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**June 19-21, 2018** | Boston, MA, USA
www.sdd-summit.com

# SDD Scleroderma Drug Development

## Solve the Translational Challenges Limiting Disease Modifying Scleroderma Therapeutic Development

## 18 Expert Speakers Include:

**Marek Honczarenko**
Vice President
Immunology Development
**AbbVie**

**Jeffrey Siegel**
Global Head
Rheumatology &
Rare Diseases
**Genentech**

**Donald Zoz**
Senior Associate Director
Clinical Development &
Medical Affairs IPF/ILD
**Boehringer Ingelheim**

**Mark Tepper**
President &
Chief Scientific Officer
**Corbus Pharmaceuticals**

"Highly interactive conference with excellent presentations and exciting data" **Ablynx**

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**www.sdd-summit.com**

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# Welcome to **Scleroderma Drug Development Summit**

## Identify & Validate Disease Modifying Targets, Establish Clinically Effective Outcome Measures Beyond the Rodnan Skin Score & Leverage Experiences of Preclinical Models to More Robustly Inform *In Vitro & In Vivo* Decisions

SDD is industry's first drug developer dedicated discussion and networking forum committed to **solving the translational challenges limiting disease modifying scleroderma therapeutics.**

Built with 20+ research heavyweights including **University of Michigan, Genentech** and **Boehringer Ingelheim**, this intimate summit will benchmark the latest developments, insights and science to elevate clinically effective scleroderma therapeutic pipelines.

**Join your peers to:**

- Outline advancements in clinical trials, including the re-direction of successful candidates in idiopathic pulmonary fibrosis (IPF), to **enhance the clinical development of your candidate**
- Deepen your understanding of fibrosis and autoimmune pathological triggers driving systemic sclerosis to **better identify therapeutically effective targets**
- Objectively discuss and analyze the biomarker landscape supporting scleroderma pipeline development to **inform future predictive, prognostic and pharmacodynamics biomarker decisions**

You'll leave this comprehensive forum equipped with the knowledge and connections to advance your next 12 months of scleroderma research.

## What Previous Hanson Wade Event Attendees Have Said:

"Speed networking and round table discussions were great"
**Genentech**

"An excellent opportunity to find out what other pharma are doing and what's emerging. Very valuable"
**AstraZeneca**

"Very valuable useful information – one of the best meetings I've ever attended"
**Takeda**

## Top 5 Reasons to Attend SDD:

**1.** Debate and outline **promising and achievable clinical endpoints that reach the satisfaction of regulatory bodies** with Corbus Pharmaceuticals

**2.** Investigate the successes of re-purposed candidates with Boehringer Ingelheim and Celgene to **better understand the potential of your anti-fibrotic and anti-inflammatory drug**

**3.** Benchmark against positive preclinical and clinical results with Genentech, TherimuneX and Emerald Health Pharmaceuticals to **heighten your understanding of the current drug landscape**

**4.** Address the limitations of *in vitro* and *in vivo* preclinical models in the context of fibrosis recapitulation and systemic sclerosis multi-organ pathology with iBio to collectively **drive innovation needed to improve translatability into the clinic**

**5.** Discuss the value and limitations of the current biomarker landscape with AbbVie, with a view to **determine the most promising prognostic, predictive and pharmacodynamic biomarkers to optimize clinical trial design**


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www.sdd-summit.com

# Your 18 Expert Speakers

**Alain Rolland**
Vice President, Product Development
**Emerald Health Pharmaceuticals**

**Barbara White**
Chief Medical Officer
**Corbus Pharmaceuticals**

**Bruce Riser**
Chief Executive Officer
**BLR Bio**

**Carol Artlett**
Director of Fibrotic Disease
**TherimuneX Pharmaceuticals**

**Donald Zoz**
Senior Associate Director, Clinical Development & Medical Affairs IPF/ILD
**Boehringer Ingelheim**

**George Tsokos**
Senior Medical Research Advisor
**TherimuneX Pharmaceuticals**

**Gerald Horan**
Director Translational Science
**Celgene**

**James Thacker**
Chief Executive Officer
**TherimuneX Pharmaceuticals**

**Janet Pope**
Professor of Medicine, Division of Rheumatology & Epidemiology & Biostatistics
**University of Western Ontario**

