Value inflection points in product development & asset valuation

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Paul Holmes PhD
Managing Director
Commercial Advisory
Syneos Health
paul.holmes@syneoshealth.com

Dr. Prateet Minhas
Managing Director
Value & Access Consulting
Syneos Health
prateet.minhas@syneoshealth.com

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

CLINICAL SOLUTIONS				MEDICAL AFFAIRS			COMMERCIAL SOLUTIONS			
Translational Science	Phase I	Full-Service Phase II-IV	FSP	Evidence Generation	Stakeholder Engagement	RWLP and Data Analytics	Brand Strategy	Payer Engagement / Communications	Brand PR & Communications	Deployment Solutions

FULLY INTEGRATED BIOPHARMACEUTICALS SOLUTIONS ORGANISATION

PAST FIVE YEARS

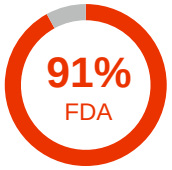
2,700+ Full-Service Studies

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).

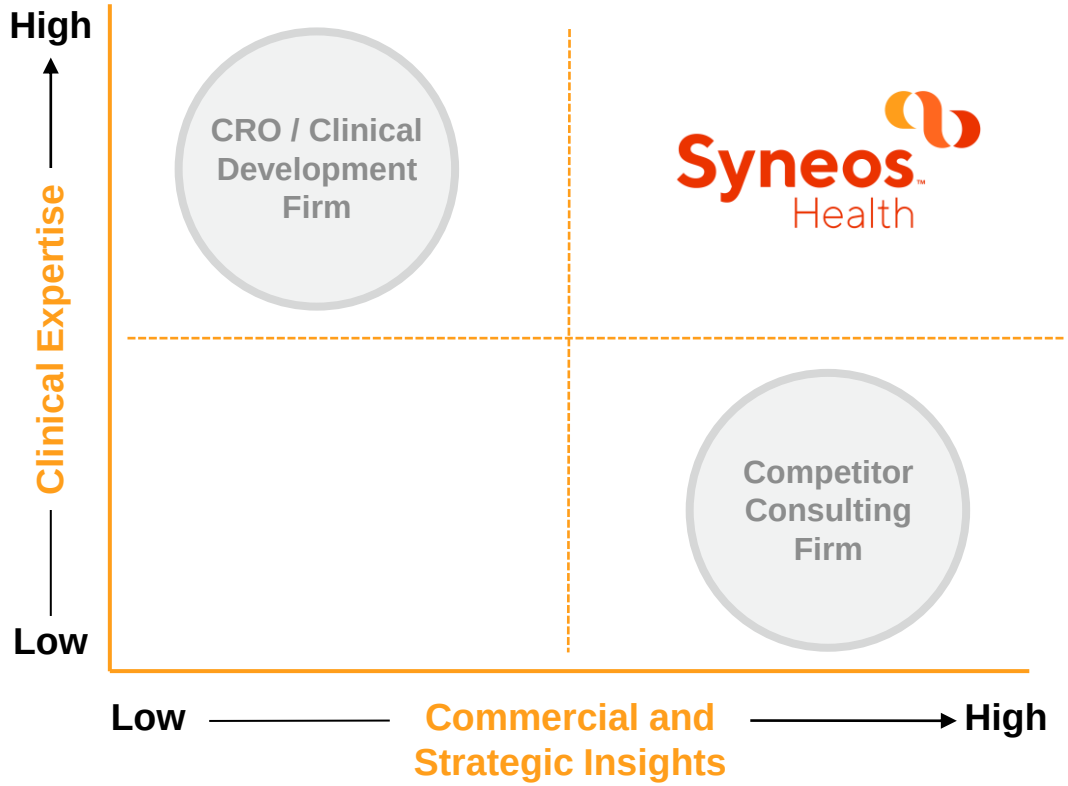


Syneos Health has helped to develop or commercialise 94% of products granted marketing authorisation by the European Medicine Agency (EMA) in the last five years (2018-2022).

