

GENERAL TERMS AND CONDITIONS OF PMU CORE FACILITY BIOSTATISTICS FOR COOPERATIONS IN SCIENTIFIC STUDIES

1. **User group**. All members of clinics and institutes of Paracelsus Medical University (PMU) as well as external scientists can use the statistical support and the data analysis services of PMU Core Facility Biostatistics for their scientific studies. These services are offered as a cooperation with cost co-sharing by the PMU.

2. Initial consultation.

- a) The initial aim is to clarify the procedure, which can vary depending on the progress of the study: if the study is in the planning phase, for example, topics such as ethics committee application, proper data collection using a database, planning the necessary sample size or study design (open, blind, randomized, controlled, mono- or multicenter, pilot study, etc.) are addressed.
- b) If the data has already been collected, the main questions and objectives of the study are clarified. All available project documents (e.g. project description, list of questions to be investigated, data collection form, etc.) should be brought along to the initial consultation.
- c) A decision on future cooperation in the project will be made during the initial consultation. The statistician reserves the right to refuse cooperation in the event of serious shortcomings from a statistical point of view.
- d) After the initial consultation, PMU Biostatistics will provide a cost estimate. This includes an estimate of the required working hours and a cost rate per hour. For students of the PMU PhD program Medical Science, only an estimate of the required working hours is provided, as the costs are fully covered by PMU in this case. Users must confirm this cost estimate with their signature on a "Standard Operating Procedures" (SOP) form.
- e) If the effort estimate turns out to be too low and is exceeded by 10%, PMU Core Facility Biostatistics can either (i) decide to stop working on the current project or (ii) demand the completion of an updated SOP with a revised effort estimate in order to continue the work in a followup project.

3. Data preparation & data handling.

- a) Data must be prepared according to the "Dataset Preparation Instructions for Cooperation with PMU Core Facility Biostatistics".
- b) Data that is not prepared according to (a) will not be accepted and will be sent back for rechecking.
- c) PMU Core Facility Biostatistics reserves the right to refuse further cooperation if sufficient data quality according to (a) cannot be established.
- d) PMU Core Facility Biostatistics archives all transmitted datasets in their original state.

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- 4. **Software**. The complete analysis of the study data is carried out using modern mathematical-statistical methods. As far as possible, freely available open source software (e.g., "R", "python") is used, which makes results transparent and reproducible. However, other specialized software may also be used.
- 5. **Transmission of results & objectives**. Results will be sent via e-mail as a PDF file or another suitable format. The aim is publication of the results in medical journals or the approval of a diploma/dissertation/habilitation.
- 6. **Statistician as a co-author**. In accordance with the "<u>Guidelines for Ensuring Good Scientific</u> <u>Practice</u>" at PMU, users confirm that the responsible statistician will be listed as a co-author in all publications that include results from the specific collaboration. If a publication is released without naming the statistician, a report is made to the Dean of Research Affairs in accordance with the "Guidelines for Ensuring Good Scientific Practice". The user and the head of the clinic or institute (and the supervisor, if applicable) will be informed of this in writing.