INFORMED CONSENT FORM
FOR CLINICAL TRIALS WITH IMP ON ADULT PATIENTS

A study to find out whether BI 765423 has an effect on lung function in people with idiopathic pulmonary fibrosis (IPF) with or without standard treatment

Official title of the trial: A double-blind, randomised, placebo-controlled, parallel group, Phase IIa trial to evaluate safety, tolerability, pharmacokinetics, pharmacodynamics, and efficacy of BI 765423 administered intravenously with or without standard of care in patients with idiopathic pulmonary fibrosis

Participant number:_____

EU Number: 2025-520658-12

Trial number: 1493-0002

Sponsor(s) of the trial: Boehringer Ingelheim International GmbH, Binger Strasse 173, 55218 Ingelheim am Rhein, Germany

Contract Research organisation: IQVIA LTD, 3 Forbury Place, 23 Forbury Road Reading, RG13JH, United Kingdom

Site name: *official name of site*

Main address of site: *address of site*

Document Revision History

Version No.	Version Date	Revision description
Main_V1.0BEL3.0	30Oct2025	N/A (Initial ICF)
Main_V3.0BEL2.0	18Jun2026	Global Protocol Update V2.0

Who can I contact in case of questions?

Name	Function	In case of	Contact Details
Surname, First name	Principal Investigator of the site	Information, problems or concerns	Phone N°, E-mail
	The trial staff	Information, problems, concerns	Phone N°, E-mail
	Contact for urgent trial-related questions	Urgent information, problems, concerns	Phone N°
	Ombudsperson for patient rights of the site	Concerns/ questions about your rights as a participant in a clinical trial	Phone N° from the site
Allianz Global Corporate and Specialty SE (Belgium Branch)	Insurance Company of the sponsor	In case of disagreement or complaint on a damage claim	Policy number: BEL000420 Uitbreidingstraat 86 B-2600 Berchem Phone: +32 (0)3 304 16 00 Fax: +32 (0)3 304 16 99
	Data protection officer of the **site**	Questions about the confidentiality of your data	Phone N° E-mail:
	Belgian Data Protection Authority	Complaints relating to the confidentiality of your data	+32 (0)2 274 48 00 E-mail : contact@apd-gba.be

● To manage complaints not resolved by the investigator, you can contact the trial site ombudsman at the above address.

● According to the GDPR, you have the right to access the processing of your data. For questions about this, you can contact the trial site's Data Protection Officer at the above address.

● You also have the right to lodge a complaint about the way your data are processed with the Belgian supervisory authority responsible for compliance with data protection legislation: Data Protection Authority (GBA), above.

TABLE OF CONTENTS

Document Revision History **1**
Who can I contact in case of questions? **2**

THE TRIAL AT A GLANCE **6**

CHAPTER I – DESCRIPTION OF THE TRIAL AND YOUR RIGHTS WHEN PARTICIPATING **8**

1. Why is this trial being conducted? **8**
2. Why am I being asked to take part? **8**
3. Do I have to take part in a trial? **8**
4. What will happen during the trial? **8**
5. Will I benefit from the trial? **10**
6. What are the possible risks and discomforts of taking part? **11**
6.1. What are the possible side effects of BI 765423? 11
6.2. What are the possible risks or discomforts of the examinations during the trial? 12
6.3. Can I take other medicines during the trial? 12
6.4. Will my participation to the trial have an impact on my daily activities and what are my responsibilities? 12
6.5. Can I get pregnant, conceive a child or breastfeed during the trial? 13
7. What if something goes wrong within the trial? **13**
8. What if other treatment options or new information on the IMP of the trial become available during the course of the trial? **14**
9. Can my participation in the trial end prematurely? **14**
9.1. You decide to withdraw your consent 14
9.2. You decide to discontinue treatment with the IMP 15
9.3. The investigator decides to end your trial participation or to discontinue your treatment with the IMP 15
9.4. Other entities may interrupt or end the trial 16
10. Which treatment will I get after my participation in the trial? **16**
11. Will my participation in the trial involve extra costs for me? **16**
11.1. Examinations and treatments paid by the sponsor 16
11.2. Other expenses paid by the sponsor 16
12. Which data are collected about me during the trial and what will happen with them? **17**
12.1. Which data are collected and processed during the trial? 17
12.2. How will the investigator treat my personal data? 17
12.3. How will my data be handled? 18

12.4. Do I have access to my data collected and processed during the trial and can I rectify them? ... 18
12.5. Who, other than the Investigator and his trial staff, has access to my personal data? ... 19
12.6. What will happen to the results of the trial? ... 20
12.7. Will my data be used for other purposes than for the trial in which I take part? ... 20
12.8. How long will my data be kept? ... 21
13. Which biological samples are collected from me during the trial and what will happen with them? ... 21
13.1. Which biological samples are collected from me during the trial? ... 21
13.2. What will happen to the collected biological samples within the context of the trial? ... 22
14. What if the trial reveals meaningful information about your health? ... 22
15. Who has reviewed and approved the trial documents? ... 22

APPENDIX A: VISIT SCHEDULE ... 23

APPENDIX B: TRIAL PROCEDURES AND RISKS ... 25

APPENDIX C: POSSIBLE SIDE EFFECTS OF THE TRIAL MEDICINE ... 29

APPENDIX D: ACCEPTABLE METHODS OF BIRTH CONTROL ... 31

CHAPTER II - INFORMED CONSENT ... 32
PARTICIPANT ... 32
IMPARTIAL WITNESS / INTERPRETER (REF. 3) ... 34
INVESTIGATOR ... 35

GLOSSARY ... 36

REFERENCES ... 37

THE TRIAL AT A GLANCE

Dear Patient,

You are being asked to take part in a clinical trial (further on referred to as “the trial”) because you have a condition known as idiopathic pulmonary fibrosis (IPF).. The information in this document should help you to decide if you would like to participate.

Your participation in this trial is voluntary. Your decision will not affect your future medical care. Your condition may or may not improve if you decide to participate in the trial. But the information we get from this trial might help other people with the same condition in the future.

If you decide to participate, you will be asked to sign and date at the end of this form. Your signature confirms that you agree and accept to take part in this trial and to the confidential handling of your data as described in this form.

After that, your participation in the trial starts. Please keep in mind, you can withdraw from the trial at any time without any negative effect on your regular medical care.

This trial is to find out if a medicine called BI 765423 can improve lung function in people with IPF. BI 765423 is a [redacted] being developed to help reduce lung scarring and improve lung function by [redacted] involved in lung fibrosis and it may help slow down or stop the progression of lung fibrosis.

This trial compares BI 765423 with a placebo to see if there is a difference in lung function [redacted] and [redacted] of receiving BI 765423 or the placebo. Changes in certain blood test results and walking ability change over [redacted] related to lung health will also be looked at.

The placebo looks like BI 765423 but does not contain any medicine.

You will receive either BI 765423 or the placebo. It will be decided by chance [redacted] which one you will receive. You will receive BI 765423 or the placebo as an intravenous (IV) infusion (a slow injection directly into a vein).

You will receive the IMP [redacted] Neither you nor the investigator will know if you will get BI 765423 or the placebo.

