FOR HEALTH

ALCEDIAG

The power of RNA & AI for diagnostics in mental health

November 2025

ALCEDIAG at a glance

ALCEDIAG activity

Diagnostics

RNA & epigenetics

Artificial Intelligence

Neurosciences
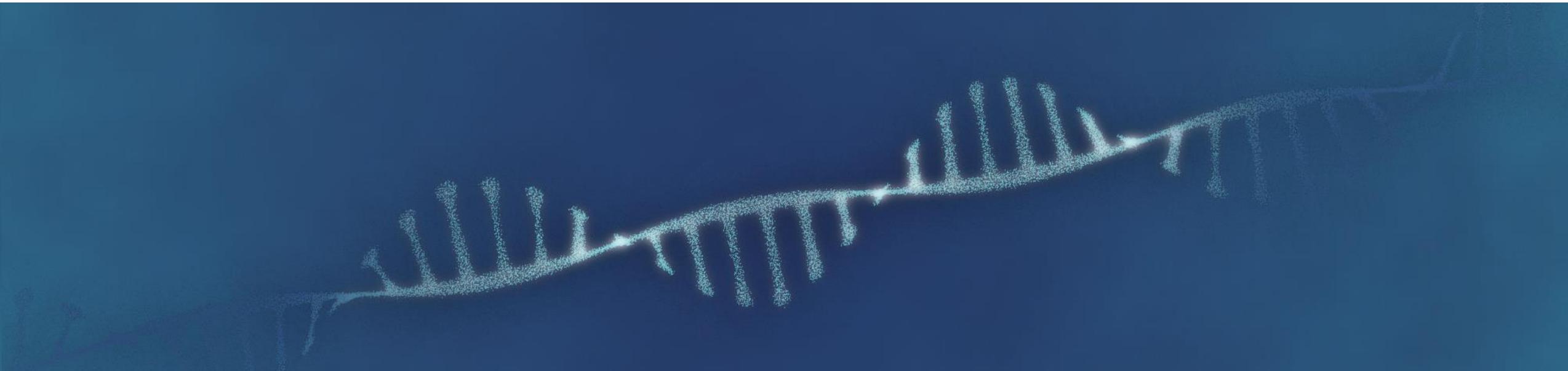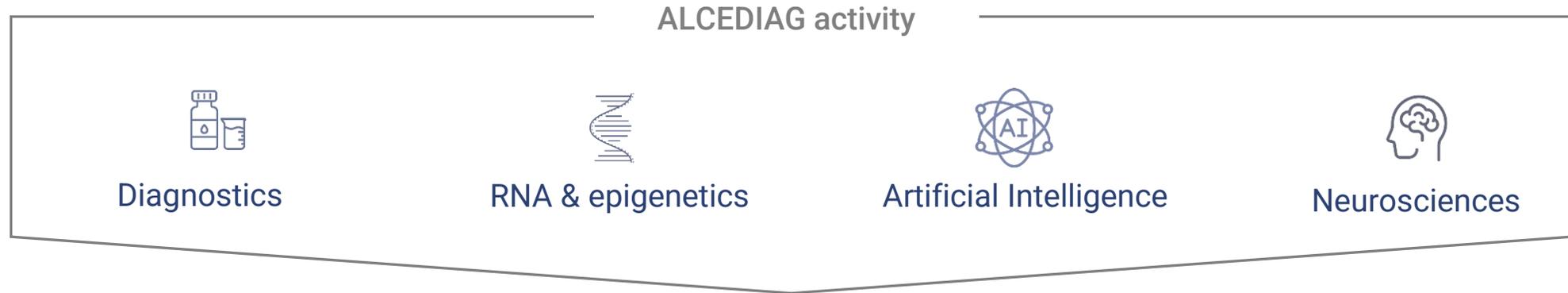
Precision Psychiatry

EDIT-B
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The first blood test for bipolar disorder, a game changer for millions of patients

ALCEDIAG team : strong management, key interdisciplinary experts and a network of KOLs

ALCEDIAG team:

Management team

A. Prieux, MS, MBA

CEO | **MIT** MANAGEMENT SLOAN SCHOOL | McKinsey & Company

D. Weissmann, PharmD, PhD

Dep. CEO / CSO | SANOFI | cnrs | CBO

D. Staner, MS Economics

moderna | Lilly

And key experts for…

Molecular biology

Artificial intelligence

Neurosciences

Clinical development

IP protection

Market access

A strong network of KOLs:

David Kupfer
Distinguished Professor Emeritus of Pittsburgh Univ. Psychiatric Dpt, Head of DSM5 planning committee

Pr. E Vieta
Full professor of psychiatry Clinic Barcelona, Spain
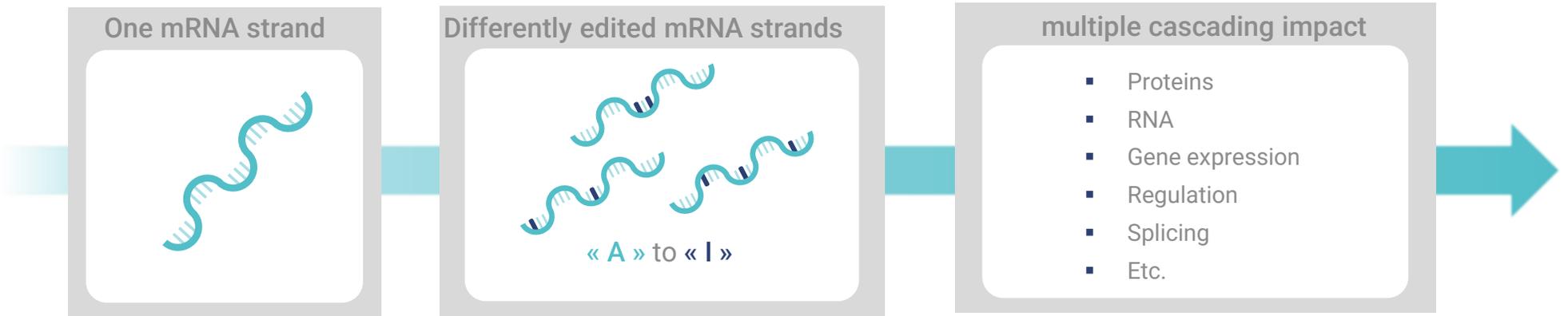Head of the Dpt of psychiatry

Pr. C. Henry
Full professor of psychiatry, GHU Paris France
Coordinator of the European Network of Centers of Excellence on Bipolar Disorders

Pr. L. Kessing
Full professor of psychiatry
Chair of Copenhagen Affective Disorder research Center (CADIC)

RNA editing, a key mechanism with critical cascading consequences

A - to - I RNA Editing, deamination of an adenosine (A) are deaminated into an inosine (I)

One mRNA strand

Differently edited mRNA strands

« A » to « I »

multiple cascading impact

- Proteins
- RNA
- Gene expression
- Regulation
- Splicing
- Etc.

RNA editing & the brain

Regulation of synaptic signal transmission

- Serotonin
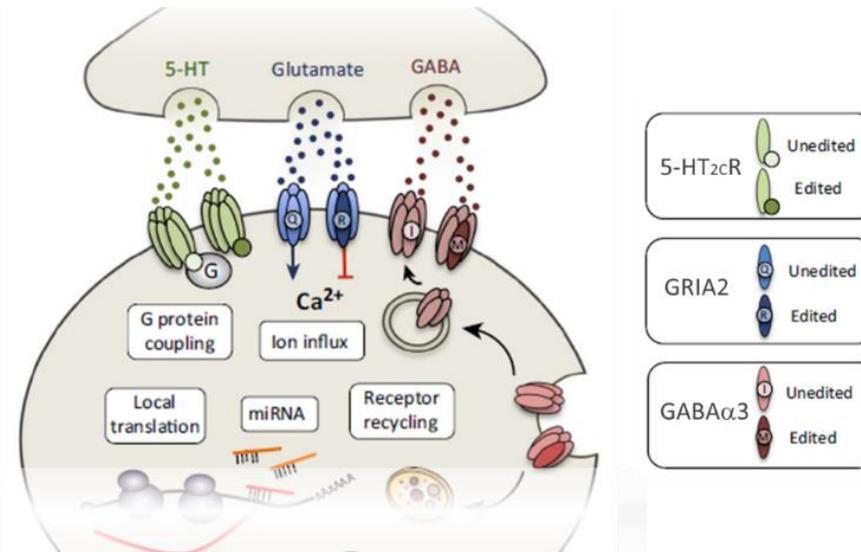- Glutamate
- GABA

Impact in many neuropsychiatric disorders

- Bipolar disorder
- Depression
- Schizophrenia
- Alzheimer
- Etc.

