

INCEPTUA
HELPING PHARMA · HELPING PATIENTS

Inceptua

Leaders in Global Medicines Access



Our Business Areas



Experts in global early and managed access programs, licensed and unlicensed medicines distribution and unlicensed medicine on demand.



Leading providers in global clinical trial supply: medicines and ancillaries, packaging and labelling, storage and distribution.

Early Access - Motivations for Pharma



Provide patients with no alternatives access to potentially life-improving or life-saving treatment



Pre-launch physician and payor experience



Provide continued access to treatment after clinical trial / more cost-effective than an OLE



Generate revenue prior to commercial launches in each country



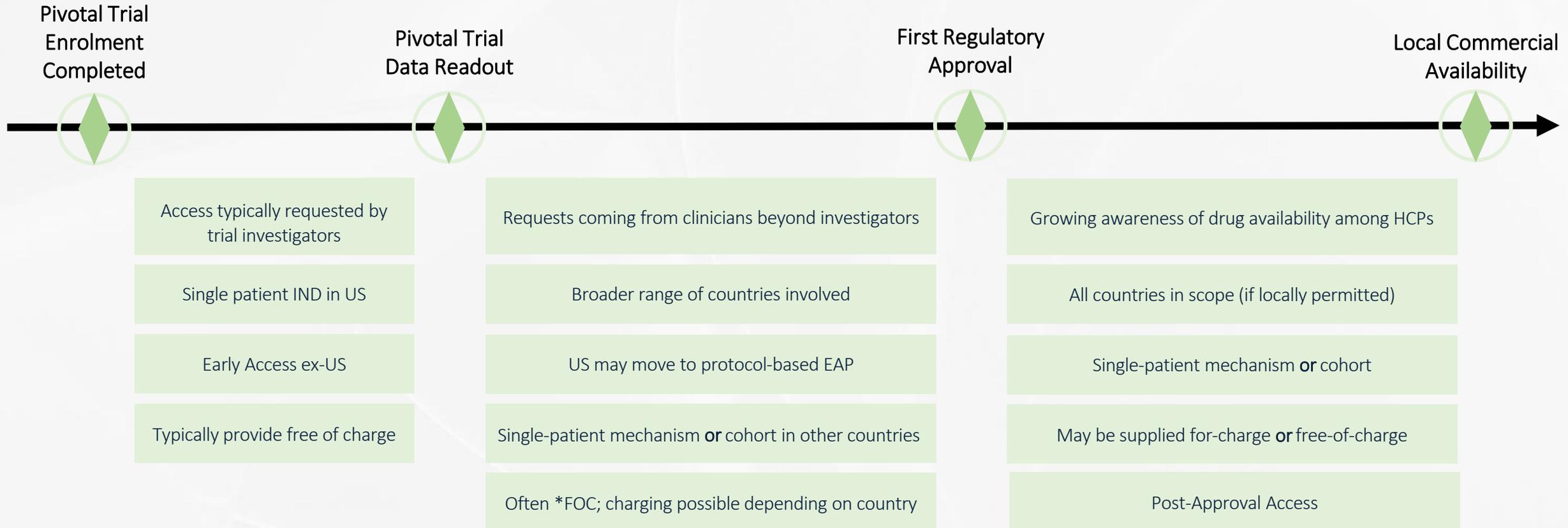
Greater product awareness, possibly driving higher immediate uptake at launch



Collection of real-world evidence and safety data



Typical Early Access Program Lifecycle



* FOC = Free-of-charge



Inceptua:

25+ years a Partner of Choice for Pharma & Biotech

Inceptua Overview



INCEPTUA

Providing solutions, addressing clients' most challenging needs

Early Access Programs

Clinical Trial Services

Clinical Trial Sourcing

A Leader in Early & Managed Access

Thought Leadership & Expertise

- Leadership team consisting of **domain experts** and **industry thought-leaders** having developed **industry standards**
- In-house **experience in 300+ programs**

Global Capabilities

- **Global program coverage** with programs active in **North America** and **Europe, LATAM** and **APAC**
- Exceptional **in-house regulatory expertise** ensuring the **highest level of compliance** of programs **covering 100+ countries**

End-to-End Capabilities

- **Comprehensive capabilities** ranging **from strategy**, program design and implementation **to commercial supply**

Program -Specific Real-World Data

- **Broad spectrum of early access data** (Real World Data, patient-reported outcomes, and physician perception data) **to support successful global launches**
- Created the **first EA-specific, custom-built EDC system**

Strong Global Presence

Direct presence in Europe, the US, China and Japan

- Luxembourg (HQ)
- Berlin, Germany
- Windsor, UK
- Princeton, NJ, US
- Lugano, Switzerland
- Kobe, Japan
- Stockholm, Sweden
- Shanghai, China