You will be in this trial for up to [redacted] During this time, you will attend up to [redacted] trial site visits.

The investigator will also regularly check your health and take note of any unwanted effects. Unwanted effects are any health problems that may be caused by the IMP. The investigator will decide if these were caused by the IMP.

There are risks to taking part in any clinical trial. Your symptoms might improve, or your condition might not improve, or it could get worse during the course of this trial. Side effects may occur. Some of those side effects can be treated. Some may go away when you stop taking the IMP. Some can be mild, but others may continue longer or become permanent.

Your participation in this clinical trial helps doctors and researchers find medicines for others in the future. You may benefit from the additional care and attention from the trial staff.

You can take part in this trial only if you are unable to become pregnant due to the reasons mentioned in Appendix D. You are not allowed to get someone pregnant during the trial and for some time after it. The appropriate method of contraception will be discussed with you.

You will not be paid for participating in this trial. You will only receive compensation for some out-of-pocket expenses.

After you stopped the treatment with the IMP, the investigator will assess your health. If necessary, he/she will prescribe you the best standard treatment available or refer you to another treating physician of your choice.

You will be asked:

- to agree that the investigator informs the treating physicians regarding participation in the trial
- to communicate the relevant information related to the state of health, other medication taken or the symptoms experienced
- to carry the "Trial Identification Card" at all times

The sponsor of this trial, the company Boehringer Ingelheim has taken out insurance for this trial.

The sponsor has designed the trial. The trial site receives compensation from the sponsor for setting up and carrying out the trial in the trial site.

You do not have to pay to participate. All treatments and examinations that you will receive and undergo in the context of the trial will be paid by the sponsor and will not be charged to you or your mutual insurance fund unless they are considered as standard of care by your investigator.

The documents of the trial have been reviewed by the Belgian competent health authorities (FAMHP) or if applicable by the competent national health authorities of other EU members states and an independent Belgian Ethics Committee.

The investigator will explain the purpose of the trial and the possible benefits and risks of your participation. Please ask questions about anything that is unclear at any time. Take your time to decide. Feel free to discuss with your family, friends, or treating physician.

If you have any questions about the trial, please contact your investigator or trial staff listed in the section “Who can I contact in case of questions?” above.

CHAPTER I – DESCRIPTION OF THE TRIAL AND YOUR RIGHTS WHEN PARTICIPATING

1. Why is this trial being conducted?

This clinical trial (further on referred to as “trial”) will evaluate the investigational medicinal product (IMP), BI 765423 for the treatment of idiopathic pulmonary fibrosis (IPF). The purpose of this trial is to find out whether the IMP, BI 765423, helps participants who have IPF, and to see if BI 765423 is safe and well tolerated compared to participants who receive the placebo.

The IMP, BI 765423, may help reduce lung scarring and improve lung function by [redacted] involved in lung fibrosis and it may help slow down or stop the progression of lung fibrosis. BI 765423 has not been approved as a treatment for any condition in any country. Thus, its use in this clinical trial is experimental.

2. Why am I being asked to take part?

You are being asked to take part in a clinical trial because you have a lung condition known as IPF.

The investigator or trial staff will discuss with you the requirements to be allowed to enter the trial.

Instead of participating in this trial, you might have other options. You may:

- remain on your current standard-of-care treatment
- receive approved treatments such as, [redacted] or other treatments that are approved in your country.
- receive comfort care, also called palliative care to treat your symptoms

Or you may decide not to be treated for your condition. You may also take part in another clinical trial.

Your investigator will discuss these options with you and explain potential risks and benefits. This happens before you decide whether you will take part in this trial.

3. Do I have to take part in a trial?

Your participation in a trial is voluntary and must remain free of any coercion. This means that you have the right not to take part in the trial or to withdraw at any time without giving a reason, even if you previously agreed to take part. Your decision will not affect your relationship with the investigator or your treating physician nor will it affect the quality of your future medical care.

If other treatments are available for your condition, the investigator or his/her delegate will discuss these treatments with you.

4. What will happen during the trial?

This trial will include about [redacted] participants worldwide, including about [redacted] in Belgium.

In the following text and flow charts you will find the treatments or examinations that you will have to undergo, with the specifications which ones are trial specific and which ones are part of your standard care. The treatments and examinations that are trial specific will be paid by the sponsor and will not be charged to you. The standard procedures or examinations for your condition (i.e. standard of care) will be charged to you or reimbursed by your mutual insurance fund (Belgian social security).

If you need more details or if you are not affiliated with a mutual insurance fund (Belgian social security), please contact the trial staff.

Overall, your participation in the trial will last up to [redacted] and involve up to [redacted] visits.

If you meet all the conditions required to be enrolled in the trial and agree to take part in the trial, you will undergo the below-mentioned tests and examinations.

Consultations and treatments resulting from an adverse reaction are also considered trial specific.

> You can find out in detail what will happen at each visit and how long each visit will take in Appendix A. The tests and checks done at the visits are described in Appendix B. Your investigator and the trial staff will go through these details with you.

Description of the trial

This trial is comparing BI 765423 with a placebo. During this trial, you can continue to take certain standard of care treatments for your IPF.

It will be decided by chance whether you will receive BI 765423 or the placebo. This is called randomisation. You will have an [redacted] of getting BI 765423 or the placebo.

You will not know if you will receive BI 765423 or the placebo. The investigator and trial staff will not know either. This way, the results of this trial will not be favoured one way or another. If it becomes necessary for your care, your investigator will be able to find out if you are receiving BI 765423 or the placebo.

After this trial ends, you could ask to find out if you received BI 765423 or the placebo. This may not be possible until [redacted] after your last trial visit.

The term 'IMP' refers to BI 765423 and the placebo, if not otherwise specified in this form.

Trial Procedures

This section summarises what you can expect during visits for this clinical trial.

Screening visit

Before you receive BI 765423 or the placebo, you will attend a screening visit. At this visit, the trial staff will do some tests and checks to find out whether this is the right trial for you.

If the results of the screening tests show that you cannot participate this time, you may be able to participate in this trial or another trial in the future. Keep in mind, the tests are done to check if it is safe for you to take part in this trial.

Regular visits while taking the IMP

At Visit 2, the trial staff will do additional tests and checks to confirm that you can safely participate in this trial. Once it is confirmed, you will receive the IMP.

You will be given the IMP [redacted] by an intravenous (IV) infusion at the trial site, which may either be at a hospital or at a specialized medical center. You will receive the IMP for [redacted]

During this time, you will attend regular trial site visits, where any effects of the IMP will be recorded.

At these visits, the investigator will check your IPF symptoms and collect information on any health problems.

At most visits, you will have breathing tests, the oxygen levels in your blood will be measured, and a [redacted] will be done. You will also be asked to complete a questionnaire about your IPF symptoms.

The investigator will regularly check your health and take note of any changes and unwanted effects.

End of Treatment Visit

When you stop receiving the IMP, you will need to attend an end-of-treatment visit. Most of the trial procedures will be repeated during this visit. These trial procedures are needed to help to understand the effects of the IMP on your health over time. Your investigator will discuss your future care and medicines with you.

Follow-up Period/Visit

After the end-of-treatment visit, you will remain in this trial for [redacted] During this follow-up period, 2 visits will be done.

