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17th of December 2020

Position Paper on the Recommendations 01/2020 on measures that supplement transfer tools to ensure compliance with the EU level of protection of personal data.

Comments from:

MyData-TRUST

When DATA PROTECTION Meets Life Sciences

MyData-TRUST is a company registered under Belgian Laws, active since 2017 in the DATA PROTECTION area. Its Multi-Disciplinary Team Includes Data Privacy Lawyers, IT Security Specialists and Clinical Experts providing GDPR related services (such as privacy risk assessments, external DPO -, DPR - as a service etc…) to company's clients. Our clients include among others pharma, biotech and device companies, CROs (Contract Research Organisations), healthcare providers and associations.

KEY MESSAGES

- There is an urgent need for **clarification of transfer tools and provision of realistic solutions for all frequent scenarios in the field of Life Sciences and specifically clinical trials**.

- GDPR is sufficiently restrictive with regards to the transfers outside EEA. The EDPB should not add further constraints to the transfer of data to third countries but, on the contrary, endeavour **to establish a scale of risks** based on several factors, including but not limited to the nature of the data transferred in relation to the risk sources.

- It is essential **to ensure a harmonised approach** between the EDPB and the European Commission with coherent and consistent messages and set of practical tools enabling compliance with GDPR, including by SMEs.

- We fully agree that mapping transfers is key to ensure compliance. However, **mapping of flows shall not be seen separately from the mapping of responsibilities**, clarification of roles and application of the territorial scope.

- MyData-Trust would like to stress its **willingness to further provide its expertise and extensive experience in implementing GDPR in Life Sciences** in defining standards and contributing to future developments towards a Common European data economy. Our Company looks forward to collaborating with the European Data Protection Board and fully supports the EU's policy objective of a transparent, sustainable and nurturing ecosystem.

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Introduction and general comments

MyData-Trust (MD-T) welcomes this opportunity to provide feedback on European Data Protection Board (EDPB) recommendations which reflect an important effort to provide concrete solutions addressing the needs arising from almost the only GDPR[1] obligation which is currently nearly impossible to comply with in many situations. Representing the experience GDPR implementation in a wide range of European and international SMEs, MyData-Trust highlights in this position the **current legal and regulatory obstacles are hindering the EU's ability to lead in the data economy and innovation** where intervention from European policymakers can make a positive difference.

We would like to thank EDPB for bringing a number of interesting clarifications in relation to some aspects of data transfers. However, recommendations do not add much on the tools available to enable better compliance with legislation and recommendations, but rather increase the complexity of assessments required at prior and thus creating new areas of even bigger uncertainties.

In many instances, in practice, data have practically no GDPR compliant way to leave the EEA (i.e., **data localisation**). Without naming it, the EDPB and the European Commissioner for the Internal Market, Thierry Breton[2], are moving in this direction. This European digital sovereignty promotes this quest for European autonomy. However, this position implies economic costs, risks of cybersecurity and inconsistencies between policies. It is essential for Europe, and more particularly for the EDPB, to further study the negative consequences of data localisation not only on the EU market and its economy, but also on the research and innovation.

GDPR recognises that flows of personal data to and from countries outside the EEA and international organisations are necessary for the expansion of international trade and international cooperation (Rec 101) and that protection of personal data must be considered in relation to other fundamental rights, which includes the freedom to conduct a business (Rec 4). It also reinforces in several instances the need to ensure measures in place are adapted to the SMEs (Rec 13, 132 & 167). In our opinion, current guidelines and recommendations are working against these aims.

Following the Schrems II judgment, the difficulty for supervisors to assess the adequacy of third country laws has been highlighted. The current version of the recommendations much the responsibility from legislators to data controllers and data processors and adds complexity and incertitude. We suggest establishing a certain category of data transfers considered as "low-risk" (e.g., professional data of a personal nature to be transferred to the public sector).

We suggest that the EDPB should not prohibit per se the transfer of data, including readable data, to third countries but, on the contrary, endeavour to establish a scale of risks based on several factors, including but not limited to the nature of the data transferred to ensure consistency of risk assessments by data controllers. Other measures adapted to low-risk situations could be included, alongside those provided for high-risk situations, in the technical measures set out in the recommendations. Organisational and contractual measures would be sufficient for low-risk situations.

[1] 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),
[2] Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on European data governance (Data Governance Act) COM/2020/767 final.

