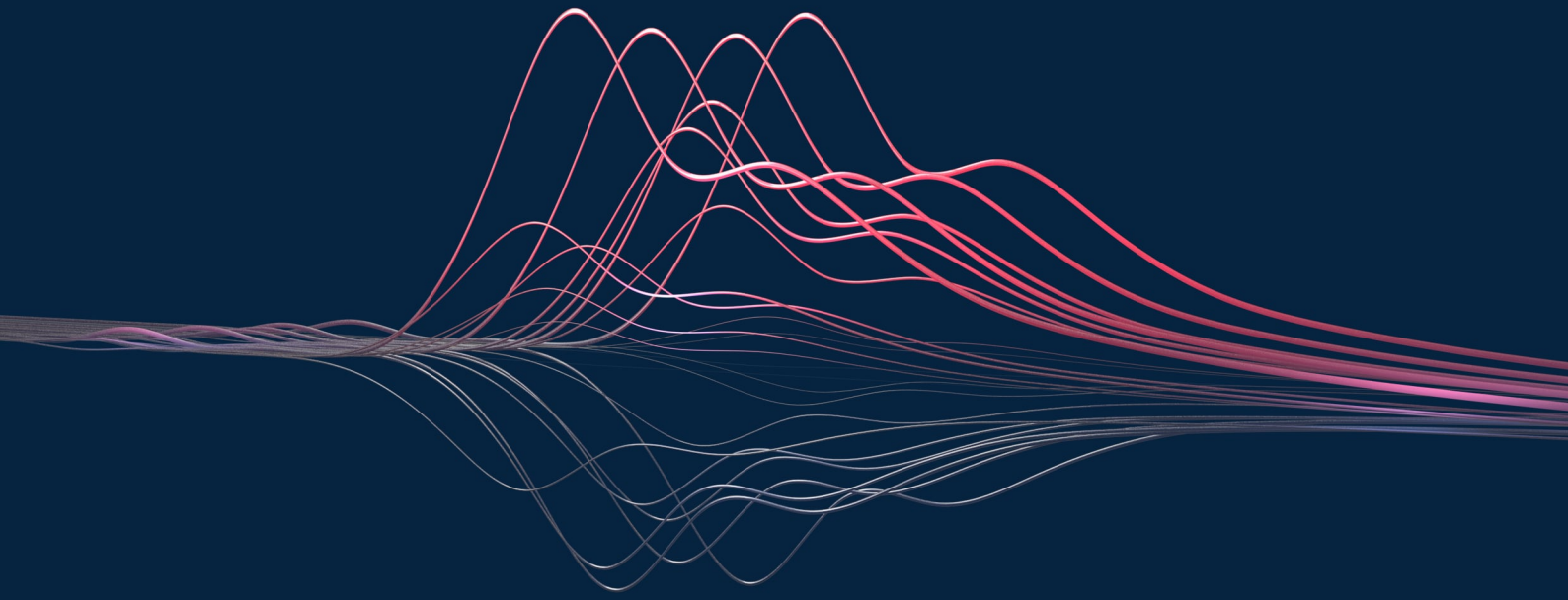
FULL HANDBOOK

Cross-border Guide to Clinical Trials and Privacy



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About this guide

Clinical trials often take place on a cross-border basis, involving sites in a number of different jurisdictions. However, experience shows that it can be difficult to understand and manage the privacy requirements for cross-border trials. In a large part, this is due to differences in local law and interpretation relating to the interplay between privacy laws and clinical trials. This is the case even within the EU: although the GDPR is directly applicable in all member states, there are often differences in the way these countries, and their national privacy and medicines regulators, interpret and apply the Regulation to the context of clinical trials.

This Guide – created by privacy professionals from our global Life Sciences sector team – covers privacy requirements in 25 jurisdictions and provides useful guidance for industry.

It offers an overview of the main privacy-related issues arising within clinical trials and answers questions pertaining to:

- Extraterritorial applicability of legislation.
- Legal ground for processing personal data in conducting clinical trials and performing pharmacovigilance activities.
- Privacy role of the stakeholders involved.
- Key-coded clinical trial data.
- Secondary use.
- International transfer of personal data.

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Albania

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Local laws

Has the local regulator published any guidelines/regulations addressing privacy matters on clinical trials and/or pharmacovigilance? ('Regulator' may mean either the local data protection authority, or the local medicines authority.)

Yes, with regard to clinical trials. The Albanian Data Protection Commissioner ("**Commissioner**") has approved Instruction no. 18 as of 03.07.2012 "On the processing of personal data in the context of clinical trials of drugs" ("**Instruction no. 18**").

The instruction is available online.

No guidelines or regulations have been published with regard to pharmacovigilance.

Extraterritorial applicability

Do the privacy laws and regulations applicable to clinical trials in your jurisdiction provide for extraterritorial applicability?

No.

Law no. 9887 "On the Protection of Personal Data", as amended (Data Protection Law) does not provide an extraterritorial applicability.

However, the domestic Data Protection Law does extend to controllers located outside the territory of the Republic of Albania who process personal data with "means" located within the territory of the Republic of Albania. The law does not provide any definition of "means" however the Commissioner has confirmed verbally on several occasions that "means" shall be understood as anything from equipment (i.e., servers), apps or persons located in Albania to collect personal data.

In case the controller (i.e., sponsor) is located outside the Republic of Albania, it must appoint a designated representative located within the territory of the Republic of Albania.

Processing of personal data in clinical trials

What is the preferred legal ground for the processing of the personal data of the participants in a clinical trial in your jurisdiction?

Article 4.2 of the Instruction no. 18 states that personal data is processed only if consented by the test subject. Therefore, consent is a mandatory legal ground for processing of the personal data. Further, based on article 4.3 of Instruction no. 18, personal data of clinical trial participants can be processed only for the following purposes:

- If necessary for granting the registration permit of a drug;
- To prove the clinical effect and safety of a drug during the scientific research process;

- To reassess the efficiency and safety of a drug after its release in the market.

Processing of personal data for pharmacovigilance

What is the legal ground for the processing of the personal data in respect of pharmacovigilance in your jurisdiction?

The processing of patients' personal data in respect of pharmacovigilance activities is based on the existence of a legal obligation based on Article 6.1. of the Data Protection Law.

In cases of adverse effects of a certain medicine/drug, the legal ground for conducting data processing activities can also be considered the protection of vital interests of the data subject (Article 6.1.c of the Data Protection Law).

Role of sponsor, principal investigator and others

Indicate the role from a data protection perspective of various parties involved (i.e in respect of the processing of the personal data of the clinical trial).

Role	Notes
Sponsor	Data controller of the participants' data.
Principal Investigator	Data controller of the participants' data in connection to data processing activities that arise from the performance of investigation activities.
Clinical Trial Site	Data controller for the purpose of helping the investigation.
Monitor	Sponsor's data processor monitoring the investigation.
CRO	Sponsor's data processor when performing activities that involve access by the CRO to the participants data.

Key-coded clinical trial data

Is key-coded clinical trial data considered personal data under your jurisdiction's data protection laws? (Key-coded clinical trial data is where the identity of the individual clinical trial participant is replaced with a unique subject identification code, and the 'key' which can be used to re-identify the participant is held by the Principal Investigator.)

Yes.

There is no definition of key-coded information under the Data Protection Law, however as long as the key-coded information is accessible through a "key", data subjects are at some point or somehow identified/identifiable regardless of who is holding the key to access the information, therefore key coded information is considered personal data under the Data Protection Law.

Re-use of personal data

Is it possible to re-use the personal data obtained for the purposes of conducting the clinical trial? If so, what requirements need to be satisfied?

Yes.

It is possible to re-use the personal data obtained for the purpose of conducting clinical trials conditional as a general rule only upon consent of the data subject. Other legal grounds for the processing need to be satisfied in a case-by-case basis (e.g., protection of vital interests of the data subject).

Hence, if the consent and/or the legal ground for processing of data extends to the re-use/ re-processing scenario, there is no need to obtain a second consent or to conduct processing on different legal grounds as there is already a valid legal ground in place for processing of personal data i.e., in case of research for the same purpose.

In light of the above, please consider that the consents given and/or the legal ground allowing the processing of data obtained for the purpose of conducting clinical trials do not automatically and in any case, extend to the re-use of the personal data for other/latter purposes unless those are specified.

Cross-border data transfer

What requirements, if any, need to be satisfied if clinical trial data is transferred internationally?

As with health data, clinical trial data are considered sensitive data. Any processing (including transfer) of sensitive data is expressly prohibited. However, processing of sensitive data is allowed in certain exceptional cases prescribed by the Data Protection Law, among others, if the data subject has given his/her consent.

Generally speaking, international data transfer is only limited to those countries offering adequate levels of data protection as provided by the Decision of the Council of Ministers no.934, dated 2 September 2009 "On the determination of the countries which have a sufficient level of personal data protection" i.e., EU and EEA member states; signatory countries of the Strasbourg convention etc.

However, as an exception, international data transfer may take place freely even if made to a country which does not provide adequate protection provided the data subject has granted consent. Other exceptions include scenarios where the international transfer is necessary for the performance of a contract between the data subject and the data controller or in case the transfer is a legal obligation of the controller; the international transfer is necessary for protecting vital interests of the data subject; the transfer constitutes a legal requirement over an important public interest or, for exercising and protecting a legal right; the transfer is done from a register that provides information to the general public etc.

Exceptionally, if none of the scenarios above are applicable, international data transfer is also possible with the prior authorization of the Commissioner, if the Commissioner is satisfied that adequate safeguards with relation to privacy and other fundamental rights of the data subject are in place. The Commissioner can additionally provide for conditions and obligations under which the data transfer should take place.

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Australia

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Local laws

Has the local regulator published any guidelines/regulations addressing privacy matters on clinical trials and/or pharmacovigilance? ('Regulator' may mean either the local data protection authority, or the local medicines authority.)

Yes.

The *Privacy Act 1988* (Cth) (Privacy Act) makes provision for circumstances where the handling of personal information and health inform may take place where it is impracticable for researchers to obtain the individual's consent.

This recognizes:

- The need to protect health information from unexpected uses beyond individual healthcare.
- The important role of health and medical research in advancing public health.

To promote these ends, the Privacy Commissioner (the regulator) has approved two sets of legally binding guidelines, issued by the National Health and Medical Research Council (NHMRC):

- *Guidelines under Section 95 of the Privacy Act 1988*, which set out procedures that Human Research Ethics Committees (HRECs) and researchers must follow when personal information is disclosed from a Commonwealth agency for medical research purposes.
- *Guidelines under Section 95A of the Privacy Act 1988*, which provide a framework for HRECs to assess proposals to handle health information held by organisations for health research (without individuals' consent). They ensure that the public interest in the research activities substantially outweighs the public interest in the protection of privacy.

Extraterritorial applicability

Do the privacy laws and regulations applicable to clinical trials in your jurisdiction provide for extraterritorial applicability?

Depending on factual analysis.

The Australian Privacy Principles (the APPs) (as set out in Schedule 1 to the Privacy Act) extend to an act done, or practice engaged in, outside Australia by an organization that has an Australian link (s 5B(1A)).

An organization has an Australian link where it is:

- An Australian citizen or a person whose continued presence in Australia is not subject to a legal time limitation
- A partnership formed, or a trust created, in Australia

- A body corporate incorporated in Australia, or
- An unincorporated association that has its central management and control in Australia (s 5B(2))

An organisation that does not fall within one of those categories will also have an Australian link where:

- It carries on business in Australia, and
- It collected or held personal information in Australia, either before or at the time of the act or practice (s 5B(3))

Note: The phrase 'carries on business in Australia' in s 5B(3)(c) is not defined in the Privacy Act. However, it arises in other areas of law, including corporations and consumer law. Guidance may be drawn from judicial consideration of the phrase in those contexts.

Processing of personal data in clinical trials

What is the preferred legal ground for the processing of the personal data of the participants in a clinical trial in your jurisdiction?

Subject to the exceptions set out in our answer to Question 1, the collection of sensitive information (including health information) requires the individual's consent.

The applicable provision is found in APP 3.3.

An agency or organization (an APP entity) must not collect sensitive information about an individual unless:

- The individual consents to the collection of the information and:
  - If the entity is an agency – the information is reasonably necessary for, or directly related to, one or more of the entity's functions or activities; or
  - If the entity is an organisation – the information is reasonably necessary for, or directly related to, one or more of the entity's functions or activities;
- Or subclause 3.4 applies in relation to the information (Note: Subclause 3.4 provides various carve outs for law enforcement, court orders, and most relevant to this enquiry is 3.4(c) a permitted health situation exists.

Permitted health situations are defined section 16B of the Privacy Act and set the circumstances where the collection, use or disclosure of health information is permitted without obtaining the individual's consent.

Use or disclosure of personal information

APP 6 sets out the conditions by which an APP entity may use or disclose personal information.

- 6.1 In general, If an APP entity holds personal information about an individual that was collected for a particular purpose (the primary purpose), the entity must not use or disclose the information for another purpose (the secondary purpose) unless:
  - The individual has consented to the use or disclosure of the information; or
  - Subclause 6.2 or 6.3 (note 6.3 only applies to government agencies) applies in relation to the use or disclosure of the information.

Note: APP 8 sets out requirements for the disclosure of personal information to a person who is not in Australia.

- 6.2 This subclause applies in relation to the use or disclosure of personal information about an individual if:
  - The individual would reasonably expect the APP entity to use or disclose the information for the secondary purpose and the secondary purpose is:

- If the information is sensitive information (e.g. health information) directly related to the primary purpose; or
- If the information is not sensitive information--related to the primary purpose; or

- The use or disclosure of the information is required or authorised by or under an Australian law or a court/tribunal order; or
- *Not applicable*
- The APP entity is an organisation and a permitted health situation exists in relation to the use or disclosure of the information by the entity; or
- *Not applicable.*

Consent – the regulator has published non-binding guidelines on consent to the handling of personal information, and the following recommendations are also consistent with findings from the regulator's investigatory powers. In general consent must be informed, voluntary, current and specific, the individual must also have capacity to provide consent.

Processing of personal data for pharmacovigilance

What is the legal ground for the processing of the personal data in respect of pharmacovigilance in your jurisdiction?

The legal grounds for processing personal data in respect of pharmacovigilance are as set out in Local laws.

Role of sponsor, principal investigator and others

Indicate the role from a data protection perspective of various parties involved (i.e in respect of the processing of the personal data of the clinical trial).

Role	Notes
Sponsor	The Privacy Act does not contain the concept of controller and processor, to the extent the Sponsor is an APP entity with an Australian link (as described more fully in our answer to Question 3) collecting or handling personal information, the Sponsor will be bound by the Privacy Act and the APPs.
Principal Investigator	The Privacy Act does not contain the concept of controller and processor, to the extent the Principal Investigator is an APP entity with an Australian link (as described more fully in our answer to Question 3) collecting or handling personal information, the Sponsor will be bound by the Privacy Act and the APPs.
Clinical Trial Site	The Privacy Act does not contain the concept of controller and processor, to the extent the CTS is an APP entity with an Australian link (as described more fully in our answer to Question 3) collecting or handling personal information, the Sponsor will be bound by the Privacy Act and the APPs.
Monitor	The Privacy Act does not contain the concept of controller and processor, to the extent the Moniotor is an APP entity with an

	Australian link (as described more fully in our answer to Question 3) collecting or handling personal information, the Sponsor will be bound by the Privacy Act and the APPs.
CRO	The Privacy Act does not contain the concept of controller and processor, to the extent the CRO is an APP entity with an Australian link (as described more fully in our answer to Question 3) collecting or handling personal information, the Sponsor will be bound by the Privacy Act and the APPs.

Key-coded clinical trial data

Is key-coded clinical trial data considered personal data under your jurisdiction's data protection laws? (Key-coded clinical trial data is where the identity of the individual clinical trial participant is replaced with a unique subject identification code, and the 'key' which can be used to re-identify the participant is held by the Principal Investigator.)

To the extent key-coded clinical trial data cannot reasonably identify an individual it is likely to be De-identified personal information for the purpose of the Privacy Act.

De-identified personal information is no longer personal information for the purpose of the Privacy Act.

In general, personal information will be de-identified if:

- Direct identifiers are removed; and
- One or both of the following steps have been taken:
  - The removal or alteration of other information that could potentially be used to re-identify an individual, and/or;
  - The use of controls and safeguards in the data access environment to prevent re-identification

The regulator has issued the following guidance on de-identification:

- De-identification and the Privacy Act;
- The De-identification decision making framework (as adapted from the UK version);
- Guide to data analytics and the Australian Privacy Principles.

Re-use of personal data

Is it possible to re-use the personal data obtained for the purposes of conducting the clinical trial? If so, what requirements need to be satisfied?

Yes, but only in limited circumstances.

This is because under APP 6.1 if an APP entity holds personal information about an individual that was collected for a particular purpose (the primary purpose), the entity must not use or disclose the information for another purpose (the secondary purpose) unless:

- The individual has consented to the use or disclosure of the information; or
- Subclause 6.2 or 6.3 (*note 6.3 only applies to government agencies*) applies in relation to the use or disclosure of the information.

Note: APP 8 sets out requirements for the disclosure of personal information to a person who is not in Australia.

6.2 This subclause applies in relation to the use or disclosure of personal information about an individual if:

- The individual would reasonably expect the APP entity to use or disclose the information for the secondary purpose and the secondary purpose is:
  - If the information is sensitive information (e.g. health information) directly related to the primary purpose; or
  - If the information is not sensitive information--related to the primary purpose; or
- The use or disclosure of the information is required or authorised by or under an Australian law or a court/tribunal order; or
- *Not applicable*
- The APP entity is an organisation and a permitted health situation exists in relation to the use or disclosure of the information by the entity; or
- *Not applicable.*

Cross-border data transfer

What requirements, if any, need to be satisfied if clinical trial data is transferred internationally?

Before an APP entity discloses personal information to an overseas recipient, the entity must take reasonable steps to ensure that the overseas recipient does not breach the APPs in relation to the information (APP 8.1). There are exceptions to the requirement in APP 8.1 to take reasonable steps and to the accountability provision in s 16C.

Note: an APP entity that discloses personal information to an overseas recipient is accountable for any acts or practices of the overseas recipient in relation to the information that would breach the APPs (s 16C).

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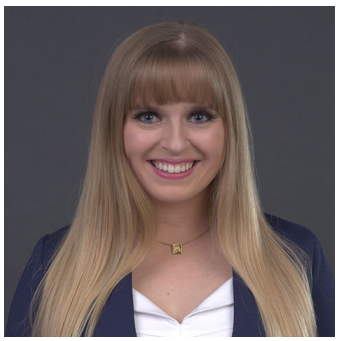

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Austria

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Local laws

Has the local regulator published any guidelines/regulations addressing privacy matters on clinical trials and/or pharmacovigilance? ('Regulator' may mean either the local data protection authority, or the local medicines authority.)

No.

Extraterritorial applicability

n/a

Processing of personal data in clinical trials

What is the preferred legal ground for the processing of the personal data of the participants in a clinical trial in your jurisdiction?

In Austria, the preferred legal processing ground is the participants' consent (Article 6 (1) (a) and Article 9 (2) (a) GDPR). This is because in clinical trials, health data are predominantly processed and there is no other practical legal basis available. Usually, sponsors provide an "Informed Consent Form" to the clinical trial site which the clinical trial sites use to obtain participants' consent.

Processing of personal data for pharmacovigilance

What is the legal ground for the processing of the personal data in respect of pharmacovigilance in your jurisdiction?

Article 6 (1) (c) GDPR in connection with the respective provisions of the Austrian Medicine Act (*Arzneimittelgesetz*).

Role of sponsor, principal investigator and others

Indicate the role from a data protection perspective of various parties involved (i.e in respect of the processing of the personal data of the clinical trial).

Sponsor	(Joint) Controller
Principal Investigator	No own role (employee of the Clinical Trial Site)

Clinical Trial Site	(Joint) Controller
Monitor	Depends on the specific circumstances and the tasks of the Monitor. Usually, the Monitor is a processor of the Sponsor since it acts on behalf and under the instructions of the Sponsor.
CRO	Depends on the specific circumstances and the tasks of the CRO. Usually, the CRO is a processor of the Sponsor since it acts on behalf and under the instructions of the Sponsor.

Key-coded clinical trial data

Is key-coded clinical trial data considered personal data under your jurisdiction's data protection laws? (Key-coded clinical trial data is where the identity of the individual clinical trial participant is replaced with a unique subject identification code, and the 'key' which can be used to re-identify the participant is held by the Principal Investigator.)

Yes, key-coded clinical data is personal data if it is possible to re-identify the data subjects using the key-coded data (i.e., if it is possible to lift pseudonymization).

Re-use of personal data

Is it possible to re-use the personal data obtained for the purposes of conducting the clinical trial? If so, what requirements need to be satisfied?

Generally, it is possible to re-use such data with (additional) consent. Apart from that, re-use must be justified by an appropriate legal basis both under Article 6 and Article 9 GDPR. On one hand, re-use for clinical trials is possible if participants granted so-called "*broad consent*" for certain broader defined research areas in advance. On the other hand, re-use outside of clinical trials is possible for scientific purposes and / or for scientific institutions, both under rather narrow requirements which are challenging to fulfil in practice.

Cross-border data transfer

What requirements, if any, need to be satisfied if clinical trial data is transferred internationally?

Where the clinical trial data is key-coded and it is not possible to re-identify the data, such data are not personal data and thus international data transfer regulations do not apply.

