

# UNISUS Research Study

For Healthcare Providers

The information contained in this section of the website is intended for U.S. healthcare providers only.

## Are You A Healthcare Provider?

Click on the appropriate button below:

YES

NO

## Are you treating an adult who has pulmonary arterial hypertension (PAH)?

The purpose of this study is to compare a higher dosage of an investigational medication against the lower, approved dosage to see if it is well tolerated, safe, and useful for treating patients with pulmonary arterial hypertension (PAH). The investigational medication is approved by regulatory agencies around the world at a lower dosage for pulmonary arterial hypertension. The primary objective is to demonstrate superiority of a higher dose of an investigational drug in prolonging the time to the first clinical events committee (CEC)-adjudicated morbidity or mortality (M/M) event in participants with symptomatic pulmonary arterial hypertension (PAH) compared to a lower dose.

Please be assured that the research doctor's involvement with your patient will be strictly study-related. If your patient decides to enroll in the study, with their permission, you can be informed of their progress in the study.

### Key Study Inclusion Criteria:

- At least 18 years of age
- Symptomatic PAH in WHO FC II, III or IV
- PAH diagnosis confirmed by hemodynamic evaluation at rest at any time prior to screening:
- Mean pulmonary artery pressure (mPAP) > 20 mmHg, AND
- Pulmonary artery wedge pressure (PAWP) or left ventricular end diastolic pressure (LVEDP) ≤ 15 mmHg, AND
- Pulmonary vascular resistance (PVR) > 3 Wood Units (i.e. > 240 dynes/cm<sup>5</sup>)

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- Pulmonary vascular resistance (PVR) ≥ 3 Wood Units (i.e., ≥ 240 dyn•sec•cm<sup>-5</sup>)
- On stable background treatment for PAH or PAH treatment-naïve

For more information about the UNISUS Study, please visit <https://clinicaltrials.gov/ct2/show/NCT04273945>. You may also download a copy of the HCP flyer. *This flyer is for healthcare professional use only. It is not to be shown or shared with patients.*

## If you have a PAH patient that may be a candidate for the UNISUS Study, you can:

### Share the Study Website

Share the study website to provide education and awareness about the UNISUS Study to your patients who may qualify and be interested in the study.

[Send email](#)

### Encourage Pre-Screening

Potential patients can take a short self-assessment to see if they may be eligible to participate in the UNISUS Study. If they pass the self-assessment, he/she will have the opportunity to speak with a Trialbee medical professional to ask any questions.

### Download & Share the Patient Brochure

Download a copy of the patient brochure with more information about the UNISUS Study to share with your patients who may qualify and be interested in the study.

[Download pdf](#)

## Locate a Participating Study Site

Review the list of participating study sites and contact the Primary Investigator to refer a potential participant.

▼ Site Name	▼ Doctor Name	▼ City (filter)	▼ State (filter)	▼ Contact Information
Lorem ipsum	Dr John Johnson	Kansas	Texas	Lorem Ipsum, Lorem Hospital, 1234 XX Lorem Ipsum
Lorem ipsum	Dr John Johnson	Kansas	Texas	Lorem Ipsum, Lorem Hospital, 1234 XX Lorem Ipsum
Lorem ipsum	Dr John Johnson	Kansas	Texas	Lorem Ipsum, Lorem Hospital, 1234 XX Lorem Ipsum
Lorem ipsum	Dr John Johnson	Kansas	Texas	Lorem Ipsum, Lorem Hospital, 1234 XX Lorem Ipsum

# Research offers a different path for PAH patients

People living with pulmonary arterial hypertension (PAH) often struggle with activities that once took little-to-no effort. Simple things, like playing with your dog or bringing in the groceries, may now cause you to stop and catch your breath.

As part of this study, medical professionals will provide study-related monitoring of your PAH and overall health.

[Do I Qualify?](#)

## About PAH

Pulmonary arterial hypertension (PAH) is a type of high blood pressure that affects arteries in the lungs. Symptoms of PAH may include shortness of breath, fatigue, dizziness or fainting, and chest pressure or pain.

