Case Study | October 2022

# A blood-based biomarker panel for non-invasive diagnosis of non-alcoholic steatohepatitis: a multi-centre prospective and validation study

IVD Clinical Research | Analytical Performance | Data Management | Biostatistics

## The Case

A late-stage biopharmaceutical company dedicated to metabolic and chronic liver diseases is developing an in vitro diagnostic (IVD) test for NASH at-risk patients.

The test integrates four independent biomarkers – miR-34a-5p, A2M, YKL-40, and HbA1c. The output is a 0-10 score with threshold values, identifying patients with low risk or high risk of developing NASH.

The main objective of this study is to evaluate the physiological stability of these biomarkers between the fed and fasting state in patients with the target condition (NAFLD) over a 30-day period.

## The Challenges

To design, submit, and implement a large-scale, multi-center, longitudinal intervention study in Europe.

To ensure patient enrollment and follow-up visits for 30 days at 9-time points, biobanking of samples, and transition to our technical platform.

To evaluate the robustness of this test predictive algorithm in different physiological states through a biostatistical study correlating clinical and biological data collected.

## How we responded

Co-collaboration between our internal team of NASH pathologists, Regulatory, Clinical Research and Statistical Officers with our Partner Hospitals in Europe for scientific validation and protocol design and submission.

Ensure the availability of a dedicated team of CRAs and home nurses to ensure the project's successful completion.

A premium courier transportation to guarantee the timely testing of the samples and storage at -80°C.

## Top Takeaways

Cerba Xpert provided the client with a complete and tailored service ranging from scientific validation to its execution.

Our global footprint and in-depth knowledge in IVD allowed a fast-track validation of the protocol by the ethics committee and a rapid study start up.

All samples were successfully collected, transported to our technical platforms and correctly biobanked.

This groundbreaking study is a major step for our structure to bring to market a non-invasive diagnostic test specifically designed for the early identification of NASH with high specificity and sensitivity.

## Timeline

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| June '21 – Submissions to ethical committee | 1st September '21 Start up | 15th November '21 First patient | November '21 – July '23 (24 months) Enrollment period | July '23 Final report |

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# Overview of Study Process

Clinical pathologists, Regulatory, Clinical Research, and Statistical Officers (Internal team).

Reimbursement officers (External).

Principal investigator (External), CRA.

Principal investigator (External), CRA, home nurses (External).

Lab technicians in our platforms of Paris and Ghent.

Biobanking manager.

Logistics manager.

PI (External), CRA, Statistical officers.