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BAYER

Hello!

Welcome to the OCEANIC-AF study, sponsored by Bayer.

OCEANIC-AF (Phase 3 program of the Oral faCtor Eleven A iNhibitor asundexIan as novel antithrombotiC – Atrial Fibrillation study)

FOR MORE DETAILED INFORMATION ABOUT THE STUDY, PLEASE REFERENCE THE INFORMATION SHEET FOR PARTICIPANTS

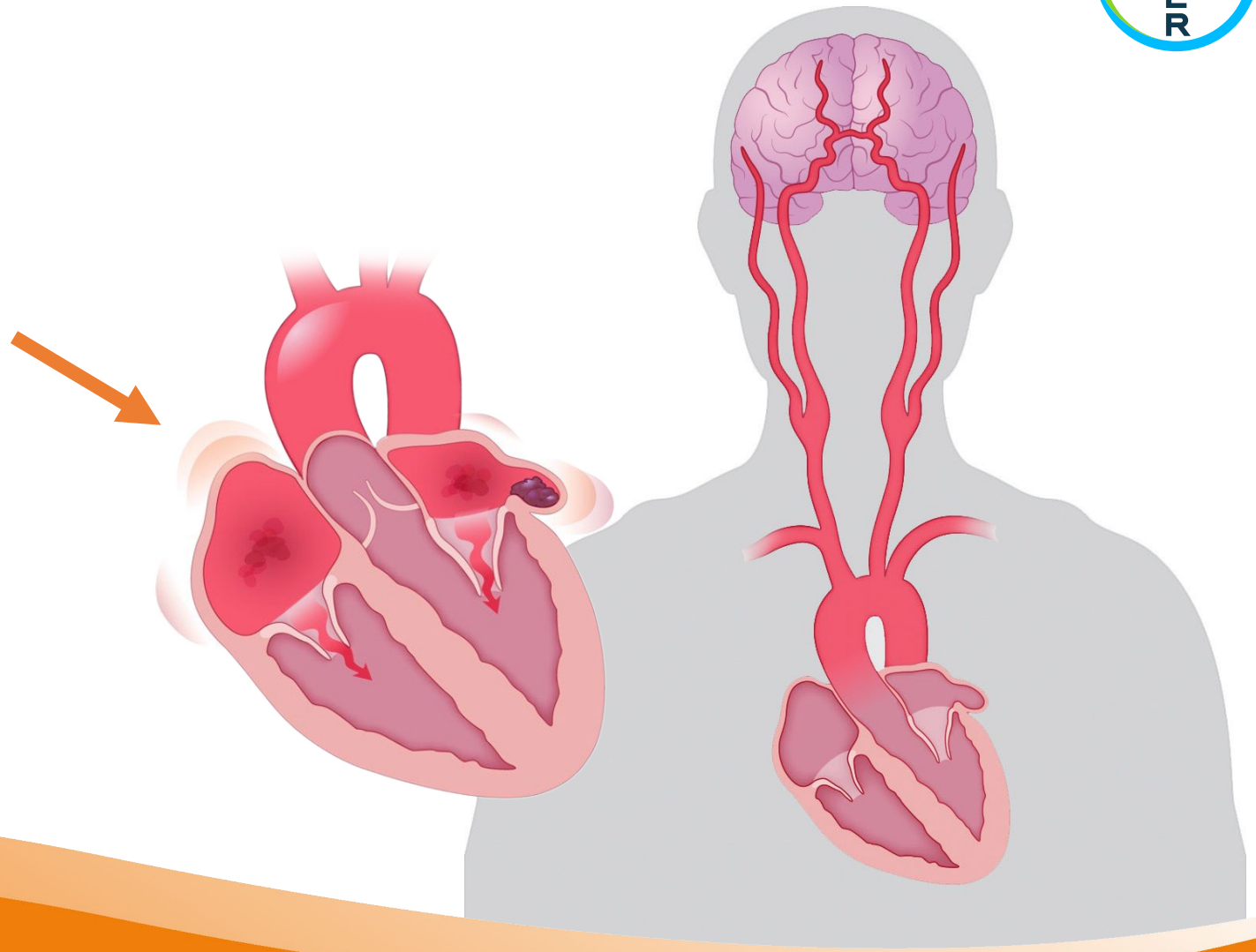
THE OCEANIC-AF STUDY IS NOW LOOKING FOR PARTICIPANTS

OCEANIC-AF will evaluate the use of an investigational drug called **asundexian** (BAY 2433334) in patients with **atrial fibrillation** and **at risk for stroke.**

WHAT IS
ATRIAL FIBRILLATION?

