DACC NEWS

Volume 32, Number 3, November 2016

ANIMAL CLINICAL CHEMISTRY

2016 Fall Edition

Message from the Chair

We are halfway through the fall season, past peak leaf-peeping, and have already turned our clocks back - how quickly the year has gone. The holidays will be here soon and when we ring in the new year, Doug Thudium will take over as Chair of the division and I will transition into the Past-Chair role.

The division continued to have a productive year of scientific discussion and presentation, with a great topic and good attendance at the Annual Meeting in Philadelphia. The Lunch and Learn topic of "Immunoassay Method Selection and Validation for the Pre-Clinical Lab" garnered good attendance from the division. A survey of attendees at the event showed that members are interested in hearing more of these types of presentations on method selection. It is clear that as a division comprised of many industry professionals, the challenges of method selection and validation of laboratory methods, across the scientific spectrum, is shared commonly among us, regardless of the size or focus of our individual organizations. The executive committee is using this feedback to craft future meetings to meet this interest. Please contact one of us if you have an idea or interest that you would like to see developed into a future seminar.

This Fall, via a generous WebEx hosting by Merck, the division provided a free webinar for members, asking two of our Spring Meeting presenters to share their knowledge again. This webinar provided an opportunity for those members who were unable to attend the Spring Meeting to hear these excellent presentations, and offered those of us who did attend, a second opportunity. Thanks to both our speakers, Deidre Dalmas Wilk from GSK and Ray Gonzalez from Merck, for offering their time to our division.

Doug is busy working on a Spring Meeting topic that we hope will generate a good turnout in 2017. Plan ahead and set aside some budget dollars and educational development time to attend the Spring Meeting – we'll send out an announcement in early 2017 when we finalize the date and topic, but it is expected to be hosted in the PA/NJ region.

For the Annual Meeting in San Diego next year, I have submitted a proposal, co-sponsored with the Clinical Translational Sciences division, titled the "Application of Emerging Translational Safety Biomarkers in Drug Development and Clinical Practice". With a topic that focuses on both preclinical and clinical environments, we hope to also attract interest from our human health care colleagues. I hope that that the session is approved; I believe this is a very interesting set of speakers and would attract a varied audience. A big thank you to Kay

In This Issue:

Criswell for providing a lead to the topic and helping me to develop the program. For those of you who are intimidated by taking on leadership roles in the division, this type of collaboration from Executive Committee members is an example of how the division is able to develop educational programs all the time: it wouldn't be just you shouldering the responsibility. Without the members working together, we couldn't have the educational programs we offer.

As we close out 2016, congratulations to our new executive committee members: Chair-Elect Lisa Manson, Treasurer Samantha Wildeboer, coming back to serve the division for yet another term (thank you Samantha!), and Matt Larkin, taking on his first role for the division on the Nominating Committee, after serving as a poster judge this past summer at the Annual Meeting. I want to thank these members for taking on these leadership roles in the division.

Enjoy what remains of the year, specifically the holiday season, and the pleasure of having election day behind us - I'm sure I'm not the only DACC member happy to having this election over, but wondering with trepidation what lies ahead. Regardless of the outcome, I have the comfort of knowing professional friends and colleagues will be steadfast in their support of science and healthcare, a consistency in a sea of change all around us.

All the best,

❖ *Amy*

Amy Hudak
DACC Chair

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DACC 2016 Committees

Nominating (Year as Chair)
Tammy Lambert (2016)
Peter Szczerba (2017)
Susan Haley (2018)
Joseph Sansone (2019)
Amy Hudak*
**Exec Comm Rep*

Membership
Volunteers Needed!

Fund Raising
Jon Kimball
Chris Perigard
Samantha Wildeboer*
**Exec Comm Rep*

Awards
Jon Kimball (Chair)
Kay Criswell
Bob Emmons
Doug Neptun

Scientific Program & Long Range Planning
Amy Hudak[1,3]
Susan Emeigh Hart[2]
Doug Thudium[4]
Kay Criswell
Jon Kimball

Principal Organizer: 1: 2016 Spring Symposium, 2: 2016 Annual Meeting Symposium, 3: 2017 Annual Meeting Symposium, 4: 2016 Annual Meeting Lunch & Learn

