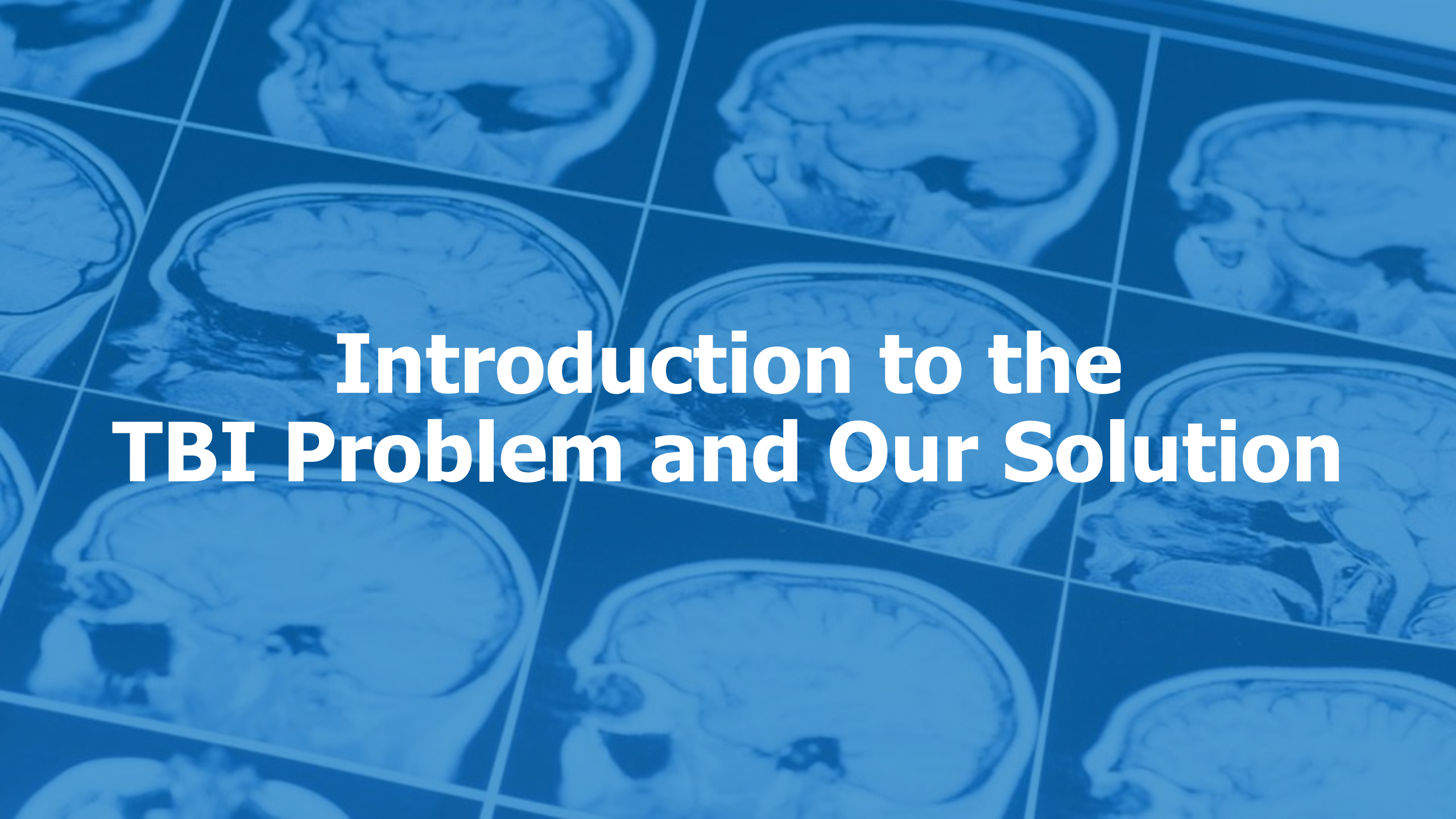
Developing a portable test for detection of mild traumatic brain injury

June 2025

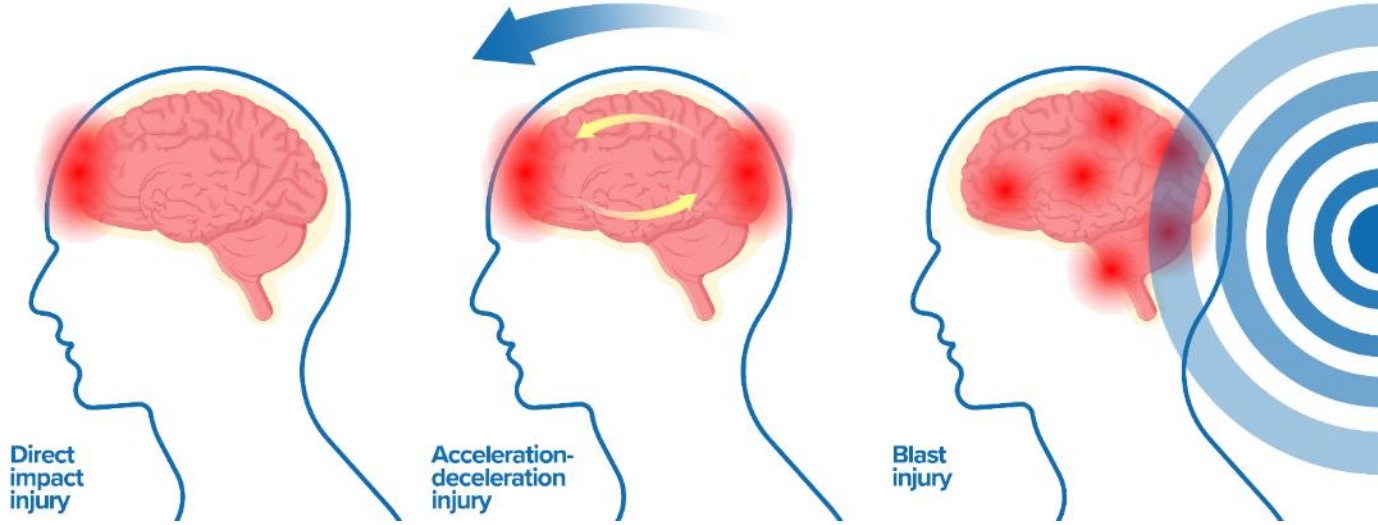
Confidential



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 harmful agents such as metal ions, free radicals and inflammation
  - Sets off a cascade of chemical reactions that damages surrounding healthy tissue
- Mild – moderate – severe TBI

