

Traumatic Brain Injury

Complex problem – Creative solution

November 2023

The background of the slide is a grid of brain MRI scans. The scans are arranged in a 4x4 pattern, with each cell containing a different cross-section of a human brain. The scans are rendered in a monochromatic blue color scheme, which is consistent with the overall theme of the slide. The text is centered over the grid.

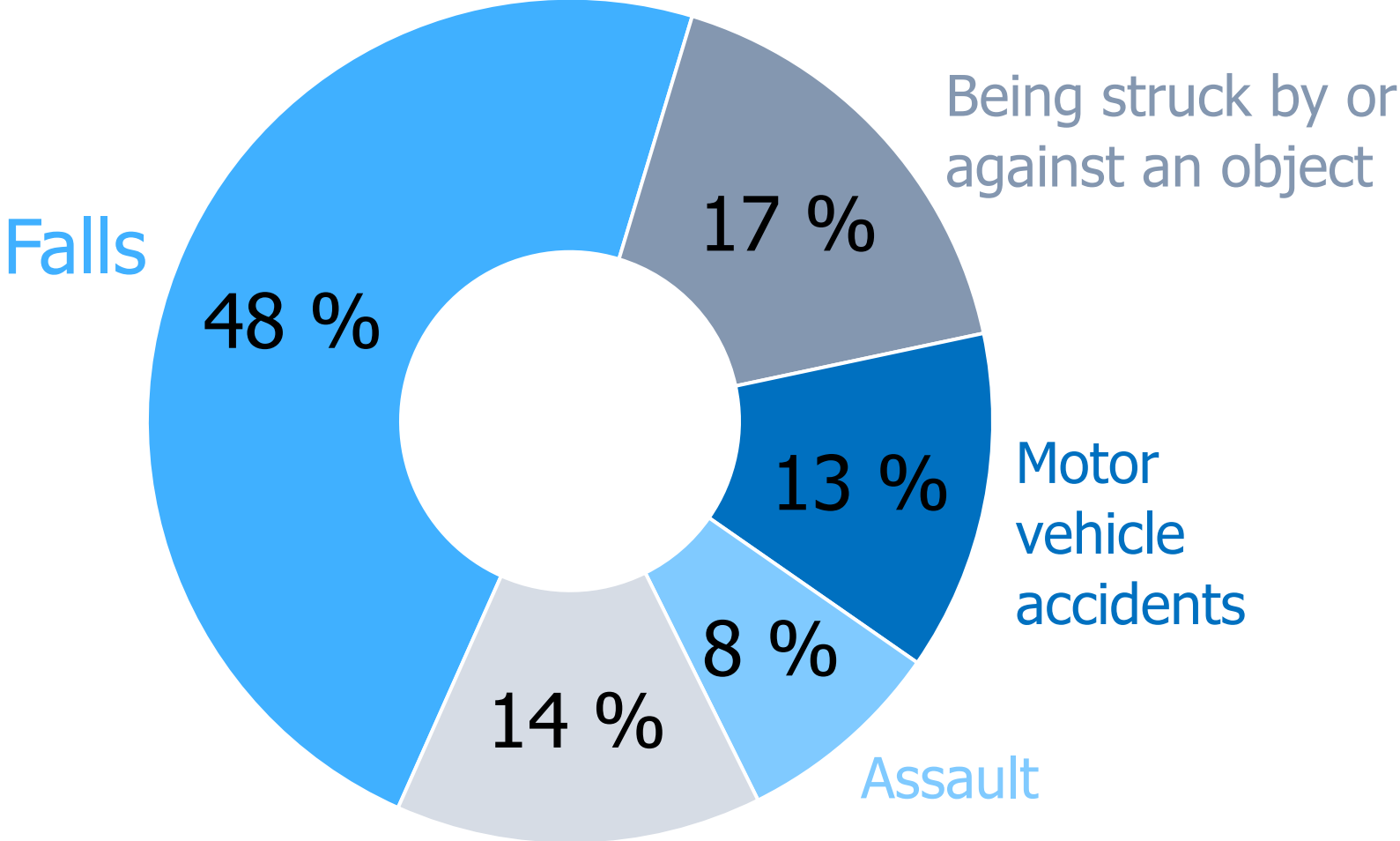
Introduction to the TBI Problem and Our Solution

Traumatic Brain Injury (TBI)

- TBI occurs after a hit to the head
 - For example, in falls, vehicular accidents, contact sports, and blasts
- It causes immediate physical damage to brain tissue
- However, it also exposes the healthy part of the brain to metal ions, free radicals and inflammation
 - Sets off a chemical reaction that damages surrounding healthy tissue



Leading Causes of TBI



Other or unknown cause E.g. blasts and explosions, firearms, medical procedures

TBI – A Global Problem

New cases each year

- Around 69 million TBI cases globally *
 - 2.8 million in the US **
 - 2.5 million in Europe ***
 - 0.6 million in Australia
 - 0.5 million in Canada
- ~90% of TBI cases are mild
 - Risky condition but difficult to detect
- **The Need:** Accurate and rapid detection of head injuries



