7th-9th October, 2024 | London, UK

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EXPERT SPEAKERS

AGENDA

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3rd Annual

Operationalise: Early Access Programmes Summit EUROPE

Navigate Complex Regulatory & Operational Hurdles to Improve Global Access to Life Changing Therapeutics

Expert Speakers Include:

Sara Radenovic
Director – Managed Access Program
GSK

Alberto Calabro
Patient Access Program & Supply Lead
Roche

Eva Gallagher
Vice President Global Medical Affairs
Agios Pharma

Nora Pontynen
Global Capability & Early Access Treatments
Boehringer Ingelheim

Ramona Reichenback
Head of Managed Access Centre of Excellence
Novartis

Vilem Guryca
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Welcome to the 3rd Operationalise: Early Access Programmes Summit Europe

3rd Annual Operationalise: Early Access Programmes Summit EUROPE

7th-9th October, 2024 | London, UK

A surge of companies are opening Early Access Programmes, but with inherent challenges in managing costs, selecting vendors, establishing eligibility criteria and collecting real-world data, it is critical to share insight with industry peers.

Even for companies with long-established access programmes, the challenges remain in clearly defining an exit strategy, navigating the matrix of global regulations, and maintaining ethical responsibility to patients that have participated.

But one thing is clear. If we can do it, then we should do it.

The **3rd Operationalise Early Access Programmes Summit Europe** is uniting stakeholders executing Early Access, Expanded Access, Managed Access, and Post-Trial Access Programs to enable the sharing of cross-industry case studies and open discussion to successfully bridge the gap between clinical research and commercial supply.

From establishing the right parameters for access to drugs outside the clinical trial setting to interrogating what types of real-world data can be collected to support payer negotiations, join the community of 140+ experts in **Access**, **Clinical Operations**, **Medical Affairs** and **Clinical Supply** to elucidate country-specific regulatory pathways in Europe and beyond and bring meaningful therapies to patients faster.

What last year's attendees had to say:

"It was great being able to discuss some of the challenges with operationalizing EAP with other colleagues from different companies. It was a great and open dialog as we all have similar challenges that we approach in many different ways"

Daiichi Sankyo

KEY BENEFITS OF ATTENDING

Identify the essential data required to develop a reliable supply forecasting model for predicting patient request volume, in collaboration with **Novartis**

Determine which data should be collected, avoided, and mandated across different European countries to comply with regulatory standards, with expert insights from **Roche**

Explore the most effective strategies to support patient journeys and enhance education and awareness about EAPs **from the patient's perspective**

Understand the role of forecasting in planning for Early Access Programs to ensure efficient resource allocation, presented by **GSK**

Examine the regulatory, budgeting, and anticipated challenges of EAPs across various indications, discussed by **GSK**, **Roche**, and **AstraZeneca**

"This conference is a place of true collaboration amongst those managing EAPs. Speakers were knowledgeable, and there was ample time for questions (and there were many asked and answered)"

GSK

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Your Expert Speakers

Aimee Davidson
Portfolio Director
Bionical Emas

Alberto Calabro
Patient Access Program & Supply Lead
Roche

Allison Webb
Senior Project Manager
Blueprint Medicines

Ana Tediosi
Head of Expanded Access Strategy
WEP Clinical

Ann Watkins
Associate Director, Evidence Optimisation and Managed Access Team, Medical Affairs EUR / International
Jazz Pharmaceuticals

Anne B. Cropp
Chief Scientific Officer
Early Access Care

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

Anke Friedetzky
Senior Consultant Medical Affairs, Cell & Gene Therapy
Pierre Fabre Group

Benjamin Rotz
Associate Vice President, Global Medical Policy Strategy & Operations
Eli Lilly & Co

Bethany Bearden
Associate Director, Early Access Program Operations
Blueprint Medicines

Bethany Jordan
Global Medical Affairs Oncology Managed Access Program Lead
GSK

Carole Scrafton
Director / Co-Founder, Patient Advocate & Patient Speaker, Patient Author and Researcher, Patient reviewer of Plain language Summaries
Flutters & Strutters

Carolina Cela Ramos
Medical Affairs Operations Manager
Incyte Corp

Danielle Rafferty
Associate Director, Medical Operations
Biogen

Dennis Akkaya
Chief Commercial Officer
myTomorrows

Eva Gallagher
Vice President Global Medical Affairs
Agios Pharmaceuticals

Gordon Lundie
Executive Director – Market Access
Gilead Sciences

Harpreet Ram
Founder & Executive Director
GARDaccess

Helen Dean
Associate Director, Evidence Optimisation & Managed Access Team, Medical Affairs EUR / International
Jazz Pharmaceuticals

