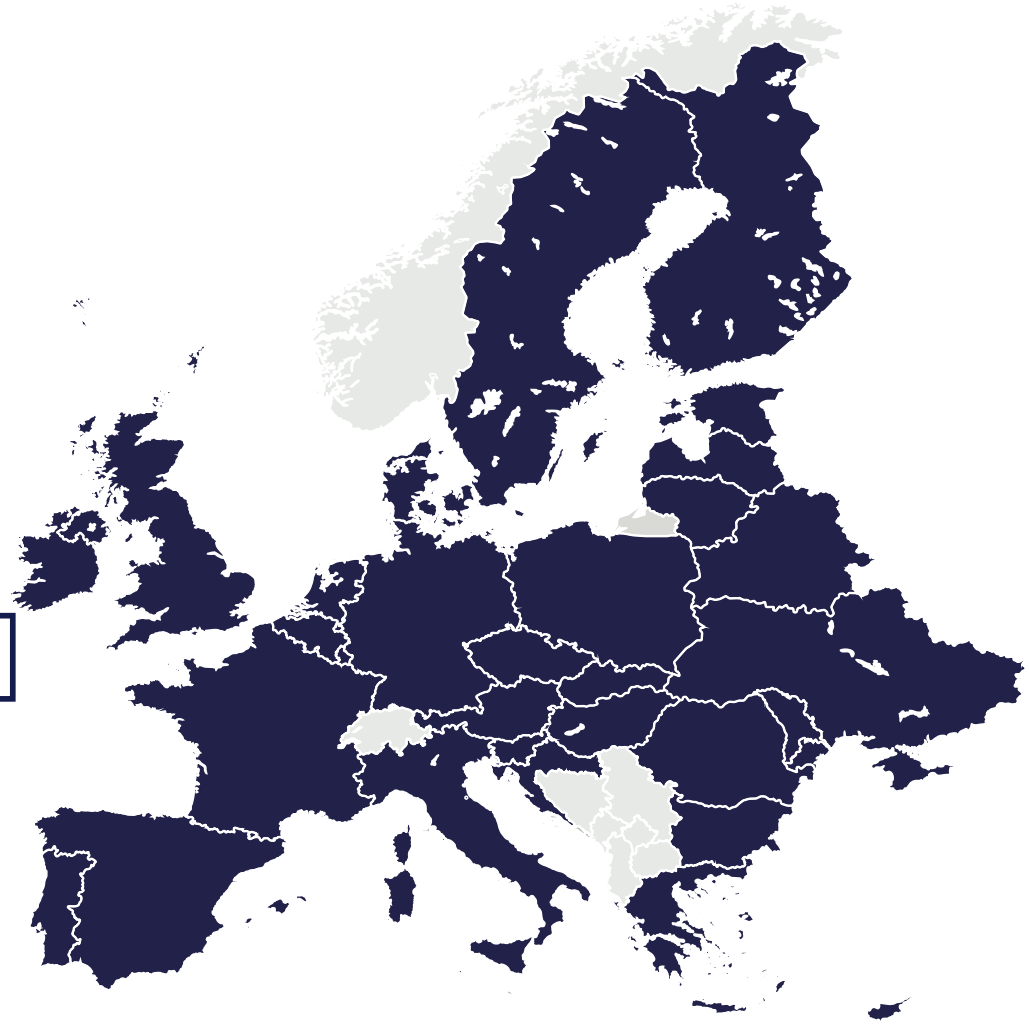
TaylorWessing

Data Protection Law in Clinical Trials – Local Country Report

As at March 2023

- AUSTRIA
- BELGIUM
- CZECH REPUBLIC
- DENMARK
- FRANCE
- GERMANY
- GREECE
- HUNGARY
- ITALY
- IRELAND
- NETHERLANDS
- POLAND
- PORTUGAL
- ROMANIA
- SLOVAKIA
- SPAIN
- SWEDEN
- SWITZERLAND
- UK



TaylorWessing

AUSTRIA

Question 1	Question 2	Question 3
What are the common data protection roles (controller or processor) typically assigned to sponsors and sites in practice with respect to the processing of personal data in the context of clinical trials?	**What are the common legal bases relied upon in practice for the processing of personal health data in the context of clinical trials (e.g., informed consent or research privilege)?**	**What are the common legal bases relied upon in practice for the processing of personal health data in the context of secondary use for research purposes (e.g., informed consent or research privilege)?**
Sponsors and sites are usually considered as **joint controllers**. These roles are common practice and reflect the opinion of the Austrian Data Protection Authority.	The legal basis for the processing of personal health data within clinical trials is usually Art. 9 para. 2 lit. a) GDPR (**explicit consent**). Relevant local provisions include: ■ Sec. 41 para. 1 of the Austrian Medicines Act; ■ Sec. 27 para. 1 of the Austrian Medical Devices Act; and ■ Sec. 2d para. 3 of the Austrian Research Organisation Act. In this context, Sec. 2d para. 3 of the Austrian Research Organisation Act provides for a facilitated possibility to obtain 'quasi-consent' within the scope of the Research Organisation Acts "*if the data subject voluntarily, in an informed manner and unambiguously expresses his or her will in the form of a declaration or other unambiguous affirmative act.*"	The legal basis for the processing of personal health data for secondary use is usually Art. 9 para 2 lit. a) GDPR (**broad consent**). This results from Sec. 2d para. 3 of the Austrian Research Organisation Act which allows broad consent trial subject's consent can be given for broad areas of research without the need for detailed specification of the exact scope of the research. For acquiring broad consent, the trial subject must consent voluntarily, unequivocal and in an informed way. Furthermore, special provisions for processing based on the research privilege are in place for repositories and biobanks (Sec. 2f of the Research Organisation Act).