**Jeffrey Browning**
Research Professor
**Boston University**

**Jeffrey Siegel**
Global Head Rheumatology & Rare Diseases
**Genentech**

**Jeremy Caldwell**
(former) Executive Vice President & Chief Scientific Officer
**Ardelyx**

**Marek Honczarenko**
Vice President, Immunology Development
**AbbVie**

**Mark Tepper**
President & Chief Scientific Officer
**Corbus Pharmaceuticals**

**Nicolas Wisniacki**
Head of Translational Medicine Experimental Medicine Unit/ Immunoinflammation
**GSK**

**Robert Simms**
Clinical Core Principal Investigator
**Boston University Scleroderma Center of Research Translation**

**Terrence Ryan**
Chief Scientific Officer
**iBio**

**Timothy Radstake**
Professor of Translational Immunology
**Academic Medical Center Utrecht**

> I like Hanson Wade's way of putting together smaller, but more specific meetings. It's definitely my favourite and I'm coming back next year
> **EMD Serono**

# Conference Day One | Wednesday, June 20

**Janet Pope**
Professor of Medicine, Division of Rheumatology & Epidemiology & Biostatistics
**University of Western Ontario**

**8.20 Chair's Opening Remarks**

## Understanding Systemic Sclerosis as a Disease & Therapeutic Target

**Janet Pope**
Professor of Medicine, Division of Rheumatology & Epidemiology & Biostatistics
**University of Western Ontario**

**8.30 Should SSc Drug Development Look More Like Rheumatoid Arthritis or Systemic Lupus Erythematosus?**

- Contrasting RA development where often treatment is added on to a background therapy with inadequate response vs. SLE where approximately half the patients are on background immune suppression
- Understanding that highly effective drugs in RA have at most 60 to 70% of patients getting 20% better (ACR20) vs. SLE where sample sizes are very optimistic and drugs often don't meet the hurdle
- Comparing outcome measures where in SLE sub scores are 'all improved' vs. 'not' whereas in RA there can be a percentage improvement

**Barbara White**
Chief Medical Officer
**Corbus Pharmaceuticals**

**9.00 Achieving Meaningful Clinical Benefit for Systemic Sclerosis Without Immunosuppression**

- Outlining the mechanism of action of anabasum – an oral selective CB2 agonist effective in the resolution of inflammation and fibrosis
- Reviewing the latest results from Phase 3 RESOLVE-1 study

**9.30 Speed Networking**

This session is your opportunity to get face-to-face time with many of the brightest minds working with scleroderma drug development. Share your advancements in one-to-one conversations with peers and establish meaningful business relationships to pursue for the rest of the conference.

**10.30 Morning Refreshments**

## More Robustly Manipulating Preclinical Models for Improved Translation into the Clinic

**Terrence Ryan**
Chief Scientific Officer
**iBio**

**11.30 Novel Plant-Manufactured Biologic with Significant Anti-Fibrotic Properties**

- Detailing a fusion protein that reduces collagen content of ex vivo scleroderma and IPF human lung tissue
- Demonstrating the reduction of pulmonary fibrosis in mouse bleomycin model comparable to pirfenidone
- Showcasing reduction in mouse skin thickening after TGFβ induction and established fibrosis when administered i.p. or orally

**Marek Honczarenko**
Vice President Immunology Development
**AbbVie**

**Jeremy Caldwell**
(former) Executive Vice President & Chief Scientific Officer
**Ardelyx**

**Terrence Ryan**
Chief Scientific Officer
**iBio**

**12.00 Think Tank Roundtables Sessions**

More practical and highly interactive breakout roundtables where attendees can crowd-source solutions and share opinions around pre-assigned topic areas. A valuable chance for attendees to unite around hot topics and debate best practice. No more sitting quietly, this is a dedicated opportunity for you to voice your experiences and identify unique solutions.