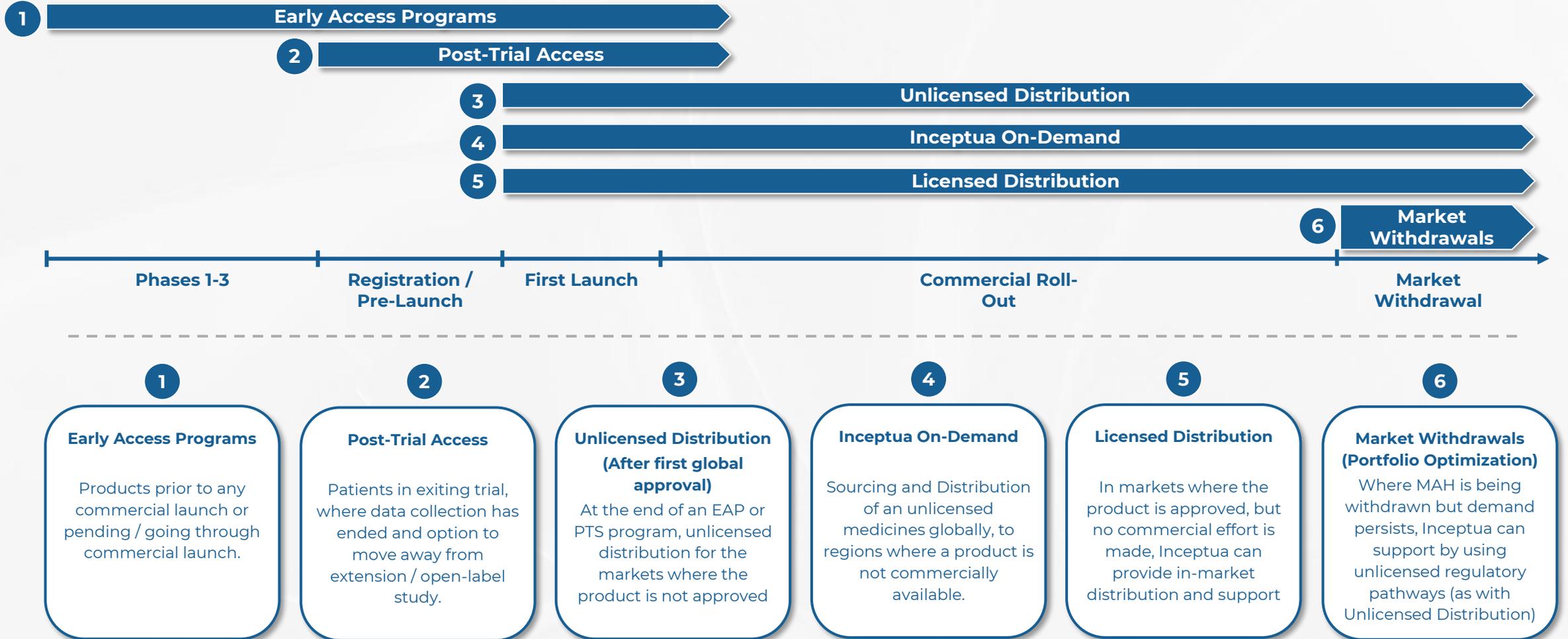
- Inceptua office
- Local warehouse
- Depot

Inceptua – a strong partner in China

- Operating in China for 20 years
- Local office in China - Mandarin speakers in Europe / US
- Direct access to China's Largest Named Patient Procurement Program; Orphan, Paediatric and Clinically Urgent Products
- Clinical services partner for labeling, packaging, storage, and distribution
- Warehousing in free trade zone providing fast transit clearance and reduced customs duties
- Access to Hainan Boao Lecheng International Medical Tourism Zone and other China pilot zones

