



Value inflection points in product development & asset valuation

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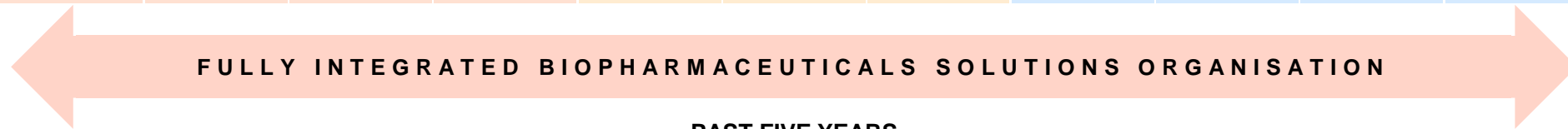
Syneos Health is a leading fully-integrated biopharmaceuticals solutions organisation constantly working to bring new treatment innovations to patients



Serving **top Biopharma**
& **emerging Biotech**
companies



~29,000
Employees in 110
countries



PAST FIVE YEARS

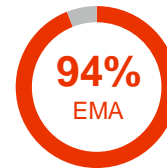
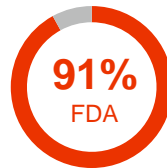
2,700+
Full-Service Studies

90,000+
Sites

743,000+
Trial Patients

110+
Countries

Syneos Health has helped to develop or commercialise 91% of novel new drugs approved by the FDA in the last five years (2018-2022).



Syneos Health has helped to develop or commercialise 94% of products granted marketing authorisation by the European Medicine Agency (EMA) in the last five years (2018-2022).

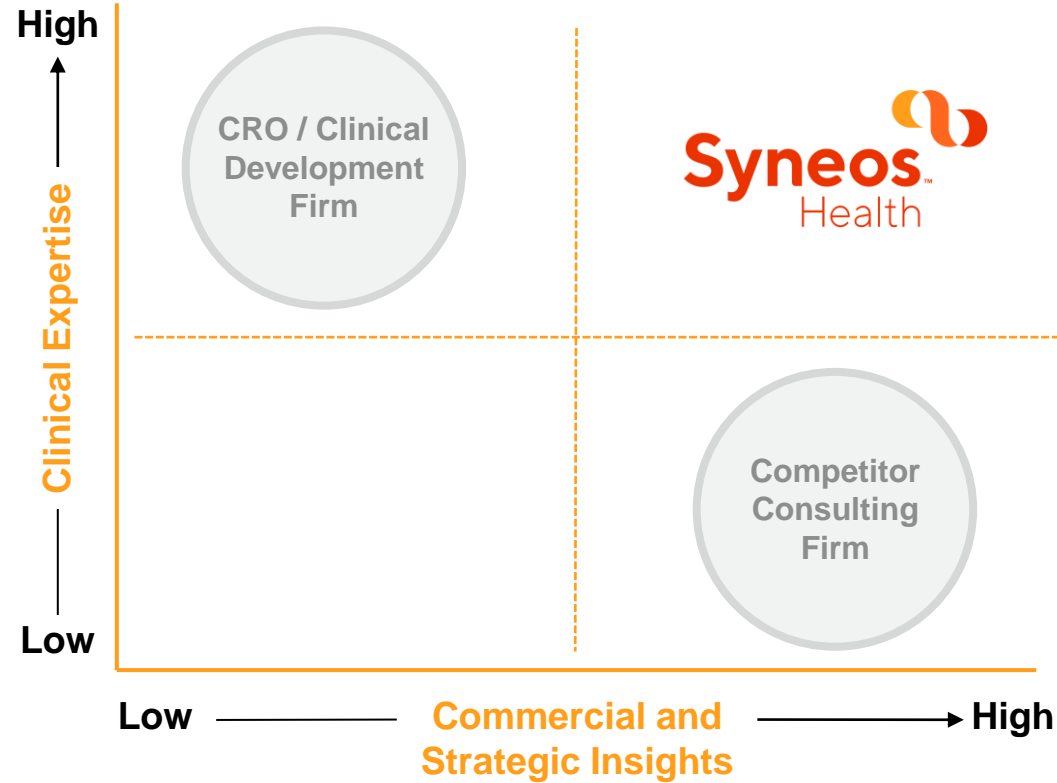
Syneos Health: Why Are We Different?



