DACC NEWS

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ANIMAL CLINICAL CHEMISTRY

A DIVISION OF AACC

2013 Spring Edition

Message from the Chair

Sitting here authoring my first *Message from the Chair* for the 2013 DACC Newsletter, Spring seems so far away *as* the East Coast is being hammered once again by another snow storm. For those living on the East Coast, Mother Nature has sure taken a toll on the emotions of our friends and families. First, Hurricane "Sandy", and then a blizzard named "Nemo" (yes we found him), which left over two feet of snow. The face of our coastline and beaches have drastically changed due to nature's wrath but the community has rallied together to restore the coastline back to its original beauty.

Just as the profile of our beaches have changed, so, too has the faces of DACC committee members and volunteers. With new membership there is always a learning curve and a "getting to know you phase", but I am confident from past experience that 2013 will prove to be an even better year for the division. Welcome to our newly elected members and volunteers for 2013! I'm looking forward to working with the DACC Executive Committee and all of its volunteers for the continued success of this division.

Many thanks to Past-Chair Kay Criswell for her continued commitment to the DACC as Chair for 2012, it's a privilege and honor to follow in your footsteps. Additionally, many thanks to all of the outgoing members of the DACC committees without your help the success of this division would not be possible. Your continued dedication and passion for science inspires all of us to continuously move our division forward.

On behalf of the DACC membership, a hearty thank you to all of our contributing sponsors for their continued support of our mission. If it were not for our sponsors, volunteers, and membership, providing and delivering educational opportunities would not be feasible.

The first educational event sponsored by the DACC in 2013 was a free webinar delivered

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via WebEx. This webinar speaker was Dr. Rounak Nassirpour who presented "***Introduction to miRNA as Biomarkers***". With approximately 50 attendees, the DACC Executive Committee considered this free webinar a success. Due to the success of this webinar, the DACC will be offering another free webinar in the Fall of 2013. Stay tuned for more information regarding the topic for this Fall webinar.

This year's second educational event is the DACC Spring Meeting being held on April 19th entitled "***Cardiac and Skeletal Muscle Injury In Drug Development: Advances in Biomarkers, Assessment and Clinical Translation***". This symposium will be hosted and sponsored by the Drug Safety Department of Novartis Pharmaceutical Research & Development in East Hanover, NJ. This educational event which includes eight industry experts, who will explore scientific issues related to skeletal and cardiac injury spanning from mechanisms of acute and chronic skeletal and cardiac injury, preclinical predictive assays and models currently in use or being evaluated to reduce clinical skeletal and cardiac injury in late-stage clinical trials, the use of routine and exploratory skeletal and cardiac biomarkers, and evaluation of consortium activities to develop new skeletal and cardiac biomarkers. Drug-induced cardiac and skeletal muscle injury are common preclinical and clinical toxicities observed in drug development. Current biomarkers for detecting cardiac and skeletal muscle injury are both insensitive and nonspecific, and improving the ability to detect drug-induced cardiac and skeletal muscle injuries will help facilitate preclinical and clinical drug development and ensure patient safety. Understanding mechanisms of both skeletal and cardiac injury and developing new assays, models, and biomarkers to more accurately predict these toxicities at earlier stages of drug development remains a critical issue. This symposium promises to be a great scientific meeting with the opportunity to network and catch up with old friends. See you in New Jersey!

Looking ahead, the 2013 AACC Annual meeting in Houston Texas is just a short time away. The following DACC activities are scheduled throughout the week:

- The DACC Executive Committee will have its Business Meeting to be held on Monday July 29th. This is an open DACC business meeting and would encourage all to attend. This will give you the opportunity to participate in this meeting.
- Dave Desmond who is the 2013 Chair–elect is organizing the DACC Lunch-n-Learn session to be held on Monday, July 29th. This session will include scientific presentations as well as a presentation from the recipient of the DACC's 2013 Award for Outstanding Contributions to Animal Clinical Chemistry.
- Kay Criswell who is the Past-Chair organized a DACC translational medicine symposium entitled "Advances in Translational Medicine: Understanding Translatability at the Platform, Organ, and Therapeutic Area Levels". This session will take place on Thursday, August 1st at the AACC Annual Meeting.

As highlighted earlier, the success of the DACC is dependent upon volunteers, as well as, a core group of individuals that are willing to help new members in these leadership roles. If you are interested in volunteering, please feel free to contact me anytime.

See you soon at the DACC Spring Meeting.

