

Proposals for data protection regulation endanger research in the European Union

Professor Frans Van de Werf, Chair of the ESC European Affairs Committee, explains why the European Society of Cardiology (ESC) is concerned with the European Union legislation in the making and how it has engaged alongside other health and research stakeholders to encourage a favourable outcome



Personal data protection is more than ever a burning topic on the European Union (EU) scene as the legislative process that will lead to the European General Data Protection Regulation (GDPR) reaches its final stages. Decisions by EU policy-makers aimed at preserving people's privacy could seriously affect all businesses processing data. For our health and scientific community, the use of individual patient records for research purposes could become impossible.

The EU framework on personal data protection dates back to 1995, way ahead of the digital era. Under Directive 95/46/EC, health data could be processed without a specific consent when justified by important reasons of public interest such as public health and social protection. The prohibition to process personal data concerning health was also waived 'where processing of the data is required for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health-care services, and where those data are processed by a health professional subject under national law or rules established by national competent bodies to the obligation of professional secrecy or by another person also subject to an equivalent obligation of secrecy' (Directive 95/46/EC Art 8.3).

To fill the anachronistic gap, 3 years ago, in January 2012, the European Commission proposed to review the rules for the processing and free movement of personal data so that existing rules are adapted to modern technologies and people's rights are strengthened both on and offline. The European Commission proposal set out specific conditions for the processing of personal data for scientific research purposes. In particular, although it required a specific and explicit consent for the use and storage of personal data, it also obliged Member States to ensure specific safeguards for processing data for health purposes, provided strong ethical and governance safeguards were met. These provisions were widely supported by health stakeholders, including the ESC, as they allowed reconciling the needs of scientific research with individuals' privacy protection.

As the legislative process progressed, there has been a call for even stricter requirements. In particular, amendments put forward by the European Parliament, which reviewed the European Commission draft text in March 2014, suggested making it mandatory for researchers to obtain specific consent by data subjects—unless the research is serving a 'high public interest'—for the use, re-use, and storage of

personal data (such as individual patient records) even when data are anonymized and/or pseudonymized. This is of course unacceptable. As indicated in the ESC position paper and in the statement of the Alliance for Biomedical Research in Europe (BioMed Alliance), of which the ESC is a founding member and holder of the current Presidency, such provisions would penalize health and scientific research in Europe by imposing more administrative work, leading to higher costs and longer delays. What is worse, the work pursued through cohort studies, biobanks, and disease registries could become unmanageable.

The stakes are high: health research is the key to identifying causes of disease and developing strategies for health promotion and prevention, as well as diagnosis and treatment—it helps to save lives. Scientific research is also a key driver for innovation, economic growth, and social well-being.

On 15 June 2015, a deal reached by Ministers in the Council of the European Union, which reviews and approves legislation together with the European Parliament, marked positive progress for medical research. Above all, it granted research important derogations for the further processing and storage of personal data and it allows using personal data in research where the necessary safeguards are in place to protect individuals.

The cardiovascular community represented by the ESC is widely mobilized to ensure a positive outcome for health and scientific research within the framework of the EU negotiations on data protection. The ESC leadership has already raised its concerns in face-to-face meetings with the EU Commissioner for Health and Food Safety, Dr Vytenis Andriukaitis, and with the EU Commissioner for Research, Science and Innovation, Dr Carlos Moedas. Thanks to the valuable cooperation with the EU National Cardiac Societies, the position of the cardiology profession has also successfully been voiced to National Ministers of Health and of Research. Meetings with relevant policy-makers have already been scheduled also through the BioMed Alliance in the coming months.

Overall, EU politicians and civil servants have proved to be well aware and quite receptive to the researchers' community concerns. Nonetheless, further changes might be introduced during the tri-party negotiations that started in June 2015 between the European Commission, the European Parliament, and the Council of Ministers and before the final deal is sealed (most likely in 2016). The ESC

European Affairs activities are thus not only timely, but essential to secure momentum and ultimately ensure a policy environment favourable to cardiovascular research in Europe.

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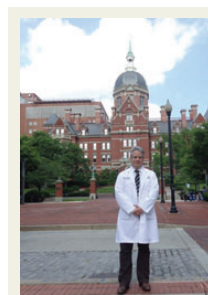
Molecular imaging: the ultimate success story of a 'golden' career?

Trained as an internist, with a distinguished research career in cardiac nuclear medicine, Dr Thomas H. Schindler, Johns Hopkins University, Baltimore, USA, is exploring whether PET imaging of key myocardial receptors can enable physicians to prescribe personalized medicine for their patients, reports Barry Shurlock PhD

One of the lessons of the last decades of the 20th century was that much of the previously inalienable turf of cardiac surgeons could be covered by physicians and radiologists manipulating devices at the end of catheters. Interventional cardiology has unquestionably revolutionized the treatment of cardiovascular disease. Now, watching and waiting in the wings is another aspiring procedure in the hands

of nuclear medicine specialists that could shrink the horizon of the physician.

This is molecular imaging, the concept that mapping key receptors on the myocardium enables prescription of optimal therapy, based on current understanding of the mechanisms of action of cardiovascular drugs. This is the Holy Grail being pursued in the Johns



Thomas Schindler with Johns Hopkins Hospital Dome