Information letter for participants

Study title: Study on the acceptability of information sessions and self-testing in cervical cancer prevention

Dear,

You have been invited to participate in a study. Before you decide to participate in this study, please take the time to read this information letter carefully and discuss it with the investigator or his/her representative. Also, take the time to ask questions if there are any uncertainties or if you would like additional information. This process is called informed consent to participate in an experiment. Once you have decided to take part in the study, you will be asked to sign the consent form at the end.

1. DESCRIPTION AND PURPOSE OF THE STUDY

The International Centre for Reproductive Health (ICRH) at the University of Ghent is conducting a study on the acceptability of information sessions and self-testing in the prevention of cervical cancer among women between 25 and 65 years who do not get screened or get screened insufficiently. We kindly ask you to take the time to participate in such an information session and to fill in some questionnaires. This will take about 30-45min of your time. Three months later we will call you for a short concluding conversation (15min).

This study was pre-approved by an independent Medical Ethics Committee affiliated with Ghent University Hospital and Ghent University. The study is conducted in accordance with the guidelines for good clinical practice (ICH/GCP) and the Declaration of Helsinki drawn up to protect people taking part in clinical trials.

The sponsor of this study is Ghent University. Data collection is performed under the supervision of Prof. Dr. O. Degomme. Students of the University of Ghent will be part of the research team.

2. CONSENT AND REFUSAL

Participation in this study is entirely voluntary. You can refuse to fill in the questionnaires or attend the information session without having to give a reason and without this affecting in any way your future relationship with the researcher.

3. BENEFITS

Participation in this study will provide you with more information on cervical cancer screening. The results obtained may lead to new and more effective methods of encouraging women to be screened for cervical cancer.

4. COSTS

Participation in this study does not entail any additional costs for you, but neither does it offer any financial benefit.

5. PROCESSING OF PERSONAL DATA

In accordance with the General Data Protection Regulation (or GDPR) (EU) 2016/679 of 27 April 2016 (in force from 25 May 2018) and the Belgian law of 30 July 2018, on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, your privacy will be respected and you may access the data collected about you. Any incorrect information may be corrected at your request.
Your other rights (being the right to have your data deleted in certain circumstances, to withdraw your consent and to file a complaint) are also monitored.
For more information about the rights you have and how you can exercise them, please visit the UGent website (https://www.ugent.be/nl/univgent/privacy/privacystatement.htm).

Your participation in the study means that your data will be processed for the purpose of the study. This processing of data is based on your consent, as stated in Article 6, paragraph 1 (a) and is necessary for the purpose of scientific research according to Article 9, paragraph 2 (j) of the General Data Protection Regulation.

All information collected during this study will be pseudonymised (this will still allow you to link your data back to your personal file). The key to the codes will only be accessible to the researchers or their appointed replacement. In this study, data will also be collected by means of a telephone conversation 3 months after the information session. To this end, you will be asked to provide your telephone number on which you wish to be called. If you agree, this telephone conversation will be recorded.

Only pseudonymised data will be used for data analysis and in any documentation, reports or publications (in medical journals or conferences) concerning the study. Confidentiality of your data is thus guaranteed at all times. Both personal data and data concerning your health will be processed and kept up to at least 10 years after the end of the study and for safety reasons with regard to the study performed and its follow-up (if any).
The person responsible for processing the data is the institution of the principal investigator of the study, Prof. O. Degomme (UGent). His research team will have access to your personal data.
In the context of data protection, the data will be processed by persons belonging to the research team and appointed by and under the responsibility of the principal investigator including internal staff members with a non-healthcare profession.

Should your data need to be transferred to a country outside the European Economic Area (EEA) or to an international organisation, U(Z) Gent will ascertain whether the country of destination offers an adequate level of protection. If the country to which U(Z) Gent wishes to transfer data does not provide an adequate level of protection, U(Z) Gent shall, by means of standard contracts made available by the European Commission or other accepted measures, ensure that it provides adequate protection itself. Your explicit consent to this data transfer is requested in the consent form below.

To obtain more substantive information about the study and to be able to exercise your rights, please contact the study team.
The Data Protection Officer can provide you with more information on the protection of your personal data. Contact details : Hanne Elsen, privacy@ugent.be .

