

FACULTY

Robert S. Rosenson (co-chair)

MD, FACC, FAHA, FACP, FESC, FNLA, Icahn School of Medicine at Mount Sinai, New York, NY

Paul D. Thompson (co-chair)

MD, FACC, FAHA, Hartford Hospital, Hartford, CT

Erik S. G. Stroes (co-chair)

MD, PhD, Academic Medical Center, Amsterdam, Netherlands

Steven Baker

MD, MSc, FRCPC, Mc Master University, Hamilton, ON

Maciej Banach

MD, FAHA, FNLA, FESC, Medical University of Lodz, Poland

Ken Borow

MD, MediMergent, Philadelphia, PA

Lynne Braun

PhD, CNP, FAHA, FAANP, FPCNA, FAAN, Rush University Medical Center, Chicago, IL

Eric Bruckert

MD, Hôpital de la Pitié Salpêtrière, Paris, France

Liam R. Brunham

MD, PhD, University of British Columbia, Canada

Robert M. Califf

MD, MACC, FDA, New Hampshire

Alberico Catapano

PhD, University of Milan, Milan, Italie

Andrew L. Mammen

MD, PhD, National Institutes of Health, Bethesda, Maryland

John Mancini

MD, University of British Columbia, Vancouver, Canada

Patrick Moriarty

MD, FACC, FACP, University of Kansas, Kansas city, KS

Paul Muntner

PhD, University of Alabama, Birmingham, AL

Kausik Ray

MD, MPhil, Imperial College London, London, UK

Beth Taylor

PhD, University of Connecticut, Hartford, CT

Valérie Taylor

MD, PhD, University of Toronto, Ontario, Canada

Gerald Watts

DSc, MB, BS, PhD, DM, FRCP, FRACP, Royal Perth Hospital, Perth, Western Australia, Australia

A TMA CONSENSUS BUILDING FORUM

ON STATIN ASSOCIATED MUSCLE COMPLAINTS

13th & 14th

JANUARY 2017

WASHINGTON DC, USA

GENERAL INFORMATION

Where?

The Hotel at Arundel Preserve
7795 Arundel Mills Boulevard
Hanover, MD 21076

General information

TMA Foundation

Charles Schoen

Email: charles.schoen@tmacademy.org

Tel.: +33 (0) 6 08 18 77 08

Grant Sponsorship Opportunities (including CME, Advisory Boards & Customized Grants)

William Melhuish / Yann Colardelle

TMA Grant office

Tel.: + 33 (0) 6 16 54 81 57

Email: yanncol@tmacademy.org and

william.melhuish@tmacademy.org

Contact organization

Anne-Sophie Squiban

Email: annesophie.squiban@tmacademy.org

Tel.: +33 (0) 6 74 52 37 09

REGISTRATION

tmacademy.org >> Events

AGENDA

A TMA CONSENSUS BUILDING FORUM

ON STATIN ASSOCIATED MUSCLE AFFLICTIONS

13th & 14th

JANUARY 2017

WASHINGTON DC, USA

Optimizing utilization of Evidence-Based therapies
and new solutions outcomes



TRANSLATIONAL
MEDICINE ACADEMY

AGENDA

The Translational Medicine Academy (TMA) is an international academic Foundation with focused activities in mission critical areas of high public health importance having significant professional and patient therapeutic and educational gaps.

Why a Statin Associated Muscle Afflictions Building Forum?

Statins have consistently been shown to reduce cardiovascular events, and their continued use remains the first priority in high-risk individuals. Unfortunately, statins have side effects that make them intolerant to 10 to 20 percent of individuals. Statin intolerance is associated with more hospitalizations for cardiovascular events in patients previously hospitalized for myocardial infarction. The most common and reproducible manifestation of statin intolerance results from statin associated muscle afflictions (SAMS). In order to reduce cardiovascular morbidity, reduce medical costs and improve the quality of life for patients who are intolerant to statins, the major objective of this conference is to collaborate on clinically useful and validated tools for the identification of SAMS that are useful for patients of different ethnicities, races and regions of the world; develop clinical algorithms that provide a rationale and evidence-based approach to the re-introduction of statins; and provide guidance based on published reports for the use of non-statin cholesterol lowering therapies.

PRELIMINARY PROGRAM

1st Session - Day 1

Meeting goals and objectives

8:00 a.m. - 8:15 a.m. - Chair: Robert S. Rosenson

How are the guidelines developed?

What you can & cannot expect guidelines to say: levels of recommendations, strengths of evidence & the review process

8:15 a.m. - 8:45 a.m. - Kausik Ray (30 min.)

Scope of the problem; Statin Intolerance in clinical practice versus clinical trials

8:45 a.m. - 10:45 a.m. - Chair: Robert S. Rosenson and Erik. Stroes

- Definitions — Review of Consensus Documents - John Mancini (20 min.)
- Review of registry and health claims data - Eric Bruckert (20 min.)