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RNA editing, a mechanism impacting synaptic transmission

RNA editing & neurotransmitters

Regulation of several key networks

- Serotonin
- Glutamate
- GABA

Adapted from Behm & Ohman 2016 Trends in genetics

Example of Serotonin
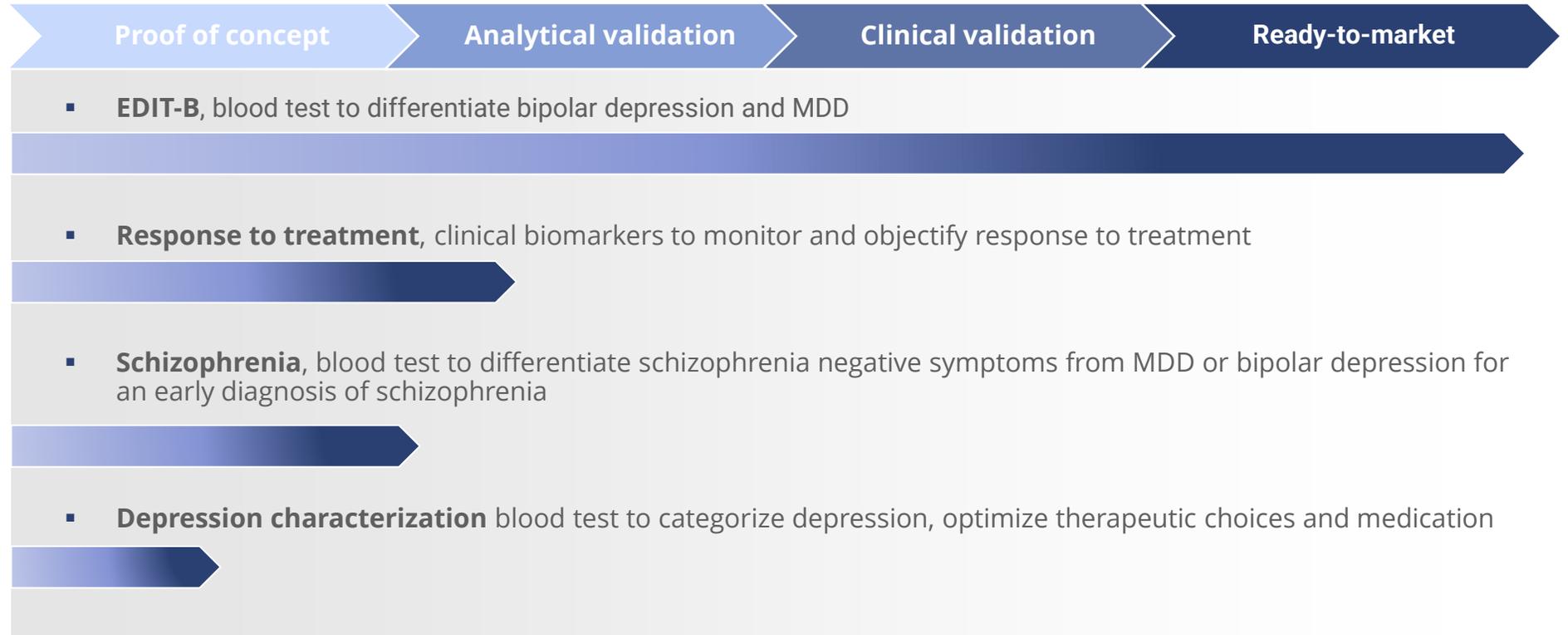
Editing of 5HT2C post synaptic receptor

- alters the binding to G-protein
- affects signal transmission

While

- SSRI antidepressants increase serotonin in the synaptic cleft

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ALCEDIAG− pipeline

Proof of concept	Analytical validation	Clinical validation	Ready-to-market

- **EDIT-B**, blood test to differentiate bipolar depression and MDD

- **Response to treatment**, clinical biomarkers to monitor and objectify response to treatment

- **Schizophrenia**, blood test to differentiate schizophrenia negative symptoms from MDD or bipolar depression for an early diagnosis of schizophrenia

- **Depression characterization** blood test to categorize depression, optimize therapeutic choices and medication

Depression and bipolar disorder: an overview

Depression, MDD

Sadness, loss of interest, weight and sleep issues, etc.

