



WHAT ARE THE PRICING AND MARKET ACCESS LAUNCH CHALLENGES FACING COMPANIES TODAY?

Remap Consulting

July 2019

Executive summary: While internal barriers to PMA launch success are decreasing, payer evidence gaps still remain



We surveyed 15 industry executives to understand the drivers and challenges for a successful PMA launch, and the areas that can be improved for future launches



Internal company barriers (e.g. budget/personnel) are rarely considered a significant challenge by PMA teams



PMA teams now form a core part of the Commercial launch team and are considered a 'strategic partner' in 31% of cases



Most recent PMA launches faced evidence challenges during payer negotiations, such as endpoint and comparator selection, and patient subpopulation data



PMA teams must be involved earlier in the clinical development process to ensure that the necessary clinical and economic evidence is available at launch



Senior leadership should be educated as to EU price expectations and evidence requirements, to maintain sufficient investment to maximise PMA launch success

PMA: Pricing and market access

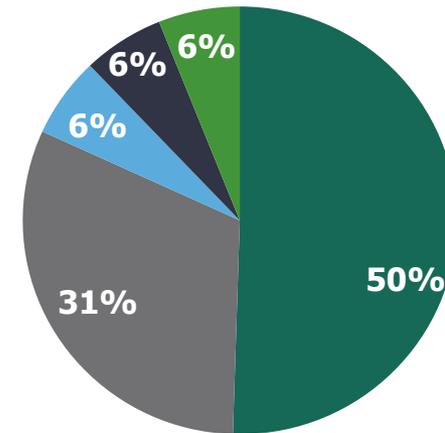
We surveyed 15 industry executives across top global pharma companies, as well as several smaller companies



Our sample comprised a mix of personnel across different internal teams, including:



Overview of products launched our respondents



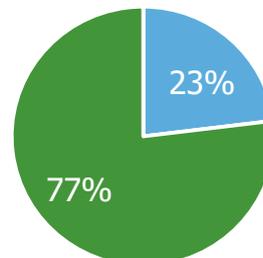
- Innovator biologic
- Innovator small molecule
- Established products in new markets
- Hybrid dossier
- None

Internal company barriers are rarely considered a significant challenge by pricing and market access teams

- ▶ Getting PMA right is increasingly seen as vital to successful product launches, with greater focus on integrating PMA teams earlier into the development process and ensuring they are adequately resourced.
- ▶ This is reflected in our survey results, with respondents rarely finding obtaining resources more than a slight challenge. It also shows an improvement from our 2017 training survey, where 41% of respondents stated a lack of internal investment in market access.
- ▶ Despite this, 77% of our sample faced significant evidence challenges when negotiating with payers/HTA bodies. Clinical evidence in patient subpopulations is often inadequate for payers, leading to price misalignment and a poor commercial outcome.



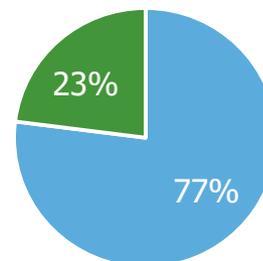
Internal company challenges



Includes insufficient budget / resources for payer materials, delayed decision making, and unrealistic management expectations



