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EORTC comments to three guidelines issued by the Article 29 Data Protection Working Party in relation to the implementation of the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 (General Data Protection Regulation)

EORTC

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Table of Contents

1 Executive summary

The executive summary contains the main suggestions of EORTC. Section 3 contains more detailed suggestions.

- Guidelines for identifying lead supervisory authority
  - EORTC suggests adding a clear statement that the sponsor of a clinical trial is the clinical trial data controller as a third example on page 6.
  - EORTC suggests including an example on how to identify the lead authority in case of co-sponsorship of clinical trial (either in the text of the guideline or in the annexes): "the data protection authority of the country of the main establishment of the sponsor being a contact point for receiving all questions regarding the clinical trial from subjects, investigators or any Member State concerned, shall be the lead authority for the purpose of GDPR".
- Guidelines on Data Protection Officers
  - EORTC suggests clarifying if the processing on a large scale of special categories of pseudo-anonymised data requires a mandatory designation of a DPO. EORTC suggests that this aspect (pseudo-anonymisation) is also taken into account in the future guideline of data protection impact assessments ("DPIAs") and clarifications to the notion of "high risk".
  - EORTC suggests adding a clarification that DPO is not required to directly communicate with data subjects in case of working with pseudo-anonymised data.
  - EORTC suggest clarifying that the fact that DPIA is the task of data controller does not prohibit a DPO from performing or coordinating a DPIA: "It should be possible that a DPIA is conducted or coordinated by a DPO or by another person in the organization or a third party; when DPIA is not performed nor coordinated by DPO, its advice shall be requested.
- Guidelines on the right to data portability
  - EORTC suggests clarifying on the EU level how the right to data portability applies in the scope of controllers who process only the pseudo-anonymised data.
  - EORTC would suggest that as the right to data portability already applies to patient medical file, sponsors of clinical trials and, so controllers of clinical pseudo-anonymised data base are released from the obligation to release the data in the scope of data portability right.
  - EORTC suggest clarifying on the distinction between "provided by virtue" or "inferred and derived" data by providing few examples relevant to the field of clinical research would be welcome.

2 Relevance & legal basis

The European Organisation for the Research and Treatment of Cancer ("EORTC") is a unique organization in Europe that brings together European cancer clinical research experts from all disciplines for trans-national collaboration. EORTC core business is clinical research (for more background on EORTC, please see chapter 4).

EORTC comments and suggestions focus on issues relevant to clinical research. Though EORTC acknowledges that the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) ("GDPR") is a general regulation, it however has specific modalities and recommendations in relation to the specific area of scientific research. Therefore, we believe it would make sense to take into account specific aspects relevant to this particular area.

Moreover, despite the fact that in the field of scientific research and with regard to the processing of genetic data, biometric data or data concerning health, Member States may introduce additional derogations, EORTC strongly recommends to provide as much guidance as possible on the EU level in order to limit divergences. Indeed, divergences in the area of international clinical research would heavily jeopardise EU capacity for innovation and its attractiveness for research.

Last, but not the least, recital 156 of the GDPR states that "The processing of personal data for scientific purposes should also comply with other relevant legislation such as on clinical trials". As of 2018 the relevant legislation on clinical trials will be the Regulation (EU) No 536/2014 of the

European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC ("CTR"). Therefore, clarifications about the implementation of the GDPR in the specific scope of projects under CTR shall be formulated as much as possible on the EU level.

Consequently, EORTC invites the Article 29 data protection working party to support the harmonization of the implementation of GDPR in the area of clinical research by specifically and systematically considering clinical research in its guidelines and opinions.

3 Comments

3.1 Guidelines for identifying a controller or processor's lead supervisory authority

EORTC comments are provided in the table below.

