EORTC CONTRIBUTION TO THE PUBLIC CONSULTATION CONCERNING EDPB GUIDELINES 01/2022 ON DATA SUBJECT RIGHTS - RIGHT OF ACCESS

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Prepared by EORTC International Affairs and Policies Team

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1. GENERAL COMMENTS

Since 25 May 2018, when the European General Data Protection Regulation (GDPR) entered into force, it became the subject of significant debate among the scientific community, in particular concerning its interplay with the highly heterogeneous legal framework for clinical trials.[1] Lack of harmonisation continues to be one of the biggest hurdles for clinical research.

As an independent, non-profit cancer research organisation, the European Organisation for Research and Treatment of Cancer (EORTC)[2] has been active in sharing its decades of experience in the field. The EORTC has frequently expressed its concerns and proposals for solutions and continues to do so.[3]

The EORTC welcomes the adoption of Guidelines 01/2022 on data subject rights – Right of access (hereafter the Guidelines). The Guidelines play an important role by providing practical and detailed advice on how controllers should address data subjects' requests to exercise the right of access. However, the EORTC is concerned about the lack of examples from the field of scientific research in general, and biomedical research in particular. Due to the high complexity and specificity of the applicable rules in the area of biomedical research, the omission of relevant examples and a targeted discussion in the Guidelines presents a risk for misinterpretations and could foster further legal uncertainty in the field.

[1] See e.g., Evert Ben van Veen, 'Observational health research in Europe: Understanding the General Data Protection Regulation and underlying debate', European Journal of Cancer (104) (2018) 70–80; Jacques Demotes-Mainard et al., 'How the new European data protection regulation affects clinical research and recommendations?', Therapie (74) (2019) 31–42; Marcelo Ienca et al. 'How the General Data Protection Regulation changes the rules for scientific research. Study for the European Parliament Panel for the Future of Science and Technology (STOA)', July 2019, available at: http://www.europarl.europa.eu/thinktank/en/document.html?reference=EPRS_STU(2019)634447

[2] About the EORTC: https://www.eortc.org/our-mission/

[3] See e.g., EORTC contribution to the EMA Discussion Paper for Medicines Developers, Data Providers, Research-Performing and Research-Supporting Infrastructures entitled "The General Data Protection Regulation: Secondary Use of Data for Medicines and Public Health Purposes Discussion Paper for Medicines Developers, Data Providers, Research-Performing and Research-Supporting Infrastructures", 10th July 2020, available at: http://www.eortc.org/app/uploads/2020/09/EMA-_Secondary-use-of-health-data_Discussion-Paper_Stakeholders-consultation.pdf; Anastassia Negrouk and Denis Lacombe, 'Does GDPR harm or benefit research participants? An EORTC point of view', The Lancet Oncology (19) (2018) 1278–1280; Anastassia Negrouk, Denis Lacombe, Françoise Meunier, 'Diverging EU health regulations: The urgent need for co-ordination and convergence', 17 J. CANCER POLICY 24–29 (2018)

2. SPECIFIC COMMENTS

The Guidelines aim to clarify the responsibilities of the controller. In the clinical trials field, the sponsor (i.e., the "individual, company, institution or organisation which takes responsibility for the initiation, for the management and for setting up the financing of the clinical trial", Art. 2(14) of the Clinical Trials Regulation (EU) No 536/2014, hereafter CTR) is typically considered to be the controller as regards the processing of personal data. The investigator (i.e., the "individual responsible for the conduct of a clinical trial at a clinical trial site", Art. 2(15) of the CTR) is the processor[4] (notwithstanding the existing divergencies in national interpretations about the roles of controller and processor in clinical research).

It is of high importance to note that the Guideline for Good Clinical Practice of the International Council of Harmonisation (ICH GCP) establishes that the sponsor receives only pseudonymised (key coded) data concerning study subjects (Principles 1.58 and 5.5.5.), and the identification key rests with the investigator. The sponsor does not have the right to obtain the key code from the investigator and study subjects cannot be directly contacted by the sponsor. All relevant information about the clinical trial (including data protection and privacy notices) is provided to the patient via the investigator (treating physician). The applicable legal and ethical rules thus establish a communication channel with the data subjects (clinical trial subjects) which is patently different than any of the examples included in the Guidelines.

