

Get ahead of time

COMPANY PROFILE





Alzheimer's disease (AD) is a neurodegenerative disorder characterized by memory loss, cognitive deterioration, and progressive functional dependence, ultimately leading death.

AD is not a consequence of normal aging. Many experts believe that the underlying pathological processes may begin 20 years or more before the first symptoms are evident, suggesting that early detection will be key to preventing, slowing, and ultimately stopping this disease.



Alzheimer's disease

Prevention

Identification of people at risk is key for the effectiveness of preventative measures and consequently, APOE ε4 carriers were defined as a priority population where preventative treatments should be directed 4,5. Accordingly, several ongoing, prevention clinical trials include APOE ε4 as an inclusion factor (NCT02565511, NCT03131453, NCT02569398) and large-scale screening programs are being established to identify APOE ε4 carriers for AD preventive clinical trials⁶.

Intensive efforts are being placed to define effective strategies to prevent or delay AD. Recently, it has been shown that multimodal intervention of modifiable vascular and life-style risk factors could improve or maintain cognitive functioning in at-risk elderly people⁷. Interestingly, this multimodal intervention consisting in diet, exercise, cognitive training and vascular risk monitoring has been shown effective also in APOE ε4 carriers⁸, suggesting that early detection of APOE ε4 carriers could be relevant for reducing AD prevalence through adoption of these vascular and life-style recommendations.

(1) World Alzheimer Report 2018. The state of the art of dementia research: New frontiers. Alzheimer's Disease International

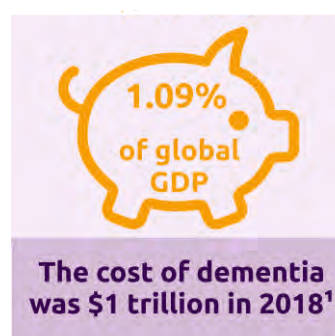
(2) Prince, M et al (2015). World Alzheimer Report 2015, The Global Impact of Dementia: An analysis of prevalence, incidence, cost and trends. Alzheimer's Disease International

(3) World Alzheimer Report 2011, The benefits of early diagnosis and intervention. Alzheimer's Disease International

(4) World Alzheimer Report 2016, Improving healthcare for people living with dementia. Alzheimer's Disease International

(5) Alzheimer's Association. 2018 Alzheimer's Disease Facts and Figures.

Awareness



Currently, only 45% of AD patients are accurately diagnosed, due in part to a lack of awareness about AD, which many consider a “natural disease”, as well as the absence of standardized diagnostic tests.



Biocross is a biotechnology Company that seeks to improve the life expectancy and quality of life of individuals with neurodegenerative diseases through the design of innovative diagnostic systems

Unmet Need

No blood tests have been validated for the diagnosis of Alzheimer's disease.

Current diagnostic approaches are not very accurate; they are based on clinical criteria that allow diagnosis of Alzheimer's disease with a maximum of probability of 70%. This lack of accuracy is even more pronounced in the early phases of the disease.

Efficacious use of treatments currently in development will be dependent on early and accurate diagnosis of the disease, as they will most likely be administered during early disease stages.

New diagnostic techniques for Alzheimer's disease will face huge demand.

Commercialization of a new Alzheimer's disease treatment will entail a massive demand for new diagnoses. Only simple and automated techniques will be capable of efficiently addressing this demand.

Reliable

Biocross has designed its products with a commitment to providing diagnostic tests of higher sensitivity and specificity than any currently available



Early Diagnosis

Biocross provides diagnostic solutions that can be used during the asymptomatic phase of the disease and enable early detection of individuals with increased risk of developing dementia

Our goal

To provide neurologists with an integrated diagnostic solution that can be applied to any stage of the disease, including earliest, asymptomatic phase

Non-invasive

All of our diagnostics tests are based on the analysis of blood samples, and are applicable in hospitals settings, thus ensuring patient safety and comfort





Team

A team of medical and biotechnology specialists focused on the development of diagnostic tests for neurodegenerative diseases.

Matt Mittino, CEO

He currently provides operations expertise as a portfolio company CEO, board member, and advisor to VC funds, start-ups, and multinationals.



Cristina Pérez, FM

Economist with 15 years' experience in several biotechnology companies and Master on corporate tax and legal advisory services. experience.



Sergio Veiga, PhD I+D Manager.

