March 18-20, 2025 | Boston, MA
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WELCOME
EXPERT SPEAKERS
AGENDA
PARTNER WITH US
REGISTER YOUR PLACE

5th Annual
Operationalize: Expanded Access Programs Summit
Improving Global Access to Life Changing Therapeutics

Navigate Complex Regulatory & Operational Hurdles to Operate Successful Early Access, Expanded Access, Managed Access & Post-Trial Access Programs

Expert Speakers Include:

Annie Drelles
Senior Director & Head, Office of Medical Access, Global Oncology Medical Affairs
Daiichi Sankyo

Laura Carr
Executive Director & Head, GOMA Clinical Trial Management, Resources, Operations, & Governance
Daiichi Sankyo

Helen Kellar-Wood
Global Head of Patient Access
BMS

Alberto Calabrò
Patient Access Program & Supply Leader
Roche

Michelle Clausen
Senior Director, Expanded Access Enterprise Medical Community
Pfizer

Becket Feierbach
Managed Access Programs Lead
Gilead Sciences

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Welcome to the 5th Operationalize: Expanded Access Programs Summit!

5th Annual Operationalize: Expanded Access Programs Summit
March 18-20, 2025 | Boston, MA

An influx of companies are opening managed access programs, trying to disentangle a matrix of country-specific regulations, and navigating complicated operational challenges in conducting pre-approval and post-trial access programs. But while putting the patient first is at the heart of every conversation, questions remain surrounding the operational management of programs.

- How much real-world data should we collect?
- How can we predict patient request volume?
- How can we navigate patient transitions, exit plan strategies and reimbursement?

The **5th Operationalize: Expanded Access Programs Summit** is uniting stakeholders executing Early Access, Expanded Access, Managed Access, and Post-Trial Access Programs to provide a forum to share case studies in **successfully bridging the gap between innovative clinical research and patients in need**.

From providing a team of one with the experience needed to compliantly set up an expanded access program, to uniting the experts that have been grappling with regulatory challenges for years to streamline processes surrounding exit strategies, proactively planning a Post-Trial Access programs and more, join the community of **120+ experts** in **Access**, **Clinical Operations**, **Medical Affairs** and **Clinical Supply** to improve global access to life changing therapeutics.

What our speakers have to say:

"With so many industry professionals in one place, I learned about numerous aspects of managed access and met experienced vendors who can provide support. On a personal note, this meeting has a **non-competitive atmosphere**, where different companies can learn from one another's best practices, ultimately making it better for patients around the world"

Gilead

"The **openness and collective sharing were invaluable**. Hearing from different sized companies with varied histories around access really helped pressure test options and philosophies that could be implemented"

Biogen

KEY BENEFITS OF ATTENDING

Turbocharge your understanding of country-specific regulatory considerations to successfully operate compliant global Access Programs, with expert insights from **EMD Serono**, **Shionogi**, **Novartis**, and **The Max Foundation**

Gain insights into the unique operational challenges of running Access Programs in low-to-middle income countries, ensuring equitable access for patients, guided by **GARDaccess**

Navigate the regulatory complexities of transitioning patients from free-of-charge to commercial programs, ensuring sustainable continuity of care, with insights from **Blueprint Medicines**

Explore a novel funding model that generates actionable insights, supplements clinical trial data, and informs regulatory decisions, led by **Biomed Valley Discoveries**

Master the regulatory and operational nuances of Post-Trial Access Programs to ensure continued patient access to medicines, with implementable insights from **Pfizer**

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What's New in 2025?

5th Annual Operationalize: Expanded Access Programs Summit
March 18-20, 2025 | Boston, MA

Brand New Tracked Workshop Content:

No matter how experienced you are, the 5th Operationalize: Expanded Access Programs Summit provides an opportunity for all EAPs professionals to gain in-depth, practical insights covering:

Opening Your First Expanded Access Programs:

- Delving into the essential considerations for planning and executing an EAP that aligns with your company's vision, product pipeline, and patient needs
- Exploring stakeholder engagement, including best practices for gaining internal buy-in, cross-functional collaboration and CRO management
- Providing critical insights into crafting effective exit strategies, ensuring a seamless transition for patients to commercially available treatments

Advanced Challenges in Expanded Access Programs:

- Understanding the key regulatory considerations and compliance issues when moving patients from free-of-charge programs to commercially available treatments
- Analysis factors that need to be taken into account when deciding whether to execute a PTA study and what are the alternative options
- Highlighting several scenarios of hurdles that might arise when planning and executing an transition strategy, including no reimbursement, delayed reimbursement, and changes in companies' strategy

Exploring Region-Specific Access Case Studies to Enhance Global Program Success:

Join industry leaders from **Novartis**, **Scensus**, **The Max Foundation**, and **GARDaccess** as they guide you through in-depth case studies from **LATAM**, **Europe**, **South & East Asia**, and other **LMIC** regions. Delve into critical topics including supply chain logistics, labeling, regulatory hurdles, importation, and licensing to better understand how to tailor your programs to the unique challenges and opportunities in each region's access landscape.

Innovative Approaches to Supporting Patients in Need:

Discover inspiring stories of how industry peers are enabling patient access to life-saving therapies through alternative strategies beyond traditional access pathways. These include physician-NGO collaborations to tackle rare disease access challenges, the development and evaluation of Pre-Approval Access Exceptions for rare cancers and pediatric conditions, and solutions to overcome barriers in the most challenging environments.