DACC Supporters

Benefactors

SIEMENS Boehringer Ingelheim Pfizer

Patrons

Bristol-Myers Squibb gsk MERCK Be well

Contributors

NOVARTIS Stago sysmex

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Jennifer Colango – ***Pfizer, Inc.***
Steven Cotton – ***Ohio State Univ Wexner Med Ctr***
Kay Criswell – ***Pfizer Global R&D***
Christopher deFilippi – ***VCU***
Bradley Enerson – ***Pfizer, Inc.***
Robert Emmons – ***DACC News Editor Emeritus***
Ashley Frazer-Abel – ***National Jewish Health***
Raymond Gonzalez – ***Merck Research Labs***
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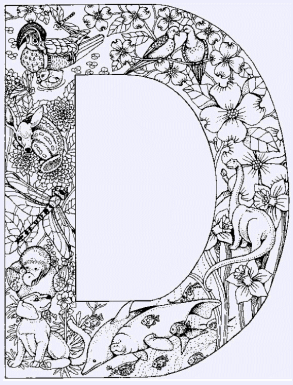
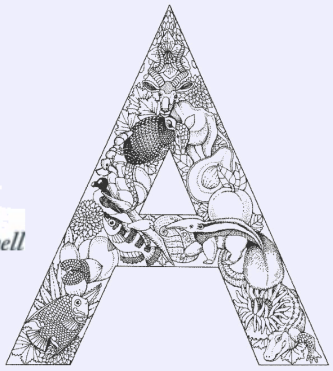
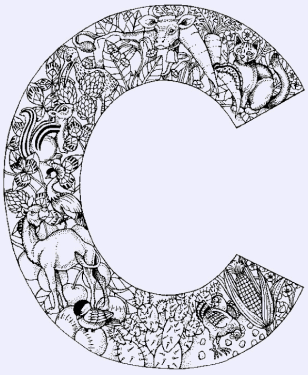
Simon Lavallee – ***Charles River Laboratories***
Purvish Patel – ***Quanterix Corporation***
Jennifer Price – ***Bristol-Myers Squibb***
Rana Samadfan – ***Charles River Laboratories***
Eric Schultze – ***Lilly Research Laboratories***
Jacqueline Tarrant – ***Genentech***
Michael Thibodeau – ***Boehringer Ingelheim***
Gail Walter – ***Clinical Pathology Consulting***
Deidre Dalmas Wilk – ***GlaxoSmithKline***
Victoria Zhang – ***Univ Rochester Medical Center***



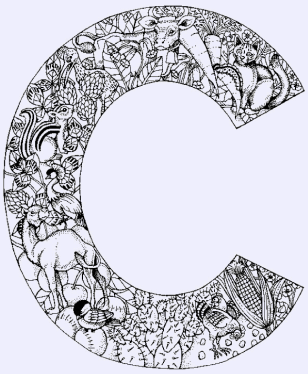
The Division of Animal Clinical Chemistry (DACC) welcomes all persons interested in advancing clinical laboratory science in animals by promoting and encouraging the study, exchanging knowledge, and expanding and improving the practice of clinical laboratory science in animals.



Our division provides a forum for sharing of information relevant to methods of analysis, reference intervals for different animal models, selection of appropriate species for research, and feasibility of transferring relevance of the data to human medicine. The DACC supports the development of methods to detect specific target organ effects and cellular changes associated with xenobiotic agents and/or disease processes.



The Division publishes this newsletter and sponsors regional and national meetings as a means for promoting education, research, and service. We encourage members to pursue professional interactions with AACC as well as within other professional groups. Our membership represents scientists working in interdisciplinary fields, industry, academia, and governmental laboratories.



Susan Emeigh Hart Receives the Royden N. Rand Award

In 2005, the DACC began a tradition of honoring its immediate past chair via the Roy N. Rand past-chair award. Dr. Rand was integral in the formation of the DACC in the mid 1970's, and the past-chair award, conveyed in his honor, is presented as recognition of the time, work and dedication to service that is required by the role of the division chair.

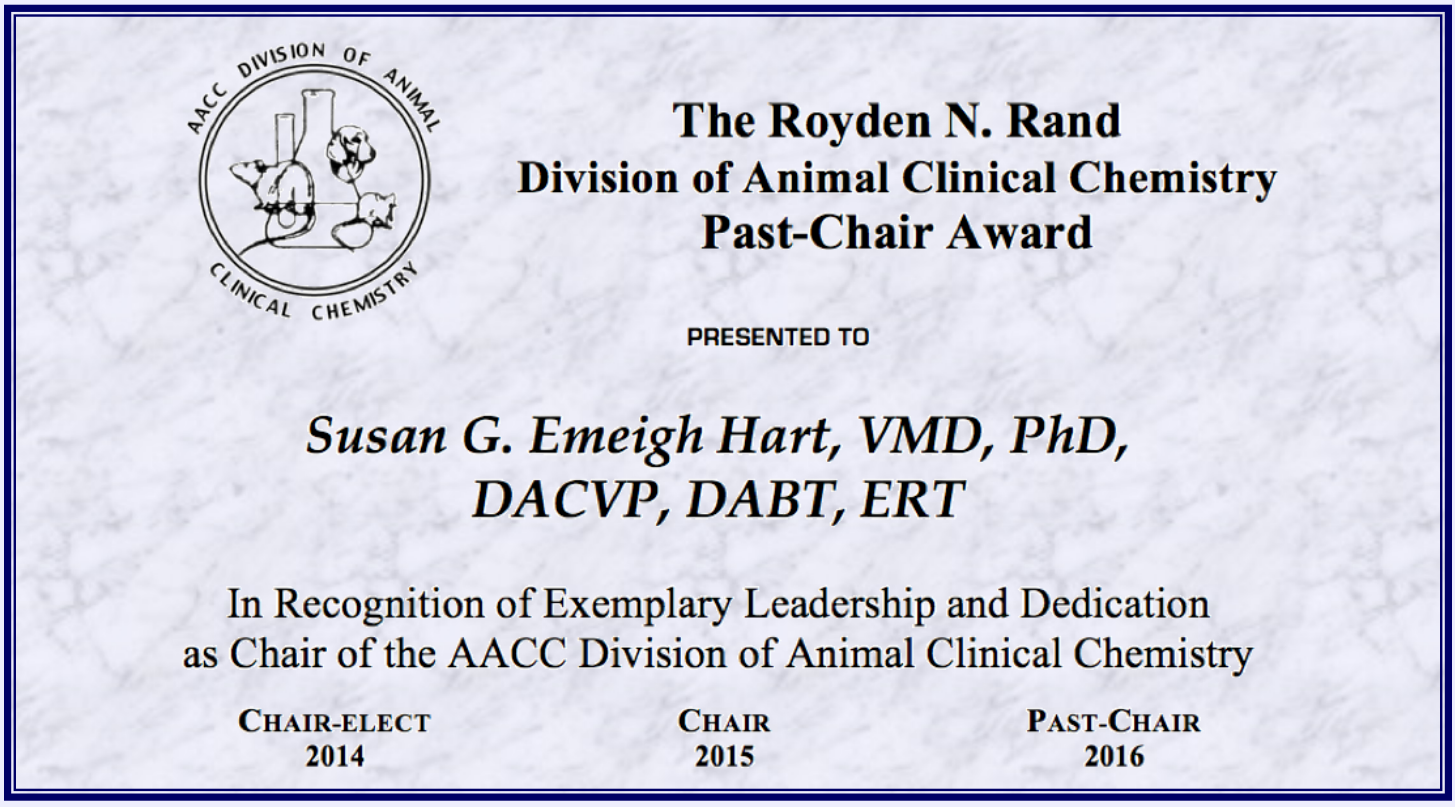
Following that tradition, we thank Susan Emeigh Hart for her leadership as she finishes her tenure as past chair at the end of this year. Susan is currently the Director of Experimental Pathology at Boehringer Ingelheim Pharmaceuticals, responsible for the management of Pathology and both the Histology and Clinical Pathology laboratories. Leadership of the DACC for the past few years has focused on her clinical pathology skills, but Susan's dual boarding as both clinical and anatomic veterinary pathologist brought a different viewpoint of leadership to the division.

