INDEPENDENT GRANT REQUEST
MSD ONCOLOGY POLICY GRANT PROGRAMME

Realising the full benefit of innovative cancer treatment

MSD Oncology is launching a Policy Grant Programme with the goal of establishing a global community of health policy researchers driving evidence-based and forward-looking health policy recommendations that will improve health outcomes for cancer patients.

Through a competitive process, the Programme will provide up to five grants in its first year. Grants will be awarded up to $100,000 (U.S. Dollars). Each grant will provide funding for health policy projects and will create opportunities to encourage dialogue and dissemination of findings as they relate to access to cancer care.

Prospective applicants should note that the focus of this independent grant Programme is on health policy – in other words: government legislation, regulation, programmes and actions related to cancer. This Programme will not consider grants for research focused on specific clinical therapies or the outcomes associated with such therapies.

Grant disbursal is subject to successful completion of an up to two-month due diligence process for each of the selected applicants.

ABOUT THE MSD ONCOLOGY POLICY GRANT PROGRAMME

For more than a century, MSD has been inventing for life, bringing forward medicines and vaccines for many of the world's most challenging diseases.

Cancer represents one of the world's most urgent unmet medical needs. Worldwide, more than 14 million new cancer cases were diagnosed in 2012.[1] This number is expected to grow to more than 20 million by 2030.[2]

We believe that policy researchers play a critical role – through their research work, educational activity and public outreach – in informing valuable policy dialogues through evidence. Through this *Independent Oncology Policy Grant Programme*, MSD aims to enable institutions to enhance their capacity in research, teaching and dissemination. Beyond supporting independent research, the Programme will provide a forum for researchers to share ideas on emerging cancer policy issues and identify new areas for policy study.

Countries have taken very different approaches setting cancer-related policy goals. Some have developed ambitious and well-resourced national cancer control strategies, while others have not. It is of interest to explore what drives more or less robust approaches to national cancer policy; what characterises national strategies that have had a greater impact on the quality of treatment and health outcomes; and how qualitative evaluation of these has been conducted.

MSD's *Independent Oncology Policy Grant Programme* seeks to encourage research around the following themes:

[1] Ferlay J, Soerjomataram I, Ervik M, Dikshit R, Eser S, Mathers C, Rebelo M, Parkin DM, Forman D, Bray, F. GLOBOCAN 2012 v1.0, Cancer Incidence and Mortality Worldwide: IARC CancerBase No. 11 [Internet]. Lyon, France: International Agency for Research on Cancer; 2013. Available at: http://globocan.iarc.fr/Pages/fact_sheets_cancer.aspx. Accessibility verified on September 12, 2014.

[2] American Cancer Society. Global Cancer Facts & Figures. 2nd Edition. Available at: http://www.cancer.org/acs/groups/content/@epidemiologysurveilance/documents/document/acspc-027766.pdf. Accessibility verified on September 12, 2014.

Theme 1: The social value of cancer treatment

Cancer treatment provides value to society beyond the clinical outcomes of individual patients.[i] Due to the emphasis on patient survival, the non-clinical gains of cancer treatment – such as economic and societal benefits – may currently be undervalued in policy discussions. Policy makers may not consider benefits such as productivity or efficiency gains[ii] when allocating funding to health even though these benefits are of significant importance to patients and the broader community.

Breakthrough therapies can have significant system-wide impacts that affect human resource and other spending not only in health, but in the welfare system and broader economy.

a) *Decision-making, medicines access and health outcomes*

Health authorities in different countries use different data standards, value assessment methodologies, and evaluation processes in deciding whether to reimburse medicines. These standards and methods are not implemented uniformly meaning reimbursement decisions vary greatly between countries.[iii,iv] This can impact patient access and health outcomes.

One study of reimbursement agencies in eight European countries found that while each agency assessed similar types of data, the analysis methods they used varied greatly. It has been suggested that these agencies' decisions could have been improved with greater transparency of the methodologies that they employed.[v]

Differences in evaluation processes can cause (a) delays between countries from the regulatory approval of a product to the reimbursement decision and (b) variations in population of patients gaining access[vi, vii,viii].

It would be valuable to examine the relationship between the speed and scope of reimbursement decisions and the access that patients in different countries have to medicines, with a focus on the health outcomes resulting from their treatment.

