New Horizons in Value-Added Medicines

Value Added Medicines Week

Full Agenda of Sessions and Symposia for VAM Week 2023 (Oct 16-20, 2023)

Monday October 16

10:00AM-11:00AM — **Conference Open organizations:** A look at the week ahead and update on the host — Join Session

Meeting ID: 833 5635 2896
Passcode: 052703

Hosts: Steve Casey (505b2 Platform), Ed Allera (505b2 Platform), Keith Gallicano (SAAMnow), Charlie DiLiberti (SAAMnow)

11:00AM-12:00PM — *Business/Commercialization – Session 1* — Join Session

Success Stories

Meeting ID: 833 5635 2896
Passcode: 052703

Moderators: Steve Casey (505b2 Platform), Ed Allera (505b2 Platform)
Guest of Honor: Vicente Anido Former Chairman and CEO of Aerie Pharmaceuticals (now Alcon)
Session Summary:
Session will be a discussion with Vicente Anido our guest of honor and a legendary CEO's/C-level executive who has successfully built and sold value-added medicines companies. We will discuss their investment and development strategies as well as their considerations for when to financially exit their investments/companies.
Vicente has successfully worked in the Value-added medicines market for many years and most recently built and sold Aerie, a publicly traded ophthalmology company to Alcon Labs for ~5.5 times revenue.

12:00PM-1:00PM — **Clinical Development Satellite Symposium** **Axis Clinicals** — Join Symposium

Meeting ID: 833 5635 2896
Passcode: 052703

1:00PM-2:00PM — *Scientific/Clinical - Session 1* — Join Session

Snatching a 505(b)(2) Victory from the Jaws of an ANDA Defeat

Meeting ID: 833 5635 2896
Passcode: 052703

Moderator: Keith Gallicano, PhD (President, SAAMnow)
Speakers: Sandeep Singh, MD (Vice President, Clinical Operations, CBCC Global Research) and Sajeev Chandran, PhD (Vice President, Pharma R&D, Lupin Ltd.):
Session Summary:
Session will focus on repurposing generics, with emphasis on developing ophthalmic products, for 505(b)(2) NDA submission. Examples of where a repurposed generic may have a clinical advantage such as supra bioavailability, lower dose, less food effect, or fewer adverse events will be presented.

Tuesday October 17

10:00AM-11:00AM

Cybersecurity Satellite Symposium KnectIQ

Speaker: Ken Morris

Join Symposium

Meeting ID: 833 5635 2896
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11:00AM-12:00PM

Business/Commercialization – Session 2

Combination Products: Using Combos to Your Advantage

Join Session

Meeting ID: 833 5635 2896
Passcode: 052703

Moderator: Matthew Fedowitz (Buchanan Ingersoll & Rooney)
Panelists: Thomas Goss (Managing Partner, BeaconOne Healthcare Partners); Thomas Cassels (President & CEO at Rock Health); and Steve Casey (Managing Partner Omni commercialization companies)
Session Summary:
Session will focus on the use of devices, digital health, and AI assets to add value to drug products. Measuring clinical improvement, optimizing reimbursement, access to formularies and proper distribution models are evolving. Patenting and Orange Book listing strategies are now interrelated and under scrutiny. The panel of investors, reimbursement specialists, and lawyers will discuss this dynamic market.

12:00PM-1:00PM

Reimbursement Symposium – RSM

Flow of the Dollar: Examining the current Reimbursement Landscape from Pre-commercial to Commercial

Join Symposium

Meeting ID: 833 5635 2896
Passcode: 052703

Speaker: Tom Evegan, Principal, National Consulting Leader, Life Sciences RSM
Symposium Summary
Discussion will cover Reimbursement and Access; The IRA and Government Outlook; M&A, Licensing, Capital Markets; Updates to Drug Pricing and Impact of the IRA

1:00PM-2:00PM

Scientific/Clinical – Session 2

Combination Products and Digital Health – Technical Challenges and Opportunities

Join Session

Meeting ID: 833 5635 2896
Passcode: 052703

Moderator: Ruth Stevens, PhD, MBA (Senior Advisor to Premier Consulting)
Speakers: William Salminen, PhD, DABT, PMP (Vice President, Nonclinical Safety and Toxicology, Premier Consulting) and Enric Calderon, MSc (Associate Director R&D Unit, Device R&D, Teva)
Session Summary:
Session will cover the nuances of the regulatory and commercial aspects of combination product development, including the 505(b)(2) NDA pathway, and how to leverage existing information for the drug and/or device constituent components to streamline overall combination product development, including combination products that incorporate a digital device component. A case study of the development journey of the Digihaler System, its technical and regulatory challenges, and the potential benefits that the technology will bring to asthma and COPD treatment will be presented.

Wednesday October 18

10:00AM-11:00AM

Non-profit Showcase Symposium

Join Symposium

Meeting ID: 833 5635 2896
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Learn about non-profit organizations working in the value-added medicines space, what they do, and how you might collaborate.
Featuring: Cures Within Reach, Civica Foundation, and Every Cure
Speakers: Clare Thibodeaux - Cures Within Reach; Allen Coukell - Civica Foundation; and David Fajgenbaum - Every Cure

11:00AM-12:00PM

Business/Commercialization – Session 3

Commercialization: The B2 Marketing Challenge

Join Session

Meeting ID: 833 5635 2896
Passcode: 052703

Speakers: Steve Casey, MBA (Omni group of commercialization companies) Mark Aikman, PharmD (Vice President Regulatory, Piramal Critical Care)
Session Summary:
Session will cover the challenges of commercializing a 505(b)(2) in today's market. The discussion will focus on the hidden differences between a b2 and b1 products and how best to avoid mediocrity in your 505(b)(2) commercial efforts.