Ita Vickery
Mother & Patient Caregiver

Karen Frascello
Senior Director – Medical Affairs
Alnylam Pharmaceuticals

Karlijn Doorn
Head of Partnerships & Customer Success
myTomorrows

Katja Berg
Innovation Value & Access Strategy, Global Market Access & Pricing
AstraZeneca

Kjersten Teeter
Director, Head of Medical Affairs Operations
Blueprint Medicines

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

Lyn McNeil
Supply Chain Solutions Manager
Almac

Margaret Radford
Unlicensed Medicines Services Manager
Almac

Michael Wrigglesworth
VP, Programs Operations
The Max Foundation

Nora Pontynen
Global Capability Owner & Early Access Treatments
Boehringer Ingelheim

Nathalie Caizergues
Medical Affairs Director
Clinigen

Your Expert Speakers

Natalia Coptu
Site Manager Lead
myTomorrows

Nicky Wisener
Vice President, Business Development, Unlicensed
Clinigen

Nico Laschi
Business Development Manager
Marken

Olivia Vickery
Patient Advocate

Paul Stanton
Senior Director, Global Strategy
Inceptua

Petra Stubbe
Mother & Patient Advocate

Phoebe Luk
Associate Director, Regulatory Affairs
Bionical Emas

Rachel Harrison
Pre-Approval Access Program Lead, Global Medical Affairs
argenx

Ramona Reichenback
Head of Managed Access Centre of Excellence
Novartis

Rebecca Bibby
Group Director of Medicines Access & UK General Manager
BAP Pharma

Ruth Rostron
Director, Early Access Programs
Uniphar

Sara Radenovic
Director – Managed Access Program
GSK

Sarah Alummootil
Associate Director
Early Access Care

Sarah Flynn
Director Managed Access/ Post-Trial Access
Novartis

Uri Ilan, MD
Clinical researcher PHD Student
Coordinator of the International Leukemia/ Lymphoma Target Board at Prinses Maxima Center for Pediatric Oncology

Victoria Scott
Global Medical Affairs
Novartis

Vilem Guryca
Expanded Access Programs
BeiGene

Warsame Ali
Global Early Access Program Lead
Marken

> "The group of participants elevate this conference to the next level! Their passionate for connecting patients with investigational treatments, willingness to support each other and work together as an industry is inspiring"
>
> **Incyte Corp**

Pre-Conference Workshop Day
Monday 7th October

7.30 Morning Coffee & Registration

Beginning Topics in Early Access Programmes

8.30 EAPs 101: Understanding Diverse Terminology & Establishing a Comprehensive Resource Guide for Effective Implementation

- Examining the nuances between Named Patient, Managed Access, Early Access, and Compassionate Use Programs and the implications of different terminology on programme structure
- Identifying the roles, responsibilities, and resources required to successfully launch and manage a program, including team structure and planning
- Developing an educational program to familiarize internal stakeholders with different terminologies, best practices for establishing programs, and the key individuals and stages involved

Helen Dean, Associate Director, Evidence Optimisation & Managed Access Team, Medical Affairs EUR / International, **Jazz Pharmaceuticals**

11.00 Establishing a Successful & Comprehensive Standard Operating Procedure (SOP) to Streamline Processes & Improve Efficiency

- Examining best practises for creating a detailed SOP that serves as a reliable resource across various departments, ensuring consistent processes and clear communication
- Explore factors that may not be covered in the SOP, such as exit strategies and their impact on program continuity and success
- Understanding the importance of maintaining the program effectively, including supply chain considerations, timelines, and collaboration with cross-functional teams
- Assessing RWE and determining what essential information must be shared with internal teams

Nora Pontynen, Global Capability Owner, Early Access Treatments, **Boehringer Ingelheim**

Ann Watkins, Associate Director, Evidence Optimisation and Managed Access Team, Medical Affairs EUR / International, **Jazz Pharmaceuticals**

2.00 Best Practices for Optimizing Stakeholder Engagement & Communication to Enhance Collaboration & Project Success

- Ensuring that we are engaging and education the right stakeholder
- Exploring strategies for maintaining compliance and emphasizing the critical nature of programs as a last resort for patients
- Discovering methods for enhancing communication among HCPs across different countries while adhering to local regulations

Annie Drellas, 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**

Advanced Topics in Early Access Programmes

8.30 Innovative Approaches for Equitable Patient Access & Creating Effective Humanitarian Donation Programs

- Learning how to design and organize these programs, including the key team structures required for successful management and execution
- Gaining insights into budgeting and forecasting for humanitarian programs and long-term plans, emphasizing efficient resource allocation and strategic planning
- Exploring critical regulatory implications when developing humanitarian donation plans, ensuring adherence to local laws and best practices for compliance
- Navigating Free-of-Charge Donation Programs to overcome affordability challenges