Atrial fibrillation is a heart disease. It is the most common type of arrhythmia (irregular heartbeat).

During atrial fibrillation, atria (the upper chambers of the heart) shake (quiver) rather than contract. This causes an irregular heart rhythm.



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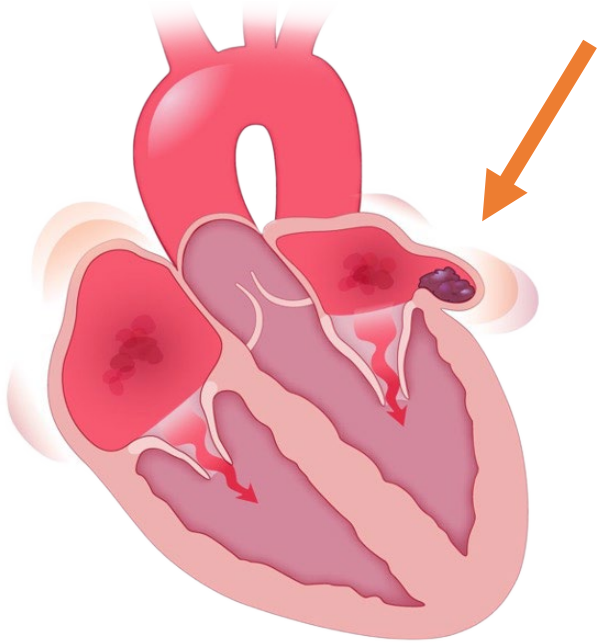
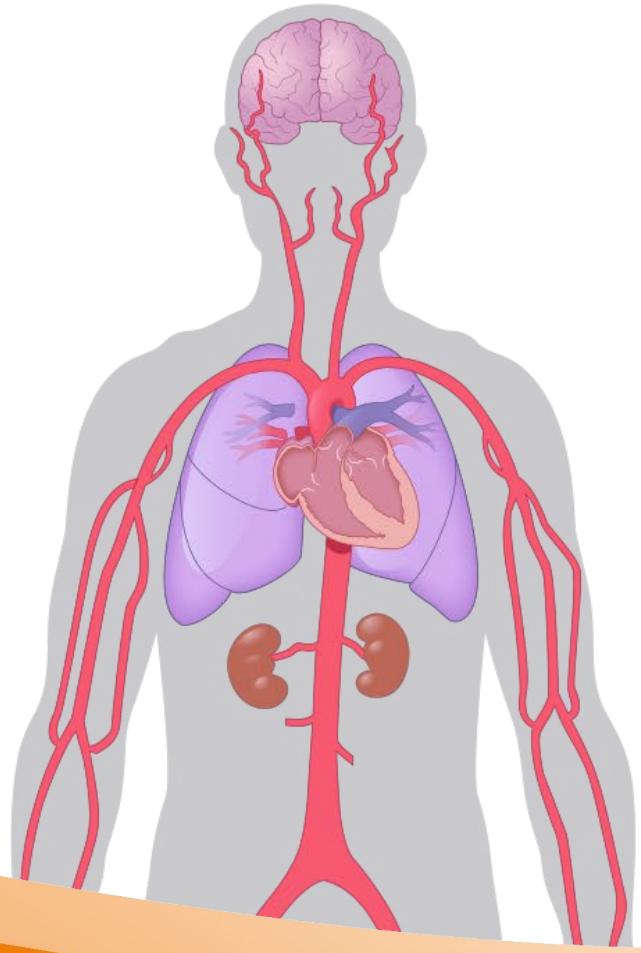
Atrial fibrillation can cause the formation of a blood clot inside the heart.