Doctor in Biology, and specialist in degenerative diseases, he has 21 papers in international neuroscience journals.



Pablo Cabello, CSO

He specialized in Molecular Genetics. He was responsible for the creation of the Molecular Genetics Lab at the Hospital Ramón y Cajal.



Andrés Rodríguez, Research Assistant

A medical laboratory scientist since 2003. He has accrued extensive experience in the field of neuroscience since 2005.



Isabel Jiménez, BDM

EXMMS at IE Business School. As specialist in the marketing of IVD tests she contributes to the preparation of the company's products for market introduction.



Advisory Board



José Luis Molinuevo, MD, PhD

Neurologist. He directed the Alzheimer's disease unit at the Hospital Clinic de Barcelona since 2003. He joined the Barcelonabeta Brain Research Center (BBRC) in 2014, where he is the Scientific Director of the Alzheimer Prevention Program, mainly dedicated to research on AD prevention from a clinical, cognitive, genetic, and biomarker, including wet and neuroimaging, perspective. Member of the European Alzheimer Disease Consortium is principal investigator of multiple clinical trials and research studies on AD and, with an h-index of 53, he has published over 300 international scientific papers that have been cited 11000+ times, several books and over 20 book chapters on neurodegenerative diseases.



Guillermo García-Ribas, MD

He is a specialist in Neurology in the Dementia Unit since 1994 at the Ramón y Cajal Hospital in Madrid and coordinator of the Neurology Service and member of the Clinical Research and Clinical Trial Committee of the Ramón y Cajal Hospital (Madrid). Fundamentally it is dedicated to the evaluation of cognitive deterioration and behavioral alterations with suspicion of neurodegenerative diseases. It also collaborates with the Psychiatry Service for the assessment of atypical behavioral disorders in adults. He has participated as a principal investigator in 12 clinical trials focused on Alzheimer's disease with promoters such as Pfizer-Janssen, Eisai or Roche Pharma. The last clinical trial, CCNP520A2202J (GENERATION), in asymptomatic subjects ApoE4 (+).



Miguel Calero, PhD

He holds a degree in Chemical Sciences, a PhD in Science, and a Masters in Direction and Management of R+D+i in Health Sciences. He is currently a research scientist at the Instituto de Salud Carlos III and CIBERNED, and director of the Chronic Diseases Program of the CIEN Foundation. He is the head of the national reference center for molecular diagnosis of human transmissible spongiform encephalopathies, a collaborator with the ECDC program for training and formation of microbiologists. An author of 94 articles with more than 3,000 citations and a h index of 28 (data from Scopus), his expertise is based on wide-ranging experience studying neurodegenerative disorders, mainly cerebral amyloidoses (including Alzheimer's disease).



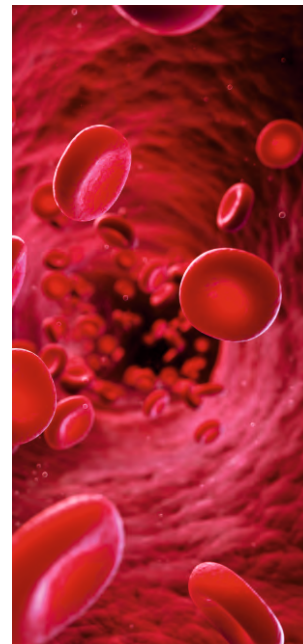
Alberto Rábano, PhD

Neuropathologist and neuroscientist who since 2009 has served as Head of Neuropathology and Scientific Director of the CIEN Tissue Bank at the CIEN Foundation (Research Institute for Neurological Diseases, part of the Carlos III Health Institute). From 1997–2009 he was Head of Pathology and Research Director of a University Hospital in Madrid, during which time he oversaw the development of 3 brain banks in Madrid, Murcia, and Salamanca. He is currently member of the steering committee of the National Platform of Biobanks in Spain. His research interest center on diagnostic and molecular neuropathology of neurodegenerative diseases. He is author of 105 original scientific papers and 5 book chapters.