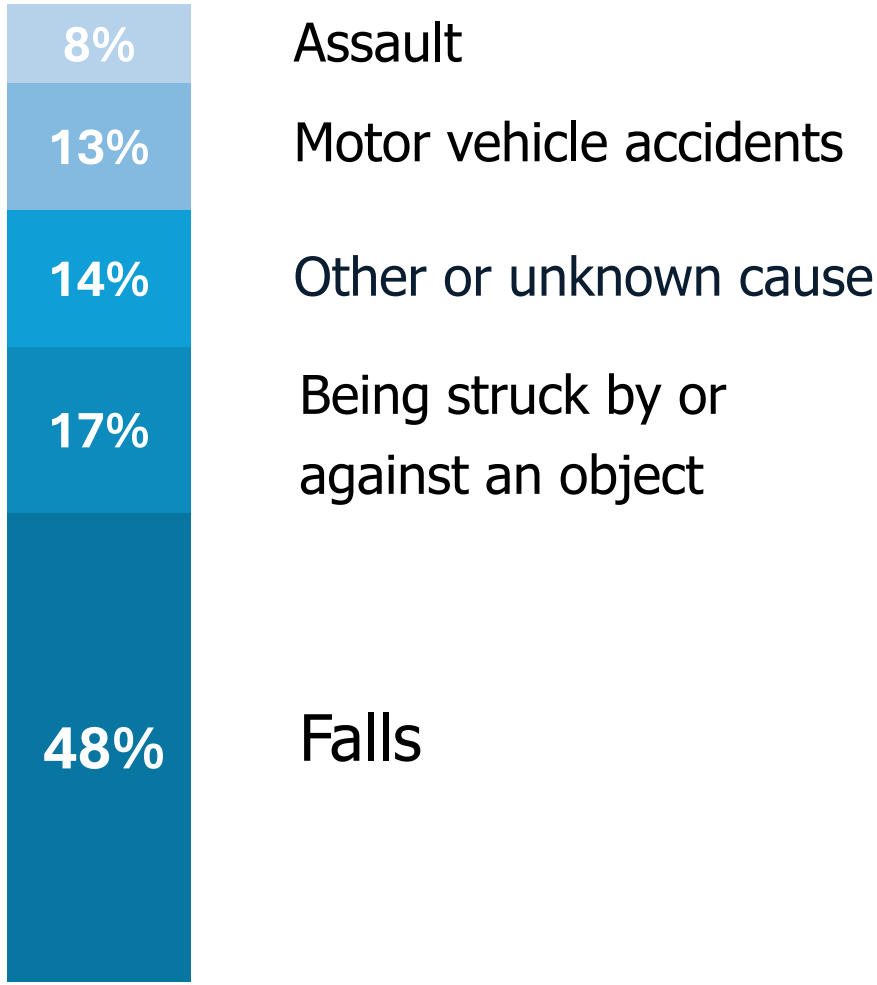


TBI – A Global Problem

New cases each year

- Around 69 million TBI cases globally *
  - 2.8 million in the US **
  - 2.5 million in Europe ***
- Most cases are closed head injuries
  - Difficult to detect, potentially risky situation
  - ~90% of cases are categorized as "mild TBI"

Leading causes of TBI:



Reference: U.S. CDC

* Dewan et al. (2019) J Neurosurg 130: 1080-1097
** Centers for Disease Control and Prevention (CDC)
*** CENTER-TBI EU

Limitations of Current Diagnostics

- Neurological examination of patient's responses: Glasgow Coma Score (3 - 15)
  - Vulnerable to confusion, paralysis, intubation, intoxication
- Computer tomography (CT) and Magnetic resonance imaging (MRI)
  - Require hospital environment
  - Expensive procedures
  - Exposure to irradiation (CT)
  - Potential anaesthesia/sedation, especially for children
  - Cannot detect mild injuries
- FDA-approved blood protein tests
  - Require hospital environment and equipment
  - Invasive

Medicortex's Solution for Diagnostics

- Medicortex is developing a non-invasive, point-of-injury test based on saliva or urine samples
- Our biomarkers are *glycans* – carbohydrate structures
  - Degradation products released to the circulation after the brain cell damage