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Current tools and restrictions added by EDPB

EDPB recommendations follow the recent judgment C-311/18 (Schrems II)[3] of the Court of Justice of the European Union (CJEU) which unvalidated one of mechanisms of transfer of data to USA and brought the emphasis on the need for additional checks in the scope of the application of the Article 46 GDPR.
However, the debate raised by this judgment cannot be explained exclusively by the decisions taken, but rather wakes up the underlaying and much larger problematic with data transfers.

Indeed, GDPR itself provides several solutions (see Figure 1) which may be used instead of the Privacy Shield but are not enforceable in practice due to the lack of tools (SCCs models), additional restrictions provided by EDPB in its guidelines[4] (i.e., use of derogations) or to the absence of clear instructions in relation to the necessary practical steps (i.e., notification of use of legitimate interests or consent to DPAs).

Figure 1: GDPR transfer tools

We take the opportunity of this consultation to mention the fact that the use of the entire Article 49 GDPR is currently restricted in line with the EDPB recommendations, to the occasional uses. Thus, despite the fact that GDPR allows the use of most of derogations, except consent on a non-occasional basis, this restriction is detrimental specifically with regards to the use of the Article 49(1)(d) GDPR, which is essential in the case of clinical trials.

We invite the EDPB to re-consider its position on derogations, specifically provided the limitations of currently available safeguards.

We believe that facilitating transfer of existing personal data from the controller to the processor, in line with the GDPR, could be made easier. We believe it is more efficient to set-up less exigent, but realistic rules that all types of businesses will be able to comply with.

Proposed methodology

We praise the idea from EDPB of providing a clear methodology with a limited number of steps. However, in some specific areas, such as the area of the life sciences and specifically clinical research where most of our clients operate, four out of six steps are currently largely not feasible. The figure below explains this position further.

[3] Case C-311/18: Judgment of the Court (Grand Chamber) of 16 July 2020 (request for a preliminary ruling from the High Court (Ireland) — Ireland) — Data Protection Commissioner v Facebook Ireland Ltd, Maximillian Schrems,
[4] Guidelines 2/2018 on derogations of Article 49 under Regulation 2016/679.

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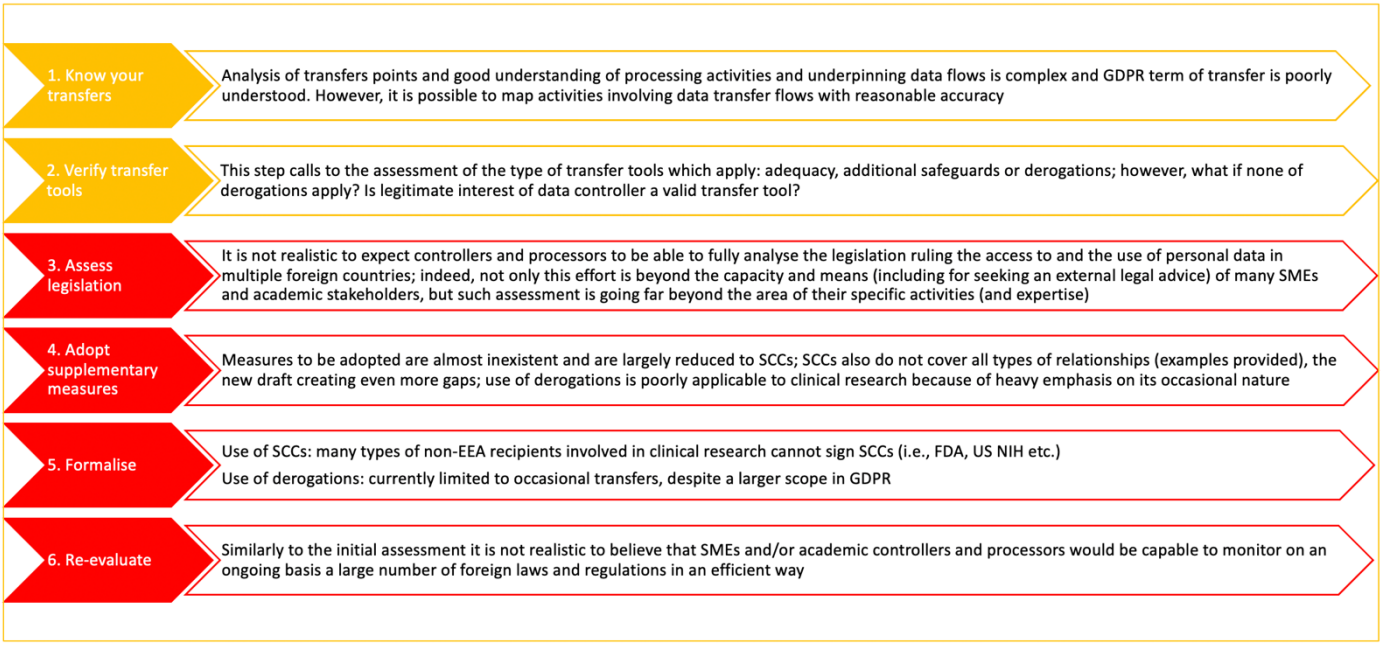
Figure 2: Challenges of six step methodology