However, where the re-identification of the participants' personal data is possible, international data transfer requirements including adequate guaranteed measures must be met if the recipient is in a country which does not offer an adequate level of protection according to the GDPR (this especially concerns requirements set out by Article 44 et seq. GDPR together with the ECJ Schrems II decision).

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Belgium

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Local laws

Has the local regulator published any guidelines/regulations addressing privacy matters on clinical trials and/or pharmacovigilance? ('Regulator' may mean either the local data protection authority, or the local medicines authority.)

No.

The Belgian Data Protection Authority has not (yet) published specific guidelines on clinical trials or pharmacovigilance. It has, however, published guidelines on the more general topic of 'Research' which are available in Dutch and French.

Extraterritorial applicability

Does the GDPR/UK GDPR apply to a clinical trial sponsor situated outside the EEA?

Yes. If a sponsor is not established in the EEA but carries out clinical trials on data subjects in Belgium this will likely amount to the sponsor monitoring data subjects in the EEA, and, therefore, comes within the scope of the GDPR by virtue of Article 3(2)(b).

There are no particular considerations for Belgium with regard to this assessment of the territorial application of the GDPR. In any case, the facts of the case would need to be assessed against the constitutive elements of Articles 3(1) and 3(2) GDPR.

Processing of personal data in clinical trials

What is the preferred legal ground for the processing of the personal data of the participants in a clinical trial in your jurisdiction?

The Belgian Data Protection Authority has adopted the view that the legal basis for the processing of (sensitive) health data in the context of clinical trials is to be found in a combination of Article 6(1)(e) GDPR ("task carried out in the public interest") or Article 6(1)(f) GDPR ("legitimate interest"), and Article 9(2)(j) GDPR ("archiving in the public interest, scientific and historical research or statistical purposes"). Article 6(e) is relevant both to the public and private sector sponsors (for the latter, when governmental tasks are outsourced to private entities). Both sectors may rely on this processing ground. Article 6(f) may not be relied upon by a public sector sponsor in the performance of their tasks. This processing ground is thus only relevant for private sector sponsors.

Processing of personal data for pharmacovigilance

What is the legal ground for the processing of the personal data in respect of pharmacovigilance in your jurisdiction?

The processing of personal data in respect of pharmacovigilance obligations is based on the existence of a legal obligation (article 6(1)(c) GDPR). The personal data is processed on the basis of obligations laid down in Directive 2010/84/EU, transposed into Belgian law via the Act of 3 August 2012 amending the Act of 25 March 1964 on medicines for human use, and Regulation 726/2004 (as amended). The

corresponding legal ground for lawful processing of special categories of data in the context of these obligations is in principle Article 9 (2)(i) GDPR ("reasons of public interest in the area of public health"). Therefore, the guidance does not to rely on consent. Article 6(e) is relevant both to the public and private sector sponsors (for the latter, when governmental tasks are outsourced to private entities). Both sectors may rely on this processing ground. Article 6(f) may not be relied upon by a public sector sponsor in the performance of their tasks. This processing ground is thus only relevant for private sector sponsors.

Role of sponsor, principal investigator and others

Indicate the role from a data protection perspective of various parties involved (i.e in respect of the processing of the personal data of the clinical trial).

Role	Notes
Sponsor	(Joint) controller; Any joint controllership would be in relation to the principal investigator where the sponsor would (jointly with the principal investigator) determine the essential means and purposes of the clinical trials.
Principal Investigator	(Joint) controller or processor depending on the degree of involvement in the decision and design process of the clinical trial. Any joint controllership would be in relation to the sponsor (as per above). If the principal investigator just accepts the protocol drafted by the sponsor, the investigator can be considered as a processor.
Clinical Trial Site	Data controller of the participants' personal data for the purposes of providing adequate healthcare assistance which is independent/must be distinguished from the processing of this data for research purposes.
Monitor	Sponsor's data processor, in charge of supervising the correct development of the research.
CRO	Typically acts as a processor because of the intermediary function between a number of investigators (trial centers) and the sponsor in the clinical trial. However, to the extent the CRO becomes more involved in the decision and design process of the trial, it may also be considered a joint controller.

As a general note: we have indicated above the most likely qualifications. However, this remains largely a factual determination based on the specifics of the case.

Key-coded clinical trial data

Is key-coded clinical trial data considered personal data under your jurisdiction's data protection laws? (Key-coded clinical trial data is where the identity of the individual clinical trial participant is replaced with a unique subject identification code, and the 'key' which can be used to re-identify the participant is held by the Principal Investigator.)

Key-coded clinical trial data qualifies as pseudonymized data which constitutes personal data under the GDPR.

Re-use of personal data

Is it possible to re-use the personal data obtained for the purposes of conducting the clinical trial? If so, what requirements need to be satisfied?

Yes. The re-use of personal data constitutes a further use which must meet the requirements of Articles 5(1)(b) and 6(4) GDPR.

If clinical trial data are further used for statistical and research purposes, a presumption of compatibility applies to such further use subject to compliance with the conditions of Article 89(1) GDPR which states that 'appropriate safeguards' must be implemented (Recital 50 GDPR).

Aside from the exceptions to data subject rights under the GDPR, the Belgian Act of 30 July 2018 on the protection of personal data ("Data Protection Act") also contains an 'exception regime' that allows to derogate from certain data subject rights (i.e. access, rectification, restriction and objection) for processing of data for statistical and research purposes to the extent that such rights are likely to render impossible or seriously impair the achievement of the specific purposes. This 'exception regime' can apply to further processing. However, it only applies when specific conditions are met, some of which differ depending on whether the original controller is the controller for the further processing of the data (Title 4 Data Protection Act). General requirements include 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) concern, for example, the obligation to conclude an agreement with the original controller and requirements to anonymise and pseudonymise the data.

Cross-border data transfer

What requirements, if any, need to be satisfied if clinical trial data is transferred internationally?

Unless the data is anonymized, data transfers outside the European Union are in principle prohibited, unless an adequate level of protection is ensured through an adequacy decision or appropriate safeguards (e.g. standard contractual clauses) are applied or a derogation under Article 49 GDPR exists. Where standard contractual clauses are used, a transfer impact assessment must be performed.

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Bosnia and Herzegovina

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Local laws

Has the local regulator published any guidelines/regulations addressing privacy matters on clinical trials and/or pharmacovigilance? ('Regulator' may mean either the local data protection authority, or the local medicines authority.)

No.

Extraterritorial applicability

Do the privacy laws and regulations applicable to clinical trials in your jurisdiction provide for extraterritorial applicability?

No.

The Law on Protection of Personal Data of Bosnia and Herzegovina (the "**Law**") is the main law governing data protection and privacy in Bosnia and Herzegovina ("**BH**") and in the absence of guidelines/regulations specifically addressing privacy matters on clinical trials, general provisions envisaged by the Law are applicable to the clinical trials as well. The Law lacks provisions envisaging its extraterritorial effect, therefore it is generally not applicable to foreign data controllers. In addition, to the best of our knowledge, the BH Data Protection Agency ("**DPA**") has never taken actions against foreign data controllers as it lacks instruments for enforcement of the Law against foreign entities.

Processing of personal data in clinical trials

What is the preferred legal ground for the processing of the personal data of the participants in a clinical trial in your jurisdiction?

In practice, the processing of the data of clinical research participants is based on the necessity for compliance with a legal obligation to which the data controller is subject pursuant to the Article 6 paragraph 1, item a) of the Law. However, in case of processing of other categories of personal data which fall outside the scope of the data necessary to be processed in a clinical trial, pursuant to the legislation applicable to clinical trials, it is necessary to obtain the data subject's consent.

Processing of personal data for pharmacovigilance

What is the legal ground for the processing of the personal data in respect of pharmacovigilance in your jurisdiction?

The processing of the data within the scope of pharmacovigilance activities is based on the necessity for compliance with a legal obligation to which the data controller is subject pursuant to the Article 6 paragraph 1, item a) of the Law, and in cases where there is an

adverse effect, it is understood that the legal ground for the data processing can also be considered the protection of vital interests of the data subject pursuant to the Article 6 paragraph 1 item c), however in this case the consent of the data subject must be obtained without delay.

Role of sponsor, principal investigator and others

Indicate the role from a data protection perspective of various parties involved (i.e in respect of the processing of the personal data of the clinical trial).

Role	Notes
Sponsor	Data controller of the key-coded data of participants.
Principal Investigator	Data controller of the participants personal data in connection with the data processing activity that arise because of performing the investigation activities.
Clinical Trial Site	Data controller of the participants personal data for the purpose of providing adequate healthcare assistance within the scope of the investigation.
Monitor	Sponsor's data processor, in charge of supervising the correct development of the investigation.
CRO	Sponsor's data processor when (i) performing monitoring tasks, and (ii) in the event that the Sponsor subcontracts other tasks to the CRO that involve access by the CRO to encrypted participant data.

Key-coded clinical trial data

Is key-coded clinical trial data considered personal data under your jurisdiction's data protection laws? (Key-coded clinical trial data is where the identity of the individual clinical trial participant is replaced with a unique subject identification code, and the 'key' which can be used to re-identify the participant is held by the Principal Investigator.)

The key-coded clinical trial data is not defined by the applicable legislation due to the lack of special guidelines/regulations addressing privacy matters on clinical trials. However, pursuant to the Law, personal data is defined as any information related to an identified or identifiable natural person, therefore pursuant to this definition, any information related to an identified or identifiable natural person is deemed as personal data irrespective of the fact who is holding the identification "key".

Re-use of personal data

Is it possible to re-use the personal data obtained for the purposes of conducting the clinical trial? If so, what requirements need to be satisfied?

Yes.

Yes, to the extent that there are legal grounds for this processing.

In cases where the participants' consent has been previously obtained for the processing of his/her personal data within the scope of conducting a clinical trial, the data can be re-used for further research related to the same field.

Cross-border data transfer

What requirements, if any, need to be satisfied if clinical trial data is transferred internationally?

Pursuant to the Law, heath data, i.e., clinical trial data, falls under the category of special data, whose processing (which also implies transfer) is generally prohibited. However, processing of special data is allowed if *inter alia* the data subject has explicitly granted their consent.

Under the assumptions that the data subject has granted their consent, and that the data processing agreement is concluded between the controller and the processor, health data may be transferred to another country that implements adequate safeguards for personal data set by the Law.

Adequacy of safeguards is evaluated on the basis of specific characteristics of each particular transfer, such as the types of personal data, purpose and period of the processing, country to which data is to be transferred, statutory rules in force in the respective country and other relevant circumstances.

Generally, it is considered that the EU countries and signatories to the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data, undertake adequate safeguards, so that the data may be transferred to them.

Further, personal data may also be transferred to a country which does not provide adequate safeguards in the aforementioned sense, among others in the following cases envisaged by the Law: (i) prior consent was obtained from the person whose data are transferred and the person was informed on the potential consequences of the data transfer; (ii) the disclosure of personal data is necessary for fulfilling the contract between the data subject and the controller or the fulfilment of pre-contractual obligations undertaken at the request of the person whose data are processed.

Exceptionally, even if none of the aforementioned cases is applicable, the data can be legitimately transferred out of BH if the DPA approves such transfer if a data controller in that country provides adequate safeguards for the protection of privacy and fundamental rights and freedoms of individuals or provision of similar rights arises from the provisions of a special agreement.

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Croatia

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Local laws

Has the local regulator published any guidelines/regulations addressing privacy matters on clinical trials and/or pharmacovigilance? ('Regulator' may mean either the local data protection authority, or the local medicines authority.)

No, the Croatian Personal Data Protection Agency has not published such a document.

The Agency for Medicinal Products and Medical Devices of Croatia has published a Guide for patients on clinical trials. In this guide it is briefly stated that the clinical trials involve processing of special categories of personal data and is additionally noted that most trials use codes instead of the name of the data subjects to ensure anonymity. The Guide is available only in Croatian language and can be found on the following link.

Extraterritorial applicability

Does the GDPR/UK GDPR apply to a clinical trial sponsor situated outside the EEA?

Yes, to the extent that clinical trial participants (data subjects) are located in the EU, based on Article 3(2)(b).

In case the sponsor is not located within the EU, it must appoint a representative located within the EU, as required by Article 27 of the GDPR.

Processing of personal data in clinical trials

What is the preferred legal ground for the processing of the personal data of the participants in a clinical trial in your jurisdiction?

The Croatian legislator has not regulated this matter directly nor has the Croatian Personal Data Protection Agency issued any official opinions on this topic. In addition, currently there is no relevant practice dealing with the legal basis for the processing of personal data in the clinical trials.

However, we are of the opinion that an appropriate legal ground for the processing of personal data would be the existence of a legal obligation to process such data, pursuant to the Article 6.1 c) in connection with the Article 9.2 i) and j) of the GDPR.

Namely, conducting clinical trials is necessary for placing medicinal products on the market. Persons who choose to participate in a clinical trial have to, inevitably disclose their personal data to the sponsor, i.e., the investigator. Simultaneously, the sponsor and investigator are obliged to keep data on the clinical trial for at least 25 years pursuant to the Article 58 of the Regulation (EU) No 536 /2014.

Processing of personal data for pharmacovigilance

What is the legal ground for the processing of the personal data in respect of pharmacovigilance in your jurisdiction?

Processing of trial participants' personal data within the scope of pharmacovigilance activities is based on the existence of a legal obligation of a medical worker to inform the competent authority (Agency for Medicinal Products and Medical Devices of Croatia) of a medication's side-effects.

The obligation to process personal data of trial participants experiencing the side-effects of medications is prescribed, inter alia, by the Croatian Ordinance on pharmacovigilance (Official Gazette no. 83/2013, 145/2021). Therefore, the Article 6.1 c) of the GDPR is applicable to such data processing.

In addition, in certain cases, processing personal data may be considered as performance of a task carried out in the public interest pursuant to the Article 6.1 e) of the GDPR.

Role of sponsor, principal investigator and others

Indicate the role from a data protection perspective of various parties involved (i.e in respect of the processing of the personal data of the clinical trial).

Role	Notes
Sponsor	Data controller.
Principal Investigator	Data controller (jointly with the sponsor) but may only be a data processor depending on the structure of the clinical trial.
Clinical Trial Site	Sponsor's data processor, in charge of providing adequate healthcare assistance within the scope of the clinical trial.
Monitor	Data processor engaged by the sponsor to supervise the correct development of the clinical trial.
CRO	Sponsor's data processor but can be a joint data controller if CRO and the sponsor jointly determine why and how personal data is processed.

Key-coded clinical trial data

Is key-coded clinical trial data considered personal data under your jurisdiction's data protection laws? (Key-coded clinical trial data is where the identity of the individual clinical trial participant is replaced with a unique subject identification code, and the 'key' which can be used to re-identify the participant is held by the Principal Investigator.)

There are no local regulations defining key-coded data as personal data in Croatia.

However, based on the decision of the CJEU in the case no. C582/14, Breyer v. Bundesrepublik Deutschland, key-coded clinical trial data would be considered personal data if the person holding the data has the means that may likely and reasonably be used to access the key needed for decoding and combine it with the coded data.

Therefore, if the identification of the trial participants is prohibited by law or practically impossible on account of the fact that it requires a disproportionate effort in terms of time, cost and man-power, so that the risk of identification appears in reality to be insignificant, key-coded data would not be considered personal data.

Re-use of personal data

Is it possible to re-use the personal data obtained for the purposes of conducting the clinical trial? If so, what requirements need to be satisfied?

Yes, the clinical trial data can be reused.

Such processing of the trial participants' personal data needs to follow GDPR's principles relating to processing of personal data, especially the principle of transparency (when data is collected), data minimisation and the principle of integrity and confidentiality.

Cross-border data transfer

What requirements, if any, need to be satisfied if clinical trial data is transferred internationally?

If it is impossible for the recipient of key-coded clinical trial data to have access to a key needed for decoding, such data will not be considered as personal data in the scope of the GDPR, and thus, strict EU regulations regarding international transfers of personal data are not applicable.

If, however, the data can be considered as "personal data" as defined by the GDPR (and the CJEU's decision cited above), international data transfers may only be carried out in full compliance with the GDPR, and should be based on either:

- Appropriate safeguards (most commonly the EU Commission Standard Contractual Clauses coupled with a transfer impact assessment); or
- A derogation under Article 49 GDPR. For example, it may be possible to justify transfers of personal data necessary for pharmacovigilance purposes on the basis of Article 49(1)(d) (important reasons of public interest).

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Czech Republic

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Local laws

Has the local regulator published any guidelines/regulations addressing privacy matters on clinical trials and/or pharmacovigilance? ('Regulator' may mean either the local data protection authority, or the local medicines authority.)

There is no such guideline or regulation in the Czech Republic addressing privacy matters on clinical trials and / or pharmacovigilance specifically.

Please note, in 2004 the Czech Data Protection Authority (UOOU) issued an opinion addressing privacy matters on clinical trials (which was revised in 2013).

However, due to the adoption of the GDPR and the effectiveness of the Czech Act No. 110/2019 Coll., on the processing of personal data, this opinion has become invalid and, thus, is no longer applicable.

It is further to be noted that, currently, the Czech Data Protection Authority is relying mostly upon the Opinion No. 3/2019, on questions and answers on the interaction between the Clinical Trials Regulation and the General Data Protection Regulation, issued by the European Data Protection Board ("**EDPB**").

Extraterritorial applicability

Does the GDPR/UK GDPR apply to a clinical trial sponsor situated outside the EEA?

Yes, to the extent that clinical trial participants (data subjects) are located in the EU, based on Article 3(2)(b).

In those cases where the sponsor is not located within the EU, it shall appoint a representative within the EU, as required by Article 27 of the GDPR.

Processing of personal data in clinical trials

What is the preferred legal ground for the processing of the personal data of the participants in a clinical trial in your jurisdiction?

Czech law does not provide an explicit answer as to what is the preferred legal ground for the processing of the personal data of the participants in a clinical trial, as there are no Czech regulations or guidelines specifically addressing privacy matters on clinical trials.

The previous practice based on the opinion issued by the Czech Data Protection Authority has preferred the clinical trial participant's consent as the legal ground for processing of his/her personal data. However, due to the adoption of the GDPR and the effectiveness of the Czech Act No. 110/2019 Coll., on the processing of personal data, the abovementioned opinion has become invalid and, thus, is no longer applicable.

We have consulted the Czech Data Protection Authority and they have assured us that, currently, they are relying mostly upon the Opinion No. 3/2019, on questions and answers on the interaction between the Clinical Trials Regulation (Regulation (EU) No. 536/2014) and the GDPR issued by the EDPB. For the sake of completeness, it is further to be noted that the Directorate-General for Health and Food Safety of the European Commission has also issued the document which aims to explain the interplay between the abovementioned regulations.

Therefore, the preferred legal grounds for the processing of the personal data of the clinical trial participants recommended by the EDPB and the Directorate-General for Health and Food Safety and, most importantly, accepted by the Czech Data Protection Authority are:

- For the processing activities related to reliability and safety purposes a legal obligation within the legal basis of Article 6(1)(c) of the GDPR in conjunction with Article 9(2)(i) of the GDPR;
- For all other processing activities purely related to research activities:
  - The public interest under Article 6(1)(e) in conjunction with Article 9(2)(i) or Article 9(2)(j) of the GDPR;
  - The legitimate interests under Article 6(1)(f) in conjunction with Article 9(2)(j) of the GDPR; or
  - Under specific circumstances, when all conditions are met, the clinical trial participant's explicit consent under Article 6(1)(a) and 9 (2)(a) of the GDPR.

Processing of personal data for pharmacovigilance

What is the legal ground for the processing of the personal data in respect of pharmacovigilance in your jurisdiction?

Czech law does not provide an explicit answer as to what is the legal ground for the processing of the personal data in respect of pharmacovigilance, as there are no Czech regulations or guidelines specifically addressing privacy matters on pharmacovigilance.

However, it could be considered that the processing of patients' personal data within the scope of pharmacovigilance activities is based on the existence of a legal obligation (pharmacovigilance obligation under the Czech Act No. 378/2007 Coll., on pharmaceuticals, as amended) within the legal basis of Article 6(1)(c) of the GDPR.

Moreover, in the situation where there is an adverse effect to the health of the patient (i.e., the data subject), the legal ground for the processing of the personal data can also be considered to be the protection of vital interests of the patient under Article 6(1)(c) of the GDPR.

Role of sponsor, principal investigator and others

Indicate the role from a data protection perspective of various parties involved (i.e in respect of the processing of the personal data of the clinical trial).

Role	Notes
Sponsor	Data controller of the key-coded data of participants.
Principal Investigator	Data controller of participants' personal data in connection with data processing activities, for the purpose of carrying out research activities.
Clinical Trial Site	

	Data Controller of participants' personal data for the purposes of providing healthcare within the scope of investigation.
Monitor	Sponsor's data processor, in charge of supervising the correct development of the investigation.
CRO	Sponsor's data processor in performing monitoring tasks and other tasks involving CRO access to encrypted participant data.

Key-coded clinical trial data

Is key-coded clinical trial data considered personal data under your jurisdiction's data protection laws? (Key-coded clinical trial data is where the identity of the individual clinical trial participant is replaced with a unique subject identification code, and the 'key' which can be used to re-identify the participant is held by the Principal Investigator.)

Key-coded clinical trial data constitutes pseudonymized personal data. unless the codification procedure ensures that re-identification of participants is not possible and in such case data will be anonymised.