* [Dewan et al. \(2019\) J Neurosurg 130: 1080-1097](#)

** Centers for Disease Control and Prevention (CDC)

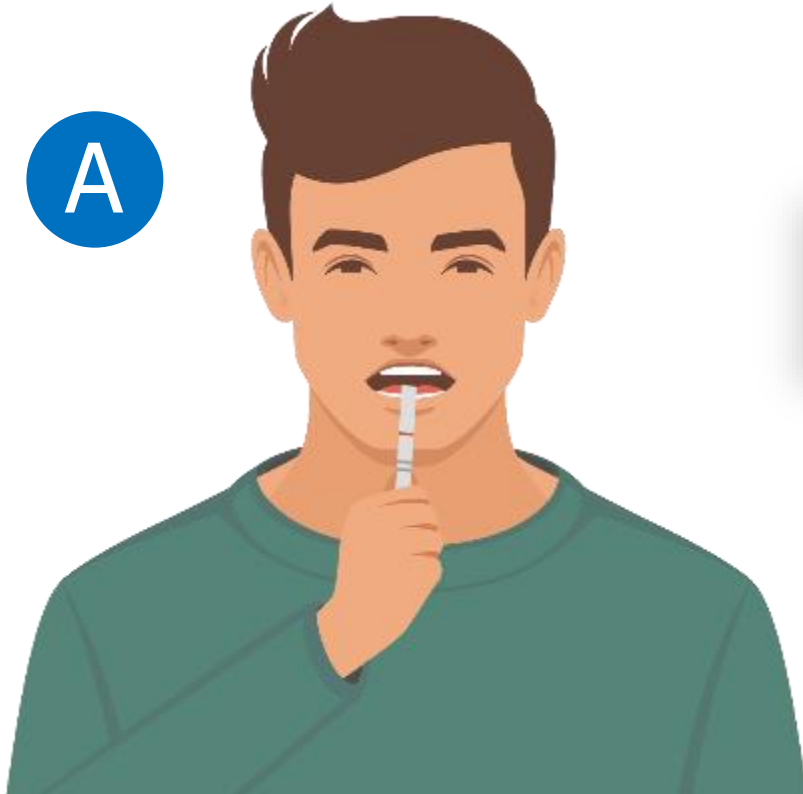
*** CENTER-TBI EU

Our Solution for Diagnostics



An easy test detecting a biomarker in **saliva** or **urine** (ProbTBI™)

A



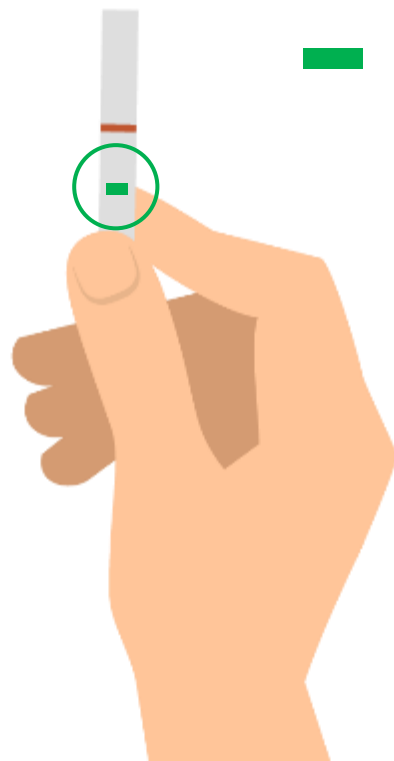
B



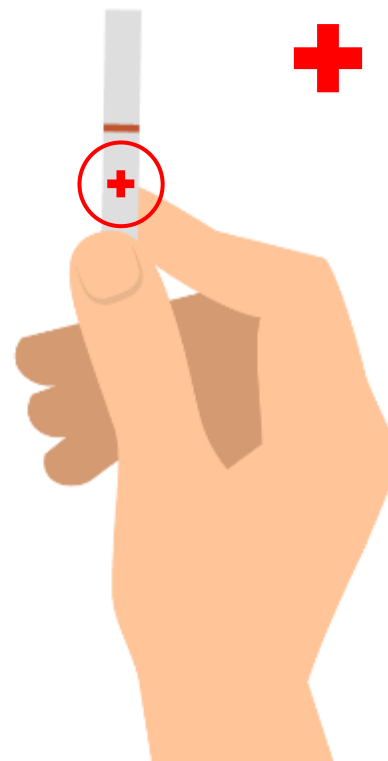
1st Generation Qualitative Test



The strip responds to biomarkers that appear in urine and saliva shortly after brain injury and develops a visual signal.



