
Participant Follow-up and Withdrawal of Consent Checklists

Approved

INSTRUCTIONS TO SITES

If the participant temporarily or permanently discontinues from study drug, it is important that the scheduled study visits, data collection and procedures continue according to the study protocol until the study ends.

These checklists should only be discussed with a participant if the participant requests one of the following:

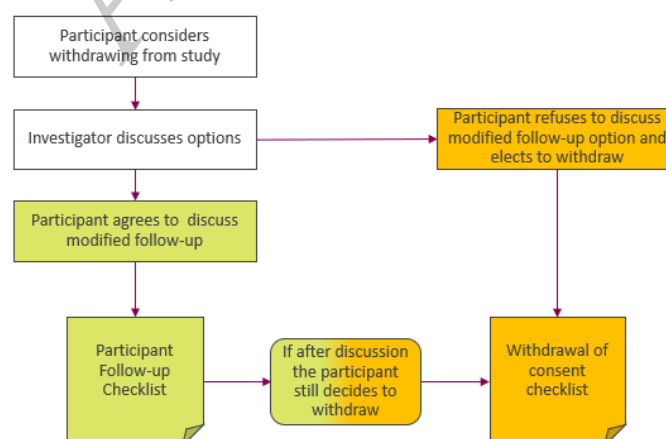
- **Modification of their follow-up**
- **Complete withdrawal from the study,**
- **Withdrawal from optional tests or procedures**
- **Withdrawal from future sample or data use**
- **Withdrawal their consent after they have permanently discontinued study drug**

These checklists facilitate the discussion between the investigator and participants who wish to modify their follow-up or withdraw their consent from all or some study activities.

Discontinuation from study medication or specific study sampling or procedures is not the same as withdrawing completely from the clinical study.

When initiating the conversation with the participant or their Legally Accepted Representative, it is important to establish what the exact wishes are and complete the correct sections of the form to ensure that their samples and data are used and maintained according to their wishes.

Complete Participant Follow-up Checklist or Withdrawal of Consent Checklist depending on the participant decision and leave the other checklist blank.



The discussion and the outcome of the discussion **MUST** be documented in the site medical records and the checklist(s) should be used to facilitate the documentation. If the checklist is used as a source document, it should be stored in the participant's medical records at site.

Relevant information must be recorded in the eCRF.

If, at a later timepoint, the participant wishes to change their mind and select another option for follow-up or withdrawal, either another checklist must be completed and dated, or the original form can be updated with changes signed and dated as per good documentation practice. Relevant information must be recorded in the eCRF

If a participant changes their mind about how they participate in the study including any optional procedures, it should be made clear that AstraZeneca cannot remove any personal information already collected for this research study prior to their revised decision.

Approved

If using Participant Follow-up Checklist follow the instruction below:

If the participant temporarily or permanently discontinues from study medication, it is important that the scheduled study visits, data collection and procedures continue according to the study protocol. If the participant does not agree, modified follow-up should be arranged and the Participant Follow-up Checklist can be used to document the arrangement.

The purpose of this checklist is to facilitate the discussion with the participants who want to modify their follow-up after having discontinued all study treatment/s, and to clarify to what extent the participant is opting to remain part of the clinical study.

Use this checklist if a participant who has discontinued all study treatment/s decides to either:

- Modify the follow-up visit schedule specified in the clinical study protocol (CSP)
- or
- Change the previously agreed method of follow-up.

The discussion and its outcome must be documented in the medical records and the outcome needs to be recorded in the electronic Case Report Form (eCRF: “Participant Follow Up”, available as an Add Event).

The follow-up options in the checklist are presented in the order they are preferred from a study perspective.

Participants who agree to any kind of modified follow up are still participating in the study. The modified visits and procedures that are done will be recorded in the eCRF. Modified follow-up does not require a separate consent, the visits and procedures are not different than what the participant agreed to. However, some procedures might be limited or excluded from the planned visit schedule.