Carolina Cela Ramos, Medical Affairs Operations Manager, **Incyte Corp**

Michael Wrigglesworth, VP, Programs Operations, **The Max Foundation**

10.30 Morning Break & Networking

11.00 Access Strategies for Rare Disease Treatment

- Exploring initiatives that provide drugs to children with rare diseases, focusing on specialized approaches and strategies
- Highlighting the steps and regulatory considerations involved in establishing managed access programs for rare conditions
- Discussing potential loopholes and challenges in providing very early access to drugs for super rare diseases without robust clinical data
- Suggesting practical measures that regulatory agencies can implement to facilitate drug development and access for patients with rare conditions
- Engaging with patient communities groups

Eva Gallagher, Vice President, Head of Medical Affairs, **Agios Pharma**

Danielle Rafferty, Associate Director, Medical Operations, **Biogen**

1.00 Lunch Break & Networking

2.00 Establishing a Robust Forecasting Model for Anticipating Request Volume

- Identifying the critical information needed to create an accurate forecast
- Determining which stakeholders can provide input for improved planning and decision making
- Examining the challenges and essential variables that contribute to a forecast's precision
- Exploring future potential models to predict patient request volume

Sarah Flynn, Director Managed Access/Post-Trial Access, **Novartis**

Victoria Scott, Global Medical Affairs, **Novartis**

4.00 Afternoon Break & Networking

4.30 **Mastering Request Management in Expanded Access Programs**

- Recognize the most common challenges and pitfalls in expanded access request management.
- Understand the nuances of expanded access policies and their relationship to clinical trials
- Learn to configure digital workflows for compliant and efficient request capture and physician engagement
- Discover how an integrated platform approach can drive centralized oversight for full traceability and real-time reporting

Dennis Akkaya
Chief Commercial Officer
myTomorrows

Karlijn Doorn
Head of Partnerships & Customer Success
myTomorrows

6.30 **End of Workshop Day**

> "It was great being able to discuss some of the challenges with operationalizing EAP with other colleagues from different companies. It was a great and open dialog as we all have similar challenges that we approach in many different ways"
>
> **Daiichi Sankyo**

Conference Day One
Tuesday 8th October

8.00 **Coffee & Registration**

Dennis Akkaya
Chief Commercial Officer
myTomorrows

8.55 **Chair's Opening Remarks**

Empowering Patients & Caregivers: Building Stronger Connections

9.00 **Panel Discussion: Comprehensive Look at Expanded Access: Patient, Caregiver & Industry Perspectives**

- **Evolution of Patient Involvement -** How patient roles have evolved in Expanded Access programs
- **Insights from Patients and Caregivers -** Sharing their experiences with advocacy, navigating access challenges, and collaborating with industry and regulatory agencies
- **Defining Patient Roles -** further understanding the active roles patients and caregivers play in EA programs
- **Awareness and Engagement -** Best practices for engaging patients and raising compliant awareness in EA programs
- **What's Next for Patients? -** Future directions and patient-centric best practices for Expanded Access

Carole Scrafton
Director / Co-Founder, Patient Advocate and Patient Speaker, Patient Author & Researcher, Patient reviewer of Plain language Summaries
Flutters & Strutters

Rachel Harrison
Pre-Approval Access Program Lead, Global Medical Affairs
argenx

Olivia Vickery
Patient Advocate

Ita Vickery
Mother & Patient Caregiver

9.45 **Panel Discussion: Harmonising European Regulations & Approaches to Compassionate Use Programs**

- Providing an overview of alternative Pre-Approval Access pathways in Europe
- Exploring the potential for harmonizing rules across European countries and compare company practices and requirements in managing access
- Comparing the different requirements/criteria of individual patient programs versus larger group programs and the use of commercial material from different countries
- Analysing the challenges of cross-indication and off-label approval

Ramona Reichenbach
Head of Managed Access Center of Excellence
Novartis

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

10.15 **Interview: The Family Journey of Early Access**

- Access to investigational medical products for treatment, outside of participation in a clinical trial, is available in most countries. Behind every request for a pediatric patient is a parent and care provider with an unabashed advocacy for their loved one. Beyond the operational aspects of medicines delivery lies the patient and family journey. This session will provide one mom's perspective of a 5-year family journey of early access - the uncertainties, joys and emotional experiences of investigational medicines through Early Access.

