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July 30 - August 1, 2018 | Boston, MA, USA

www.ndd-summit.com

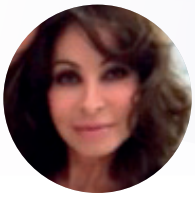
NDD Neuropsychiatric Drug Development

Bringing Next Generation Neuropsychiatric Therapeutics to Market

23 Expert Speakers Including:

Niels Plath
Vice President
Psychiatry
Lundbeck

Janet Nicholson
Director
CNS Research
Boehringer Ingelheim



Brigitte Robertson
Vice President
Clinical Development
Head of
Neuropsychiatry
Shire

Mickey Matsumoto
Executive Director
Astellas

Bill Potter
Senior Advisor
National Institute of Mental Health

"Excellent networking and learning opportunity for pharma scientists" **Matthew Kennedy, Director, Merck**

Tel: +1 617 455 4188 **Email:** info@hansonwade.com

hansonwade

Welcome to Neuropsychiatric Drug Development

Identify Novel Mechanisms of Action for Improved Patient Response, Enhance Clinical Trial Design to Support 'Fast Acting' Drug Development & Evaluate the Role of Biomarkers in Clinical Trials

Built with industry thought leaders at **Roche, Johnson & Johnson** and **Lundbeck** the inaugural Neuropsychiatric Drug Development (NDD) Summit will **solve the challenges preventing you from bringing next generation neuropsychiatric therapeutics to market.**

Focused on drug development, NDD will curate cutting-edge insight and the latest lessons learned empowering you to **develop more clinically effective neuropsychiatric drug candidates.**

With **emphasis on depressive disorders**, this summit will enable you to:

- **Improve your clinical trial design** by better understanding the risks and defining more meaningful endpoints
- **Confidently demonstrate superior efficacy** of next generation NDD therapeutics preclinically
- **Enhance patient response** by discovering novel mechanisms of action

Join your peers at this definitive forum to exchange novel ideas, gather lessons learned and create new connections. Don't miss this opportunity to **power the next 12 months of your neuropsychiatric research** and **transform your clinical trial approach.**

Testimonials from World CNS, our sister Summit:

"I was impressed by many of the speakers and learnt a significant amount, which I was able to bring back to our discovery team"
Stephen Krause, Senior Principal Scientist, Eisai

"One of the best CNS therapeutics meetings to attend"
P2D Bioscience

"Essentially every speaker was excellent. A very informative and thought provoking series of presentations"
National Institute Neurologic Disease & Stroke

Your Top 5 Reasons to Attend NDD:

1. Explore **novel targets and mechanisms of action** for the necessary efficacy of **next generation NDD therapeutics** with Roche and Karuna Pharmaceuticals

2. Address how **mitigating and eliminating risk** in clinical trials can lead to more efficacious studies with UC Irvine and Homology Medicines

3. Review the advantage of **back translation** and the benefit of this over using preclinical models for clinical trials with Boehringer Ingelheim

4. Evaluate **the preclinical and clinical biomarker** landscape to more robustly translate preclinical results into the clinic with GSK and Anvyl

5. Learn strategies to **mitigate placebo response** and improve clinical compliance with Vistagen

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Your 23 Expert Speakers

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Chief Developmental Officer
Concert Pharmaceuticals

Niels Plath
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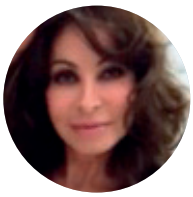

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Srinivas Rao
Chief Medical Officer
Axial Therapeutics

Mark Smith
Chief Medical Officer
Vistagen

Christopher Missling
Chief Executive Officer
Anavex Life Sciences

Venkatesha Murthy
Global Clinical Science & CNS
Takeda

Eva Kohegyi
Senior Director Global Clinical Development CNS
Otsuka

Thomas Hudzik
Scientific Leader
GlaxoSmithKline

David Putman
Chief Operating Officer
Anvyl

Bill Potter
Senior Advisor
National Institute of Mental Health

Daniel Umbricht
CNS Head, Psychiatry & Neurodevelopmental Disorders
Roche

Steve Brannan
Chief Medical Officer
Karuna Pharmaceuticals

Remy Luthringer
Executive Chairman & Chief Executive Officer
Minerva Neuroscience