Re-use of personal data

Is it possible to re-use the personal data obtained for the purposes of conducting the clinical trial? If so, what requirements need to be satisfied?

If there are legal grounds for re-use, yes, even without the need for subject consent.

Cross-border data transfer

What requirements, if any, need to be satisfied if clinical trial data is transferred internationally?

Assuming the clinical trial data is not anonymized, transfers to countries outside of the EU which do not benefit from an adequacy decision approved by the EU Commission should be based on either:

- Appropriate safeguards (most commonly the EU Commission Standard Contractual Clauses coupled with a transfer impact assessment; or
- A derogation under Article 49 GDPR. For example, it may be possible to justify transfers of personal data necessary for pharmacovigilance purposes on the basis of Article 49(1)(d) (important reasons of public interest).

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Denmark

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Local laws

Has the local regulator published any guidelines/regulations addressing privacy matters on clinical trials and/or pharmacovigilance? ('Regulator' may mean either the local data protection authority, or the local medicines authority.)

No.

A brief introduction to the area can be found on the Datatilsynet website. This text does, however, not provide any supplementary guidance, but is merely an overview of the fundamental rules and the interplay with other legislation, such as the Act on Research Ethics Review of Health Research Projects (Act no 1338 of 1 September 2020), according to which clinical trials in Denmark must be preapproved by the Ethical Committee.

Extraterritorial applicability

Does the GDPR/UK GDPR apply to a clinical trial sponsor situated outside the EEA?

Yes, where data subjects are located within the EU, the GDPR will apply, pursuant to GDPR article 3(2)(a) and/or article 3(2)(b).

Furthermore, if data subjects are located in Denmark, the Danish Data Protection Act (the "**Act**") will apply, pursuant to section 4(3)(1) of the Act, which is equivalent to article 3(2)(a) and/or section 4(3)(2) of the Act, which is the equivalent to article 3(2)(b) with the exception that the geographic scope is narrowed down from EU to Denmark.

Processing of personal data in clinical trials

What is the preferred legal ground for the processing of the personal data of the participants in a clinical trial in your jurisdiction?

The Danish Data Protection Act section 10 ("Data as mentioned in Article 9(1) and Article 10 of the General Data Protection Regulation may be processed where the processing takes place for the sole purpose of carrying out statistical or scientific studies of significant importance to society and where such processing is necessary in order to carry out these studies") is probably the most frequently used legal basis (see Act No. 502 of 23 May 2018 for further details).

However, we are aware that at least some of the larger medical companies are switching to GDPR article 6(1)(f) as the legal basis where possible (no special categories of data involved) due to restrictions on transfer of personal data processed under the above mentioned section 10.

Processing of personal data for pharmacovigilance

What is the legal ground for the processing of the personal data in respect of pharmacovigilance in your jurisdiction?

GDPR article 6(1)(c), as the processing is necessary in order for the data controller to comply with chapter 5 of the Danish Medicines Act.

Role of sponsor, principal investigator and others

Indicate the role from a data protection perspective of various parties involved (i.e in respect of the processing of the personal data of the clinical trial).

Role	Notes
Sponsor	Data controller.
Principal Investigator	Data controller.
Clinical Trial Site	Data controller.
Monitor	Presumably a data controller for personal information about research staff – does usually not process data of participants in the study.
CRO	Depends on the actual role assigned to the CRO, in particular with regards to the level of responsibility. Where the CRO is merely performing analyses specified by others and returning the "raw" results, the CRO would generally be considered a data processor, while broader instructions, requiring the CRO to interpret results and possibly make own decisions on (parts of) the processing would indicate that the CRO would be a data controller.

Key-coded clinical trial data

Is key-coded clinical trial data considered personal data under your jurisdiction's data protection laws? (Key-coded clinical trial data is where the identity of the individual clinical trial participant is replaced with a unique subject identification code, and the 'key' which can be used to re-identify the participant is held by the Principal Investigator.)

Yes.

Re-use of personal data

Is it possible to re-use the personal data obtained for the purposes of conducting the clinical trial? If so, what requirements need to be satisfied?

In relation to GDPR, yes. Personal data can be re-used for scientific research purposes (without having to establish a separate lawful basis) provided a controller complies with the safeguards under Article 89(1) GDPR.

However, if data is being re-used in other clinical trials than the one for which they were originally collected, the new trials must be approved by the Ethical Committee, and data subjects may be required to consent to the use of their data for such new trials. This consent is a consent to participate in the clinical trial and should not to be confused with a consent for the processing of personal data, even though the consent must meet the criteria for a valid consent as per GDPR.

Furthermore, disclosure of data processed on the basis of section 10 of the Danish Data Protection Act requires prior authorization from the Data Protection Agency if the disclosure

- Is made for the purpose of processing outside the territorial scope of the General Data Protection Regulation, see Article 3 of the General Data Protection Regulation;
- Relates to biological material; or
- Is made for the purpose of publication in a recognised scientific journal or similar.

Furthermore, the Data Protection Agency may lay down further terms and restrictions for disclosure of data processed under section 10; even if the disclosure is not covered by the three scenarios described above.

Cross-border data transfer

What requirements, if any, need to be satisfied if clinical trial data is transferred internationally?

Where clinical trials are conducted on the basis of section 10(1) of the Danish Data Protection Act (see also question 4 above), international transfer of clinical trial data constituting personal data requires prior approval from the Danish Data Protection Agency. This also applies to disclosure of biological material and disclosure of information for the purpose of publication in recognized scientific journals or similar, regardless if the recipient is within our outside EU.

Where clinical trials are conducted using a different legal basis than section 10 of the Danish Data Protection Act, the general rules on export of personal data as laid down in chapter V of GDPR must be observed. Therefore, the data exporter must ensure that the data subjects will – also in the countries to which data are exported – enjoy a level of protection that is essentially equivalent to the level of protection within EU. This will always involve the application of a valid transfer mechanism as per GDPR article V, but would also require supplementary measures in situations, where the legislation in the countries of destination does not provide sufficient protection, as per the ruling of the European Court of Justice in the case C-311/18.

Key-coded data will still be considered personal data, but key-coding may serve as a supplementary measure (as referred to above), provided that the key is protected by measures ensuring that it can never become available to the data importers.

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Finland

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Local laws

Has the local regulator published any guidelines/regulations addressing privacy matters on clinical trials and/or pharmacovigilance? ('Regulator' may mean either the local data protection authority, or the local medicines authority.)

Yes.

The Finnish national legislation addresses privacy matters in relation to clinical trials.

The Data Protection Act regulates processing of special category data in scientific research in section 6. The English translation of the act is available here.

The Medical Research Act regulates clinical trials, and it addresses processing of personal data in clinical trials in section 21a. The English translation of the act is available here.

The Act on Clinical Drug Trials regulates clinical drug trials, and it addresses processing of personal data in the trials in section 33. The act is only available in Finnish here.

The Medicines Act regulates medicinal products and their safe and proper use. It also regulates pharmacovigilance in chapter 4 a. The act does not address privacy directly, but it creates a legal obligation to collect personal data and a specific retention period for the data collected in section 30e. The current version of the act is only available in Finnish here.

In addition, the Finnish data protection authority has issued guidelines on its website on scientific research, which follow the requirements arising from the GDPR. These guidelines can be found here.

Extraterritorial applicability

Does the GDPR/UK GDPR apply to a clinical trial sponsor situated outside the EEA?

Finland does not have any country specific guidance on this matter and the general EU approach is followed.

Article 3(2)(a) GDPR applies if the data subjects are located in the EU.

However, since depending on a case-by-case assessment it cannot be excluded that Article 3(2)(b) would not apply instead of Article 3(2)(a). Data subjects are often offered the possibility to participate in a clinical trial and they receive compensation from this participation. Therefore, it can be assessed that the clinical trial is offered as a service and falls under the scope of Article 3(2)(a). However, in some cases Article 3(2)(b) can be applicable depending on how the clinical trial is arranged.

Processing of personal data in clinical trials

What is the preferred legal ground for the processing of the personal data of the participants in a clinical trial in your jurisdiction?

It is Article 6(1)(c) ('performance of a legal obligation') or (e) ('task carried out in the public interest') in conjunction with Article 9(2)(i) ('reasons of public interest in the area of public health') of the GDPR. This is defined in the relevant national legislation (Medical Research Act section 21a and Act on Clinical Drug Trials section 33).

Processing of personal data for pharmacovigilance

What is the legal ground for the processing of the personal data in respect of pharmacovigilance in your jurisdiction?

It is Article 6(1)(c) ('performance of a legal obligation') in conjunction with Article 9(2)(i) ('reasons of public interest in the area of public health') of the GDPR. There is a legal obligation to process personal data (Medicines Act section 30e).

Role of sponsor, principal investigator and others

Indicate the role from a data protection perspective of various parties involved (i.e in respect of the processing of the personal data of the clinical trial).

Role	Notes
Sponsor	Data controller / joint controller
Principal Investigator	Data controller / joint controller / processor
Clinical Trial Site	Data controller / joint controller / processor
Monitor	Processor
CRO	Processor

Note: The assessment on the roles of the parties needs to be made on a case-by-case basis. The controller alone determines the purposes and means of processing personal data. If several parties act as joint controllers, they define the purposes and methods of personal data processing together and share the controller's responsibility. A processor processes personal data on behalf of a controller. Processors operate according to the controller's instructions and under its supervision.

Key-coded clinical trial data

Is key-coded clinical trial data considered personal data under your jurisdiction's data protection laws? (Key-coded clinical trial data is where the identity of the individual clinical trial participant is replaced with a unique subject identification code, and the 'key' which can be used to re-identify the participant is held by the Principal Investigator.)

Finland does not have any country specific guidance on this matter and the general EU approach is followed.

In accordance with the GDPR, key-coded clinical trial data that can be used to re-identify the data subject is considered to be pseudonymized data. Pseudonymized data is personal data. If the clinical trial data is made into a format from which data subjects cannot be re-identified anymore, the data is anonymized meaning that it is not anymore personal data.

Re-use of personal data

Is it possible to re-use the personal data obtained for the purposes of conducting the clinical trial? If so, what requirements need to be satisfied?

The Finnish national legislation does not give any national level guidance on this, and the EU approach is followed. Therefore, personal data can be re-used for scientific research purposes (without having to establish a separate lawful basis) provided a controller complies with the safeguards under Article 89(1) GDPR. There are no additional safeguards prescribed under Finnish law.

If the above is not applicable, any processing would require another specific legal ground, other than the one used for the primary purpose. The chosen legal basis can be the same as the one for the primary use.

Cross-border data transfer

What requirements, if any, need to be satisfied if clinical trial data is transferred internationally?

The transfer needs to be made in accordance with GDPR Chapter V, meaning that the transfer should be based on appropriate safeguards, for example standard contractual clauses and appropriate supplementary safeguards should be implemented if needed.

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France

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Local laws

Has the local regulator published any guidelines/regulations addressing privacy matters on clinical trials and/or pharmacovigilance? ('Regulator' may mean either the local data protection authority, or the local medicines authority.)

Yes.

Notably:

The French data protection authority (**CNIL**) has issued a methodology of reference ("**MR**") on 3 May 2018 on personal data processing carried out in health research with the data subject's consent (**MR-001**) which covers, notably clinical trials as defined by Regulation (EU) 536/2014 of the European Parliament and of the Council of April 16, 2014 on clinical trials of medicinal products for human use, and repealing Directive 2001/20/EC, except for clinical trials the person does not object to participating in, in accordance with the terms of Article 30 of the Regulation (cluster trials).

The MR-001 is available here in French.

The French data protection authority (**CNIL**) has issued a methodology of reference on 3 May 2018 on the personal data processing carried out in health research that does not require the data subject's consent (**MR-003**) which covers, notably clinical trials in which the research subject does not object to participating, in accordance with Article 30 of Regulation (EU) 536/2014 of the European Parliament and of the Council of April 16, 2014 on clinical trials of medicinal products for human use, and repealing Directive 2001/20/EC (cluster trials).

The MR-003 is available here in French.

Controllers that commit to comply with a methodology of reference are authorized, without further formalities, to conduct their processing if they satisfy the criteria set out in said methodology of reference.

Any personal data processing that exceeds the framework of the methodology requires a specific authorization from the CNIL.

Up to 5 MR exist to date to cover various research in the health sector.

The CNIL has also published a standard on 18 July 2019 concerning the processing of personal data for the purpose of vigilance in the health sector, including pharmacovigilance. Controllers that commit to comply with this standard shall be authorized to conduct processing if they satisfy the criteria set out in these provisions. Any personal data processing that exceed the framework of the standard should filed a specific authorization request to the CNIL.

This standard is available here in French.

The French Ministry of Solidarities and Health has published Q&A on its website regarding the impact of the GDPR on clinical trials.

Extraterritorial applicability

Does the GDPR/UK GDPR apply to a clinical trial sponsor situated outside the EEA?

As provided by Article 3(2)(b), if a data controller located outside the EU monitors the behaviour of data subjects located within the EU, the GDPR applies to that data controller. According to the guidelines published by the European Data Protection Board ("**EDPB**") on the territorial scope of the GDPR, the application of Article 3(2)(b) encompasses a broad range of monitoring activities, including monitoring or regular reporting on an individual's health status.

Therefore, in the context of a clinical trial, if the sponsor processes personal data of data subjects located in France, the sponsor would have to comply with the GDPR by virtue of Article 3(2)(b).

In those cases where the sponsor is not located within the EU, it shall appoint a representative within the EU, as required by article 27 of the GDPR. This is aligned with the clinical trials regulation (article 39 of the Royal Decree 1090/2015, which regulates clinical trials with medicinal products) that sets forth that when the Sponsor is located outside the EU, it shall have a legal representative within the EU.

Processing of personal data in clinical trials

What is the preferred legal ground for the processing of the personal data of the participants in a clinical trial in your jurisdiction?

Either (i) the performance of a task carried out in the public interest, (ii) the legitimate interests pursued by the data controller, or (iii) (less preferably) consent (under Article 6 GDPR) and scientific research purposes (under Article 9).

The French Data protection Law (FDPA) provides that processing of data in the health sector can only be rolled out when justified by public interest. Ensuring high standards of quality and safety of healthcare and medical products or medical devices is a public interest purpose. The MR-001 and MR-003 provide that the only purpose for which research subjects' personal data may be processed is to conduct research in the public interest.

Taking into account the EDPB opinion, the French Ministry of Solidarities and Health indicates in its Q&A that there is no pre-determined legal basis, which can depend on the trial. The legal basis available for the processing of the personal data of the participants in a clinical trial could be (i) the performance of a task carried out in the public interest, (ii) the legitimate interests pursued by the data controller, or (iii) consent. In addition, for certain processing operations which are mandatory by law, compliance with a legal obligation is another possible legal basis, in particular for clinical trials of medicinal products falling within the scope of EU Regulation 536/2014, for purposes related to data reliability and individuals' safety.

The French Ministry of Solidarities and Health also mentions that the "recommended" legal basis are (i) the performance of a task carried out in the public interest (for public entities, like public hospitals), (ii) the legitimate interests pursued by the data controller (for private entities, like pharmaceutical companies).

In addition, article 9.2(j) of the GDPR is applicable.

Consent is not considered as the most appropriate legal basis, notably since a person may be constrained to participate in a clinical trial, for example when suffering from a serious illness for which there is still no cure. In such a case, the person's consent to the data processing may not satisfy the criteria set forth in the GDPR (i.e., be freely given, specific, informed and unambiguous). To be noted, consent for participation to the clinical trial (regulatory consent based on French Public health Code) and consent to the processing of personal data should not be confused and should be separately requested.

Processing of personal data for pharmacovigilance

What is the legal ground for the processing of the personal data in respect of pharmacovigilance in your jurisdiction?

As per the CNIL's standard, the appropriate legal basis for health monitoring is the data controller's legal obligations, as set out in the Articles R5121-150 and following French Public Health Code.

Role of sponsor, principal investigator and others

Indicate the role from a data protection perspective of various parties involved (i.e in respect of the processing of the personal data of the clinical trial).

Role	Notes
Sponsor	The MR-001 and MR-003 state that the sponsor is the data controller.
Principal Investigator	Processor for the purposes of performing the protocol defined by the Sponsor or joint controller if the Principal Investigator launches the clinical trial with the Sponsor. The MR-001 and MR-003 do not specify whether Principal Investigators should be considered as data controllers or data processors. In the absence of specific guidance in France, the EDPB guidance (guidelines 07/2020 on the concepts of controller and processor in the GDPR) is followed: i.e., if the investigator does not participate to the drafting of the protocol (he just accepts the protocol already elaborated by the sponsor), and the protocol is only designed by the sponsor, the investigator should be considered as a processor and the sponsor as the controller for this clinical trial. This is to be distinguished from the investigator's processing of patient data outside of the context of the clinical trial / performance of the protocol, where the investigator will be acting as a controller.
Clinical Trial Site	The MR-001 and MR-003 state that the clinical site is a data processor.
Monitor	Not clearly mentioned in the MR-001 and MR-003 but should act as data processor since they are in charge of supervising the correct development of the investigation on behalf of the sponsor.
CRO	The MR-001 and MR-003 state that the CRO is a data processor.

Key-coded clinical trial data

Is key-coded clinical trial data considered personal data under your jurisdiction's data protection laws? (Key-coded clinical trial data is where the identity of the individual clinical trial participant is replaced with a unique subject identification code, and the 'key' which can be used to re-identify the participant is held by the Principal Investigator.)

Yes, given that the "key" can be used to re-identify the data subjects. The key-coded data would only be considered as pseudonymized and thus fall within the scope of the GDPR.

Re-use of personal data

Is it possible to re-use the personal data obtained for the purposes of conducting the clinical trial? If so, what requirements need to be satisfied?

Further to the CNIL guidance on distinction between research and health data storage dated 28 November 2019 (accessible here), the answer is yes, provided the re-purposing addresses a specific question and is made on a one-time basis, and subject, in particular, to the following requirements:

- Compliance with the appropriate methodology of reference or otherwise the specific authorization of the CNIL;
- Notice to the data subjects.

Cross-border data transfer

What requirements, if any, need to be satisfied if clinical trial data is transferred internationally?

Subject to recent development further to Schrems II decision, the MR-001 and MR-003 provides the following:

Data that indirectly identifies research subjects and data that directly or indirectly identifies research professionals may be transferred out of the European Union when the transfer is strictly necessary to conduct the research or to exploit its results and complies with Chapter V of the GDPR.

The transfer may be made in connection with the commitment to comply with this methodology when any of the following conditions is satisfied:

- The transfer is made to a country or an international organization recognized by the European Commission as providing an adequate level of protection, in accordance with Article 45 of the GDPR (adequacy decision);
- The transfer is made subject to the appropriate safeguards listed in Article 46(2) of the GDPR (in particular: standard data protection clauses approved by the European Commission, binding corporate rules, codes of conduct, and certification mechanisms);
- In the absence of an adequacy decision or appropriate safeguards, the transfer may be based on one of the exceptions set out in Article 49 of the GDPR when such a transfer is not repetitive, concerns only a limited number of data subjects, and is not structured.

The controller must have informed the data subjects in advance of the transfer of their personal data to third countries outside the European Union, of the existence or absence of an adequacy decision or appropriate safeguards, and of the means to obtain a copy of the appropriate or suitable safeguards in accordance with Article 13(1)(f) of the GDPR.

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Local laws

Has the local regulator published any guidelines/regulations addressing privacy matters on clinical trials and/or pharmacovigilance? ('Regulator' may mean either the local data protection authority, or the local medicines authority.)

Not specifically.

There is a guideline on joint controllership issued by the German data protection conference (*Datenschutzkonferenz*) where the sponsor and the clinical trial site are exemplarily mentioned as joint controllers in accordance with Art 26 GDPR. However, without deeper legal justification. Moreover, the guideline is currently under revision. The current version can be found online (German version only).

Extraterritorial applicability

Does the GDPR/UK GDPR apply to a clinical trial sponsor situated outside the EEA?

Yes, to the extent that clinical trial participants (data subjects) are located in the EU, based on Article 3(2)(b), as the sponsor is monitoring the behaviour of the data subjects. (See example "Monitoring or regular reporting on an individual's health status" of the European Data Protection Board in their Guidelines 3/2018 on the territorial scope of the GDPR, Version 2.1, 12 November 2019).

Processing of personal data in clinical trials

What is the preferred legal ground for the processing of the personal data of the participants in a clinical trial in your jurisdiction?

It is common practice in Germany that the legal ground for the processing of personal data of the participants is their consent according to Art. 6 (1) (a) GDPR and Art. 9 (2) (a) GDPR. This is because of the excessive processing of health data as special categories of personal data and the lack of another legal basis which is appropriate to justify such processing. In Germany it is common market standard that the sponsor provides an "Informed Consent Form" to the clinical trial site which the clinical trial sites provides to the participants of the clinical trial.

Processing of personal data for pharmacovigilance

What is the legal ground for the processing of the personal data in respect of pharmacovigilance in your jurisdiction?

The legal basis for the processing of the patients personal data for the purpose of pharmacovigilance is the legal obligation under Art. 6 (1) (c) GDPR in connection with the respective provisions of the German Medicine Act (*Arzneimittelgesetz*) or respective laws of the German federal states.

Role of sponsor, principal investigator and others

Indicate the role from a data protection perspective of various parties involved (i.e in respect of the processing of the personal data of the clinical trial).

