

Guidance for the Applicants:

Gilead Sciences Nordic Fellowship Programme 2017

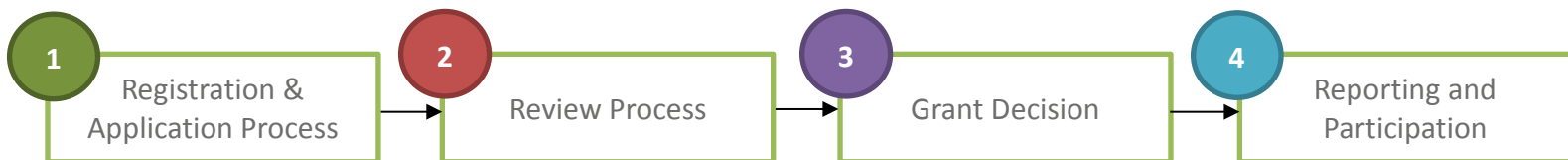
This is the fifth year of the Gilead Sciences Nordic Fellowship Programme.

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

Applications are accepted from April 3, 2017 to June 30, 2017. 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 Review guidance documents, register your organization and receive log-in details, respond to questions within application, upload Nordic questionnaire and submit application.
- 2 Nordic affiliate conducts preliminary assessment to ensure application completeness. Application is routed for review, denial or to request additional information from the applicant.
- 3 Funding decision is communicated via email to applicant and payment is electronically transmitted upon contract execution and receipt of a valid invoice.
- 4 All funded projects will require budget reconciliation, submission of progress reports at predefined intervals, and the grantee are asked to participate in Gilead best practices sharing program.

2. WHAT IS THE AIM OF THE PROGRAMME?

The aim of the Gilead Sciences Nordic Fellowship Programme is to award financial grants to encourage the development, exploration and dissemination of new ideas which generate and promote best practice in the delivery of patient-centred care through innovative and reproducible models in three areas – HIV, viral hepatitis (including hepatitis B virus (HBV) and hepatitis C virus (HCV)), 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 11 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 (either at a local or national level) in the Nordics, 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 2017, NORDIC FUNDING AMOUNTING TO SEK 3,000,000 IN TOTAL WILL BE AWARDED TO APPLICANTS WHOSE PROPOSALS BEST DEMONSTRATE A PLAN TO DELIVER:

HIV

- Projects aiming to reduce new infections and the pool of undiagnosed individuals (eg. public awareness projects to recognize, modify 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.
- Establishment or evolution of nation-wide quality registries. Nordic collaboration is encouraged.
- Pre-clinical research projects on HIV inflammation.

Viral hepatitis (HBV and/or HCV)

- Disease awareness projects with emphasis on screening and linkage to care.
- Documentation of burden of disease, patient reported and/or treatment outcomes.
- Epidemiological outcomes from national/regional registries.
- Pre-clinical research projects within HBV looking at comorbidities.

Hematology/Oncology (ONC)

- Establishment or evolution of nation-wide/Nordic quality registries.
- Ways to improve patient management within indolent 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.

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. WHAT DOES MY APPLICATION NEED TO INCLUDE?

The outline below indicates what should be included. Further information on judging criteria is listed in section 11.

- Purpose of 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
- Outline of your publication plans
- A clear methodology including:
 - 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
 - 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
- Clear details of the budget (see section 9 for further details)

8. 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 goran.skoglund@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.

9. 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.**

10. 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.

11. WHAT ARE THE JUDGING CRITERIA?

- Clear purpose and rationale for the project (including innovation)
- Methodology:
 - Deliverables in terms of measurable objectives and outcomes
 - Illustration of how outcomes will improve patient care
 - Collection/reporting of actual project-related costs
 - Clear timelines and milestones
- Budget clarity

12. 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 2019 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.

13. 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.

14. CAN I RECALL AN APPLICATION TO MAKE CHANGES?

Yes, on the condition that the application is re-submitted by the final deadline on June 30, 2017. To recall a submitted application, email: rebecca.frigell@gilead.com

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

All successful applicants will be notified by August 31, 2017 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 2020/2021.

16. 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.

17. 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 2017.

18. 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 2020/2021 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”.

19. 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.

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

Yes, applicants who are unsuccessful in 2017 can apply to the 2018 programme.

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

Supplementary Questions for Applicants

1. WHAT WOULD BE YOUR KEY MEASURES OF SUCCESS AND HOW WOULD YOU MEASURE THESE? – AND HOW DOES THIS PROJECT ACHIEVE INNOVATION?

Describe your key measures of success, how you would measure these and how this project achieves innovation

2. PLEASE DESCRIBE HOW YOU WOULD ASSESS PATIENT-RELATED OUTCOMES, IF APPLICABLE (PREFERABLY VALIDATED TOOLS).

If applicable, please describe how to assess patient-related outcomes

3. WILL YOU REQUIRE ETHICS APPROVAL FOR YOUR PROJECT?

Yes No

If yes, please specify if this has been submitted and the expected timeline for review:
 Please specify timeline for ethics review

4. WHERE DID YOU HEAR OF THE GILEAD SCIENCES NORDIC FELLOWSHIP PROGRAMME?

- Email/Letter from Gilead Sciences Nordic Word of mouth
 Medical association Gilead Sciences Nordic personnel
 Other (please state):

5. ACKNOWLEDGEMENT

- I agree that the project will be completed by end of December 2019.
- If my application is successful, I (or a nominee) agree to engage with members of the Gilead Sciences Nordic Medical Affairs department and complete standardised status reports at 6 and 12 months and a final report no later than 24 months.
- If my application is successful, I agree to work with Gilead Sciences Nordic to present the project findings at a Gilead Sciences Nordic-organised meeting to share best practice in 2020/21.
- I will 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 should be acknowledged in any publication in connection with the grant stating that “this has been supported by an unrestricted grant from Gilead Sciences”.
- I have examined the project and confirm this is not an interventional study based on the EU directive definition, and thus fulfill the criteria of the fellowship program.

Name:

Date:

After submission, an acknowledgement will be sent to the email address you have entered on your application form to confirm receipt.