# International Workshops on Myositis Outcome Measures and Clinical Trial Design Issues

**Second Workshop - Developing Consensus on Outcomes and Clinical Trial Design Issues in Adult and Juvenile Myositis**

**The International Myositis Assessment and Clinical Studies Group (IMACS)**

The Pan American Life Conference Center, New Orleans, Louisiana, USA  
October 22-23, 2002

## AGENDA

**WORKSHOP DAY 1 - Tuesday, October 22nd**

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
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<tbody>
<tr>
<td>08:00 AM</td>
<td>Bus leaves the W Hotel for trip to the Pan American Life Conference Center</td>
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<tr>
<td>08:15 – 8:30 AM</td>
<td>Registration – Hallway outside Bayou Rooms 1 and 2</td>
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------------- **Introduction, Background and Goals of the Workshop**  -------------

**Joint Meeting of the Adult and Juvenile Myositis Working Groups – Bayou Rooms 1 and 2**

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
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<tr>
<td>08:30 - 08:40 AM</td>
<td>Welcome and Introduction – Ann Reed</td>
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<tr>
<td>08:40 – 09:00 AM</td>
<td>Background and Goals of the Workshop - Fred Miller</td>
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----- **Development of Preliminary Definitions of Improvement for Myositis**  -----

<table>
<thead>
<tr>
<th>Time</th>
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<tr>
<td>09:00 - 09:10 AM</td>
<td>Review of What was Learned at the Previous Workshop - Lisa Rider</td>
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<tr>
<td>09:10 – 10:10 AM</td>
<td>Developing a Preliminary Definition of Improvement: General Concepts and Prior and New Approaches - Edward Giannini and Peter Lachenbruch</td>
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<tr>
<td>10:10 – 10:25 AM</td>
<td>Break</td>
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10:25 – 10:45 AM  Development of a Common Definition of Improvement for both Adult and Juvenile Myositis: Advantages and Disadvantages - Fred Miller and Lisa Rider

10:45 – 11:00 AM  Presentation of Top Candidate Definitions of Improvement for Adult and Juvenile Myositis – Lisa Rider and Edward Giannini

11:00 – 11:15 AM  Summary and Review of Nominal Group Technique Methodologies - Edward Giannini

**Separate Meetings of the Adult (Bayou 3 Room) and Juvenile (Bayou 4 Room) Myositis Working Groups**

11:15 – 12:15 PM  Development of Consensus on the Preliminary Definitions of Improvement by Ranking top Definitions using Nominal Group Technique within each Working Group – Edward Giannini, Nicola Ruperto and Participants

12:15 – 1:00 PM  Lunch – pre-ordered in the Pontchartrain Room

**Joint Meeting of the Adult and Juvenile Myositis Working Groups – Bayou Rooms 1 and 2**

1:00 – 1:30 PM  Presentation of the Results of both Working Groups, Joint Discussion of the Preliminary Definitions of Improvement – Hermine Brunner, Edward Giannini, Nicola Ruperto and Participants

1:30 – 2:30 PM  Development of Consensus on the Preliminary Definitions of Improvement by Ranking top Definitions using Nominal Group Technique – Edward Giannini, Nicola Ruperto and Participants

2:30 – 2:45 PM:  Final discussion of the Preliminary Definitions of Improvement for Adult and Juvenile Myositis. Hermine Brunner, Edward Giannini, Nicola Ruperto, Fred Miller, Lisa Rider and Participants

2:45 – 3:00 PM:  Logistic Regression Approaches for Preliminary Definitions of Improvement to be Explored in Clinical Trials – Peter Lachenbruch, Lisa Rider

3:00 – 3:30 PM  Break
Joint Meeting of the Adult and Juvenile Myositis Working Groups – Bayou Rooms 1 and 2

3:30 – 4:00 PM  Background and Review of Delphi Consensus Achieved in the Myositis Clinical Trial Design Surveys for Adult and Juvenile Myositis - Chet Oddis and Lisa Rider

4:00 - 4:15 PM  Overview of the Initial Clinical Trial Design Issues to Be Discussed - Chet Oddis and Lisa Rider

Separate Meetings of the Adult (Bayou 3 Room) and Juvenile (Bayou 4 Room) Myositis Working Groups

4:15 – 6:15 PM  Development of Consensus on the Initial Clinical Trial Design Issues by Nominal Group Technique within each Working Group – Edward Giannini, Nicola Ruperto and Participants
  a. Adult Group: Classification Criteria for PM and DM, Concomitant therapy
  b. Pediatric Group: Classification Criteria for JPM, Concomitant therapy and Concomitant Illnesses