We are the unique combination of the best clinical and commercial minds

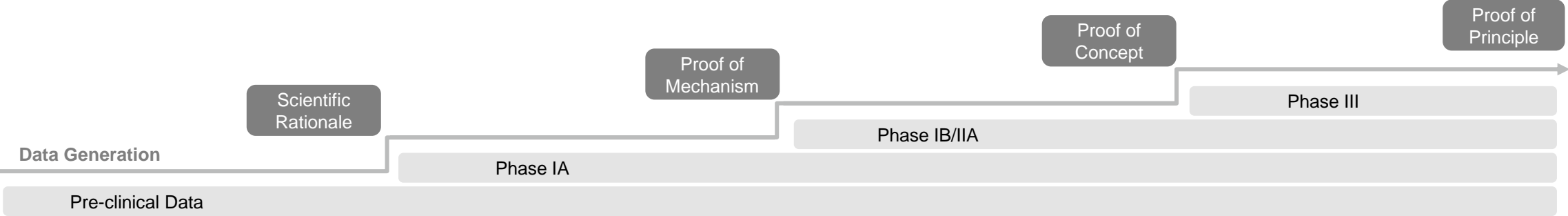


We strive to accelerate and optimise product development & commercialisation



We are uniquely positioned to approach asset development and commercialisation holistically, by integrating clinical, medical, and commercial capabilities to address market realities

Key value Inflection points in the development pathway of new therapy



Speed, differentiation, and de-risking are critical to generate value and attract investment

Speed

- Which therapeutic area and indication allows us to get to market fastest?
- What clinical strategy enables a speed to market approach?
- How should we design the protocol to ensure optimal clinical feasibility?

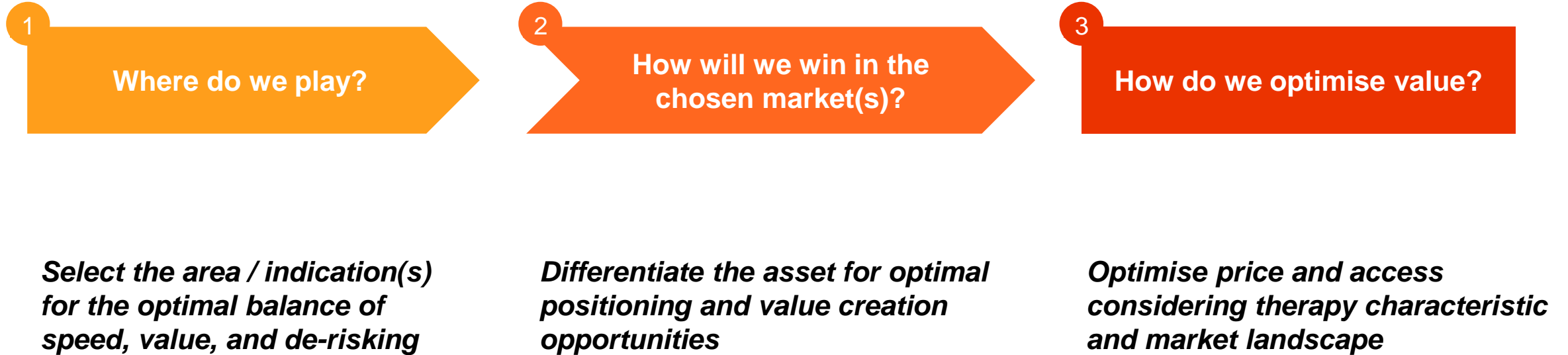
Differentiation

- Are we targeting the right patient population?
- What endpoints can help us differentiate the asset for payers and physicians as well as support competitive claims?
- Do we have a clear understanding of the competitive environment and market access landscape to make decisions about endpoints?

De-risk

- How do we maximise the regulatory probability of success?
- How do we maximise the technical probability of success?
- How should we design the protocol to ensure clinical feasibility, investigator and patient support?