Here's what's planned for you in 2025:

70% new speaker faculty, including 11 new companies such as Kura Oncology, Gilead Sciences, Takeda, Pfizer and more!

30 new case studies, panels, and audience discussions aimed to assist you in overcoming global regulatory and operational challenges to bring life changing therapies to patients, faster

10+ hours of networking, including a dedicated speed networking session to connect you with the whole room of 120+ access experts

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Your Expert Speakers

Alberto Calabrò
Patient Access Program & Supply Leader
Roche

Alix Hall
Head of Patient Centricity
Bionical Emas

Amber Bifolck Fisher
Senior Clinical Research Manager, Expanded Access & Investigator Initiated Study Programs
Kura Oncology

Anne B. Cropp
Chief Scientific Officer
Early Access Care

Annie Drelles
Senior Director & Head, Office of Medical Access, Global Oncology Medical Affairs
Daiichi Sankyo

Becket Feierbach
Managed Access Programs Lead
Gilead Sciences

Brent Kreider
President
Biomed Valley Discoveries

Bryan Berger
Product Manager
myTomorrows

Dennis Akkaya
Chief Commercial Officer
myTomorrows

Harpreet Ram
Founder & Executive Director
GARDaccess

Helen Kellar-Wood
Global Head of Patient Access
BMS

Jasmina Ahrens
Global Lead, Rare Humanitarian Operations
Sanofi

Jeff Waldron
Executive Director of the Bipolar Action Network
Massachusetts General Hospital

Kirsten Hoyer
Associate Director
Ascendis Pharma

Laura Carr
Executive Director & Head, GOMA Clinical Trial Management, Resources, Operations, & Governance
Daiichi Sankyo

Laura Gagnon
Director, Global Oncology Expanded Patient Access Programs
Takeda

Lea Ann McNee
Director, Communication & Stakeholder Engagement
Reagan-Udall Foundation for the FDA

Leigh-Ann Durant
Head of North America Medical Governance, Chief Medical Officer Governance & Operations
EMD Serono

Margaret Radford
Unlicensed Medicines Services Manager
Almac

Mark Bainbridge
Senior Director, Business Development
Inceptua

Michael Wrigglesworth
Vice President, Programs Operations
The Max Foundation

Michelle Clausen
Senior Director, Expanded Access Enterprise Medical Community
Pfizer

Nicole Garmon
Director, Clinical Supply Strategy & Management
Pfizer

Paul Stanton
Senior Director, Global Strategy
Inceptua

Ryan Bursiek
Director, Business Development
Inceptua

Sarah Gilmore
Director Managed Access Programs, Global Medical Affairs
Gilead Sciences

Stephanie Ferket
Director, Expanded Access Strategy & Customer Success
myTomorrows

Susan Allen
Associate Director, Global Patient Safety Evaluation
Takeda

Simon Morgan
Team Lead, Qualifies Person
Pfizer

Ivan Verrastro
Business Development Manager
BAP Pharma

Pre-Conference Workshop Day
Tuesday March 18, 2025

7.30 Registration & Coffee

Opening Your First Expanded Access Programs

8.30 Guiding Principles for Successfully Establishing & Managing an Early Access Program (EAP)

- Delving into the essential considerations for planning and executing an EAP that aligns with your company's vision, product pipeline, and patient needs
- Exploring strategic approaches to managed access, including identifying critical requirements, anticipating common challenges, and understanding the core principles needed from program inception
- Address system development strategies, providing insights on what can be achieved and how to implement effective solutions

Laura Carr, Executive Director, Head GMA Oncology Trial Management, Resources & Operations, **Daiichi Sankyo**

Annie Drelles, Senior Director & Head, Office of Medical Access, Global Oncology Medical Affairs, **Daiichi Sankyo**

Advanced Challenges in Expanded Access Programs

8.30 Navigating Regulatory Requirements in Transitioning from Free-of-Charge to Commercial Programs

- Understanding the key regulatory considerations and compliance issues when moving patients from free-of-charge programs to commercially available treatments
- Identifying the stakeholders who should be engaged in this transition process to ensure a smooth and compliant shift

Harpreet Ram, Founder & Executive Director, **GARDaccess**

10.30 Morning Break

11.00 EAP Procedures: Stakeholder Management, Internal Alignment & Ethical Considerations

- Deciphering which stakeholder will be involved in setting up programs and the key roles of each function
- Setting up a singular tracking system and portal to ensure cross-functional alignment
- Exploring stakeholder engagement, including best practices for gaining internal buy-in, cross-functional collaboration and CRO management
- Identifying the ethical considerations that need to be taken into account

Becket Feierbach, Managed Access Programs Lead, **Gilead Sciences**

Sarah Gilmore, Director Managed Access Programs, Global Medical Affairs, **Gilead Sciences**

Alberto Calabrò, Patient Access Program & Supply Leader, **Roche**

11.00 Operationalizing Post-Trial Access: Planning & Running to Ensure Continued Access to Medicines

- Analysis factors that need to be taken into account when deciding whether to execute a PTA study and what are the alternative options?
- Highlighting the ideal time to start having conversations around running a PTA program
- Exploring are the labelling and supply requirements for a PTA depending on the country you are running it in
- Deciphering the data requirements for a PTA depending on the country you are running it in
- Evaluating whether to use commercial or clinical supply for PTA and what are each countries guidance on this