During her tenure in the chair role, Susan organized educational sessions focused on coagulation (2014 Lunch and Learn) and inflammation & immunity (2015 spring meeting). This past year, Susan directly offered her personal knowledge and experience to the AACC organization by hosting a brown bag session on species differences relevant to clinical laboratory parameters at this year's annual meeting.

We thank Susan for her service to the organization and congratulate her as the latest recipient of the Roy N. Rand Past-Chair award.

Susan's commendable service to the DACC includes:

Chair-Elect	2014
Chair	2015
Past-Chair	2016



Penelope Jones Receives a Certificate of Recognition

During a DACC awards reception at this year's AACC Annual Meeting **Penny Jones** of the AACC was presented a certificate of recognition in honor of her meritorious service, and administrative and educational support for the AACC's Division of Animal Clinical Chemistry (DACC) enhancing and advancing the practice and profession of animal clinical laboratory medicine.

Penny's loyal, and much appreciated, support for the DACC dates back to the 1980s.

Siemens Healthcare Diagnostics Receives a Certificate of Recognition

During a DACC awards reception at this year's AACC Annual Meeting David Metrena accepted a certificate of recognition, on behalf of **Siemens Healthcare Diagnostics**, in honor of continuing technology innovation and educational support for the AACC's Division of Animal Clinical Chemistry (DACC) enabling enhancing and advancing the practice and profession of animal clinical laboratory medicine.

Siemens loyal, and much appreciated, support for the DACC dates back to 1976, and began by providing refreshments for the very first Animal Group meeting.

DACC Fall Webinar Focuses on Drug-induced Vascular Injury

The DACC's commitment to providing relevant scientific education was further evidenced by this November's webinar, which focused on novel genomic and imaging strategies to detect drug-induced vascular injury (DIVI). The session featured the following excellent talks:

Vascular Imaging of Matrix Metalloproteinase Activity as an Informative Preclinical Biomarker of Drug-Induced Vascular Injury

Raymond J Gonzalez, PhD
Analytical and Biochemical Toxicology- Safety Assessment
Merck Research Laboratories, West Point, PA

Lack of widely applicable biomarkers that are specific to and either predictive or diagnostic of drug-induced vascular injury (DIVI) continues to be a major obstacle during drug development. Biomarkers derived from universal physiologic responses to vessel injury, such as inflammation and vascular remodeling, could make good candidates, however, they characteristically lack specificity for vasculature. We evaluated whether vascular remodeling-associated protease activity as well as expected changes to vessel permeability resulting from DIVI could be visualized *ex vivo* in affected vessels, thereby allowing for direct visual monitoring of the pathology to address the specificity gap. We found that visualization of MMP activation accompanied by increased vascular leakage (permeability), in the mesentery of rats treated with agents known to induce vascular injury correlated well with incidence and severity of DIVI histopathological findings and its associated inflammation, as well as with circulating levels of TIMP-1 and NGAL. The weight of evidence approach reported here shows promise as a collective DIVI preclinical tool by means of complementing non-invasive monitoring of circulating biomarkers of inflammation with direct imaging of affected vasculature, and thus lending specificity to its interpretation. These findings are supportive of a potential strategy that relies on translational imaging tools to complement circulating biomarker data for monitoring of vascular injury both preclinically and clinically.

