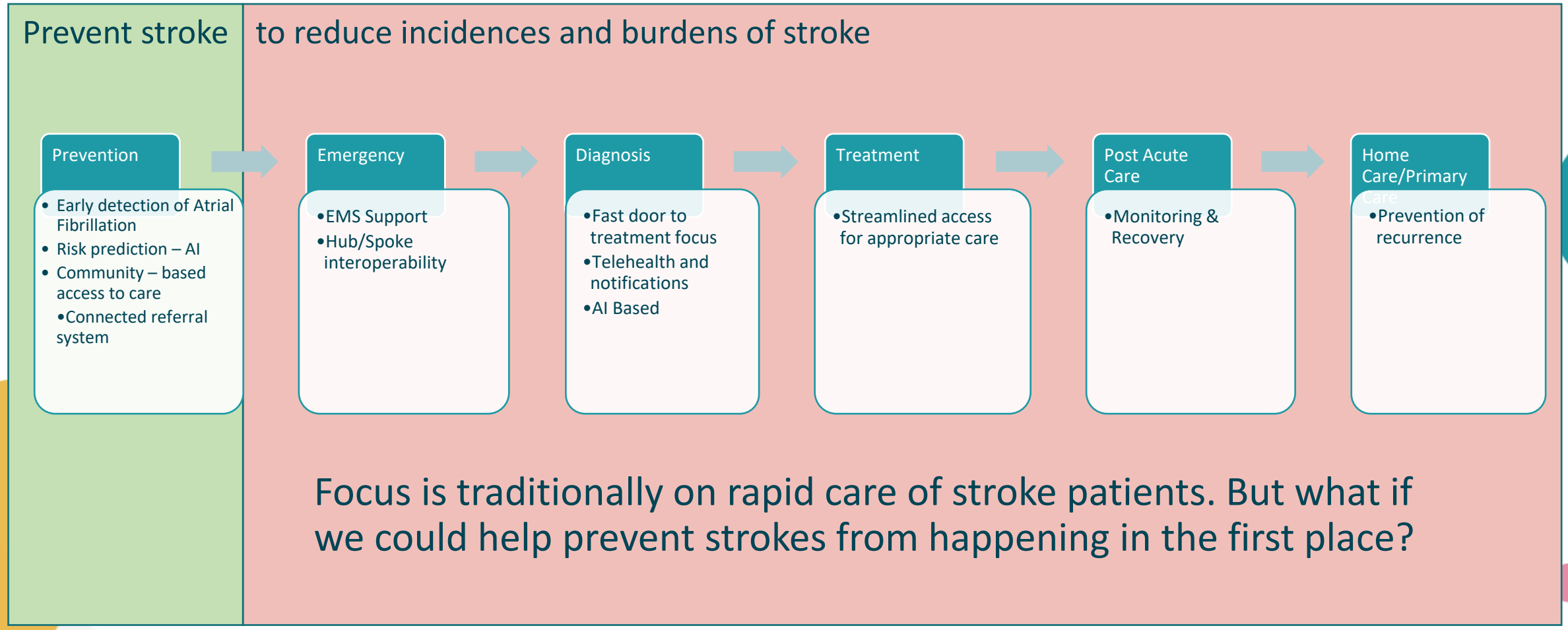
Stroke Statistics:

In Europe in 2017, nearly 1.5 million people suffered a stroke, nine million Europeans lived with a stroke, and more than 430,000 people died due to a stroke. The total cost of stroke in that year was a €60 billion. The number of new strokes and the number of people living with stroke is set to rise due to ageing population of Europe, as age is the greatest, non-modifiable risk factor for stroke.

Atrial fibrillation Statistics:

- A chronic disease that affects 25 million people globally.
- Causes approx. 1 in 7 strokes.
- Strokes causes by atrial fibrillation tend to be more severe;
- Persons with atrial fibrillation are 5 times more likely to suffer a fatal stroke than from other etiologies.
- 11-20% of patients are estimated to be underdiagnosed.
- Of these diagnosed, 23% of those will discontinue their therapy and only 4% will go on to have cardiac ablation therapy.[5]

