Case Study | 13th February 2023

Set-up of a clinical trial to evaluate the clinical performance of the non-invasive prenatal testing as a first-line screening test for trisomy 21, 18, 13 and sex chromosome aneuploidy

Patient Recruitment | Prospective Minimal Risk Interventional Study | IVD Clinical Performance | Data Management | Biostatistics

The Case

Aneuploidies are a major cause of perinatal mortality and infant disability. Invasive procedures, such as amniocentesis or chorionic villus sampling (CVS), are associated with a 0.5 - 1% risk of fetal loss due to miscarriage. Advances in molecular biology have allowed the development of highly accurate non-invasive prenatal tests (NIPT) based on cell-free fetal DNA (cfDNA).

This study supported by a first class IVD laboratory focuses on the development and validation of a new method for non-invasive prenatal testing, based on a next generation digital PCR system to screen for the probability of trisomy 21, 13, 18, sex chromosomal aneuploidies and 22q11.2 micro deletion from cell-free fetal DNA found in maternal plasma.

The Challenges

Regulatory and scientific expertise for the writing of the protocol and the submission of the study to the ethics committee for approval.

Identification and implementation of the study in 6 public hospitals (AP-HP) around Paris. Cerba Research serves as a CRO and AP-HP as an investigator during this trial.

Ensure regular monitoring visits with the hospital medical staff to ensure proper progress of the study.

Coordination and transport of the samples collected between the hospitals and our technical platform.

How We Responded

Establishment of an expert working group dedicated to the project (pathologist, a coordinating investigator at the head of the Gynecology-Obstetrics Department at the hospital, clinical research associates, a project manager, and a biostatistician).

Successful implementation of the study in all selected hospitals.

Enrollment of 60/1790 patients and collection of 180/5370 samples in 2 months - which corresponds to our estimated recruitment rate.

Design and implementation of an eCRF to track patient records and capture analysis data.

Top Takeaways

Build a trusting relationship between Cerba Research and the sponsor through scientist-to-scientist collaboration, communication, and state-of-the-art reports.

A part of the samples were successfully collected, transported to our technical platforms to provide clinical validation of the new IVD.

This project aims to develop NIPT based on a new generation digital PCR system as a first level test and to compare it to the Standard of Care of Cerba Speciality Lab.

Timeline

Jan ‘22
Submissions to ethical committee

Jun ‘22
Start up

Dec ‘22
First inclusion

Dec ‘22 – Jun ‘24 (18 months)
Inclusion period

Jul ‘2024
Final report

Cerba Research