Role	Notes
Sponsor	(Joint) Controller
Principal Investigator	Employee of the Clinical Trial Site – no own role from a data protection perspective
Clinical Trial Site	(Joint) Controller
Monitor	Depends on the specific circumstances and the tasks of the Monitor in regard to the data processing. Usually the Monitor is acting on behalf and under the instructions of the sponsor and is therefore to be considered as processor of the sponsor.
CRO	Depends on the specific circumstances and the tasks of the CRO in regard to the data processing. Usually the CRO is acting on behalf and under the instructions of the sponsor and is therefore to be considered as processor of the sponsor.

Key-coded clinical trial data

Is key-coded clinical trial data considered personal data under your jurisdiction's data protection laws? (Key-coded clinical trial data is where the identity of the individual clinical trial participant is replaced with a unique subject identification code, and the 'key' which can be used to re-identify the participant is held by the Principal Investigator.)

Yes, as long as it is possible to re-identify the data subjects with the key-coded data, it shall be considered as personal data under GDPR.

Re-use of personal data

Is it possible to re-use the personal data obtained for the purposes of conducting the clinical trial? If so, what requirements need to be satisfied?

In general it is possible to re-use the personal data obtained for the purposes of conducting the clinical trial. Such re-use, however, must be justified by an appropriate legal basis both under Art. 6 and Art. 9 GDPR.

It is, for example, possible to include a certain re-use of the personal data of the data subjects in the informed consent form in order to obtain valid consent of the data subjects for such processing activities. Please note that the requirements on consent under the GDPR must be met, in particular, consent must be granted for a specific processing activity and may not constitute a general consent for various processing activities in the future.

Cross-border data transfer

What requirements, if any, need to be satisfied if clinical trial data is transferred internationally?

In those cases where the clinical trial data is key-coded and it is not possible to re-identify the data, the information received by the recipient would not be considered as personal data, and thus, the regulations that apply to international transfers of personal data are not applicable.

In those cases where the re-identification of the participants' personal data is possible, international data transfer shall count with adequate guarantee measures if the recipient is located in a country which does not offer an adequate level of protection to GDPR. In particular, the requirements under Art 44. et seqq. GDPR alongside the Schrems II case law of the European Court of Justice shall be met.

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Local laws

Has the local regulator published any guidelines/regulations addressing privacy matters on clinical trials and/or pharmacovigilance? ('Regulator' may mean either the local data protection authority, or the local medicines authority.)

No.

The Hellenic Data Protection Authority ("**HDPA**") has not issued any guidance n clinical trials or pharmacovigilance.

The National Ethics Committee has issued a guidance for protocols and the document with clarifications on the implementation of GDPR in the framework of clinical trials. Please note that the aforementioned documents are available only in Greek language.

On the other hand, no pharmacovigilance specific guidance / statute has been issued in the Greek jurisdiction.

Extraterritorial applicability

Does the GDPR/UK GDPR apply to a clinical trial sponsor situated outside the EEA?

Yes, GDPR applies to clinical trials executed by sponsors not established in the EU, to the extent that processing activities entail data processing of data subjects in the EU, subject to Article 3(2)(a) of the GDPR. In addition, Greek Law 4624/2019 supplementing the GDPR applies to the extent that data are processed within the territory of Greece.

In those cases where the sponsor is not located within the EU, it shall appoint a representative within the EU, as required by article 27 of the GDPR. This is in line with Article 74 of the Clinical Trials Regulation (CTR) – implemented by Article 13 of the Ministerial Decision 5 /59676 of Ministers of Finance, Development and Health (Government Gazette vol. , 4131/22.12.2016) – according to which a Sponsor not be established in the EU shall appoint a legal representative (natural or legal person) established within the EU territory.

Processing of personal data in clinical trials

What is the preferred legal ground for the processing of the personal data of the participants in a clinical trial in your jurisdiction?

According to market practice, the processing of clinical research participants' data is based on their consent (Article 6(1)(a) of the GDPR).

Processing of personal data for pharmacovigilance

What is the legal ground for the processing of the personal data in respect of pharmacovigilance in your jurisdiction?

According to market practice, the processing of clinical research participants' data within the scope of pharmacovigilance activities is based on the need to comply with a legal obligation (Article 6(1)(c) of the GDPR).

Role of sponsor, principal investigator and others

Indicate the role from a data protection perspective of various parties involved (i.e in respect of the processing of the personal data of the clinical trial).

Role	Notes
Sponsor	According to the above-mentioned National Ethics Committee document, sponsor shall act under its capacity of data controller.
Principal Investigator	Pursuant to the aforementioned document, investigator shall act as data processor. In practice, in most clinical trial agreements principal investigator is considered as data controller of the clinical trial participants' personal data in connection with the data processing operations performed in conducting the investigation activities set forth in the Protocol.
Clinical Trial Site	Pursuant to the aforementioned document, clinical trial site shall act as data processor, acting on behalf of the sponsor. In practice, in most clinical trial agreements the clinical trial site is qualified as data controller of clinical trial participants' personal data for the purposes of providing adequate healthcare assistance within the scope of the investigation.
Monitor	the extent such party would be in charge of supervising the correct development of the investigation on behalf of the sponsor, said party shall qualify as data processor. Normally, this role is assumed by the CRO.
CRO	Pursuant to the aforementioned document, CRO shall be the data controller. However, in practice most clinical trial agreements are formulated as tri-party agreements between sponsor or CRO, principal investigator and clinical trial site. Therefore, either sponsor or CRO are appointed as data controllers.

Key-coded clinical trial data

Is key-coded clinical trial data considered personal data under your jurisdiction's data protection laws? (Key-coded clinical trial data is where the identity of the individual clinical trial participant is replaced with a unique subject identification code, and the 'key' which can be used to re-identify the participant is held by the Principal Investigator.)

Pursuant to the Announcement No. 3/8/2017 issued by the National Ethics Committee, key-coded clinical trial data, mentioned as anonymized data of clinical trial participants, are considered personal data.

Re-use of personal data

Is it possible to re-use the personal data obtained for the purposes of conducting the clinical trial? If so, what requirements need to be satisfied?

Yes, to the extent that there are legal grounds for this processing, key-coded clinical trial data can be re-used without having to obtain the data subjects' consent.

In particular, personal data can be re-used for scientific research purposes (without having to establish a separate lawful basis) provided a controller complies with the safeguards under Article 89(1) GDPR.

Under Article 89(1), safeguards must take the form of technical and organizational measures, in particular to ensure respect for the principle of data minimization. This may involve pseudonymizing data, where possible in connection with the research.

Otherwise, personal data can be re-used to the extent that such use is compatible with the original purpose of processing (i.e., closely related to the clinical trial purpose) or there are legal grounds for this processing, clinical trial data can be re-used without having to obtain the data subjects' consent.

Cross-border data transfer

What requirements, if any, need to be satisfied if clinical trial data is transferred internationally?

Provided that re-identification of the participants' personal data is possible and therefore data protection legislation is applicable, restrictions laid down in Chapter V of the GPDR and conditions set forth therein shall apply.

This means that personal data, including health data, can be lawfully transferred in case one of the following requirement is met:

- There is a European Commission Adequacy Decision, stating that the recipient country provides adequate protection for individuals' personal data; or
- The data exporter and importer (i) adopted appropriate safeguards pursuant to Articles 46 et seq. of the GDPR (e.g. Standard Contractual Clauses, Binding Corporate Rules, etc.), (ii) conducted a proper transfer impact assessment pursuant to EDPB's recommendations 1/2020, and (iii) implemented further adequate contractual, organizational, and technical measures, as needed according to said transfer impact assessment.

Moreover, Article 49 of the GDPR provides for possible exceptions to the above-mentioned requirements, that can be applied only whether specific circumstances are met.

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Local laws

Has the local regulator published any guidelines/regulations addressing privacy matters on clinical trials and/or pharmacovigilance? ('Regulator' may mean either the local data protection authority, or the local medicines authority.)

No. However, the Hungarian Data Protection Authority ("**NAIH**") would most probably rely on the Opinion 3/2019 of the European Data Protection Board concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection regulation (GDPR) (art. 70.1.b)) adopted on 23 January 2019. Additionally, the European Commission (DG SANTE) issued a document on "Questions and Answers on the interplay between the Clinical Trials Regulation (CTR)1 and the General Data Protection regulation (GDPR)" (available at this link) after a consultation with the EDPB.

The Hungarian National Institute of Pharmacy and Nutrition also published certain answers to frequent questions related to healthcare services, which include some general recommendations related to clinical trials in line with the above-referred Opinion 3/2019. Such recommendations are available at the following link (in Hungarian only).

In addition to the above, the Clinical Pharmacology Ethical Committee of the Medical Research Council (ETT KFEB) has also published a guidance on data protection requirements for clinical trial package leaflets (available at the following link – in Hungarian only).

Extraterritorial applicability

Does the GDPR/UK GDPR apply to a clinical trial sponsor situated outside the EEA?

Yes, to the extent that clinical trial participants (data subjects) are located in the EU, based on Article 3(2)(a).

In those cases where the sponsor is not located within the EU, it shall appoint a representative within the EU, as required by article 27 of the GDPR.

Processing of personal data in clinical trials

What is the preferred legal ground for the processing of the personal data of the participants in a clinical trial in your jurisdiction?

Since the NAIH has not yet adopted any guidance or definite practice in this matter, reference should be made to the above-mentioned European Data Protection Board's Opinion 3/2019.

According to this Opinion 3/2019, the preferred legal ground may differ depending on the purpose pursued:

- Processing operations purely related to research activities in the context of a clinical trial may either fall under the data subject's explicit consent (Article 6(1)(a) in conjunction with Article 9(2)(a)), or a task carried out in the public interest (Article 6(1)(e)), or the legitimate interests of the controller (Article 6(1)(f)) in conjunction with Article 9(2)(i) or (j) of the GDPR.

- Processing operations expressly provided by the Clinical Trial Regulation (CTR) and by relevant national provisions, and which are related to reliability and safety purposes, can be considered as falling within a legal obligation (Article 6(1)(c) of the GDPR in conjunction with the provisions of Article 9(2)(i)).

Processing of personal data for pharmacovigilance

What is the legal ground for the processing of the personal data in respect of pharmacovigilance in your jurisdiction?

Since the NAIH has not yet adopted any guidance or definite practice in this matter, reference should be made to the above-mentioned European Data Protection Board's Opinion 3/2019.

According to this Opinion 3/2019, the preferred legal ground for the processing of patients' personal data within the scope of pharmacovigilance activities would be the existence of a legal obligation (Article 6(1)(c) in conjunction with the provisions of Article 9(2)(i) of the GDPR).

Role of sponsor, principal investigator and others

Indicate the role from a data protection perspective of various parties involved (i.e in respect of the processing of the personal data of the clinical trial).

Role	Notes
Sponsor	Data controller.
Principal Investigator	Sponsor's data processor (However, in accordance with Guidelines 07/2020 of the European Data Protection Board on the concepts of controller and processor in the GDPR, the PI may qualify as a joint controller with the sponsor if they collaborate together to the drafting of the study protocol (i.e. purpose, methodology /design of the study, data to be collected, subject exclusion /inclusion criteria, database reuse (where relevant) etc.) as they jointly determine and agree on the same purpose and the essential means of the processing. (see example 4 after paragraph 66))
Clinical Trial Site	Joint controller with the sponsor, or sponsor's data processor, for the same reasons specified above with respect to the PI.
Monitor	Sponsor's data processor, in charge of supervising the correct development of the investigation.
CRO	Sponsor's data processor when (i) performing monitoring tasks, and (ii) in the event that the Sponsor subcontracts other tasks to the CRO that involve access by the CRO to encrypted participant data.

Key-coded clinical trial data

Is key-coded clinical trial data considered personal data under your jurisdiction's data protection laws? (Key-coded clinical trial data is where the identity of the individual clinical trial participant is replaced with a unique subject identification code, and the 'key' which can be used to re-identify the participant is held by the Principal Investigator.)

Key-coded clinical trial data would not be considered personal data as long as the codification procedure ensures that re-identification of participants by the Sponsor is not possible. Hence, this condition is met if personal data is truly anonymous, not merely pseudonymized.

Re-use of personal data

Is it possible to re-use the personal data obtained for the purposes of conducting the clinical trial? If so, what requirements need to be satisfied?

Yes, to the extent that there is a relevant legal ground for this processing. Anonymized clinical trial data can be further re-used without having to rely on a legal basis.

Furthermore, due account must be taken to Article 5(1)(b) of the GDPR which provides for a presumption of compatibility of purposes, subject to the conditions set for in Article 89(1) GDPR, when further processing is carried out for purposes of scientific research. In any event, even when the presumption of compatibility applies, data used outside the protocol of the clinical trial must be processed in compliance with all other applicable data protection provisions, as stated under Article 28(2) CTR. Therefore, the controller must comply with other obligations set forth by data protection law in any case, for example with regard to fairness, lawfulness (i.e. in accordance with applicable EU and national law), necessity and proportionality, as well as data quality (see paragraph 31 of the Opinion 3/2019 issued by the European Data Protection Board).

Cross-border data transfer

What requirements, if any, need to be satisfied if clinical trial data is transferred internationally?

In those cases where the clinical trial data is key-coded and it is not possible to re-identify the data (i.e. the personal data is anonymous), the information received by the recipient would not be considered as personal data, and thus, the regulations that apply to personal data (incl. international transfers thereof) are not applicable.

In those cases where the re-identification of the participants' personal data is possible, cross-border transfers must be carried out in accordance with Articles 45 et seq. of the GDPR. This means that personal data, including health data, can be lawfully transferred in case one of the following requirement is met:

- There is a European Commission Adequacy Decision, stating that the recipient country provides adequate protection for individuals' personal data; or
- The data exporter and importer (i) adopted appropriate safeguards pursuant to Articles 46 et seq. of the GDPR (e.g. Standard Contractual Clauses, Binding Corporate Rules, etc.), (ii) conducted a proper transfer impact assessment pursuant to EDPB's recommendations 1/2020, and (iii) implemented further adequate contractual, organizational, and technical measures, as needed according to said transfer impact assessment.

Moreover, Article 49 of the GDPR provides for possible exceptions to the above-mentioned requirements, that can be applied only whether specific circumstances are met.

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Local laws

Has the local regulator published any guidelines/regulations addressing privacy matters on clinical trials and/or pharmacovigilance? ('Regulator' may mean either the local data protection authority, or the local medicines authority.)

In Ireland, data controllers engaged in Health Research, including processing of any personal data (regardless of whether the data includes individually identifiable health data), are subject to Health Research Regulations 2018 ("**HRRs**")[1] and must comply with mandatory suitable and specific measures for processing of personal data for the purposes of health research.

The Department of Health in Ireland issued *"Guidance on Information Principles for informed consent for the processing of personal data for health research"* (the "**Guidance**") which is available here. This guidance sets out the requirement to obtain explicit consent where health data are processed for health research purposes and lists a comprehensive inventory of information which is required to be provided to the individual for such consent to be valid when they provide their personal data for health research purposes.

In January 2021, amendments to the HRRs were published (the "**Amendments**")[2], along with a suite of guidance prepared by Department of Health, the Secretariat to the Health Research Consent Declaration Committee (HRCDC)[3] and the Health Service Executive and in consultation with the Irish Data Protection Commission ("**DPC**"):

- Guidance on Explicit Consent Amendment
- Guidance on Pre-Screening Amendment
- Guidance on Retrospective Chart Review Amendments
- Guidance on Deferred Consent Amendments
- Guidance on Informed Consent under EU Directive Amendments

[1] S.I. No. 314 of 2018 Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018
[2] S.I. No. 18/2021 – Data Protection Act 2018 (Section 36(2)) (Health Research) (Amendment) Regulations 2021
[3] The HRCDC was established as part of the Health Research Regulations made under the Data Protection Act, 2018.

Extraterritorial applicability

Does the GDPR/UK GDPR apply to a clinical trial sponsor situated outside the EEA?

Yes, to the extent that the sponsor is processing personal data in the context of the activities of an establishment of a controller or processor in the EU based on Article 3(2)(a), or if clinical trial participants (data subjects) are located in the EU, based on Article 3(2)(b).

In Ireland, in cases where the sponsor is not established within the EU, it shall appoint a representative within the EU responsible for ensuring compliance with the sponsor's obligations pursuant to the Clinical Trials Regulation and Irish implementing legislation.

(15) Where a natural or legal person is established in the European Union as the legal representative of a sponsor not established in the Union in accordance with Article 74(1) of the Clinical Trials Regulation, that representative shall be responsible for ensuring compliance with the sponsor's obligations in the State, pursuant to the Clinical Trials Regulation and these Regulations.[1]

A "legal representative" means the natural or legal person established in the European Union as the legal representative of a clinical trial sponsor who is not established in the Union.

[1] S.I. No. 99/2022 - European Union (Clinical Trials on Medicinal Products for Human Use) (Principal) Regulations 2022 (Part 2, S. 15)

Processing of personal data in clinical trials

What is the preferred legal ground for the processing of the personal data of the participants in a clinical trial in your jurisdiction?

Explicit consent is the required legal ground for processing personal data for health research purposes in Ireland.

This is the preferred ground as expressly indicated by:

The Guidance

The Guidance expressly requires explicit consent to process personal data for health research purposes:

"A person proposing to process personal data for health research purposes requires the explicit consent of any individual (data subject) whose data he or she is proposing to process and in order that such consent should be valid and lawful it must be (a) informed and (b) appropriately recorded (thereby making it explicit)."

There are specific requirements included in the Guidance for this consent to be "informed" and therefor valid. In addition, the Amendments introduce further requirements for explicit consent (as detailed below).

Guidance from the EU Commission[1]

In addition, the EU Commission has stated the importance of consent in research and indicated the need to keep records of consent and consent procedure.

"You must keep records documenting the informed consent procedure, including the information sheets and consent forms provided to research participants, and the acquisition of their consent to data processing."

The Amendments

The Amendments further re-state the importance of explicit consent in the context of health research and provides that explicit consent is obtained from the data subject:

- As a suitable and specific measure;
- Recorded and retained by the controller, and a copy of which is provided to the data subject prior to the commencement of the health research; and
- In accordance with international best practice on the ethical conduct of health research (which includes informed consent, transparency and independent ethical oversight).

The Amendments specifically puts in place the requirement that:

"explicit consent has been obtained from the data subject, as a suitable and specific measure recorded and retained by the controller, and a copy of which is provided to the data subject prior to the commencement of the health research in accordance with international best practice on the ethical conduct of health research (which includes informed consent, transparency and independent ethical oversight) for the processing of his or her personal data for the purpose of specified health research, either in relation to a particular area or more generally in that area or a related area of health research, or part thereof."

[1] European Commission: Ethics and data protection

Processing of personal data for pharmacovigilance

What is the legal ground for the processing of the personal data in respect of pharmacovigilance in your jurisdiction?

The Health Products Regulatory Authority ("**HPRA**")[1] collects pharmacovigilance personal data and operates the national system for recording and reporting details of suspected adverse reactions occurring in Ireland which are notified in association with the use of medicines.

The legal basis for processing of personal data in adverse reaction reports is firstly, Article 6(1)(c) of the GDPR: compliance with legal obligation to which the controller is subject.

Secondly, in terms of special categories of personal data, the HPRA relies on the exception provided by Article 9(2)(i) of GDPR, (processing special category data for reasons of public interest).

As part of its statutory role in the regulation of medicines (pharmacovigilance), the HPRA is legally obliged to collect adverse reaction reports to human medicines. The legal basis for such collection is processing data in compliance with a legal obligation, Article 6(1) (c), and the relevant piece of legislation is the Medicinal Products (Control of Placing on the Markets) Regulations 2012. These Regulations require the HPRA is to transmit details of adverse reaction reports to the EudraVigilance Database.

[1] Privacy Notice – Pharmacovigilance and EudraVigilance Database

Role of sponsor, principal investigator and others

Indicate the role from a data protection perspective of various parties involved (i.e in respect of the processing of the personal data of the clinical trial).

In Ireland, there is no specific guidance which determines the role of the various parties involved in clinical trials. The Irish Health Service Executive Research and Development Framework sets out the Key Roles in the Governance and Management of Health Research, however, does not give specific indication on the data protection roles. Rather, it is noted that the legal responsibility for the various aspects of the study (including data protection), may reside with one or several parties (i.e., the organisation responsible for accepting and managing the research funding, the clinical investigators and their employers, and the data controller(s) may be any one or all of the participating organisations).

It is noted that a clear, factual and formal identification of controller (e.g., independent / joint controllers) and/or data processors is required on a case-by-case basis.

