OMERO STUDY: AN EXAMPLE OF APPLICATION OF THE NEW DIGITAL TECHNOLOGIES IN CLINICAL RESEARCH

Marco Morina[1], **Marco Angelo Scatigna**[1]
[1]*Medical Affairs Division, Sanofi SpA, Milan - Italy*

Background: In recent years, interest in the use of digital technology in the management of clinical trials is growing in order to simplify the procedures, increase the reliability of the data collected and safety for patients. Patients can also benefit from the application of new technologies in clinical research, through the provision of services that improve their involvement and reduce the burden of activities related to their participation.

Materials and methods: The OMERO study, Observational, prospective, multicentre study on long-term effectiveness and tolerability of alirocumab in the real life clinical practice in Italy) is an observational, prospective and multi-center phase IV study designed to evaluate the effectiveness and tolerability to long-term alirocumab (a monoclonal antibody anti-PCSK9), in real clinical practice. The study uses digital technologies that can be considered innovative in the field of clinical research exploring the possibilities offered by these through an integrated platform that includes the study portal and other applications.

Results: The main innovation implemented consists of a pilot project for collecting the informed consent in electronic version (eIC) which provides the possibility for the patient to listen to an audio file that summarizes the highlights of the document and to verify the effective understanding through a quiz. The tool is also able to automatically archive the consent, ensuring compliance with Good Clinical Practice, the use of the most recent version of the document and timed signing. Furthermore, an application, ePRO (Patient Reported Outcome), was implemented for the Injection treatment acceptance questionnaire (I-TAQ) and the quality of life questionnaire (EQ-5D-5L), to minimize the missing data in the database and to limit errors. The electronic case report form allows to perform remote data checks and minimizes data entry errors by cross-checking the information collected and setting plausibility limits. The system is also integrated with the eIC app, with ePRO and with the automated system for reporting adverse events, that, simultaneously with the recording of the event, directly transmits a notification to the Pharmacovigilance Service, allowing the real-time identification of signals to protect the safety of the patients. The integration among these systems increases the guarantees of compliance with Good Clinical Practices (GCP), for example by preventing the registration of data without first acquiring consent. All data collected through the various electronic tools flow into the Investigator Site File (ISF) and in the Trial Master File (TMF), a single electronic archive of the study that tracks any data entry or modification, simplifying the database cleaning work and the interaction between the Contract Research Organization (CRO) and the investigators.

Discussion: Overall, the use of these systems allows to have all the necessary documentation readily available in the event of inspections and to improve the quality of the data collected. Another important aspect is the possibility of remote monitoring of risk indicators concerning the quality of the data collected, the punctuality of the insertion, the respect of the milestones, the quality of management at the level of the investigator center and the safety data. Through data analysis it is possible to identify trends worthy of attention in real time and to intervene in a targeted manner.

Conclusions: The use of digital technologies, as part of the OMERO study, made it possible to have a database constantly updated in real time and to increase the guarantees for the patient in terms of safety, quality of the data collected and compliance with the GCP. In general, the use of digital technologies in the world of clinical research will allow optimizing the work of the investigators and improving the experience of the participating patients.