External company challenges



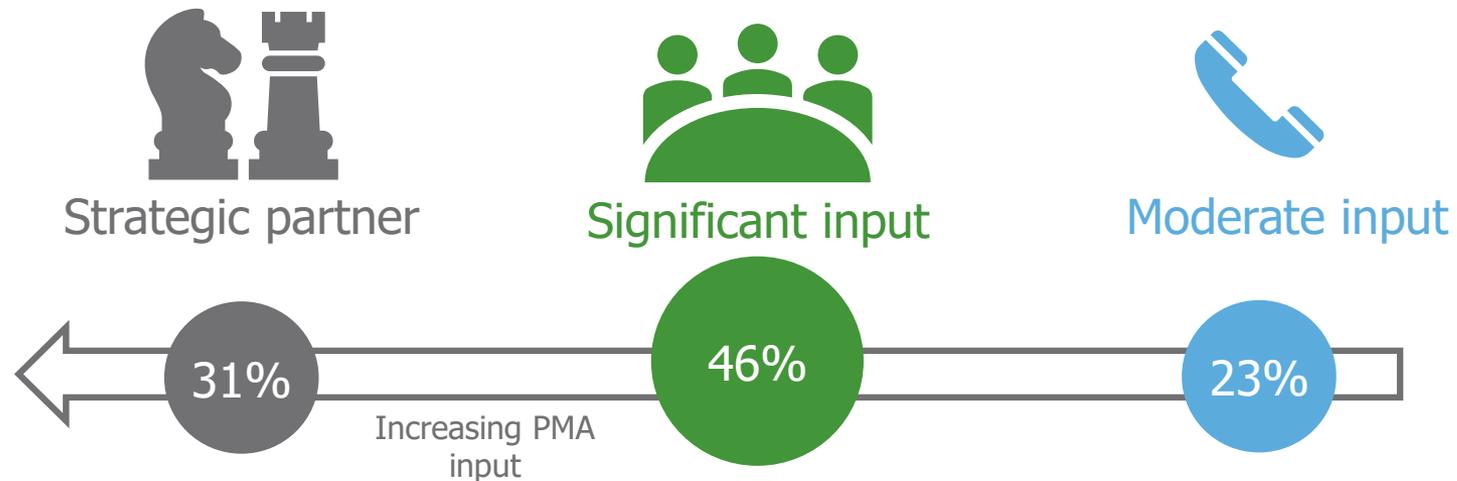
Includes insufficient clinical data at HTA submission, differing comparator expectations, challenges around the patient populations, and health economic evidence challenges

- Significant / Highly significant challenge
- Moderate challenge or less

HTA: Health technology assessment; PMA: Pricing and market access

Pricing and market access teams form a core part of the Commercial launch team in most cases

- ▶ A strong link should be established between PMA and Commercial teams to avoid a 'silo' mentality and create a more integrated cross-team strategy that will allow the Commercial team to leverage market access insights.
- ▶ Our survey indicates that this is increasingly taking place. 77% of respondents considered the PMA team to either be a "strategic partner" to Commercial, or having significant input into the Commercial launch team.
- ▶ However, it is unclear whether this greater PMA commercial input is also being reflected in greater PMA input into the clinical development process.

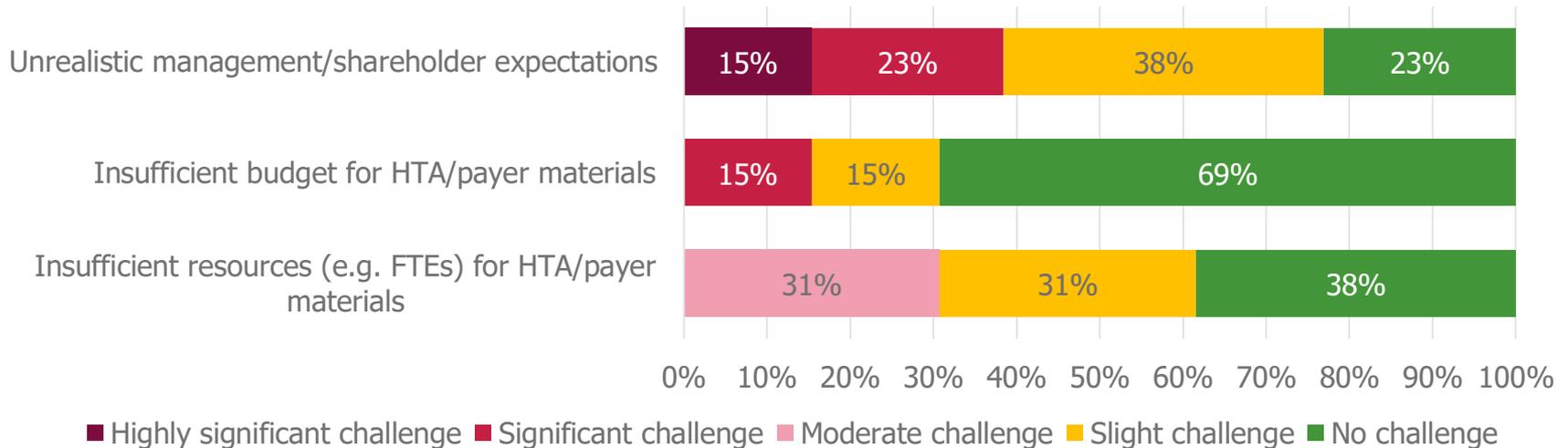


PMA: Pricing and market access

A lack of budget or resource is rarely an issue for PMA teams, although internal misalignment presents challenges

- ▶ Insufficient budget for developing payer materials (e.g. value propositions, dossiers) has rarely proved a major challenge for respondents, with 69% facing no challenge in this regard.
- ▶ More of an issue is a lack of internal knowledge, understanding and alignment, which can result in unrealistic expectations from senior management around price and evidence requirements.