BELGIUM

Question 1	Question 2	Question 3
What are the common data protection roles (controller or processor) typically assigned to sponsors and sites in practice with respect to the processing of personal data in the context of clinical trials?	**What are the common legal bases relied upon in practice for the processing of personal health data in the context of clinical trials (e.g., informed consent or research privilege)?**	**What are the common legal bases relied upon in practice for the processing of personal health data in the context of secondary use for research purposes (e.g., informed consent or research privilege)?**
Sponsors and sites are usually considered as **joint controllers**. The role of sites, however, ultimately depends on their involvement in the development of the protocol and its implementation, and needs to be assessed on a case-by-case basis.	The legal basis for the processing of personal health data within clinical trials is usually Art. 9 para. 2 lit. j) GDPR (**scientific research purposes**) in conjunction with Art. 6 para. 1 lit. e) GDPR (**public interests**) or Art. 6 para. 1 lit. f) GDPR (**legitimate interests**). This results from official guidance of the Belgian Data Protection Authority, wherein it sets out the following: ■ When processing personal health data in the context of clinical trials, a clear distinction must be made between informed consent, which is mandatory for participation in the clinical trial, and a possible consent that serves as a legal basis for the processing of personal data in the context of the GDPR; ■ A person who agrees to participate in a clinical trial cannot refuse the processing of his/her personal data in this respect, as it is difficult to obtain a freely given consent, as required by Art. 4 no. 11 GDPR; ■ Moreover, a consent, which by definition can be withdrawn at any time (Art. 7 para. 3 GDPR), does not always seem to be the most stable and therefore the most recommended legal basis for clinical trials, and for scientific research in general. Hence, the Belgian Data Protection Authority considers Art. 9 para. 2 lit. a) GDPR (explicit consent) not to be an appropriate legal basis for the processing of personal heath data within clinical trials.	The legal basis for the processing of personal health data for secondary use is usually Art. 9 para 2 lit. j) GDPR (**scientific research**), provided that the conditions of Art. 89 para. 1 GDPR are fulfilled, which requires the implementation of adequate safeguards. This results from official guidance by the Belgian Data Protection Authority. Hence, there is no need for an (additional) legal basis, such as the trial subject's explicit consent. However, this 'exception regime' only applies when specific conditions are met, which may differ depending on whether the original controller is the controller for the further processing of the data (see Title 4 Belgian Data Protection Act). The general requirements include, for example, the appointment of a DPO if the processing can constitute a high risk, and the inclusion of additional justifications in the record of processing activities. Other requirements (applicable depending on the scenario) relate, for example, to the obligation to conclude an agreement with the original controller and requirements to anonymize and pseudonymize the data.

CZECH REPUBLIC

Question 1	Question 2	Question 3
What are the common data protection roles (controller or processor) typically assigned to sponsors and sites in practice with respect to the processing of personal data in the context of clinical trials?	**What are the common legal bases relied upon in practice for the processing of personal health data in the context of clinical trials (e.g., informed consent or research privilege)?**	**What are the common legal bases relied upon in practice for the processing of personal health data in the context of secondary use for research purposes (e.g., informed consent or research privilege)?**
Sponsors are considered as **independent controllers**. Sites are usually considered as **processors**. **No regulatory guidance** exists. The role of sites therefore ultimately depends on their involvement in the development of the protocol and its implementation, and needs to be assessed on a case-by-case basis.	The legal basis for the processing of the trial subject's personal health data within clinical trials is usually Art. 9 para 2 lit. i) and j) GDPR (**interests of public health and scientific research**). This is emphasized in the guidance of the Czech Office for Personal Data Protection. The Czech data protection law explicitly provides for processing personal data for scientific research purposes as a legal basis if corresponding data protection measures are taken (Sec. 16 of the Czech Data Processing Act No. 110/2019 Coll.).	**No local legal framework or regulatory guidance** exists with regard to secondary use of personal health data. Hence, the permissibility of secondary use must be assessed on a case-by-case basis, based on the general requirements of data protection law.