❖ *Rich*

Pre-Meeting Activity

Thursday – April 18th, 2013, 8:00am – 3:30pm

Siemens Multispecies User's Group Meeting

Scientific Presentations and Lunch
Hanover Marriott

Hosted by Siemens Healthcare Diagnostics

Volunteer to Make a Presentation
Contact: Dave Zelmanovic
zelmanov@aol.com
845-425-9711

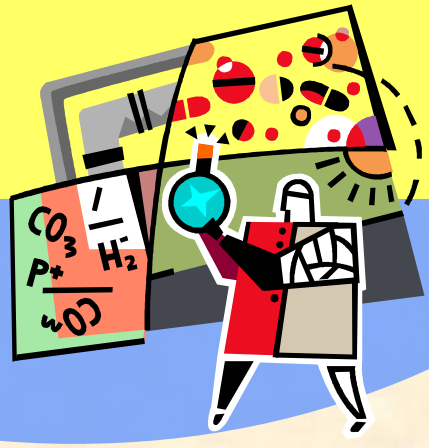
Registration or Other Info
Contact: Lois Brisben
lois.brisben@siemens.com
847-236-7208

A BIG DACC THANKS!

To:

Novartis Pharmaceutical Research & Development

For Hosting the Upcoming 2013 DACC Spring Meeting at Their East Hanover, NJ Facility and for Providing Printed Handouts, Breakfast and Lunch to the Attendees



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2013 DACC Spring Meeting

Cardiac and Skeletal Muscle Injury in Drug Development: Advances in Biomarkers Assessment and Clinical Translation

Thursday – April 18

DACC Executive Committee Meeting — 5:00pm – 6:30pm

Hanover Marriott 3rd Floor Conference Room
Open to All Members! Come Join in the Planning of DACC Activities!

DACC Meet the Speakers and Poster Travel Award Reception/Mixer

Hanover Marriott, in the 'Seeds Restaurant' — 6:30pm – 8:30pm
Supported by **IDEXX Laboratories** — **Free Food & Beverages!**
RSVP (*Yeses Only*) to Rich at richard.p.giovanelli@pfizer.com by April 12

Friday – April 19

Registration and Continental Breakfast — 8:00am – 8:30am

at Novartis Institutes for BioMedical Research
One Health Plaza, East Hanover, NJ
Host Site Contact: **Liane Yanas**

Welcome from the DACC Chair — 8:30am – 8:45am

Richard Giovanelli, DACC Chair and Symposium Moderator,
Clinical Pathology Lead, Pfizer Global Research & Development, Groton, CT

Session on Skeletal Muscle Injury

Application of MSD Muscle Injury Panels Across Species — 8:45am – 9:05am

Richard Goldstein, BS, MT(ASCP), Senior Scientist, Biomarker Development and Translation
Pfizer Inc., Groton, CT

Novel Skeletal Muscle Toxicity Biomarkers: Preclinical Qualification and Clinical Translation — 9:05am – 9:45am

Warren Glaab, PhD, Director, Systems Toxicology, Investigative & Laboratory Sciences
Safety Assessment and Laboratory Animal Resources, Merck Research Laboratories, West Point, PA

<BREAK> — 9:45am – 10:00am

Identification and Clinical Translation of Early Predictive Biomarkers Using Modern Metabolic Approaches — 10:00am – 10:40am

Brante Sampey, PhD, Senior Study Director,
Metabolon, Research Triangle Park, NC

2013 DACC Spring Meeting

Cardiac and Skeletal Muscle Injury in Drug Development: Advances in Biomarkers Assessment and Clinical Translation

Friday – April 19

NMR-Based Metabolomics Discovery of 1- and 3-Methylhistidine as Biomarkers for Drug-related Myotoxicity — **10:40am – 11:20am**

Nelly Aranibar, PhD, Pharmaceutical Candidate, Optimization R&D
Bristol-Myers Squibb, Princeton, NJ

Balancing Efficacy versus Safety: Learning's from Development of Myostatin Inhibitors — **11:20am – 12:00pm**

Carl Morris, PhD, Director, Protein Therapeutics and Muscle Biology
Rare Disease Research Unit, Pfizer, Inc. Cambridge, MA

<LUNCH> — **12:00pm – 1:00pm**

Session on Cardiac Injury

Role of Contractility Measurements in Preclinical Cardiovascular Safety Assessment — **1:00pm – 1:40pm**

Gregory Friedrichs, PhD, Global Head, Safety Pharmacology,
Novartis Pharmaceuticals Corporation, East Hanover, NJ

Regulatory Qualification and the Use of Cardiac Troponin as a Preclinical Biomarker — **1:40pm – 2:20pm**

William J. Reagan, DVM, PhD, Dipl, ACVP, Research Fellow,
Pfizer Global Research & Development, Groton, CT

<BREAK> — **2:20pm – 2:35pm**

The Application and Translatability of N-Terminal Proatrial Natriuretic Peptide in Non-Clinical Drug Safety Evaluation — **2:35pm – 3:15pm**