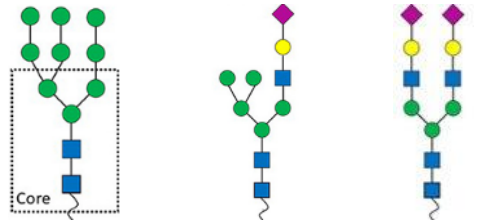
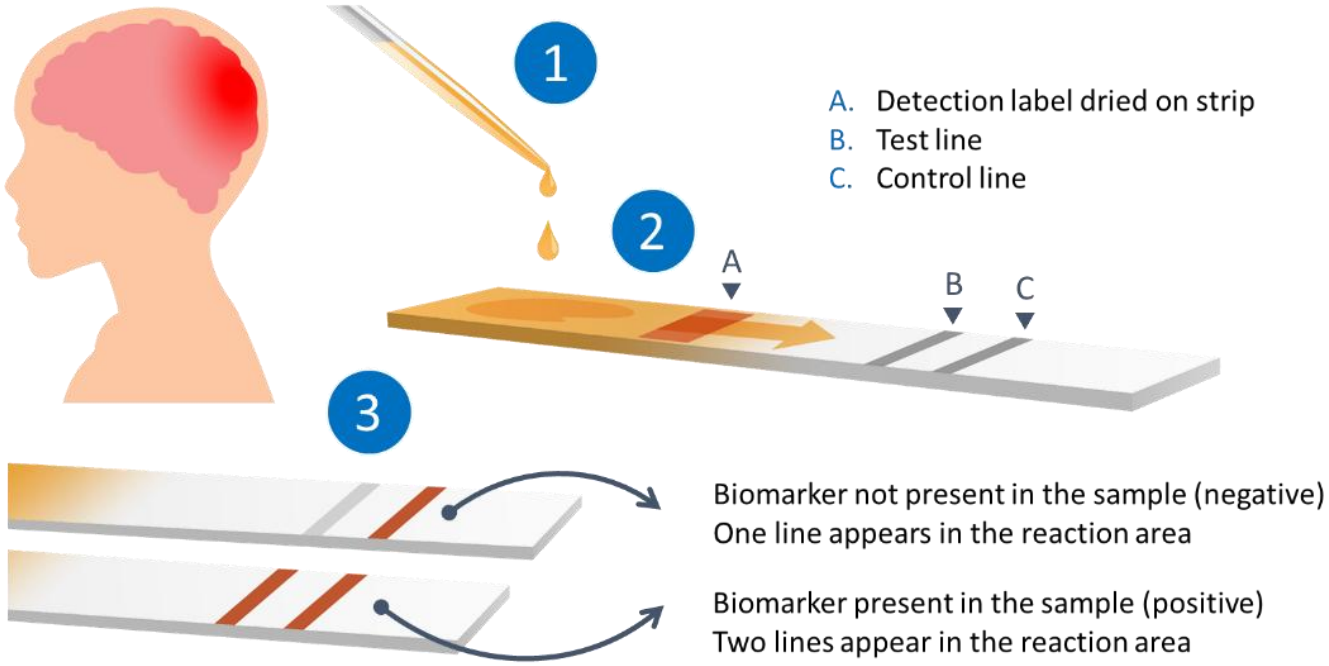


Illustration. Different glycan structures.

Medicortex's Diagnostic Test

1. A **urine** (ProbTBI™) or **saliva** (IndicateTBI) sample is applied on a test strip
2. The sample migrates along the strip
3. The result is readable on the strip



ProbTBI™ test kit

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

Glycan Profiling in Saliva and Urine: Exploring Potential Biomarkers for Mild Traumatic Brain Injury.
Manuscript being finalized

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 Trials – 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.

Urine Test Prototype

Developed in our 2nd project funded by the US Department of Defense (DoD)

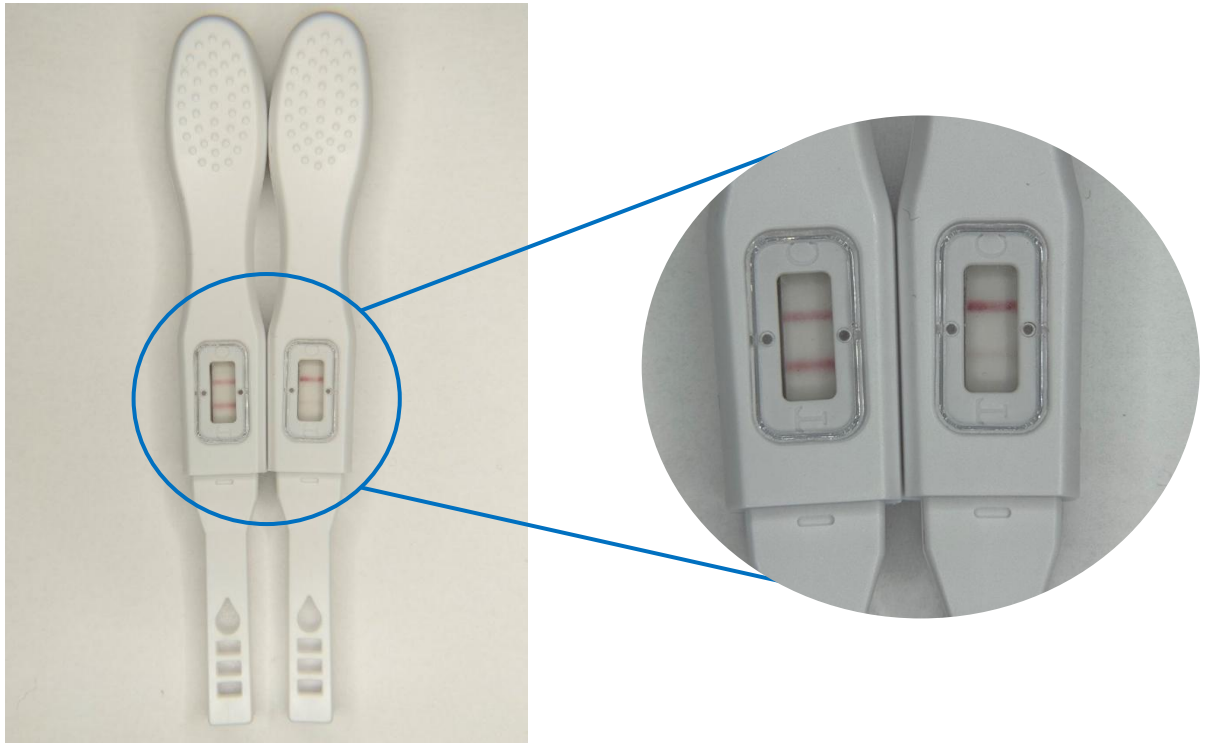
ProbTBI™ - a prototype **glycan detection method** for **urine** samples, in a lateral flow immunoassay cassette – which is:

- Utilizing the best-performing detection chemistry configuration set up in the project (lectins)
- Evaluated tentatively in-house using the previously collected clinical samples
- Ready for further development

ProbTBI™ **test kit**

2nd DoD-project – Closure

- Fully assembled protype tests were shipped to the DoD Q1 2025



Saliva Test Development

Being developed in the 3rd DoD-funded project

The objective of the **project** is to develop a **prototype strip test** for mild TBI based on the detection of unique glycan biomarkers in saliva – with an ultimate goal of early assessment and diagnosis of soldiers suffering head injury.

