APPROVED BY SALUS IRB: 20 SEPTEMBER 2023

Caregiver Participant Information Sheet and Consent Form: Survey (UK)

Sponsor:	AbbVie
Protocol Number and Title:	21091; Patient Preference Study in Advanced Parkinson's Disease
Investigator:	Marco Boeri, PhD
Address of Study Site(s):	OPEN Health 20 Old Bailey London EC4M 7AN United Kingdom
Telephone:	+44 (0) 1628 48112

PART 1

Invitation to take part

We would like to invite you to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully and talk to other friends, relatives or your General Practitioner (GP) about this study if you wish. A member of our team will go through this Caregiver Participant Information Sheet with you and answer any questions you have.

- **Part 1** tells you the purpose of this study and what will happen to you if you take part; and
- **Part 2** gives you more detailed information about how this study will be conducted.

If you agree to take part in this study, a research team member will ask you to indicate your consent verbally and this will be audio recorded before the start of the interview. If there is anything that is not clear or if you would like more information, please ask.

The names of the sponsor for this study and its local representative are listed in the table above, and they are together referred to as "AbbVie" in this consent. AbbVie hired a research company called OPEN Health to conduct this study.

What is the purpose of this study & why have you been invited?

The purpose of this study is to understand how patients with advanced Parkinson's disease would rate different aspects of their treatment/devices, and what they feel is the importance of different aspects of their treatment, in terms of their benefits, risks, and in the way they are administered.

Your participation involves completing an online survey about preferences for treatment for Parkinson's disease. The survey is hosted by Global Perspectives, a firm specializing in healthcare research, and is expected to take approximately 30 minutes to complete. A total of approximately 350 patients ages 30 years or older or

APPROVED BY SALUS IRB: 20 SEPTEMBER 2023

caregivers ages 18 or older from the United States, United Kingdom, and Germany will be participating in the survey.

If you agree to take part in this study, you will indicate your consent at the end of this form.
You have been invited to participate in this study because you are an adult who cares for someone who has been diagnosed with advanced Parkinson's disease and is currently taking an oral medication for the treatment of the disease.

There are no other parts of the study.

Note: This study is not intended to change the current treatment, management or care of any patient. No drugs or other treatments/interventions are given as part of this study. In case you contact the study research team and mention any safety concern, this concern needs to be reported to the sponsor. Therefore, the study research team may ask you for additional information about your concern so they may follow a specific reporting procedure.

Do you have to take part?
No. It is totally up to you to decide whether or not to take part. If after reading this form, you decide you want to take part, you will indicate that at the end before being shown the survey.

What do you have to do?

1. **During the survey, you will be asked to answer questions about the following:**
    1. Demographic (such as age and sex) information about you and the person for whom you provide care and background health information about the person for whom you provide care.
    2. Preferences for hypothetical treatments for Parkinson's disease in activities called "choice tasks"
        a. Choice tasks are hypothetical (example) scenarios where you are presented with multiple options (possible treatment options not based on actual care or treatment) and asked to make a choice between them.
        b. Sometimes the same options are presented but in different ways and sometimes you may see the same options but in different combinations.
        c. You will be presented with several hypothetical options and asked to choose amongst them based on their characteristics and what you think the person for whom you provide care would prefer. There are no right or wrong answers, we only would like to understand preferences.
        d. You will also be asked to answer some additional questions relating to the understanding of health information.
2. **Possible follow-up for safety concerns related to Parkinson's treatment:** Even though no drug or treatment will be given to you as a part of this study, any side-effects that the person you care for may have experienced of any

APPROVED BY SALUS IRB: 20 SEPTEMBER 2023

drug produced by the sponsor must be reported. If during the survey, you report a safety concern related to Parkinson's treatment that is required to be reported to the sponsor, then the study research team may ask you for additional information after you have completed the survey. You will be asked if you are willing to be contacted for additional questions about the reported safety concern, in order to follow reporting procedures required by the study sponsor.

If you feel that this study would take up too much of your time or you do not think you can meet the responsibilities highlighted in this section, you should not agree to be in this study.

What are the possible disadvantages and risks of taking part?

AbbVie, OPEN Health, and Global Perspectives have implemented security measures to protect the confidentiality of the study data that each maintains. However, there is no guarantee that unauthorized individuals will not gain access to your personal information collected for this study.

By participating in this study, you are not being exposed to any health risks. Some of the questions may make you feel uncomfortable. You may stop and exit the survey at any point in time. Participation in this research study does not mean that you cannot be considered for, or already be in another research study.

What are the possible benefits of taking part?

The information that is obtained from this study may be useful scientifically and thus may be helpful to others in the future. Since this study deals with the collection and use of data only, it is not anticipated that the study will directly benefit you or the person for whom you provide care.

What happens when the research study stops?

Your participation in this study ends at the completion of the survey. There are no additional study visits.

If you start participating in the study, you may stop at any time without further explanation. You will not be punished or lose any benefits to which you are otherwise entitled.

