Welcome

PharmaRelations
The Life Science Consulting Group

SETTERWALLS

Please note that any information in this presentation shall not be regarded as legal advice, but merelly as an account for the state of law as of the 5 september 2023.

GDPR in Clinical Trials

Sponsor Perspective

PharmaRelations
The Life Science Consulting Group

SETTERWALLS

PharmaRelations
The Life Science Consulting Group

Services through the product development

Pre-Clinical Phase

- Regulatory
- Toxicology
- Strategies moving into clinical phase
- Audits
- Quality Assurance (GxP)
- Medical writing

Clinical Phase

- Clinical Operations
- Biometrics
- Regulatory
- Safety
- Quality Assurance (GxP)
- Medical engineering
- Medical advisors
- Medical writing
- Audits
- Market entry

Post-marketing Phase

- Regulatory
- Safety
- Quality Assurance (GxP)
- Sales & Marketing
- Digital & Social media
- Market access
- Data & technology

PharmaRelations Academy — Business Transformation

The speakers

Jonatan Blomqvist works continuously with the review of agreements such as agreements for clinical studies both from a general legal and GDPR perspective.

Karolina Jivebäck Pap works with various legal questions within those fields of law. In addition, she is a part of Setterwall's GDPR team, and those various practice areas are often combined.

Emma Perlhamre has 20 years of experience in Clinical Development. She has worked in different roles within Project Management, Clinical Operations, and Business Development. She has experience in managing global as well as local teams within the Nordics.

SETTERWALLS

PharmaRelations
The Life Science Consulting Group

What is personal data?

- Personal data is any information which, directly or indirectly, relates to an identifiable natural person, such as name, address, personal identification number, an IP-address or a picture.
- Sample data and patient IDs are also personal data.
- Special categories of personal data means personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation.

Clinical trials

When processing personal data in clinical trials the legal basis “legitimate interest” could be suitable as a basis.

However, clinical trials often involve the processing of special categories of personal data (Article 9 GDPR) in the form of health data and medical history. For lawful processing of such data the research exemption could be relied upon. This exemption is to be found in article 9.2.j of the GDPR and can be used when the study has been approved by the Ethical Review Board.

NOTE: Consent to participate in the clinical according the Ethical Review Act is not the same as consent according to GDPR. Also remember that participants’ consent is not preferred as a legal basis for the processing of personal data in clinical trials.