Any changes to your health that continue after the IMP has been stopped will be followed until considered resolved by the investigator.

Can I provide feedback on my trial experience?

Yes, you can fill in the trial participant questionnaire that will be shared with you at the beginning, in the middle, and at the end of your trial participation. This helps us to learn from your experience as a trial participant. Please note, this questionnaire is optional, so you do not have to do it. The questionnaire will ask for your consent before you complete the questions. Your decision to participate in this trial is not dependent on your decision to complete the questionnaire.

5. Will I benefit from the trial?

The information obtained during a trial may contribute to a better understanding of the use of the investigational medicinal product (referred to as “IMP”) or to the development of a new medicinal product for the treatment of yourself or future patients.

The IMP may or may not be beneficial in treating your condition or relieving your symptoms. Even if it is beneficial to you, a potential return or worsening of symptoms, illness or disease is still possible.

6. What are the possible risks and discomforts of taking part?

6.1. What are the possible side effects of BI 765423?

Participation in a trial involves some risk.

Any medical procedure or treatment has risks, and therefore, any clinical trial has risks. Your condition might not improve, or it could get worse during this trial.

Please be aware that you may receive the placebo that looks like BI 765423 but does not contain any medicine.

Regardless of the IMP you receive, if you are currently receiving chronic stable standard of care treatment for your condition at the time you join this trial, you will continue to receive standard of care treatment for your condition. Your investigator will explain to you the requirements for the standard of care treatment.

The investigator and the trial staff will monitor your safety carefully. The IMP may be stopped or paused any time if any safety issues are noted.

If you receive BI 765423, side effects may occur. Many side effects can be treated. Some may go away when you stop receiving BI 765423. Others may continue or become permanent.

As with any medicine, an allergic reaction can occur. Common symptoms of an allergic reaction are rash, itching, skin problems, swelling of the face and throat, or breathing difficulties. If you think you are having an allergic reaction, call the investigator right away. If you are having trouble breathing, call 112.

Side effects, including allergic reactions may be mild, but some may be life-threatening or fatal. Possible side effects of BI 765423 are provided in Appendix C**.** The investigator or the trial staff will go through these with you. Ask any questions you might have.

Your health will be monitored throughout this trial, and changes to your health will be documented. Effects on your health may occur during this trial or after you have left this trial. The investigator may complete additional health assessments, if they think it is necessary. If the effects on your health seem related to your participation, the investigator will inform the sponsor.

Because this IMP is still under investigation, other currently unknown risks and discomforts could occur. **Therefore, it is very important that you report <u>any</u> new or worsened health problems immediately to the investigator, regardless of whether or not you think it has to do with the trial (or with BI 765423), and even when it is already described in this document. If you need to use other medication, discuss this with the investigator beforehand. If, for any reason, you consult another treating physician during the trial you must inform him/her that you are taking part in a trial and present your trial identification card. This could be important in determining a diagnosis and giving you the correct treatment if needed.**

6.2. What are the possible risks or discomforts of the examinations during the trial?

Medical procedures performed during this trial and their risks are described in Appendix B**.**

6.3. Can I take other medicines during the trial?

You should not take other medication that the one prescribed by your investigator during the trial. Please tell the investigator about all prescription and non-prescription medicines, herbal preparations, and food supplements that you are taking or planning to take. There may be some foods and medicines that you should avoid while in this trial.

Tell the investigator before you receive any vaccines. Live vaccines are not allowed within 4 weeks before your first dose of the IMP, during this trial, and for [redacted] after your last dose of the IMP. This is to lower the chance of getting an infection.

Do not hesitate to ask your investigator for more explanation about the use of other medicines and food supplements (including aromatherapy, phytotherapy, homeopathy…).

6.4. Will my participation to the trial have an impact on my daily activities and what are my responsibilities?

If you decide to participate in this trial, we ask you to follow a few rules. This is to protect your safety and to make sure the trial results are valid.

- Follow the instructions provided by the trial staff. Come to all scheduled trial visits.
- Do not participate in another clinical trial or in this clinical trial at another trial site. You may harm yourself if you participate at multiple trial sites.
- Tell the investigator if you have participated in a clinical trial within the last year.
- Tell the investigator if you participated in a clinical trial and received BI 765423 or any medicine that [redacted]
- Tell the trial staff if you are treated by another doctor during this trial. It is important that they understand what happened.
- Complete the questionnaires as instructed.
- Smoking, vaping, and the use of a water pipe should be avoided throughout this trial and are not allowed 1 hour before the breathing tests.
- Before trial site visits when breathing tests are done, you must refrain from strenuous activity at least [redacted] to the breathing tests, and you should also avoid cold temperatures, environmental smoke, dust, or areas with strong odours (such as perfumes). You should also wear loose-fitting clothing that allow you to breathe deeply during the breathing tests.
- If you are using bronchodilators (a medicine that helps to open the airways), you will be given information on when to stop using them before trial site visits

when breathing tests are done. You should bring your bronchodilators with you to the trial site to be used after certain tests are completed, if needed.

6.5. Can I get pregnant, conceive a child or breastfeed during the trial?

> ! If you can have children and are sexually active, please read this section, Appendix C and Appendix D carefully before choosing to participate in this trial.

If you are able to become pregnant, you may not take part in this trial. We cannot exclude the possibility that BI 765423 may affect the growth and development of your unborn baby. Animal studies showed an early end to pregnancy and birth defects in offspring.

If you are a woman, you can take part in this trial only if you are unable to become pregnant due to the reasons mentioned in Appendix D.

If you are a man who plans to father a child during the time of this trial, plus an additional [redacted] after the last dose of the IMP, do not take part in this trial. This is because the IMP may stay in the body for an extended period, and a longer timeframe is required to ensure reproductive safety. We do not know how BI 765423 may affect your unborn baby. You should also not donate sperm while taking part in the trial and for [redacted] after the last dose of the IMP for the same reason as above.

You should tell your female sexual partner that you are participating in this trial. If you take part in this trial, you will be required to use male contraception unless abstinence from male-female sex is a part of your regular sexual practice. Contraception is required to prevent pregnancy, as the potential effects on an unborn baby are not known. You will be required to inform the trial staff if your partner becomes pregnant.

Please read about the methods of birth control in Appendix D and talk to your investigator about the best method for you to use.

7. What if something goes wrong within the trial?

Even if there is no fault, the sponsor is liable for harm caused to you whether directly or indirectly related to your participation in the trial. The sponsor has taken an appropriate insurance (a so called “NO FAULT INSURANCE”) for this liability. A copy of the insurance certificate can be obtained from the investigator or trial staff.

If you (or in the event of death, your rightful claimants) seek compensation for a harm to your health as a direct or indirect result of participating in the trial, you must inform your investigator or trial staff promptly.

If the investigator believes that a link between the new or worsened health problem(s) and the trial is possible, he/she will inform the trial sponsor. The sponsor will then immediately initiate the declaration procedure to its insurance company. If the company considers it necessary, it will appoint an expert to assess whether there is a link between your reported health problem(s) and the trial. The insurance does not cover the natural progression of your disease/condition or the known side effects of

the treatment you would have received without taking part to the trial (*that is* your standard treatment).