Michael Dunn, PhD, Non-Clinical Safety,
Hoffmann-La Roche, Inc., Nutley, NJ

Discussion/Closing Remarks — **3:15pm – 3:30pm**

Meeting Abstracts

DACC Spring Meeting Friday, April 19, 2013

Application of MSD Muscle Injury Panels Across Species

Richard Goldstein, BS, MT(ASCP)
Senior Scientist, Biomarker Development and Translation,
Pfizer Inc., Groton, CT

Evaluation of biomarkers related to cardiac and skeletal damage is an important part of compound safety assessment during drug development. The classic biomarkers of myotoxicity, creatine kinase and aspartate aminotransferase lack target tissue specificity and sensitivity. MesoScale Discovery (MSD) released rat and mouse specific multiplex immunoassay muscle injury panels (MIP) that include the analytes: cardiac Troponin I (cTnI), cardiac Troponin T (cTnT; rat only), Fatty Acid Binding Protein 3 (FABP3), Myosin Light Chain 3 (Myl3) and skeletal muscle Troponin I (sTnI). These analytes have demonstrated improved specificity and/ or sensitivity for detection of myotoxicity.

This presentation will provide insight from laboratory data into the utility of the MIP assays to monitor/ differentiate muscle injury, cardiac and skeletal in the intended species, rat and mice and the assays cross-reactivity and utility in dog and non-human primates. ❖

Novel Skeletal Muscle Toxicity Biomarkers Preclinical Qualification and Clinical Translation

Warren Glaab, PhD
Director, Systems Toxicology, Investigative & Laboratory Sciences,
Safety Assessment and Laboratory Animal Resources,
Merck Research Laboratories, West Point, PA

Drug-induced skeletal muscle injury is a common preclinical and clinical toxicity observed in drug development, and has resulted in the withdrawal of several pharmaceutical agents from the market. Current biomarkers for detecting skeletal muscle injury are both insensitive and nonspecific, and improving the ability to detect drug-induced skeletal muscle injuries will help facilitate preclinical and clinical drug development and ensure patient safety.

Qualification of novel skeletal muscle toxicity biomarkers is an on-going initiative using a consortium approach through the Critical Path Institute's Predictive Safety Testing Consortium (PSTC). Preliminary preclinical data from the PSTC Skeletal Muscle Working Group support a Biomarker Qualification Submission (BQS) to seek regulatory endorsement from both the FDA and EMA, demonstrating the added value of these novel biomarkers in detecting drug-induced skeletal muscle injury. In order to translate these novel biomarkers from preclinical to clinical settings, the Skeletal Muscle Working Group has developed a clinical translation strategy.

This presentation will outline the working group's translational strategy, and review currently monitored clinical skeletal biomarker endpoints used routinely in the clinic. Identification of clinical assays for the novel biomarker candidates will be presented, as well as early validation work on these existing assays including available clinical baseline data. The presentation will conclude with identification of normal and/or disease populations needed to establish baseline measurements for the novel biomarkers, and the next steps needed to secure clinical samples from drug-induced skeletal muscle toxicities. Establishing these novel biomarkers in the clinic will be essential to fully leverage the preclinical qualification efforts and further enable clinical drug development. ❖

Meeting Abstracts

DACC Spring Meeting Friday, April 19, 2013

Identification and Clinical Translation of Early Predictive Biomarkers Using Modern Metabolic Approaches

Brante Sampey, PhD
Senior Study Director,
Metabolon, Research Triangle Park, NC

Existing biomarkers for organ toxicology may not reflect the complex underlying physiology or provide early prediction of toxic outcomes of a biological system. This presentation will convey how a deep understanding of the underlying biology is needed to drive predictive clinical success and safety. Understanding the physiology of the system through a high-throughput metabolic approach can provide essential insight to the mode of action for better biomarker identification in a preclinical setting. Further, metabolomic studies that demonstrate the merits of this approach for predictive translation from discovery, development and clinical application will be detailed as it relates to identification of novel therapeutic targets and biomarkers of skeletal muscle disease. ❖

NMR-Based Metabolomics Discovery of 1- and 3-Methylhistidine as Biomarkers for Drug-related Myotoxicity

Nelly Aranibar, PhD
Pharmaceutical Candidate, Optimization R&D, Bristol-Myers Squibb, Princeton, NJ

Metabolomic evaluation of biological fluids affords the opportunity to assess systemic metabolic changes that may be directly related to myotoxicity. Metabolomics has been widely used in the last decade to define tissue metabolic profiles, investigate mechanisms of toxicity and to identify biomarkers of pharmacologic or adverse effect. Preclinical drug-induced skeletal muscle toxicity is routinely evaluated by histopathology because commonly used serological proteins, including creatine kinase (CK), aspartate aminotransferase (AST) and aldolase lack sensitivity and specificity.

