Compliance with Member State applicable rules for the collection, storage and future use of human biological samples (Article 7.1h)

Full title of the clinical trial	**EU trial number**
A Phase 3, randomized, double-blind, placebo-controlled, parallel-group, 3-arm, multinational, multicenter study to evaluate the efficacy and safety of amlitelimab by subcutaneous injection in participants aged 12 years and older with moderate-to-severe atopic dermatitis on background topical corticosteroids.	2023-506558-20
Responsible entity for the samples (legally): Sanofi R&D	

How to use this document

This form may be used by Sponsors of clinical trials in the Part II application dossier to provide information about “compliance with the applicable rules for the collection, storage and future use of biological samples from clinical trial subjects" [Regulation (EU) No 536/2014, Article 7.1 (h)]. This is not a mandatory form and different national arrangements may be in place, which should be confirmed prior to submission.

If the information is already provided elsewhere in the Application Dossier, a reference should be provided.

This Part II template has been developed by the EU Clinical Trials Expert Group to comply with Regulation (EU) No 536/2014 Clinical Trials on Medicinal Products for Human Use.

I - Description of the biological samples involved in the clinical trial

Section 1 - Does this clinical trial involve new sampling of the subjects (newly collected samples)?

☒ Yes, please fill in the requested information in section 1

☐ No, not applicable. Please continue with section 2

Note: The Sponsor needs to fill in *at least one* of the sections 1 or 2

1.1 What type(s) of samples will be collected from the subject?

State the original material that is collected from the patient e.g., blood, tissue (state type of tissue), urine, saliva etc. Do not include information on the preparation of the sample.

Blood, tissue (skin biopsy), urine, upper respiratory tract (nasopharyngeal or oropharyngeal) exudate

1.2 Total number of samples, fragments (e.g., aliquots, tissue blocks, sections) and the total volume (if applicable) per individual subject:

Adults:
Number of samples: 102 samples (mandatory and optional, from screening to EOS)
The approximate total blood volume drawn throughout the study will be no more than 277.8 mL including menopausal status confirmation, optional biomarkers, and genetics samples.

Adolescents: 80 samples (mandatory and optional, from screening to EOS)
The approximate total blood volume drawn throughout the study will be no more than 135.3 mL including optional samples for patients over 30 Kg, and 129.1 mL for patients with less than 30 Kg.

ADULTS	N. Mandatory samples	N. Add. Samples for WOCBP of for menopausal status confirmation	N. Opt. samples	Opt. Skin Biopsies	Total N. Samples
Blood samples	66		12		78
Urine	9	8			17
Skin Biopsy				5	5
Exudate	2				2
Totals	77	8	12	5	102

ADOLESCENTS	N. Mandatory samples	N. Add. Samples for WOCBP	N. Opt. samples	Total N. Samples
Blood samples	58		3	61
Urine	9	8		17
Exudate	2			2
Totals	69	8	3	80

1.3 The maximum number of samples and maximum volume (if applicable) on one single occasion:

Adults: Max of 49.4 mL blood volume (at Visit 9/Week 24)

Adolescents: Max of 22 mL blood volume (at Visit 9/Week 24) – patients over 30 Kg
Max of 19.3 mL blood volume (at Visit 10/Week 40) – patients with less than 30 Kg

1.4 Will the samples be collected as part of routine health care?
No

Section 2 - Does this clinical trial involve the collection of existing archive samples (e.g., archived diagnostic material or other biobank material)?

☐ Yes, please fill in the requested information in section 2

☒ No, not applicable. Please continue with section 3

Note: The Sponsor needs to fill in at least one of the sections 1 or 2

2.1 What type(s) of archived material/samples will be used?

2.2 Provide the total number of samples, fragments (e.g., aliquots, tissue blocks, sections) and total volume (if applicable) that the Sponsor needs access to from each individual subject.

Example: 20 sections per biopsy from each individual subject is needed

2.3 Will new consent be obtained for the use of the archive samples in the clinical trial (if in line with national legislation)? If not, explain. (if applicable, add the text of the original consent)

II – Use, storage, and transfer of biological samples

Section 3 – Use of samples for a purpose within the objective of this clinical trial (i.e., for use described in the protocol)

Note: This section must be filled in for both newly collected and existing archive samples

3.1 Where will the samples be analyzed?

i.e., within the clinical laboratory, within/outside the Sponsor's organization, within/outside the Member State where collected or within/outside EU/EEA.

Samples will be analyzed within the Sponsor's organization, study sites and/or at Service Providers contracted for the study conduct, within and outside of the EU/EEA.

3.2 If the samples will be sent to another organization for analyses (as part of the trial), how will they be managed after the analyses have been carried out?

i.e., destroyed, returned to responsible entity for the samples (legally), stored at the site where analysed, anonymized, etc.

