

# Privacy Notice and Consent Agreement for Telephone interview

Version 3.0: 14 December 2018

## About this document

This document has three parts:

- 1) Study Information
- 2) Privacy Notice
- 3) Consent Agreement

## Study Information

Please ensure you have read the document **Participant Information Sheet – Interview**

### Introduction

BresMed Health Solutions Ltd is an independent health economic and outcomes research consultancy. BresMed is conducting interviews regarding the burden of acute porphyrias. This research is on behalf of the sponsor, Alnylam Pharmaceuticals, with the assistance of the British Porphyria Association. We would value understanding your experience.

The purpose of the research is to better understand the impact of acute porphyria on you as a patient or as the caregiver of someone with acute porphyria. The questions are aimed to better understand the acute and chronic symptoms experienced, disease management, and impact on work, social life and overall quality of life. It will take the form of a telephone interview which will take approximately one hour to complete. The telephone interview can be completed at any location with suitable privacy and telephone access and will take place between January 2019 and March 2019.

Sharing your experience will help to further understand the burden of acute porphyria and could benefit future research and development of treatment procedures. Your participation is highly appreciated. If you have any questions, please contact Nicola Mason at BresMed Health Solutions Ltd by email [nmason@bresmed.com](mailto:nmason@bresmed.com)

## Privacy Notice

To conduct the telephone interviews, we will collect and process your name, email address, telephone number or mobile number and an audio recording of the interview.

Any information you provide will be treated as confidential. It will be combined with feedback from other patients or caregivers of those living with acute porphyria. You will remain anonymous unless you give permission to be identified.

BresMed Health Solutions Ltd. will record or document your session in several formats or media. This may include notes taken by the interviewer and by audio recordings, details of which will be given to you at the beginning of the interview session. BresMed Health Solutions Ltd. will keep all resulting notes, recordings and other documentation for viewing, transcribing, analysing and data processing purposes. BresMed Health Solutions Ltd. will present anonymised findings of the study in a report to The British Porphyria Association and Alnylam Pharmaceuticals. The report may contain anonymised quotes from the interviews. The report will not include information that directly personally identifies you, such as your name and date of birth.

The research will comply with applicable data protection laws and the British Healthcare Business Intelligence Association legal and ethical guidelines.

Your information will only be used for the research described and will not be passed to any other organisation without your permission. The sponsor may use this anonymised information (including anonymised quotes and aggregated information combining all the responses to this research) in three main ways: 1) to develop models of the personal and economic burden of acute porphyria, which support applications to groups which assess the value of new treatments. 2) as part of ongoing disease education to healthcare professionals and patient organisations. 3) in publications in medical journals or presentation at medical congresses.

We will collect and use any information about you only if you provide your consent to do so. We will not keep any personal data you give us for longer than 12 months to allow completion of the aggregated data report.

We are required to pass on to Alnylam Pharmaceuticals any details of side effects or product complaints relating to their products that are mentioned during the interview. This is to help them comply with applicable laws and regulations and learn more about the safety of their medicines. If this happens, we will need to collect details and report the side effects or product complaint. In this instance, you will be asked to give permission for us to pass your details to the company's drug safety department for follow-up. This will have no impact on the confidentiality and anonymity associated with the interview itself.

If the interviewer has reasonable cause to suspect that a vulnerable individual they come into contact with during the research, either directly or indirectly, is suffering or is likely to suffer significant harm, and a referral must be made to the appropriate authority without delay in order that the individual can be protected the interviewer must ensure that any disclosure of a confidential nature, which may be potentially harmful to the individual, must be dealt with in a sensitive and responsible manner.

You have the right to refuse to answer questions or withdraw at any time. For more information about your rights, or to obtain a copy of our privacy notice please contact Sarah Laycock by email [info@bresmed.com](mailto:info@bresmed.com)

We also remind you that you are also entitled to lodge a complaint with the supervisory authority, the Information Commissioner's Office (ICO), for the protection of personal data if you consider that your statutory rights have not been respected or that you have not received a response to your requests according to the law. The ICO is the UK's independent authority set up to uphold information rights in the public interest, promoting openness by public bodies and data privacy for individuals. You can contact the ICO at their helpline (0303 123 1113) or by visiting their website (<https://ico.org.uk/make-a-complaint/>).

## Consent Agreement

Project Title: Interviews to elicit the burden of illness of acute porphyria in and patients and caregivers

Subject and purpose of Study: The purpose of the research is to better understand patients' journeys to a diagnosis of acute porphyria as well as the impact of acute porphyria on patients and caregivers, including the acute and chronic symptoms experienced, disease management, and impact on work, social life and overall quality of life.

Location: Telephone Interview  
Duration: ~1 hour  
Date: January to March 2019

### Consent

Consent Section to be sent back to BresMed Health Solutions Ltd by email [nmason@bresmed.com](mailto:nmason@bresmed.com)

YES, I [INSERT NAME, SURNAME, ADDRESS] wish to take part in the telephone interview.

- I have read and understood the information for the above research and have had the opportunity to ask questions about it.
- I understand that the research is being conducted on behalf of a pharmaceutical company.
- I understand that my interview will be documented by BresMed Health Solutions Ltd., but my personal identifiable information will not be shared with the sponsor or other third parties as outlined above.
- I understand that my participation is voluntary and that I am free to withdraw from the research and my consent at any time, without giving any reason.
- I consent to the collection and use of my personal data as described above.
- I consent to the use of the results derived from this research as described above.
- I agree to take part in the above research.

In this regard, I confirm that I have received and read the information in the Privacy Notice and Consent Statement sent to me by email.

I understand that my interview will be audio recorded and documented in various electronic and non-electronic media by BresMed Health Solutions Ltd.,

### Sponsor

The sponsor and data controller of this research is Alnylam Pharmaceuticals Ltd, Braywick Gate, Maidenhead, SL6 1DA.

### Data Protection Officer

Alnylam Pharmaceuticals has designated a Data Protection Officer ("DPO"). The DPO can be contacted via the following communication channel: [EUdataprivacy@alnylam.com](mailto:EUdataprivacy@alnylam.com)

Short Title: Qualitative burden of illness study in UK AHP patients/carers v3.0