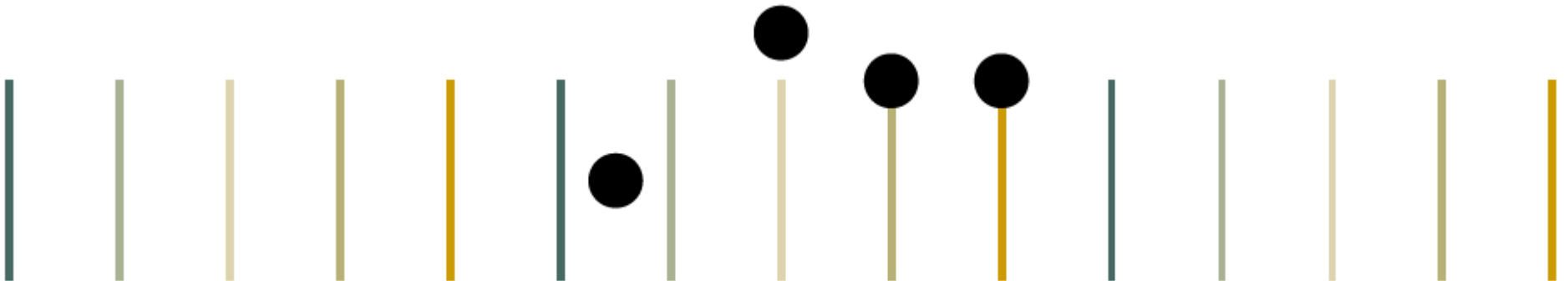
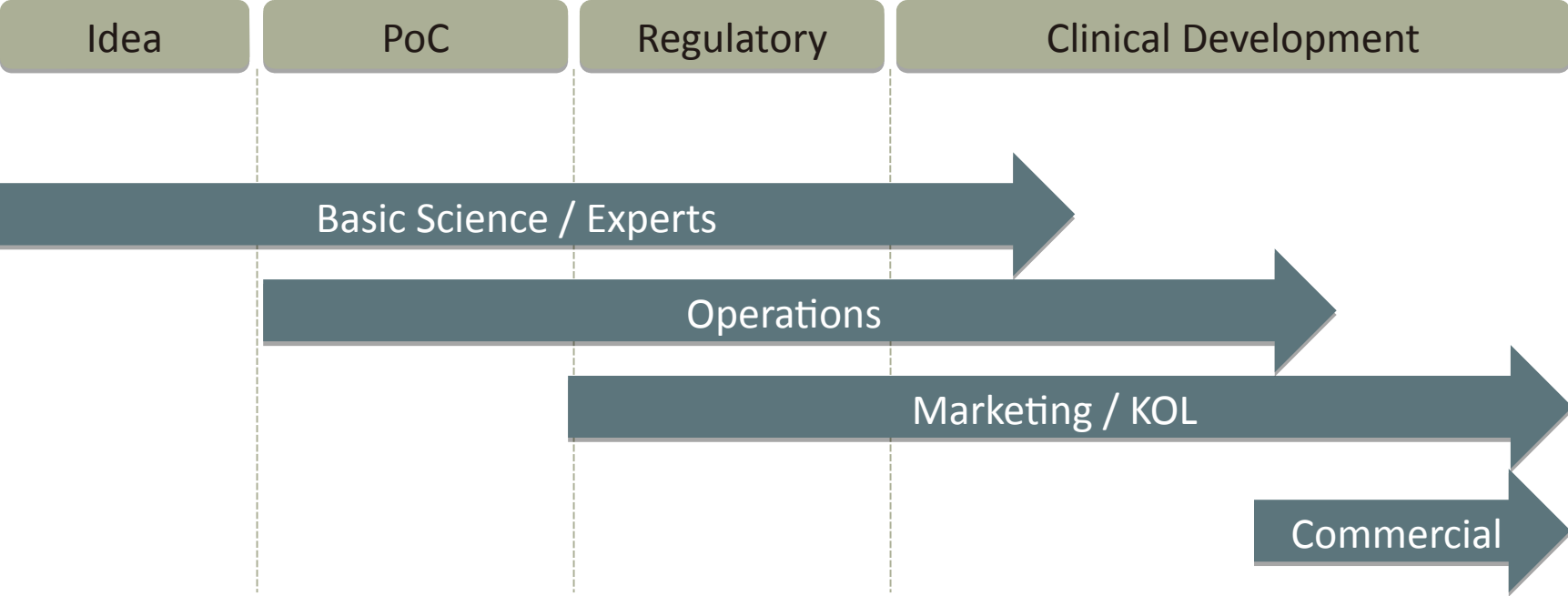


