

Animal Clinical Chemistry



“Cardiac and Skeletal Muscle Injury In Drug Development: Advances in Biomarkers, Assessment and Clinical Translation”

AACC Animal Clinical Chemistry Division Spring Meeting
April 19th, 2013

CONFERENCE INFORMATION

Who Should Attend

Leaders in the field of clinical pathology, clinicians, pathologists, laboratory directors, laboratory scientists, and professionals engaged in biomarker research and development, laboratory consultants, pharmaceutical scientists, diagnostic manufacturers, and other individuals interested in cardiac and skeletal muscle injury, biomarker advancement, assessment and clinical translation.

Purpose of Meeting

The purpose of the AACC 2013 Spring Meeting is to 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 assay, models, and biomarkers to more accurately predict these toxicities at earlier stages of drug development remains a critical issue.

Learning Objectives

After attending this conference, participants will be able to:

- 1) Explain the current preclinical in vitro assays and models used to improve drug development attrition and predict skeletal and cardiac injury
- 2) Describe the role of established and emerging biomarkers for prediction of skeletal and cardiac toxicity in drug development.
- 3) Recognize major mechanisms of skeletal and cardiac toxicity and drug-induced skeletal and cardiac injury.

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Symposium Planning Committee

Richard Giovanelli, DACC Chair, Principal Organizer

Kay Criswell, DACC Past Chair

Jon Kimball

Support

This meeting is hosted and sponsored by the Drug Safety Department of Novartis Pharmaceutical Research & Development.

PROGRAM: “Cardiac and Skeletal Muscle Injury In Drug Development: Advances in Biomarkers, Assessment and Clinical Translation”

The meeting will be held at: **Novartis Institutes for BioMedical Research**, East Hanover, NJ

Friday, April 19th, 2013

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

8:30 – 8:45am **Welcome from the DACC Chair**
Richard Giovanelli, Clinical Pathology Lead
Pfizer Inc., Groton CT

Skeletal Muscle Injury

8:45 – 9:05am **Application of MSD Muscle Injury Panels across Species**
Richard Goldstein BS/BS MT (ASCP), Senior Scientist
Biomarker Development and Translation
Pfizer Inc., Groton, CT

9:05 – 9:45am **Novel Skeletal Muscle Toxicity Biomarkers: Preclinical Qualification and Clinical Translation**
Warren Glaab, Ph.D.
Safety Assessment and Laboratory Animal Resources, Systems Toxicology,
Investigative & Laboratory Sciences, Merck Research Laboratories
West Point, PA

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- 9:45 – 10:00am **Break**
- 10:00 – 10:40am **Identification and Clinical Translation of Early Predictive Biomarkers Using Modern Metabolic Approaches**
Brante Sampey, Ph.D.
Senior Study Director
Metabolon
- 10:40 – 11:20am **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
- 11:20am-12:00 **Balancing Efficacy versus Safety: Learning's from Development of Myostatin Inhibitors**
Carl Morris, PhD., Director, Protein Therapeutics and Muscle Biology
Pfizer Rare Disease Research Unit
Cambridge MA
- 12:00 – 1:00pm **Lunch**
- Cardiac Injury**
- 1:00 – 1:40pm **Role of Contractility Measurements in Preclinical Cardiovascular Safety Assessment**
Gregory Friedrichs, Ph.D
Global Head, Safety Pharmacology
Novartis Pharmaceuticals Corporation
East Hanover, NJ

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1:40 – 2:20pm **Regulatory Qualification and the Use of Cardiac Troponin as a Preclinical Biomarker**
Dr. William J. Reagan, Research Fellow,
Pfizer Global Research & Development
Groton, CT

2:20 – 2:35pm **Break**

2:35 – 3:15pm **The Application and Translatability of N-Terminal Proatrial Natriuretic Peptide in Non-Clinical Drug Safety Evaluation**
Michael Dunn, PhD
Non-Clinical Safety, Roche
Nutley, NJ

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

MEETING COST:
\$85 – Members
\$125 – Non-members

Electronic Registration for the 2013 DACC Spring Meeting is Open

Please register at: <http://www.aacc.org/events/conferences/pages/default.aspx#>

TRAVEL & HOTEL
Hanover Marriott
1401 Route 10 East, Whippany, NJ 07981
GPS Address is 2 Ridgedale Ave, Cedar Knolls NJ

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Novartis Institutes for BioMedical Research

PCS Clinical Laboratory

USEH, 406-218

Novartis Pharmaceuticals Corporation

One Health Plaza

East Hanover, NJ 07936-1080

USA

Directions from Hanover Marriott Hotel to Novartis Institutes for BioMedical Research, Novartis Pharmaceuticals Corporation site:

- From Hanover Marriott, 1401 Route 10 East, Whippany, NJ 07981, 973-538-8811
- Exit front entrance of hotel, turn right on to Route 10 East,
- Continue approx. 3.5 miles and turn right onto Ridgedale Avenue South. Novartis entrance will be on the left.
- Arrive at Novartis, One Health Plaza, East Hanover, NJ 07936

Parking at Novartis:

Enter at Novartis, see security for instructions

Hotel Accommodations

Hotel name: Hanover Marriott Whippany NJ

Hotel address: 1401 RT-10, Whippany, NJ

Hotel phone: 1-973-538-8811

Hotel web address: www.marriott.com/hotels/travel/ewrho-hanover-marriott/

Room rate: \$179 for a standard room: Please use **DACC Meeting** when calling in to obtain the group rate).