3rd DoD-project – Aims in Timeline

Specific Aim / Milestone	Months																	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
1 - Synthesis of the glycan biomarker																		
2 - Development of a lectin-based detection method for the glycan biomarker in saliva																		
3 - Raising specific antibodies and aptamers against the glycan biomarker																		
4 - Development of an advanced lateral flow assay																		

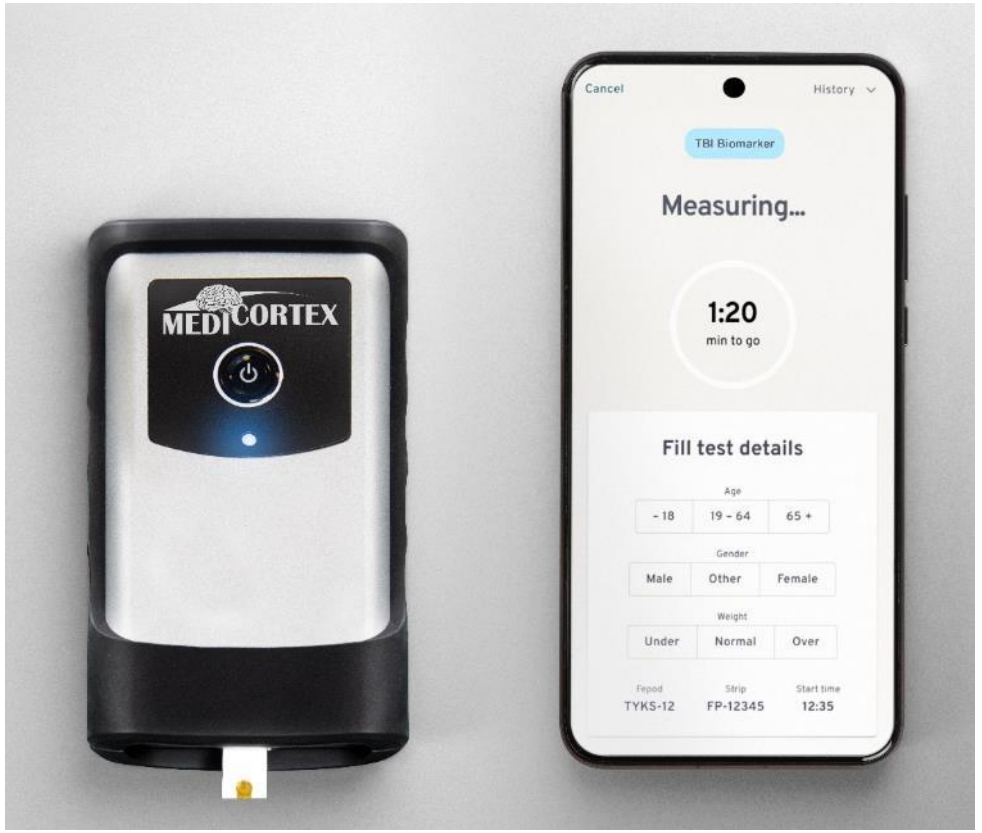
June 2024

Dec 2025

2nd Generation Test: Additional Benefits

Enables **quantitative** and **repeated** measurement beneficial for patient monitoring

- Electrochemical sensor and device (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)
- Funding is searched for expanding the project

