IRB APPROVED
Feb 20, 2024

Information & Consent Notice: Survey to better understand the patient journey of preterm born people with respiratory dysfunctions.

TITLE:	Patient journey of preterm born people with respiratory dysfunctions, EMPOWER survey
PROTOCOL NO.:	None WCG IRB Protocol #20240665
SPONSOR:	Chiesi
INVESTIGATOR:	Cynthia Lesbros, PhD 1 Rue de Stockholm Paris 75008 France
STUDY-RELATED PHONE NUMBER(S):	0033-1-84-17-42-71

Taking part in this research is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have any questions, concerns, or complaints or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

What should I know about this study?
Taking part in this research is voluntary. Whether you take part is up to you.

You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.

You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.

The time to answer the full questionnaire is estimated to 20 minutes.

What is the aim of this survey?
The objectives of this study are to:

- ✓ Understand patient's awareness about preterm status and its influence to further develop comorbidities, including respiratory diseases,
- ✓ Evaluate the impact of preterm status on chronic respiratory disease management and quality-of-life,
- ✓ Understand how the preterm status is considered by HCPs along the patient care journey.

What is expected from me to complete the study and how long will it last?
This study includes one online questionnaire of thirty-four questions. The questionnaire asks about general questions on profile, preterm awareness and patient care journey.

Inclusion and Exclusion criteria
Inclusion criteria:

- Having given electronic informed consent prior to participation,
- Aged 18 years old and over,
- Living in France, Germany, Spain, United Kingdom or United States of America,
- Born prematurely
- Living with Asthma and/or Chronic Obstructive Pulmonary Disease (COPD)

No exclusion criteria have been defined in order to avoid any selection bias that may result in patients' exclusion.

Could being in this study hurt me?

- Some questions may be personal or upsetting. You can quit the survey at any time.
- Anytime you share information online there are risks that your data could be hacked or intercepted. We're using a secure system to collect this data but we can't completely eliminate this risk.
- Breach of confidentiality: There is a chance your data could be seen by someone who shouldn't have access to it. We're minimizing this risk in the following ways:
    - The data collected are not directly identifiable, but pseudonymized.
    - We limit the data collected to what is necessary for the purposes of the processing activities, in order to reduce the identifying nature of the data and the accumulation of such data.
    - We will only share aggregated data with the sponsor, which will not allow the identification of individual participants.
    - We'll store all electronic data on a secure server.
    - We'll keep your identifying information separate from your research data, but we will be able to link it to you.

Will it cost me money to take part in this research?
No.

Will being in this research benefit me?
There are no direct benefits to you from taking part in this research. However, we hope that your participation in the study will help understand more about the patient journey of preterm born people with chronic respiratory disease.

What happens with your data?
No personal data collected through this survey will be transmitted to a third party.

Your Personal Data will be used to conduct this survey, conduct the analysis, reporting and regulatory submission, as the case may be, meet the above-mentioned goals of the survey, as well as for statistical purposes. We will not use your Personal Data for other purposes.

Personal questions (gender, date of birth and country of residence) can also be used to complete your Carenity profile and to offer you a personalised content on Carenity.

The data is shared pseudonymously and in aggregate form, and thus do not allow any personal identification of the participants. The study results will be transmitted to a pharmaceutical company committed to the care and improvement of the quality of life of people suffering from respiratory diseases, including asthma and COPD, as well as with representatives of Patient Advocacy and the HealthCare Professionals who have been involved in the development of this survey. The aggregated results will also be shared with WCG IRB, the Institutional Review Board (IRB) that reviewed this research.

The analysed results can be subject to scientific publications or communications during scientific congresses.

Your personal data is stored by Else Care SAS until the final report on the results has been completed or until the study results have been published, after which your personal data will remain archived for the period of 5 years before being completely deleted.

Who can answer my questions about this research?
If you have questions about this project or if you have a research-related problem or concern, you may contact the project manager, Cynthia Lesbros, at this email address cynthia@carenity.com, the following phone number +33 1 84 17 42 71, or the following address:

1 rue de Stockholm
75008 Paris, France

If you have any questions regarding your rights and welfare in research, you may also contact WCG IRB at this email address: clientcare@wcgclinical.com, the following numbers: 855-818-2289.

What rights do you have regarding your data?
According to the current legislation, you have the right to:

- Access and rectify your personal data;
- Object to and delete your personal data;
- Withdraw your consent at any time;
- Request restriction of processing;
- Be forgotten and to erasure of personal data;
- The portability of your data;
- Lodge a complaint with the CNIL.

To exercise your rights, you may, if you are logged into your Carenity account, send a private message to your Community manager by clicking here.

You may also contact the ELSE CARE SAS data Protection Officer for any questions regarding your personal data, at the following e-mail address: dpo@carenity.com.

Within what framework are your data collected?
Your participation is voluntary. The treatment of your health data is conducted based on your explicit consent, which is formalised by the click on the "Start" button on the survey's introduction page. You may withdraw your consent at any time without providing a reason, without affecting the lawfulness of the processing carried out prior to the withdrawal of your consent.

Who is responsible for the treatment of my data?
Carenity is the data controller. The data controller may be contacted at the following email address: dpo@carenity.com.

Can I be removed from this study without my approval?
The person in charge of this study can remove you from this study without your approval. Possible reasons for removal include:

- Too little time spent on a questionnaire: respondents who will spend less than 5 seconds per question will be excluded, which corresponds to less than 3 minutes.
- Similar patterns when rating scales (e.g. always the same mark, obvious sequence of numbers like 1,2,3,4,5,6)
- Duplicated entries

What happens if I agree to be in the research, but I change my mind later?
Your participation in this online study is voluntary and you may withdraw consent for data collection at any time.

If you withdraw consent for the use of your data, the data controller will not keep record or use any data collected before the withdrawal.

Will I be paid for taking part in this research?
You will not be paid for completing the survey.