Internal company launch challenges



"The competitor environment is not well understood"

"A lack of internal acceptance and agility is an issue"

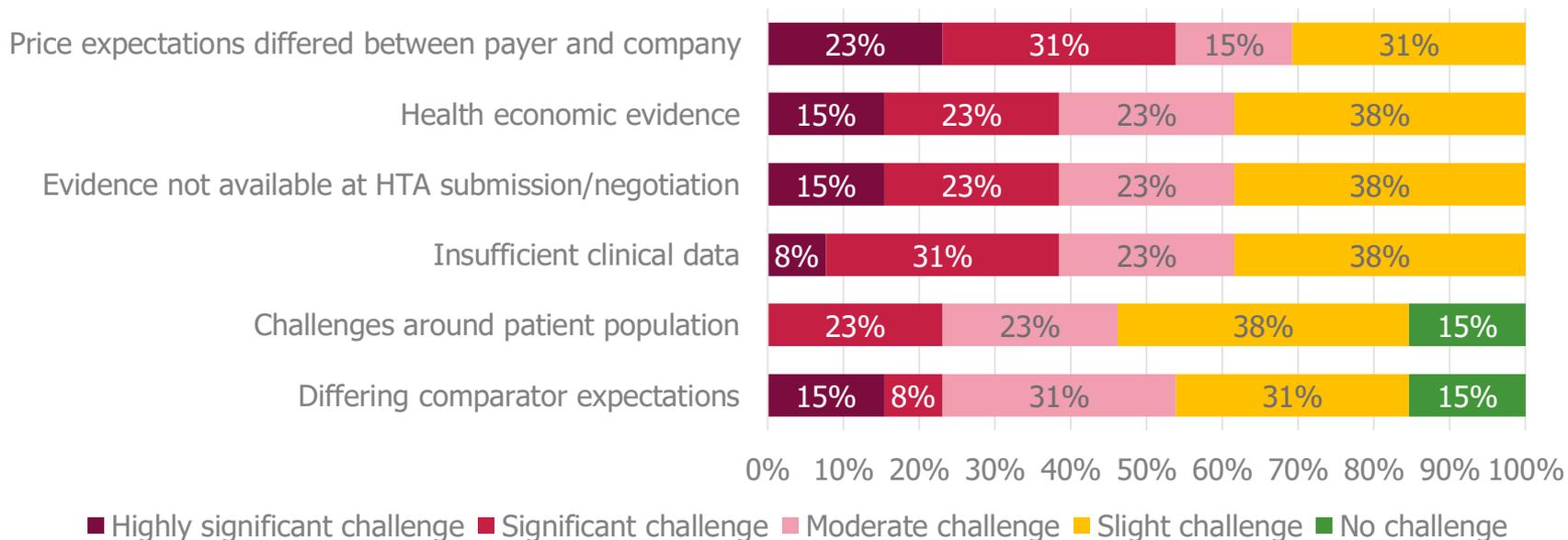
"[There is a] lack of internal understanding of market access challenges"

FTE: Full-time equivalent; HTA: Health technology assessment; PMA: Pricing and market access

The majority of recent PMA launches have faced significant challenges during negotiations with payers

- ▶ 77% of our sample faced at least one significant challenge during discussions with payers/HTA bodies, typically around a lack of sufficient clinical and/or economic evidence to justify the targeted price.
- ▶ No single area stands out as being a particular challenge, with deficiencies in both economic and clinical evidence contributing to a weaker negotiating position and an unsatisfactory price.