12:00PM-1:00PM

Commercialization & Patient Access Symposium – Apollocare Copay

The Patient Access Journey

Join Session

Meeting ID: 833 5635 2896
Passcode: 052703

Speakers: Todd Smith & Ben Bove
Symposium Summary
Learn about commercial access and copay strategies. The discussion will include ways to improve existing channels and forge new pathways that transform the prescription journey and improving affordability, access, and adherence for products.

1:00PM-2:00PM

Scientific/Clinical – Session 3

The Crucial Impact that a 505(b)(2)'s Clinical Development Program Has on its Commercial Potential

Join Session

Meeting ID: 833 5635 2896
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Moderator: Alicia Baker McDowell, DRSc, MS (Head of Regulatory Strategy, Product Development & Market Access Consulting, Fortrea)
Speakers: David Rosen, BS Pharm, JD (A partner at Foley & Lardner LLP), Abie Ekangaki, PhD (Vice President, Statistical Consulting, Premier Consulting), Siva Vaithiyalingam, PhD (Sr. Vice President, Regulatory Affairs, Cipla Ltd.)
Session Summary:
Session will cover the connection between clinical study design, labeling, and commercial viability/success.

Thursday October 19

10:00AM-11:00AM

Artificial Intelligence Satellite Symposium Delve LLC

Speakers: Ken Norton & Jeff Berkowitz

Join Symposium

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11:00AM-12:00PM

Business/Commercialization – Session 4

Regulatory: Gathering Evidence for Value-added Medicine

Join Session

Meeting ID: 833 5635 2896
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Moderator: Edward Allera (Buchanan Ingersoll & Rooney)
Speakers: Dr. Kevin Bugin (U.S. Food and Drug Administration) and Dr. Paul Aliu (Novartis)
Session Summary:
This session will be a panel discussion with FDA and industry experts. The focus will be on new methods for gathering clinical data to support new indications. Momentum is growing for the use of decentralized clinical trials and other types of new technologies to gather evidence from real world patients. FDA will discuss new approaches they have seen and where problems are arising. An industry representative will discuss the problems that have arisen in gathering the information and gaining acceptance by regulators.

12:00PM-1:00PM

Data & Analytics Management Symposium - EDM Council

Speakers: Mike Meriton

Join Session

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1:00PM-2:00PM

Scientific/Clinical – Session 4

Effective Collection and Use of Post-Approval Safety/Efficacy Data

Join Session

Meeting ID: 833 5635 2896
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Moderator: Janet Vaughn, BSc (Vice President, North America Gx Regulatory Affairs, Teva)
Speakers: Mary T. Thanh Hai, MD (Deputy Director for Clinical Science, Office of New Drugs, Center for Drug Evaluation and Research, U.S. Food and Drug Administration); Delphine Saragoussi, MD, MScPH (Executive Director, Epidemiology and Scientific Affairs, PPAS & RWE, Clinical Research, PPD, part of Thermo Fisher Scientific)
Panelist: Aysha Amman, Pharm D (Director, Head of NAPV Operations and Compliance & US Local Safety Officer, Teva)
Session Summary:
Session will discuss collection and evaluation of post-marketing surveillance and Phase IV study safety and efficacy data. Areas such as lifecycle management, shared REMS program, mining post-approval data such as adverse events, and commitment for post-approval studies will be emphasized.

Friday October 20

10:00AM-11:00AM

Washington DC Update

Speaker: Michael Strazzella (Buchanan Ingersoll & Rooney)

Join Session

Meeting ID: 833 5635 2896
Passcode: 052703

Symposium Summary:
Learn about the current state of affairs in Washington and how it will affect the life sciences industry and value-added medicine development, approval and commercialization.

11:00AM-12:00PM

Business/Commercialization – Session 5

Commercialization: Value-added Medicines Beyond the U.S

Join Session

Meeting ID: 833 5635 2896
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Moderator: Barbara Binzak Blumenfeld (Buchanan Ingersoll & Rooney)
Speakers: Le Tong (China), Viswaprasad Varanasi (India), Fernando Braune (Brazil)
Session Summary:
Session will cover value-added medicines outside the US. We will review specific countries including China, India and Brazil to learn how these countries are participating in the VAM market. The discussion will focus on any regulatory pathways that promote VAMs and how the countries pharmaceutical industry participates in the VAM market.

12:00PM-1:00PM

Artifex in 505(b)(2)'s Symposium – (Buchanan Ingersoll & Rooney)

Join Symposium

Meeting ID: 833 5635 2896
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Symposium Summary:
Learn how AI can be used to improve analysis and preparation for regulatory submissions and market analysis

1:00PM-2:00PM

Scientific/Clinical – Session 5

Parlaying Drug Approvals to and from the US – Focus on 505(b)(2)s

Join Session

Meeting ID: 833 5635 2896
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Moderator: Raluca Radu (Value Added Medicines Policy Manager, Medicines for Europe)
Speakers: Kaitlyn Huff, PhD (Director, Strategic Regulatory Consulting, PPD, part of Thermo Fisher Scientific) and Simion Oros, (Head of Regulatory Affairs, Cipla (EU) Ltd.)
Session Summary:
Session will present strategies to minimize duplication of clinical trials to support submission to US (505(b)(2) NDA), EU, India and China.

2:00PM-2:30PM

Conference Close

Summary of the week's events and update on future events

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Hosts: Steve Casey (505b2 Platform), Ed Allera (505b2 Platform), Keith Gallicano (SAAMnow), Charlie DiLiberti (SAAMnow)

Hosted By:

The 505(b)(2) PLATFORM®

SAAMnow
Scientists Advancing Affordable Medicines