300M people

Similar depression episodes
BUT
Different medications

Bipolar disorder

Alternation of depression and mania /hypomania

48M diagnosed people

Diagnostic delay ~**8 years**
100M+ undiagnosed patients

Avoidable consequences of the late diagnosis

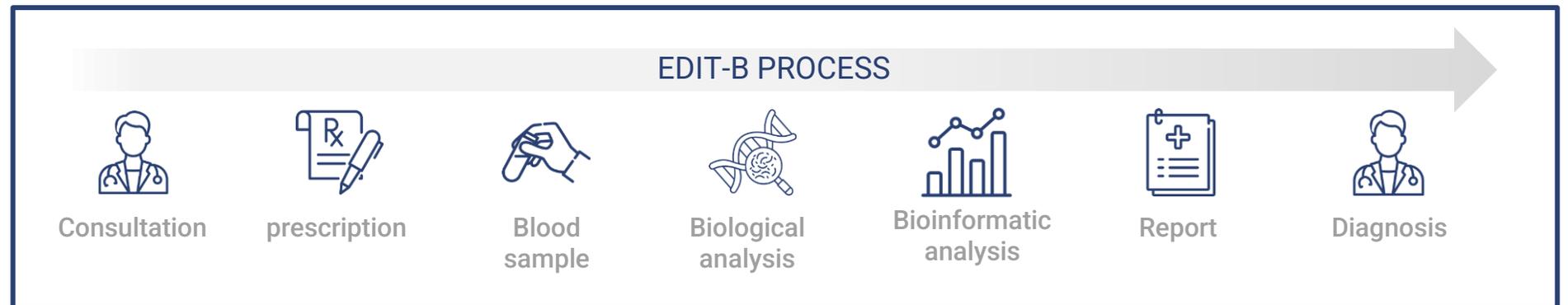**Deterioration of physical and mental health**

Damaged quality of life

High costs

Up to 30k$/year/patient

EDIT-B™, a highly-awaited world-class innovation

EDIT-B ALCEDIAG

Blood test to differentiate unipolar versus bipolar disorder in patients treated for a major depressive episode

- Aid to diagnosis for clinicians
- Clinically validated
- **High sensitivity and specificity (>80%)**
- CE marked
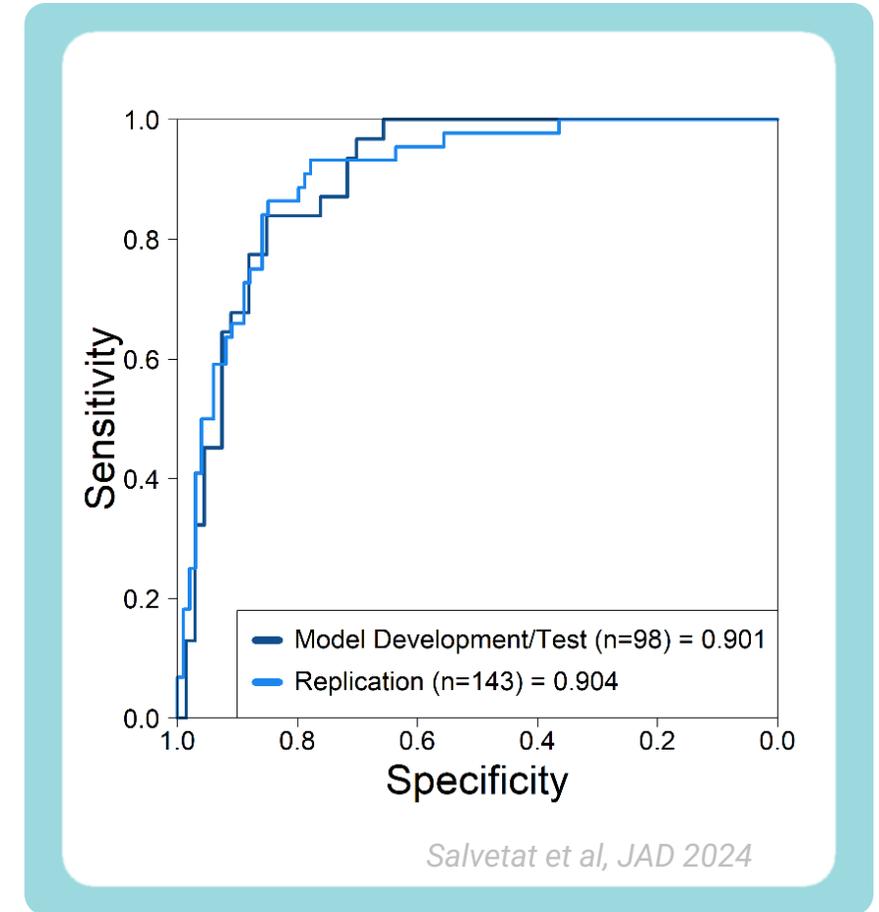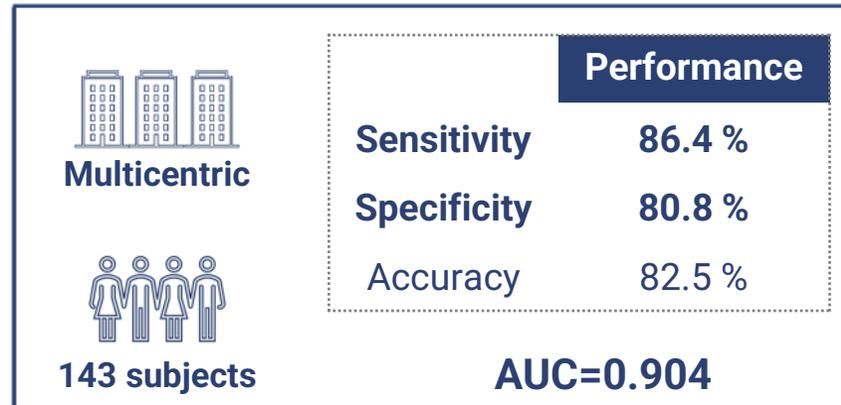- Available in several European countries