The blood clot can travel with blood and block blood vessels in different parts of the body, particularly the brain.

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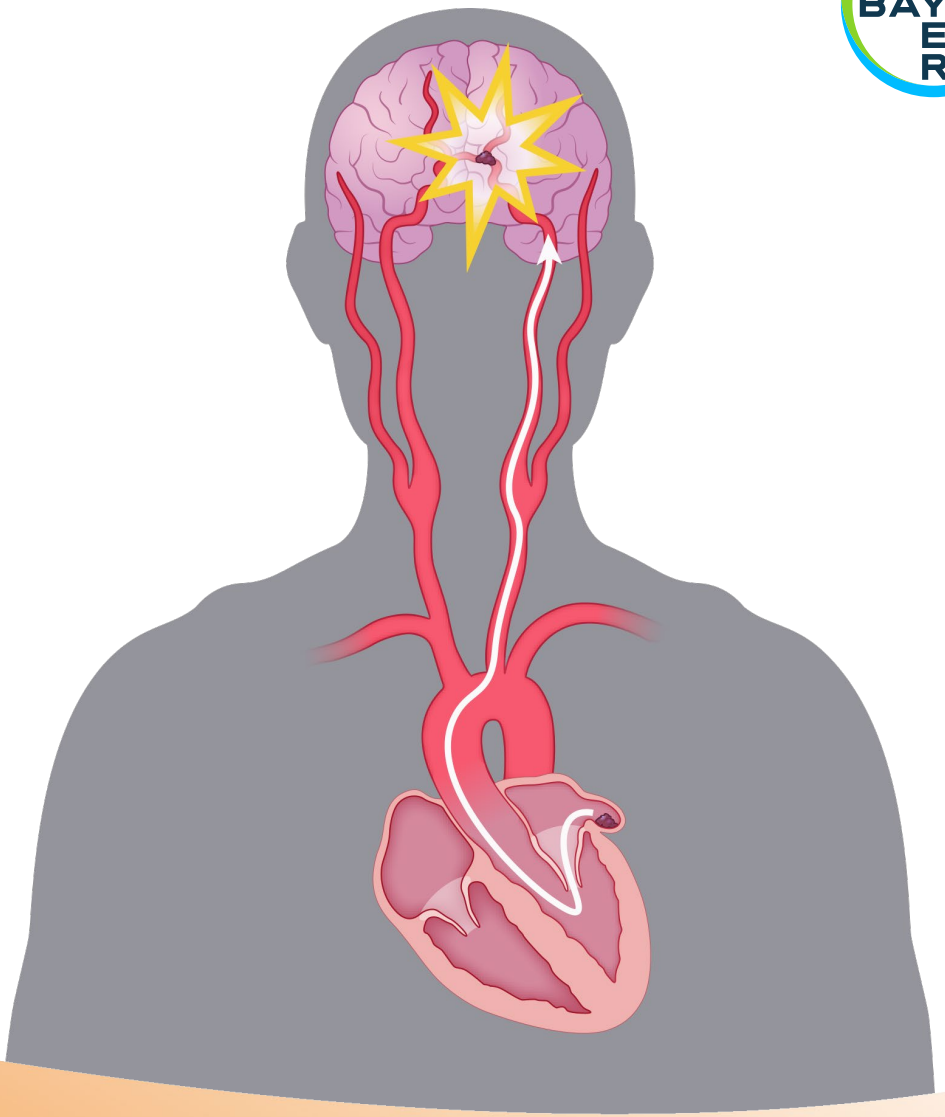
If the blood clot travels to the brain, it can block the blood supply to an area of the brain and cause a stroke.

A stroke is a life-threatening emergency.



