

Guidance for the Applicants:

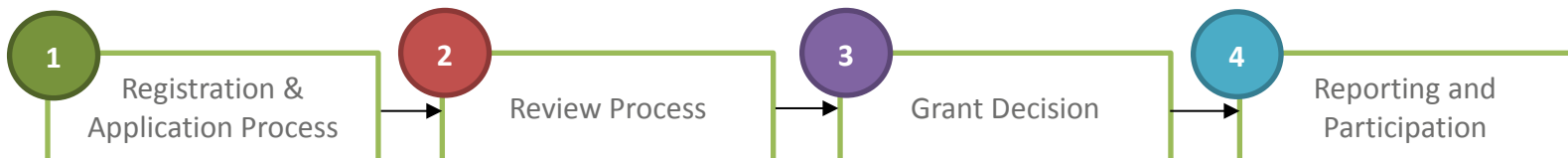
Gilead Sciences Nordic Fellowship Programme 2018

This is the sixth year of the Gilead Sciences Nordic Fellowship Programme. Applications are invited from health-care organisations and/or academic institutions.

Applications are accepted from April 3, 2018 to June 29, 2018. The following information will be helpful in assisting you to prepare your application.

1. HOW TO APPLY?

Go to: <http://www.gilead.com/responsibility/corporate-contributions/europe/europe-grant-application-process>



1 Register your organization and receive log-in details; respond to all the questions within the application (objective, activities, budget etc), and then submit application.

2 Nordic medical affiliate conducts preliminary assessment to ensure application completeness. Application is routed for review by the judging committee (see section 9), with a decision of either full approval, partial approval or a decline.

3 Funding decision is communicated via email to all applicants, and for the approved projects, payment is electronically transmitted upon full contract execution.

4 All funded projects will be required to submit progress reports at predefined intervals, and the grantee are asked to participate in Gilead best practices sharing event (BPSE).

2. WHAT IS THE AIM OF THE PROGRAMME?

The aim of the Gilead Sciences Nordic Fellowship Programme is to award financial grants to projects (local, national or Nordic) that encourage the development, exploration and dissemination of new ideas, generating best practice in the delivery of patient-centred care in three areas – HIV, liver diseases (LVD), and hematology/oncology (ONC).

The projects supported under the Gilead Sciences Nordic Fellowship Programme are independent of the use of any particular therapeutic agent.

Applications for financial grants and support will be judged according to the criteria specified in section 10 and awarded to organisations or groups, which are responsible for providing, planning, evaluating or supporting services in the relevant therapy areas.

Evidence generated from Fellowship projects provides the opportunity to shape public health policy and practice, or to generate new studies or joint ventures to shape clinical care pathways.

Gilead Sciences Nordic Fellowship Programme only funds projects within the Nordic countries, i.e. Sweden, Norway, Finland, Iceland and Denmark (incl. Greenland and Faroe Islands).

Applications are invited from health-care organisations and/or academic institutions.

3. IN 2018, NORDIC FUNDING AMOUNTING TO SEK 3,000,000 IN TOTAL WILL BE AWARDED TO APPLICANTS WHOSE PROPOSALS BEST DEMONSTRATE A PLAN TO DELIVER:

HIV

- Innovative strategies aiming to reduce new infections and the pool of undiagnosed individuals (eg. public awareness projects to recognize or avoid risk behaviour and projects to encourage testing).
- Projects aiming at identifying and managing comorbidities and/or improving the quality of life among PLWHIV.
- Pre-clinical HIV compartment research.*

Liver diseases (LVD)

- Disease awareness projects with emphasis on risk behaviour and screening and linkage to care.
- Ways to improve patient management. Documentation of burden of disease, patient reported and/or treatment outcomes.
- Outcomes from national/regional registries.
- Basic research projects within liver diseases.*

Hematology/Oncology (ONC)