Transportation from closest airports to hotel:

Newark Liberty International Airport (EWR)

- Distance 24.0 miles SE to hotel
- From NEWARK AIRPORT: Exit Newark Liberty Int'l Airport. Take Rte 78 West to Rte 24 West (Morristown) to Rte 287 North to Exit 39 (Route 10 West). Go through one stoplight; take next u-turn, hotel on right.

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La-Guardia Airport (LGA)

- Distance 45 miles
- Take Grand Central Parkway to the Tri Boro Bridge to Major Degan Expressway North to the George Washington Bridge to 80 West to exit 43 to 287 south to exit 39B-Route 10 West. Take the Cedar Knolls U-turn and the hotel will be on the right

JFK International Airport (JFK)

- Distance: 61.0 Miles
- Take the Van Wyck Expressway to The Whitestone Expressway. Go over Bronx Whitestone Bridge, to the Cross Bronx Expressway to the George Washington Bridge. Take Route 80 West to Exit 43, 287 South. Take Exit 39B, Route 10 West. Go through first traffic light (you will see the hotel on other side of highway at this point), stay in right lane and take second right after the light (sign reads Cedar Knolls U-Turn). This will bring you to Route 10 East. We are the first entrance on right.

FROM ATLANTIC CITY/JERSEY SHORE

Take the Atlantic City Expressway West to the Garden State Parkway North to Route 287 North. Follow to Exit 39, Route 10 West. Go through first traffic light (you will see the hotel on other side of highway at this point), stay in right lane and take second right after the light (sign reads Cedar Knolls U-Turn). This will bring you to Route 10 East. We are the first entrance on right.

FROM NORTHWEST NEW JERSEY/POCONO AREA

Take local roads to I-80 East. Take I-80 East. Exit 43 to I-287 South. Take Exit 39B, Route 10 West. Go through first traffic light (you will see the hotel on other side of highway at this point), stay in right lane and take second right after the light (sign reads Cedar Knolls U-Turn). This will bring you to Route 10 East. We are the first entrance on right.

FROM CENTRAL & SOUTHWEST JERSEY

Take NJ Turnpike North to Exit 10, Route 287 North. Follow Route 287 North to Exit 39, Route 10 West. Go through first traffic light (you will see the hotel on other side of highway at this point), stay in right lane and take second right after the light (sign reads Cedar Knolls U-Turn). This will bring you to Route 10 East. We are the first entrance on right.

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FROM THE LINCOLN TUNNEL

Take Lincoln Tunnel to Route 3 West to I-80 West. Take I-80 West to I-287 South. Take Exit 39B, Route 10 West. Go through first traffic light (you will see the hotel on other side of highway at this point), stay in right lane and take second right after the light (sign reads Cedar Knolls U-Turn). This will bring you to Route 10 East. We are the first entrance on right.

FROM THE GEORGE WASHINGTON BRIDGE

Take bridge over to New Jersey and follow signs for I-80 West. Take I-80 West to I-287 South. Take Exit 39B, Route 10 West. Go through first traffic light (you will see the hotel on other side of highway at this point), stay in right lane and take second right after the light (sign reads Cedar Knolls U-Turn). This will bring you to Route 10 East. We are the first entrance on right.

FROM THE TAPPAN ZEE BRIDGE

Take the bridge to Route 87 North, to I-287 South. Take Exit 39B, Route 10 West. Go through first traffic light (you will see the hotel on other side of highway at this point), stay in right lane and take second right after the light (sign reads Cedar Knolls U-Turn). This will bring you to Route 10 East. We are the first entrance on right.

Train /Hotel Shuttle

- Station Name: Morris Plains on the Morris/Essex Line
- Direct train from NY Penn Station as well as Penn and Broad Street in Newark
- No Hotel Shuttle Available
- Broadway Elite for shuttle arrangements outside 5 miles www.broadway-elite.com

Special Events

April 18th: 2013 Siemens Advia Users Group meeting

- Please contact Lois Brisben via email at lois.brisben@siemens.com or contact her at 847-236-7208 or 847-323-9793.

April 18th: Division of Animal Clinical Chemistry (DACC) Speaker Reception/DACC Mixer

- Private Dining Room in Seeds Restaurant Hanover Marriott, 1401 Route 10 East, Whippany, NJ 07981 (GPS Address is 2 Ridgedale Ave, Cedar Knolls NJ) 6:30 – 8:30 p.m. – Sponsored by IDEXX.

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Please confirm your plans to attend the Speaker's Reception by close of business April 12th, 2013 to richard.p.giovanelli@pfizer.com

For DACC Spring Meeting questions please contact Richard Giovanelli DACC Chair at richard.p.giovanelli@pfizer.com or 860-686-2176 or 860-204-6698