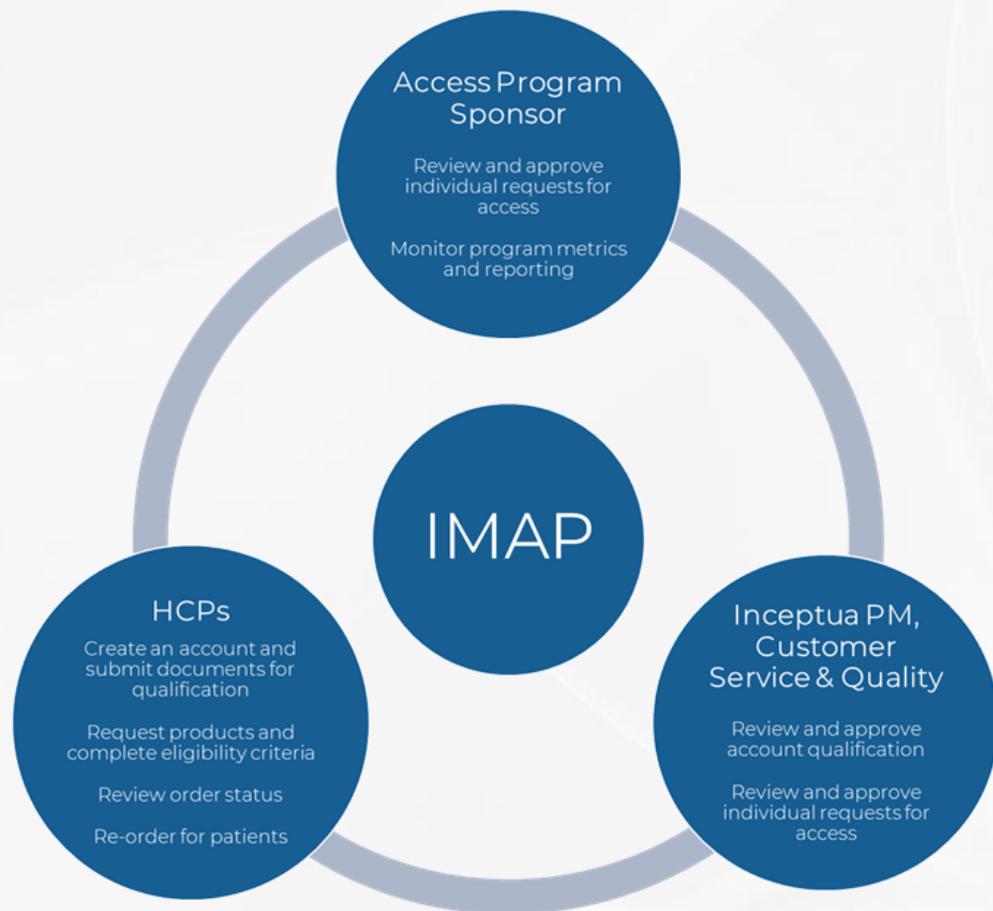


Comprehensive Service Offering Across the Product Lifecycle...



Custom Built, In-House Developed Ordering Platform (IMAP)

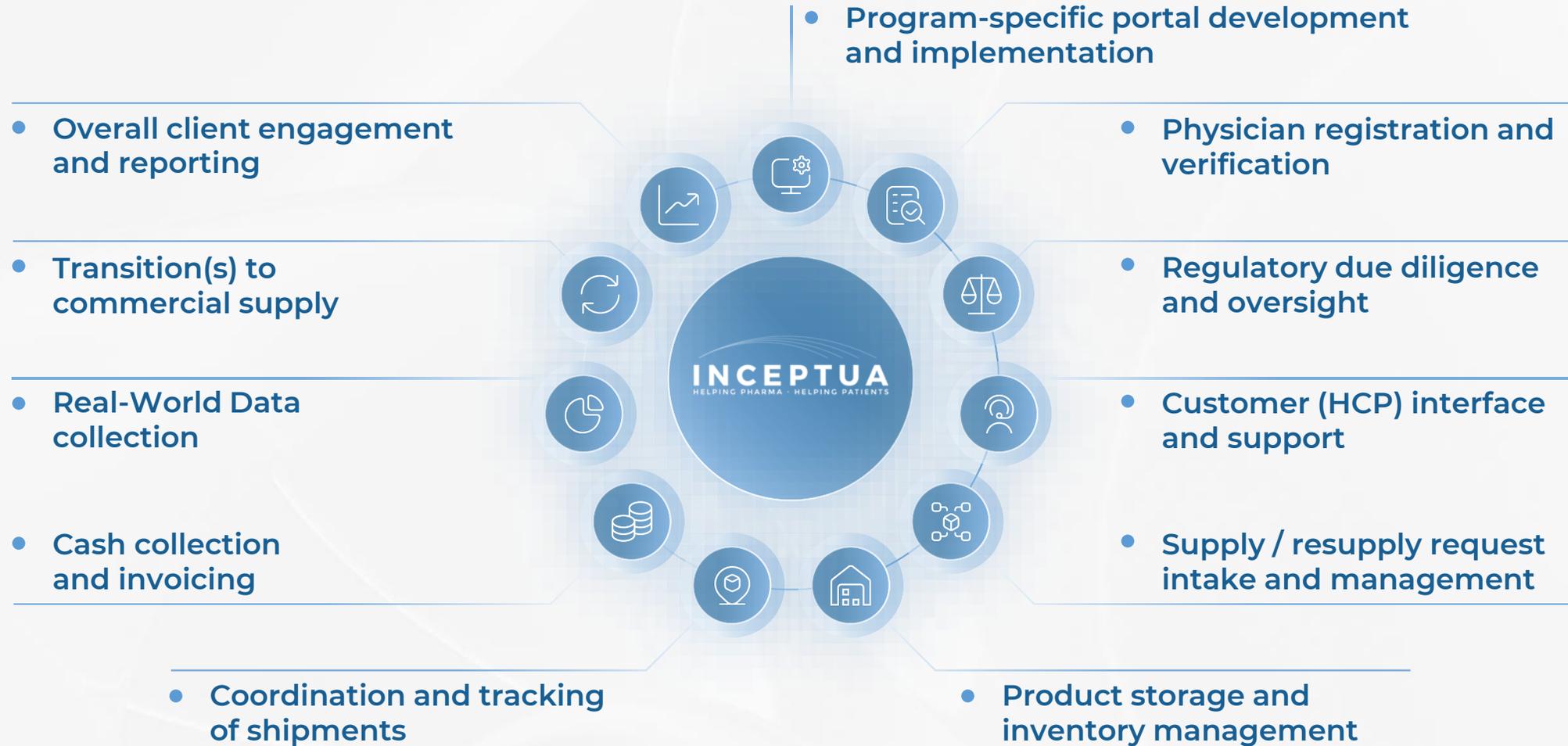
Inceptua Medicines Access Portal (IMAP)