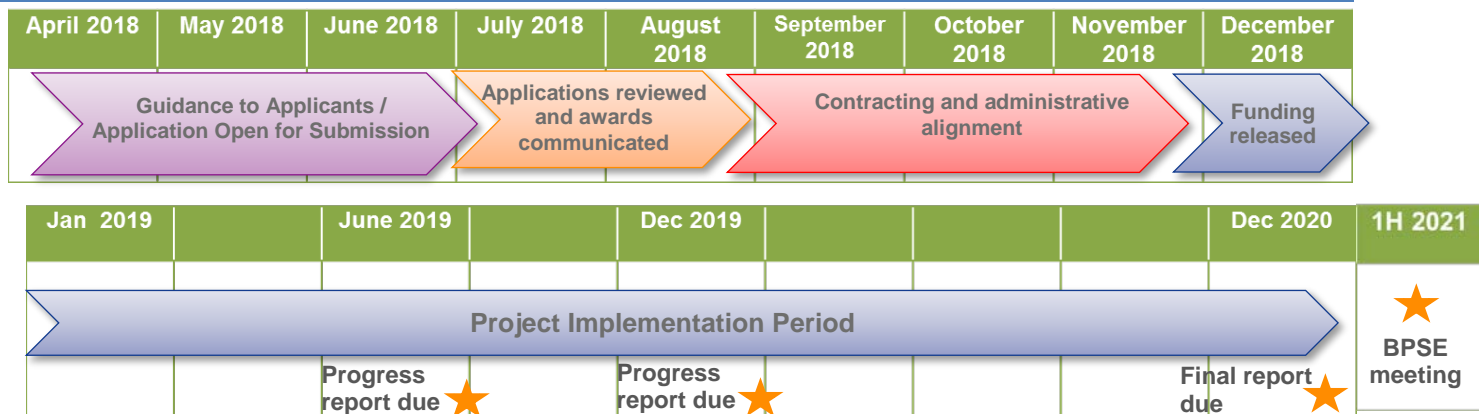
- Establishment or evolution of nation-wide/Nordic quality registries.
- Ways to improve patient management within B-cell lymphomas. Documentation of epidemiology, burden of disease, patient reported and/or treatment outcomes.
- Pre-clinical research projects with a focus on molecular genetics in B-cell lymphomas.*

**Excluding proposals that meet the criteria for a clinical trial under the EU Clinical Trials Directive 2001/20/EC or investigator sponsored trials. Such projects will not be funded under the fellowship program.*

4. CAN I APPLY FOR 100% OF PROJECT FUNDING TO COME FROM GILEAD SCIENCES NORDIC?

Yes.

5. WHAT IS THE TIMELINE FOR THE FELLOWSHIP PROGRAMME?



6. DO APPLICATIONS NEED TO INCLUDE REFERENCES?

Appropriate citations should be provided for all statistics and references should be listed in the application.

7. YOU MUST CONSIDER WHETHER YOUR PROPOSED PROJECT COMPRISES A CLINICAL TRIAL

If your project meets the EU directive definition of an interventional study it will not be funded under the fellowship program. Such projects should instead be sent to rebecca.frigell@gilead.com for consideration as an investigator sponsored trial.

EU directive definition of interventional study must meet any of the following three criteria:

1. Assignment of the subject to a particular therapeutic strategy is decided in advance and does not fall within normal clinical practice (i.e., the treatment regime typically followed to treat, prevent, or diagnose a disease or a disorder) of the member state concerned.
2. The decision to prescribe the investigational medicinal products is taken together with the decision to include the subject in the clinical study.
3. Diagnostic or monitoring procedures in addition to normal clinical practice are applied to the subjects.

8. WHAT INFORMATION SHOULD BE INCLUDED IN THE BUDGET?

All applications must include full details of the amount of funding being requested. A justification must be provided for all items in the budget table on the application.

Funding requests for additional staff can only be considered for project-dedicated staff time to execute the project. **Applications without an appropriately completed budget table cannot be considered.**

9. WHO IS ON THE JUDGING COMMITTEE?

The voting committee consists of senior representatives from the Medical, Regulatory, Legal and Finance departments within Gilead Sciences Nordic. In addition, the General Manager of Gilead Sciences Nordic will be present at the judging sessions as a non-voting member.