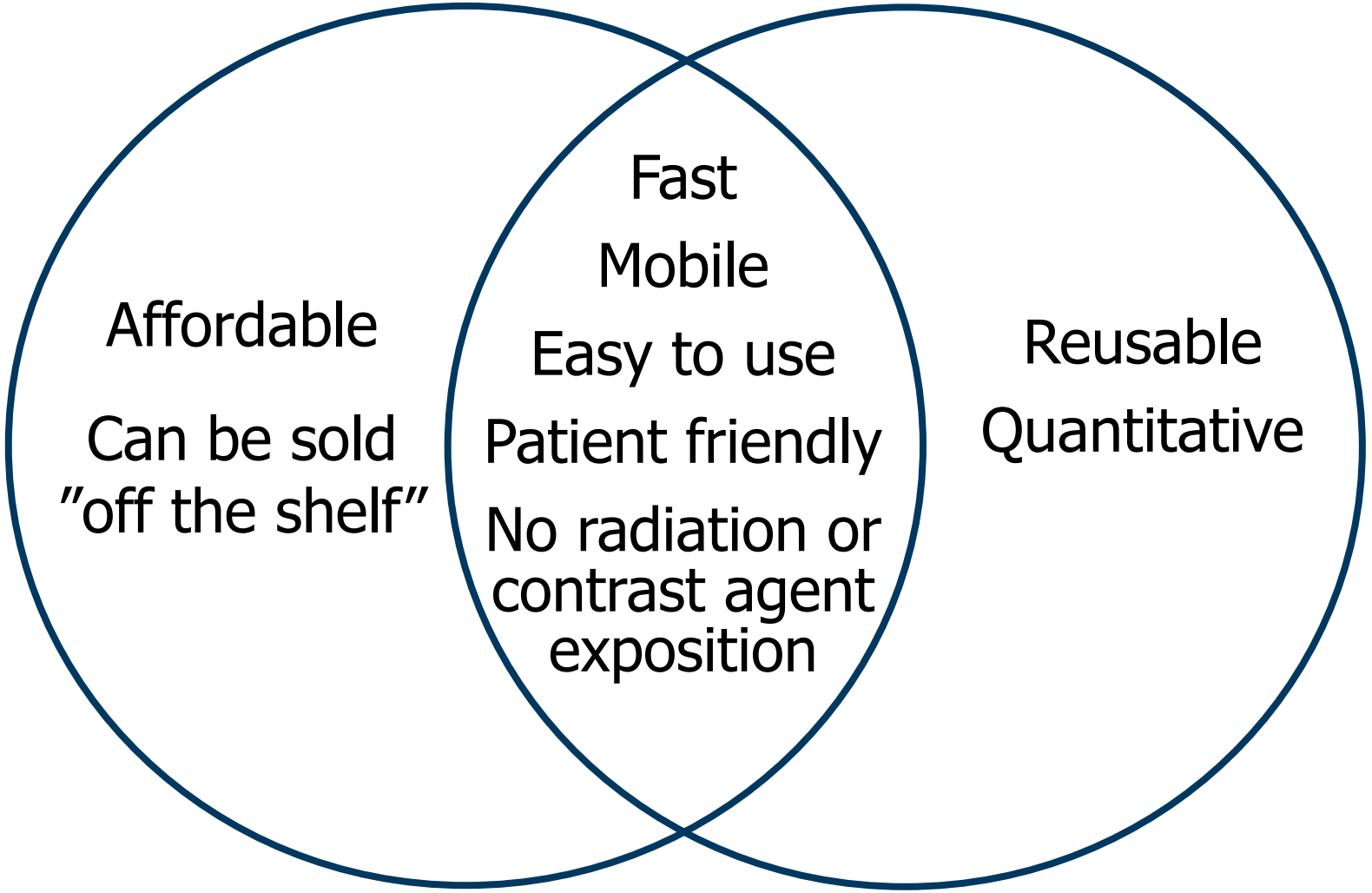


Illustration

Medicortex Test Advantages

ProbTBI™ Kit

TesTBI Device



Our Potential Clients

Medicortex is targeting **B2B institutional customers**

Military

Paramedics & first responders

Schools & nursing homes

Sports organizations

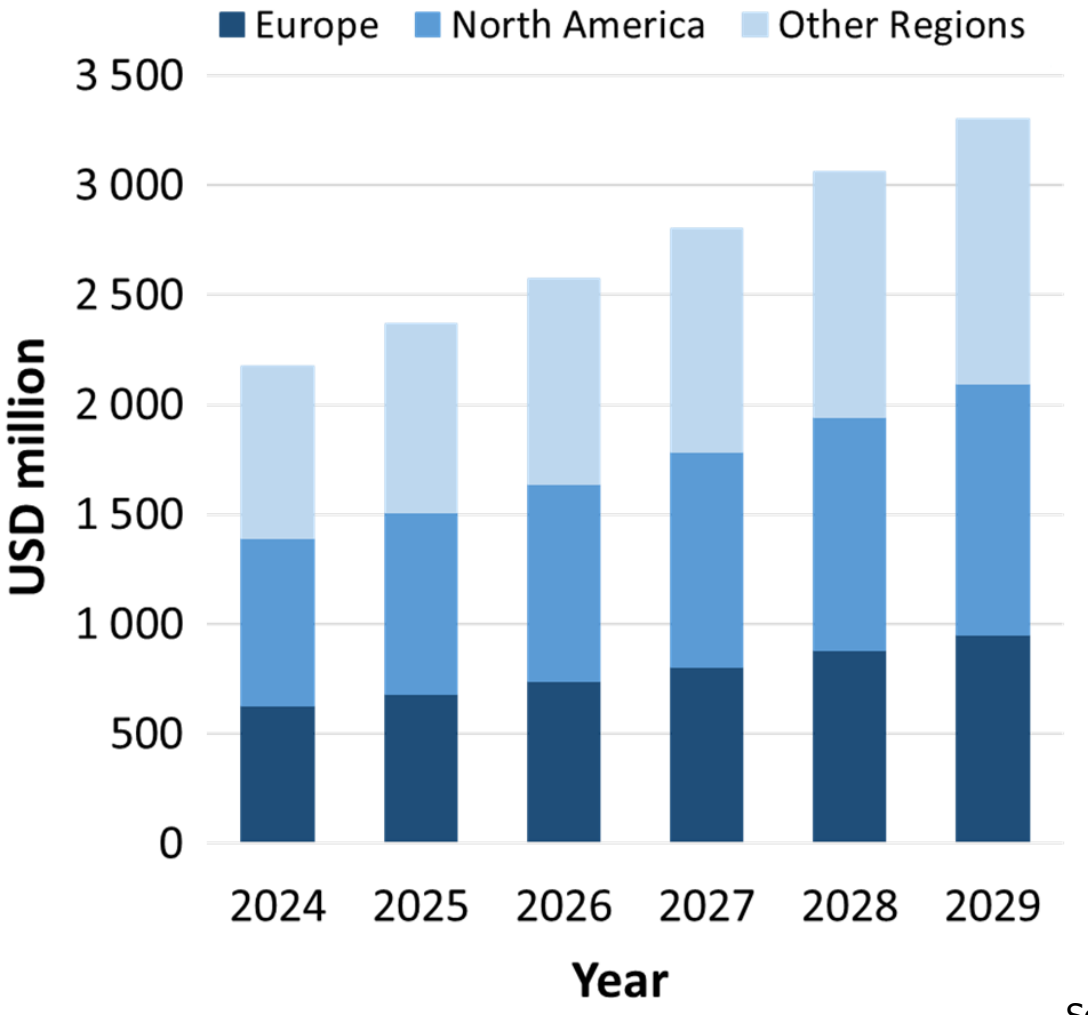
Hospitals and emergency rooms

Pharma companies

Insurance companies

TBI Market

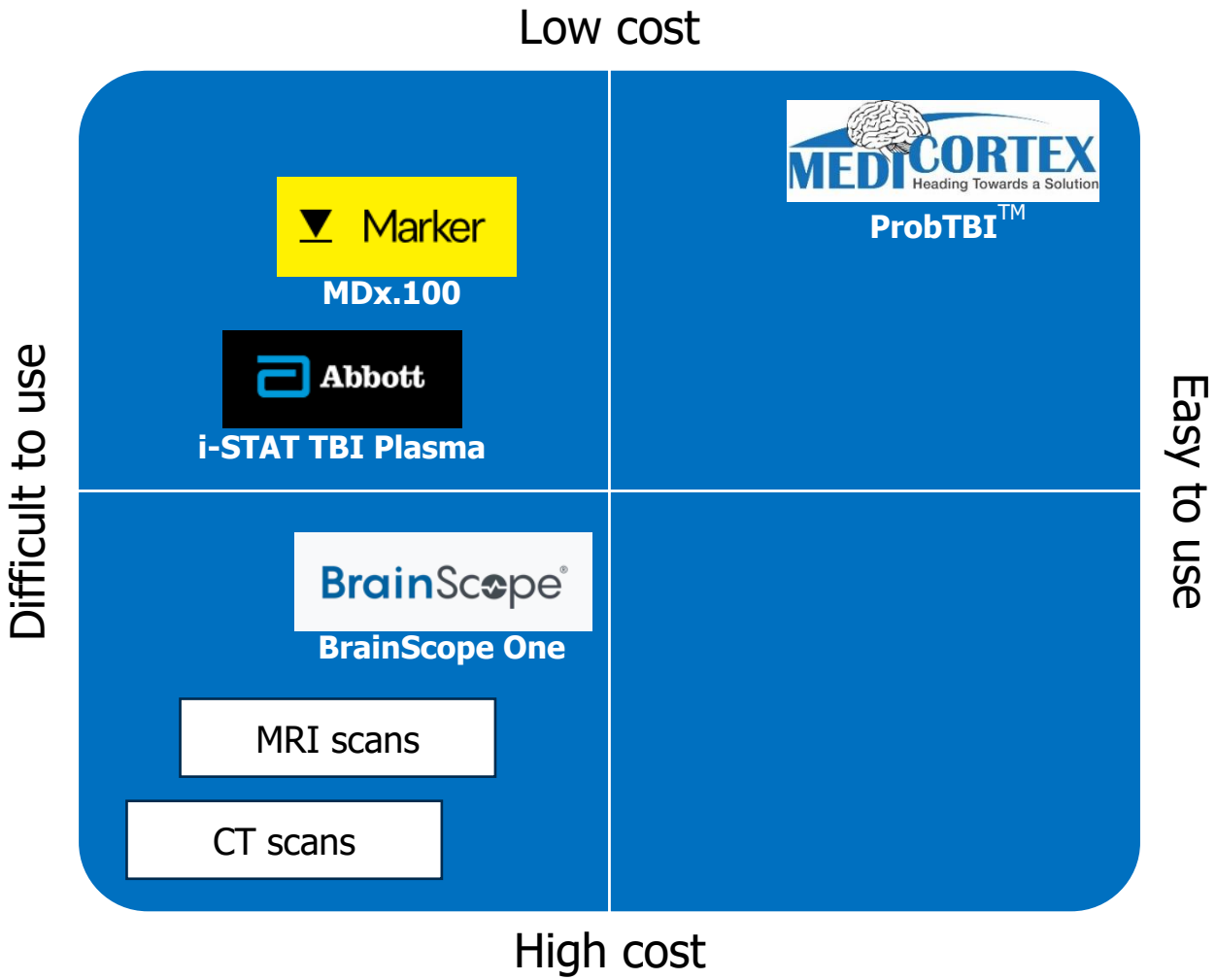