Although progress has been made in developing medications for PAH, many people are still affected by the disease. As a result, there is still a need for medications that can help treat and slow the progression of the disease.



## Who is eligible to be in the UNISUS Study?

To pre-qualify for this study, you must be:

- ✓ At least 18 years of age, and
- ✓ Diagnosed with PAH

All study-required visits, tests, and medications will be provided at no cost. In addition, reimbursement for study-required travel may be available.

## About the UNISUS Study

The UNISUS research study is dedicated to people with PAH. The study will compare the effectiveness and safety of a higher dose of an investigational medication against a lower dose.

The investigational medication has been approved by regulatory agencies in many countries around the world at a lower dosage to treat PAH. The doctors conducting the research want to learn more about the safety and effectiveness of the investigational medication at a higher dosage that has not been approved in any country for any condition. This higher dose is currently being studied in people with pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension (CTEPH).

The results of the UNISUS study will provide more information about the investigational medication's effectiveness and safety when it is given at a higher dose to adults with PAH.

## What is my role in the study as a participant?

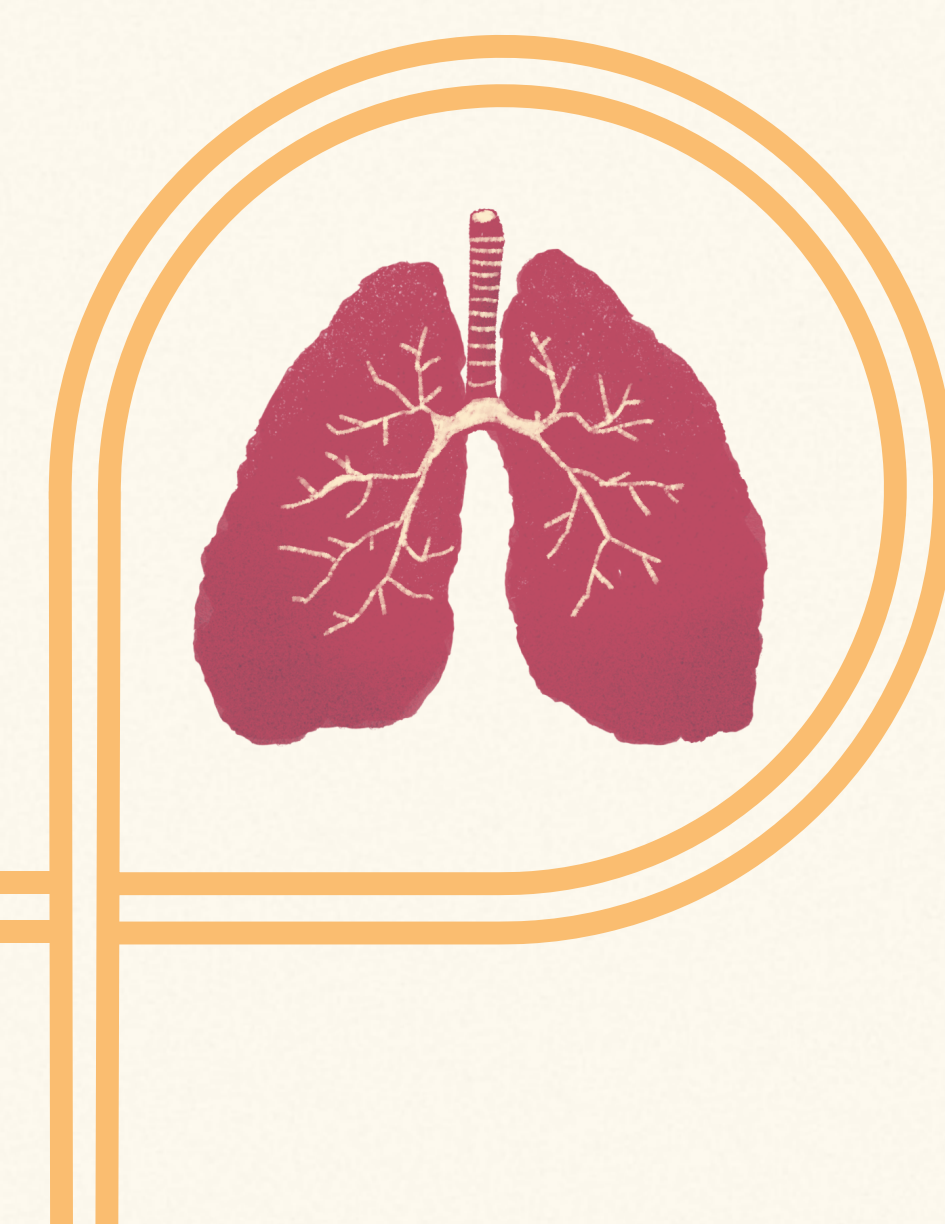
If you are eligible and agree to be in this study, you will be randomly assigned (by chance) to receive either the higher or lower dose of the investigational medication as well as a matching placebo. A placebo looks like the investigational medication and is given in the same manner but does not have any active medication. You have an equal chance of being assigned to receive either dose of the investigational medication. If you are currently taking medicine to treat your PAH, you may be able to continue taking it while in the study.

