REQUEST FOR PROPOSALS
PROSTATE CANCER CLINICAL TRIAL AWARD

SWITZERLAND AND FRANCE

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16 OCTOBER 2014

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SWITZERLAND AND FRANCE PROSTATE CANCER CLINICAL TRIAL AWARD

RESEARCH PROGRAM OBJECTIVES

The Movember Foundation funds innovative research that is aimed at accelerating improved clinical tests and treatments that eliminate death from prostate cancer and enhance physical and mental wellbeing of men living with the disease.

From the Movember 2013 and 2014 campaigns in France and Switzerland, the Movember Foundation is funding one industry independent Phase 2 or 3 clinical trial, with participation and funding across both countries. A total of € 1.5 million is planned to be available for a trial of up to four (4) years in duration.

In contributing to our goal of eliminating death from prostate cancer, the Movember Foundation is mindful of the cost, time and access to new prostate cancer treatments in many health systems, including France and Switzerland. There is a growing body of evidence that widely available, low cost drugs (including prescription and off patent drugs) and innovative application of existing clinical treatments have the potential to slow or stop the progression of lethal prostate cancer. The purpose of this program is to support the acceleration of these treatment modalities towards low cost, affordable and widespread clinical application.

We will fund an industry independent Phase 2 or 3 clinical trial that demonstrates an innovative application of treatment modalities that has the potential to slow or stop lethal disease progression, including the associated side effects of disease progression. While this Award will provide funding only to Swiss and French researchers, Movember Foundation will support participation in the clinical trial from other countries provided that the trial is led by a Swiss or French institution and funding for clinical trial activities outside of Switzerland and France is secured through other sources before this Award is funded.

Movember Foundation will only consider projects that are completely focused on prostate cancer.

ABOUT THE MOVEMBER FOUNDATION

The Movember Foundation is the leading global organisation committed to changing the face of men’s health.

The Movember community has raised over €409 million (CHF 536 million), funding over 800 programs and projects in 21 countries. This work is saving and improving the lives of men affected by prostate cancer, testicular cancer and mental health problems.

The Movember Foundation challenges men to grow moustaches during Movember (formerly known as November), to spark conversation and raise vital funds for its men’s health programs. To date, 4 million moustaches have been grown worldwide, but we won't stop growing as long as serious men’s health issues exist.

AIMS OF THE MOVEMBER FOUNDATION CLINICAL TRIAL AWARD

The Movember Foundation will fund, one (1) Phase 2 or 3 clinical trial in France and Switzerland that has the potential to slow or stop lethal disease progression through the innovative application of the following treatment modalities:

- Currently available prescription (including off-patent) drugs or
- Existing clinical treatments that can slow or stop lethal disease progression.

The Movember Clinical Trials Award is designed to:

- Harness existing strengths in these countries;
- Seize future opportunities;
- Foster a collaborative approach to research; and,
- Enable the French and Swiss prostate cancer research communities to have a significant impact on the clinical management of prostate cancer that has the potential to be available to men quickly and affordably.

KEY ELEMENTS OF THE PROGRAM

In order to achieve the aims of the award, a core funded team of high calibre scientists and clinicians is required. We are looking to support a multi-institutional team (a minimum of 2 institutions in each country) across Switzerland and France that has all the skills required to implement a successful trial.

The collaborative approach is expected to produce transformational results by:

- Breaking down silos;
- Building real collaborative efforts and partnerships;
- Focusing on prostate cancer patients at the centre of all the team's activities; and,
- Sharing ideas and data amongst team members.

FUNDS AVAILABLE

The total amount available for this initial funding opportunity is € 1.5 million for up to 4 years. Approximately €1.1 million is expected to be allocated to the Swiss component of the trial and €400,000 to the French component. This allocation of funds is consistent with the level of Movember funds projected to be available from the Movember campaigns in Switzerland and France. The final amount available for this trial is subject to funds raised in 2014 in Switzerland and France. Should funding levels decrease, Movember Foundation reserves the right to reduce financial contributions to the trial.

Movember Foundation will support participation in the clinical trial from other countries provided that the trial is led by a Swiss or French institution and funding for clinical trial activities outside of Switzerland and France is secured through other sources before this Award is funded.