Objectives of the Forum

- Review the spectrum of statin intolerance (muscle events).
- Develop a uniform nomenclature for the various manifestations of SAMS.
- Provide a structured assessment for the evaluation of statin muscle intolerance including a clinical statin associated adverse muscle event index for the practicing healthcare professional and the patient. This effort will involve development of a smart phone/computer application.
- Review and develop objective clinical tools for the assessment of statin intolerance.
- Discuss the use of genetic markers in the diagnosis of various manifestations of SAMS.
- Review treatment approaches that include challenge and re-challenge with a second statin agent, alternate day dosing regimens, combination therapy with low dose statin and non-statin therapy.
- Discuss published trials on novel therapies in SAMS individuals.
- Develop prototype clinical design for evaluation and management of SAMS.

- Claims based algorithm for the assessment of statin intolerance and clinical events in statin intolerant individuals - Economic challenges for use of novel therapies - Paul Muntner (25 min.)
- Disconnect between patient surveys and randomized clinical trials - Kausik Ray (20 min.)
- Discussion

// BREAK //

Clinical trials for statin muscle intolerance: Strengths and weakness of available data

- 11:15 a.m. - 12:45 p.m. - Chair: Kausik Ray
- GAUSS 1, 2 and 3 - Erik Stroes (15 min.)
 - Odyssey Alternative - Patrick Moriarty (15 min.)
 - ACL Inhibitor (bempedoic acid) - Paul Thompson (15 min.)
 - Discussion

//LUNCH//

2nd Session - Day 1

Pathophysiology, Mechanisms underlying Statin intolerance: What do we know?

1:45 p.m. - 3:15 p.m. - Chair: Paul Thompson

- Histopathology and mechanisms - Steven Baker (15 min.)
- Autoimmune myositis - Andrew L. Mammen (15 min.)
- Marker of underlying neuromuscular disorders and genetic markers - Liam R. Brunham (15 min.)
- Special populations: Autoimmune arthritis and fibromyalgia - Thyroid disease: Steven Baker (15 min.)
- Discussion

// BREAK //

Diagnosis, Statin intolerance evaluating diagnostic tools

3:15 p.m. - 5:00 p.m.: Chair: Beth Taylor

- Assessment of muscle function - Beth Taylor (15 min.)
- Muscle biopsy - Steven Baker (15 min.)
- Genetic talks (2) - Paul Thompson, Erik Stroes (30 min.)
- Validation of clinical tools - Beth Taylor (15 min.)
- Discussion

Therapeutic Approach: solutions

5:30 p.m. - 7:00 p.m. - Chair: Alberico Catapano

- Drug Interactions and polypharmacy - Alberico Catapano (15 min.)
- HIV and ART: Experience from MarketScan and CNICS - Robert S. Rosenson (15 min.)
- Vitamin D, Coenzyme, Q10 - Maciej Banach (15 min.)
- Nutraceuticals - Gerald Watts (15 min.)
- Discussion

3rd Session - Day 2

Patient Perspectives

8:15 a.m. - 9:15 a.m. - Chair: Lynne Braun, Beth Taylor

- Psychosocial aspects - anxiety and depression (15 min.) Valerie Taylor
- Treatment Adherence - Lynne Braun (15 min.)
- Discussion

Regulatory Perspective on Statin Intolerance - (KEYNOTE LECTURE)

9:15 a.m. - 10:15 a.m. - Chair: Robert M. Califf (30 min.)

- Discussion

// BREAK //

Systems approaches to early identification of statin muscle intolerance:

10:45 a.m. - 12:00 p.m. - Chair: Eric Bruckert

- Real life studies - Paul Muntner (30 min.)
- Real-world evaluation of statin intolerance — The patient perspective - Ken Borow (20 min.)
- Discussion

Industry Roundtable discussion // 12:00 p.m. — 12:45 p.m.

Format

A series of short presentations and discussions with a focus on practical examples, case studies and dynamic interactive dialogues originating from areas of specialized expertise.

Goal

Deliver a consensus document leading to a more comprehensive understanding of statin intolerance and advance therapeutic approaches. Develop tools for patient self-identification of statin associated muscle adverse events and promote adherence to medical therapies to improve long-term health outcomes and quality of life.

Who is attending?

Industry representatives, clinical research organizations, health insurance system professionals, pharmacy benefits managers and all those interested in statin intolerance from a scientific, regulatory, educational and cost-benefit management perspective.

++ Expert Panel Session Working Groups (Faculty only) - 1.00 p.m. — 4:00 p.m.: Includes Lunch Break

- Panel 1 // Guidance on optimal clinical research study design for evaluation of statin intolerance/Clinical Algorithm: - Chair Robert Rosenson
- Panel 2 // Genetic Tools - Chair: Paul Thompson
- Panel 3 // Tools for patients - Chair: Lynne Braun, Beth Taylor
- Panel 4 // Managing co-morbidities and drug interactions, - Chair: Alberico Catapano

Saturday 4:00 p.m. - 5:30 p.m. Meeting report and publications