A metabolomics approach was used to identify potential biomarkers of skeletal muscle toxicity in female and male Sprague-Dawley rats following toxic doses of cerivastatin - a well characterized skeletal muscle toxicant. NMR-based metabolomic analysis of the urine revealed two unknown metabolites which were highly correlated to sex-, dose- and time-dependent development of cerivastatin-induced myotoxicity. The unknown molecules were isolated and identified as the acetylated forms of 1-methylhistidine (1-MH) and 3-methylhistidine (3-MH), which are the major excretion forms of 1-MH and 3-MH in the rat. Subsequently, the distribution and concentration of 1- and 3-methylhistidine (1- and 3-MH) were quantified in different tissues. 1-MH was most abundant in skeletal muscle whereas the concentration of 3-MH was greatest in skeletal, cardiac and smooth muscle, with no muscle fiber or sex differences observed. The translational relevance of these biomarkers will be discussed. ❖

Register for the Spring Meeting
Via the AACC website:
www.aacc.org/events/meetings/pages/meetingdetail.aspx?MeetingID=8154

Reserve a Room at the Hanover Marriott Hotel
1401 RT-10, Whippany, NJ, 973-538-8811
www.marriott.com/hotels/travel/ewrho-hanover-marriott
Discount Group Code: "**DACC Meeting**"

Meeting Abstracts

DACC Spring Meeting Friday, April 19, 2013

Balancing Efficacy versus Safety: Learning's from Development of Myostatin Inhibitors

Carl Morris, PhD
Director, Protein Therapeutics and Muscle Biology,
Rare Disease Research Unit, Pfizer, Inc. Cambridge, MA

Therapeutic inhibition of myostatin, a member of the TGFβ-family and a negative regulator of muscle mass, may provide significant benefit in indications such as sarcopenia, cachexia and muscular dystrophy. A key factor for developing anabolic agents is balancing necessary efficacy against potential safety risks.

Previous work has shown that ActRIIB-Fc, a soluble decoy receptor-fusion protein that binds several TGFβ-family proteins (e.g. Activin A&B, GDF8, BMP -9 and -11), significantly increased muscle and bone mass in mice, whereas more specific myostatin neutralizing antibodies (e.g MYO-029) had no effect on bone mass and were less efficacious in stimulating muscle growth. This enhanced efficacy of ActRIIb-Fc in mice supported studies to determine the safety and efficacy in cynolomogous monkeys (NHPs). NHPs were dosed weekly with vehicle, ActRIIB-Fc, or MYO-029 for 16 weeks. As expected, significant increases in lean body mass and muscle volume were observed in ActRIIb-Fc-treated NHPs, when compared to both the vehicle-treated and MYO-029-treated groups. However, serious ActRIIb-Fc-related adverse events, including spontaneous nosebleeds and significant pericardial and/or pleural effusions were also observed. Most ActRIIb-Fc treated NHPs (11/13) presented with effusions versus only one in the MYO-029 group (1/6) and none in the vehicle group. The safety findings were unexpected, as no adverse events had been observed or reported previously in ActRIIb-Fc-treated mice. These results caused a rethink of the therapeutic potential of this promiscuous receptor approach and drove the development of new, more specific myostatin inhibitors. This suggested the requirement for both efficacy and safety to be performed in multiple species to de-risk the compounds, and ultimately the mechanism.

Mouse studies with the selective inhibitors showed improved efficacy over MYO-029, but to determine if there was a safe path forward, NHP studies were completed, with very encouraging results. Following treatment with the inhibitors, significant increases in both lean mass and muscle volume were determined while no clinical adverse events or treatment-related pericardial or pleural effusions were observed. These data provide optimism around continued myostatin inhibitor development for the treatment of muscle dysfunction. ❖

Role of Contractility Measurements in Preclinical Cardiovascular Safety Assessment

Gregory Friedrichs, PhD
Global Head, Safety Pharmacology,
Novartis Pharmaceuticals Corporation, East Hanover, NJ

Cardiac contractility is an important parameter of cardiovascular function. Contractility measurements have been performed successfully for decades in *cardiovascular research*, their usefulness for *preclinical cardiovascular safety* assessment, however, has yet to be established. Currently a poor understanding and translation exist between assays and species, e.g., in vitro and in vivo results, translation of preclinical data to man. Activities are ongoing to better understand which preclinical profiles of contractility effects are considered a clinical risk and what is the role of disease models. Emerging new methods have potential in early screening. A thorough evaluation of cardiovascular function including cardiac contractility is necessary for an integrated preclinical cardiovascular safety assessment to provide safer molecules for clinical development and submission. ❖