**1.** Comparing and contrasting the similarities and differences in fibrosis tissue to ascertain whether fibrosis is just an *in vivo* phenomenon or whether a general fibrosis model is achievable

**2.** Debating the involvement of various cell types for a multi-cellular *in vitro* model

**3.** Achieving an aligned view on highest valued and more relevant *in vivo* model with specific focus on avoiding false positive results

**12.30 Moderator Feedback & Audience Debate**

Moderators will be assigned to each roundtable to facilitate discussion and collate the findings. Following the roundtables, they will present back to the entire delegation as part of a panel discussion for information dissemination.

**1.00 Lunch & Networking**

## Reviewing the Pathological Triggers of Systemic Sclerosis to Identify Novel Therapeutic Targets

**Timothy Radstake**
Professor of Translational Immunology
**Academic Medical Center Utrecht**

**2.00 Novel Pathways Driving Fibrosis Independent of the Usual Suspects**

- Critically reviewing the inflammation-fibrosis paradigm
- Isolating and analyzing transcriptomics, epigenomics, metabolomics and proteomics to identify patient specific causative molecular pathways

**James Thacker**
Chief Executive Officer
**TherimuneX Pharmaceuticals**

**2.30 Evaluating the NLRP3 Inflammasome as Driving Immunopathology in Fibrotic Disease**

- Discussing the key role of the store operated calcium channel protein (TRPC1)
- Identifying a new signaling peptide "acALY18" excised from TRPC1
- Down regulating active NLRP3 and detailing the roles of acALY18 and spliced X-box protein (XBP1s), as well as the role of the unfolded protein response (UPR)

**Carol Artlett**
Director of Fibrotic Disease
**TherimuneX Pharmaceuticals**

**3.00 The Mechanism of NLRP3 Inflammasome Dysregulation in Scleroderma**

- Outlining the mechanism of NLRP3 activation
- Demonstrating the role of MIR-155 and IL-1b in Scleroderma

**3.30 Afternoon Refreshments & Networking**

## Addressing the Lack of Biomarkers to Improve & Inform Preclinical Translation & Clinical Trial Design

**Marek Honczarenko**
Vice President, Immunology Development
**AbbVie**

**Jeremy Caldwell**
(former) Executive Vice President & Chief Scientific Officer
**Ardelyx**

**Bruce Riser**
Chief Executive Officer
**BLR Bio**

**Nicolas Wisniacki**
Head of Translational Medicine Experimental Medicine Unit/ Immunoinflammation
**GSK**

**4.15** **Panel Discussion: Predictive, Prognostic & Pharmacodynamic Biomarkers in SSc – How Near Are We?**

- Benchmarking the limitations of auto-antibodies as biomarkers
- Hypothesizing the potential for alternative serological markers and biomarkers to inform how to treat and the success of candidates
- Debating the importance of patient selection against the limitation of shrinking clinical trial population size

## Establishing Anti-Fibrotic Efficacy Prior to Targeting Systemic Sclerosis

**Gerald Horan**
Director Translational Science
**Celgene**

**5.00** **Highlighting the Role of C-Jun N-Terminal Kinase (JNK) as a Key Mediator in the Pulmonary Fibrotic Process**

- Evaluating the preclinical efficacy of the JNK inhibitors, CC-930 & CC-90001, in preclinical fibrosis models and in a phase I/II trial in IPF patients
- Demonstrating the ability of CC-930 inhibition of JNK enzymatic activity in modulating systemic markers in IPF patients, including MMP-7, tenascin C and SP-D plasma protein levels
- Assessing how CC-930 JNK inhibition supports the use of these biomarkers for tracking disease progression and the potential clinical benefit of this novel intervention in IPF

**Janet Pope**
Professor of Medicine, Division of Rheumatology & Epidemiology & Biostatistics
**University of Western Ontario**

**5.30** **Chair's Closing Remarks**

**5.40** **Scientific Poster Session**
After the formal presentations have finished, the learning and networking carries on. The Poster Session allows you to connect with your peers in a relaxed atmosphere and continue to forge new and existing relationships.