EDIT-B PROCESS

Consultation · prescription · Blood sample · Biological analysis · Bioinformatic analysis · Report · Diagnosis

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EDIT-B is clinically validated with 2 independent cohorts - published

Clinical Validation

Single center

245 subjects

	Performance
Sensitivity	**80.6 %**
Specificity	**85.1 %**
Accuracy	83.7 %

AUC=0.901
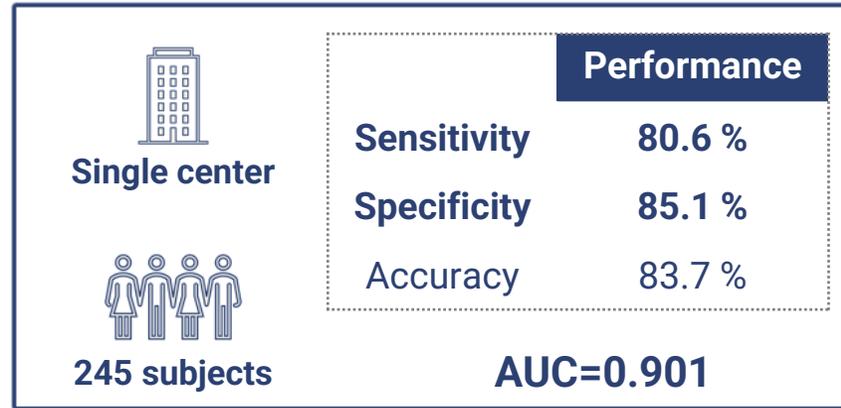
Replication Study on an independent cohort − External Validation

Multicentric

143 subjects

	Performance
Sensitivity	**86.4 %**
Specificity	**80.8 %**
Accuracy	82.5 %

AUC=0.904

ROC curve legend:
- Model Development/Test (n=98) = 0.901
- Replication (n=143) = 0.904

Salvetat et al, JAD 2024

And our most recent results – to be published

**EIT Health
external Validation study**

4 centers   **393 subjects**

	Performance
Sensitivity	**82.6%**
Specificity	**80.3%**
PPV	73.1%
NPV	87.6%
Accuracy	**81.2%**

AUC=0.873

CI 95% [0,837 - 0,909]

EIT Health study results

AUC = 0.873

AUC-Algo2 v1 (Salvetat & al; 2024) =0.904
AUC-EITH - All_Centers_n393_V1: 0.873
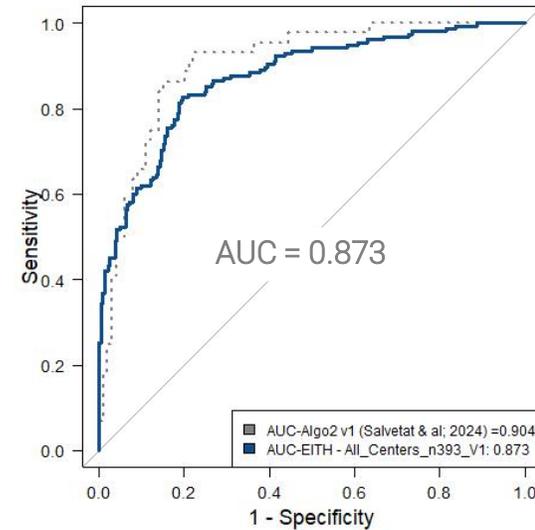
**Comparison with Salvetat 24
published data**

