# INDEPENDENT GRANT REQUEST
# MSD ONCOLOGY POLICY GRANT PROGRAM

*Realizing the full benefit of innovative cancer treatment*

The MSD Oncology Policy Grant Program aims to establish a global community of health policy researchers driving evidence-based and forward-looking health policy recommendations that will improve health outcomes for cancer patients.

Being competitive based, the program seeks to provide eight grants in 2020. Each grant will be valued at up to $50,000 (USD), and will provide funding for health policy projects and to 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 program is on health policy – in other words: government legislation, regulation, programs and actions related to cancer. This program 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 PROGRAM**

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]

At MSD, we remain committed to turning breakthrough biomedical innovations into novel therapies that help extend and improve the lives of people with cancer worldwide.

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

MSD's Independent Oncology Policy Grant Program 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.

a) *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 significantly important 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.

At a higher level, 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 would be of interest exploring what drives robust approaches to national cancer policy, and what characterizes national strategies that have had a greater impact on the quality of treatment and health outcomes.

b) *Financing approaches and access*

Healthcare spending continues to rise globally.[iii,iv] Payers who are concerned with the high cost of healthcare are evaluating various approaches to financing medicines with the goal of containing costs.[v,vi] However, these have the potential to result in restricted access to treatment.[vii]

Involvement of government stakeholders to ensure right resources are in the right places is critical. 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 minimizing cost burden, while improving patient access.[viii] 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. Studies of interest may set out to find alternative and innovative solutions to reallocate resources and generate budget headroom.

c) *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.[ix] 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.[x]

There is concern that the pharmaceutical industry's "license to operate" is under threat due to general discontent about the cost of medicines. While there have been some attempts to put alternatives to patent protection in place to incentivize pharmaceutical research,[xi] 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.

Minimal research describes or analyzes other sustainable models, which would allow for and support ongoing R&D. Additionally, there are few critical analyses which assess the negative consequences of short-term policy fixes affecting intellectual property (IP) measures on long term innovation. Assessment of the possible impact of changes to the existing IP infrastructure to currently untreatable diseases is needed. For cancer, this is particularly relevant to the study of new indications for existing therapies, where market exclusivity is limited.

Another valuable topic of study would be the value of innovation in cancer research vs innovation in other economic or social sectors. In establishing the returns that the community gains from these changes, the clinical, economic, social and emotional benefits from health improvement could be considered against gains from other technological advances.

d) *Cancer and COVID-19*

The COVID-19 pandemic has brought to light tough challenges for society, around many fronts. In relation to cancer, it is important to learn from this global crisis and to ensure to capture what are the durable policy lessons from the pandemic and its future impact on cancer care, especially when it comes to social value (how can cancer be prioritized) and room for 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 maximize the benefit from innovative cancer care no later than end of Q2 2021.
e) Submit 1 manuscript to a local or regional, relevant peer-reviewed journal no later than Q4 2021.
f) Publish 2 or more opinion pieces or other publications to disseminate key insights from the primary research by the end of Q3 2021.
g) Meaningfully disclose MSD's funding and project methodology.

**ASSESSMENT**

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 organization
    b. Address and contact information
    c. Name of principal investigator and co-principal investigators
    d. Not-for-profit status of organization
    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) Estimated project timeline including:
    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 no later than Q2 2021.
    c. Planned timing for manuscript submission to relevant peer-reviewed journal no later than Q4 2021.
    d. Planned timing for publication of 2 or more pieces in grey literature (e.g. opinion pieces), to disseminate key insights from the primary research by the end of Q3 2021.
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 shall be sent via e-mail to MSD Global Oncology Policy at oncopolicy02@merck.com

**DEADLINES**

| | |
|---|---|
| August 14th, 2020 | Proposals due |
| October 23rd, 2020 | Final awardees notified, and contract signed |
| November 1st, 2020 | Grants Disbursed |

**APPENDIX A: ORGANIZATIONAL REQUIREMENTS**

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

- Activities that include measuring or modeling of safety, effectiveness, or the clinical outcome of a tool, one of our products, or a class of drug/vaccine in which our company has a product;
- Activities that include research, analysis, or modelling of (i) utilization of any of our Company's products or a class of drug/vaccine for which our Company has a product, and (ii) epidemiology, disease burden, or health economics;
- Organizations or other entities which purchase, recommend, use, reimburse, or prescribe MSD products or have the ability to influence the purchase, utilization, 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.
- Projects that *directly influence* or advance MSD's business, including the purchase, utilization, prescribing, formulary position, pricing, reimbursement, referral, or recommendation of or payment for its products
- For-profit organizations
- Political organizations, campaigns, and activities
- Fraternal or labor organizations and activities
- Religious organizations or groups whose activities are primarily sectarian in purpose

- Organizations 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 program
- 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 program
- Organizations that request a grant greater than 50% of their current annual budget

[i] Quinn, C., Palmer, S., Bruns, J., Borras, J. M., Grant, C., Sykes, D., & Kaura S. (2015). Innovation in Oncology: Why focusing only on breakthrough innovation may be counter-productive. *Haematologica, Biel, 1*(100).

[ii] Hanly, P., Soerjomataram, I., & Sharp, L. (2015). Measuring the societal burden of cancer: The cost of lost productivity due to premature cancer-related mortality in Europe. *International Journal of Cancer, 136*(4). E136-E145.

[iii] PharmacoEcon Outcomes News (2016) 762: 11. https://doi.org/10.1007/s40274-016-3387-4

[iv] Ludwig, W. D. (2016). Current prices of innovative drugs are too high. *Oncology Research and Treatment, Supplemnet 3, 39*(114).

[v] Gonçalves, F. R., Santos, S., Silva, C., & Sousa, G. (2018). Risk sharing agreements, present and future. *Ecancer, 12*(823).

[vi] Aggarwal, S., Topaloglu, H., & Messenger, M. (2013). Novel reimbursement models for cancer drug market access (2010-2013). *Value in Health, 16*(3). A153.

[vii] Colasante, W., Alexander, R., Clark, J., Hickson, S., & Li, X. (2014). The downward trend in oncology drug pricing, speed to market and access. *Value in Health 17*(3). A99.

[viii] Rupasinghe, B., Gilbane, A., Schlegel, C. R., Walsh, K., & Degun, R. (2017). Launching combination therapies in rare diseases: Is high cost burden restricting access?. *Value in Health, 20*(9). A550.

[ix] Sikora, K. (2007). Development and Innovation in Cancer Medicine. *Innovation in the Biopharmaceutical Industry*.

[x] Atun, R., Harvey, I., & Wild, J. (2007). Innovation, Patents, and Economic Growth. *International Journal of Innovation Management* (11). 279-297. 10.1142/S1363919607001758.

[xi] Kiddell-Monroe, R., Greenberg, A., & Basey, M. (2015). Re:Route: A map of the alternative biomedical R&D landscape. *Universities Allied for Essential Medicines.*