Timothy Peters-Stickland
Senior Director Global Clinical Development CNS
Otsuka

Jerry Maguire
Professor & Chair Psychiatry & Neuroscience
UC Riverside

Adrian Preda
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Ottavio Vitolo
Vice President Clinical Development
Homology Medicines

Michael Gold
Vice President Neuroscience Development
AbbVie

Rich Daly
Chief Executive Officer
Neuralstem

Michael Palfreyman
Chief Scientific Officer
Amorsa Therapeutics

> "One of the best CNS therapeutics meetings to attend"
> **P2D Bioscience**

Conference Day One | Tuesday, July 31

Jim Cassella
Chief Developmental Officer
Concert Pharmaceuticals

8.30 Chair's Opening Remarks

Niels Plath
Vice President Psychiatry
Lundbeck

8.40 Keynote: Overview of the Current & Future Landscape for Neuropsychiatric Therapeutics

- Addressing the lack of understanding of the biology of the space and what can be done to overcome this
- Understanding how to frame better questions to develop drugs against neuropsychiatric diseases in areas where knowledge is lacking
- Hypothesizing the future landscape of the neuropsychiatric space, what is exciting and what can we look forward to

Janet Nicholson
Director CNS Research
Boehringer Ingelheim

9.10 Keynote: A Circuits & Symptoms Approach to Drug Discovery in Psychiatry

- Exploring the use and utility of back translated tests
- Predictivity of preclinical models and how back translation can be used to design clinical trials to eliminate risk
- Application of the Research Domain Concept (RDoC)
- Reviewing how to develop a strong reverse translational pathway with Optogenits

9.40 Speed Networking

This session is a great opportunity to introduce yourself to the attendees that you would like to have more in depth conversations with. This session is the ideal opportunity to get face-to-face time with many of the brightest minds working in the neuropsychiatry drug development field and establish meaningful business relationships.

10.30 Morning Refreshments

Evaluating the Latest Novel Targets & Understanding Factors Driving Disease Progression for Neuropsychiatric Drug Development

Mickey Matsumoto
Executive Director
Astellas

11.00 The Impact of Genetics on Future Drug Discovery in Psychiatric Disorders

- Deciphering patient stratification based on biology is likely to be essential, given the complex, biologically heterogeneous nature of psychiatric disorders
- Learning to take advantage of advances in lower-cost genomic sequencing, transgenic model creation and new gene-editing strategies to establish better understanding of pathophysiological underpinnings of the disease
- Understanding the confluence of technological advances in patient-specific medicine, genomics and biomarker detection is likely to become essential in the formation of next-gen drugs for psychiatric disorders

Srinivas Rao
Chief Medical Officer
Axial Therapeutics

11.30 Revealing the Role of Gut Microbiome & Exploring How it can be Used to Treat Neuropsychiatric Diseases

- Critically reviewing both preclinical and clinical studies points to a contributory role of the microbiome to symptom severity in a range of neuropsychiatric diseases
- Exploring mechanisms by which gut microbes may impact behaviour include the production of neuroactive substances as well as by direct impact on the vagus nerve
- Modulating the gut microbiome—through both live biological therapy as well as gut-restricted small molecules—represents a promising and novel approach to reducing the symptoms burden of neuropsychiatric diseases

Mark Smith
Chief Medical Officer
Vistagen

12.00 Addressing the Challenges & Opportunities Associated with Clinical Drug Development in Depression & Anxiety Disorders

- Identifying "real patients"
- Approaches to mitigate the placebo response
- Strategies to improve compliance
- Will we ever have biomarkers and objective endpoints in psychiatry?

