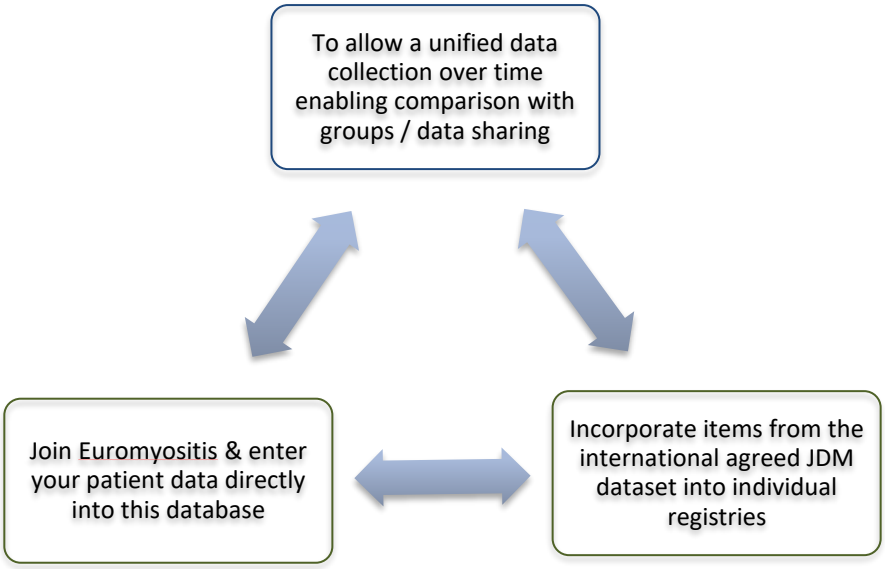
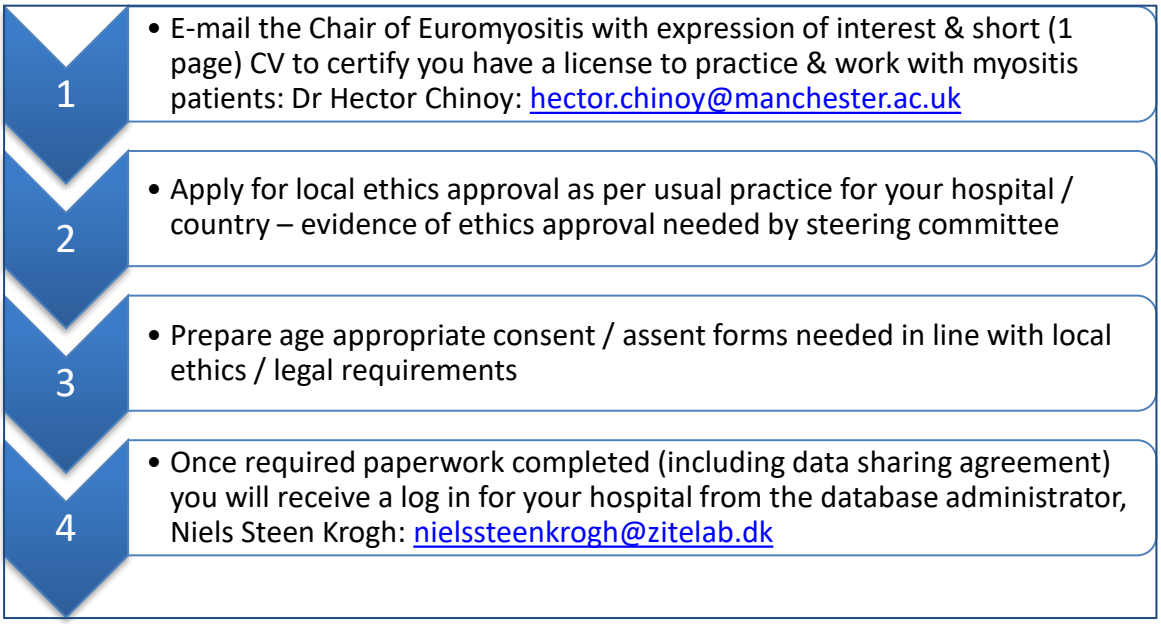
JDM PReS Working Party and Euromyositis position statement.

- The following document sets out options to aid data sharing in the future, allowing us to capture information from the largest possible number of patients with JDM from research registries.
- The PReS JDM working party aims to bring together clinicians and JDM researchers to increase knowledge and facilitate research in JDM, working collaboratively on an international platform. To this end, we encourage collaborative data collection within registries where possible but we acknowledge that every contributing centre / country has legal and ethical considerations regarding data sharing.
- If individual centres / countries are revising / updating their current data collection or starting a new dataset / registry, we kindly ask them to consider the following options:



Option A: Joining Euromyositis:

- Clinicians / researchers can choose to enter data into the Euromyositis Registry. This database has been created in order to obtain uniform, longitudinal data over adult and juvenile myositis cases in order to achieve increased knowledge on disease course and prognosis of myositis. This registry can be used as a tool in the clinic to assess your patients. Within the normal (adult) euromyositis 'hospital' there is a link to the 'JDM sub-module' where juvenile onset cases can be entered.
- How to join Euromyositis:



- For more information about Euromyositis, refer to appendix 1: Frequently Asked Questions.