"First class meeting - incredible opportunity to meet directly with a broad range of decision makers in this growing field"
**Quanta Biodesign**

# Conference Day Two | Thursday, June 21

**Barbara White**
Chief Medical Officer
**Corbus Pharmaceuticals**

**8.50 Chair's Opening Remarks**

## Standardizing Outcome Measures & Clinical Endpoints

**Robert Simms**
Clinical Core Principal Investigator
**Boston University Scleroderma Center of Research Translation**

**9.00 Application of Genomics to Clinical Trial Design & Outcome Measures**
- Overcoming regulatory and logistical difficulties in identifying the respondent patient cohorts
- Applying selection biomarkers and diagnostic platforms in the clinical setting
- Defining relevant outcomes in pre-selected patient populations and designing clinical trials to achieve these

**Jeffrey Siegel**
Global Head Rheumatology & Rare Diseases
**Genentech**

**Donald Zoz**
Senior Associate Director, Clinical Development & Medical Affairs IPF/ILD
**Boehringer Ingelheim**

**Robert Simms**
Clinical Core Principal Investigator
**Boston University Scleroderma Center of Research Translation**

**Mark Tepper**
President & Chief Scientific Officer
**Corbus Pharmaceuticals**

**9.30 Panel Discussion: Beyond the Rodnan Skin Score, Outcome Metrics in Systemic Sclerosis**
- Reaching approval to the satisfaction of regulatory bodies – can we work with and through regulatory bodies to integrate endpoints more specific and sensitive to patient outcomes
- Addressing challenges in variability and subjectivity associated with the modified rodnan skin score and forced vital capacity as accepted primary and secondary endpoints in systemic sclerosis
- Achieving a metric that is both clinically meaningful and more responsive to therapy to enhance clinical success - is CRISS an acceptable outcome and should there be a threshold response?
- Understanding how to dissect the specific positive effect based upon CRIS result
- Seeking improvement in primary outcome without deterioration in other manifestation: Avoiding 'Trading One Disease for Another'

**10.15 Morning Refreshments & Networking**

## Critically Assessing the Value of Emerging Therapeutics to Improve Decision Making Earlier in Candidate Development

**Jeffrey Siegel**
Global Head Rheumatology & Rare Diseases
**Genentech**

**11.15 Exploring the Role of Interleukin-6 in Systemic Sclerosis**
- Outlining considerations for a successful proof of concept study
- Sharing clinically meaningful endpoints for clinical trials
- Evaluating the importance of understanding the patient perspective

**George Tsokos**
Senior Medical Research Advisor
**TherimuneX Pharmaceuticals**

**11.45 Naclynamide™: A New Drug Candidate Targeting Fibrosis in Scleroderma**
- Proving efficacy in the Bleomycin mouse model
- Comparing the efficacy of Naclynamide™ versus Perfinidone (Esbriet®)
- Demonstrating skin/pulmonary fibrosis, ASMA in lung/skin, alveolitis metrics

**Alain Rolland**
Vice President
Product Development
**Emerald Health Pharmaceuticals**

**12.15** **Targeting Complementary Pathways with Cannabinoid Derivatives: A Pharmacological Approach in Scleroderma**
- Outlining a multi-target strategy to address specific pathophysiology in scleroderma
- Highlighting specific targets and how they can be affected to treat the disease

**12.45** **Lunch & Networking**

**Bruce Riser**
Chief Executive Officer
**BLR Bio**

**1.45** **Regulation of Matricellular Signaling: A Novel Approach to the Treatment of Scleroderma Through Multiple, Specific Pathways**
- Describing the background on matricellular signalling and the CCN family (extracellular matrix associated proteins)
- Evaluating evidence for how CCNs drive scleroderma, derrived through the use of cell and animal models
- Assessing our approach to the creation and use of small peptides as drugs

**Nicolas Wisniacki**
Head of Translational Medicine Experimental Medicine Unit/ Immunoinflammation
**GSK**

**2.15** **Experimental Medicine Approaches to Improve Decision Making in Early Development in SSc**
- Discussing the benefits of understanding target engagement in drug development for SSc
- Analyzing potentials for frequent measurement of lung function as a tool in early development
- Exploring other experimental medicine approaches in SSc