DENMARK

Question 1	Question 2	Question 3
What are the common data protection roles (controller or processor) typically assigned to sponsors and sites in practice with respect to the processing of personal data in the context of clinical trials?	**What are the common legal bases relied upon in practice for the processing of personal health data in the context of clinical trials (e.g., informed consent or research privilege)?**	**What are the common legal bases relied upon in practice for the processing of personal health data in the context of secondary use for research purposes (e.g., informed consent or research privilege)?**
Sponsors are usually considered as **independent controllers** or **joint controllers**. Sites are usually considered **joint controllers, independent controllers** or **data processors**. Specific circumstances may affect this assessment. Ultimately the roles must be determined based on the specific setup and on a case-by-case basis.	The legal basis for the processing of the trial subject's personal health data within clinical trials is usually Art. 9 para 2 lit. i) GDPR (**interests of public health**), however, the processing may also be carried out under the following legal bases: ■ Personal data can be processed for **statistical and scientific studies** if the processing is of societal importance and necessary for the project (Sec. 10 of the Danish Data Protection Act); ■ Personal data that are obtained from medical records can be used: **(i)** for clinical trials, if the clinical trials have been approved by an ethical committee; **(ii)** for statistical purposes of societal importance (Sec. 42 d para. 2, para. 2b of the Danish Healthcare Act); **(iii)** for specific research projects of significant societal interest after approval by the regional council, which sets the conditions for the processing, including potential subsequent disclosure (Sec. 46 para. 2 of the Danish Healthcare Act); **(iv)** for statistics or planning with authorisation from the regional council in the region where the researcher works (Sec. 47 of the Danish Healthcare Act).	The Danish Data Protection Agency considers **broad consent invalid** if, at the time of data collection, the purpose of data processing for secondary use cannot be defined in a sufficiently transparent manner. However, the Danish Healthcare Act permits use of personal health data for secondary use based on the **approval from one of the ethics committees** (see for example Sec. 46 of the Danish Healthcare Act).

FRANCE

Question 1	Question 2	Question 3
What are the common data protection roles (controller or processor) typically assigned to sponsors and sites in practice with respect to the processing of personal data in the context of clinical trials?	**What are the common legal bases relied upon in practice for the processing of personal health data in the context of clinical trials (e.g., informed consent or research privilege)?**	**What are the common legal bases relied upon in practice for the processing of personal health data in the context of secondary use for research purposes (e.g., informed consent or research privilege)?**
Sponsors are considered as **independent controllers**. Sites are usually considered as **processors**. However, in exceptional cases, sites may also be considered as **joint controllers** together with sponsors if sites are sufficiently involved in the development of the protocol and its implementation.	The legal basis for the processing of the trial subject's personal health data within clinical trials is usually Art. 9 para 2 lit. j) GDPR (**scientific research**) in conjunction with Art. 6 para. 1 lit. e) GDPR (**public interests**, for example in the case of public bodies) or Art. 6 para. 1 lit. f) GDPR (**legitimate interests**, for example in the case of private actors). This is emphasized in the guidance of the French National Commission on Informatics and Liberty (CNIL). Art. 9 para. 2 lit. a) GDPR (explicit consent) can also be used as a legal basis. But as consent may be withdrawn at any time, the CNL rather recommends to base the data processing on the legal bases for scientific research.	The legal basis for the processing of personal health data for secondary use is usually Art. 9 para 2 lit. j) GDPR (**scientific research**) in conjunction with Art. 6 para. 1 lit. e) GDPR (**public interests**) or Art. 6 para. 1 lit. f) GDPR (**legitimate interests**). This results from official guidance by CNIL. Should the initial purpose of processing rely on the trial subject's consent (Art. 9 para. 2 lit. a) GDPR), according to the CNIL consent is only valid if it was obtained for a specific purpose. Consequently, the processing of personal data for secondary use shall generally require a **second consent**.

GERMANY

Question 1	Question 2	Question 3
What are the common data protection roles (controller or processor) typically assigned to sponsors and sites in practice with respect to the processing of personal data in the context of clinical trials?	**What are the common legal bases relied upon in practice for the processing of personal health data in the context of clinical trials (e.g., informed consent or research privilege)?**	**What are the common legal bases relied upon in practice for the processing of personal health data in the context of secondary use for research purposes (e.g., informed consent or research privilege)?**
Sponsors and sites are usually considered as **joint controllers**. These roles are common practice and in line with the joint opinion of the German data protection authorities. However, in exceptional cases, sites may also be considered as **processors**. This depends on the involvement of the site in the development of the protocol and its implementation, and needs to be assessed on a case-by-case basis.	The legal basis for the processing of personal health data within clinical trials, subject to regulatory requirements, is usually Art. 9 para. 2 lit. a) GDPR (**explicit consent**). Regulatory requirements include: Sec. 40b para. 6 of the German Medicinal Products Act for pharmaceuticals; and Sec. 29 of the German Medical Device Law Implementation Act for medical devices. These provisions provide for specific consent requirements and information obligations for the processing of personal health data. If **no** regulatory requirements apply (such as for non-interventional studies), data processing may be based on other legal bases, such as **research privileges** in accordance with Sec. 27 para. 1 of the German Federal Data Protection Act or other specific local state data protection laws, which applicability must be examined on a case-by-case basis. But also, outside of regulated clinical trials, it is common practice to obtain explicit consent from data subjects (Art. 9 Abs. 2 lit. a) GDPR).	The German data protection authorities consider **broad consent invalid** if, at the time of data collection, the purpose of data processing for secondary use cannot be defined in a sufficiently transparent manner. In exceptional cases, certain local state data protection laws permit the use of personal data for secondary use based on **research privileges** (e.g., Art. 8 para. 1 no. 5 of the Bavarian Data Protection Act). However, **no general legal framework exists** in Germany as to the conditions under which secondary use is permissible, such as under the general research privilege in accordance with Sec. 27 para. 1 of the German Federal Data Protection Act. The German data protection authorities have issued a joint statement on the data protection-compliant processing of health data in scientific research with recommendations for future legislation (the so-called "Petersberg Declaration" of November 24, 2022). A general "Health Data Usage Act" governing data processing in the context of scientific research is currently in the legislative process. A newly created Research Data Center Health is expected to begin operations in 2023 and, together with other national institutions currently being established (Center for Cancer Registry Data, Central Office for Medical Registries), will form the basis for the use of aggregated and pseudonymized data for scientific research. From today's perspective, however, the full potential of data usage cannot be fully exploited due to a lack of standards and harmonization. Therefore, it must be examined on a case-by-case basis which legal provisions are applicable.