- Negative – no brain injury



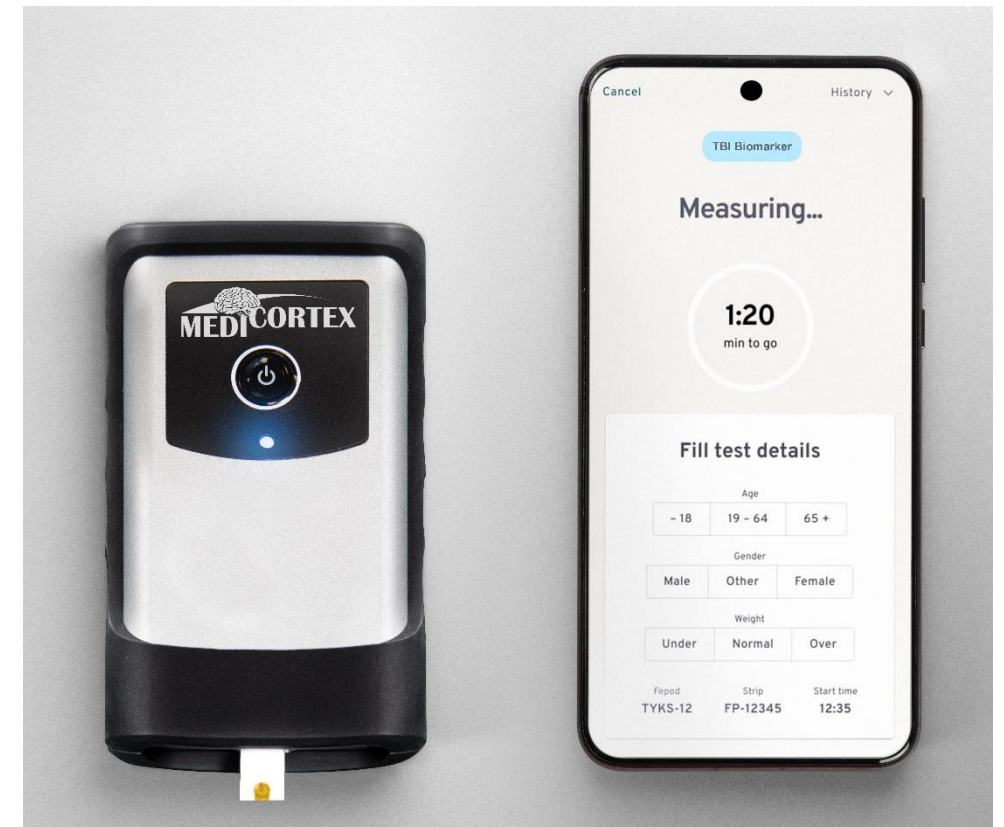
+ Positive – brain injury has occurred

Next Generation Quantitative Test



Electrochemical sensor and device for quantitative measurement (TesTBI)

- Recognition of the biomarker in sample by highly specific synthetic binding molecules (aptamers)
- Biomarker in sample triggers an electric signal on sensor which is translated to quantitative value through unique software
- Collaboration with Fepod Oy Ltd (www.fepod.fi)
- The current share issue raising funds for starting the electrochemical sensor development for TBI detection



Illustration

Why Are the Tests Needed?

- No accurate and definite diagnostic tools exist for brain injuries
- MRI and CT have low resolution, are costly to society, require electricity and specialists, and are not available everywhere
- Children need anaesthesia for the process, and patients are exposed to irradiation or contrast dyes
- Current methods are also inaccurate in detecting mild cases



- Medicortex is developing biomarker tests based on saliva or urine samples which are less investigated for this purpose
- Medicortex is targeting glycoproteins and cellular enzymes, which are exposed to each other due to cell damage
- Medicortex has the know-how to capture and identify these proteolytic breakdown products
- Medicortex's tests will together provide qualitative and quantitative detection of brain injury biomarker



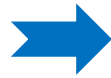
Research and Development: Performed and Planned

Three Clinical Studies – Published Results



1st Clinical trial: Proof-of-Concept

	Patients
Patients with suspected TBI	12
Healthy controls	12



Results published:

Kvist M, Välimaa L, Harel A, et al. (2021) Glycans as Potential Diagnostic Markers of Traumatic Brain Injury. *Brain Sciences* **11**:1480. <https://doi.org/10.3390/brainsci11111480>

2nd Clinical trial: TBI vs. Healthy & Orthopedic trauma

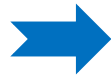
Patients with suspected TBI	24
Patients with orthopedic injury	16
Healthy controls	29



Manuscript under preparation

3rd Clinical trial: Children

Children with suspected TBI	28
Healthy control children	30



Results published:

Kvist M, Välimaa L, Harel A, Malmi S & Tuomisto A (2023) Glycans as Potential Diagnostic Markers of Traumatic Brain Injury in Children. *Diagnostics* **13**:2181. <https://doi.org/10.3390/diagnostics13132181>

Clinical Studies – Conclusions



- Biomarkers showed **statistically significant** differences between injured and healthy subjects – correspondence with prior animal data results
- Biomarkers were recognized by their ability to bind to several lectins
- Individual glycan profiling by mass spectrometry revealed several structures that were different between injured and healthy subjects
- Medicortex reached a significant milestone -> **a proof-of-concept**



Analysis of the samples collected in the second clinical trial was enabled by a grant received from the US Department of Defense (DoD) / U.S. Army Medical Research and Materiel Command.