Syneos Health: Why Are We Different?

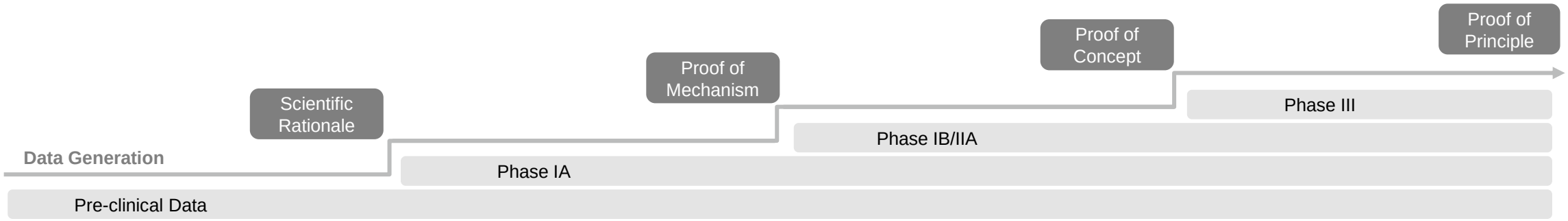
We are the unique combination of the best clinical and commercial minds

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

1. **Where do we play?**
   Select the area / indication(s) for the optimal balance of speed, value, and de-risking
2. **How will we win in the chosen market(s)?**
   Differentiate the asset for optimal positioning and value creation opportunities
3. **How do we optimise value?**
   Optimise price and access considering therapy characteristic and market landscape

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

1

Align on prioritisation criteria

Agree evaluation criteria and prioritisation mechanism, tailored to the companies' unique balance of priorities.

2

Data-driven indication assessment

First conduct high-level diligence to knock-out initial indications. Second conduct advanced diligence to understand evolving market dynamics.

3

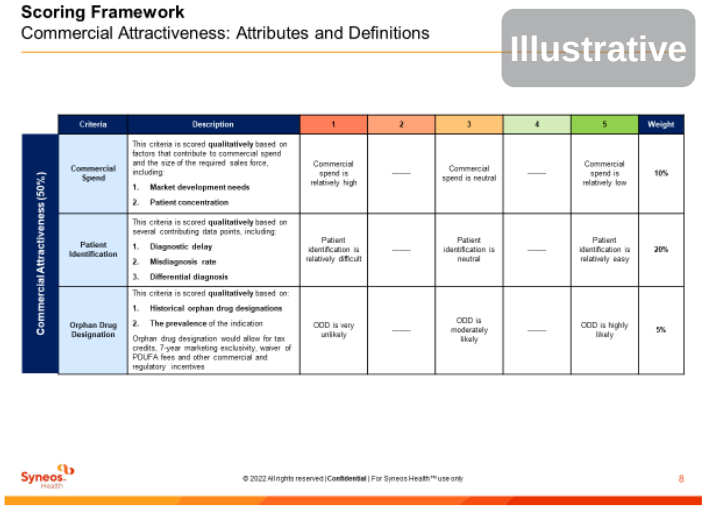
Strategically filter and develop indication strategy

Weigh options against company priorities and develop the optimal sequencing of indications.

Indication Strategy – Sample Approach/Analyses

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

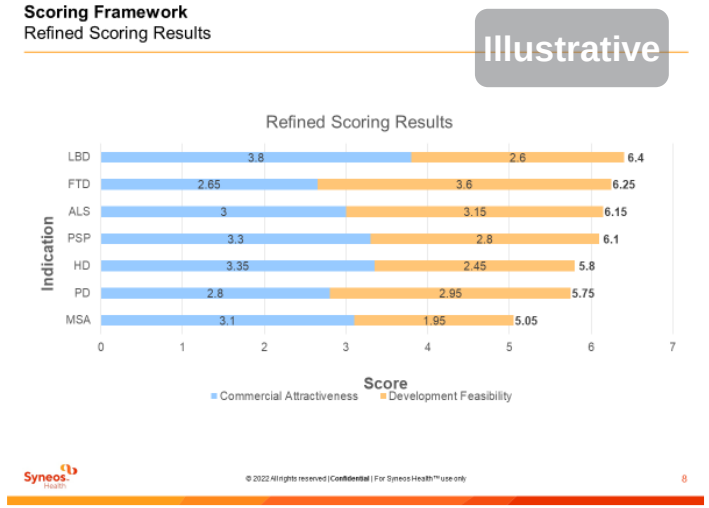
Assessment Framework



Including:

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

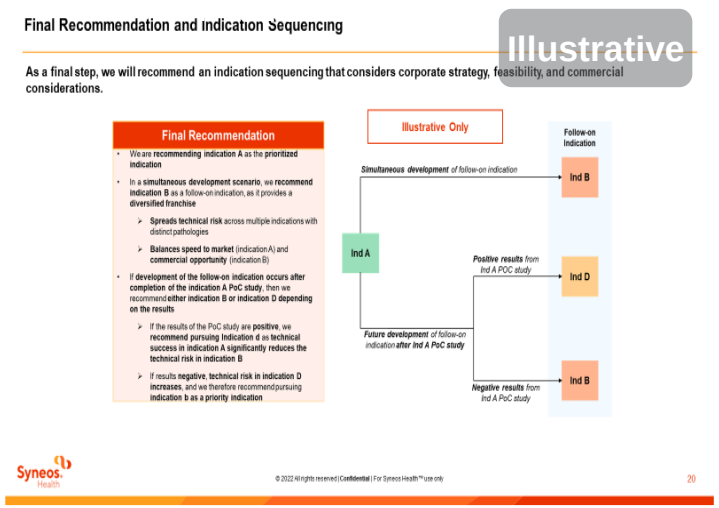
Indication Scoring & Ranking



Including:

- Scored indications
- Refined list of scored indications

Indication Strategy



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

1

Market landscaping and hypothesis development

Understand the evolving market dynamics and key unmet needs for Target Product Profile (TPP) development.

2

TPP development and testing

Cross-functional input from clinical, regulatory, medical, and commercial to develop TPP scenarios for stakeholder validation. Then adjust according to market insights.

3

Optimal label, clinical development plan, and revenue potential

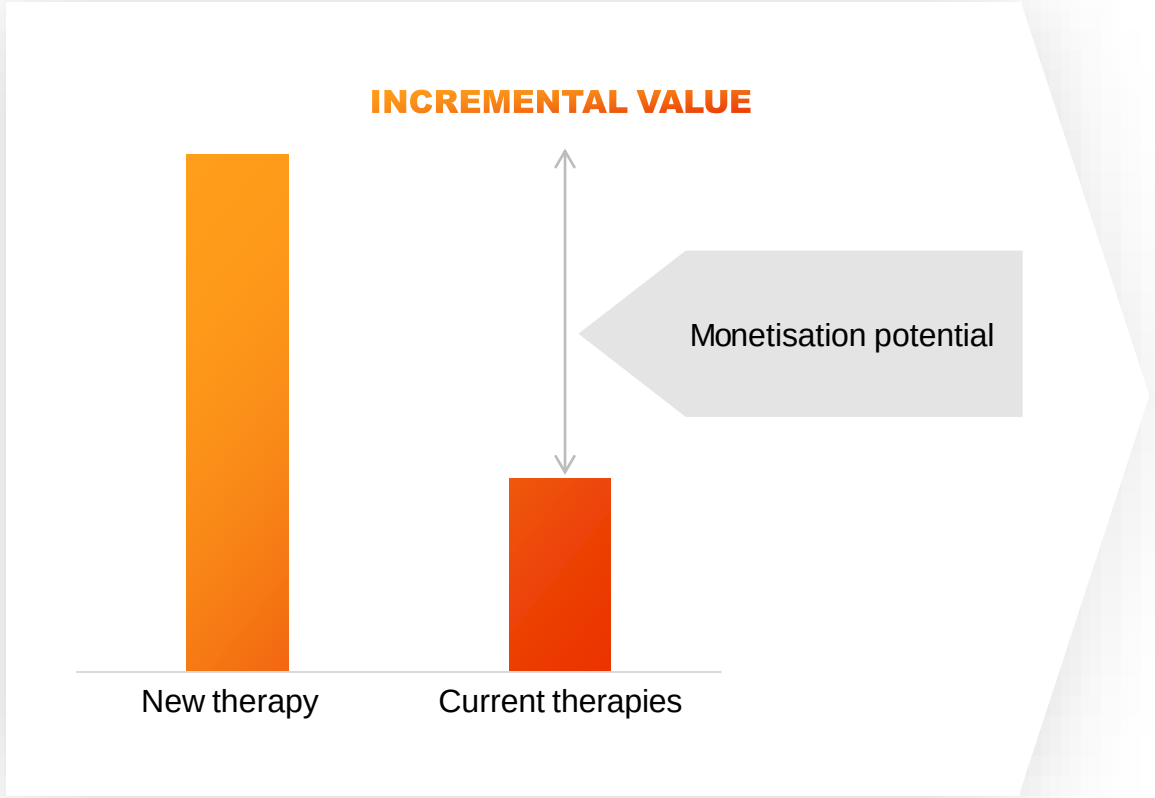
Plan how to optimise label language for maximum asset value. Develop an accelerated clinical development plan to reach the market with speed.