Evaluation of the team's progress will be metric driven; the team will clearly define its specific goals and how it will measure progress.

THE TEAM

The team must include:

- A leadership structure that includes representation from Switzerland and France;
- A single **Principal Investigator** who is an **independent investigator**;
- Co-applicants (Co-Principal Investigators and Co-Investigators) who are also **independent investigators;**
- The Principal Investigator, Co-Principal Investigators and Co-Investigators must be formally affiliated with **eligible institutions;** and
- A named study coordinator/sponsor who will guide the protocol through ethics and regulatory approval, coordinate activities from all sites participating in the trial, and coordinate patient accrual.

The **Principal Investigator** will:

- be responsible for the direction of the proposed activities;
- assume the administrative and financial oversight for the entire trial;
- assume the financial responsibility for their own portion of the trial at their own institution; and,
- receive all related correspondence from Movember Foundation.

An **independent investigator** is an individual who:

- has an academic or research appointment which:
    - must commence by the effective date of funding; and
    - allows the individual to pursue the proposed research project, to engage in independent research activities for the entire duration of the funding, to supervise trainees, and to publish the research results; and
    - obliges the individual to conform to institutional regulations concerning the conduct of research, the supervision of trainees, and the employment conditions of staff paid with Movember Foundation funding.
- will assume financial responsibility for their portion of the award at their own institution and will be responsible for reporting this information back to the Principal Investigator as well as to Movember Foundation.

Eligible institutions must meet the following requirements:

- The institution type must fall under one of the following categories:
    - Swiss or French post-secondary institutions and their affiliated institutions including hospitals and research institutes.
    - French or Swiss non-governmental, not-for-profit organisations (including community or charitable organisations) with an explicit research or knowledge translation mandate.
- The institutions must be recognised legal entities.
- The institutions must have the necessary accounting systems and financial controls in place to manage Movember Foundation funds.
- The institutions must ensure that the researchers will have the time and infrastructure that will permit the pursuit of the planned research and the freedom to publish the results.

ALLOWABLE COSTS

The following expenditures will be considered eligible for funding received through this funding opportunity:

- Salary costs, including study sponsorship/coordination
- Research supplies
- Purchase of small equipment and maintenance contracts for common services and shared infrastructure essential to the proposed research program (maximum 5% of the total budget)
- Clinical costs
- Travel between collaborating institutions
- Costs of national and international networking, including collaborations, planning, and knowledge translation activities (including Movember Foundation annual research review meetings)
- Costs involved in linking downstream translation and dissemination of research findings to those who will use the results as appropriate to the particular research aim. The application must provide a detailed justification of all costs.

INELIGIBLE EXPENDITURE

- Indirect costs associated with the conduct of research (including, but are not limited to, heating, lighting, ethics review, intellectual property and commercialisation activities)
- Fringe benefits for students and post-doctoral fellows
- Conference travel except as outlined above
- Entertainment and hospitality costs
- Membership fees, tuition fees, union dues

KNOWLEDGE TRANSLATION PLAN

Knowledge Translation can be defined "as the methods for closing the gaps from knowledge to practice." http://www.cmaj.ca/content/181/3-4/165.full

The Knowledge Translation Plan should be developed with this definition in mind and must go well beyond traditional dissemination endeavours (i.e. publications, conferences).

The team is required to develop a comprehensive knowledge translation plan and demonstrate that a meaningful collaborative research approach is being used. The knowledge translation plan must include evidence that prostate cancer clinical experts, young investigators and end users are active participants and are engaged in the entire research process. For example, these individuals should shape the research process by collaborating to determine the trials research questions, deciding on the research methodology, interpret the findings, and assist with the dissemination of research results. In addition, the applicants are required to articulate their knowledge sharing/dissemination plan to demonstrate that the results achieved are relevant and useful to end users.

GOVERNANCE AND ADMINISTRATION OF THE AWARD

An international peer review panel will be established to evaluate the applications. The peer review process and reporting will be undertaken by Swiss Cancer Research Foundation/Krebsforschung Schweiz.

