



MOVEMBER GLOBAL ACTION PLAN 6 (GAP 6)

INITIATIVE IN OLIGOMETASTATIC PROSTATE CANCER

EXPRESSION OF INTEREST TO BE PART OF THE PROJECT TEAM

**PROVIDING CLINICAL SAMPLES AND PERFORMING
TRANSLATIONAL RESEARCH**

LAUNCH DATE: 22 JANUARY, 2016 (AEDT)

CLOSING DATE: 4 MARCH, 2016 (AEDT)

ABOUT THIS EXPRESSION OF INTEREST

The Movember Foundation would like to announce the launch of its sixth project under the banner of the Global Action Plan (GAP) Program, which will focus on oligometastatic prostate cancer.

There are currently multiple clinical trials being conducted around the world investigating the effects of different radiation therapies, surgery and /or high intensity frequency ultrasound (HIFU) in patients with oligometastatic/low volume prostate cancer. These trial designs have a high degree of variability with regard to definition of oligometastasis, treatment technology, outcome measurement and the imaging methods used to detect oligometastatic lesions.

The Movember Foundation aims to bring together different disciplines within the prostate cancer research community to leverage retrospective and prospective clinical trials and invest in a complementary translational research project to answer critical clinical questions regarding tumour heterogeneity and treatment response.

These clinical trials will likely include patients who have bony lesions or distant metastases, where ablation or surgical removal of these lesions could lead to longer progression-free survival and potentially delay the need for systemic therapy. The GAP6 initiative will focus on better understanding the biology of tumour heterogeneity as well as the mechanisms of relapse and response to radiotherapeutics, surgery and HIFU in different oligometastatic prostate cancer patient populations.

A mandatory expectation for involvement in, and the appropriation of funds as part of the GAP6

project, will be the sharing of material and data created from ongoing or planned clinical oligometastatic prostate cancer trials so that samples from these trials can be utilized by the wider prostate cancer research community to address key clinical questions.

As suggested by the Movember Global Scientific Committee, the aim in the first instance is not to invest in a new oligometastatic clinical trial, but to consolidate existing or planned clinical trials and focus on translational research opportunities.

ABOUT THE MOVEMBER FOUNDATION

The Movember Foundation is committed to driving awareness of men's health issues and strategically investing in key problem areas, helping men to live happier, healthier and longer lives. Since 2003, millions have joined the movement, raising over \$685 million to fund breakthrough research and support services.

With aims of accelerating outcomes for men living with prostate or testicular cancer, the Movember Foundation is breaking down barriers to research and building powerful collaborative teams.

With a global presence across 21 countries, the Movember Foundation is uniquely placed to address key prostate and testicular cancer research challenges by facilitating and funding novel, collaborative and global approaches that will fast track translational research. Each project within the Global Action Plan (GAP) seeks to identify and fund research where integrated transnational collaboration has the potential to accelerate outcomes for the ultimate benefit of patients.

PROJECT DESCRIPTION, AIMS AND OBJECTIVES

The key objectives of the GAP6 project are to integrate and leverage retrospective and prospective clinical trials on oligometastatic prostate cancer at a global level to:

- Bring inter-disciplinary unity to the definition of oligometastatic disease
- Reach consensus on how to distinguish oligometastatic and synchronous metastasis of prostate cancer
- Determine the utility of tissue, urine and serum biomarkers collected from clinical trials to better stratify patients with oligometastatic disease for optimal treatment and post-treatment management
- Investigate the biology of oligometastatic disease and tumour heterogeneity in the context of treatment history and clinical outcomes
- Investigate effects of radiotherapy / surgical treatment/HIFU on disease lethality, disease progression and quality of life
- Explore genomic and immunological effects of radiotherapy, especially in the tumour microenvironment
- Consolidate trial designs, imaging modalities and radiation therapy technologies
- Bring together the imaging, radiation oncology, medical oncology, urology and prostate cancer research communities

PROCESS TO DATE

For the purpose of the Expression of Interest (EOI) process it is important that applicants understand the governance and development of the project.

- In January 2015, Movember solicited ideas from the global prostate cancer research community as to what is the area of greatest unmet clinical need in prostate cancer research that would benefit from a global collaborative effort via a Movember Global Action Plan project.
- The prostate cancer community suggested 78 topics for consideration for the GAP6 project and oligometastatic disease was mentioned several times.
- In March 2015, the Movember Global Scientific Committee (GSC) met to discuss these topics.
- The GSC short-listed oligometastatic prostate cancer as a potential focus of GAP6.
- Due diligence / feasibility was performed in April-June 2015 and in July 2015 the Movember Board approved that the GAP6 project would focus on prostate cancer oligometastatic disease as recommended by the GSC.
- In August/September 2015, Movember appointed a specialist multi-disciplinary GAP6 Research Advisory Committee (RAC) to oversee the project from a governance perspective. The composition of the GAP6 RAC is outlined on page 4.

