



Duchenne **UK**
Connect

Duchenne UK Connect Registry Module



Helping Improve
Understanding of Duchenne
Muscular Dystrophy

In collaboration with



Duchenne
UK



duchenneukconnect.org

Contents

1. What is the Registry and why is it important?
2. Why am I being invited and do I have to join?
3. What taking part involves
4. What information will be collected?
5. How may Registry information be used?
6. Benefits, burdens and possible risks
7. How we protect your information
8. Who may access, receive or link information?
9. Your choices and withdrawing
10. Governance, funding and research findings
11. Questions, concerns and complaints
12. Help and contact details

REGISTRY ONLY This leaflet is about the Registry module. Joining the Registry does not enrol you in the Care, Research or In Case of Emergency modules. Those parts have their own information and consent where required.

OUR COMMITMENTS TO YOU



- We will put the interests of people with Duchenne at the centre of Registry decisions.



- People with lived experience of Duchenne will be involved in Registry governance.



- Registry information will only be used for approved purposes with suitable safeguards.



- We will never share your data with any unauthorised third parties.



- We will be open about important changes and how Registry information is used.



- We will protect your privacy and keep your information secure.



1. What is the registry and why is it important?

The Registry is one part of Duchenne UK Connect, a secure online platform and app for people living with Duchenne muscular dystrophy in the UK.

The Registry allows people affected by Duchenne to record information about diagnosis, health, treatments, mobility, daily life, care and quality of life. It also helps you keep this information together in one place, where you can view and update it over time.

Information collected directly from people with Duchenne can show aspects of living with the condition that may not appear in clinical records. When many people contribute and update information regularly, the Registry can help build a clearer picture of how Duchenne affects people and how needs change over time.

What is the Registry trying to achieve?

- Maintain a UK-wide Registry using information provided by people affected by Duchenne.
- Understand health, mobility, daily living, treatments, assistive devices, care, services and quality of life.
- Understand how Duchenne and people's needs change over time.
- Support research into Duchenne treatments and its wider effects on everyday life.
- Improve questionnaires about health, quality of life and experiences of care.
- Help identify gaps, differences or inequalities in care and support.
- Support responsible research, treatment development and evidence after treatments become available.
- Give approved researchers access to suitable coded information under strict controls.

INFORMATION SHAPED BY LIVED EXPERIENCE By keeping information up to date, you can help create evidence that reflects the real experiences and priorities of people affected by Duchenne.

2. Why am I being invited and do I have to join?

Why am I being invited?

You are being invited to join the Duchenne UK Connect Registry module because you live in the UK and one of the following applies:

- you have been diagnosed with Duchenne muscular dystrophy;
- you are the parent or legal guardian of a child or young person with Duchenne; or
- you are a caregiver or authorised person supporting someone with Duchenne, where appropriate.

WHAT WE MEAN BY 'YOU' In this leaflet, 'you' may mean the person with Duchenne or the person providing information on their behalf.

Do I have to join?

No. Taking part is entirely your choice. You may take time to decide and discuss the Registry with people you trust. Choosing not to join will not affect your clinical care, legal rights, access to services or support from Duchenne UK.

You can join the Registry module without joining other Duchenne UK Connect modules. You can also leave the Registry module without leaving any of the other Duchenne UK Connect modules.

What if I need help deciding or using the Registry?

The Registry team can answer questions about taking part or help with the platform. They cannot provide personal medical advice. For questions about your health or treatment, contact your usual healthcare team.

YOUR DECISION Please ask any questions that are important to you before you agree to join online.

3. What taking part involves

What will I be asked to do?

1. Create a secure account and provide basic details about yourself or the person with Duchenne.
2. Read the participant information sheet(s) and complete the consent form(s) for the parts of Duchenne UK Connect you want to use.
3. Choose which parts you want to join. You do not have to agree to every module.
4. If you join the Registry, answer questions about diagnosis, genetics, health, treatments, mobility, daily activities, care, wellbeing and quality of life.
5. Update information from time to time, usually every six months when you are invited to complete a follow-up questionnaire.
6. If you wish, provide information about your diagnosis, by uploading documents such as genetic reports, clinic letters or medication information.

How long will it take?