Creating value for healthcare: Early Stage Market Access: a payer's perspective

Company profile- 2019



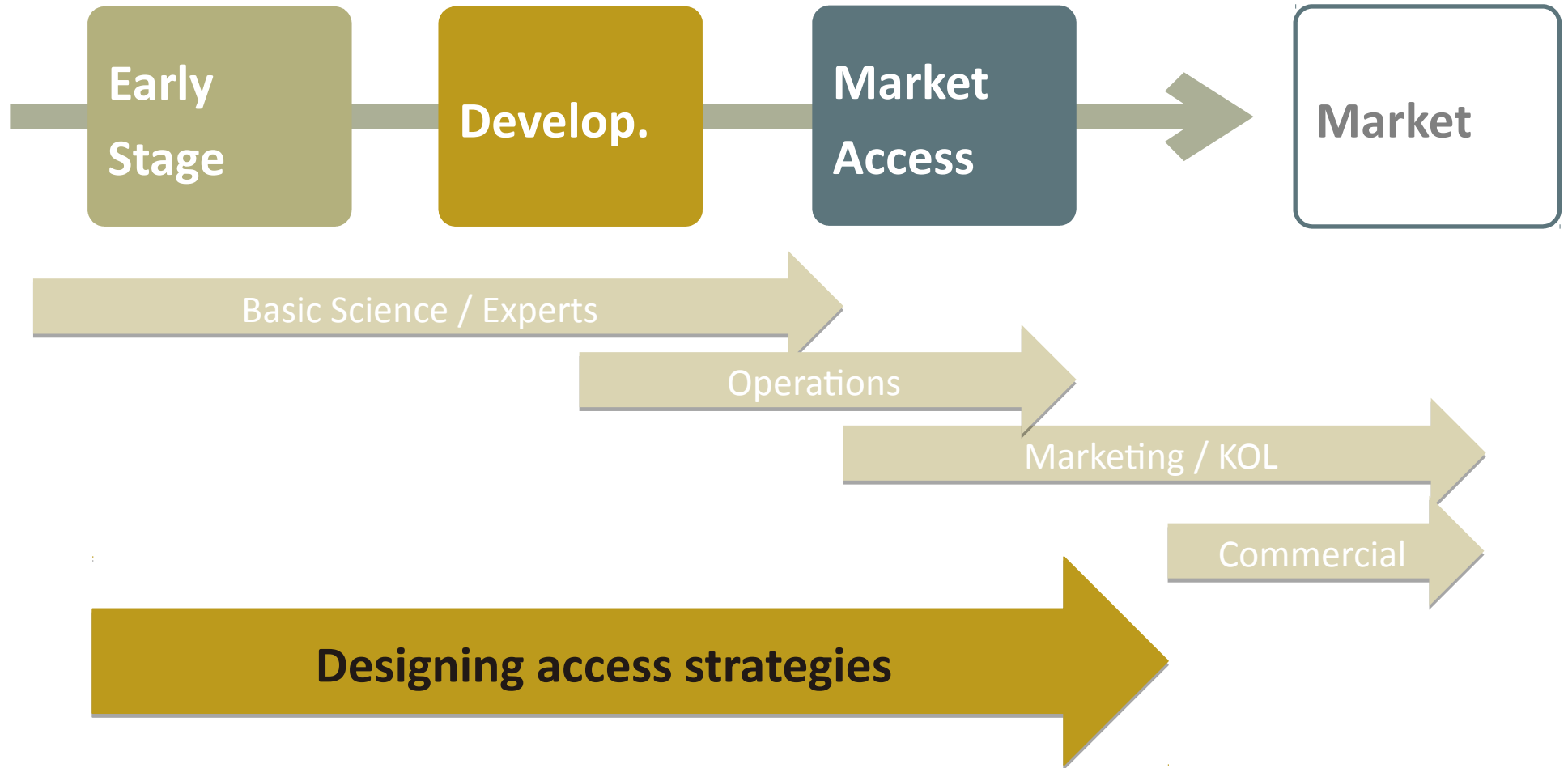
The current strategy...