POSTED-AFIB – Connected Care Pathway for stroke

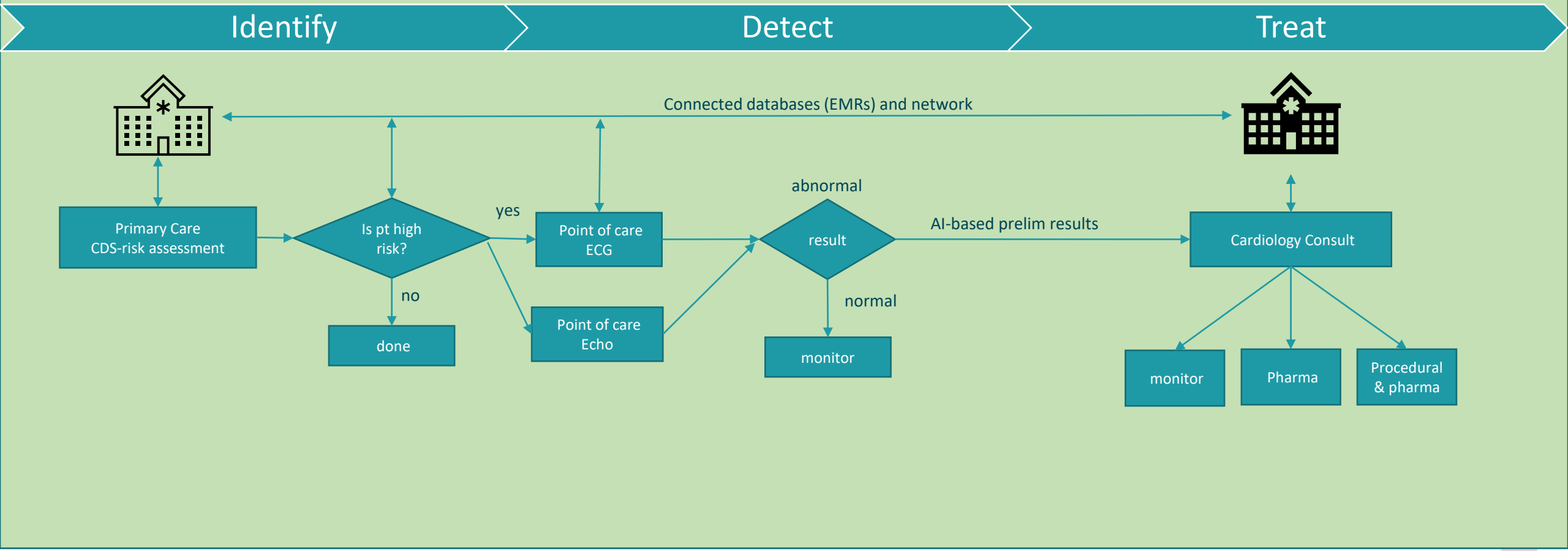


Focus is traditionally on rapid care of stroke patients. But what if we could help prevent strokes from happening in the first place?

POSTED-AFIB – Connected Care Pathway for stroke

Prevent stroke through earlier identification of Afib – major contributor to debilitating strokes

By identifying and diagnosing patients who may be at risk, or currently have atrial fibrillation at the point of primary care, the patients can then be directed towards optimal care pathways established in the ESC atrial fibrillation guidelines, thus improving their outcomes towards stroke prevention and care.



POSTED-AFib

Technical Challenges	Technical Goals and Opportunities
Disconnected hub and spoke care delivery network that may have network bandwidth constraints	• IT solutions to connect, consolidate, organize and standardize disparate EMR data – cloud based
Data-Centric Information Database with data avalanche	• Patient-Centric Display of Care Journey that organizes relevant data
Generalized care plans	• Precise-Personalized Care plans from validated clinical decision support algorithms
High turnover and/or sub-optimally trained diagnostic technologists and caregivers	• Easy to use, point of care, AI-enhanced diagnostic, review and reporting tools for workflow and result optimization
Care delivery at tertiary centers are out of reach for rural citizens	• Cloud based easy to use POC devices • Optimize multidisciplinary patient care and referral network through telehealth and secure information access

POSTED-AFib

Technology goals AI-Enhanced Clinical Decision Support for Identification of high-risk patients through EMR

- Cloud-based AI-Enhanced point of care, easy to use ECG and Echocardiography systems and with automated reporting/predictive analysis and EMR integrations
- Hub and Spoke cloud-based secured networked platform for patient-centric image and data consolidation, standardization and sharing amongst caregivers
- Network supports patient-friendly engagement tools for compliance and transparency in their own care.
- Analytics and dashboards to identify, track and trend populations to ensure healthcare equity

POSTED-AFib

Outcome Impacts

- Economic
  - Health system – expected to achieve cost savings through reduction of severe debilitating strokes, also through optimal use of hospital/medical system resources (personnel, equipment, supplies)
  - Society – expected to achieve cost savings through reduction expensive debilitating strokes or death (healthcare expenses, loss of wages/tax revenues)
  - Industry (device/pharma/other) – expected to achieve revenue increase as more patients are identified and require diagnostic and therapeutic measures in the aim to prevent strokes through identification and treatment of Afib

Expected duration / budget (optional)

- Estimated 5 years and budget - $20M€ (estimate)

POSTED-AFib

Partners

- GE Healthcare
  - Cardiology Solutions, Modality, Digital business units
- IDOVEN
- Pharma with focus on Afib treatments – not yet secured
- Clinical research partners with connections related to Cardiology, Electrophysiology, Emergency Stroke Triage, Primary Care
- Project Management assistance appreciated

Pitching Session

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8	Marc	Serra	CBD	ROBOPEDICS	Rehab after stroke: Robopedics

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IHI Call Days | Call 5

Compliant and safe data collaborations for comprehensive stroke management

Partner seeking consortium

Contact person name: Maria Scoz
Organisation: Decentriq
E-mail: maria.scoz@decentriq.com

Link to:

- Marketplace opportunity
- Participant profile

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Challenges and objectives

- Stroke is a heterogeneous, multifactorial disease regulated by non-modifiable (e.g., age, sex, family history) and modifiable risk factors
- Data needs to be integrated along the whole stroke pathway to allow for better risk identification, early diagnosis and better outcomes but:
  - Needs security
  - Privacy regulations
  - Needs efficiency and scalable solutions

- **Integrating data for AI and ML for risk segmentation and personalized care in a privacy preserving and secure way**

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Main activities

- Curate and make rich datasets available for discovery and analysis
- **Implement confidential data clean room infrastructure for sustainable data collaboration and analysis**
- Develop granular patient segmentation models
- Identify risk factors and predictive/prognostic models
- Test and deploy treatment prediction and recommendation models
- Increased accuracy of diagnosis and efficacy of treatments
- Right treatment for the right patient at the right time

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Expertise and resources offered

- Decentriq is a SaaS company with technical and practical expertise on implementing safe **data collaboration infrastructures for EU consortiums**
- We can offer the core infrastructure for privacy preserving and flexible data collaboration, analytics and model development
- Expertise in onboarding cohort owners
- A plan for data capture, storage and collaboration in a federated platform
- Input on data privacy regulations and secure international/inter-disciplinary collaborations

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Expected partner contribution

- **Partners**
  - SMEs, academia, industry, regulators, healthcare professionals, patients and patient advocacy groups, digital health companies, biostatisticians, legal experts, policy makers…
  - Cohort owners
- **Expertise**
  - For social, ethical, regulatory aspects
  - To generate & validate risk models
  - To develop models for short- and long-term economic consequences
  - For biomarker identification
- **Coordination**
  - Project management, dissemination & exploitation