Three key questions are among the most common hurdles in development for successful value creation



Where do we play?

Common Challenges

- Identifying and selecting potential therapeutic areas / indication(s) during early development with very limited and narrowly focused data
- Weighing commercial impact sufficiently early in the program, alongside technical and clinical development considerations

Deciding the optimal focus area for your innovation benefits from a highly-tailored and data-driven approach that can weigh the companies' unique priorities appropriately



Indication Strategy – Sample Approach/Analyses

The following outputs are examples of deliverables from key steps of the Indication Prioritisation process.

Assessment Framework

Scoring Framework

Commercial Attractiveness: Attributes and Definitions

Illustrative

Criteria	Description	1	2	3	4	5	Weight
Commercial Attractiveness (80%)	Commercial Spend This criteria is scored qualitatively based on factors that contribute to commercial spend and the size of the required sales force, including: 1. Market development needs 2. Patient concentration	Commercial spend is relatively high	—	Commercial spend is neutral	—	Commercial spend is relatively low	10%
	Patient Identification This criteria is scored qualitatively based on several contributing data points, including: 1. Diagnostic delay 2. Misdiagnosis rate 3. Differential diagnosis	Patient identification is relatively difficult	—	Patient identification is neutral	—	Patient identification is relatively easy	20%
Orphan Drug Designation	This criteria is scored qualitatively based on: 1. Historical orphan drug designations 2. The prevalence of the indication Orphan drug designation would allow for tax credits, 7-year marketing exclusivity, waiver of FDCA fees and other commercial and regulatory incentives	ODD is very unlikely	—	ODD is moderately likely	—	ODD is highly likely	5%

Including:

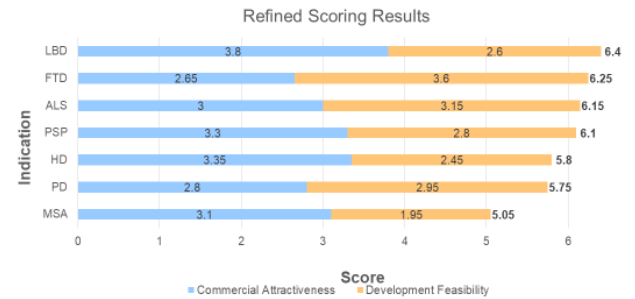
- Translational feasibility
- Regulatory feasibility
- Commercial attractiveness
- Strategic fit

Indication Scoring & Ranking

Scoring Framework

Refined Scoring Results

Illustrative



Including:

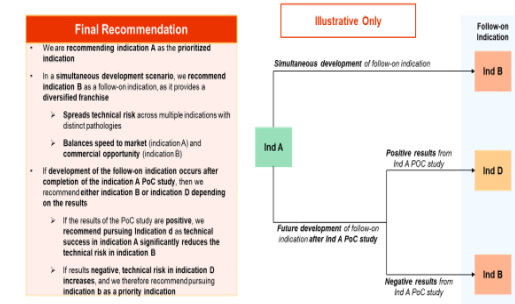
- Scored indications
- Refined list of scored indications

Indication Strategy

Final Recommendation and indication Sequencing

Illustrative

As a final step, we will recommend an indication sequencing that considers corporate strategy, feasibility, and commercial considerations.



Including:

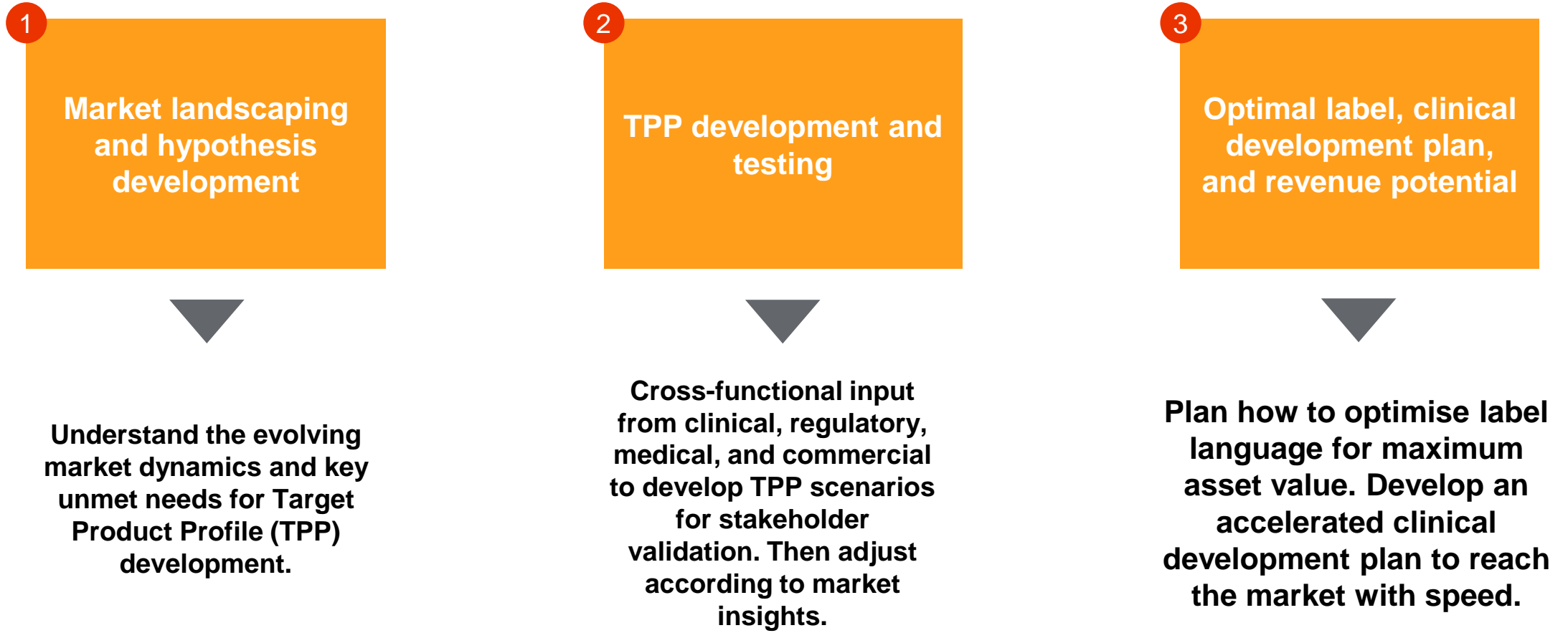
- Initial and sequenced indications and rationale

How to win?

Common Challenges

- Making decisions in a highly ambiguous environment due to the limited predictability of future disease treatment and competitive landscape
- Developing a solid understanding of key stakeholder needs (patients, HCPs and payers) in evolving and complex markets

Differentiation of your asset is key to commercial success; early cross-functional input, market validation, and scenario planning are critical to optimising the development strategy and label