Anne Cropp
Chief Scientific Officer
Early Access Care

Petra Stubbe
Mother & Patient Advocate

Sarah Alummootil
Associate Director
Early Access Care

10.45 **Speed Networking Session**
Join our speed networking session tailored for Early Access experts, 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 connecting within the space.

11.15 **Morning Break & Networking**

Conference Day One
Tuesday 8th October

Optimizing Data Collection, Post-Trial Access & Stakeholder Alignment: Strategies & Compliance

11.45 Panel Discussion: Driving EAP Success: The Power of Strategic Compliance Collaboration and Stakeholder Alignment

- Exploring how cross-functional collaboration and precision logistics strategies, like lane mapping and real-time data, drive efficiency in EAP execution while enhancing patient experience.
- Discovering strategies for managing complex regulatory landscapes, cross-border laws, and evolving standards, ensuring compliance and mitigating risks throughout EAP programs.
- Learning how emerging technologies and patient-first approaches are shaping the future of EAPs, improving access, safety, and outcomes while setting new standards for excellence


Nico Laschi
Business Development Manager
Marken


Warsame Ali
Global Early Access Program Lead
Marken


Karlijn Doorn
Head of Partnerships & Customer Success
myTomorrows


Aimee Davidson
Portfolio Director
Bionical Emas


Phoebe Luk
Associate Director, Regulatory Affairs
Bionical Emas


Alberto Calabro
Patient Access Program & Supply Lead
Roche

12.15 Optimizing Data Collection Practices

- Identifying the types of data that can, should, and cannot be collected for optimal research and compliance
- Learning methods for successful data collection that align with legal and ethical standards
- Exploring how data can be used or restricted in various countries, and how to navigate differing regulations
- Learning how different companies navigate the legal challenges of data collection, especially when data control and processing centres are in different countries than the program location

12.45 Panel Discussion: Supporting Pediatric Patient Populations: The Case for Expanded Access

- Understand the critical treatment gaps in pediatric care and learn how Expanded Access Programs can bridge these gaps.
- Recognize how to navigate and engage with key stakeholders involved in pediatric Expanded Access requests.
- Gain practical insights from real-world Expanded Access case studies, offering actionable strategies for implementing pediatric access initiatives.


Anke Friedetzky, PhD
Senior Consultant Medical Affairs, Cell & Gene Therapy
Pierre Fabre Group


Karlijn Doorn
Head of Partnerships & Customer Success
myTomorrows


Natalia Coptu
Site Manager Lead
myTomorrows


Uri Ilan, MD
Clinical researcher PHD Student
Coordinator of the International Leukemia/Lymphoma Target Board at Prinses Maxima Center for Pediatric Oncology

1.15 Lunch Break & Networking


Karen Frascello
Senior Director – Medical Affairs, Early Access & Global Diagnostics
Alnylam Pharma

2.15 Post-Trial Access: Global Regulatory Considerations

- Exploring options for continuity of care post trial
- Highlighting mandatory post trial access requirements
- Best practices for transition to PTA programs

Tackling Transitions to Commercial Products & Improving Equitability in LATAM & Africa

2.45 Future-Proofing EAPs: Strategic Planning for Informed Transitions to Commercial

- Insights into early and effective planning and stakeholder engagement
- Key considerations and best practices for managing the timeline-driven shift from expanded access to commercial
- Real-world experiences and strategies to ensure your transition is informed and seamless


Aimee Davidson
Portfolio Director
Bionical Emas


Phoebe Luk
Associate Director, Regulatory Affairs
Bionical Emas


Bethany Bearden
Associate Director, Early Access Program Operations
Blueprint Medicines


Allison Webb
Senior Project Manager
Blueprint Medicines

Conference Day One
Tuesday 8th October

Harpreet Ram
Founder & Executive Director
GARDaccess

3.30 **Enhancing Access to Rare Disease Care in LMICs: A Proof-of-Concept Project by GARDaccess**

- Identifying key challenges faced by individuals with rare diseases in accessing healthcare services in LMICs
- Designing and implementing targeted interventions to address these challenges
- Evaluating the impact of these interventions on improving access to diagnosis, treatment, and support services for rare diseases

4.00 **Afternoon Break & Networking**

Ruth Rostron
Director, Early Access Programs
Uniphar

4.30 **Charging for Access Can Allow a Broader Population of Patients to Benefit from Treatment, But Does it Fit the Eexisting Model? A Case Study for an Alternative Approach**

- Where companies have aspirations for novel ATMPs and rare disease treatments to reach patients wherever they are in the world, charged access can provide a sustainable route. However, increasingly this doesn't easily fit into the traditional EAP paradigm and sponsors are exploring alternative approaches to operationalising such programs