Ref.	Observation	Suggestion
p.4.A & Annex II p. 1	Clinical trials, including international, are run most of the time with pseudo-anonymised data. Therefore, it is not clear if processing of pseudo-anonymised data in the scope of international clinical trial would be considered as substantially affecting data subjects. Clinical trials may use large amount of sensible data from different Member States, but transferred in a pseudo-anonymised form. EORTC understands different Member States may consider differently the pseudo-anonymisation in the scope of national implementations measures foreseen by the art.89 of the CTR, which would largely complicate the interpretation of the applicability of the consistency mechanism.	EORTC suggests clarifying if processing of pseudo-anonymised data in the scope of international clinical trials is still considered as substantially affecting data subjects since there is no direct link with the data subjects.
P.5 A 1. & Annex I	This chapter assumes that it is always obvious which organisation is a controller; it also considers there is only one controller. However, there is a need to clarify the relationship that exists between the sponsors, as defined in the art. 2.2.14 of the CTR 536/2016, and data controller in the scope of a clinical trial. Though most agree that it is obvious for the sponsor to be the data controller, there is currently no clear consensus on the question whether the sponsor of a clinical trial conducted in several EU Member States shall be considered as the data controller. Currently, at least Portugal seems to consider hospitals are data controllers, but not the sponsor directly. If such a discrepancy in interpretations remains in the scope of international clinical trial, the application of the GDPR will become overly complex. Last, but not the least, clinical trial sponsors being the controller of the clinical trial database, shall not modify the responsibilities for the patient medical file; indeed, controller of the patient medical file shall be the hospital and/or the doctor.	EORTC suggests adding a clear statement that the sponsor of a clinical trial is the clinical trial data controller as a third example on page 6. However, hospitals remain data controller over the medical files from their visiting patients, for the decisions on purposes and means of processing taken by them. Similarly, EORTC suggests adding the following type of wording in Annex I, page 11: "Which organisation is the data controller? For the sake of clarity, the sponsor of a clinical trial or its EU legal representative shall be considered as data controller of the clinical trial database; hospitals and doctors remain the controller of the patient medical file."
p.5 A 1.	It is possible as per art. 72 of CTR 536/2016 that a trial has more than one sponsor and is run as co-sponsorship. The CTR stipulates that one shall appoint "a sponsor responsible for being a contact point for receiving all questions from subjects, investigators or any Member State concerned regarding the clinical trial and providing answers to them" (art 72 §1.b of	EORTC suggests including an example on how to identify the lead authority in case of co-sponsorship of clinical trial (either in the text of the guideline or in the annexes): "the data protection authority of the country of the main establishment of the sponsor being a

	CTR). EORTC believes current guidance does not provide a clear view on how such situations shall be considered.	contact point for receiving all questions regarding the clinical trial from subjects, investigators or any Member State concerned, shall be the lead authority for the purpose of GDPR".

3.2 Guidelines on Data Protection Officers ("DPOs")

EORTC comments are provided in the table below.

Ref.	Observation	Suggestion
P5.2.1.	Art. 37.1 (c) of the GDPR suggests mandatory designation of a DPO "where the core activities of the controller or the processor consist of processing on a large scale of special categories of data [...]." This consideration does not take into account the use of pseudo-anonymised data. EORTC understands different Member States may consider differently the pseudo-anonymisation in the scope of national implementations measures foreseen by art.89 of the GDPR. Controllers shall comply with rules set by their supervisory data protection authority. If some countries do not mandate DPO in case of pseudo-anonymised data, but others do, collaboration between controllers and processors from these respective countries may be rendered complicated or even not possible. Moreover, in case of claims, the concerned authority from a Member State that requires a DPO may not find the adequate way of communication with the data controller from a Member State which does not require a DPO [...].	EORTC suggests clarifying if the processing on a large scale of special categories of pseudo-anonymised data requires a mandatory designation of a DPO. EORTC suggests that this aspect (pseudo-anonymisation) is also taken into account in the future guideline of data protection impact assessments ("DPIAs") and clarifications to the notion of "high risk".
p.8 2.1.3.	Examples provided on the page 8 about what does or does not constitute a large scale processing do not include any case using pseudo-anonymised data, nor clinical trials.	EORTC suggests adding an example of processing of pseudo-anonymised sensible data in the scope of a clinical trial.
p.10. 2.3 & throughout the document	It is mentioned several times that DPO shall be accessible to data subjects. However, when a DPO is required for organizations processing only pseudo-anonymised data, DPO cannot communicate with data subjects, considering that their identity is not supposed to be known and re-identification exposes data subjects to higher risks.	EORTC suggests adding a clarification that DPO is not required to directly communicate with data subjects in case of working with pseudo-anonymised data.
p.10. 2.4	This section does not clarify whether DPO skills and expertise need any certification. Different service providers offer DPO training and certification. Though the regulation itself does not require such a certification, any clear statement with this regard would be welcome to help controllers and DPOs to evaluate the value of such certifications.	EORTC suggests adding considerations about DPO & relevance of certification of its skills and expertise in the scope of GDPR.
p.11 professional qualities	The guidance states: "Knowledge of the business sector and of the organisation of the controller is useful." EORTC believes that there are sectors of activity that are very specific and technical, such as clinical research. In this context, a DPO must have at least some knowledge of the sector as otherwise important aspects may be overlooked.	EORTC suggest changing this phrase to: "Knowledge of the business sector and of the organisation of the controller is useful, unless for highly specialized areas, where more specific expertise may be required".
p.16 4.1& section 4 of FAQs	EORTC could not find any reference to the possibility to adapt monitoring performed by DPO to the risks different types of processing may represent.	EORTC suggests clarifying that monitoring compliance with the GDPR is also "risk based" – more sensitive processing shall be watched closer as