It would also be of interest to assess views on the efficiency and effectiveness of reimbursement systems from the perspectives of patients and providers, in contrast with the perspective of other stakeholders including payers.

b) *Financing approaches and access*

Healthcare spending continues to rise globally.[ix,x] Payers who are concerned with the high cost of healthcare are evaluating various approaches to financing medicines with the goal of containing costs.[xi,xii] However, these have the potential to result in restricted access to treatment.[xiii]

Multi-year/ multi-indication-based agreements and other innovative funding mechanisms have been used in ways that accelerate patient access while improving budget and price predictability and reducing the workload of evaluation agencies.

Existing research has examined innovative pricing and contracting approaches to determine their effect on minimising cost burden, while improving patient access.[xiv] This has shown that both complex outcomes-based financing approaches and simpler discount schemes can be beneficial.

More research is needed to better anticipate the patient health outcomes of various financing mechanisms, including access to treatments for patients in need. It would be interesting to assess the

role of health care providers and payors, and their collaboration, in the development and execution of these mechanisms.

c) *Headroom for innovative medicines*

Payers are under pressure to maximise the benefit generated from limited healthcare budgets. This pressure is prompting payers to examine efficiencies in health spending. They are working to reduce or eliminate spending on low-value health interventions to create budget headroom for higher-cost, higher-value therapies and the budget headroom for increased utilisation for patients.[xv]

The value of cancer treatment is rarely considered in relation to other resource use. Where new therapies are shown to be highly cost-effective, it may benefit the health system to reallocate funding away from less valuable interventions to these new therapies.

There is the opportunity to compare new therapies with existing interventions both in health and in the public sector more broadly. This could include areas such as: assessing roles and responsibilities of health provider teams along the pathway of care and optimisation of skills through multidisciplinary teams; and, long term workforce planning focused on the absorption of treatment innovations. This research could potentially lead to identification of resources that could be reallocated. Research is needed to inform efficient means through which reallocations can take place[xvi].

d) *Innovation in cancer treatment*

The innovative pharmaceutical industry has delivered significant advances in the treatment of cancer and many other disease areas through its significant investment in research and development, driven by its ability to recoup the high cost of those uncertain, long-term investments.[xvii] It does this through the temporary market exclusivity provided through the patent system, which results in higher costs for new medicines over a limited period of time.[xviii]

There is ongoing debate regarding the pharmaceutical industry's "license to operate" in relation to the cost of medicines. While there have been some attempts to put alternatives to patent protection in place to incentivise pharmaceutical research,[xix] including research "prizes" and non-commercial R&D operations, intellectual-property rights still provide a significant incentive to fuel the vast majority of R&D in the medicines sector.

It would be of interest to assess how effective existing intellectual property provisions have been in shifting capital into highly risky investments, and relatedly, to estimate the potential consequences of any IP policy changes might be on the development of effective treatments for currently untreatable diseases, including cancers.

It would also be of interest to compare innovation in cancer research with innovation in other economic or social sectors, considering major historical innovations in other areas. This may involve evaluating the value that communities have gained from major non-healthcare / non-cancer innovations in terms of individual, economic, social and emotional benefits and considering them alongside similar measures of the value of cancer innovation.

ELIGIBILITY AND REQUIREMENTS

The principle investigator will be responsible for the successful execution and timely completion of the proposed research. In order to be eligible, applicants must demonstrate the ability to:

a) Complete original, high-quality and independent research, consistent with the proposal submitted in applying for the grant.
b) Maintain independence in completing the research – it is required that researchers maintain full independence in completing and drawing conclusions from their research, both from MSD and from any other third party.
c) Participate in discussion with other successful applicants to explore common themes and issues that arise across the different countries participating in this research.
d) Execute local, researcher-led seminars open to policy makers, clinicians and other key opinion leaders to begin a community of discourse on policy changes needed to maximise the benefit from innovative cancer care no later than end of Q2 2019.
e) Submit 1 manuscript to a local or regional, relevant peer-reviewed journal no later than Q3 2019.
f) Publish 2-3 opinion pieces or other publications to disseminate key insights from the primary research before October 2019.
g) Meaningfully disclose MSD's funding and project methodology.

ASSESMENT

Selection of grantees is based upon a competitive application and review process. This process is informed by the recommendations of a review committee which includes representation from various functions within MSD.

The following criteria will be used to select top grant requests to be considered for the due diligence process:

Policy and contextual relevance of the application.

