IMACS Outcomes Repository

International Myositis Assessment & Clinical Studies Group

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Outcomes Repository

- Collection of prospective clinical trials and natural history studies that are utilizing common core set measures, demographic/clinical features and outcomes
- Purpose: To prospectively validate and improve definitions of improvement and clinical trial design consensus proposals, especially for therapeutic trials, develop predictors of treatment responses
  - Allows for pooled analyses with sufficient power
  - Contributing investigators qualified for manuscripts using their data

- Restricted access to an Oracle internet database to enter core set measures, demographic, clinical features, and outcomes
  - Password protection for data entry after study approval, AND/OR
  - Submit study's database once completed with a codebook
- Data is one-way de-identified. Investigator maintains code, but does not share with IMACS

Outcomes Repository– Steps for Data Submission

- IRB approval or ethics exemption for contribution to registry
  - All sites must have U.S. DHHS OHSPR Federal Wide Assurance Agreement and IRBs must have DHHS approval: http://ohrp.cit.nih.gov/search/asearch.asp#ASUR
  - Submit copy of IRB approval to IMACS/NIH
- Data Transfer Agreement with NIEHS confirming data to be submitted and use of that data
- Format of data submission
  - Submit existing database + variable list, OR
  - Use IMACS Oracle database as your study's primary database – extract data for your study analysis, OR
  - Combination of these

Outcomes Repository – Composition

- Required data (minimum 2 time points):
  - Core demographic, clinical features and response to therapy data
  - IMACS Core Set Activity Measures
  - Assessment of Study Outcome
  - Medication receiving in trial
  - Clinical Trial Design Elements (1 for each study)
- Optional data:
  - PRINTO/PRCSG Activity Measures: CMAS, DAS (encouraged!)
  - MD and Patient/Parent Global Damage, Myositis Damage Index
  - Patient-Reported Outcomes: SF-36, CHQ-PF50
  - Ancillary data specific to your study: Submit as a data file to be archived in the registry

Outcomes Repository– Plans for Coming Year(s)

- Data being submitted now and over the coming months to the repository from clinical trials and therapeutic studies
  - 15 trials/clinical studies with ~375 patients
- Adult and Pediatric Working Groups to be formed
  - Rate cases as improved/not improved/worse
  - Participate in internet-based consensus conferences
  - Participate in Delphi survey(s)
- Consensus Conference to develop new outcome measures for therapeutic trials and clinical trial design consensus

- Those interested in participating in data submission or Working Groups, contact IMACS Coordinators

Research Study Proposals for Use of IMACS Repository

- IMACS Outcomes Repository will be open to IMACS investigators for use
- IMACS members submit research proposal to IMACS Outcomes Research Advisory Committee
  - Composed of contributors to IMACS Outcomes Repository
- Proposal approved by local IRB (copy to NIH), Data Use Agreement completed
- Investigator receives portion of IMACS database for their study: deidentified
- Investigator includes IMACS repository contributors as co-authors on publications

Enter Basic Study Information to Register Your Study and Investigators

https://dir-apps.niehs.nih.gov/imacs/index.cfm?action=study.edit&studyid=1   Go

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Study Information

Study Number	001
Name of Trial	IMACS NIH Natural History Study
Type of Trial	○ Clinical Trial ⦿ Natural History Study
Principal Investigator	Rider, Lisa
Assessor Number The PI will automacially be added to the Assessor List below. You may assign a differnet Assessor Number if you wish.	001

Centers
001 -- Environmental Autoimmunity Group (NIH)

Add New Center	Choose a Center if you wish to Add one
Center Number It is recommended that you use the defualt value. If you have used different values in your study, please enter your values here.	

Update And Return To This Form

Assessors
001 -- Lisa Rider
003 -- Frederick Miller
093 -- Michael Harris-Love
182 -- Minal Jain
603 -- Michelle Smith

Add New Assessor	Choose an Assessor if you wish to add one to this study
Assessor Number It is recommended that you use the defualt value. If you have used different values in your study,	

Add Patients to Register Your Study's Patients and Assign ID Numbers

Links to Add or Edit Specific Core Set Data

IMACS International Myositis Assessment & Clinical Studies Group

IMACS >> My Studies >> Study Details

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Study Details

You may perform the following action(s)

Edit Basic Study Information -- If you need to make changes to the study information, add centers, or assessors

Add Patients -- If you need to add a new patient

Add/Edit Core Patient data for this Study -- Enter Update and Certify Data for Core Patient (Form 1)

Add/Edit MD Global Acitivity data for this Study -- Enter Update and Certify Data for MD Global Acitivity (Form 2)

Add/Edit Patient Global Activity data for this Study -- Enter Update and Certify Data for Patient Global Activity (Form 3a)

Add/Edit Parent Global Activity data for this Study -- Enter Update and Certify Data for Parent Global Activity (Form 3b)

Add/Edit MMT data for this Study -- Enter Update and Certify Data for MMT (Form 4)

