

Lupus Nephritis Trials Network

Membership Meeting San Diego, CA, October, 28 2013

Executive Summary

Meeting agenda:

- Welcome (Elena Massoratti)
- Brief update on active projects (David Wofsy)
- Report on Outcomes Measures in Lupus Nephritis Trials project (Maria Dall'Era)
- Brief update on operations (Patti Tosta)
- Discussion of project review procedures (Elena Massoratti)
- LNTN Publication Policy (Elena Massoratti)

Attendees

Approximately 65 LNTN members attended the meeting.

Brief Summary

I. Brief update on 6 active LNTN projects:

a. Practical Considerations

- Projects that can be completed quickly.
- Projects that already have a source of funding.
- Projects that can be done inexpensively.

b. Large-Scale (investigator-initiated) Clinical Trials

1. Rituximab in LN with Remission as a Goal (RING) **Enrollment underway (18 European countries, 4 South American, Japan, Morocco)**
2. Rituximab Plus MMF Without Oral Steroids (RITUXILUP) **Protocol complete; target start is early 2014 (mostly UK sites so far)**
3. Rituximab Followed by Belimumab to Promote Return of a Non-Autoimmune B Cell Repertoire (CALIBRATE) **Collaboration among ITN, Genentech, GSK; protocol complete; target start is early 2014**
4. Analysis of the Utility of Azathioprine Metabolite Levels in Guiding Treatment of Lupus Nephritis (MANAGED). **Project in development.**

c. Other Projects

1. Retrospective Analysis of the Prognostic Significance and Therapeutic Implications of Thrombotic Microangiopathy in Lupus Nephritis. **Site identification underway.**
2. Develop Evidence-Based Recommendations for Outcome Measures in Lupus Nephritis. **Project underway as note below.**

II. Report on Outcomes Measures in Lupus Nephritis Trials project

a. Overarching project goals

- Develop a set of renal response outcome measures for use in lupus nephritis trials that correlate with long-term preservation of renal function and reduction in lupus nephritis flares.
- FDA acceptance of these outcome measures for use in lupus nephritis trials.

b. Project consists of three phases

1. Review of lupus nephritis clinical trial literature (each trial reviewed by two investigators and data entered into Excel spreadsheet). **Status complete. 16 LNTN members participated in this review.**
2. Analyses of primary data from large datasets (randomized clinical trials and longitudinal cohorts). **In process. Commitment to provide longitudinal cohort data from 10+ centers. Commitment to provide data for 3+ clinical trials.**
3. Derivation of consensus recommendations for clinical trial outcome measures and definitions of terms. **To be done.**

c. Next steps

- Create a web-based system to store and manage the large patient data sets.
- Begin analyses on primary data received from trials and longitudinal cohorts.
- Consider setting aside subset of data as validation cohort.
- Continue to enlist participation of trials and cohorts.

III. Brief update on operations

a. Status update was provided on accomplishments during 2013 including:

- LNTN membership review and collaboration on 2012 submitted projects.
- LNTN website launched in June.
- Increased membership:

- 126 members including adult and pediatric rheumatologists, nephrologists, internists and immunopathologists from 27 countries.
- 20 new members, from 14 different countries since website launch.
- Online proposal submission and review capabilities.

b. Future plans

- Website expansion in terms of both content and functionality.
- Members were encouraged to visit the website and provide their feedback.

IV. Discussion of project review procedures

The project review operational processes were outlined and the following specific issues were considered:

- “Rolling” time line for proposals vs. specified deadlines.
- Modifications to feedback process.
- ? Progress reports for the entire LNTN.

Membership input on these topics included: concept proposal submissions should continue according to specific deadlines; online review system needs to be made more user friendly; goal should be to foster membership participation in project review rather than requiring it; and project status updates (e.g., quarterly) should be posted on the LNTN website.

v. LNTN Publication Policy

The LNTN publication policy was discussed during a previous membership meeting and is now posted on the LNTN website.

VI. Other discussion

- Interest expressed in fostering mentorship for junior members.
- Interest expressed in fostering project opportunities that allow greater collaboration across the full network.