**2.45** **Afternoon Refreshments & Networking**

## Understanding Rationale, Protocol & Opportunity for Drug Redirection into Systemic Sclerosis

**Donald Zoz**
Senior Associate Director, Clinical Development & Medical Affairs IPF/ILD
**Boehringer Ingelheim**

**3.45** **Outlining the Re-Direction of Idiopathic Pulmonary Fibrosis Candidates to Treat Systemic Sclerosis**
- Discussing how fibrosis unites, yet the lung diseases are quite different
- Expanding upon IPF metrics in a heterogeneous, multi-system disease

**Gerald Horan**
Director Translational Science
**Celgene**

**4.15** **Understanding the Rationale for JNK Inhibition in Ssc with a Focus on SSc-ILD**
- Translating efficacy of JNK inhibition in IPF to SSc-ILD
- Outlining the potential for alternative IPF candidates to target SSc-ILD

## Mapping Out the Future for Systemic Sclerosis Therapeutics

**Mark Tepper**
President & Chief Scientific Officer
**Corbus Pharmaceuticals**

**4.45** **Looking Forward – Is Systemic Sclerosis the "Green Field" for Therapeutics Against Chronic Inflammatory & Fibrotic Disease**
- Evaluating the most successful candidate mechanisms of action from SSc therapeutics
- Assessing failings to inform future candidate decisions and debating re-direction out of SSc to treat alternative chronic inflammatory pathologies
- Hypothesizing what the next 12 months of SSc research will look like

**Janet Pope**
Professor of Medicine, Division of Rheumatology & Epidemiology & Biostatistics
**University of Western Ontario**

**5.15** **Chair's Closing Remarks**

# Pre-Conference Workshop Day | Tuesday, June 19

## Workshop A

### Addressing the Complexities of Systemic Sclerosis Pathology in the Context of a Heterogeneous Population

**9:00am – 12:00pm**

**Workshop Leader**
**Jeffrey Browning**
Research Professor
**Boston University**

Although the hypothesis of insult by inflammation preceding progressive fibrosis in diseases such as systemic sclerosis holds a lot of value, the specific aetiology and mechanisms of fibrosis manifesting in distinct organs remains uncertain.

Coupled with inter individual variability within a relatively small population size, the challenges of running a successful clinical trial are significantly greater.

**Join this workshop to discuss:**

- What is normal and how pathology reflects dysfunction
- Critically debating and asking the question: Is inflammation driving fibrosis just a hypothesis?
- The emerging role of the immune system in systemic sclerosis, specifically IL-6, toll like receptors and the use of autoantibodies as serological markers
- Speculating the likelihood of achieving a broad spectrum anti-fibrotic and successful combination therapies effective in a wider population

## Workshop B

### A Systems Medicine Approach to Understand, Re-classify & Treat Systemic Sclerosis in a Personalized Way

**1:00pm – 4:00pm**

**Workshop Leader**
**Timothy Radstake**
Professor of Translational Immunology
**Academic Medical Center Utrecht**

Scleroderma biology is both complex and much debated by current researchers. Driven by dynamic cross-talk between inflammation, autoimmunity, tissue injury and fibrosis, the success of a 'blanket' anti-fibrotic could herald a breakthrough in fibrotic disease beyond scleroderma.

That being said, are the next generation therapeutics more personalized or is there genuine plausibility for a "one for most" therapeutic?

**Be part of this workshop to:**

- Critically investigate complex immune networks leading to systemic sclerosis pathology
- Understand why and how integration of multiple data layers from patient's immune cell subsets will revolutionize the possibility of targeted therapeutics
- Learn how the molecular classification of SSc to define molecular fingerprints has identified disease progression as well as aided the identification of novel therapeutic targets
- Hypothesize translating molecular understanding into identifying signature biomarkers for population cohorts

# Partnership Opportunities

## Demonstrate Your Capabilities of Running Clinical Trials in Scleroderma & Showcase Innovations in Your Preclinical Models

