12 Studies within the European Union

As UMG has faced denial of transmission of personal data from participating hospitals in several European countries by virtue of legal obstacles, we have asked six partner law firms in European countries (Italy, Poland, Portugal, Serbia, Slovenia, Spain) to deliver a legal opinion on their national data protection regulations regarding the processing of personal data for the purpose of scientific research. In detail (cf. tab. 2), the first question aimed to see if the transmission of IDAT and documents containing IDAT to a central register in Germany is restricted by national regulations beyond GDPR (**1.**). Secondly, the question was asked whether in certain situations IDAT cannot be transferred to the central register in Germany despite the consent given by the patient and for legal reasons beyond GDPR (**2.**).

The legal information provided by the partner law firms dates from December 2018 and January 2019. In all relevant countries, the transposition of GDPR provisions into national law is still in progress. In principle, legal adjustments can be made at any time. In case of a specific research project in one of these countries, we therefore recommend reviewing the national regulations of the respective country.

Tab. 2 Legal opinions on national data protection regulations regarding the processing of personal data for the purpose of scientific research from Italy, Poland, Portugal, Serbia, Slovenia and Spain

	1. Regulations regarding the transmission of IDAT to a central register (beyond GDPR)		2. Particular use cases of illegal transfer from IDAT to Germany despite the consent of participant (beyond GDPR)	
Country	**Regulatory Requirements**	**Level of restriction[43]**	**Regulatory Requirements**	**Level of restriction**
Italy	■ No additional restrictions identified. ■ Italian Data Protection Authority confirmed the compatibility of the "General Authorisation to process of personal data for scientific research purposes" and the "Deontological Rules concerning the process of personal data for scientific research purposes" with the GDPR. ■ To date, no specific measures for the conduct of clinical trials have been issued by the Italian Data Protection Authority.	*	■ No additional restrictions identified. ■ The Ethic Committees approve also the used forms of the declaration of consent; their approval may vary.	*
Poland	■ Restrictions possible if IDAT are qualified as data of "medical records" (if surnames, first names, dates of birth, gender, address or place of residence, social security numbers, identification of the healthcare providers or description of the patient's health are contained). ■ Without the patient's consent, "medical records" data can only be transferred to universities and research institutes, but IDAT shall not be included. If the patient's consent has been obtained, IDAT can be transferred.	**	■ Additional restrictions identified. ■ In case of "medical record" data, the purposes of processing IDAT shall be clearly defined in the patient's declaration of consent. ■ In case of a "significant experiment", a prior positive voting of a Bioethics committee is required. ■ Depseudonymization may be inadmissible.	**

43 The following visualizations stand for: * no additional restrictions identified; ** additional restrictions identified; *** transmission of IDAT illegal in certain cases

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Country	**Regulatory Requirements**	**Level of restriction[43]**	**Regulatory Requirements**	**Level of restriction**
Portugal	■ No additional restrictions identified. ■ The Ethics Committees approve the clinical trial by a risk-benefit-evaluation, taking into consideration also the used forms of the declaration of consent; their approval may vary. ■ The sponsor of the clinical study is responsible for compliance with the legal requirements for processing IDAT.	*	■ Additional Restrictions identified. ■ Information security regulations to be complied with. ■ IDAT have to be processed by persons subject to a legal obligation of professional secrecy.	**
Serbia	■ No additional restrictions identified. ■ The Ethics Committee and the Commissioner for the Protection of Personal Data approve the used forms of the declaration of consent and the export of IDAT; their approval may vary. ■ The intended processing of IDAT (e.g. manner of processing) and the declaration of consent (e.g. exact number and names of persons IDAT are disclosed to) have to be described precisely.	*	■ Additional restriction identified. ■ Export of IDAT to a country that is not a signatory to the Convention on the Protection of Individuals with regard to the automatic processing of personal data of the Council of Europe is illegal.	***
Slovenia	■ No additional restrictions identified. ■ IDAT cannot be transferred by physically transferring the original medical records or documentation being part of the original medical record.	*	■ No additional restrictions identified. ■ Physical transfer of original medical records or documentation being part of the original medical record cannot be consented to.	*

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Country	**Regulatory Requirements**	**Level of restriction[43]**	**Regulatory Requirements**	**Level of restriction**
Spain	■ Additional restrictions identified. ■ The Ethics Committees approve the processing of pseudonymised data for research purposes; their approval may vary. ■ Access to pseudonymized data by TTP requires a confidentiality agreement. ■ De-pseudonymisation permitted only under certain conditions.	**	■ No additional restrictions identified.	*