Conference date: Tuesday 9 November 2021
Digital Conference

Early And Managed Access Programmes Europe

Putting the Patient at the Centre of Medicines Access

Conference Agenda

All timings are in GMT

This is a live document that changes daily. For up to date information regarding the forum please contact Joanna Edwards, Client Relations Director & Event Director, on Joanna.edwards@iqpc.co.uk

Early and Managed Access Programmes

Putting the Patient at the Centre of Medicine Access: The Only Forum to Map the Challenges of Pre-Approved Access Programmes from End-to-End

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There has never been a greater global focus on providing access to medicine, as the COVID-19 crisis brings pre-approval programmes to the frontline in fighting epidemic outbreaks. Of course, utilsing expanded access programmes to fight the pandemic is just part of the story, and they remain of critical importance in providing patient access to medicine across the entire spectrum of illnesses and diagnosed conditions.

In many cases, critical patient or environmental conditions means that any delay in access can be fatal.

In the current environment, there has never been greater global focus on providing access to medicine. As this push for the pharma industry to increase patient access continues, it is critical that they understand the risks and challenges associated with Pre-Approval Access programmes and prepare for the ethical and regulatory pressures that come with these front-line medical developments. Pharmaceutical companies of all sizes require partners who can support the management of their managed and expanded access programmes.

The Early and Managed Access Programmes Digital Summit – our digital partner to the annual London based iteration, first launched in 2020 - is the perfect environment to engage with industry experts who are managing these EMAPs under Covid-19, across global markets. Building on the success of last year's digital summit, the 2021 edition will bring together leading figures in early and managed access development, and the speaker panel will combine patient advocacy and medical ethics experts to address challenges at the very heart of this vital yet, complex, field. Ensure that you place the patient at the very centre of medicine access!

Determine your next steps – during the ongoing COVID-19 crisis and beyond by joining the conversation this November:

- Optimise your pre-approved access programme by streamlining your approach to clinical operations
- View your pre-approved access programme as part of a continuum of development by effectively and compliantly collecting Real World Data
- Safeguard your patient's access to medicine by hearing best practice case studies in logistical strategy
- Ensure your pre-approved access programme is truly patent-centric by discovering how to engage patients at each stage of the programme, from early planning to close out, and beyond

Conference Programme: Tuesday 9th November	
13:00 GMT (08:00 EST)	**Conference Welcome**
13:10 GMT (08:10 EST)	**EAP and RWD Collection: Learning from the Past and Looking Towards the Future** • Review of regulatory and payor perspectives on RWD collection with EAP • RWD collection strategy • Pitfalls of data collection and how to avoid them • Example case studies that highlight specific uses of RWD Tobias Polak, Director RWD, **MyTomorrows**
13:45 GMT (08:45 EST)	**Panel Discussion: Co-Creating with Patients to Bridge Information Gaps in Expanded Access** • Win-win: why co-creation with patients is mutually beneficial for everyone • Method or madness—knowing our audience (and listening to them) • Guide to Expanded Access Update **Panelists include:** Christine MacCracken, MSHEd, BSN, Senior Director & Head, Patient Strategies & Solutions, Office of the Chief Medical Officer, Global Medical Organization, **Janssen** Tom Watson, Executive Vice President, Early Access Programmes, **Bionical Emas** Alix Hall, Managing Director: Policy, Patient Support, and Industry Liaison, **The Isaac Foundation**
14:25 GMT *(09:25 EST)*	Content Break
14:50 GMT (09:50 EST)	**Collecting RWD and RWE: Examples from the COVID-19 Pandemic** • Establishing the differences between RWD and RWE and why both are important • Decisions on collecting data - what is meaningful and what you can draw evidence from? • Considering examples from the COVID-19 pandemic including Convalescent Plasma Hayley Belli, Assistant Professor - Biostatistics Division, Department of Population Health, **NYU School of Medicine**
15:25 GMT (10:25 EST)	**Best Practices for Management of an Expanded Access Program** • Defining program objectives • Creating processes to meet your program needs • Tracking KPIs during your program to ensure opportune delivery Paula Singer, Global Medical Affairs, Senior Manager Early Access Programs, **Alnylam Pharmaceuticals**
16:00 GMT (11:00 EST)	Content Break
16:25 GMT (11:25 EST)	**Panel Discussion: Prioritising Patient-Centricity When Delivering Managed Access Programmes** Keeping the patient at the centre of your Expanded or Managed Access Programme

	• Developing collaborative partnerships to deliver sustainable, successful managed access programmes across patient groups, manufacturers and service providers • Addressing the logistical challenges of delivering Managed Access Programmes • How can companies develop communication strategies to become more patient-centric? **Panelists include:** Nina Vas, Vice President, Clinical Distribution, Cell and Gene Supply Chain, **Marken** Rick Thompson, CEO, **Findacure** Annie O'Keefe Martin, Lead Medical Governance, Global Access Programs, **Sanofi Genzyme*** ***NB. Opinions expressed will be the speaker's personal opinions***
17:00 GMT (12:00 EST)	**Patient Advocacy Panel Discussion: Amplifying the Patient Voice and Bringing Lived Experience to Expanded Access Programmes** **Moderator:** Christine Von Raesfeld, Founder & CEO, **People with Empathy** **Panelists include:** Michael Mittelman, Ambassador, Rare Disease Patient & Cyber Security Consultant, **Patient-Center Outcomes Research Institute (PCORI)** Atif Qureshi, President & Founding Member, **Lysosomal Storage Disorder Society** Stephanie Azout-Chaki, Caretaker & Mother of Michelle, President, **FAST LATAM (Foundation for Angelman Syndrome Therapeutics Chapter in Latin America)**
17:45 GMT (12:45 EST)	**Expanded Access to Gene Therapies: Ethical Considerations and Recommendations for Companies** • Understand the ethical imperative for gene therapy companies to proactively develop expanded access policies • Review obstacles developers face in providing expanded access to gene therapy products • Recognise that conditions with limited windows for treatment deserve special consideration in expanded access Lisa Kearns, MS, MA, Senior Research Associate, Member, Working Group on Compassionate Use and Pre-Approval Access & Member, Working Group on Paediatric Gene Therapy & Medical Ethics, Division of Medical Ethics, **NYU Grossman School of Medicine**
18:20 GMT (13:20 EST)	**Conference Closing Remarks**