



European Registry of Lipodystrophy based on the OSSE-Framework

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Introduction

The European Consortium of Lipodystrophy (ECLip) is in the process of setting up a registry for patients with Lipodystrophy using the OSSE (www.osse-register.de/en) open source software and toolbox. The consortium consists of an association of European experts in the field of lipodystrophy. As lipodystrophy is an extremely rare disease divided into even rarer subtypes, research in this area is extremely difficult and international cooperation is essential, so to speak.

The technical development and configuration of the registry was carried out by the Medical Informatics Group at the University Hospital Frankfurt supported by the IT administration team of the Institute of Epidemiology and Medical Biometry of the University Ulm.

Methods

The Open Source Software OSSE (Open Source Registry System for Rare Diseases in the EU) provides a framework and an organizational process to set up a rare disease specific registry [1]. The fundamental goal of OSSE is to provide patient associations, doctors and other stakeholders the possibility to create and establish a patient registry without extensive IT knowledge. The platform is web based and focuses on a federated approach that allows to perform distributed searches which are designed to comply to data protection requirements and preserve data sovereignty. Before running the registry, the designated server needs to be set up and the data structure as well as the case report forms (CRF) have to be defined. The future users of the different sites of the ECLip Group were involved very early in this process to define a harmonized dataset for the registry. In addition, based on two templates provided by the development team at the University Hospital in Frankfurt, the group developed a patient consent form and a data protection (elements collected in the registry [2,3]. The goal of this approach is to have consistent records with detailed descriptions and units of each items.

Thus, it is possible to improve the quality of the documentation. After defining the data elements, the medical forms that are divided into basic forms and longitudinal forms were created. After this step, a first phase of testing began.

Results

The final result was a patient registry for the collection of data on patients with Lipodystrophy, based on the software system OSSE. In the process, more than 400 collected data elements were created in finally 35 different [base- or longitudinal](#) CRF. [Moreover](#), the productive system was started and the first patient data was entered after a positive ethic vote of the individual locations.

Discussion

OSSE fosters data harmonization and sharing in compliance with data protection rules in a free system and thus a good opportunity for researchers to create and run a registry for rare diseases. By providing a platform for the networking of different experts for lipodystrophy from different countries and medical [disciplines](#), it will become possible to compare diagnosis of and care for affected patients across Europe. Apart from new insights into the pathophysiology of lipodystrophy this will help to develop improved therapeutic options for the patients. Furthermore, this registry strives to compile information material for patients, families and relevant professionals.

References

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