feetme	Consent form for participants in research involving the human person entitled : "A randomised, controlled, open-label, multi-centre study to evaluate the efficacy of FeetMe® home-based rehabilitation program in comparison to conventional physiotherapy in patients with Parkinson`s Disease using connected insoles." - Reconnect- ID-RCB NO.: 2023-A00150-45	Promoter: FeetMe 157 bd MacDonald 75019 Paris, France Coordinator : Prof. Caroline Moreau Neurologist - Lille University Hospital Medical Director FeetMe Caroline.Moreau@feetme.fr

This information is intended to help you decide whether to participate in research involving human subjects. Please read this document carefully and take your time before making your decision. During this period of reflection, you can ask the study doctor for any additional information you may require. If you decide to take part in this research, you will be asked to sign a written consent form.

1) What is the aim of this research?

Physical rehabilitation is essential in the management of patients with Parkinson's disease. The French National Authority for Health (HAS) recommends physical therapy as a complement to pharmacological treatment to reduce the progression of motor symptoms.

Despite the proven benefits of rehabilitation programs on walking and balance, patients face difficulties in accessing conventional physiotherapy due to territorial inequality in the distribution of practices and very high demand. An effective and easily accessible rehabilitation program for Parkinson's patients is therefore an unmet need.

FeetMe® Rehabilitation is a home-based rehabilitation program that guides users through rehabilitation exercises specifically developed for Parkinson's patients. To complete the program, an adapted physical activity (APA) professional remotely monitors patients' progress and adapts the exercises proposed to them according to the results obtained. Thanks to FeetMe® Rehabilitation, patients can train remotely and in their own home environment, facilitating access to this essential treatment.

The aim of this study is to assess the effectiveness of the FeetMe® Rehabilitation home-based rehabilitation program compared with conventional care in participants with Parkinson's disease.

2) Presentation of the Medical Device under study

As a study participant, you will receive and use FeetMe® Monitor insoles during the study.

If you are assigned to the FeetMe® Rehabilitation program, you will use the FeetMe® Rehabilitation mobile app. If you are not assigned to the FeetMe® Rehabilitation program, you will have the option of joining it later (after 3 months). Your doctor will introduce you to the insoles and the application.
FeetMe® connected insoles are a medical device manufactured by FeetMe® that combines pressure sensors, inertial units and on-board computing capability for real-time measurement. The insoles can continuously record gait parameters and can capture up to two weeks of data in autonomy. They are adapted to your shoe size, so you can put them in flat, closed shoes. You'll have your own pair of insoles. Otherwise, the insoles are always

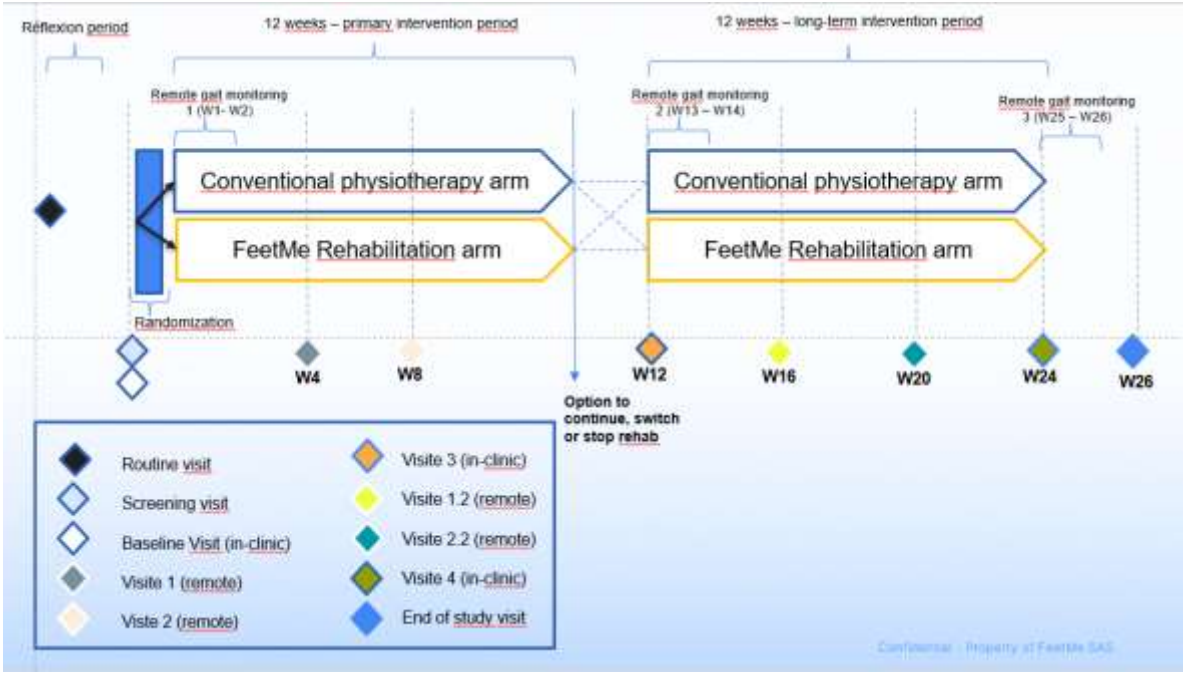
disinfected between patients and used with single-use protective socks to ensure hygiene. During the study, you'll need to wear the insoles as indicated.