10. WHAT DOES MY APPLICATION NEED TO INCLUDE? - WHAT ARE THE JUDGING CRITERIA?

- Clear purpose and rationale for the project
- Objectives and overview of the project, including specific goals and population to be targeted
- Description of how the project achieves innovation
- Information regarding the applicant's capacity to initiate and implement the project in a timely manner
- Methodology:
 - Specific, measurable, achievable, realistic and time-sensitive project milestones and action steps required to meet project goals
 - Process for data collection and analysis, including which staff members will analyse the data
 - Deliverables in terms of measurable objectives and outcomes
 - Clear description of project outcome data and how they will improve patient care including relevant patient-related outcome data, if applicable (which should ideally be measured using validated tools)
 - Methodology for the collection and reporting of cost-effectiveness data, if applicable
- Outline of your publication plans
- Clear details of the budget (see section 9 for further details)

11. CAN I APPLY FOR SUPPORT ON A CURRENTLY ONGOING PROJECT?

Yes, as long as the funding will be used to extend or expand an existing project that will be completed before the end of December 2020 and the proposal meets the criteria. The application must highlight why additional funding is required for the completion of the project. This must be explained in the application form.

12. WILL FEEDBACK BE PROVIDED ONCE APPLICATIONS HAVE BEEN SUBMITTED?

All submissions will be reviewed prior to judging for completeness of applications.

If, for any reason, further clarity is needed on an application, an email will be sent to the applicant to seek clarification (and, if needed, re-submission) before the closing date.

13. CAN I RECALL AN APPLICATION TO MAKE CHANGES?

Yes, on the condition that the application is re-submitted by the final deadline on June 29, 2018. To recall a submitted application, email: rebecca.frigell@gilead.com

14. WHAT CAN I EXPECT IF MY APPLICATION IS SUCCESSFUL?

All successful applicants will be notified by August 31, 2018 and will be asked to sign a grant agreement letter. The Grant Agreement Letter summarises the core requirements of the grant award, the amount of grant and the responsibilities for each party including the right of Gilead Sciences Nordic to review any potential publications from the project.

Successful applicants will be required to engage with members of the Gilead Sciences Nordic Medical Affairs department and should provide Gilead Sciences Nordic with an interim written report concerning the progress of the project 6 and 12 months after project initiation. In the event that the project has not commenced or adequately progressed, Gilead Sciences Nordic in its sole discretion may request payback of some or all the funding.

Final reporting: in addition to the interim reports, the applicant should provide Gilead Sciences Nordic with a final report on the project which includes the final findings and conclusions no later than at completion of the project.

A standardised reporting template for interim and final reports will be made available by Gilead Sciences Nordic.

The applicant must also present the project findings at a meeting organised by Gilead Sciences Nordic to share best practice (BPSE) in 2021/2022.

15. ON A SUCCESSFUL APPLICATION, WHEN DOES THE WORK FOR THE PROJECT HAVE TO BE COMPLETED?

It is expected that projects will be completed within 24 months.

16. WHEN WILL FUNDING BE PROVIDED?

On the successful award of a Fellowship grant, Gilead Sciences Nordic will state which items of the project will be supported and full project payment will be made by year end 2018.

17. WHAT COMMITMENTS MUST SUCCESSFUL APPLICANTS MAKE?

Successful applicants will:

- Provide Gilead Sciences Nordic with standardised interim and final reports on their project
- Attend a Gilead Sciences Nordic-organised meeting in 2021/2022 to share best practice (BPSE meeting):
 - Give an oral presentation describing their project results and best practices
- Strive to make the results generated during this fellowship publically available in some format, e.g. poster, manuscript etc. All draft material must be supplied to Gilead Sciences Nordic for review at least 10 working days prior to any public communication. Gilead Sciences Nordic should be acknowledged in any publication in connection with the grant stating that “this has been supported by an unrestricted grant from Gilead Sciences”.

18. WILL UNSUCCESSFUL APPLICANTS GET FEEDBACK?

The judging panel can supply feedback for unsuccessful applicants within 6 weeks of the judging decision. This will be available on request only.

19. CAN APPLICANTS WHO ARE UNSUCCESSFUL THIS YEAR RE-APPLY NEXT YEAR?

Yes, applicants who are unsuccessful in 2018 can apply to the 2019 programme.

If you have any questions regarding the application process or more specific application queries, please send them to rebecca.frigell@gilead.com.