Neither you, the study doctor, or the study staff will know which study medication dose you'll be receiving. However, in case of an emergency, that information can be provided to your study doctor.

You will take 2 tablets (study medication + placebo) once a day as instructed by the study doctor while you are in the study.

After completing the treatment period, you will continue into the treatment extension period which will consist of two phases. During the first phase, you will receive either a higher or lower dose of the investigational medication along with a matching placebo for 4 weeks. During the last phase called the open-label phase, all participants will have the option to receive the higher, target dose of the investigational medication.

Your total study participation may last 3 to 6 years. During your study participation, you will be asked to attend regular study clinic visits to evaluate your health. You will also receive phone calls from the study staff to discuss the study and check in on how you are feeling.



## What are the potential benefits and risks related to the UNISUS study?

While it's possible your PAH could improve as a participant in this study, that cannot be guaranteed. However, your study participation may help people with PAH in the future.

It is possible that you could experience one or more side effects during this study. Before you begin the study, the study doctor will talk you through the potential study-related risks and side effects.

This study has been approved by an independent review board that is responsible for patient safety. Because participation in this study could affect your health, you will be closely monitored throughout the study. Study researchers designed a protocol that explains the study in detail, and the protocol must be followed exactly as written.

For additional information about clinical studies please see the FAQ section.

## Short Study Summary

**Medical condition**  
Pulmonary Arterial Hypertension (PAH)

**Study Duration**  
3 to 6 years

**Locations**  
This is a global study which will enroll approximately 900 participants across North America, South America, Europe, and Asia-Pacific.

**Phase**  
3

## Frequently Asked Questions

+ What is a clinical study?

- Why is clinical research important?

Clinical research adds to medical knowledge and helps bring new treatments to people with medical conditions. In order to make new treatments available to the public they need to be studied in clinical trials.

Clinical trials rely on the participation of volunteers in order to succeed. On average, it can take up to 8 years for a new treatment to reach the public, the major hold-up being how long it takes to complete the clinical trials (often due to shortage of participants).

All new medical treatments and drugs have gone through clinical trials to make sure that they are safe and effective.

+ Who runs clinical studies?

+ What are the phases of clinical research studies?

+ What does it mean to participate?

## PRIVACY POLICY

Last Update: March 18, 2022

Janssen Research & Development, LLC cares about your privacy and wants you to be familiar with how we collect, use, and disclose information. This Privacy Policy describes our practices in connection with information that we or our service providers collect through the website or application (hereinafter the "Service") which is operated and controlled by our partner, Trialbee AB. By providing personal information on this website or by using the Service, you acknowledge that you have read and understand this Privacy Policy.

Please note that the clinical research study, which this website is related to, is managed by Janssen Research & Development, which is a global organization that operates through different legal entities in various countries. Therefore, the legal entity acting as the sponsor for Janssen Research & Development studies may vary and may be different from the legal entity that is the owner of this website.