Whenever you feel it is appropriate or if you or your rightful claimants disagree either with the investigator or with the expert appointed by the insurance company, you may contact the insurance company or proceedings may be brought against the insurance company. You will find the contact details in the section “Who can I contact in case of questions?” of this form.

8. What if other treatment options or new information on the IMP of the trial become available during the course of the trial?

During the course of the trial, important new information might become available, possibly affecting your decision to (further) participate. For example, other treatments for your condition or important new information on the IMP may become available. It is the duty of the investigator to discuss this new information in a timely manner with you and to give you the opportunity to re-consider your participation in the trial.

If you decide to stop taking part in the trial or if you are no longer able to participate, your investigator will see to it that you continue to receive the best possible medical care.

9. Can my participation in the trial end prematurely?

As explained in detail below, your trial participation may end prematurely when:

- you decide to stop IMP, but agree to continue participation and/or continue to be contacted
- you decide to withdraw your consent or to discontinue treatment with the IMP,
- the investigator decides to end your trial participation, or to discontinue your treatment with the IMP, or
- other entities interrupt or end the trial.

In any case, if your trial participation ends prematurely, the investigator will discuss your future medical care with you. Data collected before you terminate your participation will continue to be used as described in this form. This is to avoid skewing / biasing results of the trial (as described in Chapter I, § 12.4).

Depending on your situation, the investigator will discuss with you whether follow-up visits or procedures are needed.

If you experience a side effect at the time you stop taking the IMP, the investigator may contact you afterwards to determine whether or not the side effect disappeared after your participation in the trial ends.

If you experience a new side effect after stopping your participation in the trial, you may contact the investigator and ask for follow-up.

9.1. You decide to withdraw your consent

You are entitled to withdraw your consent for any reason, at any time, without having to justify your decision. However, for your safety, you should inform the investigator of your decision. Although it is not mandatory, it may be useful for the investigator and

for the sponsor to know the reason of this decision (for example side effects, frequency of clinical visits,…).

If you withdraw your consent, this means you decide to stop:

- the treatment with the IMP, and
- all trial-related visits and examinations.

No new data will be collected and sent to the sponsor.

If your biological samples (e.g. blood samples, urine samples) have already been used or analysed before the withdrawal of your consent, the sponsor still has the right to use the results from those tests.

The biological samples that have been collected (but not tested) before the withdrawal of your consent and the data obtained from it, can also still be used by the sponsor. You may ask for a destruction of those samples. If this impacts the validity of the trial, the destruction may be postponed till the end of the trial.

9.2. You decide to discontinue treatment with the IMP

You may decide to stop treatment with the IMP but agree to continue participating in the trial and be contacted by trial staff.

If you decide to stop treatment with the IMP, you may continue to come to the trial-related consultations. The trial staff will ask you if they can contact you by phone, email or post to ask about your general health status and/or to follow-up long-term side effects. If you stop the IMP early for any reason and are unable to complete your scheduled visits, a trial staff member may contact you or someone you choose (for example, a family member or your treating physician). This is done to ask about your current health status at [redacted] and [redacted] after the IMP is started and at the time your last follow-up visit would have occurred. They may also ask your permission to look for this information in your medical records (or in public records) until the end of the trial. This information is important for the scientific value of the trial and to correctly interpret its results. You are free to refuse these two contacts. Please inform your investigator if you don't want to be contacted. Your decision will not affect your future medical care.

9.3. The investigator decides to end your trial participation or to discontinue your treatment with the IMP

The investigator may end your trial participation because:

- he/she thinks it is better for you (e.g. based on your test results, when you develop certain health problems, when the protocol defines that you should not get pregnant and you get pregnant anyway, ...),
- he/she determines that you are not following the instructions given to participants, or
- any other reason that will be explained.
- the entire trial should be discontinued for all participants (see next paragraph).

If that happens, the trial staff will explain why and ensure appropriate follow-up.

9.4. Other entities may interrupt or end the trial

The sponsor and the competent Belgian health authorities may interrupt or end the trial because

- the information gathered shows that the IMP is not effective (does not deliver a sufficient level of improvement in the health of the trial participants),
- the IMP causes more (serious) side effects than anticipated, or
- any other reason that will be duly motivated by such party.

10. Which treatment will I get after my participation in the trial?

If you stop the trial, the investigator will assess your health. If necessary, he/she will prescribe you the best standard treatment available or refer you to another treating physician of your choice.

The sponsor will give you free access to the IMP after this trial if the sponsor determines that the following conditions are met

- the benefit/risk ratio is favourable for the participants and no other equivalent or satisfactory and reimbursable treatment is available on the market in Belgium,
- the competent Belgian health authorities approve this access,
- the development and manufacturing of the IMP is continued, and the nature and the mode of action of the IMP allow for it.

11. Will my participation in the trial involve extra costs for me?

11.1. Examinations and treatments paid by the sponsor

As described in section 4, the treatments and examinations that are trial specific will not be charged to you. The standard procedures or examinations for your condition (i.e. standard of care) will be charged to you or reimbursed by your mutual insurance fund (Belgian social security).

The sponsor has arranged to compensate the site for:

- the time devoted to the trial by the investigator and the trial staff,
- the visits/consultations and all scheduled examinations specific to the trial,
- the investigational treatment (IMP and any other medication and material specifically used for the trial).

11.2. Other expenses paid by the sponsor

You will receive compensation for certain expenses related to your participation in the trial. The reimbursement received by Belgian participants as part of this trial are not subjected to income tax in Belgium.

The table below describes what you will be compensated for and the amounts you will receive. This compensation will be in the form of a bank transfer. You have the right to withdraw your decision for any form of compensation for any reason at any time without having to justify your decision. If you encounter any problems in receiving your compensation, do not hesitate to contact the trial staff.

You will receive a compensation for the following expenses:

Type	Amount
Mandatory contraception	Reimbursement of your actual costs, as per receipt.
Travel costs, public transport, parking	Compensation of [redacted] per trial site visit. If you live further than 50 km from the trial site, you may receive [redacted] extra per 50 km extra distance (e.g. if you live at 160 km from the trial site, you will receive [redacted]
Meals and drinks (if visits are longer than 4 hours on the trial site)	[redacted] per visit
Time investment and efforts	[redacted] per visit / procedure

12. Which data are collected about me during the trial and what will happen with them?

12.1. Which data are collected and processed during the trial?

The collected and processed personal data concern information about your health and medical condition. The investigator and the trial staff will collect data that includes your medical history, some of your background information (for example your age and sex) and the results of examinations required by the trial.

