Online Information letter and participation form for participants – Version X.X *(enter the version number of the final ICF here)* dd. YYYY-MM-DD *(enter the date of the final ICF here)*

Information letter for participants

**Title of the study:** **Enter the official title as stated in the research portal or the protocol**

Sponsor: Ghent University Hospital ***OR*** Ghent University

Investigator(s):

U(Z) Ghent: Name, address, telephone number

Central commission for medical ethics: affiliated with Ghent University Hospital and Ghent University

Data protection officer U(Z) Ghent:

Katya Van Driessche, [dpo@uzgent.be](https://zenya.uzgent.be/management/hyperlinkloader.aspx?hyperlinkid=f97095e9-66a3-4a43-a51b-c8e82b0c2005) ***OR***Hanne Elsen, [privacy@ugent.be](https://zenya.uzgent.be/management/hyperlinkloader.aspx?hyperlinkid=8c65ef48-91c0-4fb2-9a8c-8282b0d5c16c)

No fault insurance: Allianz Global Corporate & Specialty; Uitbreidingstraat 86, 2600 Berchem; Tel: +32 33 04 16 00

Data Protection Authority: Drukpersstraat 35 – 1000 Brussels – Tel +32 2 274 48 00 – mail: [contact@apd-gba.be](https://zenya.uzgent.be/management/hyperlinkloader.aspx?hyperlinkid=54101cb4-90d7-4b61-9a45-fa2216f9a769) – website: www.dataprotectionauthority.be.

# PARTICIPATING IN A STUDY

You are invited to participate in a study. Before you agree, we ask that you read the following information carefully so that you can make an informed decision about it.

If you wish, you can contact the investigator or his/her representative in case of questions or if you require additional information.

If you wish to participate in the study, you can click through to the end of this information letter, thereby giving your consent and confirming that you have received the necessary information about this study.

This document consists of 3 parts: 1) basic information about the study, 2) additional information and 3) the participation form.

# BASIC INFORMATION

We invite you to participate in a study xxx.

## What does participation in the study include?

For the purpose of this study, we kindly ask you to xxx.

The questionnaires for the study will be sent to your personal e-mail address.

## Costs and compensation

Participation in this study involves no additional costs for you.

You will not receive any compensation for your participation in this study.

# additional INFORMATION

This study was approved in advance by the independent medical ethics committee(s). The study is conducted according to the guidelines for good clinical practice (ICH/GCP) and the Declaration of Helsinki drawn up to protect people participating in studies. Under no circumstances should you consider approval by the medical ethics committee as an incentive to participate in this study.

Students from the department xxx will be part of the study team.

# *Advantages of participating in the study*

Participation in this study will probably bring no benefit to you. Your participation in the study may possibly help patients in the future.

The chance that you will experience any harm as a result of participating in this study is extremely low.

# *Your rights*

Participation in this study is entirely free and voluntary. You can refuse to participate in the study and you are free to withdraw from this study at any time, without having to give a reason. Ending your participation will not affect your continued relationship with the investigator.

The information collected during the study is pseudonymized. Pseudonymisation is also called “coding”. This means that your data can be linked back to your personal file via a code. The key to the codes will only be accessible to the investigator or his/her designated representative.

If you are withdrawn from the study or if you decide to terminate your participation, the pseudonymised data already collected (that is, identifiable only by a unique code) will remain in the database for analysis. No new data will be added in this case.

# *Protection of your personal data*

Participation in the study means that your personal data will be processed for the purpose of this study. This processing of your personal data is necessary for the performance of a task carried out in the public interest and for the purpose of scientific research (according to article 6, paragraph 1 (e) and article 9, paragraph 2 (j) of the General Data Protection Regulation and the Coordinated Hospitals Act of July 10, 2008).

Your personal data will be protected at all times. In accordance with the Belgian law of August 22, 2002 on patient rights, the General Data Protection Regulation (or GDPR) (EU) 2016/679 of April 27, 2016 and the Belgian law of July 30, 2018, on the protection of natural persons with regard to the processing of personal data and on the free movement of such data.

You may request access to the data collected about you. Any data can be corrected at your request. Your other rights (including the right to limit the processing of your (personal) data and the right to submit a complaint) will also be guarded.

For more information about your rights and how to use them, please visit the website of UZ Ghent ***OR*** UGhent.