NAME	INSTITUTION & COUNTRY	DISCIPLINE
Prof Rob Bristow (Chair)	Ontario Cancer Institute / Princess Margaret Hospital, Canada	Radiation Oncology and Translational Research
Prof Jelle Barentsz	Radboud University, The Netherlands	Radiology and Imaging research
Prof Chris Logothetis	MD Anderson, USA	Medical Oncology and Translational Research
Prof Ralph Weichselbaum	University of Chicago, USA	Radiation Oncology and Translational Research
Prof Bertrand Tombal	Cliniques Universitaires Saint-Luc, Belgium	Urology and Translational Research
Prof Noel Clarke	The Christie Clinic, UK	Urology and Translational Research
Prof Peter Croucher	Garvan Institute, Australia	Translational Research and Bone Biology
Dr Jennifer Bishop	Vancouver Prostate Centre, Canada	Immunology
Prof Jiaoti Huang	UCLA, USA	Pathology

FUTURE PROCESS

- This EOI is not a call for detailed project proposals. The purpose of this EOI is to garner interest and assess the resources and capabilities for the development of a global research collaboration in the oligometastatic prostate cancer space.
- The Movember Management team will facilitate and coordinate the EOI process and subsequent project design phase, but does not select investigators or determine the project scope – this is the remit of the GAP6 RAC.
- The RAC is responsible for selecting a complementary team of investigators from the EOI submissions and will provide ongoing governance and scientific feedback throughout the life of the project.
- Investigators with a relevant track record and access to relevant clinical samples who are selected by the RAC to participate in the GAP6 project will move into a ‘design phase’ where the scope of the GAP6 project will be refined with governance oversight from the RAC and GSC.
- All selected Investigators will have the opportunity to play key roles in the design of the GAP6 project.
- From the team of Investigators asked to join the design phase, a multidisciplinary project Steering Committee (SC) will be established by Movember and the GAP6 RAC. The SC will consensually design the project, define the scope of work and recommend funding allocations for review by the GAP6 RAC.

MILESTONES	DATES
Expression of interest launched	22 January, 2016
Q & A session on application process	28 January, 2016, 7 a.m. AEDT
Q & A session on application process	23 February, 2016, 8 p.m. AEDT
EOI closes	4 March, 2016, 12 noon AEDT
Pre-screening of EOIs	March 2016
Review of EOIs by Research Advisory Committee	March/April 2016
Notification of selected applicants	End April 2016
Formation of Steering Committee / project design team	May 2016
Notification of award funding	TBD upon completion of project design, delineation of deliverables and budgets and endorsement by RAC

REVIEW PROCESS AND EVALUATION CRITERIA

Applications will be evaluated against the following criteria:

- Access to relevant existing or prospective clinical trials on oligometastatic prostate cancer
- Collection of biospecimens (serum, tissue, urine) as part of the clinical trial
- Access to or proposed prospective collection of bony and distant metastatic tissue from these clinical trial patients
- Significant experience in clinical and translational research in prostate cancer
- Existing or attainable ethics approvals allowing sharing of samples and data as part of the GAP6 project

SUBMISSION GUIDELINES

It is critical that all applicants follow the instructions in this section. It is the sole responsibility of the applicant to ensure their application is in the acceptable format and received before the deadline. Applications that do not comply with these instructions may not be accepted for review.

The application must be submitted electronically via the Movember Foundation online application system - which can be accessed via gap6.fluidreview.com

Hardcopy and emailed notices and applications will not be accepted. **The application questions can be downloaded in Excel format for offline viewing upon signing up to the online system.**

By submitting an application, the applicants are deemed to have accepted the Terms and Conditions set out in the online application system.

Applicants will need to create a login for the online system, which will then allow them to create and submit their applications. Updates, FAQ and dial-in details for the Q & A sessions will be sent to all applicants who have created online accounts.

The application in the online system may be edited any number of times before the closing date and time, even after submission.

Applications must be submitted by 12:00 noon (AEDT) on Friday, 4 March, 2016. Convert to local time [here](#).

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

CONTACT US

Questions and feedback related to this call for expressions of interest can be e-mailed to the GAP6 Project Manager, Ariel Achtman: ariel.achtman@movember.com

Questions will be responded to in a timely manner. Please note, responses may be shared with all interested parties as FAQ throughout the application process.

There will also be Q&A teleconference sessions (see key dates) on 28 January, 2016 (7 a.m. AEDT) and on 23 February, 2016 (8 p.m. AEDT). Dial-in details will be provided to interested parties (please e-mail Ariel Achtman).

ALLOWABLE COSTS

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

- Research operating costs for the proposed research project, which must be distinct in its objectives from those for which the PI or project team members currently receive funding.

- Costs of data collection, database management, database integration and maintenance.
- Costs of regional, national or international networking activities, including collaboration, planning, and knowledge exchange activities.
- Salaries of research assistants, coordinators, technicians, administrative staff, and other personnel who will enhance the collaborative research productivity of the team.
- Costs involved in linkage with and dissemination and translation of research findings to those who benefit from the new knowledge generated by the team.

INELIGIBLE COSTS

- Institutional overhead costs
- Tuition and professional membership dues
- Capital costs, including costs associated with construction, renovation or rental of offices, laboratories or other supporting facilities.

PERFORMANCE MEASUREMENT

The Movember Foundation is committed to collecting, evaluating and disseminating information on the outputs and impacts of the research it funds. This information is an important part of the Foundation's policy of accountability and transparency with its donor community.

A funded Principal Investigator will be required to submit high level yearly progress reports and an end of project report.

PUBLICITY

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