External payer launch challenges



HTA: Health technology assessment; PMA: Pricing and market access

Evidence gaps were focused on endpoint and comparator selection, leading to challenges in showing additional benefit

General evidence gaps

"Outside the US, PFS was not accepted as an endpoint, and OS data would not be available for several years"

"We faced difficulties in delivering the necessary payer evidence to secure our target price"

"The available quality of life data was insufficient, both from our trials and the public literature"

"There was a lack of biomarkers of prognostic factors to show long-term outcomes"

"We lacked the necessary evidence to meet the expectations of the HTA bodies"

Subgroup data

"Slice of patient populations by the HTA bodies"

"Our evidence was insufficient in our target patient population"

Comparator selection / differentiation

"Our choice of comparator was unsatisfactory for some markets"

"It was difficult to differentiate our product from the comparators"

"Demonstrating value vs. the current standard of care was a challenge"

"We were not able to show an additional benefit vs. the current standard of care"

HTA: Health technology assessment; OS: Overall survival; PFS: Progression-free survival

These challenges are reflected in the countries considered most challenging from a PMA launch perspective

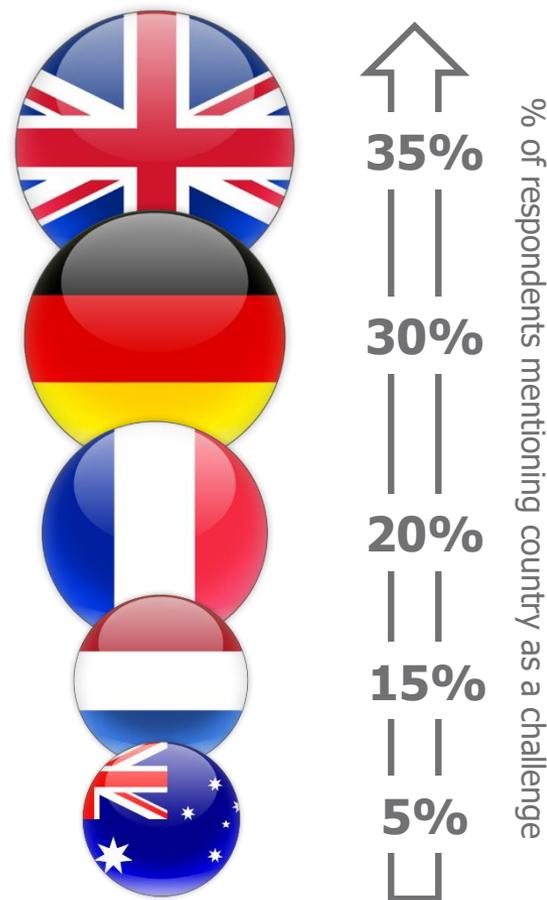
- ▶ 85% of respondents considered the UK or Germany to be particularly challenging PMA launch countries, with 20% mentioning France.
- ▶ The clinical focus of the G-BA in Germany and HAS in France reflects the challenges highlighted with providing sufficient clinical evidence at launch.
- ▶ Successfully navigating NICE and SMC evaluations, as well as the UK's changing political environment, were also commonly mentioned challenges.

"The UK is challenging in terms of value demonstration"

"Germany and France are the most challenging due to the comparators considered and evidence required. There was no possibility to apply for restrictions"

"Germany has been the most challenging due to our lack of data against the appropriate comparator therapy"

Most challenging PMA launch countries

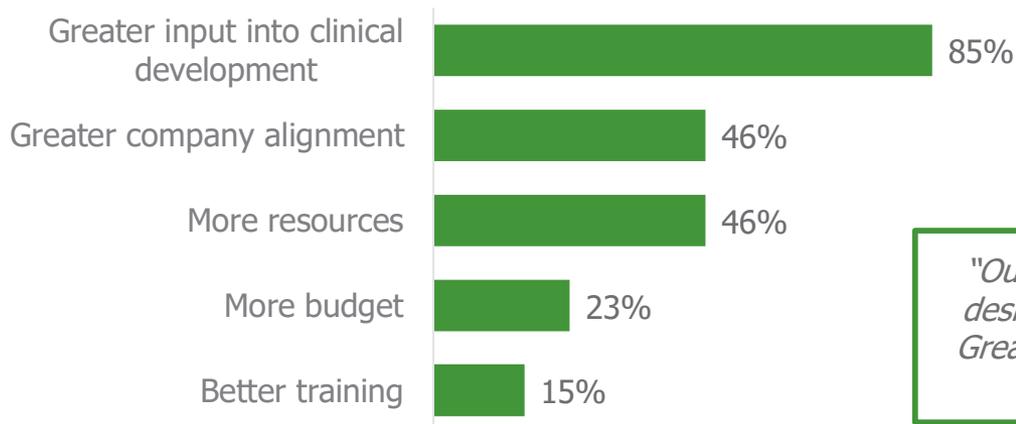


G-BA: Federal Joint Committee; HAS: Haute Autorité de Santé; NICE: National Institute for Health and Care Excellence; PMA: Pricing and market access; SMC: Scottish Medicines Consortium

