February 20, 2012

To: WSAVA Board

From: David Polzin and Larry Cowgill

Co-Chairs, WSAVA Renal Standardization Project
George Lees, Bill Spangler, and Astrid van Dongen
Members, Management Committee, WSAVA Renal Standardization Study
Chuck Mohr and Rachel Cianciolo, Pathology Study Group Representatives

Re: 2012 Project Progress Report - WSAVA Renal Standardization Study

**Summary of Progress of the WSAVA Renal Standardization Project to Date**

As per your request, this report is not an exhaustive review of the committee's activities over the past year but rather a summary, focusing on the key accomplishments and plans for the upcoming year. A thorough review of the activities of the WSAVA RSP activities and accomplishments was submitted to the board on August 8, 2011.

**Key Accomplishments in 2011:**

1. The pathology group met every two weeks to discuss cases that have been previously scored by all of the pathologists and to arrive at a consensus for the scoring of the different lesion parameters. The first 84 cases, which will serve as the basis of the prototype model for the classification scheme, have nearly been completed. This is the cohort of cases that will serve as the basis for publication of the classification system.

2. Preliminary cluster analyses based on lesions observed in the biopsies has been performed on this group of cases with encouraging preliminary results. The latest model has identified 8 distinct lesion groupings of which 2 are renal amyloidosis and normal dogs. There is also some suggestion of sub-grouping within the larger groups. The clinical data has not been merged with the pathologic data yet, so the effect and utility of this combination has yet to be determined.

3. The clinical group met weekly to discuss and score the same set of cases that have been reviewed by the pathology group. Data from these scorings are in the process of being tabulated and distributed among the clinical group for preliminary assessment of the clinical findings. The method for selection of the attributes or descriptors to add to the pathology data is as yet being discussed. The goal is to identify the clinical markers that may be useful to enhance or to predict the pathologic diagnosis.

4. Case accrual into the WSAVA database continues for the purpose of pursuing phase 2 of the study, validation of the classification system and evaluation of the clinical value of the classification system. To date, 741 renal biopsies have been submitted to the Texas A&M Diagnostic Renal Pathology Center (DRPC), of which 681 renal biopsies are from dogs and 60 from cats. During 2011, 150 cases were submitted – the largest volume since this
DRPC was established in 2005. Of these 150 cases, 27 were WSAVA sponsored cases. The Utrecht RDPC processed 37 renal biopsies in 2011, 21 of which were enrolled as WSAVA cases. The net number of WSAVA RSP cases enrolled in 2011 was 48 cases. During January and the initial week of February 2012, a total of 8 new WSAVA RSP cases have been added between the 2 DRPC. Note that not all cases included in the WSAVA RSP are “WSAVA Sponsored” cases; some cases are drawn from the non-sponsored group (the study pays for data collection, entry, and analysis in these cases, but not for the biopsy itself). We anticipate this will also be true for a substantial number in the phase 2 study.

5. We have identified a cohort of 60 cat biopsies which have been collected in the database since project inception. These biopsies provide a substantial insight into the current use and role of renal biopsy in this species. We are currently discussing ways that this data can be presented in manuscript form under the auspices of the WSAVA RSP. It is our belief that none of the considered alternatives for generating substantial renal biopsies for analysis are likely to achieve the targeted 60 cases within a reasonable time line for completion of this project. The only timely way in which this number of renal pathology specimens could be generated within the time-line of this project would be to use post-mortem samples of cats with chronic kidney disease (CKD). However, we have chosen not to pursue this option because we do not believe that it will provide any real new or innovative findings because of the nature of CKD in cats and the limitation of using postmortem samples.

6. The WSAVA Renal Standardization Study was showcased at both the ACVIM Forum in Denver, CO, USA in June 2011 (presented by Drs. Chuck Mohr and Rachel Cianciolo) and ECVIM Meeting in Seville, Spain in September 2011 (presented by Dr. Luca Aresu). These two meetings are the premier scientific meetings of Veterinary Internal Medicine Specialists worldwide. The presentations were enthusiastically received by large audiences of influential ACVIM and ECVIM Board Certified Specialists. This is the group of veterinarians most likely to utilize renal pathology effectively as part of their practice. The support provided by the WSAVA and the sponsors, Hills and Bayer, were prominently displayed as part of these presentations. In addition, multiple members of the WSAVA RSP have also provided numerous continuing education lectures around the world which further informed veterinary audiences about the project and emphasized the sponsors of the project, including presentations by Drs. Aresu, Brovida, Cowgill, Lees, and Polzin at Associazione Italiana Veterinari Piccoli Animali Annual Meeting, 26th and 27th February 2011, Modena, Italy. Dr. Astrid vanDongen will be presenting a report on the study at the BSAVA/WSAVA Meeting in Birmingham, UK in 2012.

Goals/Plans for 2012:

1. Pathology Data:
   a. Complete cluster and statistical analyses.
   b. Development of prototype renal pathology classification system.

2. Clinical Data:
a. Compilation and review of clinical data,
b. Generation of “models” of various clinical presentations for canine proteinuric kidney diseases.

3. Merge clinical and pathology databases to determine whether the combination enhances clinical diagnosis.

4. We are tentatively planning on scheduling a joint meeting of all study members to work on integrating all of the data into a comprehensive overview of canine glomerular disease and a synopsis of how diagnostics contribute to the final diagnosis. This meeting would also be used to further define the validation study (phase 2).

5. Complete and submit a manuscript(s) describing the Prototype Renal Pathology Classification (phase 1 of the WSAVA RSP Study).

6. Continue enrolling study cases (both WSAVA and non-sponsored cases) to generate follow-up data on the cases for the Prototype Renal Pathology Classification validation study (phase 2).

7. Prepare a manuscript describing findings of the 60 cat biopsies.

8. Present a program at the ECVIM meeting in September to continue communicating the importance of the study and role of the sponsors.

**Budget Modifications:**

The only change in the 2012 Budget reflects an additional year of case accrual. Budgetary implications of extending the study through the year 2012 are: 1) 5th year of Aperio service contract ($7,453), 2) additional year of Vision database ($12,300), and 3) additional year of on-line communication subscription ($1500). These changes will amount to an additional $21,253; however, the current on-line communication budget is overbudgeted by about $17,000, thus the total change to the project would be only $4,253. These additional costs would necessarily be charged against the case accrual budget (reduction by 7 cases). The project would request no additional funding to offset these additional costs.

**Other relevant study deadlines remain unchanged:**

Completion of Data review and preliminary preparation of Phase 2 manuscript –2014

Monograph on Pathology of Canine and Feline Proteinuric Kidney Disease –2014

Presentation of Findings – WSAVA meeting (and other meetings) following completion of preliminary manuscript