IMAP Highlights

- **Custom built and fully in-house developed platform** designed as an end-to-end workflow for qualifying physicians and managing the entire order process
- **Integrates a task flow system** so requests for **account set-up and validation**, and **subsequent product requests are triaged to the relevant teams**
- Designed with **hands-on experience executing EAPs** and multiple other such systems
- Supports data collection for RWE
- **Fully validated** in accordance with **GAMP5 certification** to ensure full **GxP and GDPR**
- Language-specific flows for different countries involved in a programme
- **Country specific Regulatory Information** available **on-demand**
- Fully customisable based on client needs
- **Mobile phone compatible** – App in development
- **Direct client access** for **generating reports** and monitoring the programme progress
- **Continuously running since 2018**
- **1000's of orders processed** through the platform **each year**

Inceptua Program Support



Worldwide Regulatory Experts

Inceptua experience covers
> 120 countries
for early access supply



Supply Chain and Logistics Requirements

Inceptua's global network consists of **30+ warehouses and depots** in EU, US, LATAM, MENA and APAC regions

- A global network allows the flexibility to accommodate a wide range of products, storage conditions and urgency of delivery
- Allows for a centralized, regional or local inventory strategy
- Due to the size of our network, we can **quickly adapt** our inventory strategy and transfer inventory even post go live

From **integrators to premium couriers**

- Integrators: smaller shipper sizes to ensure individual patient shipments can be **done compliantly at lowest possible cost**
- Premium: covers everything from standard temperature ranges to shippers using dry-ice and liquid nitrogen for frozen products
- Courier portfolio is set up so there is **always an alternative** if the preferred courier can't meet our requirements and demand

Marine insurance for our entire 3PL network including storage and transportation making sure our clients' product are insured at all times throughout the supply chain

Inceptua will have its own, **dedicated central warehouse** up and running towards the end of 2026

Inceptua Warehousing, Storage and Labelling

Warehouse Location	Capabilities
UK	-15 to -25, 2-8 and 15-25 storage. Utilized for EAMS (UK-specific programs)+ ROW
Sweden	-180, -90, -15 to -25, 2-8 and 15-25 storage. Utilized for EU+ ROW programs + labelling
Netherlands	-15 to -25, 2-8 and 15-25 storage. Utilized for EU+ ROW programs + labelling
New Jersey, US	Regional distribution US and Canadian programs
Uruguay	Regional distribution LATAM programs + labelling
Singapore	Regional distribution AsiaPac programs + labelling

- Globally positioned warehouses allows much greater flexibility to adapt to the wide variety of client and product requirements necessary for global early access competence
- All Inceptua's warehouses are regularly audited by Inceptua
- All warehouses abide by GMP/GDP standards (EU/WHO)
- Additionally, all warehouse staff are in-person trained on all new Inceptua programs, so they understand the particular requirements of the product and the patients
- In addition to the above central & regional warehouses Inceptua has a set of local depots in APAC & LATAM

Maximising Data Collection Opportunity through Custom Platform (IMAP)

Maximization of Data Collection

● Program Metrics

- ✓ Unsurpassed reporting and program activity insights in real-time
- ✓ System easily adapted to support specific client requirements
- ✓ In-house, custom-built system, designed based on experience with multiple other vendors

● Physician Perception Data

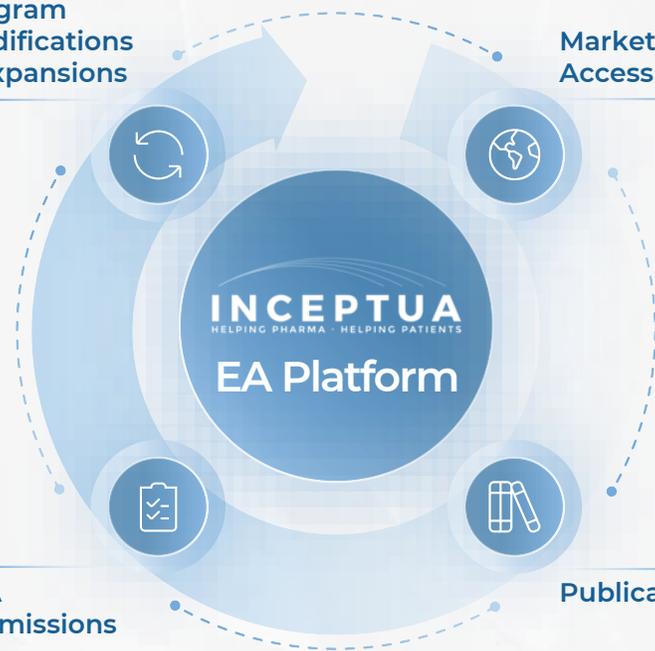
- ✓ Understand physician perceptions of products to guide in-country launch
- ✓ How do physicians perceive your product against available therapies?
- ✓ What are their thoughts on pricing
- ✓ All such subjective information can support launch activities