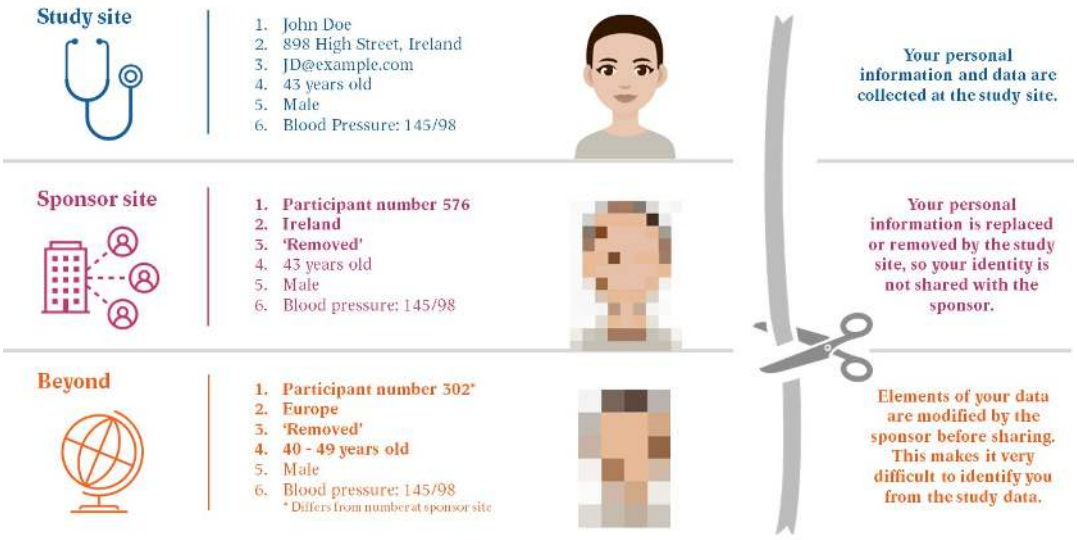
Ethnic origin data are collected to ensure that research data are processed in the broadest possible population.

12.2. How will the investigator treat my personal data?

The investigator (and the trial staff) is bound by professional secrecy or by a confidentiality agreement about the data collected.

This means that he/she will never reveal your identity, including in a scientific publication or a lecture and that he/she will encode your data (Ref. 1) (that is by replacing your identity by an identification code in the trial) before sending them to the sponsor. In other words, this code will not contain any personal identifier or combination of identifiers such as name, first name, initials, full or partial date of birth, file number, etc.

The following diagram shows how your personal data are protected that is to say coded before being shared with the sponsor and its subsidiaries by the trial site or anonymized by the sponsor before being shared with external researchers.



Therefore, the investigator and the trial staff under the responsibility of the investigator, will be the only ones able to establish a link between your identity and the data transmitted during the trial, with the exceptions listed under section 12.5.

The data transmitted to the sponsor will not allow the sponsor to identify you.

12.3. How will my data be handled?

Your trial data will be processed in accordance with the current European and Belgian data protection legislation.

The reason that your personal data may be processed for the purposes of the trial is that it is processed for the conduct of scientific research and we, Boehringer Ingelheim, have legitimate interests because we need to use this information to carry out our responsibilities when developing and checking the safety and quality of the IMP. This helps us understand how the IMP works, monitor any side effects, and make improvements so it can be used safely in the future.

12.4. Do I have access to my data collected and processed during the trial and can I rectify them?

You have the right to:

- review which of your data are collected and being used,
- request for erasure of your personal data,
- restrict the processing and use of your data,
- object to the use of your data or to ask to have incorrect data corrected,

- file a complaint with your local data protection authority or with the Data Protection Officer of your site (using contact details provided in the section “who can I contact in case of questions?”).

Please keep in mind you will not be able to review some of the data or receive a copy of it until the trial has completed worldwide.

If you wish to apply any of your data privacy rights, or have any questions, please inform the investigator (using contact details provided in the section “Who can I contact in case of questions?”), who can then refer you to the trial site´s Data Protection Officer.

12.5. Who, other than the Investigator and his trial staff, has access to my personal data?

To verify the quality of the trial, it is possible that your personal **un**coded data or information in your medical records relevant for the trial, will be examined by people outside the trial staff but under the responsibility of the investigator. These persons must be subject to professional secrecy or a confidentiality agreement. The following might be considered:

- the personnel designated by the sponsor of the trial (MONITORS and AUDITORS), and people or organisations providing services for or collaborating with the sponsor. They will however never transfer your name and contact details to the sponsor.
- inspectors of competent health authorities worldwide
- an independent audit group
- people designated by the Ethics Committee

For the needs of the trial, the coded trial data and biosamples may be sent to other EU and non-EU countries and may be reviewed by:

- personnel (other than the inspectors) of competent health authorities of Belgium (Federal agency for medicines and health products, FAMHP) and other EU and non-EU countries,
- the evaluating Belgian Ethics Committee(s),
- external researchers,
- the sponsor of the trial, personnel designated by the sponsor, and people or organisations providing services for or collaborating with the sponsor, and/or
- group companies of the sponsor in Belgium, and in other EU and non-EU countries.

The European regulation and the Belgian legislation on data protection have requirements for transferring data to non-EU countries. The sponsor must ensure equivalent guarantees regarding personal data protection standards before transferring the coded data to non-EU countries. If for this purpose, there is a data protection agreement, a copy of this agreement may be obtained via the investigator. You can always contact your investigator to obtain more information about any such transfers.

In case another organization takes over development or commercialisation of the IMP, your coded data or biosamples may be transmitted to them. They will then have to protect your data and biosamples in the same way as described herein.

12.6. What will happen to the results of the trial?

After trial closure, a description and the results of this clinical trial will be published in specialised medical journals. A copy of the scientific publication or a summary for laypersons can be obtained from the investigator or the trial staff.

A description of the trial and its results will also be available on https://euclinicaltrials.eu/search-for-clinical-trials/?lang=en . You can search these websites at any time using the information on the front page of the informed consent form. Within 1 year after the trial's completion, the website will include a (lay) summary of the results in accordance with the European Commission's guidelines.

The results of this trial will be summarized in an easy-to-understand summary. You will be able to access this summary and a scientific summary on the sponsor's clinical studies website https://www.mystudywindow.com/completed.

The results may also be published in local clinical trial registries of the participating countries.
We are committed to publish results in scientific journals and share them at scientific meetings.

These websites or publications will not include information that can identify you.

A description of this clinical trial will be available on https://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time (Ref. 2).

12.7. Will my data be used for other purposes than for the trial in which I take part?

The coded data will be used in this trial and other related research activities in order to:

- understand how the IMP and similar drugs work in the body and the mode of action of the IMP
- better understand yours, related diseases and associated health problems
- develop diagnostic tests for, or drugs to treat yours and related diseases
- learn from past studies to plan new studies or improve scientific analysis methods
- publish research results in scientific journals or use them for educational purposes

Any additional research outside of the trial and therefore not described in the above points, must be approved by a Belgian recognized Ethics Committee.

As shown in the diagram above, your personal data are protected before they are shared as coded data by the trial site or by the sponsor. Beyond, the sponsor may only share trial data if they were anonymized. This means all information that could identify you were removed as shown in the diagram above. Such data can help external researchers to answer further medical questions.

12.8. How long will my data be kept?

After the end of the trial your coded data will be retained for at least 25 years in accordance with the European clinical trial regulation to ensure the validity of the research. This will also be the case if you stopped trial participation prematurely.

13. Which biological samples are collected from me during the trial and what will happen with them?

13.1. Which biological samples are collected from me during the trial?

Biological samples are samples of human body material.