The study research team may end your participation in this study for any reasons, including the following:

1. If you are unable to complete the survey
2. If the study is cancelled by the sponsor, regulatory authorities, or Salus IRB
3. For administrative reasons

Payments, expenses and costs

You will be paid £75 for your time and to cover any incidental expense incurred as a result of your participation in this study. Payment shall not exceed a total of £75.

APPROVED BY SALUS IRB: 20 SEPTEMBER 2023

You must complete the survey in order to receive payment for participation in this study.

AbbVie is not required to share any profits in relation to the development of new tests, procedures and commercial products with you.

What if there is a problem?
Any complaint about the way you have been dealt with during this study is addressed in Part 2 of this Caregiver Participant Information Sheet.

If the information in Part 1 has interested you and you are considering participating in this study, please read the additional information in Part 2 before making any decision.

PART 2
What if relevant new information becomes available?
If we learn any new information about this study that might make you change your mind about participating in it, we will tell you.

What if there is a problem?
If you have a concern about any aspect of this study you should contact the study staff who will do their best to answer your questions. Their contact details are found on the first page, with additional details at the end of this Caregiver Participant Information Sheet.

You may contact Salus IRB if you:

- would like to speak with someone unrelated to the research,
- have questions, concerns, or complaints regarding the research study, or
- have questions about your rights as a research participant.

Salus IRB
Phone: 855-300-0815 between 8:00 AM and 5:00 PM Central Time
Email: salus@salusirb.com

If you would like additional information about your rights, research in general, or IRBs, you may visit www.salusirb.com.

INFORMATION AND CONFIDENTIALITY AND DATA PROTECTION
This confidentiality section describes your rights and explains how personal information about you including information derived from information collection during the survey will be used, shared and protected. This type of information is referred to as "**Personal Data**" and it is protected by European Union (EU) data protection law. AbbVie and OPEN Health staff working on this study must comply with this law. Before Personal Data is transferred to AbbVie, OPEN Health will replace any information that could directly identify you with a generic code which AbbVie cannot link to your identity. Personal Data without identifying information is referred to as "**Coded Data**." The Sponsor is the data controller of the Personal Data

APPROVED BY SALUS IRB: 20 SEPTEMBER 2023

collected or created for the purposes of the study because the Sponsor is responsible for deciding what Personal Data will be collected for the study and how it will be used. This includes both the Coded Data shared with AbbVie, as well as Personal Data contained in the study documents maintained by OPEN Health.

In this section we explain how we collect, use and share your Personal Data with others if you participate in the study. If you don't agree, you will not be able to participate in the study or the optional research.

What Personal Data about you will be Collected?

To help answer the research questions, OPEN Health will collect Personal Data about you from you so that they can understand your medical history. They will collect information self-reported by you as well as their observations of you.

The following are examples of Personal Data that may be collected during the study:

- your age, race/ethnicity and gender, and that of the person for whom you provide care;
- information about your Parkinson's disease, such as year of diagnosis and current treatment;
- any information you provide during the course of the survey

AbbVie will only receive Coded Data and will not be able to directly identify you.

How will your Personal Data be used?

Listed below are examples of how your Personal Data may be used for the purposes of this study (if you agree to participate):

- to determine if you can participate in this study;
- to assess your preferences for treatments for Parkinson's disease
- to learn more about the disease(s) or health condition(s) that are the subject of the study or optional research;
- to report safety data, such as adverse reactions or events (side effects), product complaints, or pregnancies, related to a medical product and/or device used in this study to its manufacturer;
- to provide you with reimbursement for interview participation

Your Coded Data collected for this study may also be used in continued medical research projects, the specific details of which may not be known at present. They could include:

- further examination of the disease(s) or condition(s) that are the subject of the study or similar diseases or conditions; and
- analysis of how AbbVie can improve its research processes.

Your Coded Data is used to conduct research to improve health and care. As a pharmaceutical company, AbbVie has a legitimate interest in using information relating to your health and care for research studies, when you agree to take part in a research study. AbbVie may also use your Coded Data if required to comply with a legal obligation.

APPROVED BY SALUS IRB: 20 SEPTEMBER 2023

Who will receive your Personal Data?

OPEN Health will share your Coded Data with AbbVie and its representatives for the purposes described above. OPEN Health may share your Coded Data with AbbVie's affiliates, as well as with its research partners in countries around the world.

OPEN Health may share your Personal Data and AbbVie may share your Coded Data with regulatory authorities in countries around the world and with the ethics committee responsible for oversight of this study. These bodies are responsible for ensuring that the research is being conducted properly, in accordance with laws and ethical requirements, and they may use your Personal Data/Coded Data in order to fulfil their duties. Regulatory authorities may also use your Personal Data/Coded Data to evaluate and confirm the validity of the study findings.

AbbVie may share Personal Data contained in safety data with the manufacturer of the medical product and/or device used in this study. AbbVie shares safety data with the manufacturer based on its legitimate interest in supporting safety reporting requirements.

The results of this study may be published in study reports or scientific presentations and publications. Information that identifies you or that reasonably could be used to identify you will not be included in such reports, presentations and publications.

How will your Personal Data be protected?

