

Privacy Notice ORION-4 trial staff and investigators

This Privacy Notice is provided to comply with the General Data Protection Regulation (GDPR) 2018 and other relevant regulation. It aims to inform you how we will use, store and process personal data about you in connection with the ORION-4 study.

Who is responsible for your data?

The University of Oxford is the data controller with respect to the processing of your personal data for the purposes of the ORION-4 study. The Information Commissioners Office (ICO) registration number for the University of Oxford is Z575783X.

Types of personal data

In connection with the ORION-4 Study, the personal data that we process could include your name and contact information (e.g. phone, email, business address), your participation in the ORION-4 Study and your role (e.g. Principal Investigator, Research Co-ordinator etc.), your date of birth, work experience and professional qualifications, curriculum vitae (CV) and educational background (if you have provided these details), information provided by you in any Financial Disclosure Forms (if relevant) and processing of personal data arising from your use of *Stellar* (the ORION-4 web-based system).

Purposes for which we process your personal data

We are processing your personal data for the purposes of conducting the ORION-4 trial in accordance with the protocol. This may include

- Monitoring, source data/document verification, audits, pharmacovigilance etc.
- Processing of personal data arising from your use of the ORION-4 study web-based systems, for example IP addresses and information gathered through cookies. Cookies are small text files that are placed on your computer by websites that you visit. For more information about cookies you can visit <http://www.allaboutcookies.org>.

We may also process your personal data in order to select investigators for future studies.

Where we store and process your data

The data is stored on secure servers managed by the University of Oxford. We ensure that your personal data is protected against unauthorised access, unlawful use, accidental loss, corruption or destruction.

Sharing your data

We may share your personal data for the purposes mentioned above with service providers (including third party electronic Trial Master File providers).

The ORION-4 study data or reports, including your personal data, may be shared with third parties in line with the principles for responsible clinical trial data sharing.

Your personal data may be shared with ethics committees/institutional review boards, governmental or regulatory authorities and Novartis and its designated representatives.

Some of the recipients may be based in countries outside the European Union. In compliance with applicable law, we have taken steps to ensure that your data remains secure.

How long do we keep your data?

We will keep your personal data for up to 25 years after the end of the ORION-4 trial. Because of planned follow-up of study participants after the scheduled treatment period, the end date of the ORION-4 trial has not been specified but will not be later than 2060.

What is the legal basis for processing your data according to GDPR?

The University of Oxford is using your personal data for research purposes, it will only process personal data as necessary to undertake research that is being carried out in the public interest. Under data protection law the "legal basis" for processing your personal data is GDPR article 6(1)e.

Your rights

Full details on your rights to access and modify your personal data are available at <https://compliance.admin.ox.ac.uk/individual-rights>.

Complaints

If you wish to raise a complaint about how we have handled your personal data, you can contact our Data Protection Officer, data.protection@admin.ox.ac.uk, who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the ICO <https://ico.org.uk/concerns/handling/>.

Contact us

If you would like to contact us directly for more information about how we process and protect data collected for research, please email: CCO-Orion4@ndph.ox.ac.uk