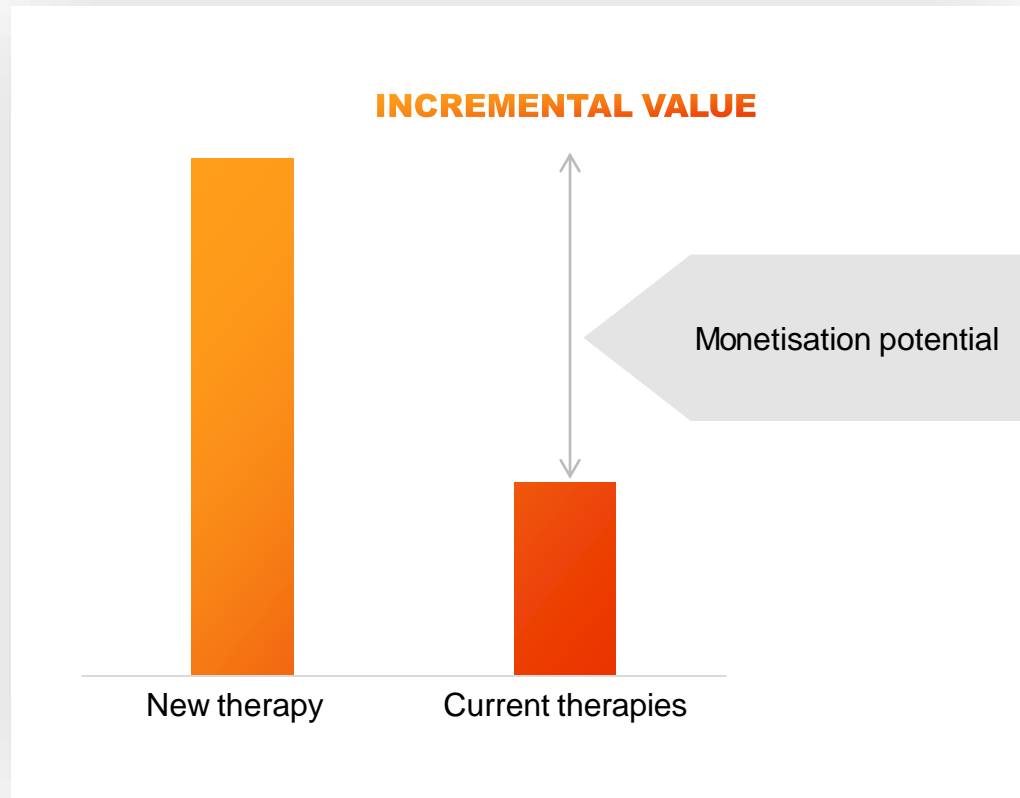


How do we optimise value?

Common Challenges

- Better understand the perceived value of the product to optimise price and access potential of a new therapy
- Estimation of the monetisation of value monetisation (price premium) based on incremental benefit vs. current and future landscape

Payers are looking to price new therapies based on their incremental value over existing treatment



Value determination market archetype	Example countries
Clinical Effectiveness	   
Cost-effectiveness	  
Budget Impact	 

Key Questions



LANDSCAPE

What is the current and expected future access landscape and unit of monetisation for value?

- What is the current treatment and access landscape?
 - What is the key SoC/ analogues, and the pricing and reimbursement status?
 - What is the **unit of value in the disease area and what is payers' willingness to pay for the unit of value** (monetisation)?
- What are the unmet needs from physician and payer perspective?
- What is the expected future treatment and access landscape at time of product launch?



PERCEIVED VALUE

What value does the product represent to payers and what are the value drivers and barriers?

- How do payers perceive the overall product proposition vs. current/future SoC/competitor?
- What **drivers and barriers** exist that influence reimbursement and willingness to pay?
- What **HTA outcome** is expected and how will it influence pricing?
- What **gaps exist** to support the product proposition and how can they be filled?



PRICE POTENTIAL

What is the achievable net price and how can the access and pricing potential be optimised?

- What is the **(incremental) value and how does it translate into price?**
- What are the target price, price bands and floor price for each market?
- How can the **pricing potential be maximised while ensuring optimal access?**

Depending on product and development status, a combination of 3 approaches can be used to determine pricing potential



ANALOGUE ASSESSMENT

- Leverage historical data and access outcomes to estimate potential performance of the asset
- Identify asset's optimal price range by benchmarking against suitable historical analogues

VALUE-BASED PRICING (Early Cost-effective)

- Determine price potential based on the magnitude of the novel therapy's added-value, in terms of QALY, over the SOC
- Demonstrate differentiated value in terms of clinical and economic effectiveness to justify the price vs established therapies

SEMI-QUANTATIVE PAYER RESEARCH

- Assess payer perceptions of existing therapies, needs, objectives and adoption trends
- Generate insights on price, reimbursement restrictions with supporting data to refine economic models

Develop the 'right story for the right investor'

In today's market, every successful developer must be prepared provide data-driven qualitative and quantitative insights on the commercial attractiveness and feasibility of their own technology, giving investors a feel for the financial and strategic opportunity.

DIFFERENTIATED LABEL

What is the optimal target product profile based on market dynamics and product characteristics?

How can the asset be best positioned in the evolving landscape?