Meeting Abstracts

DACC Spring Meeting Friday, April 19, 2013

Regulatory Qualification and the Use of Cardiac Troponin as a Preclinical Biomarker

William J. Reagan, DVM, PhD, Dipl, ACVP
Research Fellow,
Pfizer Global Research & Development, Groton, CT

Cardiac troponin (cTn) is a sensitive and specific tool for assessing cardiac myodegeneration/ necrosis. A group of scientists, including Malcolm York of GlaxoSmithKline, Matt Jacobsen of Astra Zeneca, and William J. Reagan led by Peter J. O'Brien from the University College, Dublin, Ireland submitted a document to the FDA entitled "Qualification of Troponin as a Biomarker of Cardiac Toxicity." Based on this document, which was mainly a review of the historical literature, troponin was recently qualified by the FDA as a marker of cardiotoxicity in pre-clinical toxicity studies. Briefly, the FDA sanctioned the following context of use in rats and dogs. When there is histological evidence of cardiac myodegeneration/necrosis in preclinical safety assessment studies, cTn can be used to determine the lowest toxic dose. When there is cardiac structural damage with a pharmacologic class of drugs and histopathologic analyses do not indicate cardiac structural damage (myodegeneration/ necrosis), cTnI may be used to support or refute the inference of low cardiotoxic potential of the compound. Lastly, cTnI also can also be used in a reflex manner when unexpected cardiac structural damage is found in a preclinical study to help determine a no observed adverse effect level (NOAEL). This presentation will review the qualification process including the proposed and approved context of use. Also to be discussed are some of the critical factors how to use troponin effectively in pre-clinical safety assessment that were outlined by the FDA, as well as based on the experience of the presenter. The effective use of troponin in non-human primates (NHP) will especially be emphasized, since at the time of the original application there was paucity of data to support the context of use of cTn in NHP. ❖

The Application and Translatability of N-Terminal Proatrial Natriuretic Peptide in Non-Clinical Drug Safety Evaluation

Michael Dunn, PhD
Non-Clinical Safety Hoffmann-La Roche, Inc., Nutley, NJ

The current paradigm for the non-clinical development of molecules is lacking accessible biomarkers for identifying drug-induced hemodynamic perturbations. Many of these drug-induced cardiovascular changes can lead to cardiac hypertrophy, decreased left ventricular ejection fraction (LVEF) and ultimately heart failure. Routine histopathology lacks the sensitivity to detect early changes leading to pathologic hypertrophy. Functional analysis using echocardiography has the ability to characterize early hemodynamic changes however this imaging technique is rarely utilized in routine and long-term toxicology studies. Natriuretic peptides (NP's) are hormones secreted by cardiomyocytes in response to stretch resulting from increased cardiac pressure or volume. NP's in humans have proven to be non-invasive, diagnostic and prognostic markers for the assessment of heart failure. Given their proven utility in humans, NP's are candidates for circulating translational biomarkers that can potentially be used during drug development in non-clinical species. The Cardiac Hypertrophy Working Group (CHWG) of the Predictive Safety Testing Consortium (PSTC) initiated an effort to qualify N-terminal proatrial natriuretic peptide (NT-proANP) for use as a non-clinical cardiovascular safety biomarker for compounds in development. The group has evaluated serum NT-proANP concentrations during rat toxicology studies, from which concentrations were correlated with cardiac hypertrophy, as defined by increased heart weight and/or left ventricular mass. The group evaluated the preclinical performance of NT-proANP during drug-induced concentric and eccentric pathologic cardiovascular adaptation as well as during the induction of physiologic hypertrophy. Serum NT-proANP provides the non-clinical space with a unique and physiologically relevant biomarker that has a translatable application and the potential to improve risk assessments for cardiovascular toxicity in patients. ❖

In Memoriam

Jiro "Jerry" Kaneko Passes at 88

Veterinarian, researcher, teacher, author, administrator, soldier, politician, dynamic multifaceted organizer, magnificent and generous human being, are just some of the things that Jerry Kaneko was. When he passed away on January 12, 2013 at age 88 he left a unique vacuum in his profession and community that will be difficult, if not impossible, to fill.

Jiro J. Kaneko, DVM, PhD, DVSc (h.c.) was respected world-wide for his contributions to the practice and teaching of students in Clinical Pathology. Jiro "Jerry" Kaneko received his AB (Chemistry) from the University of California, Davis in 1952. He went on to receive his DVM (1956) and PhD (Comparative Biochemistry) (1959) from the same university.