Pipeline

Biocross' objective is to develop a series of blood tests for the diagnosis of Alzheimer's disease, thus providing neurologists with an integrated diagnostic solution that can be applied to any stage of the disease, including the earliest, asymptomatic phase



e4Risk

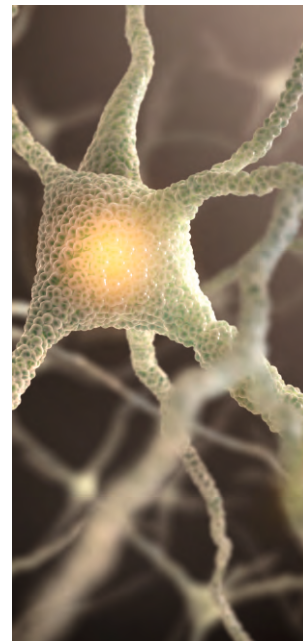
Currently, APOE4 is detected by PCR (the reference technique) or by ELISA, but no test is available that can be easily incorporated into routine hospital testing procedures.

Biocross proposes a non-genetic test to identify *APOE ε4* carriers which is designed to be used for early risk assessment of AD, and as a potential pharmacological treatment guide for targeted therapies. This blood-based test can be run on standard automated chemistry systems to identify individuals with elevated risk of developing late-onset Alzheimer's disease.

The following are some of the advantages of the **e4Risk**:

- >Detection of at-risk patients (APOE 4) would enable physicians and patients to make lifestyle based interventions that could prevent or delay the development of the disease.
- >ApoE4 detection is currently being used to guide enrichment strategies and stratify patients in the latest clinical trials evaluating experimental ADF treatments.
- >Early identification of ApoE4 carriers will allow regular monitoring of this at-risk population so that treatment can be administered as soon as symptoms develop, thereby maximizing neural tissue preservation.

This test is currently ready to be marketed with CE marking.



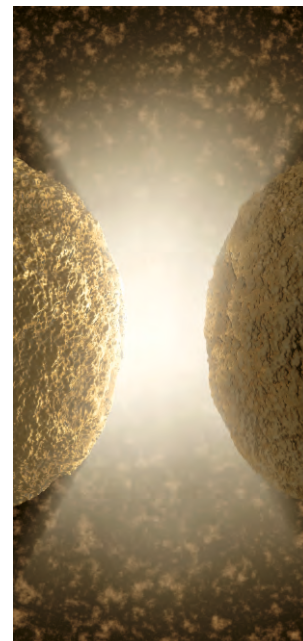
AD Dementia test

From the outset, we have insisted on a meticulous sample selection process in order to identify highly sensitive and specific biomarkers. We have analyzed samples from patients with other Alzheimer's-like forms of dementia, including frontotemporal dementia, the symptoms of which can be confused with those of Alzheimer's disease.

A second clinical trial has demonstrated high levels of accuracy for our blood test and has laid the foundations for a multicenter study for validation of the procedure.

Our multiparametric assay combines different types of biomarkers, including metabolites, disease-related peptides, and protein markers. Because the test involves analysis of a simple blood sample, it is easily standardized and can be adapted to standard hospital laboratory equipment.

We obtained a diagnostic algorithm that is able to discriminate AD patients from healthy controls with an accuracy of 87% (AUC=0,96). Additionally, we obtained another algorithm that can discriminate FTD from healthy controls with 85% accuracy. The test is currently in the validation phase.