### USE OF SITE BY MINORS

The Service is not directed to individuals under the age of 18, and we request that these individuals not provide personal information through the Service. If your child has submitted Personal Information and you would like to request that such Personal Information be removed, please contact us as explained below under Contacting Us.

### INFORMATION COLLECTION

Some areas of the Site may ask questions related to your health to assist the study site staff in determining your eligibility for the study. In addition, the Site may ask you to submit personal information, such as your name, telephone number, and email address in order for you to be contacted by a member of the study site staff. You will be informed what information is required and what information is optional.

The personal information that you choose to provide through the Site is processed by Trialbee AB on behalf of Janssen Research & Development and then provided to your selected study site, should you pass the pre-qualification process. The clinical trial site will receive and retain your information to contact you regarding potential participation in the clinical trial. Trialbee AB will not provide any information that directly identifies you (e.g. your name or contact information) to Janssen.

If you submit any personal information relating to another individual to us, you represent that you have the authority to do so and to permit us to use the information in accordance with this Privacy Policy.

### SENSITIVE INFORMATION

Unless we specifically request or invite it, we ask that you not send us, and you not disclose, any sensitive personal information (e.g., Social Security numbers, information related to racial or ethnic origin, political opinions, religion or philosophical beliefs, health, sex life or sexual orientation, criminal background, or trade union membership, or biometric or genetic data for the purpose of uniquely identifying an individual) on or through the Service or otherwise to us.

### AUTOMATIC INFORMATION COLLECTION AND USE

We and our service providers may also automatically collect and use information in the following ways:

**Through your browser:** Certain information is collected by most browsers, such as your Media Access Control (MAC) address, computer type (Windows or Mac), screen resolution, operating system name and version, and Internet browser type and version. We may collect similar information, such as your device type and identifier, if you access the Service through a mobile device. We use this information to ensure that the Service functions properly.

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You can refuse to accept these cookies by following your browser's instructions; however, if you do not accept them, you may experience some inconvenience in your use of the Service. You may also not receive advertising or other offers from us that are relevant to your interests and needs. To learn more about cookies, please visit <http://www.allaboutcookies.org>.

**IP address:** Your IP address is a number that is automatically assigned to your computer by your Internet Service Provider. An IP address is identified and logged automatically in our server log files whenever a user visits the Service, along with the time of the visit and the pages visited. Collecting IP addresses is standard practice and is done automatically by many online services. We use IP addresses for purposes such as calculating Service usage levels, diagnosing server problems, and administering the Service. We may also derive your approximate location from your IP address.

**Device Information:** We may collect information about your mobile device, such as a unique device identifier, to understand how you use the Service.

### How We Use and Disclose Information

We use and disclose information you provide to us as described to you at the point of collection.

Where required by applicable law, we will obtain your consent to our use of your personal information at the point of information collection.

We may also use information from or about you as necessary to perform a contract, to comply with a legal obligation (for example, due to our pharmacovigilance obligations), or for our legitimate business interests. Our legitimate business interests may include any or all of the following:

- to respond to your inquiries and fulfill your requests, such as to send you documents you request or e-mail alerts;
- to send you important information regarding our relationship with you or regarding the Service, changes to our terms, conditions, and policies and/or other administrative information; and
- for other business purposes, such as data analysis, audits, developing new products, enhancing our website, improving our products and services, identifying Service usage trends, better understanding your interests so that we can serve you better, personalizing your experience on the Service by presenting products and offers tailored to you, and determining the effectiveness of our promotional campaigns.

We also disclose information collected through the Site:

- to our affiliates for the purposes described in this Privacy Policy. The affiliate that is acting as the Sponsor in relation to your country is the party responsible for the management of the jointly-used Personal Information;
- to our third-party partners with whom we offer a co-branded or co-marketed promotion;
- to our third-party service providers who provide services such as website hosting and moderating, mobile application hosting, data analysis, payment processing, order fulfillment, infrastructure provision, IT services, customer service, e-mail and direct mail delivery services, credit card processing, auditing services, and other services, in order to enable them to provide services; and
- to a third party in the event of any reorganization, merger, sale, joint venture, assignment, transfer, or other disposition of all or any portion of our business, assets, or stock (including in connection with any bankruptcy or similar proceedings).