Program
modifications
& Expansions

Market
Access

HTA
Submissions

Publications



● Real-World Data

- ✓ Patient outcomes to complement clinical trial data
- ✓ From lab data to PROs
- ✓ Compliant, validated system collects data in same format as clinical trial data, for each of integration/analysis
- ✓ Data cleanse and analysis capabilities
- ✓ Inceptua-collected RWD presented by clients at major international conferences

● Discontinuation Data

- ✓ Automated analysis explaining why physicians did not re-supply products
- ✓ Understanding why a physician did not order further product for a particular patient can provide vital insight

Strategy and Policy

Public-facing policies on access are just the tip of the iceberg...

An effective policy is based on a comprehensive global strategy on access, which reflects your company's corporate ethos and covers:



When in the development process?



On what evidence?



Who should oversee it?



In which territories?



Charged-for or free-of-charge?



When will it end?



What do our peers do?

Inceptua Early Access has unmatched experience in developing effective corporate strategies and policies on access.

Consultancy Services



Feasibility Studies

Detailed country- and asset-specific analysis to determine in which countries it makes sense to open an Early Access Program

Understand awareness, perception, local treatment pathways, and the specific country regulations governing Early Access to help you plan for success



Pipeline Review

A detailed assessment of each individual asset, with regard to the various criteria which underpin successful Early Access

Understand whether, when and how to provide access for each of your assets



Real-World Data Asset Mapping

Identify existing data assets which may be used to supplement RWD obtained through your Early Access Program

Many local sources of data are available which can help provide historical/local controls for your Early Access RWD studies. Identifying these sources in advance can lead to informed decision-making and improved study design



Routes of Payment Analyses

Routes of payment for unlicensed medicines vary by country, and even regionally within a country

Understanding the local dynamics prior to implementing an Early Access Program ensures allows informed decision-making

Compliant Communications

Promotion of an unlicensed medicine is prohibited.
But compliant awareness-raising of access programs is permissible.

