Implementation of the Regulation on the European Health Data Space (EHDS) in Croatia

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Abstract. Since the European Commission has published a Proposal for a Regulation – The European Health Data Space, Croatia is actively working on the implementation. Public sector bodies including the Croatian Institute of Public Health, Ministry of Health and Croatian Health Insurance Fund play a key role in this process. The establishment of a Health Data Access Body is the main challenge in this effort. Potential challenges and obstacles in this process and projects that follow the efforts are described in this paper.

Keywords. European Health Data Space, Health Data Access Body, health data

1. Introduction

On May 2022 the European Commission has published a Proposal for a regulation – The European Health Data Space. [1] This regulation is a follow-up and first domain-specific regulation on The European strategy for Data and will be an integral part in the creation of a European Health Union. [2] As a member state of the European Union, Croatia has the obligation to implement the Regulation on national level. The aim of this paper is to identify the key stakeholders responsible for the implementation in Croatia, map the projects that are a part of the implementation process and to list potential challenges and obstacles in the implementation.

2. Stakeholders

Public sector bodies play a key role in the implementation of the EHDS Regulation, mainly, Croatian Institute of Public Health (CIPH), Ministry of Health (MIZ) and Croatian Health Insurance Fund (CHIF). The Ministry of Health plays a role by directly implementing legislation on a national level, while CHIF is a data holder. CIPH is also a data holder and processor and is already responsible for the maintenance of 16 national registries related to health data. In the framework of this Regulation, CIPH is devoted to create the first Health Data Access Body (HDAB) as a part of its institution through projects with MIZ and CHIF as partners.

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3. Projects

The European Commission encourages member states to implement the Regulation with financial and logistic support through Direct Grants and Joint Actions. Croatia has successfully performed the project TEHDAS - Joint Action Towards the European Health Data Space as part of this effort. Currently CIPH is taking part in HealthData@EU - European health data space pilot for secondary use of health data with the aim to test and evaluate the IT infrastructure on five concrete cases from which Croatia takes part in three. Data sources used in these pilots include the National Public Health Information System (NAJS) linked to databases held by CHIF and Tax administration of the Ministry of Finance. Croatia will also apply for Direct grants to Member states for setting up services by health data access bodies - secondary use of health data (HDAB), Direct grants to Member states for expansion of MyHealth@EU Digital Service Infrastructure (eHDSI) with new services and to more member states and Direct grants to Member States’ authorities: preparatory actions for a European Health Data Space; primary use of data (for healthcare) and reuse of data.

4. Challenges and Obstacles

The biggest challenge for Croatia is the establishment of the first and only planned Health Data Access Body (HDAB) led by the CIPH. Human and financial resource limitations in the establishment of such a new part of the institution are the main concern. Technical infrastructure building, achievement of interoperability with other member states and connection of data stored internally in hospitals adds to the complexity of the project. Croatia has not yet built a metadata catalogue which is also obligatory in the achievement of interoperability with other states. Since MIZ and CHIF are working in partnership with CIPH on most of the activities, they face the same problems. Communication and harmonization of activities between those three public sector bodies in Croatia is essential in achieving the goal of successful implementation of the EHDS Regulation.

5. Conclusion

Three public sector bodies in Croatia are actively working on the implementation of the Regulation on the EHDS: Ministry of Health, Croatian Institute of Public Health and Croatian Health Insurance Fund. The establishment of the first and only Health Data Access Body as part of CIPH is the biggest task to be fulfilled. Financial and human resource limitations are among the most concerning obstacles that all institutions face.

References