Jerry spent his career at the University of California, Davis. He began as a Lecturer in 1957 and advanced to Full Professor. In 1960 he became the Head of the Clinical Biochemistry Section of the Clinical Pathology Diagnostic Laboratory of the Veterinary Medical Teaching Hospital, University of California, Davis. In 1969 he became Chairperson, Dept. of Clinical Pathology and in 1975 he became Chief of Service - Clinical Pathology Diagnostic Laboratory of the Veterinary Teaching Hospital. Dr. Kaneko was the Acting Associate Dean for Education, School of Veterinary Medicine from 1979 – 1980. From 1994 until his passing Jerry was Professor emeritus, School of Veterinary Medicine, and University of California, Davis. His co-edited book "Clinical Biochemistry of Domestic Animals" is now in its 6th edition and is probably the best known and most used text in the field.

Jerry held visiting professorships at universities in eight countries and held membership in several societies including Phi Beta Kappa, Sigma Xi, Phi Zeta, and Phi Kappa Phi. He received many honors including Doctor of Veterinary Science (Honoris causa) from the University of Gent (1980), University of California, School of Veterinary Medicine Alumni Achievement Award (1995), ISACB Award for Outstanding Contributions in Animal Clinical Biochemistry (1995), American Association for Clinical Chemistry: Outstanding Contributions in Education Award (1994) to name a few. In 1993, he was the first recipient of the AACC Division of Animal Clinical Chemistry: Outstanding Contributions to Animal Clinical Chemistry Award. In 2011, Jerry was selected as one of the first inductees into the recently established European Society of Veterinary Clinical Pathology (ESVCP), Hall of Fame.

In addition to the many scientific organizations and committees of which he was a member, he was also very active in his community. Jerry held a seat on the Davis, California City Council, and was the council's liaison to the Human Relations Commission and Senior Citizens Commission. In 2004, the city presented him with a lifetime achievement award.

Our condolences go out to his wife Teresa and his family. The AACC Division of Animal Clinical Chemistry, in which he played an active role, will miss him greatly. ❖

Edith R. Williams, Patricia L. Carthage, and Rosemary C. Nicklaus to be Honored for Meritorious Service, Dedication, and Contributions to the DACC

Three Division of Animal Clinical Chemistry members and former members will be honored during the speakers reception at this year's Spring Meeting. Each will be presented with a DACC/AACC Certificate of Recognition for their Meritorious Service, Dedication, and Contributions to the AACC Division of Animal Clinical Chemistry for enhancing and advancing the practice and profession of animal clinical laboratory medicine. Those to be so honored are Edith R. Williams, Patricia L. Carthage, and Rosemary C. Nicklaus. The division has benefited greatly from the contributions of these three. It has been our good fortune that they chose to become members.

Edith R. Williams was appointed a member of the Animal Clinical Chemistry Committee of the Laboratory Animal Clinical Analysis Group (LACAG) in 1981. The following year she was a member of this committee when it submitted to the AACC Board an Application for Animal Chemistry Division of American Association For Clinical Chemistry. She is listed on the cover sheet of this application as one of the committee members. In 1987, after several years of provisional division status, the Division of Animal Clinical Chemistry was awarded full recognition as the first division approved by the AACC.

Edie held several key positions in those formative years. They included treasurer in 1985 and 1986. She was a member of the membership committee in 1987 and presented a paper during Clinichem-87. In 1988 & 1989 she served on the Nominating, Fund Raising, and Long Range Planning committees. Edie also served on a special ad hoc executive committee during 1988 that was establish to aid elected officers.

Edith continued her participation by reviewing papers and writing articles that were published in this newsletter. She coauthored annual meeting posters in 1993 and 1994. Edie remained active in the DACC until 1994 when she moved to the Janssen Research Foundation and then a year later joined Johnson and Johnson Consumer Products as a Project Manager. ❖

Patricia L. Carthage was the first Publications Chair and as such the DACC newsletter Editor and Publisher. When provisional divisional status was granted there were a number of criteria that had to be met before full recognition as a permanent AACC division could be achieved. One of those things was the establishment of a division newsletter. Patricia was the person that first gave the division newsletter its format, solicited, and organized materials to be communicated to the membership, and arranged for its printing, proof reading, and mailing. She also saw to it that the newsletter was published on a schedule. In the days before electronic publishing this was an enormous task. Pat held this position until June of 1991 when she began her new position as R.W. Johnson Pharmaceutical Research Institute, Manager of Drug Safety Evaluations Operations.

Patricia has been recognized as one of those whose efforts were responsible for the DACC achieving permanent division status. On June 15, 1981 Pat and her staff hosted an Eastern Regional Meeting at Ortho Pharmaceuticals. Patricia served as DACC liaison to Immunotoxicology in 1987. In 1995 she spoke on Computer Validation in the Clinical Laboratory at the Spring Meeting at Sandoz. Patricia wrote a two part article for the 1997 March and June issues of the DACC news on Retrospective Evaluation in her role as Senior Validation Consultant for Taratec Development Corporation. ❖

Honorees for Meritorious Service Dedication, and Contributions to the DACC

continued . . .