5.00 **Panel Discussion: Navigating Early Access Programs in LATAM & Africa to Improve Equitability**

- Discovering how companies establish and manage early access programs in LATAM and Africa, even without plans for commercial launches
- Identifying key regulations the industry must consider when launching and managing early access programs in these regions
- Exploring the difficulties of providing access to low-income countries and potential strategies to overcome them

Sara Radenovic
Director – Managed Access Program
GSK

Katja Berg
Innovative Value & Access Strategy, Global Market Access & Pricing, Biopharmaceutical Business Unit Professional
AstraZeneca

Harpreet Ram
Founder & Executive Director
GARDaccess

Dennis Akkaya
Chief Commercial Officer
myTomorrows

5.30 **Chair's Closing Remarks**

5.40 **Operationalise: Early Access Programmes' Drinks' Reception**
Grab a Glass! Join our dedicated drinks reception to further connect and network with like-minded experts!

6.40 **End of Day One**

"The group of participants elevate this conference to the next level! Their passionate for connecting patients with investigational treatments, willingness to support each other and work together as an industry is inspiring"

Incyte Corp

Conference Day Two
Wednesday 9th October

8.20 **Coffee & Networking**

Rachel Harrison
Pre-Approval Access Program Lead, Global Medical Affairs
argenx

8.50 **Chair's Opening Remarks**

Managing Supply, Financial & Pricing Hurdles to Overcome Barriers in Early Access

Bethany Jordan
Global Medical Affairs Oncology Managed Access Program Lead
GSK

9.00 **Enhancing Proactive Planning & Response to Optimize Supply Forecasting for Early Access Programmes**

- Understand the role of forecasting in planning for Early Access Programs to ensure efficient resource allocation
- Identifying challenges in program planning and explore potential solutions to optimize the alignment between program size and product availability
- Examining the criteria used to predict request volumes and guide planning decisions for different disease indications and programmes sizes

Rebecca Bibby
Group Director of Medicines Access & UK General Manager
BAP Pharma

9.30 **Roundtable Discussion: Streamlining Global Labelling & Supply Complexities Across Borders for Efficient Drug Delivery**

- Investigating the potential for establishing consistent guidelines for early access medical labelling and language that span different countries, stakeholders, and vendors
- Exploring innovative techniques for making shipments more efficient and reducing their environmental footprint
- Developing working relationships or collaborations with regulators in order to streamline processes, ensuring efficiency, meeting required timelines and cost-effectiveness
- Interrogating the regulatory landscape surrounding labelling and how different interpretations may influence global harmonization efforts

Vilem Guryca
Expanded Access Programs
BeiGene

10.00 **Optimizing Financial, Operational, & Governance Models for Cost-Effectiveness to Understand the Value of Early Access Programmes**

- Analysing various governance structures, development strategies, and decision-making processes tailored for companies planning EAPs
- Evaluating operational frameworks, including patient intake processes, supply chain logistics, and vendor management, to ensure efficient program implementation
- Exploring strategies to enhance the cost-effectiveness of EAPs by examining patient cost management, associated fees, and overall financial planning

10.30 **Morning Breaks & Networking**

11.30 **MAPs Under the Microscope: Embracing Supply Flexibility with Just in Time Manufacturing**

- Exploring the importance of supply chain agility and efficiency
- Mitigating challenges to ensure patient centricity
- Showcasing real-life MAP case studies demonstrating the successful adoption of patient-focused, flexible solutions

Margaret Radford
Unlicensed Medicines Services Manager
Almac

Lyn McNeil
Supply Chain Solutions Manager
Almac

Conference Day Two
Wednesday 9th October

Gordon Lundie
Executive Director – Market Access
Gilead

12.00 Understanding the Impact of Market Access & Pricing in Early Access Programmes

- Examining how market access and pricing vary across key markets like the US, Europe, Japan, and China, and their influence on setting up early access programs
- Identifying potential hurdles in market access and pricing for early access programs and explore effective strategies to address them
- Discussing which countries pose significant challenges in managing programs concerning pricing and reimbursement
- Analysing how market access and pricing impact the commercialization of drugs and shape exit strategies in early access program

Ana Tediosi
Head of Expanded Access Strategy
WEP Clinical

12.30 Navigating the Transition of Assets with an Expanded Access Program

- Defining key milestones and timelines effectively
- Selecting the appropriate stakeholders for involvement
- How to effectively manage communication and leadership when multiple companies are involved

1.00 Lunch & Networking

Navigating Patient Transitions & Exit Plan Challenges

Ben Rotz
Associate Vice President, Global Medical Policy Strategy & Operations
Eli Lilly

