

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



Study staff

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



Patient

...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...).

Exclusion from study¹



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

Contact blocking



Patient no longer wishes to be contacted.

Complete withdrawal



Patient withdraws consent completely.

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

- 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

- Form **withdrawal/exclusion from study**, select process **contact blocking** and send it via Upload-Ticket to the Trusted Third party
- In the eCRF in secuTrial: 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*

Data and biosamples: *remain*

Further data collection²: *not possible*

Further contact: *not possible*

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

Further data collection²: *not possible*

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).