Avicenna Alliance
Association for Predictive Medicine

Avicenna Alliance

Impact of the General Data Protection Regulation (GDPR) and Clinical Trials Regulation (CTR) on Scientific Research

Introduction

This briefing paper was drafted to provide Avicenna and VPH Members with an overview of the current legislative developments affecting the framework for conducting scientific research in the European Union. It covers two essential legislative documents, the General Data Protection Regulation (GDPR) and the Clinical Trials Regulation (CTR). Through the efforts of VPH and its partners' since 2012, the European institutions adopting these legislations have agreed that they should contain provisions ensuring the future of scientific research. This brief will explain these provisions and their implications, and provide the next steps needed to translate these successes into tangible results for the research community.

The General Data Protection Regulation (GDPR) is the essential legislation in the European Union protecting citizens' fundamental rights to privacy and protection of their personal data. Personal data means any information relating to an identified or identifiable natural person. On 15 December 2015, the European Parliament, the Council of the European Union (the Council of the EU) and the Commission reached agreement on the new data protection rules. On 8 April, the Council formally adopted its position at first reading.i This paves the way for the final adoption of the legislative package by the European Parliament on 14 April 2016. VPH together with key stakeholders, with the support of Rohde Public Policy, has been actively engaged with the process and have been advocating to support health research. Through VPH allies, close contact was maintained with the Rapporteur and the Shadow Rapporteur throughout the process and the concerns of the research community were represented. These engagements included promoting the concept of "one-time consent" and a derogation for population-based disease registries from consent. The Council of the EU and the European Parliament have agreed with these proposed concepts and have included them in the Regulation.

The Clinical Trials Regulation (CTR), adopted in 2014, is the European Union legislation covering the conduct of clinical trials. VPH has worked to ensure that in the context of prospective research, provisions are adopted by the legislators, the European Parliament and the Council of the EU, that allow scientific researchers the opportunity to make the most of data thus collected. The Regulation provides that universities and other research institutions are allowed to collect data from clinical trials and use it for future scientific research, based on the patient's consent.

At the end of these four years of sustained efforts, and based on the success fostered so far, it is essential that implementation at national level is consistent and it ensures that these results are translated into tangible benefits for health researchers.

I. Review of the General Data Protection Regulation and the Clinical Trials Regulation

1. Background

The European Commission, European Parliament and the Council of the EU have been working on a new legislative text on Data Protection – a Data Protection Regulation, which would replace the 1995 Directive on Data Protection. The European Commission published the proposal in 2012, and the European Parliament adopted its position in late 2013.The Council of the EU agreed their General Approach in the spring of 2015.

On 15 December 2015 the negotiations between the European Parliament, the Council of the EU and the Commission were successfully concluded. The compromise text was brought before the Civil Liberties, Justice and Home Affairs Committee of the European Parliament which adopted the compromises made by their representatives. The Presidency of the Council of the EU also presented the document to the other Member States on 16 December which was met by a majority of approval. After the Council adopted formally its position on 8 April, all members of the European Parliament voted on the text in plenary on 14 April 2016 without amendments and thus finalising the adoption of the General Data Protection Regulation (GDPR). This completes the legislative phase of this crucial Regulation. Implementation is foreseen to take place in the next two years, prior to entry into force in June 2018.

On 16 April 2014 the new Regulation on Clinical Trials (CTR) was adopted. Clinical trials are investigations in humans intended to discover or verify the effects of one or more investigational medicinal products. Provisions on the conduct of the clinical trials in the EU had been previously included in the Clinical Trials Directive from 2001. The CTR aims to create an environment that is favourable for conducting clinical trials, with standards of patient safety, for all EU Member States. The Regulation entered into force on 16 June 2014, however it will not become applicable until October 2018. Until the CTR becomes applicable, all clinical trials performed in the EU are required to be conducted in accordance with the Clinical Trials Directive. The Directive will be repealed on the day of entry into application of the new legislation. It will however still apply three years from that date to clinical trials applications submitted before the entry into force and clinical trials applications submitted within one year after the entry into force if the sponsor opts for the old system.[ii]

2. Relevant concepts of the GDPR

a) One-time consent for retrospective research (Recital 133)

The final text of the General Data Protection Regulation promotes the concept of "one-time consent", allowing retrospective research to be carried out on already collected data. Policy makers understood the concerns faced by the research community and have ensured that pan-European research remains possible. Keeping in mind the 28 different legislative systems, each containing its own laws and safeguards, they aimed to allow enough flexibility within the Regulation text itself whilst at the same time providing a common interpretation of the text.[iii]
The document balances the rights of data subjects with the understanding that future scientific purposes are not always known. Hence, it gives Member States the ability to promote health research while ensuring safeguards for data subjects.
Furthermore, personal data that is further processed for scientific purposes is not considered incompatible with the initial purposes of that data collection. This means that data subjects have the ability to submit a one-time, withdrawable, consent that allows the use of their data to a wide range of scientific studies.
In addition, the text referencesiv the Clinical Trials Regulation by stipulating that "For the purpose of consenting to the participation in scientific research activities in clinical trials the relevant provisions of Regulation (EU) No 536/2014 of the European Parliament and of the Council should apply." The Clinical Trials Regulation specifically names the concept of one-time consent in Recital 29 and in Article 28(2). Through these provisions, both retrospective and prospective research is enabled to use one-time consent. This ensures that the right of patients to the protection of their personal data is guaranteed, whilst allowing valuable health research to be carried out without overburdening researchers, particularly hospital and university researchers.