Earlier PMA input into clinical development is therefore considered key to improving product launches in future

- ▶ The challenges around clinical and economic evidence at launch emphasise the need to involve the PMA team earlier in the clinical development process.
- ▶ Trials should be designed with both payers and regulators in mind, including the clinical and economic endpoints to enable effective payer value demonstration. Leaving this too late significantly compromises a company's ability to gain reimbursement at an optimal price.
- ▶ When asked what they would improve for their next launch, 85% of our respondents believe that greater PMA input in clinical development is still needed.

Suggestions to improve the next PMA launch



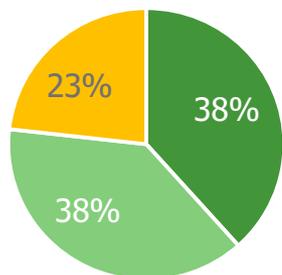
"We could influence the choice of comparator, or make the case for smaller supporting trials required from a PMA perspective"

"Our clinical evidence is not currently designed to meet payer expectations. Greater earlier input would allow us to generate payer-suitable data"

PMA teams consider recent launches successful, but there is a misalignment with company expectations

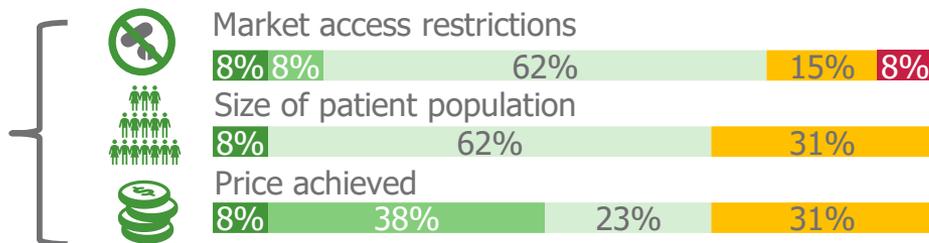
- ▶ Interestingly, despite these payer/HTA challenges, 77% of respondents rated their PMA launches as “very successful” or “quite successful”. Those launching innovator biologics consistently declared their PMA launches successful. 46% stated that the price achieved exceeded their expectations.
- ▶ These findings somewhat contradict our respondents’ stated challenges around providing sufficient evidence to secure a high price with payers, and highlight internal misalignment between PMA teams and senior management.
- ▶ The PMA teams have a more realistic understanding of the achievable price based on the available evidence, but this may not be adequately being conveyed to senior management and translating into the expectations of the company as a whole.

Overall success of PMA launch approach



■ Very successful ■ Quite successful ■ Average

Launch success based on specific criteria



■ Significantly exceeded ■ Exceeded
 ■ Met ■ Partially met
 ■ Did not meet

HTA: Health technology assessment; PMA: Pricing and market access

As such, senior leadership must be educated regarding EU price expectations and associated evidence requirements

- ▶ Our survey indicates a lack of understanding from senior leadership around how the HTA process works, and the level of evidence needed to secure the desired price levels.
- ▶ Payers in general do not consider MoA and 'innovation' in decision making, and a new product will not secure a high price simply because it is new.
- ▶ Failing to achieve unrealistic market access goals risks senior leadership becoming disillusioned with highly evidence-driven EU markets, and not providing sufficient investment for PMA launches.
- ▶ PMA teams must therefore be integrated into decision making with senior management, and have sufficient high-level involvement to ensure price and reimbursement expectations are aligned across stakeholder groups.

"There has been frustration from senior leaders that an innovative therapy that changed the SoC and was considered a breakthrough by HCPs, got such low prices in the EU. When designing trials now, EU revenues are basically zeroed out, and so additional EU payer evidence needs will never be met"

"It is important that senior leadership is educated on what success looks like. Better alignment would allow us to all pull in the same direction"

"Better alignment between functions would help to ensure that the expectations of all stakeholders are met"

HCP: Healthcare professional; HTA: Health technology assessment; MoA: Mechanism of action; PMA: Pricing and market access; SoC: Standard of care

Remap Consulting is a specialist pharmaceutical pricing and market access consultancy

We work with people responsible for the pricing and market access of products who are asking:

LAUNCH IMPLEMENTATION



Have we got the right evidence to support pricing and market access at launch?