12.30 Lunch & Networking

Improving Innovation in Clinical Trial Design to Enhance Execution & Meaningful Endpoints

Michael Palfreyman
Chief Scientific Officer
Amorsa Therapeutics

Christopher Missling
Chief Executive Officer
Anavex Life Sciences

Eva Kohegyi
Senior Director Global Clinical Development CNS
Otsuka

1.30 Panel Discussion: What are the Right Kinds of End Points, Where There Aren't Any Approved?

- Exploring areas where endpoints haven't been approved and understanding why this is
- Discussing the benefits and disadvantages of hard and soft endpoints in neuropsychiatry
- Reviewing why certain endpoints haven't been approved and how to overcome this

Christopher Missling
Chief Executive Officer
Anavex Life Sciences

2.00 Delving into Technology & Enablers, How They can be Used to Enhance & Transform Clinical Trials

- Using early on Population PK, i.e. non-linear mixed effect (NLME) modelling an formal concept analysis (FCA)
- Include early on both RNA whole exome and DNA denome sequencing of patients
- Goal is to increase clinical success in pivotal studies

Venkatesha Murthy
Global Clinical Science & CNS
Takeda

2.30 Challenges in Operationalizing Pivotal Clinical Trials in Psychiatry & Potential Solutions

- Nonadherence with study medication
- Duplicate and professional patients
- Addressing proof of concept in depression and schizophrenia

Eva Kohegyi
Senior Director Global Clinical Development CNS
Otsuka

3.00 Exploring the Unique Challenges & Current Landscape in Neuropsychiatric Pediatric Clinical Development

- Reviewing the unique challenges of pediatric drug development in the CNS therapeutic area
- Understanding the current landscape in the regulatory environment as it relates to pediatric development
- Learning how to effectively execute pediatric trials for neuropsychiatric disease in order to reach desired clinical outcomes

3.30 Afternoon Refreshments & Networking

Exploring Preclinical Animal Models for Improved Translation into Clinical Trials

Thomas Hudzik
Scientific Leader
GlaxoSmithKline

4.30 Improving the Predictive Power of Animal Models by Heightening Scientific Rigor

- The 'Reproducibility Crisis' in biology is due in part to lack of rigor in study designs
- Neuropsychiatric drug discovery and developmental are among the most impacted therapy areas
- Rigor must extend from bench to clinic

David Putman
Chief Operating Officer
Anvyl

5.00 Exploring Preclinical Animal Models: An Enigma in CNS Drug Development

- Why we call them animal models of CNS diseases
- Anthropomorphism of CNS animal studies-it's human nature
- Future thoughts-is it insanity to do the same thing in CNS drug discovery, expecting a different outcome?

Jim Cassella
Chief Developmental Officer
Concert Pharmaceuticals

5.30 Chair's Closing Remarks

5.45 Scientific Poster Session

After the formal presentations have finished, the learning and networking carries on. The Poster Session is allows you to connect with your peers in a relaxed atmosphere and continue to forge new and existing relationships. During this session scientific posters will be presented on the latest advancements in next generation therapeutics, preclinical models and identification of biomarkers in neuropsychiatric drug development.

"The absolute best neuroscience meeting I have attended in years"

Rene Anand, Professor,Department of Pharmacology, Ohio State University

Conference Day Two | Wednesday, August 1

Jim Cassella
Chief Developmental Officer
Concert Pharmaceuticals

9.00 Chair's Opening Remarks

Brigitte Robertson
Vice President Clinical Development Head of Neuropsychiatry
Shire

9.10 Keynote: Evaluating the Use & Integration of New Technologies & Biomarkers in Optimizing Clinical Development

- Evaluating integration of technology that aims to revolutionize clinical trials
- Improving clinical practice and understanding with innovative biomarkers
- Optimizing clinical outcomes, differentiation for the benefit of patients
- Connecting the clinic to the trial with real data

Bill Potter
Senior Advisor
National Institute of Mental Health

9.40 Fire Side Debate: Resolved: Targeted Intermittent Device Delivered Interventions will Ultimately Prove Superior to Maintenance Treatment with Drugs for Brain Disorders

- Anatomic and electromagnetic specificity from device vs molecular specificity of drugs
- Brain response to intermittent stimulation vs continuous steady-state biochemical alterations
- Complementary vs competing approaches

10.10 Morning Refreshments & Networking

Reviewing Mechanisms of Action for the Development of Neuropsychiatric Therapeutics