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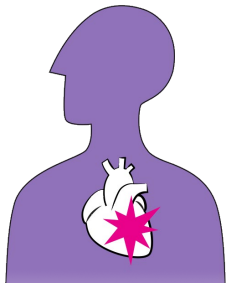
The risk of stroke is particularly high
if you have atrial fibrillation
and other risk factors such as:

OLDER AGE

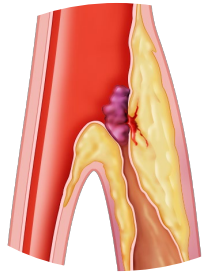
HIGH BLOOD PRESSURE

DIABETES



HEART FAILURE OR CORONARY ARTERY DISEASE

PRIOR STROKE



VASCULAR DISEASES

HOW CAN
STROKE RISK BE LOWERED?

In patients at risk of stroke, **anticoagulant drugs** (commonly known as blood thinners) may be prescribed.

These drugs influence the blood coagulation process and therefore the formation of blood clots.

However, anticoagulants may increase the risk of bleeding.

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WHICH STUDY DRUG IS BEING INVESTIGATED?

The study drug is an investigational anticoagulant drug.

Investigational means that this drug is not approved for use or prescribing in your country and can only be used in clinical studies like this one.

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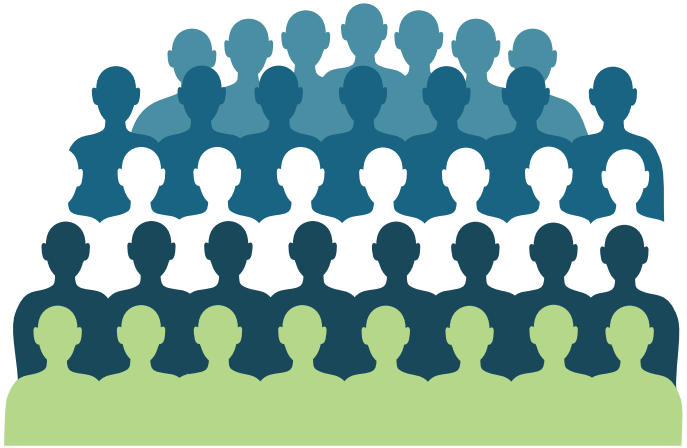
The investigational drug has been tested in:

PHASE 1 STUDIES, among small groups of healthy people

PHASE 1 STUDIES

PHASE 2 STUDIES, among a group of people with the disease to identify side effects and measure effectiveness



PHASE 2 STUDIES

The investigational drug is now in a phase 3 clinical study called OCEANIC-AF.

PHASE 3 STUDIES involve larger groups of patients. If the treatment or drug successfully passes phase 3, it is ready to obtain approval to be commercialized by respective health authorities in each country.

PHASE
3 STUDIES

WHAT IS THE
PURPOSE OF THE OCEANIC-AF STUDY

Does the study drug help to prevent stroke?

Is it effective?

Does the study drug lower the risk of bleeding?

Is it safe?

Compared to an approved anticoagulant drug.

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WHAT ARE THE POTENTIAL BENEFITS?

It is not known whether you will get any benefit from participating in this study.

The information collected in this study will help doctors to learn more about this study drug. This information may help future patients with atrial fibrillation.

ARE THERE SIDE EFFECTS?

As with any drug, side effects may take place with the investigational drug. There may be side effects that are not yet known.

The main side effect that scientists think may happen is bleeding.

FOR THE FULL LIST OF SIDE EFFECTS AND SYMPTOMS, PLEASE REFERENCE THE INFORMATION SHEET FOR PARTICIPANTS.

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You should tell your study doctor
about any new symptoms
you may have during the study.

ABOUT OCEANIC-AF

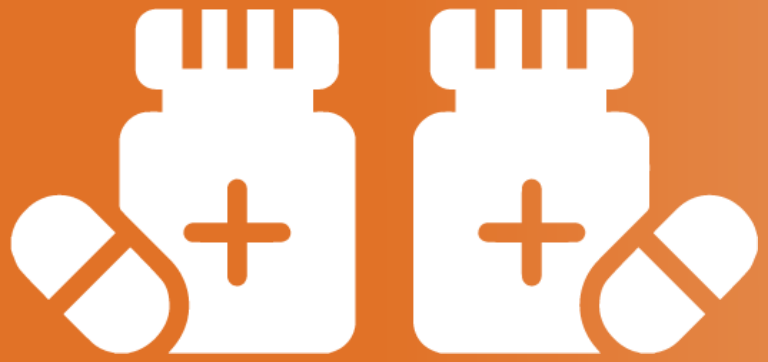
THE OCEANIC-AF STUDY IS:

MULTI-CENTER

The study will be conducted in many different hospitals.
Approximately 18,000 patients will be involved across the world.