In addition, we use and disclose information collected through the Site as we believe to be necessary or appropriate: (a) as permitted by applicable law, including laws outside your country of residence; (b) to comply with legal process; (c) to respond to requests from public and government authorities, including public and government authorities outside your country of residence; (d) to enforce our terms and conditions; (e) to protect our operations or those of any of our affiliates; (f) to protect our rights, privacy, safety, or property, and/or that of our affiliates, you, or others; and (g) to allow us to pursue available remedies or limit the damages that we may sustain. We may also use and disclose information collected through the Site in other ways, with your consent.

We may use and disclose information we collect automatically as described above, under "Automatic Information Collection and Use."

In addition, where allowed by applicable law, we may use and disclose information that is not in personally identifiable form for any purpose. If we combine information that is not in personally identifiable form with information that is identifiable (such as combining your name with your geographical location), we will treat the combined information as personal information as long as it is combined.

### CHOICES AND ACCESS

How you can access, change, or delete your personal information

If you would like to review, correct, update, restrict, or delete your personal information, or if you would like to request to receive an electronic copy of your personal information for purposes of transmitting it to another company (to the extent these rights are provided to you by applicable law), please contact us via email at [privacy@trialbee.com](mailto:privacy@trialbee.com). We will respond to your request as soon as reasonably practicable and no later than one month after receipt. If circumstances cause any delay in our response, you will be promptly notified and provided a date for our response.

### CROSS-BORDER TRANSFER

Your personal information may be stored and processed in any country where we have facilities or service providers, and by using our Service or by providing consent to us (where required by law), you agree to the transfer of information to countries outside of your country of residence, including to the United States, which may provide for different data protection rules than in your country. Appropriate contractual and other measures are in place to protect personal information when it is transferred to our affiliates or third parties in other countries.

### SECURITY

We seek to use reasonable organizational, technical, and administrative measures designed to protect personal information under our control. Unfortunately, no data transmission over the Internet or data storage system can be guaranteed to be 100% secure. If you have reason to believe that your interaction with us is no longer secure (for example, if you feel that the security of any account you have with us has been compromised), please immediately notify us in accordance with the "Contacting Us" section below.

### RETENTION PERIOD

We will retain your personal information for as long as needed or permitted in light of the purpose(s) for which it was obtained. The criteria used to determine our retention periods include: (i) the length of time we have an ongoing relationship with you and provide the Service to you; (ii) whether there is a legal obligation to which we are subject; and (iii) whether retention is advisable in light of our legal position (such as in regard to applicable statutes of limitations, litigation, or regulatory investigations).

For example, if we collect your personal information for your participation in a Clinical Trial, we may need to store it for a period of life time of the investigational product that is in scope of the Clinical Trial + 20 years.

Please note, however, that this is not an exhaustive list of retention periods. Your personal information may be stored for a longer period using the criteria set forth in the first paragraph of this section, especially points (ii) and (iii).

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This Privacy Policy does not address, and we are not responsible for, the privacy, information, or other practices of any third parties, including any third party operating any site or online service (including, without limitation, any application) that is available through this Service or to which this Service contains a link. The availability of, or inclusion of a link to, any such site or property on the Service does not imply endorsement of it by us or by our affiliates.

### CONTACTING US

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If you have any questions about this Privacy Policy, please contact us via email at [privacy@trialbee.com](mailto:privacy@trialbee.com).

### UPDATES TO THIS PRIVACY POLICY

We may change this Privacy Policy. Any changes to this Privacy Policy will become effective when we post the revised Privacy Policy on the Service. Your use of the Service following these changes means that you accept the revised Privacy Policy. We recommend that you regularly review the Privacy Policy when you visit the Service. This policy was last updated on March 18, 2022.

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Last updated March 18, 2022

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We may at any time terminate your use of or access to the Website and may delete any or all of your User Content without prior notice if we have a good reason to do so which includes any breach by you of these Terms of Use and the Community Guidelines. We will not be responsible for any loss or harm you may suffer as a result of termination of your use of the Website in these circumstances. In the event of any termination you must stop using the Website and you agree that the provisions of the Agreement regarding Ownership, Trademark Notices, Indemnification, Disclaimer or Warranties, Limitations of Liability, and Applicable Law shall survive any such termination.