Representatives of the sponsor, auditors, the Medical Ethics Committee and competent authorities, all bound by professional secrecy, have direct access to your medical records to check the procedures of the study and/or the data, without breaching confidentiality. This can only be done within the limits permitted by the relevant laws. By signing the consent form, after prior explanation, you agree to this access.

The Belgian supervisory authority responsible for enforcing data protection legislation can be contacted via the contact details below:

Gegevensbeschermingsautoriteit (GBA)
Drukpersstraat 35 – 1000 Brussel
Tel. +32 2 274 48 00
e-mail: contact@apd-gba.be
Website: www.gegevensbeschermingsautoriteit.be

6. INSURANCE

The sponsor will provide compensation and/or medical treatment in the event of damage and/or injury resulting from participation in this clinical study. For this purpose, insurance has been taken out with no-fault liability in accordance with the law on experiments on the human person of 7 May 2004, the Belgian law of 7 May 2017 on clinical trials with medicinal products for human use and the Belgian law of 22 December 2020 on medical devices (Allianz Global Corporate & Specialty; Uitbreidingstraat 86, 2600 Berchem; Tel: +32 33 04 16 00; policy number for UZ Gent BEL001889 - policy number for UGent BEL000862).

7. CONTACT

If an injury occurs as a result of the study, or if you would like additional information about the study or your rights and obligations, please contact the investigator or a member of his or her team:

Name: Prof. O. Degomme
Address: Corneel Heymanslaan 10, 9000 Ghent
Telephone number: 09/332 35 64

CONSENT FORM FOR PARTICIPANTS

I have read and understood the document "Information letter for participants" pages 1 to 3 and have been given a copy. I have been explained the nature, purpose and duration of the study and what is expected of me.
I understand that participation in the study is voluntary and that I may withdraw from the study at any time without giving a reason for this decision and without being affected in any way.
I am aware that this study has been approved by an independent Medical Ethics Committee attached to UZ Gent and Ghent University and that this study will be conducted in accordance with the guidelines for Good Clinical Practice (ICH/GCP) and the Declaration of Helsinki, drawn up to protect people participating in experiments. This approval was in no way the impetus for deciding to take part in this study.
I have been informed that both personal data and data concerning my health will be processed and kept for at least 10 years after the end of the study. I have been informed that I have the right to access and correct this data. As these data are processed for medical scientific purposes, I understand that access to my data may be delayed until after the research has been completed. If I wish to access my data, I will contact the researcher responsible for processing it.

Tick by participant if agreed

I agree to participate in the following parts of the study:	
1) I agree to cooperate fully with the researcher.	
2) I agree to follow the information session.	
3) I agree to complete the questionnaires within this study.	
4) I agree that my phone number will be used to contact me 3 months after the info session.	
5) I agree that this telephone conversation will be recorded	
6) I agree that my data should be transferred to a country outside the European Economic Area (EEA) or to an international organisation.	

Name and first name of the participant	Signature	Date
Name and first name of the investigator*	Signature	Date

2 copies must be completed. The original is kept by the researcher in the hospital for at least 10 years, the copy is given to the participant.

*Tick by researcher if agreed

I declare that I have provided the necessary information concerning this study (its nature, purpose and foreseeable effects) orally and have given a copy of the information document to the participant.	
I confirm that no pressure was exerted on the participant to agree to participate in the study and I am prepared to answer any additional questions.	

Study number	1-9-_ _._ _._ _ _ _ - 1_ _ - _ _. _ _ . _ _ _ _

Information letter for the participants of an experiment

Study title: Study on the acceptability of information sessions and self-testing in cervical cancer prevention

Official title: EarLy dEtection of cerVical cAncer in hard-to-reach populations of women through portable and point-of-care HPV Testing - Country-specific strategy to reach hard-to-reach women with cervical cancer screening programmes

Dear,

You have been invited to participate in a clinical study. Before you decide to take part in this study, please take the time to read this information letter carefully and discuss it with the investigator or his/her representative or with other persons of your choice. You should also take the time to ask questions if there is anything unclear or if you would like additional information. This process is called informed consent to participate in an experiment. Once you have decided to participate in the study, you will be asked to sign the consent form at the end of this booklet.