AUC-Algo2 v1 Salvetat&al(2024) = 0.904
AUC-EIT-H - All_Centers_n393_V1: 0.873
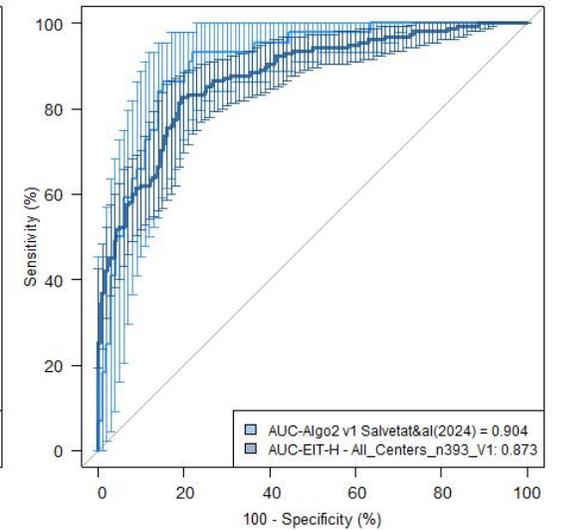
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Towards a successful market access

Key stakeholders

Priorities

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Regulatory, reimbursement, bioinfo analysis

KOL engagement

Local SAB, sponsors & early adopters

Medical laboratory

Biological analysis

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Reimbursement

Clinical utility & Health economics

Awareness & adoption

Local congresses, patients' association

Promotion partner

Promotion, marketing, reimbursement

Key partnerships

Major hospitals, clinics, foundation

A global methodology to be adapted to each country specificity

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Real-life pilot with Clariane

A mixed-methods pilot (qualitative & quantitative) involving the distribution of **63** (30 in Spain, 33 in France) EDIT-B tests by Alcediag for routine use among **clariane** in 🇪🇸 🇫🇷

Psychiatrist **Satisfaction** Level	**Patient's Acceptation** (Psychiatrist Point of View)	EDIT-B test's **Recommendation to Colleagues**
8,9/10	**8,8/10**	**9 /10**

💬 "A long-awaited innovation"

💬 "Clinical support for diagnosis and treatment acceptance "

💬 "Tool that can assist in diagnosis"

EDIT-B competitive landscape

➤ **No equivalent in the World**

	EDIT-B ALCEDIAG	MindX Sciences	psyomics	Psykonos	NeuralDx
Test type	Blood test Aid to diagnosis	Questionnaire + Blood test Screening / exploratory test			Medical Device Electrovestibulography
Description	Blood test to objectively diagnose bipolar disorder and to differentiate patients with bipolar disorder from patients with depression.	• Target: large panel of mental health conditions • Questionnaire • Blood test to screen for disease and risk of future events	• Target: panel of 15 mental health conditions • Questionnaire with up to 635 mental health related questions • Blood test including 17 biomarkers	• Target: MDD and BD for general practitioners • Questionnaire to be included in an app • Blood test based on cytokines biomarkers.	A neuro-electrophysiological measurement platform to identify biomarkers of mental and neurological disorders.
Performance	Sensitivity & specificity >80% (AUC 0,9)	65% blood test accuracy	71% blood test accuracy	AUROC: 0,83	80% accuracy
Commercialization	✔	✔ Available in the US	✔ Available in some centers in the UK	✘ Earliest Q3 27	? Unclear timeline – website not up to date
Comments		• Designed to help assess disease severity and guide treatment	• Some ongoing research on metabolomic biomarkers	• Validation study not started as of Sept. 24	• Unclear status

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EDIT-B in Europe

- Available in France, Italy and Switzerland

- Coming soon in Spain

- Rest of Europe and beyond in progress

Our lab partners

Our clinical partners

France

Spain

Other

Where we are, where we are going

EDIT-B commercialization

Today

- **Commercialization**
  - Available in several EU countries
  - Discussions outside EU
  - Discussions with large industrials
- **Reimbursement**
  - Clinical utility study ongoing (1,3M€ grant)
  - HEOR modelling ongoing for EU
  - Positive pilot feedback from psychiatrists and patients

