

ORION-4 ELIGIBILITY CHECKLIST: ARE YOU SUITABLE TO TAKE PART?

If you have received an invitation to take part in ORION-4, you can use this checklist to find out if you are suitable to join the study.

Please read the Participant Information Leaflet before completing the checklist (you received the Leaflet with your invitation letter and you can find a copy on our website in the [Downloads](#) section).

If you want to discuss any part of the study or are unsure how to answer these questions please call us on 0800 585323 or e-mail us via our website [Contact Us](#) page.

To be able to take part in ORION-4 you must have at least one of the conditions in the inclusion list, and none of the conditions in the exclusion list.

- **INCLUSION LIST** – to take part you must be age 40 or older for men, 55 years or older for women, be willing to stay in the study for about 5 years, and answer **Yes to at least one** of these questions:

INCLUSION QUESTIONS	ANSWER
1. Have you had a heart attack? Note: If you have had a heart attack in the last 4 weeks you are not currently able to take part, however please call us as you may be able to take part in the future.	Yes / No
2. Have you had a stroke? Note: If you have had a stroke in the last 4 weeks you are not currently able to take part, however please call us as you may be able to take part in the future.	Yes / No
3. Have you had surgery or a procedure to unblock or bypass the arteries in your legs (e.g. angioplasty, stent or bypass operation)?	Yes / No
4. Have you had an aortic aneurysm repair?	Yes / No

If you answered Yes to at least one of these questions then you may be eligible to take part. Please continue to the Exclusion List below.

- **EXCLUSION LIST** – you must be able to answer **No to all** of these questions to be able to take part. If you are unsure about your answers to these questions, please call us to discuss.

EXCLUSION QUESTIONS	ANSWER
5. Do you have a coronary revascularization procedure (angioplasty or bypass graft) planned within the next 6 months?	Yes / No
6. Do you have liver disease?	Yes / No
7. Are you receiving dialysis or is dialysis planned?	Yes / No
8. Have you had a kidney transplant or is a kidney transplant planned?	Yes / No
9. Have you ever had treatment with injections to lower cholesterol including evolocumab (Repatha™) or alirocumab (Praluent) or inclisiran or been in a research study testing one of these treatments?	Yes / No
10. Are you currently taking part in a clinical trial with an unlicensed drug or device?	Yes / No
11. Do you have any other serious illness or condition that might make it difficult to stay in the trial for the whole duration (e.g. cancer or severe lung disease)?	Yes / No

- **NEXT** – If you answered **Yes to at least one** of the **Inclusion List** and **No to all** of the **Exclusion list**, and are interested in taking part in ORION-4, please call us on 0800 535323 to confirm or change your appointment.