HEALTH **I**NNOVATION NE**X**T GENERATION **P**AYMENT & PR**I**CING MODELS **(HI-PRIX):**

Balancing Sustainability of Innovation with Sustainability of Health Care

D1.1: Stakeholders judgement on barriers and enablers of novel payment/pricing schemes

WP1 – Mapping of payment schemes for health innovation in the EU: implementation, barriers, and enablers

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LIST OF ABBREVIATIONS

IPM	Innovative Pricing and Payment Model
OBA	Outcomes-Based Agreement
FBRSA	Financial-Based Risk Sharing Agreement
PoBA	Portfolio or Bundling Agreement
IaAP	Instalments and Amortisation Payments
NG	Nominal Group
mNGT	Nominal Group Technique
SD	Standard Deviation
NGT	Nominal Group Technique
EU	European Union

Executive summary

Across Europe, countries are struggling to balance access to innovation with healthcare system financial sustainability. Where uniform pricing falls short, innovative payment models (IPMs) can provide a solution—improving patient access while maintaining financial viability. Despite successful implementation in some countries, IPMs often face barriers that delay or prevent adoption. Conversely, key enablers can facilitate implementation. This research aims to identify the most important barriers and enablers to IPM implementation, as perceived by stakeholders, and to assimilate policy recommendations to leverage critical enablers and overcome key barriers.

Methods

We focused on five commonly used IPMs: Outcomes-Based Agreements (OBAs), Indication-Based Pricing (IBP), Instalments and Amortisation Payments (IaAPs), Financial-Based Risk-Sharing Agreements (FBRSAs), and Portfolio or Bundling Agreements (PoBAs). To identify the barriers and enablers for each IPM, we used a two-stage qualitative approach. In the first stage, we surveyed 31 experts from eight European countries and the UK, asking them to identify barriers and enablers across four phases of implementation. We synthesised these results into long lists for each IPM. Participants also identified the most important barriers and enablers overall and for each phase, informing the development of shorts lists for each IPM to be used in the next research stage.

In the second stage, we held two virtual nominal group (NG) discussions, each focused on a selection of IPMs. Prior to the NGs, participants received a pre-read containing both long and short lists, and they were invited to propose additional items or to request clarifications. During the virtual sessions, participants ranked short-listed items using a 0-100 scale, discussed the results, and re-ranked items based on group discussion and feedback. The sessions concluded with a roundtable on policy recommendations to address the barriers considered most challenging and to leverage the enablers deemed most important.

We analysed the results using raw scores and normalised scores to account for individual variation in scoring. We calculated consensus-weighted importance indices to understand perceived importance of each item, along with the level of consensus generated. Barriers and enablers were mapped to their relevant implementation phases, allowing us to assess where challenges and supports may be concentrated. In addition, we explored differences in scoring patterns by stakeholder type, combining insights from both the NG and survey.

Results

For each IPM, we report the top three enablers and barriers; however, cross-cutting themes emerged across several IPMs. Data infrastructure limitations, legal

and regulatory barriers, and difficulties negotiating an acceptable model design (e.g., IPM complexity, contract details, agreement on the optimal model to use) consistently ranked as the most difficult barriers. Conversely, sufficient data infrastructure, supportive legal environments, and pre-existing experience emerged as critical enablers across multiple IPMs.

Payment model-specific insights revealed distinct implementation challenges and opportunities across IPMs. OBAs were viewed as facing unique operational burdens, particularly around data collection and monitoring requirements that strain clinical staff, though data accuracy was also seen as a key enabler, reflecting a tension between aligning outcomes and payments, and mobilising the people responsible for collecting outcome data. IBP, conversely, showed a particularly strong alignment between barriers and enablers, suggesting that targeted investments in data infrastructure and legal adaptations could simultaneously overcome obstacles and harness critical supports.

Stakeholders noted that IaAPs face distinctive financial management complexities related to payment timelines, and they also considered agreed conditions of termination if the technology fails to be the most significant enabler. Together, these insights highlight the importance of financial planning and risk-mitigation strategies for IaAP implementation. In addition, legal and regulatory hurdles were perceived as having a disproportionately large impact on IaAPs, likely reflecting legal limitations in some countries, which can restrict the use of instalments.

FBRSAs emerged as potentially attractive alternatives to more complex payment models, with stakeholders valuing their relative simplicity and capacity to reduce financial uncertainty, though infrastructure limitations were viewed as a key constraint. PoBAs stood apart in requiring strong stakeholder relations and early dialogue, which participants suggested may be due to limited experiences with PoBAs.

Finally, the policy roundtables highlighted the need for targeted interventions addressing shared challenges—particularly legal frameworks, data infrastructure, and knowledge-sharing networks. Interim solutions like cloud platforms, third-party data providers, and alternative invoicing were proposed where infrastructure or legal constraints exist. Stakeholders also highlighted that HTA bodies should have a role in identifying the uncertainties that IPMs can address, and both groups emphasized the importance of knowledge-sharing networks and commercial frameworks to support IPM adoption—particularly in countries with less experience.

Discussion

Barriers related to data infrastructure limitations, challenges negotiating acceptable designs, and legal or regulatory constraints were consistently viewed as critical for different IPMs. Key enablers across payment models tended to be the direct counterparts of these barriers—for instance, having sufficient infrastructure, an enabling legal environment, and pre-existing frameworks to guide

implementation. As these barriers and enablers recur across various IPMs, policies addressing them should be implemented flexibly to support effective and efficient IPM implementation across different types.

Our analysis revealed that barriers and enablers tend to have the most significant impact on Phase 1 of implementation (the Inception & Design phase), indicating that early investments are necessary to harness enablers and overcome the most decisive barriers. Negotiating an optimal design and adapting legal and regulatory environments—two of the most difficult to overcome barriers considered across IPMs—occur in this phase, highlighting the initial struggle to adopt an IPM that addresses access issues while remaining compatible with a country's legal context. Infrastructure challenges, however, are more likely to arise in later phases as IPMs become operational, indicating that each phase requires different types of expertise and resources. Nonetheless, planning for these challenges should begin early, reinforcing the importance of initial investments for successful implementation.

Stakeholder-specific perspectives revealed three key differences in priorities. For IaAPs, payers uniquely identified financial sustainability as a critical barrier, reflecting concerns about budget impact, given their role in assessing value for money. For OBAs, payers also highlighted pre-existing frameworks, experience and leadership and willing and well-trained as critical enablers. This differences likely reflect the contrasting priorities of those studying IPMs holistically versus those implementing them in practice. Beyond these distinctions, stakeholder-specific insights aligned with the overall group's findings.

A key insight emerged regarding the distinction between different enablers. They can be grouped into either 'hows', which facilitate implementation, and 'whys,' which motivate IPM use. Across IPMs, stakeholders consistently prioritised the 'how' enablers, suggesting that while incentives can drive, operational support is critical for effective implementation. This implies that a country must first build the capacity to implement an IPM before realising its full benefits. Policymakers aiming to increase the adoption of IPMs should therefore focus on harnessing the 'how' before addressing the 'whys.'

Our two-stage approach provided richer insights than the initial survey alone. While the survey had more respondents, the NGs' smaller, purposefully composed groups enabled all participants to share their views through discussion. The NGs also better captured the relative importance of each barrier and enabler, clarified participants' motivations behind their scores, and allowed us to assess consensus levels. Although limitations remain—including small numbers within stakeholder groups and limited country diversity—the strong alignment between NG results and survey findings, along with participants' expressed satisfaction with the final rankings, suggests the approach successfully achieved its primary objective of building consensus around the most challenging barriers and important enablers.

Conclusion

While each IPM presents unique challenges and facilitators, several cross-cutting themes emerged through this research, highlighting areas for targeted policy intervention. Phase-specific insights showed that both barriers and enablers tend to have the largest impact on the first phases of implementation, indicating that early investments are necessary to fully harness and overcome the most decisive enablers and barriers. Ultimately, this study lays the groundwork for tailored policy approaches to support IPM implementation and highlights the need for cross-country collaboration to enable consistent, sustainable IPM implementation across Europe.

1. Introduction

What and how we pay for new medicines impact which therapies are developed, adopted and accessed by patients. While scientific advancements offer opportunities for better patient outcomes, they also present new challenges for value assessment and affordability. In particular, challenges around budget impact and value uncertainty are becoming increasingly common, as the landscape for pharmaceutical innovation shifts toward high cost, targeted and/or personalized therapies with potentially uncertain benefits at the point of reimbursement. Innovative payment models (IPMs) refer to alternative methods of structuring how pharmaceuticals are paid for, with the goal of addressing challenges to affordability, aligning incentives, or reducing risk.

Pricing and payment models play a central role in balancing the sustainability of health innovation with the sustainability of health care systems[1–9]. Simple price discounts do not provide the right solution to many patient access challenges[10–19]. IPMs, successfully implemented in several European countries[20], can facilitate access to pharmaceutical innovations while addressing this dual sustainability objective. However, their implementation faces significant barriers, which can delay and/or increase the burden of implementing agreements and, in some cases, prevent their adoption entirely[13,21–24].

Many different stakeholders have a role to play in facilitating access to pharmaceutical innovation. However, the perspectives of these stakeholders do not always align, including on the value of innovations and how uncertainties should be managed[21]. Therefore, to support effective and efficient implementation of IPMs it is important to build an understanding of stakeholders' views on the implementation of IPMs, including the key enablers that facilitate their use and the barriers that hinder their uptake and the ease of implementation. Applying implementation science theory can strengthen this process by providing a structured way to examine barriers and enablers, which in turn can help leverage the full benefits of implementing IPMs.

1.1. Aims

In this research we aim to better understand the dynamics of IPM implementation, by identifying key barriers and enablers to IPM implementation in Europe and building consensus on the most important enablers and the most challenging barriers. Additionally, we aim to gather insights on best practices and the provision of support to stakeholders in developing solutions.

The remainder of this document explains how we achieved these aims (Section 2 – Methodology) and presents the findings of this research (Section 3 – Results). Following this, we discuss the knowledge gained from the research and provide

guidance on how the findings can support the development of solutions (Section 4 – Discussion). Finally, we provide a summary (Section 5 – Conclusion).

2. Methodology

We used a modified nominal group technique (mNGT) to elicit experts' views on the barriers and enablers of a selection of five IPMs.

The nominal group technique (NGT) typically consists of 6 stages that are covered during a nominal group (NG) discussion[25]:

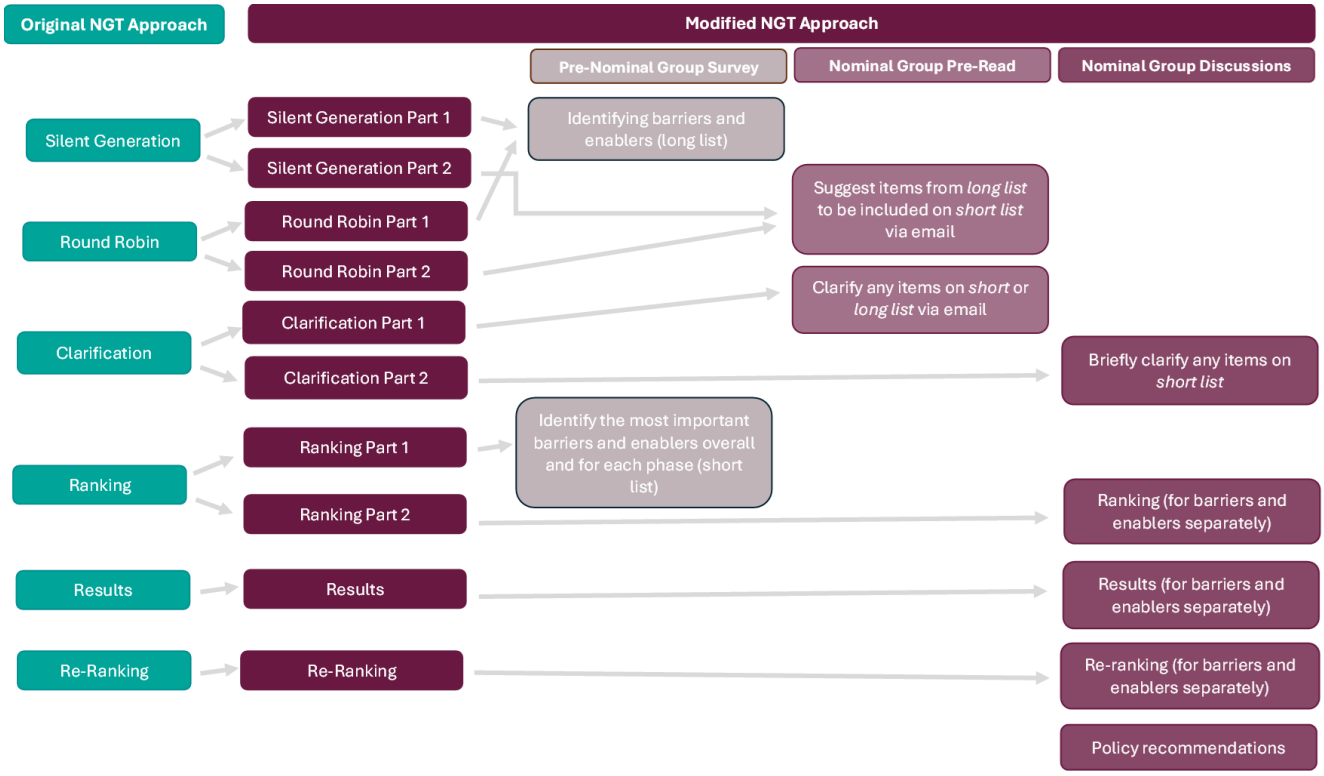
1) Silent generation: Participants are given time to reflect on a question(s) sent to participants in advance of the nominal group.
2) Round robin: Each participant has the opportunity to volunteer an idea to the group to be considered for ranking. This continues until no new ideas are provided.
3) Clarification: Participants are given the chance to clarify any unclear ideas, group together any similar ideas and to exclude, include, or alter ideas.
4) Ranking: Participants rank ideas by importance using a scoring process where higher numbers indicate higher importance or by rating on a Likert scale.
5) Results discussion: Participants discuss the results.
6) Re-ranking: Participants will be given the opportunity to re-score the ideas based on the results discussion.

We implemented a modified NGT (an mNGT) using a two-phase qualitative approach. First, we surveyed expert stakeholders to gather insights on IPM implementation barriers and enablers, and potential solutions. Further details of the survey, including how the long lists of barriers and enablers —identified from survey responses—were used to develop short lists for consideration in the second phase, are detailed in sub-section 2.1.

In the second phase, we held NG discussions with a subset of survey respondents to discuss commonalities and differences, aiming to build consensus on IPM barriers and enablers. Participants were provided a pre-read, which included the short lists of barriers and enablers for consideration in the discussion. Participants were given the opportunity to refine these lists by email and to ask for clarifications before the discussion, via email, and at the start of the group discussion. During the discussions, participants ranked barriers and enablers, discussed the results and then were given the opportunity to re-rank. The discussions finished with a short discussion on policy recommendations. Further details of the pre-read and the NG discussions are provided in sub-section 2.2. Following these two qualitative phases we analysed the results, our approach to which is detailed in sub-section 2.3.

In our mNGT approach, we conducted stages 1 and 2 and parts of stages 3 and 4 of the typical NG approach prior to the NG discussion. We conducted the remaining parts of stages 3 and 4 and all of stages 5 and 6 during the NG discussions. **Figure 1** provides a visual representation of which stages from the original NGT are adapted in our mNGT.

Figure 1. Mapping of the original NGT stages to our mNGT approach



2.1. Defining Barriers and Enablers

We defined barriers as obstacles that hinder or prevent the implementation of IPMs. While implementation costs are not inherently barriers, they become so when they obstruct adoption. For example, significant time investments or legal expenses may discourage stakeholders from adopting a particular model, or the cost of a new data monitoring system may impede effective implementation.

We defined enablers as factors that facilitate the implementation of IPMs. While benefits are not always enablers, they become so when they actively support adoption. For example, if a new payment model aligns with good financial or healthcare management practices, organisations may see it as a responsible and worthwhile approach, increasing the chances of implementation.

2.2. Selection of IPM types

Previous research by Hofer et al.[26] identified the most commonly cited IPM types, including the University of Bocconi taxonomy matrix[20]. We focused on the five most commonly implemented IPM types for this research, namely Outcomes-Based Agreements (OBA), Financial-Based Risk-Sharing Agreements (FBRSA), Portfolio or Bundling Agreements (PoBA), Instalments and Amortization Payments (IaAP) and Indication-Based Pricing (IBP). **Table 1** provides descriptions of each payment model. It is important to note that, in practice, IPMs may incorporate features from multiple models or combine elements from different model types. For example, IaAPs and OBAs are often used together to address access challenges for novel cell and gene therapies with long-term expected effects, such an in agreements for Luxturna™ [27], Zolgensma™ [28,29], Yescarta™ [30] and Kymriah™ [30].

Table 1. IPM descriptions

Innovative Payment Model Type	Description	Example
Outcomes-Based Agreement (OBA)	Payment is tied to clinical outcomes achieved in real-world practice.	• Spark Therapeutics agreements for *Luxturna*.[27] • AveXis agreements for *Zolgensma™*.[28,29] • Genentech and Priority Health agreement for *bevacizumab (Avastin™)*.[31] • AstraZeneca and Catalan Health System agreement for *gefitinib (Iressa™)*.[32]
Financial-Based Risk Sharing Agreement (FBRSA)	The unit price of the product depends on the volume purchased. These can be implemented at the population-level, such as in a price-volume agreement or volume-delinked subscription model, or at the patient-level.	• Population-level: o subscription model agreement between Australian government and DAA manufactures for Hep-C patients.[33] o revenue guarantee partially delinked model agreement for antibiotic access between Sweden and four antibiotic manufacturers.[34,35] o agreement between Spark Therapeutics and Italy for *Luxturna™*.[36]

		• Patient-level dose-capping: ○ NICE TA for ranibizumab (Lucentis™).[37]
Portfolio or Bundling Agreement (PoBA)	A 'bundle' or 'portfolio' of two or more medicines are purchased at an agreed 'overall' price.	• Vertex portfolio agreements with several EU Member States for Cystic Fibrosis medicines.[38–42] • Arrangements between manufacturers and payers in New Zealand.[43] • Arrangements of multiple vaccine producers.[44]
Instalment and Amortization Payments (IaAP)	Payments are split into several instalments spread over time. Instalments can be risk-sharing. Split payments may or may not be outcomes-based.	• Novartis agreements for *Kymriah*™ in Italy and Spain.[45] • Kite (Gilead) agreements for *Yescarta*™ in Spain and Italy. [45] • Spark Therapeutics agreements for *Luxturna*™.[27] • AveXis (Novartis Gene Therapies)agreements for *Zolgensma*™.[28,29]
Indication-Based Pricing (IBP)	The price of the medicine depends on the specific patient subgroup (or 'indication') in which it is used.	• Various examples in EU member states, although these are typically implemented with blended prices or separate brands.[46]

2.3. Survey

The aim of the survey was to identify barriers and enablers for each of the five IPMs and to develop a short list of the most challenging barriers and most important enablers for each IPM.