Analysis of the samples from the third clinical study was supported by Business Finland.

Biomarker Detection on a Strip

Demonstration of biomarker detection on a nitrocellulose strip using colloidal gold label

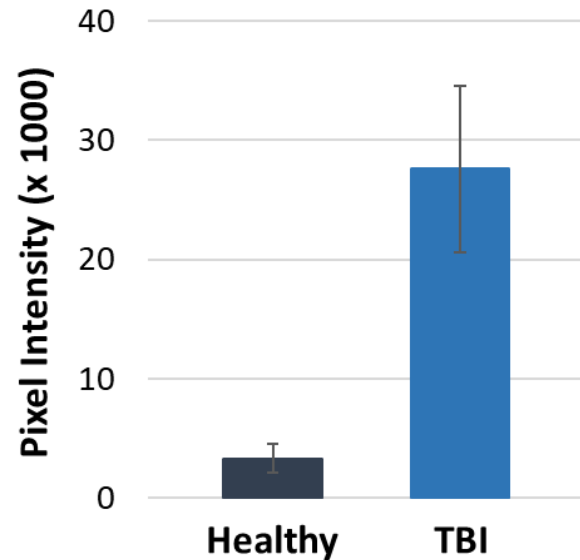
Saliva samples

Visual outlook

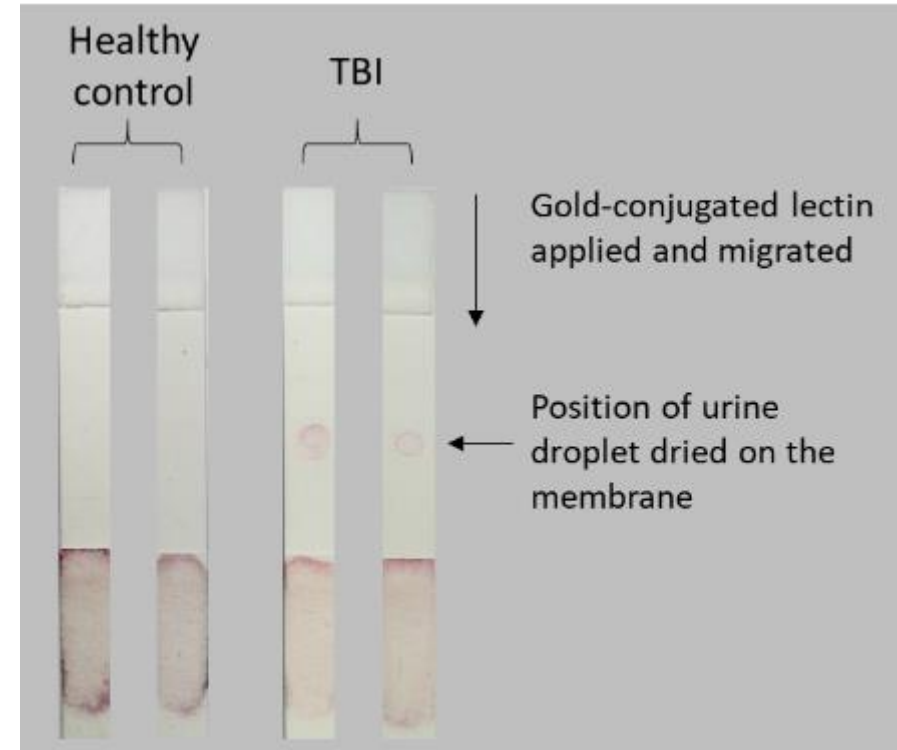


Healthy TBI

Measured darkness of spots



Urine samples



R&D plan for the strip test development	2023/Q3	2023/Q4	2024/Q1	2024/Q2	2024/Q3	2024/Q4	2025/Q1	2025/Q2
Strip test development for mTBI								
Medical prototype device development								
Evaluation of the prototype								
Initiation of regulatory process								
Production of prototype batch								
Clinical evaluation of the final product								
New patent applications								