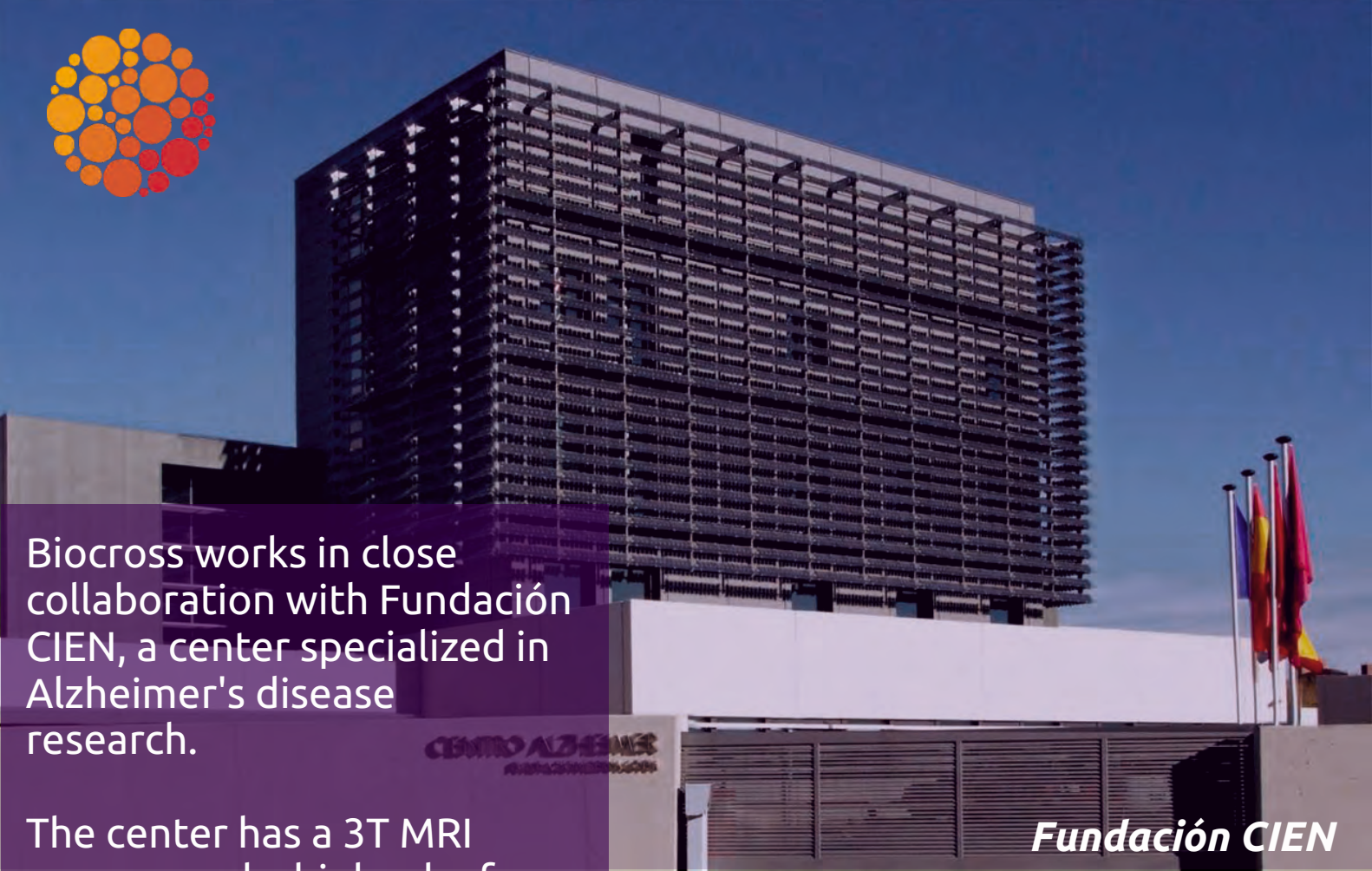
Deneration dementia test

The objective of this test is to screen asymptomatic patients and patients with mild cognitive impairment and identify those with and without neurodegeneration caused by Alzheimer's disease or frontotemporal dementia.

In the medium-term, after development of an effective treatment for Alzheimer's disease, this product will constitute the first step of an overall treatment strategy, allowing the physician to detect patients with neurodegeneration due to AD or FTD. In the case of a positive result, the physician can proceed to the confirmatory AD Dementia test. Practitioners will thus have a sufficient range of diagnostic tools to monitor and/or treat patients.

The Degenerative Dementia test is a multi-parametric blood-based biochemical and metabolite test that can be performed using a standard automated chemistry system.

The test is currently in the research and developmental phase, where the diagnostic accuracy of a preliminary algorithm combining 5 proteins is being refined by the addition of AD, FTD biomarkers.