For each IPM, survey respondents were first asked of their level of experience with that payment model. They were only asked to answer questions on the IPM if they indicated that they had some level of experience. We produced three versions of

the survey with the IPMs in different orders in each version. The potential survey respondents were randomly allocated to a survey version to reduce the impact of respondent fatigue on the number and detail of responses for the IPMs in the latter part of the survey.

To better understand how the barriers and enablers affect implementation, we specifically asked respondents to identify barriers and enablers according to four different phases of implementation for each IPM[24]. These phases are listed and defined below.

1. Inception & Design: The phase in which stakeholders design and choose the IPM and determine the specific objectives of the IPM. This could include negotiating and agreeing on the IPM.
2. Adoption & Implementation: The phase in which the IPM is set up. For example, this might include the establishment of necessary infrastructure for collecting data and monitoring outcomes, upskilling staff, accrediting treatment centres, and/or testing the scheme in real-world settings.
3. Sustainment & Maintenance: The phase involving the ongoing operation of the scheme during which the use of the product is covered under the IPM. This could include ongoing costs resulting from additional data collection on usage or outcomes, for instance.
4. Wrapping Up & Closing: The phase in which the product is no longer covered under the IPM, but there could be additional work related to the reconciliation of payments, costs, investments, etc.

Respondents were asked to consider which phase(s) each barrier/enabler affects. For instance, periodic renegotiation clauses, though established in Phase 1, affect Phase 3, as they support the maintenance and sustainment of the IPM and help prevent future contract disputes.

The barriers and enablers provided by respondents for each phase were used to generate a comprehensive long list of barriers and enablers for each IPM. This process included consolidating barriers/enablers where different terminology was used to describe the similar barrier/enabler themes. The long list was also supplemented with barriers and enablers identified for IPMs explored in the case study interviews (previous research conducted to explore costs, benefits, barriers and enablers of implementing IPMs)[24]. This part of the survey partly replicates the 'silent generation' and 'round robin' stages of the standard NGT approach, with the second part in our modified approach occurring via email prior to the NG discission (outlined in section 2.2).

The survey also asked participants to select:

- the three overall most important barriers and three overall most important enablers for each IPM, and

- the most important barrier and most important enabler for each phase for each IPM.

A short list of barriers and enablers was then derived for each IPM from survey responses where participants selected the overall top three most challenging barriers and most important enablers. Note that barriers/enablers were organized into thematic categories to reduce redundancy and reflect shared underlying issues. This short list was taken forward and used for ranking and consensus-building during the NG discussions.

2.3.1. Survey Participant Selection

This research focused on the implementation of IPMs in the European Union (EU). We additionally included the UK as it is an influential former member of the EU that is considered a leader in health technology assessment, pricing and reimbursement and the implementation of IPMs. To ensure we included a variety of perspectives, we developed a taxonomy to assess characteristics of each EU country and the UK. We developed the taxonomy based on European region (Northern, Eastern, Western, Southern or Central Europe)[47], national GDP per capita[48], health expenditure per capita[49], whether the health system is primarily funded by compulsory health insurance or taxation, whether reimbursement takes place at the national or regional level, and level of IPM experience. IPM experience was assessed as high (at least 3 IPMs documented in literature), medium (1-3 IPM documented in literature), low (anecdotal evidence of IPM implementation or no evidence identified).

Based on this taxonomy, we selected eight countries that would provide a diversity of context in terms of region, wealth, expenditure, health system funding and IPM experience, and used these to focus our recruitment of experts for survey completion. These countries were Austria, Estonia, France, Germany, Lithuania, Poland, Spain and the United Kingdom. Across each country, we also aimed to involve a variety of stakeholders that represent the key stakeholders across all four phases of IPM implementation. This included targeting

- Payers and HTA officials: Public authorities responsible for reimbursement decisions. They lead the negotiations during the inception and design phase and sign contracts with manufacturers. Additionally, they control the financial resources to fund the health technology innovation and possess the legal power to mandate its adoption by providers.
- Manufacturers: Owners of the health technology innovation who hold the legal marketing authorization for its use. They participate in discussions with payers to negotiate the terms and design of the IPM. Upon successful agreement, their innovative health technology is reimbursed (under certain conditions) and integrated into healthcare systems. They also sign the contract that obligate them to supply the innovation under specified conditions, ensuring its availability to healthcare providers.

- Data experts: Responsible for the design of data infrastructure to support the overall implementation of the IPM and data collection for supporting compliance with the terms of the IPM contract.
- Patient representatives: Patients are ultimate beneficiaries of the innovation. They are the only group not subject to legal obligations or responsibilities specific to the IPM. However, because IPMs are designed to benefit patients, they should be designed with patient input to ensure implementation meets patient needs. For example, in outcomes-based agreements, this means measuring outcomes that are meaningful to patients.

Table 2 provides an overview of the level of experience the 31 respondents indicated they had with each payment model.

Table 2. Survey respondents (N = 31) IPM experience

	Definition	OBA	FBRSA	PoBA	IaAP	IPM
No experience	*no exposure*	7	11	13	11	15
Minimal	*basic familiarity or some indirect exposure*	6	5	7	9	4
Moderate	*some involvement or practical understanding*	13	8	9	7	6
Significant	*extensive involvement in the implementation*	5	6	1	4	5
Expert	*recognized authority in this IPM, extensive experience leading or shaping implementation*	0	1	1	0	1

Only participants who indicated they had some level of experience with an IPM were asked to answer questions on the IPM (i.e., those who indicated they had no experience were not asked to answer questions on the IPM, with those responding that they have minimal, moderate, significant or expert levels of experience being asked to respond to questions on the IPM). **Table 3** provides the characteristics of the survey respondents for each IPM. Note that participants were able to select multiple stakeholder types and country expertise. We did not receive any responses from Estonian experts we contacted, meaning that we did not have representation from a country with a GDP per capita and health expenditure in the lowest third of the EU and the UK. We also did not receive any responses from providers and physicians.

Table 3. Survey respondent characteristics

	OBA	FBRSA	PoBA	IaAP	IBP
Respondents	**24**	**20**	**18**	**20**	**16**

Academic	12					
Data Expert	2					
Healthcare Commissioner	1					
HTA (Official)	10					
Manufacturer	3					
Patient (Representative)	1					
Payer	6					
Pharmacist	3					
Policymaker	4					
Regulator	1					
Other: Pricing and Reimbursement	1					
Other: Pharmaceutical Association	2					
Other: Government Health Agency	1					

Belgium France Germany Italy Lithuania Netherlands Portugal Spain Sweden United Kingdom USA Pan-European Theoretical Expert

Note: A theoretical expert is an expert with knowledge of the concepts of the IPMs implementation but does not have knowledge on the implementation of the IPMs in a particular geographic setting.

2.3.2. Nominal Group Discussion Participants

In the selection of participants, we prioritised ensuring that there were representatives from both primarily social insurance and taxation-funded health systems and that a variety of stakeholders were represented in each NG. While most participants completed the survey prior to their selection as NG discussion participants, three experts were added at this later stage.

We ran two NGs—one group covering OBAs, IBP, and IaAPs; and another covering FBRSAs and PoBAs. Selected participants only participated in one NG each.

Table 4 provides an overview of the characteristics of the participants in each NG. Note, participants were able to select multiple stakeholder types and country expertise and not all stakeholder types reflected in the survey were reflected in the NG.

Table 4. NG participant characteristics

	OBA, IBP, and IaAP		FBRSA and PoBA	
Participants	**7**		**8**	
Academic	3		3	
Healthcare Commissioner	0		1	
HTA (Official)	3		1	
Manufacturer	1		1	
Patient (Representative)	1		1	
Payer	1		2	
Pharmacist	0		1	
Policymaker	1		2	
Other: Pricing and Reimbursement	0		1	
Other: Government Health Agency	0		1	

Belgium Italy Netherlands Portugal Spain Sweden United Kingdom Pan-European Theoretical Expert

Note: A theoretical expert is an expert with knowledge of the concepts of the IPMs implementation but does not have knowledge on the implementation of the IPMs in a particular geographic setting.

2.4. Nominal Group Pre-Read

Prior to the nominal group discussion (at least one week before), participants were provided with pre-reading material, which included both the long and short list of barriers and enablers for the payment models to be discussed in the NG they were participating in, along with a description of how the short and long lists were developed. Participants were also provided with the agenda for the nominal group, including the questions that were to be asked in the NG.

Participants were asked to reflect on the materials in the pre-read package and consider whether any barriers or enablers that were missing from the *short list*. In addition, they were asked to identify any barriers or enablers from the *long list* that they felt should be added to the *short list* of the most important barriers and enablers. This was considered the second part of the *silent generation and round robin* of our mNGT approach.

Participants were also asked to email if they required any clarification on any barriers/enablers in the *long* or *short list*. This process was considered part 1 of the *clarification stage* in our mNGT approach.

2.5. Nominal Group Discussions

The NG discussions had two objectives:

1. Reflect on the findings from the previously conducted survey to generate consensus on the most important barriers and enablers.
2. Elicit experience-based knowledge from the participants to inform actionable policy recommendations for overcoming the most important barriers/facilitating the most crucial enablers.

In this part of the research, we focused on the most challenging barriers to overcome and most important enablers for implementation (i.e. the short lists for each payment model).

The NGs were held virtually using Microsoft Teams. The first NG, covering OBAs, IBP and IaAPs, lasted three hours, with the second NG, covering FBRSAs and PoBAs, lasting two hours. At the start of the NGs, participants were given an additional, final opportunity to ask for any final further clarifications on the barriers/enablers included in the *short list* (part 2 of *clarification stage* in our mNGT approach). Participants were also given the opportunity to ask for clarification on anything relating to the process for achieving consensus on the most important barriers and enablers in the nominal group.

To achieve the first objective—generating consensus on the most important barriers and enablers—participants were asked the following two questions for each IPM in turn:

1) What barriers are the most difficult to overcome in implementing the IPM?
2) What enablers are the most important in facilitating the implementation of the IPM?

During the ranking process during the NG, participants were asked to score each barrier and enabler on the short list using a Microsoft Form. Responses were entered in a free text response box for each item, with participants providing integer scores from 0 to 100. For barriers, a score of 100 indicated the highest level of difficulty to overcome, while 0 indicated the lowest level of difficulty to overcome (i.e., extremely easy). For enablers, 100 represented the highest level of importance in facilitating IPM implementation, and 0 the lowest. As the scores provided to rank the barriers and enablers are based on the individuals perception of difficulty and importance the scores should be considered qualitative.

After the initial rankings, all the participants in the NG were shown the group's aggregated ranking of the barriers and enablers, including the mean score for each item, on a Microsoft Whiteboard. Participants were then invited to share comments and reflections on the ranked lists (discussion stage of the modified NGT). They were encouraged to identify barriers or enablers they felt were ranked incorrectly, suggest changes to the wording, or propose additions or removals. Any

discussed wording changes were agreed by the group and then made on the Whiteboard.

Following the discussion, participants were given the opportunity to re-score the short list *(re-ranking phase* of the mNGT), with any changes from the discussion incorporated into the choices presented to participants. When re-scoring was carried out, participants used Microsoft forms to edit their previous scores for each barrier or enabler. This approach ensured that any variation in scores reflected intentional changes rather than misremembering their previous entries. After re-scoring, participants were shown the final rankings for each IPM along with the mean score for each barrier and enabler. This process for generating consensus was carried out for each IPM in turn.

To achieve our second objective, the NGs concluded with a discussion of policy recommendations. Participants discussed policies that could help overcome the three most challenging barriers and facilitate the three most important enablers for the IPMs.

2.6. Nominal Group Discussion Analysis

The final ranking scores of each participant for each IPM were used to generate the insights in this analysis. For each IPM—and for both barriers and enablers—we present raw scores alongside normalised scores, including the mean and standard deviation (SD) for each item.

The scores reflect the perceived difficulty of each barrier and importance of each enabler, and the level of consensus among participants. We normalised scores—using a min-max normalisation—to account for individual variability in scoring. For each individual, we normalised their scores relative to their own maximum and minimum values, using the following formula:

$$Normalised\ Score = \frac{(Raw\ Score) - (Minimum\ Score)}{(Maximum\ Score) - (Minimum\ Score)} * 100$$

We provide an illustrative example of how we applied this formula to participants' scores in the Appendix.

The normalised mean for a given barrier reflects the average relative importance of that barrier compared to the other barriers, across participants. A higher normalised mean indicates that, on average, participants scored this barrier closer to the most difficult barrier (within their own ranking), whereas a lower normalised mean reflects that, on average, participants scored it closer to the least difficult barrier. In sum, this value tells us which barriers/enablers were consistently rated as more or less significant, regardless of each participant's raw scoring behaviour.

Likewise, the SD of the normalised scores for each barrier reflects the degree of consistency—or variability—in how participants ranked that barrier relative to the other barriers. In other words, the normalised SD captures the extent to which

participants agreed or disagreed on the relative difficulty of each barrier. A low normalised SD means that participants scored that barrier similarly relative to the other barriers, while a high normalised SD indicates greater variation. As such, the normalised SD provides an approximation of rank order consistency across participants, reflecting how similarly participants evaluated each barrier's relative difficulty within their own scoring range.

In addition to the normalised and raw means and SDs, we also present the consensus-weighted importance index (CWII)—an index that combines the mean and standard deviation into a single measure—for each ranked barrier and enabler. We computed this using the following formula:

$$CWII = \frac{mean}{(1 + SD)}$$

A higher CWII represents either a higher level of consensus, higher average value, or a combination of the two. A lower CWII reflects the opposite.

We contextualise these quantitative figures and measures with qualitative insights from the NG discussion to analyse the drivers and motivations behind the results.

For each IPM, we also map each barrier and enabler to its corresponding phase of implementation to assess whether certain phases are more affected —positively or negatively—by the barriers and enablers under consideration.

In addition, we present an analysis of stakeholder-specific scoring results. Since the NG included a small number of participants within each stakeholder group, we contextualised stakeholder-specific insights from the NG with the pre-NG survey results, which had a larger sample of respondents across stakeholder types. This allowed us to identify broader scoring patterns by stakeholder type.

3. Results

3.1. Survey Results

This section provides an overview of the results from the survey.

As discussed in sub-section 2.1, from the survey responses we developed a long list (a comprehensive list of the barriers and enablers for each IPM) and short list (the most challenging barriers and most important enablers) of barriers and enablers for each payment model. The short lists for each payment model are provided below (**Table 5**-**Table 9**), with the long lists provided in the Appendix.

Barriers and enablers were grouped into thematic categories to reduce redundancy and reflect shared underlying issues. The long lists in the Appendix show how that was done. We present the results of the survey below.