Michelle Clausen, Senior Director – Expanded Access Enterprise Medical Community, **Pfizer**

Nicole Garmon, Director – Clinical Supply Strategy & Management, **Pfizer**

1.00 Lunch

Pre-Conference Workshop Day
Tuesday March 18, 2025

2.00 Strategic Exit Planning for Transitioning Patients from EAPs to Commercial Products

- Providing critical insights into crafting effective exit strategies, ensuring a seamless transition for patients to commercially available treatments
- Exploring the key drivers for program termination and learning how to plan exit strategies in advance
- Addressing the complexities of handling multiple programs across different countries, considering local regulations, management challenges, and financial constraints, laying out various scenarios for transitioning patients from ongoing programs to commercial access

Debra Litwak, Senior Director, Global Medical Affairs, Investigator Initiated Trials & Compassionate Use Programs, **BeiGene**

Leigh-Ann Durant, Head of North America Medical Governance, Chief Medical Officer Governance & Operations, **EMD Serono**

2.00 Examining Nuanced Scenarios for Transitioning Patients from EAPs to Commercial Products

- Highlighting several scenarios of hurdles that might arise when planning and executing an transition strategy, including no reimbursement, delayed reimbursement, and changes in companies' strategy
- Brainstorming strategies to support end-to-end access for patients, navigating reimbursement approval timelines, local regulations and managing off-label requests

Laura Gagnon, Director, Global Oncology Expanded Access, **Takeda**

Susan Allen, Associate Director, Global Patient Safety Evaluation, **Takeda**

4.00 Afternoon Break & Networking

4.30 Navigating Regulatory Complexity & Streamlining Ad-hoc Request Management in Expanded Access

- Discover how technology is transforming expanded access management with real-time visibility, enhanced coordination, and seamless reporting
- Understand the challenges of regulatory complexity in expanded access request handling and compliance
- Learn how digital tools can enhance regulatory pathways decision-making, streamline request management, and improve patient enrollment
- Explore solutions for managing unplanned, ad-hoc expanded access requests with greater efficiency and coordination

Stephanie Ferket, Director Expanded Access Strategy & Customer Success, **myTomorrows**

Bryan Berger, Product Manager, **myTomorrows**

6.30 End of Pre-Conference Workshop Day

"Robust engagement and discussions during workshops. Hearing constructive thoughts and opinions as well as the networking opportunities were extremely valuable"
Daiichi Sankyo

"Expertise of presenters, curated content, supportive and friendly attendees"
GSK

Conference Day One
Wednesday March 19, 2025

7.30 Coffee & Registration

Dennis Akkaya
Chief Commercial Officer
myTomorrows

8.40 Chair's Opening Remarks

Cross-Industry Collaboration & Innovative Ways to Support Patients

8.45 **Panel Discussion: Streamlining Collaborations Between Industry, HCPs, & NPOs to Better Support Each Stakeholder**

- Understanding the role of each subgroup, and what is and isn't in their controls
- Exploring the common pain points between each group
- Highlighting how each group can better support each other
- Exploring available resources to better educate stakeholder groups

Moderator: Jeff Waldron
Executive Director of the Bipolar Action Network
Massachusetts General Hospital

Amber Fisher
Senior Clinical Research Manager: Expanded Access & Investigator Initiated Study Programs
Kura Oncology

Lea Ann McNee
Director of Communication & Engagement
Reagan-Udall Foundation for the FDA

Michelle Clausen
Senior Director, Expanded Access Enterprise Medical Community
Pfizer

Anne B. Cropp
Chief Scientific Officer
Early Access Care

9.30 **Post Trial Access - Exploring the Point of Divergence & the Path Beyond**

- Exploring the range of possibilities for program goals
- Highlighting considerations for successful PTA planning and set up
- Achieving successful transition from trial

Helen Kellar-Wood
Diversity & Patient Engagement Immunoscience Lead
BMS

10.00 **Thinking Outside the Box to Put Patients First**

- Showcasing success stories of providing access to patients with rare cancers and pediatric diseases
- Exploring the development process of Pre-Approval Access Exceptions and the evaluation procedure that goes into this
- Exploring which stakeholders are involved in this evaluation procedure and which functions come together to support this process

10.30 **Speed Networking**
Join our speed networking session tailored for Compassionate Use professionals, like yourselves, to connect with fellow industry peers to facilitate rapid yet meaningful exchanges of insights and expertise. Elevate your networking experience during this session designed for impactful connections within the space.

11.00 Morning Break

Success Stories of Equitable Programs to Ensure Continuity of Patient Access

Harpreet Ram
Founder & Executive Director
GARDaccess

11.30 **Providing Access to Low-to-Medium Income Countries & Emerging Markets to Ensure Sustainable Medical Access**

- Engaging the right stakeholder to design a sustainable program depending on the country's healthcare infrastructure
- What are the operational considerations of running these types of programs?
- What are the success stories and what are the lessons learnt?