1 WHAT IS THE PURPOSE OF THE STUDY?

We invite you to participate in a clinical trial with the aim of investigating the acceptability of information sessions and willingness to self-test in the context of cervical cancer prevention among women who do not or insufficiently get screened. If you are a woman, over 25 years of age, you are not currently pregnant and you have not undergone uterine removal surgery in the past, you are eligible for this study.
The client of this study is the International Centre for Reproductive Medicine (UGhent) under the direction of Prof. O. Degomme. Students of Ghent University will be part of the research team.

2 WHAT DOES PARTICIPATION IN THE STUDY MEAN FOR YOU?

In connection with your participation in the study, we would like to invite you to an information session about cervical cancer and its prevention. One of the possibilities for testing for cervical cancer is through a vaginal self-test. This test detects the Human Papillomavirus (HPV), the primary cause of cervical cancer. After the information session, you will be offered such a test and have the opportunity to take it on the spot in a private room. In this self-test you will take a sample vaginally with a small brush. These samples are then delivered to the lab for analysis. We will be able to inform you of the result of this test after 2 to 3 weeks.
Before and after the session and after taking the self-test (if desired), you will be asked to complete a questionnaire. Three months later we may call you again for a final talk.

3 HOW MANY PARTICIPANTS WILL TAKE PART IN THIS STUDY?

A total of 1110-1120 women will participate in this study, of whom 250-260 are in Belgium. Half of the participants will be invited to take a self-test.

4 WHAT IS THE DURATION OF THIS STUDY?

The total expected duration of the study for you is about 30-60 min (info session + questionnaires + self-test). Three months after this session, you will be contacted once more by telephone for a short follow-up interview (+-10min).

5 WHAT IS EXPECTED FROM THE PARTICIPANT?

Women are eligible to participate if they are between the ages of 25 and 65.

For the study to be successful, it is extremely important that you cooperate with the researcher and that you follow his/her instructions. Completing the questionnaires will add value to the study.

In addition, you should observe the items listed below if you would accept the self-test:
- You must not be pregnant
- You must not have undergone an operation to remove the uterus in the past (=hysterectomy)
- You must not have a diagnosis of or be in treatment for cervical cancer

6 WHAT PROCEDURES TAKE PLACE DURING THE STUDY?

6.1 Procedures and study progress:

- Information session in group
- Vaginal self-test* (= cervical cancer screening) and accompanying questionnaire if required
- Questionnaire before and after information session
- Telephone interview for follow-up 3 months later

** Women will only be notified if they have a positive result (i.e. you are infected with the HPV virus). You can choose whether you will be notified by telephone, via Whatsapp or by email.*

6.2 Collection of biological samples:

Your sample will be divided into 2 equal parts. One part will be sent to the laboratory of the University Hospital in Ghent and will be tested for the presence of HPV. The results will be reported back to you.

The other part of your sample will be stored in the ELEVATE biobank. A biobank is a facility in which human body material (such as blood, urine, tissue samples...) together with additional data relating to this material is stored. Your samples will be kept for the duration of the study and will be used to perform the study-specific analyses. At the end of this period, your samples will be transferred to a prospective research biobank for future scientific research. Any such new study must be submitted to and approved by the ethics committee.

The medical manager of this biobank is Prof. Dr. Padalko: elizaveta.padalko@uzgent.be, telephone: 09/332.21.08 UZ Gent | Laboratorium Klinische biologie, Ingang 22 - route 300, C. Heymanslaan 10, 9000 Gent, België.
However, you remain the "owner" of your body material. This means that you can always demand that the biobank destroy your stored samples. To do this, you must contact the researcher responsible for the study (UGhent), who will then see to it that your stored body material is destroyed. Your samples that are collected and analysed within the framework of this study will always be pseudonymised after collection.

7 WHAT ARE YOUR RIGHTS IN PARTICIPATING IN THIS STUDY?

7.1 Rights when participating in the study

Participation in this study is entirely voluntary; there can be no coercion of any kind. You can refuse to take part in the study and you can withdraw from the study at any time without having to give a reason and without this in any way affecting your further relationship with the researcher. This will also not have a negative impact on your supervision trajectory within the organisation.

You may be withdrawn from the study prematurely by the researcher if you do not follow the procedures described in this information letter properly or if you do not respect the items described.
If you are withdrawn from the study, the pseudonymised data already collected will remain in the database for analysis, but no new data will be added.

