



Duchenne **UK**
Connect

Duchenne
Hub UK

FOR CLINICAL RESEARCH



Duchenne
UK



Duchenne UK Connect

Research Module

**Find clinical trial research opportunities
that may be suitable for you.**



Helping Connect People with
Duchenne Muscular Dystrophy
to Research Opportunities

In collaboration with



Duchenne
UK



duchenneukconnect.org

Contents

1. What is the Research module 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 does research matching work?
6. What happens if a study may be suitable?
7. Benefits, burdens and possible risks
8. How we protect and share your information
9. Your choices, updates and withdrawing
10. Governance, funding and research findings
11. Questions, concerns and complaints
12. Help and contact details

RESEARCH MODULE This leaflet is about the Research module. Joining it does not enrol you in the Registry, Care or In Case of Emergency modules. Those modules 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 decisions.



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



- We will use a clear and fair process when identifying people for research opportunities.



- We will only share information with approved research sites and organisations for agreed purposes.



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



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



1. What is the Research module and why is it important?

The Research module is part of Duchenne UK Connect, a health platform and app to empower people with Duchenne muscular dystrophy and accelerate research and future treatments. Duchenne UK Connect has several parts (modules), and this booklet is only about the research module.

The Research module has the central recruitment database (CRD) embedded within it. It is a UK-wide resource for children and adults with Duchenne muscular dystrophy who are interested in taking part in clinical research (study).

This module is part of Duchenne Hub UK, a programme run jointly by Duchenne UK and the John Walton Muscular Dystrophy Research Centre at Newcastle University. It helps approved UK research sites identify people who may be suitable for a particular Duchenne study.

Duchenne studies may only be available at a small number of specialist centres. This can make it harder for people to hear about opportunities, especially if they do not receive their usual care at a study site. The Research module aims to make access clearer and fairer, wherever people live in the UK.

What is it trying to achieve?

- Help people affected by Duchenne hear about relevant research opportunities.
- Support fairer access to research across the UK.
- Help research sites identify people who may meet a study's main requirements.
- Reduce the need for families to contact many research sites themselves.
- Help researchers understand whether enough potentially eligible people are available in the UK.
- Support the planning and delivery of more Duchenne research in the UK.

IMPORTANT Joining the Research module may increase your chance of hearing about research, but it does not guarantee that you will be contacted, found eligible or offered a place in a study.

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 Research 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. Joining is entirely your choice. You may take time to decide and discuss it with people you trust. Choosing not to join will not affect your healthcare, legal rights, access to services or support from Duchenne UK.

You can join the Research module without joining other Duchenne UK Connect modules. You can also leave this module later without leaving any other module you use.

What if I need help deciding?

The project team can answer questions about the module or help you use the platform. They cannot provide personal medical advice. For questions about 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 an account on the Duchenne UK Connect website or app.
2. Read this leaflet.
3. Confirm online that you agree to join the Research module.
4. Complete questions about your health and your preferences for taking part in research.
5. Review and update your information approximately every six months.
6. Tell us if important information or your research preferences change.

How long will it take?

Creating an account should take a maximum of ten minutes. The time needed for the research questions depends on your answers. You can pause and return later. Updates every six months are usually shorter.

Do I have to answer every question?

Some basic information is required to create and safely manage your account. Other questions may be optional. Required questions will be clearly marked with a red asterisk.

How will you contact me?

We will normally use the contact details you provide. You may receive reminders to update your information and messages about research opportunities that may be relevant to you.

A SEPARATE DECISION FOR EVERY STUDY Joining this module does not automatically enrol you in research studies. Instead, research trial centres can use information from this module to help identify people who could be eligible for their trial. You may be contacted about the trial if you are, and can then decide if you would like to be assessed to take part in the trial.

4. What information will be collected?

The information will help the CRD team identify patients that may be potentially eligible for studies running at approved research sites. Depending on your circumstances, this may include:

- your name, age, contact details and where you live;
- the details of your parent, guardian or authorised representative, where relevant;
- the clinic and healthcare professionals involved in your Duchenne care;
- your diagnosis and genetic diagnosis;
- your health and medical history;
- mobility, motor function and wheelchair use;
- medicines and treatments;
- your preferences about different types of research;
- how far you may be willing or able to travel; and
- information about referrals and their outcomes.

Information from your healthcare team

Where you have agreed, the project team or an approved research site may contact the healthcare professionals responsible for your care to check or update information about your diagnosis and condition. Relevant information may then be added to your record.

New questions

If a new questionnaire is added you will receive information explaining why the questions are being asked and how the answers may be used.

KEEPING INFORMATION ACCURATE You will be contacted every six months to update your information but can also log in to view and amend your details at any time. Accurate and up-to-date information helps us identify suitable opportunities and reduces unnecessary contact.

5. How does the research study referral process work?

- An approved UK research site asks the project team for help finding potentially eligible people for a particular study.
- The project team checks the study's main requirements against the information held in the CRD on the Research module.
- If more people match than the site can enrol, a computer will select people from the matching group at random. This supports a fair and equitable process.
- The project team securely shares the necessary details of selected people with the approved research site.
- The research site may contact the person's neuromuscular specialist and the person or their representative to discuss the study and check eligibility in more detail.

Who makes the final decision?

The research site's Principal Investigator, who is the doctor responsible for that study at the site, decides who is eligible and can be offered a place. The Duchenne UK Connect project team does not make or influence recruitment decisions.

Planning future studies

Researchers, clinicians or companies may ask how many people in the database appear to meet broad study requirements. They will receive

numbers or summaries, not names or contact details. This may help them decide whether a study could be set up in the UK.

