

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

08:15 – 8:30 AM Registration – Hallway outside Bayou Rooms 1 and 2

----- Introduction, Background and Goals of the Workshop -----

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

08:30 - 08:40 AM Welcome and Introduction – *Ann Reed*

08:40 – 09:00 AM Background and Goals of the Workshop - *Fred Miller*

----- Development of Preliminary Definitions of Improvement for Myositis -----

09:00 - 09:10 AM Review of What was Learned at the Previous Workshop - *Lisa Rider*

09:10 – 10:10 AM Developing a Preliminary Definition of Improvement: General Concepts and Prior and New Approaches - *Edward Giannini and Peter Lachenbruch*

10:10 – 10:25 AM Break

- 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

----- **Developing Consensus on Clinical Trial Design Issues - Part 1** -----

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 22nd

- 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 22nd

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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