		compared to less sensible data.
p.16 4.2	This section suggests that DPO shall not perform a DPIA. However, in the regulation we do not see any obstacle for DPIA at least to be coordinated by DPO.	EORTC suggest clarifying that the fact that DPIA is the task of data controller does not prohibit a DPO from performing or coordinating a DPIA: "It should be possible that a DPIA is conducted or coordinated by a DPO or by another person in the organization or a third party; when DPIA is not performed nor coordinated by DPO, its advice shall be requested.

3.3 Guidelines on the right to data portability

3.3.1 Background and observations

The guideline states: "Pursuant to Article 20(1), to be within the scope of the right to data portability, data must be:
- personal data concerning him or her, and
- which he or she has provided to a data controller";

EORTC, as sponsor of clinical trials never receives data directly from data subjects, but from doctors in hospitals (though patients sign consent to the fact that data will be provided to EORTC). It is not clear in this scope if data are to be considered as "directly provided", specifically that EORTC receives them in a pseudo-anonymised form, so not able to identify patients.

The key to patient identification is detained by doctors, not even by patients themselves. Shall patients be made aware of their clinical trials number, clinical trial sponsors have no possibility to authentify an individual that would request a copy of the data (as patient may have shared this number with other persons or simply be mistaken in a digit). Any attempt to put in place a process of authentication would require collection of several other direct identifiers and therefore would put patients under a greater risk of accidental de-identification. Moreover, large proportions of data about data subject are generated by doctors and hospitals (e.i. blood test results) and are not directly provided by patients. Last, but not the least, some test may be performed at a central laboratory; outside hospital premises. Part of results of these tests would be returned to the hospitals and become part of the patient medical file (as those are usually clinically relevant tests); results of other, experimental tests, would usually not be communicated back, given their unverified validity and/or clinical relevance.

Besides the fact that working with pseudo-anonymised data prevents controllers from the capacity to directly identify the data subject and to effectively release relevant data to the right data subject, EORTC considers that, in case the data controller would need to re-identify data subjects or to implement an authentication procedure, he would have to process additional personal data to identify the data subject. This would create an additional risk to the protection of the personal data of the patient.

In this particular situation it shall be reasonable to accept, under condition that all clinically relevant data are made part of the patient medical file (which the hospital is the controller of as opposed to the clinical trial data base) that sponsors of clinical trials are exempted from the obligation to make data available to data subjects directly.

Further while data "provided by the data subject by virtue" fall clearly within the scope, inferred and derived data are out of the scope of the right to data portability. However, it remains unclear whether certain types of data are considered to be included in the former or the latter category. For instance, genetic data resulting from a validated genetic test used in routine clinical practice, does this consist of "provided by the data subject by virtue"? Furthermore, genetic data resulting from

experimental (not yet fully validated) genetic test with no proves of clinical relevance, does this consider inferred data?

