Implementation of PREMIER guidelines to SPP2395

1. Introduction

The DFG programme SPP23 is a big consortium of scientific groups working on microglia function in health and disease. To increase the value and outcome of experimental results, data management of the consortium will be supported by a supervisor and the implementation of a quality assurance protocol (PREMIER) which was intended for scientific groups and collaborations according to DIN EN ISO 9001:2008. This manuscript gives an overview over the different PREMIER modules and statements of if and how these can be used in SPP2395.

The PREMIER "house" is built up by 4 major blocks, namely Governance (1), Key Processes(2), Supporting (3) and Measruring/Improvement (4; see different color codes in Fig. 1). In the following sections, each of these blocks will be explained in detail and evaluated for usability in SPP2395.

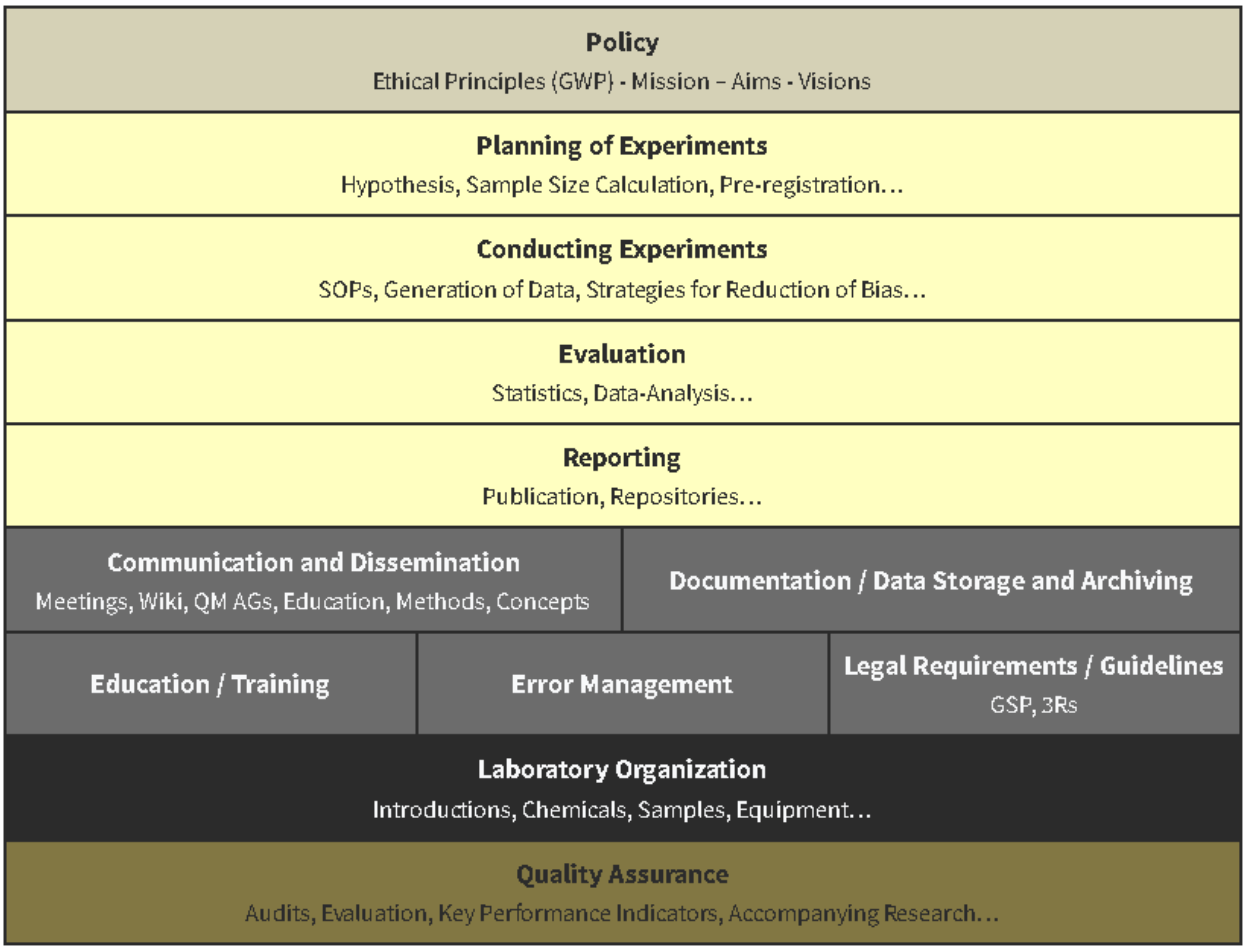

Fig.1 PREMIER house; guideline modules

2. PREMIER block 1: Governance

The major issue in the governance block is to generate a policy statement the includes (https://premier-qms.org/premier/policy):

- A general statement on research quality, describing what quality means in a given context, where quality is most important and what the goal of your research unit or organization is in terms of research quality.

- Risks that arise from non-compliance with the policy.

