



Mesure de la Fonction Motrice
pour les maladies neuromusculaires

Charter and agreement to the database

This charter is signed between the MFEM steering committee and

Doctor.....

working at..... (name and address of the hospital/center).

The steering committee is composed of elected members and delegate members.
(www.motor-function-measure.org/steering-committee)

The MFEM steering committee defines the conditions of submission of the data in the MFEM database.

The steering committee guarantees the database use for scientific publications. Any use of partial or complete data of the database is subjected to the approval of the steering committee. The scientific exploitation of the database will be possible after submission of draft to the steering committee and their agreement is required before the beginning of a project.

The steering committee meets at least once a trimester.

The steering committee reserves the right not to attend any more a person or a center that neglects the database charter.

The decisions of the steering committee are unanimously taken.

The curator guarantees the integrity of the data and the good functioning of the database. He (she) is the privileged interlocutor of the users.

He (she) is a member of the steering committee. The steering committee has to choose the curator for a minimal duration of 2 years. He (she) can be relieved of his (her) functions by the committee if he (she) does not perform his (her) responsibility.

MFEM database objectives

To refine descriptive and evolving results in different neuromuscular diseases with more important patient groups. To study the MFEM in unexplored diagnostic groups during the validation study and to appreciate the value of the scale depending on pathologies.

The objectives of the MFEM database are to:

- ✓ Evaluate the motor function and its evolution in patients with neuromuscular disorders (NMD)
- ✓ Collect exhaustive data in the purpose to describe the natural history of the motor function and the effects of therapeutics on this motor function in the various NMD
- ✓ Participate to the study of the genotype-phenotype correlations performed by the locus specific databases using the UMD system, via data link with all these locus specific databases.

- ✓ Validate the MFM scale in NMD not evaluated during the validation study and in patients with age range different from the 6-60 years old range used in the validation study
- ✓ Increase the number of data from patients with NMD included in the validation study

The steering committee has sent a declaration to the “Commission Nationale de l’Informatique et des Libertés” (CNIL). Data processing will be made respecting the declaration of accordance of the Association Institut de Myologie to the reference methodology established by the CNIL for database management and processing.

Database access

The database access is limited to the persons authorized by the steering committee.

The access is given by the opening of an account to the physiotherapists and the physicians (or other person authorized by the curator) of the approved hospital or center realizing MFM. Charter must be signed by the physician in charge of the activity before the opening of this account.

Each center obtains an identifier and a password. The curator must be informed of the identity of all the persons using identifier and password of each center.

Data collection and management

Before collecting the MFM data, the referent physician in every center has to give the patient or his/her legal representative an information form on the MFM database and obtain if possible his written consent for data entry.

The referent physician makes sure the patient is informed of:

- ✓ The purposes of the processing for which the data are collected
- ✓ The categories of data concerned and the anonymisation of the data before processing
- ✓ The existence of the right of access to and the right to rectify the data concerning him (her). This is a legal obligation according to the French laws (N° 2004-801, N°78-17) and to the European directive (95-46-EC).

The curator of the MFM database and the clinical research assistant can have access, after informing the referent physician and in respect of confidentiality, to source documents and electronic files to check quality of data collected.

Each center has access to its own data. The referent physician is free to publish his (her) own data in a scientific purpose. If he (she) wants to use data from other centers, he (she) must submit a request to the steering committee, who transmits this request to the other referent physicians involved in the data to be analysed, in order to obtain their approval. The MFM database must then be identified as the source of the data, and other physicians who contributed to the work must be mentioned in the publication. The steering committee will decide and give approval of oral communication and scientific publications using the MFM database.

Participation in the MFM study group

Physicians who have signed the charter and their physiotherapist colleagues, who have entered data in the MFM databank, are part of the MFM study group. The members of this Group are listed on the website: www.mfm-nmd.org.

The name "MFM study Group" is given in the authors of publications and the names of the members of the Group are listed in the publication.

SIGNATURES

Referent physician: Dr: _____

Date ___/___/___

Signature

Names of the associated physiotherapists:

Steering committee representative: Name _____ First name _____

Date ___/___/___

Signature

Send this signed document to Dr Christine PAYAN, curator of the MFM database:

✓ by e-mail to: « christine.payan@psl.aphp.fr »

✓ by post to: Dr Christine PAYAN
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You will receive the instructions, identifier and password allowing the connection to the MFM database.