Stephanie Ferket
Director, Expanded Access Strategy & Customer Success
myTomorrows

12.00 **Optimizing Expanded Access: Strategic Considerations for Enhanced Efficiency and Scalability**

- Understand governance structures and strategies for cross-functional collaboration and early planning
- Discover methods for managing requests, ensuring global oversight, and supporting physicians
- Develop adaptable SOPs and understand the role of supply chain management in program efficiency

Conference Day One
Wednesday March 19, 2025

12.30 **Lunch & Networking**

1.30 **Overcoming Operational Barriers Associated with Compassionate Use in Challenging Environments**

Jasmina Ahrens
Associate Director
Sanofi

- Exploring operational models in challenging environment, using a case study from Sanofi
- Understanding how to best collaborate with NGOs to support programs, such as medical transport and patient support
- Analyzing the role vital role of the Physician to ensure access to medications

Elucidating Common Supply, Labelling, Shipping & Resource Constraints

2.00 **Navigating Chargeable Programs: Insights, Initiatives & Challenges**

Ivan Verrastro
Business Development Manager
BAP Pharma

- Exploring the key differences between Free of Charge and Chargeable Programs, analysing the operational challenges
- Navigating the Regulatory, Financial and Ethical considerations when implementing a Chargeable Program
- Reviewing practical strategies for ensuring an efficient, transparent and fair program
- Examining key insights from case studies on funding and reimbursement options across the APAC region

2.30 **Roundtable Discussion: Labelling, Product Supply & Distribution: Successfully Managing Cross-Functional Operations**

- Exploring global regulatory challenges in distribution and stocking
- In-house or outsource? Setting up internally or qualifying local vendors for compliant labelling
- Navigating QP release, importation, licencing and inventory management

3.00 **Afternoon Break & Networking**

3.30 **Streamlining QP Release for Early Access Programs for Seamless Operation**

Simon Morgan
Team Lead, Qualified Person
Pfizer

- Investigating the role of QP release in safeguarding patient safety and how it ties into broader regulatory and ethical considerations
- Exploring the most efficient approaches companies use to ensure quick QP release for early access programmes
- Examining how companies integrate QP release into their overall early access program strategy for seamless operation

4.00 **Roundtable Discussion: Supply Hurdles for Global Access to Life-Changing Therapeutics**

- Examining a case study highlighting common supply challenges for MAP delivery
- Exploring the considerations for labelling, inventory control, forecasting and shelf-life management
- How selecting the right strategy can ensure a robust supply chain

Harpreet Ram
Founder & Executive Director
GARDaccess

Amber Fisher
Senior Clinical Research Manager: Expanded Access & Investigator Initiated Study Programs
Kura Oncology

Michael Wrigglesworth
Vice President, Program Operations
The Max Foundation

Margaret Radford
Unlicensed Medicines Services Manager
Almac

Dennis Akkaya
Chief Commercial Officer
myTomorrows

4.30 **Chairs Closing Remarks**

4.35 **End of Day One**

4.40 **1 Hour Drinks Reception**

Conference Day Two
Thursday March 20, 2025

7.45 **Coffee & Registration**

Michelle Clausen
Senior Director, Expanded Access Enterprise Medical Community
Pfizer

8.20 **Opening Remarks**

Harmonizing Regulations & Data Strategies for Successful Access Programs

8.30 **Fire-Side Discussion: Increasing Efficiency & Streamlining Global Regulatory Landscapes**

- Exploring the alternatives to pre-approved access pathways in the US and beyond, including for second indications and off-label
- Evaluating the benefits and draw backs of the US system and other regional systems
- Highlighting what can we do and what is being done to advocate for more harmonized regulatory frameworks

Annie Drelles
Senior Director & Head, Office of Medical Access, Global Oncology Medical Affairs
Daiichi Sankyo

Leigh-Ann Durant
Head of North America Medical Governance, Chief Medical Officer Governance & Operations
EMD Serono

Atalah Haun
Vice President, Medical Affairs
WEP Clinical

9.00 **Aligning Patient's Needs with Commercial Goals: The Value of Collecting Real-World Data in EAPs**

- Understanding Expanded Access Programs and their role
- The strategic value of real-world data in EAPs
- Aligning patient-centricity with commercial goals
- Operational considerations for successful EAP implementation aligned with drug development path and commercial goals

Alberto Calabrò
Patient Access Program & Supply Leader
Roche

9.30 **Advancing Safety in Managed Access Programs**

- Strengthening collaboration with safety organizations
- Enhancing pharmacovigilance and safety science activities
- Optimizing safety data usage and documentation

10.00 **Morning Break & Networking**

11.00 **Roundtable Discussion: Rapid Response in an EAP: A Unique Challenge for Early Access**

Paul Stanton
Senior Director, Global Strategy
Inceptua

Mark Bainbridge
Senior Director, Business Development
Inceptua

Ryan Bursiek
Director, Business Development
Inceptua

Michael Wrigglesworth
Vice President, Program Operations
The Max Foundation

11.30 **Navigating Operational & Regulatory Hurdles of South & East Asian Humanitarian Donation Programs**

- Examining case studies of successful South and East Asian Humanitarian Donation Programs to understand best practices and identify potential challenges
- Identifying the key stakeholders involved and interrogating the regulatory requirements for clinical and commercial supply, import licenses and labeling

Conference Day Two
Thursday March 20, 2025

Enhancing Patient-Centricity in Programs & Compliant Transitions to Commercial Programs

Graham Sidorowicz
Chief Operating Officer,
Bionical Emas

Alix Hall
Head of Patient Centricity
Bionical Emas

12.00 **Designing Patient-Centric Resources & Programs: Approaches for Supporting the Patient & Site Experience**

