

**UK Duchenne Muscular
Dystrophy Registry
Governance Policy**

ACTION DUCHENNE LTD

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1. Introduction

The UK Duchenne Muscular Dystrophy Registry (The Registry) is a project that has been developed by Action Duchenne Ltd to create a database to collect certain clinical treatment and research information on all those diagnosed with Duchenne or Becker Muscular Dystrophy in the UK.

Action Duchenne is committed to high standards of information governance. Action Duchenne has compiled this governance document to describe the governance of the Registry.

2. Purpose and Mission

The Registry has a number of purposes:

- Develop and encourage more research into Muscular Dystrophy
- Facilitate research by collecting relevant data and making it available for specified research purposes
- Use the information provided to understand the disease better
- Establish contact between clinicians, other health professionals, researchers and Registry participants
- Enhance clinician's and other health professionals' ability to deliver treatments for this disease

Important Facts about the Registry:

- The Registry is subject to the provisions of the Data Protection Act (1998) and the General Data Protection Regulation (GDPR) 2018
- Participation is totally voluntary and subject to individual informed consent
- No one can find out the identity of any participant in the Registry, except for the purposes specified
- No information will be given to insurance or related companies
- Joining the Registry will not affect participants medical care or legal rights
- Authorised research projects and authorised health professionals will look at participants' data in prescribed circumstances
- Information which is processed will be anonymised in all circumstances where it is practical
- The creation of the Registry has been approved by the UK Multi Centre Medical Ethical Committee
- Individuals may withdraw their participation at any time, and may request that their data will be deleted
- Withdrawal of participation will not change the participants medical care or legal rights
- The web address for the Registry is <https://www.dmdregistry.org>

3. Committees

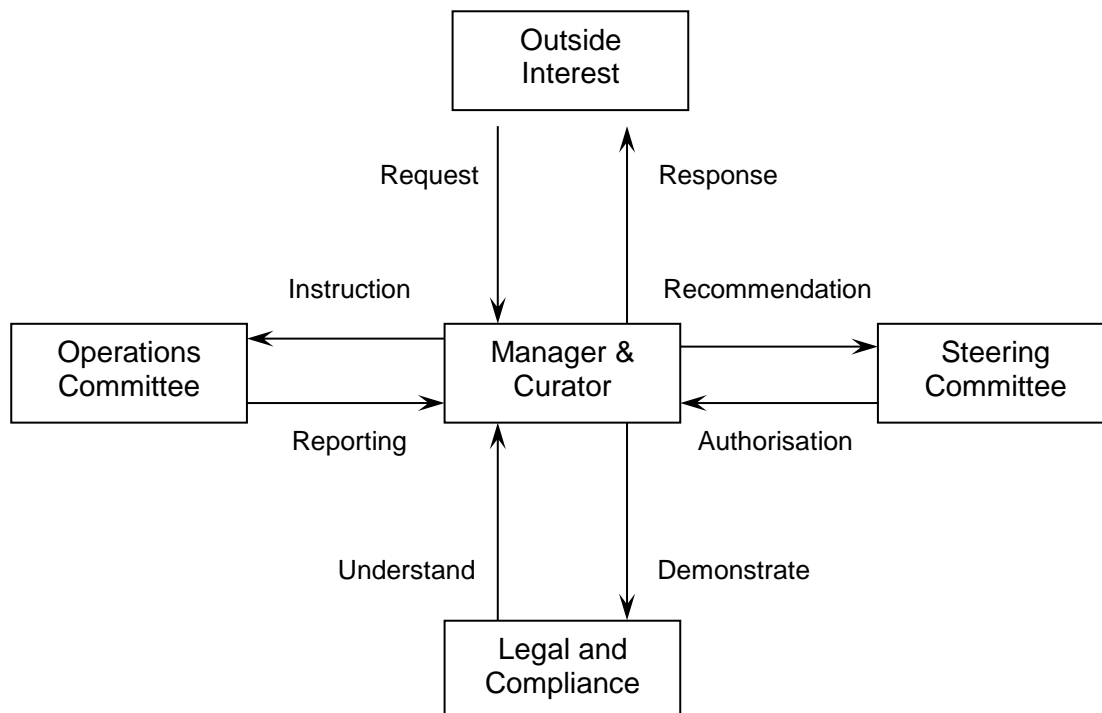
3.1 General

Action Duchenne has resolved to establish a number of committees consisting of directors and senior appointees to manage the governance of the Registry.

The Board of Action Duchenne has approved the following Committees and Managers: -

- The Registry Manager and Registry Curator
- The Action Duchenne Management Team
- The Steering Committee

The diagram below illustrates the Registry Governance structure, the Committees and their key relationships.



3.2 The Registry Manager and Registry Curator

The Registry Manager will be responsible for developments, which may affect the overall operation of the Registry and the compliance responsibilities of Action Duchenne (such as new legislation).