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Pitching Session

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IHI Call Days | Call 5

Topic 3: Improved prediction, detection, and treatment approaches for comprehensive stroke management

Remote monitoring of vital functions focused on stroke - prediction, detection, and treatment

Contact person name: Dr. Richard Cimler

Organisation: University of Hradec Kralove

E-mail: richard.cimler@uhk.cz

Link to:

- Marketplace opportunity
- Participant profile

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Challenges and objectives

- Challenge: Difficult monitoring of people at risk of stroke at home
- Use of **AI methods for remote monitoring** of vital functions of persons
- Ballistocardiography methods for detailed analysis of cardiovascular system
- Use of **unobtrusive pads** under mattress for monitoring body micro vibrations
- Monitoring physical activity, sleep patterns and circadian rhythm of patients with stroke risk and during rehabilitation using **wearable devices**

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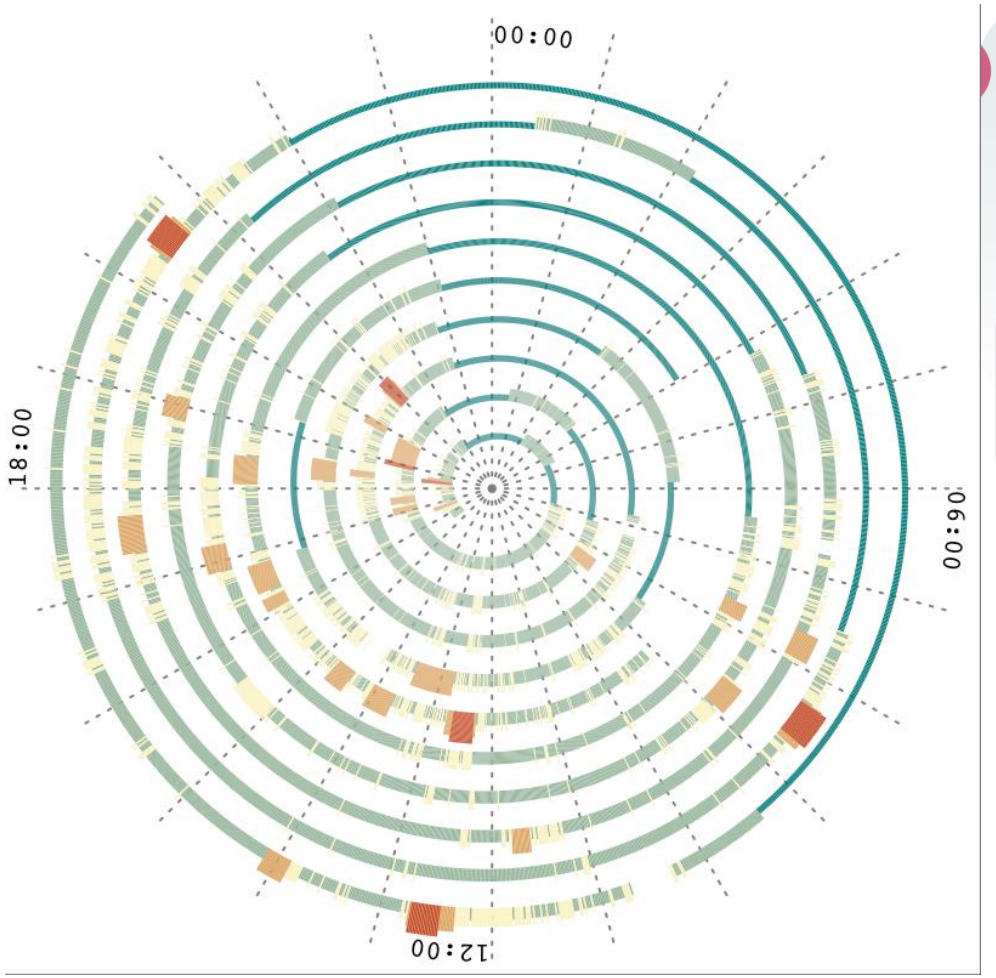
Main activities

- Unobtrusive monitoring of persons with stroke risk before and after stroke occurrence
- Comparison and analysis of BCG and ECG data
- Monitoring circadian rhythm including steps, activity and sleep patterns using wearable devices
- Evaluation of QT intervals
- Usage of AI methods for
  - identifying people at risk
  - diagnosis
  - evaluation of post-stroke rehabilitation progress
- Following circadian rhythm of patients



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Expertise and resources offered

- Hardware solution for unobtrusive data collection and evaluation **- sensor pads and/or wearables** measuring HRV, respiration rate, micro-vibrations, pulse wave velocity, ABI index, tremor.
- Software tools for **remote vital signs monitoring and mHealth interventions**.
- Server and **smartphone application for studies management** enabling sending questionnaires and prompts based on current data and complex rules.
- **Algorithms development** based on advanced signal processing.
- Infrastructure **for neural networks** long-term training & HPC Cluster.
- Team of experts focused on vital data collection and analysis using **advanced statistics and machine learning** methods.
- We can also bring SME as a project partner

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Expertise requested

- Hospitals – experts on stroke problematics
- Research institutes with access to patients
- Care providers
- Industry partners

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Pitching Session

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IHI Call Days | Call 5

Topic 3: *Improved prediction, detection, and treatment approaches for comprehensive stroke management*

Communication Infrastructure for Early Stroke Detection and Efficient Treatment

Contact person name: **Buse Bilgin**

Organisation: **TURKCELL**

E-mail: **buse.bilgin@turkcell.com.tr**

Marketplace opportunity: https://ihi-call-days.ihi.b2match.io/marketplace/opportunities/UGFydGljaXBhdGlvbk9wcG9ydHVuaXR5OjcwNjA5

Participant profile: https://ihi-call-days.ihi.b2match.io/participations/264348

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Challenges and objectives

- Research shows sufficient blood pressure management is important in preventing and treating stroke, as high blood pressure is a major risk factor in **25–50%** of strokes[1].
  - Regular monitoring of **blood pressure** and **heart rhythm** is important for stroke diagnosis and post-stroke follow-up.
  - In addition to the data collecting, it is of great importance to **analyze** and **share** it to the emergency services quickly.
  - A **trustworthy**, **seamless** and **fast end-to-end connection** is required for remote patient monitoring and disease diagnosis.