In this trial, the following biological sample(s) will be taken:

Biosample type	Used to	Stored up to
Blood and urine for 'routine safety'	Check your general health.	7 days after sample collection
Blood for 'menopause testing' (if needed)	Confirm postmenopausal status.	7 days after sample collection
Blood 'pharmacokinetic'	See how BI 765423 is taken up, distributed, and removed from the body.	5 years
Blood 'biomarker' A biomarker is a biological molecule found in blood, other body fluids, or tissues that indicates a normal or abnormal process, or of a condition or disease.	Measure how BI 765423 affects functions and substances of the body.	Up to 2 years
Blood '[redacted]	Measure your[redacted]	5 years
Blood 'Infectious Disease'	Check if you have hepatitis (a disease that affects the liver), HIV (human immunodeficiency virus) infection, and t[redacted]	7 days after sample collection

The samples are stored both within and outside the sponsor's organization, located in EU and/or Switzerland.

The procedure to encode your biological samples is the same as that used for your personal data in accordance with Belgian legislation on the use of human body material (see I § 12.2). Samples sent to the sponsor or to organisations working in collaboration with the sponsor, will only be labelled with your trial identification code. The sponsor ensures that the location of your biological samples is always tracked. The use of your biological samples is linked to the processing of the associated coded personal data.

Your biological samples are deemed to be a “donation”. You will not receive any financial benefit associated with the development of new therapies derived from the use of your biological samples, and which may have commercial value.

13.2. What will happen to the collected biological samples within the context of the trial?

These biological samples will be analysed for the objectives of the trial.

Since scientific progress in this area is constant, the sponsor would like to retain the remainders of your biological samples for up to 5 years (as per above table) after the finalization of the clinical trial report. The sponsor will use them for additional research that remains within the context of the current clinical trial and thus with the same disease or the same treatment/drug as in this trial.

14. What if the trial reveals meaningful information about your health?

We may discover new information about your health during the course of the trial. If this information may be important to your health, the sponsor will inform the researcher. With your consent, the researcher will inform you and your treating physician about your results and the possible consequences. If necessary, the researcher and/or the treating physician will advise you on what to do next.

You can let the researcher know whether or not you agree to be informed about meaningful information discovered about your health by ticking the relevant checkbox in Chapter II. The researcher/your treating physician will inform you about this information in any case where not being informed may cause serious harm to your health or that of third parties.

15. Who has reviewed and approved the trial documents?

The documents of the trial have been reviewed by:

- The Belgian competent health authorities (FAMHP) or if applicable by the competent national health authorities of other EU members states and
- An independent Belgian Ethics Committee

It is the task of the competent health authorities and the Ethics Committees to protect people who take part in a trial. The health authorities will ensure that the trial is conducted in accordance with the applicable legislation.

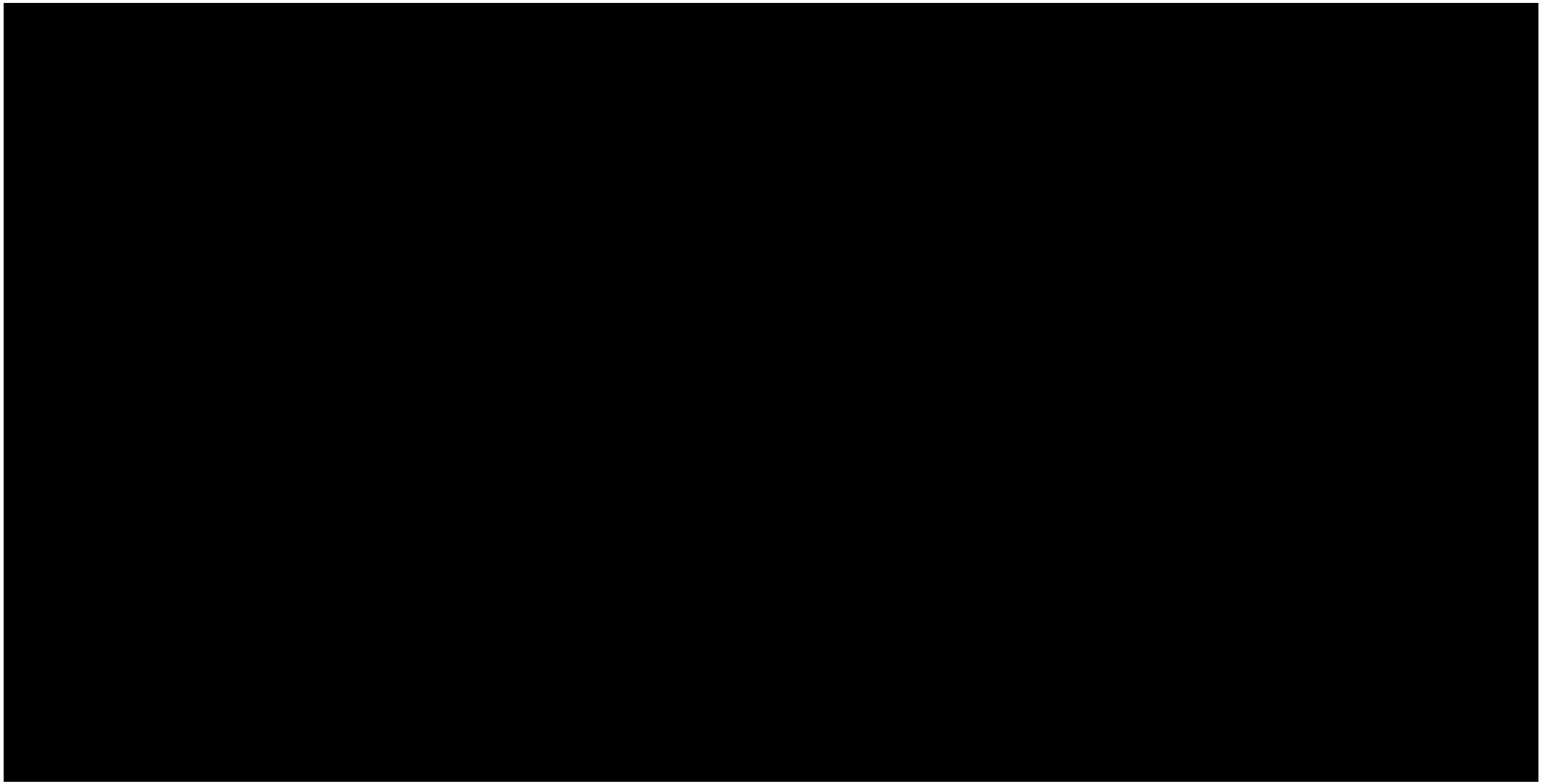
You should not under any circumstances take their approval as an incentive to take part in the trial.

APPENDIX A: VISIT SCHEDULE

On the next page is a chart showing your visit schedule. The pictures (icons) in the chart show what happens at each of your visits. Please refer to the picture guide on this page while viewing the visit schedule.