- Exploring compliant, tangible strategies that support patients, HCPs, and sites, focusing on transparency and equitability
- Highlighting the importance of centering the patient and site experience within an EAP or PTA program
- Discussing case studies of patient-centric activities that have been implemented throughout a program's design, delivery, and exit strategy

12.45 **Lunch & Networking**

Kirsten Hoyer
Associate Director
Ascendis Pharma

1.45 **Navigating Compliant Engagement & Effective Collaboration for a Successful Commercial Launch**

- Providing guidelines on what types of information can be exchanged between functions to maintain legal and ethical standards
- Showcasing approaches to managing discussions that balance preparation for launch with the integrity of compassionate use programs
- Discussing how to effectively leverage the expertise of commercial teams while preserving the core values of compassionate use initiatives
- How to align EAP protocol with the USPI (label)

2.15 **Roundtable Discussion: Navigating Europe's Regulatory Landscape for Compassionate Use Programs**

- What are the key lessons learned from successful compassionate use programs in Europe, and what challenges have been encountered?
- How do you determine the most appropriate regulatory pathway for compassionate use, and who typically leads this decision-making process?
- How do European regulations on data collection impact compassionate use programs, and which countries allow or restrict data collection?
- What are the critical regulatory considerations for clinical and commercial supply, including import licenses and labeling?

Use of Data Collection to Supplement Regulatory, Clinical Trial, & Therapeutic Development

Brent Kreider
President
Biomed Valley Discoveries

2.45 **Differentiated Approach to EAPs Using a Reimagined Model for Sourcing & Advancing Therapeutics**

- Analysing a novel funding model that is solely focused on delivering "hope for life" to patients
- Exploring lessons learned about gathering actionable clinical insights from the program
- Compliantly tracking longitudinal patient data to enable actional insights, supplement clinical trial data, inform regulatory decision-making and advance cancer treatment decisions

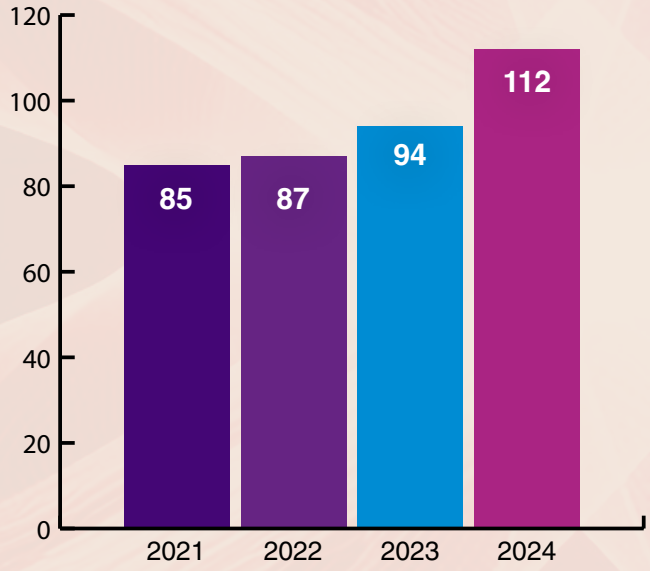
3.15 **Chairs Closing Remarks**

3.20 **End of Conference**

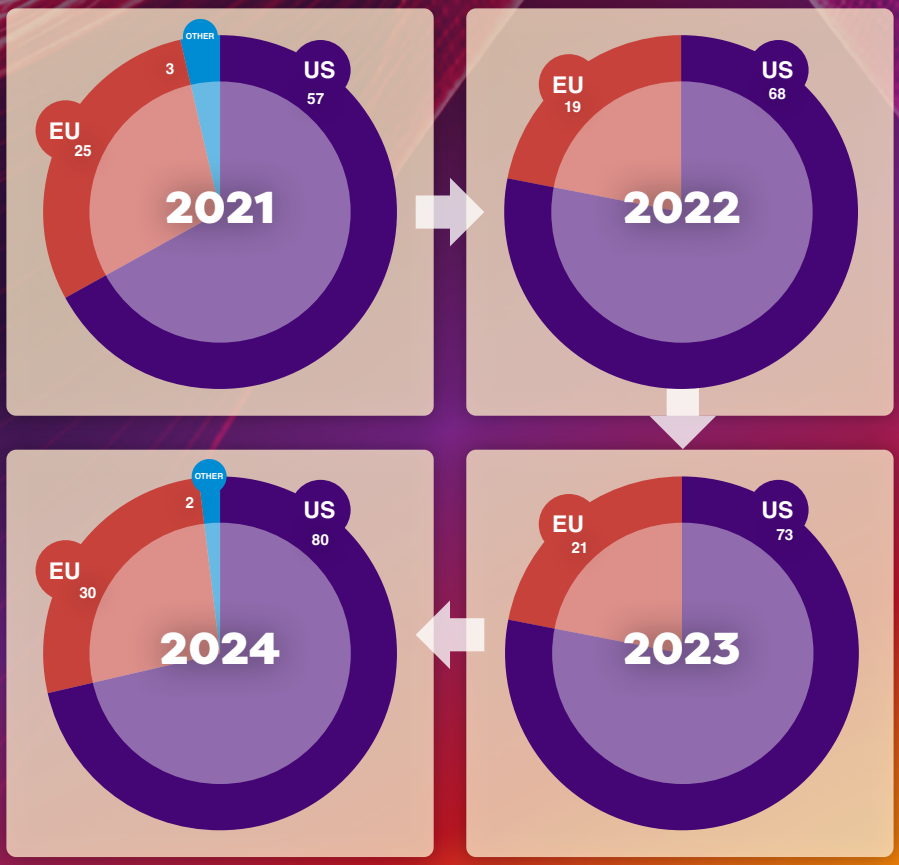
Operationalize: Expanded Access Programs Summit Over the Years