Note: An agreement (Material Transfer Agreement or equivalent) that regulates how the sample are to be handled shall be established with the recipient

After analysis, the leftovers of study participants' biological samples will remain at the Sponsor's or projects contracted Service Provider locations and will be destroyed at the end of the study unless study participants authorize the Sponsor to retain them for use in future research.

3.3 Where will the samples be stored?
i.e., within/outside the Sponsor's organization, within/outside the Member State where collected or within/outside EU/EEA

Samples will be stored within the Sponsor's organization and/or at the Service Providers contracted for the study conduct, within and outside of the EU/EEA.

3.4 How long will the samples be stored?

Samples will be stored for the duration of the study, unless study participants authorize the Sponsor to retain them for use in future research projects (as described in Section 4).

3.5 What type of connection is available between samples and individual subjects?

☒ **Direct connection** (samples marked with e.g., initials, date of birth) for the study site (investigator, study staff) and Service Providers performing services for which the direct contact with study participants is needed and which is listed in the delegation of duty,

☒ **Pseudonymized connection (samples marked with code) for the Sponsor and its Service Providers and Partners involved in the conduct of the study.**

☐ No connection, samples are anonymized *(i.e., samples can neither directly nor indirectly, with reasonably means according to recital 26 of the General Data Protection Regulation (EU) 2016/679, be linked to the sample donor)*

3.6 Who will have access to the samples?

Only authorized persons from the Sponsor company and those working for or with the Sponsor, and/or the central laboratory contracted for conducting the analysis of the samples for the purpose within the objective of this clinical trial will have access to these samples.

3.7 Who will have access to the sample code list (if applicable)?

The sample code list (correspondence between sample ID and study participant ID number) will be available to the Sponsor and Service Providers. The study participant identification log (correspondence between study participant ID number and name) will only be available at the Investigator's clinical site for 25 years after the end of the study.

Section 4 - Will newly collected samples or existing archive samples be stored for future use?
For other use than described in the protocol. Note that some purposes (secondary use of samples) may require additional approval, in Most Member States by an Ethics Committee

☒ Yes, please fill in the requested information in this section
☐ No, samples will be destroyed, please continue with section 5

4.1 What is the purpose of the future use?

Use of biological samples for future scientific research will be conducted under a research plan for the purpose of diagnosing, evaluating, preventing or treating diseases or if imposed by the applicable local law, future use will be restricted to the scientific domain/therapeutic area/project as indicated in the ICF.

4.2 How long will the samples be stored?

At least 25 years after the end of the study in a secure way by the Sponsor or a Service Provider acting on its behalf, provided that the study participant has provided his/her consent for the future use of his/her samples and/or has not withdrawn his/her consent on such future use.

4.3 Where will the samples be stored?
Samples will be stored within the Sponsor's organization and/or at contracted biorepository for the future use of samples, within and outside the EU/EEA.

4.4 What type of connection is available between samples and individual subject?

☐ Direct connection *(samples marked with e.g., initials, date of birth)*
☒ **Pseudonymized connection (samples marked with code), or**
☒ **No connection, samples are anonymized** *(i.e., samples can neither directly nor indirectly, with reasonably means according to recital 26 of the General Data Protection Regulation (EU) 2016/679, be linked to the sample donor)*

4.5 Who will have access to the samples?

Only authorized persons from the Sponsor and/or its affiliates acting alone or in collaboration with research Partners, such as Universities, research Institutions or industrial Partners will have access to the samples.

4.6 Who will have access to the sample code list (if applicable)?

The sample code list (correspondence between sample ID and study participant ID number) will be available to the Sponsor.

4.7 Will the donor be recontacted to give new consent to the use of the samples in future research? If not, explain

Sanofi will comply with the applicable legislation for each donor and will collect new consent if imposed by such local laws and/or Ethics Committees.

4.8 If secondary future use of the samples will be in question, will an Ethics Committee or biobank committee be reviewing whether the purpose of the new study is within the scope of the original provided consent (if applicable according to national legislation)? Yes, if required by the applicable local law.
4.9 Who will be able to make use of the samples? Future Research Projects will be conducted under the Sponsor's and/or its affiliates' control, acting alone or in collaboration with research Partners such as Universities, research Institutions or industrial Partners with whom coded data may be shared.
4.10 How will unsolicited findings be handled? Consent will be collected from the study participants on whether or not he or she agrees to be informed of any unsolicited findings. If such consent is provided and unsolicited findings are found, Sanofi will make its reasonable efforts to inform the study doctor and/or physician, whose contact is in the ICF, so that the study doctor and/or physician can address the unsolicited findings and contact the concerned study participant.
III – Additional information
Section 5 - Additional information that is required by the current Member States national arrangements and regulations. The Sponsor should confirm this prior to submission **Note: This section will only be filled in if applicable**
5.1 Provide any information (not described above) that is of relevance to the Member State applicable rules on collection, storage, transport and future use of the samples, e.g., on specific national arrangements and regulations regarding the use of human biological samples.