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The evolving landscape of pre-approval access to orphan drugs

This presentation will cover the evolution over the last 10 years of pre-approval access (expanded access/early access/compassionate use/named patient supply) to drugs, with an emphasis on orphan drugs and rare diseases.

- The presentation will include;
- How has the landscape changed over the last 10 years?
- What are the driving forces behind these changes?
- How have the regulations changed in recent years, and what has the impact been?
- What are the commercial opportunities provided by pre-approval access to orphan drugs?
- What do the next 5-10 years hold for pre-approval access to orphan drugs?

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Biography

Stuart has more than 20 years of healthcare and pharma consulting experience, with a particular focus in unlicensed medicines and pre-approval access. He is one of the senior management team responsible for establishing Inceptua Medicines Access and is responsible for Inceptua's consulting engagements, covering strategy and policy, real-world evidence, communications and market access. Prior to Inceptua, Stuart set up the Consulting Dept. at Idis/Clinigen, pioneering the development of global corporate strategies on pre-approval access and developing the first pre-approval-specific EDC for real-world data collection. He has formerly held roles as: Principal, Real-World Evidence at IQVIA, Director, Informatics Initiative, UK Dept. of Health, Consultant to the European Association of Neuro-Oncology and Director of Communications for the European Cancer Organization.

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