Tomorrow

- **Commercialization**
  - Open "Low-hanging fruits" countries
  - Focus on US
  - International development
- **Reimbursement**
  - Secure reimbursement in key countries

New products

Today

- Several proofs of concept and ongoing collaborations

Tomorrow

- A range of diagnostic solutions
- Collaborations with Pharma companies

Key take aways

A fully validated innovation

Independent cohorts & external validations

A major unmet need & a large market

12M+ tests /year in key countries

Positive feedback from psychiatrists & patients

Pilot studies

Patented & first in class

No equivalent on the market

A pipeline of future products

Schizophrenia, treatment response

Our project:

Fundraising 10M€

Commercialize EDIT-B across key international countries
Secure reimbursement
Develop future tests & solutions

Exist in ~3 years (IPO or acquisition by large player)

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APPENDIX

Our customers & partners

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Alcediag publications

➤ **RNA editing-based biomarker blood test for the diagnosis of bipolar disorder: protocol of the EDIT-B study**
A. Miranda-Mendizabal, et al. Annals of General psychiatry, 2025, DOI: 10.1186/s12991-024-00544-8

➤ **AI algorithm combined with RNA editing-based blood biomarkers to discriminate bipolar from major depressive disorders in an external validation multicentric cohort**
N. Salvetat, et al. Journal of Affective Disorder, 2024, DOI: 10.1016/j.jad.2024.04.022

➤ **Euthymic and depressed bipolar patients are characterized by different RNA editing patterns in blood**
M. Hayashi, et al. Psychiatry Research, 2023 DOI: 10.1016/j.psychres.2023.115422

➤ **A game changer for bipolar disorder diagnosis using RNA editing-based biomarkers**
N. Salvetat, et al. Translational Psychiatry, 2022 DOI: 10.1038/s41398-022-01938-6

➤ **PDE8A to discriminate in blood samples depressed patients and suicide attempters from healthy controls based on A-to-I RNA editing modifications.**
N. Salvetat, et al. Translational Psychiatry, 2021, DOI: 10.1038/s41398-021-01377-9

➤ **RNA editing blood biomarkers for predicting mood alterations in HCV patients;**
N. Salvetat, et al: J. NeuroVirol, 2019, DOI: 10.1007/s13365-019-00772-9

➤ **Brain region-specific alterations of RNA editing in PDE8A mRNA in suicide decedents.**
F. Chimienti, et al: Translational Psychiatry 2019 Mar14;9(1):112

➤ **Emerging RNA editing biomarkers will foster drug development**
S. Van der Laan, et al: Drug Discovery Today 2017 Jul;22(7):1056-1063. Review

➤ **Region-specific alterations of A-to-I RNA editing of serotonin 2c receptor in the cortex of suicides with major depression**
D. Weissmann, et al: Translational Psychiatry. 2016 Aug 30;6(8):e878. DOI: 10.1038/tp.2016.121