Role	Notes
Sponsor	'Sponsor' is the term used for the responsible legal entity for regulated clinical trials means an individual, company,

	institution or organisation which takes responsibility for the initiation, for the management and for setting up the financing of the clinical trial.[1] All clinical trial information shall be recorded, processed, handled, and stored by the sponsor or investigator, as applicable, in such a way that it can be accurately reported, interpreted and verified while the confidentiality of records and the personal data of the subjects remain protected in accordance with the applicable law on personal data protection. Appropriate technical and organisational measures shall be implemented to protect information and personal data processed against unauthorised or unlawful access, disclosure, dissemination, alteration, or destruction or accidental loss, in particular where the processing involves the transmission over a network.[2] A statement by the sponsor or his or her representative that data will be collected and processed in accordance with Directive 95/46/EEC (which has been repealed by the GDPR) shall be provided.[3] In light of the responsibilities of the Sponsor, it is likely that the Sponsor will be controller of personal data of participants in health research / clinical trials. This is also confirmed by the Guidelines 07/2020 of the European Data Protection Board on the concepts of controller and processor in the GDPR, where it is stressed that the PI / Trial Site may be qualified as a joint controller with the Sponsor if they collaborate together to the drafting of the study protocol (i.e. purpose, methodology/design of the study, data to be collected, subject exclusion/inclusion criteria, database reuse (where relevant) etc.), as they jointly determine and agree on the same purpose and the essential means of the processing (see example 4 after paragraph 66).
Principal Investigator	'Principal investigator' means an investigator who is the responsible leader of a team of investigators who conduct a clinical trial at a clinical trial site;[4] and is responsible for the day-to-day management of the research study at the research site. The Principal Investigator retains ultimate responsibility for the management of the research study, even if tasks are delegated to other research staff. A principal investigator shall ensure compliance of a clinical trial at a clinical trial site with the requirements of the Regulation. The principal investigator shall assign tasks among the members of the team of investigators in a way which is not compromising the safety of subjects and the reliability and robustness of the data generated in the clinical trial at that clinical trial site.[5] In light of the responsibilities of the Principal Investigator, it is likely that they can be controllers of personal data of participants in health research / clinical trials, whether they are individuals or organisations.
Clinical Trial Site	In Ireland this is commonly referred to as the Research Site or Host Site and is a facility, location or service (e.g. hospital) where the research is being conducted. This includes:

- the organisation or organisations where the research is taking place; and/or,
- the organisation whose service users, patients or staff are involved in the research; and/or
- the organisation that provides research staff, primary data, infrastructure or premises to facilitate the research.

Given the involvement of the Research Site, it is likely to be a controller of the participants personal data for the purposes of providing adequate healthcare assistance within the scope of the investigation. This is also confirmed by the Guidelines 07/2020 of the European Data Protection Board on the concepts of controller and processor in the GDPR, where it is stressed that the PI / Trial Site may be qualified as a joint controller with the Sponsor if they collaborate together to the drafting of the study protocol (i.e. purpose, methodology /design of the study, data to be collected, subject exclusion /inclusion criteria, database reuse (where relevant) etc.), as they jointly determine and agree on the same purpose and the essential means of the processing (see example 4 after paragraph 66).

Monitor

The HPRA Guidance does not provide for a "monitor" per se but does provide that a sponsor is required to carry out monitoring procedures. These include plans for on-site monitoring, central monitoring and data committee monitoring.

The sponsor must be able to demonstrate that it has oversight of trial conduct and GCP compliance and has mechanisms in place to continuously monitor the benefit-risk balance.

The HPRA, in their review of adequate Clinical Trial protocols, may request documents including risk assessment, monitoring plans, follow-up letters, GCP non-compliance escalations, data committee charters and meeting minutes.[6]

CRO (Chief Research Organization)

A CRO can contractually assume one or more of a clinical trial sponsor's obligations if that sponsor does not have particular expertise.

The services that CROs provide include:

- Preclinical research activities
- Clinical research monitoring
- Protocol design
- Clinical trial management
- Preparation and submission of regulatory materials to the relevant regulatory agency
- Completing post approval regulatory obligations and reports.

The CRO mainly acts as the Sponsor's data processor when (i) performing monitoring tasks, and (ii) in the event that the

Sponsor subcontracts other tasks to the CRO that involve access by the CRO to encrypted participant data.

[1] Article 2(14) Regulation (EU) No 536/2014
[2] Article 56 Regulation (EU) No 536/2014
[3] 1.3 R. 73 Regulation (EU) No 536/2014
[4] Article 2(16) Regulation (EU) No 536/2014
[5] Article 73 Regulation (EU) No 536/2014
[6] HPRA Guide to Clinical Trials in Ireland: 8.9

Key-coded clinical trial data

Is key-coded clinical trial data considered personal data under your jurisdiction's data protection laws? (Key-coded clinical trial data is where the identity of the individual clinical trial participant is replaced with a unique subject identification code, and the 'key' which can be used to re-identify the participant is held by the Principal Investigator.)

Personal data is information relating to a natural person who is identified or identifiable and so the principles of data protection should apply to any information concerning an identified or identifiable natural person.

Where key-coded clinical trial data is used, this is akin to pseudonymization which, involves *"the processing of personal data in such a way that the data can no longer be attributed to a specific data subject without the use of additional information."* In this case, additional information is the "key" used to re-identify the individuals.

While it does provide additional safeguards, pseudonymized data, unlike anonymized data, is still unequivocally considered personal data under the GDPR, as noted in Recital 26.

Additionally, guidance from the EU Commission also notes that, *"if there is a significant prospect of re-identification of persons whose data have been collected, the information should be treated as personal data".*[1]

[1] European Commission: Ethics and data protection

Re-use of personal data

Is it possible to re-use the personal data obtained for the purposes of conducting the clinical trial? If so, what requirements need to be satisfied?

Yes, subject to conditions set out in HRRs s1. The HRRs limit processing and mandate that a controller processing (or further processing) personal data for the purposes of health research must ensure suitable and specific measures are taken to safeguard the fundamental rights and freedoms of the data subject. One of those measures is to ensure that arrangements are in place so that personal data shall be processed as necessary to achieve the objective of the research and, to ensure that personal data are not processed in such a way that damage or distress is or is likely be caused by the data subject.[1]

In addition, the controller must provide written confirmations demonstrating that the collection and use of the personal data will go no further than is necessary for the attainment of the research objective, and there will be no disclosure of the personal data unless that disclosure is required by law, or the data subject has given his or her explicit consent to the disclosure.

[1] S.I. No. 314 of 2018 Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018 (Sections 3(1)(a) and 26(c))

Cross-border data transfer

What requirements, if any, need to be satisfied if clinical trial data is transferred internationally?

In those cases where it is not possible to re-identify the data subject, i.e. where the health data collected is truly anonymized, the information received by the recipient would not be considered as personal data, and thus, the regulations that apply to international transfers of personal data are not applicable.

In those cases where the re-identification of the participants' personal data is possible, i.e. where the health data are pseudonymized, international data transfer rules (as set out in Chapter V of GDPR) shall be applicable to any transfers outside of the EEA or to a jurisdiction or international organization which is not subject to an adequacy decision.

In short, these data transfers must be subject to appropriate safeguards, required country assessments and adequate technical and security measures if the recipient is located in a country which does not offer an adequate level of protection to GDPR.

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Local laws

Has the local regulator published any guidelines/regulations addressing privacy matters on clinical trials and/or pharmacovigilance? ('Regulator' may mean either the local data protection authority, or the local medicines authority.)

Yes.

The Italian Data Protection Authority ("**Italian DPA**") has issued the Guidelines for Data Processing within the Framework of Clinical Drug Trials on 24 July 2008 ("**Guidelines**"). Although the Guidelines have been issued before the GDPR entered into force, most of their provisions are still valid and effective.

The Guidelines are available at the following link.

Extraterritorial applicability

Does the GDPR/UK GDPR apply to a clinical trial sponsor situated outside the EEA?

Yes, to the extent that either:

- Clinical trial participants (data subjects) are located in the EU, based on Article 3(2)(a); or
- Clinical trial in the EU entails the monitoring of relevant participants and/or personnel located in the EU, based on Article 3(2)(b).

In those cases where the sponsor is not located within the EU, it shall appoint a representative within the EU, as required by Article 27 of the GDPR.

Processing of personal data in clinical trials

What is the preferred legal ground for the processing of the personal data of the participants in a clinical trial in your jurisdiction?

The preferred legal ground is consent, because of market practice. Indeed:

- The Italian Medicines Agency ("*Agenzia Italiana del Farmaco*" – "**AIFA**") issued a clinical trail agreement template ("**Template Agreement**") according to which the principal investigator shall obtain patients' consent to the processing of their data; and
- The Italian DPA's Guidelines specify that the sponsor obtain patients' consent to the processing of their personal data for the purpose of the trial.

Nonetheless, according to the European Data Protection Board ("**EDPB**") Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection regulation (GDPR) (art. 70.1.b)) of 23 January, 2019 ("**Q&A on Clinical Trials**"), although all processing operations carried out in the context of a specific clinical trial protocol during its whole

lifecycle are to be considered as primary use of clinical trial data, not all processing operations relating to such "primary use" of this data pursue the same purposes and fall within the same legal basis.

In particular, processing operations purely related to research activities in the context of a clinical trial may either fall under:

- The data subject's explicit consent (Article 6(1)(a) in conjunction with Article 9(2)(a) of the GDPR);
- A task carried out in the public interest (Article 6(1)(e) of the GDPR); or
- The legitimate interests of the controller (Article 6(1)(f)) in conjunction with Article 9(2)(i) or (j) of the GDPR.

Therefore, controllers should rely on different legal grounds to process personal data in the context of a clinical trial.

Processing of personal data for pharmacovigilance

What is the legal ground for the processing of the personal data in respect of pharmacovigilance in your jurisdiction?

According to the EDPB's Q&A on Clinical Trials, the processing of patients' personal data performed for reliability and safety purposes (as per the CTR and/or relevant national provisions) is based on the existence of a legal obligation according to Article 6(1)(c) of the GDPR or Article 9(2)(i), depending on the nature of the personal data processed.

Moreover, in cases of adverse effect, the legal ground for the data processing activity may also be considered the protection of vital interests of the data subject, as per Article 6(1)(d) of the GDPR.

Role of sponsor, principal investigator and others

Indicate the role from a data protection perspective of various parties involved (i.e in respect of the processing of the personal data of the clinical trial).

Role	Notes
Sponsor	Data controller. In particular, according to the DPA's Guidelines the Sponsor may act as controller or joint controller, together with the Clinical Trial Site. This is also confirmed by the Guidelines 07 /2020 of the European Data Protection Board on the concepts of controller and processor in the GDPR, where it is stressed that the PI / Trial Site may be qualified as a joint controller with the Sponsor if they collaborate together to the drafting of the study protocol (i.e. purpose, methodology/design of the study, data to be collected, subject exclusion/inclusion criteria, database reuse (where relevant) etc.), as they jointly determine and agree on the same purpose and the essential means of the processing (see example 4 after paragraph 66). As a consequence, a case-by-case analysis is necessary. That said, the default position provided for in the Template Agreement issued by the AIFA is that Sponsor is qualified as independent controller.
Principal Investigator	In most cases (i.e., where the PI is an employee of the Clinical Trial Site) the PI will be treated as an agent of the Clinical Trial Site, pursuant to Art. 29 of the GDPR.

	Where this is not the case, then the PI will either the Sponsor's data processor or, where the PI needs to process personal data to provide medical care outside of the context of the trial protocol, they will be an independent controller. That said, the default position provided for in the Template Agreement issued by the AIFA qualifies the Principal Investigator as person in charge of the processing of participants' data, pursuant to Art. 29 of the GDPR.
Clinical Trial Site	According to the Italian DPA's Guidelines, Clinical Trial Site is qualified as controller or joint controller, together with the Sponsor, of participants' data, for the purposes of providing adequate healthcare assistance within the scope of the investigation. However, the Guidelines 07/2020 of the European Data Protection Board on the concepts of controller and processor in the GDPR stress that the Clinical Trial Site may be qualified either as a joint controller with the Sponsor or processor acting on behalf of Sponsor, depending on factual circumstances. As a consequence, a case-by-case analysis is necessary.
Monitor	According to the Italian DPA's Guidelines, processor acting on Sponsor's behalf, in charge of supervising the correct development of the investigation.
CRO	Processor acting on Sponsor's behalf when (i) performing monitoring tasks, and (ii) in the event that the Sponsor subcontracts other tasks to the CRO that involve access by the CRO to participant data.

Key-coded clinical trial data

Is key-coded clinical trial data considered personal data under your jurisdiction's data protection laws? (Key-coded clinical trial data is where the identity of the individual clinical trial participant is replaced with a unique subject identification code, and the 'key' which can be used to re-identify the participant is held by the Principal Investigator.)

Yes, as specifically clarified by the Italian DPA's Guidelines. Indeed, key-coded clinical trial data constitutes pseudonymized personal data.

Re-use of personal data

Is it possible to re-use the personal data obtained for the purposes of conducting the clinical trial? If so, what requirements need to be satisfied?

Personal data can be re-used for scientific research purposes (without having to establish a separate lawful basis) provided a controller complies with the safeguards under Article 89(1) GDPR.

Under Article 89(1), safeguards must take the form of technical and organisational measures, in particular to ensure respect for the principle of data minimisation. This may involve pseudonymising data, where possible in connection with the research.

Otherwise, personal data can be re-used to the extent that such use is compatible with the original purpose of processing (i.e., closely related to the clinical trial purpose) or there are legal grounds for this processing, clinical trial data can be re-used without having to obtain the data subjects' consent.

Moreover, as per the Ministerial Decree of 30 November 2021 issued by the Italian Ministry of Health ("**Decree**"), personal data collected or otherwise obtained in the context of non-profit clinical trials can be lawfully transferred for registration purposes.

Anonymized clinical trial data can be further re-used without having to rely on a legal basis.

Cross-border data transfer

What requirements, if any, need to be satisfied if clinical trial data is transferred internationally?

Assuming the clinical trial data is not anonymized, cross-border transfers must be carried out in accordance with Articles 45 et seq. of the GDPR. This means that personal data, including health data, can be lawfully transferred in case one of the following requirement is met:

- There is a European Commission Adequacy Decision, stating that the recipient country provides adequate protection for individuals' personal data; or
- The data exporter and importer (i) adopted appropriate safeguards pursuant to Articles 46 et seq. of the GDPR (e.g. Standard Contractual Clauses, Binding Corporate Rules, etc.), (ii) conducted a proper transfer impact assessment pursuant to EDPB's recommendations 1/2020, and (iii) implemented further adequate contractual, organizational, and technical measures, as needed according to said transfer impact assessment.

Moreover, Article 49 of the GDPR provides for possible exceptions to the above-mentioned requirements, that can be applied only whether specific circumstances are met.

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Local laws

Has the local regulator published any guidelines/regulations addressing privacy matters on clinical trials and/or pharmacovigilance? ('Regulator' may mean either the local data protection authority, or the local medicines authority.)

No, the *Commission National pour la Protection des Données* (National Commission for Data Protection – "**CNPD**") has not published any guidelines concerning clinical trials or pharmacovigilance.

However, the CNPD refers to the European Data Protection Board's Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation ("**CTR**") and the General Data Protection regulation ("**GDPR**") (art.70.1.b)) on its website, which is used as basis for interpretation of the questions herein.

Another relevant document that is taken into account by the CNPD is the Question and Answers on the interplay between the Clinical Trials Regulation and the General Data Protection Regulation published by the European Commission.

It should be taken into account that according to Grand Ducal Regulation of 30 May 2005 concerning the application of good clinical practice in conducting clinical trials for medicinal products for human use (the "**GDRCT**") *"detailed indications concerning the filing of the application and documents to be furnished to apply for the opinion of the ethics committee, in particular in regards to information provided to participants, as wells as the appropriate guarantees to ensure the protection of personal data, formulated by the Commission, are applicable in Luxembourg from its publication at the European Union Official Journal".*

In addition, it should be noted that Sections 63 to 65 of the Act of 1 August 2018 (the "**Data Protection Act**") set general rules for processing for the purposes of scientific or historical research that can be applicable to clinical trials.

Extraterritorial applicability

Does the GDPR/UK GDPR apply to a clinical trial sponsor situated outside the EEA?

Since there are no specific guidelines and the practice of the CNPD is not particularly extended in this regard, the general provisions of Section 3 GDPR will apply. Therefore, the GDPR would be applicable to a Sponsor outside the EEA if it:

- Offers goods or services to data subjects in the EU (Article 3(2)(a) GDPR);
- Monitors the behaviour of data subjects in the EU (Article 3(2)(b) GDPR).

There are no clear rules regarding on which of the two bases the GDPR will be applicable to Sponsors not established in the EEA. The European Commission Q&A mentioned above does not shed too much light on the question either.

A case-by-case basis would therefore be necessary.

Processing of personal data in clinical trials

What is the preferred legal ground for the processing of the personal data of the participants in a clinical trial in your jurisdiction?

The legal basis for the processing of data would depend on the purpose of the processing.

According to Opinion 3/2019 of the European Data Protection Board, where processing within the context of a clinical trial has as purpose safety and reliability, then the *"fulfilment of a legal obligation"* (6)(1)(c) GDPR) basis can apply. This would be the case of reporting obligations under Articles 41-43 of the Clinical Trial Regulation or Sections 14 and 15 of the GDRCT.

Other processing, those conducted for the purpose of the research itself, may fall under the following legal basis:

- Consent (6)(1)(a) GDPR)
- Public interest (6)(1)(e) GDPR). It should be noted that regarding special categories of data, Section 64 of the Data Protection Act expressly provides for the possibility to process such data for the purposes of scientific research or in the public interest, if the requirements of Section 65 (which requires the adoption of additional appropriate measures, such as appointment of a DPO, encryption, anonymisation or pseudonymisation techniques, DPIA) are met.
- Legitimate interest of the data controller (6)(1)(f) GDPR)

In practice, entities carrying out clinical trials rely on all of them without making special distinctions. See, for instance, the Privacy Notice of the Luxembourg Institute of Health (p. 2).

Processing of personal data for pharmacovigilance

What is the legal ground for the processing of the personal data in respect of pharmacovigilance in your jurisdiction?

The legal basis for the processing of the personal data in respect of pharmacovigilance in not explicitly specified either in Luxembourg legal texts or guidelines.

A Data protection notice for pharmacovigilance declarations (*Notice de protection des données concernant les déclarations de pharmacovigilance*) indicates that the *Division de la pharmacie et des médicaments – Direction de la santé*, which is the authority that collects and processes pharmacovigilance declarations in Luxembourg has to comply with the requirements of the GDPR. However, this notice does not identify any specific article of the GDPR as the legal basis for the processing of the personal data in respect of pharmacovigilance.

From our point of view, these three options may be considered:

- Consent (article 6)(1)(a) of the GDPR): A pharmacovigilance declaration form is available on the official website Guichet.lu. Prior to filing this form, the person reporting adverse reactions has to give its consent to the processing of its personal data. Although it is not clearly stated by the Luxembourg law, it seems that the legal basis for the processing of the personal data related to pharmacovigilance in Luxembourg is consent, in accordance with article 6(1)(a) of the GDPR.
- Performance of a task carried out in the public interest (article 6)(1)(e) of the GDPR): Pursuant to Recital 17 of the Regulation (EU) No 520/2012 of 19 June 2012 on the performance of pharmacovigilance activities, the purpose of the processing of personal data in pharmacovigilance activities is safeguarding public health which *"constitutes a substantial public interest"*. Therefore, we believe that the ground for the processing of the personal data in respect of pharmacovigilance could also be European regulations and more precisely the Recital mentioned above together with article 6(1)(e) of the GDPR.
- Fulfilment of a legal obligation (Article 6)(1)(c) GDPR) in the case of notification of adverse effects, as the entity concerned is obliged to register them and analyse the notifications made according to Section 45-4 of the Grand Ducal Decree of 15 December 1992, as amended by Grand Ducal Regulation 10 September 2012.

In most cases, for pharmacovigilance, fulfilment of a legal obligation, alone or in combination with other legal basis, could be a valid legal basis for processing.

Role of sponsor, principal investigator and others

Indicate the role from a data protection perspective of various parties involved (i.e in respect of the processing of the personal data of the clinical trial).

Role	Notes
Sponsor	Data controller, as it defines the selection criteria of the participants in the trial and the overall purpose of the processing. This is also confirmed by the Guidelines 07/2020 of the European Data Protection Board on the concepts of controller and processor in the GDPR, where it is stressed that the PI / Trial Site may be qualified as a joint controller with the Sponsor if they collaborate together to the drafting of the study protocol (i.e. purpose, methodology/design of the study, data to be collected, subject exclusion/inclusion criteria, database reuse (where relevant) etc.), as they jointly determine and agree on the same purpose and the essential means of the processing (see example 4 after paragraph 66).
Principal Investigator	He/she could be considered data controller, as they will determine the purposes of the processing of the data for the immediate actions related to the clinical trial (participant assistance and development of the investigation). It should be noted that in most cases (i.e., where the PI is an employee of the Clinical Trial Site) the PI will be treated as an agent of the Clinical Trial Site, pursuant to Article 29 of the GDPR. Depending on the circumstances, he/she might also be considered as data processor for the Clinical Trial Site, where he/she only processes data on behalf and upon instructions of the Clinical Trial Site (and he/she is not an employee thereof), but this has to be assessed on a case-by-case basis
Clinical Trial Site	Data controller for the same reasons as the principal investigator. This is also confirmed by the Guidelines 07/2020 of the European Data Protection Board on the concepts of controller and processor in the GDPR, where it is stressed that the PI / Trial Site may be qualified as a joint controller with the Sponsor if they collaborate together to the drafting of the study protocol (i.e. purpose, methodology/design of the study, data to be collected, subject exclusion/inclusion criteria, database reuse (where relevant) etc.), as they jointly determine and agree on the same purpose and the essential means of the processing (see example 4 after paragraph 66).
Monitor	Usually, they will be considered data processor as they process the data on behalf of the Sponsor.

CRO	Usually, they will be considered data processor as they process the data on behalf of the Sponsor.

Key-coded clinical trial data

Is key-coded clinical trial data considered personal data under your jurisdiction's data protection laws? (Key-coded clinical trial data is where the identity of the individual clinical trial participant is replaced with a unique subject identification code, and the 'key' which can be used to re-identify the participant is held by the Principal Investigator.)