FAIR SELECTION Matching the main requirements is only a first check. Random selection may be used when places are limited, and the research site must carry out a full assessment before anyone can join.

6. What happens if a study may be suitable?

You may be contacted

An approved research site may contact you if the information held suggests that a study could be suitable and there is a space available. The site may also contact your neuromuscular specialist, where you have agreed, to check relevant medical information related to inclusion criteria.

Every study has detailed rules about who can and cannot take part. These are called eligibility criteria. The research site will check these criteria with you.

You decide whether to take part

Being contacted about a study does not mean you have to take part. The team running the study must explain it to you, including what you would need to do and the possible benefits and risks. You can ask questions and decide freely whether to proceed.

Other research opportunities

The project team may also contact you about other Duchenne research opportunities approved through the Duchenne UK Connect governance process, including opportunities that fall outside the usual trial matching process (e.g. non interventional studies).

Will I be paid for joining the part?

No. You will not be paid for joining the Research module. If you take part in a research study, they may offer to cover your expenses, but that will be explained separately by the recruiting study team before you agree to participate.

NO GUARANTEE Registration does not guarantee contact, an assessment, eligibility, recruitment, access to a treatment or any direct health benefit.

7. Benefits, burdens and possible risks

Possible benefits

- Keeping research preferences and relevant information together in one place.
- Hearing about research opportunities that may be suitable.
- Having a fairer chance to be considered, wherever you live in the UK.
- Helping research sites find people more efficiently.
- Supporting the planning and delivery of Duchenne research in the UK.

These benefits are not guaranteed. Joining may not benefit you personally and will not directly change your medical care.

Possible burdens and risks

- Time and effort: You will need to complete questions and keep your information updated.
- Sensitive information: Questions about health, genetics, mobility or treatment may feel private or upsetting.
- Disappointment: You may not be contacted, may not meet all study requirements or may not receive a place.
- Privacy and security: No digital system can remove the risk of unauthorised access completely, although strong safeguards are used.

IF YOU NEED SUPPORT You can pause, skip an optional question or contact the project team. For health or emotional support, speak to your healthcare team or an appropriate support service.

8. How we protect and share your information

Keeping information secure

Information is encrypted and stored on secure servers in the UK. Access is limited to authorised members of the project team and other authorised people who need it for an approved purpose.

Sharing with approved research sites

A key purpose of the module is to share necessary personal and health information with approved UK research sites so they can check possible eligibility and contact you about a study. Sites and their staff are checked before they can use this module, and information is shared securely.

Sharing coded or combined information

Approved organisations, such as universities, charities, patient organisations or companies, may receive coded information or combined results for approved research or planning. They will not normally receive names or contact details.

Who will not receive your information?

Information will not be provided to employers, insurers or educational institutions for decisions about you. It will not be shared with other family members unless this is appropriate, authorised or required by law.

How long is information kept?

Information will be kept only as long as needed for the project and may be retained for up to six years after the project ends, in line with the retention rules of Duchenne UK and Newcastle University.

RESEARCH MODULE CONTROLLERS Duchenne UK and Newcastle University are jointly responsible for deciding how personal information in the Research module is used and protected.

9. Your choices, updates and withdrawing

What choices do I have?

- Whether to join the Research module.
- Whether to answer optional questions.
- Which types of research you are interested in.
- Your travel, type of trial and contact preferences.
- Whether information may be reused from another module you have joined.

Keeping your details updated

You can amend your information at any time. We will normally contact you every six months to ask you to check that your details and research preferences are still accurate.

Can I withdraw?

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

You can manage module participation through your account, delete your account through profile settings, or contact the project team for help. You can download a copy of your information before deletion.

What happens to information already used?

Information already shared with a research site or included in completed work may not always be removable. The site or organisation may need to keep some information for legal, safety, regulatory or research integrity reasons. Sites are asked not to store information sent for recruitment purposes past the screening phase.

HOW TO WITHDRAW Use the Research module or account options in Duchenne UK Connect, or contact the project team. We may ask you to confirm your identity before making changes.

10. Governance, funding and research findings

Who is responsible?

Duchenne UK sponsors the overall Duchenne UK Connect platform. For the Research module, Duchenne UK and Newcastle University are joint data controllers. This means they share responsibility for deciding how personal information is used and protected.

How are decisions made?

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

Independent review

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.

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.



Other academic, charitable, public or appropriate industry funding may support the programme. Funding does not give an organisation automatic access to information or change participant rights.

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.

11. Questions, concerns and complaints

What if I have a question or problem?

Contact the project 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 project. The project team can provide the Committee's contact details on request.

What if my concern is about personal information?

You can contact the Data Protection Officer at Duchenne UK or Newcastle University using the details in section 12. 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 the project team before contacting the Information Commissioner's Office, although giving the team an opportunity to address the issue may resolve it more quickly.

12. Help and contact details

Medical help

The Research module 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 treatment or care, contact your neuromuscular team, GP or another healthcare professional.

Project team

Duchenne Hub UK email: dmdhub@ncl.ac.uk

Telephone: 0191 241 8621

Website: www.dmdhub.org

Duchenne UK Connect email: duchenneukconnect@duchenneuk.org

Telephone: 07467 856878

Website: www.duchenneukconnect.org

Data protection

Duchenne UK Data Protection Officer: dataprotection@duchenneuk.org

Newcastle University Data Protection Officer: rec-man@ncl.ac.uk,
www.ncl.ac.uk/data.protection/

Duchenne UK privacy information: www.duchenneuk.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.

Thank you for considering the Duchenne UK Connect Research module.

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.