Locations and visit duration:	 At the trial site	 Phone call from the trial staff	 The approximate time a visit takes

Procedures performed			
	You give your consent to enter this trial.		
	Your medical history is recorded, and you are screened for this trial.		An electrocardiogram (ECG) is performed on you.
	At all visits you will be asked about your health, and what medications you have taken since your last visit. You will be asked about breathing related hospitalisations throughout this trial.		Lung function tests are performed on you.
	A physical exam is performed on you, your vital signs are recorded, your weight is taken, and your height will be measured.		Measure the amount of oxygen in your blood.
	Samples of your blood and urine are collected.		You get an IV infusion of the IMP.
			The trial feature or procedure represented by the icon occurs during that visit.
	You fill out a questionnaire about your health.		



APPENDIX B: Trial procedures and risks

To conduct this trial, the procedures listed below will be performed. The trial staff will describe them to you and explain any risks. Please read about the procedures carefully and ask any questions you might have.

Physical Exam

The physical exam is done to check your overall health and your condition. It includes checking your general appearance, neck, lungs, heart, stomach, legs, arms, and skin, but may include other health checks.

The physical exam will also include checking your vital signs, other measurements like weight, and height (at screening).

Your vital signs will be recorded, which includes body temperature, pulse rate (or heart rate), breathing rate, and blood pressure, but may include other measurements.

These tests are generally painless and have little risk.

Blood sampling

Your blood biosamples will be used to:

- check your general health
- see how BI 765423 is taken up in the body
- measure how BI 765423 affects functions and substances of the body
- assess your immune response to BI 765423
- check for infectious disease
- check for postmenopausal status, if needed

The trial staff uses a small needle to take blood from your arm or hand. The blood is collected into a tube. This usually takes less than 5 minutes.

For each biosample, the total volume of your blood drawn will not be above 10 ml.

Over your entire time in this trial, about 500 ml of your blood will be drawn. This is about the amount that is donated at once when donating blood.

Blood sampling includes a risk of mild pain, local irritation, bleeding or bruising (a black and blue mark) at the site where the needle is inserted. There is also a small risk of light-headedness and/or fainting. In rare cases, the site where the needle is inserted can become infected or nerves may be damaged and may cause long-lasting abnormal sensations, damaged sensation of touch and lasting pain. Frequent blood collection may cause anaemia (fewer red blood cells than normal), which may create a need for blood transfusions.

Urine sampling

Your urine samples are used to check your general health.

As urine samples are collected as part of normal urination, there should not be any discomfort, and there are no known risks.

ECG (electrocardiogram)

An ECG checks the health of the heart by measuring your heart's electrical activity.

For an ECG, electrodes with sticky pads are placed on the skin on your chest and other parts of the body (like arms or legs). The electrical activity of your heart is viewed on a monitor.

An ECG is a painless and safe procedure. There may be minor irritation to the skin due to and especially after removing the sticky pads.

Lung function tests

These tests will be done to see how well your lungs are working.

- **Pulmonary function tests:**

  While wearing a nose clip and using a mouthpiece, you will be asked to exhale quickly and forcefully through a tube connected to a machine.

- [redacted]

You may feel some discomfort on your nose or tightness around your mouth. You may feel light-headed (dizzy), have shortness of breath, a headache, or you may cough for a little while. If you feel light-headed, the test may be stopped.

Oxygen blood levels (Pulse Oximetry)

A device will be placed on your finger, earlobe, or forehead to measure the amount of oxygen in your blood. There should be little or no discomfort from this test.

[redacted]

[redacted]

Questionnaires

You will be asked to answer questions about your IPF symptoms and how pulmonary fibrosis impacts your life.

It is important that you complete the questionnaires yourself and not ask others to do it for you.

The questionnaires will take about 30 minutes to complete.

You might find the questionnaires take a long time or are tiring to complete. You might not like some of the questions or feel uncomfortable answering them.

Infusion of medicine

You will receive the IMP by infusion into a vein. A needle or catheter will be placed into a vein, usually in your arm. A catheter is a long, hollow, flexible tube that makes it easier to deliver the medicine to your bloodstream.

The infusion will take [redacted]. During Visit 2, after receiving the infusion you will stay at the trial site for [redacted] to be monitored. At all other visits, you will be monitored at the trial site for [redacted] after receiving the infusion.

An IV infusion reaction may occur during or after an infusion. The investigator will explain the options on how an infusion reaction may be managed. This may include stopping the infusion, slowing down the infusion, as well as treatments you may receive depending on how bad the infusion reaction may be. Risks from getting an infusion include:

- an infection or inflammation at the infusion site
- a collapsed vein
- an air bubble entering a vein

- a reaction to the infusion, which could cause the following: cough, facial flushing, fever, chills, headache, itching, muscle or joint pain and stiffness, nausea, rash or hives, shortness of breath, or swelling of hands, legs, ankles, feet, tongue, lips, or eyelids.

Risks from the IV needle or catheter: You may experience mild pain, local irritation, bleeding or bruising (a black and blue mark) at the site where the needle is inserted. There is also a small risk of light-headedness and/or fainting. In rare cases, the site where the needle is inserted can become infected or nerves may be damaged and may cause long-lasting abnormal sensations, damaged sensation of touch and lasting pain.

APPENDIX C: Possible side effects of the trial medicine

Your investigator will closely look for any changes to your health that happen while you take part in this trial.

- Taking any medicine has risks. Receiving BI 765423 may cause you to have one or more possible side effects listed below.
- Possible side effects are changes to your health that may be caused by BI 765423.
- The investigator or trial staff will go through descriptions of the possible side effects with you. Ask any questions you may have.
- If any side effects happen, the investigator will assess your condition and discuss options with you.
- Tell the investigator or trial site staff if you have any changes to your health while taking part in this trial. This is important even if you don't think it was caused by the IMP.
- In addition to the side effects listed, there is always the risk of developing side effects which are not known at this time.

Possible side effects of BI 765423

So far, only a small group of participants took BI 765423. Participants reported changes to their health that could be caused by BI 765423. These were not serious.

The most commonly reported possible side effects were:

- Headache
- Back pain
- Common cold (nasopharyngitis)
- Influenza-like illness (flu)

Are there any other risks?

[redacted]
but no problems with the blood were seen when BI 765423 was given to animals or humans. The investigator and trial staff will closely check for this by measuring levels in your blood samples.

[redacted] No serious or rare infections have been seen in animals or humans who have been given BI 765423. The investigator and trial staff will check your blood for some rare infections at the start of this trial and will monitor you for signs of infection at the trial site.

An [redacted] medicines like BI 765423. These reactions can be [redacted] Although no participant has experienced a [redacted] a few trial participants experienced mild reddening of the skin (flushing) after receiving

BI 765423, which resolved on its own. The investigator and trial staff will closely monitor your body's response to BI 765423.

Some medicines that are similar to BI 765423 may cause other medicines you may be taking to work too strongly (causing more side effects of that medicine) or too weakly (causing the medicine to not work as well). Although this has not been seen with BI 765423, please inform your investigator if you are taking any of the below medicines, as these are the most likely to be affected by an interaction of another medicine, such as BI 765423:

tizanidine, theophylline, paclitaxel, warfarin, phenytoin, S-mephenytoin, alfentanil, astemizole, cisapride, cyclosporine, dihydroergotamine, ergotamine, fentanyl, pimozide, quinidine, sirolimus, tacrolimus, terfenadine, and thioridazine.

This list may not be complete, so it is important that you should inform your investigator about any medicines you are taking.