The insoles will be used with two different mobile applications. For specific gait assessments carried out in clinic, your doctor will use the FeetMe® Evaluation app, downloaded onto a dedicated mobile phone. If you are assigned to the conventional therapy group, you will also use this app to record your daily gait data at various times. If you are assigned to the FeetMe® Rehabilitation program, you will be able to record your data using the FeetMe® Rehabilitation app.

Along with your insoles, you will receive a mobile phone on which the FeetMe® Rehabilitation application will be installed. This application has been specifically developed for the rehabilitation of patients suffering from Parkinson's disease. It contains a set of exercises widely used in physiotherapy practice, including static exercises (targeting balance and muscle strengthening) and dynamic exercises (targeting gait quality and endurance).
If you are assigned to the FeetMe® Rehabilitation program, you will be asked to wear your insoles during your daily life and you will be prescribed a program tailored to your needs combining different exercises. You will need to use the app and the insoles to perform the workout at home. You'll receive real-time feedback (for example, telling you your success rate for a given exercise) as you train. You'll also have regular phone calls with an APA professional to monitor your progress and make modifications to the program if necessary. You'llalso use the app to import all your walking data at various times.
If you are assigned to the conventional therapy program, you will be asked to wear your insoles daily for 14 days on several occasions, and to use the FeetMe® Evaluation application to import your walking data.

3) How will the research be carried out?

Reflection and informed consent
If your doctor thinks you could take part in this study, he or she will suggest it and present the medical device to you. You have a reflexion period of between 15 and 30 days. Your doctor will give you this document and explain its contents, allowing you to handle the insoles and associated applications. You will also be given a leaflet describing the FeetMe® Rehabilitation application and a link to a video describing the entire service (https://www.youtube.com/watch?v=DZe9Q_0kQ0w). If you have any further questions during your reflexion period, please contact the study coordinating center on 03 20 44 59 62. If you wish to take part in this study, you will need to date and sign the informed consent form, and you will be given an appointment for the screening and baseline visits. The study will run for around seven months, as described in detail in the paragraphs and diagram below.



Recruitment (screening)

The pre-screening takes about an hour, during which your doctor will evaluate:

- The current stage of your disease, using a brief routine assessment (Hoehn and Yahr assessment scale, H&Y) during which you will be asked about your symptoms and asked to perform a few short exercises (e.g. walking or getting up from a chair);

- Your thinking skills by asking you to make a short test (Montreal Cognitive Assessment, MOCA) consisting of several tasks (for example, remembering a list of words or drawing an object). The purpose of this test is to evaluate various cognitive functions.

During the study, you will be asked to use FeetMe® medical devices and mobile applications, and whether you feel comfortable using digital technologies (e.g. a smartphone).

During the study, you will be contacted by a specialist on a regular basis, and you will be required to comply with the rehabilitation program. Your agreement with these conditions will also be assessed.

If you meet the conditions set out in the study protocol, you will be assigned to one of the two groups.

Reference visit

Regardless of the group, the reference visit (or BL basic visit) will follow the screening. During this visit, you will wear your insoles as much as possible. You will undergo a series of walking tests with your doctor, and will be

asked to complete various surveys and questionnaires. During the tests, a doctor or member of the medical staff will always be present to support you and help you if you need it.

Here you will find a complete list of the data that will be collected and the assessments that will be requested of you during the reference visit.

- Demographic data: month and year of birth, gender, weight, leg length, height, shoe size.

- Medical history, medication taken, rehabilitation history: your doctor will gather information about your medical history, any medication you have recently taken or are currently taking, and your experience of physiotherapy or other forms of rehabilitation.