GREECE

Question 1	Question 2	Question 3
What are the common data protection roles (controller or processor) typically assigned to sponsors and sites in practice with respect to the processing of personal data in the context of clinical trials?	**What are the common legal bases relied upon in practice for the processing of personal health data in the context of clinical trials (e.g., informed consent or research privilege)?**	**What are the common legal bases relied upon in practice for the processing of personal health data in the context of secondary use for research purposes (e.g., informed consent or research privilege)?**
Sponsors are considered as **independent controllers**. Sites are usually considered as **processors**. These roles are common practice and are in line with regulatory guidance.	The legal basis for the processing of personal health data within clinical trials is usually Art. 9 para. 2 lit. a) GDPR (**explicit consent**). **No regulatory guidance** exists as to whether the data processing can also be based on other legal bases.	**No local legal framework or regulatory guidance** exists with regard to secondary use of personal health data. Hence, the permissibility of secondary use must be assessed on a case-by-case basis, based on the general requirements of data protection law.

HUNGARY

Question 1	Question 2	Question 3
What are the common data protection roles (controller or processor) typically assigned to sponsors and sites in practice with respect to the processing of personal data in the context of clinical trials?	**What are the common legal bases relied upon in practice for the processing of personal health data in the context of clinical trials (e.g., informed consent or research privilege)?**	**What are the common legal bases relied upon in practice for the processing of personal health data in the context of secondary use for research purposes (e.g., informed consent or research privilege)?**
Sponsors and sites are usually considered as **joint controllers.** **No regulatory guidance exists**. The role of sites therefore ultimately depends on their involvement in the development of the protocol and its implementation, and needs to be assessed on a case-by-case basis.	The legal basis for the processing of personal health data within clinical trials is usually Art. 9 para. 2 lit. a) GDPR (**explicit consent**). This is based on Art. 4 para. 3 of the Act No. XLVII of 1997 (Medical Data Act) stating that "*processing of health data may be carried out in its entirety or for specific processing activities with the consent of the data subject or his or her legal or authorised representative, which is based on adequate information, voluntarily expressed, and demonstrated through a credible means of making a valid declaration*".	The Clinical Pharmacology Ethics Committee of the Scientific Council for Health, in its recommendation of 31 May 2021, emphasizes that in cases where the data is not anonymous and the data subject was not informed of the secondary use at the time of the original collection, the data subject's new informed consent is required. Hence, secondary use of personal health data based on **broad consent** or the research **privilege is not permissible**.

ITALY

Question 1	Question 2	Question 3
What are the common data protection roles (controller or processor) typically assigned to sponsors and sites in practice with respect to the processing of personal data in the context of clinical trials?	**What are the common legal bases relied upon in practice for the processing of personal health data in the context of clinical trials (e.g., informed consent or research privilege)?**	**What are the common legal bases relied upon in practice for the processing of personal health data in the context of secondary use for research purposes (e.g., informed consent or research privilege)?**
Sponsors and sites are usually considered as **joint controllers.** These roles are in line with the guidance of the Italian Data Protection Authority and the Clinical Trial Agreement template approved and published on the website of the Italian National Coordination Centre of Local Ethics Committees for Clinical Trials.	The legal basis for the processing of personal health data within clinical trials is usually Art. 9 para. 2 lit. a) GDPR (**explicit consent**). This is emphasized in the Opinion pursuant to Article 110 of the Code and Article 36 of the Regulations – 30 June 2022 by the Italian Data Protection Authority. If no explicit consent to the data processing can be obtained, in certain very exceptional cases, Art. 110 of the Italian Data Protection Act provides for the processing of personal health data within clinical trials without explicit consent.	Personal health data and biological samples from trial subjects may be used in future clinical trials and research only if the trial subjects have been adequately informed in advance and have given their **express, separate written consent**. This is emphasized in the *Guidelines for Data Processing* within the Framework of Clinical Drug Trials – 24 July 2008 by the Italian Data Protection Authority. Hence, secondary use of personal health data based on **broad consent** or the research **privilege is not permissible**.