From an Idea to the Product

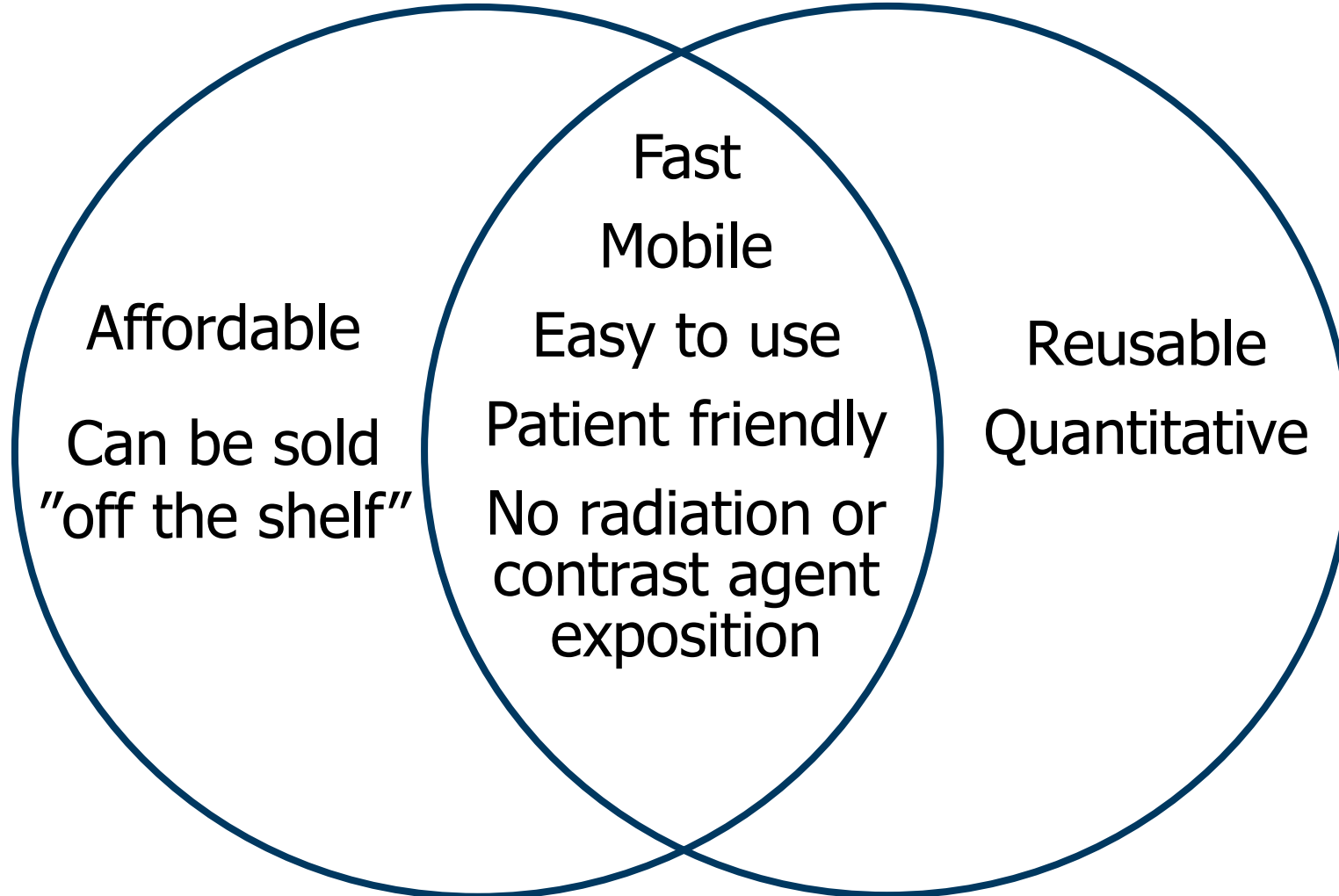


Medicortex Test Advantages



ProbTBI™ Kit

TesTBI Reader Device



Our Potential Clients



**Army
paramedics**



**Hospitals and
emergency rooms**



Paramedics



**First
responders**



**Sport
teams**



Schools



**Nursing
homes**



**Private
people**



**Insurance
companies**

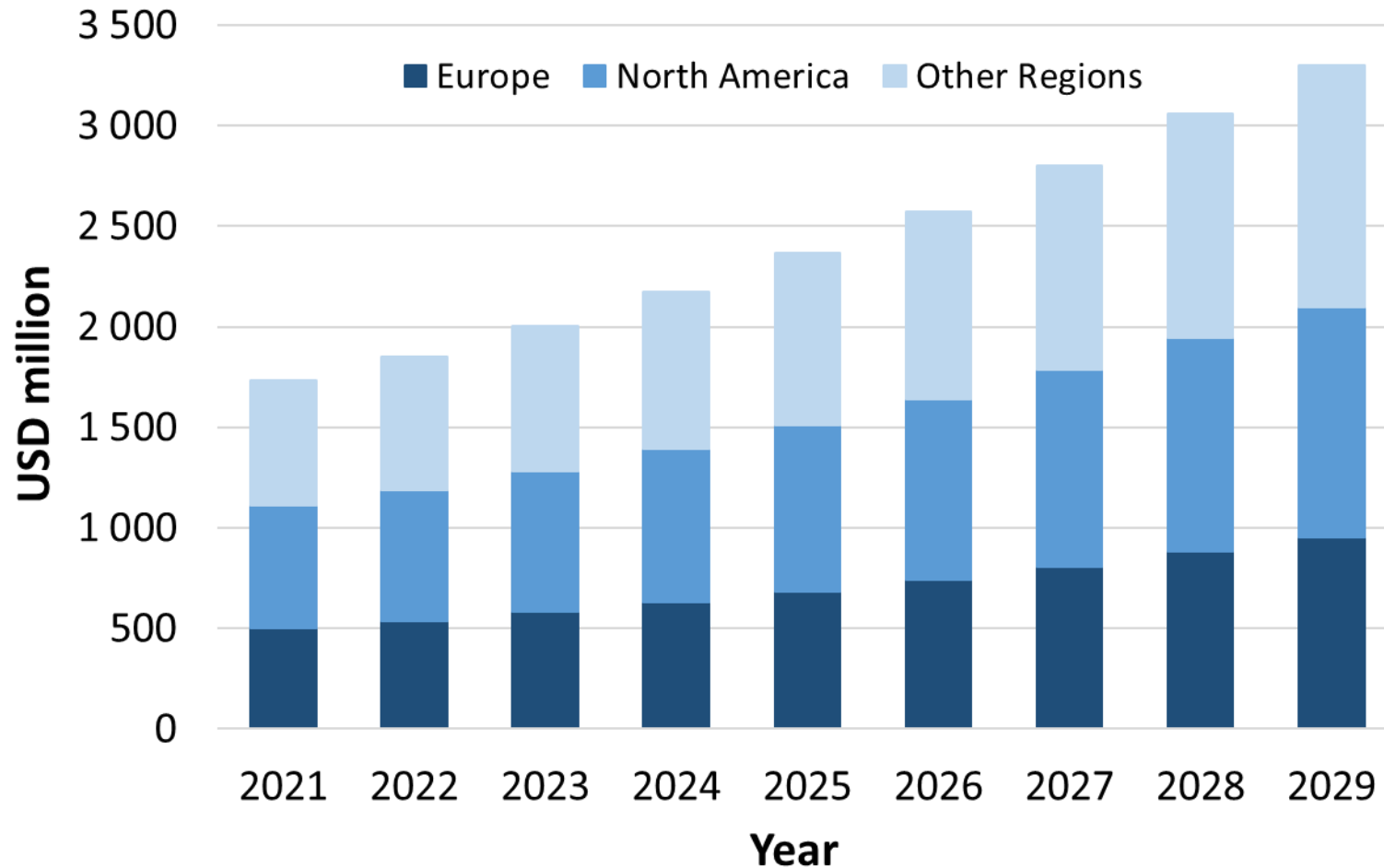


**Pharma
companies**

Market Potential



Traumatic Brain Injury diagnostic global market expected to reach **\$3.3 billion** by 2029



Source:
Cognitive Market
Research (2021)

Market growth can be related to increase in population, aging population, increased number of vehicles on the road, and extra leisure time to get engaged with risky activities, as well as enhanced clinical classification and diagnostics.

The background is a solid blue color with several faint, semi-transparent charts and graphs overlaid. In the upper left, there is a bar chart with approximately 10 bars of varying heights. In the upper right, there is a line graph with a grid, showing a fluctuating line with data points. In the lower right, there is another bar chart with about 10 bars, some of which are taller than others. The overall aesthetic is professional and data-oriented.

Intellectual Property Position

Patents for the Biomarker and Diagnostics



1. Prognostic and Diagnostic Glycan-based Biomarkers of Brain Damage

- European patent No. 3283880
- US patent No. 10,739,335
