EORTC
European Organisation for Research and Treatment of Cancer
The future of cancer therapy

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EORTC CONTRIBUTION

RECOMMENDATIONS 01/2020 ON MEASURES THAT SUPPLEMENT TRANSFER TOOLS TO ENSURE COMPLIANCE WITH THE EU LEVEL OF PROTECTION OF PERSONAL DATA

(ADOPTED ON 10 NOVEMBER 2020)

Prepared by EORTC Privacy team

21st December 2020

1. GENERAL COMMENTS

Since the European General Data Protection Regulation (GDPR) entered into force on 25 May 2018, 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. This issue has been especially challenging for the EU and non-EU stakeholders involved in conducting health research (sponsors, academic universities, investigators).

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 experience in the field for decades. The EORTC has frequently expressed its concerns and proposals for solutions, and continues to do so.[3]

[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] 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)

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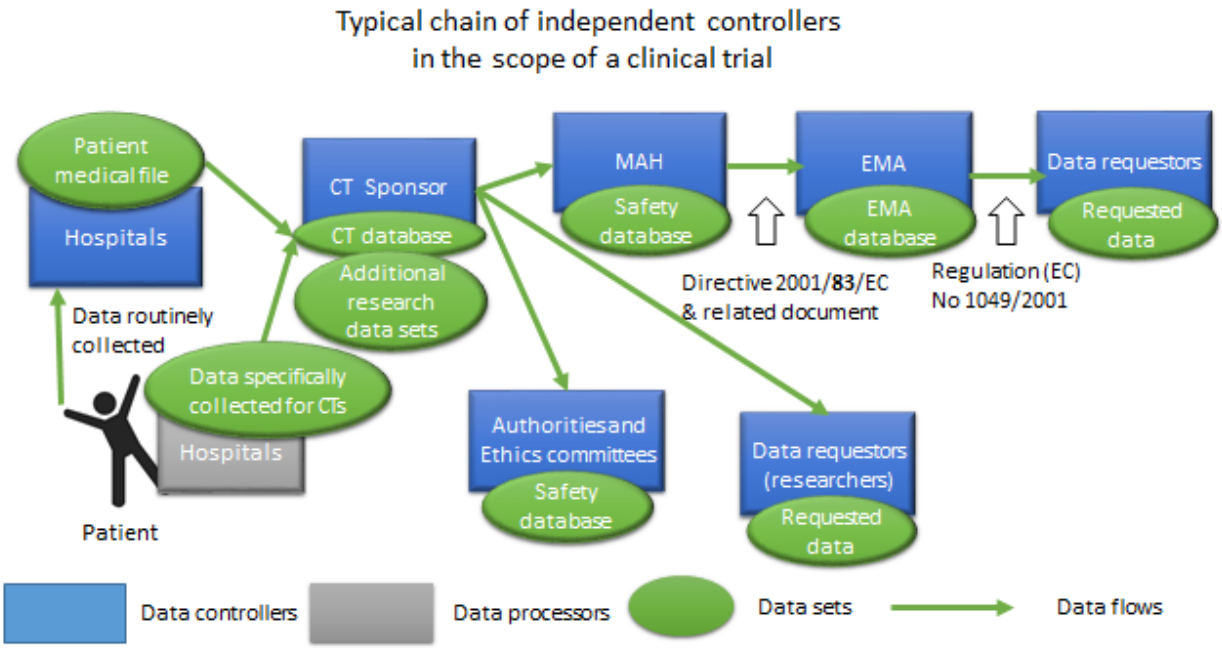
The EORTC welcomes the adoption of RECOMMENDATIONS 01/2020 on MEASURES THAT SUPPLEMENT TRANSFER TOOLS TO ENSURE COMPLIANCE WITH THE EU LEVEL OF PROTECTION OF PERSONAL DATA (hereafter the Recommendations). The Recommendations play an important role in dispelling legal uncertainty concerning the additional safeguards that the updated "Commission implementing decision EU on Standard Contractual Clauses for transfer of personal data to 3rd countries pursuant to GDPR"(paragraph 4 of the draft 12/11/2020).

2. SPECIFIC COMMENTS AND SUGGESTIONS

The RECOMMENDATIONS carefully outline that the Exporter needs to ensure that the "data transferred is afforded in the 3rd country of a level of protection essentially equivalent to that guaranteed in the EU". Or that the Exporter needs "to compensate for any lack of data protection". We believe that this is a very general approach, that definitely needs to be better explained/detailed by the EDPB and also should be considered from the perspective of sector specific laws, to which Exporter is subjected as well, not necessarily incompatible, but very challenging/ problematic to put on hold or interrupt transfers with short deadlines or even from a day to another.

It is very common that scientific research and processing of personal data in this scope is conducted during many years, as most of cases in clinical trials. During such a long period of time, it is normal that privacy laws and recommendations are updated to align with the new technologies. However, stakeholders in this field do not always have choices or alternatives in the EU, and, hence, rely on the collaborations outside. Interrupting the research initiatives and the associated processing activities such international transfers from a day to another are simply not compatible with the other



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obligations to which exporter is subjected, such as maintenance of data integrity and accuracy, performance of the research as planned presented already to the patient, and which usually occurs years after the data were collected. The most relevant example are Pharmaceutical companies based outside the EU and which need to receive from the academic study sponsor based in the EU safety data (patient data) for their own compliance with the law of the 3rd country (becoming controller on their own). On the other hand, the drug-providing company provides the drug and is usually also processor for other study related activities. Hence, the transfer mechanism will need to contain at least two sets of EU SCC (C-C, C-P) which complicates any study set-up in this context and will also need to have several types of additional measures, as recommended in the RECOMMENDATIONS.