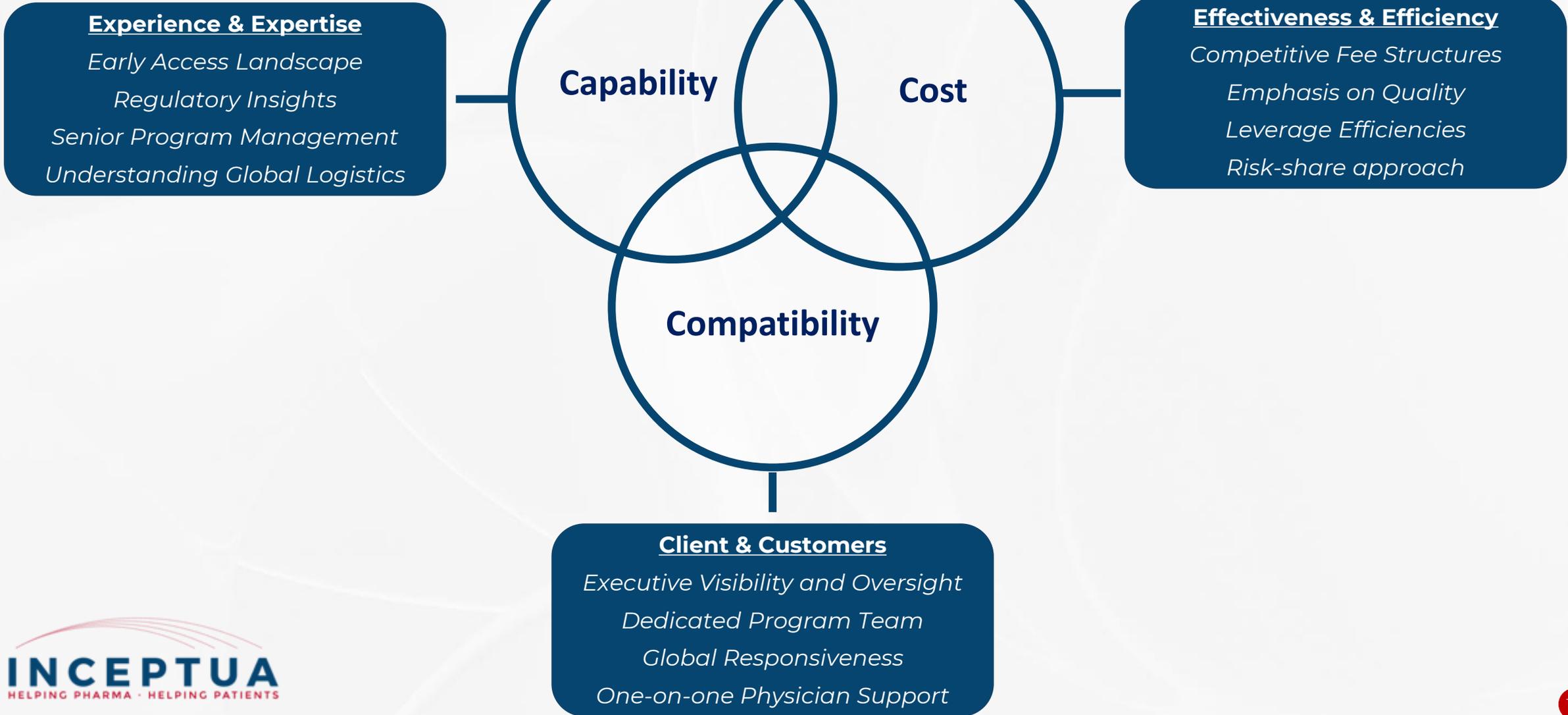


Business-relevant press release, compliant microsite, training materials for MSJs and conference staff to ensure they remain compliant, whilst ensuring appropriate information is shared.



Inceptua Early Access has many years' of experience in guiding clients and ensuring their reputations are protected, whilst allowing physicians who seek access to a product can find the information they need.

Why work with Inceptua?



Inceptua Early Access

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Case Studies

Case Study 1: Strategy and Policy



Situation

A top tier pharmaceutical company was approaching the launch of a major new immuno-oncology asset.

A competitor in the same indication already had an access program in place, and was using it in an aggressive (but legitimate) manner to maximize its success.

Anticipating significant pre-license demand and, being aware of the changing landscape with regard to access, they wished to develop a forward-looking and ambitious approach to access.



Process

Senior management interviews (CEO, CMO, Global Business Unit Heads).

Workshop with client team to agree points of principle (e.g. at what point in development should we consider access?, Who should own access?, In what territories will we provide access? Will access be free-of-charge or charged-for? etc.).

Competitor bench-marking and strategic guidance around compliance, industry direction and competitive advantage.

Development of a Global Strategy, an Internal Policy, modifications to SOPs and a robust External Policy.



Outcome

Formation of a Committee to oversee all early access decisions.
Centralization and control of access programs.

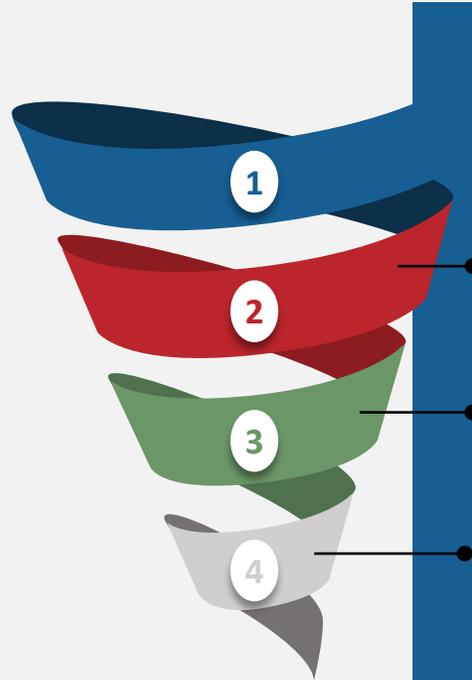
Trigger point on clinical development process at end of PII to consider access.

Consideration given on a case-by-case basis with regard to ancillary opportunities e.g. real-world data capture, market research etc.

Template to ensure suitability for an access program is judged against uniform criteria.

Case Study 2 - Feasibility Analysis

- An international pharmaceutical company was developing a novel therapy for a high-profile rare disease
- The therapy was in Phase 3 development and the company wanted to provide Early Access to patients in need
- From a target of 227 countries, the company wanted to understand which countries would meet certain criteria and where to focus Early Access supply



Focus: From 227 countries, identify those that meet high-level criteria e.g. patient numbers and GDP

Refine: Consecutive rounds of elimination based on detailed criteria: e.g., ability to charge, collect data, regulatory feasibility, competitor landscape, ongoing clinical trials, in-country awareness etc.