Novel Genomic Strategies to Detect and Predict NonClinical Drug Induced Vascular Injury

Deidre A Dalmas, PhD, GSK Fellow
In Vitro & In Vivo Translation / Investigative Transcriptional and Cellular Safety
GlaxoSmithKline, King of Prussia, PA

Nonclinical drug-induced vascular injury (DIVI) is a challenging safety issue impacting various structural classes of potential pharmaceuticals which leads to attrition due to a lack of understanding of predictivity for clinical risk and lack of sensitive and/or translational biomarkers. Innovative strategies were developed to identify risks during precandidate screening enabling educated decision making to identify the "best molecule". Rats were given 28 different vascular toxicants with each toxicant given for 1 to 4 days at 3 different doses plus corresponding vehicle. Mesentery was collected using a novel technique and endothelial and vascular smooth muscle cells (EC, VSMC, respectively) were microdissected from each artery followed by GeneChip analysis. A novel panel of genes representing those which showed a dose responsive pattern for all treatments in which DIVI was histologically observed was developed and verified in EC- and VSMC-enriched samples and whole mesentery using TaqMan. Usefulness of the mRNA VI panel for prediction of DIVI was evaluated and confirmed in formalin-fixed paraffin embedded mesentery and in serum of rats administered two well established vascular toxicants. The novel gene panel has been utilized in an integrated fashion along with a strategy incorporating off-target *in vitro* screening for activity known to be reflective of vascular toxicants (e.g. PDE4 inhibitor (i)), and standard cardiovascular (CV) functional assessments. Application of the DIVI strategy in an *in vivo* case study following oral administration of 2 precandidate (PC) kinase inhibitors of unknown mechanism with/without in vitro PDE4i activity were conducted to identify DIVI potential. Utilization of the strategy, resulted in classification of 1 of the 2 PCs as a potential vascular toxicant based on *in vitro* evidence of PDE4i activity and alterations in genes shown to be predictive of DIVI; thus, enabling selection of the "best molecule" for further development. The comprehensive genomic VI tissue and circulating mRNA panels offer a refined list of candidate genes associated with and predictive of DIVI irrespective of compound class. This, collectively, with *in vitro* evaluation for off target activity and CV functional assessments, provides an integrated approach for detection and prediction of DIVI that can and has been utilized to aid in target and candidate selection and/or proactive design of development strategies to mitigate these potential risks. Overall, the candidate genes will hopefully lead to further refinements which are a critical first step in identification of translational clinical markers of DIVI.

William J. Reagan DVM, PhD, Diplomate ACVP Receives the 2016 DACC Award for Outstanding Contributions to Animal Clinical Chemistry

During a DACC awards reception at this year's AACC Annual Meeting the DACC Executive and Award Committees proudly presented **Bill Reagan**, from Pfizer, Groton, with the 2016 *DACC Award for Outstanding Contributions to Animal Clinical Chemistry*. This recognition reflects Dr. Reagan's extensive contributions and leadership in several areas of clinical pathology. Dr. Reagan is presently Research Fellow and Leader of the Global Clinical Pathology Discipline Group at Pfizer, Groton, CT.

Dr. Reagan has coauthored or authored over 85 publications including 40 peer-reviewed manuscripts, 12 books/chapters, and 35 posters.

For a more comprehensive description of Bill's focus of research, accomplishments, and contributions please see the July Edition of the DACC News.

In Memoriam of Gwen Edwards

Gwendolyn Edwards passed away unexpectedly in Philadelphia following the conclusion of the AACC Annual Meeting on Thursday, August 4, with her husband and children at her bedside.

Gwen was born in Gary, IN on March 16, 1960. She met her husband at Goshen College in 1978 and they married in 1980. Upon relocating to New Jersey after a stint in Florida, Gwen graduated Summa Cum Laude from Kean University in 1992 with a degree in Medical Technology. After working as a generalist at Chilton Memorial Hospital for 9 years, she began working in a GLP pharmaceutical environment for Johnson & Johnson PRD in Raritan, NJ. Bristol-Myers Squibb had the good fortune of hiring Gwen for their GLP clinical pathology lab in New Brunswick, NJ in 2011. Gwen attended numerous DACC Spring and Fall meetings, Siemens Multi-species Users Meetings and AACC Annual Meetings.

Gwen was also active in her church, sang in two choirs and directed the children's choir. She was also very involved in civic organizations and held various offices and served on several committees in a variety of capacities. Gwen loved to travel, adored her two grandchildren, and recently began golfing to spend more time with her husband. She was an excellent co-worker, an accomplished research scientist, energetic and always in good spirits. She will be greatly missed. ❖

DACC Travel Award for Best Poster Presentation at 2017 Annual Meeting

Abstract Deadline
Feb. 22, 2017

2017 AACC
Annual Meeting
San Diego, CA

For Award Consideration
Submit Your Abstract for
Inclusion in the
Animal Clinical Chemistry Session

The **DACC Travel Award** is given for the best poster featuring outstanding research in the area of Animal Clinical Laboratory Medicine presented at the Annual Meeting by DACC members, associates, or trainees (in academia or industry) in multispecies Clinical Pathology. Up to two posters may be selected for this award based on merit.