➤ **In vitro screening for drug-induced depression and/or suicidal adverse effects: a new toxicogenomic assay based on CE-SSCP analysis of HTR2C mRNA editing in SH-SY5Y cells.**
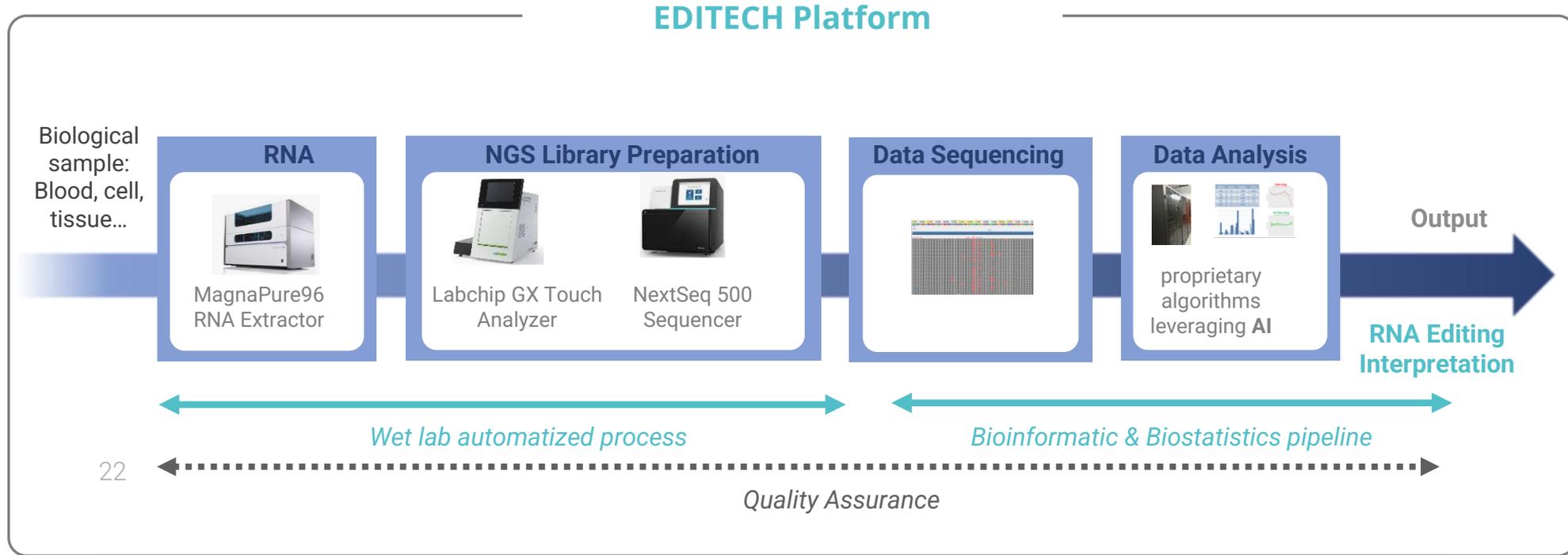*L. Cavarec, et al: Neurotox Res. 2013 Jan;23(1):49-62*

Alcediag Intellectual Property

Patent	Description	Jurisdiction	Status
WO 2008/152 146	Editing blood biomarkers for diagnosis in psychiatry, treatment monitoring, patient stratification	🇨🇦 🇯🇵 🇨🇳 🇪🇺	Granted
WO 2010/070 074	In vitro method to evaluate drug-induced psychiatric side effects	🇺🇸 🇨🇦 🇯🇵 🇪🇺	Granted
WO 2011/161 253	Use of PDE8A as a biomarker to diagnose, predict and assess therapeutic efficacy and/or potential adverse side effects	🇺🇸 🇯🇵 🇪🇺	Granted
WO 2017/153849	NGS method and algorithm to assess drug-induced psychiatric side effects	🇪🇺 🇯🇵 🇨🇳 🇮🇱 🇺🇸 🇨🇦 🇧🇷	Granted
WO 2018/020042	Blood biomarkers and algorithm to evaluate suicide risk in patients	🇺🇸 🇪🇺 🇨🇦 🇯🇵 🇨🇳 🇧🇷 🇮🇱	Granted
PCT/EP 2020/081458	Diagnosing mood disorders using blood RNA editing biomarkers	🇪🇺 🇺🇸 🇨🇦 🇯🇵 🇨🇳 🇧🇷 🇮🇱	Granted
PCT/EP 2020/081459	Differential diagnosis of bipolar disorder and unipolar depression using blood RNA editing biomarkers	🇪🇺 🇺🇸 🇨🇦 🇯🇵 🇨🇳 🇧🇷 🇮🇱	Granted
PCT/EP 2023/087115	Differential diagnosing of bipolar versus unipolar disorder in patient during depression phases using A to I RNA editing ZNF267 gene	Filed in Europe	Pending
US63/642982	Method for differentiating patients across healthy control, bipolar disorder, schizophrenia, and schizoaffective groups	Filed in the US	Pending

Legend
🇺🇸 Granted
🇺🇸 In progress

ALCEDIAG studies RNA editing on it own proprietary platform that combines Sequencing, data science & AI

EDITECH Platform

Input

Biological sample: Blood, cell, tissue...

RNA
MagnaPure96 RNA Extractor

NGS Library Preparation
Labchip GX Touch Analyzer
NextSeq 500 Sequencer

Data Sequencing

Data Analysis
proprietary algorithms leveraging **AI**

Output

RNA Editing Interpretation

Wet lab automatized process

Bioinformatic & Biostatistics pipeline

Quality Assurance

22

Proprietary Products In Mental Health
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Collaborations & Services: biotech and pharma collaborations

ISO CERTIFIED ISO 13485 ISO CERTIFIED

Confidential

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