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### Indemnification

You agree to indemnify and hold harmless Site Owner and its affiliates and their respective directors, officers, employees, agents, or other representatives from and against all claims, liability, damages and expenses, including without limitation all legal fees and costs arising from or relating to (a) your breach of these Terms of Use; (b) your use of this Website including without limitation transmission or placement of information or material by you on this Website; and (c) any claim or allegation that any of your User Content infringes the intellectual property or other proprietary rights, or privacy rights, of any third party.

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We may make changes to the Terms of Use from time to time in our sole discretion, by updating these Terms of Use on this Website, and specifying the effective date of the new version of the Terms of Use. The "Last Modified" date at the top of these Terms of Use will indicate when the latest changes were made. Your continued use of the Website following the posting of a new version of the Terms of Use constitutes your acceptance of any such changes. Accordingly, whenever you visit this Website, you should check to see if a new version of the Agreement has been posted.

### Contact Information

If you have any questions or concerns with respect to these Terms of Use or the Website you may contact us as identified in the Privacy Policy or the "Contact Us" section of this Website.

### Severability of Agreement

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# Research offers new path for PAH

People living with pulmonary arterial hypertension (PAH) often struggle with activities that require little-to-no effort. Simple things, like walking your dog or bringing in the groceries, can leave you to stop and catch your breath.

As part of this study, medical professionals will provide study-related monitoring of your PAH and overall health.

[Do I Qualify?](#)

## About PAH

Pulmonary arterial hypertension (PAH) is a type of high blood pressure that affects

## Who is eligible to be in the UNISUS Study?

To pre-qualify for this study, you must be

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# Research path for

People living with pulmonary arterial hypertension (PAH) often struggle with little-to-no effort. Simply walking your dog or bringing in your mail can leave you to stop and catch your breath.

As part of this study, we will provide study-related resources to help improve your overall health.

[Do I Qualify?](#)

## About PAH

Pulmonary arterial hypertension (PAH) is a type of high blood pressure that affects

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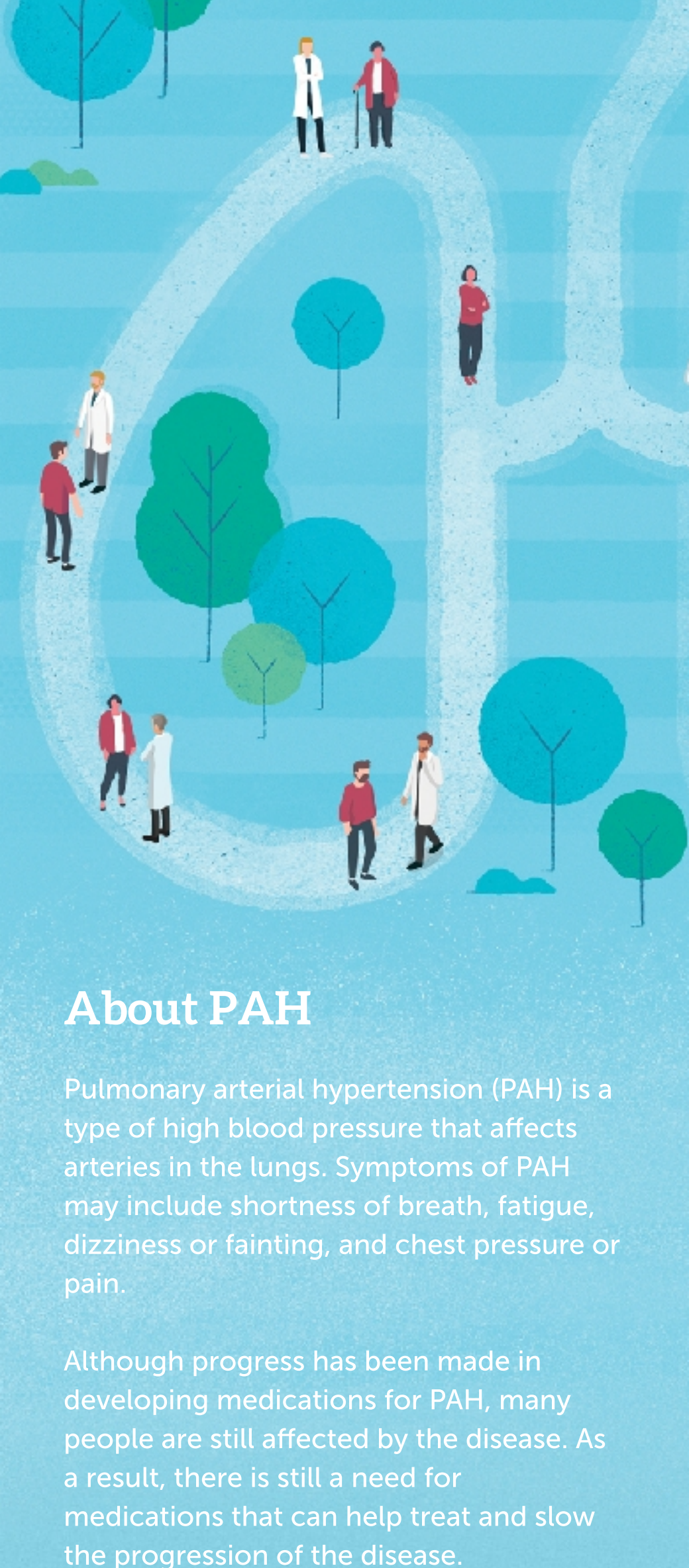
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# Research offers a different path for PAH patients

