# 2003 Update on Myositis Outcome Measures, Clinical Trial Design Issues and Planned Studies

The International Myositis Assessment and Clinical Studies Group (IMACS)

Sheraton World Resort, 10100 International Drive, Orlando, FL 32821, USA Tampa Bay 1 & 2 Conference Rooms; Phone: 407-352-1100

October 25, 2003, 5:00 - 9:30 P.M.

AGENDA	
5:00 – 5:15 PM	Welcome and Introductions with Buffet Dinner
5:15 – 5:35 PM	Working dinner - Review of MITAX/MyoAct tools and studies  Shabina Sultan and David Isenberg
5:35 – 6:05 PM	Review of the IMACS Core Set Measures and Consensus on Definitions of Improvement  Lisa Rider
6:05 – 6:30 PM	Review of the IMACS Consensus on Clinical Trial Design Issues  Chet Oddis, Ann Reed, Lisa Rider, Fred Miller
6:30 – 7:00 PM	Summary of PRINTO/PRCSG Definitions of Improvement and other PRINTO study activities  Nicola Ruperto
7:00 – 7:25 PM	Summary of ENMC Consensus on Outcome Measures and Clinical Trial Design Issues for Myositis Therapeutic Trials  Anthony Amato, Ingrid Lundberg
7:25 – 8:00 PM	Discussion of Integration of IMACS, PRINTO and ENMC efforts – Fred Miller, Moderator
8:00 – 8:15 PM	Break

#### 8:15 - 9:00 PM

Update of other current and planned clinical studies

## **Therapeutic Trials:**

- Etanercept in US Adult IIM Anthony Amato
- Etanercept in US IBM David Saperstein, Richard Barohn
- Etanercept vs. MTX in US Juvenile DM Daniel Lovell and Edward Giannini
- Infliximab in US Adult DM/PM Mark Gourley and Paul Plotz
- Infliximab in Adult IIM Ingrid Lundberg
- Rituximab in UK IIM Jonathan Edwards, Jo Cambridge, Shabina Sultan
- Rituximab in US PM/DM Chet Oddis and Ann Reed
- UK SELAM trial for Adult PM/DM Ernest Choy
- Methotrexate vs. Glucocorticoids Jiri Vencovsky and Ingrid Lundberg
- Rapamycin in IBM Matthew Meriggioli

### **Natural History Studies:**

- Multicenter Validation of IMACS DOI's in Mexican PM/DM-Ignacio Garcia de la Torre
- Assessment of Disease Activity in Hungarian IIM Katalin Danko
- Validation of IMACS tools in IBM Sabine Krause and Dieter Pongratz
- Assessment of Disease Activity/Damage in Italian and UK Juvenile IIM Angelo Ravelli and Clarissa Pilkington
- Validation of IMACS and PRINTO DOIs and tools in JIIM and IIM Lisa Rider et al.

9:00 - 9:30 PM

Plans for an IMACS website, database repository, and future needs and future plans

Fred Miller, Lisa Rider and David Isenberg

#### **END OF MEETING**