2.00 Patient Transition: Discussing the Different Options for Patients After Post-Trial or Early Access Programmes

- Explore strategies for transitioning patients from post-trial or expanded access to regular medical care, including potential hurdles and ideal scenarios
- Discuss the potential outcomes and obligations to patients if a medicine does not get approved after trial participation or expanded access
- Engage in a conversation about the varying obligations and approaches to supporting patients in different access contexts

2.30 Fire-Side Discussion: Medical Science Liaisons - The Forgotten Front Line in an Early Access Programme (EAP)

- What is the role of a MSL in the context of an EAP
- What do both the EAP vendor and sponsor see as the main pitfalls working with MSLs as part on an EAP
- How to improve collaboration between vendor and sponsor, specifically related to utilising the MSL resource
- What is the best practice to effectively working with MSLs to support an EAP

Paul Stanton
Senior Director, Global Strategy
Inceptua

Ben Rotz
Associate Vice President, Global Medical Policy Strategy & Operations
Eli Lilly

Kjersten Teeter
Director, Head of Medical Affairs Operations
Blueprint Medicines

3.00 Navigating Reimbursement Considerations of Exit Plans

- Exploring how companies manage the trade-offs between providing affordable access to patients and ensuring successful commercial availability and reimbursement
- Examining lessons learned on structuring programs to mitigate risks associated with indefinite patient access and complex reimbursement discussions
- Discussing how opening programs earlier can benefit patients while managing challenges in reimbursement paths, with a focus on structuring sustainable access strategies

3.30 Afternoon Break & Networking

Conference Day Two
Wednesday 9th October

Exploring the Nuances of Early Access Programmes

4.00 **Charging for Treatment as Part of a Managed Access Program, Spotlight on France**

- Exploring the various rationale for charging for treatment in a Managed Access Program, how common it is to charge, and if the trends varies from country to country
- Focusing on France and the operational considerations of providing charged for product into the country

Nicky Wisener
Vice President, Business Development Unlicensed
Clinigen

Nathalie Caizergues
Medical Affairs Director
Clinigen

Sara Radenovic
Director – Managed Access Program
GSK

4.30 **Effective Management of Named-Patient Requests: Strategies and Considerations**

- Discovering the range of methods organizations use to handle named-patient requests efficiently and effectively
- Understanding how named-patient requests differ from other programs, particularly in terms of the approval process and regulatory routes
- Learning how to balance individual patient needs with ethical considerations and fair access to treatments for all patients
- Delving into the compliance, strategic, and market access factors involved in managing named-patient requests

Rachel Harrison
Pre-Approval Access Program Lead, Global Medical Affairs
argenx

5.00 **Chair's Closing Remarks**

5.10 **End of Conference**

"Great expertise in the room with a willingness to share experiences candidly"
Fulcrum Therapeutics

"This summit contained important content not found in any other conference and colleagues with whom you can connect"
Eli Lilly

"It is a non competitive intelligence forum between key stakeholders that share the common hope and dedicate their engagement to bring new treatment options and innovations for patients"
Servier

Partner With Us

3rd Annual Operationalise: Early Access Programmes Summit EUROPE

7th-9th October, 2024 | London, UK

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

As more companies launch Early Access Programs, and with existing programs becoming more advanced, the industry increasingly depends on solution providers to offer specialized expertise in setting up and running EAPs, managing clinical supply resources, ensuring regulatory compliance, facilitating site communication, connecting with patients, and collecting data.

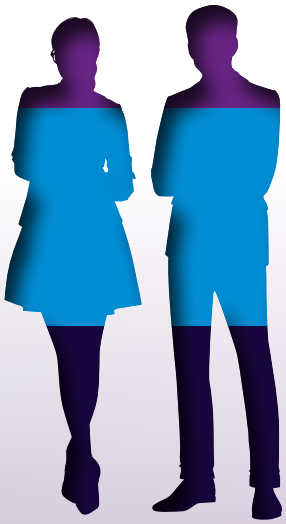
With over 140 Access, Clinical Operations, Medical Affairs, and Clinical Supply professionals attending the summit this October, here are three reasons to partner:

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.

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.

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, and biotechs new to setting up Early Access Programmes. Initiate conversations that could lead to your next long-term partnership.