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 exis**t 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 QUALY, 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?

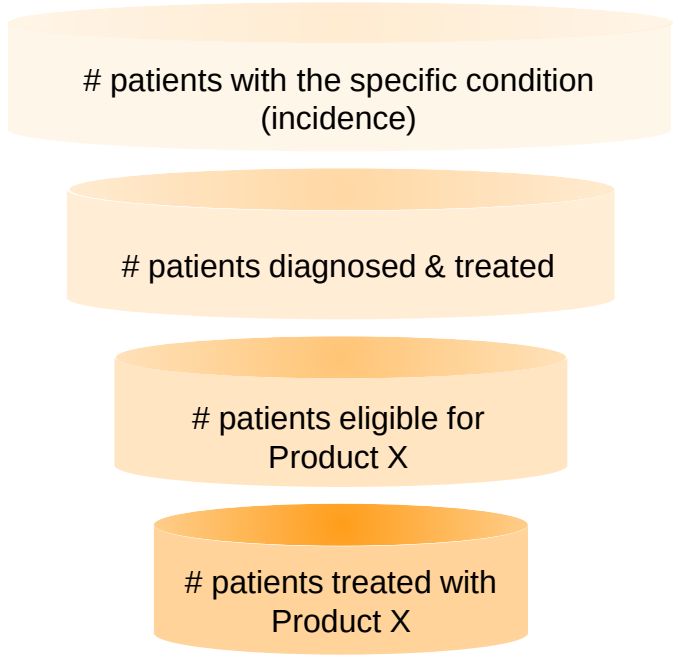
TPP Scenario Analysis

OPPORTUNITY SIZING

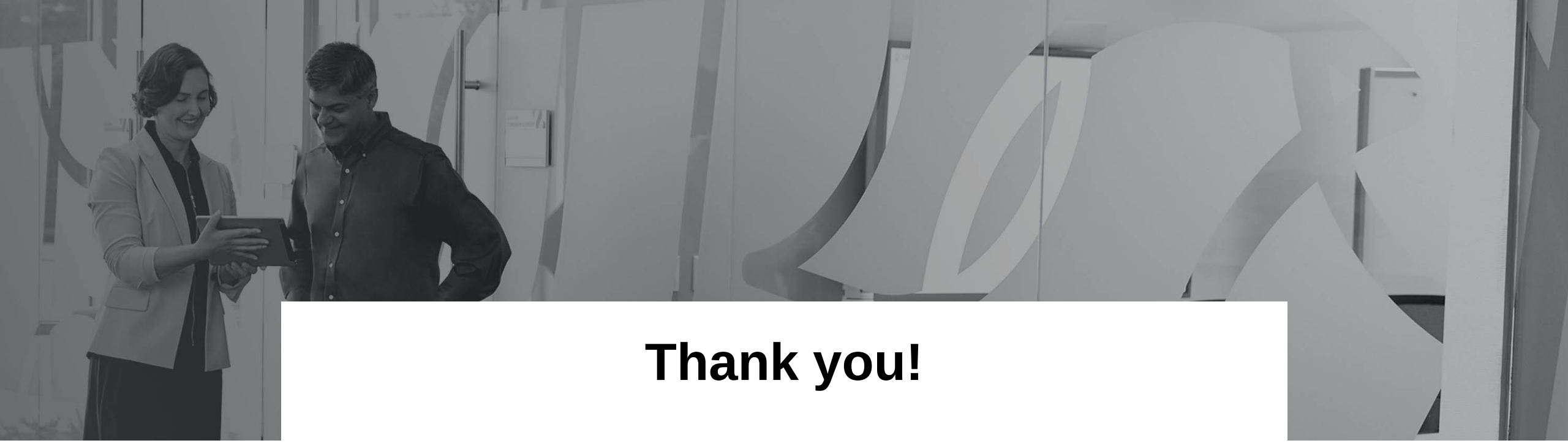
What is the real incidence vs the diagnosed incidence?

What proportion of patients are diagnosed?

How big is the treated population?