Table 5. OBA barriers and enablers short list

Most Challenging Barriers to Overcome	Most Important Enablers for Implementation
Negotiating an acceptable OBA design (e.g., what to measure, how to measure, complexity of design)	Sufficient infrastructure and funding (e.g., for data collection and management)
Lack of infrastructure for data collection and monitoring (e.g., registries, reporting mechanisms, etc.)	Data accuracy and optimisation to achieve OBA's goals
Financial sustainability	Pre-existing frameworks, clinical experience, and leadership to guide implementation
Negative perception of OBAs and lack of trust among stakeholders	Willing and well-trained staff members (e.g., HCP, administrative staff, etc.)
Uncertainty in results (e.g., inconclusive evidence/findings or inconsistent data quality and reporting across sites)	Early stakeholder engagement and buy-in (e.g., agreement on goals, shared commitment to managing uncertainty)
Financial management challenges (e.g., aligning payment schedules with fiscal years, managing delays, etc.)	Safeguards against misuse (e.g., independent third party, solid audit mechanisms)
External changes (e.g., introduction of new therapeutic alternatives, or changes to healthcare affecting outcomes)	Solid mechanisms to wrap-up and close OBAs once they have met their pre-defined goal
Burden on clinical staff (training staff, and administrative burden of data collection and data entry)	Fair pricing
Rigid governance requirements (e.g., data confidentiality, independent oversight, etc.)	Clear legal and regulatory guidelines
	Good communication to communities who will be treated

Table 6. IPB barriers and enablers short list

Most Challenging Barriers to Overcome	Most Important Enablers for Implementation
Designing optimal model (e.g., selection of most appropriate implementation model; complexity of design, details of regression model)	Established data infrastructure and monitoring systems (e.g., routine clinical data used for tracking use by indication, pre-existing data collection)
Lack of stakeholder buy-in or trust (e.g., loss of value surplus due to price discrimination, resistance to adopting new model)	Rational design and application of IBP (e.g., acceptance of selected implementation model, appropriate granularity / number of indications, pre-established regression models, use of proxy data)
Infrastructure and data limitations (e.g., billing infrastructure, use-tracking challenges, burden of data collection)	Mechanisms for informed, inclusive implementation (e.g., stakeholder education, multi-stakeholder discussions, information sharing)
Data reconciliation and price adjustment challenges (e.g., reconciling usage data with an updated price, unexpected outcomes leading to re-negotiations)	Flexibility for use only in certain indications
Legal and regulatory barriers (e.g., VAT complicating rebates, laws limiting use of IBP, lack of ability to use confidential rebates, etc.)	Safeguards against misuse (e.g., effective auditing mechanisms, clear arrangements preventing stakeholders from manipulating the system, confidentiality)
Uncertainty for future interventions (e.g., impact on future interventions and the impact of new competition on product price at indication-level and feasibility for scheme implementation)	
Challenges restricting prescription to the relevant authorised indications (i.e. prevention of arbitrage)	

Table 7. IaAP barriers and enablers short list

Most Challenging Barriers to Overcome	Most Important Enablers for Implementation
Negotiating an acceptable model (e.g., complexity of design, choosing the optimal model, etc.)	Existing infrastructure (e.g., data registries)
Stakeholder relations and trust (e.g., issues engaging all stakeholders, and lack of trust)	Pre-existing experience or frameworks to guide implementation
Financial sustainability (e.g., budget impact, risk of high prices being hidden behind deferred payments)	Safeguards against misuse (e.g., independent oversight or effective auditing)
Complex financial management (e.g., coordinating payment schedules with fiscal years, dealing with uncertainty in payments or late payments, reconciliation)	Risk mitigation (i.e. managing high upfront costs and long-term clinical uncertainty, desire to improve odds of reimbursement)
Recording necessary data	Perceived high unmet need
Innovation from new or improved drugs	Transparency and fair pricing
Legal and regulatory hurdles	Agreed conditions of termination of the agreement if the technology fails during the amortization period
	Accommodating legal environment

Table 8. FBRSA barriers and enablers short list

Most Challenging Barriers to Overcome	Most Important Enablers for Implementation
Negotiating an acceptable FBRSA design (e.g., complexity of design, choosing the optimal model and reimbursement amount)	Sufficient infrastructure (e.g., utilization databases) and funding
Infrastructure and data limitations (e.g., data needs, financial data collection challenges, agreeing on monitoring systems, coordinating volume-based agreements with several payers)	Design of FBRSA (e.g., well-designed protocol, alignment on assumptions, clear threshold)
Lack of stakeholder trust or resistance to adopting a new model	Capacity to reduce financial uncertainty (e.g., budget predictability, reduced pressure of cost-containment, helps avoid penalties in case of stockouts)
Financial sustainability and planning	Fair prices
Challenges for potential market evolution (e.g., evaluating new products using RSA-covered comparator, potential for new entry)	Safeguards against misuse (e.g., effective auditing mechanisms)

Disagreements over final payments or reconciliation	Simplicity/ease of implementation (e.g., limited additional data required)
Contract renewal and extension	Flexible contract terms

Table 9. PoBAs barriers and enablers short list

Most Challenging Barriers to Overcome	Most Important Enablers for Implementation
Negotiating an acceptable PoBA (e.g., complexity of design, choosing the optimal model)	Ealy dialogue between stakeholders
Infrastructure and data limitations (tracking usage, understanding real prices used)	Budget predictability (i.e. of costs and revenues) and affordability
Budget impact (e.g., risk of increasing costs and potential burden on healthcare system)	Increased patient access to complementary technologies
Challenges with stakeholder relations and buy-in (e.g., stakeholder trust and engagement, secrecy concerns, resistance to extending public funding of innovative medicines)	Clear endpoints
Impact on future HTA (e.g., evaluating new products using covered comparator, aligning HTA and negotiations to prevent delays)	Regulatory exceptions
Follow-up and defining criteria for contract extension	Enhanced financial planning and collaboration (e.g., improved methodology of budget impact assessment and transparent shared funding schemes)
Reconciliation	
Newly launched drugs and incremental improvements in original drugs	
Potential competition law issues	
Interactions between various financial mechanisms	

3.2. Nominal Group Discussion Results

This section presents the results of the two NGs, highlighting the barriers participants deemed to be the most difficult to overcome and the enablers identified as being the most important for the implementation of the five IPMs.

3.2.1. Outcomes-Based Agreements (OBAs)

3.2.1.1. Barriers

Figure 2 presents the results of the NG on OBA barriers, including raw scores and min-max normalised scores, and **Figure 3** presents the CWIIs for the OBA barriers.

The results indicate that the most difficult barrier to overcome in OBA implementation is a *lack of infrastructure for data collection and monitoring*. This barrier received the highest mean score across both normalised and raw scores, as well as the lowest SD, indicating a shared perception of its importance. **Figure 3** highlights this, as *lack of infrastructure for data collection and monitoring* shows the highest CWII by a significant margin.

Negotiating an acceptable OBA design was ranked as the second-most difficult barrier to overcome in terms of raw scores but third in terms of normalised scores. This barrier also had the highest normalised standard deviation, as there was significant variation in rank order among NG participants. Indeed, two academics—one from Spain and one from Italy—assigned their lowest scores to this barrier, while a Spanish provider/payer and an industry representative assigned this barrier their highest scores. This difference could reflect how issues related to OBA design—such as determining clinical endpoints and the timing of data collection—might be theoretically easy to resolve, but in practice, lead to significant disagreement.

Conversely, *burden on clinical staff* ranked third for raw scores and second for normalised scores, meaning its relative importance increased when adjusted for individual variability. *Burden on clinical* staff had a relatively low raw SD and higher normalized SD, suggesting consensus around its absolute difficulty but divergence in terms of its difficulty relative to the other barriers—that is, most people prescribed high scores, but may have ranked it below other barriers they deemed as more difficult to overcome.

The CWII graph highlights that *lack of infrastructure for data collection and monitoring* had the highest CWII, with the second-ranked barrier, *burden on clinical staff*, trailing by a substantial margin.

Figure 2. OBA barriers means and standard deviations

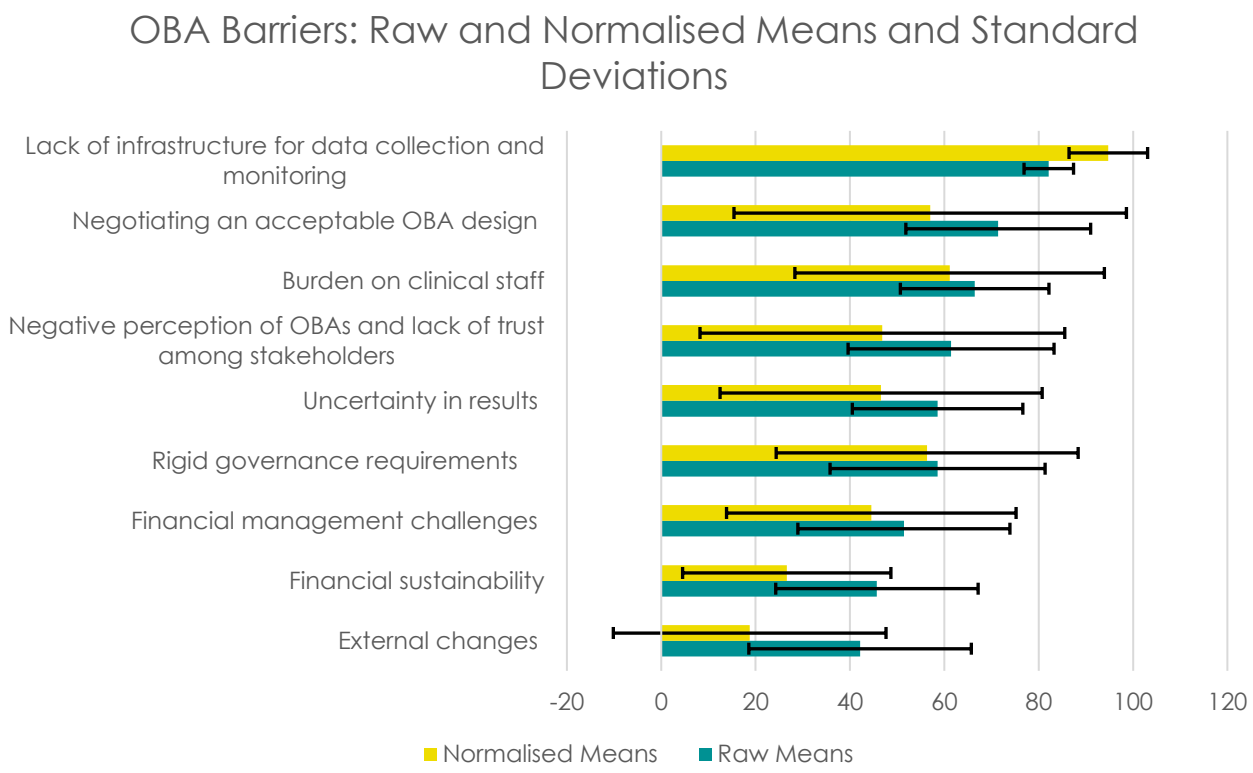
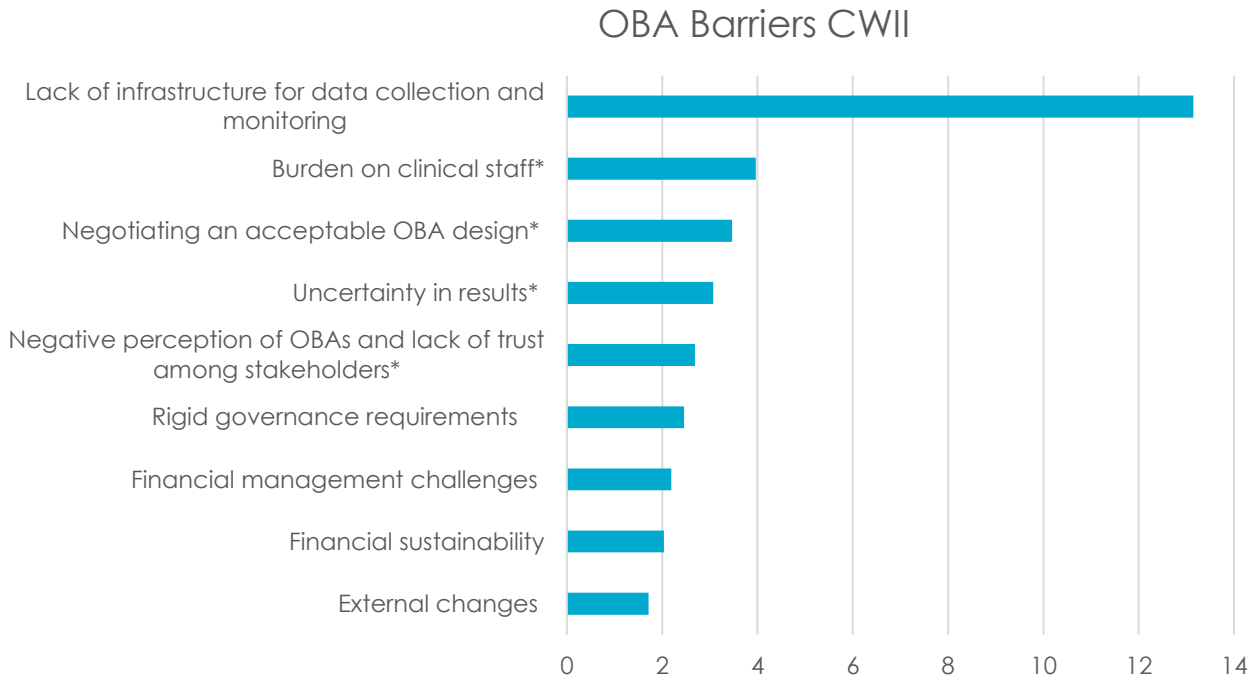


Figure 3. OBA barriers CWII



* Indicates a change in position relative to the order of means

Changes from Initial Rankings to Post-Discussion Ranking

Table 10. OBA Barriers: Change in scores

Barrier	Initial Mean	Final Mean	Change in Mean	Initial SD	Final SD	Change in SD
Lack of infrastructure for data collection and monitoring	80.71	82.14	**1.43**	4.16	5.25	**1.08**
Negotiating an acceptable OBA design	70.00	71.43	**1.43**	19.27	19.59	**0.32**
Burden on clinical staff	66.43	66.43	**0.00**	15.75	15.75	**0.00**
Uncertainty in results	57.14	58.57	**1.43**	19.06	18.07	**-0.99**
Negative perception of OBAs and lack of trust among stakeholders	55.71	61.43	**5.71**	23.97	21.83	**-2.14**
Rigid governance requirements	52.86	58.57	**5.71**	22.02	22.79	**0.77**
Financial management challenges	52.86	51.43	**-1.43**	18.49	22.47	**3.99**
External changes	45.00	42.14	**-2.86**	25.50	23.58	**-1.91**
Financial sustainability	40.71	45.71	**5.00**	22.59	21.45	**-1.14**

Table 10 highlights the changes to barriers' scores after the discussion phase of the NG. *Rigid governance requirements* (e.g., data confidentiality, independent oversight) experienced one of the largest absolute changes (+5.71) in mean raw scores. During the discussion, a Swedish academic highlighted it as a key issue, expressing surprise at its relatively low score. He noted that he had observed the cancellation of OBAs due to this very factor. Subsequently, three participants assigned it higher scores in the re-ranking round, leading to a 5-point increase in its raw mean score, but an overall increase of 0.774 in its raw SD; this result was driven by the fact that the participants increasing their scores led to greater deviation from the mean, as the other participants kept their scores the same.

Notably, *negative perception of OBAs and lack of trust among stakeholders* also experienced a large absolute change in mean raw score, though this was not a focus of the discussion. This change was driven by an Italian academic changing his score from 30 to 70, likely in response to observing the group's aggregate score of this barrier.

On the whole, the post-discussion rankings saw an average decrease in standard deviation of 0.002—a non-significant amount, suggesting that the discussion did little to increase consensus around barriers' scores. However, when presented with the final rankings, participants largely agreed that the rank order and relative differences between barriers seemed sensible.

Stakeholder-Specific Insights

Table 11. Top three OBA barriers for each stakeholder type

Stakeholder Type	Most Difficult Barrier	2nd Most Difficult Barrier	3rd Most Difficult Barrier
Academics	Lack of infrastructure for data collection and monitoring (81.67)	Rigid governance requirements (68.33)	Negative perception of OBAs and lack of trust among stakeholders (63.33)
Industry	Negotiating an acceptable OBA design (100)	Negative perception of OBAs and lack of trust among stakeholders (90)	Lack of infrastructure for data collection and monitoring (80)
Patient	Lack of infrastructure for data collection and monitoring (80)	Negotiating an acceptable OBA design (70)	External changes (70)
Payer	Burden on clinical staff (87.5)	Lack of infrastructure for data collection and monitoring (85)	Negotiating an acceptable OBA design (80)

Mean scores assigned by stakeholders in parentheses

Table 11 highlights stakeholder-specific results from the NG, indicating each stakeholder type's three highest-scored barriers by mean. These results should be interpreted with caution, given the small number of participants within each stakeholder category. However, the pre-NG survey provides valuable contextualisation; where stakeholder groups emphasized the same priorities across both the NG and the pre-NG survey, the results can be more confidently interpreted as reflective of stakeholder-specific perspectives.

For OBA barriers, the results from the overall group generally aligned with the stakeholder-specific results. Where differences did exist between the stakeholder-specific scores and the overall group's scores, the results from the pre-NG survey were not consistent with such divergences. Indeed, the stakeholder-specific results from the pre-NG survey were mostly similar to the NG's aggregate scores.

The results from the patient and industry representatives should be interpreted with caution, as only one individual from each of these groups participated in the NG. The patient representative in the NG was also the only patient who completed the survey. Two industry representatives completed the survey, including the one who took part in this NG. Still, it is worth noting that the survey results from the two industry representatives aligned with the overall group scores and, importantly, did not highlight *negative perceptions of OBAs and lack of trust among stakeholders*, suggesting that these issues may not be of particular concern within the industry stakeholder group, even if highlighted in this NG.

Phased Approach

Table 12. OBA barriers and implementation phases

Barriers	Phase 1	Phase 2	Phase 3	Phase 4
Lack of infrastructure for data collection and monitoring		13.15	13.15	
Negotiating an acceptable OBA design	3.47			
Burden on clinical staff		3.97	3.97	
Negative perception of OBAs and lack of trust among stakeholders	2.69			
Rigid governance requirements			2.46	2.46
Uncertainty in results			3.07	3.07
Financial management challenges			2.19	2.19
Financial sustainability	2.19			
External changes			2.19	

Numbers correspond to each item's CWII. Green indicates a CWII above 5, yellow indicates a CWII between 3 and 5, and red indicates a CWII below 3. Phase 1: Inception & Design, Phase 2: Adoption, Phase 3: Sustainment & Maintenance, Phase 4: Wrapping Up & Closing

Table 12 delineates which OBA barriers impact the different phases of implementation, with corresponding CWII values and a colour code. While all barriers must be considered during the early phases of IPM implementation to successfully overcome them, this table indicates the phases where each barrier will have its most direct impact during implementation. As such, this helps identify where barriers are likely to create the greatest challenges in practice, enabling stakeholders to anticipate implementation bottlenecks in the phases where specific barriers will be most acutely felt.

The results suggest that the phases of OBA implementation most encumbered by the barriers under study are Phases 2 and 3, as *lack of infrastructure for data collection and monitoring*, and *burden on clinical staff* were the barriers with highest CWIIs, with both impacting the Phases 2 and 3. Additionally, several of the barriers with less consensus around their scores likewise affect Phase 3. This ultimately suggests that, for OBAs, the most critical implementation bottlenecks are not necessarily in the initial planning phase, but rather in the operational phases where systems must actually function and be maintained.

3.2.1.2. Enablers

Figure 4 presents the results of the NG on OBA enablers, including both the normalised and raw scores, and **Figure 5** provides the CWIIs of the OBA enablers. The enabler considered most important for facilitating OBA implementation was *sufficient infrastructure and funding*, which received the highest mean score and lowest SD in both normalised and non-normalised scoring. It also received the highest CWII, reflecting a strong sense of consensus for this as a critical enabler for OBA implementation. This finding mirrored the top-ranked barrier, which

underscores infrastructure as a pivotal determinant of OBA implementation success.

Clear legal and regulatory guidelines and *data accuracy and optimisation to achieve OBA's goals* were the second and third most important enablers—as indicated by raw scores—respectively. However, both had slightly high SDs, especially in the normalised scores, indicating disagreement on their relative rank order. This was particularly pronounced for *data accuracy and optimisation to achieve OBA's goals*, which had a significantly lower CWII, indicating not only disagreement on its relative rank order, but also disagreement on its absolute value.

