Apêndice 2. Proposta de grelha de avaliação para 3 revisores incluindo 2 clínicos e 1 metodologista (painel internacional)

Proposal type
- Draft proposal
- Full proposal

Study type (The funding should be attributed to interventional clinical studies. Observational studies should be funded only if the study investigates a highly relevant research question that cannot demonstrably be answered by an interventional design)
- Interventional trial (Pharmaceutical trials; Diagnostic trials; Prognostic trials)
- Epidemiological research

Trials must prove efficacy and the sample size should be large enough – unicentric studies are discouraged. Several study centres must be involved in the recruitment.
A prerequisite for the funding of an interventional trial is initial evidence of the efficacy of the method being investigated (from feasibility studies and/or pilot studies conducted by applicants or third parties) as well as cogent preparatory work on the effect size and the sample size, the practicability of the randomisation procedure and the investigation of the planned study design. The preparatory work must justify the undertaking of a confirmatory and correspondingly large-scale interventional trial.
Funding is not available for studies involving direct commercial interest or a patent-protected investigational agent or method

1. Scientific quality / originality / clinical relevance / ethics
- Potential impact of relieving the burden of disease and/or improving health?
- What is the novel aspect?
- What impact will the results have on clinical practice?
- Ethically acceptable?

2. Evidence
- Description and discussion of the evidence
- Does the presented evidence support the trial rationale?

3. Hypothesis/research question

4. Design
- Is there an appropriate design to answer the research question?
- Is the estimated effect size well founded?
- Is the study population representative?
- Are the selection criteria appropriate?
- Are the treatments / procedures (duration/dose/mode of application) appropriate and feasible?
- Are the outcomes measures clinically relevant?
- Are appropriate measures implemented to prevent bias and confounders?

5. Feasibility
- Is the trial feasible?
- Are the recruitment rates feasible?
- Have the enrolment, potential drop-out rates and compliance of patients been adequately assessed?
- (If applicable) In interventional trials: How feasible are the interventions? Are the trial drugs or medicinal products available? Are the training and quality control measures for complex interventions or complex outcome assessments adequate?
- (If applicable) In observational trials: Have the applicants convincingly explained why the research question cannot be answered using an interventional design? Since the significance and the controllability of observational trials can be very limited, they can only be funded

6. Team
- Is the team of investigator qualified to conduct the trial?
- Is the trial management and coordinating assured?

7. Quality assurance and safety
- Are advisory bodies / independent experts / study monitors for quality assurance and safety necessary and adequately defined?

8. Conflicts of interest
- Are there any conflicts of interest?
- Could a company have substantial economic benefit from the potential trial results?

9. Timelines and costs
- Are the timeline and the proposed budget adequate?

10. Overall merit