1: Gorelick, Philip B et al. “Blood Pressure Management in Stroke.” Hypertension (Dallas, Tex. : 1979) vol. 76,6 (2020): 1688-1695. doi:10.1161/HYPERTENSIONAHA.120.14653

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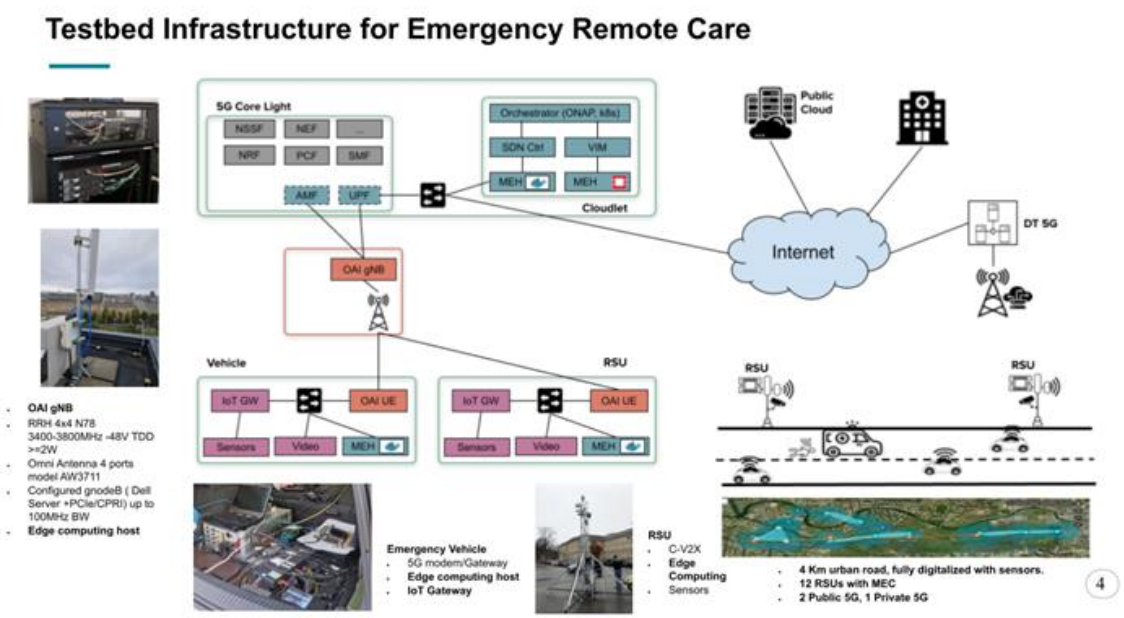
Main activities



https://health5g.eu/use-cases/

As Europe's 4th largest operator, Turkcell provides a **secure, fast** and **seamless** communication service by establishing an **end-to-end communication infrastructure** with its extensive coverage and R&D experience.

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Expertise and resources offered

Turkcell has experience in providing **communication infrastructure**, **end-to-end secure data sharing**, **data processing**, and **developing predictive models** for future patients with the help of previous data.

By getting involved in 9 Horizon 2020/Europe projects, Turkcell has gained a lot of experience in **developing international projects** and performing **large-scale tests** of developed technologies in Turkiye.

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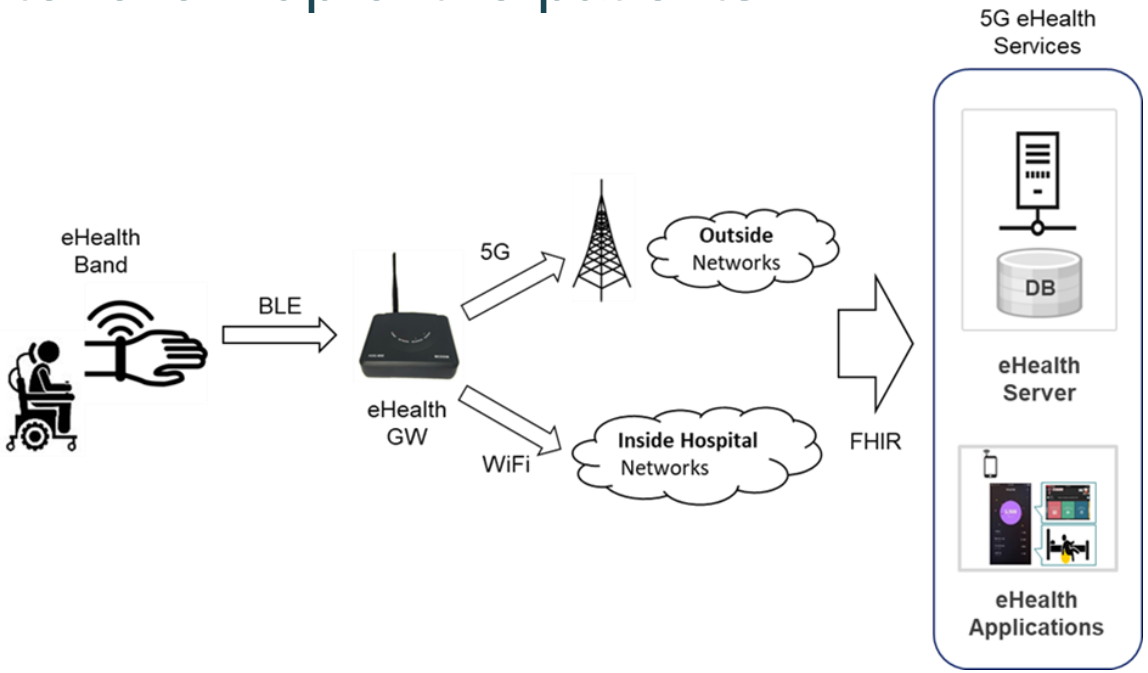
Expertise requested

Turkcell wish to support existing consortia by providing a **communication infrastructure** for sensors targeted for mass-scale testing or remote follow-up of the patients.



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Pitching Session

Call 5 – topic 3 – Stroke management – 28 June 2023

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5	Thierry	Fumeaux	CEO	Acthera Therapeutics	Hard-Shelled Liposomes (HSL) Improved thrombolytic therapy for acute ischemic stroke
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7	Harald	Schmidt	Professor	Maastricht University - Pharmacology and Personalised Medicine	SAVEBRAIN+
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Improved prediction, detection, and treatment approaches for comprehensive stroke management

Hard-Shelled Liposomes (HSL)

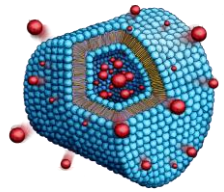
Improved thrombolytic therapy for acute ischemic stroke

Contact person name: Thierry Fumeaux, MD, EMBA

Organisation: Acthera Therapeutics

E-mail: fumeaux@actheratx.com

acthera



Links:

- https://ihi-call-days.ihi.b2match.io/marketplace/opportunities/UGFydGljaXBhdGlvbk9wcG9ydHVuaXR5OjcwNzc4
- https://ihi-call-days.ihi.b2match.io/participations/264722

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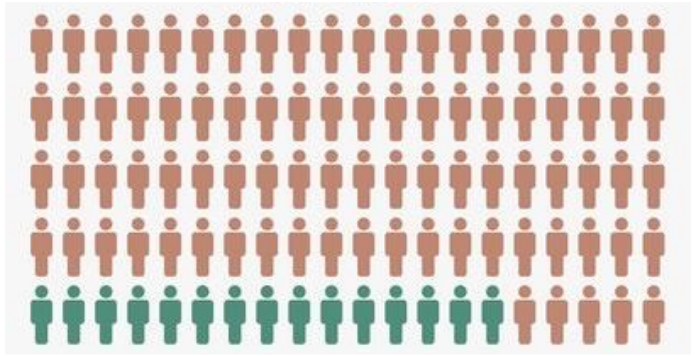
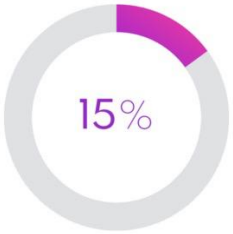
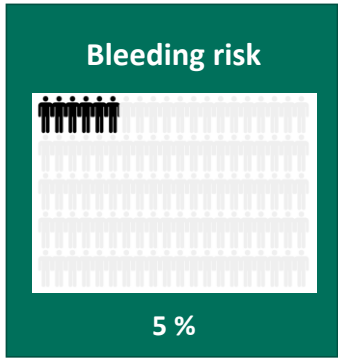
Acute Ischemic Stroke: remaining challenges

Stroke patients: >80 % are currently **NOT treated** with a thrombolytic drug



Reperfusion success rate of thrombolysis:

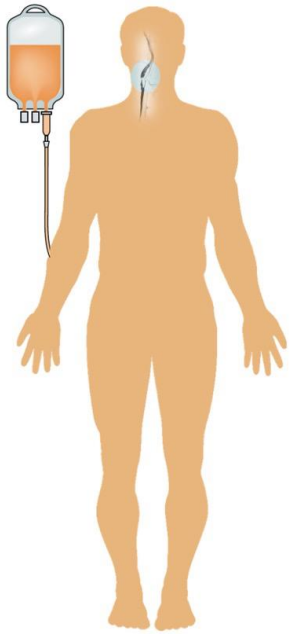


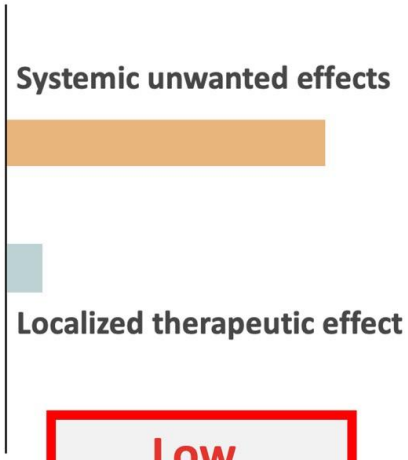


Undertreatment, lack of efficacy, and bleeding are persistent issues

How to solve the issue?

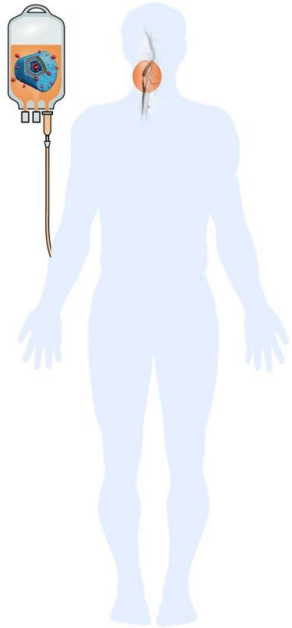
Untargeted delivery

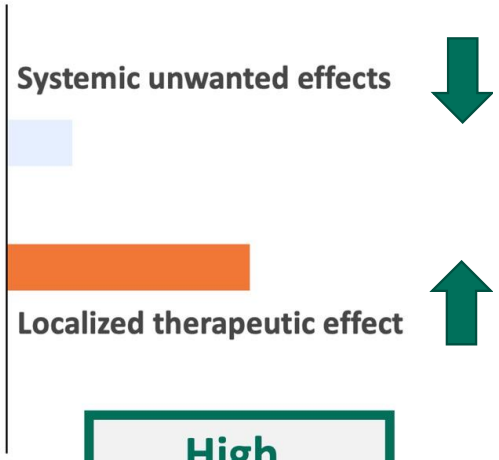




Low efficiency

Targeted delivery





High efficiency

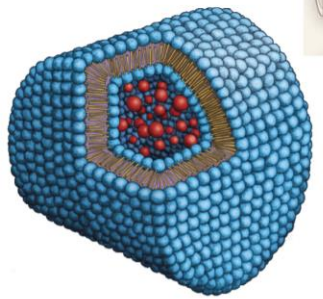
Our objective: delivering the drug at the site of action