Know your transfers

In the current recommendations, the roadmap suggested by the EDPB is not revolutionary but emphasises the need for good practice since the Schrems II ruling.[5] It is necessary to map data transfers when the country of destination is outside the EEA.

1) Terminology

GDPR does not define the term of "data transfer". EDPB recommendations provides a very welcome clarification that *"… remote access by an entity from a third country to data located in the EEA is also considered a transfer."*

From our experience, full EU solutions are very rare in current IT environment. Indeed, EU based cloud hosting or SAAS hosted on EU cloud frequently rely on support information systems or technical support not based in EU. We invite all key EU stakeholders to scrutinise the full list of information systems used in their work, including by their direct subcontractors and to evaluate the proportion of these solution which involve non-EU intervention (including just for technical support and maintenance purposes).

We believe, in the current environment, it is almost impossible to ensure that all the tools used are fully European, at least in case of organisations involved in international activities.

2) Actors and their responsibilities

We fully agree that mapping transfers is key to ensure compliance. However, mapping of flows shall not be seen separately from the mapping of responsibilities, clarification of roles and application of the

[5] *Ibid*.

territorial scope. Our recommendation is to propose to align the GDPR terminology and maximise the use of GDPR terms (i.e., controller and processor instead of importer and exporter).

Shortcuts in tools available

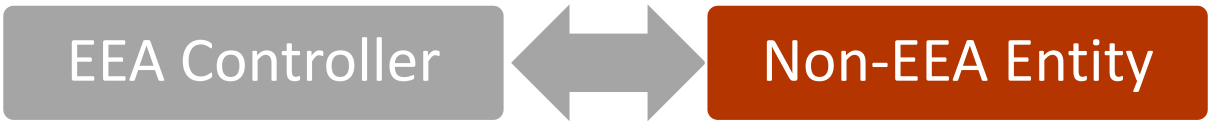
Taking into consideration typical flows in clinical research available tools (mostly SCCs) do not enable the desired degree of compliance of stakeholders (both controllers and processors).

These recommendations place heavy and extra demands on businesses but do not provide solutions that are quite adapted to the very real and practical challenges that businesses face – enabling and protecting personal data flows so that our global economy and society can function. We would like to present you some cases that affect us in particular in the life sciences sector, and which support the arguments we have exposed.

Case studies

With two case studies, we will highlight some shortcomings of the 01/2020 recommendations.
Let's figure out an International Multicentric clinical trial.
Sponsor, sites (EEA & non-EEA), 2 processors (1 EEA, one non-EEA), FDA.

USE CASE 1: Sponsor in EEA



Let's take example of the legally mandatory transfer of personal data related to safety of the drugs used in a clinical trial by an EEA Sponsor (controller) to an entity outside the EEA (e.g., a government agency such as the Food and Drug Administration). In this case, since the flow of safety data is necessary and based on a legal obligation to which Sponsor is bound, how can the controller document the data transfer in this case? Entity such as FDA cannot be party to SCCs. Which supplementary measures can be used to ensure the international data transfer is lawful? Could the derogation of the Article 49(1)(d) GDPR be the solution in this case?

USE CASE 2: Sponsor non-EEA

Exchange of personal data in relation to the safety of the trial drugs by a Sponsor (controller) based outside of the EEA, but subject to the GDPR, to an EEA processor. SCCs can be a mechanism of transfer, but currently there is no model which enables documentation of transfer from processor to a controller (nor from processor to a sub-processor). New models proposed would only cover transfers to entities outside the GDPR scope (which is not the case in our example).