Daniel Umbricht
Translational Medicine Leader
Roche

11.00 Challenges & Solutions in the Development of Drugs targeting Negative Symptoms of Schizophrenia

- The shortcomings of current assessment methods and the promise of ecologically momentary assessments
- The threat of the placebo response and methods to reduce it
- The challenge of the best of patient selection: Insights from recent trials
- The role of experimental medicine in developing drugs for negative symptoms

Steve Brannan
Chief Medical Officer
Karuna Pharmaceuticals

11.30 Evaluating Approaches for Developing Drugs for Psychosis & Cognition

- Ensuring that selected tests are sensitive to cognitive improvements associated with drug MoA and appropriate time points for testing are selected
- Mitigating learning/placebo effects associated with cognitive tests
- Being aware of how circadian rhythms can affect measurements
- Carefully selecting positive symptoms and their severity at entry to ensure you get an acute exacerbation of psychosis

12.00 Lunch & Networking

Evaluating, Identifying & Validating the role of Biomarkers & How They can be Used to Enhance Clinical Trial Design

Remy Luthringer
Chief Executive Officer
Minerva Neuroscience

1.00 Assessing the Use of Biomarkers at an Earlier Stage to Gain Greater Understanding of the Disease & to Streamline Drug Development of Innovative Molecules

- Importance of applying "translatable" biomarkers in preclinical development
- Why implementing biomarkers and pharmacodynamic assessments in phase 1 human studies can fill the gap between preclinical and first patients studies
- Usefulness of integrating biomarkers in early patient trials in parallel with the standard clinical endpoints

Timothy Peters-Stickland
Senior Director Global Clinical Development CNS
Otsuka

1.30 **Discovering Digital Medicine: The Future is Here**
- Defining digital medicine
- Discussing the world's first digital medicine
- Addressing clinical and regulatory pathway
- Future thought and directions

2.00 **Afternoon Refreshments & Networking**

Examining the Role of the Patient & Importance of Correct Patient Popultations in Clinical Trials to Reach Meaningful Endpoints

3.00 **Round Table: Deepening Understanding & Analysis of the Role of Neuropsychiatric Diseases in Neurodegenerative & Other Diseases**

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. Evaluating the Treatment of Psychiatric Disorders Prevalent in Neurodegenerative Diseases and Chronic Physical Disorders

2. Exploring How to Develop New Approaches for Developing Drugs for Psychosis in Alzheimer's

3. Evaluating Different Types of Pharmocometrics Particularly for Neuropsychiatry & Neurodegeneration that we can Embed & Enhance Studies

Michael Palfreyman
Chief Scientific Officer
Amorsa Therapeutics

4.00 **Discovering New Approaches to Therapy Resistant Depression - can we Improve on the Old Drugs?**
- Going beyond biogenic amines
- Addressing new pathways including NMDA
- Exploring new treatment strategies, addressing dosage and patient populations

Commercialization of Neuropsychiatric Therapeutics

Jerry Maguire
Professor & Chair Psychiatry & Neuroscience
UC Riverside

4.30 **Improving Strategic Approach to Securing Partnerships with Pharmaceutical Companies**
- Understanding fulfilling an unmet medical need
- Reviewing market potential of product
- Patient centric focus on development

Jim Cassella
Chief Developmental Officer
Concert Pharmaceuticals

5.00 **Chair's Closing Remarks**

Pre-Conference Workshop Day | Monday, 30 July

Workshop A

Mitigating & Removing Risk in Clinical Trials

10:00am – 1:00pm

The frustrations and challenges in the neuropsychiatry space over the years have been evident. With large studies failing at phase II/III this can be a huge burden economically as well as wasting a lot of time. If the initial risk can be removed from the trial this will lead to more effective and productive trials.

Attendees will discuss in detail:

- Using clinically validated paradigms that don't rely on pre-clinical models to mitigate risk in clinical trials
- Drug repurposing and redeveloping to mitigate future risks
- The ability to use a drug that is already known to work and look at the disease states and make small alterations to these

Workshop Leader
Adrian Preda
Psychiatry Residency Programme Director
UC Irvine

Workshop Leader
Ottavio Vitolo
Vice President Clinical Development
Homology Medicines

Workshop B

Crafting New Regulatory Pathways for Cognitive Diseases

2:00pm – 5:00pm

With Novel mechanisms, biomarkers and technology constantly evolving, it is difficult to keep up with what is approved and what is likely/not likely to be approved. This workshop will provide an update and show you how to navigate the regulatory landscape of the field in detail.

