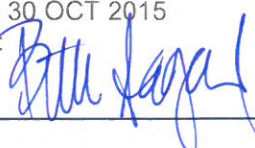
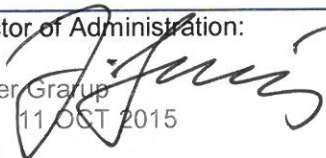


Statistical analyses

COH-PM-002-1.0

Replaces: None	Authors Al Cozzi-Lepri, Marie Helleberg & Amanda Mocroft Date 09 SEP 2015	Effective by: Date: 30 OCT 2015
Approved by		
QA responsible person: Bitten Aagaard Date 30 OCT 2015 Sign: 	Centre director as proof of the Executive Committee decision: Jens D. Lindgren Date 09 SEP 2015 Sign: 	Director of Administration:  Jesper Grarup Date 11 OCT 2015 Sign:

1. PURPOSE AND SCOPE

To provide general guidance for the allocation of a new scientific idea within PERSIMUNE to the statistical team for data analyses. To ensure appropriateness and validity of statistical analyses in scientific projects within PERSIMUNE. These guidelines apply to all scientific projects within PERSIMUNE.

2. RESPONSIBILITY

Project Proposer

- Formulate the scientific question and generate a proposal and ensure proposal submission
- Suggest possible names for person responsible for statistical analyses and supervision, as well as operational project manager, where needed

Project statistician may also be project supervisor or PhD student

- Help the project proposer to put together the proposal by suggesting the analysis design and an appropriate methodology to answer the question set out to be answered. Prepare feasibility for a project including sample size calculations and estimation of statistical power
- Seek help from a trained statistician (supervisor) if needed from the start of the project. The EC can decide that a project statistician needs to be supervised by either a more senior statistician or the project supervisor
- Create a flow chart specifying inclusions and exclusions from analyses so that the basic study population can be reconstructed by an independent statistician/data analyst if required
- Perform the statistical analysis described in the analysis plan



- Log and document all changes made from raw data as well as all statistical analyses
- Document any assumptions made in analyses of data (e.g. assumptions regarding missing values)
- The coding of all statistical analyses should be logged to ensure that all analyses can be reconstructed, evaluated and validated. Use of literate programming is encouraged. The resulting documentation allows authors to restart their own thought processes at any later time, and allows other programmers to understand the construction of the program more easily.
- Provide access for the study group and the PERSIMUNE statistical team to log file containing codes for statistical analyses upon request
- Keep data securely and according to PERSIMUNE guidelines
- Store programs and data for generating study results for 10 years, with back ups as appropriate
- Transfer a copy of the final data set and all final programs to CHIP for security back up
- Review and approve final results prior to submission of the work

Operational project manager

- Ensure that follow-up and status on project decisions

Project supervisors

- General overview of statistical methods employed in analyses of data
- If paired to a junior statistician for a specific project should help from the beginning to put together the study proposal and general review of proposed methodology and analysis plan
- Help the regular review of both output data and coding files

PERSIMUNE executive committee

- Ensure that there is an appropriate and adequate plan for statistical analyses in the study protocols that are approved by PERSIMUNE

PERSIMUNE statistical team

- Assist the PERSIMUNE executive committee in assessment of the statistical plan
- Provide assistance for planning, conducting and validating statistical analyses in specific projects according to capacity and need for support in individual studies (the level of involvement in specific projects is in agreement between the statistical



team and the core study group and planned prior to study initiation. In case of unforeseen challenges, the plan for involvement of the statistical team can be revised during the study, after approval and agreement of roles and responsibilities)

- To resolve unforeseen challenges that cannot be resolved by project statistician and or his/her supervisor. This might be done by the lead of the Statistical team or another member of the team indicated by the Lead.

3. DEFINITIONS AND MATERIALS

Project Proposer

The person initially formulating the scientific question and forming the proposal group – will often be a clinician continuing as Clinical Project Lead

Clinical Project Lead

Proposals/projects will always have a Clinical and a Statistical Project Lead to ensure cross fertilization

Statistical Project Lead

The Lead statistician of the project – not necessarily the supervising statistician

Project Supervisors

Senior clinical and statistical professionals supervising younger clinical and statistical leads on projects

Operational Project Manager

The Operational person from PERSIMUNE Core that is responsible for following up on all actions and decisions and ensure timely deliverables.

4. PROCEDURES

- Persons who perform and supervise data analyses are named prior to the initiation of the study
- It is encouraged to include a trained statistician in the core group of data analysts in each specific project within PERSIMUNE. This is mandatory if PhD students perform the analyses
- The form in appendix 1 is submitted by the Project proposer together with the study proposal to the the PERSIMUNE executive committee
- Study proposals submitted to the PERSIMUNE executive committee should include a description of statistical analyses and power considerations
- If there is a need for statistical support, a detailed description of the level of statistical support needed should be described in the form
- If there is a need for statistical support it should be indicated whether the study group apply for statistical support from the PERSIMUNE statistical team



- If the PERSIMUNE statistical team is asked for support, they should be involved early in the planning of the study and participate in planning of study design, methods and analyses
- Dates for availability of data for analyses, timelines and key dates for conferences between data analysts, supervisors and statisticians are described and agreed upon by all those involved
- The plan for validation of statistical analyses should be clearly described
- Deviations from the original plan for data analyses should be documented with a justification
- Preliminary results of analyses are reviewed and discussed within the core group of the specific project regularly during the process of data analyses to ensure that the plan for statistical analyses is followed and that any uncertainties are addressed in a timely manner
- Sensitivity analyses are employed to ensure validity of results
- In case of uncertainties regarding validity of results arise any time during data analyses the procedures and analyses should first be reviewed by the main data analyst and the primary supervisor. If they cannot resolve the problem the PERSIMUNE statistical team should be asked for advice.

Data Handling

- Data are always stored and handled in accordance with guidelines from the Danish Data Protection Agency
- An “untouched” copy of the raw data is stored separately from working data sets
- Any changes made from the raw data received from CHIP should be documented such that the final data set used for analysis can be reconstructed by an independent statistician

5. REFERENCES

6. HISTORY LOG - CHANGES PERFORMED

First version – no changes

7. ATTACHMENTS

COH-PM-002-1.0 Attachment 1: Plan for statistical analyses. Form to be filled and submitted together with study proposal to the PERSIMUNE executive committee
COH-PM-002-1.0 Appendix 2: Project proposal. Flow chart



Plan for statistical analyses

Version 1, August 2015

Project title:

Project lead:

Name

Title

Address

Phone

Email

A detailed plan of statistical methods is described in the study proposal and attached to this form (mandatory) (Y/N):

Comments:

Power considerations are described in the study proposal (Y/N):

Comments:

Statistical support is needed for the data analyses (Y/N):

If yes: Support is needed for (detailed description):

Statistical support is applied for from the PERSIMUNE statistical group (Y/N):

Persons involved in data analyses

Name

Initials

Title/position

Role and responsibilities

Name

Initials

Title/position

Role and responsibilities

Name

Initials

Title/position

Role and responsibilities



Name
Initials
Title/position
Role and responsibilities

Plan for supervision of junior analyst (if applicable):

Plan for validation of statistical analyses:

Timelines:

Key dates (e.g. conferences between data analysts, supervisors and statisticians):

Date and signature:

