CASE STUDY

PES-SLEEP PROJECT

PATIENT INPUT INTO MEDICAL DEVICE DEVELOPMENT: A MISSED OPPORTUNITY

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Since the revised Medical Devices Ordinance (**MedDO**) and the new Ordinance on Clinical Trials with Medical Devices (**ClinO-MD**) came into effect in Switzerland in May 2021, clinical investigators have encountered challenges in correctly categorising their research projects and identifying whether their projects pertain to the category of clinical studies with medical devices (governed by the ClinO-MD) or are considered human research other than clinical trials (governed by Chapter 2 of the Human Research Ordinance (**HRO**)). In this article, we discuss the PES-SLEEP project in order to illustrate a practical approach to this categorisation challenge between the lighter HRO regulatory framework and the more demanding ClinO-MD pathway. We also present the important points that were considered by the ethics committee for the canton of Vaud (**EC Vaud**) in order for the study to be approved as an HRO research project.

The PES-SLEEP project (registered title: Technical feasibility of measuring sleep physiological parameters using piezo-electric materials) is an ongoing exploratory observational study in humans. The study aims to collect information about the feasibility of recording signals that inform physiological sleep parameters by using a thin mat composed of pressure sensors. In this study, participants sleep on an experimental mat for one night, during which a standard examination for the measurement of sleep physiology (polysomnography (**PSG**)) is also recorded. Variables recorded with the mat are correlated (using machine learning techniques) with physiological parameters recorded with PSG (such as heart rate or breathing rate).

Professor Paul Franken (UNIL sponsor representative for the project) and Doctor Shanaz Diessler (principal investigator for the study) developed their research protocol with the help of the Clinical Research Centre (**CRC**) Lausanne and submitted it to the EC Vaud as an HRO project (Chapter 2, human research other than clinical trials), first with healthy participants (without sleep complaints) and then with participants with sleep complaints (after amending the research protocol).

During the study's protocol development phase in October 2021, the CRC Lausanne, which is in charge of coordinating the Regulatory Affairs Platform of the Swiss Clinical Trial Organisation (SCTO), had the opportunity to co-organise the annual roundtable meeting between Swissmedic, swissethics, and the SCTO. At this meeting, the criteria for considering a technical object to be a medical device were discussed, and some illustrative case studies were challenged. It appeared that Swissmedic's main criterion was related to the purpose of a technical object within a study. In the PES-SLEEP study, the mat with pressure sensors is not a standard product but was developed by Professor Franken's research team specifically for the study. In addition, it was used in a proof of concept stage with, first and foremost, a feasibility objective. The research project is not being conducted in order to assess the safety or the performance of the set-up as a medical device designed for sleep recordings for diagnosis purposes. Instead, the research team aims to collect information about the feasibility of recording any useful signals (in terms of sleep physiology) by using such pressure sensors in a "mat" configuration. These are the reasons why the project falls within the scope of an observational prospective study involving humans and is thus governed by the HRO instead of the ClinO-MD. Moreover, the PES-SLEEP study does not expose participants to any particular personal safety risk. The pressure sensors in the mat are not in direct contact with participants since the sensors are placed on the underside of the mat, which is beneath the bed sheet, and they operate without external voltage or current source; only discomfort related to sleeping with electrodes (for PSG) may be felt by participants. The study thus falls within risk category A since the planned measures entail only minimal risks and burden for participants. The research team estimated that recording twenty participants would allow for a sufficiently robust association analysis in this observational study.

The PES-SLEEP study was first designed for healthy participants without sleep complaints, who were recruited by the Center for Integrative Genomics (**CIG**) at the University of Lausanne (**UNIL**). The study received approval from the EC Vaud in January 2022. After the inclusion of 6 out of 20 healthy participants, the data recorded were of good quality, and the initial analysis demonstrated that signals recorded with the mat could give highly accurate estimates of heart and breathing rates, thus forming a solid starting basis. Given these promising results, the research team wanted to study a more representative sample of the population (with more variability) by recording not only good sleepers (i.e. healthy participants) but also people with poor sleep (i.e. participants with sleep complaints). Therefore, an amendment to the PES-SLEEP project was submitted to the EC Vaud in July 2022 to include 50 participants with sleep complaints, to be recruited by a second recruitment site: the Center for Investigation and Research in Sleep (**CIRS**) at Lausanne University Hospital (**CHUV**). These participants were referred to the CIRS because they had a priori disturbed sleep; they were not selected for the study on the basis of a diagnosis for a specific sleep disorder. The measures with the experimental mat as well as the sleep analysis (PSG) is conducted by UNIL. Data from the experimental device will not be used for diagnosis and will not impact participants' health in any way, which is why the project still qualifies as an observational study. The amended protocol received the approval of the EC Vaud in September 2022.

In conclusion, the PES-SLEEP study demonstrates that it is possible to carry out the proof of concept phase of a device within the framework of an observational study insofar the device in the study is used to verify the feasibility of measurements of the experimental device and not to verify its safety or its performance for the purpose of making a diagnosis.