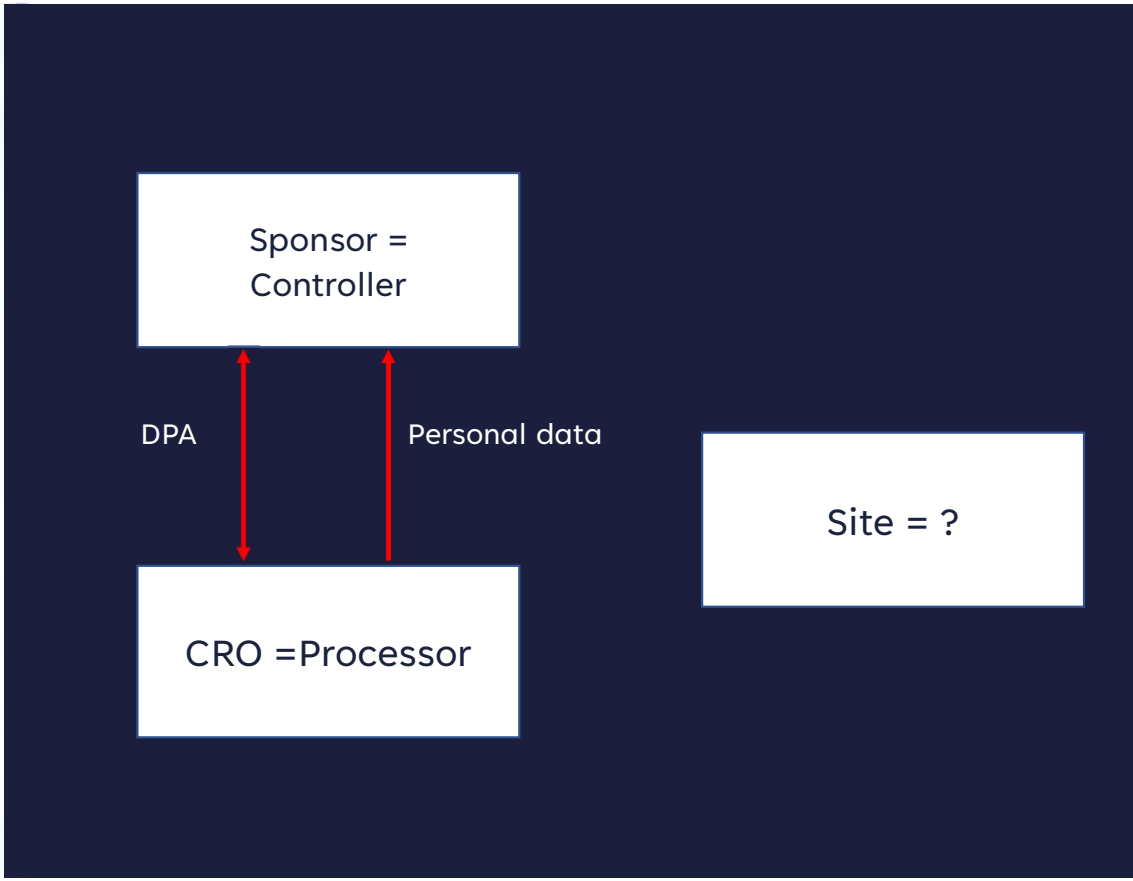
Clinical trials

- Security measures when processing for scientific research purposes – Article 89.1:
- Those safeguards shall ensure that technical and organisational measures are in place in particular in order to ensure respect for the principle of data minimisation.
- Those measures may include pseudonymisation provided that those purposes can be fulfilled in that manner.
- Where those purposes can be fulfilled by further processing which does not permit or no longer permits the identification of data subjects, those purposes shall be fulfilled in that manner (Anonymization).

→ Remember that pseudonymization is not the same as anonymization.

The role of the Sponsor/CRO/Site

- The assessment must be made on a case-by-case basis
- Different "industry practices".
- The Sponsor is often considered the Controller.
- The CRO is often considered the Processor.
- The role of the Site is often discussed.

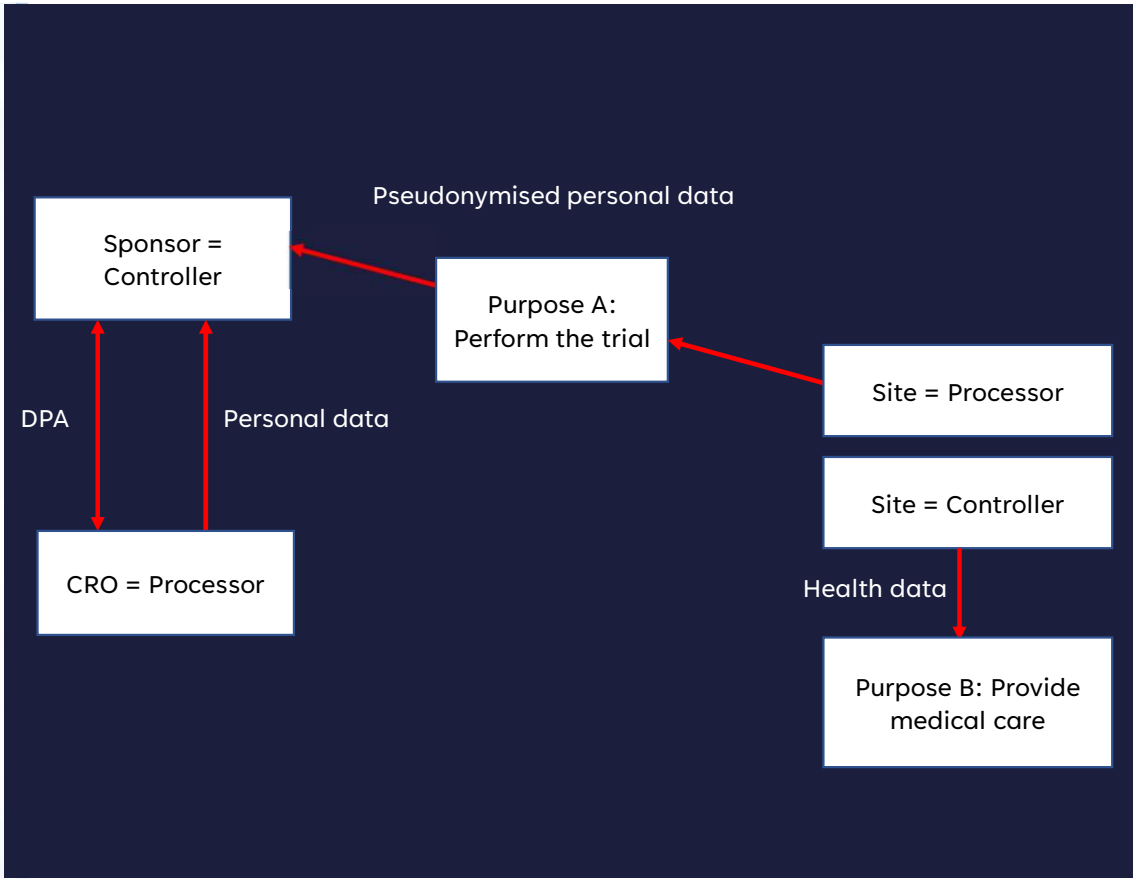


The role of the Sponsor/CRO/Site

Our assessment

We usually arrive at the following assessment:

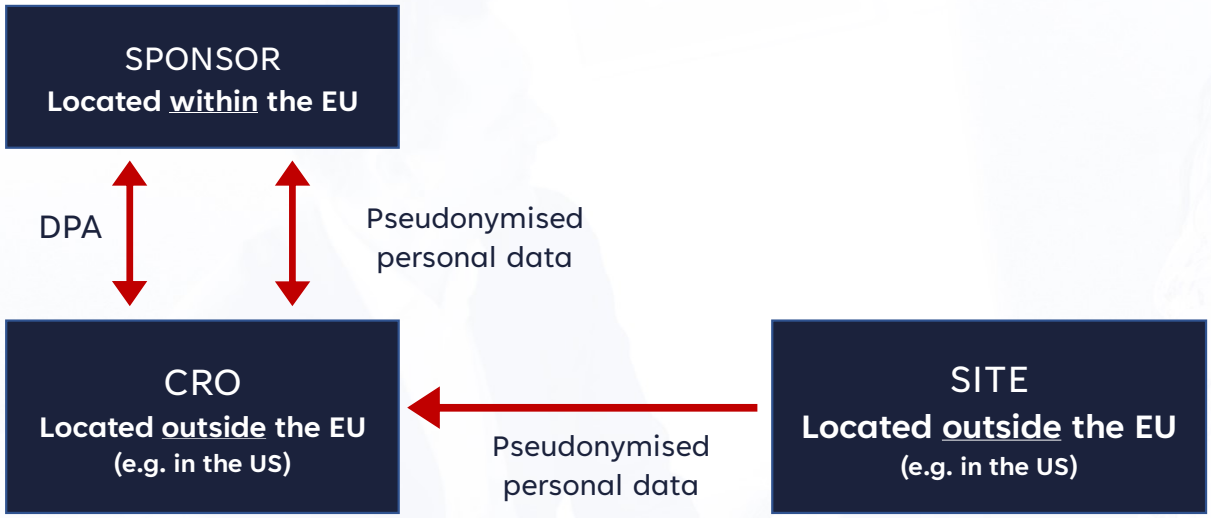
- Sponsor is the Controller.
- CRO is the Processor.
- Site is both the Controller and the Processor.



Territorial scope

Article 3 of the GDPR defines the direct scope.

Indirect application can take place through data processing agreements (DPA:s).



SPONSOR → Determines the purpose and means of the processing activities → Data controller

CRO → Process the personal data on behalf of the Sponsor → Data processor

CRO and **SITE** needs to enter into DPA:s → need to comply with the requirements of Art. 28 GDPR becomes indirectly applicable to the situation at hand

Territorial scope

Specifically on transfer of personal data to the US

There are other factors to take into consideration:

The US was until recently considered not to offer sufficient protection of personal data.

- Not enough to base such transfer on Standard contractual clauses (SCC).
- Additional security measures?

Decisions of the Swedish Supervisory Authority from the 3 July 2023:

Bolag måste sluta använda Google Analytics

Publicerad: 3 juli 2023

Integritetsskyddsmyndigheten (IMY) har granskat hur fyra bolag använder Google Analytics för besöksstatistik. IMY utfärdar sanktionsavgift mot två av bolagen. Ett av bolagen har på eget initiativ nyligen slutat använda statistikverktyget medan IMY förelägger övriga tre att också sluta använda det.

Territorial scope

Specifically on transfer of personal data to the US

However, on the 10 July 2023, the EU Commission adopted a new adequacy decision for transfer of personal data to the US.

Thus, as long as the recipient of data (in the US) obtains the relevant certifications stipulated under the adequacy decision, there will be a new, lawful basis for safe EU-US data flows.

Territorial scope

Site and data subject outside the EU

If the site and the data subjects are located outside the EU → transfer data to the EU → GDPR is not applicable.

Our position on transferring data back to the site outside of the EU = no need for SCC/additional security measures.

Case T-557/20 (appealed)

Clarification on when pseudonymised data is in fact to be considered anonymised → not to be regarded as personal data.

Setterwalls

Jonatan Blomqvist

Associate

- +46 10 690 04 10
- +46 72 529 90 51
- jonatan.blomqvist@setterwalls.se

Karolina Jivebäck Pap

Associate

- +46 10 690 04 75
- +46 70 771 81 89
- Karolina.JivebackPap@setterwalls.se