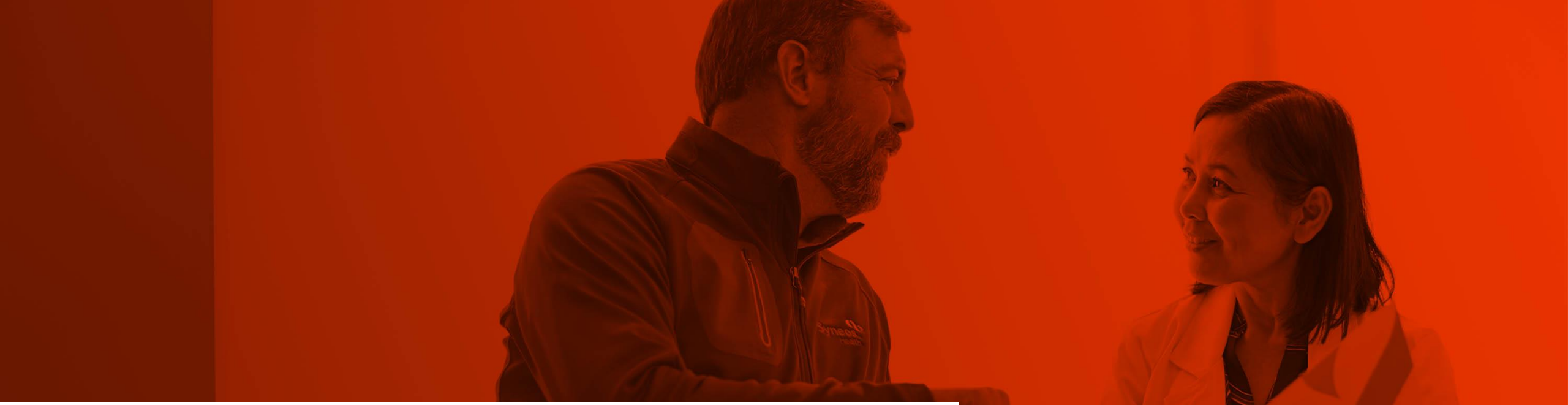


Any reasoned investor decision is based on the product-market fit and a credible forecast.



Thank you!

Time for Q&A



Shortening the Distance from Lab to Life®.

Paul Holmes PhD
Managing Director, Commercial Advisory Group
Paul.Holmes@syneoshealth.com
T: 07436 560 230

Dr Prateet Minhas
Managing Director, Value and Access
Prateet.Minhas@syneoshealth.com
T: 07436 560 227

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