Walking tests

- 6-Minute Walk Test (6MWT): your doctor will ask you to walk along a corridor at a comfortable pace and cover as much distance as possible for a total of six minutes while wearing the insoles. The distance you cover during this period and many other walking parameters measured by the FeetMe® insoles will be recorded. You will be asked to perform this task twice, once at the beginning and once at the end of your visit.

- MiniBESTest: your doctor will ask you to perform a series of 14 simple exercises to test your balance and posture while wearing the insoles (for example, getting up from a chair or stepping over an obstacle).

You may find these exercises tiring; if so, please let your doctor know. A member of the study team will be close by to record your data and help you if necessary.

Cognitive function test

Questionnaires

- Unified Parkinson's Disease Rating Scale (MDS-UPDRS): this is a standard questionnaire developed for Parkinson's patients, consisting of fifty questions and tasks designed to assess the progression of your disease and its impact on your various functions. This questionnaire will be completed with your doctor

- Freezing questionnaire (FOG-Q): During your visit to the center, you will be asked to complete a 6-question questionnaire about your own experience of freezing (involuntary inability to take a step).

- Parkinson Disease Sleep Scale 2 (PDSS2): you'll be asked to complete 15 questions on the qualityof your sleep and the existence of any sleep disorders.

- Parkinson's disease questionnaire (PDQ-39:) During in-clinic visits, you will be asked to complete 39 questions on the impact of your disease on your quality of life (mobility, daily activities). A smaller version of this questionnaire will be presented to you during remote visits (PDQ-8).

- Clinical Global Impression of Severity (CGI): your doctor will assess the severity of your illness and rate it on a standard scale.

- Patient Global Impression of Severity (PGI): During in-center visits, you will be asked to complete a questionnaire consisting of a question about the severity of your illness, and to rate it on a standard scale.

- Visual Analog Scale (VAS): you'll be asked to rate the level of pain you've experienced over the past week on a scale ranging from zero (no pain) to ten (the worst pain imaginable).

The total time required to complete the self-questionnaires is estimated at 30 minutes. If you feel the need, a clinical research associate can help you fill them in.

Intervention phase

After the baseline visit, there will be two phases of the study, an initial 12-week phase where you will be assigned to a group, and a second 12-week phase where you can choose to change groups or continue in your group.

Whichever patient group you belong to, you will be asked to use your insoles continuously on three occasions for two weeks:

- At the start (week 1 and week 2)
- In the middle (weeks 13 and 14)
- At the end of the study (weeks 25 and 26), so that you can record your walk at home.

During these three two-week periods, you'll be asked to wear the insoles as much as possible every day and recharge them every evening, as well as to import your walking data using the app on a regular basis. You'll also receive a user manual with detailed instructions.

In addition, you'll be asked to make a weekly note of any falls or near-falls (for example, when you almost fall because you're dizzy) you've experienced. One and two months after the baseline visit, you'll be asked to fill in the same questionnaires as at the start, to monitor your progress. All these questionnaires will be completed remotely using an online system. Three and six months after the referral visit, you'll need to visit the hospital in person. The same assessments will be carried out as at the referral visit, including gait assessments.

Throughout the study, adverse events, changes in your treatment, any complaints you may have about the device and your satisfaction with it will be collected on several occasions.

<u>Initial phase</u>

For all participants, you will be asked to wear the insoles daily for 15 days on 3 occasions: immediately after the baseline visit, at visit 3 and visit 4.
So you'll need to wear the insoles as much as possible during the day, and import the data in the evening by removing the shoes and using the phone and app supplied.

Conventional therapy group (physical therapy)

If you are in the conventional treatment group, you will either continue your usual physiotherapy or start it as planned and follow it for 12 weeks (3 months). You will need to fill in a form on a regular basis to keep track of the type of physiotherapy you are receiving. If you don't find one, not taking therapy during this period will not compromise your participation in the study. If you find a therapy later in the 12 weeks, you will be asked to inform your health-care team, and to follow it for 12 weeks.

Groupe FeetMe® Rehabilitation

If you're part of the FeetMe® Rehabilitation patient group, you'll start your FeetMe® rehabilitation program via your app.