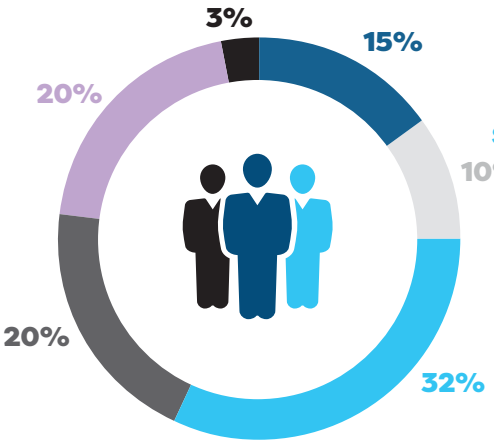
Your target market are actively seeking partners that will enable them to; **demonstrate man's aetiology in preclinical models to effectively translate into the clinic; design their clinical trial to enable maximum patient enrolment** and **confidently meet regulator endpoints.**

Bringing together the scleroderma drug development community, SDD will be your **opportunity to demonstrate your experience and capabilities to the scleroderma drug development field.**

We'll work with you to build a bespoke partnership to **ensure that you meet your 2018 business objectives**. Whether you need to communicate exciting progress to the field's decision makers, generate quality leads or get a grasp of next generation investments in this market, you can rely on our ability to advise on, and deliver the right solution for you.

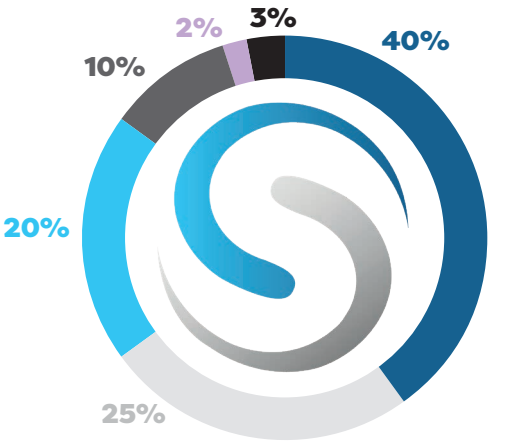
To **learn more about how we can support your business objective in scleroderma**, get in touch today at **sponsor@hansonwade.com**

## Audience Seniority*




*Based on market research and previous events' statistics

## Attending Companies*




*Based on market research and previous events' statistics

## Companies that Attend Hanson Wade Events

Allergan, AnaMar, Bayer, Bristol-Myers Squibb, cytori, Digna Biotech, FibroGen, Galápagos, Genentech A Member of the Roche Group, Halozyme, inventiva, Kadmon, MedImmune A member of the AstraZeneca Group, Novartis, Roche, Stemline, VIDA Therapeutics, VivaCell Biotechnology España

## Get Involved Today

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Partnerships Manager
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# READY TO REGISTER?

## 3 EASY WAYS TO BOOK

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Email: register@hansonwade.com

## TOP 3 BENEFITS OF ATTENDING:

1. Critically review the fibrotic and inflammatory aetiology of scleroderma to identify and validate disease modifying targets
2. Establish clinically effective outcome measures beyond the Rodnan Skin Score to optimize clinical trial success
3. Leverage peer experience of pre-clinical models to more robustly inform *in vivo* and *in vitro* decisions

### Team Discounts*

- **20% discount – 5 or more delegates**
- **15% discount – 4 delegates**
- **10% discount – 3 delegates**

Please note that discounts are only valid when three or more delegates from one company book and pay at the same time. Contact: register@hansonwade.com

# SECURE YOUR PLACE

| Package Details | Register & Pay before Friday April 6, 2018 | Register & Pay before Friday May 11, 2018 | Standard Prices |
|---|---|---|---|
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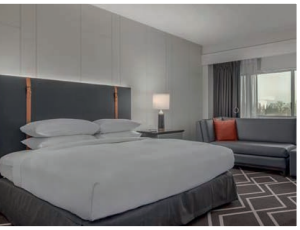
| **SILVER** Conference + 1 Workshop | $3198 **(save $300)** | $3298 **(save $200)** | $3398 **(save $100)** |
| **BRONZE** Conference Only | $2599 **(save $200)** | $2699 **(save $100)** | $2799 |
| Workshops (each) | $699 | | |

*Special 40% off for academics available upon request



# VENUE

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