MEDICORTEX
Heading Towards a Solution

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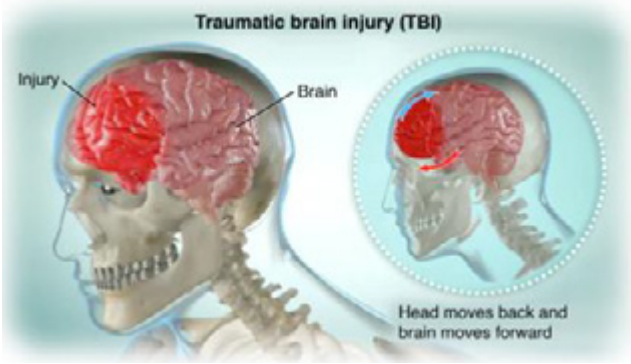
Medicortex Finland Oyj is dedicated to improving the diagnostics and treatment of Traumatic Brain Injury (TBI). Current focus is on the development of biomarker diagnostics to evaluate the extent and severity of concussion and traumatic brain injury. Once the development of the diagnostic kit is more advanced, the next goal is to expand the program to the development of an innovative drug to halt the progression of brain injury.

Every 12 seconds, someone in the United States suffers a new head injury. Head injuries constitute a global epidemic with more than 69 million cases each year worldwide. The total number is as high as the incidence of Alzheimer's disease, Parkinson's disease, and multiple sclerosis combined, and they are more frequent than breast cancer and AIDS. Unfortunately, there are no reliable diagnostic tests to assess the presence or severity of brain injury. Undiagnosed concussions have led to a number of life-changing conditions that could have been avoided – of the 2.8M people treated in hospital emergency rooms each year in the US, 80,000 become permanently disabled and a countless number of patients experience long-term neurological issues.



Accurate diagnostics would benefit especially mild cases of TBI (concussions), which, if repeated, may cause neurodegenerative conditions such as Chronic Traumatic Encephalopathy. Current detection methods that are based on head imaging by CT or MRI cannot reliably detect mild cases, which represent 90 % of all head injuries. Mild injuries may externally look innocent but can still lead to chronic diseases or debilitating conditions. TBI is currently recognized as a "silent epidemic". Improved diagnostic methods are required to increase awareness of TBI and to tackle the predisposition to long-term neurological issues.

Diagnostic Kit for TBI Detection

Medicortex has identified new brain injury biomarkers and is working towards the development of a disposable, hand-held diagnostic kit which uses non-invasive samples such as urine and saliva. A point-of-care test, which gives a reliable result rapidly and does not require medical professionals to interpret the result, would greatly benefit patient management, thus improving patient outcome and reducing the cost of diagnosis considerably. The Medicortex test can be used, for example, in emergency response situations such as traffic accidents, sports injuries and military activity.

To date, non-invasive biomarker tests have not been approved by regulatory agencies for detection of TBI. Medicortex is one of the few companies that is developing a test that can be used on saliva or urine. Additionally, where most other tests focus on blood proteins, Medicortex's test detects carbohydrate based glycans.

Potential Market

Every year, millions of people suffer from the effects of TBI. The global market for TBI diagnostics is expected to grow at an annual rate of about 8% and reach the size of $3 billion in 2028. The North American market alone is expected to yield $1 billion and the European market $0.9 billion (Cognitive Market Research 2021).

Pre-Clinical Studies

Medicortex has performed preclinical research comparing fluid biopsies from normal and injured lab animals. The research brought up unique biomarkers released as biodegradation products after head injury. The data served as the basis and confirmation for patent applications to protect the novel biomarker idea.

Clinical Development

The first clinical study with Turku University Hospital (Tyks) demonstrated that the new biomarker is applicable for clinical detection of brain injury. Samples collected from 12 TBI patients were compared to 12 healthy volunteers, and the level of biomarker was found to be increased in TBI patients in a statistically significant manner. The result was a significant milestone for Medicortex.

The second clinical study focused on mild cases solely and on early hours soon after the injury. Samples were collected from patients with suspected mild TBI (mTBI), patients with an orthopedic injury, and from uninjured healthy controls (total of 69 subjects) in two Finnish hospitals. The biochemical analysis results confirmed the ability of the biomarker to detect mild cases of TBI specifically without significant interference from orthopedic injuries (leg or arm fracture). The sample analysis and clinical report compilation were funded by a grant from the US Department of Defense. More information about the study is available at ClinicalTrials.gov/NCT03306563.

The third clinical study demonstrated the biomarker feasibility to detect concussion in head injured children. The sample collection was conducted by Satasairaala hospital in Pori, Finland. A total of 58 children and adolescents of age 0–17 years were recruited: 28 with suspected mild TBI and 30 healthy controls. Results of the sample analysis reinforce the biomarker research results and provide evidence for the potential usability in children.

Regulatory Status

Medicortex estimates that a prototype diagnostic kit can be presented in two years for the regulatory process provided sufficient funds. To further expedite the entry to market, Medicortex may outsource the approval process for the CE-mark acquisition. In parallel, approval efforts will be made in Canada, Israel and UK.

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

Two years development plan for one diagnostic kit.