Attendees will discuss in detail:

- How to ensure biomarkers and endpoints are accepted by regulators
- Addressing policies and regulations surrounding apps and wearables

Workshop Leader
Michael Gold
Vice President Neuroscience Development
AbbVie

Workshop Leader
Rich Daly
Chief Executive Officer
Neuralstem

"The quality of the talks was high and the discussion very interesting."
Claudio Babiloni, Associate Professor, University of Rome

Partnership Opportunities

Your opportunity to demonstrate your expertise in neuropsychiatry drug development. Your brand, your message, your reputation showcased in front of the leading minds of neuropsychiatry drug development

With the neuropsychiatric drug development community converging at NDD, this forum will be a unique opportunity for you to demonstrate how your company can enable drug developers to overcome the barriers preventing the development of next generation neuropsychiatric drugs.

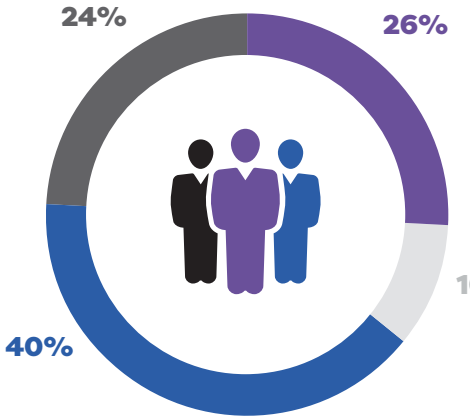
Drug developers are actively seeking partners to help them:

- Identify novel biomarkers and technology that can be used to enhance clinical trials and reach meaningful endpoints and better diagnose diseases
- Learn about novel pre-clinical models that can effectively translate into the clinic
- Design clinical trials in order to mitigate risk and ensure the right patient is participating in the right trial

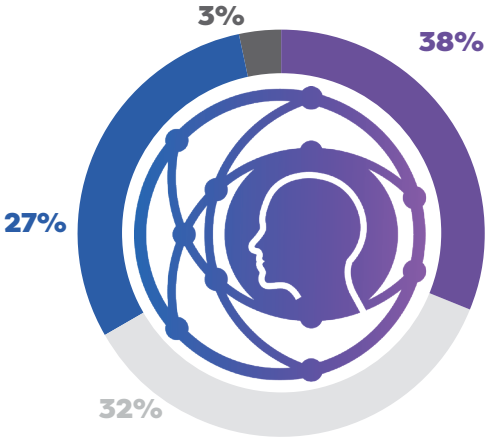
We'll work with you to build a bespoke partnership **to ensure that you meet your 2018 objectives.**

Get in touch today to learn more about how we can support your business in neuropsychiatry. Email us at **sponsor@hansonwade.com**

Audience Seniority



Attending Companies



Companies that Attend Hanson Wade Events

abbvie · Boehringer Ingelheim · Eisai · gsk · Johnson & Johnson · Lundbeck · MERCK · NOVARTIS · Otsuka · Pfizer · Roche · Shire · Takeda · TEVA

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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Top 3 Benefits of Attending:

1. Compare methods for improving clinical trial design by understanding the risks and the importance of reaching meaningful endpoints
2. Evaluate pre-clinical models and biomarkers to show necessary efficacy of next generation NDD therapeutics
3. Identify novel mechanisms of action for improved patient response

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 27	Register & Pay before Friday 25 May	Register & Pay before Friday June 22	Standard Pricing
GOLD Conference + 2 Workshops	$3597 **(save $600)**	$3697 **(save $500)**	$3797 **(save $400)**	$3897 **(save $300)**
SILVER Conference + 1 Workshop	$3098 **(save $400)**	$3198 **(save $300)**	$3298 **(save $200)**	$3398 **(save $100)**
BRONZE Conference Only	$2499 **(save $300)**	**$2599 (save $200)**	$2699 **(save $100)**	$2799
Workshops (each)	$699			

*Special 40% off for academics available upon request

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