‘I’d wish I had included this in my analysis’

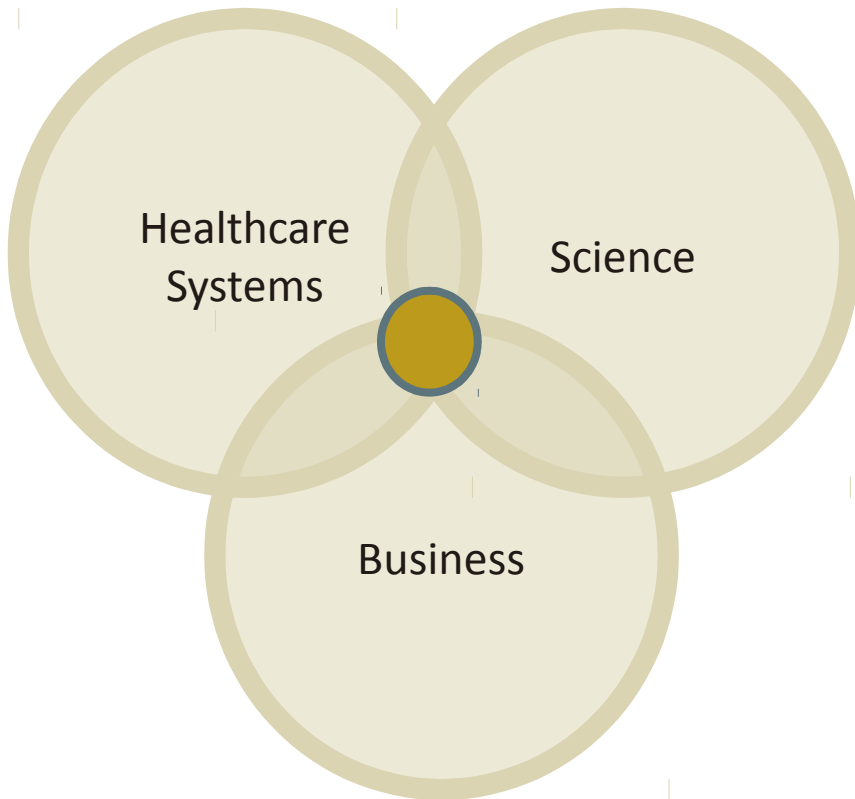


HiTT's approach

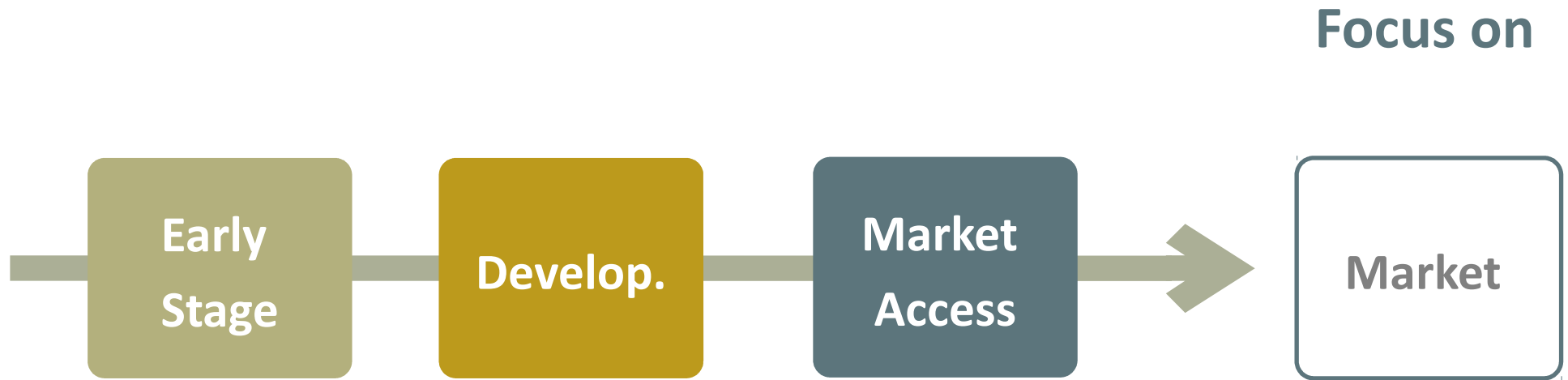


HiTT's proposal

testing the science with market perspective



- Hands on Experience
- Extensive payer network in EU5
- Independent review
- International (EU& North America) perspective
- In-depth knowledge of approval process and pricing schemes
- International reputation



