

Type:

Cardiology

Geography:

Europe

Study Type:

Pilot Study

Client:

Diagnostic Solution
Pharma Company

PROJECT TITLE:

“Evaluation of the usability of a mobile health application and web browser for heart failure patients to optimize patient self-management and effective follow-up by treating physicians in the post-COVID era”

Objective:

To perform consultation on clinical investigation design, project management, medical writing, clinical monitoring, data management and statistical functions for a national (Greek) and to pilot clinical investigation to determine the usability and acceptability of a mobile health application by heart failure patients and cardiologists.

Project Challenges:

- COVID-19 has accelerated the development of remote monitoring technologies for high-risk patients
- Mobile health applications qualify as medical devices under the Medical Device Regulation (MDR)
- Usability testing is mandatory for medical devices
- Determine acceptability (satisfaction, successful navigation) of mobile health application by both patients and health care professionals

Excelya Solutions:

- Multiple services (medical writing, data management, statistical analysis, monitoring)
- Consultation on clinical investigation design to comply with MDR
- Single protocol, Separate ICFs and CRFs for patients and cardiologists
- Mock tests to optimize mobile health application (patient and cardiologist interfaces)
- Project / Site management

2 sites

23 heart failure patients

Single visit

15 cardiologists

Benefits for the Client:

Proactive strategies delivered to meet goals of a challenging pilot study, in an evolving regulatory landscape.