The Travel Award consists of a certificate of scientific merit, a **$500 cash award**, and travel reimbursement (up to $1000) to support the awardees' expenses to attend (registration fee waived) a DACC Spring Meeting. This Award is Sponsored by the DACC Executive and Awards Committees.

DACC Program Submitted for the 2017 Annual Meeting

Proposed* DACC Symposium

2017 AACC
Annual Meeting
San Diego, CA

"***Application of Emerging Translational Safety Biomarkers in Drug Development and Clinical Practice***"

**pending acceptance/rejection by the AACC*

This session will provide understanding of how/why the **biomarker translational gap** between preclinical and clinical studies exists and how new markers may bridge the gap to improve clinical trials in drug development and reduce attrition of new drug compounds during late stage clinical development, and to improve patient care via disease appropriate diagnostics to provide earlier and effective treatments.

Proposed Speakers:

Jiri Aubrecht
Pfizer
"Case Study: Use of GLDH as a Marker of Clinical Hepatotoxicity"

John-Michael Sauer
Critical Path Institute
"Case Study: Qualification of New Biomarkers of Acute Kidney Injury for Clinical Trials"

Vincent Ricchuiti
LabCorp
"Validation of LDTs Under CLIA Regulation"

2017 Division of Animal Clinical Chemistry Award for Outstanding Contributions to Animal Clinical Chemistry

The DACC has established a Division Award which recognizes Outstanding Contributions in the field of Animal Clinical Chemistry. This Award consists of a plaque, an honorarium and a reception for the individual so honored, and is usually presented at the AACC Annual Meeting. The DACC Awards Committee would like to invite all members and friends of the DACC to nominate such an honoree.

The Award is to recognize the achievements of an individual who has made significant contributions in the field of animal clinical chemistry in its broadest sense including teaching, training, practicing and research. Activities and achievements of this person, which have significantly benefited the science and advancement of this discipline, as well as enhanced the public awareness and understanding, are also taken into consideration.

The recipient of this prestigious award will be selected from nominations submitted by an AACC member or group of members such as division, local section, committee or commission. Nominations will also be considered from non-member individuals and organizations. Please submit your nomination by letter or e-mail. The submission should consist of a statement of the nominee's accomplishments and a current curriculum vitae and bibliography. Two seconding letters of support from colleagues detailing the candidate's accomplishments not given in the primary letter of nomination should be included. The latter will play an important role in the Awards Committee deliberations.

Previous recipients of the DACC award were:

Jiro J. Kaneko, DVM, PhD	1993	John H. (Tim) Lumsden, DVM, DACVP	2005
Eitan Bogin, PhD	1994	Douglas J. Weiss, DVM, PhD, DACVP	2006
Donald T. Forman, PhD	1995	W. Jean Dodds, DVM	2007
Robert E. Emmons, BS	1996	N. Leigh Anderson, PhD	2008
Walter F. Loeb, DVM, PhD	1997	Kay A. Criswell, PhD, DABT	2009
Thomas J. Reimers, PhD	1998	P. David Eckersall, BSc, MBA, PhD	2010
Jon P. Kimball, PhD	1999	Peter J. O'Brien, DVM, DVSc, PhD	2011
Dai T. Davies, PhD	2000	Jean-Pierre Braun, Dr Vét, Dr Sc,	2012
Walter E. Hoffmann, DVM, PhD	2001	Joseph F. Dooley, PhD, DABCC, FACB	2013
John W. Harvey, DVM, PhD	2002	Mary M. Christopher, DVM, PhD, ACVP	2014
Douglas A. Neptun, BS, MT/ASCP	2003	David Zelmanovic, PhD	2015
Charles C. Capen, DVM, PhD	2004	William Reagan, DVM, PhD, Dipl ACVP	2016

Nominations must be received no later than February 28, 2017.
Please submit completed nomination documents to:
Jon P. Kimball, PhD, DACC Awards Committee
1732 Old Lystra Road, Chapel Hill, NC 27517, 919-967-4016
Email: JonKimball@msn.com

Notes from Recent DACC Executive Committee Meetings

- Membership has decreased in the past few years, but is holding steady at this time.
- M&As and consolidations across our industry has led to travel budget reductions and decreased attendance at meetings.
- Attendance at this year's Spring Meeting held in CT provided rationale that future meetings should be held in the NJ / PA area to optimize turnout.
- A survey in early 2017 will assess prospects for member travel to optimize best location and topics.
- A survey conducted at this year's Annual Meeting determined which topics would attract the highest attendance, and these involve method development, instrument selection, and case studies in hematology and immunoassays.
- Member participation in the Artery continues to be relatively low, showing that it's not an ideal substitute for our previous Listserv, communication is on-going with the AACC to make improvements.
- AACC 2017 Annual Meeting in San Diego – based on the remote location attendance by DACC members is anticipated to be low.
- The DACC has collaborated with the Clinical Translation Science Division to co-sponsor a symposium at next year's Annual Meeting titled "Application of Emerging Translational Safety Biomarkers in Drug Development and Clinical Practice".
- The DACC continues to enjoy the support from Siemens Healthcare Diagnostics, Diagnostica Stago and Sysmex USA.

