General Data Protection Regulation (GDRP) compliant Patient Registration and Pseudonymisation for Rare Disease Research

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INTRODUCTION

The REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (**General Data Protection Regulation - GDPR**) comes into effect as of May 25th 2018. This peace of law brings new challenges in almost all areas where personal data are processed. In a cross-boarder setting the healthcare and the clinical research field are affected as well, as national exceptions in how to deal with data for research and statistics will not be effective.

The **European Patient Identity (EUPID) Services**, are a set of web services, initially developed for the European Paediatric Oncology community which, in the meantime, raised strong interest in the Rare Disease community as well. The EUPID Services allow an independent third party-based registration and pseudonymisation of patients, also considering the patient consent as well as the context of the performed registration. This results in a context-specific patient registration, i.e. one and the same patient receives different pseudonyms in different contexts. As a distinctive feature, the EUPID Services know the relationships between the pseudonyms in the different contexts – thus, provided the availability of the necessary patient consent, the EUPID Services can make an aggregation of data from different contexts available at a later stage. The fact that the EUPID Services do not store unencrypted versions of identifying variables like names or the date of birth, is often referred to as privacy preserving record linkage (PPRL).

In accordance with the upcoming GDPR on processing non-anonymised data the GDPR has to be considered and appropriate measures have to be taken. Therefore, the EUPID services were verified concerning the compliance with the new terms.

METHODS

As the EUPID Services provide supporting services for research but do not process any research data, exceptions concerning such data do not have to be considered. Beside general requests of the GDPR the following GDPR requirements for patients concerning their data (personal rights) were verified:

- Right on Rectification,
- Right on Erasure / Right to be forgotten,
- Right on Restriction of Processing,
- Right on Data Portability
- Right on Objection

RESULTS

As the GDPR constitutes pseudonymisation to be an appropriate measure for achieving data protection through technology and to diminish the risk potential for a personal data breach the **EUPID Services support consuming third-party systems in being GDPR-compliant**.

The EUPID Services follow the principals of Privacy by Design (data minimalization, pseudonymisation, separation of identity layer and data processing layer, encoding e.g. hashing, encrypting, and key sharing restrictions including Trusted Third Parties) and Privacy by Default (as less as possible personal data processing, data has to be encoded before sending the data to the services). Further, the EUPID Services contain multiple measures to fulfill the personal rights defined by the GDPR. In conclusion, the **EUPID Services are compliant with the applicable terms of the GDPR** concerning the treatment of patient identification data and their registration as well as pseudonymisation.

EUPID

DISCUSSION

For the future, the EUPID Services will be extended to provide more advanced functionalities supporting data protection, in particular a patient-centred decision-making concerning the use of their (personal) data. For this reason, the range of functionalities is planned to be enhanced by a patient self-management and a patient consent management.

Further information: **https://eupid.eu**

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