Global TBI diagnostic market expected to reach **$3.3 billion** by 2029



Source: Cognitive Market Research

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

Competitors Landscape



Medicortex's solution for diagnostics is unique:

Our test combines **affordability** with **ease of use**

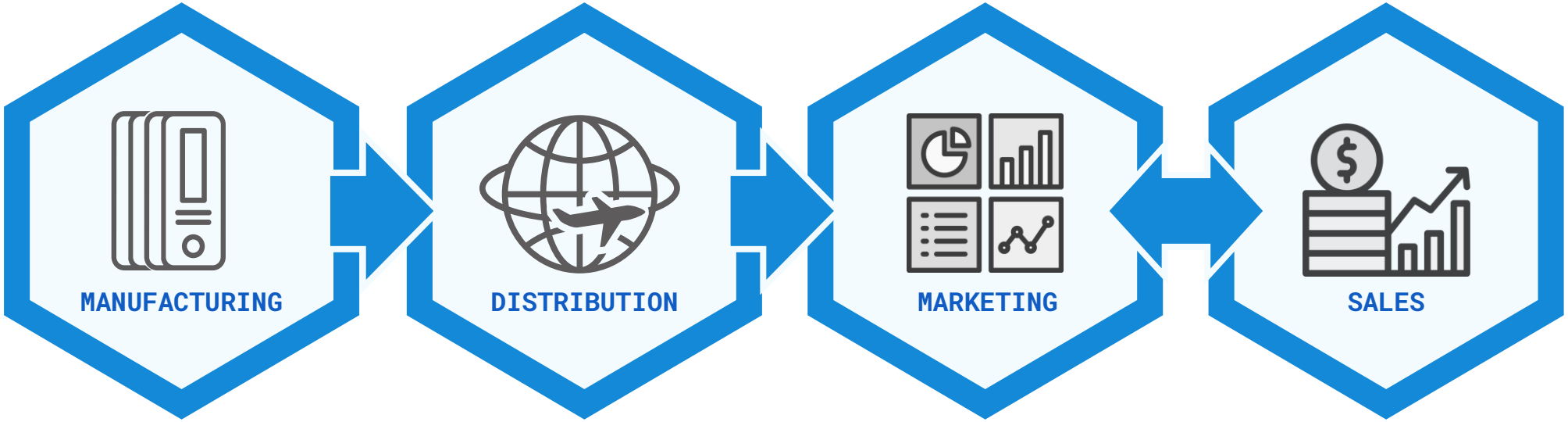
Blood-based tests:
- **Abbot: i-STAT TBI Plasma** & Alinity i TBI
- Roche: Elecsys® S100
- Quanterix: Simoa™ N4PA Advantage Kit

