

Appendix 15.2.1: LETI MIAU-KAT 2022 federal state specific ICF versions

federal state	ICF version	Description of differences
ICF versions accepted by the leading EC Cologne	LETI Cat_ICF_Erwachsene_V1-1_20220228" and LETI Cat_ICF_Jugendliche_V1-1_20220228 and LETI Cat_ICF_Sorgeberechtigte_V1-1_20220228	n.a. (general templates)
Baden-Württemberg	LETI Cat_ICF_Erwachsene_V1-2-BW_20220421 and LETI Cat_ICF_Sorgeberechtigte_V1-2-BW_20220421	<ul style="list-style-type: none"> - page 1: study is financed and accounted for by ClinCompetence - page 2: duration of the documentation of adverse events of the patient is 4-2-10 minutes - page 2: you will be informed about newly occurring adverse events - page 2: The study was presented to the responsible ethic committee. There were no objections given. - page 2: (common up dosing or quick up dosing) - page 6: in case of adverse events: to LETI Pharma GmbH, to the responsible ethical committee and to responsible authorities
Baden-Württemberg	LETI Cat_ICF_Jugendliche_V1-2-BW_20220421	Wording adaptations in order to reflect a style more suitable for adolescents; no content-related changes.
Nordrhein	LETI Cat_ICF_Erwachsene_V1-2-Nordrhein_20220523 and LETI Cat_ICF_Sorgeberechtigte_V1-2-Nordrhein_20220523	<ul style="list-style-type: none"> -title page 1: patient information and declaration of consent according to data protection regulations - page 3: data will be deleted upon expiry of retention period - page 4: insertion of a cross reference to the contact details of responsible person for data processing - page 5: insertion of contact details of the responsible data protection officer - title page 7: declaration of consent according to data protection regulations

Nordrhein	LETI Cat_ICF_Jugendliche_V1-2-Nordrhein_20220523	- title page 1: patient information and declaration of consent according to data protection regulations
Sachsen	LETI Cat_ICF_Erwachsene_V1-2-Sachsen_20220512 and LETI Cat_ICF_Sorgeberechtigte_V1-3-Sachsen_20220512	- page 1: The investigator receives a fee for the documentation and observation of enrolled patients - page 2: The study was presented to and agreed upon by the ethical committee for consultation of participating physicians . There were no objections. - page 5: Do I have a right to appeal? You have the right to appeal at any time against the processing of your personal data , and you can demand the deletion of your data in case of withdrawal. - page 6: insertion of contact details of the responsible data protection officer
Sachsen	LETI Cat_ICF_Kinder und Jugendliche_V1-2-Sachsen_20220512	- page 1: Dear child, dear adolescent - page 1: In total,and 100 children /adolescentswill participate - page 3: consent of participation children from 12 years and adolescents - page 3: ...as described in the handed over information and consent of participation.... - page 3, legend of signature field: name of child or adolescent (in block letters) - page 3: ..., and I have received the approval of the child or the adolescent. I am convinced, that the child or the adolescent has understood everything
Sachsen-Anhalt	LETI Cat_ICF_Erwachsene_V1-2-Sachsen-Anhalt_20220530	- page 5: insertion of contact details of the responsible data protection officer
Sachsen-Anhalt	LETI Cat_ICF_Sorgeberechtigte_V1-2-Sachsen-Anhalt	- page 4: insertion of contact details of the responsible data protection officer