The rehabilitation program begins with an initial remote training session, during which a specialist in adapted physical activity (APA) will ask you about your daily habits (physical activity, walking outdoors, need for assistance) to propose an adapted program. He or she will explain how to use the equipment, safety instructions and describe the program. Exercises and how to perform a walking test will be tested during this training. Depending on the program recommended, you will have between 3 and 5 independent rehabilitation sessions per week, lasting between 30 minutes and an hour. You will also be asked to practice free walking for between 30 minutes and an hour a week, and this program may evolve over the first 12 weeks. Follow-up calls are scheduled with your APA. During the initial phase (12 weeks), calls will be made on a weekly or bi-monthly basis. During the call, a series of standard questions will be systematically asked, but you will also be able to discuss your motivation, any difficulties you may be encountering, advice on movements to be performed and a review of the results obtained. Each call is documented in a report. If it turns out that an adaptation of your rehabilitation program is necessary, an increase or decrease in intensity will be applied according to your needs.

Your application will guide you through your rehabilitation sessions, telling you how to put on and connect your insoles, the sequence of exercises and safety instructions. You'll get audio, sensory and visual information to monitor your performance and, if necessary, correct your position during the exercises. To give you this information, the application uses data supplied by the insoles and by you via the touch screen. You will therefore be asked to keep your phone close with the possibility to see the screen during sessions, to avoid holding it in your hand during static exercises, and to carry it with you for walking exercises. A user guide will be supplied with your application and insoles.

Extension phase

After 12 weeks in your initial program, for the following 12 weeks, you can choose to

- Continue in the group to which you have been assigned
- Change group (move to conventional therapy group or FeetMe® Rehabilitation group)

- Stop all rehabilitation

If you decide to initiate conventional therapy, you will need to find your own physiotherapist, and you will be monitored as described under 'conventional physiotherapy'.

If you decide to initiate rehabilitation with FeetMe® Rehabilitation, you will be cared for as described under 'FeetMe® Rehabilitation'.

If you decide to continue in the FeetMe® Rehabilitation group, you will continue with the current program as a routine for the next 12 weeks.

If you decide to stop all rehabilitation, you will be asked to remain in the study to collect your clinical and gait data.

End-of-study visit (duration approx. 20 minutes)

After 6 months of rehabilitation and the last 2 weeks of gait recording, you will be contacted by your doctor to answer a few final questions about side effects and satisfaction. Your participation in the study will be considered complete once you have completed this end-of-study visit.

On the following page, you'll find a table showing a simplified version of the different assessments you'll take part in during the study. The blue boxes correspond to distance visits or assessments (at home), while the yellow boxes correspond to clinic visits.

feetme	Consent form for participants in research involving the human person entitled : "Randomized, controlled, multicenter study to evaluate the efficacy of the FeetMe® home rehabilitation program compared with conventional physical therapy in Parkinson's disease patients using connected insoles." - Reconnect- ID-RCB NO.: 2023-A00150-45	Promoter: FeetMe 157 bd MacDonald 75019 Paris, France Coordinator : Prof. Caroline Moreau Neurologist - Lille University Hospital Medical Director FeetMe Caroline.Moreau@feetme.fr

	Preselection	Initial intervention phase				Extension phase			End-of-study visit
		Baseline visit	V1 (W4)	V2 (W8)	V3 (W12)	V1.2 (W16)	V2.2 (W20)	V4 (W24)	(W26)
H&Y	x								
MOCA	x								
6MWT		x			x			x	
Mini-BESTest		x			x			x	
MDS-UPDRS		x			x			x	
PDQ-39		x			x			x	
EVA (5 minutes)		x	x	x	x	x	x	x	
Parkinson Disease Sleep Scale 2 (PDSS2) (10 minutes)		x	x	x	x	x	x	x	
Patient's global impression of severity (CGI-S and PGI-S)		x							
Global impression of clinical and patient severity (CGI-I and PGI-I)					x			x	
FOG questionnaire		x			x			x	
PDQ-8 (10 minutes)			x	x		x	x		
Falls questionnaire			Weekly for the duration of the study						
Continuous gait recording			W1-W2			W13-W14			W25-W26

4) What are the potential risks of this research?

There are no known risks to participating in this research. More than two thousand people suffering from various illnesses have already used FeetMe® insoles safely, and dozens of Parkinson's patients have tried the rehabilitation program without side effects.

Some of the walking exercises included in this study involve light physical activity and may make you feel tired. If at any time you feel tired or uncomfortable, please let your investigator know; you are allowed to slow down and recover your strength. Also, during visits, your doctor may ask you questions about your health. You have the right not to answer questions if you wish.

When performing rehabilitation exercises following the instructions on the FeetMe® rehabilitation app, you should always ensure that you perform them as instructed during the initial training. For example: have something (e.g. a chair) to hold on to if necessary. You should always inform the APA specialist if you think a given exercise is too difficult for you, so that it can be adapted to your needs.