REVIEW PROCESS AND EVALUATION

A two-step process will be used to review proposals

Step 1 – Pre-Proposal

Step 2 – Invitation to submit a Full Proposal

An international peer review panel, comprising international experts will be convened to evaluate the Pre-Proposals and Full Proposal. The panel will be created specifically for this funding opportunity. Panel members will be selected based on their breadth of knowledge and expertise in prostate cancer and clinical trials.

STEP 1 – PRE-PROPOSAL

Applicants may submit an Pre -Proposal in accordance with the guidelines detailed in this document.

The Proposal must address the following, using the five headings below:

1. ***Title*** of the proposal
2. ***Lay Summary*** (maximum 250 words)
   Provide a brief summary in non-scientific language of the proposal

3. ***Clinical Impact*** (one page limit)

   Describe how the clinical trial has the potential to slow or stop lethal disease progression through the innovative application of the following treatment modalities –

   - prescription (including off-patent) drugs and / or
   - clinical treatments for other applications to slow or stop lethal disease progression

4. ***Clinical trial proposal*** (maximum 1500 words)

   The clinical trial proposal must include an overall description of the trial plan and must clearly outline the following elements:

   - Background and hypothesis: Present the scientific rationale and preliminary data, including critical review and analysis of the literature and laboratory and preclinical evidence that support the proposed trial and its feasibility.
   - State the aims of the clinical trial, how they integrate together, and describe the approach to achieving the aims

5. ***The Research Team*** (two page limit)

   Briefly describe the composition, expertise and organisation of the team and each member's role, including the sponsor/study coordinator, with a particular focus on the way in which applicants will collaborate as one team and the roles of leaders and young investigators. If the proposal includes members/funding sources outside of France and Switzerland, those members and resources should be specified.

Supporting documentation

- Provide a short bibliography for any references cited in the Pre-Proposal.
- Team member's curriculum vitae. : Attach one document that includes brief (maximum 2-page per team member) free-form CVs for the Principal Investigator and each Co-Principal Investigator (but not Co-Investigators).
- Written support from the coordinating centre that will participate in carrying out the study. Attach one document. The letter of support must confirm the coordinating centre's interest in collaborating with the applicants.
- Details of available facilities & other resources.
- Description of existing equipment
- Institutional letters supporting the collaboration (if applicable).

Pre proposals will be reviewed against the following evaluation criteria:

Clinical Impact

- How the clinical trial, if successful, could slow or stop lethal disease progression.
- Preliminary preclinical or clinical data and rationale for the trial intervention.
- How this clinical trial, if successful, could provide new treatment modalities that are low cost, and readily accessible.

Personnel

- How the clinical trial team's background and expertise are appropriate to accomplish the proposed work (i.e., statistical expertise, expertise in the disease, and clinical trials).

STEP 2 – INVITATION TO SUBMIT A FULL PROPOSAL

Successful Pre proposal Applicants will be invited to submit a Full Proposal. Guidelines for successful Pre proposal Applicants and application forms will be made available at the time of notification.

Full Proposals will be reviewed against the following evaluation criteria:

Trial Design

- How the scientific rationale and preliminary data, including critical review and analysis of the literature and laboratory and preclinical evidence, support the proposed trial and its feasibility.
- How well the aims, hypothesis(es) or objectives, experimental design, methods, data collection procedures, and analyses are developed.
- How the logistical aspects of the proposed clinical trial (e.g., communication plan, data transfer and management, and standardisation of procedures) are adequate.
- How the recruitment, informed consent, and screening processes for volunteers will be conducted.
- Whether the inclusion, exclusion, and randomization criteria are adequate.

Clinical Impact

- How the clinical trial, if successful, could slow or stop lethal disease progression
- How this clinical trial, if successful, could provide new treatment modalities that are low cost, and readily accessible
- The appropriateness of clinical treatment to be tested in the clinical trial.
- The availability and quality control of the substance(s) to be used in the clinical trial (if applicable).
- Documentation that an IND/IDE has been submitted (if applicable).

