

Medicortex Finland 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 2.5M 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 occurring repeatedly, 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 the mild cases, which represent 90 % of all head injuries. Mild injuries may externally look innocent but still they can lead to chronic

diseases or debilitating conditions. Currently TBI is recognized as a “silent epidemic”. Improved diagnostic methods are required to increase awareness of TBI and to combat 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 the 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. Furthermore, a new diagnostic kit would also become an end point evaluation of clinical trials in TBI, and insurance companies would rely on the test when processing brain injury related claims. To date, only one blood test has been approved by regulatory agencies for TBI diagnostics. Medicortex is the first company focusing on a saliva or urine based test, which is enabled by the proprietary biomarker that the company has discovered.

### Potential Market

Every year, millions of people suffer from the effects of TBI. Yet, to this date, the market is lacking a rapid biomarker test to diagnose TBI. Arrowhead Publishers (USA) conservatively estimates that the global potential of TBI diagnostic device (POC) market will exceed €2 billion annually. It can be estimated that

the expected US sales alone would be in the range of 400–500 M€ per year. Medicortex Finland’s solution ProbTBI™ kit is extremely desirable for several users such as first responders and sport organizations.

### 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 trial is underway. The body fluid samples were collected in two Finnish hospitals and currently they are being analyzed in research laboratories. Patients with a suspected TBI or orthopedic injury and healthy controls were recruited in the study

### New cases each year



(total of 69). The study addresses, for example, the specificity and sensitivity of the biomarker and its time-dependent appearance after the injury, the overall objective being to confirm the clinical relevance of the biomarker. The sample analysis and clinical report compilation is being funded by a grant from the [US Department of Defense](http://www.usdo.gov). More information about the study is available at [ClinicalTrials.gov/NCT03306563](http://www.clinicaltrials.gov/NCT03306563).

A third clinical trial was started in March 2020 in Finland and it aims to demonstrate the biomarker feasibility to diagnose concussion in head injured children. A total of 60 children in age 0–17 years will be recruited: 30 suspected mild TBI patients and 30 healthy controls. More than half of the study subjects have already been recruited at the Finnish site and the study is extendable to two foreign sites, depending on funding.

### Regulatory Status

Medicortex estimates that a prototype diagnostic kit can be presented in two years for the regulatory process. Generally, diagnostic tests have a relatively short approval process and 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 the UK and Canada.

### From an Idea to the Product



## Intellectual Property Status

Medicortex holds the following pending patents for the biomarker development:

1. "Prognostic and diagnostic glycan-based biomarkers of brain damage"; Granted EP 3283880; US Notice of Allowance.
2. "Non-invasive brain injury diagnostic device" WO/2018/154,401.
3. "Device and method for detecting of brain injury in a subject" FI application 20196004.
4. "A method for determining a lectin binding glycan indicative to traumatic brain injury" US application 16/840,931.

R&D plan for kit development	-2020/ Q1	2020/ Q2	2020/ Q3	2020/ Q4	2021/ H1	2021/ H2
2 <sup>nd</sup> clin. trial sample analysis & reporting						
Pediatric clinical sample collection						
Pediatric sample analysis						
Strip test development & optimization						
Medical prototype development						
Clinical evaluation of the prototype						
Initiation of regulatory process						
New patent applications						

## Drug for Brain Injury Treatment

Medicortex has designed several chemically verified proprietary NCE's (new chemical entities), each with several neuroprotective functions e.g. 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 studies.

### Regulatory Status

Medicortex will initiate clinical trials and regulatory applications once funding and adequate resources are guaranteed. The intention is to use an EMA agency and hospitals in the EU region for its Phase I clinical trials.

## Use of Funds

Medicortex intends to raise 2 M€ in this financing round for continuing and extending the pediatric clinical trial and prototype development. This investment could be partially matched by grants from Finnish or European funding institutions such as the Horizon 2020 program, or US national organizations and institutions e.g. NIH and DoD.

**The biomarker development program consists of the following phases:**

1. Identification of a biomarker in human brain-injured patients.
2. Analytical and biochemical testing of the biomarker.
3. Building of a prototype diagnostic device/kit to identify brain injury.
4. Clinical validation of the biomarker and approval for CE-mark acquisition.

### 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.
2. "Compositions, and compositions for use in preventing or treating of brain damage and neurodegenerative diseases" PCT/FI2020/050533.

### Potential Market

TBI is one of the leading causes of death and disability in young adults. 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.

**Total investment needed for the entire project in 2020–2022 is 4 M€.**

Medicortex has received a total of 1.9 M€ from private investors. In July 2019, the company was granted a \$1.1 M grant from the US Department of Defense. Additionally, Medicortex has received approximately 300 k€ from various sources (H2020, Business Finland, Foundations, Competitions).

Medicortex offers investors a clear path towards value creation. While the risk is initially relatively high, it will be reduced as each milestone is achieved, simultaneously increasing the company's value. Given the immense market potential, the risk-benefit ratio is looking extremely favorable.

# Medicortex Finland Oy

## Board Of Directors

- Chairman of the Board **Adrian Harel**, PhD, MBA.
- Member **Mårten Kvist**, MD, PhD, Associate Professor, Medical Director.
- Member **Tom Palenius**, MSc, COO, Turku Science Park Ltd.

## Scientific And Clinical Advisory Board

- **Heikki Rauvala**, Chairman of the SAB, Professor, Neuroscience Center, University of Helsinki, Finland.
- **Antti Kaipia**, MD, PhD, Associate Professor. Chief, Department of Urology, Tampere University Hospital, Finland.
- **Lauri Kangas**, PhD, Associate Professor. Pharma Scientific Adviser, Chief Scientific Officer, Finland.
- **Timo Kurki**, MD, PhD, Associate Professor. Neuroradiologist, Chief of Medical Imaging, Terveystalo Oy, Finland.
- **Risto O. Roine**, Professor, Chief Physician. Division of Clinical Neurosciences, Turku University Hospital and University of Turku, Finland.
- **Markku Tuominen**, MD, PhD, Chief Physician. CEO, Medisport Oy, Tampere, Finland.

## Information

- **Established** 2014
- **Name:** Medicortex Finland Oy (ID 2625992-6)
- **Facilities:** PharmaCity, Itäinen Pitkääkatu 4 B, 4th floor, FI-20520 Turku, Finland
- **Company's Activity:** Development of brain injury diagnostics kit
- **Current valuation:** 8,9 M€
- **Post-Money Valuation:** 10,9 M€

## Personnel

- **Founder and CEO:** Adrian Harel (PhD, MBA)
- **CFO:** Marjukka Iitti
- **Medical Director:** Mårten Kvist (MD, PhD, Associate Professor)
- **Head of R&D:** Lasse Välimaa (PhD)
- **VP Sales & Marketing:** Tomas Ward (MBA)
- **Product Manager:** Begüm Utz (PhD)
- **Project Manager:** Maria Grönman (PhD)
- **Research Coordinator:** Oskar Haavisto (BSc)
- **Laboratory Assistant:** Venla-Mari Nurmi (BSc)

## Contact

**Adrian Harel**, PhD, MBA, CEO  
Tel. +358 (0) 400 488 817  
adrian.harel@medicortex.fi  
[www.medicortex.fi](http://www.medicortex.fi)