Here's what you need to do as study staff if...



...you are aware of reasons that speak against a further active participation in the study.



...a patient no longer wishes to be contacted or to participate.

End of study¹





Patient no longer wants study medication/intervention; study is no longer feasible (relocation, death...).

This is what you have to do:

- In the eCRF in secuTrial: fill out end of study form
- The Trusted Third Party does not have to be informed

Exclusion from study¹



Patient no longer meets inclusion criteria according to study protocol or has an exclusion criterion.

- Form withdrawal/exclusion from study, select process exclusion from study and send it via Upload-Ticket to the Trusted Third Party
- In the eCRF in secuTrial: fill out end of study form and document reason for exclusion

Contact blocking





Patient no longer wishes to be contacted.

- Form withdrawal/exclusion from study, select process contact
- In the eCRF in secuTrial:

Complete withdrawal



Patient withdraws consent completely.

- blocking and send it via Upload-Ticket to the Trusted Third party
- Fill out end of study form

- Form withdrawal/exclusion from study, select process complete withdrawal and send it via Upload-Ticket to the Trusted Third Party
- In the eCRF in secuTrial: Fill out end of study form

These are the consequences

Data and biosamples: remain

Further data collection: possible

Further contact: possible



Data and biosamples: remain

Further data collection: not possible

Further contact: possible





Further contact: not possible

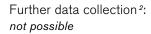
remain



Further data collection 2: not possible

Data and biosamples:

Data and biosamples: Deletion/destruction possible³ (only upon request)



Further contact: not possible







¹ If there are any questions or uncertainties please contact the principal investigator.

² Timely documentation of already created visits possible.

³ Is dependent on consent or other legal bases (e.g., CTR, MDR).