ABOUT OCEANIC-AF

THE OCEANIC-AF STUDY IS:



ACTIVE COMPARATOR-CONTROLLED

The investigational drug will be compared to an already approved anticoagulant called apixaban.

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THE OCEANIC-AF STUDY IS:

RANDOMIZED

A computer will randomly choose who takes the investigational drug and who takes the comparator, apixaban.

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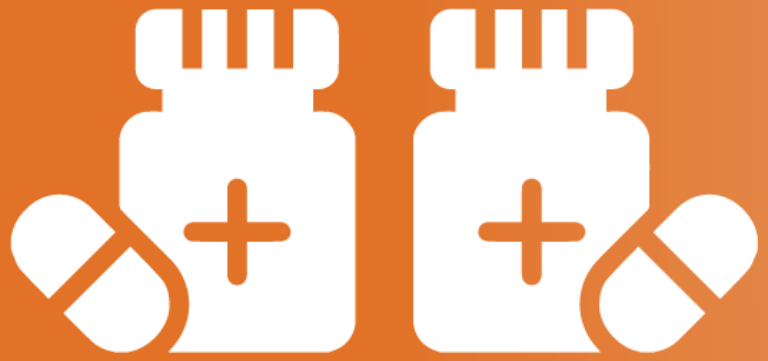
THE OCEANIC-AF STUDY IS:

DOUBLE-BLIND

No one (neither you, nor the study doctor) will know which treatment you will be receiving but, whenever there is a need to “unblind” the information, your doctor can find out!

ABOUT OCEANIC-AF

THE OCEANIC-AF STUDY IS:



DOUBLE-DUMMY

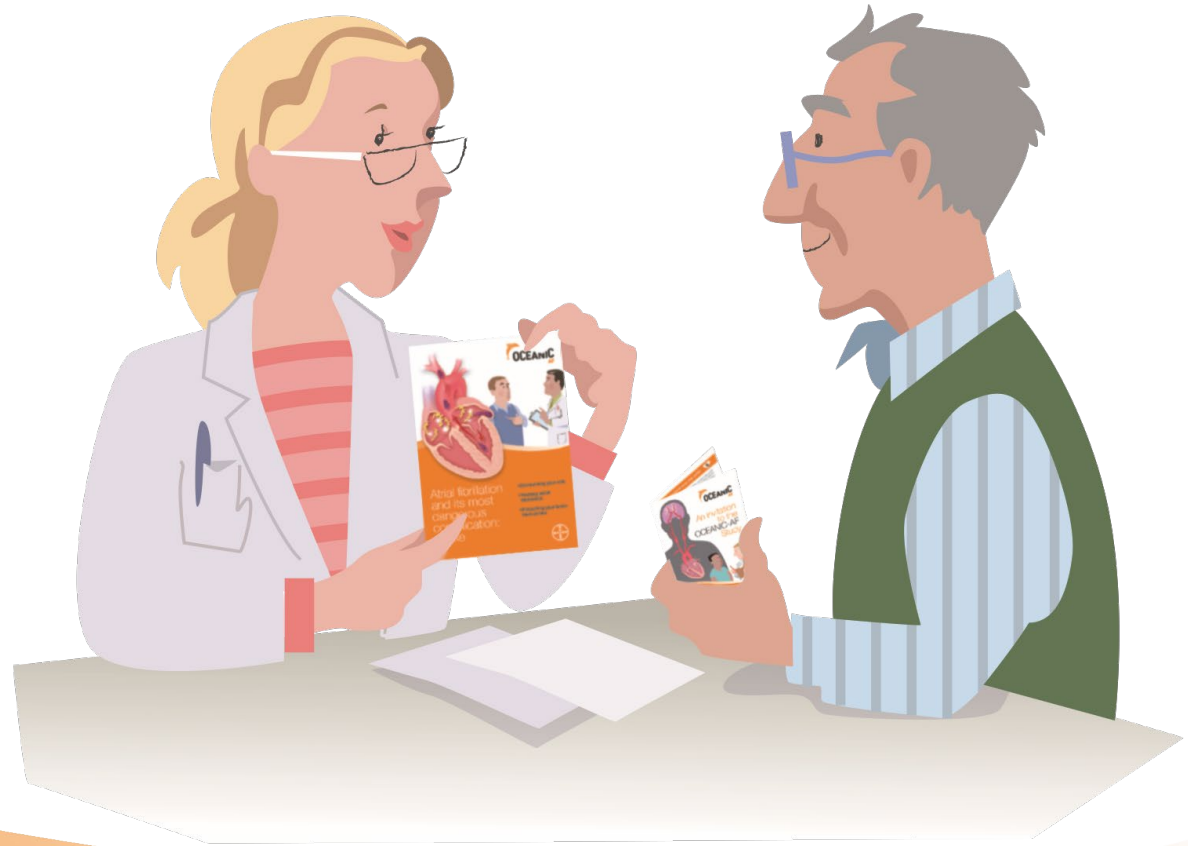
You will have to take 2 different types of tablets. One will be the study drug or the comparator (apixaban) and the other one will be a placebo (a tablet looking like the study drug or the comparator, but without any active drug in it).
Neither you nor your doctor will know which is which.