Figure 5 highlights that *safeguards against misuse*, despite having a lower score relative to the other enablers, had one of the highest CWIIs, which is indicative of its lower standard deviation. Thus, there was shared recognition that *safeguards against misuse* are important—its mean score is still above 60—but participants generally did not see it as the most critical enabler for OBA implementation.

Fair pricing was the enabler with the largest level of disagreement in terms of both normalised and raw scores. Indeed, the industry representative assigned it an extremely low score, arguing that pricing must already be resolved before OBAs are considered. By contrast, two academics assigned it the highest possible score, highlighting fair pricing's role in ensuring fairness and preventing opportunism. Notably, discussion led to an increase in score variability, suggesting that dialogue deepened—rather than resolved—disagreement on the role of fair prices in OBA implementation.

Figure 4. OBA enablers means and standard deviations

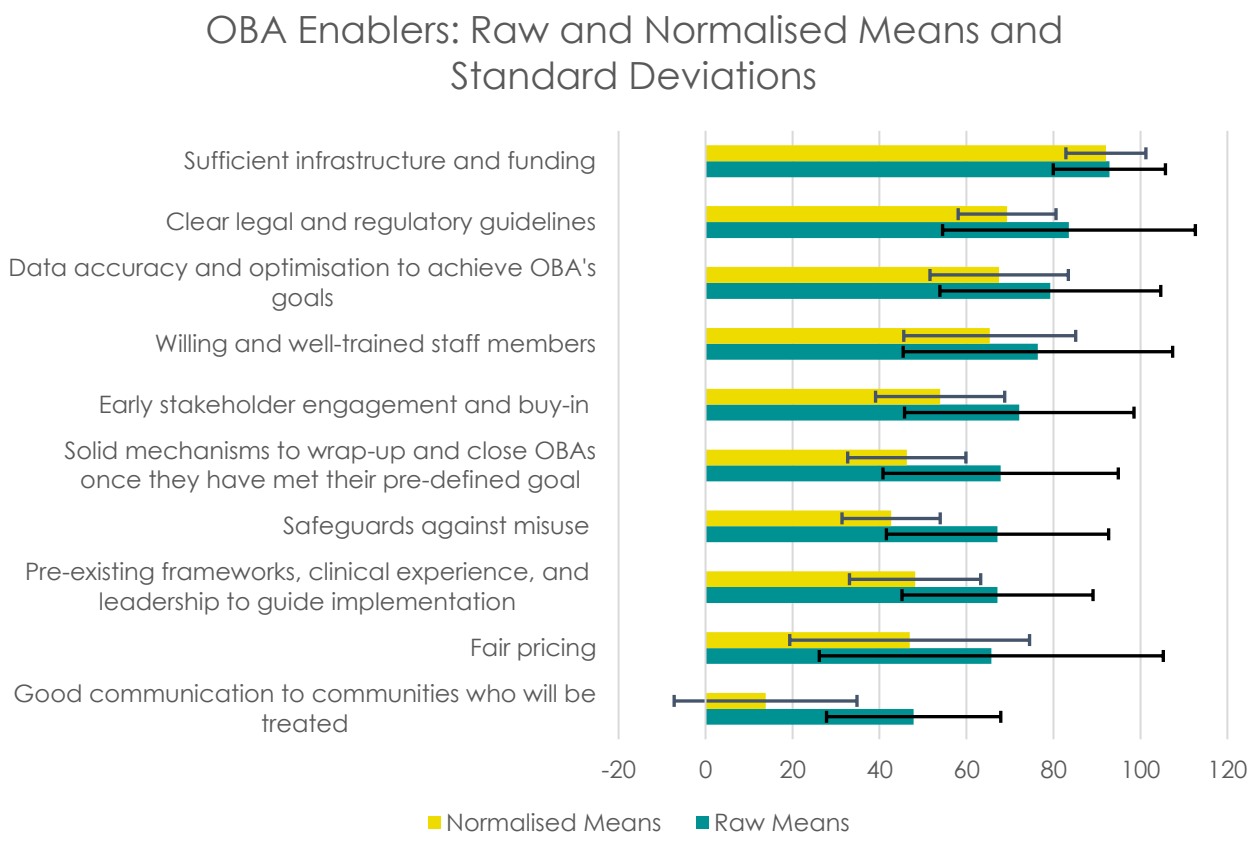
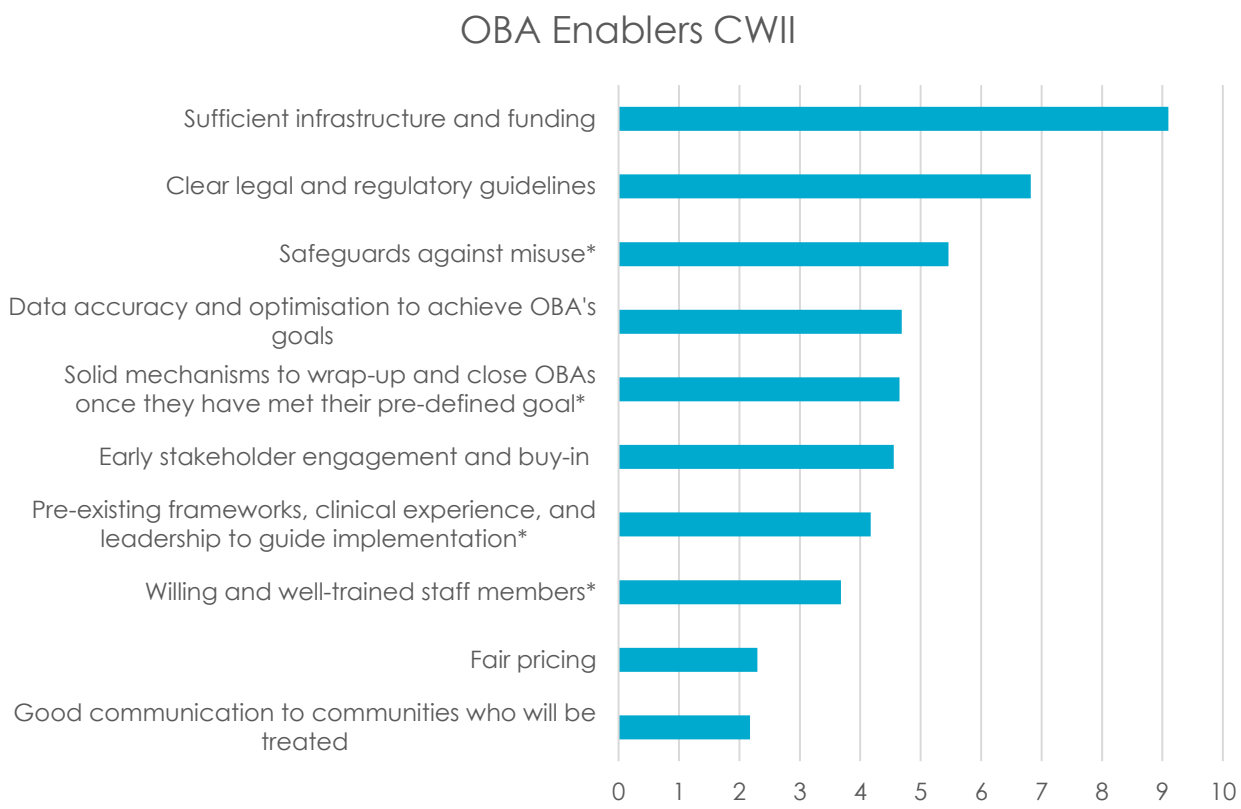


Figure 5. OBA enablers CWII



* Indicates a change in position relative to the order of means

Changes from Initial Rankings to Post-Discussion Rankings

Table 13. OBA enablers: Change in scores

Enablers	Initial Mean	Final Mean	Change in Mean	Initial SD	Final SD	Change in SD
Sufficient infrastructure and funding	92.86	92.86	**0.00**	9.20	9.20	**0.00**
Clear legal and regulatory guidelines	83.57	83.57	**0.00**	17.26	11.25	**-6.01**
Data accuracy and optimisation to achieve OBA's goals	78.57	79.29	**0.71**	13.01	15.91	**2.89**
Willing and well-trained staff members	77.86	76.43	**-1.43**	21.02	19.77	**-1.25**
Early stakeholder engagement and buy-in	66.43	72.14	**5.71**	18.07	14.85	**-3.22**
Solid mechanisms to wrap-up and close OBAs once they have met their pre-defined goal	68.57	67.86	**-0.71**	9.90	13.59	**3.69**
Pre-existing frameworks, clinical experience, and leadership to guide implementation	58.57	67.14	**8.57**	17.26	15.08	**-2.18**
Safeguards against misuse	67.14	67.14	**0.00**	11.29	11.29	**0.00**
Fair pricing	66.43	65.71	**-0.71**	22.15	27.57	**5.42**
Good communication to communities who will be treated	47.86	47.86	**0.00**	21.02	21.02	**0.00**

Table 13 presents the changes from initial to post-discussion rankings. Overall, average SDs decreased by 0.66, which is not statistically significant, suggesting that the discussion did little to reduce score variability for each of the enablers. The largest mean change occurred for *pre-existing frameworks, clinical experience, and leadership to guide implementation*. This change was likely motivated by the discussion, when a Spanish payer explained that, in her experience, pre-existing experience was key to implementing IPMs. After this discussion, four of the seven participants increased their scores for this enabler, increasing its mean and decreasing variability around it.

Stakeholder-Specific Insights

Table 14. Top three OBA enablers for each stakeholder type

Stakeholder Type	Most Important Enabler	2nd Most Important Enabler	3rd Most Important Enabler
Academics	Sufficient infrastructure and funding (91.67)	Clear legal and regulatory guidelines (81.67)	Early stakeholder engagement and buy-in (76.67)
Industry	Sufficient infrastructure and funding (90)	Willing and well-trained staff members (90)	Data accuracy and optimisation to achieve OBA's goals (90)
Patient	Sufficient infrastructure and funding (100)	Willing and well-trained staff members (100)	Clear legal and regulatory guidelines (100)
Payer	Sufficient infrastructure and funding (92.5)	Willing and well-trained staff members (87.5)	Pre-existing frameworks, clinical experience, and leadership to guide implementation (87.5)

Mean scores assigned by stakeholders in parentheses

Table 14 highlights stakeholder-specific results from the NG, indicating each stakeholder type's three highest-scored enablers on average. *Sufficient infrastructure and funding* was ranked as being the most important enabler by all four groups, which is consistent with the overall rankings. *Clear legal and regulatory guidelines* and *data accuracy and optimisation to achieve OBA's goals* were also captured in the stakeholder-specific rankings.

In general, where differences exist between stakeholder-specific rankings and the group's rankings, these should not be interpreted as meaningful takeaways about broader stakeholder priorities. However, some exceptions do exist. For instance, academics scored *early stakeholder engagement and buy-in* as the third most critical barrier in the NG, which is consistent with results of the pre-NG survey, where this same enabler was ranked as one of the most important barriers among the larger sample of academic respondents. This consistency strengthens the interpretation that academics—more so than the other stakeholder types—view stakeholder engagement as central to successful OBA implementation.

Similarly, payers scored *willing and well-trained staff members* and *pre-existing frameworks, clinical experience, and leadership to guide implementation* as two of the most pivotal enablers. These priorities were also reflected in the survey results for payers, suggesting that for HTA and payer bodies, mechanisms such as knowledge sharing and structured frameworks could be key enablers to operationalise these IPMs, along with the education of the people who will be operationalising the IPM in their daily lives.

Phased Approach

Table 15. OBA enablers and implementation phases

	Phase 1	Phase 2	Phase 3	Phase 4
Sufficient infrastructure and funding		9.10	9.10	
Clear legal and regulatory guidelines	6.82			
Data accuracy and optimisation to achieve OBA's goals		4.69	4.69	
Early stakeholder engagement and buy-in	4.55			
Solid mechanisms to wrap-up and close OBAs once they have met their pre-defined goal				4.65
Pre-existing frameworks, clinical experience, and leadership to guide implementation	4.17			
Safeguards against misuse				5.46
Fair pricing	2.30			
Good communication to communities who will be treated		2.17	2.17	2.17

Numbers correspond to each item's CWII. Green indicates a CWII above 5, yellow indicates a CWII between 3.0 and 5.0, and red indicates a CWII below 3. Phase 1: Inception & Design, Phase 2: Adoption, Phase 3: Sustainment & Maintenance, Phase 4: Wrapping Up & Closing

Table 15 illustrates the CWII of each of the OBA enablers and the corresponding phases each enabler affects. In contrast to the OBA barriers, the enablers are spread relatively evenly, with high-CWII enablers affecting each phase. This even spread suggests that OBA implementation success depends on maintaining comprehensive supportive factors rather than relying on any single critical enabler at a specific phase.

3.2.1.3. Summary of OBA Insights

Overall, our analysis showed that the barriers identified as the most difficult to overcome by stakeholders were *lack of infrastructure for data collection and monitoring*, *negotiating an acceptable OBA design*, and *burden on clinical staff*. For enablers, stakeholders scored *sufficient infrastructure and funding*, *clear legal and regulatory guidelines*, and *data accuracy and optimisation to achieve OBA's goals* the highest. Taken together, these results underscore the criticality of infrastructure for OBA implementation, given that items related to infrastructure had the highest CWIIs as both a barrier and enabler.

Burden on clinical staff as a barrier and *data accuracy and optimisation* as an enabler point to OBA's reliance on clinical data. Healthcare professionals must deal with data entry, and this data must be accurate and reflective of treatment outcomes. This challenge highlights a tension in OBAs: while they intend to align payment with results, they simultaneously can create additional administrative burdens. Thus, the success of OBA implementation hinges on designing systems that minimise administrative burdens while maximising data quality. Ultimately, this emphasises the importance of infrastructure for OBA implementation—which can mitigate such burdens—but also lends insight into why negotiating an acceptable OBA design is perceived as a particularly difficult barrier.

Our results suggest that Phases 2 and 3—the operational phases of implementation—are likely to be the most impacted by barriers, due to the perceived difficulty of overcoming infrastructure limitations and burdens to clinical staff. Conversely, the key enablers are spread across the various phases of implementation, suggesting that a comprehensive range of enablers are critical for implementation to progress through each stage.

Stakeholder-specific results generally aligned with the overall findings, though some differences reflect distinct priorities. Specifically, academics identified *early stakeholder engagement and buy-in* as being especially crucial for implementation. This difference between academics and the group at large could suggest that what might appear to be critical theoretically differs from practitioners' views of what is imperative for the actual operation of the IPM. Payers, conversely, scored *willing and well-trained staff* and *pre-existing frameworks, experience and leadership* higher than the rest of the group. This divergence could point to payers' heightened awareness of the operational realities of such models and their reliance on healthcare providers, especially considering that some of the payer representatives in the NG also have experience as providers.

3.2.2. Indication-Based Pricing (IBP)

3.2.2.1. Barriers

Figure 6 and **Figure 7** present key results from the NG on IBP: **Figure 6** shows the raw and normalised scores for the barriers and **Figure 7** presents the corresponding CWIIs.

Across both normalised and non-normalised scores, the barrier with the highest mean score was *infrastructure and data limitations*, followed by *legal and regulatory barriers* and *designing an optimal model*. The graphs indicate that there was a relatively strong sense of consensus around the difficulty of overcoming *infrastructure and data limitations* and more variation around *legal and regulatory barriers*.

Legal and regulatory barriers was highlighted during the NG by an industry representative, who explained that, without support from the law, it is impossible to implement IBP agreements. Post-discussion, several members of the NG increased their scores for this barrier; however, two academics still assigned it some of their lowest scores, thereby contributing to its high standard deviation relative to *infrastructure and data limitations*.

The CWIIs highlight the high variability associated with *legal and regulatory barriers*, while *designing optimal model* and *lack of stakeholder trust or buy in* had higher CWIIs. This indicates that although these two barriers received lower mean scores, there was greater consensus on their absolute value. This may suggest that, while not viewed as the most difficult barriers, there was a shared agreement that they still pose meaningful challenges to IBP implementation.