The key operational responsibilities of the Registry Manager and DMD Registry Curator are:

- To receive and review requests to use the Registry from Outside Interests
- To recommend requests use of the Registry to the Steering Committee
- To receive Authorisation to use the Registry from the Steering Committee
- To understand the Legal and Compliance Issues related to the Registry
- To demonstrate that Legal and Compliance Obligations have been exercised

Specific Legal and Compliance responsibilities of the Registry Manager and DMD Registry Curator are:

- To monitor and scrutinise the operation of the Registry in terms of corporate compliance
- Monitor compliance with and maintenance of an up to date Data Protection Policy and GDPR 2018
- Monitor the notification to the Data Protection Registry and GDPR Registry and to determine whether there has been any change of purpose which requires notification
- Monitor Compliance with the Security Policy
- Monitor relationship between Action Duchenne Ltd and Nvisage Ltd
- Compliance with Legal and Regulatory requirements
- Review Policy, Documents, web site other materials

The Registry Manager is required to attend each all Board meetings of Action Duchenne and is available to answer any questions referred to him/her by the Chairman.

The current Registry Manager is:

- Action Duchenne Director of Research (to be confirmed)

The current Registry Curator is:

- Angela Stringer

3.3 The Action Duchenne Management Team

The general function of the Management Team will be to manage and operate the Registry on day to day basis.

The responsibilities of the Management Team are:

- To ensure that the Registry is operational
- To decide on design and implementation issues
- To review the registration of the Registry with the Information Commissioner and to maintain the notification in the Data Protection Register/GDPR
- To advise the Registry Manager of any changes in processing activity which may require a change in notification to the Data Protection Committee
- Monitor Compliance with the Security Policy

The corporate member of the Management Team is:

- Action Duchenne Ltd (<https://www.actionduchenne.org>)

The corporate member will appoint a designated officer(s) to carry out the role. The Management Team will report quarterly in writing to the Board of Action Duchenne on any significant updates to the Registry and any significant developments which may occur, which may affect the overall operation of the Registry and the compliance responsibilities of Action Duchenne.

3.4 The Steering Committee

The Steering Committee will meet at regular intervals and to include an annual meeting to consider:

- Any proposed changes to the purpose of the Registry
- Any applications for a Research project to be added to the Registry
- Any requests for access to sensitive personal data by any Clinician or other Health Professional

The responsibilities of the Steering committee are:

- Monitor compliance of the Registry with the Data Protection Policy in terms of third party access issues
- Authorise changes to the Purpose of the Registry
- Authorise new access to the Registry
- Appointment of new Steering Committee members
- Report to the Board of Action Duchenne (DMD Registry Curator quarterly reports)

The members of the Steering Committee are:

Professor Kate Bushby
Dr Joanne McCauley
Dr Ros Quinlivan
Dr Stephen Abbs
Professor Hanns Lochmuller
Dr Michela Guglieri
Dr Anne-Marie Childs
Dr Emma Ashton
Mr Nick Catlin
Mr Jack Bosanquet
DMD Registry Manager
Mrs Angela Stringer (Secretariat)

4. Internal Control

The Board of Action Duchenne is responsible for managing the internal control of the Registry and for reviewing its effectiveness and will receive quarterly reports from the Registry Manager (Registry Curator quarterly reports) and Committees referred to above.

Procedures have been designed and will be maintained, revised and updated for safeguarding the Registry against unauthorised use; for the reliability of information used within the Registry or for publication, for compliance with the Data Protection Act 1998,

GDPR 2018 and Action Duchenne`s Data Protection policy. The procedures are also enable Action Duchenne Ltd to discharge their obligations under the Computer Misuse Act (1990).

5. Operational and Reputational Risks

Action Duchenne Ltd regularly update their policies and procedures for safeguarding against operational and reputational risks. This is an evolutionary process, which involves developing best practice when responding to social, ethical and medical risks. The safeguarding of the reputation of the Registry is of paramount importance to Action Duchenne Ltd. It's continued use and is the responsibility of every member of staff of Action Duchenne Ltd. Action Duchenne Ltd has always aspired to the highest standards of conduct and, as a matter of routine, takes account of reputational risks to the Registry.

6. Communication with Stakeholders

Communication with stakeholders is given high priority. Extensive information about the Registry's activities is provided on the web site and in regular newsletters. There is regular dialogue with the Steering Committee and enquiries from individuals on matters relating to their information. All stakeholders are encouraged to attend the Annual General Meeting of Action Duchenne Ltd to discuss the Registry.

7. Complaints

Should you wish to make a complaint regarding the Registry please contact Action Duchenne at info@actionduchenne.org or write to the address below:-

Action Duchenne CEO
Epicentre
41 West Street
Leytonstone
London E11 4LJ