Discontinuation from study medication is not the same as complete withdrawal of consent for the study. Only if the participant has **explicitly** refused all the options in the “Participant follow-up checklist”, then the participant is considered to have withdrawn consent. This decision to withdraw consent must be recorded in the medical records and in the eCRF. The “Withdrawal of consent checklist” can be used as reference. If the participant withdraws consent, the vital status will be collected from available public sources to support analyses as specified in the ICF.

Participant Follow-up Checklist

Study title: ARTEMIDE-Biliary02

Protocol ID: D702NC00001

Country:

Participant E-code:

E							
---	--	--	--	--	--	--	--

Follow-up options

The participant permanently stopped study medication and:

(please ensure that only ONE option from the list below is selected)

<i>Agrees to continue according to the current CSP visit plan / schedule.</i>	☐
<i>Agrees to continue in the study with a modified visit plan. Ensure that the modified visit plan is documented in the patient records.</i>	☐
<i>Agrees to continue in the study but will not come to the site for visits but can be contacted by phone according to CSP visit plan.</i>	☐
<i>Agrees to come to the site at the end of the study <<or at time of data analysis >> but does not want to be contacted or come to the site until then.</i>	☐
<i>Agrees to be contacted by phone at the end of the study <<or at time of data analysis >> but does not want to be contacted or come to the site until then.</i>	☐
<i>Does not want to be contacted but agrees that personal and medical information about him or her can be collected from medical records.</i>	☐
<i>Agrees to be contacted by phone when needed but will not come to the site for visits.</i>	☐
<i>Agrees for contact to be made with a treating physician or relative but will not come to the site for visits.</i>	☐

By signing this document, I confirm that all options were discussed with the participant.

Signature of investigator, or delegate, conducting the discussion

Date and time of Signature

Printed name of investigator, or delegate, conducting the discussion

The discussion and the outcome of the discussion must be documented in the medical records. The outcome needs to be recorded in the electronic Case Report Form (eCRF).

If using Withdrawal of consent Checklist follow the instruction:

To be used if a participant decides to withdraw their informed consent for the study and/or withdraw from optional test/procedures, to precisely document participant's decision with respect to the use of their samples and data.

General principles and background information for confirmed ICF withdrawal:

- Sample/data re-use for this participant is dependent upon the responses to the withdrawal checklists.
- If the samples are no longer linked to the participant, it might not be possible to have them destroyed.
- Data from already analysed samples cannot be destroyed/removed in order to guarantee the validity of the study and comply with regulatory requirements.
- In cases where a participant has withdrawn consent for the study and where there is no documentation/documented evidence detailing whether or not consent has been withdrawn related to use of samples/data, the business decision is that samples will be used as originally consented for, unless there is a specific information in the Informed Consent or country legislation that would prevent this.
- At the time of withdrawal of consent, sampling must stop in line with the withdrawal options selected.
- If the participant withdraws from the study and any use of biosamples, no samples should be collected at a withdrawal of consent visit (if scheduled).
- Countries may have different legislation when it comes to sample analysis at time of withdrawal.
- If permissible by local law, analysis will continue on all mandatory samples. Mandatory samples and analysis are defined as all samples/analysis that are part of the main Clinical Study Protocol to determine the primary and any secondary objectives.

Examples :

If the participant wishes to withdraw from optional tests / procedures:

- Check the last Informed Consent signed by the participant
- If the participant consented for optional tests/ procedures, then complete the Withdrawal of Consent Checklist – fill in Study title, Protocol ID, Country and Participant E-code
- check “Yes” to question in section 1 “*Withdraw their consent for optional tests/ procedures that have been consented for*”

- For other questions in section 1, check “NO” if the participant continues their optional consent, or check “NA” if the participant did not consent in the last consent form

If the participant wishes to withdraw their consent for samples being used for future research:

- Check the last Informed Consent signed by the participant
- If the participant consented for future research, then complete the Withdrawal of Consent Checklist – fill in Study title, Protocol ID, Country and Participant E-code
- check “Yes” to question in section 1 “*Withdraw their consent for usage of their coded data (including images), biosamples and analysis of genetic information for future research*”
- For other questions in section 1, check “NO” if the participant continues their optional consent, or check “NA” if the participant did not consent in the last consent form

If the participant wishes to withdraw from the study, but agrees to continue to the use of their samples and data:

- complete the Withdrawal of Consent Checklist – fill in Study title, Protocol ID, Country and Participant E-code
- Check “Yes” in section 2 “Decision regarding study withdrawal”, question “*Withdrawal from the study, but the patient agrees for data and biosamples to be used as consented for the current study*”
- Check the last Informed Consent signed by the participant
- For questions regarding future research and Optional Genomics Initiative, check “Yes” if the participant withdraws their optional consent, “NO” if the participant continues their optional consent, “NA” if the participant did not consent in the last consent form

If the participant wishes to withdraw from the study, but does not provide any detailed information:

- complete the Withdrawal of Consent Checklist – fill in Study title, Protocol ID, Country and Participant E-code
- Check “Yes” in section 2 “Decision regarding study withdrawal”, question “*Patient withdrew informed consent without providing any detailed information*”

- All samples provided already by the participant will be used according to the most recent consent form, unless there is a specific information in the Informed Consent or country legislation that would prevent this

Approved

Withdrawal of Consent

Study title: ARTEMIDE-Biliary02

Protocol ID: D702NC00001

Country:

Participant E-code:

E							
---	--	--	--	--	--	--	--

1. The participant decision <u>regarding their consent to study optional consents</u> is: (Either Yes or No or NA should be selected for every question below)	Yes	No	NA
Withdraw their consent for optional blood test that have been consented for.	☐	☐	☐
Withdraw their consent for optional biopsy at first day of cycle 3 of study treatment that have been consented for.	☐	☐	☐
Withdraw their consent for optional biopsy if their cancer become worse (disease progression) that have been consented for.	☐	☐	☐
Withdraw their consent for use of optional services and transfer of contact details to service providers as consented for.	☐	☐	☐
Withdraw their consent for usage of their coded data (including images), biosamples and analysis of genetic information for future research (as described in part 2: Future Research Information”).	☐	☐	☐
Withdraw their consent for optional multi-omics research and analysis of their multi-omics information, including their genetic information (only if additional consent form for Optional Genomics Initiative research was signed).	☐	☐	☐

*Please select
NA if
participant
has not
consented for
this option on
the main ICF.*

2. The participant decision <u>regarding study withdrawal</u> is: Select <u>only one</u> of the choices below that best reflects the participant's decision:	
	Yes
Withdrawal from the study , but the patient agrees for data and biosamples to be used as consented for the current study, including the samples and data collected during the withdrawal visit. Note: If yes is selected, please ensure that the patient's decision regarding the use of samples and data for future research and multi-omics has been captured above, if applicable.	☐
Withdrawal from the study and any use of already collected biosamples (including data <i>and biosamples</i> for future research <i>and multi-omics</i> , if applicable). Note: if yes is selected, none of the optional consents can be marked as no.	☐
Patient withdrew informed consent without providing any detailed information. Note: This option means that in cases where a patient has withdrawn consent and where there is no documentation/documented evidence detailing whether or not consent has been withdrawn related to use of samples/data, the business decision is that samples will be used according to most recent signed consent form, unless there is a specific information in the Informed Consent or country legislation that would prevent this.	☐

By signing this document, I confirm that all options were discussed with the participant.

Signature of investigator, or delegate, conducting the discussion

Date and time of Signature

Printed name of investigator, or delegate, conducting the discussion

The discussion and the outcome of the discussion must be documented in the medical records. The outcome needs to be recorded in the electronic Case Report Form (eCRF).