The pseudonymised data collected in this study may be shared with other researchers. Reuse of your pseudonymised data in future academic research can only occur when the research is compatible with the current study. This reuse of data must always be submitted and approved in advance by an ethics committee or Data Access Committee.

In case your data would be used for commercial purposes or by commercial organizations in the context of future research, you must give your consent via the checkboxes in the participation form. This processing of your data is done on the basis of consent (as stated in GDPR, article 6, paragraph 1(a)).

In reports or publications about this study (such as in medical journals or conferences), the data will be processed in such a way that you are not directly identifiable as an individual. Also, when the datasets within this study are made public on an online platform, your personal data will not be made public. Your personal data will always be protected appropriately.

Both your personal data and sensitive personal data (like for example health data) will be processed and kept within this study for at least 10 years after the end of the study.

The data controller is the institution of the study's principal investigator, Dr. xxx (indicate the study's principal investigator here) (UZ Ghent ***OR*** UGhent). His/her study team will have access to your personal data. The data will be processed for data protection purposes by individuals within the study team, under the responsibility of the principal investigator. This team also includes employees with non-health care professions.

In case your data should be transferred to a country outside the European Economic Area (EEA), U(Z) Ghent will verify whether the destination country provides an adequate level of data protection. If that country does not provide adequate guarantees, U(Z) Ghent will enforce adequate guarantees itself, for example, through model agreements. For this, you must give your consent via the checkboxes in the participation form.

When the procedures and/or the data collected within the study need to be monitored by representatives of the sponsor, auditors, the medical ethics committee or the appropriate authorities, these parties may have access to your data. These individuals will not violate confidentiality.

To obtain more detailed information about the study and to exercise your rights, please contact the study team.

The Data Protection Officer can also provide you with more information about the protection of your personal data. In addition, you have the right to file a complaint with a supervising authority. In Belgium this is the Data Protection Authority (see contact information at the top).

# *Insurance*

The sponsor provides compensation and/or medical treatment in the event of damage and/or injury resulting from participation in this study. Therefore, insurance has been taken out with no-fault liability, in accordance with the law on experiments on the human person of May 7, 2004, the Belgian law of May 7, 2017 on clinical trials of medicines for human use, the Belgian law of December 22, 2020 on medical devices and the Belgian law of June 15, 2022 on in vitro diagnostic medical devices. If the investigator believes that there is a possible connection to the study he/she will initiate the declaration procedure with the insurance company. At that time, your data may be transmitted to the insurer.

**PARTICIPATION FORM**

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| I have read and understood the document “Information letter for participants” and I can download a copy. I have been informed about the nature of the study, its purpose, the duration and what is expected of me. |
| I understand that participation in the study is voluntary and that I can withdraw from the study at any time without giving a reason for this decision and without this having any influence on my further treatment or relationship with the investigator. |
| I am aware that this study has been approved by the independent medical ethics committee(s) and that this study will be conducted in accordance with the guidelines for good clinical practice (ICH/GCP) and the Declaration of Helsinki, established to protect people participating in studies. This approval should under no circumstances be taken as an incentive to participate in this study. |
| I have been informed that personal data, including health data, will be processed and kept for at least 10 years after the end of the study. I am informed that I have the right to access and correct this data. Since this data is processed for medical scientific purposes, I understand that access to my data may be delayed until after the study ends. If I want access to my data, I will contact the investigator who is responsible for the processing of the data. |
| I am aware that my pseudonymised data will be used for the **current** study. |
| I am aware that my pseudonymised data may be used for **future academic scientific research** compatible with the current study. Such new study should always be submitted and approved by an ethics committee or Data Access Committee. If I wish my data not to be used for future research, I will contact the investigator. |

I consent to participate in this study consisting of the following **mandatory items** (if I do not consent to these items, I cannot participate in the study):

O I confirm that I have reached the age of majority.

O I agree to participate in this study which includes xxx.

O For this study, data transfer to a country outside the EEA is possible. By checking this box, I consent to this.

**Optional items** of the study:

O I agree that my pseudonymized data may be used for commercial purposes or by commercial organizations.

O I agree to be contacted again as part of a new follow-up study.

O If I complete this form digitally, I agree that my name, e-mail address, mobile phone number and date of birth will be collected in the sponsor's electronic study database.

START THE QUESTIONNAIRE