Creating an account and completing the joining steps should take about 10 minutes. The first set of Registry questions may take up to one hour in total, depending on your answers and whether you take breaks. Updates every six months are usually shorter.

Do I have to answer every question?

Some questions are needed to make a particular part of the platform work. These will be clearly marked. Other questions may be optional. If a question is optional, you do not have to answer it if you feel uncomfortable or do not want to. You can leave at any time, save your progress and return later to complete any remaining questions.

How will you remind me?

Approximately every six months, you may be invited to review and update your information through the app, email or text message, depending on

your communication preference. You can also log in at any time and go to your account settings to change your communication preferences.

ENTER INFORMATION ONCE Where relevant, information already provided in another Duchenne UK Connect module may be reused in the Registry if you have consented. This avoids asking for the same information again and does not enrol you in another module.

4. What information will be collected?

Depending on the modules you participate in, Duchenne UK Connect may collect:

- profile and contact details;
- details about your/your child's condition and medical history;
- information about medicines, treatments, equipment and care;
- information about mobility, daily activities, wellbeing and quality of life;
- documents or emergency information you choose to add;
- technical and security information needed to protect your data.

Genetic diagnosis information

If you consent, the Duchenne UK Connect team may obtain, record, check and update information about your genetic diagnosis, including a copy or confirmation of a genetic test result where needed. This helps confirm your diagnosis and maintain an accurate record. You will be able to view this information in your account or ask for a copy.

Keeping information accurate

You can log in at any time to review, update or correct your answers. You may be invited to update information sooner than six months if there is an important change in your health, care or treatment.

YOUR CONTROL You choose what optional information to provide. Skipping an optional question will not remove you from the Registry.

5. How may Registry information be used?

Registry information may be used to support approved research, understand and improve care and services, raise awareness of Duchenne, and help plan future healthcare and support services for people living with Duchenne. Examples include:

- understanding how Duchenne changes over time;
- studying symptoms, treatments, outcomes and quality of life;
- understanding the effect of Duchenne on patients, families and services;
- developing or checking questionnaires about health, daily life and care;
- identifying gaps or inequalities in care and support;
- supporting the development and evaluation of treatments; and
- producing evidence to support healthcare decision-making and service planning.

Who may carry out approved work?

Approved work may involve universities, NHS organisations, charities, public bodies or commercial organisations such as pharmaceutical or technology companies. Every request must follow the Registry application and governance process. Funding or commercial status does not guarantee access.

What information will researchers receive?

Only information needed for the approved purpose will be provided. External organisations will normally receive coded information or combined results, rather than names.

Will I be paid?

No. You will not be paid for joining the Registry and will not normally receive a share of any financial benefit arising from research that uses Registry information.

NO AUTOMATIC RESEARCH CONTACT Joining the Registry does not guarantee that you will be invited to a study or clinical trial. The separate Research module is used for research opportunity identification and contact.

6. Benefits, burdens and possible risks

Possible benefits

- Helping build knowledge and understanding of DMD that may improve future research, care and services.
- Keeping important health and care information organised in one place.
- Creating an emergency profile that can be quickly viewed or shared with medical teams and others when needed.
- Helping the Duchenne community be better represented in research.

Possible burdens and risks

- Time and effort: The first surveys may take up to an hour, and you will be invited to provide updates.
- Sensitive questions: Questions about health, independence, personal care or quality of life may feel private or upsetting.
- Privacy and security: No digital system can remove the risk of unauthorised access completely, although strong safeguards are used.
- No guaranteed opportunity: Joining does not guarantee better care, a research invitation, a clinical trial place or access to a treatment.
- Future risks: New research or technology may create risks that are not currently known. Important changes will be reviewed and communicated.

IF A QUESTION IS UPSETTING You can skip an optional question, pause the survey or stop. For health or emotional support, speak to your healthcare team or an appropriate support service.