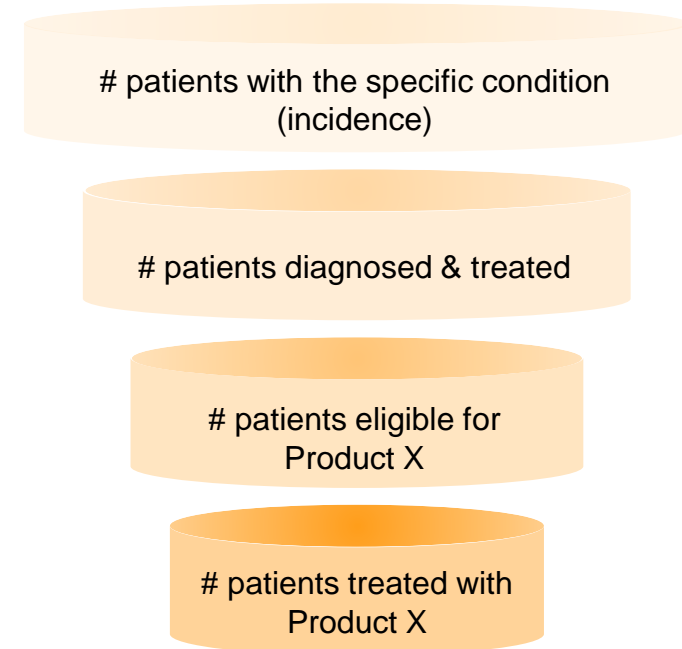


OPPORTUNITY SIZING

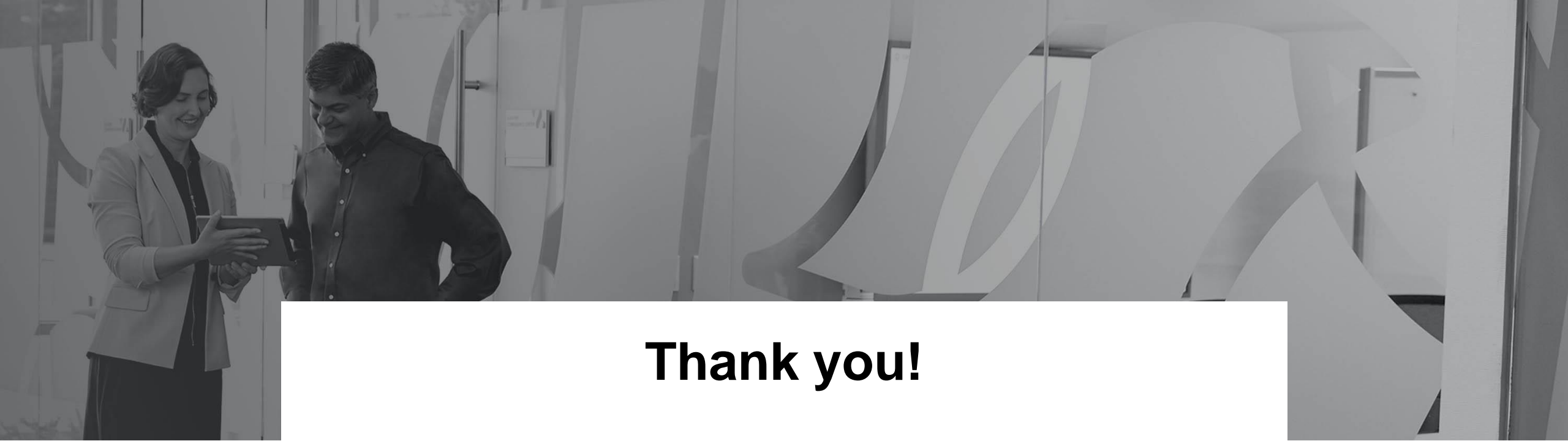
What is the real incidence vs the diagnosed incidence?

What proportion of patients are diagnosed?

How big is the treated population?



Any reasoned investor decision is based on the product-market fit and a credible forecast.



Thank you!

Time for Q&A

Shortening the Distance from Lab to Life[®].



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