**Template for Preparation of a Final Report**

**(clinical research)**

*Graphics and photographs may be inserted in section 11!*

We would like to remind you to hand in your final report (signed original and Word/ PDF file) according to the date scheduled in your grant agreement of your research project.

**Please note: In case of a clinical trial two additional documents (“Consort checklist” and “Consort flow diagram”) must be submitted with the final report.**

Project Title:

Project Code:

Project Period:

Project Leader

Date of Report:

Status of Report:

|  |
| --- |
| **CONFIDENTIALITY STATEMENT**  The information provided in this document is strictly confidential. No disclosure should take place without the written authorization from      . |

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nature(s)

**Project Leader**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature Date

**1. Cooperation Partner**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature Date

**2. Cooperation Partner**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature Date

# **Overview**

|  |  |
| --- | --- |
| **Project Leader** | 1. •      First name, last name, academic title 2. •      Employment status 3. •      Date of birth, nationality 4. •      Institution and department (complete name) 5. •      Postal address 6. •      Telephone 7. •      Fax 8. •      E-mail address |
|  |  |
| **1. Cooperation partner** (delete where appropriate) | 1. •      First name, last name, academic title 2. •      Employment status 3. •      Date of birth, nationality 4. •      Institution and department (complete name) 5. •      Postal address 6. •      Telephone 7. •      Fax 8. •      E-mail address |
|  |  |
| **2. Cooperation partner**  (delete where appropriate) | 1. •      First name, last name, academic title 2. •      Employment status 3. •      Date of birth, nationality 4. •      Institution and department (complete name) 5. •      Postal address 6. •      Telephone 7. •      Fax 8. •      E-mail address |
|  |  |
| **Title of the project** |  |
|  |  |
| **Project code** |  |
|  |  |
| **Type of sponsorship** (Please mark) | Project funding Small project: yes  no  Young scientist sponsorship |
|  |  |
| **Objectives/ Milestones** *(as specified in grant application and agreement on support)* | Step 1:  Step 2:  Step 3: |
|  |  |
| **Duration of the project** | Report period:  - Commencement date:        - Finishing date: |

# **Introduction (Scientific background, hypotheses, objectives)**

# 

# **4 Material and Methods**

# 

# **5 Results**

# 

# **6 Discussion**

# 

*Please discuss your findings. Have the objectives proposed in the grant application been achieved? Please relate your results to the milestones proposed in the grant application.*

# **7 Difficulties and Troubleshooting**

# 

*If there are/ were any deviations from the milestones described in your full grant application, please specify and give appropriate comments. Please give an evaluation of the results of the project.*

*A*re there any problems/ important changes concerning

*-* Staff? , if yes, please specify

- Technical feasibility (e.g. equipment)? , if yes, please specify

- Timetable? , if yes, please specify

- Budget? , if yes, please specify

# **8 Perspective**

# 

*Are the results applicable/ relevant for CF-therapy? Which next steps are necessary to achieve a benefit for the patients?*

# **9 Summary**

# 

# **10 Publication(s)/ Abstract(s)/ Poster(s)/ Lecture(s)**

# 

*Are there any publications (submitted or accepted), abstracts, poster(s), or lecture(s) about the project results? If so, please list the references here and add reprints.*

# **11 Graphics and photographs**

# **12 Short and clear report on the results of the project appropriate for publication on our webpage (therefore preferred German language)**

**Projekttitel:**

**Projektnummer:**

**Beteiligte Wissenschaftler:**

**Laufzeit:**

**Datum**

**Projektabschluss:**

**Fördervolumen:**

Ziel des Projekts: (bitte max. 1.500 Zeichen)

Ergebnisse: (bitte max. 1.500 Zeichen)

CONSORT checklist of information to include when reporting a randomised trial\*

|  |  |  |  |
| --- | --- | --- | --- |
| Section/Topic | Item No | Checklist item | Reported on page No |
| Title and abstract | | | |
|  | 1a | Identification as a randomised trial in the title |  |
| 1b | Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts) |  |
| Introduction | | | |
| Background and objectives | 2a | Scientific background and explanation of rationale |  |
| 2b | Specific objectives or hypotheses |  |
| Methods | | | |
| Trial design | 3a | Description of trial design (such as parallel, factorial) including allocation ratio |  |
| 3b | Important changes to methods after trial commencement (such as eligibility criteria), with reasons |  |
| Participants | 4a | Eligibility criteria for participants |  |
| 4b | Settings and locations where the data were collected |  |
| Interventions | 5 | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered |  |
| Outcomes | 6a | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed |  |
| 6b | Any changes to trial outcomes after the trial commenced, with reasons |  |
| Sample size | 7a | How sample size was determined |  |
| 7b | When applicable, explanation of any interim analyses and stopping guidelines |  |
| Randomisation: |  |  |  |
| Sequence generation | 8a | Method used to generate the random allocation sequence |  |
| 8b | Type of randomisation; details of any restriction (such as blocking and block size) |  |
| Allocation concealment mechanism | 9 | Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned |  |
| Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions |  |
| Blinding | 11a | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how |  |
| 11b | If relevant, description of the similarity of interventions |  |
| Statistical methods | 12a | Statistical methods used to compare groups for primary and secondary outcomes |  |
| 12b | Methods for additional analyses, such as subgroup analyses and adjusted analyses |  |
| Results | | | |
| Participant flow (a diagram is strongly recommended) | 13a | For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome |  |
| 13b | For each group, losses and exclusions after randomisation, together with reasons |  |
| Recruitment | 14a | Dates defining the periods of recruitment and follow-up |  |
| 14b | Why the trial ended or was stopped |  |
| Baseline data | 15 | A table showing baseline demographic and clinical characteristics for each group |  |
| Numbers analysed | 16 | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups |  |
| Outcomes and estimation | 17a | For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval) |  |
| 17b | For binary outcomes, presentation of both absolute and relative effect sizes is recommended |  |
| Ancillary analyses | 18 | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory |  |
| Harms | 19 | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) |  |
| Discussion | | | |
| Limitations | 20 | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses |  |
| Generalisability | 21 | Generalisability (external validity, applicability) of the trial findings |  |
| Interpretation | 22 | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence |  |
| Other information | | |  |
| Registration | 23 | Registration number and name of trial registry |  |
| Protocol | 24 | Where the full trial protocol can be accessed, if available |  |
| Funding | 25 | Sources of funding and other support (such as supply of drugs), role of funders |  |

\*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see [www.consort-statement.org](http://www.consort-statement.org).

**CONSORT Flow Diagram**

***Follow-Up***

Analysed (n= )  
 Excluded from analysis (give reasons) (n= )

***Analysis***

Analysed (n= )  
 Excluded from analysis (give reasons) (n= )

Lost to follow-up (give reasons) (n= )

Discontinued intervention (give reasons) (n= )

Lost to follow-up (give reasons) (n= )

Discontinued intervention (give reasons) (n= )

***Enrollment***

Allocated to intervention (n= )

 Received allocated intervention (n= )

 Did not receive allocated intervention (give reasons) (n= )

***Allocation***

Allocated to intervention (n= )

 Received allocated intervention (n= )

 Did not receive allocated intervention (give reasons) (n= )

Randomized (n= )

Excluded (n= )

  Not meeting inclusion criteria (n= )

  Declined to participate (n= )

  Other reasons (n= )

Assessed for eligibility (n= )