Only in the case where the data is fully anonymized it would not be considered personal data. Key-coded data would not be considered personal data if it can be guaranteed that no reidentification of the data subject is possible.

Therefore, in those cases, the processing of key-coded data by any entity who does not hold the key will not be data processing in the sense of the GDPR.

Re-use of personal data

Is it possible to re-use the personal data obtained for the purposes of conducting the clinical trial? If so, what requirements need to be satisfied?

Since there are no specific guidelines or case law in Luxembourg regarding this topic, we should consider the general EU-level framework.

The secondary uses are expressly foreseen in Section 28(2) of the CTR and require the specific informed consent (within the meaning of the CTR, not GDPR) of the participant. Secondary uses are possible, but only for scientific purposes.

According to the European Commission in its Q&A, consent for the secondary use must be sought from the data subject either before the beginning of the trial or at a later stage.

However, it is the opinion of the EDPB that, relying on the presumption of compatibility of Article 5(1)(b) GDPR, it could be possible to continue to process the data for secondary uses relying on the same legal basis, without the need for a new one.

Cross-border data transfer

What requirements, if any, need to be satisfied if clinical trial data is transferred internationally?

As no specific guidelines have been approved in Luxembourg, the general requirements for international transfers of Article 45 and following GDPR have to be followed:

- If the country offers an adequate level of protection as assessed by the European Commission, then no transfer tool will be necessary.
- If the country does not offer an adequate level of protection, then the appropriate measures (transfer tools) have to be put in place.

The Recommendations 01/2020 on measures that supplement transfer tools to ensure compliance with the EU level of protection of personal data published by the EDPB are a good instrument for compliance. Also the CNPD has published its Guidelines on International Data Transfers that should be followed.

In any case, it should be borne in mind that this only would apply where there is personal data concern. If the data transferred is completely anonymized or provided only in aggregate, as it could be the case for many clinical trials, then the GDPR rules will not be applicable.

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Local laws

Has the local regulator published any guidelines/regulations addressing privacy matters on clinical trials and/or pharmacovigilance? ('Regulator' may mean either the local data protection authority, or the local medicines authority.)

No laws in Montenegro address privacy matters specifically in clinical trials and/or pharmacovigilance as such.

Privacy matters in the context of clinical trials are not specifically regulated under healthcare or similar laws which would specifically deal with the interplay between data protection and healthcare, but enjoy only the general protection under the Personal Data Protection Law of 2008, as amended (the "**DP Law**"). The DP Law is at the moment unharmonized with the GDPR, even though Montenegro expects a harmonized law to be passed in the foreseeable future.

Exceptionally, the Law on Medicines (the "**Law on Medicines**"), as the main law dealing with medicines (including clinical trials thereof) stipulates that clinical trial of the drug is conducted in compliance with the principles of medical ethics and mandatory protection of privacy and data of participants in accordance with the regulations adopted on the basis of the Law on Medicines and the Guidelines of Good Clinical Practice. Nevertheless, mentioned regulations were not adopted and the Guidelines do not go into further detail on this matter.

On the other hand, the relevant authorities which are associated with data protection or clinical trials have not yet adopted any specific guidelines which would explain the interplay between the two. In the absence of such, it is reasonably expected that acting in accordance with (i) the general principles of the DP Law and (ii) the international standards of data protection in clinical trials (such as the European Data Protection Board's Opinion concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the GDPR) would be a good way to go.

Extraterritorial applicability

Do the privacy laws and regulations applicable to clinical trials in your jurisdiction provide for extraterritorial applicability?

Yes, the DP Law provides for one situation where the DP Laws applies extraterritorially.

Namely, Article 5 of the DP Law stipulates that the DP Law applies to a controller established outside Montenegro or which does not have a permanent residence in Montenegro, when the equipment used to process the personal data is located in Montenegro (unless it is being used solely for the purposes of transferring data through the territory of Montenegro).

Thus, while the DP Law formally recognizes extraterritorial applicability, there is only a narrow set of situations which would result in the applicability of the DP Law. In the clinical trials context, the extraterritorial applicability would be triggered only in situations where (i) the controller of clinical trial personal data is established someplace other than Montenegro (e.g., USA), and (ii) the equipment used to

process personal data of participants in the clinical trial Montenegro (regardless of whether the participants are located in/nationals of Montenegro). Relevant equipment may include any hardware (e.g., servers, mainframes), which is used to perform processing in the clinical trial.

Processing of personal data in clinical trials

What is the preferred legal ground for the processing of the personal data of the participants in a clinical trial in your jurisdiction?

There is no legally mandated legal basis or court decision for the processing of personal data in clinical trials, i.e., the legal basis is determined in accordance with the general principles of the DP Law.

The appropriateness of a particular legal basis depends on the activities within the clinical trial to which the processing activities are related to, i.e., one legal basis may be appropriate for some of the activities, and not for the others.

In particular, in case of processing operations which are necessary for compliance with a legal obligation to which the controller is subject to (i.e., any obligation under the Law on Medicines), such controller can rely on compliance with a legal obligation (Article 10 (2) (1) of the DP Law) as an appropriate legal basis.

On the other hand, processing activities in the context of clinical trials purely associated with research purposes, with no underlaying legal obligations of the controller under the applicable laws, should rely on one of the remaining legal basis, depending on the particularities of the case, including public interest, legitimate interest of the controller or consent.

It is important to note that consent as a legal basis for processing should not be confused with consent which is a precondition for participants to participate in a clinical trial. In that sense, consent of the participants is a non-negotiable requirement under the Law on Medicines, which stipulates that a participant must provide an informed, freely-given, revokable prior consent. Such consent should always be regarded separately from consent as a legal basis for processing of personal data. Nevertheless, given that the practice in Montenegro is rather scarce, it is not unusual that controllers rely on informed consent of a participant as a legal basis for processing of his personal data. Similarly to the approach taken in the EU under the relevant EDPB guidelines, controllers in Montenegro should carefully assess the circumstances of the clinical trial before relying on consent as a legal basis for the processing of personal data for the purposes of the research activities of that trial.

Processing of personal data for pharmacovigilance

What is the legal ground for the processing of the personal data in respect of pharmacovigilance in your jurisdiction?

Subject to the argumentation laid down in the answers to the previous question, the controller should be able to rely on fulfillment of legal obligation of the controller as an adequate legal basis. This is because the Law on Medicines, inter alia, provides for a wide set of reporting obligations associated with pharmacovigilance with respect to participants in a clinical trial.

Role of sponsor, principal investigator and others

Indicate the role from a data protection perspective of various parties involved (i.e in respect of the processing of the personal data of the clinical trial).

Role	Notes
Sponsor	Data controller*.
Principal Investigator	

	Data controller, with respect to processing activities which represent Principal Investigator's responsibilities in the specific clinical trial*.
Clinical Trial Site	Data controller, with respect to processing activities which represent Clinical Trial Site's responsibilities in the specific clinical trial*.
Monitor	Data processor on behalf of the Sponsor, with respect to processing activities which represent Monitors' responsibilities in the specific clinical trial*.
CRO	Data processor on behalf of the Sponsor, with respect to processing activities which represent CRO's responsibilities in the specific clinical trial*.

*** Please note that the roles for each of the involved parties depend also greatly on the circumstances of each particular trial, i.e., the extent of the roles awarded to each of them. In that sense, whenever a party is authorized to (or in fact is) determining the purposes and means of the processing of personal data, such a party would bear the role of a controller. This note applies to other roles in clinical trials respectfully.**

Key-coded clinical trial data

Is key-coded clinical trial data considered personal data under your jurisdiction's data protection laws? (Key-coded clinical trial data is where the identity of the individual clinical trial participant is replaced with a unique subject identification code, and the 'key' which can be used to re-identify the participant is held by the Principal Investigator.)

The DP Law, nor any of the applicable healthcare laws do not regulate whether key-coded clinical trial data should enjoy the status of personal data.

Given the general rules and principles of the DP Law, as well as the general international practice which the Montenegrin Data Protection Authority (the "**DPA**") would likely take into consideration, key-coded clinical trial data would not be considered as personal data, as long as such data does not directly, or indirectly, allow for identification of the participants. Therefore, to the extent that the Sponsor receives anonymized trial data, which by itself, or together with any other information Sponsor might encounter, does not allow identification of the participant, such data would not be considered as personal data.

Re-use of personal data

Is it possible to re-use the personal data obtained for the purposes of conducting the clinical trial? If so, what requirements need to be satisfied?

Personal data obtained for the purposes of conducting the clinical trial may be used only for the purposes for which it was primarily obtained, and the participant duly informed of. Re-use of such personal data is only permissible provided that there is an adequate legal basis for such "extended" processing, and provided that the participant was duly informed of any such subsequent purpose prior to the initiation of processing.

On the other hand, key-coded personal data which does not have status of personal data is not subject to any restrictions for reusage from privacy perspective. Nevertheless, this key-coded non-personal data is subject to regulatory requirements (e.g., protection of secrecy under the Law on Medicines and Law on Rights of the Patients).

Cross-border data transfer

What requirements, if any, need to be satisfied if clinical trial data is transferred internationally?

Key-coded non-personal data

Transfer of clinical trial key-coded data which does not enjoy status of personal data is not subject to the transfer provisions of the DP Law.

Personal data

On the other hand, transfer of personal data arising from clinical trial is subject to the general transfer provisions of the DP Law.

Under the DP Law, personal data may be transferred to countries or international organizations which provide for an adequate level of personal data protection exists, but only subject to the approval of the DPA. The DPA issues such approval only where it establishes that adequate measures for the protection of personal data are undertaken (criteria for the adequacy assessment include, for example, the type of the data and the statutory rules in force in the country to which the data is to be transferred).

However, in certain cases the DPA's approval is not required for data transfers out of Montenegro, as explicitly prescribed by the DP Law (e.g., if the data subject consented to the transfer and was made aware of possible consequences of such transfer, or the data is transferred to the European Union or European Economic Area or to any country that the EU Commission has determined ensure adequate level of the data protection).

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North Macedonia

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Local laws

Has the local regulator published any guidelines/regulations addressing privacy matters on clinical trials and/or pharmacovigilance? ('Regulator' may mean either the local data protection authority, or the local medicines authority.)

No.

The regulator of North Macedonia has not published any guidelines/regulations that address privacy matters on clinical trials and/or pharmacovigilance so far.

General laws and bylaws regulating these issues are applicable to clinical trials and/or pharmacovigilance as well, including:

- The Law on Medicines and Medical Devices ("**Law on Medicines**");
- The Law on Personal Data Protection ("**DP Law**");
- The Rulebook on the Necessary Documentation and the Manner of Reporting Clinical Trials of Medical Devices and Changes Occurred and, Reporting on Adverse Reactions and Events, i.e., Incidents, as well as the Conditions to be Fulfilled by Legal Entities that Perform Clinical Trials of Medical Devices ("**Rulebook on Clinical Trials of Medical Devices**");
- The Rulebook on the Manner of Reporting, the Content of the Form for Reporting the Adverse Reactions to Medicines and the Manner of Organization of the Pharmacovigilance System ("**Rulebook on Reporting of Adverse Reactions to Medicines**");
- The Rulebook on the manner and Procedure for Pharmacological-Toxicological and Clinical Examination of Medicines ("**Rulebook on PT and Clinical Examination of Medicines**");
- The Guidelines on the Principles of Good Clinical Practice ("**Principles of Good Clinical Practice**").

Extraterritorial applicability

Do the privacy laws and regulations applicable to clinical trials in your jurisdiction provide for extraterritorial applicability?

Yes, the DP Law has the same extraterritorial scope as the GDPR and in accordance with Article 3 paragraph 2(a) applies to the processing of personal data of data subjects from the Republic of North Macedonia by a controller or processor not established in the Republic of North Macedonia, where the personal data processing activities are related to the (i) offering of goods and services to local consumers, regardless whether they are required to make payments, or (ii) monitoring the behaviour of the personal data subjects, if that behaviour takes place in the Republic of North Macedonia.

Consequently, by analogy with the GDPR, it can be assumed that the sponsor will be considered subject to the DP Law based on the 'monitoring of behaviour' limb. In some contexts, the 'offering of goods and services' limb may also be relevant in the context of providing the service of medical investigation to improve a patient's health

Note that the DP Law as *lex generalis* is the only regulation that provides extraterritorial applicability for matters related to personal data protection, i.e., there is no specific regulation of clinical trials that provides for extraterritorial applicability.

Processing of personal data in clinical trials

What is the preferred legal ground for the processing of the personal data of the participants in a clinical trial in your jurisdiction?

Consent is the preferred legal ground for processing of personal data of participants in a clinical trial.

The Law on Medicines and the Principles for Good Clinical Practice stipulate that the clinical trials can be conducted only if the investigator obtains written consent from the participant.

Explicit consent is also one of the conditions for processing of special categories of personal data, including health data. The DP Law defines consent as any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her.

In addition to consent, performance of a contract can also be considered as a legal ground for processing in case the participants have signed a contract with the investigator.

Finally, the existence of a legal obligation can also represent legal grounds for processing.

While the local data protection authority has not published any guidelines in regard to clinical trials, the above indicated grounds for processing can be considered as the usual market practice when processing special categories of personal data (such as health data).

Additionally, the local data protection authority needs to issue prior approval for the processing of health data, even when the participant as data subject has given explicit consent.

Processing of personal data for pharmacovigilance

What is the legal ground for the processing of the personal data in respect of pharmacovigilance in your jurisdiction?

Processing of personal data in respect of pharmacovigilance is based on the existence of a legal obligation to implement a pharmacovigilance system under the Law on Medicines.

The protection of the vital interests of the participants as data subjects can also be considered as a legal ground for processing in case of the occurrence of any adverse effects which have to be notified to the local authority supervising the market of medicinal products.

Role of sponsor, principal investigator and others

Indicate the role from a data protection perspective of various parties involved (i.e in respect of the processing of the personal data of the clinical trial).

Role	Notes
Sponsor	Data controller.
Principal Investigator	Data controller.

Clinical Trial Site	Data controller.
Monitor	Data processor.
CRO	Data processor.

Key-coded clinical trial data

Is key-coded clinical trial data considered personal data under your jurisdiction's data protection laws? (Key-coded clinical trial data is where the identity of the individual clinical trial participant is replaced with a unique subject identification code, and the 'key' which can be used to re-identify the participant is held by the Principal Investigator.)

In line with the GDPR, the DP Law defines personal data broadly as any information relating to an identified or identifiable natural person. An identifiable natural person is one who can be identified, directly or indirectly, in particular by a reference to an identifier such as the first and last name, personal identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

Key-coded clinical trial data, as pseudonymized data, is considered as personal data. This is because the existence of a key to re-identify the participant can be considered as additional information which could identify the participant.

Re-use of personal data

Is it possible to re-use the personal data obtained for the purposes of conducting the clinical trial? If so, what requirements need to be satisfied?

Yes. One of the main principles for data processing is the principle of purpose limitation. This means that personal data must be collected for specific, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes. Therefore, it would not be possible to re-use the personal data for any purpose other than the initial purpose for which the same were collected. However, further processing of the collected personal data for scientific purposes (pursuant to certain conditions and safeguards), is possible, since this will not be considered to be incompatible with the initial purposes.

The safeguards should ensure that technical and organizational measures are in place, in a particular order to ensure respect for the principle of data minimization. Such measures may include pseudonymization, provided that the purposes can be fulfilled in such manner. In situations where those purposes can be fulfilled by further processing which does not permit (or no longer permits) identification of data subjects, those purposes can be fulfilled in such manner.

Cross-border data transfer

What requirements, if any, need to be satisfied if clinical trial data is transferred internationally?

The DP Law prescribes different rules on cross-border data transfer, depending on the country of the recipient.

When transferring personal data, including clinical trial data, to the EU or EEA, the data controller or processor must notify the local data protection authority at least 15 days before the transfer occurs.

Transferring personal data to a third country or international organization may be conducted only if the local data protection authority deems that the third country or international organization provides adequate levels of protection. The DP Law prescribes the following safeguards: (i) transfer of data based on an adequacy decision; (ii) transfers of data which are subject to appropriate safeguards; (iii) binding corporate rules; (iv) transfers or disclosure pursuant to international agreements. In specific situations, such transfer may occur upon fulfillment of certain conditions prescribed with the DP Law (such as explicit consent of the data subject, execution of a contract between the controller and data subject, etc.).

In practice, the local data protection authority insists on approving each of the above transfers. Furthermore, since 01 January 2022, the data protection authority requires that each request for approval of cross-border data transfer, aside from the legal ground for such transfer, is also accompanied by a Transfer Impact Assessment. Note that an approval is not required if the controller uses binding corporate rules of the group to which the controller belongs, if the same have been approved by the European Commission.

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Norway

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Local laws

Has the local regulator published any guidelines/regulations addressing privacy matters on clinical trials and/or pharmacovigilance? ('Regulator' may mean either the local data protection authority, or the local medicines authority.)

Yes.

The Norwegian Medicines Agency has published information regarding the Regulation (EU) No. 536/2014 which is implemented as a Norwegian regulation. They have published answers to frequently asked questions and information about transitional rules. They will provide updated information but for the time being they provide a link to the information on EMA- and European commission web pages (Clinical trial guidelines). The information can be found on this page.

In Norway all clinical trials must be pre-authorised by the Norwegian Medicines Agency as well as by the Norwegian Research Ethics Committees (REK).

The Norwegian DPA has no guidelines regarding clinical trials in particular, but clinical trials are like all medical research regulated in the Health Research Act in addition to the clinical trials regulation.

All medical and health research projects need ethical prior approval from REK. The project manager / researcher is responsible for consulting with his or her own institution, and to clarify whether the processing of information is of such a nature that it requires a special assessment of privacy consequences.

Extraterritorial applicability

Does the GDPR/UK GDPR apply to a clinical trial sponsor situated outside the EEA?

Yes, to the extent that either:

- Clinical trial participants (data subjects) are located in the EU, based on Article 3(2)(a); or
- Clinical trial in the EU entails the monitoring of relevant participants and/or personnel located in the EU, based on Article 3(2)(b).

The Health Research Act is considered as additional national regulation and the act applies to medical and health research on Norwegian territory, or when the research takes place under the auspices of a research manager established in Norway.

The Clinical Trials Regulation states that a sponsor located outside EEA must have a legal representative in the EEA-area and that the representative must document this authorization to the Norwegian Medicines Agency.

Processing of personal data in clinical trials

What is the preferred legal ground for the processing of the personal data of the participants in a clinical trial in your jurisdiction?

The Health Research Act applies consent as the main legal ground for participation in clinical trials. Regarding the processing of personal data the Act refers to the GDPR.

The Norwegian Personal Data Act § 9 is a national regulation opening for the processing of article 9 data without consent when necessary for research purposes on certain conditions.

A decision giving the trial dispensation from duty of confidentiality is considered to serve as a guarantee according to article 89, in addition to the Health research act regulating the ethical and organizational part of the trial.

The Health Research Act sets out a general rule of consent in order to be able to research human biological material and health information. This applies whether data is collected directly from those to whom the information applies, or is obtained from patient records, other health registers, observations, biobanks or other research projects.

All research is subject to the main rule of consent. However, exceptions are permitted in studies where data being used is already collected – especially when data are collected from health registries.

If, however the patient group in the study is in such a state that makes it hard to consider a consent as freely given, for instance if your life depends on this trial-case, it may be hard to argue a consent can be used as a legal ground for participating and for the processing of personal data. If so, (also if the patient is not capable to consent) someone close to the patient consents to the trial on his behalf. The legal grounds for processing the data may in these cases be article 6 (c) or (e) and article 9.2 i) and j) as it is mandatory for those executing the trial to document the data collected form the trial when the patient has agreed to participate in the trial.

Processing of personal data for pharmacovigilance

What is the legal ground for the processing of the personal data in respect of pharmacovigilance in your jurisdiction?

The Norwegian Medicines Agency is responsible for the pharmacovigilance and is actively contributing to the European Medicines Agency's Committee for pharmacovigilance, Pharmacovigilance Risk Assessment Committee (PRAC).

Any processing of personal health data for the purpose of pharmacovigilance would be based on article 6 (e) and 9 (2)(i) or (j) and the Medicines Act with regulations like the Adverse Effect Registry regulating the processing of personal data for the purpose of collecting data for pharmacovigilance purposes.

Role of sponsor, principal investigator and others

Indicate the role from a data protection perspective of various parties involved (i.e in respect of the processing of the personal data of the clinical trial).

Role	Notes
Sponsor	According to the Clinical trials Regulation the sponsor has a legal obligation (the responsibility) to make sure the trial is performed in accordance with the regulation and that the data involved is processed in accordance with relevant regulation. (GDPR and national legislation). By definition this would make the Sponsor the controller of the data processed in the trial. If the sponsor isn't involved in any data-processing it would be necessary to discuss if in fact the role as a controller should be shared with the P.I. or if it is the P.I who is the controller alone.

Principal Investigator	Normally the P.I would be the controller in a medical trial or any research-project if he/she is not an employee of the Clinical Trial Site.
Clinical Trial Site	The Data controller of the participants personal data for the purposes of providing adequate healthcare assistance within the scope of the investigation.
Monitor	Sponsor's data processor, in charge of supervising the correct development of the investigation.
CRO	Sponsor's data processor when performing monitoring tasks, and in the event that the Sponsor subcontracts other tasks to the CRO that involve access by the CRO to encrypted participant data.