Option B: Incorporating items from the internationally agreed consensus dataset

- For countries / centres that have their own local database / registry, in order to allow collaboration / data sharing in the future, we would encourage them to incorporate items from the internationally agreed JDM consensus dataset: https://ard.bmj.com/content/77/2/241 **[McCann LJ**, Pilkington CA, Huber AM et al. Ann Rheum Dis. 2018 Feb;77(2):241-250. doi: 10.1136/annrheumdis-2017-212141. Epub 2017 Oct 30. https://www.ncbi.nlm.nih.gov/pubmed/29084729].
- This dataset was agreed through an international Delphi process involving 181 clinicians and 301 patients / parents, with the final dataset defined by experts in

myositis representing all major international paediatric rheumatology and Myositis groups.

- ❖ Items within the consensus core dataset have been incorporated into the Euromyositis JDM Registry and also into the new CARRA JDM registry https://carragroup.org/research-registry/registry-faq in North America. The items will also be incorporated into the UK Juvenile Dermatomyositis Cohort Biomarker Study and Repository (JDCBS), https://www.juveniledermatomyositis.org.uk/.
- ❖ The complete dataset with glossary of definitions and muscle strength-testing sheets can be found in the website of University of Liverpool http://ctrc.liv.ac.uk/JDM/ and/or within the online supplementary Table S5, McCann et al, Ann Rheum Dis 2018; 77:241-250. https://ard.bmj.com/content/77/2/241

Further information / references:

- **Euromyositis** website: https://euromyositis.eu/
- **Lilleker JB** et al, **The Euromyositis registry**: an international collaborative tool to facilitate research. Ann Rheum Dis 2017; doi:10.1136/annrheumdis-2017-211868
- Lundberg IE, Svensson J. Registries in inflammatory myopathies. Current Opin Rheumatol 2013;25:729-34
- Rider LG, Danko K, Miller FW. Myositis registries and biorepositories: powerful tools to advance clinical, epidemiological and pathogenic research. Curr Opin Rheumatol 2014;26:724-41
- **McCann LJ**, Pilkington CA, Huber AM Ravelli A, Appelbe D, Kirkham JJ, Williamson PR, Aggarwal A, Christopher-Stine L, Constantin T, Feldman BM, Lundberg I, Maillard S, Mathiesen P, Murphy R, Pachman LM, Reed AM, Rider LG, van Royen-Kerkof A, Russo R, Spinty S, Wedderburn LR, Beresford MW. **Development of a consensus core dataset in juvenile dermatomyositis for clinical use to inform research**. Ann Rheum Dis. 2018 Feb;77(2):241-250. doi: 10.1136/annrheumdis-2017-212141. Epub 2017 Oct 30.

Appendix 1: Frequently Asked Questions about Euromyositis

The following questions and answers have been written on behalf of the Euromyositis Steering Committee in collaboration with the UK Juvenile Dermatomyositis Research Group. If you have any further questions, not addressed by this information, please contact a member of the Euromyositis Steering Committee (e-mails below).

What is Euromyositis?

- The Euromyositis database was created with the aim of obtaining uniform, longitudinal data on adult and juvenile myositis cases in order to achieve increased knowledge on disease course and prognosis of myositis. It can also be used as a useful tool in the clinic area to assess patients. The registry includes longitudinal collection of clinical data (internet forms) as well as a Bio-bank for blood (sera / DNA) / muscle biopsy specimens. The registry currently holds data on > 4800 patients with myositis.
- The database is organised into two major areas: (1) Patient data containing basic information on features relevant to myositis, ever been present during the duration of the disease. This part is obligatory to fill in and all known information should be provided in every patient entered into the database. (2) Individual visits may be described in more detail and are meant to follow the longitudinal disease course in each patient. These visits contain details on the disease activity, including extramuscular symptoms, laboratory parameters, muscle weakness, physical abilities, treatment, autoantibodies, biopsy results and damage caused by the disease.
- The Euromyositis Registry was developed within the integrated European FP6 Autocure project, which led to a creation of the basic database. From 2010, further development and support was provided for 5 years through the European Science Foundation Research Networking Programme EuMyoNet (European Myositis Network).
- The database is administered by company ZiteLab Aps, represented by Niels Steen Krogh.

What are the advantages to joining Euromyositis?

- Each centre (hospital) only has access to their own data and each centre is responsible for maintenance of its database content.
- The data entry forms provide an aid-memoir for symptoms and signs that are important to consider when looking after a patient with myositis. When used in clinic, this can be a useful tool, particularly beneficial for trainees with less experience of the condition.
- By entering data into Euromyositis, you will be helping to enable a large number of patients with juvenile onset and adult onset myositis to be analysed over time. This will lead to a greater understanding of disease processes and help to improve outcome for patients in the future.
- Applications can be made to access coded data from the entire database for specific research projects after approval of the Steering committee.
- Contributors to Euromyositis will be listed in the acknowledgment of publications on common data. Contributors may also be listed as authors when they have had specific input into planning, analysing or carrying out a specific study.
- Euromyositis provides a unique opportunity to provide longitudinal follow-up of patients with juvenile onset disease into adult life – allowing research opportunities to determine long-term prognosis and outcome.