This criterion refers to strategic and policy relevance in terms of:

a) Expected contributions and ability to advance existing knowledge,
b) Added value and alignment to at least one of the policy areas outlined above; and
c) Relevance to the local social, cultural and policy context.

Innovation and technical quality of the application.

This criterion considers the ability to meet technical quality in the areas of:

d) Innovative ideas and nature of the research,
e) Clear and thorough articulation of aims and objectives, methods, anticipated outcomes; and
f) Full dissemination plan that defines how research findings would be most effectively disseminated.

Ethics and management quality of the application.

This criterion checks if the application is respectful with ethical values and checks if the proposal meets eligibility requirements as stated in the previous section.

Grant disbursal is subject to successful completion of a two-month due diligence process for each of the selected applicants.

APPLICATION PROCEDURE

Grant requests should be succinct and clearly written. Grant requests are limited to no more than 5 pages, not including abbreviated CVs. Full application packages should be single-spaced, 12-point, Calibri typescript with one-inch margins.

Each request must include the following elements:

a) Cover page including:
    a. Name of organisation
    b. Address and contact information
    c. Name of principal investigator and co-principal investigators
    d. Not-for-profit status of organisation
    e. 2-3 sentence summary of the grant request
    f. Project dates
    g. Budget summary
    h. Lead applicant signature
b) An abstract of up to 100 words
c) A proposal narrative not to exceed three-pages
    a. Brief summary of the project
    b. Research hypothesis and corresponding literature review used to develop the hypothesis
    c. Research objectives, methods and anticipated outcomes
    d. Significance of the proposed research including expected contributions to existing knowledge, added value to the field of health policy and adequacy with the local social, cultural and policy context.
    e. Full dissemination plan including stated dissemination requirements.
d) Project timeline which includes:
    a. Planned timing for research findings draft and revisions.
    b. Planned timing of 1-2 local, researcher-led seminars to disclose research plan, preliminary hypothesis and allow for stakeholder input in Q2 2019.
    c. Planned timing for manuscript submission to relevant peer-reviewed journal in Q3 2019.
    d. Planned timing for publication of 2-3 pieces in grey literature (e.g. opinion pieces), to disseminate key insights from the primary research before October 2019.
e) A bio-sketch, not exceeding one page, that includes:
    a. Track record in completing independent, high quality health policy research
    b. Key related publications and grants for principal investigator and co-principal investigators.
    c. Professional appointments and degrees awarded to principal investigator and co-principal investigators.

The application package should be sent via e-mail to: cancerpolicygrant@rabinmartin.com

DEADLINES

September 24, 2018	Proposals due
October 5, 2018	Applicants to begin local due diligence process
December 1, 2018	Final awardees notified
December 15, 2018	Grants Disbursed
March 31, 2019	Completion of local, research-led seminars

APPENDIX A: ORGANISATIONAL REQUIREMENTS

Organisations or projects that meet any of the following criteria are **NOT** eligible for support:

- Organisations or other entities which purchase, recommend, use, reimburse, or prescribe MSD products or have the ability to influence the purchase, utilisation, prescribing, formulary position, pricing, reimbursement, referral, or recommendation of or payment for MSD products, such as a patient, healthcare professional (HCPs) or payer. Note that academic centers in universities with hospitals may be eligible for support following local review.
- Organisations or other entities which provide services to MSD relating to the promotion of its medicines
- Projects that *directly influence* or advance MSD's business, including the purchase, utilisation, prescribing, formulary position, pricing, reimbursement, referral, or recommendation of or payment for its products
- For-profit organisations
- Political organisations, campaigns, and activities
- Fraternal or labor organisations and activities
- Religious organisations or groups whose activities are primarily sectarian in purpose
- Organisations that discriminate on the basis of race, caste, gender, sexual orientation, marital status, religion, age, national origin, veteran's status, or disability
- Capital campaigns, including new construction and renovation of facilities, and endowments
- Basic or clinical research projects, including epidemiological studies, clinical trials, outcomes research, real-world evidence research or other pharmaceutical studies
- Purchase of supplies or equipment unrelated to the proposed project or Programme
- Direct medical care or services, including medical screening or testing, family planning services, purchase of medicines, contraceptive supplies, vaccines or medical devices
- Development of new products
- Fund-raising events, such as benefit dinners/galas
- Payment of staff salaries not aligned with the proposed project or Programme
- Organisations that request a grant greater than 50% of their current annual budget

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