Key-coded clinical trial data

Is key-coded clinical trial data considered personal data under your jurisdiction's data protection laws? (Key-coded clinical trial data is where the identity of the individual clinical trial participant is replaced with a unique subject identification code, and the 'key' which can be used to re-identify the participant is held by the Principal Investigator.)

Yes, key-coded data is regarded as personal data as long as there is a technical possibility to re-identify the dataset. However we have national regulations that allows transfer of key-coded data on certain conditions.

Re-use of personal data

Is it possible to re-use the personal data obtained for the purposes of conducting the clinical trial? If so, what requirements need to be satisfied?

It is regarded inconsistent with a consent to re-use data based on a consent to purposes not included in the initial information. If necessary, one would need a new consent.

REK the ethical committees may allow re-use based on the Medical Research Act § 15 if the new purpose is of significant interest of the society and the integrity and wellbeing of the individuals are ensured.

It is possible to give a broad consent to research – this would mean a consent to within a certain branch of medicine and it requires updated information to the data subject to make sure the consent still can be seen as informed an freely given.

Key-coded datasets are used for medical research on a daily basis without consent, but these data normally are collected from health registries based on special regulations with legal grounds to export data for the purpose of research, but not necessarily clinical trials These datasets can be reused in the extent that the new purpose has the necessary approvals.

Cross-border data transfer

What requirements, if any, need to be satisfied if clinical trial data is transferred internationally?

Transfer of clinical trial data would be dependent on the general rules in the GDPR and national regulation regarding the duty of confidentiality.

If an international study the participants abroad will be considered parties in the project and the P.I must make sure the data is processed in compliance with the GDPR internationally.

Poland

Last modified 17 December 2024

Local laws

Has the local regulator published any guidelines/regulations addressing privacy matters on clinical trials and/or pharmacovigilance? ('Regulator' may mean either the local data protection authority, or the local medicines authority.)

Yes.

The primary piece of legislation governing the processing of personal data in clinical trials of medicinal products for human use is the Act on clinical trials of medicinal products for human use of March 2023. Article 8 of this Act concerns limitation of the application of the GDPR provisions in the case of the conduct of clinical trials that are scientific studies. In addition, on 11 December 2023 Polish local data protection authority ("The President of Personal Data Protection Office", or "PUODO") has approved the "Code of Conduct for the Healthcare Sector" prepared by the Polish Federation of Hospitals.

Extraterritorial applicability

Does the GDPR/UK GDPR apply to a clinical trial sponsor situated outside the EEA?

Yes to the extent that either:

- Clinical trial participants (data subjects) are located in the EU, based on Article 3(2)(a); or
- Clinical trial in the EU entails the monitoring of relevant participants and/or personnel located in the EU, based on Article 3(2)(b).

In those cases where the sponsor is not located within the EU, it shall appoint a representative within the EU, as required by article 27 of the GDPR.

Processing of personal data in clinical trials

What is the preferred legal ground for the processing of the personal data of the participants in a clinical trial in your jurisdiction?

In typical market practice, the legal ground for processing of personal data in clinical trials is Article 6(1)(a) in conjunction with Art. 9(2)(i) of the GDPR.

The Act on Clinical Trials has provided the possibility to restrict certain rights of data subjects. Pursuant to the Act, it is permitted to restrict the application of certain provisions of the GDPR. These include the rights of access, rectification, restriction of processing and objection (art. 15, art. 16, art. 18 and art. 21) if their exercise prevents or seriously obstructs achieving the objectives of the clinical trial and if such restriction is necessary to achieve the objectives of the trial.

However, Article 8 of this law does not provide a limitation on the application of Article 17 of the GDPR, i.e. the right to erasure ("right to be forgotten").

Under the findings in EDPB Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation ("CTR"), alternative legal basis may be cited as well, i.e.

- Art. 9(2)(i) of the GDPR *("processing is necessary for reasons of **public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices**, on the basis of Union or Member State law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy").*

- In relation to scientific research, Art. 9(2)(j) of the GDPR may also be used *("processing is necessary for archiving purposes in the public interest, **scientific** or **historical research** purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject").*

While an informed voluntary consent is a valid and permitted legal ground for processing, depending on the actual details of the clinical trial, the legal ground may also be necessity of the processing for the performance of a task carried out in the public interest from Article 6(1)e of the GDPR in conjunction with Article 9(2)(i) and/or (j) of the GDPR. However, under Article 8 of the Clinical Trials Act, the legal basis for the processing of a patient's data in the form of that patient's consent poses certain risks. This is because the patient can withdraw this consent at any time and Article 8 does not include an exception to the right to be forgotten as set out in Article 17 of the GDPR.

Processing of personal data for pharmacovigilance

What is the legal ground for the processing of the personal data in respect of pharmacovigilance in your jurisdiction?

In the light of EDPB Opinion 3/2019, the relevant legal ground for the processing of the personal data in respect of pharmacovigilance may be Article 6(1)(c) of the GDPR in conjunction with Article 9(2)(i) of the GDPR.

Role of sponsor, principal investigator and others

Indicate the role from a data protection perspective of various parties involved (i.e in respect of the processing of the personal data of the clinical trial).

Role	Notes
Sponsor	Data controller of the key-coded data of participants, as it determines the purposes and means of the processing of personal data during the clinical trial.
Principal Investigator	For the purpose of patient care within the clinical trial and performance of its own legal obligations or interests in this regard, Principal Investigator is a data controller. Depending on the role in drafting of the research protocol and trial agreement, *where the PI is not an employee of the trial site* it might also be considered either a joint controller along with the Sponsor or a data processor on behalf of the Sponsor.
Clinical Trial Site	

	Data controller of the participants' personal data for the purposes of providing adequate healthcare assistance within the scope of the investigation and data processor subject to the Sponsor within the investigation itself.
Monitor	Sponsor's data processor, in charge of supervising the correct development of the investigation.
CRO	Sponsor's data processor when (i) performing monitoring tasks, and (ii) in the event that the Sponsor subcontracts other tasks to the CRO that involve access by the CRO to encrypted participant data.

Key-coded clinical trial data

Is key-coded clinical trial data considered personal data under your jurisdiction's data protection laws? (Key-coded clinical trial data is where the identity of the individual clinical trial participant is replaced with a unique subject identification code, and the 'key' which can be used to re-identify the participant is held by the Principal Investigator.)

Under GDPR pseudonymised data would still considered personal data. However, key-coded clinical trial data might not be considered personal data if the codification procedure ensures that re-identification of participants by the Sponsor is not possible by any means, e. g. no additional data available to Sponsor or third parties may allow its re-identification.

No specific local laws nor guidelines in this regard, other than GDPR and EDPB's guidelines were published on this subject.

Re-use of personal data

Is it possible to re-use the personal data obtained for the purposes of conducting the clinical trial? If so, what requirements need to be satisfied?

No, if the legal ground for the processing was data subject's consent for particular trial, unless the data subject was provided with sufficient information on re-use and appropriate safeguards prior to giving consent. Otherwise, a separate consent for re-use would be necessary.

However, in the light of EDPB Opinion 3/2019, to the extent that there are other legal grounds for this processing, such as Article 6(1)e of the GDPR in conjunction with Article 9(2)(i) and/or (j) of the GDPR, in line Article 89(1) and Article 6(4) of the GDPR, key-coded clinical trial data can be re-used without having to obtain the data subjects' consent.

Generally, re-use is possible for scientific research and when the data is kept key-coded.

Additionally, according to Article 28(2) of the CTR the Sponsor might ask for the participant's consent to the use of their data outside the protocol of the clinical trial exclusively for scientific purposes.

Cross-border data transfer

What requirements, if any, need to be satisfied if clinical trial data is transferred internationally?

In those cases where the clinical trial data is key-coded and it is not possible to re-identify the participants (see our answers above), the information transferred would not be considered as personal data, and thus, the regulations that apply to international transfers of personal data would not be applicable.

In those cases where the re-identification of the participants' personal data is possible, international data transfer must comply with Art. 45 and further of the GDPR, in particular, if the recipient is located in a country which does not offer an adequate level of protection to GDPR, appropriate safeguards must be ensured.

No specific local laws nor guidelines in this regard, other than GDPR and EDPB's guidelines were published on this subject.

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Portugal

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Local laws

Has the local regulator published any guidelines/regulations addressing privacy matters on clinical trials and/or pharmacovigilance? ('Regulator' may mean either the local data protection authority, or the local medicines authority.)

There are no updated guidelines issued by Data Protection Supervisory Authority "**CNPD**". However, prior to General Data Protection Regulation (GDPR), CNPD published the resolution no. 1704/2015 which addresses personal data processing related aspects within the context of clinical research and resolution no. 219/2009 which addresses personal data processing related aspects within pharmacovigilance context. Although both resolutions remain accurate in terms of general principles, certain aspects are not aligned with GDPR.

In 2018 the Commission of Ethic for Clinical Trials ('**CEIC**') published a paper (hereinafter '**CEIC Paper**'), briefly addressing certain data protection issues that might arise with the processing of personal data, within the context of clinical trials. However, this seemed to be more of an informative nature, even if, considering CEIC attributions and involvement in clinical trials matters, it can be understood as a guideline for the processing of personal data in this context.

Extraterritorial applicability

Does the GDPR/UK GDPR apply to a clinical trial sponsor situated outside the EEA?

Yes, to the extent that either:

- Clinical trial participants (data subjects) are located in the EU, based on Article 3(2)(a); or
- Clinical trial in the EU entails the monitoring of relevant participants and/or personnel located in the EU, based on Article 3(2)(b).

In those cases where the sponsor is not located within the EU, it shall appoint a representative within the EU, as required by article 27(1) of the GDPR.

Processing of personal data in clinical trials

What is the preferred legal ground for the processing of the personal data of the participants in a clinical trial in your jurisdiction?

Depending on the specific circumstances of the case, the lawful basis for the processing the participants in a clinical trial may be the compliance with legal obligation under Article 6(1)(b) and the public interest in the area of public health under Article 9 (1) (i) of GDPR or the explicit consent of the data subject under Articles 6(1)(a) and 9(2)(a). This should be assessed in a case-by-case basis.

Processing of personal data for pharmacovigilance

What is the legal ground for the processing of the personal data in respect of pharmacovigilance in your jurisdiction?

The processing of personal data within the scope of pharmacovigilance activities is based on the compliance with a legal obligation under Article 6 (1) (c) of GDPR in connection with Article 9 (1) (i) of GDPR. In those cases where there is an adverse effect, it is understood that the legal ground for the data processing activity can also be considered the protection of vital interests of the data subject Article 6 (1) (d) of GDPR, but this would have to be assessed on a case-by-case basis.

Role of sponsor, principal investigator and others

Indicate the role from a data protection perspective of various parties involved (i.e in respect of the processing of the personal data of the clinical trial).

Role	Notes
Sponsor	Data controller of the personal data of participants.
Principal Investigator	Where the PI is not an employee of the trial site it is generally considered a processor. However, the qualification as (joint) data controller or processor should be assessed in a case-by-case basis depending on the level of participation on the clinical trial.
Clinical Trial Site	Data controller of the participants personal data for the purposes of providing adequate healthcare assistance within the scope of the investigation.
Monitor	Sponsor's data processor, in charge of supervising the correct development of the investigation.
CRO	Sponsor's data processor when (i) performing monitoring tasks, and (ii) in the event that the Sponsor subcontracts other tasks to the CRO that involve access by the CRO to encrypted participant data.

Key-coded clinical trial data

Is key-coded clinical trial data considered personal data under your jurisdiction's data protection laws? (Key-coded clinical trial data is where the identity of the individual clinical trial participant is replaced with a unique subject identification code, and the 'key' which can be used to re-identify the participant is held by the Principal Investigator.)

Law no. 58/2019 of 8 August does not provide for a definition of pseudonymized or anonymized data. However, considering the legal definition of pseudonymization foreseen in Recital 26 and Article 4(5) of GDPR, to the extent it is possible to re-identify the data subject, it is likely that the key-coded clinical trial data is considered personal data. However, this should be assessed in a case-by-case basis in view of the specific technical and organizational measures adopted.

Re-use of personal data

Is it possible to re-use the personal data obtained for the purposes of conducting the clinical trial? If so, what requirements need to be satisfied?

Yes, to the extent that there are lawful grounds for this processing under GDPR, key-coded clinical trial data can be re-used.

In cases where the participants' consent has been previously obtained for the processing of their personal data within the scope of conducting a clinical trial, prior to re-using the data for further investigations, it shall be exactly ascertained to what the data subject has consented to.

Furthermore, according to Law no. 58/2019, the processing for scientific research purposes shall respect the principle of data minimization and include the anonymization or pseudonymization of such data, whenever the referred purposes can be achieved by one of these means.

Cross-border data transfer

What requirements, if any, need to be satisfied if clinical trial data is transferred internationally?

Assuming that re-identification of the participants' personal data is possible, international transfers shall comply with GDPR requirements.

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Romania

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Local laws

Has the local regulator published any guidelines/regulations addressing privacy matters on clinical trials and/or pharmacovigilance? ('Regulator' may mean either the local data protection authority, or the local medicines authority.)

No.

Extraterritorial applicability

Does the GDPR/UK GDPR apply to a clinical trial sponsor situated outside the EEA?

Yes, the GDPR applies, to the extent that either:

- Clinical trial participants (data subjects) are located in the EU, based on Article 3(2)(a); or
- Clinical trial in the EU entails the monitoring of relevant participants and/or personnel located in the EU, based on Article 3(2)(b).

In those cases where the sponsor is not located within the EU, it shall appoint a representative within the EU, as required by article 27 of the GDPR. This is aligned with the clinical trials legislation (article 67 (2) Order no. 904/2006 for the implementation of good clinical trial practices) that sets forth that when the Sponsor is located outside the EU, it shall have a legal representative within the EU.

Processing of personal data in clinical trials

What is the preferred legal ground for the processing of the personal data of the participants in a clinical trial in your jurisdiction?

The market practice varies, and we are aware of cases where consent is (still) the legal ground of choice. However, pursuant to EDPB guidance, we consider that the processing of the personal data of clinical trials participants should be based on the existence of a legal obligation (Article 6.1 c) of the GDPR in connection with the provisions of Article 9.2 i) and j).

Processing of personal data for pharmacovigilance

What is the legal ground for the processing of the personal data in respect of pharmacovigilance in your jurisdiction?

No formal opinion from the supervisory authorities was issued. The processing of patients' personal data by the marketing authorization holder within the scope of pharmacovigilance activities should be based on the existence of a legal obligation (Article 6.1 c) of the GDPR in conjunction with Article 9.2 i) of the GDPR.

Further to the above, and in those cases where there is an adverse effect, we believe that the legal ground for the data processing activity may also be considered the protection of vital interests of the data subject (Article 6.1 d in conjunction with Article 9.2 c)).

We are aware however of a still ongoing preference of the market for the use of consent – especially for processing of personal data for follow up contacting of the data subject.

Preliminary note

Clinical trials in Romania are performed in public or private sites. In private sites, the sponsor usually engages the site for all clinical trial related services: site, PI, study staff.

In case of public sites, the sponsor contracts separately with the main actors in the clinical trials (site, PI) for the services each provide. This means that each of them needs to be qualified from a data protection point of view.

Role of sponsor, principal investigator and others

Indicate the role from a data protection perspective of various parties involved (i.e in respect of the processing of the personal data of the clinical trial).

Role	Notes
Sponsor	Data controller of the personal data of clinical trial participants.
Principal Investigator	(When contracted separately from the site) Data controller of the personal data of the clinical trials participants.
Clinical Trial Site	Data controller of the personal data of the clinical trials participants during the provision of healthcare assistance within the clinical trials.
Monitor	If they are a separate legal entity, the monitor company is the Sponsor's data processor.
CRO	Sponsor's data processor.

Key-coded clinical trial data

Is key-coded clinical trial data considered personal data under your jurisdiction's data protection laws? (Key-coded clinical trial data is where the identity of the individual clinical trial participant is replaced with a unique subject identification code, and the 'key' which can be used to re-identify the participant is held by the Principal Investigator.)

No guidance is given by legislation or the data protection supervisory authority.

Re-use of personal data

Is it possible to re-use the personal data obtained for the purposes of conducting the clinical trial? If so, what requirements need to be satisfied?

Yes, to the extent that the sponsor is able to rely on legal ground(s) for this processing and all the other privacy safeguards are put in place (such as the proper information of the clinical trials participants, appropriate technical and organizational measures, etc).

Cross-border data transfer

What requirements, if any, need to be satisfied if clinical trial data is transferred internationally?

International data transfer shall be based on adequate safeguards if the recipient is located in a country which does not offer an adequate level of protection for personal data.

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Local laws

Has the local regulator published any guidelines/regulations addressing privacy matters on clinical trials and/or pharmacovigilance? ('Regulator' may mean either the local data protection authority, or the local medicines authority.)

No laws in Serbia address privacy matters specifically in clinical trials and/or pharmacovigilance as such.

Privacy matters in the context of clinical trials are not specifically regulated under healthcare or similar laws which would specifically deal with the interplay between data protection and healthcare, but enjoy only the general protection under the Personal Data Protection Law of 2018, which represents a general data protection law and is a copy of the GDPR in most of its text (the "**DP Law**").

Exceptionally, the Law on Medicines and Medical Devices (the "**Law on Medicines**"), as the main law dealing with medicines and medical devices (including clinical trials thereof) stipulates that clinical trials may only be undertaken provided that, inter alia, privacy and data protection of subjects participating in the clinical trial is ensured. Nevertheless, the Law on Medicines does not go into further detail to explain any such mechanism.

Ever since the Personal Data Protection Law came into force in 2019, it sought to initiate a chain of reaction with other, sectorial laws (such as the Law on Medicines), by stipulating that they too shall be adjusted to fit the specifics of the data protection regime. However, this did not yet occur and therefore, there are no specific rules which apply to the processing in clinical trials and/or pharmacovigilance.

On the other hand, the relevant authorities which are associated with data protection or clinical trials have not yet adopted any specific guidelines which would explain the interplay between the two. In the absence of such, it is reasonably expected that acting in accordance with (i) the general principles of the DP Law and (ii) the international standards of data protection in clinical trials (such as the European Data Protection Board's Opinion concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the GDPR) would be a good way to go.

Extraterritorial applicability

Do the privacy laws and regulations applicable to clinical trials in your jurisdiction provide for extraterritorial applicability?

Yes, the DP Law provides for extraterritorial applicability.

Article 3 of the DP Law introduces substantially the same exterritorial applicability as the GDPR. In that sense, the DP Law applies to processing performed by a controller or processor with its registered office, residence or domicile in the territory of the Serbia, within the activities performed on the territory of the Serbia, regardless of whether the processing itself is performed in that territory. In the case of a controller with a registered office in Serbia, for example, whose server is located outside of Serbia and which processes data for the needs of his business, the applicability of the Law is unquestionable, and the controller is obliged to comply with the provisions of the DP Law even in relation to the data stored outside Serbia.

Also, the DP Law shall apply in cases when the controller or processor have no registered office, residence or domicile in the territory of Serbia, but process personal data of persons with residence or domicile in Serbia, if the processing operations are targeting Serbian residents/domiciled individuals by (i) offering goods or services, irrespective of whether a payment of the data subjects is required or (ii) monitoring their behaviour (for example, by using cookie trackers).

Putting the general exterritorial applicability provisions of the DP Law in the context of clinical trials, there are considerable arguments that the processing of personal data of Serbian participants performed by sponsor (who does not have registered office in Serbia) triggers the extraterritorial applicability of the DP Law (in particular, behaviour monitoring requirement). In the absence of official governance of the Serbian privacy/clinical trials authorities, the arguments for this fall mainly on the EDPB Guidelines 3/2018 on the Territorial Scope of the GDPR, which explains that "Monitoring or regular reporting on an individual's health status" is an example of behaviour monitoring which triggers the extraterritorial applicability of the GDPR. Given that the DP Law is basically a copy of the GDPR, the competent authorities would likely rely on how GDPR is understood by the relevant authorities and follow its example.

Processing of personal data in clinical trials

What is the preferred legal ground for the processing of the personal data of the participants in a clinical trial in your jurisdiction?

There is no legally mandated legal basis or court decision for the processing of personal data in clinical trials, i.e., the legal basis is determined in accordance with the requirements of the DP Law.

The appropriateness of a particular legal basis depends on the activities within the clinical trial to which the processing activities are related to, i.e., one legal basis may be appropriate for some of the activities, and not for the others.

In particular, in case of processing operations which are necessary for compliance with a legal obligation to which the controller is subject to (i.e., any obligation under the Law on Medicines), such controller can rely on compliance with a legal obligation (Article 12 (1) (3) of the DP Law) as an appropriate legal basis.

On the other hand, processing activities in the context of clinical trials purely associated with research purposes, with no underlaying legal obligations of the controller under the applicable laws, should rely on one of the remaining legal basis, depending on the particularities of the case, including public interest, legitimate interest of the controller or consent.

It is important to note that consent as a legal basis for processing should not be confused with consent which is a precondition for participants to participate in a clinical trial. In that sense, consent of the participants is a non-negotiable requirement under the Law on Medicines, which stipulates that a participant must provide an informed, freely-given, revokable prior consent. Such consent should always be regarded separately from consent as a legal basis for processing of personal data. Nevertheless, given that the practice in Serbia is rather scarce, it is not unusual that controllers rely on informed consent of a participant as a legal basis for processing of his personal data. Similarly to the approach taken in the EU under the relevant EDPB guidelines, controllers in Serbia should carefully assess the circumstances of the clinical trial before relying on consent as a legal basis for the processing of personal data for the purposes of the research activities of that trial.

