

50% Recruitment milestone reached in clinical validation study of EDIT-B blood test: An aid for differential diagnosis of bipolar disorder based on RNA Editing biomarkers

- **EDIT-B is an innovative blood test utilizing RNA sequencing technology and Artificial Intelligence (AI) for the differential diagnosis of bipolar disorder (BD) and major depressive disorder (MDD) in adults displaying symptoms of depression.**
- **The study adopts a cross-sectional design, maintaining a 1:1 ratio between the two studied populations (unipolar and bipolar patients), and is conducted in expert clinical centers across Europe¹.**

Paris & Montpellier, France, November, 7th, 2023 - ALCEDIAG, a diagnostic company specializing in mental health diseases and dedicated to advancing precision psychiatry in clinical practice, is delighted to announce that the trial of EDIT-B has achieved a significant milestone, with 218 out of 436 participants successfully recruited.

EDIT-B is a comprehensive blood test designed to serve as a decision-support tool for mental healthcare professionals, enabling them to expedite the differentiation of patients suffering from depression into two distinct categories: MDD (unipolar) or BD (bipolar). This innovative test leverages RNA editing modifications of specific targets measured in blood and individualized patient data.

This ongoing clinical study seeks to confirm the clinical findings previously observed and aims to address the longstanding diagnostic challenge associated with bipolar disorder, which often entails an average of 8 years of uncertainty. The primary objective is to categorize patients based on their unique EDIT-B signature, distinguishing between those with unipolar depression and those with bipolar depression.

In total, the trial aims to enroll a cohort of 436 patients and is being conducted across four (4) expert clinical centers:

1. Hospital Clínic de Barcelona, Spain, under the leadership of Prof. Eduard Vieta as the Principal Investigator.
2. The Center of Psychiatry of the Copenhagen region, Denmark, led by Prof. Lars Kessing.
3. GHU Paris Psychiatrie & Neurosciences, France, led by Prof. Chantal Henry
4. Parc Sanitari Sant Joan de Déu, Spain, with Dr. Josep Maria Haro also serving as one of the investigators.

The EDIT-B study has been awarded with a co-funding from the European Institute of Innovation and Technology for Health as part of the EDIT-B Consortium, named after the test. Launched in early 2022, this collaborative effort brings together ALCEDIAG, the four aforementioned clinical centers, along with PLG and Synlab.

¹ <https://clinicaltrials.gov/study/NCT05603819?intr=EDIT-B&rank=1>

"I am delighted that we are continually expanding the substantial dataset for EDIT-B test. We eagerly anticipate advancing toward this additional validation of EDIT-B performance throughout the new European regulation for IVD. The aim being to offer all mental health specialists across Europe a highly accurate and precise diagnostic tool, ultimately enhancing patient care." Says Dr. Dinah Weissmann, CSO of ALCEDIAG.

"The EDIT-B test will potentially revolutionize the diagnosing and differentiation of depression as part of recurrent depressive disorder or as part of bipolar disorder. It is one of the clinically most important decisions in relation to the individual patient to validly make the accurate initial diagnosis as treatment pharmacologically and psychologically differ substantially for recurrent depression and bipolar disorder" Declared Prof. Lars Kessing, trial investigator, from Copenhagen.

About ALCEDIAG:

ALCEDIAG is an innovative diagnostics company focusing on mental health, developing and commercializing innovative in-vitro-diagnostics tests thanks to its platform harnessing cutting-edge molecular biology and Artificial Intelligence to discover and utilize new proprietary RNA editing based biomarkers in clinical routine. ALCEDIAG is a subsidiary of ALCEN, an industrial diversified French group with a strong focus on innovation advancing societal challenges. For more information visit: www.alcediag-alcen.com

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