

Preparation Instructions

Clinical Trials Programme – Interim Report



Please write your interim report in English and use the **Interim Report Template** (DFG form 17.041).

www.dfg.de/formulare/17_041

The report must not exceed 5 pages (DIN A4, 10 point Arial for the regular text, single line spacing). All headings must remain as listed. Make an entry under every heading/subheading.

Submit your **interim report** to the following e-mail address: Clinicaltrials@dfg.de

1 General Information

- Please make an entry under each heading below.

1.1 Applicant/Coordinating investigator

1.2 Title of trial

1.3 Type of trial

- Please mark the trial type for which you are requesting funding under this programme.

Interventional trial:

Observational trial:

1.4 DFG project number of the proposal

1.5 Report date

1.6 Reporting period

2 Status Report

- Please make an entry under each heading below and explain/justify in case milestones have not been achieved.

2.1 Trial registration

- Please state the date and trial number of the registration as well as the name of the database.

2.2 Trial protocol publication

- Please state the date and title of the publication as well as the name of the database.

2.3 Dates of competent authority approval

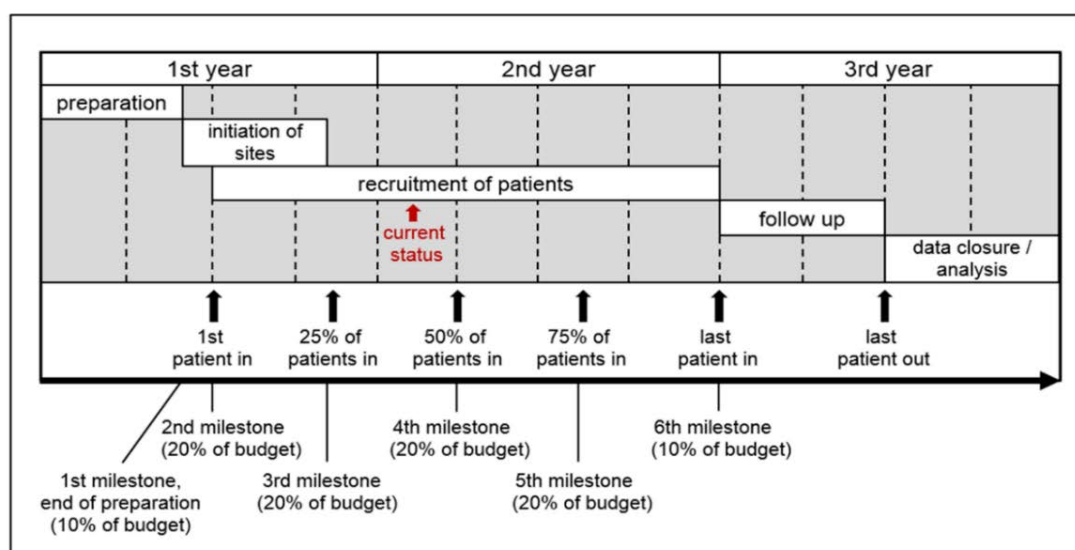
- Please state the dates of competent authority approval(s) (e.g. BfArM or BfS).

2.4 Approval by the ethics committee

- Please state the date of the original approval letter from the ethics committee as well as the approval date of amendments.

2.5 Trial time flow

- Please provide an updated diagram (see example below) reflecting the following: preparation, pre-trial visits, initiation of centres/sites, recruitment, follow-up, and data cleaning/analysis. Indicate the current status of your trial. As DFG funding depends on the trial's progression and is linked to the milestones, please indicate the amount of funding required to reach each milestone.



2.6 Number of patients to be recruited

- Please state the number of patients you plan to recruit during the entire trial.

2.7 First patient in (date)

- Please state the date when the first patient was recruited.

2.8 Total number of patients in/Percentage of patients in

- Please state the number and percentage of patients recruited so far. Also indicate the recruitment goal, i.e. the total number of patients to be recruited to this trial.

2.9 Number of patients in follow-up

- Please state the number and percentage of patients in follow-up.

2.10 Last patient in (date)

- Please state when the last patient was recruited to this trial. If recruitment is still ongoing, please calculate the date when the last patient will be recruited according to the current recruitment rate.

