



Natural History Study Project Application

Project detail can be found online at:

<http://rarediseases.org/patient-registries/nord-fda>

Project Application Timeline

Application period opens: December 8, 2015 at 9am EST
Application period closes: January 29, 2016 at 8pm EST
Awards announced: February 29, 2016, Rare Disease Day!

Project Overviews:

Webinar 1: December 22, 2015 at 1pm EST
Webinar 2: January 7, 2016 at 1pm EST
Webinar 3: January 20, 2016 at 1pm EST

Application Criteria

1. 501(c)(3) Organizational Member of NORD
2. Commitment and resources to administer a registry and collaborate with NORD for at least five years to properly evaluate outcomes
3. Support from disease community and experts who will be able to contribute to the design and success of the project, including selecting disease-specific questions and ensuring patient engagement and retention

Selection Criteria

1. Unmet medical needs
2. No existing or limited natural history data
3. Research gaps that could potentially be addressed by a natural history study

Complete applications should be sent to research@rarediseases.org



Organization Detail

Name of Organization

Key Contact

Name

Title

Phone Number

Email Address

Disease Detail

Disease or diseases intended for natural history study

Name

Physiological system

Link to disease information

Patient Engagement

How large is the US patient population?

How large is the International patient population?

How many are members of your organization?

How would you plan to recruit for the natural history study?

Please describe the diagnostic challenges and prognosis for patients with the disease?



Study Impact

Is there an existing natural history study or patient registry? If yes, please tell us why another study would be beneficial.

Are you currently collecting any disease information from your members via a survey? If so, please tell us more about this effort.

Is there any ongoing research related to the disease? If so, please tell us more about this effort.

Are there any existing treatments or treatments currently being developed?

How would developing a natural history study as part of this project help the disease population?



Project Team

Project Manager

Medical, Scientific, or Disease Experts to support question development

Long-term Support

Do you have the staff and budget to support the management and maintenance of the study for at least 5 years?

- Implementation Fee – waived
- Enhancements, maintenance and support services - \$500/month

Yes No

Is there anything else you would like us to consider as we review this application?