OPEN Health will store your Personal Data in a limited-access, secure storage space. They are required by law to protect the confidentiality of your Personal Data and to use and disclose it only as described in this document. Representatives of AbbVie, regulatory authorities, and the ethics committee overseeing this study may be provided with access to Personal Data controlled by OPEN Health to verify that the study data is being reported accurately and that the study and optional research is being conducted properly. OPEN Health will retain your Personal Data for as long as required by local laws and regulations or for a longer period if required by an agreement with AbbVie.

AbbVie will store the Coded Data that it receives in a limited-access, secure storage space. AbbVie has implemented security measures to prevent unauthorized individuals from accessing your Coded Data. AbbVie will only use your Coded Data for the purposes described in this document. Before sharing your Coded Data, AbbVie will require each of its affiliates or research partners to sign a written agreement requiring them to protect your Coded Data and use it only for the purposes described in this document. AbbVie may retain the Coded Data reported to it for as long as the study drug is used or longer if required by EU or local laws and regulations, consistent with Good Clinical Practices (GCP) and clinical trial related laws and regulations.

Some of AbbVie's affiliates and research partners may be located outside your country or the EU where data protection laws may offer less protection than in the EU. Any Coded Data that is transferred to AbbVie's parent company, AbbVie Inc., in the United States, or other AbbVie affiliates is done under internal agreements

APPROVED BY SALUS IRB: 20 SEPTEMBER 2023

which include an EU approved model contract pertaining to data transfers to controllers. A copy can be obtained by sending an email to privacyoffice@abbvie.com. Any transfers of Coded Data to AbbVie's research partners outside the EU will be done in compliance with the international data transfer restrictions that apply under EU data protection laws.

Can You See Your Study Records; what rights do you have?
Your rights to access, change or move your information are limited, as OPEN Health and AbbVie need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, the information about you that was already obtained will be kept (please refer to the information below for more details.) To safeguard your rights, the minimum personally-identifiable information possible will be used.

VOLUNTARY WITHDRAWAL

Can you change your mind?
Entering a research study is completely voluntary. You can decide not to take part in this study without giving a reason and without penalty or loss of benefits. If you start the study, you may stop at any time without further explanation. This study may be stopped without your consent, at any time and for any reason by AbbVie, the ethics committee or organisations that regulate research in the UK or other countries.

If you want to stop participating in the study for any reason, you must let OPEN Health know either verbally or in writing. You will not lose any benefits to which you are otherwise entitled.

What will happen if you don't want to carry on with this study?
If at any time you decide to stop taking part in this study, you should talk to OPEN Health.

What will happen to your Personal Data?

Personal Data
If you withdraw or are withdrawn from the study, there will be no additional follow-up from OPEN Health or anyone else associated with this study.

Even after your withdrawal, OPEN Health and AbbVie may be required to include your information in analysis and aggregate study results, but in a way that will not identify you.

Who is organising and funding the research?
The research study is being organised and funded by AbbVie. AbbVie will pay OPEN Health for their services in conducting this study.

APPROVED BY SALUS IRB: 20 SEPTEMBER 2023

Who will review this study?

All research is looked at by an independent group of people, called an independent review board (IRB) to protect your safety, rights well-being and dignity. A favourable opinion has been obtained from Salus IRB for this study.

Further information and contact details

Please contact OPEN Health at the number listed on page one of this form if you would like more information about any part of this study, the optional research, your rights as a participant or in the case of a study related injury.

You can find out more about how your Coded Data and Personal Data is being used and shared by contacting Open Health at the number listed on page one of this form.

You have the right to object to the Personal Data processing activities described in this consent form that are based on AbbVie's legitimate interests.

AbbVie's Data Protection Officer can be contacted by going to abbvie.com/privacy-inquiry.html or by sending a letter to AbbVie.

This Caregiver Participant Information Sheet and Consent Form is governed by the laws of England.

Thank you for taking the time to read this Caregiver Participant Information Sheet.

Please let us know if you have any questions or if you would like further information.

APPROVED BY SALUS IRB: 20 SEPTEMBER 2023

Caregiver Participant Initials:_____ Caregiver Participant number:_____

CONSENT FORM

Study Title: Patient Preference Study in Advanced Parkinson's Disease

Investigator: Sumitra Sri-Bhashyam, PhD, MSc, OPEN Health

1 I confirm that I have read the Caregiver Participant Information Sheet and all my questions regarding participation in this research study and the optional research have been answered.

2 I understand that relevant sections of data collected during this study may be looked at by OPEN Health, individuals from AbbVie, their representatives/ agents, and regulatory authorities.

3 I acknowledge that my Personal Data will be accessed, collected, processed and transferred as described in the Caregiver Participant Information Sheet.

4 I understand that I *or my legal representative* will receive a copy of this Caregiver Participant Information Sheet and Consent Form.

5 I understand that my participation in this study is voluntary and that I am free to withdraw at any time without giving any reason and without my medical care or legal rights being affected.

6 I agree to take part in this study.

7 I understand that checking the boxes below has the same legal authority as signing a document

Please select one of the following:

☐ Yes, I consent to participate in this study.

☐ No, I do not consent to participate in this study.

FOR SALUS IRB USE ONLY		
Initial draft	pe: 10Feb22	kw: 20Sep23