2.11 Last patient out (date)

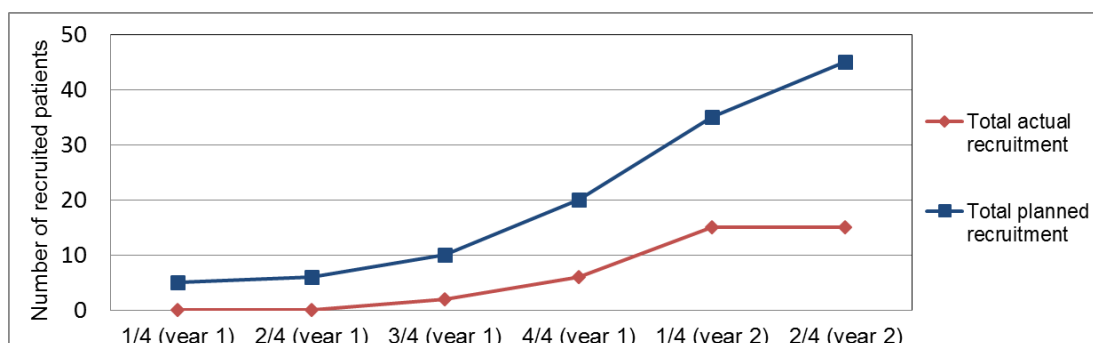
- Please state when the last patient reached or will reach the planned milestone representing the completion of the trial.

2.12 Recruitment of patients

- Please make an entry under each heading (2.12.1 – 2.12.5) and explain any problems which may have occurred.

2.12.1 Recruitment graph

- Please create a chart that indicates the progress of patient recruitment on a cumulative monthly (or quarterly, or biannual) basis for all centres/sites involved (not for each single centre/site). By doing so, also compare your current/actual recruitment rate to your originally planned recruitment rate as anticipated in the full proposal. Begin your timeline with the month/quarter/half year in which the first patient was planned to be recruited and end your timeline with the current status. The chart below represents an example.



2.12.2 Recruitment table

- Please create a table that indicates the progress of screened, recruited and followed-up patients on a cumulative monthly basis for all centres/sites involved (not for each single centre/site). Also, indicate the envisaged end of recruitment by extrapolating your current recruitment rate. The table below represents an example. Mark the current status.

Table 1: Cumulative number of screened, recruited and followed-up patients per time period (e.g. month, quarter, biannual)

	1/4 (year 1)	2/4 (year 1)	3/4 (year 1)	4/4 (year 1)	1/4 (year 2)	2/4 (year 2) - current quarter	4/4 (year 3)
Total screened	0	0	3	16	28	31	
Total recruited	0	0	2	6	15	15	// recruitment goal achieved
Total followed up	0	0	0	0	5	10	

2.12.3 Recruitment problems

- Please analyse and explain recruitment problems, if applicable.

2.12.4 Improvement of patient recruitment

- State and explain approaches that have been and will be taken to improve the recruitment rate.

2.12.5 Conclusion

- Please state and explain your conclusions regarding the new recruitment plan with respect to your trial time flow.

3 Changes in Trial Design Aspects and Statistical Analysis

- If applicable, please briefly describe any changes regarding the design of the trial and/or the statistical analysis using the headings below. Focus on changes that have been made with respect to your full proposal. Also, explain the impact of changes on the relevance/originality of the question/hypothesis and quality of your study.

3.1 Control(s)/Comparator(s)

3.2 Dose, mode and scheme of intervention

3.3 Additional treatments

3.4 Inclusion and exclusion criteria

3.5 Determination of primary and secondary measures

3.6 Methods against bias

3.7 Proposed sample size/Power calculations

3.8 Originality and quality of the study

3.9 Statistical analysis

Do not exceed a maximum of 5 pages for headings 1 to 3.

4 Quality Assurance and Safety

4.1 Declaration by the DSMB

- Please provide a recent declaration by the Data and Safety Monitoring Board (DSMB) stating that no concerns exist regarding the continuation of the trial. Please attach this statement as an addendum to this report.