Processing of personal data for pharmacovigilance

What is the legal ground for the processing of the personal data in respect of pharmacovigilance in your jurisdiction?

Subject to the argumentation laid down in the answers to the previous question, the controller should be able to rely on fulfillment of legal obligation of the controller as an adequate legal basis. This is because the Law on Medicines, inter alia, provides for a wide set of reporting obligations associated with pharmacovigilance with respect to participants in a clinical trial.

Role of sponsor, principal investigator and others

Indicate the role from a data protection perspective of various parties involved (i.e in respect of the processing of the personal data of the clinical trial).

Role	Notes
Sponsor	Data controller*.
Principal Investigator	Data controller, with respect to processing activities which represent Principal Investigator's responsibilities in the specific clinical trial*.
Clinical Trial Site	Data controller, with respect to processing activities which represent Clinical Trial Site's responsibilities in the specific clinical trial*.
Monitor	Data processor on behalf of the Sponsor, with respect to processing activities which represent Monitors' responsibilities in the specific clinical trial*.
CRO	Data processor on behalf of the Sponsor, with respect to processing activities which represent CRO's responsibilities in the specific clinical trial*.

* Please note that the roles for each of the involved parties depend also significantly on the circumstances of each particular trial, i. e., the extent of the roles awarded to each of them. In that sense, whenever a party is authorized to (or in fact is) determining the purposes and means of the processing of personal data, such a party would bear the role of a controller. This note applies to other roles in clinical trials respectfully.

Key-coded clinical trial data

Is key-coded clinical trial data considered personal data under your jurisdiction's data protection laws? (Key-coded clinical trial data is where the identity of the individual clinical trial participant is replaced with a unique subject identification code, and the 'key' which can be used to re-identify the participant is held by the Principal Investigator.)

The DP Law, nor any of the applicable healthcare laws do not regulate whether key-coded clinical trial data should enjoy the status of personal data.

Given the general rules and principles of the DP Law, as well as the general international practice which the DPA would likely take into consideration, key-coded clinical trial data would not be considered as personal data, as long as such data does not directly, or indirectly, allow for identification of the participants. Therefore, to the extent that the Sponsor receives anonymized trial data, which by itself, or together with any other information Sponsor might encounter, does not allow identification of the participant, such data would not be considered as personal data.

Re-use of personal data

Is it possible to re-use the personal data obtained for the purposes of conducting the clinical trial? If so, what requirements need to be satisfied?

Personal data obtained for the purposes of conducting the clinical trial may be used only for the purposes for which it was primarily obtained, and the participant duly informed of. Re-use of such personal data is only permissible provided that there is an adequate legal basis for such "extended" processing, and provided that the participant was duly informed of any such subsequent purpose prior to the initiation of processing.

Exceptionally, the DP Law recognizes the so-called presumption of compatibility, whereby further processing of data solely for research shall 'not be considered to be incompatible with the initial purposes' for which the data was collected. This provision enables re-use of data for further research purposes.

On the other hand, key-coded personal data which does not have status of personal data is not subject to any restrictions for reusage from privacy perspective. Nevertheless, this key-coded non-personal data is subject to regulatory requirements (e.g., protection of secrecy under the Law on Medicines and Law on Rights of the Patients).

Cross-border data transfer

What requirements, if any, need to be satisfied if clinical trial data is transferred internationally?

Key-coded non-personal data

Transfer of clinical trial key-coded data which does not enjoy status of personal data is not subject to the transfer provisions of the DP Law.

Personal data

On the other hand, transfer of personal data arising from clinical trial is subject to the general transfer provisions of the DP Law. Transfer provisions in the DP Law generally follow the ones from the GDPR, and provide that controller or processor may rely on the following mechanisms to convey a lawful transfer:

1. **Transfer based on adequate level of protection** – A transfer of personal data to another country may be performed without prior approval if it is determined that such other country provides an adequate level of protection of personal data. In short, this includes all European countries, as well as the ones which are included on the EU's or the Serbian Government's list of countries providing an adequate level of data protection.
2. **Transfer with appropriate safeguards** – In order to undertake a lawful transfer in territories which do not fulfil adequate level of protection, controller and/or processor will have to ensure that any of the safeguards are implemented (including e.g., standard contractual clauses (SCCs) prepared by the Serbian Data Protection Authority (the "**DPA**"), binding corporate rules (BCRs) or codes of conduct (CoCs)).
3. **Transfer in specific situations (so-called residual mechanism)** – such as data subject's explicit consent, necessity for the establishment, exercise or defence of legal claims, legitimate interests etc.

It is practically important to notice that unlike the GDPR, the DP Law insists on appropriate authorisation of the relevant transfer safeguards/legal grounds (e.g., SCCs, BCRs, CoCs) by the DPA/Serbian authorities, rather than by the EU Commission/EU supervisory authorities.

For example, the SCCs, BCRs and codes of conduct can be used for transfers from Serbia to third countries, but only if they are approved by the DPA, meaning that the ones approved by the EU authorities would not be sufficient.

Finally, the DP Law recognises only the Controller-to-Processor SCCs, while the European Commission's SCCs cover all mutual relations between controllers and processors (Controller-to-Processor, Controller-to- Controller, Processor-to-Controller, and Processor-to-Processor), and enable more than two parties to join in on the clauses.

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Spain

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Local laws

Has the local regulator published any guidelines/regulations addressing privacy matters on clinical trials and/or pharmacovigilance? ('Regulator' may mean either the local data protection authority, or the local medicines authority.)

Yes.

The Spanish Data Protection Commissioner ("**AEPD**") in collaboration with Farmaindustria - the industry association that brings together the majority of pharmaceutical companies established in Spain – has approved the "Code of conduct regulating the processing of personal data in the field of clinical trials and other clinical research and pharmacovigilance" (the "**Code**").

The Code is available in the following link.

Extraterritorial applicability

Does the GDPR/UK GDPR apply to a clinical trial sponsor situated outside the EEA?

Yes, to the extent that either:

- Clinical trial participants (data subjects) are located in the EU, based on Article 3(2)(a); or
- Clinical trial in the EU entails the monitoring of relevant participants and/or personnel located in the EU, based on Article 3(2)(b).

In those cases where the sponsor is not located within the EU, it shall appoint a representative within the EU, as required by article 27 of the GDPR. This is aligned with the clinical trials regulation (article 39 of the Royal Decree 1090/2015, which regulates clinical trials with medicinal products) that sets forth that when the Sponsor is located outside the EU, it shall have a legal representative within the EU.

Processing of personal data in clinical trials

What is the preferred legal ground for the processing of the personal data of the participants in a clinical trial in your jurisdiction?

According to the Code, the processing of the data of clinical research participants is based on the existence of a legal obligation (Article 6.1 c) of the GDPR in connection with the provisions of Article 9.2 i) and j).

The Code considers that the processing has two main purposes: (i) to ensure compliance with the legal obligations imposed to ensure a high level of quality and safety of the medicinal product; and (ii) it is carried out for scientific research purposes on the basis of the rules of Spanish and European Union law, which impose the legal obligation to carry out the research activities prior to the marketing of a drug, as well as the performance of post-authorization studies.

Processing of personal data for pharmacovigilance

What is the legal ground for the processing of the personal data in respect of pharmacovigilance in your jurisdiction?

According to the Code, the processing of patients' personal data within the scope of pharmacovigilance activities is based on the existence of a legal obligation (Article 6.1 c) of the GDPR.

Further to the above, and in in cases of adverse effect, the legal ground for the data processing activity may also be considered the protection of vital interests of the data subject as per Article 6 (1((d), according to the Code.

Role of sponsor, principal investigator and others

Indicate the role from a data protection perspective of various parties involved (i.e in respect of the processing of the personal data of the clinical trial).

Role	Notes
Sponsor	Data controller of the key-coded data of participants.[1]
Principal Investigator	Data controller of the participants personal data in connection with the data processing activity that arise because of performing the investigation activities set forth in the Protocol.
Clinical Trial Site	Data controller of the participants personal data for the purposes of providing adequate healthcare assistance within the scope of the investigation. However, in accordance with Guidelines 07/2020 of the European Data Protection Board on the concepts of controller and processor in the GDPR, the PI / Trial Site may qualify as a joint controller with the sponsor if they collaborate together to the drafting of the study protocol (i.e. purpose, methodology/design of the study, data to be collected, subject exclusion/inclusion criteria, database reuse (where relevant) etc.) as they jointly determine and agree on the same purpose and the essential means of the processing. (see example 4 after paragraph 66). As a consequence, a case-by-case analysis is necessary.
Monitor	Sponsor's data processor, in charge of supervising the correct development of the investigation.
CRO	Sponsor's data processor when (i) performing monitoring tasks, and (ii) in the event that the Sponsor subcontracts other tasks to the CRO that involve access by the CRO to encrypted participant data.

[1] Although the Code considers that key-coded clinical trial data could not be considered personal data, it sets forth the role of the Sponsor as data controller of the participants key-coded data, but modulates its responsibility accordingly, and in particular in comparison with the responsibilities held by the Principal Investigator and the Clinical Trial Site.

Key-coded clinical trial data

Is key-coded clinical trial data considered personal data under your jurisdiction's data protection laws? (Key-coded clinical trial data is where the identity of the individual clinical trial participant is replaced with a unique subject identification code, and the 'key' which can be used to re-identify the participant is held by the Principal Investigator.)

As per the Code, key-coded clinical trial data is not considered personal data as long as the codification procedure ensures that re-identification of participants by the Sponsor is not possible.

Re-use of personal data

Is it possible to re-use the personal data obtained for the purposes of conducting the clinical trial? If so, what requirements need to be satisfied?

Yes, to the extent that there are legal grounds for this processing, key-coded clinical trial data can be re-used without having to obtain the data subjects' consent.

In those cases where the participants' consent has been previously obtained for the processing of his/her personal data within the scope of conducting a clinical trial, the same can refer to a research branch, and not to a concrete investigation. That would permit re-using the data for further investigations related to the same health branch (e.g. oncological research).

Cross-border data transfer

What requirements, if any, need to be satisfied if clinical trial data is transferred internationally?

In those cases where the clinical trial data is key-coded and it is not possible to re-identify the data, the information received by the recipient would not be considered as personal data, and thus, the regulations that apply to international transfers of personal data are not applicable.

In those cases where the re-identification of the participants' personal data is possible, international data transfer shall count with adequate guarantee measures if the recipient is located in a country which does not offer an adequate level of protection to GDPR. Thus, cross-border transfers must be carried out in accordance with Articles 45 et seq. of the GDPR. This means that personal data, including health data, can be lawfully transferred in case one of the following requirement is met:

- There is a European Commission Adequacy Decision, stating that the recipient country provides adequate protection for individuals' personal data; or
- The data exporter and importer (i) adopted appropriate safeguards pursuant to Articles 46 et seq. of the GDPR (e.g. Standard Contractual Clauses, Binding Corporate Rules, etc.), (ii) conducted a proper transfer impact assessment pursuant to EDPB's recommendations 1/2020, and (iii) implemented further adequate contractual, organizational, and technical measures, as needed according to said transfer impact assessment.

Moreover, Article 49 of the GDPR provides for possible exceptions to the above-mentioned requirements, that can be applied only whether specific circumstances are met.

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Sweden

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Local laws

Has the local regulator published any guidelines/regulations addressing privacy matters on clinical trials and/or pharmacovigilance? ('Regulator' may mean either the local data protection authority, or the local medicines authority.)

No.

The Swedish Authority for Privacy Protection does however state on its website that a data protection impact assessment should be done with respect to processing of pseudonymized sensitive personal data relating to data subjects from research projects or clinical trials (checked 26 May 2022).

Extraterritorial applicability

Does the GDPR/UK GDPR apply to a clinical trial sponsor situated outside the EEA?

General GDPR requirements apply. In our view, both Article 3(2)(a) or Article 3(2)(b) could apply.

A factual analysis should be done with respect to the clinical trial at hand. To our knowledge, the Swedish regulator has not issued any opinion on what circumstances that should be taken into account. That would thus need to be assessed with respect to the specific trial at hand.

In those cases where the sponsor is not located within the EU, it shall also appoint a representative within the EU, as required by article 27 of the GDPR.

Processing of personal data in clinical trials

What is the preferred legal ground for the processing of the personal data of the participants in a clinical trial in your jurisdiction?

There is no "preferred legal ground". Each processing activity and its purpose should be analyzed separately.

In our experience, for Sponsor and Clinical Trial Site, legal obligation (Article 6.1 c) of the GDPR in conjunction with the provisions of Article 9.2 i) and j) of the GDPR would be relevant for the purposes of conducting the Clinical Trial at hand.

Processing of personal data for pharmacovigilance

What is the legal ground for the processing of the personal data in respect of pharmacovigilance in your jurisdiction?

The processing of patients' personal data within the scope of pharmacovigilance activities is based on the existence of a legal obligation (Article 6.1 c) of the GDPR[1].

[1] Medical Products Agency's regulations (LVFS 2012: 14) on safety monitoring of medicinal products for human use

Role of sponsor, principal investigator and others

Indicate the role from a data protection perspective of various parties involved (i.e in respect of the processing of the personal data of the clinical trial).

Role	Notes
Sponsor	Data controller for the processing of key coded (pseudonymized) personal data needed to fulfill the Sponsor's processing purposes and responsibilities set forth in the Protocol and by applicable law. Joint-controller together with Clinical Trial Site for conducting the study, at least where the Protocol has been jointly decided.
Principal Investigator	Where the PI is an employee of the trial site, it will be considered: • Data controller for the data processing activity that arises because of the performance of the investigation activities set forth in the Protocol. • Joint-controller with Sponsor for conducting the study if the Principal Investigator together with the Sponsor decides the purpose and the means for the trial.[1]
Clinical Trial Site	Data controller for the processing of the participants' personal data for the purposes of providing adequate healthcare assistance within the scope of the investigation.
Monitor	Sponsor's data processor, in charge of supervising the correct development of the investigation.
CRO	Sponsor's data processor when (i) performing monitoring tasks, and (ii) in the event that the Sponsor subcontracts other tasks to the CRO that involve processing of personal data on behalf of the Sponsor, e.g. access by the CRO to encrypted participant data.

[1] Please see EDPB's guidelines s 07/2020 on the concepts of controller and processor in the GDPR p. 23.

Key-coded clinical trial data

Is key-coded clinical trial data considered personal data under your jurisdiction's data protection laws? (Key-coded clinical trial data is where the identity of the individual clinical trial participant is replaced with a unique subject identification code, and the 'key' which can be used to re-identify the participant is held by the Principal Investigator.)

Yes. The GDPR applies. If it is in any way possible to re-identify the data subject, the data at hand qualifies as personal data.

Re-use of personal data

Is it possible to re-use the personal data obtained for the purposes of conducting the clinical trial? If so, what requirements need to be satisfied?

Re-use of personal data obtained for the purposes of conducting the clinical trial for other purposes requires a new consent.

Cross-border data transfer

What requirements, if any, need to be satisfied if clinical trial data is transferred internationally?

In those cases where the clinical trial data is completely anonymized and it is not possible to re-identify the data, the information received by the recipient would not be considered as personal data, and thus, GDPR's restrictions that apply to international transfers of personal data are not applicable.

In those cases where the re-identification of the participants' personal data is possible, international data transfer shall count with adequate guarantee measures if the recipient is located in a country which does not offer an adequate level of protection to GDPR.

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Local laws

Has the local regulator published any guidelines/regulations addressing privacy matters on clinical trials and/or pharmacovigilance? ('Regulator' may mean either the local data protection authority, or the local medicines authority.)

Yes. The Health Research Authority ("**HRA**") published GDPR guidance for researchers and study coordinators in 2018 that covers the following areas: (i) consent; (ii) controllers and personal data in health and care research; (iii) transparency; (iv) safeguards; (v) data subject rights; and (vi) data protection impact assessments.

In April 2022, the Information Commissioner's Office ("**ICO**") published draft guidance on the research provisions under the UK GDPR and Data Protection Act 2018 (including scientific research). This guidance covers issues including: (i) the definition of scientific research; (ii) legal basis; (iii) data subject rights; and (iv) purpose limitation / re-purposing personal data for scientific research.

Extraterritorial applicability

Does the GDPR/UK GDPR apply to a clinical trial sponsor situated outside the EEA?

Yes. Where clinical trial participants (data subjects) are located in the UK, the sponsor will normally be considered subject to the UK GDPR based on Article 3(2)(b) (which mirrors the wording of the same Article of the EU GDPR). In some contexts, Article 3(2)(a) may also be relevant in the context of providing the service of medical investigation to improve a patient's health.

In such cases the sponsor is required to appoint a representative in the UK, as required by Article 27 of the UK GDPR.

Processing of personal data in clinical trials

What is the preferred legal ground for the processing of the personal data of the participants in a clinical trial in your jurisdiction?

Both the HRA and the ICO agree that the most appropriate lawful bases for processing personal data of clinical trial participants are either a task carried out in the public interest (Article 6(1)(e)) (for public sector sponsors), or the legitimate interests of the controller (Article 6(1)(f)) (for private sector sponsors) in conjunction with Article 9(2) (j) of the UK GDPR and Section 19 of the Data Protection Act 2018. Therefore, the guidance in the UK is not to rely on consent.

Processing of personal data for pharmacovigilance

What is the legal ground for the processing of the personal data in respect of pharmacovigilance in your jurisdiction?

Safety reporting which is required by the Clinical Trials Regulations 2004 should be based on legal obligation (Article 6(1)(c)) in conjunction with Article 9.2 (i) UK GDPR.

Role of sponsor, principal investigator and others

Indicate the role from a data protection perspective of various parties involved (i.e in respect of the processing of the personal data of the clinical trial).

Role	Notes
Sponsor	Data controller.
Principal Investigator	In most cases (i.e., where the PI is an employee of the trial site) the PI will be treated as an agent of the Clinical Trial Site and not a controller / processor in its own right. Where this is not the case, then the PI will be the Sponsor's data processor (see comments below in relation to clinical trial site). However, where the PI needs to process personal data to provide medical care outside of the context of the trial protocol, they will be an independent controller.
Clinical Trial Site	Sponsor's data processor. This is the default position provided for in the HRA's Model Clinical Trial Agreement. However, in accordance with Guidelines 07/2020 of the European Data Protection Board on the concepts of controller and processor in the GDPR (which remain highly influential in the UK post-Brexit), the PI / Trial Site may qualify as a joint controller with the sponsor if they collaborate together to the drafting of the study protocol (i.e. purpose, methodology /design of the study, data to be collected, subject exclusion /inclusion criteria, database reuse (where relevant) etc.) as they jointly determine and agree on the same purpose and the essential means of the processing. (see example 4 after paragraph 66)
Monitor	Sponsor's data processor, in charge of supervising the correct development of the investigation.
CRO	Sponsor's data processor when (i) performing monitoring tasks, and (ii) in the event that the Sponsor subcontracts other tasks to the CRO that involve access by the CRO to encrypted participant data.

Key-coded clinical trial data

Is key-coded clinical trial data considered personal data under your jurisdiction's data protection laws? (Key-coded clinical trial data is where the identity of the individual clinical trial participant is replaced with a

unique subject identification code, and the 'key' which can be used to re-identify the participant is held by the Principal Investigator.)

Key-coded clinical trial data constitutes pseudonymized personal data (see, for example, the guidance of the Medical Research Council).

Re-use of personal data

Is it possible to re-use the personal data obtained for the purposes of conducting the clinical trial? If so, what requirements need to be satisfied?

Yes.

Personal data can be re-used for scientific research purposes (without having to establish a separate lawful basis) provided a controller complies with the safeguards under Article 89(1) UK GDPR and section 19 Data Protection Act 2018.

Under Article 89(1), safeguards must take the form of technical and organisational measures, in particular to ensure respect for the principle of data minimisation. This may involve pseudonymising data, where possible in connection with the research.

Under section 19 of the DPA 2018 research related processing will not satisfy Article 89 if the processing: (i) is likely to cause substantial damage or substantial distress to data subjects; or (ii) is carried out for the purposes of measures or decisions about particular individuals, except in the case of approved medical research

Anonymized clinical trial data can be further re-used without having to rely on a legal basis.

All other re-use of clinical trial data must either: (i) be compatible with the original purpose of processing (i.e., closely related to the clinical trial purpose) (Article 6(4) UK GDPR); (ii) be based on the data subject's consent; or (iii) benefit from an exemption under Schedules 2 – 4 Data Protection Act 2018.

Cross-border data transfer

What requirements, if any, need to be satisfied if clinical trial data is transferred internationally?

Assuming the clinical trial data is not anonymized, transfers to countries outside of the UK which do not benefit from an adequacy decision approved by the UK Government[1] should be based on either:

- Appropriate safeguards (most commonly either (i) the EU Commission Standard Contractual Clauses, as amended by the UK International Data Transfer Addendum; or (ii) the UK International Data Transfer Agreement).
- A derogation under Article 49 UK GDPR. For example, it may be possible to justify transfers of personal data necessary for pharmacovigilance purposes on the basis of Article 49(1)(d) (important reasons of public interest).

[1] At the date of writing, this includes all EU and EEA states, as well as all countries benefitting from an EU Commission adequacy decision in force as at 31 December 2020.

Key contacts

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