For SPP2395, such a statement will be drafted by Dr PD Wolf and Dr. Semtner and discussed and revised by all the committee PI's. It will include the scientific goals of the SPP programme general guidelines including "Good Scientific Practice" and more specific aims including the use of common material, data storage and public work.

Timeline:

Feb2023: Finish Polocy draft

Mar-Apr2023: Discussion and Revision with and by SPP2395 PI's

May2023ff: Approval by all comittee members, regular instructions to the groups and scientists

3. PREMIER block 2: Key Processes

This block consist of 4 different sub-modules that guide through the different steps of an experiment, ranging from planning to conducting, evaluating to its reporting.

3.1 Planning of experiments

The first major issue of experimental planning is to formulate a specific scientific question and to look for an experimental setting that answers this question. The second issue is to plan a good experimental design that must include specific hypothesis and parameters that can be statisctically compared and/or evaluated. Basis for the design is the question if the study is exploratory or confirmatory.

3.2 Condicting of experiments

Major issue in the conduction of experiments is to keep reproducability as high as possible. For that, SOPs are needed to be generated and complied.

3.3 Evaluation of experiments

Evaluating means how to primarily analyze the data and which statistical method is to be used

3.4 Reporting of the Results

Reporting of data should be transparent, ie. Open platform should be taken, including the use of Open Access Journals and Open Data Platforms.

For SPP2395, it seems unrealistic for the project coordination team to supervise this block for all of the 18 project partners. Experimental planning, conduction, evaluation and reporting should be done by the work groups themselves, however, support by the data manager is possible.

As one of our aims, we will therefore try to look for data repositories that might be commonly used in the consortium for specific techniques and try to work together on SOP for specific, commonly used experimental settings to harmonize the workflow in the microglia field.

4. PREMIER block 3: Support Processes

This block consist of 6 different sub-modules that ensure quality management in the scientific infrastructure. Blocks include Commiunication and documentation guidelines, education/training, error management and legal requirements. Thus, all actions regarding this block are targeted on the laboratory and institutional environment.

4.1. Communication and Dissemination

“In order to be effective and efficient with PREMIER, either as a QM system or by using the modular application, it is important to involve all employees in the corresponding processes. The aim is therefore to develop a suitable communication and dissemination strategy for the laboratory and/or the entire organisation so that all participants are informed at all times.” (https://premier-qms.org/premier/communication-and-dissemination).

Actions include **internal** communication:

-meeting schedule

-electronic lab book

-Protocols

-Teams/zoom

And **external** communication:

-cooperations

-Website

Social Media/Blogs

For SPP2395, we want to implement this module as comprehensive as possible, i.e. internal communication means to set up regular meetings with parts of the consortium and to set up trainings for the students. It will be evaluated the use of common electronic lab books is suitable and if and protocols (SOPs) can be shared and implemented in the single work group’s systems.

4.2. Documentation, data storage and Archiving

This module mainly refers to the use of electronic lab books (ELN) and internal storage of raw data and secondary data.

For SPP2395, the data manager will check if every group is already using an ELN and offer trainings. It will be also evaluated if there is a way to share data and protocols between different ELN and data storage systems to accelerate data and protocol sharing.

4.3. Education, Training

This package refers to the training of new students or existing staff to novel techniques. Guidelines rather refer to the treatment within scientific groups that within a big consortium consisting of multiple groups. However, for SPP2395, regular trainings and instructions will be offered with regard to the use of ELN (see above) and data storage.

4.4. Risk and Error Management

“Basic reporting of errors and critical incidents is important to provide transparency about the experimental work performed in a laboratory. The aim is to learn from mistakes and avoid them in the future.” (https://premier-qms.org/premier/risk-and-error-management)

This module is clearly intended to document and handle incidents within specific work groups and will not be implemented by the data management team of SPP2395.

4.5.Legal Requirements and Guidelines

This module includes the handling of legal conditions (e.g. MTA’s), animal welfare, good scientific practice and independency declarations.

This module is intended to handle legal affairs within specific work groups and institutions and will not be implemented by the data management team of SPP2395.

4.6. Laboratory Maintenance

This module is intended to organize and manage the daily laboratory business, including responsibilities and duties, resource management (money, server space…), method implementation, materials and ordering as well as safety management and instructions. Laboratory Organization is definitely required and the responsibility is on each PI. The data management group of SPP2395 will not deal with this module but offers support in terms of tools and trainings.

5. Quality assurance

“Quality assurance is intended to ensure that PREMIER's requirements as well as the own requirements that the organization / laboratory has set itself, are implemented and continuously improved.“ (https://premier-qms.org/premier/quality-assurance)

Includes the following points:

-Define performance indicators

-Impact analysis

-Monitoring and Evaluation (internal and external)

-Validation (internal and external)

-Audits

-Risk Assessment

Most of the points in this module again refer to the daily business in specific work groups and not to the coordination of multiple work groups in a consortium. However, the progresses in consortium’s data management, impact of trainings and courses, ELN usage, sharing of protocols and data will be validated in a yearly fashion by a SPP2395-wide survey.