Rosemary C. Nicklaus has been an extraordinary leader of the DACC! In September of 1998 she was a candidate for Treasurer. Rosemary won that election and in 2000 was re-elected for a second term. That same year Rosemary and her staff hosted the DACC Spring Meeting at Hoffmann-La Roche. She would host this meeting at her company again in 2004 and 2010. Each time the meetings were superb.

Rosemary continued her involvement: She was a member of the DACC Fund raising Committee in 2003 and the Membership Committee from 2004-2012. In 2007 Rosemary was chosen as DACC's Chair-Elect, and she assumed that position in 2008, became DACC Chair in 2009, and Past-Chair in 2010. During those three years Rosemary provided leadership to all DACC committees. In 2011 she was elected to the Nominating Committee. Her involvement in Membership, Spring & Fall meeting planning, and the Scientific Program and Long Range Planning Committee's continued through 2012.

Along with all the aforementioned contributions to the DACC, Rosemary also presented scientific papers at meetings such as LabMed-2002 and AACC Lunch and Learn. She was also a frequent co-author of posters presented during AACC Annual meetings.

Rosemary will be retiring from Hoffman-La Roche in 2013. We will miss her very much! ❖

Our Own Kay Criswell Receives SOT's Risk Assessment Specialty Section Best Paper Award!

Each year the Society of Toxicology (SOT) Risk Assessment Specialty Section presents a **Best Paper Award** at the SOT's Annual Meeting. The section reviews all papers published during the previous year that pertain to risk assessment and they evaluate the relevance and impact of the publications. This year's Best Paper Published in 2012 demonstrating the strongest application of Risk Assessment was given to **Kay Criswell**, current Past-Chair of the DACC. Kay lead a team of Pfizer scientists over the past ten years to understand a specific mode of action and publish the paper: **Mode of Action Associated with Development of Hemangiosarcoma in Mice Given Pregabalin and Assessment of Human Relevance.** Kay A. Criswell, Zbigniew Wojcinski, David Pegg, Jon Cook, James Herman, David Wesche, John Giddings, Joseph Brady, and Timothy Anderson. (*Toxicological Sciences* 2012 Jul;128(1):57-71)

Read the abstract at:
www.ncbi.nlm.nih.gov/pubmed/22539620

Pictured L-R:
Jon Cook (Past-President SOT)
Kay Criswell (Lead Author)
John Lipscomb (President of SOT's Risk Assessment Specialty Section)

DACC Annual Meeting Symposium
Thursday, August 1st, 2013

Advances in Translational Medicine: Understanding Translatability at the Platform, Organ, and Therapeutic Area Levels

Translational and precision medicine have become extensively utilized terms in drug development. Translational medicine is a process of turning biological research discoveries in preclinical (nonhuman) models into new drugs and biological devices to improve patient care. Whereas, precision medicine is an approach to discovering and developing medicines and vaccines that has the potential to deliver superior outcomes for patients by coupling clinical and genomic or molecular information to understand the biological basis of human disease. Although better understanding of the translation of preclinical results and application of precision medicine approaches are beginning to improve diagnostic and treatment options, it is not without significant challenges and further hurdles.

This 3-speaker session will address the challenges of translatability at the platform, organ, and therapeutic area levels. Some platforms, such as hematology, are believed to be highly translatable from preclinical species to human. The first presentation will explore whether animal models of hematologic toxicity are good predictors of human toxicity, and will also focus on hematologic disturbances associated with biotherapeutic administration and their relevance to human adverse events.

Even when new biomarkers achieve regulatory acceptance as predictive of organ toxicity in animals, confirming translation to humans remains elusive. In 2010, the PSTC (Predictive Safety Testing Consortium) published a number of newly qualified preclinical kidney safety biomarkers. The tests used to determine drug safety have not changed in decades. These new markers have the potential to improve the predictivity of kidney toxicity. The second presentation will provide a view into the complexity and progress of the on-going clinical trials to translate these new kidney markers in humans.

Finally, it has long been recognized that even though patients have the same disease, they do not respond similarly to the same medication. The third lecture will focus on a precision medicine approach for drug development. Cancer is a disease of the genome, and each tumor has its own unique genetic changes. By understanding the molecular targets that underlie tumors it becomes possible to subgroup patients with similar genetic and physical characteristics to predict which patients will benefit most from certain drugs.

Non-clinical Hematologic Toxicity and its Relevance to Human Safety

Nancy Everds, Amgen, Inc., Seattle, WA

This presentation will explore whether animal models of hematologic toxicity are good predictors of human toxicity, and will also focus on hematologic alterations associated with biotherapeutic administration and their relevance to human safety. Even when new biomarkers achieve regulatory acceptance as predictive of organ toxicity in animals, confirming translation to humans remains elusive.

