

# Compliance with Member State applicable rules for the collection, storage and future use of (personal) data (article 7 (1 d) of EU Regulation 536/2014)

<b>Full title of the clinical trial</b>	<b>EU trial number</b>
Click or tap here to enter text.	Click or tap here to enter text.
<b>Responsible entity for the data (legally controller (article 4 (7) GDPR):</b>	
Click or tap here to enter text.	

<b>Section 1 – Newly collected (personal) data</b>
<p><b>1.1</b> What of the following (personal) data<sup>1</sup> will be collected from the subject?</p> <p><input type="checkbox"/> Not applicable</p> <p><input type="checkbox"/> Racial or ethnic origin, if so please explain why <b>Click or tap here to enter text.</b></p> <p><input type="checkbox"/> Social security number, if so please explain why <b>Click or tap here to enter text.</b></p> <p><input type="checkbox"/> Other revealing personal data, i.e. political opinions, religious or philosophical beliefs, trade union membership, genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning a natural person's sex life or sexual orientation, namely: <b>Click or tap here to enter text.</b></p>
<p><b>Section 2 - Does the clinical trial involve the collection of already existing (personal) data (derived from e.g. treating physician, family doctor, or previous participation in a study).</b></p> <p><input type="checkbox"/> Yes, please fill in the requested information in section 2</p> <p><input type="checkbox"/> No, not applicable. Please continue with section 3</p>
<p><b>2.1</b> What existing (personal) data will be used?</p> <p><input type="checkbox"/> From treating physician/medical specialist</p> <p><input type="checkbox"/> From previous studies, please enter EudraCT or EU clinical trial number: <b>Click or tap here to enter text.</b></p> <p><input type="checkbox"/> Other, please indicate: <b>Click or tap here to enter text.</b></p>
<p><b>2.2</b> Will new consent be obtained for the use of these data in this clinical trial?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No, please explain: <b>Click or tap here to enter text.</b></p>
<b>Section 3 – How will the (personal) data for the purpose of the clinical trial (i.e. for use described in the protocol) be handled?</b>

<sup>1</sup> Only the collection and processing of special categories of personal data have to be included here. Collection and processing of health data, as a special category of personal data, is part of clinical trial as described in protocol and does not have to be repeated here.

<p><b>3.1.</b> Where will the data be analysed? <i>Please fill in the name of the country (and if this concerns the USA, also the name of the organisation) where the data will be analysed.</i> <b>Click or tap here to enter text.</b></p>
<p><b>3.2</b> Where will the data be stored during the clinical trial? <i>.Please fill in the name of the organisation and in which country the data will be stored during the clinical trial.</i> <b>Click or tap here to enter text.</b></p>
<p><b>3.3</b> If the data is sent to countries outside the EU/EEA, on what basis is it transmitted?</p> <p><input type="checkbox"/> Not applicable, data is not transmitted to countries outside EU/EEA</p> <p><input type="checkbox"/> Subject to appropriate safeguards (article 46 through 48 GDPR) And if so, what safeguards (e.g. binding corporate rules, standard contract clauses): <b>Click or tap here to enter text.</b></p> <p><input type="checkbox"/> On the basis of an adequacy decision (article 45 GDPR)</p>
<p><b>3.4</b> How long will the data be stored? <i>Indicate the term allowed by law and communicated to the participant in the SIS. A longer term must be justified..</i> <b>Click or tap here to enter text.</b></p>
<p><b>3.5</b> What type of connection is available between data and individual subjects?</p> <p><input type="checkbox"/> Direct connection (<i>data marked with e.g. initials, date of birth</i>)</p> <p><input type="checkbox"/> Pseudonymised connection (<i>data marked with code, e.g. 001-2022, 002-2022</i>)</p> <p><input type="checkbox"/></p>
<p><b>3.6</b> Who will have access to the directly identifiable (non-pseudonymised) data? <b>Click or tap here to enter text.</b></p>
<p><b>3.7</b> Who will have access to the data code list? <b>Click or tap here to enter text.</b></p>
<p><b>3.8</b> Where will the data code list be stored? <b>Click or tap here to enter text.</b></p>
<p><b>Section 4 – Will the collected (personal) data be stored for future use?</b> <i>(I.e. for use <u>NOT</u> described in the protocol)</i></p> <p><input type="checkbox"/> Yes, please fill in the requested information in this section</p> <p><input type="checkbox"/> No, please continue with section 5</p>
<p><b>4.1</b> What is the purpose of the future use? <b>Click or tap here to enter text.</b></p>
<p><b>4.2</b> Will the data for future use be stored for a longer period than described in 3.4 of this form?</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes, how much longer?: <b>Click or tap here to enter text.</b></p>

<p><b>4.3</b> Where will the data for future use be stored? <i>Please fill in the name of the organisation and in which country the data will be stored for future use.</i> <b>Click or tap here to enter text.</b></p>
<p><b>4.4</b> If the data for future use is sent to countries outside the EU/EEA, on what basis is it transmitted?</p> <ul style="list-style-type: none"><li><input type="checkbox"/> Not applicable, data is not transmitted to countries outside EU/EEA</li><li><input type="checkbox"/> On the basis of an adequacy decision (article 45 GDPR)</li><li><input type="checkbox"/> Subject to appropriate safeguards (article 46 through 48 GDPR). And if so, what safeguards (e.g. binding corporate rules, standard contract clauses): <b>Click or tap here to enter text.</b></li></ul>
<p><b>4.5</b> What type of connection is available between data and individual subjects?</p> <ul style="list-style-type: none"><li><input type="checkbox"/> Direct connection (<i>samples marked with e.g. initials, date of birth</i>)</li><li><input type="checkbox"/> Pseudonymised connection (<i>samples marked with code</i>)</li><li><input type="checkbox"/> No connection, data are anonymized (<i>i.e. data can neither directly nor indirectly (with reasonably means according to recital 26, GDPR) be linked to the sample donor</i>)</li></ul>
<p><b>4.6</b> Who will have access to the data for future use? <b>Click or tap here to enter text.</b></p>
<p><b>4.7</b> Who will have access to the data code list? <b>Click or tap here to enter text.</b></p>
<p><b>4.8</b> Will the subject be recontacted to give new consent to the use of the data in future use? <b>Click or tap here to enter text.</b></p>
<p><b>Section 5 - Additional information on the collection, storage and future use of the (personal) data</b></p> <p><b>Note: This section has only to be filled in if applicable</b></p>
<p><b>5.1</b> Provide any information (not described above) that is of relevance to the applicable rules on collection, storage, transport and future use of the data <b>Click or tap here to enter text.</b></p>