WHAT HAPPENS IN THE STUDY?

Before enrollment, the study doctor will explain the study and ask you to sign an informed consent form.

Remember that your participation is entirely voluntary.

You can stop the study drug at any time without giving a reason and remain in the study or you can stop study participation fully.



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If you decide not to take part in this study, you will continue to receive standard of care treatment from your hospital and doctors.

AFTER ENROLLMENT, YOU WILL TAKE PART IN

SCREENING

An initial screening period that will allow the doctors to collect information on your health conditions.

AFTER SCREENING, YOU WILL TAKE PART IN

SCREENING

TREATMENT

A treatment phase, in which you will be taking the study tablets each day.

Doctors expect the treatment phase to last between 9 and 33 months. However, it could be extended and therefore last longer for some participants if further data is needed to answer the study questions.

You will have a call with the site staff after 1 month and a site visit 3 months after starting the study drug. After that, you will have either a call or a site visit every 3 months until the end of the study.

AFTER TREATMENT, YOU WILL TAKE PART IN

A follow-up phase that will start once treatment ends. You will go to an End of treatment visit and will have a follow-up telephone call after 2 weeks.

When you stop investigational drug treatment earlier than planned you will have to continue with phone visits (or visits at the site) at 3-month intervals. This is so the study doctors can collect data for the study until all participants complete the study and participate in the End of treatment visit.

SCREENING → TREATMENT → FOLLOW-UP

WHAT WILL HAPPEN
AT STUDY VISITS?

The doctor will check your health status, ask which medications you are taking and if anything changed in your medications or health.

At the first visit your heart rate and blood pressure will be measured.

