

Department of Clinical Research

Information sheet

Estimation of recruitment numbers based on routine data

Data from routine clinical practice can be used to estimate the maximum recruitment numbers for a planned clinical study. This type of preliminary assessment is important for realistic study planning. It can greatly help to conduct the planned study within the desired time and budget.

General remarks

- Based on the inclusion and exclusion criteria defined for a planned clinical study, routine data are used to determine how many potential study participants were treated at the University Hospital Basel (USB) during a defined period.
- The quality and effort required to extract this number from the routine data depends on the characteristics and complexity of the defined inclusion and exclusion criteria, the degree of structuring of the data in the clinical systems, and the uniformity of the processes by which data collection has taken place.
- Examples for data of good analytical quality include laboratory data, administrative information (such as patient demographics, billing-related data), inpatient administered medication, and vital signs. On the other hand, information which was recorded as free text (such as diagnoses and anamnestic information) often needs increased effort to yield reliable statements. Depending on the degree of complexity, this type of information is of decreasing quality.

Procedure

- Please send us your request using the DKF Contact Form.
- We clarify whether the desired data are available and find out whether legal requirements such as approval by the ethics committee, consent by participants and/or a data protection statement are still required.
- After clarification of these points, the number of patients who were hospitalised at the USB during the requested period and who would qualify for study participation according to the inclusion and exclusion criteria is determined.

More informationen regarding the request for routine data at the University Hospital Basel (USB) can be found at the <u>DKF webseite</u>.

For individual consulting tailored to your clinical research project and support regarding the usage of routine data from clinical practice please contact us: <u>https://contactform.dkfbasel.ch</u>