With these two case studies, which are present in many clinical trials, we highlight gaps that the recommendations do not currently cover.

Could the sponsors of clinical studies rely on a derogation to transfer data from European participants to the United States, more specifically to the FDA in the context of an international trial? If not, what means should they use?

Assess legislation and risk analysis

We very much welcome the direction that has been taken towards a DPIA related to the GDPR, but we are concerned about the EDPB's approach to determining legislation assessment and risk analysis. At the level of evaluation and analysis of the law, we understand the rationale. However, legislation assessment requirement is not only poorly feasible for SMEs but would make EU a highly inefficient since multiple organisations from the same sector will be required to independently evaluate same legal frameworks, arriving potentially to contradictory decisions. Thus, not only this will result in a waste of resources, including public resources, but would create an additional barrier for collaboration and building of innovative consortiums (such as EU or Innovative Medicines Initiative consortiums) as results of analyses would diverge.

From our point of view, Member States should be encouraged to create this open source, or at least contribute to it, and stimulate initiatives to accumulate extra knowledge and experience sector by sector – and in particular to support the field of health and clinical research. Specifically, the EU life sciences field needs an open-source tool, or a database centrally monitored and regularly updated by EU.

Risk analysis pathway is welcome and interesting. We would however welcome further clarity from the EDPB on what the risk analysis is attached to – to the use of SCCs? To derogations? Or to legitimate interests? Or all?

Following the Privacy Shield and with the Brexit transition period being soon over, companies need some breathing space and visibility for the future. The majority of companies have found or will find themselves in inextricable situations of conflict of laws. The EDPB, EU institutions and DPAs should support small businesses, starting with the integration of a risk-based approach in the final recommendations.

Last, but not the least, since it remains impossible to determine how an organisation would know whether additional measures are required, in our view, risk analysis is not sufficient.

Formalise

For step 5, the EDPB does not mention whether a similar reasoning could be applied to the new SCCs on which the European Commission is currently working on.[6]

[6] On 12 November 2020, the European Commission has published its draft Implementing Decision on standard contractual clauses for the transfer of personal data to third countries which will be open for public consultation until 10 December 2020. The draft SCCs can be consulted at https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12741-Commission-Implementing-Decision-on-standard-contractual-clauses-for-the-transfer-of-personal-data-to-third-countries

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Harmonisation within EU

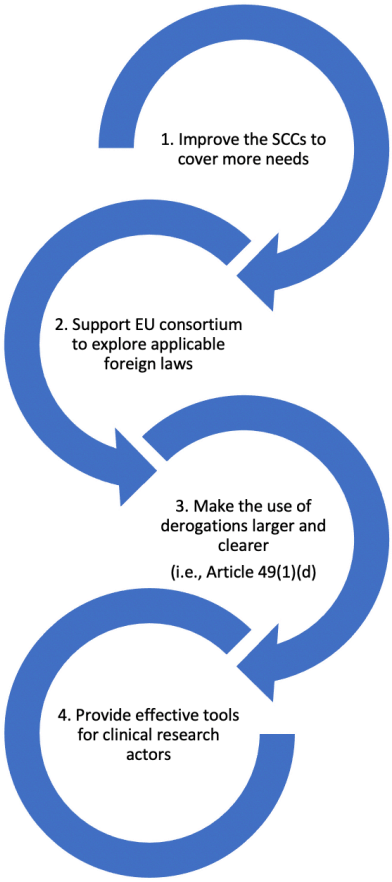
GDPR need harmonised guidelines for addressing practical issues especially concerning data transfers. EDPB recommendations and draft SCCs proposed by the Commission present an important number of discrepancies and contradictions.

There seems to be a problem alignment between EDPB recommendations and the Commission's new model of SCCs. Indeed, SCCs are detached from the geographical framework (scope GDPR/not GDPR), and transfers are based on geography. The draft presented by the Commission takes another perspective that poses a problem for us.

We suggest intensifying the dialogue between the two organisations to ensure a harmonised European approach to data transfers.

Conclusion

MyData-Trust calls to EDPB and legislators to urgently provide pragmatic solutions to the problematic of the data transfers and specifically in the life sciences and clinical trial sector.



We recommend to:

We are committed to share our expertise in the field and we remain at your disposal should you require further information or clarifications.