Identify: Immediate Phase 1 Early Access launch countries and Phase 2 follow on countries

227
COUNTRIES

17
Phase 1
countries

11
Phase 2
countries



1,000
PATIENTS

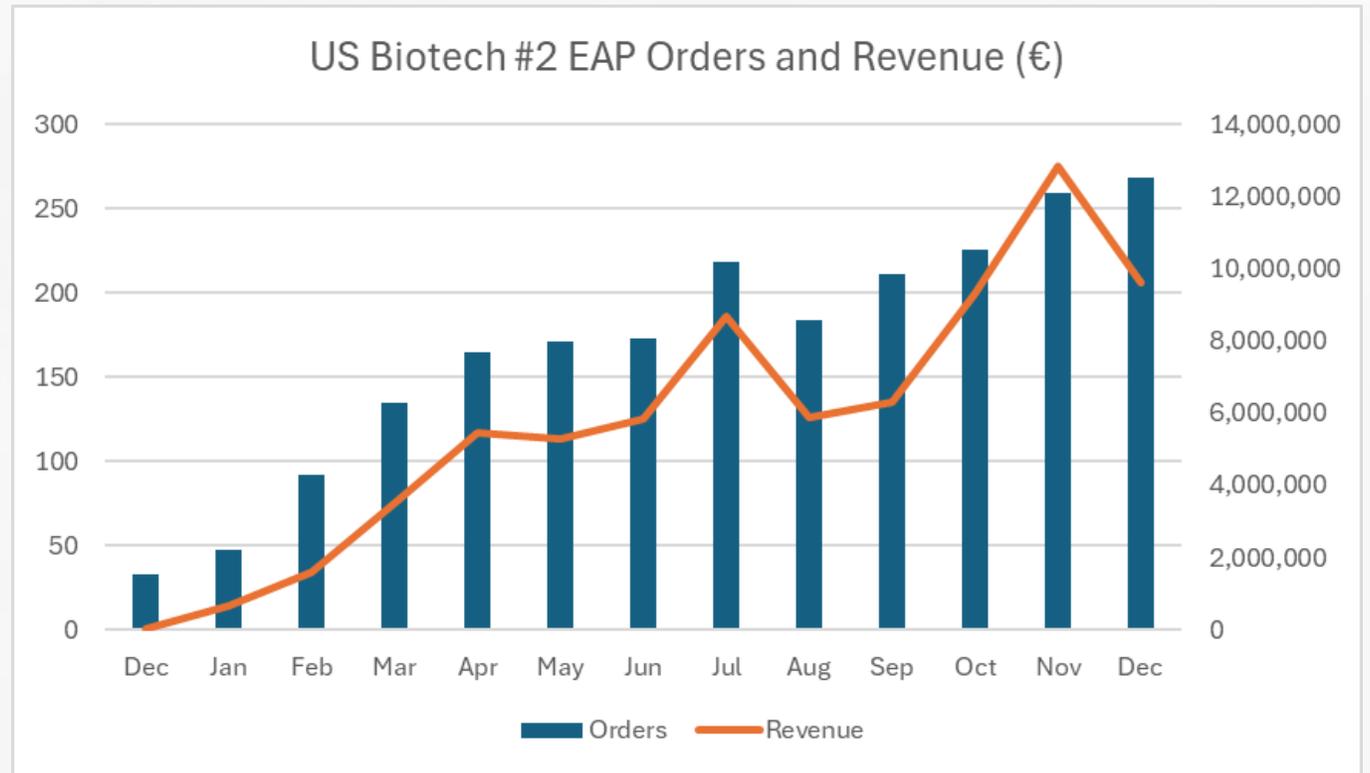
- The company was able to optimize the timing of the Early Access program via the feasibility analysis that identified and prioritized specific markets in a phased approach
- The company was able to plan and manage the investment and inventory required for Early Access to ensure successful and compliant supply to patients in need

Case Study 3 - Post-Trial Access

- **Post-trial access support is a common requirement** for Inceptua clients, as more companies seek to move away from the cost-intensive approach of open-label extension studies
- **Some countries have specific post-trial access regulatory routes**, but the majority do not
- **Post-trial access is relatively straightforward** as direct communication with site investigators is permitted
- Inceptua is currently putting in place a large post-trial access program, working in **a three-way partnership with the 2 companies** who are collaborating on the development of the asset
- To add to the complexity of the 3-way partnership, one of the partners is already using a different vendor to support access, so **the program involves transition of site investigators from an existing post-trial access program**
- Inceptua guided the 2 companies through the **strategic planning and complex contractual process to ensure seamless transition, and shared visibility** across all regions covered by the respective partners

Case Study 4 – Revenue Generation Through EAP #1

- US Biopharma company approached Inceptua, looking for support for an EAP for their recently-launched US product
- The asset was the first approved medication for a serious rare disease and saw immediate demand from physicians around the world
- Inceptua opened the program initially in Europe, expanding afterwards to high-income countries in the Middle-East, and progressively to AsiaPac, taking in Australia, Hong Kong, Taiwan, Singapore etc.
- The program scope is defined by demand and requests from physicians and opens in new countries once demand is established