This study was pre-approved by an independent Medical Ethics Committee affiliated with Ghent University Hospital and Ghent University. The study is being conducted in accordance with the guidelines for good clinical practice (ICH/GCP) and the Declaration of Helsinki drawn up to protect people taking part in clinical trials. Under no circumstances should you consider the approval by the Medical Ethics Committee as an inducement to participate in this study.

7.2 Rights with regard to the processing of personal data

In accordance with the General Data Protection Regulation (or GDPR) (EU) 2016/679 of 27 April 2016 (in force from 25 May 2018) and the Belgian law of 30 July 2018, on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, your privacy will be respected and you may access the data collected about you. Any incorrect information may be corrected at your request. Your other rights (being the right to have your data deleted in certain circumstances, to withdraw your consent and to file a complaint) are also monitored. For more information about the rights you have and how you can exercise them, please visit the UGent website (https://www.ugent.be/nl/univgent/privacy/privacystatement.htm).

Your participation in the study means that your data will be processed for the purpose of the clinical trial. This processing of data is based on your consent, as stated in Article 6, paragraph 1 (a) and is necessary for scientific research in accordance with Article 9, paragraph 2 (j) of the General Data Protection Regulation.

All information collected during this study will be pseudonymised (this will still allow you to link your data back to your personal file). The key to these codes will be accessible only to the researcher or his/her appointed replacement. In this study, a follow-up phone call will be made and you will be asked for a personal phone number on which you can be contacted. If you agree, the telephone conversation will be recorded. If you also take the self-test and you wish to be informed of a positive test result by e-mail, we will also ask for your e-mail address.
Only pseudonymised data will be used for data analysis and in any documentation, reports or publications (in medical journals or conferences) concerning the study. Confidentiality of your data is thus guaranteed at all times. Both personal data and data concerning your health will be processed and kept for at least 10 years after the end of the study and for safety reasons with regard to the study performed and its follow-up. The data controller is the institution of the principal investigator of the study, Prof. O. Degomme (ICRH UGent). His research team will have access to your personal data. In the context of data protection, the data will be processed by persons belonging to the research team and appointed by and under the responsibility of the principal investigator, including internal staff members with a non-healthcare profession.

Should your data need to be transferred to a country outside the European Economic Area (EEA) or to an international organisation, U(Z) Gent will ascertain whether the country of destination offers an adequate level of protection. If the country to which U(Z) Gent wishes to transfer data does not provide an adequate level of protection, U(Z) Gent shall, by means of standard contracts made available by the European Commission or other accepted measures, ensure that it provides adequate protection itself. Your explicit consent to this data transfer is requested in the consent form below.

To obtain more substantive information about the study and to be able to exercise your rights, please contact the study team.
The Data Protection Officer can provide you with more information on the protection of your personal data if you wish. Contact details: Hanne Elsen, privacy@ugent.be.

Representatives of the sponsor, auditors, the Medical Ethics Committee and competent authorities, all bound by professional secrecy, have direct access to your medical records to check the procedures of the study and/or the data, without breaching confidentiality. This can only be done within the limits permitted by the relevant laws. By signing the consent form, after prior explanation, you agree to this access.

The Belgian supervisory authority responsible for enforcing data protection legislation can be contacted via the contact details below:

Gegevensbeschermingsautoriteit (GBA)
Drukpersstraat 35 – 1000 Brussel
Tel. +32 2 274 48 00
e-mail: contact@apd-gba.be
Website: www.gegevensbeschermingsautoriteit.be

8 INSURANCE

The sponsor provides for compensation and/or medical treatment in case of damage and/or injury resulting from participation in this clinical study. For this purpose, an insurance has been taken out with faultless liability in accordance with the law on experiments on the human person of 7 May 2004, the Belgian law of 7 May 2017 on clinical trials with medicinal products for human use and the Belgian law of 22 December 2020 on medical devices (Allianz Global Corporate & Specialty - policy number client UZ Gent BEL001889 - policy number client UGent BEL000862). If the investigator is of the opinion that there is a possible link with the study (there is no link with the study in case of damage due to the natural course of the disease or due to known side effects of the standard treatment), he/she will start the declaration procedure with the insurance company. At that time, your details may be passed on to the insurance company. In the event of a disagreement with the investigator or with the expert appointed by the insurance company, and whenever you consider it necessary, you or, in the event of your death, your successors may sue the insurance company directly in Belgium (Allianz Global Corporate & Specialty; Uitbreidingstraat 86, 2600 Berchem; Tel: +32 33 04 16 00).

