Clinical trials: the first neurological Early Feasibility Study on a medical device starts in Italy.

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IIn January, Gemelli Hospital started an innovative experiment aimed at assessing the feasibility of integrating the ARC intellicare rehabilitative solution into the care path for different types of neurological patients, compared to their respective standard care.

It is a pilot project to be carried out within an Early Feasibility Study (EFS) program for medical devices to be adopted in neurology. This exploratory project is very important and useful for acquiring information, knowledge, and experience to be used in future EFS programs, allowing for a deeper understanding of the "linkage" between the European regulations and the U.S. regulations on EFS.

An Early Feasibility Study is a clinical investigation of a device in its early stages of development, usually before the device design is finalized, for a specific indication (e.g. innovative device for a new intended use, marketed device for a new clinical application). It can be used to evaluate the device design concept with respect to initial clinical safety and device functionality in a limited cohort of subjects when this information cannot practically be obtained through pre-clinical or laboratory assessments. The early clinical experience gained from an EFS is associated with greater efficiency in the device development process, as it can be used to identify appropriate modifications to the procedure or device.

There are multiple reasons why EFS can be conducted, for example to obtain initial information regarding: the technical success of the system adoption, the usability, the evaluation of human factors such as understanding of procedural phases, the clinical safety of the device (e.g. assessment of serious adverse events related to the device), the evaluation of device functions, i.e. if the device serves its intended purpose, the evaluation of the possibility of device failures, the patient characteristics that can affect

device performance (e.g. anatomical limitations), the evaluation of therapeutic parameters (e.g. applied energy, sizing, dose delivered) associated with device use.

The new model aims to make treatments that use medical devices increasingly tailored to patients through actions focused on ensuring higher appropriateness and adherence to treatments, overcoming possible inequities in access to research, guaranteeing greater attention to health needs and patient requirements, reducing organizational costs with benefits for research, patient health, and the sustainability of the healthcare system.

To achieve these objectives, a temporary consortium has been set up between the Agostino Gemelli University Hospital, where the clinical trial will be carried out, the Interdepartmental Research Center CRISPEL, which will ensure compliance with the regulations and the correct legal implementation of the project, and the Center for Applied Health Economics Research (C.R.E.A. Sanità), which, with its expertise in health economics and medical statistics, will be responsible for evaluating the sustainability of the object of the trial within the National Health Service.

The purpose of the study is to test the feasibility of integrating a rehabilitation solution called ARC intellicare (ARC) into the care path of various types of neurological patients compared to the respective standard of care.

Unlike current clinical practice, ARC enables patients to perform different types of exercises directly at their own homes, with autonomy and full safety, according to the individual rehabilitation plan prescribed by the professional.

The device is designed to be easy and intuitive to use, to meet the needs and satisfaction of patients and, at the same time, to be a tool capable of supporting and enhancing the important work done by clinicians.

Thanks to the use of inertial sensors and validated and patented artificial intelligence algorithms, ARC analyses in real-time the movement performed by the patient, recognizes the repetitions completed, and automatically counts those performed correctly. The entire rehabilitation process can be remotely

monitored and updated by the healthcare professional, who receives the data related to therapeutic adherence and the patient's health status on a dedicated tablet, and who can also contact the patient by means of the integrated video call function. ARC operates in full compliance with current regulations and required standards, from the European Medical Devices Regulation to GDPR, for safe data handling and user privacy protection.

"We are proud to have been selected for this important project, of which we share the vision and objectives. Thanks to the work and effective collaboration of our team of professionals dedicated to the development process of the device, today we strongly believe that ARC can meet the current needs of the various actors involved in hospital-territory care: from the patient to the professional, to the healthcare facilities and the National Health Service," says **Luca Ascari**, Chief Technology Officer of Henesis, the company manufacturing the device. "This project will allow us to cooperate with important partners to verify and quantify the benefits derived from the use of ARC, in the hope that our contribution can accelerate the definition of tele-rehabilitation care pathways as well as the introduction of innovative and validated medical devices to support them."

"The study is a starting point that can certainly be improved, but even now we believe it has the strength to bring about change, which we hope can be implemented through further projects in other areas, and in this perspective, we are available to start virtuous paths with individual realities," says Professor **Paolo Calabresi**, Director of the Neurology Department and Principal Investigator of the trial. "Only the measurement of concrete application can tell us how to integrate and possibly modify the model, with the goal of making it continuous. The project, born from collective work, can only be consolidated through joint work with health professionals."

But how should the conduction of all the phases of the clinical trial investigations materialize and what are the benefits?

Firstly, the project outlines a series of reciprocal commitments between the experimenters of the three partner centres and the manufacturer, with the

aim of recognizing the role and significant contribution of each to the progress of medicine, promoting dialogue, and providing continuous information and preliminary results to the Ministry of Health and major stakeholders. The partners, thanks to their skills and experience, will collaborate with the experimenters during all phases foreseen in the experimental protocol.

The pilot program will carry out a preliminary action for the definition of a validated conduct model in the management of medical device trials from the design phase of new studies and the elaboration of the clinical investigation plan. The fundamental advantage would be to be able to define the objectives of the trials in a way that is more responsive to the real needs of patients in terms of efficacy, safety, functionality and survival, promoting a personalized approach to treatments.

"We expect the project not to be limited to the success of the first trial, but to have a more general meaning in the knowledge and appreciation of research on medical devices," observes **Giovanni Arcuri**, Technical Director of ICT and Technological Innovation. "Starting from an early feasibility study, it is now possible to develop a discussion on ethically relevant issues: the methods of recruitment for trials, the information to be given to patients, the choice of priorities and objectives of clinical studies, and the communication of results."