Saliva-based tests:
- **Marker: MDx.100** (laboratory environment required)

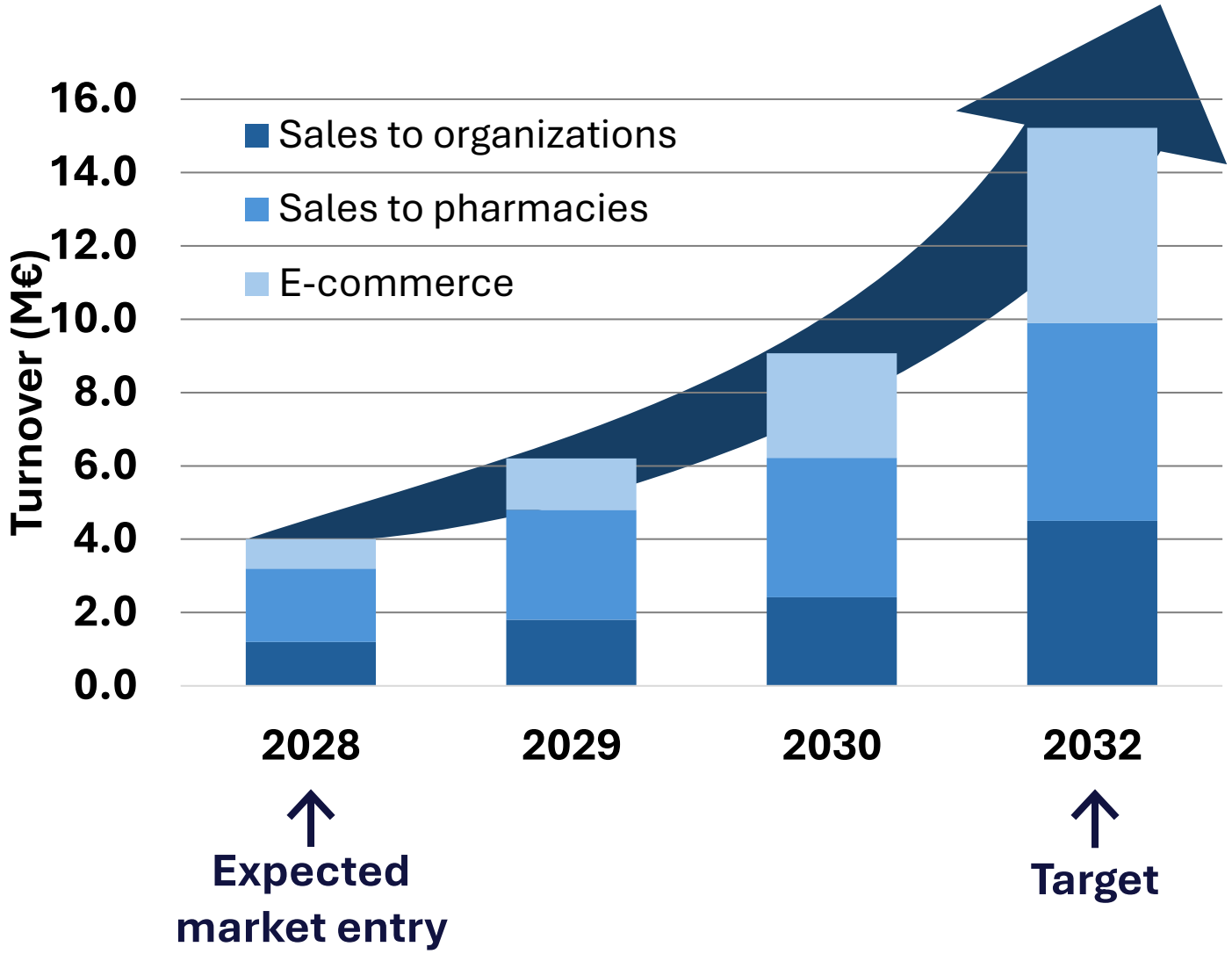
EEG methods:
- **BrainScope: BrainScope One**
- Firefly Neuroscience: BNA™
- Neurovigil: iBrain™

Marketing Strategy for ProbTBI™

- The preferred option – subcontracting manufacturing and using professional distribution companies, as well as contracting professional marketing and sales service providers
- The main focus of marketing and sales will be B2B



Sales Forecast ProbTBI™



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
   - South African patent (number pending)
   - Israeli patent No. 268 793
   - Utility model granted in China and Australia
3. Device and Method for Detecting of Brain Injury in a Subject
   - 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
   - European patent No. 4133279
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
   - Divisional Finnish patent No. 130798
   - 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

Patents for the Drug Development

1. Multivalent Compounds for Use in the Treatment and Prevention of Brain Damage
   - US patent No. 9,975,846
   - Finnish patent No. 127024
   - Israeli patent No. 251407
   - European patent No. 3201173
2. Conjugates and Conjugates for Use in Preventing or Treating of Brain Damage and Neurodegenerative Diseases
   - Finnish patent No. 130262

Patent for COVID-19 Diagnostics

1. Method for Determining Coronavirus and Kit for the Same
   - European patent No. 3911956

Public and Private Financing

Equity up to Now

- About 3.4 M€ from the founder and 299 private investors
- Total number of shares issued about 22.1 million
- Current price per share 1.00 € and total valuation 22.1 M€

