



## UK Myotonic Dystrophy Patient Registry

**Principal Investigator/Data Controller: Dr Chiara Marini Bettolo,  
Translational and Clinical Research Institute, Newcastle University**

### Information for parents

**Your child is being invited to take part in a research study. Before you accept or decline the invitation on behalf of your child, it is important for you to understand why the research is being done and what it will involve. Please read the following information and discuss it with your child, and any friends or relatives, or your GP if you wish. If you have any further questions, please ask (contact details overleaf). Take time to decide whether you would like your child to take part or not.**

#### **Why has my child been asked to take part?**

Your child is being invited to take part in this research because they have myotonic dystrophy and we are trying to collect more information on patients, like your child, with similar conditions. An information sheet for your child can be provided.

#### **Why is this research being done?**

The aim of this research is to establish a database of patients in the UK with myotonic dystrophy. This will be a computer record from which we can identify groups of patients easily, who may be able to take part in clinical trials and help develop, or try out, new treatments for myotonic dystrophy. The database will contain information needed by the researcher, including your child's diagnosis and other key details of their disease. The TREAT-NMD neuromuscular network and the John Walton Muscular Dystrophy Research Centre (Newcastle University) are responsible for maintaining this database.

Before you consider registering your child's details it is important that you understand what is involved and what will be done with the information that you provide. This information sheet contains answers to some of the questions you may have about the database. After reading this information sheet, you will be given time to think about the study, and to ask any additional questions that you may have (contact details overleaf). We will then ask if you wish for your child to be registered on the database. You will be asked to sign a consent form stating you agree for your child to join and assent will be obtained from your child.

#### **How will my child benefit from registering?**

The database aims to benefit adults and children with myotonic dystrophy. By holding clinical information on the database we will be able to identify suitable patients to help assess possible new treatments (clinical trials), and contact you to ask for your help. You, or your child, would not receive any payment or other financial benefit as a result of joining the database. Nevertheless, there may be other benefits to your child being involved, including:

- Informing you about suitable clinical trials that you may wish your child to join
- Updates on new developments on your child's condition
- Providing information for healthcare professionals interested in the best standards of care for your child's disease

## **Data linkage to the Newcastle MRC Centre Biobank for Rare and Neuromuscular Diseases**

The Newcastle MRC Centre Biobank for Rare and Neuromuscular Diseases is a repository that creates a 'bank' of samples including: DNA and cells obtained from blood, urine, saliva, skin, muscle and nerve from healthy people, as well as from those with diagnosed diseases, for use in future research. A biobank is the term used to describe a collection of samples stored for research.

We are working to anonymously link your child's registration on the DM national registry to samples contained in the biobank should these be available. Linking the registry data with data that may be held in the biobank will help enhance the information available to researchers when accessing the samples or the registry, therefore facilitating research. Data would be linked via a unique identifier which ensures confidentiality is preserved.

### **I want my child to be involved in a clinical trial – is this guaranteed if we register?**

Although the database will make it easier to identify patients suitable for recruitment to clinical trials, there is no guarantee that you and your child would be automatically approached to take part in clinical trial. Doctors organising clinical trials will review your child's details on the database and if they appear suitable will invite your child to join. All patients invited to join a clinical trial will be assessed in greater detail at this stage to ensure there are no reasons for them not to take part, which was not obvious from the information recorded on the database.

### **Will information about my child be kept confidential?**

All information that we receive about your child will be treated confidentially. The information will be converted into code and stored on a secure computer located in the UK. Details of your child's specific diagnosis as well as personal information (name, age, address, gender) will be stored on the database. This information will allow us to identify your child easily should the need arise. Only specified members of Dr Marini Bettolo's team will be given access to look at this data. If we publish any research, or other studies, based upon information on the database this will not identify your child by name.

### **Does my child have to register? Can we change our decision?**

Joining the database is entirely voluntary, and declining the invitation to join the database will not affect your child's clinical care in anyway. If you wish to withdraw your child's details from the database at anytime, and for whatever reason, you are free to do so without having to provide an explanation. Again this will not change the clinical care that your child receives. Contact details are provided below.

### **How will details about my child be collected?**

During your child's planned clinic visits, information will be collected for the database. You can contact us at any time if your child's details change, or if you wish for your child to be removed from the database. There is also the option for you to enter details directly onto the database via the site address [www.dm-registry.org/uk](http://www.dm-registry.org/uk).

### **Who is funding the research?**

The project is funded by MDSG (Myotonic Dystrophy Support Group) and MD UK (Muscular Dystrophy UK). No additional payments will be received by Dr Marini Bettolo, or other members of the research team, for adding your child's details on to the database.

**Who has reviewed the project?**

All research conducted within the NHS has to be reviewed by an ethics committee to ensure we are not doing anything harmful to your child, or their personal information, in the project. This research has been reviewed and approved by North East- Newcastle and North Tyneside 1 Research Ethics Committee.

**What if I have any concerns or further questions?**

If you have any concerns, or other questions, about this study or the way it has been carried out, you should contact the Principal Investigator/Data Controller: Dr Chiara Marini Bettolo

**Tel:** 0191 2418606

**Email:** Chiara.Marini-Bettolo@newcastle.ac.uk

If you feel that your child has been treated unfairly throughout the research, or would like to comment on the conduct of any aspect of this research, please contact the Patient Advice and Liaison Service (PALS) 0800 0320202

**Thank you for taking the time to read this information sheet**