

Cancer Immunotherapy Research Grant Announcement: Call for applications

The Danish Health Authority hereby calls for applications for the Danish National Grant: *Immunotherapy – Grant to strengthen Research*. At this second call 29.4 million Danish Kroner is provided to fund a number of projects for the period 2020-2021. The application deadline is September 2nd 2019. The call procedure and associated material are approved by Innovation Fund Danmark according to Section 5 in the ‘Lov om Danmarks Innovationsfond’.

Background

Immunotherapy as a cancer treatment is characterized by making use of the patient’s own immune system to fight cancer cells. This can be done through several different mechanisms, either by enhancing the ability of the immune system to recognize and fight cancer cells, or by weakening the cancer cells’ ability to defend themselves. Immunotherapy can be based on several different types of mechanisms: Antibodies, cytokines, cancer vaccine (treatment), or T-cell therapy.

Immunotherapy – Grant for strengthened research is a part of the Danish Finance Act of 2018, which allocates 60 million Danish Kroner to be granted in the four year period of 2018-2021, please confer to the excerpt in Danish cited below from the Danish Finance Act of 2018.

16.33.40 Pulje til forskning i immunterapi

Kontoen er oprettet i forbindelse med ændringsforslagene med 15,0 mio. kr. årligt i perioden 2018-2021 til forskning i immunterapi, jf. aftale mellem regeringen og Dansk Folkeparti om finansloven for 2018.

Midlerne afsættes til at styrke forskning og udvikling inden for immunterapi, herunder potentialer for at udbrede behandlingen til andre kræftformer eller blive bedre til at målrette behandlingen til dem, der kan få gavn af behandlingen og udmøntes som en pulje, der administreres af Sundhedsstyrelsen.

English Translation of the state of purpose of the Grant in the Danish Finance Act: These Means (the Grant) are allocated to strengthen research and development in immunotherapy, including potentials to widen this treatment to other cancer forms, or to better target the treatment to those, who may benefit from the treatment, and is paid as a Grant administered by the Danish Health Authority.

After the first call for applications in 2018 29.2 million Danish Kroner was granted to seven applicants.

Objective

The primary objective of the Grant is to support scientific research which contributes to:

- development or testing of new immunotherapeutic treatments or new indications for established treatments.

- strengthen the research in the adverse effects of immunotherapy.
- strengthen the research in new methods for selecting patients for immunotherapeutic treatment.
- conduct phase IV studies, defined as studies that contribute to a national mapping of the clinical data of safety and efficacy concerning immunotherapy, through the use of existing databases and registries/repositories.

Additionally, it is essential that the Grants contribute to:

- secure that patients from all relevant hospitals across the country, when relevant will be offered the opportunity to be included in protocols testing new treatments involving immunotherapy.
- spread the knowledge about immunotherapy including enhancing patients' potential to participate in decisions concerning their treatment.

Application requirements

The application must be in written in English and must contain the following information about the research project.

- Project description: see the requirements below (Project Description)
- Budget described in the budget form, accounting for the use of funds in 2020 and 2021. Projects planned to run past 2021 are encouraged to apply for funding, but funding is only granted for the period 2020-2021. Self-financing and co-financing must be described. In the case of partial financing, the projects' total budget must be attached.
- Signatures from all involved investigators, institutes, regions, hospitals and departments concerning the application's content, as well as signed collaboration statements. Collaboration is not a requirement but projects with planned collaboration will be prioritized.
- Approval from The National Committee on Health Research Ethics ideally at the time of application or at latest at November 1st 2019
- Approval from other relevant authorities.
- Projects that received a Grant for the 2018-2019 in the first call for applications are encouraged to apply at this second call if relevant.

Project description [max. 4000 words; front, plain language summaries and references not included]

- Front including project name; name of principal investigator name of primary institution
- Plain language summary [max 250 words] in Danish and in English
 - This must outline the objective of the project, the expected scientific results and the scientific perspective related to future patient treatment.
- The objective of the project
 - The core problem or the main hypothesis must be outlined. It should be clear which scientific area of immunotherapy the project concerns. It must also be stated whether the project is basic research or clinical research.
- Background information
 - The scientific background of the project must be described with systematical reference to relevant literature.
- Motivate the necessity of the project.

- It should be outlined how this project contributes knowledge, which directly or indirectly will benefit Danish patients.
- Project design
 - The research design and scientific materials and methods must be described and if needed including statistics and power considerations as well as considerations regarding inclusion/exclusion criteria and end points. The specific design/method must be accounted for. The potential risks for patients and staff involved in the project must be described.
- Facilities and equipment
 - Research facilities and equipment relevant to the project must be stated, whether present or to be applied for.
- Project timetable
 - The different phases of the project must be clearly communicated and scientific benchmarks described for at least every calendar year must be listed.
- Expected scientific results
 - The expected scientific results related to the core problem/the main hypothesis must be outlined.
- Dissemination of the scientific results
 - It must be outlined how the applicant intends to publish the scientific results in peer-reviewed scientific journals, and shared through other channels.
 - It must be outlined how public dissemination of the results to relevant groups of patients and health professional will be achieved
- Participants, organization and collaboration
 - Principal investigator and primary institution/region/hospital/department must be listed. A list of the scientific publications for the last 5 years must be attached for the principal investigator.
 - Co-investigators as well as primary institution/region/hospital/department of the co-investigators must be listed, with clear affiliations. A list of the scientific publications for the last 5 years must be attached for the co-investigators
 - Planned collaboration including part/assignments in the project and the degree of involvement for investigators, institutions/region/hospital/department, and other members of staff – such as technical staff, students and/or scientific assistants – must be described.
- Institutional embedment of the project
 - It must be described how the project is embedded in the general research strategy of the involved institutions/regions/hospitals/departments. It must be outlined how research activities related to the project will carry on after the expiration of the Grant

What can be applied for?