IRELAND

Question 1	Question 2	Question 3
What are the common data protection roles (controller or processor) typically assigned to sponsors and sites in practice with respect to the processing of personal data in the context of clinical trials?	**What are the common legal bases relied upon in practice for the processing of personal health data in the context of clinical trials (e.g., informed consent or research privilege)?**	**What are the common legal bases relied upon in practice for the processing of personal health data in the context of secondary use for research purposes (e.g., informed consent or research privilege)?**
Sponsors are considered as **independent/joint controllers**. Sites are usually considered as **processors**. These roles are consistent with the Irish Pharmaceutical Healthcare Association's Model Clinical Trial Agreement and are therefore the default position. However, in exceptional cases, sites may also be considered as **joint controllers** together with sponsors if sites are sufficiently involved in the development of the protocol and its implementation.	The legal basis for the processing of personal health data within clinical trials is usually Art. 9 para. 2 lit. a) GDPR (**explicit consent**). This is emphasized in the guidance of the National Office for Research Ethics Committees. If explicit consent to processing is not or cannot be obtained, anonymized data may be processed only, or a **consent declaration can be sought from the Health Research Consent Declaration Committee** which has to make sure that the public interest in carrying out the health research significantly outweighs the requirement for explicit consent of the individual (Statutory Instrument No. 314 of 2018).	Under the Data Protection (Health Research) Regulations 2018 (amended in 2019 and 2021) (DPHRR) the default legal basis for any health research (including secondary use) is **explicit consent**. It is possible (but difficult) to gain permission for secondary processing of health data without explicit consent. To gain permission a controller must **request a statement from the Health Research Consent Declaration Committee** that the public interest in conducting health research significantly outweighs the public interest in obtaining the explicit consent of the individual. The applicant must carry out a DPIA in accordance with Art. 35 para. 1 GDPR; obtain ethical approval from the Research Ethics Committee and submit a written request to the Health Research Consent Declaration Committee demonstrating that the public interest in conducting the health research significantly outweighs the public interest in requiring the explicit consent of the individual.

NETHERLANDS

Question 1	Question 2	Question 3
What are the common data protection roles (controller or processor) typically assigned to sponsors and sites in practice with respect to the processing of personal data in the context of clinical trials?	**What are the common legal bases relied upon in practice for the processing of personal health data in the context of clinical trials (e.g., informed consent or research privilege)?**	**What are the common legal bases relied upon in practice for the processing of personal health data in the context of secondary use for research purposes (e.g., informed consent or research privilege)?**
Sponsors and sites are usually considered as **joint controllers**. This is common practice and reflects the opinion of the Dutch Data Protection Authority.	The legal basis for the processing of personal health data within clinical trials is usually Art. 9 para. 2 lit. a) GDPR (**explicit consent**). This is based on Art. 6(1), 6(5) and Art. 12 Medical Research Involving Human Subjects Act, which provide for specific consent requirements, including information obligations, for the processing of personal health data.	In general, secondary use requires the data subject's **informed consent** (Art. 9 para. 2 lit. a) GDPR), unless requesting consent proves impossible or requires disproportionate effort. Under local law, health data collected for medical treatment may, in exceptional cases, be (secondary) used in anonymized form for research purposes if the data subject has not objected to such use. However, please note that general uncertainty exists with regard to the secondary use of personal health data for research purposes (Art. 9 para 2 lit. j) GDPR). Therefore, any intended secondary use needs to be assessed on a case-by-case basis to determine whether special legal bases for data processing apply.

POLAND

Question 1	Question 2	Question 3
What are the common data protection roles (controller or processor) typically assigned to sponsors and sites in practice with respect to the processing of personal data in the context of clinical trials?	**What are the common legal bases relied upon in practice for the processing of personal health data in the context of clinical trials (e.g., informed consent or research privilege)?**	**What are the common legal bases relied upon in practice for the processing of personal health data in the context of secondary use for research purposes (e.g., informed consent or research privilege)?**
Sponsors are considered as **independent/joint controllers**. Sites are considered as joint **controllers** or **processors**. The role of sites ultimately depends on their involvement in the development of the protocol and its implementation, and needs to be assessed on a case-by-case basis. However, experience shows that a lot of sites tend to argue that they do not decide on the purposes and means of data processing and therefore refuse to enter into joint controller agreements.	The legal basis for the processing of personal health data within clinical trials is usually Art. 9 para. 2 lit. a) GDPR (**explicit consent**). **No regulatory guidance** exists as to whether the data processing can also be based on other legal bases. Therefore, as laid down in the EDPB's Opinion 3/2019, it is possible that in exceptional cases the processing of personal health data may be based on other legal grounds, such as Art. 9 para. 2. lit. i) GDPR (**interests of public health**) or Art. 9 para. 2 lit. j) GDPR (**scientific research**).	**No local legal framework or regulatory guidance** exists with regard to secondary use of personal health data. Hence, the permissibility of secondary use must be assessed on a case-by-case basis, based on the general requirements of data protection law.

PORTUGAL

Question 1	Question 2	Question 3
What are the common data protection roles (controller or processor) typically assigned to sponsors and sites in practice with respect to the processing of personal data in the context of clinical trials?	**What are the common legal bases relied upon in practice for the processing of personal health data in the context of clinical trials (e.g., informed consent or research privilege)?**	**What are the common legal bases relied upon in practice for the processing of personal health data in the context of secondary use for research purposes (e.g., informed consent or research privilege)?**
Sponsors are considered as **independent controllers**. Sites are usually considered as **processors**. These roles are consistent with the Deliberation No. 1704/2015 of the Portuguese National Data Protection Commission applicable to the processing of personal data carried out in the scope of clinical trials. The role of sites, however, ultimately depends on their involvement in the development of the protocol and its implementation, and needs to be assessed on a case-by-case basis.	The legal basis for the processing of personal health data within clinical trials is usually Art. 9 para. 2 lit. a) GDPR (**explicit consent**). This is based on Art. 31 para. 4 Law No. 58/2019 – National Data Protection Law, stating that "*consent for the processing of data for scientific research purposes may cover several research areas or may be given only for certain specific research domains or projects, and in any case ethical standards recognized by the scientific community shall be respected*". Although the National Data Protection Law is not exactly clear regarding the applicable legal basis, the consent requirement complies with the understanding of the Portuguese Data Protection Authority in its Deliberation No. 1704/2015.	The Portuguese National Data Protection Commission considers **broad consent invalid**, i.e., consent must be linked to the purpose of a specific clinical trial and cannot be defined broadly as clinical research. **No local legal framework** exists with regard to secondary use of personal health data. Hence, the permissibility of secondary use must be assessed on a case-by-case basis, based on the general requirements of data protection law.