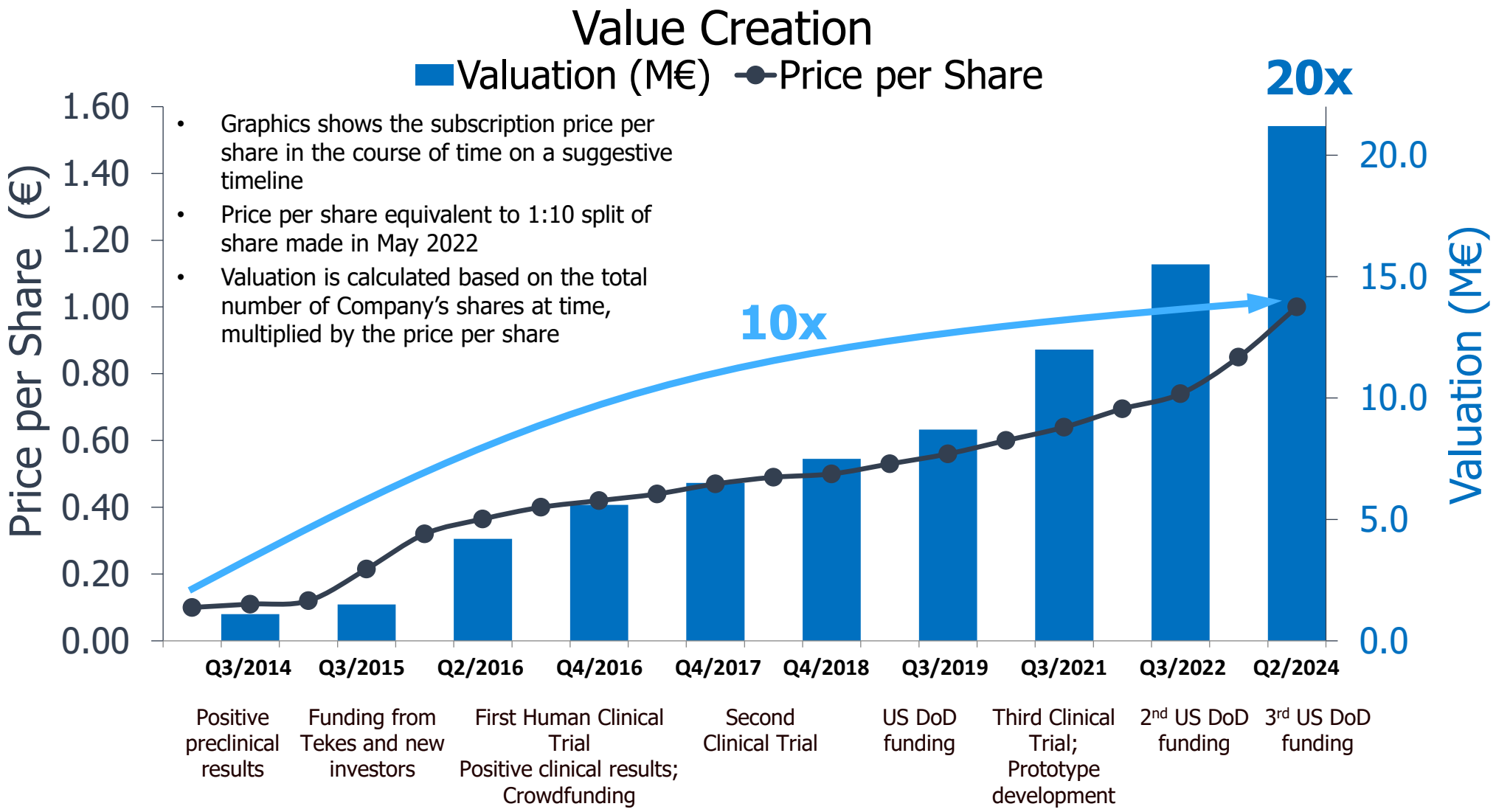
Subsidies in the Past / Ongoing

- Total of 5.2 M€ in grants
  - Including 4.6 M dollars from the US Department of Defense
- 70 k€ in awards
- **Medicortex is looking for investors:**
  - https://www.medicortex.fi/eng/investors/

Funded by the European Union

ELY Centre

From 2014–2024 Increase in Value



Use of Funds 2025-forward

The company is looking for 5M€ that will be used for:

- Further development/improvement of diagnostic assay chemistry
- Prototype test development and assembly
- Prototype manufacturing
- Validation in clinical experiments
- Initiation of the regulatory process

Board of Directors

- Chairman of the Board - Anna Tenstam, MSc, MBA, served as a manager and board member in several companies
- Dependent Member – Adrian Harel, PhD, MBA, Founder and CEO of Medicortex
- Independent Member - Nils Grönberg, experienced Executive in many companies and foundations
- Independent Member - Ville Ranta-Panula, MSc, MBA, experienced drug development and business development professional

The Team

CEO, Founder
Adrian Harel
PhD, MBA

CSO
Lasse Välimaa
PhD

COO
Pihla Miettinen
MSc

Research Scientist
Leonardo Lara-Valderrábano
PhD

Product Manager
Begüm Utz
PhD

Senior Scientist
Ivette Bañuelos-Cabrera
PhD

Development Engineer
Kaisa Leppä
MSc tech.

YouTube videos

- How repeated concussions affect your brain
- Concussion in sports and Medicortex test
- Concussion in army personnel and Medicortex test

LinkedIn™ group

- The Science Behind TBI
  - Posts and discussion about science and research on TBI
  - >3,000 members

www.medicortex.fi

Contact:
Dr Adrian Harel, CEO
adrian.harel@medicortex.fi

M&A and Deals

Examples:

- Teladoc Health to acquire Catapult Health for $65M to enhance preventive care and at-home testing (USA, 2025)
- Aditxt Subsidiary Pearsanta Acquires MDNA Life Sciences Cancer Testing Platform for Over $25M (USA, 2024)
- Biosynex completes acquisition of Chembio Diagnostics for $17.2M to expand rapid diagnostic test offerings (USA, 2023)