



Biomedical Alliance in Europe

BioMed Alliance expresses concerns on GDPR implementation

The EU General Data Protection Regulation (GDPR) came into effect in May 2018 and has had a considerable impact on European health research. The Biomedical Alliance in Europe (BioMed Alliance) supports the strengthened protection of personal data but is concerned about the practical implications of the GDPR on biomedical research in Europe.

We would like to highlight certain concerns based on specific cases (presented in the annex) where the GDPR has had an impact on health research activities.

- General

In general, BioMed Alliance Members see the GDPR as very complex and this is especially the case for its implementation. This complexity affects cooperation between researchers and medical professionals. For example, when it comes to the diagnosis of rare diseases, there are many different specialists involved in the process and the GDPR further contributes to this complexity.

In addition, healthcare organisations have highlighted that there are not enough Data Protection Officers to assist in the implementation of the GDPR.

- Diverging interpretations and implementation

The most prominent concern among researchers and research organisations is fragmentation and particularly the diverging interpretation and implementation of the GDPR. A different interpretation from country to country, or sometimes even from hospital to hospital, hinders cooperation, is very time consuming and can hamper research. The lack of harmonisation also leads to a longer start up time for clinical trial set-ups in different countries.

Researchers also experience that exchanging bio samples and health data for medical and research purposes is complicated due to data processing protection measures that may differ from member state to member state. They argue for a harmonisation of regulations for the distribution of data and biomaterial for medical research in all European countries.

- Re-use of data for scientific purposes

Researchers have indicated that the GDPR and data protection considerations have prevented them from completing a number of studies that could have had a beneficial effect on both patients and public health.

For example, researchers were not allowed to analyse leftover filter paper blood samples of new-borns for a study on metabolic variables. In a different study, researchers were not permitted to contact the families of children that participated in a randomised intervention clinical trial a few years before that may have had adverse effects on their health. In both cases, important studies could not take place due to data protection considerations.

In addition, universities have indicated that the GDPR prevents medical students from analysing patient records for research purposes. For example, in Ghent University Hospital there were major problems with retrospective observational studies as students could no longer gain access to electronic health records.

- Time and budgetary constraints

Member organisations are also concerned about the time requirements and budgetary implications associated with the implementation of the GDPR. In order to comply with the



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provisions of the GDPR, organisations need to invest in training and personnel. In addition, setting up studies and ensuring research activities and data collection, processing and sharing comply with GDPR provisions require a time commitment and the necessary expertise. For example, in the case of international activities, differing interpretations of the GDPR from member state to member state make it time consuming to implement the rules accordingly.

Organisations also report that each single patient study requires a number of documents, including a Data Protection Impact Analysis which needs to be conducted by a team of experts.

- **Controllership**

Members also referred to issues related to controllership and particularly regarding the fact that there is a lack of sector-specific and internationally validated interpretations of general concepts in the GDPR such as controller, processor and joint-controller.

Conclusions

Data saves lives, helps advance research and can thus help to provide the best outcomes for patients. It is essential to provide a healthy regulatory environment which supports researchers and clinicians to excel in their work. We fear that the GDPR implementation is not only too complex, but it has severe impact on the performance of research in Europe.

Taking into account the complexity of the issue along with fragmented implementation and interpretation of the GDPR, the BioMed Alliance calls for:

- **a code of conduct for using personal data in health research, aimed at ironing out differences in national application of this and related impending EU laws;**
- **more education and guidance;**
- **the creation of a clear and harmonised guidance on GDPR implementation throughout Europe;**
- **a review of the impact of the regulation on health research;**
- **eventually more derogations to allow researchers and clinicians to continue the excellent work by conducting studies that may have a beneficial effect on public health.**



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Annex - Examples of research projects impacted by the GDPR implementation