- Canadian patent No. 2,982,503
- Israeli patent No. 254 980

2. Non-invasive Brain Injury Diagnostic Device

- PCT-application WO/2018/154,401, has entered into national phases
- South African patent (number pending)
- Utility model granted in China and Australia

3. Device and Method for Detecting of Brain Injury in a Subject

- PCT-application WO 2021/099677
- Australian innovation patent No. 2020104474
- Finnish Utility model No. 13179



Patents for the Biomarker and Diagnostics

(continues)



4. A Method for Determining a Lectin-binding Glycan Indicative to Traumatic Brain Injury
 - PCT-application WO 2021/205059
5. A Method for Diagnosis of Traumatic Brain Injury
 - Finnish patent No. 130340
 - PCT-application WO 2023/161557
6. Method of Detecting Tissue Damage
 - Finnish patent No. 130428
 - PCT-application WO 2023/161553
7. A Hand-held Liquid Sample Collection and Testing Device
 - Finnish utility model No. 13331
 - German utility model No. 20 2023 100 246
 - Austrian utility model pending



The background is a solid blue color with a semi-transparent overlay of financial data. At the top, there is a line of text: "-0.92% 12.73.0M +3.32%". Below this, there are several faint, semi-transparent images: a stack of coins on the left, a bar chart in the center, and a pie chart on the right. The text "Public and Private Financing" is centered in a large, white, bold font. At the bottom left, there is another line of text: "+16.28%".