ROMANIA

Question 1	Question 2	Question 3
What are the common data protection roles (controller or processor) typically assigned to sponsors and sites in practice with respect to the processing of personal data in the context of clinical trials?	**What are the common legal bases relied upon in practice for the processing of personal health data in the context of clinical trials (e.g., informed consent or research privilege)?**	**What are the common legal bases relied upon in practice for the processing of personal health data in the context of secondary use for research purposes (e.g., informed consent or research privilege)?**
Sponsors and sites are usually considered as **joint controllers**. **No regulatory guidance** exists. The role of sites therefore ultimately depends on their involvement in the development of the protocol and its implementation, and needs to be assessed on a case-by-case basis.	The legal basis for the processing of personal health data within clinical trials is usually Art. 9 para. 2 lit. a) GDPR (**explicit consent**). **No regulatory guidance** exists as to whether the data processing can also be based on other legal bases.	**No local legal framework or regulatory guidance** exists with regard to secondary use of personal health data. Hence, the permissibility of secondary use must be assessed on a case-by-case basis, based on the general requirements of data protection law. Please note that Art. 3 para. 2 of the Romanian Law No. 190/2018 provides that processing of health data for the purpose of ensuring public health, cannot be subsequently performed for other purposes by third entities.

SLOVAKIA

Question 1	Question 2	Question 3
What are the common data protection roles (controller or processor) typically assigned to sponsors and sites in practice with respect to the processing of personal data in the context of clinical trials?	**What are the common legal bases relied upon in practice for the processing of personal health data in the context of clinical trials (e.g., informed consent or research privilege)?**	**What are the common legal bases relied upon in practice for the processing of personal health data in the context of secondary use for research purposes (e.g., informed consent or research privilege)?**
Sponsors are considered as **independent/joint controllers**. Sites are considered as **joint controllers** or **processors**. **No regulatory guidance** exists. The role of sites therefore ultimately depends on their involvement in the development of the protocol and its implementation, and needs to be assessed on a case-by-case basis.	**No local legal framework exists** with regard to the processing of personal health data within clinical trials. Hence, controllers must choose an appropriate legal basis under the GDPR and the Slovakian Data Protection Act. However, the Slovakian Office for Personal Data Protection agrees with the EPDB's Opinion 3/2019 and considers Art. 9 para. 2 lit. i) or j) GDPR (**interests of public health** or **scientific research**) in conjunction with Art. 6 para. 1 lit. 1 lit. c), e) or f) GDPR (**legal obligation**, **public** or **legitimate interests**) as the most appropriate legal bases for processing personal data for the purposes of clinical trials.	Under the Slovak Data Protection Act, secondary use of personal health data for **scientific research purpose** is usually considered as **compatible** with the original purpose, provided that such processing is subject to **appropriate safeguards** for the rights and freedoms of the data subject. Apart from that, **no local legal framework or regulatory guidance exists** with regards to broad consent or secondary use of personal health data. Hence, the permissibility of secondary use must be assessed on a case-by-case basis, based on the general requirements of data protection law.

SPAIN

Question 1

What are the common data protection roles (controller or processor) typically assigned to sponsors and sites in practice with respect to the processing of personal data in the context of clinical trials?

Sponsors and sites are usually considered as **independent data controllers**.

These roles are in line with the provisions of a sectorial "Code of Conduct" on clinical trials and research, as approved by the Spanish Data Protection Agency on February 2022.

Question 2

What are the common legal bases relied upon in practice for the processing of personal health data in the context of clinical trials (e.g., informed consent or research privilege)?

The legal basis for the processing of the trial subject's personal health data within clinical trials is usually Art. 9 para. 2 lit. a) GDPR (**explicit consent**).

However, following the EDPB's Opinion 3/2019, other legal basis for data processing are possible (e.g. Art. 9 para. 2 lit. i) and lit. j) GDPR).

The legal basis most common used in practice is Art. 9 para. 2 lit. j) GDPR (**scientific research**), provided the conditions of Art. 89 para. 1 GDPR are met.

According to the sectorial "Code of Conduct" approved by the Spanish Data Protection Agency states that the data processing can also be based on Art. 9 para. 2 lit. i) or j) in connection with Art. 6 para. 1 lit. c) GDPR (**compliance with legal obligations**).

Compliance with legal obligations exists in particular in relation to (i) ensuring the quality and safety of medicinal products and (ii) legal regulations concerning scientific research purposes on the guarantee and rational use of medicinal products and medical devices, which provide for a legal obligation to conduct research activities before a medicinal product is placed on the market and to conduct studies after marketing authorisation.

Question 3

What are the common legal bases relied upon in practice for the processing of personal health data in the context of secondary use for research purposes (e.g., informed consent or research privilege)?

