DSZ-HNO, Scientific Review of Study Proposals

CLINICAL TRIAL OUTLINE

1 Evidence and the Need for a Trial

Which medical problem is to be addressed? What is the novel aspect of the proposed trial?
Which principal research questions are to be addressed? Bring them into order indicating major and minor motivations/starting hypotheses of the investigation planned.

Set your trial into perspective. What is the rationale for the intervention? Which trials have been conducted either by you or by others? What is the relevance of their results? Give references to any relevant systematic review(s) and/or (own) pilot studies, feasibility studies, relevant previous/ongoing trials, case reports/series. State what your study adds to the totality of evidence when your study is added to previous work (cf. Clark and Horton: Putting research into context – revisited. Lancet 2010; 376: 10-11). Include a description of how you searched for the evidence (databases, search terms, limits). If you believe that no relevant previous trials have been done, give details of your search strategy for existing information.

How significant is the trial in terms of its potential impact of relieving the burden of disease and/or improving human health? What impact will the results have on clinical practice? How will the individual patient benefit from the trial? Describe any potential commercial interest of a company in the results of the trial or explain why no such interest exists.

Discuss briefly the acceptability of the risk incurred by the individual participant versus the potential benefit for the participant/population concerned.

2 Study Description

2.1 APPLICANT / COORDINATING INVESTIGATOR

Name, address, telephone, fax, e-mail
In case of multiple applicants the principal investigator/coordinating investigator of the trial who will assume responsibility for conducting the clinical trial, should be listed first.

2.2 TITLE OF STUDY

The title of the trial should be as precise as possible. Acronym is optional.

2.3 CONDITION

The medical condition being studied (e.g. Head-and-Neck-Cancer, Hearing loss, Tonsillitis…)

2.4 OBJECTIVE(S)

Which principal research questions are to be addressed? Specify clearly the primary objective of the trial. This has to be reflected in the primary endpoint (cf. 2.7) that determines sample size calculation.

2.5 INTERVENTION(S)

Description of the experimental and the control treatments or interventions as well as dose and mode of application. For diagnostic tests or procedures the index test and the reference procedure (gold standard) should be described.

Experimental intervention / index test:

Control intervention / reference test:

Duration of intervention per patient:

Follow-up per patient:

2.6 KEY INCLUSION AND EXCLUSION CRITERIA

Key inclusion criteria:

Key exclusion criteria:

2.7 OUTCOME(S)

Primary endpoint:

Secondary endpoint(s):

2.8 STUDY TYPE

e.g. randomized/non-randomized, type of masking (single, double, observer blind), type of controls (active/placebo), parallel group/crossover, prognostic, diagnostic

2.9 SAMPLE SIZE

Planned number of trial patients total: **(n =)**

2.10 TRIAL DURATION

Duration of the whole trial (months):
Recruitment period (months):

2.11 PARTICIPATING CENTRES

Please indicate whether this is a monocenter trial, a multicentre national or multicenter international trial. Give number and location of sites.
Please indicate if this is a cooperative study group trial. Give name of study group.

3 Organisational and Administrative Parameters

3.1 MAJOR PARTICIPANTS

Please indicate persons responsible for design, management and analysis of the trial.

#	Name	Affiliation	Responsibility / Role
1			Coordinating investigator
2			Trial statistician*

** Please indicate, if statistical planning of the trial has been done already.*

3.2 TRIALS EXPERTISE

Please indicate trials expertise of all above-mentioned participants. Has training course (Prüferkurs) been completed, as Coordinating Investigator at least 2 years experience in clinical trials mandatory.

3.3 SOURCES OF FUNDING

Has a financial plan been outlined? Please indicate the sources of public (e.g. DFG, BMB, Krebshilfe) and industry funding. Is funding planned, applied for, or granted?