We incorporate **payer's perspective**

- To consolidate **early strategic decisions to steer value** for health products & services
- To support **access strategies & market development**
- To generate data for **reimbursement decisions** at any decision level

Optimising development pathways

Early Stage

- Early Stage Market Access
 - CPG review and trends; literature search
 - Outcome needs
 - Trends, SoC, pricing forecasts
- Design and implement roadmap
 - Align regulatory & pricing & HTA strategy
 - Design and implement clinical & data strategy
- Business Plans
 - Definition of clients, buyers and value proposition
 - Market research



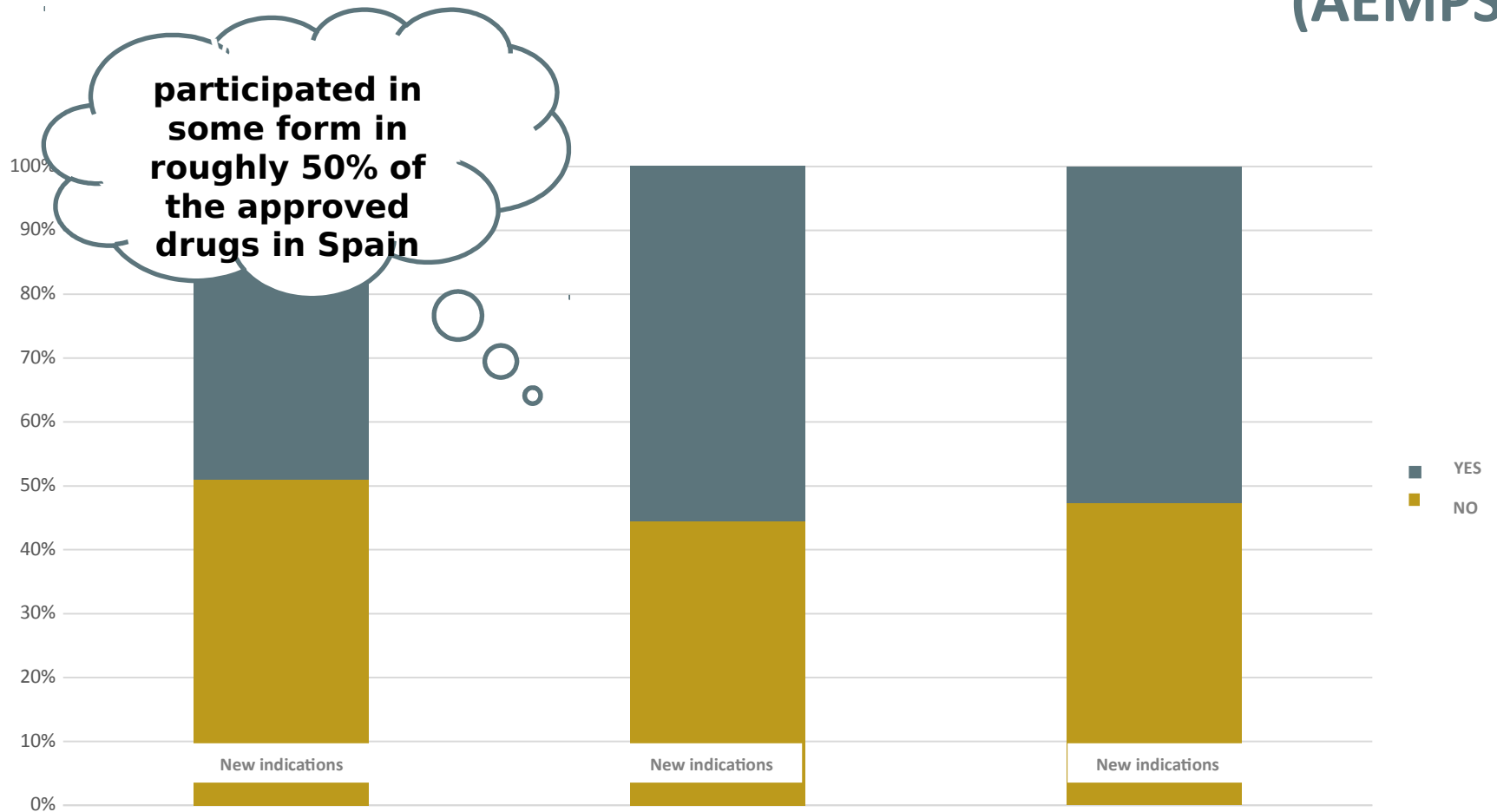
Optimising development pathways

Early
Stage

- *Developmental* Due Diligence
 - Regulatory and HTA hurdles
 - Validate expected outcomes & revenues
 - Pricing corridor
 - Partners and main stakeholders
 - Validate timelines
 - Early stage investing strategy
 - Framework analysis / competitor landscape