Figure 6. IBP barriers means and standard deviations

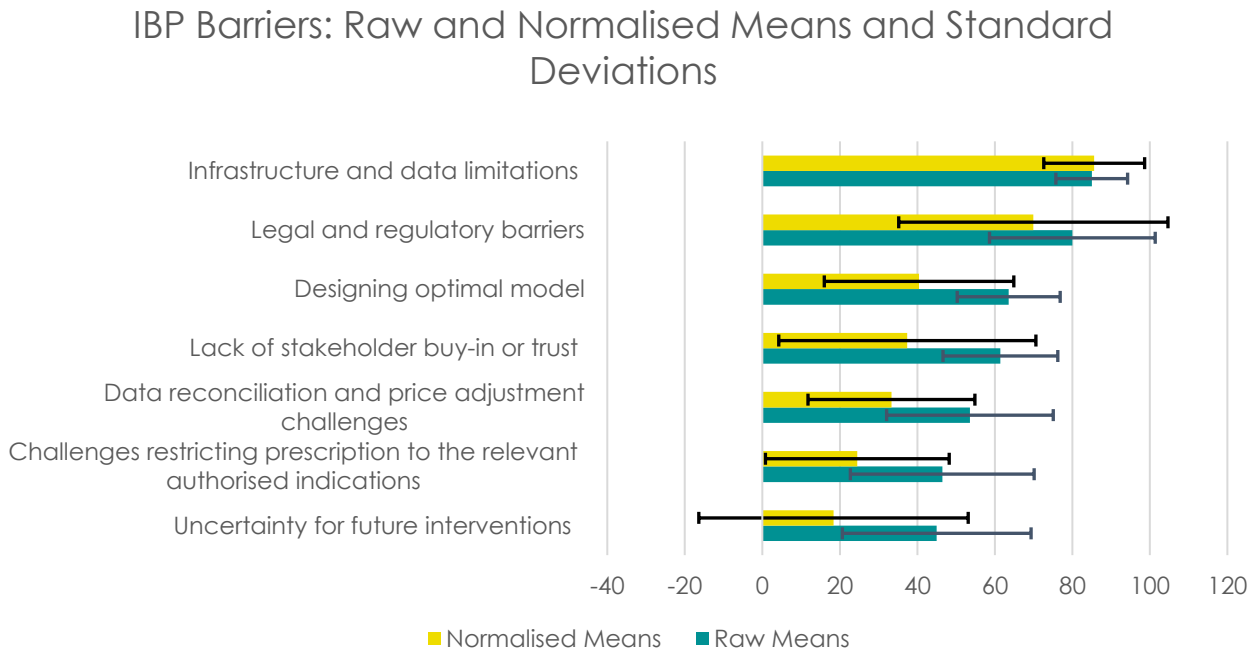
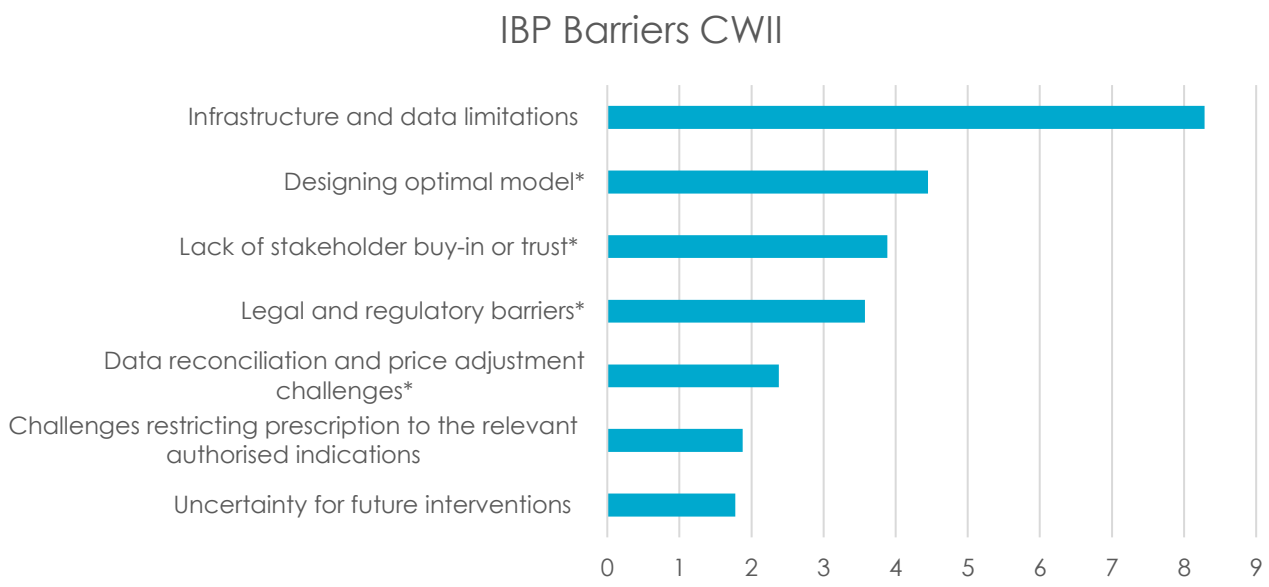


Figure 7. IBP barriers CWII



* Indicates a change in position relative to the order of means

Uncertainty for future interventions, though it scored the lowest in terms of difficulty, had the highest raw SD and second-highest normalised SD. While most participants assigned it their lowest scores, an English representative assigned it his highest score, citing NICE's concern over setting high price points for certain indications and then having to pay high prices for broader indications as a result. A Swedish academic partly agreed, noting that the only way to implement IBP in Sweden would be through confidential rebates, making the benchmark for future cost-effectiveness analyses difficult to set.

Changes from Initial Rankings to Post-Discussion Rankings

Table 16. IBP barriers: Change in scores

Barrier	Initial Mean	Final Mean	Change in Mean	Initial SD	Final SD	Change in SD
Infrastructure and data limitations	79.29	85.00	**5.71**	17.81	9.26	**-8.56**
Legal and regulatory barriers	72.86	80.00	**7.14**	21.19	21.38	**0.19**
Designing optimal model	58.57	63.57	**5.00**	24.01	13.29	**-10.72**
Lack of stakeholder buy-in or trust	65.71	61.43	**-4.29**	17.81	14.81	**-3.00**
Data reconciliation and price adjustment challenges	65.00	53.57	**-11.43**	15.81	21.50	**5.69**
Challenges restricting prescription to the relevant authorised indications	47.14	46.43	**-0.71**	19.06	23.71	**4.65**
Uncertainty for future interventions	43.57	45.00	**1.43**	24.31	24.35	**0.04**

Table 16 highlights differences between initial and post-discussion scores. Final rankings showed that SDs decreased by an average of 1.67, although this change was not statistically significant. In particular, the SDs for *designing an optimal model* and *infrastructure and data limitations* decreased by 10.73 and 8.56, respectively, suggesting that the discussion fostered stronger consensus around these barriers. *Infrastructure and data limitations* was explicitly raised by a Spanish payer in the discussion, who explained that without the proper infrastructure and clinical data, IBP becomes extremely complicated. Notably, *designing an optimal model* was not mentioned throughout the discussion, but its decrease in SD can be explained by the industry representative changing his score from 15 to 60 upon seeing the results of the group before re-ranking.

In terms of mean scores, the largest changes occurred for *data reconciliation and price adjustment challenges* (-11.43) and *legal and regulatory barriers* (+7.14). The change in score for *legal and regulatory barriers* may have been motivated by the industry representative highlighting its importance, as three participants increased their scores for this barrier after the discussion, with a Spanish payer increasing his score from 70 to 100. *Data reconciliation and price adjustment challenges* was notably not mentioned during the discussion, and the decrease in score was due to the industry representative revising his rating from 90 to 10.

Stakeholder-Specific Insights

Table 17. Top three IBP barriers for each stakeholder type

Stakeholder Type	Most Important Enabler	2nd Most Important Enabler	3rd Most Important Enabler
Academics	Infrastructure and data limitations (75)	Legal and regulatory barriers (70)	Designing optimal model (57.5)
Industry	Legal and regulatory barriers (100)	Lack of stakeholder buy-in or trust (90)	Infrastructure and data limitations (80)
Patient	Uncertainty for future interventions (90)	Legal and regulatory barriers (80)	Infrastructure and data limitations (80)
Payer	Infrastructure and data limitations (75)	Legal and regulatory barriers (70)	Designing optimal model (57.5)

Mean scores assigned by stakeholders in parentheses

Table 17 presents stakeholder-specific insights, showing the three highest-ranked barriers for each stakeholder group based on their average score assigned to each. Overall, the stakeholder-specific results were consistent with the results of the group overall. As with the other IPMs, these results must be interpreted with caution, given the small number of NG participants in each stakeholder group.

Indeed, while payers in the NG assigned high scores to *data reconciliation and price adjustment challenges*, this was not consistent with the results of the survey. Likewise, the generalizability of insights for these stakeholder groups is limited, as the patient in the NG was the only patient representative who completed the survey, and only two industry representatives completed the survey, so it is difficult to validate these NG results against those of the survey.

Phased Approach

Table 18. IBP barriers and implementation phases

Barriers	Phase 1	Phase 2	Phase 3	Phase 4
Infrastructure and data limitations		8.29	8.29	
Legal and regulatory barriers	3.57	3.57		
Designing optimal model	4.45			
Lack of stakeholder buy-in or trust	3.88			
Data reconciliation and price adjustment challenges			2.38	2.38
Challenges restricting prescription to the relevant authorised indications			1.88	
Uncertainty for future interventions			1.78	1.78

Numbers correspond to each item's CWII. Green indicates a CWII above 5, yellow indicates a CWII between 3.0 and 5.0, and red indicates a CWII below 3. Phase 1: Inception & Design, Phase 2: Adoption, Phase 3: Sustainment & Maintenance, Phase 4: Wrapping Up & Closing

Table 18 provides the CWII of each barrier, mapping each barrier to the corresponding phase of implementation that it impacts. While the highest-CWII barrier, *infrastructure and data limitations*, affects both Phase 2 and Phase 3, Phase 1 and Phase 2 are those encumbered by the barriers agreed to be the most difficult to overcome. Thus, IBPs are seemingly characterised by early-stage vulnerability, where the most cumbersome challenges are faced during initial conceptualisation and early implementation. Ultimately, this could suggest that successful IBP implementation requires intense upfront investments to overcome design and adoption barriers.

3.2.2.2. Enablers

Figure 8 presents the raw and normalised means and standard deviations of the IBP enablers, while CWIIs are shown in **Figure 9**.

Established data infrastructure and monitoring systems and *changes in the legal framework to allow IBP* were the most highly ranked enablers, with the former generating the highest consensus, as well.

These were followed by *rational design and application of IBP* and *safeguards against misuse*. When looking at raw scores, both these enablers have similar average values and standard deviations, but their normalised values highlight differences between them. *Rational design and application of IBP* had a higher

normalised mean value and lower normalised standard deviation than *safeguards against misuse*—though both had higher normalised standard deviations than their raw scores. This reflects consensus on the absolute importance of both enablers, but some variation in their relative rankings—on average, participants scored *rational design and application of IBP*—higher.

Figure 9 highlights that *change in legal framework to allow IBP* was controversial enabler. Despite having a higher raw score than both *rational design and application of IBP* and *safeguards against misuse*, it had a lower CWII, meaning this result was driven by a lack of consensus. Further analysis revealed that the high variability around this enabler was driven by a Swedish academic who assigned it a score of 50, whereas every other participant scored it 80 or higher.

Figure 8. IBP enablers means and standard deviations

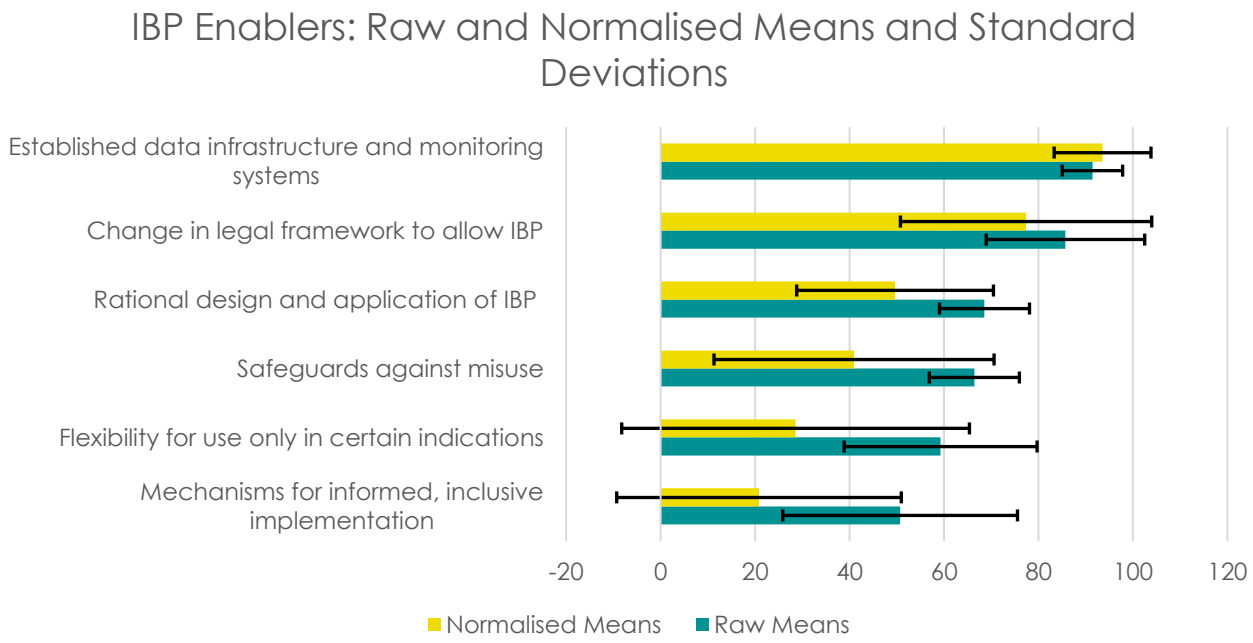
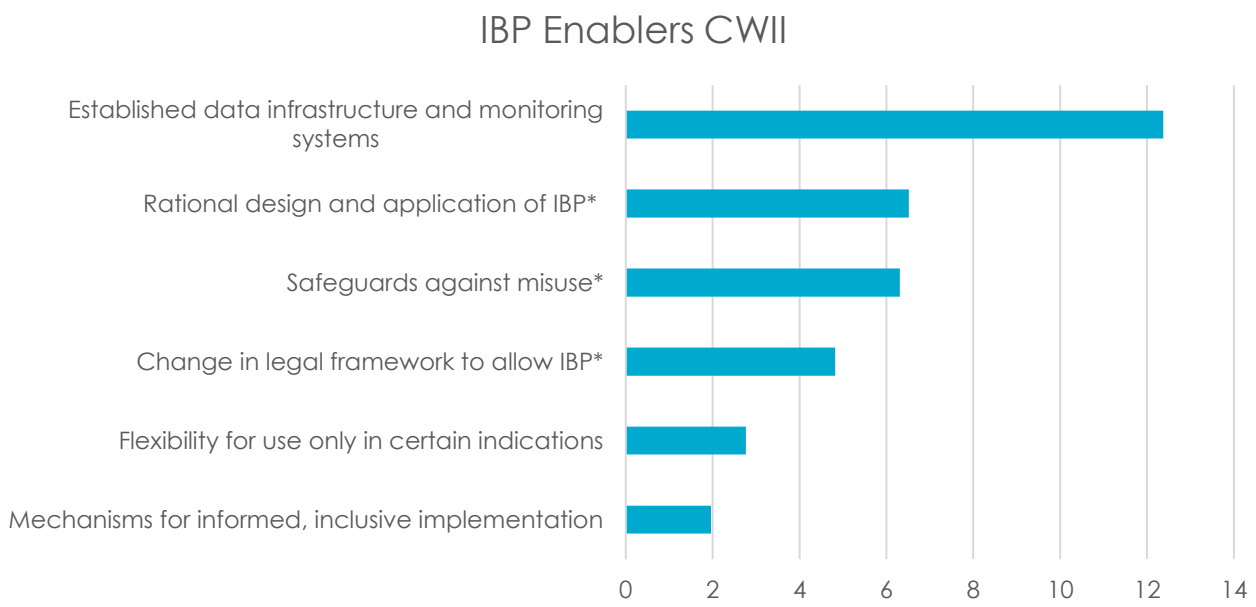


Figure 9. IBP enablers CWII



* Indicates a change in position relative to the order of means

Changes from Initial Rankings to Post-Discussion Rankings

Table 19. IBP enablers: Change in scores

Enabler	Initial Mean	Final Mean	Change in Mean	Initial SD	Final SD	Change in SD
Established data infrastructure and monitoring systems	80.71	91.43	**10.71**	14.74	6.39	**-8.35**
Change in legal framework to allow IBP	-	85.71	**-**	-	16.78	**-**
Rational design and application of IBP	60.71	68.57	**7.86**	23.67	9.53	**-14.14**
Safeguards against misuse	69.29	66.43	**-2.86**	14.74	9.53	**-5.21**
Flexibility for use only in certain indications	60.00	59.29	**-0.71**	27.26	20.43	**-6.83**
Mechanisms for informed, inclusive implementation	52.14	50.71	**-1.43**	24.76	24.85	**0.08**

Table 19 highlights how scores changed from initial scoring to post-discussion scoring. Standard deviations decreased, on average, by 6.89, though this is not a statistically significant result. The largest changes in standard deviations were observed for *rational design and application of IBP*, which had a decrease of 14.14, and *established data infrastructure and monitoring systems*, which had a decrease of 8.36. During the discussion, the industry representative highlighted that he misunderstood *rational design and application of IBP*. After clarifying it, he

changed his score from 10 to 70, driving the observed decrease in standard deviation. *Established data infrastructure and monitoring systems* was only discussed in terms of its relationship to *safeguards against misuse*, as an Italian academic suggested that safeguards against misuse become less necessary with sound infrastructure. Subsequently, three participants assigned *established data infrastructure and monitoring systems* higher scores in the post-discussion scoring.

The same enablers had the highest changes in mean score, as well. *Established data infrastructure and monitoring systems*' mean score increased by 10.71 and *rational design and application of IBP*'s score increased by 7.86.

The discussion also led to the addition of *changes in legal framework to allow IBP* as an enabler, which had not been included in the initial list. A Spanish academic pointed out that an enabler was needed to reflect the fact that some countries do not currently permit IBP, and the rest of the participants agreed with this addition. Notably, this enabler ended up being ranked the second most important for facilitating IBP implementation, thereby mirroring the results of the IBP barriers.

Stakeholder-Specific Insights

Table 20. Top three IBP enablers for each stakeholder type

Stakeholder Type	Most Important Enabler	2nd Most Important Enabler	3rd Most Important Enabler
Academics	Established data infrastructure and monitoring systems (96.67)	Change in legal framework to allow IBP (80)	Safeguards against misuse (65)
Industry	Change in legal framework to allow IBP (100)	Established data infrastructure and monitoring systems (80)	Rational design and application of IBP (70)
Patient	Established data infrastructure and monitoring systems (90)	Change in legal framework to allow IBP (80)	Rational design and application of IBP (80)
Payer	Established data infrastructure and monitoring systems (90)	Change in legal framework to allow IBP (90)	Mechanisms for informed, inclusive implementation (77.5)

Mean scores assigned by stakeholders in parentheses

Table 20 presents stakeholder-specific insights, showing the three highest-ranked enablers for each stakeholder group based on their average scores. Overall, the stakeholder-specific results were consistent with the results of the group as a whole. Where differences did exist, the differences were not consistent with the results of the pre-NG survey, which included a larger number of respondents within each stakeholder type.