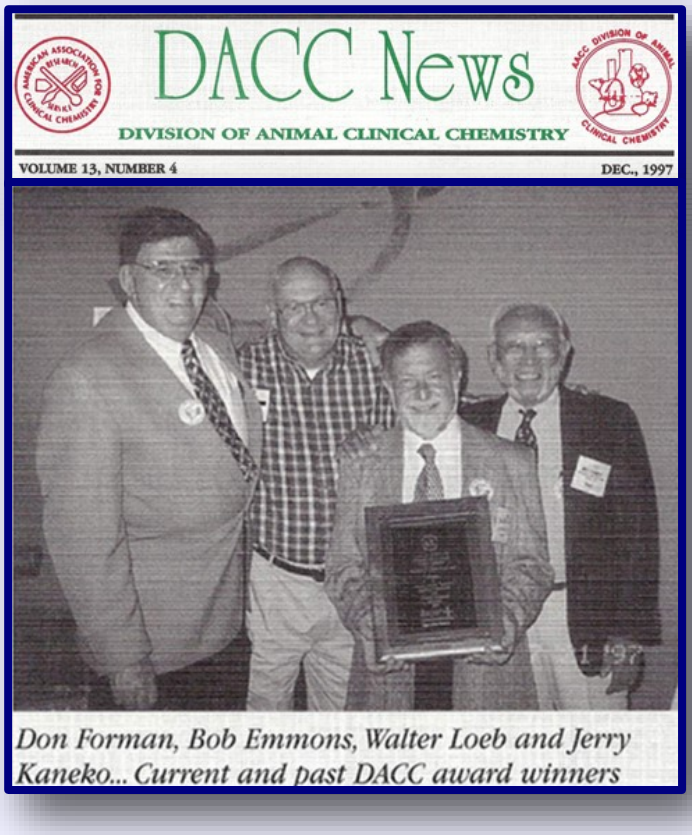
Remembering Our History

The APTT was first described in 1953 by researchers at the University of North Carolina at Chapel Hill explaining the 'Carolina Blue' Vacutainer tube top color.

Dr. Kenneth M. Brinkhous, who developed the first effective treatment for hemophilia was the first scientist to receive 50 years of continuous, research funding from the National Institutes of Health. He discovered numerous coagulation factors and assays which also gave rise to 'blue top' coag tubes.

Dr. Brinkhous discovered that hemophiliacs could not make a blood-clotting factor he named antihemophilic factor and which now is called factor VIII. Although not the disease's cause, lack of the protein results in life-threatening symptoms such as uncontrolled bleeding. At Chapel Hill, he and colleagues explained the genetics underlying disease transmission and showed that hemophilia also occurs in females.

They also developed a test to detect clotting disorders, the partial thromboplastin test, that is still used millions of times a day around the world and showed they could control hemophilia by first replacing Factor VIII through blood plasma. Another breakthrough was learning to purify and concentrate Factor VIII so that it worked far better. Brinkhous also became a world leader in explaining von Willebrand's disease, the clotting effects of snake venom and blood clotting leading to stroke and heart attacks.


DACC News

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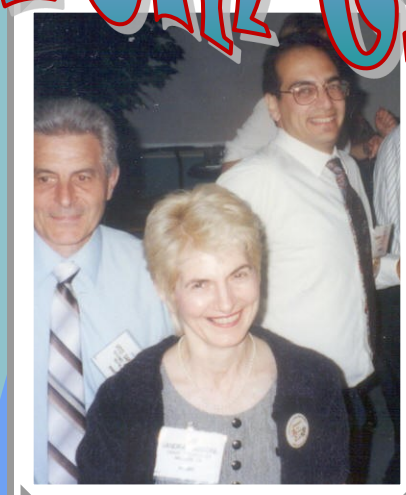
VOLUME 13, NUMBER 4 DEC., 1997

Don Forman, Bob Emmons, Walter Loeb and Jerry Kaneko... Current and past DACC award winners

Blast From The Past



1997 AACC Annual Meeting Atlanta

DACC Elections and New Officers

Lisa Manson
Charles River - Ashland
DACC's 2017 Chair-Elect

Lisa obtained a BS in Medical Technology from the University of Cincinnati. She worked in several hospital laboratories as a generalist, LIS coordinator, and hematology supervisor among many other responsibilities. In 2007 Lisa joined WIL Research in Ashland Ohio, currently Charles River Laboratories. She started out as a generalist and learned much about how a research lab operated, and trained in flow cytometry and became a project leader. Due to her expertise in lab computer systems she joined the validation team representing clinical pathology. Before long she was preforming all change controls, validations, and method validations for the lab. Her title then transitioned to supervisor. Lisa oversaw the technical staff in the laboratory, method developments, and the instrumentation. Writing technical documents and troubleshooting has been an important part of her profession (SOP's, validations, protocols and preliminary reports). Lisa has been a participant of many abstracts, worked as a principal investigator, and has been involved with global harmonization of laboratories. Lisa has not only accomplished this via teleconference and email, but has also traveled across the US and to several European countries. Her communication skills and leadership roles should provide Lisa with the necessary skills to be a successful Chair-Elect.