Our liposomes are designed for this task

Thrombolytic drug encapsulation

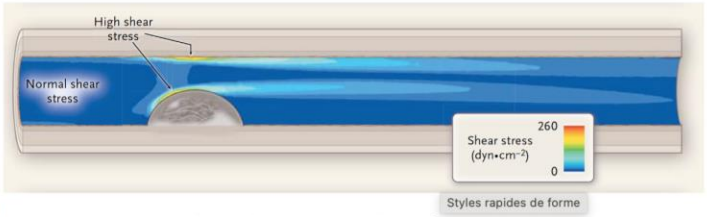
Targeted delivery at the site of occlusion

rT-PA



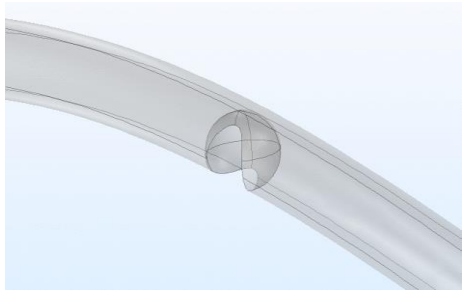
Hard-Shelled Liposomes

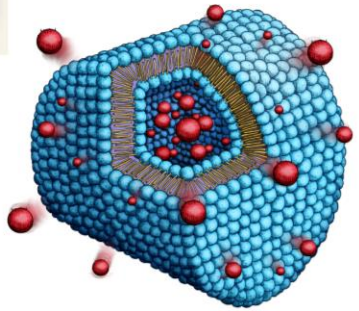
Coronary/cerebral artery obstruction



Massive increase in shear stress

Physical trigger





Efficacy ***Safety***

Hard-Shelled Liposomes: a more efficient thrombolytic treatment

Our objectives

- We want to bring a **more efficient** reperfusion therapy to the majority of acute ischemic stroke patients:
    - Greater **efficacy** → more reperfusion → less mortality/morbidity
    - Improved **safety** → less contraindications/complications
- This will extend the therapeutic time-window and reduce the contraindications, thus increasing the number of patients who will benefit from the therapy

Main activities

- **Basic research**: study of shear stress-HSL interactions
  - (micro)-fluidic systems
  - Computational Fluid Dynamics (CFD)
- **Manufacturing** process upscaling to GLP-grade:
  - Lipid & API production → Loaded HSLs manufacturing
- **Animal models** of stroke and thrombolytics:
  - Efficacy data (reperfusion)
  - Safety data (bleeding risk)

Expertise and resources offered

- A **compact** executive team
- A **supportive** Board
- A group of **experienced** SAB members, KOL and consultants
- **Selected** external partners:

Innosuisse · zhaw · SeroScience · STROKE BRNO · SEMMELWEIS UNIVERSITY 1769

We will bring in-kind contributions to Acthera's operational activities

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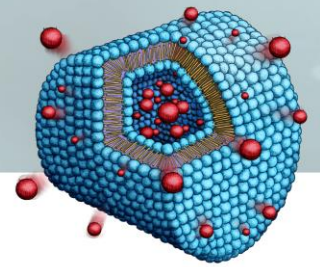
Expertise requested

We are looking for partners to build a consortium:

- SME/large companies:
  - co-development:
    - Innovative API (thrombolytic drug – ischemia-reperfusion modulation)
    - lipid/HSL manufacturing upscaling to GLP/GMP grades
    - development of companion technologies as mechanical triggers
  - licensing deals for clinical development and go-to-market
- Research institutes specialized in:
  - Shear stress (CFD/fluidic systems)
  - Thrombolytic drugs
  - Stroke animal models

Contact us!



Thierry Fumeaux
CEO

fumeaux@actheratx.com

Pierre-Alain Monnard
CSO and Co-Founder

monnard@actheratx.com

Thank you!

Pitching Session

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DISCO

Data driven Integrated solutions for Stroke Care pathway Optimization

Contact person name: Robert Hofsink

Organisation: Philips

E-mail: Robert.Hofsink@Philips.com

Link to:

- Marketplace opportunity
- Participant profile

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Rationale

global stroke prevalence

Stroke is **the leading cause of disability,** worldwide

2nd leading cause of death

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Challenges and objectives

Challenges

- Get stroke patients treated as quickly as possible
- Physicians in stroke settings are under pressure to make optimal treatment decisions
- Care teams currently lose valuable time due to gaps in communication, information, and access to data and stroke expertise

Objective

- Develop solutions to make the right decisions faster, treat more patients, more effectively, and improve patient outcome.