Numbers of Attendees

US MEETING



ATTENDEE BY GEO - US



AT LEAST 20 NEW COMPANIES ATTENDING EACH YEAR, INCLUDING:

US MEETING

YEAR 2 COMPARED TO 1

agios, astex pharmaceuticals, BeiGene, insmed, MERCK, FDA, SpringWorks Therapeutics, Taysha Gene Therapies

YEAR 3 COMPARED TO 2

ALEXION, AMYLYX, SAREPTA, ascendis pharma, BIOMARIN, ucb, GILEAD, MIRATI THERAPEUTICS

YEAR 4 COMPARED TO 3

argenx, Lilly, Jazz Pharmaceuticals, J&J, NEUROCRINE BIOSCIENCES, novo nordisk, Pfizer, sentien

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OUR 2025 PARTNERS

Expertise Partners:

Early Access Care

Early Access Care is a full-scale specialist service provider of Compassionate Use and Named Patient Programs, ranging from programme planning, protocol development, end-to-end operational management, Real World Data services, and a variety of customized service offerings. We work with biotech and pharmaceutical companies to set up and manage programs in the preand post-approval space, including post-trial access, managing all regulatory and logistical aspects of early access. Speak with one of our representatives at the EAC booth to find out more about how our service and staff may support your plans.

www.earlyaccesscare.com

Inceptua Early Access

Inceptua Group (Inceptua) is a provider of customized access solutions that enable pharmaceutical companies to overcome challenges and eliminate obstacles to reach patients with unmet medical needs and provide access to life-changing or life-extending therapies. The group was founded in 1997, initially focused on sourcing comparator products and delivering services for clinical trials. Later Inceptua was expanded in 2017 with the establishment of Inceptua Early Access, running early access programs worldwide. Inceptua's Early Access team combine regulatory and operational expertise with an ability to partner effectively with clients to confidently provide the guidance, recommendations and capabilities necessary to successfully plan for and execute global access programs. Collectively, our experience covers 300+ early access programs, involving both free-of-charge and charged for products treating a variety of conditions, including many rare and orphan indications. Our team leverage a wealth of expertise in managing the distribution of medicines to more than 120 countries around the world, including North America, the EU, LATAM, MENA, APAC regions and low/middle income countries across the globe.

www.inceptua.com

myTomorrows

myTomorrows is a global health tech company dedicated to helping patients and physicians discover and access treatment options. We have partnered with 50+ Biopharma companies to support end-to-end expanded access program delivery, generate real-world data, and streamline clinical trial recruitment through the use of our proprietary AI technology. Our proactive, and stakeholder-focused approach combined with our operational excellence, innovation and adaptability ensures the best possible outcomes for patients, physicians, and our partners.

www.mytomorrows.com

WEP

At WEP, we are With Every Patient, as we believe every patient should have access to treatment!

We operate as a Pharma Services Provider (PSP) that is committed to providing Drug Development and Treatment Access Solutions for patients worldwide. We specialize in Expanded Access Programs (EAPs) and help Sponsors deliver value-driven EAPs that are designed and fit around their specific needs and development pipeline. Our programs are delivered through High Quality, High Service, and High Value, returning a positive ROI to all Sponsors we have partnered with.

www.wepclinical.com

OUR 2025 SPONSORS

Hosting Partners:

Almac Clinical Services

Almac Clinical Services dedicated Unlicensed Medicine Services group currently manage over 200+ active Managed Access programs, delivering critical medication to patients across 80 countries worldwide. From forecasting and production through to storage and distribution, Almac provides the global reach, expert people, validated processes, and cutting-edge technology to empower sponsors to maintain ethical, compliant, and cost- effective access to unlicensed treatments.

www.almacgroup.com

BAP Pharma

BAP Pharma is an award-winning, responsive and cost-effective medicines access solutions partner, specialising in providing tailored access solutions to health care professionals and patients. Our experts in Early and Managed Access Programs (EAP/MAP) can assist and support your efforts to bring critical treatments to patients in need, ensuring they get the medicines they need, when they need them, anywhere in the world.

www.bappharma.com

Bionical Emas

Bionical Emas is a global Early Access Programs (EAP) specialist bringing life-changing medicines to patients around the world. Their comprehensive suite of services and capabilities benefit many of the world's leading pharma and biotech companies.

Bionical Emas provides in-house, highly specialized and EAP centric clinical services, including dedicated Real-World Evidence, Pharmacovigilance and Medical teams to support all program requirements. Their vast experience in oncology and rare disease, and dedicated EAP teams and processes, are essential to providing innovative EAP solutions to pharma and biotech companies globally.

With a truly patient focused approach, Bionical Emas offers a best-in-class EAP service offering ensuring patient, healthcare professional and client needs are met through passionate and tailored program delivery.

www.bionicalemas.com

Exhibition Partner:

Pinex

Pinex is a referenced logistic operator in Brazil, with expertise in Clinical Trials, NPP, and Early Access Programs categorized in Brazil as Expanded Access, Compassionate Use, and Post-Trial Access, in which Pinex can manage the approval at Anvisa and perform the regulatory activities required locally.