Public and Private Financing

Equity up to Now

- About 3.3 M€ from the founder and 275 private investors
- Total number of shares issued about 22 million
- Current price per share 1.00 € and total valuation 22 M€

Subsidies in the Past

- Total of 1.8 M€ in grants
 - Including 1.1 M dollars from the US Department of Defense
- 70 k€ in awards

Present

- A research grant of 2.1 million dollars received from the US Department of Defense (see [press release](#))
- The objective of this project is to deliver a prototype of the qualitative strip test for TBI detection



Funded by the
European Union



Share Issue November 2023



- Target to raise up to 100,000€
- Price per share 1.00€, minimum investment 2,000€ (2,000 shares)
- Campaign time 14 to 28 November 2023
- Subscription can be made by filling in, signing and sending the Subscription agreement to the company
- More information at: www.medicortex.fi/eng/funding-round

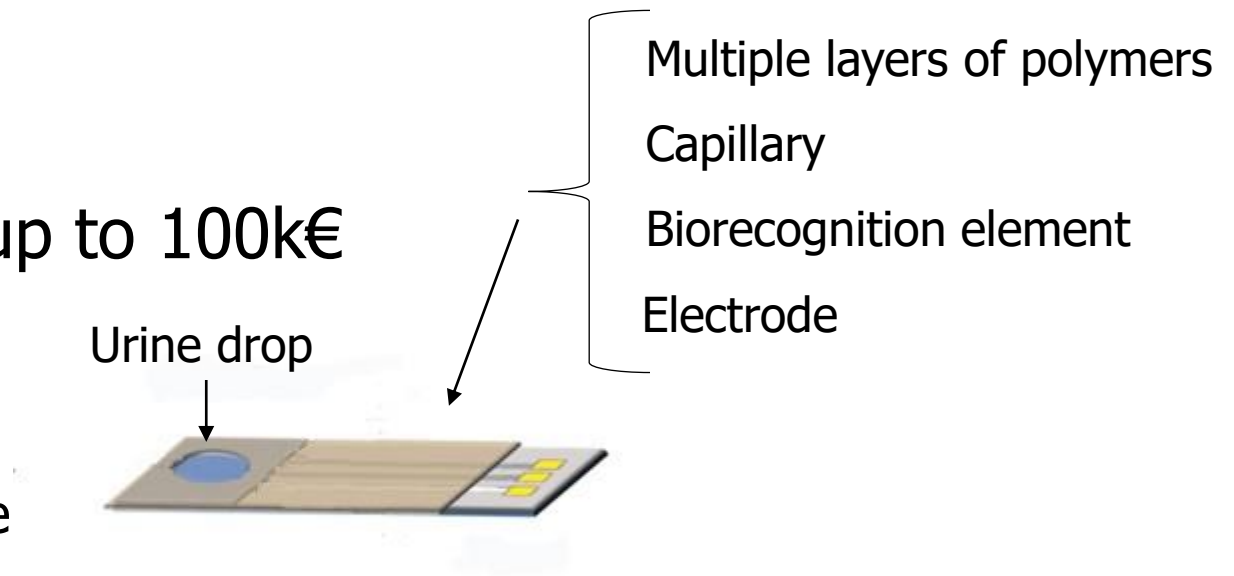
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Investments always include risks. Invest responsibly!

Use of Funds: TesTBI reader device

Feasibility study

- Set up the biomarker assay on the new sensor system and perform a feasibility study
- In collaboration with Fepod Oy Ltd
- Duration about 3 months and costs up to 100k€
- Deliverables
 - Aptamer based sensor is successfully tested
 - Concept is proven to work, and it is scalable
- Successful completion of the feasibility study warrants move to the next phase



Next phase

Piloting and upscaling

- Pre-testing with a small number of clinical samples in the stock
- Clinical study in hospitals for clinical evaluation of the system and regulatory data acquisition
- Costs >500k€ and duration >6 months
- We are drafting project plans and grant applications to get the second phase funded