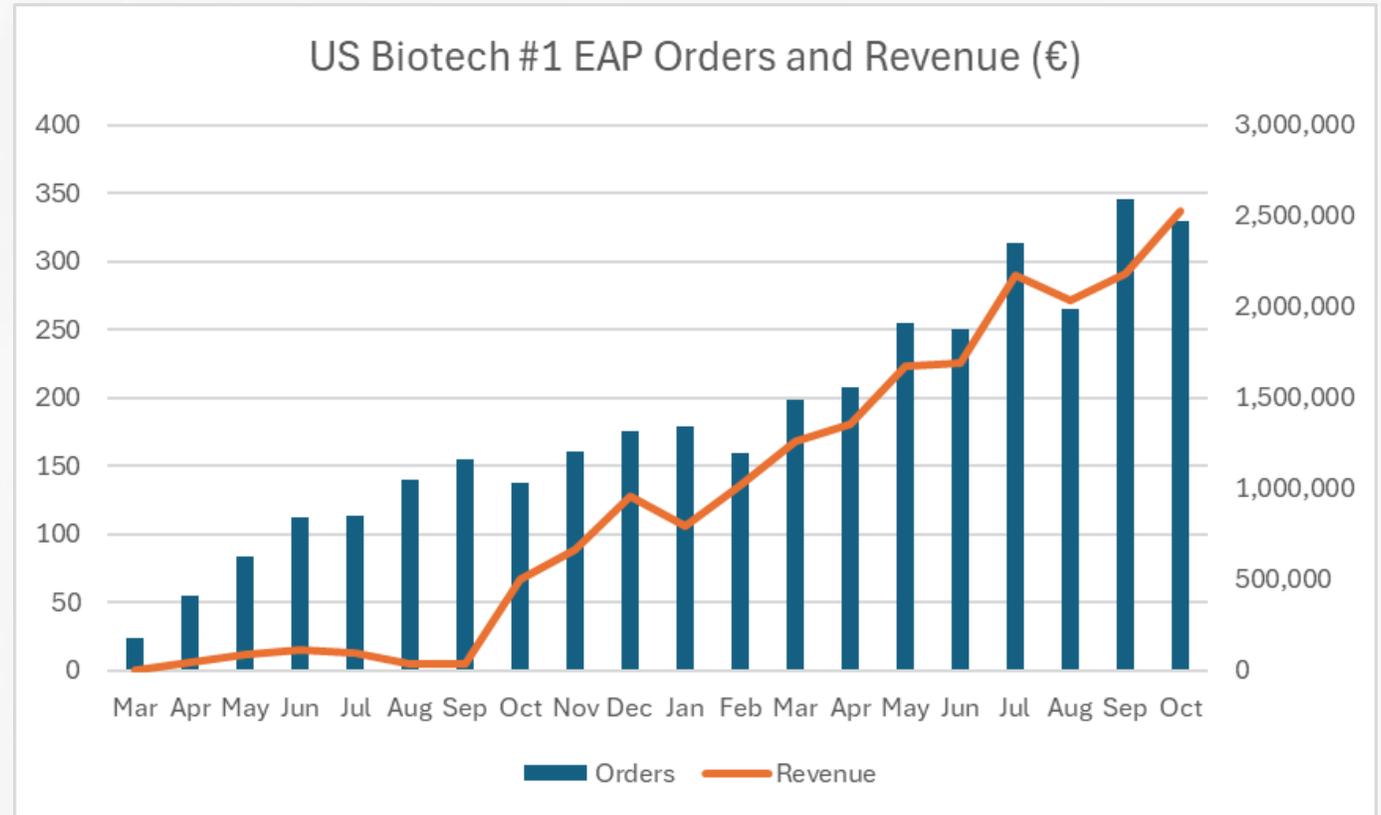


The scale of this program took the client by surprise
The program saw many of the key prescribers for this niche patient group participating in countries around the world

The company was recently acquired by a large US pharma company

Case Study 5 – Revenue Generation Through EAP #2

- A single-asset US biotech received FDA approval and launched the medicine in the US themselves
- They approached Inceptua and asked us to set up an EAP in Europe
- The company opened the EAP in Germany first (due to the significance of the market and the fact that it is the quickest market in Europe to agree a commercial price) but on a free-of-charge basis, as well as a couple of smaller countries to gauge initial demand
- This accounts for the low revenue for the first 7 months, until the program was expanded to other countries in Europe



The program exceeded the expectations of the client and saw significant demand

The company was acquired by a large pharma company who persisted with the program, given the high unmet need and the clear demand for access

Case Study 6 – Global Donations Program

- A small biotech approached Inceptua seeking to change vendors for a long-term **donations program for 2 ultra-rare disease indications** they had been running in **Africa, Middle East and Asia**
- The company wished to expand the footprint of the program to include further low-income countries, but also faced **limitations in drug supply**, requiring the implementation of a **patient cap**
- Inceptua worked with the client, and several **patient's groups and KOLs** involved in both disease areas to identify countries for expansion, and the approach for the patient cap
- **The program was rolled out late 2023**, with uptake from existing countries/physicians managed seamlessly
- Inceptua successfully managed provision of ongoing treatment into countries like **Sudan**, as well as **maintaining treatment to patients who had fled their home countries to third countries** due to conflict and persecution