SENIORITY OF ATTENDEES*

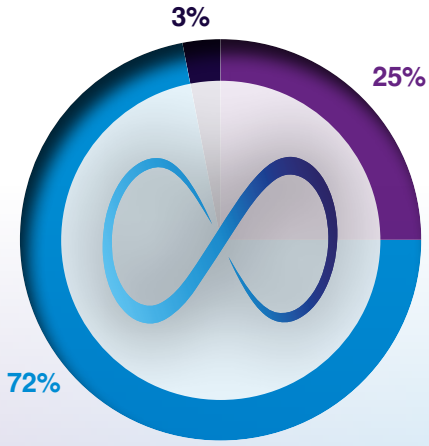


CxO/VP 14%

Director/Head 46%

Manager/Other 40%

TYPES OF COMPANIES ATTENDING*



*Statistics taken from the 2nd Operationalise: Early Access Programmes Summit Europe

GET INVOLVED

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

Our 2024 Sponsors

Expertise Partner

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

Expertise Partner

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/access-and-commercialisation/managed-access/managed-access-programs/

Expertise Partner

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

Expertise Partner

Inceptua Early Access is a global company specialising in the provision of Early Access Programs. With offices in 5 EU countries, the US, China and Japan, and a sophisticated global network of warehousing and shipping, Inceptua can supply medicines anywhere in the world. Inceptua has deep expertise in the setting up and running of complex group programs, post-trial access programs, exclusive distribution arrangements and market withdrawal scenarios. Our highly experienced management team provide unparalleled guidance and consulting services to support our clients in getting their medicines to patients in need, wherever they may be.

www.inceptua.com

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Our 2024 Sponsors

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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

Expertise Partner

Uniphar is a global healthcare company with more than 3,500 employees worldwide across 160 countries. We are a trusted global partner to Pharma and Medtech manufacturers, working to improve patient access to medicines around the world, including underserved markets in LATAM, APAC, Africa, and the Middle East. Our specialised services help to deliver unlicensed medicines to patients compliantly and on time. We're growing by leveraging the strong relationships we have with the 200+ of the world's best known pharmaco-medical manufacturers across multiple geographies, enabled by our cutting-edge digital technology and highly expert teams.

www.uniphar.com/access

Hosting Partner

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 source pre- and post-approval, orphan, and niche medicines to allow access and continuity of treatment, getting patients the medicines they need, when they need them, anywhere in the world. Exceptional Value. Unrivalled Service. Promise Delivered.

www.bappharma.com

Hosting Partner

Bionical Emas is a global Contract Research Organization (CRO) combining Clinical Development, Clinical Trial Supply (CTS) and Early Access Programs (EAP) bringing life-changing medicines to patients around the world. Their unique integrated business model, with its range of services and capabilities, benefit many of the world's leading pharma and biotech companies. This distinctive offering enables them to maximize access and generate evidence at every stage of the drug development pathway.

Early Access Programs (often called Expanded Access, Pre-approval Access, Compassionate Use, Named Patient or Managed Access Programs) deliver potentially life-saving treatments to patients around the world while adding true value to clients through a range of additional cutting-edge services.

Bionical Emas are the only specialist Early Access Program (EAP) partner to harness the full power of an established and successful Contract Research Organization. Their global EAP experience in oncology and rare disease areas is perfectly complemented by a range of in-house services.

www.bionicalemas.com

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Hosting Partner

Marken is the clinical and advanced therapy subsidiary of UPS Healthcare. With Marken, Polar Speed and BOMI Group included, the UPS Healthcare network consists of 200+ locations worldwide. Marken offers a state-of-the-art GMP-compliant depot network and logistic hubs for clinical drug product storage and distribution in 49 locations worldwide, while maintaining the leading position for cell and gene therapy services, direct-to-patient and home healthcare services, biological sample shipments and biological kit production. Marken's dedicated 2,600+ staff members manage 200,000 drug product and biological sample shipments every month at all temperature ranges in more than 220 countries and territories and have orchestrated 16,000+ home healthcare visits. Additional services such as ancillary material sourcing, storage and distribution, shipment lane verification and qualifications, as well as GDP, regulatory and compliance consultancy add to Marken's unique position in the pharma and logistics industry. Delivering What Matters From Clinical to Commercial.

www.marken.com

mytomorrows

Hosting Partner

myTomorrows is a global health tech company dedicated to helping patients and physicians discover and access treatment options. We've partnered with 50+ BioPharma companies to support global expanded access programs, gather invaluable real-world data, and streamline patient recruitment for clinical trials. We are experts in the field of expanded access, having gained experience over a decade, and we manage all aspects of expanded access - from regulatory strategy program setup to full operational execution. We distinguish ourselves by taking a proactive stakeholder-focused approach.

www.mytomorrows.com

cisiv

Exhibition Partner

Cisiv is an innovative technology company, with expertise in non-interventional and observational studies, and provides tools for real-world data collection. Cisiv has built and delivered over 300 studies for the life science industry, supporting pharma, biotech, and medical devices companies to efficiently obtain high quality real-world data.