Spain provides for a l**ocal legal framework with regard to** secondary use of personal health data based on **broad consent**.

In particular, the current Organic Law 3/2018 of 5th December 2018 on data protection and guarantee of digital rights has an Additional Seventeenth Provision dedicated to the processing of personal data for health research purposes.

This Provision expressly states that,

"The reuse of personal data for health and biomedical research purposes will be considered lawful and compatible when, having obtained consent for a specific purpose, the data is used for purposes or areas of research related to the area in which the initial study was scientifically integrated.

In such cases, the data controllers must publish the information established by Article 13 of 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 their personal data and on the free movement of such data, in an easily accessible place on the corporate website of the center where the research or clinical study is conducted, and, where appropriate, on that of the sponsor, and notify the existence of this information by electronic means to those affected. When they lack the means to access such information, they may request that it be sent in another format.

For the treatments foreseen in this letter, a prior favorable report from the research ethics committee will be required."

Therefore, a secondary use based on broad consent is permissible, provided that

- A **prior consent** of the clinical trial subject **is given** and the **secondary use is carried out for research purposes/areas related to the area of the initial trial**;
- **Sponsors and sites give** specific **information** thereof on its websites pursuant to Art. 13 GDPR; and
- A **prior favorable opinion from an ethics committee has been obtained**.

SWEDEN

Question 1	Question 2	Question 3
What are the common data protection roles (controller or processor) typically assigned to sponsors and sites in practice with respect to the processing of personal data in the context of clinical trials?	**What are the common legal bases relied upon in practice for the processing of personal health data in the context of clinical trials (e.g., informed consent or research privilege)?**	**What are the common legal bases relied upon in practice for the processing of personal health data in the context of secondary use for research purposes (e.g., informed consent or research privilege)?**
Sponsors and sites are usually considered as **joint controllers**. These roles are common practice, although **no regulatory guidance** exists.	**No local legal framework exists** with regard to the processing of personal health data within clinical trials. Hence, controllers must choose an appropriate legal basis under the GDPR. The legal basis for the processing of the trial subject's personal health data within clinical trials is usually Art. 9 para. 2 lit. i) or j) GDPR (**public interests** or **scientific purposes**) in conjunction with Art. 6 para. 1 lit. c), e) and/or f) GDPR (legal obligation, public interest and/or legitimate interest), **provided that an ethical approval under Swedish law has been granted**; either under the Act on Ethical Review of Research Involving Humans, the Act on Additional Regulation Concerning EU Regulations Concerning Medical Devices or the Act on Additional Regulation Concerning Ethical Approval Under the Clinical Trial Regulation, each constituting an ethical approval.	No local legal framework exists with regards to secondary use of study data. Broad consent for secondary use is usually not obtained in Sweden due to the legal risk that such broad consent may not be considered sufficiently specific and/or may not be considered voluntarily given. However, Swedish law permits use of personal health data for secondary use based on on Art. 9 para. 2 lit i) or j) GDPR (**public interest** or **scientific purposes**) in conjunction with Art. 6 para. 1 lit. f) GDPR (legitimate interests) or Art. 6 para. 1 lit. e) GDPR (public interests), **provided** that an **ethical approval under Swedish law has been obtained** with respect to the secondary use.

SWITZERLAND

Question 1	Question 2	Question 3
What are the common data protection roles (controller or processor) typically assigned to sponsors and sites in practice with respect to the processing of personal data in the context of clinical trials?	**What are the common legal bases relied upon in practice for the processing of personal health data in the context of clinical trials (e.g., informed consent or research privilege)?**	**What are the common legal bases relied upon in practice for the processing of personal health data in the context of secondary use for research purposes (e.g., informed consent or research privilege)?**
Sponsors and sites are usually considered as **joint controllers**. These roles are common practice, although **no regulatory guidance** exists.	According to Art. 7 para. 1 Human Research Act (**HRA**), research on humans is only permissible if the trial subject provides **informed consent or does not exercise the right to dissent after being informed accordingly**. Art. 16 ff. HRA, Art. 7 ff. Clinical Trials Ordinance (**ClinO**) and Art. 28 ff. Human Research Ordinance (**HRO**) regulate the requirements for information and consent. In particular, the trial participant must be informed orally and in writing of specific contents before consent is given. Under certain conditions, only a partial prior information is possible. Consent must be given in writing in principle.	The Federal Data Protection Act (**FADP**) and the cantonal data protection laws regularly contain **special provisions for the processing of personal data for general research purposes**, which are intended to enable and facilitate research. If the relevant requirements are complied with, the processing of personal data for research purposes is possible. The concrete form of the respective research exemption varies between private persons (companies) and federal bodies. For example, companies (private persons) may invoke the justification ground under Art. 31 para. 2 lit. e of the revised FADP by claiming an overriding interest in the processing of the data. Here, the research exemption applies if personal data is processed for research purposes and three conditions are met cumulatively: ■ Data must be anonymized as soon as the purpose of the processing permits, or, if anonymization is impossible or would require disproportionate effort, appropriate measures must be taken to prevent the identifiability of the person concerned. ■ Sensitive personal data (e.g., health data) may only be disclosed to third parties in such a way that the data subject cannot be identified. ■ The results may only be published in such a way that the persons concerned cannot be identified. However, the HRA does not have a research exemption comparable to that of the FADP. While the processing of personal data for research is largely exempted under data protection law in general, it is subject to a complex regime in the particularly important area of **human research**: As a rule, the secondary use of health-related personal data and biological material in human research is based on the **consent** of the persons concerned; in certain cases, the absence of an objection is sufficient (Art. 17, Art. 32 et seqq. and Art. 45 para. 1 lit. b HRA). In both constellations, the data subjects must have been **adequately informed** about the secondary use (consent) or informed in advance (objection; Art. 16 HRA; Art. 7 ClinO; Art. 28 et seqq. HRO). The requirements with regard to consent and prior information depend on the classification of the data (biological material / genetic data / non-genetic health-related personal data) and the type of data to be used (uncoded data / coded data / anonymized data).