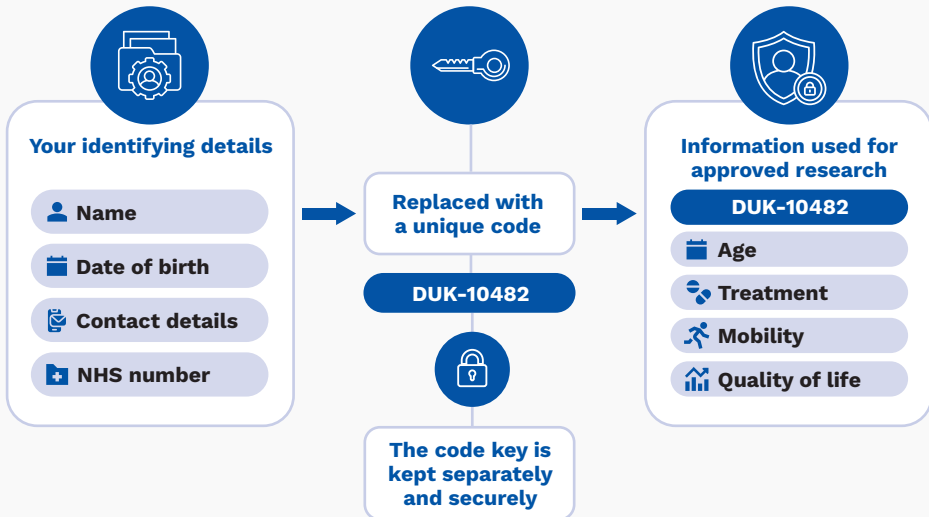
7. How we protect your information

Registry information is encrypted and stored on secure UK-hosted servers. Access is password-protected and limited to authorised people according to their role. Changes to records may be logged for security, data quality and audit purposes.

What is pseudonymisation?

Your information will be pseudonymised before sharing. Pseudonymisation means replacing direct identifiers, such as your name and contact details, with a unique code. The information that connects the code to you is kept separately and securely. Only authorised people can use that information to reconnect the code to you.

How pseudonymisation helps protect your information



 Researchers usually see coded information, not your name or contact details

 **Important:** Pseudonymised information can still be linked back to you by authorised staff. It is not anonymous and remains protected as personal data.

8. Who may access, receive or link information?

Authorised access

A limited number of authorised Duchenne UK staff may access information that identifies you when needed to run the Registry, support participants, manage joining and withdrawal choices, check information, maintain security or oversee approved uses.

Authorised service providers may process information to host, maintain or secure the platform. Auditors, regulators, ethics bodies or other oversight bodies may access relevant information where required for monitoring, compliance or governance.

External use

A group called the Data Access Committee reviews every request to use Registry information. Approved universities, charities, NHS organisations, public bodies or companies receive only the information needed for the agreed work and must follow strict rules.

Registry information will not be provided to employers, insurers or educational institutions for decisions about you. Requests for advertising, marketing or promotional use are not supported.

Data linkage

If you separately agree and the right approvals are in place, Registry information may be matched with trusted national records, such as NHS records, or relevant international registries such as TREAT-NMD. Secure methods will be used to protect your privacy.

International access or transfer

The live Registry is hosted in the UK. If an approved activity requires personal information to be accessed or transferred outside the UK, this will only happen where permitted by data protection law, with appropriate safeguards and in line with the information and consent provided to you.

9. Your participation on the platform & how you can withdraw

What choices do I have?

- Whether to join the Registry.
- Whether to answer optional questions.
- Whether to update your information.
- Whether information may be reused from another part you have joined.
- Whether genetic diagnosis information may be obtained and added to your account.

- Whether Registry information may be linked to external datasets where separate consent is requested.

Can I withdraw?

Yes. You can withdraw from the Registry at any time without giving a reason. Withdrawing will not affect your healthcare, legal rights, access to services or participation in another Duchenne UK Connect module.

You can manage participation in the module through your account, you can withdraw consent and delete your information from the registry in the account settings, or contact the Duchenne UK Connect team for help. You may be able to download a copy of your information before deletion.

What happens to information already used?

Deleting your account removes information from the live system unless some information must be kept for legal, regulatory, audit or research integrity reasons. Information already included in completed analyses, reports or datasets provided for approved research may not always be removable. Removing it could make the research unreliable.

Your data protection rights

Depending on the circumstances, you may have rights to request access, correction, deletion, restriction or portability, or to object to certain uses. Some rights may be limited for research where appropriate safeguards are in place. The privacy notice explains these rights in more detail.

