Project title: Points to Consider in the Design of Clinical Trials in Systemic Sclerosis- A Joint Project of EULAR and ACR

Project ID: CLI028

Project leader: Daniel Furst
Executive Committee: Daniel E. Furst, Dinesh Khanna, Marco Matucci-Cerinic
Epidemiologist: Robert Landewe

Objectives
To recommend ACR/EULAR standards when designing randomized clinical trials in SSc — both for limited SSc and diffuse SSc. Our central hypothesis is that the recommendations regarding the design of randomized clinical trials in SSc will facilitate drug development and encourage uniform trial design.

Envisioned benefit/impact: To standardise design and outcome in SSc clinical trials in order to maximise the experience internationally with this rare but potentially fatal disease.

Final outcome of the project by when joint publication in ARD and A&R – projected for late 2009/ early 2010.

Relevance for the field
Speedier and more comprehensive clinical trials in SSc with more investigator driven component.

Project mainly supports which of the 8 EULAR 2012 objectives¹ (please select ONLY one)?
1-8
Project supports Strategic Area goal(s): 1

Project budget (€) and payment schedule

<table>
<thead>
<tr>
<th>Total</th>
<th>€ 42,000</th>
<th>$ 42,000 (ACR)</th>
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<tr>
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<td>2008</td>
<td>2009</td>
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Milestones for release of payments:

- Literature review (requiring significant amount of time from three individuals) 28.2%
- Administrative and Secretarial Staff 18.8%
- Telephone and fax 4.7%
- Consultants-RAND, Facilitator 4.7%
- Travel and Taxis 18.8%
- Meeting (three nights and two days) 18.8%
- Overhead (5%) 4.6%
- Publication Charges 1.4%

Implementation and update
Joint ACR/ EULAR% project. ACR to contribute $ 42,000