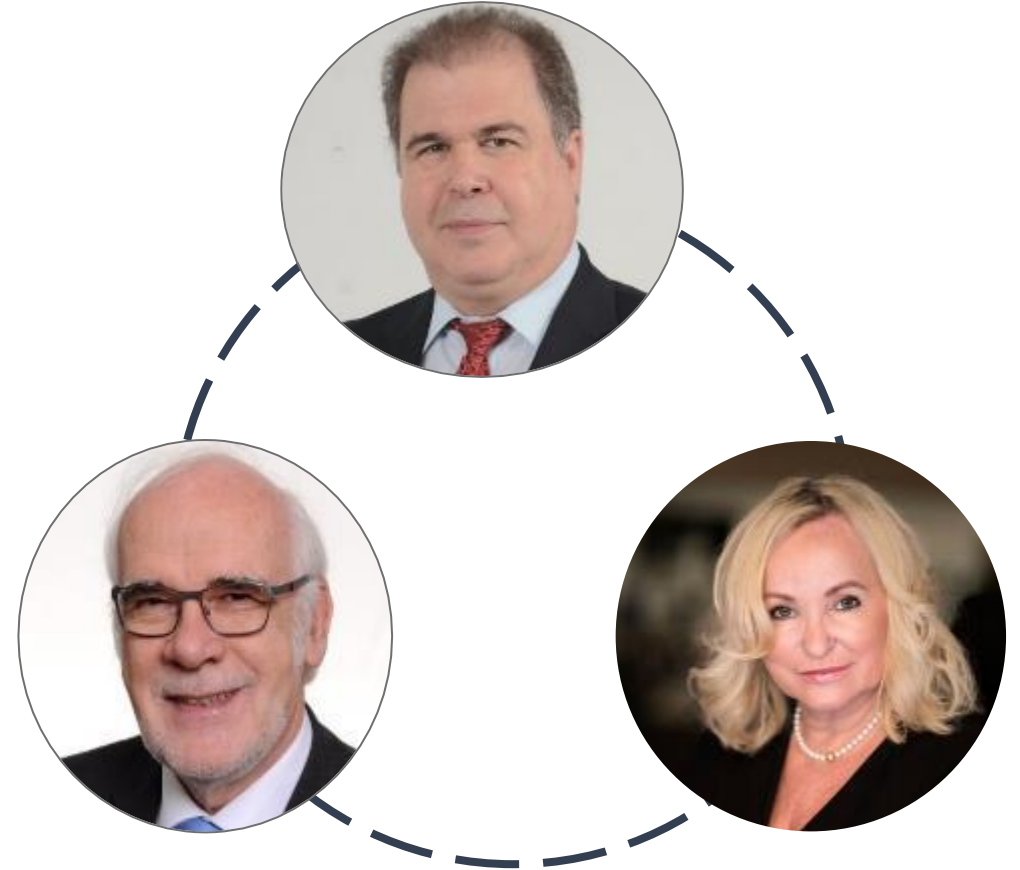


Illustration

Board of Directors



- Chairman of the Board - **Adrian Harel**, PhD, MBA
- Member - **Mårten Kvist**, MD, PhD, Associate Professor, Chairman of the Scientific and Clinical Advisory Board
- Independent Member - **Anna Tenstam**, MSc, MBA, Served as a manager and board member in several companies



Scientific and Clinical Advisory Board



Mårten Kvist, MD, PhD, Associate Professor, Chairman of the Scientific and Clinical Advisory Board, Finland.

Lauri Kangas, PhD, Associate Professor, Pharma Scientific Adviser, Chief Scientific Officer, Finland.

Risto O. Roine, Professor in Neurology and Chief Physician, Division of Clinical Neurosciences, University of Turku and Turku University Hospital, Finland.

Mika Hannula, Professor, DSc (Tech), Vice Rector, University of Turku, Finland.

Antti Kaipia, MD, PhD, Associate Professor, Chief, Department of Urology, Tampere University Hospital, Finland.

Markku Tuominen, MD, PhD, Chief Physician and CEO, Medisport Oy, Finland.

Timo Kurki, MD, PhD, Associate Professor. Neuroradiologist, Chief of Medical Imaging, Terveystalo Oy, Finland.

The Team



CEO, Founder
Adrian Harel
PhD, MBA



CSO
Lasse Välimaa
PhD



COO
Pihla Miettinen
MSc



Senior Scientist
Ivette Bañuelos
PhD



Scientific Writer
Leonardo Lara-
Valderrábano
PhD



Product Manager
Begum Utz
PhD



Research Assistant
Julia Virtanen
MSc



Development Engineer
Kaisa Leppä
BSc

Medicortex in the Press

1

[Medicortex Finland Plc signed a 2 million dollars research grant contract with the US Department of Defense](#)

2

[Medicortex Announces Receiving a 1.1 Million Dollars Research Grant from the US Department of Defense](#)

3

[Medicortex Finland Oy Announces Issuance of a Patent in the United States](#)

4

[Medicortex Finland Oy Announces Issuance of a Patent in Canada](#)

5

[Completion of Clinical Trial - a Significant Achievement for Medicortex Finland](#)

6

[Medicortex Finland Announces Patent Approval for Underlying Technology of Drug Development Plan](#)

YouTube videos

[How repeated concussions affect your brain](#)

[Concussion in sports and Medicortex test](#)

[Concussion in army personnel and Medicortex test](#)

www.medicocortex.fi



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