Practically speaking, most data subject requests (related to any right, not only access requests) would be addressed to the investigator, in the course of the normal patient-physician relationship. Afterwards, the investigator would be the one to provide the requested information to the data subject and the investigator would be the one to report to the sponsor about the exercised right, in order for the sponsor to document this. In case the scope of requested information necessitates the assistance of the sponsor (e.g., to share additional analysis), the investigator would be the one to contact the sponsor and would then transmit the additional information back to the patient/data subject, without revealing the identity of the patient to the sponsor (see *Figure 1* below). The sponsor, on the other hand, might also need to contact other involved in the clinical trial parties (such as biobanks, labs) in order to gather all required information.

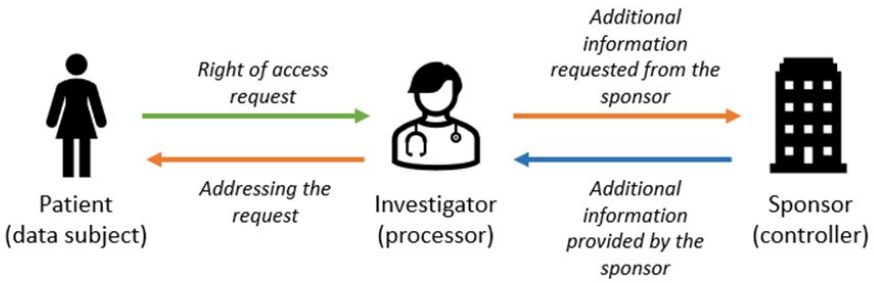

Figure 1. *Typical communication channel to exercise the right of access in the scope of a clinical trial.*

[4] As per the examples discussed in EDPB Guidelines 07/2020 on the concepts of controller and processor in the GDPR, pp. 21-22

Two main challenges and related to these recommendations stem from this:

1. In the field of health research, data subjects' requests largely overlap with patients' rights. Moreover, investigators might not always identify the requests for information as data subject requests and report them to the sponsor (controller). This puts the sponsor in front of a challenge to understand whether he complies with the accountability principle.[5]

Recommendation 1: Therefore, it would be important to clarify the difference between patients' rights requests to investigators (in the curse of the routine patient-physician relationship) and data subjects' requests under the GDPR framework.

2. The Guidelines, as currently drafted, could foster the interpretation that the sponsor (controller) would, in all cases, be obliged to re-identify personal data and to be in direct communication with clinical trial subjects who have exercised their right of access. Such interpretation goes against other applicable legal and ethical rules, as specified above.

Recommendation 2: The Guidelines should contain one or more examples focused on biomedical research. The examples should describe and discuss the specific communication channels and complex relationships typical for biomedical research. It must be clearly stated that sponsors are not obliged to be in direct communication with clinical trial subjects. At least two scenarios need to be discussed in the examples, namely: 1) patient (data subject) request to exercise their right of access by contacting the investigator; 2) patient (data subject) request to exercise their right of access by directly contacting the sponsor. As regards the latter scenario (direct request to sponsor), several questions are currently lacking clear answers, in particular: should the investigator be informed and involved? How can the sponsor validate the identity of data subjects when, per other applicable legal and ethical rules, the sponsor only has access to key-coded data and cannot know the identity of clinical trial participants (the key code rests with the investigators, as specified above).

[5] EORTC pointed to this challenge also in EORTC contribution to the EMA Discussion Paper for Medicines Developers, Data Providers, Research-Performing and Research-Supporting Infrastructures entitled "The General Data Protection Regulation: Secondary Use of Data for Medicines and Public Health Purposes Discussion Paper for Medicines Developers, Data Providers, Research-Performing and Research-Supporting Infrastructures", 10th July 2020, available at: http://www.eortc.org/app/uploads/2020/09/EMA-_Secondary-use-of-health-data_Discussion-Paper_Stakeholders-consultation.pdf