Pinex, as a licensed wholesaler, can source comparator drugs and provide the following services, Regulatory Affairs, Importation, Warehousing, and Distribution.

Home-based in Sao Paulo/Brazil, the Pinex facility meets global quality practices standards and has the capabilities to extend several services to Latam.

www.pinexgroup.com

OUR 2025 SPONSORS

Event Partners:

Cisiv

Cisiv is an innovative technology company providing software that supports the pharmaceutical industry in its work with licensed medicines and medicines distributed through MAPs. Our cutting-edge platform, Baseline Plus, is an integrated solution including Managed Access, Safety Reporting, Real World Data capture, eConsent, ePro and surveys. It has been used for over 10 years by leading global companies in extensive, international MAPs, prospective observational studies and combined activities where RWD is collected with a MAP.

Baseline Plus is compliant with all applicable global requirements including 21 CFR Part 11, GCP, GDPR, and HIPAA and. Our MAP platform enables streamlined request management, controlled approval processes and a unified experience for HCPs and pharmacists through highly configurable role-based workflows. Cisiv's mission is to provide technology to support pharmaceutical companies with the process and data capture that bring medicines closer to patients.

www.cisiv.com

MedaSystems

MedaSystems has built the industry leading cloud based software platform empowering Global Expanded and Managed Access organizations to deliver medicines for any program, any product, and in any country. Track, enforce, and automate all your request workflows, eliminate repetitive tasks, comply with regulatory requirements, collaborate with HCPs and capture RWD in a single, validated platform. Ensure your ability to support future programs and quickly adjust your processes and data collection forms with our easy, click-to-configure solution.

www.medasystems.com

Clinigen

Clinigen is a global, specialist pharmaceutical services company focused on providing ethical access to medicines for over 35 years. With experience of over 400+ Managed Access programs worldwide and lifesaving medicines delivered to more than 100,000 patients, we are the market leaders in delivering Managed Access programs and driving thought leadership with proven operational expertise within Early Access. We are dedicated to giving healthcare professionals and their patients greater access to medicines globally.

www.clinigengroup.com

Uniphar

Uniphar is a trusted global partner to pharma, medtech and biotech companies, working to improve patient access to medicines around the world. Uniphar's team of experts harness the capabilities, infrastructure and expertise of a diversified pharmaceutical service provider with more than 57 years' building success stories with 200+ multinational clients. Our understanding of the shifting market dynamics allows us to deliver tailored specialist solutions for our clients' changing needs throughout the product lifecycle, from expanded access programs to strategic regulatory support to commercial execution.

Uniphar Pharma comprises Uniphar | Access, Uniphar | Medical, and Uniphar | Commercial – together our combined capabilities allow us to be your trusted partner to unlock access to innovative therapies and optimise value for brands globally. Partnering from clinical development to commercialisation, Uniphar's global presence and in-depth market expertise across the product journey remove barriers to launch and optimise pathways to life changing therapies.

www.uniphar.com

UBC

Bio: UBC Connects specialty therapies to the patients who need them most by delivering modern, customized solutions in access, safety, and evidence generation.

We provide expert-driven real-world evidence tailored to specialty patient populations to uncover more valuable insights, maximize commercial positioning, and optimize regulatory approval for the long-term value of your therapy.

https://ubc.com/

Partner With Us

5th Annual Operationalize: Expanded Access Programs Summit
March 18-20, 2025 | Boston, MA

Your Global Platform to Foster New & Existing Relationships within the Early Access Space

Expanded Access stakeholders agree that the primary driver behind the surge in Expanded Access Programs is the ethical imperative to do the right thing. However, the industry still relies on the expertise of solution providers to assist them in in navigating diverse country-specific regulations, collecting real-world data, managing clinical supply, handling incoming requests, and efficiently setting up, running, and closing Expanded Access Programs.

This March, join your community of **120+ experts** working across **Access**, **Clinical Operations**, **Clinical Supply**, and **Medical Affairs** to demonstrate how you can assist the industry in bringing life-changing therapies to patients, faster!

3 reasons to partner:

Generate Commercial Collaborations:

Connect with C-level executives, VPs, and Directors from leading biotech and pharma companies such as **Novartis**, **GSK**, **AstraZeneca**, **Roche**, **Eli Lilly**, **Gilead**. Initiate conversations that could lead to your next long-term partnership

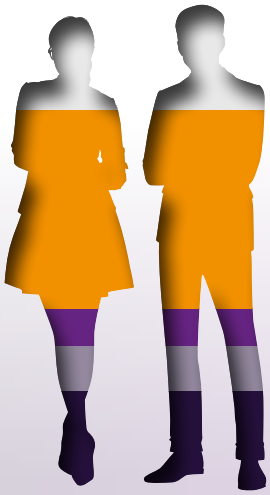
Network with Industry Leaders:

Access key decision-makers in the field who are **actively seeking solution providers to help bring their life-changing therapies to patients worldwide**. Engage with potential clients through speed networking breaks, one-on-one meetings, and informal networking opportunities

Raise Brand Awareness:

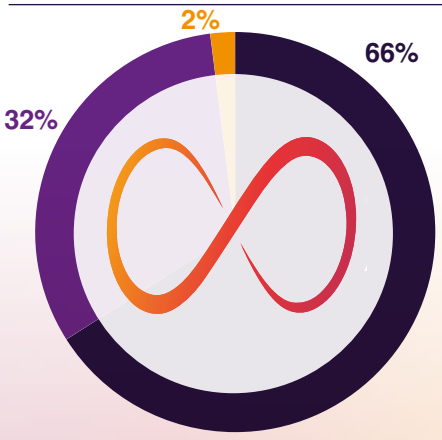
Gain extensive brand exposure to the early access community over three days, as well as before and after the event. Enhance your market position with unique branding opportunities and **differentiate your services** from other industry solution providers

SENIORITY OF ATTENDEES*



- Head/Manager: 21%
- Director: 53%
- VP: 5%
- CxO: 5%
- Senior/Other: 16%

TYPES OF COMPANIES ATTENDING*



- Biopharma
- Solution Provider
- Physicians/ Patients

Statistics Taken from the 4th Operationalize: Expanded Access Programs Summit 2024

GET INVOLVED

Adam Grosz
Partnerships Director
Tel: +1 617 455 4188
Email: sponsor@hansonwade.com

Ready to Register?

3 Easy Ways to Book

www.operationalize-eap.com/take-part/register

Tel: +1 617 455 4188

Email: info@hansonwade.com

LEARN how your peers are currently tackling common operational and regulatory challenges, including Post-Trial Access, transitioning patients to commercial programs, compliantly collaborating with Patient Advocates and Advocacy group and much more.

BUILD your understanding into the current challenges, strategies and solutions to improve global access to life changing therapies

CONNECT with your community and peers from leading pharma and biotech companies to build lasting connections and complementary collaborations that go far beyond this 3-day summit

Drug Developer Pricing*	Register & Pay in Advance	On the Door Price
Conference + Workshop Day	$4,197	$4,397
Conference Only	$2,999	$3,099

Academic & Research Pricing**	Register & Pay in Advance	On the Door Price
Conference + Workshop Day	$3,597	$3,797
Conference Only	$2,599	$2,699

Solution & Service Provider Pricing	Register & Pay in Advance	On the Door Price
Conference + Workshop Day	$5,097	$5,297
Conference Only	$3,699	$3,799

Patient Advocate & Patient Advocacy Group Pricing***	To ensure all stakeholders are present for a meaningful discussion, we have reserved 15 guest passes specifically for Patients & Patient Advocacy Groups

*To qualify for the drug developer rate your company must have a public drug pipeline. Please visit the website for full pricing options or email info@hansonwade.com
Do you work for a Not-for-Profit organization? Email us at info@hansonwade.com to inquire about attending
**To qualify for academic & research rate you must be full time academic. Please visit the website for full pricing options or email info@hansonwade.com
***Guest passes to be limited to one pass per patient advocacy group. Guest passes can only be applied if the individual does not work for industry and is not a solution/service provider. Contact info@hansonwade.com to request a guest pass

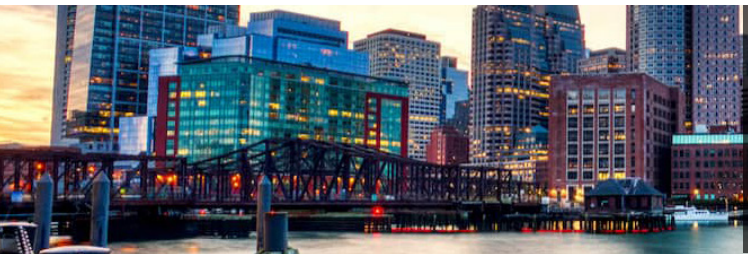
Team Discounts****

- **10% discount – 2 Attendees**
- **15% discount – 3 Attendees**
- **20% discount – 4+ Attendees**

****Please note that discounts are only valid when two or more delegates from one company book and pay at the same time.

Discounts cannot be used in conjunction with any other offer or discount. Only one discount offer may be applied to the current pricing rate.

Contact: register@hansonwade.com



Venue

The Colonnade Hotel
120 Huntington Ave, Boston, MA 02116, United States
www.colonnadehotel.com

TERMS & CONDITIONS

Full payment is due on registration. Cancellation and Substitution Policy: Cancellations must be received in writing. If the cancellation is received more than 14 days before the conference attendees will receive a full credit to a future conference. Cancellations received 14 days or less (including the fourteenth day) prior to the conference will be liable for the full fee. A substitution from the same organization can be made at any time.

Changes to Conference & Agenda: Every reasonable effort will be made to adhere to the event programme as advertised. However, it may be necessary to alter the advertised content, speakers, date, timing, format and/or location of the event. We reserve the right to amend or cancel any event at any time. Hanson Wade is not responsible for any loss or damage or costs incurred as a result of substitution, alteration, postponement or cancellation of an event for any reason and including causes beyond its control including without limitation, acts of God, natural disasters, sabotage, accident, trade or industrial disputes, terrorism or hostilities.

Data Protection: The personal information shown and/or provided by you will be held in a database. It may be used to keep you up to date with developments in your industry. Sometimes your details may be obtained or made available to third parties for marketing purposes. If you do not wish your details to be used for this purpose, please write to: Hanson Wade Ltd, Eastcastle House, 27/28 Eastcastle Street, London, W1W 8DH, United Kingdom