TRAINING



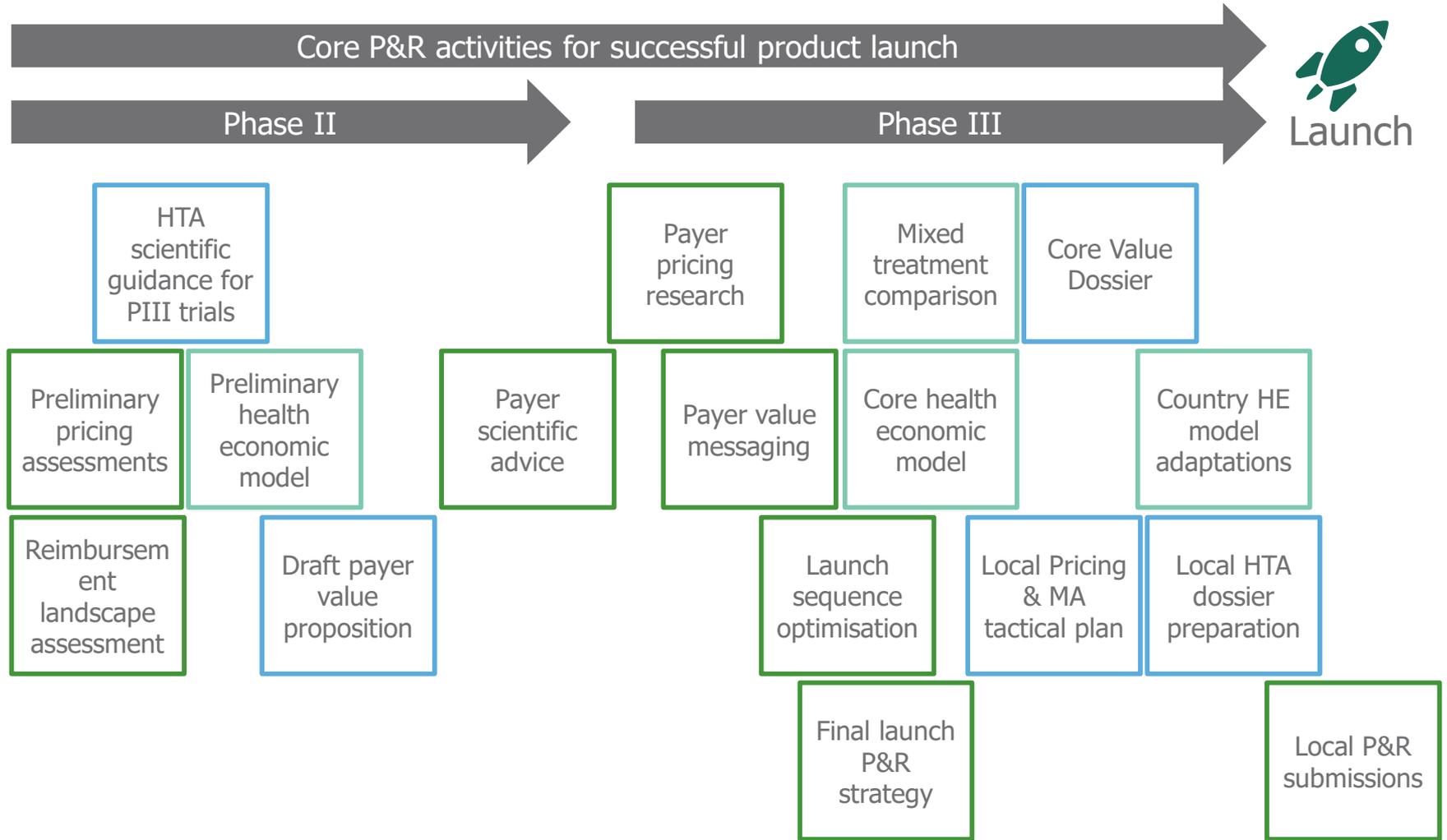
Do we have the right training capabilities to secure pricing and reimbursement?

PRICE OPTIMISATION



What is the optimal price for our product?

Remap Consulting partners with companies to support them in optimising pricing and reimbursement during launch



Key Pricing HTA requirements Health economic

Remap Consulting Launch Survey Report

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THANK YOU

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