The invalidated transfer mechanism, such as Privacy Shield, or the adoption of a new set of the EU SCC has already become a hurdle for many organisations. Third countries entities, especially in the context of cross-border EU-US scientific collaboration, still need time and resources to assess if it is acceptable for them to sign or to comply with the new requirements.

Important to note that the standard contractual clauses are not viable when the recipient entity is an arm of the US government, such as the US National Institutes of Health (NIH) or public universities or academic medical centres, because the US government cannot agree to certain terms in the standard contractual clauses including dispute resolution in European courts, and US state entities (including state universities and public hospitals) often similarly cannot agree to certain terms due to restrictions in their state or local laws. Given the large amount of international biobank research, including research occurring in the EU, that is funded by the US NIH or that involves US public universities or academic medical centres, the inability to rely upon the standard contractual clauses has proved a major obstacle to much scientific research.[4]

Additionally, we would like to highlight the fact that most of clouds and SAASs involve at least some processing activities (i.e. resolution of bugs or security issues in relation to personal data hosted) being performed outside the EU, which in our understanding constitutes a transfer (mostly to the US). So, it is almost impossible not to have any transfer in third country and IT-wise, 'only-EU conducted-research' is more and more difficult to sustain. Moreover, in the scope of safety data reporting, there may be a need for the flow of personal data to a US based Manufacturer Authorization Holder (for drug), due to regulatory reasons and compliance with non-EU laws in the field of clinical research and use of medicinal products. As result, pseudonymous date may be shared with the countries outside the EU for further regulatory reporting purposes.

[4] Peloquin D, DiMaio M, Bierer B, Barnes M. Disruptive and avoidable: GDPR challenges to secondary research uses of data. Eur J Hum Genet. 2020 Jun;28(6):697-705. doi: 10.1038/s41431-020-0596-x. Epub 2020 Mar 2. PMID: 32123329; PMCID: PMC7411058.

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Hence, we call for the European bodies to provide alternatives or solutions for very specific cases where the scientific research is jeopardized for the only reason of lack of transfer instrument. Without EU based alternatives, we believe there is a very big gap between the EU research initiatives to approach global health problems and the actual EU solutions to address important research questions.

One possibility would be to rely in this case on the last option: derogation based on consent. The pertinence of use of derogation through consent would be a possibility, for instance, where the academic partner cannot rely on any adequacy decision and cannot sign contractual clauses. However, it is still complex to understand what it "occasional" implies in the context of clinical trials. And what type of consent? What granularity? Can it be collected upfront? Can it be considered as not being bundled? Transfers for clinical trials at stake would not be systematic, nor structural. However, are they occasional? How about several clinical trials in different stages of the conduct? **Specific guidance in regards to derogations for cases such scientific research, would be useful for research community.** It is important to understand whether derogations can apply for specific compliance with another law (such safety reporting, for drug law compliance in a 3rd country).

Due to all these complexities and interpretations of the RECOMMANDATIONS, we believe that more examples and initiatives from European Data Protection Authorities and EDPB would be appreciated to clarify and avoid a lot of inconsistencies within the research community, regulatory bodies, Ethics Committees and participating sites (hospitals, institutions) in relation to the way data transfers are understood and justified.

Lastly, we believe it will be more challenging that each EU Exporter will be in position to engage in lengthy discussions with the 3rd countries entities, whereas, EU Bodies could already propose sector-specific assessments, reference to relevant laws, and create an harmonized approach to which 3rd countries entities will eventually need to raise, rather than to try to comply with the expectations and interpretations of each individual exporters.

3. CONCLUSION

In summary, based on the foregoing, the EORTC proposes the following updates to the RECOMMANDATIONS:

- Clearly define what are modalities and conditions under which exporter within the clinical research sector can continue to transfer data (e. g. safety reporting purposes) in such uncertain times for data protection, and eventually clarify the use of derogations and applicability to this sector when other transfer instruments might be challenged in court and invalidated from a day to another;
- Enrich the number of examples for the clinical research sector and clarify the current and future plans for this sector in terms of IT solutions in EU, e.g. SAASs solutions;

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- Recommend the use of additional measures in data transfer agreements, namely when the processing of personal data may fall within the scope of specific legislation in the 3rd country;
- Recommend to the regulatory bodies to work on platform, or centralized list of requirements, sector specific, where there is already an assessment of compatibility with the top countries relevant for the collaborations in that field and that can be used a standardized/ harmonized approach, especially in fields where transfers from controller to controller require a certain level of standardization.

Since its implementation, the GDPR did not lead to the termination of any of EORTC trials, studies or research projects. However, in two occasions we lost US based academic partners because of lack of harmonized approach in terms of GDPR-related risks and in: in one occasion a clinical trials was rejected for unjustified GDPR-related reasons (where an EC was clearly acting beyond its remits) and, in general, the lack of harmonisation and/or clarity around questions we raise in this document costed EORTC numerous hours of work. Namely to its Privacy Office, Regulatory Affairs and Contract Departments. The time and efforts spent on the updates of documents, including hundreds and more contracts applicable to ongoing research (work still in progress) is in our view of a little added value as compared to yet to be proved gain of protection to data subjects. Therefore, we call all EU relevant bodies (EMA, EU Commission, EDPB, DPAs) to urgently clarify, harmonise and provide viable solutions to avoid seriously harming health research and innovation in Europe.

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