The questionnaire on GDPR Compliance developed in the framework of MEDIRAD project: Results

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Introduction

MEDIRAD is a 4-year project and brings together 34 partner institutions from 14 European countries. Its purpose is to improve the scientific basis and clinical practice of radiation protection in the medical field in order to better understand and evaluate the health effects of exposure to low-dose ionizing radiation from diagnostic and therapeutic imaging and off-target effects in radiotherapy (RT). The project, for its scientific investigations, had to use patient data whose access and use is now regulated by the directive of the General Data Protection Regulation (GDPR). This has been implemented in regulatory practice with variations among European countries. Over time, compliance with the new GDPR can therefore lead to difficulties in the managing of European research projects that require access to and exploitation of personal data. In this context, Task 6.3.2 has decided **to administer an online questionnaire on GDPR compliance to MEDIRAD researchers involved in the management of patient data**.

Aim

- To identify the positive and negative experiences with respect to compliance with the GDPR
- To find out how the researchers overcame the difficulties in this field

To elaborate the recommendation aiming to help the research community to face future GDPR issues

Materials and Methods

The survey was launched on 01/02/2021 and closed on 28/02/2021. It was administrated to 124 MEDIRAD researchers involved in WP 2-6 with the invitation to respond only to those who had dealt with the management of patient data and with problems related to the GDPR.

The questionnaire was divided into three sections:

1. Collection, storage and processing of data
2. Experience with GDPR compliance
3. A list of possible suggestions, whose level of usefulness had to be rated by the respondent

Results

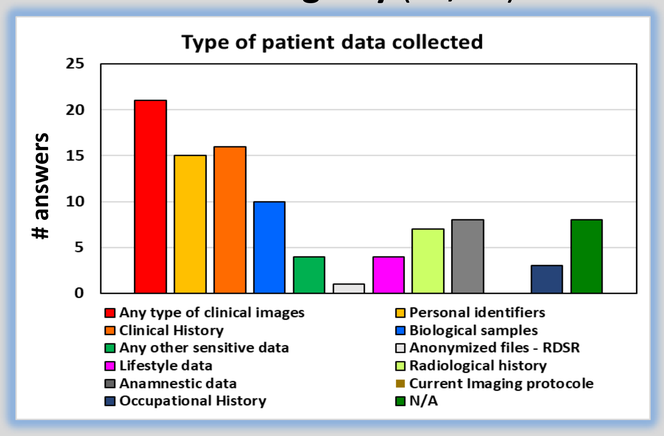
37 answers from researchers members of 21 different institutions have been collected.

DATA COLLECTION, STORAGE AND PROCESSING

The three most frequent type of data collected are:

- **Any type of clinical images** (*21/37*)
- **Clinical history** (*16/37*)
- **Personal identifiers** (*15/37*)

And the most employed method for collect them is the **clinical registry** (*24/37*).

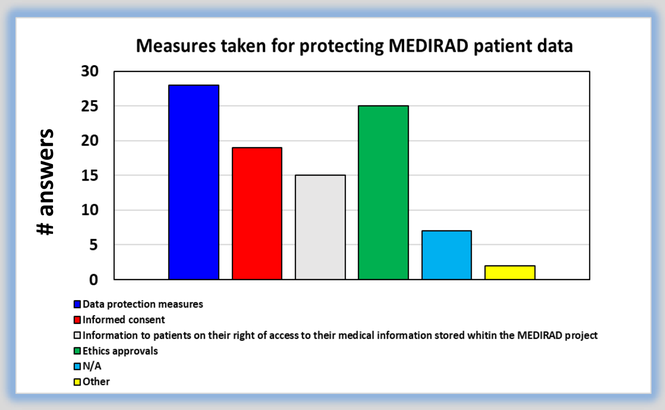


Several measures have been taken at the same time to ensure data protection during storage, management, exchange and processing. The main have been:

data protective measures (28/37) as password (51%), secure servers (49%), firewalls (41%), pseudo-anonymisation (38%) and anonymisation of the data (35%).

ethics approvals (25/37)

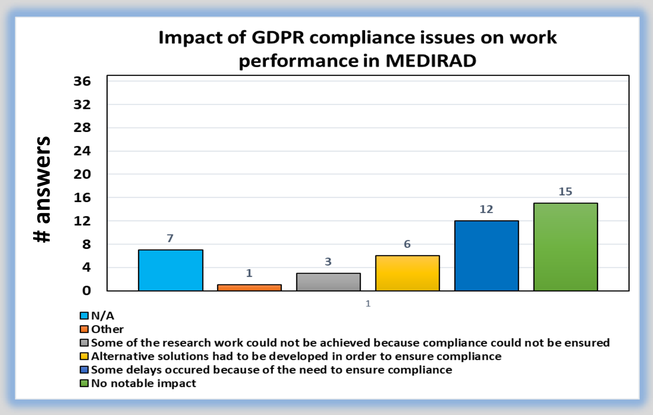
informed consent (19/37)



EXPERIENCE WITH GDPR COMPLIANCE

In general, the GDPR compliance of the project did not have a significant impact and it caused only some delays.

Difficulties encountered have been related **to technical or procedural issues (27%)** and with **the lack of harmonisation of compliance rules (22%)** between different countries or organisations.



MAIN SUGGESTIONS

Develop research oriented harmonized European guidance on GDPR compliance in order to reduce divergence of interpretations and practice at national level (84%)

Develop European training courses on GDPR compliance for researchers (78%)

Other suggestions:

- *Create a permanent expert group at the European level in order to ensure a more efficient system in the GDPR compliance process*
- *Involve DPOs from an early stage of future European research projects development*

achieved almost 60% of positive feedbacks but the percentage of undecided/neutral people increases with respect to the first two options (35% and 29% vs 13% and 16%, respectively).

Conclusions

Although the sample cannot be considered as representative, the questionnaire revealed to be a very important survey tool for the preparation of the GDPR inherent recommendation. It provided a realistic and concrete view of the problem related to GDPR compliance in biomedical research and to identify the difficulties that the researcher has to face and that could lead to delays in the development of the project activity.

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