b) No consent for population based disease registries (Recital 157)

The Council of the EU and the European Parliament have also recognised the importance of registries and included in the final text the clarification of allowing a derogation from consent for the purposes of population based disease registries.[v]
By emphasising the conditions and safeguards laid down in Union and Member State law, the text excludes consent as an essential requirement for inclusion of data into population based disease registries. In addition, the final text removes the specific reference to no consent for further processing for scientific purposes of registry data. This removal is because no consent for further processing for scientific purposes is included in Recital 54 which states that "The processing of special categories of personal data may be necessary for reasons of public interest in the areas of public health without consent of the data subject". Thus, the legislators agree that in cases of public interest, which they have defined as including public health activities such as registries, consent is not required from the data subject. Further processing of this scientific data for the purposes for which it has been collected will not require a subsequent consent from the data subject. In the context of registries, where no consent is required for collection, this means the data can be processed subject to conditions and safeguards without the consent of the data subject.

c) Other relevant provisions

i. Derogation from consent for scientific purposes

The text allows a derogation from consent for the processing of personal data for the purposes of scientific research[vi] based on Union or Member State law. In practice, this translates into the continuation of practices regarding consent at Member States' levels, with countries that did not require any consent at the moment being allowed to continue. When read in conjunction with the provisions on one-time consent it means that, at a minimum, re-consenting for each subsequent use of the data can no longer be interpreted as a requirement. Countries with a restrictive outlook, now have a legal basis to allow one-time consent, in full respect of the European legislation.

ii. Derogations for research

Further derogations for research have been introduced in the final text of the Regulation. These are:

- allowing longer storage periods for research – *Article 5(1e)*
- removing the need to notify data subjects about processing where someone else had collected the data initially – *Article 14 (5b)*
- removing the right to be forgotten – *Article 17 (3d)*
- the ability for Member States to create further derogations from data subject, where necessary, and subject to further safeguards.

iii. Use of pseudonymisation

Provisions included in the Regulation recommend the use of pseudonymisation as a means of reducing the risk for sensitive personal data, such as those regarding health. Appropriate technical and organisational safeguards are requested, so that every precaution is taken to minimize breaches and other similar risks. The Regulation however recognises that the use of pseudonymisation is not feasible for every type of data, and mandates that it should not be used where the research purposes cannot be achieved through the use of pseudonymised data.

3. Relevant concepts of the Clinical Trials Regulation (CTR)

The CTR was published in the Official Journal of the European Union on 27 May 2014. It will streamline the authorisation process and harmonise requirements for clinical trials of medicines in Europe while maintaining safety for participants.

a. Clinical trials data for future scientific research

The legislators recognised that research institutions and universities should be able to collect data from clinical trials and use it for future scientific research (e.g. medical research or natural or social sciences research). It is necessary that the subject gives consent to use his or her data outside the scope of the clinical trial and has the right to withdraw it at any time. In this sense, the GDPR is in full coordination with the CTR.[vii]

In cases where the subject is not able to give informed consent, the Regulation envisages the option for a legally designated representative to give his/her informed consent to

participate in the clinical trials and to use the data of the person that they are representing outside the protocol of the clinical trial exclusively for scientific purposes. This consent can be withdrawn at any time.[viii]

II. The Adjustment Process

1. The General Data Protection Regulation

In March 2016, the Council of the EU published a draft statement regarding its position at first reading with respect to the adoption of the GDPR. In this statement, the Council of the EU confirms that its position at first reading reflects the compromise reached in December 2015.[ix]

The GDPR was published in the Official Journal on 04 May 2016 and can be found here. The GDPR will enter into force on 24 May 2016. The implementation of the Regulation will take place over the coming two years with adjustments to national legislation and Commission implementing and delegated decisions. During this time, national authorities will take the necessary steps in terms of national decrees and orders to guarantee the application of the legislative text. **The Regulation will thus be applicable at the earliest in June 2018.**

2. The Clinical Trials Regulation

The CTR was published in the Official Journal of the European Union on 27 May 2014. Currently, national authorities are taking measures to facilitate the application of the Regulation. As prescribed by the EU legislator, Member States have at least two years for this process. When the Regulation becomes applicable it will replace the existing Clinical Trails Directive and national legislation that was put in place to implement the Directive. Additionally, as an EU Regulation rather than an EU Directive, the CTR will automatically apply to all Member States.

