



GloBE-Reg

Information Sheet for Parents of Child Participants

What is GloBE-Reg?

GloBE-Reg is an international registry of children and young people with a rare condition for which they are starting on new therapy. The project was launched in 2022 and it aims to help patients, health care professionals, researchers and industry to understand the short-term and long-term outcomes of the new therapy. To find out more about GloBE-Reg, please visit the website at <https://globe-reg.net/>.

What is a Registry?

A registry is similar to a medical database containing a range of medical records. Registries are used very often these days by doctors and scientists to perform research into rare conditions. By combining our knowledge and experiences in people with rare conditions, registries can improve our understanding of these conditions and improve the care of all those affected.

What is the purpose of the Registry?

The information that will be collected by the Registry is routinely collected by your child's doctor at the clinic. The purpose of the Registry is to encourage all users to collect this information in the same way everywhere and then share this information with researchers who want to perform research with these data. These researchers may be doctors and scientists, public health or government organisations, other registries of rare conditions, the pharmaceutical industry as well as patient organisations. These researchers will need to be approved by Globe-Reg before they are provided any data. You can ask your child's hospital doctor to show you the kind of information that is stored and you can also find out more at <https://globe-reg.net/>.

Why have I been approached?

The hospital doctor looking after you or your child and who is highlighted at the end of this leaflet is an approved user of the Registry and has provided this information to you. The Registry is open to all those who have a rare condition that affects their endocrine health or bone health and who are starting on a new form of therapy for this condition. There is another information leaflet which may suit a younger person and you can ask your doctor if you would like to read that one too. When your child reaches the age of 16 years, the Registry will send a reminder to the hospital doctor to check whether the young person would like to stay on the Registry.

My affected child is still very young – how do I know this is what my child will want?

Sometimes it can be difficult to decide on your child's behalf. Please remember that all the information can be removed from the Registry at any time by you or by your child. Your child does not need to wait until they turn 16 years old and you can discuss the Registry at an earlier age. They can also provide consent at an earlier age depending on local practice and regulations at your hospital.

Do I have to take part?

No. If you do not return the consent form then your hospital doctor will assume that you do not want the information to be stored and shared on the Registry. The care of your child's condition will not be affected by your decision.

If I take part, what will happen when the data are included on the Registry?

The Registry users will not be able to make contact with your child because the name, address and hospital number will not be recorded. Only your child's doctor and their team will be able to contact you as they can link the data in the Registry to the hospital records. Nobody else, including the researchers who are provided the data, will be able to identify you in the Registry. To understand the effects of the new therapy, your hospital doctor will enter a small amount of data in the Registry and this will include the date of birth. You can visit the GloBE-Reg website to look at the details of all the data that will be included. If you choose to have your child included in the Registry, you can also opt to view your own details as they are entered in the Registry. In addition, the Registry will also provide you with the option to enter you and your child's own experience of the condition, often called patient-reported outcomes. To obtain access to the Registry, you will need to provide an email address. You can also find out from your hospital doctor or the Registry about the studies in which your child's details have been used. As the Registry is designed to look at long-term outcome, the data shall be stored indefinitely even after the registered person has passed away.

What will happen to the information collected on the Registry?

- The data collected in the Registry might be used to perform research or develop new research studies



- The results of the studies will be published in medical journals so that other professionals and patients around the world can also benefit
- The data will help assess the benefit of existing therapies and help the development of new therapies

Will the information be kept confidential?

Your child's participation will be kept strictly confidential and all information will be handled through very secure electronic systems. The system will be password protected and only those who are directly involved with the Registry will have access. Please remember, the Registry does not collect any information about names, addresses and local hospital numbers.

What are the possible disadvantages and risks of the Registry?

There are no disadvantages to being included on the Registry that we can see. You or your child's hospital doctor do not have to pay to use the Registry. You will not be contacted by the Registry unless you have selected to do so.

What are the possible benefits of the Registry?

The Registry is designed to help scientists and doctors to improve their understanding of rare conditions and provide best care to people. The Registry will also collect information directly from yourself and this will improve your doctors understanding of how the condition affects your child. It is possible that, based on the information you provide, your doctor may want to discuss your child's condition in more detail with you.

Can I access my own record?

Yes. You can arrange access for yourself through the hospital doctor who has entered the data and you can directly view the information in the Registry. If you would like to change any of this information or would like to find out more, please ask your hospital doctor. Please remember, if you would like to view your child's information directly in the Registry, you will need to provide us with your email.

If I change my mind, have a complaint or want to provide feedback, who do I turn to?

If you wish to remove your child's details from the Registry, you can contact your child's hospital doctor or the GloBE-Reg team, directly, through the address at the end of this information sheet. If you are unhappy about any aspect of the way you have been approached or treated, you can also complain through your local health service complaints procedure. Your child's hospital doctor or family doctor shall be able to advise you about this. In addition, you can also contact the GloBE-Reg team directly through the address at the end of this information sheet. The team is very keen to hear from you so please feel free to contact them with any comments.

Who has reviewed the activity of GloBE-Reg?

At its inception, the activities of GloBE-Reg were reviewed by several international scientific societies and pharmaceutical companies. These societies and companies provide ongoing review and input into GloBE-Reg through its committees, including the Data Access Committee. Further details of all the committees are available on the GloBE-Reg website. Every 5 years, the Registry is also reviewed by the UK National Research Ethics Service and the Information Governance Office at the Greater Glasgow & Clyde National Health Service Board. It was last reviewed in 2022.

Where is GloBE-Reg based and how is it funded?

The GloBE-Reg project is managed from the Office for Rare Conditions at the University of Glasgow. The Office has experience of running and coordinating international registries for rare conditions for over 15 years. At its inception, the GloBE-Reg project received funding from Novo Nordisk, a pharmaceutical company. To continue the project, GloBE-Reg will also charge fees to researchers.

What do I have to do?

Simply talk to your doctor to decide if it suits your circumstances to put the information in the Registry, and complete the attached form. You can always change your mind later and ask your hospital doctor to remove the information from the Registry.

For further information you can contact:-

- Contact your local specialist at your hospital
- Visit the GloBE-Reg website (<https://globe-reg.net/>) and subscribe to receiving further news.
- Contact the GloBE-Reg team – info@globe-reg.net

Office for Rare Conditions, Glasgow, University of Glasgow
United Kingdom, Tel: +44 141 451 5843