END OF WORKSHOP DAY 1 - Tuesday, October 22\textsuperscript{nd}

6:30 PM  Bus departs from the Pan American Life Conference Center to return participants for the prearranged dinner at the W Hotel Restaurant

7:30 PM  Dinner at the BACCO Restaurant at the W Hotel

END OF DAY 1 - Tuesday, October 22\textsuperscript{nd}
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AGENDA

WORKSHOP DAY 2 - Wednesday, October 23rd

08:00 AM  Bus leaves the W Hotel for trip to the Pan American Life Conference Center

--------------- Developing Consensus on Clinical Trial Design Issues - Part 2  --------------

Joint Meeting of the Adult and Juvenile Myositis Working Groups – Bayou Room 1 and 2

08:30 - 09:00 AM  Presentation of the Results of both Working Groups, Joint Discussion of the Consensus on the Initial Clinical Trial Design Issues – Edward Giannini, Nicola Ruperto, Hermine Brunner and Participants

09:00 – 09:30 AM  Overview of the Final Clinical Trial Design Issues to Be Discussed – Chet Oddis and Lisa Rider
   a. Criteria for Worsening/Flare Requiring Alteration of Therapy or Withdrawal from a Trial
   b. Preliminary Definition of Complete Clinical Response/Remission
Separate Meetings of the Adult (Bayou 3 Room) and Juvenile (Bayou 4 Room)

Myositis Working Groups

09:30 – 11:00 AM  Development of Consensus on Final Clinical Trial Design Issues by Nominal Group Technique within each Working Group – Edward Giannini, Nicola Ruperto and Participants

11:00 – 11:30 AM  Break

Joint Meeting of the Adult and Juvenile Myositis Working Groups – Bayou Room 1 and 2

11:30 – 12:30 PM  Presentation of the Results of both Working Groups, Joint Discussion and Final Resolution of the Clinical Trial Design Issues – Edward Giannini, Nicola Ruperto, Hermine Brunner, Chet Oddis, Lisa Rider and Participants

12:30 – 1:15 PM  Lunch – pre-ordered in the Pontchartrain Room

----------------- Developing Consensus on Myositis Damage Issues -----------------

Joint Meeting of the Adult and Juvenile Myositis Working Groups – Bayou Room 1 and 2

1:15 – 1:45 PM  Introduction to Myositis Damage: Definition, Tools for Assessment, and Review of Adult Myositis Data from the London Workshops – David Isenberg

1:45 – 2:00 PM  Review of Juvenile Myositis Damage Data from the London Workshops – Clarissa Pilkington

2:00 - 2:20 PM  Review of Retrospective Adult and Juvenile Myositis Damage Data: Natural History and Damage Accumulation over 6 – 9 months Using the Myositis Damage Index - Lisa Rider

2:20 – 2:45 PM  Overview of the Damage Issues to Be Discussed - Ann Reed and Lisa Rider
   a. Preexisting/Coexisting Conditions as Part of a Definition of Damage
   b. How Much Damage Accumulation to Allow in the course of a 6 – 9 month clinical trial

2:45 - 3:15 PM  Break
Separate Meetings of the Adult (Bayou 3 Room) and Juvenile (Bayou 4 Room) Myositis Working Groups

3:15 – 4:15 AM  Development of Consensus on Damage Issues by Nominal Group Technique within each Working Group – Edward Giannini, Nicola Ruperto and Participants

Joint Meeting of the Adult and Juvenile Myositis Working Groups – Bayou Rooms 1 and 2

4:15 – 4:45 PM  Joint General Discussion of Myositis Damage Issues - Edward Giannini, Nicola Ruperto, Hermine Brunner, Lisa Rider, Ann Reed and Participants

---------- Introduction to a Planned Multicenter Clinical Trial of Rituximab ----------

4:45 - 5:15 PM  Introduction to a Planned Multicenter Clinical Trial of Rituximab in PM-DM – Background on Rituximab - Chet Oddis
   Preliminary Data - Todd Levine
   Trial Design - Brian Feldman
   Future Plans - Chet Oddis and Ann Reed

---------- Summary of Accomplishments, Problem Areas and Future Plans ----------

5:15 – 6:00 PM  Combined Group Discussion of Results/Problem Areas from the Workshop and Future Plans – Ann Reed, Chet Oddis, Fred Miller, Lisa Rider and Participants

6:00 PM  Adjourn – End of Second Workshop

END OF WORKSHOP DAY 2 - Wednesday, October 23rd

6:15 PM  Bus departs from the Pan American Life Conference Center Adjourn to return to the W Hotel

7:00 PM  Bus leaves the W Hotel for Dinner Jazz Cruise

8:00 – 10:00 PM  Dinner Jazz Cruise

END OF WORKSHOP