An essential component of implementing the new arrangements set out in the CTR will be the dedicated IT infrastructure – the EU portal and EU database, which the EMA must set up and maintain. This will give option for access to extensive details of each trials. Therefore, the timing of the application of the Regulation has been made dependent on the EU portal and EU database being confirmed as fully functional through an independent audit.[x]

The EMA has published the functional specification for the EU portal and EU database in December 2015. As a result, the institution plans to have the EU portal and EU database available for the independent audit by August 2017. Once the independent audit completed in November 2017, the European Commission will publish a notice in the Official Journal of the European Union. Six months after the publication of the Commission's notice the CTR will be applicable.[xi] **It is expected that the CTR will become applicable in October 2018.**[xii]

III. Timeline and Next Steps

GDPR

- 8 April – the Council adopted its position on the GDPR;
- 11-13 April – the European Parliament will acknowledge the position of the Council;
- Week of 11 April – LIBE committee voted through a recommendation to Parliament regarding acceptance of the Council position;
- 14 April – European Parliament votes through the GDPR;
- 04 May 2016 - the GDPR was published in the Official Journal of the European Union;
- 24 May – the GDPR will enter into force;
- June 2016 – June 2018 – Implementing by European Commission and EU Member States;
- June 2018 – The GDPR will be fully applicable at the earliest.

Clinical Trials Regulation

- 27 May 2014 – the CTR was published in the Official Journal of the European Union;
- August 2017 – EU portal and EU database, essential for the application of the CTR, will be available for independent audit;
- November 2017 – end of the independent audit;
- October 2018 – CTR envisaged to become applicable.

---

[i] Council of the European Union, Data protection reform: Council adopts position at first reading, available at: http://www.consilium.europa.eu/en/press/press-releases/2016/04/08-data-protection-reform-first-reading/ , consulted on 08.04.2016

[ii] European Commission, *Clinical trials – General information*, available at: http://ec.europa.eu/health/human-use/clinical-trials/information/index_en.htm#ct1, consulted on 30.03.2016

[iii] The Proposal for a Regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation), Recital 33: *"It is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection. Therefore, data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research. Data subjects should have the opportunity to give their consent only to certain areas of research or parts of research projects to the extent allowed by the intended purpose.",* available at: http://statewatch.org/news/2015/dec/eu-council-dp-reg-draft-final-compromise-15039-15.pdf, consulted on 30.03.2016

[iv] Ibid., Recital 161

[v] Ibid., Recital 157 – *"By coupling information from registries, researchers can obtain new knowledge of great value with regard to widespread medical conditions such as cardiovascular disease, cancer, depression. On the basis of registries, research results can be enhanced, as they draw on a larger population. Within social science, research on the basis of registries enables researchers to obtain essential knowledge about long-term correlation of a number of social conditions such as unemployment and education with other life conditions. Research results obtained on the basis of registries provide solid, high quality knowledge which can provide the basis for the formulation and implementation of knowledge-based policy, improve the quality of life for a number of people and improve the efficiency of social services. In*

order to facilitate scientific research, personal data can be processed for scientific research purposes, subject to appropriate conditions and safeguards set out in Member State or Union law"

[vi] Ibid., Article 9 (2i)

[vii] Recital 29 of the Clinical Trials Regulations states*: "It is appropriate that universities and other research institutions, under certain circumstances that are in accordance with the applicable law on data protection, be able to collect data from clinical trials to be used for future scientific research, for example for medical, natural or social sciences research purposes. In order to collect data for such purposes it is necessary that the subject gives consent to use his or her data outside the protocol of the clinical trial and has the right to withdraw that consent at any time. It is also necessary that research projects based on such data be made subject to reviews that are appropriate for research on human data, for example on ethical aspects, before being conducted.",* available at: http://ec.europa.eu/health/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf, consulted on 30.03.2016

[viii] Ibid., Chapter V, Article 28, par.2: "Without prejudice to Directive on data protection, the sponsor may ask subject or, where the subject is not able to give informed consent, his or her legally designated representative at the time when the subject or the legally designated representative gives his or her informed consent to participate in the clinical trial to consent to the use of his or her data outside the protocol of the clinical trial exclusively for scientific purposes. That consent may be withdrawn at any time by the subject or his or her legally designated representative."

[ix] Position of the Council at first reading with a view to the adoption of a Regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and of the free movement of such data, available at: https://www.huntonprivacyblog.com/files/2016/03/ST_5419_2016_ADD_1_EN.pdf, consulted on 30.03.2016

[x] Op. cit., Clinical Trials Regulation, Article 82 and 99

[xi] Ibid., Article 99

[xii] European Medicines Agency, Delivery time frame for the EU portal and EU database, available at: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2015/12/WC500199078.pdf , consulted on 30.03.2016