3.3.2 Suggestions

EORTC suggests clarifying on the EU level which data from those available in the scope of clinical research must be included and more largely, how the right to data portability applies in the scope of controllers who process only the pseudo-anonymised data.

EORTC would suggest that as the right to data portability already applies to patient medical file (and to hospitals as controllers of patient data in general), sponsors of clinical trials and, so controllers of clinical pseudo-anonymised data base are released from the obligation to release the data in the scope of data portability right (under the condition that all clinically relevant patient data are indeed made part of the patient medical file).

In case patients move to another hospital or even another country, they will need to refer to the primary hospital having collected their data. Shall the hospital for whatever reasons not have all the relevant data in the patient medical file, the hospital may request additional data from the clinical trial sponsor (in a pseudo-anonymised form as the key is hold by the hospital).

Further, clarification on the distinction between "provided by virtue" or "inferred and derived" data by providing few examples relevant to the field of clinical research would be welcome.

4 EORTC background

The EORTC is a unique organization in Europe that brings together European cancer clinical research experts from all disciplines for trans-national collaboration. Over the last five decades it has demonstrated that such collaboration is successful and has played a vital role in generating some of the most important advances for the treatment of all types of cancer.

One of the greatest strengths of the EORTC lies in enabling doctors to participate in the conduct of independent international clinical and translational cancer research studies. It also brings together a widely-based network upon which doctors can draw in treating patients and, by stimulating the free flow of knowledge and improvements in clinical techniques, the skills of clinicians and hence the quality of cancer care are enhanced.

It is essential to develop new therapeutic strategies for patients with rare tumors, and the EORTC contributes significantly to cancer clinical research by providing studies in rare diseases or rare sub-groups of common tumor types. Trials which answer important questions in these various fields would be less efficient, or even impossible, if they had to be conducted within the population base of a single country. Such studies, however, are feasible within the large European collaborative groups managed by the EORTC. Often these trials are complex, beyond the scope of researchers in a single institution, and for these the EORTC is able to ensure the best protocol development and data collection logistics.

Even though individual cancer centers can align with those in other countries, they are not always aware of the many pitfalls that are faced when dealing with foreign regulations and procedures, another challenge that EORTC can solve efficiently bringing investigational sites together. All EORTC studies are international and designed to meet all regulatory requirements in the countries where they are conducted.

The many EORTC Research Groups which undertake research in specific tumor types or treatments provide a valuable educational role; they run regular conferences at which the latest research is shared. Such an activity increases the exposure of doctors to innovative techniques, and is a unique opportunity for training the next generation of clinical investigators.

The activities of the EORTC complement the research being undertaken in individual countries, and in fact, by opening up European and international networks to doctors, it may address the brain drain currently faced in Europe.

4.1.1 EORTC in figures (January 2017)

- 202 EORTC Staff (employees, fellows, interim workers and consultants)
- pseudo-anonymised data on over 190 000 patients in the research database
- pseudo-anonymised data of over 23 000 patients still being collected and updated
- > 200 active clinical studies
- 53 clinical studies open to patient recruitment
- 138 ongoing research projects
- long history of transparency and sharing of data
- data collected from over 37 countries (via medical staff)
- > 1900 publications with EORTC in the titles and/or with EORTC affiliation

4.1.2 EORTC aims and mission

The aims of the EORTC are to develop, conduct, coordinate, and stimulate translational and clinical research in Europe to improve the management of cancer and related problems by increasing survival but also patient quality of life.

EORTC Headquarters, a unique pan European clinical research infrastructure, is based in Brussels, Belgium, from where its various activities are coordinated and run.

Last but not least, EORTC is actively engaged with EU and national regulators to ensure health and research policies and funding schemes in Europe are developed and implemented in a way that fosters innovation.

4.1.3 EORTCs position in the EU international academic clinical trial landscape

EORTC is presently one of the major players in the arena of large international academic clinical trials in the EU. As compared with data released in 2014 by the European Medicines Association at the Drug Information Association meeting on the number of international non-commercial trials activated in the EU, EORTC conducted a major part of the international clinical research protocols over the period between 2005-2013 with up to 20% of trials conducted in 4 to 9 countries and 42% of trials conducted in 10 or more countries, being EORTC protocols.