Animals given BI 765423 had an early end to pregnancy or birth defects in offspring. Therefore, it is important to follow the birth control and pregnancy requirements listed in Appendix D.

APPENDIX D: ACCEPTABLE METHODS OF BIRTH CONTROL

♀ For female trial participants

You can take part in this trial only if you are unable to become pregnant due to the following reasons. You are unable to become pregnant if you had your uterus removed, both of your uterine tubes removed, both of your ovaries removed, or you have been through menopause. You have been through menopause if you had no period for at least 12 months and this was not caused by another medical reason.

♂ For male trial participants

Use a condom for the duration of this trial and for [redacted] after your last dose of the IMP even if you had a vasectomy in the past and the absence of sperm was documented.

If abstinence from male-female sex is a part of your regular sexual practice, you can participate in this trial without using male contraception. **However, you should be aware that periodic abstinence is not an acceptable method of birth control.**

If your partner becomes pregnant:



- Tell the investigator or the trial staff right away
- The investigator will ask you for your partner's contact information and agreement to get information on the pregnancy and the health of the mother and baby at the time of birth
- Your partner will be asked to give consent for gathering this information.

Please do not donate sperm while taking part in this trial and for [redacted] after the last dose of the IMP.

CHAPTER II - INFORMED CONSENT

A study to find out whether BI 765423 has an effect on lung function in people with idiopathic pulmonary fibrosis (IPF) with or without standard treatment

Official title of the trial: A double-blind, randomised, placebo-controlled, parallel group, Phase IIa trial to evaluate safety, tolerability, pharmacokinetics, pharmacodynamics, and efficacy of BI 765423 administered intravenously with or without standard of care in patients with idiopathic pulmonary fibrosis

PARTICIPANT

- I declare that I have read this form and understood its information.
- I declare that I have been informed of and that I understand the purpose of the clinical trial, its duration and consequences, possible risks and discomforts, the precautions that I must take and what is expected of me. My rights have been explained to me and I have understood those rights.
- I have had enough time to think about taking part in this trial and to discuss it with a trusted person (for example friends, relatives, treating physician, …).
- I have had the opportunity to ask any questions that came to mind and have obtained a satisfactory response to my questions.
- I understand that my participation in this trial is voluntarily and free from any coercion and that I am free to stop at any time my trial participation.
- I understand that data about me will be collected and that they will be treated confidentially as described in Chapter I, §12.2.
- I am aware that my personal data is being processed as described in Chapter I, §12.
- I understand that representatives of the sponsor, the ethics committee, and competent health authorities have access to my medical record if authorised to do so (as described in Chapter I, § 12.5).
- I am aware of the collection, storage, processing, transfer and use of my biological samples as explained in Chapter I, § 13.
- I understand that the sponsor has taken out an insurance in case I should suffer any damage in connection with my participation in this trial.
- I understand that when participating in this trial, I will not have any costs except those related to the standard of care treatment of my disease.
- I understand the importance of contraception and will adhere to the recommendations provided. I will also inform my partner(s) about my participation in a clinical trial involving a drug that may be harmful to the fetus, and we will take the necessary contraceptive measures together.
- I am aware that my treating physician(s) will be informed of my participation in this trial.

- If I take part in another interventional trial, I must inform the investigator or trial team about this. I agree not to take part in any other interventional trial (e.g. with an IMP, medical device, experimental surgical technique) at the same time without first informing the investigator or the trial staff, who might not permit me to participate for a good reason.
- I understand that I need to cooperate and follow the investigator's and trial staff's instructions regarding the trial.
- I understand that participation to the trial might end for me without my consent if I need other treatment, do not follow the trial plan, have a trial-related injury, or for any other justified reason.
- I certify that all the information I have given about my medical history is correct, to the best of my knowledge. I understand that it may be harmful to me if I do not inform the investigator of possible reasons why I could not participate in the trial.

OPTIONAL CONSENT WHICH IS NO PREREQUISITE FOR YOUR PARTICIPATION IN THIS TRIAL.

1. As specified in Chapter I, §14, it may occur that meaningful information is discovered that may be important for your health or that of third parties.

   If this were to occur, would you like the investigator/your treating physician to inform you of this result?

   (Tick as appropriate)

☐ **No, I do not wish to be informed.**	☐ **Yes, I wish to be informed.**

I consent to take part in the trial, with the above restriction and I will be given a copy of the signed and dated informed consent and all the pages of this document.

Participant number:_____

Participant's surname and first name:

Date (DD/MMM/YYYY):

Participant's signature:

IMPARTIAL WITNESS / INTERPRETER (REF. 3)

I, the undersigned (Tick as appropriate),

☐ Impartial Witness

☐ Interpreter

was present during the entire process of informing the participant and I confirm that the information on the objectives and procedures of the trial was adequately provided, that the participant apparently understood the trial and that consent to participate in the trial was freely given.

I declare furthermore that acting as an impartial witness/interpreter, I am independent of the sponsor and the investigator.

Impartial Witness / Interpreter surname and first name:

Impartial Witness / Interpreter qualification:

Date (DD/MMM/YYYY):

Impartial Witness / Interpreter signature:

INVESTIGATOR

I, the undersigned investigator, confirm that:

- the participant has been verbally provided with the necessary information about the trial, has been explained the content and has been given an original signed document.
- I have verified that the participant has understood the trial.
- I have given the participant sufficient time to agree to take part and to ask any questions.
- no pressure was applied to persuade the participant to agree to take part in the trial.
- I operate in accordance with the ethical principles set out in the latest version of the “Helsinki Declaration”, the “Good Clinical Practices” and the Belgian Law on clinical trials.

Investigator’s, Surname and first name:

Date (DD/MMM/YYYY):

Investigator’s signature:

If applicable

Investigator’s delegate, surname and first name:

Investigator’s delegate, qualification:

Date (DD/MMM/YYYY):

Investigator’s delegate signature:

GLOSSARY

FAMHP: Federal agency for medicines and health products

DPA: The Data Protection Authority ensures that personal data are handled with care and thoroughly protected, and that your future privacy also remains guaranteed.

Other abbreviations that appear in the text:

NO FAULT INSURANCE:

The sponsor is liable for any injury or any damage that the participant has suffered, and which is directly or indirectly related to the clinical trial. You do not have to prove any mistake in this respect.

MONITOR and AUDITOR

Both the monitor and auditor work for the sponsor.
The monitor takes care of a continuous quality check during the entire process of the trial. The auditor performs an independent, one-time quality check at some time during the trial. They verify if the trial is being/was conducted according to the protocol, if the reported data are liable and if the clinical trial was conducted according to the applicable rules.

REFERENCES

[1] Throughout the document, the term ‘’encoding‘’ is used as a synonym for ‘’pseudonymisation‘’, the term used in General Data Protection Regulation No 2016/679.

[2] If the sponsor wishes to use the data for FDA, this sentence must be included in the ICF (CFR 50.25(c)) as described in the directive (https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm291085.pdf).

[3] The use of an impartial witness is necessary when the subject speaks and/or fully understands the language of the approved informed consent form but cannot read and write due to a physical disability or is visually impaired. An interpreter is necessary when the investigator does not speak the patient's language.