<p>Université Sorbonne Paris Cité (Descartes)</p> <p>Diagnoses of rare diseases</p>	<p>The GDPR is making the diagnostic process of rare diseases even more complicated according to Université Sorbonne. In paediatric non-Hodgkin's lymphoma, with approximately 120 new cases/year in a country of 66 million inhabitants (France), the labyrinth which a diagnostic biopsy can follow, accompanied by a series of e-mails between clinicians, pathologists and molecular haematology-oncology specialists is complex, but even more so when the patient is anonymised by a 14-numbered identifier (and there is a risk of mis-copying).</p>
<p>Faculty of Medicine of Ghent University</p> <p>Retrospective observational studies</p>	<p>Since the application of the GDPR (May 2018), researchers and students of Ghent University Hospital have witnessed major problems with performing retrospective observational studies. Until April 2018, medical and biomedical students at the Faculty of Medicine of Ghent University could use electronic health records of patients followed and treated at the hospital (after ethical approval of the study by the IRB of Ghent University Hospital). Since the GDPR, this is not possible anymore unless the patient data are pseudo-anonymised.</p>
<p>Ludwig-Maximilians-Universität München</p> <p>Analysis of leftover dried new born blood samples on filter paper</p>	<p>Data protection considerations prevented a study into metabolic variables in new-borns at Ludwig-Maximilians-Universität München. Metabolic variables during the first 1000 days of life have an important impact not only on early growth and development, but also on the programming of long-term health, well-being and disease risks until old age (developmental origins of adult health and disease). To enable precision preventive strategies, it is important to understand the interaction of genetic and environmental factors in predicting metabolic risk factors. Therefore, researchers planned to analyse genotype, epigenome and metabolome from leftover dried blood samples collected on filter paper from all new born infants after birth. The purpose was to screen for inborn metabolic or endocrine disorders, after completion of diagnostic screening tests and pseudonymisation. However, data protection considerations blocked the use of leftover filter paper blood samples.</p>
<p>Ludwig-Maximilians-Universität München</p> <p>Revisiting participants of a randomised intervention trial</p>	<p>Researchers from Ludwig-Maximilians-Universität München were unable to carry out a study into the risks of a particular intervention used in a randomised intervention trial. Several years ago, a large group of infants participated in a randomised intervention trial. At that time no parental consent was obtained for follow-up of the children after the planned end of the observation period. Recently, indications have arisen from experimental observations that the intervention used in the trial may have adverse effects on early development with a long-term impact on later health. Therefore, researchers intended to revisit the individuals who had participated in the trial many years ago, to explore the risk of such potential side effects. This would be important for assessing the benefits vs. the risks of this intervention. However, due to data protection considerations, no permission was provided to contact the participating families and the study could not be completed.</p>



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<p>Ludwig-Maximilians-Universität München –</p> <p>Exchange of bio samples for medical and research purposes</p>	<p>Researchers from Ludwig-Maximilians-Universität München also emphasise that the exchange of bio samples for medical and research purposes is hindered by the GDPR. While in the treaty of Prüm the exchange of DNA for forensic purposes has been allowed, the exchange of bio samples for medical and research purposes is restricted to the limits of Article 9(2). This provision states that the processing of personal health data must be on the basis of Union law or Member State law, which shall provide for suitable and specific measures to safeguard the data subject's legitimate interests, and processing should be necessary for carrying out obligations or protecting the interests of the subject. In practice, this strongly hampers epidemiological and original research across borders. The university argues that regulations for the distribution of data and biomaterial for medical research across all EU countries should be harmonised to facilitate the transfer of health data across borders for research purposes.</p>
<p>European Society of Anaesthesiology</p> <p>Multinational interventional trial</p>	<p>The ESA Research department is involved in clinical trial set-ups in different countries along Europe and considers GDPR implementation to be fragmented time-consuming. An example of a study where the ESA is involved is the Phoenix study: a prospective, randomised, controlled, double-blind, multi-centre, multinational study on the safety and efficacy of 6% Hydroxyethyl starch (HES) solution versus an electrolyte solution in patients undergoing elective abdominal surgery. ESA Argues that while on one hand, Europe is promoting harmonisation in the execution of clinical trials, the GDPR implementation currently has the opposite effect. Many different countries have understood and implemented the legislation in different ways, thus making it time consuming for ESA to implement the rules in each separate country accordingly and leading to longer start up times for clinical trials.</p>
<p>European Society of Anaesthesiology</p> <p>MET: REevaluation for Perioperative cArdiac Risk (MET-REPAIR) a European, Prospective, observational, multi-centre cohort study".</p>	<p>According to ESA, the consequences of GDPR implementation for observational clinical trials have been severe. They describe that observational clinical trials such as MET-REPAIR are often conducted by volunteers. The different interpretations on a hospital to hospital basis (not even per country) of GDPR provisions have caused confusion and may lead to less clinical research in certain areas.</p>