Samantha Wildeboer
Pfizer Global Research and Development
DACC's 2017 Treasurer

Samantha received her Masters of Clinical Laboratory Science from Rush University in Chicago, Illinois after attending Baylor University for her undergraduate degree. In May 2013, she graduated from Brown University with a Masters in Biology. Samantha's background includes medical technology generalist in the hospital laboratory environment, medical device pre-clinical study director, and antibacterial and cardiovascular therapeutic area project support. Samantha officially joined Pfizer in 2008, and currently works in Global Biomarkers, Clinical Pathology, Drug Safety Research and Development in Groton, CT and is currently an AACC/DACC member. Within clinical pathology, Samantha is a key operator in the hematology department and is a contact for CAP in hematology. She has performed and authored multiple instrument and assay validations and user guides, authors SOPs, has provided mentorship and training to new colleagues within the group and serves as a Cerner LIS administrator, performing appropriate training and system support. Samantha works closely with investigators to arrange sample analysis within the Clinical Pathology laboratory and providing excellent customer support. Additionally, Samantha works as a Project Manager for the ADC Investigative Project team. Samantha took over the DACC treasurer role in 2014, and was elected to her first two year term in 2015.

DACC Elections and New Officers *(continued)*

Matthew Larkin
Bristol-Myers Squibb
DACC's 2017 Nominating Committee

Matt is currently an Associate Research Scientist I in the Clinical Pathology Laboratory, Department of Drug Safety Evaluation at Bristol-Myers Squibb in New Brunswick, NJ. Matt graduated from the University of Delaware with a BS in Medical Technology. He has been working at Bristol-Myers Squibb for over 6 years and has gained valuable knowledge and expertise in all areas of veterinary clinical pathology. He was the co-author of a manuscript published this summer in the Journal of Veterinary Clinical Pathology. He has been a member of the DACC for the past 6 years and has regularly attended DACC and AACC meetings. Prior to joining Bristol-Myers Squibb, he worked at Raritan Bay Medical Center in Old Bridge, NJ in all areas of their clinical laboratory. In addition to his routine lab duties at BMS, Matt has authored several method verifications, participated in data acquisition system validations, and represented the clin path lab in extra-departmental activities. Matt is very interested in continuing to expand his involvement with the DACC.

Abstracts from the DACC Lunch & Learn -2016 Annual Meeting

Immunoassay Method Selection and Validation for the Pre-Clinical Laboratory

Steven Piccoli, PhD -Bristol-Myers Squibb

Validation expectations for biomarker assays are not the same as those for PK or TK assays. Qualification or implementation of biomarkers in drug development are evaluated such that the performance characteristics are in line with the Context Of Use and the benefit/risk profile. Assays used in the qualification or implementation of biomarkers in drug development are not sufficient for, and are not intended to be used as, de facto substitutes for an in vitro diagnostic device (IVD) or FDA approval. Qualified biomarkers are suitable for use in drug development and NDA submissions but are not assumed to be directly acceptable in, or transferrable to, clinical practice regulated by CLIA. Questions to consider for biomarker selection and validation include: Is the assay selective/specific for the analyte? Does anything interfere with the measurement? What are the measured and allowable limits? What happens beyond these limits? How much variability/error is there? How much accuracy/precision do I need? How do handling conditions affect the measurement? What preanalytical affects are important such as collection, transport, anticoagulant, sample storage/stability.

Consistent Assay Evaluation Process to Streamline Fit for Purpose Assay Validation and Transfer to GLP

Thomas Philip -Merck & Co Inc.

Presented as a practical set of guidelines for plate-based immunoassays with an example that is used within the Systems Toxicology group at Merck to factilitate validation. Outlined areas to consider in choosing to validate an assay - Creating validation sample sets, Data collection process, Added steps for GLP use, Assay comparison/Troubleshooting. Initial considerations include: GLP or non-GLP, Known species cross-reactivity, Sample type(s) required for assay, Availability of positive samples with increased values for assay evaluation, Creating correct number/type of samples for all plates (Precision, Spikes, Stability). An example plate template was shown that demonstrated how multiple facets of validation (linearity, precision, etc.) can be included on a plate to streamline data creation. An exhibit of an Excel sheet that automatically calculates the volume of sample needed to create pools and spike samples was shown. A caveat was given that once you validate an assay you must carefully monitor that it does not change due to vendor issues.

2016 DACC Travel Award Recipient: Tammy Lambert, GlaxoSmithKline

*Congratulations to **Tammy Lambert** and co-authors for winning the best poster competition for the Animal Division's Travel Award at the 2016 AACC Annual Meeting. This award is given for solid, scientific work that progresses our understanding of attributes of animal laboratory medicine. The award carries with it a $500 prize and travel to the DACC Spring Meeting.*

"Evaluation of the Meso Scale Discovery Rat Skeletal Troponin I Assay in Rat and Mouse"