Our cutting-edge platform, Baseline Plus, is the complete integrated solution for real world late phase capture, providing EDC (for RWD), ePRO, eCOA, eConsent as well as a platform for registries, managed access programmes, and pharmacovigilance. Cisiv's technology platform is compliant with all global requirements for clinical systems including 21 CFR Part 11, GCP, GDPR, and HIPAA. In 2017 Cisiv launched a new platform for pharmaceutical and biotech companies to manage requests for investigational products in Expanded Access Programs and Named Patient Programs (EAP) across therapeutic areas.

This newer platform allows BioPharma to own their data, while managing cases by roles. It allows them to streamline multiple systems into one, manage and approve requests and archive cases. The system gives a unified experience to HCPs and easily onboards HCPs and Pharmacists.

www.cisiv.com

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COREX Logistics is a full-cycle logistics solutions company based in Dublin, Ireland, with over 12 years of expertise in the pharmaceutical and biotech industries. We specialize in regulatory support, temperature-controlled logistics, global distribution, and expanded access programs (EAPs), with over 300 EAPs successfully managed. COREX connects pharma and patients by ensuring the safe, timely delivery of investigational treatments. Our patient-focused services streamline complex supply chains, empowering better healthcare outcomes for those in need.

https://corex-logistics.com

Event Partner

MebCo specializes in customizing an Early Access Program (EAP) for international pharmaceutical companies looking to enter the Mexican market. We facilitate the importation, storage, and distribution of medications after efficiently coordinating with all stakeholders. Our advanced technological tools and highest industry quality standards ensure the effective development of EAPs within a complex legislative environment.

We guarantee transparency and resource optimization, that lead to the desired outcomes. Our commitment to continuous improvement and providing a personalized experience for each of our customers is the foundation of our organization. We take great pride in delivering your cutting-edge medications to the Mexican population.

www.mebcohc.com

Event Partner

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

Event Partner

Nezar Consulting specialises in delivering Early and Post Trial Access tailored solutions to enable access to critical lifesaving medicine to patients. We provide support with internal governance and process, protocols and regulatory dossiers, program management, data collection and bespoke services. By seamlessly integrating within your business, we provide bespoke support, guiding your team through the complexities of access. Our commitment is to deliver flexible, expert-driven services that help you navigate regulatory landscapes and achieve operational excellence.

https://www.nezar-clinical.co.uk/

Event Partner

Sciensus is a global life sciences company specialising in market-leading patient access, engagement and insight solutions. Our team has extensive experience in the rare and orphan disease market and is committed to getting rare medicines to hard-to-reach patients across all Europe.

For over 30 years, we've delivered on every aspect of this vital transaction; from expanded access programs all the way to full commercialization, including real-world data collection and patient support programs.

www.sciensus.com/en-us/rare/?utm_source=event&utm_medium=website_event&utm_campaign=EAP_event&utm_content=london_october24_EAP

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Ready to Register?

3 Easy Ways to Book

www.operationalise-early-access.com

Tel: +1 617 455 4188

Email: info@hansonwade.com

Explore how top pharmaceutical and biotechnology companies are tackling the challenges of aligning with the diverse European regulations, enhancing equitable access, navigating post-trial cases for seamless continuity of patient care, and beyond.

Deepen your comprehension of the prevailing challenges, innovative strategies, and effective solutions within the Early Access landscape, all aimed at advancing global access to transformative therapeutics.

Connect with your peers and community members from leading life sciences companies at the premier European-based industry forum serving as a pivotal platform for defining global regulations and exchanging real-world case studies of Early Access programs.

Drug Developer Pricing	Register & Pay By Sunday, 6th October	On the Door Price
Conference + Pre-Conference Workshop Day	£3,497	£3,597
Conference Only	£2,499	£2,599

Academic Pricing	Register & Pay By Sunday, 6th October	On the Door Price
Conference + Pre-Conference Workshop Day	£2,897	£2,997
Conference Only	£2,099	£2,199

Vendor Pricing	Standard Rate	On the Door Price
Conference + Pre-Conference Workshop Day	£4,197	£4,297
Conference Only	£2,999	£3,099

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

**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 Do you work for a Not-for-Profit organization? Email us at info@hansonwade.com to inquire about attending

Team Discounts**

- **10% discount – 3 Attendees**
- **15% discount – 4 Attendees**
- **20% discount – 5 + Attendees**

**Please note that discounts are only valid when three 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

Millennium Gloucester Hotel London Kensington
4-18 Harrington Gardens, South Kensington, London SW7 4LH
https://www.millenniumhotels.com/en/london/millennium-gloucester-hotel-london-kensington/

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