People living with pulmonary arterial hypertension (PAH) often struggle with activities that once took little-to-no effort. Simple things, like playing with your dog or bringing in the groceries, may now cause you to stop and catch your breath.

As part of this study, medical professionals will provide study-related monitoring of your PAH and overall health.

## Do I Qualify?



## About PAH

Pulmonary arterial hypertension (PAH) is a type of high blood pressure that affects arteries in the lungs. Symptoms of PAH may include shortness of breath, fatigue, dizziness or fainting, and chest pressure or pain.

Although progress has been made in developing medications for PAH, many people are still affected by the disease. As a result, there is still a need for medications that can help treat and slow the progression of the disease.

## Who is eligible to be in the UNISUS Study?

To pre-qualify for this study, you must be:

- ✔ At least 18 years of age, and
- ✔ Diagnosed with PAH

All study-required visits, tests, and medications will be provided at no cost. In addition, reimbursement for study-required travel may be available.

## About the UNISUS Study

The UNISUS research study is dedicated to people with PAH. The study will compare the effectiveness and safety of a higher dose of an investigational medication against a lower dose.

The investigational medication has been approved by regulatory agencies in many countries around the world at a lower dosage to treat PAH. The doctors conducting the research want to learn more about the safety and effectiveness of the investigational medication at a higher dosage that has not been approved in any country for any condition. This higher dose is currently being studied in people with pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension (CTEPH).

The results of the UNISUS study will provide more information about the investigational medication's effectiveness and safety when it is given at a higher dose to adults with PAH.