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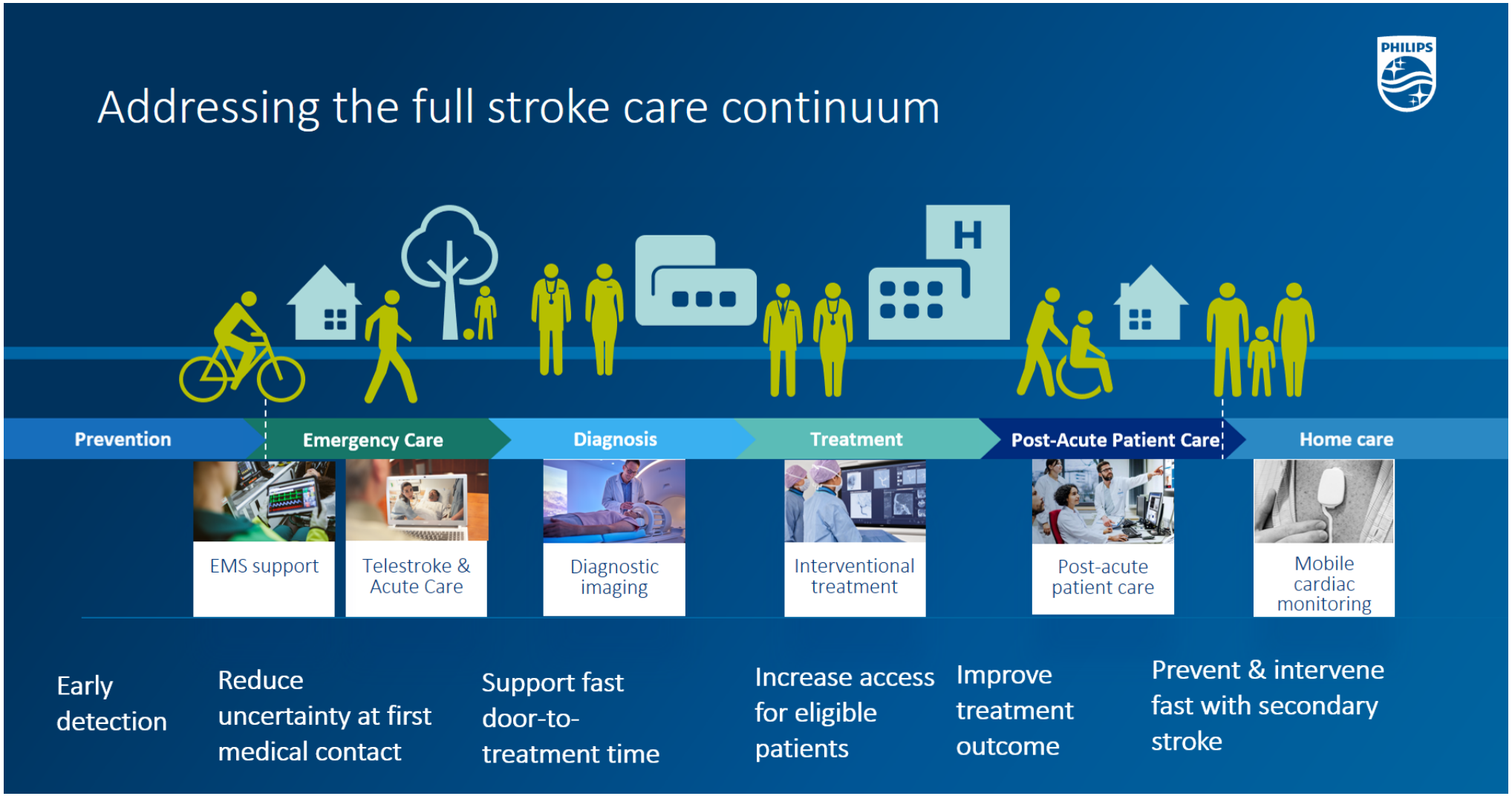
Stroke care continuum



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Main activities

- Develop intelligent data-driven solutions to improve the patient journey from emergency care, diagnosis, treatment to post-acute patient care
- Innovation directions: smart triage, AI-enabled advanced imaging techniques, modelling & prediction, intuitive visualization, monitoring tools, pharmaceutical interventions, …
- Connect technology, information and people along the full stroke care pathway

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Expertise and resources offered / requested

Partners

- NL: Philips Image Guided Therapy
- Conversations started with clinical research and technology partners
- Interest in partners with expertise in drug development for stroke treatment

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Topic: Improved prediction, detection, and treatment approaches for comprehensive stroke management

Contact person name: Prof. H. H. H. W. Schmidt
Organisation: Maastricht University
E-mail: hschmidt@ppmlab.net
Collaboration opportunity:

- https://ihi-call-days.ihi.b2match.io/participations/265468/opportunities

Profile:

- https://ihi-call-days.ihi.b2match.io/participations/265468

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SAVEBRAIN+

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SAVEBRAIN+ 4 challenges & objectives

1. **There is no neuroprotective therapy in ischemic stroke**
   - We provide phase IIa drug repurposing proof of concept
2. **Time of onset is often unknown limiting any intervention**
   - We provide plasma marker proteins indicating time of onset
3. **Secondary prevention is imprecise and often ineffective**
   - We genetically stratify patients for tailored secondary prevention
4. **Expertise in acute stroke management limited to stroke units**
   - We provide a tele-infrastructure for acute care and follow-up

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SAVEBRAIN+ 4 main activities

1. To conduct a phase IIb multi-centre, multinational PoC drug repurposing trial for mechanism-based neuroprotection in stroke
2. To identify modified plasma proteins indicating different post-stroke phases and convert this technology into a point-of-care test
3. To employ genetic and HER features to stratify patients for secondary stroke risks and their prevention
4. To expand our imaging-AI based stroke tele-medicine to remote blood based diagnosis and therapy