Feasibility

- The plans for addressing unanticipated delays (e.g., slow accrual, ethics approval) and completing the proposed study within the performance period.
- The availability of patients for the clinical trial, the prospect of their participation, and the likelihood of patient attrition.
- The progress toward obtaining local ethics approval of the clinical protocol and informed consent form.
- Available staff for conducting trial, data collection and analysis. Data monitoring, statistical support

Statistical Plan (as appropriate for phase of study)

- How the statistical plan, including sample size projections and power analysis, is adequate for the trial and all proposed correlative studies.
- The consistency of the data analysis plan with the study objectives.
- Interim analysis

Ethics and/or Regulatory Issues

- How the ethical considerations, information privacy, and assessment of risks and benefits of participation in the clinical trial will be addressed.
- The plan for dealing with adverse events, which should include named agencies or offices to be notified in this event and point of contact information.
- The plans for data disposition during and after the clinical trial.
- The procedures for protocol modifications during the course of the study.
- The plans for data and safety monitoring.

Personnel

- How the clinical trial team's background and expertise are appropriate to accomplish the proposed work (i.e., statistical expertise, expertise in the disease, and clinical trials).
- The appropriateness of the levels of effort for successful conduct of the proposed work.
- Collaborating sites, including balanced Swiss and French participation.

Environment

- The evidence of an appropriate scientific environment, clinical setting, and the accessibility of institutional resources to support the clinical trial at each participating centre
- Whether the clinical trial requirements are supported adequately by the accessibility to facilities and resources (including collaborative arrangements).
- The institutional commitment from each participating institution.

Budget

- How the budget is appropriate for the proposed research.

Knowledge Translation Plan

- The proposal contains a comprehensive knowledge translation plan detailing how knowledge produced from the project will be shared and disseminated, in alignment with the trial's goals.
- Recipients of the knowledge generated by the project have been identified and engaged in the trial's design.
- The knowledge translation plan addresses how new knowledge gained through the trial can rapidly progress towards clinical adoption.

IMPORTANT DATES

Program Launch Date	16 October 2014
Closing Date for Submissions of Pre proposals	Midday 15 December 2014
Pre-Proposal Review	6 February 2015
Invitation to Submit Full Proposals	13 February 2015
Closing Date for Submission of Full Proposals	Midday 13 April 2015
Peer Review	April 2015
Anticipated Award Announcement Date	May 2015

SUBMISSION GUIDELINES AND TERMS AND CONDITIONS

SUBMISSION GUIDELINES

It is critical that all applicants follow the instructions in this section. Applications that do not comply with these instructions may not be accepted for review.

By submitting an application, the applicants have implicitly accepted the Terms and Conditions set out below.

The Pre-Proposal and Full Proposal applications must be submitted electronically via an RFP system - which can be accessed via https://clinicaltrialaward.fluidreview.com. Hardcopy and emailed notices and applications will not be accepted.

Applicants will need to create an account through the online system, which will then allow them to complete the Pre-Proposal and also submit the Full Proposal (if applicable).

To be eligible for review, the application must adhere to the following instructions for presentation and content.

- Microsoft Word (.doc or .docx file extensions) or PDF format;
- One (1) page for the table of contents.
- A4, 8 1/2 X 11" (21.2 cm X27.5 cm)
- Arial font (regular), minimum 11-point;
- Single-spaced text;
- 1 " (2.54 cm) margin on all sides of each page; and
- A header on each page with the Principal Investigator's name in top left-hand corner, and the page number in the top right-hand corner.
- The application must comply with the requirements as outlined on pages 6 / 7 of this award description document.

The Pre-Proposal may be edited any number of times up until the closing date and time of **12:00 PM** *(midday) (***CET) on 15 December 2014**.

For Applicants invited to submit a Full Proposal, this may be edited any number of times up until the closing date and time of **12:00 PM** *(midday)* **(CEST) on 13 April 2015**.

The Movember Foundation is not obliged to consider applications received after the closing time but may do so at its sole discretion.

All correspondence and questions relating to this call are to be submitted to:

Dr Stéphanie Buvelot Frei, Swiss Cancer Research Foundation

Email: stephanie.buvelot@swisscancer.ch

All questions will be answered in a timely manner.