## What is my role in the study as a

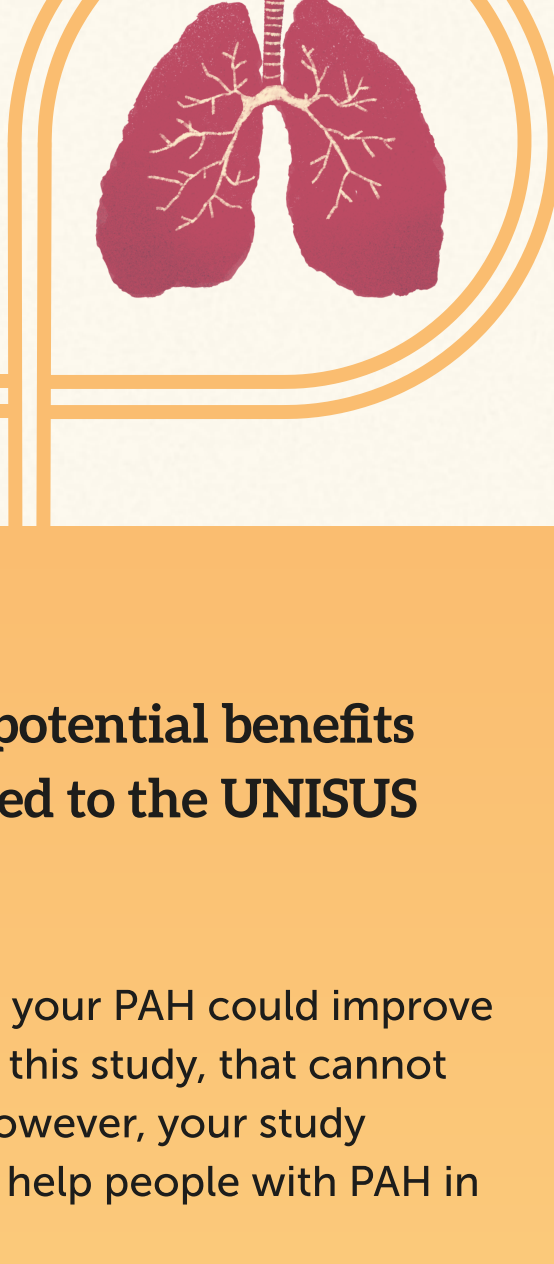
If you are eligible and agree to be in this study, you will be randomly assigned (by chance) to receive either the higher or lower dose of the investigational medication as well as a matching placebo. A placebo looks like the investigational medication and is given in the same manner but does not have any active medication. You have an equal chance of being assigned to receive either dose of the investigational medication. If you are currently taking medicine to treat your PAH, you may be able to continue taking it while in the study.

Neither you, the study doctor, or the study staff will know which study medication dose you'll be receiving. However, in case of an emergency, that information can be provided to your study doctor.

You will take 2 tablets (study medication + placebo) once a day as instructed by the study doctor while you are in the study.

After completing the treatment period, you will continue into the treatment extension period which will consist of two phases. During the first phase, you will receive either a higher or lower dose of the investigational medication along with a matching placebo for 4 weeks. During the last phase called the open-label phase, all participants will have the option to receive the higher, target dose of the investigational medication.

Your total study participation may last 3 to 6 years. During your study participation, you will be asked to attend regular study clinic visits to evaluate your health. You will also receive phone calls from the study staff to discuss the study and check in on how you are feeling.



## What are the potential benefits and risks related to the UNISUS study?

While it's possible your PAH could improve as a participant in this study, that cannot be guaranteed. However, your study participation may help people with PAH in the future.

It is possible that you could experience one or more side effects during this study. Before you begin the study, the study doctor will talk you through the potential study-related risks and side effects.

This study has been approved by an independent review board that is responsible for patient safety. Because participation in this study could affect your health, you will be closely monitored throughout the study. Study researchers designed a protocol that explains the study in detail, and the protocol must be followed exactly as written.

 For additional information about clinical studies please see the FAQ section.

## Short Study Summary


**Medical condition**  
Pulmonary Arterial Hypertension (PAH)

**Study Duration**  
3 to 6 years

**Locations**  
This is a global study which will enroll approximately 900 participants across North America, South America, Europe, and Asia-Pacific.

**Phase**  
3

## Frequently Asked Questions

 [What is a clinical study?](#)

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If this Cookie Policy changes, the revised policy will be posted on this site. This Cookie Policy was last updated March 18, 2022.

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Type of Cookie	Source	Purpose	Expiry	How to Block
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Advertising cookies and technologies	AppNexus	These cookies are used to collect information about how visitors use our website in order to provide them with advertising that is better tailored to their interests on our site and/or on other websites.	Some of the cookies set for this purpose may last for a period of up to 12 months from your last visit to our site.	You can opt out of tracking by AppNexus by visiting: <a href="http://www.appnexus.com/platform-policy#choices">http://www.appnexus.com/platform-policy#choices</a>