Phased Approach

Table 21. IBP enablers and phases of implementation

	Phase 1	Phase 2	Phase 3	Phase 4
Established data infrastructure and monitoring systems		12.37	12.37	
Change in legal framework to allow IBP	4.82	4.82		
Rational design and application of IBP	6.51			
Safeguards against misuse				6.31
Flexibility for use only in certain indications			2.77	
Mechanisms for informed, inclusive implementation	1.96			

Numbers correspond to each item's CWII. Green indicates a CWII above 5, yellow indicates a CWII between 3.0 and 5.0, and red indicates a CWII below 3. Phase 1: Inception & Design, Phase 2: Adoption, Phase 3: Sustainment & Maintenance, Phase 4: Wrapping Up & Closing

Table 21 highlights the CWII for each IBP enabler and maps each one to the implementation phases it facilitates. Similar to the OBA enablers, IBP includes high-CWII enablers across all implementation phases, indicating a relatively even distribution of enablers considered highly important for IBP implementation. However, the significantly higher CWII for *established data infrastructure and monitoring systems* suggests that the absence of this enabler could severely hinder IPM implementation in Phases 2 and 3.

3.2.2.3. Summary of IBP Insights

Our results show that the most difficult barriers to overcome for IBP implementation were considered to be *infrastructure and data limitations*, *legal and regulatory barriers*, and *designing an optimal model*. The enablers identified by stakeholders as being the most critical for implementation were *established data infrastructure and monitoring systems*, *change in legal framework to allow IBP*, and *rational design and application of IBP*. For both the enablers and barriers, there was alignment among stakeholders on their difficulty and importance.

The top three barriers and top three enablers are direct mirrors of one another, which further highlights the impacts they may have on IBP implementation. Thus, targeted investment in these elements—which are seemingly foundational to IBP success—could provide sufficient momentum for implementation by addressing the most significant barriers and establishing the key enablers.

The phased approach revealed that Phases 1 and 2 are the most encumbered by the barriers that were agreed to be difficult to overcome, suggesting the largest challenges for IBP are faced during the initial design and implementation of the payment model. Enablers identified as being particularly important affect all four phases of IBP implementation. However, while these enablers may affect various stages, they are generally operationalized in the early phases of implementation.

For instance, data infrastructure, though it affects Phases 2 and 3, is designed in Phase 1 and implemented in Phase 2. Taken together, these insights imply that initial investments in the early phases of implementation could be the catalyst for IBP success.

3.2.3. Instalments and Amortisation Payments (IaAPs)

3.2.3.1. Barriers

Figure 10 presents the raw and normalised results for the NG on IaAPs; **Figure 11** presents their respective CWIIs. The three most highly ranked barriers were *legal and regulatory hurdles*, *complex financial management*, and *negotiating an acceptable model*. In contrast to the IPMs discussed in the first NG, we observed large SDs—particularly in terms of their normalised values—for the three most highly ranked barriers. Given that their raw SDs were relatively smaller, this suggests that participants rated these three barriers generally high but fluctuated in terms of how they ranked them with respect to the other barriers, indicating differing perceptions of the most difficult barrier but general agreement on all three of the barriers being of high difficulty.

Figure 11 highlights that, while *legal and regulatory hurdles* had a higher mean score, *complex financial management* had the highest CWII, indicating a stronger sense of consensus around the difficulty of this barrier with respect to IaAP implementation. However, none of the barriers had a CWII above 6—even among the highest scoring barriers—reflecting low levels of consensus.

Figure 10. IaAPs barriers means and standard deviations

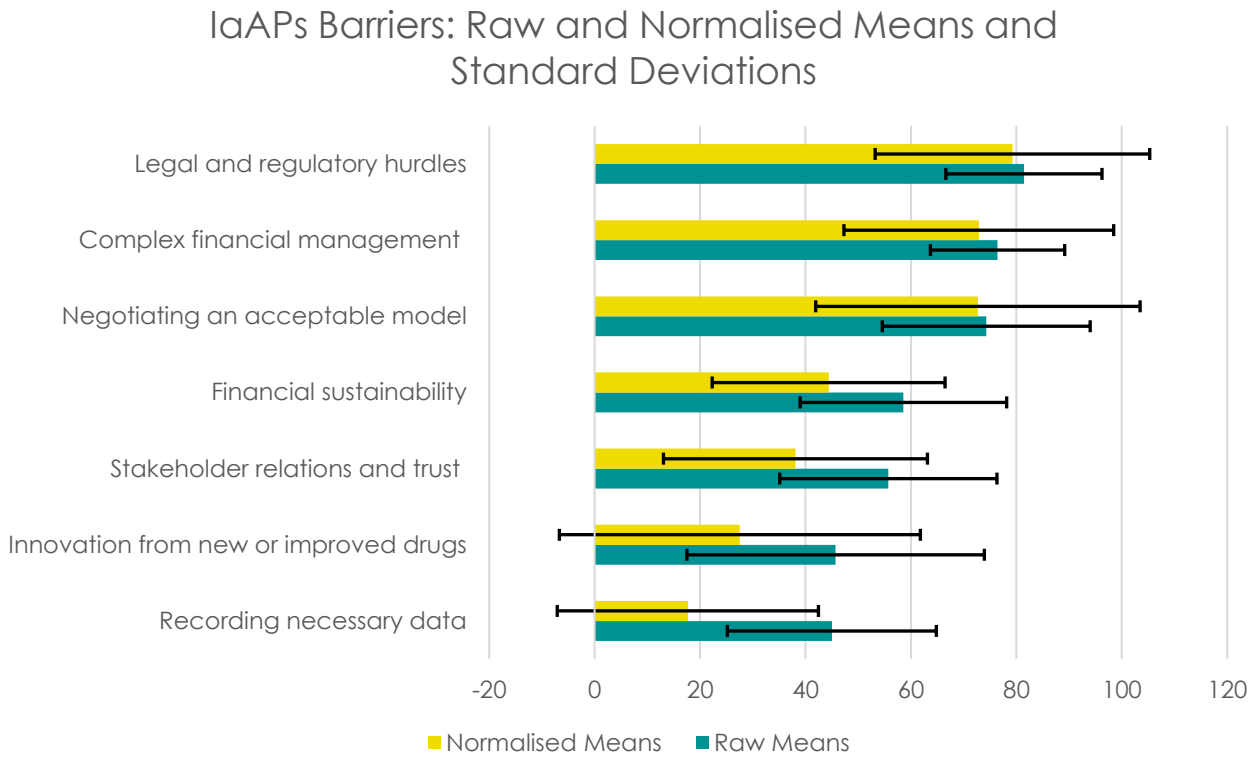
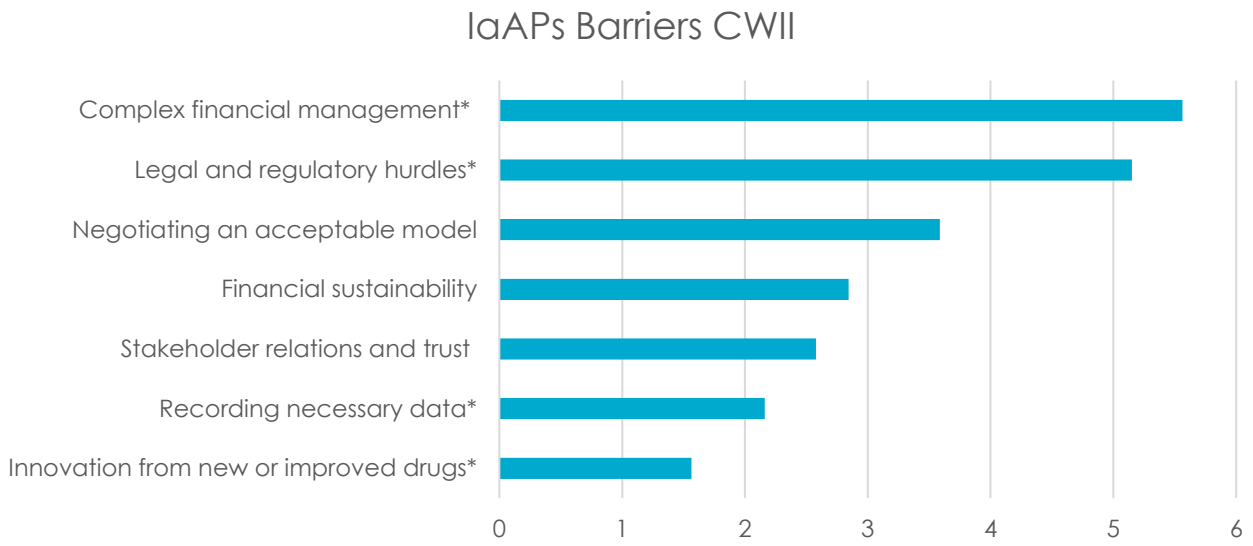


Figure 11. IaAPs barriers CWII



* Indicates a change in position relative to the order of means

Changes from Initial Rankings to Post-Discussion Rankings

Table 22. IaAPs barriers: Change in scores

Barriers	Initial Mean	Final Mean	Change in Mean	Initial SD	Final SD	Change in SD
Complex financial management	79.29	76.43	**-2.86**	15.22	12.74	**-2.48**
Legal and regulatory hurdles	79.29	81.43	**2.14**	14.25	14.81	**0.56**
Negotiating an acceptable model	76.43	74.29	**-2.14**	21.17	19.72	**-1.45**
Financial sustainability	60.00	58.57	**-1.43**	20.70	19.59	**-1.11**
Stakeholder relations and trust	55.71	55.71	**0.00**	20.60	20.60	**0.00**
Recording necessary data	46.43	45.00	**-1.43**	19.77	19.82	**0.05**
Innovation from new or improved drugs	45.71	45.71	**0.00**	28.21	28.21	**0.00**

Table 22 highlights differences in pre-discussions scores and final scores. The participants' re-ranking led to an average decrease in SD of 0.63. This modest change is not statistically significant and is consistent with the fact that the participants said they generally agreed with the rankings of the barriers and did not choose to discuss any in detail. The largest movers in terms of SD were *complex financial management*, where SD decreased by 2.48 and *negotiating an acceptable model*, where SD decreased by 1.45. Likewise, these barriers—along with *legal and regulatory hurdles*—also observed the largest changes in terms of mean scores with complex financial management decreasing by 2.86, *negotiating an acceptable model* decreasing by 2.14, and *legal and regulatory hurdles* increasing by 2.14. None of them were discussed by the participants, and, therefore, any changes in scores reflect individual participants adjusting their responses after observing the group's aggregate results.

Stakeholder-Specific Insights

Table 23. Top three IaAPs barriers for each stakeholder type

Stakeholder Type	Most Difficult Barrier	2nd Most Difficult Barrier	3rd Most Difficult Barrier
Academics	Legal and regulatory hurdles (88.33)	Complex financial management (71.67)	Negotiating an acceptable model (58.33)
Industry	Legal and regulatory hurdles (90)	Complex financial management (80)	Negotiating an acceptable model (80)
Patient	Innovation from new or improved drugs (100)	Legal and regulatory hurdles (80)	Negotiating an acceptable model (80)
Payer	Negotiating an acceptable model (92.5)	Complex financial management (85)	Financial sustainability (70)

Mean scores assigned by stakeholders in parentheses

Table 23 presents stakeholder-specific insights, showing the three highest-ranked barriers for each stakeholder group based on the average score for each. Overall, the stakeholder-specific results aligned closely with the group's aggregate rankings.

One notable exception was the high score assigned to *financial sustainability* by the payers. This aligned with the results of the pre-NG survey, in which payers also identified *financial sustainability* as one of the most challenging barriers to overcome in IaAP implementation. Given payers' roles in managing healthcare budgets, this concern is understandable, as there may be apprehension that IaAPs could be used to 'obscure' unduly high medicine prices, raising long-term affordability concerns.

Phased Approach

Table 24. IaAPs barriers and implementation phases

	Phase 1	Phase 2	Phase 3	Phase 4
Legal and regulatory hurdles	5.15	5.15		
Complex financial management			5.56	5.56
Negotiating an acceptable model	3.59			
Financial sustainability	2.84			
Stakeholder relations and trust	2.58			
Innovation from new or improved drugs			1.56	
Recording necessary data			2.16	

Numbers correspond to each item's consensus-weighted importance index (CWII). Green indicates a CWII above 5, yellow indicates a CWII between 3.0 and 5.0, and red indicates a CWII below 3. Phase 1: Inception & Design, Phase 2: Adoption, Phase 3: Sustainment & Maintenance, Phase 4: Wrapping Up & Closing

Table 24 shows the CWII for each IaAP barrier, along with the phase that each barrier impacts. The two highest-CWII barriers affect all four phases of implementation, and Phases 1 and 3 are affected by the most barriers. This highlights the vulnerability of IaAPs across their entire implementation timeline, as even after successful adoption, they can face ongoing pressures that can threaten their continuity or their effective and efficient application.

3.2.3.2. Enablers

Figure 12 presents the results of the NG on IaAPs, displaying both normalised and raw scores; **Figure 13** presents their CWIIs.

In raw scores, the enablers with the highest scored importance were *agreed conditions of termination of the agreement if the technology fails during the amortization period*, *existing infrastructure*, and *pre-existing experience or frameworks to guide implementation*. Interestingly, the strongest consensus was generated around *existing infrastructure*—though its normalised SD was higher—suggesting that participants agreed on its absolute importance but disagreed on how they scored it relative to the other enablers. The other enablers—even those that scored in the top three—were characterised by a certain degree of controversiality, suggesting that there was high variability between stakeholders' views on the enabling elements for IaAP implementation.

Figure 12. IaAPs enablers means and standard deviations

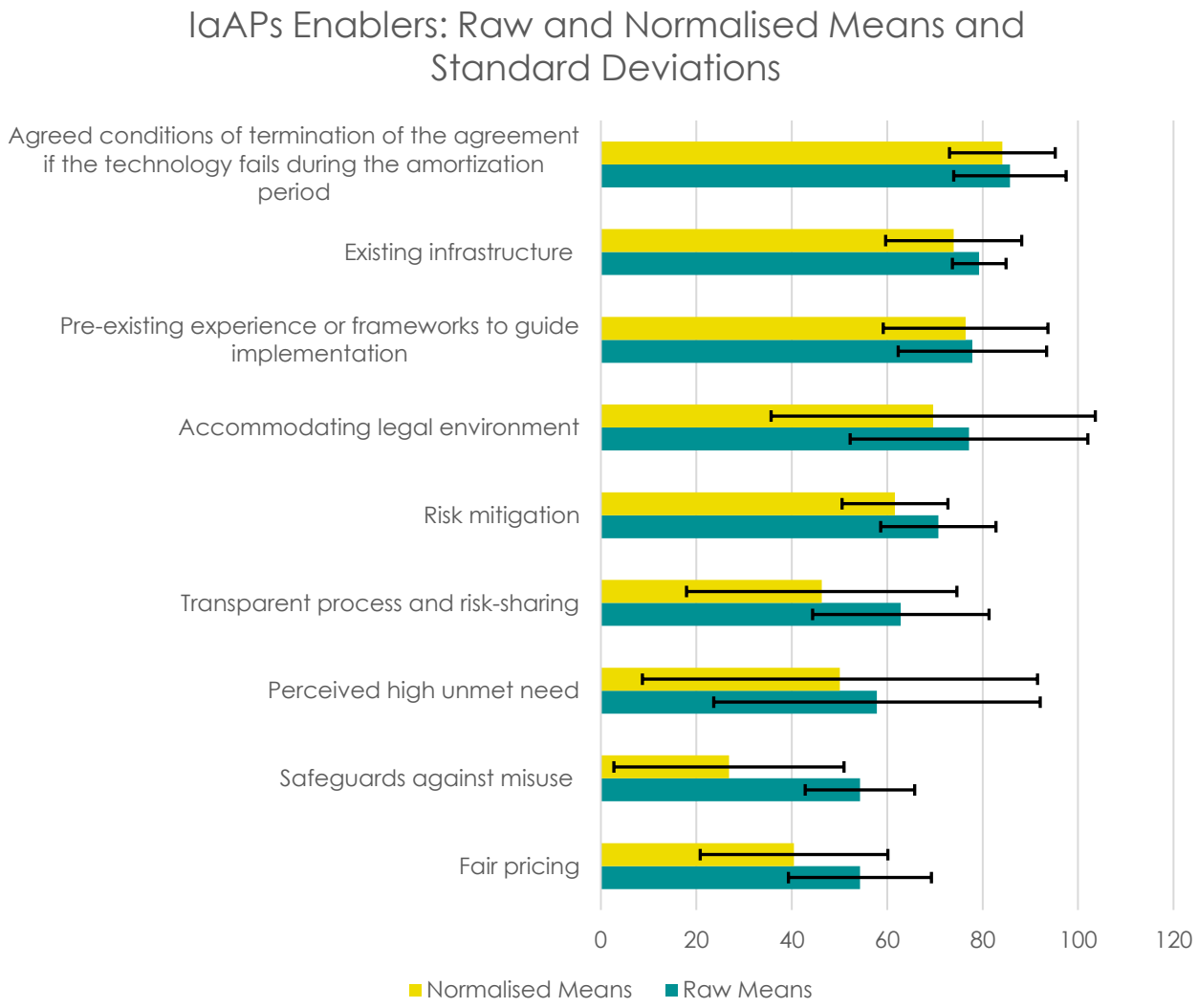
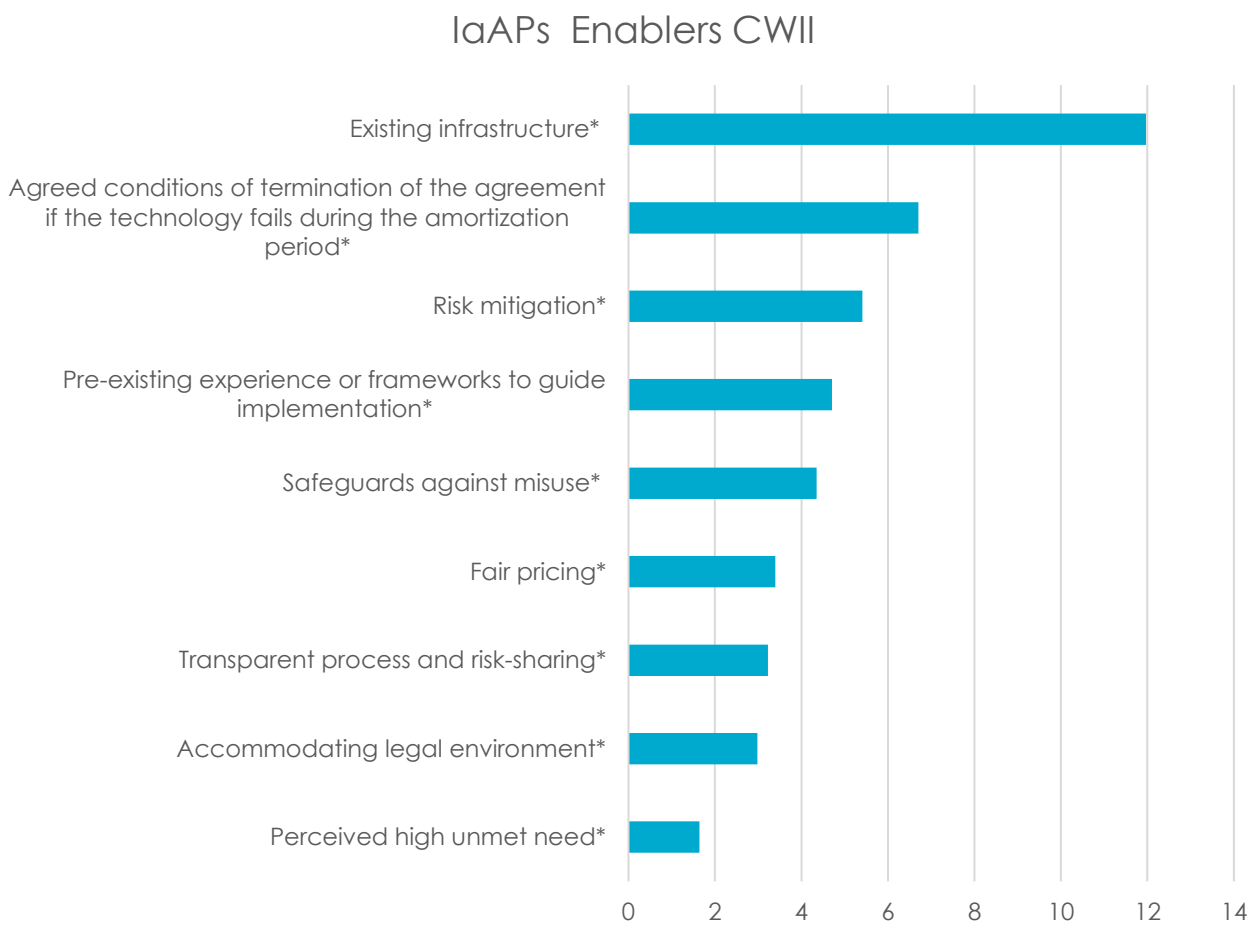