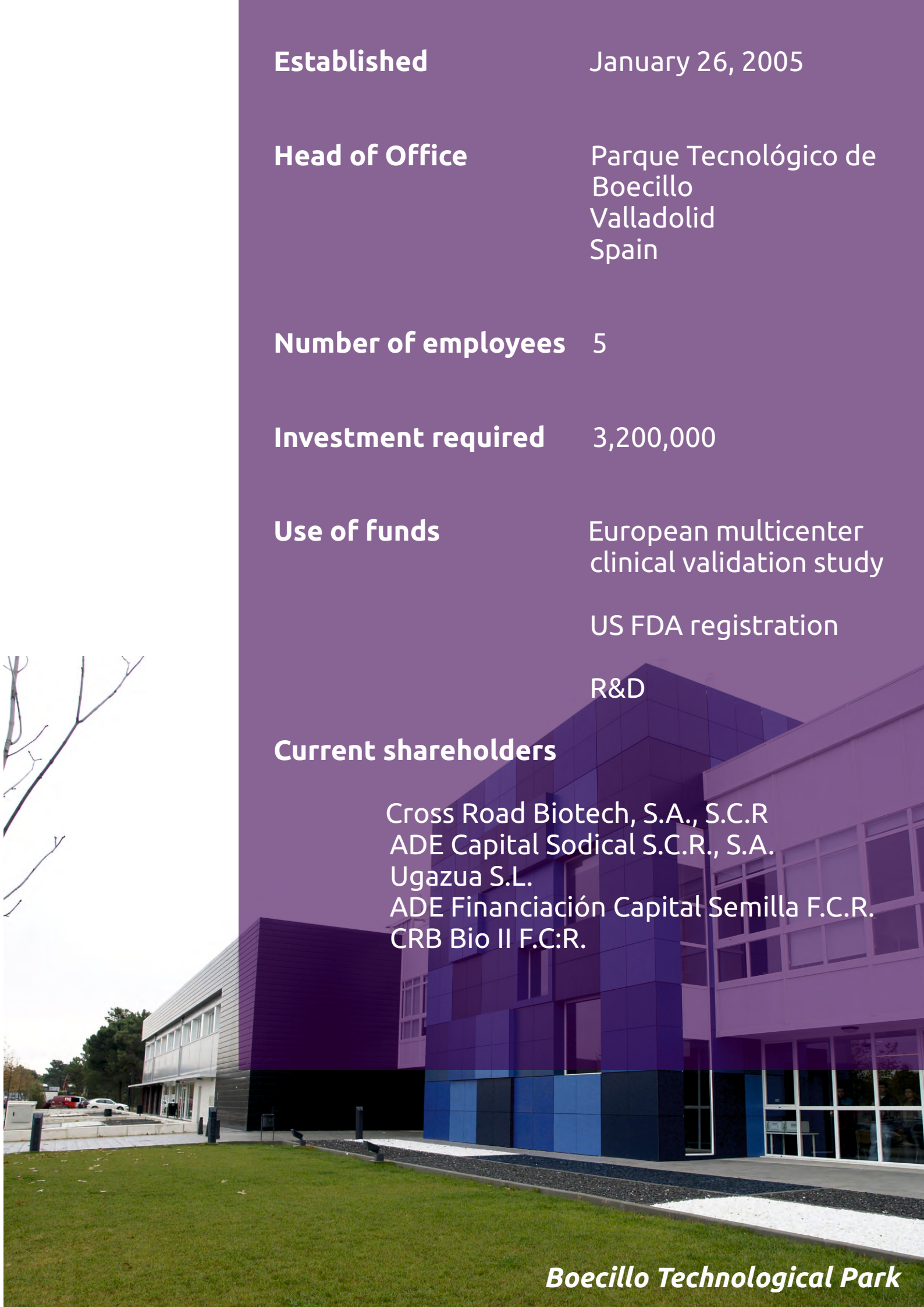
Biocross works in close collaboration with Fundación CIEN, a center specialized in Alzheimer's disease research.

The center has a 3T MRI scanner and a biobank of patient samples. A prospective study of an elderly population of more than 1,000 participants will allow complete validation of the technology developed by Biocross.

Fundación CIEN

Patents

1. Method for the diagnosis of Alzheimer's disease and mild cognitive impairment	EP14382203.9	05.30.2034
2. Method for the diagnosis of Alzheimer's disease and mild cognitive impairment	EP1438261.3	11.20.2034
3. Methods for apolipoprotein detection	EP3274725	11.02.2035
4. Methods for apolipoprotein detection (EP Divisional)	EP18201037.1	11.102038



Established January 26, 2005

Head of Office Parque Tecnológico de Boecillo
Valladolid
Spain

Number of employees 5

Investment required 3,200,000

Use of funds European multicenter clinical validation study

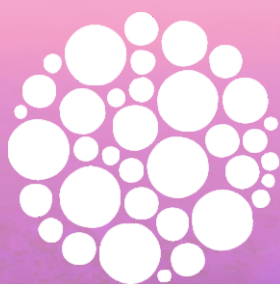
US FDA registration

R&D

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Boecillo Technological Park



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