



# Global Registry for COL6-related dystrophies

## INFORMATION FOR PATIENTS AGED 11-15 YEARS

**Principal Investigator:** Prof. Dr. Volker Straub, Newcastle University, UK

Should you have questions relating to the registry, you or your parents can contact either your local doctor or the registry curator Dr Alison Blain (you can find her contact information below).

*You are being invited to join a registry (research database) so that we can learn more about your condition. Before you decide if you want to join in it is important to understand why the project is being done and what it will mean for you. Please read this information carefully and talk about it with your family and friends. There is a glossary at the end of this information sheet to help explain what some of the words mean.*

*If you have any questions after reading this information, please talk to your parents or guardians, to your doctor, or contact the Registry Curator, Alison Blain, at: [Collagen6registry@ncl.ac.uk](mailto:Collagen6registry@ncl.ac.uk)*

*You can also download or print a copy of this information to keep.*

### ***Why are we doing this research?***

We are interested in people like you with a type of *COL-6 related dystrophy* (Ullrich Congenital Muscular Dystrophy (UCMD) or Bethlem myopathy). We want to learn more about this group of diseases and maybe help make new treatments. To help do this we want to set up a registry (*database*) made up of information about people like you. To make this registry we want to ask if it is OK with you to store information about you on a computer. If you are happy to be involved in this, please talk to your parents and ask them to complete the *consent* form so that we can collect and keep your information. You may also complete the *assent* form provided.

If new treatments are made that may help you, we can then contact you to see if you want to try them (in a '*clinical trial*'). You do not have to be involved in any *clinical trials* and we would talk to you again at a different time if this was a possibility. You and your parents would need to sign a different *consent form* at that time as well.

### ***Do I have to take part?***

You do not have to take part in this project. Deciding not to take part will not change how we look after you. If you do want to take part then you, and your parents, will be asked to sign a *consent form* to say that you agree to take part and that we can keep information about you. You will also have a copy of this form to keep.

If you change your mind and decide you don't want to be part of this project anymore then we will remove the information about you from the *database*. Again, this will not change the way we look after you.

### ***What will happen to me if I take part?***

If you are happy to be part of this project you will be asked to complete a few personal details and to answer a questionnaire together with your parents. Your doctor will also be asked to complete some information which may come from your medical notes. You will not be asked to have any extra tests done for this project and you will not need any time off school other than to come to your usual clinic appointments.

### ***How will my information be stored and used?***

Your personal details, such as your name and address, will be stored securely within the European Union and will be encrypted and protected by passwords. People who are planning the *clinical trials* or research studies can ask the registry team to give them information about the numbers of patients with your condition and in which region they live to see if it is a good idea to do a clinical trial or research study in a certain place. But those people will never get direct access to your data, nor will they be given your name or address so that they will not be able to contact you directly. If you would like to take part in a specific clinical trial or research study, and are eligible to do so, you would then be contacted by the registry. In any case, you can always let us know if you have changed your mind and do not want to be on the registry anymore, and this would not affect your care in the future.

### ***Will this project help me?***

The project may not help you specifically, but the information we collect should help us learn more about Collagen 6-related conditions and help develop new treatments in the future.

### ***What happens when the project stops?***

Muscular Dystrophy UK has provided enough money for this project to run for 3 years, but we hope to be able to keep the *database* running after that time. We would like to keep information about you for as long as possible.

### ***What if something goes wrong with the project?***

We do not think that anything will go wrong. The only people who can see the information about you are members of Professor Straub's team who help with the project. The *database* is secure and *password protected* and is looked after by Newcastle University.

### ***Will anyone else know I'm doing this?***

Only people allowed by Professor Straub will be able to see the information about you. Your parents will also need to know, as they will need to sign the *consent form*.

Some people from *research companies* may ask for information about you if they think they have a treatment that may help you. If Professor Straub thinks it may be of help he will write to you to ask if you would like to take part. This would be your decision.

### ***Who decided the project could be done?***

Before any *research* can be done it has to be checked by an *Ethics Committee*. This is to make sure that the *research* is a good idea and is safe to do.

The registry team is based at the John Walton Muscular Dystrophy Research Centre at Newcastle University, UK, and is part of the TREAT-NMD alliance (<http://www.treat-nmd.eu/>) global network of registries.

**Contact Details:**

If you would like to talk to someone about taking part, you or your parents can contact the registry curator Dr Alison Blain: [Collagen6registry@ncl.ac.uk](mailto:Collagen6registry@ncl.ac.uk)

Telephone: 0191 241 8640

Or the registry principal investigator  
Dr Volker Straub:  
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**GLOSSARY –What do these words mean?**

**Anonymous information** – information which does not contain any names or contact details  
**Clinical trial** – an experiment involving patients with a particular disease  
**Consent** – giving permission for something, or agreeing it can be done  
**Assent** - indicating that you are aware and approve of something  
**Database** – a collection of information  
**Encrypted** - converted into a code, a way of concealing information to prevent it from being read by people who don't  
**Ethics Committee** – a group of people who look carefully at research projects to make sure they are properly carried out  
**Password protected** – a way of stopping people from looking at your information  
**Research** – careful investigation of a particular subject  
**Research companies** – a business that pays for investigation of a particular subject

**Thank you for reading this information**