9 WHAT ARE THE RISKS AND EXPECTED BENEFITS OF PARTICIPATING IN THIS STUDY?

Participation in this study is unlikely to bring any immediate therapeutic benefit to you. However, your participation in the study may help us to help patients better in the future. Participation in this study will give you more information about (screening for) cervical cancer and (if you wish) more information about your own risk of cervical cancer. The likelihood that you will experience any harm as a result of taking part in this study is extremely low. After taking the test there is a small chance of a (light) bleeding. This one is harmless.

It is also possible that other risks and inconveniences may occur that are currently unknown. It is therefore very important to report any new health complaint to the investigator as soon as possible, regardless of whether you think the complaint is related to the study or not.

If you do not wish to take part in this study, we would like to draw your attention to the fact that you can always have yourself screened for cervical cancer by your GP or gynaecologist.

You have the right to ask questions at any time about the possible and/or known risks of this study. If, in the course of the study, information comes to light that could influence your willingness to continue participating in this study, you will be informed accordingly. If you do experience any disadvantage as a result of your participation in the study, you will receive appropriate treatment.

10 ARE THERE ANY COSTS INVOLVED IN PARTICIPATING IN THIS STUDY?

Participation in this study does not involve any additional costs for you.

11 IS THERE ANY COMPENSATION PROVIDED FOR PARTICIPATION IN THIS STUDY?

You will not receive any financial compensation or reimbursement of travel expenses for your participation in this clinical trial.

12 WHO CAN YOU TURN TO IF YOU HAVE PROBLEMS OR QUESTIONS?

If an injury occurs as a result of the study, or if you would like additional information about the study or your rights and obligations, you can contact the physician-investigator or a member of his or her team at any time during the course of the study:

Name: Prof. O. Degomme
Address: Corneel Heymanslaan 10, 9000 Ghent
Telephone number: 09/332 35 64

CONSENT FORM FOR EXPERIMENT PARTICIPANTS

Reference number of the participant for this study	

I have read and understood the document "Information letter for participants in an experiment" pages 1 to 6 and have been given a copy of it. I have been explained the nature, purpose, duration, foreseeable effects of the study and what is expected of me. I have been explained the possible risks and benefits of the study. I have been given the opportunity and sufficient time to ask questions about the study and have received satisfactory answers to all my questions, including medical ones.
I understand that participation in the study is voluntary and that I may withdraw from the study at any time without giving a reason for this decision and without this affecting my future treatment in any way.
I understand that auditors, representatives of the sponsor, the Medical Ethics Committee or competent authorities may wish to inspect my data in order to verify the information collected. Furthermore, I am aware that certain data will be passed on to the sponsor of the study. I understand that this may involve the transfer of my data to a country outside the European Union. My privacy will be respected at all times.
I am aware that this study has been approved by an independent Medical Ethics Committee attached to UZ Gent and Ghent University and that this study will be conducted in accordance with the guidelines for Good Clinical Practice (ICH/GCP) and the Declaration of Helsinki, drawn up to protect people participating in experiments. This approval was in no way the impetus for deciding to take part in this study.
I have been informed that both personal data and data concerning my health will be processed and kept for at least 10 years after the end of the study. I have been informed that I have the right to access and correct this data. As these data are processed for medical scientific purposes, I understand that access to my data may be delayed until after the research has been completed. If I wish to access my data, I will contact the researcher responsible for processing it.

	Tick by participant if agreed
I agree to participate in the following parts of the study:	
1) I agree to cooperate fully with the investigator. I will inform him/her if I experience unexpected or unusual symptoms.	
2) I agree to follow the info session	
3) I agree that my pseudonymised data will be used for current scientific research	
4) I agree to complete the questionnaires within this study.	
5) I agree to take a self-test for further research.	
6) I agree that my phone number will be used to contact me 3 months after the info session and (if applicable) to inform me of my test result.	
7) I agree that the telephone conversation will be recorded for scientific purposes.	
8) I agree that my e-mail address will be used to inform me (if so desired by me and if applicable) of my test result.	
9) I agree that my data may be transferred to a country outside the European Economic Area (EEA) or to an international organisation.	
10) I agree that upon completion of the study my samples may be transferred to a prospective research biobank for future scientific research solely in the context of my disease/pathology or treatment. Any such new study must be submitted to and approved by the ethics committee.	