The application must apply for a minimum of 0.5 million Danish Kroner. Grants may cover:

- Salary to scientific, technical and administrative staff
- Acquisition of equipment essential to the project, including analyzing equipment, analyses, utensils etc. Procurement of IT-equipment will only be covered provided if necessary in order to operate analyzing equipment essential to the project. Equipment expenses (analyses exempted) up to 100.000 Danish Kroner per calendar year will be covered

- Attending scientific conferences may be covered for the principal investigator with up to 10,000 DKK, if the conference has accepted an abstract related to the project for presentation (oral or poster)
- Data management, whether performed by own designated staff or by contract
- Project coordination expenses
- Fee for Open Access Publications of the project results, with up to 10,000 DKK
- Tuition fees – e.g. in relation to Ph.D. projects
- Development and dissemination of relevant information – patient information and other knowledge sharing etc.
- Administrative support (overhead) will be granted on the basis of the legal status of the participating institutions. A 44 % overhead can be granted to institutions encompassed by the regulations concerning subsidized research activity described in the Ministry of Finances budget guide (e.g. Universities). A 3.1 % overhead can be granted to Danish public hospitals.
 - Administrative support can cover non-scientific, administrative expenses directly related to the project. Administrative support can via the host institution be shared between the institutions of the main- and co-applications.
 - Administrative support is not automatically included in the Grant, and must therefore be specifically applied for in the budget.
- Travel expenses other than the above mentioned (conference) will not be covered.
- Projects that received a Grant for the period 2018-2019 in the first call for applications and who have received permission to extend the grant period into 2020 cannot apply for means coverings budget posts already covered by the extended Grant period.

Requirements for Grant recipients

Publication of results in relevant peer-reviewed journals is compulsory, regardless of the scientific results. The principal investigator and co-investigators, involved institutions and staff related to the project must oblige to the criteria stated in The Danish Code of Conduct for Research Integrity. The principal investigator is obliged to once a year supply a written follow-up to the Danish Health Authority. A follow-up form will be sent to the principal investigator. The follow-up form contains two sections; a scientific section and an administrative section. The scientific follow-up must list advancement related to the benchmarks stated in the project description, results and any divergence from the protocol/project description. Further, the main investigator should no later than three months after the expiration of the Grant submit an end report to the Danish Health Authority. The end report should include a scientifically extensive report describing the scientific results, covering the entire timeframe of the Grant. The Danish Health Authority can at any point throughout the period request details on the progression, or lack thereof, of the project. The Grant recipient is committed to supplying these data within a reasonable timeframe. The Grant recipient must also contribute with any demanded material and be available for evaluation meetings, interviews etc. in the event that the Danish Health Authority or an external party wishes to evaluate the allocation of the Grant.

Multiannual allocation

In case of multiannual allocations, it will be a requirement that the Danish Health Authority can approve ongoing scientific and administrative follow-ups. In the event that the Danish Health Authority is unable to do so, it may be required that the Grant recipient repays funds from the date of follow-up.

The scientific evaluation process

The Danish Health Authority's Scientific Committee for Immunotherapy Research (DHA-SCI) will evaluate the applications. 4-6 leading international researchers in the field of immunotherapy staff DHA-SCI. The committee will review all applications and evaluate their quality through a transparent and quantitative evaluation model (*Evaluation of research applications*). The following evaluation criteria will be used.

- Research outline including the originality, the conception, the methodology, the relevance to patients and clinical impact and perspective of the project
- Principal investigator
- Co-investigators
- Planned collaborations
- Facilities
- Scientific merit of the investigators
- Degree of national collaboration and the project's national perspective
- Description of how the scientific results will benefit Danish patients

Applications will be evaluated on equal terms whether the project application was a grant recipient at the first call for applications or not.

The scientific assessment by DHA-SCI will be approved by Innovation Fund Denmark according to Section 5 in the 'Lov om Danmarks Innovationsfond'.

The Danish Public Administration Act, including the article on right of access to documents, covers the committee's judgments.

The committee's evaluation of the individual applications will be forwarded to the applicants following the evaluation process.

DHA-SCI may advise the Danish Health Authority regarding the Grant distribution though it is The Danish Health Authority, who will decide which applicants, who will receive a Grant. These decisions by the Danish Health Authority are based on the above mentioned evaluation and the purpose of the Grant stated in the Danish Finance Act (*to strengthen research and development in immunotherapy, including potentials to widen this treatment to other cancer forms, or to better target the treatment to those, who may benefit from the treatment*). The Danish Health Authority will issue requirements for follow-up. The Grant will be transferred to the applicant's research account (forskningskonto) in the institution, which houses the project and the principal investigator, in compliance with the administrative rules on extern research funds at the applicant's institution. The Grant is dependent on the Danish parliament accepts the Danish Finance Act for respectively 2020 and 2021. The Grant can only be used as specified above for the particular project for which funding is obtained, and excess/unspent funding must be returned to the Danish Health Authority by the end of the fiscal year.

Applications in a single PDF-file must be sent by email to the Danish Health Authority at plan@sst.dk with the following text in the subject line:

- "Immunotherapy Research Grant – journalnr. 4-1612-318/1, [*name of principal investigator*]."

Application deadline is September 2nd 2019 at 15:00 CET