From an Idea to the Product

Idea and hypothesis → Preclinical data → 1st Clinical trial → 2nd Clinical trial → 3rd Clinical trial → Prototype device → Regulatory application

Intellectual Property Status – Patents for Diagnostic Kit

1. **Prognostic and diagnostic glycan-based biomarkers of brain damage**; Granted Patents: European No. 3283880; US No. 10,739,335; Canadian No. 2,982,503; Israeli No. 254980.
2. **Non-invasive brain injury diagnostic device** WO/2018/154,401, Utility model granted in China and Australia.
3. **Device and method for detecting of brain injury in a subject** WO/2021/099,677 Utility model granted in Finland and Australia.
4. **A method for determining a lectin binding glycan indicative to traumatic brain injury** WO/2021/205059.

- In addition, three new patent applications have been submitted in 2022.

Drug for Brain Injury Treatment

After successful development of the TBI test kit, Medicortex will start development of an innovative drug for halting the progression of TBI. Medicortex has designed several chemically verified proprietary NCE's (new chemical entities), each with several neuroprotective functions, such as free metal ion binding, anti-oxidation, anti-inflammation and free radical scavenger action. Previous attempts using a single biochemical mechanism have all failed, because the injury is caused by multiple cascades of biochemical reactions.

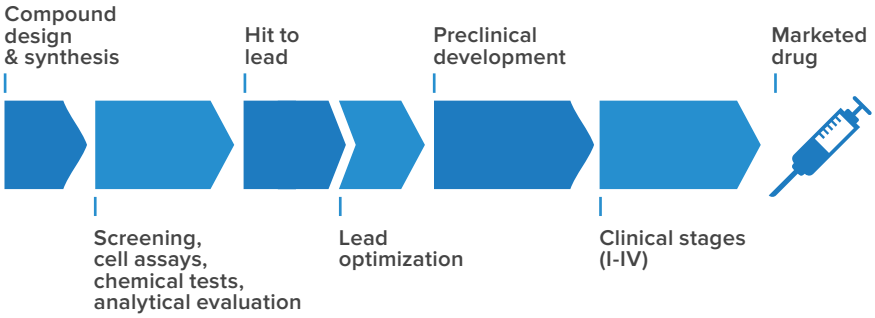
Medicortex has developed and synthesized a formulation for two first compounds (TBI-466 and MCF-013) which were found to be safe in the first preclinical tolerability studies. Medicortex will initiate further preclinical research and regulatory plans once funding and adequate resources are guaranteed.

Intellectual Property Status

1. **Multivalent Compounds for Use in the Treatment and Prevention of Brain Damage** Granted US 9,975,846; FI 127 024; IL 251 407; Europe 3201173.
2. **Conjugates and conjugates for use in preventing or treating of brain damage and neurodegenerative diseases** WO 2021/038125.

Potential Market

TBI is a major cause of morbidity and mortality worldwide. Yet, to this date, there are no approved pharmaceutical therapies for TBI. Arrowhead Publishers (USA) conservatively estimates the global potential therapeutic TBI market to exceed €10 billion per year. The US market alone is estimated to range €4–6 billion annually.



Financing

Medicortex is raising funds to achieve its goal in developing the diagnostic kit. Investments from private investors could be partially matched by grants from large institutions, such as the US Department of Defense.

Near-future investments will be used for:

1. Development and establishment of the biochemical configuration of the assay.
2. Kit prototype manufacturing and validation in clinical experiments.
3. Initiation of the regulatory process.

Previous Funding

Medicortex has received a total of about 3 M€ from private investors. In 2019, the company was granted a $1.3 M research funding from the US Department of Defense (DoD) medical research program. In September 2022, Medicortex signed a new contract of 2 million dollars with the DoD. Additionally, Medicortex has received approximately 500 k€ from various sources (H2020, Business Finland, foundations, competitions).

By investing, one may contribute to human welfare as well as benefit from a financial gain. Currently, the price per share is 0.74 € and the company's valuation is 15.5 M€. Please look at our website for more information www.medicortex.fi/investors.

Medicortex Finland Oyj

Board Of Directors

- Chairman of the Board **Adrian Harel**, PhD, MBA.
- Member **Mårten Kvist**, MD, PhD, Associate Professor, Chief Medical Officer.
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- **Mika Hannula**, Professor, DSc (Tech), Vice Rector, University of Turku, Finland.

Information

- **Established:** 2014
- **Name:** Medicortex Finland Oyj (ID 2625992-6)
- **Facilities:** PharmaCity, Itäinen Pitkäkatu 4 B, 4th floor, FI-20520 Turku, Finland
- **Company's Activity:** Development of brain injury diagnostics kit and drug development.
- **Current valuation:** 15.5 M€

Personnel

- **Founder and CEO:** Adrian Harel (PhD, MBA)
- **Chief Medical Officer:** Mårten Kvist (MD, PhD, Associate Professor)
- **Chief Scientific Officer:** Lasse Välimaa (PhD)
- **Chief Operating Officer:** Oskar Haavisto (BSc)
- **Accounting:** Marjukka Iitti
- **Product Manager:** Begüm Utz (PhD)
- **Senior Scientist:** Ivette Bañuelos C. (PhD)
- **Laboratory and Research Coordinator:** Pihla Miettinen (MSc)
- **Senior Scientist:** Iida Martiskainen (PhD)
- **Research Assistant:** Julia Virtanen (MSc)
- **Research Assistant:** Joonas Karhula (BSc)

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