HOW TO WITHDRAW You can manage participation in the module through your account, you can withdraw consent and delete your information from the registry in the account settings, or contact the Duchenne UK Connect team for help.

10. Governance, funding and research findings

Who is responsible?

Duchenne UK is responsible for the Registry and for deciding how personal information is used. In data protection law, this is called being the 'sponsor' and 'data controller'. Duchenne UK must protect your information under the UK GDPR and Data Protection Act 2018.

How are decisions made?

The Duchenne UK Connect Steering Committee oversees the programme. The Data Access Committee reviews requests to use Registry information. Both groups include people with lived experience of Duchenne and people with suitable healthcare, research, data and charity knowledge.

Funding

Duchenne UK Connect is funded and operated by Duchenne UK, with additional support through the PaLaDIn project. PaLaDIn is supported by the Innovative Health Initiative Joint Undertaking under grant agreement No. 101132943, with support from the European Union's Horizon Europe programme and participating partners. It also receives UK support through the government's Horizon Europe funding guarantee.



Additional academic, charitable, public or appropriate industry funding may support Duchenne UK Connect. Funding does not give an organisation automatic access to Duchenne UK Connect information or change participant rights.

Independent review and reporting

The project and important changes are reviewed by a UK Research Ethics Committee where required. Annual progress reports and a register of approved research projects may be published on the Duchenne UK website.

What happens to findings?

Findings may be published in reports, presentations, academic journals or accessible public summaries. Publications will not include your name or direct identifying details unless you have separately and expressly agreed. Details of completed data access requests and outputs may be published on the Duchenne UK Connect website.

11. Questions, concerns and complaints

What if I have a question or problem?

Contact the Duchenne UK Connect team using the details in section 12. The team will try to answer your question or resolve the issue as soon as reasonably possible.

What if I want to complain?

You may raise a complaint through Duchenne UK's complaints process. You may also contact the Research Ethics Committee that reviewed the study. The Duchenne UK Connect team can provide the Committee's contact details on request.

What if my concern is about personal information?

Contact Duchenne UK's Data Protection Officer at dataprotection@duchenneuk.org.

You also have the right to complain to the Information Commissioner's Office, the UK regulator for data protection.

Website: ico.org.uk/make-a-complaint

Telephone: 0303 123 1113

You do not have to contact Duchenne UK before contacting the Information Commissioner's Office, although giving Duchenne UK an opportunity to address the issue may resolve it more quickly.

12. Help and contact details

Medical help

Duchenne UK Connect does not provide emergency medical care or replace advice from your healthcare team.

For urgent medical advice, contact NHS 111 or your usual clinical team.
In an emergency, call 999.

For questions about your treatment or care, contact your neuromuscular team, GP or another healthcare professional.

Duchenne UK Connect team

Study email: duchenneukconnect@duchenneuk.org, 07467 856878

Website: www.duchenneukconnect.org

Post:

Duchenne UK, Unit G24 Shepherd's Building,
Charecroft Way, Hammersmith,
London W14 0EE

Data protection

Duchenne UK Data Protection Officer: dataprotection@duchenneuk.org

Privacy notice: www.duchenneukconnect.org/privacy-policy/

General information about patient data in research:

www.hra.nhs.uk/information-about-patients/

Principal Investigator

Professor Michela Guglieri, John Walton Muscular Dystrophy Research Centre, Translational and Clinical Research Institute, Newcastle University, International Centre for Life, Central Parkway, Newcastle upon Tyne NE1 3BZ

BEFORE YOU DECIDE Take as much time as you need to read this leaflet. Please ask any questions that are important to you before agreeing to join online.

Notes



Duchenne **UK** Connect



Find out more and download at
duchenneuk.org/duchenne-uk-connect

duchenneukconnect@duchenneuk.org



Duchenne UK Connect is developed and funded by Duchenne UK and run in collaboration with our partners at the John Walton Muscular Dystrophy Research Centre at Newcastle University.



**Duchenne
UK**



Duchenne UK is a registered charity no. 1147094. A non profit company limited by guarantee.
Registered in England no. 8030768.