TERMS AND CONDITIONS

1) Movember Foundation does not make any representation that it will, and disclaims any obligation to, proceed with or to commit to any particular future actions in relation to the subject matter of program call, including without limitation: a) accepting any application or shortlist any applicant; and b) considering, not considering, accepting or rejecting any application.
2) Movember Foundation reserves the right, at its sole discretion, to initiate another selection process, enter into negotiations with a person or persons who have not be invited to respond to this call for programs or to cancel the program.
3) Applicants must pay their own costs and expenses incurred in preparing and submitting an application.

4) To the extent permitted by law, Movember Foundation excludes all liability for any loss, costs (including legal expenses) or damages, suffered or incurred by an applicant or any person, arising out the applicant's participation in the application process.
5) The Applicant warrants that it has no actual or potential conflict of interest in relation to its participation in the application process or its delivery of the Project other than that is has disclosed in the application.
6) No legal or other obligation arises between an Applicant and Movember Foundation in relation to the outcome of the application process, unless and until Movember Foundation executes a contract with the applicants.
7) Movember Foundation is not obliged to a) accept any Pre-Proposal or Full Proposal or b) enter into any contract with any applicant or c) give reasons for not considering or accepting or rejecting all or any part of any full application, or for cancelling the full application process. Movember Foundation may, at its sole discretion, consider for acceptance a response that does not comply with the requirements of this request for applications.
8) The Applicants grants Movember Foundation, a non-exclusive license to use for the purpose of this application process, any information, processes, sketches, calculations, drawings, or other data or information submitted with or included in, the response submitted by the Applicant.
9) Each Applicant agrees to indemnify Movember Foundation against third party claims arising out of any use of any proprietary information submitting with or included in, the full application.
10) Should the Applicant find any material discrepancy, error or omission in this request for proposals, the applicant must immediately notify Movember Foundation in writing of the nature of the discrepancy, error or omission.
11) The Applicant and team members of the program acknowledge that their details, including any personal details may be disclosed to third parties including peer reviewers, for the purposes of this application process and any related purposes.
12) Movember Foundation reserves the right to fund lower rated projects based on specific areas of interest in the requested themes.

Variations

Movember Foundation may vary the requirements set out in this Request for Proposals and seek further information from the Applicants. Applicants shall supply this information on reasonable request.

Movember Foundation's Rights

Movember Foundation reserves the right to subject the Applicant to a "due diligence" enquiry, which may comprise of:

a) verifying whether the represented resources and skills are actually available; and
b) assessing experience and integrity.

Movember Foundation, at its sole discretion, reserves the right to depart from any method of evaluation set out in this call for proposals.

Reliance on Information

Movember Foundation will rely on information provided by, or on behalf of the Applicants at all stages of the application process. In providing information, Applicants represent to Movember Foundation that the information is complete and accurate in all material respects, that it is not misleading and that in preparing the information, reasonable skill and care has been exercised by the Applicant and its personnel and acknowledges that Movember Foundation may rely on that information.

Publicity

Applicants are not to make any public statement in relation to, the Pre-Proposal or Full Proposal, their response, or their participation in the application process, or contract negotiation process without Movember Foundation's prior written consent.

Communication Requirements

Funding recipients are required to acknowledge the Movember Foundation in all communication or publication related to this funding opportunity. In addition, recipients of project funding are also required to adhere to the Movember Foundation branding requirements as a condition of the project funding.

Performance Measurement

The Movember Foundation is committed to collecting and disseminating information on the impacts of its investments. This outcome information is an important part of the Movember Foundation's accountability and transparency with its community

The Principal Investigator will be required to submit annual progress reports and an end of funding report 6 months following the end of this four (4) year funding period. The format of the report will be made available to the successful applicant at the beginning of the funding period and can be updated as the project progresses.

In addition, the project leaders must contribute to the monitoring, review and evaluation of their project by participating in requested media events, evaluation studies, surveys, audits, and workshops as required for the purposes of collecting information to assess progress and results.

CONTACT INFORMATION

For further information on this project funding opportunity, please contact:

Dr Stéphanie Buvelot Frei, Swiss Cancer Research Foundation
Email: stephanie.buvelot@swisscancer.ch