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Abstract:
Skeletal troponin I (sTnI) is a member of the troponin complex of regulatory proteins required for muscle contraction. Recent evidence suggests that skeletal muscle injury results in leakage of sTnI into blood and measurement of serum or plasma levels of sTnI may provide a noninvasive biomarker of muscle injury. Our objective was to evaluate the Meso Scale Discovery (MSD) Rat Skeletal Troponin I Assay for measurement of skeletal troponin I in rat serum. Acceptable precision (CV ≤10%) and accuracy (RE ±13%) of standard curve values were observed across 10 analytical runs. Precision of sTnI values in rat serum samples was excellent (CVs ≤10%) at concentrations in the range of 5-150 µg/L; less precision was observed (CV=21%) in the area of the LLOQ (0.27 µg/L). Dilutional linearity (y=1114.8x – 4782.2; r2=0.99) and recovery (101-106%) of sTnI in rat serum was demonstrated. Serum sTnI was stable for up to 6 months at -80°C. Serum sTnI values in clinically healthy Wistar rats (n=20/sex) were below LLOQ to 11.4 µg/L for males and at or below LLOQ for females. In two nonclinical safety studies, sTnI increases (to 1984 µg/L) correlated with histologic evidence of myofiber degeneration and/or necrosis and increases in AST and aldolase. In mice, sTnI increases (474 to 1859 µg/L) were observed in plasma of muscular dystrophy mutant mice (C57BL/10ScSn-mdx/J) compared to wild-type C57BL mice (0.38 to 3.09 µg/L). In conclusion, the MSD rat skeletal troponin I assay performed well and sTnI increases correlated with skeletal muscle injury in rats and mice.

Recap of the Science and Practice Core Committee Meeting

The Science and Practice Core Committee (SPCC) is a new governance group. Under the new AACC structure, SPCC will assume the function of the Division Management Group, which was retired with the new governance structure. The SPCC is tasked with evaluating current divisions individually and the division portfolio as a whole, identifying potential overlap, opportunities for synergy, or gaps in the portfolio's breadth.

The group agreed the most important strategies for the SPCC were those relating to promoting appropriate test utilization, developing vehicles for members to network and collaborate, expanding membership beyond the traditional laboratory medicine community and strengthening the focus on science and technology. Members were particularly interested in test utilization and suggested the SPCC could contribute to this strategy by creating a list of improperly used tests. The content of the list could be developed and disseminated to multiple stakeholder groups.

Committee members also suggested that a new submission category for the Annual Meeting soliciting new and impactful research might help address the strategy of highlighting cutting-edge science. The committee also suggested tracking new laboratory technologies released in Europe to help SPCC and AACC members remain updated with emerging technology.

The SPCC discussed the drafted charge and suggested changes to reflect the focus on the activities as discussed above. The committee devised the following charge:

The Science and Practice Core Committee (SPCC) is charged with overseeing AACC's scientific activities and the translation of science and technology into clinical practice in the field of laboratory medicine. The SPCC ensures that the breadth of scientific interests of the AACC membership is represented in the association's programs and initiatives. The SPCC also contributes to identifying and fostering the latest advances in research and innovation in laboratory medicine. The committee manages AACC's engagement in science- and practice-related activities with outside organizations.

Current programs which fall under the auspices of the SPCC including management of the division portfolio, scientific liaison activities, and the Universal Sample Bank. At the meeting in Atlanta hundreds of "normal" AACC attendees gave blood. From those donations the AACC has created a bank of sample sets that were used for a troponin study. Sample sets can also now be purchased, typically by vendors.

The committee will also be tasked with overseeing AACC liaisons to outside organizations whose activities are science-focused. The SPCC will evaluate the activities individually and as a whole to identify a set of collaborations that provide maximum benefit to the association and the liaisons. Once the committee has established the optimal set of activities, it will communicate regularly with the liaisons to ensure their activities are adequately supported and that AACC is realizing the greatest possible impact from the engagement.

Much of the focus of this group is highly human clinical-based. Suggesting tests that are overused or improperly used in practice and looking at the AACC participation in outside quality groups. Of most interest to the Animal Division is a feeling among the members that AACC is not doing enough with promoting new technology and also the emphasis on encouraging more interactions between divisions.

This meeting was held at Lansdowne Resort, Leesburg, VA, 9/30/16

Photos from the 2016 AACC/DACC Annual Meeting –Philadelphia, PA

Photos from the 2016 AACC/DACC Annual Meeting *(continued)*

See More Photos from the
2016 Annual Meeting at:
https://daccphotos.shutterfly.com/pictures
Thanks to DACC Photographer
Joe Sansone!

Short Scripts.....

Congratulations to
Tammy Lambert
from GlaxoSmithKline
Best Poster Winner!

Liane Yanas & Doug Thudium:
Co-Winners of the 2016 Button Design Contest

Sue Grindle retires from Jackson Labs. She has been an invaluable asset to the DACC and a scientific resource to our industry regarding mice.

ACVP / ASVCP ANNUAL MEETING
December 3-7, 2016
New Orleans

AACC ARTERY
Animal Clinical Chemistry
Forum Resource Center

https://community.aacc.org/divisions/animal_clinical_chemistry

The Membership of the DACC Extends a Huge *THANK YOU* to Sysmex America, Diagnostica Stago, and GlaxoSmithKline for Hosting the DACC Lunch & Learn!

All DACC Committees Are Seeking Members to Join
Every Aspect of the DACC Depends on the Volunteerism of People Like YOU!