Name and first name of the participant	Signature	Date
Name and first name of the doctor-investigator*	Signature	Date

2 copies must be completed. The original is kept by the researcher in the hospital for 20 years, the copy is given to the participant.

*Tick by researcher if agreed

I declare that I have provided the necessary information concerning this study (its nature, purpose and foreseeable effects) orally and have given a copy of the information document to the participant.	
I confirm that no pressure was exerted on the participant to agree to participate in the study and I am prepared to answer any additional questions.	

Information sheet for the participants

Title of the study: ELEVATE: "EarLy dEtection of cerVical cAncer in women who do not participate in traditional screening through portable and point-of-care HPV* TEsting"

Focus group discussions

(*HPV = human papilloma virus)

Dear,

You are invited to participate in a study. Before you decide to participate in this study, take sufficient time to read this information sheet carefully. Please take time to ask questions if there are any uncertainties or if you need additional information. This process is called "informed consent". Once you have decided to participate in the study, you will be asked to sign the consent form at the end of this information sheet.

1 DESCRIPTION AND PURPOSE OF THE STUDY

You were approached by a member of our research team to participate in a study. As you know the International Centre for Reproductive Health (Ghent University) conducts an investigation to develop a new test for cervical cancer screening. This new test would be based on self-sampling and would be used to reach women who don't attend the 'regular' screening program. Since you were involved in the conduction of the 'Acceptability Study' we would like to have discussions with the people involved in the roll out of the intervention, like you, to have an idea of the feasibility of this intervention. During these discussions we will talk the things that went well, the aspects of the intervention that in your opinion should change, the feasibility of the intervention, the responses and feedback of the participants,…
We kindly ask you if you would like to take the time to participate in such a group discussion. This will take up to 2 hours (maximum) of your time.

This study was evaluated by the Ethics Committee of University Hospital Ghent and University Ghent. The study is conducted in accordance with the guidelines of good clinical practice (ICH/GCP) and the Helsinki Declaration, written to protect those involved in clinical studies.

This collection of data is carried out under the supervision of Prof. Olivier Degomme. As the study is conducted by Ghent University, students will be involved with the collection and processing of the data.

2 CONSENT AND REFUSAL

Your participation in this study is entirely free and voluntary. You are free to withdraw from this study at any time, without having to justify your decision. This will not affect your relationship with the investigator and/or your working relationship with others.

3 ADVANTAGES

Participation in this study will probably not bring you any benefits. However, the results obtained can lead to new and more efficient methods for the prevention of cervical cancer.

4 COSTS

Your participation in this study does not entail any additional costs for you. The time you free up for this study will be compensated appropriately.

5 PROCESSING OF PERSONAL DATA

In accordance with the General Data Protection Regulation (or GDPR) (EU) 2016/679 of 27 April 2016 (in force from 25 May 2018) and the Belgian law of 30 July 2018, on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, your privacy will be respected and you may access the data collected about you. Any incorrect information may be corrected at your request.
Your other rights (being the right to have your data deleted in certain circumstances, to withdraw your consent and to file a complaint) are also monitored.
For more information about the rights you have and how you can exercise them, please visit the UGent website (https://www.ugent.be/nl/univgent/privacy/privacystatement.htm).

Your participation in the study means that your data will be processed for the purpose of the study. This processing of data is based on your consent, as stated in Article 6, paragraph 1 (a) and is necessary for the purpose of scientific research according to Article 9, paragraph 2 (j) of the General Data Protection Regulation.

All information collected during this study will be pseudonymised (this will still allow you to link your data back to your personal data). The key to the codes will only be accessible to the researchers or their appointed replacement.

Only pseudonymised data will be used for data analysis and in any documentation, reports or publications (in journals or conferences) concerning the study.
Confidentiality of your data is thus guaranteed at all times. Your personal data will be processed and kept up to at least 10 years after the end of the study and for safety reasons with regard to the study performed and its follow-up (if any).