Translational Renal Safety Biomarkers: A Consortium-Based Approach

Stephan Sultana, Novartis Pharmaceutical Company, Cambridge, MA

This presentation will provide a view into the complexity and progress of the on-going clinical trials to translate these new kidney markers in humans. In 2010, the PSTC (Predictive Safety Testing Consortium) published a number of newly qualified preclinical kidney safety biomarkers. These new markers have the potential to improve the predictivity of kidney toxicity beyond the tests that have been used for decades.

The Utility of Precision Medicine Approaches to Select Patients for Clinical Trials in Oncology

James Christensen, Pfizer, Inc., San Diego, CA

This lecture will focus on a precision medicine approach for drug development. It has long been recognized that even though patients have the same disease, they do not respond similarly to the same medication. Cancer is a disease of the genome, and each tumor has its own unique genetic changes. By understanding the molecular targets that underlie tumors it becomes possible to subgroup patients with similar genetic and physical characteristics to predict which patients will benefit most from certain drugs.

The DACC Needs YOU!

Members Are Needed to Run for Office and or Volunteer to Serve the Division in the Following Capacities:

Elected Office

Candidate for Chair-Elect
Candidate for Secretary
Candidate for Nominating Committee Member

Volunteer Positions Available

Membership Committee
Scientific Program & Long Range Planning Committee
Awards Committee

Your Participation in OUR Division is Vital to Ensure Continued Quality of the DACC's Business and Educational Activities

Election Results from Last Fall Meet 2013's Newest Officers:

Chair-Elect
David Desmond, AbbVie

Nominating Committee
Tammy Lambert, GSK *(elected)*
Dirk Sprenger, GSK *(elected)*
Doug Thudium, Merck *(appointed[1])*
Karen Lynch, GSK *(appointed[2])*

The DACC Membership Offers a Big *THANK YOU* to its Outgoing Officers:

2012 Past-Chair
Barbara Litzenberger, Huntingdon L.S.

2012 Chair of Nominating Committee:
Karen Lynch, GSK
Note: After Karen dutifully completed a 4 year term at the end of 2012, she generously re-upped for another 2 year term to fill a critical need.

1: *Appointed to a 1 year term to replace J. Sansone who retired*
2: *Appointed to a 2 year term to replace D. Desmond who is now serving on the Executive Committee*

Short Scripts.....

Volunteers are needed for DACC committees. Join your colleagues in determining the future direction of YOUR division.

SOCIETY of TOXICOLOGIC PATHOLOGISTS
ANNUAL MEETING
Portland, OR
June 16-20, 2013

AMERICAN ASSOCIATION for CLINICAL CHEMISTRY
ANNUAL MEETING
Houston, TX
July 28-August 1, 2013

AMERICAN COLLEGE of TOXICOLOGY
ANNUAL MEETING
San Antonio, TX
November 3-6, 2013

ACVP / ASVCP
ANNUAL MEETING
Montreal, QC, Canada
November 16-20, 2013

DACC Mixer/Buffet Dinner and Meet the Speakers Reception

Thursday 4/18/2013, 6:30-8:30pm
Hanover Marriott, in the 'Seeds Restaurant'
1401 RT-10, Whippany, NJ, 973-538-8811

Free !! **Send RSVP for the Reception to Rich at**
richard.p.giovanelli@pfizer.com

Hosted by

IDEXX Laboratories

❖ ***Free Food & Beverages!*** ❖

2013 DACC Fall Elections

This is the Year YOU Should Run for Office
The Division Depends on YOUR Volunteerism!
See Which Positions Are Open On Page 14

DACC *NEWS*

AACC's Division of Animal Clinical Chemistry

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Chair-Elect
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Secretary
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GlaxoSmithKline R&D
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DACC 2013 Committees

Nominating (Year as Chair)
Doug Thudium (2013)
Karen Lynch (2014)
Dirk Sprenger (2015)
Tammy Lambert (2016)
Kay Criswell (Exec Rep)

Membership
Volunteers Needed!

Fund Raising
Jon Kimball
Doug Neptun
Chris Perigard
Lila Ramaiah (Exec Rep)

Awards
Jon Kimball (Chair)
Bob Emmons
Doug Neptun
1 Volunteer Needed

Scientific Program & Long Range Planning
Richard Giovanelli[1,3]
Kay Criswell[2]
David Desmond[4]
Doug Thudium
Jon Kimball
Volunteers Needed!

Principal Organizer: 1: 2013 Spring Symposium, 2: 2013 Annual Meeting Symposium, 3: 2014 Annual Meeting Symposium, 4: 2013 Annual Meeting Lunch & Learn