Add/Edit HAQ data for this Study -- Enter Update and Certify Data for HAQ (Form 5a)

Add/Edit CHAQ data for this Study -- Enter Update and Certify Data for CHAQ (Form 5b)

Add/Edit CMAS data for this Study -- Enter Update and Certify Data for CMAS (Form 05c)

Add/Edit Laboratory Measures (Enzymes) data for this Study -- Enter Update and Certify Data for Laboratory Measures (Enzymes) (Form 6)

Add/Edit Myositis Disease Activity Assessment Tool data for this Study -- Enter Update and Certify Data for Myositis Disease Activity Assessment Tool (Form 7)

Add/Edit Myositis Damage Index data for this Study -- Enter Update and Certify Data for Myositis Damage Index (Form 8)

https://dir-apps.niehs.nih.gov/imacs/index.cfm?action=study.details&studyid=1 ▾ → Go

Patients/Assessments
Completed Forms with an asterisk (*) **have not been certified** by a study assessor.

001-002
Assessment 1: 06/05/2002 (First Trial Assessment)

Completed Forms	Incomplete Forms
2 - MD Global Acitivity*	1 - Core Patient
4 - MMT	3a - Patient Global Activity
	3b - Parent Global Activity
	5a - HAQ
	5b - CHAQ
	05c - CMAS
	6 - Laboratory Measures (Enzymes)
	7 - Myositis Disease Activity Assessment Tool
	8 - Myositis Damage Index
	9 - MD Global Damage
	10 - Patient Global Damage
	11 - Assessment of Study Outcome
	12 - Disease Activity Score

Add Assessment for 001-002

001-003
Assessment 1: 01/29/2003 (First Trial Assessment)

Completed Forms	Incomplete Forms
4 - MMT	1 - Core Patient
	2 - MD Global Acitivity
	3a - Patient Global Activity
	3b - Parent Global Activity
	5a - HAQ
	5b - CHAQ
	05c - CMAS
	6 - Laboratory Measures (Enzymes)
	7 - Myositis Disease Activity Assessment Tool
	8 - Myositis Damage Index
	9 - MD Global Damage
	10 - Patient Global Damage
	11 - Assessment of Study Outcome

Physician Global Activity

Manual Muscle Testing MMT 0 – 10

Laboratory – Enzymes, Cr

Serum Levels Data

Study Number - Patient Number	001-002
Assessment Number	001 (On or near: 06/05/2002)
Assessor	Please Select an Assessor ▼
Assessment Date (month/date/year)	
Creatine Kinase (CK) (IU/L)	Result
	Upper Limit of Normal
Adolase (IU/L) Enter 1 digit after the decimal (i.e. 7.6)	Result
	Upper Limit of Normal
Aspartate amino Transferase (AST) or Serum Glutamic Oxalacetic Transaminase (SGOT) (IU/L)	Result
	Upper Limit of Normal
Alanine Amino Transferase (ALT) or Serum Glutamic Pyruvic Transaminase (SGPT) (IU/L)	Result
	Upper Limit of Normal
Lactate dehydrogenase (LDH) (IU/L)	

Options to Edit or Certify Data Once Entered

https://dir-apps.niehs.nih.gov/imacs/index.cfm?action=mdactivityassessment.details&mdactivityassessmentid=2

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Data Entry

You may perform the following action(s)

Edit This Score -- Edit the data in a Physician Global Activity Assessment record

Certify This Score -- Certify the data is complete and should not be further edited.

Add/Edit/Certify/View Other Physician Global Activity Assessment Scores -- View (and possibly edit) data for other subjects in this study.

Go to Study 001 -- Edit/View summary data of study. Enter data for study.

Notes
Disease Activity is defined as potentially reversible pathology or physiology resulting from the myositis. Clinical findings known or suspected to be due to another disease process should not be considered in this evaluation. The global assessment of disease activity is to be judged from all the information available to you today including the subject's appearance, history, physical examination, diagnostic laboratory testing and your resultant medical therapy.

Physician Global Activity Assessment Data

Study Number - Patient Number	001-002
Assessment Number	001 (On or near: 06/05/2002)
IMACS Assessor	001 -- Lisa Rider
Assessment Date (month/date/year)	10/24/2005
Physician Global Activity Assessment, Visual Analog Scale (0 - 10 cm)	9.1
Also rate global disease activity on a 5-point Likert scale	3 = severe activity
Data Entry	Lisa Rider 10/31/2005

Certifying Data Locks and Finalizes It

Summary

- IMACS Outcomes Repository is being developed with support of the ACR to validate definitions of improvement, clinical trial design issues and develop predictors of treatment responses
  - All IMACS members are encouraged to submit data from their own trials and studies to the repository
  - Regulatory requirements- local IRB approval or exemption (retrospective), register with DHHS, Data Transfer Agreement
- Repository and IMACS Group open for research proposals, following review by the research committee
  - Data use will also require local IRB approval and a Data Use Agreement

Acknowledgements – Sponsors

National Institute of Environmental Health Sciences

American College of Rheumatology