



**Background:**

According to ICH GCP, Chapter 8.3.20, there must be information on the test subjects who have been checked for possible inclusion in the study. This check is only a review of the person's background and possibly diagnosis via checking the diagnosis register and possibly journals. Personal data must never be documented on this list

**No study-specific examinations can be carried out before the person has been asked about participation in the study.**

The purpose of this list is to show how many people there are with the appropriate background or diagnosis. The information is used to provide general knowledge about the study's inclusion and exclusion criteria and also for future studies.

**Instruction:**

**Initials:** First letter of first or last name. Since many people do not meet the criteria for the study, only these individual data are documented.

**Date considered:** Date as the person was checked for possible participation in the study.

**Included Yes/No.** Answer to the question of whether the person is possibly considered to be able to meet the criteria for the study and thus will be asked for participation.

**If not included give reason.** State the reason why the person was not considered suitable for participation in the study. It may be one of the criteria for participation, as stated in the protocol, or some other reason.

**If suitable, specify enrolment no/ randomisation no and arm as applicable.** Enter the study-specific identification number that the subject/patient receives.

**Page no \_\_\_ of \_\_\_.** Enter the page number, as well as the total number of pages after the last patient is included. This aims to show that all pages that have been used are included after the end of the study.