



**IMACS**

International Myositis Assessment & Clinical Studies Group

# IMACS Outcomes Repository

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Lisa Rider, MD and Frederick Miller, MD, PhD

Environmental Autoimmunity Group,

National Institute of Environmental Health Sciences,

National Institutes of Health, DHHS

Bethesda, MD

[riderl@mail.nih.gov](mailto:riderl@mail.nih.gov)

[millerf@mail.nih.gov](mailto:millerf@mail.nih.gov)



# Outcomes Repository

- Purposes:
  - To prospectively validate and improve outcome measures for adult and juvenile myositis trials (including definitions of improvement)
  - Further develop clinical trial design consensus
  - Develop predictors of treatment responses
  - Serve as repository of data for other studies
- Collection of prospective clinical trials and natural history studies that are utilizing common core set measures, demographic/clinical features and outcomes



# Outcomes Repository – Composition

- Required data (minimum 2 time points):
  - Core demographic, clinical features and response to therapy
  - IMACS Core Set Activity Measures
  - Assessment of Study Outcome
  - Medication received in study
- Optional data:
  - PRINTO Activity Measures: CMAS, DAS, CHQ
  - MD and Patient/Parent Global Damage, Myositis Damage Index
  - Patient-Reported Outcomes: SF-36
  - Ancillary data specific to a study



# Outcomes Repository – Studies Deposited

- 2 randomized controlled trials
  - Gourley: Infliximab in PM/DM (12 patients)
  - Amato/Muscle Study Group: Enbrel in DM (16 patients)
- 7 open label trials
  - Fiorentino: Rituximab in DM (8 patients)
  - Lundberg: Infliximab, Anakinra, Exercise (13,10, 8 patients)
  - Isenberg/Sultan: Rituximab (5 patients)
  - Pilkington: Infliximab, Cyclophosphamide (12 patients)
- 3 natural history studies
  - Garcia de la Torre: adult DM/PM (21 patients)
  - Song: DM/PM/IBM (7 patients)
  - Rider/Miller: Adult and Juvenile DM/PM (80 patients)



# Outcomes Repository – Data Deposited

- What is deposited:
  - IMACS Core Set Measures, Clinical trial design form (all)
  - Demographic data, background therapy (most)
  - Assessment of outcomes (most)
  - Clinical data, Myositis Damage Index (few)
  - Ancillary data: 2 studies
  - PRINTO core set – 1 study
- All study visits: 6 trials; Key visits: 3 trials;  
Natural history studies: 2 - 4 visits
- Detailed data: 6 studies; Summary data: 6 studies  
(most committed to providing detailed data if needed)

# Clinical Trials in IMACS Outcomes Repository

<i>Principal Investigator</i>	<i>Trial/Population</i>	<i>Detailed vs. Summary Data</i>	<i>Comments</i>
Gourley, Plotz	Infliximab (RCT); 12 PM, DM	Detailed data, All study visits	Core set activity measures, Myositis Damage Index, clinical and demographic data, therapy, ancillary data
Amato (Muscle Study Group)	Etanercept (RCT); 16 DM	Detailed data, All study visits	Core set activity measures, SF-36, background therapy
Fiorentino, Chung	Rituximab; 8 DM	Detailed data, Key visits	Core set activity measures, MD assessment outcome; clinical and demographic data, therapy
Lundberg	Infliximab; 13 DM, PM, IBM	Summary data, All study visits	Core set activity measures; MD assessment outcome; therapy and autoabs
Lundberg	Anakinra; 10 DM, PM	Summary data, All study visits	Core set activity measures; MD assessment outcome; demographics, therapy, autoabs
Lundberg	Exercise training; 8 DM, PM	Summary data, All study visits	Core set activity measures, MD assessment outcome; demographic & autoabs

# Clinical Trials in IMACS Outcomes Repository

<i>Principal Investigator</i>	<i>Trial/Population</i>	<i>Detailed vs. Summary Data</i>	<i>Comments</i>
Isenberg, Sultan	Rituximab; 5 DM, PM	Summary data, All study visits	Core set activity measures; myometry
Pilkington	Cyclophosphamide 8 JDM	Summary data, Key visits	Core set activity measures, CMAS, CHQ; MD assessment outcome
Pilkington	Infliximab; 5 JDM	Summary data, Key visits	Core set activity measures, CMAS, CHQ; MD assessment outcome
Garcia de la Torre	Natural History; 21 DM/PM	Detailed data, 2 visits	Core set activity measures, Myositis Damage Index, Global Damage, MD Assessment Outcomes, Demographic and clinical data, therapy
Song	Natural History; 7 PM/DM/IBM	Detailed data; 2 visits	Core Set Activity Measures, MD Assessment Outcomes, Demographic and clinical data, therapy
Rider, Miller	Natural History; 53 JDM, 27 DM/PM	Detailed data; 2-4 visits	Core Set Activity Measures, CMAS, DAS, CHQ-PF50, Myositis Damage Index, Global Damage, MD Assessment Outcomes, Demographic and clinical data, therapy



# Research Study Proposals for Use of IMACS Repository

- Open to IMACS members for use
- Submit research proposal to IMACS Repository Research Review Committee
  - Composed of contributors to Repository
- Proposal approved by local IRB (copy to NIH), Data use agreement completed
- Investigator receives de-identified data for their study
- Include IMACS repository contributors as co-authors
- Procedures on IMACS website

<http://www.niehs.nih.gov/research/resources/collab/imacs/researchguidelines/index.cfm>



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