5) How will you be treated during and at the end of the study?

You are totally free to choose whether or not to participate in this study. If you decide not to participate, your medical care will not be modified.

Premature termination: At any time during the study, your physician may decide to suspend or terminate the study if he or she feels that your participation is no longer in your best interest. The study may also be stopped by government authorities or hospital management, as well as by the sponsor's decision.

Withdrawal of consent: You are also free to withdraw your consent at any time without giving a reason, and this does not interfere with the care you receive.

6) If you participate, what will happen to the data collected for this research?

As part of this research, your personal data will be analyzed to meet the research objectives. To this end, your data will be made indirectly identifiable by means of an alphanumeric code (initials and inclusion number). This indirectly identifying data will be transmitted to the research sponsor (FeetMe).
Indirectly identifying study data recorded by FeetMe Evaluation and FeetMe Rehabilitation are encrypted and transmitted via a secure HTTPS protocol. It is stored on an HDS-certified Google Cloud server, hosted in Europe. In accordance with European regulations, data is archived for a period of 25 years following the end of the study. Indirectly identifiable data are only accessible by authorized personnel in the context of the study.
FeetMe could use these data to develop and validate new algorithms studying gait parameters in Parkinson's disease.

Patient follow-up also requires the collection of identifying data (name, email, telephone number). The people with access to identifying data will be the clinical investigation team of the medical department carrying out the research, your APA specialist if you are carrying out the FeetMe rehabilitation program, and also the people in charge of quality control for research involving human beings (e.g. monitors, clinical research assistants, ANSM inspectors : Agence Nationale de Sécurité du Médicament). They comply with confidentiality requirements in accordance with article L. 1121-3 of the French Public Health Code. These data will be destroyed at the end of the study.

7) How is this research organized?

In application of the law, on XX/XX/XX, this study received a favorable opinion from the Comité de Protection des Personnes XXXXXX, an official and independent body whose mission is to protect the safety of people involved in research.
In addition, FeetMe, in its capacity as promoter, has taken out insurance with CRF Assurances for this study. FeetMe and all those involved in the research are committed to conducting this study in accordance with the protocol, rules and recommendations of international Good Clinical Practice, and with the legal and regulatory provisions applicable to research.

8) What are your rights as a research participant?

You are free to accept or refuse to participate in this research without having to justify your decision. You are not obliged to give us your decision immediately; you have as much time as you consider necessary to make your decision. If you agree to take part, you can change your mind at any time, without giving us any reason. In addition, during or at the end of the research, you may obtain access to your health data held by your doctor.

If an abnormality unrelated to the subject under study were to be discovered by chance during the examinations performed, and if this abnormality could have consequences for your health, you would be informed by the study doctor.

In accordance with the provisions of the amended law relating to data processing, files and freedoms and the European regulation on the protection of personal data (2016/679), you have the following rights:

Right of access: At any time during or at the end of the research, you may obtain communication of your health data held by your doctor (Article 12 RGPD).

Right to information: You have a right to information about your personal data collected, processed or, where applicable, transmitted to third parties (Article 15 RGPD).

Right to rectification: You have the right to request the correction of incorrect personal data concerning you (Articles 16 and 19 GDPR).

Right to erasure: You have the right to request the erasure of your personal data only if the data is no longer necessary for the purposes for which it was collected or if you withdraw your consent on which the processing of your personal data is based where there is no other legal basis for the processing (Articles 17 and 19 of the GDPR).

Right to limitation of processing: Under certain conditions, you have the right to request a limitation of processing. In this case, your data may only be stored but not used in connection with the processing, except with your express consent (Articles 18 and 19 GDPR).

Right to data portability: You have the right to receive the personal data that has been provided to the person responsible for the clinical trial. You can then request that this data be transferred to you or, if technically possible, to another organization of your choice (Article 20 RGPD).

Right to object: You have the right to object to the processing of your personal data at any time (Article 21 RGPD). The processing will then be stopped by the promoter, except for legitimate and compelling reasons, or for the establishment, exercise or defense of legal claims.

Consent to the processing of personal data and right to revoke such consent: The processing of your personal data is permitted on the basis of your consent and the processing necessary for the performance of a task in the public interest (Article 6 GDPR).
You have the right to revoke your consent to the processing of personal data at any time (Article 7, paragraph 3 GDPR).