Figure 13. IaAPs enablers CWII



* Indicates a change in position relative to the order of means

Changes from Initial Rankings to Post-Discussion Rankings

Table 25. IaAPs enablers: Change in scores

Enabler	Initial Score	Final Score	Change in Score	Initial SD	Final SD	Change in SD
Existing infrastructure	77.86	79.29	**1.43**	3.64	5.62	**1.98**
Pre-existing experience or frameworks to guide implementation	64.29	77.86	**13.57**	26.11	15.55	**-10.56**
Safeguards against misuse	57.14	54.29	**-2.86**	12.49	11.47	**-1.02**
Risk mitigation	72.14	70.71	**-1.43**	12.49	12.08	**-0.42**
Perceived high unmet need	47.86	57.86	**10.00**	36.44	34.21	**-2.22**
Fair pricing	-	54.29	**-**	-	14.98	**-**
Transparent process and risk-sharing	-	62.86	**-**	-	18.49	**-**
Transparency and fair pricing	49.29	-	**-**	24.56	-	**-**

Agreed conditions of termination of the agreement if the technology fails during the amortization period	88.57	85.71	**-2.86**	9.90	11.78	**1.88**
Accommodating legal environment	87.14	77.14	**-10.00**	11.61	24.91	**13.30**

Table 25 shows how the discussion changed scores. From initial rankings to final rankings, SDs increased on average by 0.42. The largest changes in SD were for *accommodating legal environment*, where SD increased by 13.30, and *pre-existing experience or frameworks to guide implementation*, where SD decreased by 10.56. These were also the enablers with the largest changes in mean scores. *Pre-existing experience or frameworks* to guide implementation's mean score increased by 13.57, moving it from the fifth-highest enabler to the third highest. *Accommodating legal environment's* mean score decreased by 10, moving it from the top-scored enabler to the fourth highest.

Interestingly, participants only expressed agreement with the high initial ranking of *accommodating legal environments*. An Italian academic highlighted that a legal environment conducive to IaAPs is critical, noting that in its absence, such agreements can face significant accounting challenges—or even be entirely disallowed. The change in mean score and SDs for *accommodating legal environment* can be completely accounted for by the industry representative changing his score from 100 to 20 post-discussion, as every other participant either scored it higher after the discussion or maintained their scores.

Pre-existing experience was also highlighted during the discussion. A Spanish payer expressed surprise with its initial score, saying that from her perspective, the first implementation of an IaAP is "a pain," but the second one is easier with the initial experience behind stakeholders. She noted that even knowledge sharing can serve as an enabler in this context. Following this, two participants—including the Spanish payer—slightly increased their scores for this enabler, while the industry representative raised his score from 10 to 90, significantly impacting mean and SD between ranking rounds.

Perceived high unmet need also experienced an increase of 10 in terms of mean score after the discussion. This enabler, however, was not highlighted during the discussion, and the driver of this change was the industry representative increasing his score from 10 to 80.

The discussion also led to *transparency and fair pricing* being split into two separate enablers: *fair pricing* and *transparent processes and risk-sharing*. Both individual enablers scored higher than their combined initial enabler, potentially reflecting misunderstanding of the initial combined enabler.

Stakeholder-Specific Insights

Table 26. Top three IaAPs enablers for each stakeholder type

Stakeholder Type	Most Important Enabler	2nd Most Important Enabler	3rd Most Important Enabler
Academics	Accommodating legal environment (93.33)	Agreed conditions of termination of the agreement if the technology fails during the amortization period (90)	Existing infrastructure (75)
Industry	Existing infrastructure (90)	Pre-existing experience or frameworks to guide implementation (90)	Perceived high unmet need (90)
Patient	Perceived high unmet need (90)	Existing infrastructure (80)	Pre-existing experience or frameworks to guide implementation (80)
Payer	Pre-existing experience or frameworks to guide implementation (92.5)	Agreed conditions of termination of the agreement if the technology fails during the amortization period (90)	Perceived high unmet need (82.5)

Mean scores assigned by stakeholders in parentheses

Table 26 displays the top three enablers identified by each stakeholder group, based on their average scores during the NG. In general, the stakeholder-specific priorities were similar to the overall group rankings, as at least two of the top three overall barriers were reflected in each of the stakeholder group's top three. Where discrepancies did appear between stakeholder-specific and overall results, they were not reflected in the pre-NG survey findings—which included broader participation across stakeholder types—suggesting that these differences may be attributable to the small number of NG participants rather than true divergences in perspective.

Phased Approach

Table 27. IaAPs enablers and implementation phases

	Phase 1	Phase 2	Phase 3	Phase 4
Agreed conditions of termination of the agreement if the technology fails during the amortization period				6.71
Existing infrastructure		11.97	11.97	
Pre-existing experience or frameworks to guide implementation	4.70			
Accommodating legal environment	2.98	2.98		
Risk mitigation	5.41			
Transparent process and risk-sharing	3.23			
Perceived high unmet need	1.64			
Fair pricing	3.40			
Safeguards against misuse				4.35

Numbers correspond to each item's CWII. Green indicates a CWII above 5, yellow indicates a CWII between 3.0 and 5.0, and red indicates a CWII below 3. Phase 1: Inception & Design, Phase 2: Adoption, Phase 3: Sustainment & Maintenance, Phase 4: Wrapping Up & Closing

Table 27 indicates the CWII for each IaAP enabler and which phase of implementation each enabler affects. Phases 2 and 3 are impacted by the enabler with the greatest consensus of importance, indicating a shared acknowledgement that existing infrastructure is critical to the success of IaAPs. However, Phase 1 is the stage most affected by enablers overall. This largely reflects the role that incentives play in enabling—and encouraging—the use of IPMs such as IaAPs. Enablers like *risk mitigation* and *perceived high unmet need* can compel stakeholders to employ IaAPs to address these challenges.

3.2.3.3. Summary of IaAP Insights

Overall, the barriers identified by stakeholders as being the most difficult to overcome were *legal and regulatory hurdles*, *complex financial management*, and *negotiating an acceptable model*. The highest-scored enablers were *agreed conditions of termination of the agreement if the technology fails during the amortisation period*, and *pre-existing experience or frameworks to guide implementation*.

Legal and regulatory hurdles being considered the most difficult barrier to overcome was likely born out of the fact that some European countries, such as Sweden and the UK, have legal restrictions that limit the use of instalments or amortization payments, making this IPM highly difficult to implement.

The second most difficult barrier—*complex financial management*—and most critical enabler—*agreed conditions of termination if the technology fails during the amortisation period*—reflect the distinct financial risks that IaAPs bring about due to their payment timelines. In particular, they point to difficulties aligning payment

schedules with fiscal years and managing late payments, as well as stakeholders perceived importance of having clear exit strategies to avoid being trapped in lengthy payment commitments for technologies that may fail or become obsolete during the period of cover. Together, these points could suggest that IaAPs may require more sophisticated financial governance and risk mitigation strategies.

There was no evidence of stakeholder groups holding divergent views from the rest of the group, except in the case of payers, who assigned higher scores to financial sustainability, indicating that this group views financial sustainability as a critical enabler for IaAPs. This difference is understandable, given payers' role in ensuring value for money in healthcare systems. They might be more inclined to view IaAPs as mechanism to obscure high-cost treatments behind prolonged payment timelines and, thus, place higher value on one an agreement that appears financially viable.

The phased analysis highlighted that the highest-CWII barriers affect all four phases of implementation, with Phases 1 and 3 being the most impacted, while Phase 1 is the stage most affected by enablers overall. This ultimately underscores how incentives might play a key role in IaAP implementation, along with early facilitating factors, like legal environments. Even so, the impact of barriers on IaAPs indicates that stakeholders continue to face significant challenges even after moving beyond Phase 1 of implementation.

3.2.4. Financial-Based Risk-Sharing Agreements (FBRSAs)

3.2.4.1. Barriers

Figure 14 presents the results of the NG on FBRSAs, showing both raw and normalised means, and standard deviations; **Figure 15** presents the CWIIs.

The three highest-ranked barriers were *negotiating an acceptable FBRSA design*, *infrastructure and data limitation*, and *financial sustainability and planning*. This order was preserved for the normalised scores. The strongest consensus was generated around *negotiating an acceptable FBRSA design*, which had the lowest raw SD, indicating a shared perception of its difficulty relative to the other barriers under consideration.

Notably, every barrier had a CWII below 5, suggesting that there was either high variability among the barriers' scores or relatively lower scores overall. Interestingly,

for the top two barriers, their normalised means were higher than their raw means, suggesting that in this NG, participants may have scored the barriers lower overall.

Figure 14. FBRSA barriers means and standard deviations

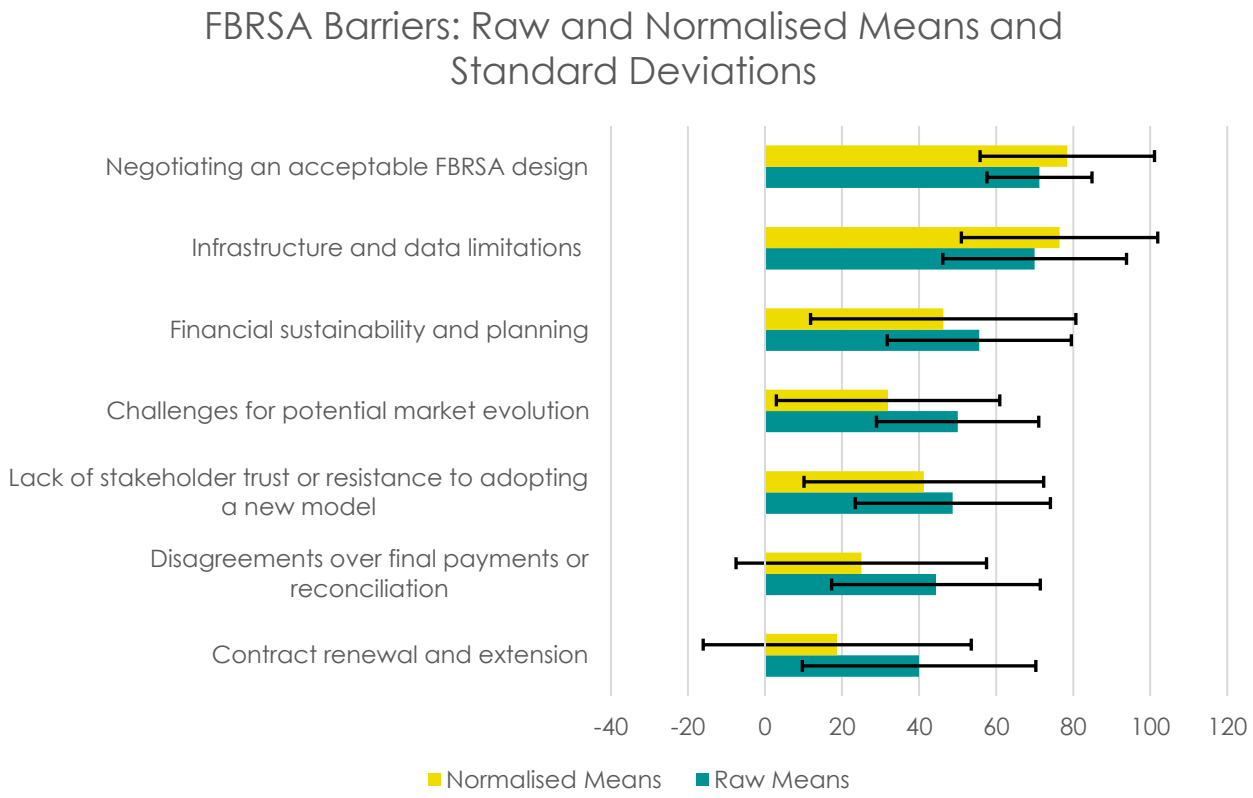
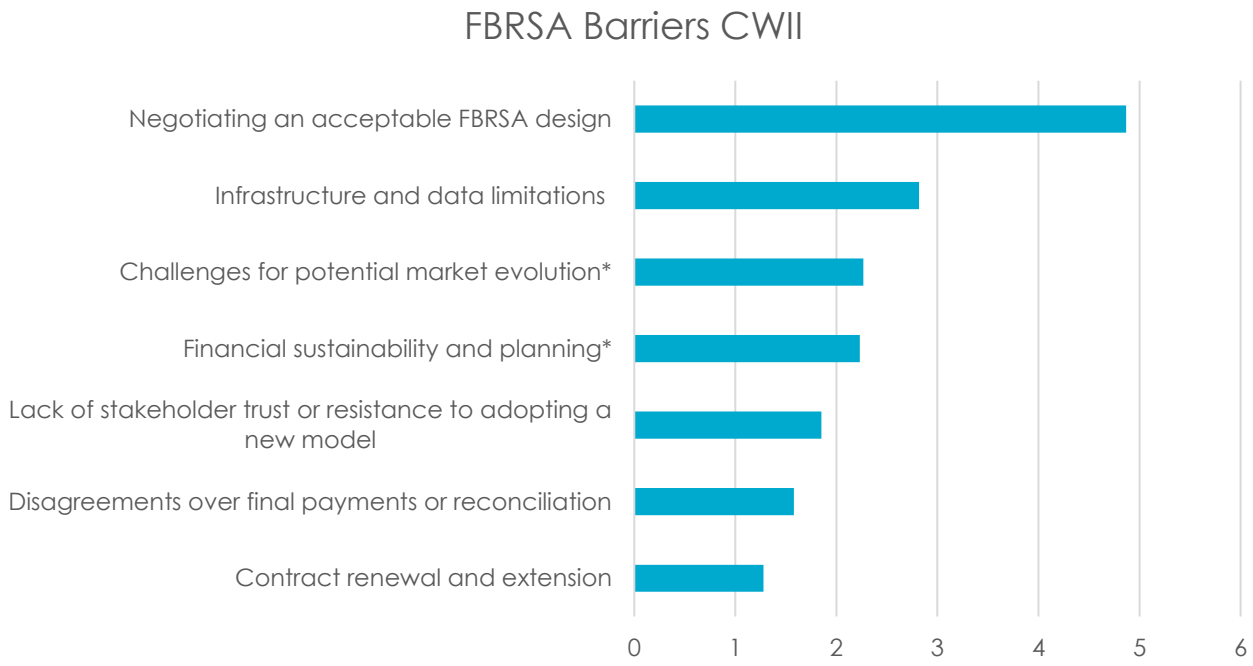


Figure 15. FBRSA barriers CWII



* Indicates a change in position relative to the order of means

During discussion, participants generally agreed with the overall ranking and scores, opting not to re-rank the barriers. Points of discussion were largely centred around the importance of infrastructure and a well-designed FBRSA. Indeed, a payer, drawing on his experience in England, highlighted that if a country does not have the infrastructure to track medicine use within different indications, then it is almost impossible to implement a risk-sharing scheme. Two academics—one based in Portugal, and one based in Spain—emphasized that the most critical barriers are *negotiating an acceptable FBRSA design* and *infrastructure and data limitations*, as if the design is right, they argued, the infrastructure would fall into place.