UK

Question 1	Question 2	Question 3
What are the common data protection roles (controller or processor) typically assigned to sponsors and sites in practice with respect to the processing of personal data in the context of clinical trials?	**What are the common legal bases relied upon in practice for the processing of personal health data in the context of clinical trials (e.g., informed consent or research privilege)?**	**What are the common legal bases relied upon in practice for the processing of personal health data in the context of secondary use for research purposes (e.g., informed consent or research privilege)?**
Sponsors are considered as **independent/joint controllers**. Sites are usually considered as **processors**. These roles are consistent with the Model Clinical Trial Agreement prepared by the National Health Service and are therefore the default position. However, in exceptional cases, sites may also be considered as (**joint**) **controllers** together with sponsors if sites are sufficiently involved in the development of the protocol and its implementation.	The legal basis for the processing of personal health data within clinical trials is usually **explicit consent** (Art. 9 para. 2 lit. a) UK GDPR) or Art. 9 para. 2 lit. j) UK GDPR (**scientific research**). For scientific research purposes, the processing must be in the public interest (Data Protection Act 2018, Schedule 1, para. 4) and must not be likely to cause someone substantial damage or distress or be used for measures or decisions about particular people (except for approved medical research) (Sec. 19 of the Data Protection Act 2018).	The Information Commissioner's Office (ICO) recently published guidance on processing for personal data for research purposes, which allows for both, the legal basis of **broad consent** (Art. 9 para 2 lit. a) GDPR) and **scientific research** (Art. 9 para 2 lit. j) GDPR). The ICO indicates that consent is not always the most appropriate lawful basis for research purposes since it can be withdrawn at any time. If it is not possible to fully comply with a request for withdrawal of consent, then the ICO recommends that you do not rely on consent as a lawful basis for research purposes.

Country	Local Key Contact
AUSTRIA	Taylor Wessing Austria, **Christopher Bakier**, c.bakier@taylorwessing.com , +43 (0)1 71 65 50
BELGIUM	Taylor Wessing Belgium, **Marie Keup**, m.keup@taylorwessing.com, +32 (0) 2 3202 252
CZECH REPUBLIC	Taylor Wessing Czech Republic, **Karin Pomaizlova**, k.pomaizlova@taylorwessing.com, +420 224 819 216
DENMARK	Bech-Bruun, **Susanne Stougaard**, sus@bechbruun.com, +45 72 27 33 08
FRANCE	Taylor Wessing France, **Marc Schuler**, m.schuler@taylorwessing.com, +33 1 72 74 18 31
GERMANY	Taylor Wessing Germany, **Dr. Tim Schwarz**, t.schwarz@taylorwessing.com, +49 (0)89 21038 405
GREECE	BERNITSAS, **Tania Patsalia**, tpatsalia@bernitsaslaw.com, +30 210 3615395
HUNGARY	Taylor Wessing Hungary, **Dániel Ódor**, d.odor@taylorwessing.com, +36 1 327 0407
ITALY	BLR&M, **Linda Longo**, linda.longo@blrm.it , + 39 06 3233001
IRELAND	Taylor Wessing Ireland, **Adam Griffiths**, ad.griffiths@taylorwessing.com, +353 89605 8097, **Jo Joyce**, j.joyce@taylorwessing.com , +44 207 300 7160

TaylorWessing

Country	Local Key Contact
NETHERLANDS	Taylor Wessing Netherlands, **Otto Sleeking**, o.sleeking@taylorwessing.com, +31 88 024 3023
POLAND	Taylor Wessing Poland, **Przemysław Walasek**, LL.M., p.walasek@taylorwessing.com, +48 22 5849740
PORTUGAL	Abreu Advogados, **Ricardo Henriques**, ricardo.henriques@abreuadvogados.com , +351 217231800
ROMANIA	D&B David şi Baias, **Laurentiu-Victor Pachiu**, laurentiu.pachiu@david-baias.ro, +40 742 056 647
SLOVAKIA	Taylor Wessing Slovakia, **Ján Lazur**, LL.M., j.lazur@taylorwessing.com, +421 25 26 328 04
SPAIN	ECIJA Madrid, **Teresa Pereyra Caramé**, tpereyra@ecija.com, +34 917 816 160
SWEDEN	Cirio, **Per Hedman**, per.hedman@cirio.se , +46 766 170 921
SWITZERLAND	Walder Wyss, **Celine Weber**, celine.weber@walderwyss.com , +41 58 658 56 17
UK	Taylor Wessing UK, **Victoria Hordern**, v.hordern@taylorwessing.com, +44 207 300 7096