Would you like to test the system before deciding if you want to apply?

You can apply to test the system on a test page.

If you would like to do this, you can use the following username on the Euromyositis.eu website (https://euromyositis.eu)

Use user id: jdmtest2014

For a Password – contact the database administrator, Niels Steen Krogh by text (sms) to +45 22673738 (password euromyositis), and he will give you the password to use.

Will patient data be secure?

- Yes. All data presented in Euromyositis is confidential and completely secure.
- Euromyositis provides access to enter myositis data through web forms or through direct transfers. All data are protected by login and password. The transfer of data is encrypted.
- The database is hosted on servers in the EU controlled under instruction by the hospitals represented in the steering committee of Euromyositis.
- A copy of the data processor agreement between the project and external providers can be provided upon request.

How do I obtain ethical approval to enter patient data into Euromyositis?

- You will need to apply for local ethics approval as per usual practice for your hospital / centre for research studies involving patient data.
- The Euromyositis steering committee will need to see evidence of ethical approval before you receive log in details for the registry.

Can Euromyositis help with my local ethics applications?

- Euromyositis are unable to directly help with local ethics applications since each application will have its own country-specific legal and language requirements. However, members of the steering committee will be able to help answer any questions that arise from ethics applications. In addition, they are happy to provide examples copies of consent / assent forms used by members.

Can Euromyositis provide consent or assent forms for patient?

- Age-appropriate consent and assent forms need to be prepared for each hospital / centre, in line with local ethics and legal requirements, in the appropriate language for that country.
- Euromyositis are happy to provide examples of consent / assent forms used in other countries for the applicant to use, but are unable to provide generic consent / assent forms due to country specific requirements.

If I already have a database of patients, can I include them in Euromyositis?

- Yes. There is a process that allows large collections of patient data to be uploaded directly into the Euromyositis database. Niels Steen Krogh does this. Before this can be done, you will need to proceed through the usual application process in the first instance by contacting the Chairperson – currently Dr Hector Chinoy.

How do I join Euromyositis?

- Please e-mail a member of the Euromyositis Steering Committee, preferably the acting Chairperson, with an expression of interest to join, along with a short CV (maximum 1 page) to certify that you have a medical license and work with myositis patients.
- Provided that the first stage of your application is approved, the steering committee will need to see evidence of local ethics approval to enter data into the electronic register, a data sharing agreement and, if applicable, a local material transfer agreement to share sera, DNA or muscle biopsies.
- Templates are available for ethics application and data sharing agreement but these will need to be modified by the applicant in line with local requirements.
- One these forms have been received, the Chair of the steering committee will countersign the data sharing agreement and you will receive a log in for your hospital.

When entering patient data, do I use the juvenile-onset or adult-onset pages?

- For patients with juvenile onset disease that are under paediatric care (ie. patients < 16 years of age), please use the juvenile-onset pages.
- If you are entering data on an adult patient (> 16-18 years of age) that had juvenile-onset disease, please enter data directly into the adult-onset myositis forms.
- If a patient is registered under the juvenile-onset pages and subsequently transfers to adult care, thus entered within the adult-onset page, Niels Steen Krogh can link the entries, or flag that they have already been entered in the juvenile-onset pages, to provide duplication of data-entry.

How can I obtain further information?

- More information can be found on the Euromyositis webpage: https://euromyositis.eu/
- For answers to specific questions, please contact a member of the Euromyositis Steering Committee.

Steering Committee membership:

- Chairperson:
  - Dr. Hector Chinoy, M.D., Ph.D., The University of Manchester, 2nd floor, Stopford Building, Oxford Road, Manchester, M13 9PT, UK. Email: hector.chinoy@manchester.ac.uk
- Administrator:
- Paul New: Paul.New@liverpool.ac.uk
- ZiteLab administrators:
- Niels Steen Krogh, ZiteLab ApS: nielssteenkrogh@zitelab.dk.
- Mohammad Tareq Alam: tareq@zitelab.dk
- Members:
  - Ingrid Lundberg: Ingrid.Lundberg@ki.se.
  - Jiri Vencovsky: venc@revma.cz.
  - Louise Diederichsen: louise.diederichsen@regionh.dk
  - Liza McCann: liza.mccann@alderhey.nhs.uk
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  - Jens Schmidt: j.schmidt@med.uni-goettingen.de
  - Mikkel Abildtoft: mikkel@zitelab.dk
  - Gouchun Wang: Guochunwang@hotmail.com
  - Olivier Benveniste: Olivier.benveniste@psl.aphp.fr
  - Patient representative: Paula Oakley. E-mail: msg.paulaoakley@gmail.com