Participation in drug development (AEMPS)



Advisor

Strategy advisor



Company advisor



Implementing strategy

Development

- Finding sites & partners
 - Early Access strategies, compassionate use
- Data – finding and data analysis
- Advisory boards (Clinical & Payers)
 - Defining relevant outcomes
- Pathway analysis
- Stakeholder Analysis
- Market development
 - Policy shaping: conferences, meetings, papers



Designing Market Access Strategies

Market Access

- Negotiating strategy (**National & Regional & Local**)
 - Align National and Regional priorities
 - Target populations, life-cycle management
- Elaborate Value Dossier content
 - Incorporate HTA & Payer's perspective
 - Mock IPT
 - Economic Evaluation & Budget Impact
- Development phase IV projects ('beyond the pill')
 - Managed Entry Schemes and Risk-Sharing Agreements
 - RWD & RWE
- Engaging stakeholders



Market Access

- Analyse trends
- Payer market research
- Price modelling
 - Price erosion
 - Effect of generics and biosimilars
 - Effect of new entries
- Life cycle management
- Negotiation strategy
 - Early access programmes
 - Managed Entry Schemes



Competitive Intelligence

Market Access

- Review approval process at the MoH and Regional level
- Review penetration and Guideline incorporation
- Benchmark with similar products or diseases
- Review tendering trends
- Propose comparative scenarios



Training & Support for Negotiation

Market Access

- Training for Market Access teams on
 - Potential hurdles
 - **Objection handler**
 - Customer needs
- Review value stories / presentations to stakeholders to strengthen messages and meet customer needs
- Prepare teams on strategy negotiations
 - Flow on clinical & financial deals to be proposed, and how to back them
- Design of **Managed Entry Schemes and Early Access Agreements**



Clients (not exhaustive)

- Start-ups



- Public institutions



Clients (not exhaustive)

- Pharma companies



Interim Medical and Market Access

Client

- A Spanish Start-up

Challenge

- Design a feasible regulatory and MA pathway

HiTT's Role

- HiTT had a MD&MAD interim role
- Provided continued support during 12 months, in the design of strategies and Business Model

Result

- Clinical Trial has been initiated
- The company was able to raise the largest amount ever in Spain for a Device



Advising Start-up development

Client

- A spin-off company from a University

Challenge

- To prepare with the management team a solid business plan to be presented to potential investors

HiTT's Role

- HiTT guided (advisor role) the development of the Business plan and landscape analysis, including Guideline review, SRE, competitor landscape and pricing corridor
- HiTT prepared a development plan, backed up with a market and competitive landscape analysis

Result

- The company raised 420 K€ from a national investor



Validating market potential

Client

- A licensing project from a research department at a University

Challenge

- To review the potential market of a newly developed patent and the potential partners & investors

HiTT's Role

- HiTT reviewed the *state of the art*, including market competitors, features, capabilities and potential markets
- HiTT developed a Cost-effectiveness analysis of the potential technology to establish its potential usage in a real world setting

Result

- Despite optimal PoC tests, the developer was discouraged from pursuing the project given the lack of a viable product.



Fundraising

Client

- A private start-up company

Challenge

- To define a development strategy and prepare an investor pitch that for first non-public investors

HiTT's Role

- HiTT prepared a development plan, backed up with a market and competitive landscape analysis
- HiTT prepared for the company investor decks

Result

- The company raised 300 K€ from several investors
- The project was presented to several multinational pharma companies



Fundraising

Client

- A private start-up company

Challenge

- To define a strategy for market and business development for a novel technology

HiTT's Role

- HiTT prepared a detailed costing plan in the context of a development plan.
- HiTT helped defining the market strategy
- HiTT prepared for the company investor decks

Result

- The company raised 300 K€ from several investors
- The project was presented to several multinational pharma companies



In Licencing

Client

- A multinational company

Challenge

- To decide whether to in-licencing an advanced therapy for RD

HiTT's Role

- HiTT analysed the potential market, the pricing landscape, target population and access hurdles
- HiTT coordinated a EU-5 analysis that was presented to the business development