The person responsible for processing the data is the institution of the principal investigator of the study, Prof. O. Degomme (UGent). His research team will have access to your personal data.
In the context of data protection, the data will be processed by persons belonging to the research team and appointed by and under the responsibility of the principal investigator including internal staff members with a non-healthcare profession.

Should your data need to be transferred to a country outside the European Economic Area (EEA) or to an international organisation, U(Z) Gent will ascertain whether the country of destination offers an adequate level of protection. If the country to which U(Z) Gent wishes to transfer data does not provide an adequate level of protection, U(Z) Gent shall, by means of standard contracts made available by the European Commission or other accepted measures, ensure that it provides adequate protection itself. Your explicit consent to this data transfer is requested in the consent form below.

To obtain more substantive information about the study and to be able to exercise your rights, please contact the study team.
The Data Protection Officer can provide you with more information on the protection of your personal data. Contact details : Hanne Elsen, privacy@ugent.be .

Representatives of the sponsor, auditors, the Medical Ethics Committee and competent authorities, all bound by professional secrecy, have direct access to your medical records to check the procedures of the study and/or the data, without breaching confidentiality. This can only be done within the limits permitted by the relevant laws. By signing the consent form, after prior explanation, you agree to this access.

The Belgian supervisory authority responsible for enforcing data protection legislation can be contacted via the contact details below:

Gegevensbeschermingsautoriteit (GBA)
Drukpersstraat 35 – 1000 Brussel
Tel. +32 2 274 48 00
e-mail: contact@apd-gba.be
Website: www.gegevensbeschermingsautoriteit.be

6 INSURANCE

The sponsor will provide compensation and/or medical treatment in the event of damage and/or injury resulting from participation in this clinical study. For this purpose, insurance has been taken out with no-fault liability in accordance with the law on experiments on the human person of 7 May 2004, the Belgian law of 7 May 2017 on clinical trials with medicinal products for human use and the Belgian law of 22 December 2020 on medical devices (Allianz Global Corporate & Specialty; Uitbreidingstraat 86, 2600 Berchem; Tel: +32 33 04 16 00; policy number for UZ Gent BEL001889 - policy number for UGent BEL000862).

7 CONTACT

If you would like additional information about the study or your rights and obligations, please contact the investigator or a member of his or her team:

Name: Prof. O. Degomme
Address: Corneel Heymanslaan 10, 9000 Ghent
Telephone number: 09/332 35 64

INFORMED CONSENT FORM FOR THE PARTICIPANTS

I have read and understood the document "Information letter for participants" pages 1 to 4 and have been given a copy of it. I have been explained the nature, purpose, duration, and what is expected of me. I have been given the opportunity and sufficient time to ask questions about the study and have received satisfactory answers to all my questions.
I understand that participation in the study is voluntary and that I may withdraw from the study at any time without giving a reason for this decision and without this affecting my relationship with the investigator.
I am aware that this study has been approved by an independent Medical Ethics Committee attached to UZ Gent and Ghent University and that this study will be conducted in accordance with the guidelines for Good Clinical Practice (ICH/GCP) and the Declaration of Helsinki, drawn up to protect people participating in experiments. This approval was in no way the impetus for deciding to take part in this study.
I have been informed that my personal data will be processed and kept for at least 10 years. I have been informed that I have the right to access and correct this data. As these data are processed for scientific purposes, I understand that access to my data may be delayed until after the research has been completed. If I wish to access my data, I will contact the researcher responsible for processing it.

Tick by participant if agreed

I agree to participate in the following parts of the study:	
1) I agree to cooperate fully with the investigator.	
2) I agree to take part in the focus group discussion.	
3) I agree that my data may be transferred to a country outside the European Economic Area (EEA) or to an international organisation.	

Name and first name of the participant	Signature	Date
Name and first name investigator	Signature	Date

2 copies must be completed. The original is kept by the investigator for a period of 10 years, the copy is given to the participant.

* Tick by the investigator if you agree

I declare that I have provided the necessary information regarding this study (the nature, the purpose, and the foreseeable effects) orally and a copy of the information document to the participant.	
I confirm that no pressure has been exerted on the participant to allow him/her to participate in the study and I am prepared to answer any additional questions.	