If you wish to exercise any of these rights, you may contact the study's investigating physician or the sponsor's Data Protection Officer (DPO) at the following address: privacy@feetme.fr.
You also have the right to lodge a complaint with the Commission Nationale Informatique et Libertés (CNIL) if you feel that your personal data is being processed in violation of your rights.

Data Protection Officer (CIL/DPO)
Sabine Ferré
FeetMe
157 Bd MacDonald
75019 Paris
privacy@feetme.fr

Contact CNIL
Commission Nationale de l'Informatique et des Libertés (French Data Protection Authority)
Postal address
3 Place de Fontenoy
TSA 80715
75334 PARIS CEDEX 07
https://www.cnil.fr/fr/webform/adresser-une-plainte

If you wish, we can send you a copy of the overall results by post at the end of the study.

You won't have to bear any additional financial burden as a result of your participation in this study.
Your data collected during the study may be kept for a period of 15 years at the end of the research.

9) Am I entitled to compensation?

Biomedical research does not give rise to any direct or indirect financial compensation for the participants, apart from the reimbursement of expenses incurred and, where applicable, compensation for constraints incurred paid by the sponsor (e.g., transportation costs to the center). Transport costs for visits outside the scope of regular follow-up (12-week visit) may be covered by the promoter on the basis of a mileage allowance. In order to be reimbursed, volunteers must provide the principal investigator with proof of address and a bank account number. This information will be forwarded to a service provider who will be responsible for reimbursement. The sponsor undertakes to reimburse expenses, if justified, within one month.

10) Who do I contact if I have questions or problems?

If you have any questions before, during or after the study, please contact :

Study coordinator :	*Center stamp*

If you agree to take part in this study, we would be grateful if you would give your written consent by signing the form below in <u>duplicate</u>. One copy will be given to the person concerned, and the other will be kept by the investigator in accordance with the law.

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Consent form for participants in research involving the human person entitled

"EVALUATING THE EFFICACY OF FEETME Rehabilitation®, A HOME-BASED REHABILITATION PROGRAM WITH REAL-TIME BIOFEEDBACK, IN COMPARISON TO CONVENTIONAL THERAPY, IN PARKINSON'S PATIENTS."

- Re-Connect -

ID-RCB NO.: 2023-A00150-45

Developer: FeetMe 157 Bd MacDonald 75019 Paris

Coordinator: Pr Caroline Moreau, neurologist,

Lille University Hospital Parkinson Center

2 avenue Oscar LAMBERT 59037 Lille Cedex

caroline.moreau@chru-lille.fr

I, the undersigned, Mrs. or Mr. (delete as appropriate) ..... freely and voluntarily agree to take part in research involving human subjects entitled "Randomized, controlled, multicenter study to evaluate the efficacy of the FeetMe® home rehabilitation program compared with conventional physical therapy in Parkinson's disease patients using connected insoles" (ID-RCB No.: 2023-A00150-45) - of which FeetMe is the promoter and which has been proposed to me by Doctor/Professor (surname/first name, department contact details).

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Provided that :

- The investigating physician, who informed me and answered all my questions, made it clear that my participation in this study is voluntary and that I can stop taking part at any time by informing him or her in advance. I have been given sufficient time to consider my decision.
- I have been clearly informed of the following: Purpose of the research - Methodology - Duration of my participation - Constraints - Foreseeable risks.
- I understand that, in order to take part in this research, I must be affiliated to a social security scheme or be the beneficiary of a person covered by social security. I confirm that this is the case.
- If I so wish, I will be informed by the doctor of the overall results of this research according to the procedures set out in the information note I have been given.
- My consent in no way relieves the physician and the promoter of all their responsibilities and I retain all my rights guaranteed by law.
- I agree that the data recorded in connection with this research may be processed by or on behalf of the sponsor. I have noted that the rights concerning my personal data provided for by the French Data Protection Act of January 6, 1978 (art. 39) and by the European Data Protection Regulation (2016/679) (Articles 12 et seq.)[1] may be exercised at any time with the doctor who is following me in the context of the research and who is aware of my

identity, or with the sponsor's Data Protection Officer (DPO). I may exercise my right to rectification and opposition by contacting this same doctor or the DPO.

- All data may be used by FeetMe for research purposes in the development of the medical device, for regulatory submissions, for the development of digital biomarkers or for the improvement of medical devices connected by FeetMe.

INVESTIGATING **PHYSICIAN**

Done at ....., on.....

Surname/First name: .....

Signature of investigating physician :

PARTICIPANT

Done at ....., on.....

Surname/First name: .....

Participant's signature :

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