Result

- Company purchased rights of the compound
- Financials were adjusted accordingly



Continued investment

Client

- A multinational company

Challenge

- To decide whether to invest in a new asset

HiTT's Role

- HiTT analysed the potential market, the pricing landscape, target population and access hurdles
- HiTT modelled the potential costs & revenues at launch in the EU market

Result

- Company discontinued the research project



Orphan Drug Value Dossier

Client

- A multinational company, broad portfolio (not only OMP)

Challenge

- To design strategy and value arguments for a new Value Dossier

HiTT's Role

- HiTT reviewed the approval records on similar diseases by the MoH, and developed a Mock IPT and raised evidence gaps.
- HiTT developed additional evidence on incidence, prevalence and unmet needs
- HiTT prepared an economic model that showed cost savings to the MoH

Result

- Product was launched successfully at the proposed price

Launching a Biosimilar

Client

- A generic company, entering for the first time into Biosimilar business

Challenge

- To decide who the stakeholders were, the potential market share and price corridors

HiTT's Role

- HiTT surveyed several regions in Spain to understand and quantify who the prescribers were
- Prepared a Business model for the company
- Suggested how to approach the market and how to build a new field team

Result

- Company is structuring its newly created business unit accordingly



Support to Market Access Team

Client

- The Spanish affiliate of a multinational company

Challenge

- Within Global plans of expansion, the company wanted to create a Market Access position, and the team

HiTT's Role

- HiTT had a MAD interim role
- Provided continued support during 18 months, in the design and implementation of the team & roles
- Helped to prepare for challenging launches

Result

- At the end of the period, the team was well established
- Spanish affiliate was well positioned at Global headquarters
- 2 successful launches were prepared



Launching in a Crowded Market

Client

- The Spanish affiliate of a multinational company

Challenge

- ... had to introduce a new compound in a crowded disease
- ... was uncertain about access strategy when facing MoH negotiation

HiTT's Role

- Report of the regional evaluation requirements
- Analysis of the regional access differences
- Estimation of evaluation times and success probabilities

Result

- Negotiation strategy was modified to allow for negotiation in Regions
- Expectations set on price, positioning and timings



Preparing a Value Dossier

Client

- The Spanish affiliate of a multinational company

Challenge

- ... had to face negotiations with MoH
- ... were uncertain about IPT result

HiTT's Role

- Prepared a Mock IPT
- Agreed with client to include added Value features (beyond GVD)
- Searched for relevant Spanish Literature to adjust for Standard of Care and relevant comparators
- Designed a neutral Budget Impact model

Result

- Company obtained desired price and access conditions
- Company could defend their position at MoH whilst having negotiation room in Regions



Managed Entry Agreements & RWD

Client

- The Spanish affiliate of a multinational company

Challenge

- ... had a challenging price given competitors
- ... were willing to establish MEA to mitigate risks at the Hospital level

HiTT's Role

- Analysed technology
- Tested alternative value arguments with KOL & Payers
- Prepared a Risk Sharing Agreement contract
- Introduced the new technology to several Hospitals across several Regions in Spain

Result

- The access curve at the regional / hospital level was less challenging
- Company is currently completing their RWD

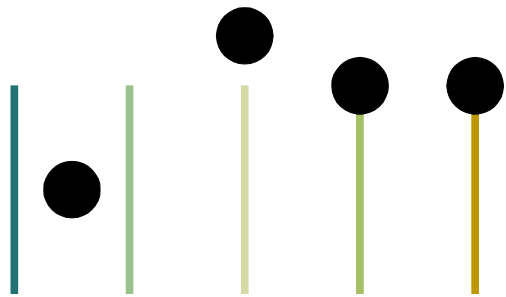


How we work

- **Independent and small dynamic team**
 - Covering broad range of expertise: MD, Economists, biotechnologists, International business
 - Knowledgeable of both the EU and US environments
 - 25+ years experience in public healthcare management
- **Broad network of collaborators**
 - former or active leading roles in public reimbursement activities at the National, Regional and Hospital levels
- **Alliances** with the best-of-breed providers.
 - Incorporating ad-hoc specialists to achieve best available expertise on a timely and high quality manner.



how can we HELP?



Health Innovation Technology Transfer

c/ Escoles Pies 40 Baixos
08017 Barcelona
T. +34 650 161 197
info@hittbcn.com

www.hittbcn.com