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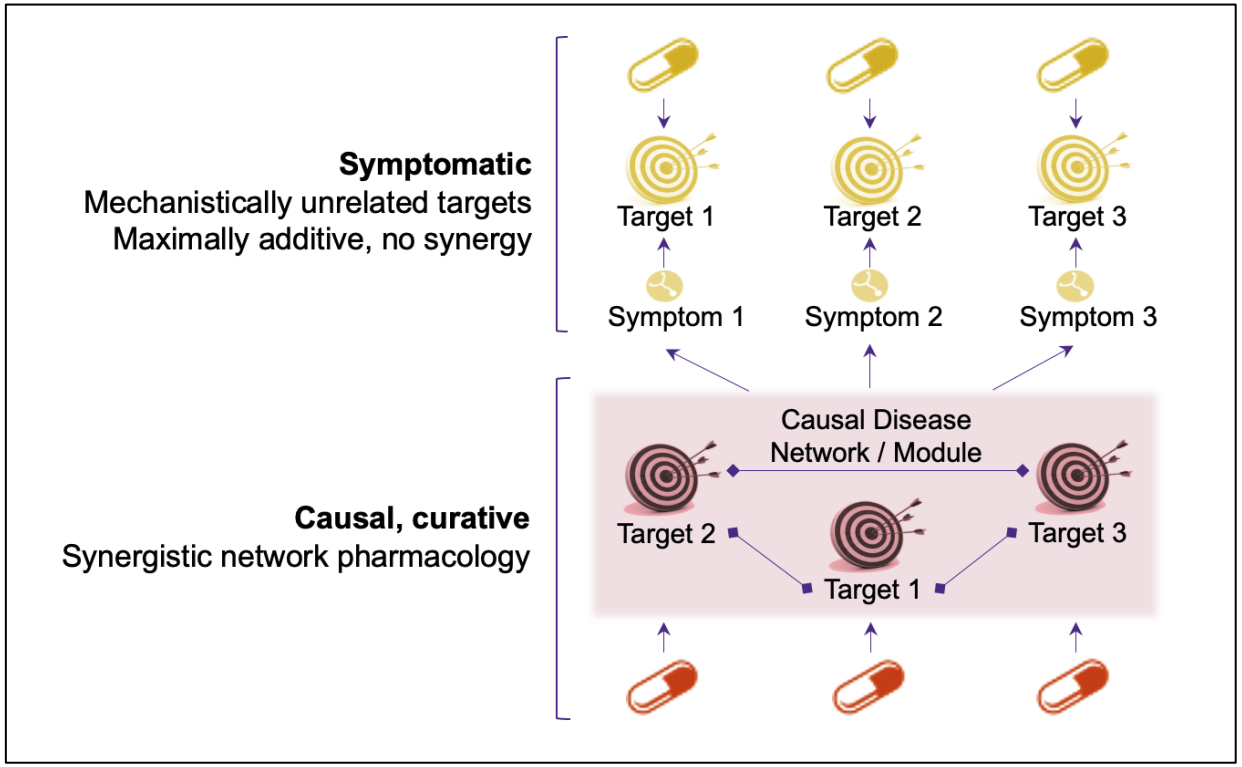
SAVEBRAIN+ concept/PERT chart

Telemedicine
LF pre-test
Imaging-AI

Acute Neuropretection



Time-point markers

AI fpr 2° Prevention
Subacute
Mid-term
Long-term

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Expertise and resources offered

- From ERC AdG RadMed, the pre-clinical target validation
- From ERC PoC SAVEBRAIN, the large animal validation
- From REPO-TRIAL, REPO-STROKE I and REPO-STROKE Iia, pre-clinical network pharmacology validation, patents and licences, diagnostics.
- From REPO4EU, bioinformatic, clinical pharmacology, trial design, industry level diagnostics, FTO, CMC, patenting and business development expertise
- Spain-based academic trial center with an international network for phase Iib
- Regulatory network to prepare multi-national approval and rapid market entry
- Advanced medical AI/ML technology to identify secondary risk prediction.
- **Contributing partners (e.g. ERC PoC, REPO-TRIAL, REPO4EU) bring in cash or in kind contributions; all private members, IKOP and IKAA**

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Expertise requested

- Commercial/industry partners to increase the TLR levels of our diagnostics
- Academic partners (outside Spain) with expertise in IITs to join our multi-centre, multi-national phase IIb efficacy trial

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Topic 3: Improved prediction, detection, and treatment approaches for comprehensive stroke management

Rehab after stroke: Robopedics

Contact person name: Marc Serra

Organisation: Robopedics

E-mail: marc@robopedics.com

Link to:

- Marketplace opportunity
- Participant profile : https://ihi-call-days.ihi.b2match.io/my

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Challenges and objectives

- The main objective of this project is to proof that early use of robotic orthosis can impact and reduce drastically the rehab time of hemiplegia patients after a stroke.
  - What problem are you trying to solve?
    - The longer you try to walk after a stroke, the longer it will take to walk again, provided patient end up walking again. The proprioception will forget the body parts if we don't use them. So, the objective is to use robotic orthosis to help walk again since the very first day.
  - Concrete example of potential results and expected impact
    - If proven right the results will be that:
      - More patients will walk again, that with current standard of care would not walk.
      - More patients will walk again earlier, that with current standard of care would take longer time to walk again.
    - Therefore, the impact in health expenses and in social impact is relevant.

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Main activities

- Test on patient the time they take to walk again with and without the robotic orthosis.
- Test on patient the brain activity related to walking again with and without robotic orthosis.

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Expertise and resources offered

- Our current partners are:
  - Dra. Conxita Closa – Head of Rehab in Hospital Clinic.
  - Dra. Esther Duarte – Head of Neurorehab in Hospital del Mar
  - CT Ingenieros- Largest Engineering company in Spain.
  - Clinica Guttmann -> Agreement for Clinical Trials
  - Our expertise relays in translating hemiplegia effects into a robotic orthosis.

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Expertise requested

- List profiles for desired partners, by category (SME, large companies, research institutes, other)
  - Institutes researching Stroke Rehabilitation.
  - SME -> Developing batteries for large Medical Devices.

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Thank you for your attention

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COCIR Advancing Healthcare

efpia

EuropaBio The European Association for Bioindustries

MedTech Europe from diagnosis to cure

Vaccines Europe

Co-funded by the European Union