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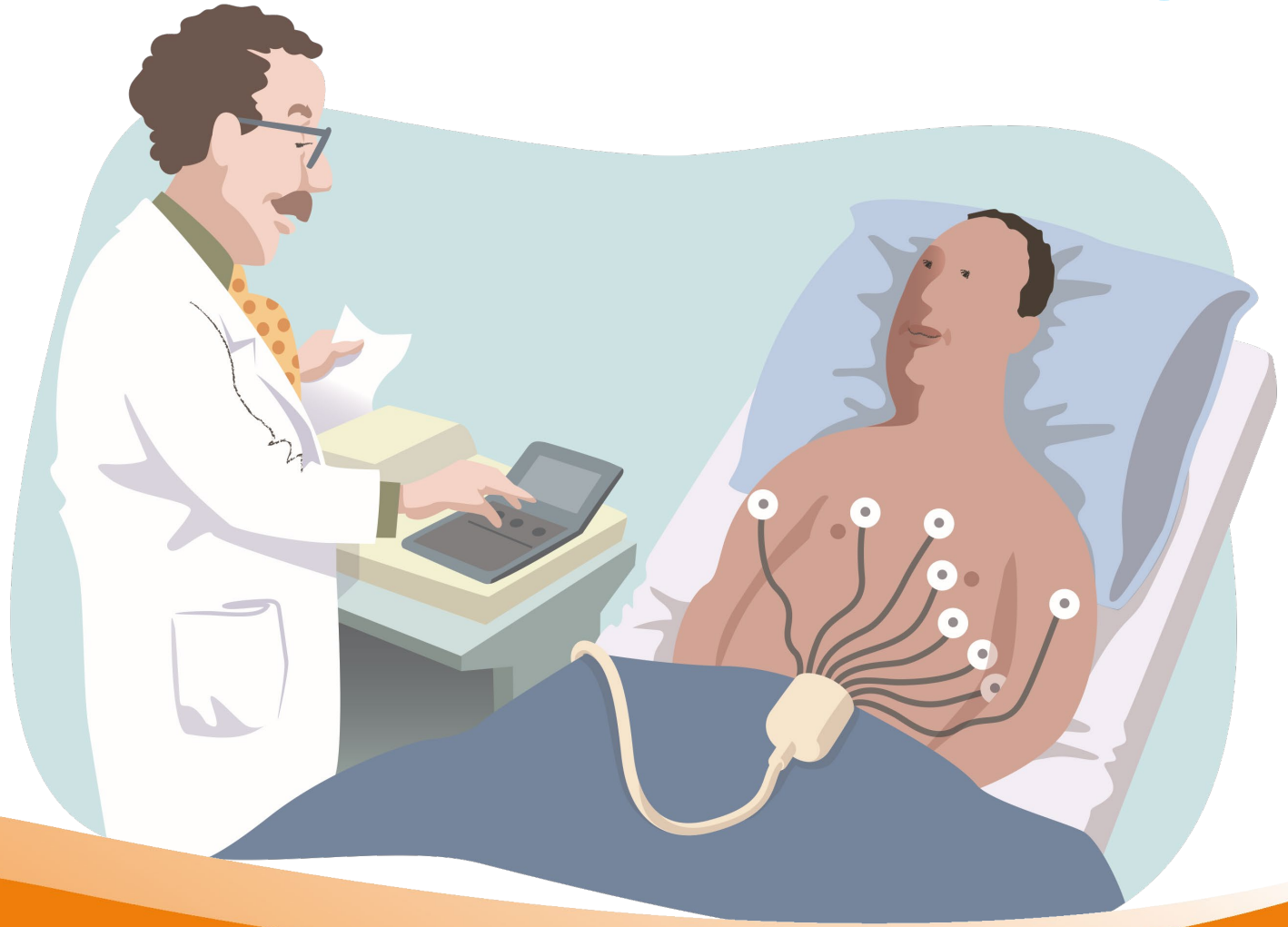
WHAT WILL HAPPEN
AT STUDY VISITS?

An electrocardiogram (also known as ECG) will be performed to confirm if you have atrial fibrillation and check your heart's rhythm and health.



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WHAT WILL HAPPEN
AT STUDY VISITS?

At some study visits, you will undergo blood draws to check

- your overall health
- the study drug concentration in your body, if this procedure is foreseen in your country/at your doctor's clinic.

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You will also be asked to complete a questionnaire on your quality of life.

More details on the OCEANIC-AF study will be given to you after your participation in the study is confirmed.

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Take your time to read through the Information Sheet for Participants
and ask doctors and nurses any questions you may have, before making your decision.

Thank you
for considering participation in the OCEANIC-AF study!

19767 OCEANIC-AF, AFIB and Study Video, English Core, Version 1.0, 10Aug22
19767 OCEANIC-AF, AFIB and Study Video, US (English), Version 1.0, 10Aug22
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