« Study ethics approval was obtained on 2012/19/06 for this document (CECIC Rhône Alpes Auvergne, Grenoble, IRB 5921) »

AFM
Association Française contre les Myopathies

Hôpitaux de Lyon

How are the data protected?

The database is hosted by a server at the Laboratory for Molecular Genetics at Montpelier (France).
Access to the database is via a secure website with the following address:
https://www.mfm-database.fr
The database has been registered with the CNIL (National Commission on Informatics and Liberty), registration number 1255105.
The Pilot Committee of the MFM acts as the guarantor for the good usage and good functioning of the database. The charter for the MFM database is signed by a referral physician for each center.

Documents available from

www.mfm-nmd.org

If you are a patient, clinician or scientist, you will find lots of information on the website in several languages: the Charter for the Database, the information notice and the consent form for the patient, the notebook for data collection and the list of members of the Pilot Committee. You will also find publications on the MFM, user manuals in several languages, dates for training sessions, a quiz for updating your training, etc.

If you need help

Database Curator : Dr Christine Payan
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Database creator : Dr Dalil Hamroun
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Chairwoman MFM Pilot Comittee: Dr Carole Bérard
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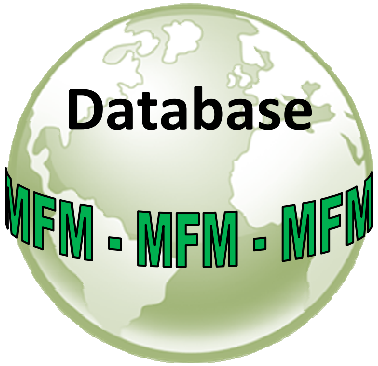
PARTICIPATION in DATABASE

MFM
Mesure de la Fonction Motrice
pour les maladies neuromusculaires

This document is intended for professionals
(physicians, physical therapists, occupational therapists…) **and for persons affected by a neuromuscular disease**



The MFM database has been available since 2007. Accessible via Internet, it makes it possible to store all the MFM results of persons with a neuromuscular disease which affects the anterior horn, the peripheral nerve or the muscle. MFMs for persons with other diseases characterized by a muscular weakness may also be stored in the database.

This database will be of interest to patients, clinicians and scientists.

More than 50 foreign and French centers contribute to the database.

Value to the patient

All patient MFM data are saved, protected and accessible to the various groups which are involved in the patient's treatment over time. Should those in charge of the treatment change or the patient moves to another town, comparison of his/her MFM scores makes it possible to evaluate the evolution of the disease objectively. If a clinical trial is being planned, the patient's physician can verify if the patient could potentially be included. If an informed consent document has been signed by the patient, his/her data may be used for research. In conformity with the dispositions of the law on databases and liberty, the patient has the right of access and rectification, and he/she (or the parent) also has the right to oppose transmission of data with no penalty that would affect the treatment followed by the patient.

The patient may access all the data which concerns him/her through his/her physician or any physician of his/her choice in application of the provisions of article L-111-7 of the Public Health Code.

Value to the clinician

Data from patients who are undergoing treatment by a physician may be accessed by her/him at any time. This data is stored securely in a single location. Calculation of the scores and follow-up curves for his/her patients is done automatically. He/she may exploit his own data. Access to data from other centers within the framework of a clinical research project is possible after permission from the curator of the database, the pilot committee and the group of physicians involved has been obtained.

Value to scientists

A large amount of data makes it possible to describe the natural history of diseases, to calculate slopes of the evolution of each diagnostic group, and to continue the metrological analysis of the MFM. In the framework of a therapeutic trial, depending on the expected effect and statistical power required, it is possible to estimate the number of patients which need to be included and the necessary duration of the trial.

How can a medical team participate?

A referral physician for the group contacts the curator and signs the charter for the database. He obtains an identifier and password (the identifier and password are common to all the persons in the group). Clinical data and MFM data are either entered directly into the database by the group after each test or is recorded in a notebook which is transmitted to a third party.

Which data is recorded?

The therapist who administers the MFM-32 or the MFM-20 logs in and records the score obtained by the patient for each item, accompanied by any commentaries. He also records information concerning motor function and cooperation of the patient on the day the MFM is administered. Medical, surgical and patient identification data must be verified and updated each time the test is administered. Any participation in a clinical study is recorded, as well as medical treatments.

The time to enter the data in the database for the first MFM is about 5 minutes, and less for recording subsequent MFMs.

Quality of the data?

For optimal exploitation of the data, the data furnished must be of high quality. The training of the therapist in the utilization of the MFM is important, and guarantees the reliability of the conditions under which the test is administered and the scoring of the items. The quality of the data furnished is checked by the center which records it and by the curator, aided by clinical research assistants who can request complementary information from the referral physician.

CONSENTEMENT for PARTICIPATION in DATABASE

MFM
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I agree that medical data concerning me (or my child), collected during the administration of the MFM, may be used for computerized treatment in the framework of the **MFM Database**. I have been informed that the data collected will remain strictly confidential and that they can only be consulted by scientists and clinicians duly appointed by the MFM Pilot Committee.

Family name and first name of the person (adult or child) taking the MFM: ……………………………………………………

Signature:

For children, family name and first name of the legal representative (mother, father, guardian): ……………………… ……………………………………………………………………………………

Signature:

Family name and first name of a third person if the legal representative is not present: ……………………………………… ……………………………………………………………………………………

Position: ………………………………………………………………………

Signature:

Last name and first name of the physician prescribing the MFM: ………………………………………………………………………

Signature:

Date : …. /…. /……

Document to be completed in two copies, one given to the patient