Stakeholder-Specific Insights

Table 28. Top three FBRSA barriers for each stakeholder type

Stakeholder Type	Most Difficult Barrier	2nd Most Difficult Barrier	3rd Most Difficult Barrier
Academics	Negotiating an acceptable FBRSA design (80)	Infrastructure and data limitations (71.25)	Lack of stakeholder trust or resistance to adopting a new model (57.5)
Industry	Disagreements over final payments or reconciliation (100)	Contract renewal and extension (100)	Challenges for potential market evolution (75)
Patient	Financial sustainability and planning (90)	Infrastructure and data limitations (90)	Lack of stakeholder trust or resistance to adopting a new model (80)
Payer	Infrastructure and data limitations (80)	Negotiating an acceptable FBRSA design (65)	Financial sustainability and planning (62.5)

Mean scores assigned by stakeholders in parentheses

Table 28 presents the top three barriers indicated by each stakeholder group as being the most difficult to overcome in the NG. Apart from the industry representative, the stakeholder groups' rankings broadly reflected that of the overall group, with at least two of their top three barriers mirroring the top three barriers of the group. Where differences did exist between the stakeholder groups' and the overall group's rankings, these were not supported by the pre-NG survey results. This suggests that the divergences were likely due to the small number of participants in the NG, rather than reflective of broader themes across stakeholder types.

Phased Approach

Table 29. FBRSA barriers and implementation phases

	Phase 1	Phase 2	Phase 3	Phase 4
Negotiating an acceptable FBRSA design	4.87			
Infrastructure and data limitations		2.82	2.82	
Financial sustainability and planning			2.23	
Challenges for potential market evolution			2.27	
Lack of stakeholder trust or resistance to adopting a new model	1.85			
Disagreements over final payments or reconciliation				1.58
Contract renewal and extension				1.28

Numbers correspond to each item's CWII. Green indicates a CWII above 5, yellow indicates a CWII between 3.0 and 5.0, and red indicates a CWII below 3. Phase 1: Inception & Design, Phase 2: Adoption, Phase 3: Sustainment & Maintenance, Phase 4: Wrapping Up & Closing

Table 29 highlights the CWII of each of the barriers considered for FBRSAs, mapping each barrier to the phases of implementation that it impacts. While Phases 1 and 3 are the most impacted by the barriers under consideration, there were no barriers with both strong consensus and a high difficulty score. The barrier with the highest CWII was *negotiating an acceptable FBRSA design*, which occurs in Phase 1, highlighting the importance of upfront investments.

3.2.4.2. Enablers

Figure 16 presents the results of the NG on FBRSA enablers, showing both the normalised and raw mean scores and standard deviations. **Figure 17** presents the CWIIs of these enablers.

The three enablers identified by participants as the most important were *sufficient infrastructure and funding*, *simplicity/ease of implementation*, and *capacity to reduce financial uncertainty*.

Like the other payment models, the strongest consensus was generated around the top enabler, and this result was consistent with the normalised scores. While *capacity to reduce uncertainty* had slightly lower raw and normalised mean scores than *simplicity/ease of implementation*, it had a significantly lower SD across both score types, driving a higher CWII. This difference was attributable to an industry representative assigning a low score of 25 to *simplicity/ease of implementation*, while every other participant scored it above 70. Thus, most participants agreed that this was a critical incentive for employing FBRSAs.

Fair prices was the enabler with the highest normalised and raw standard deviations; the discussion was consistent with this finding, as participants expressed diverging views on its criticality. Indeed, an English payer explained that he assigned *fair prices* a score of zero because he viewed a medicine having a fair price as irrelevant—it is cost-effectiveness that matters. A Portuguese academic raised that he likewise scored *fair prices* low because, he argued, to get to IPM implementation, both parties must accept the price in negotiation, which makes it fair in definition. However, an industry representative explained that he disagreed and scored it extremely high.

Figure 16. FBRSA enablers means and standard deviations

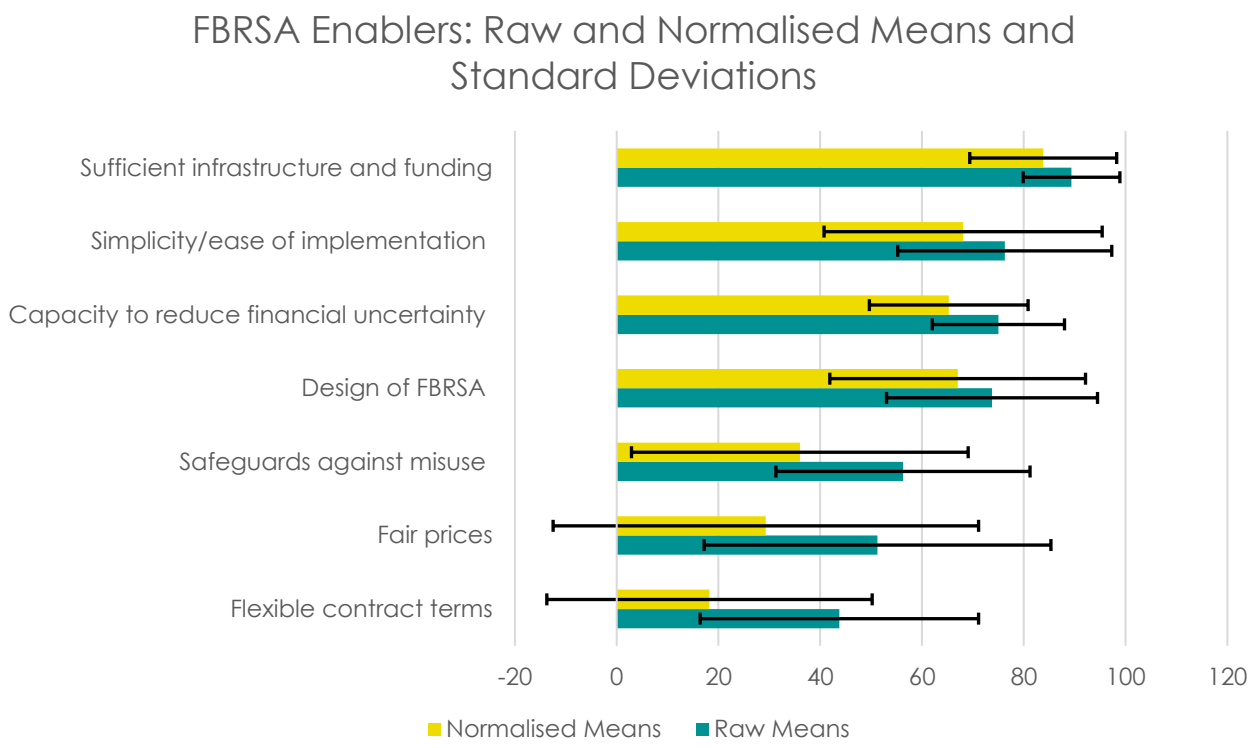
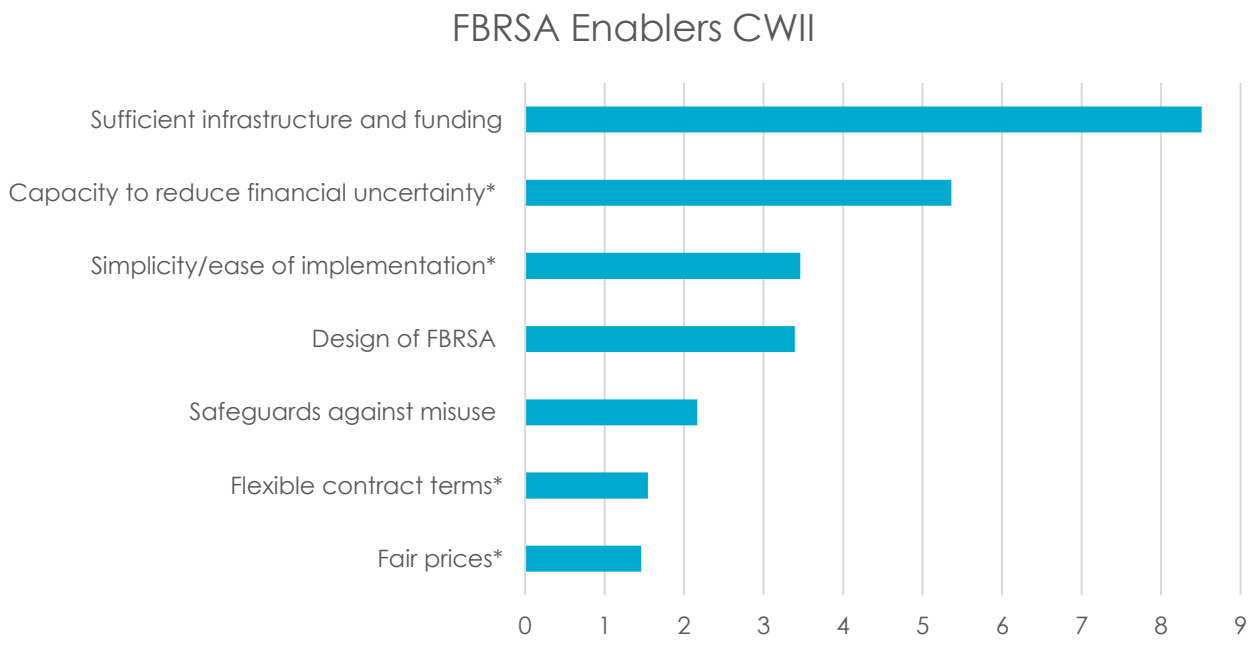


Figure 17. FBRSA enablers CWII



* Indicates a change in position relative to the order of means

A Swedish payer also used the discussion to make a high-level observation that the enablers seemed to be sorted into 'Hows' and 'Whys', where 'hows' refer to how to implement the IPM and the 'whys' refer to reasons for considering FBRSAs or

incentives to use FBRSAs. He noted that, generally, the enablers that can be grouped into the 'hows' were considered more important than the 'whys,' suggesting that once a country has the capacity to implement tools like FBRSAs, then they can understand what they can achieve with these tools. Despite areas of divergence during the discussion, participants generally agreed with the group's overall rankings and scores, choosing not to change their own scores or re-rank the enablers.

Stakeholder-Specific Insights

Table 30. Top three FBRSA enablers for each stakeholder type

Stakeholder Type	Most Important Enabler	2nd Most Important Enabler	3rd Most Important Enabler
Academics	Simplicity/ease of implementation (88.75)	Sufficient infrastructure (87.5)	Design of FBRSA (87.5)
Industry	Fair prices (100)	Sufficient infrastructure (90)	Capacity to reduce financial uncertainty (90)
Patient	Fair prices (100)	Sufficient infrastructure (90)	Capacity to reduce financial uncertainty (90)
Payer	Sufficient infrastructure (100)	Simplicity/ease of implementation (80)	Capacity to reduce financial uncertainty (65)

Mean scores assigned by stakeholders in parentheses

Table 30 presents the three most important enablers within each stakeholder group. The stakeholder groups' rankings broadly aligned with the rankings of the overall group, with at least two of their top three enablers mirroring the top three enablers of the group. Where differences existed between the stakeholder groups and the overall group's rankings, these were not supported by the pre-NG survey results. Indeed, the results of the survey aligned almost exactly with the group's aggregate rankings in the NG.

Phased Approach

Table 31. FBRSA enablers and implementation phases

	Phase 1	Phase 2	Phase 3	Phase 4
Sufficient infrastructure and funding		8.51	8.51	
Simplicity/ease of implementation	3.46	3.46		
Capacity to reduce financial uncertainty	5.36			
Design of FBRSA	3.39			
Safeguards against misuse				2.17
Fair prices	1.46			
Flexible contract terms			1.54	1.54

Numbers correspond to each item's CWII. Green indicates a CWII above 5, yellow indicates a CWII between 3.0 and 5.0, and red indicates a CWII below 3. Phase 1: Inception & Design, Phase 2: Adoption, Phase 3: Sustainment & Maintenance, Phase 4: Wrapping Up & Closing

Table 31 presents the enablers and their respective CWII scores, along with the phases of implementation they facilitate. The phases most impacted by enablers are Phases 1 and 2. This ultimately reflects the importance of incentives in enabling the decision to use FBRSAs. Enablers such as *simplicity/ease of implementation* and *capacity to reduce uncertainty* can be thought of as reasons to use FBRSAs. Results of **Table 31** also highlight the criticality of early operational enablers, like the *design of FBRSAs* and *sufficient infrastructure and funding*.

3.2.4.3. Summary of FBRSA Insights

Overall, the barriers considered by stakeholders to be the most difficult were *negotiating an acceptable FBRSA design*, *infrastructure and data limitations*, and *financial sustainability and planning*. The enablers deemed to be the most important were *sufficient infrastructure and funding*, *simplicity/ease of implementation*, and *capacity to reduce financial uncertainty*.

The most difficult barriers for FBRSAs were all considered for other IPMs, and none of FBRSAs' barriers had a CWII above 5, suggesting that these barriers may have been perceived as more controversial, or that in the case of FBRSA, there was less consensus among stakeholders about which challenges are most critical for implementation. However, infrastructure emerging as the most important enabler—with a high CWII—and as one of the most difficult barriers suggests that participants perceived its presence, or lack thereof, as either a catalyst or bottleneck for FBRSA implementation. *Simplicity/ease of implementation* and *capacity to reduce financial uncertainty*'s high scores are notably incentives to motivate use of FBRSAs. As such, this result could suggest that FBRSAs might be positioned as an appealing alternative to more complex payment models.

The phased analysis highlighted that, while none of the barriers had high CWIIs, Phases 1 and 3 are those most likely to be impacted by barriers. This is due to the difficulty of navigating the negotiation of the FBRSA design, and due to several barriers impacting Phase 3—such as challenges surrounding insufficient infrastructure, potential market evolution, and financial planning. This could suggest that, during implementation, investments should strategically be focused on the initial design process and the critical transition to operational readiness. For enablers, Phases 1 and 2 are those most affected, reflecting the importance of incentives in enabling the use of FBRSAs, along with early operational enablers that serve to address some of the key barriers identified as being challenging to navigate.

3.2.5. Portfolio or Bundling Agreements (PoBAs)

3.2.5.1. Barriers

Figure 18 presents the results of the NG on PoBA barriers, displaying the raw and normalised means and standard deviations; **Figure 19** provides the CWIIs.

The three most highly ranked barriers were *negotiating an acceptable PoBA*, *infrastructure and data limitations*, and *challenges with stakeholder relations and buy-ins*. The strongest consensus was formed around *negotiating an acceptable PoBA* in terms of both raw and normalised scores, suggesting agreement on its absolute and relative importance.

Interestingly, *impact on future HTA*, despite not having one of the highest mean scores, had the second-highest CWII, reflecting a stronger consensus around its absolute difficulty. This suggests that participants do not view *impact on future HTA* as a determining barrier to PoBA implementation, but they do agree that it is somewhat difficult to overcome, with a mean score of around 60.

The rankings of the PoBA barriers closely mirror the rankings of the FBRSA barriers, except for stakeholder relations, which was not in the top three for FBRSA. The other two, *negotiating an acceptable design* and *infrastructure challenges* were also ranked highly for FBRSAs. A Spanish academic highlighted this difference, suggesting that stakeholder relationships are less crucial for FRBSAs because they are more widely used, whereas stakeholder resistance is fundamental challenge for PoBAs because there is less experience with such payment models.

Figure 18. PoBA barriers means and standard deviations

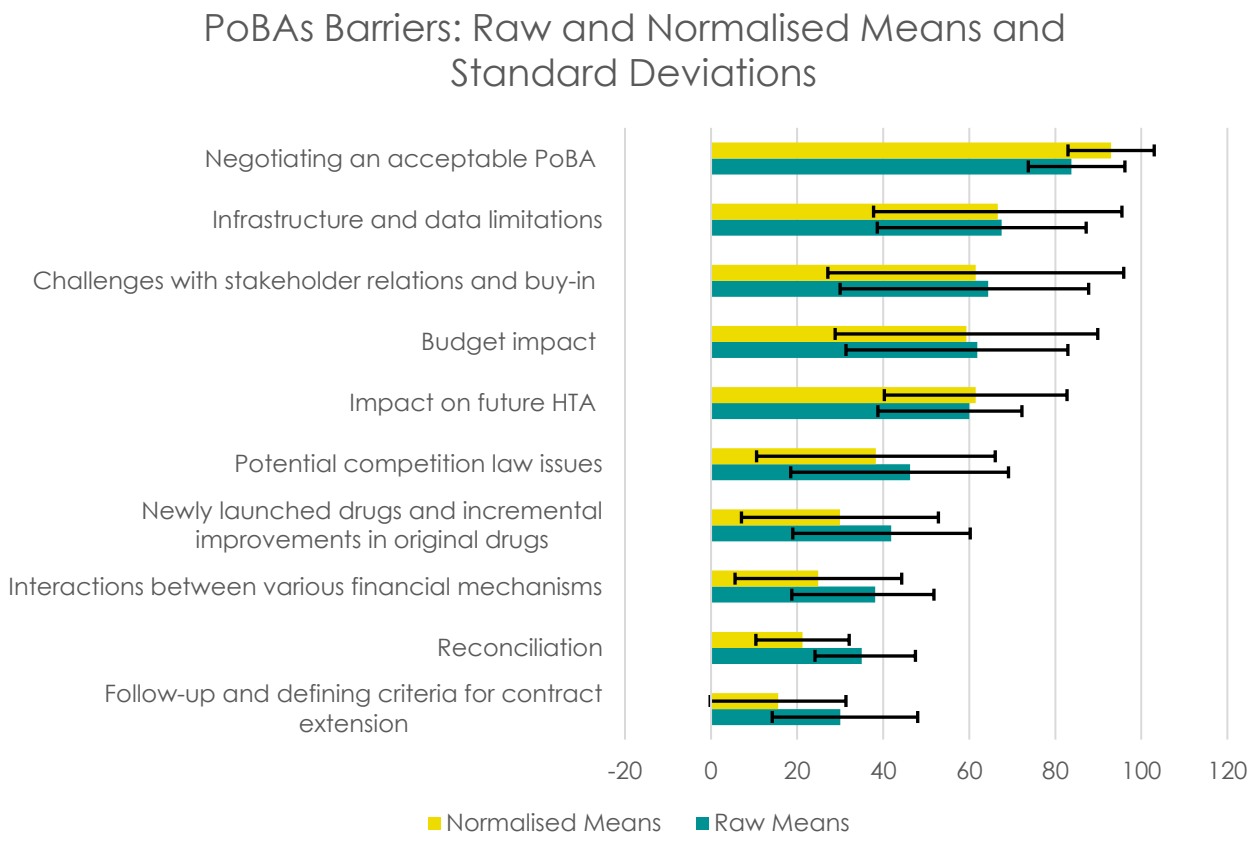
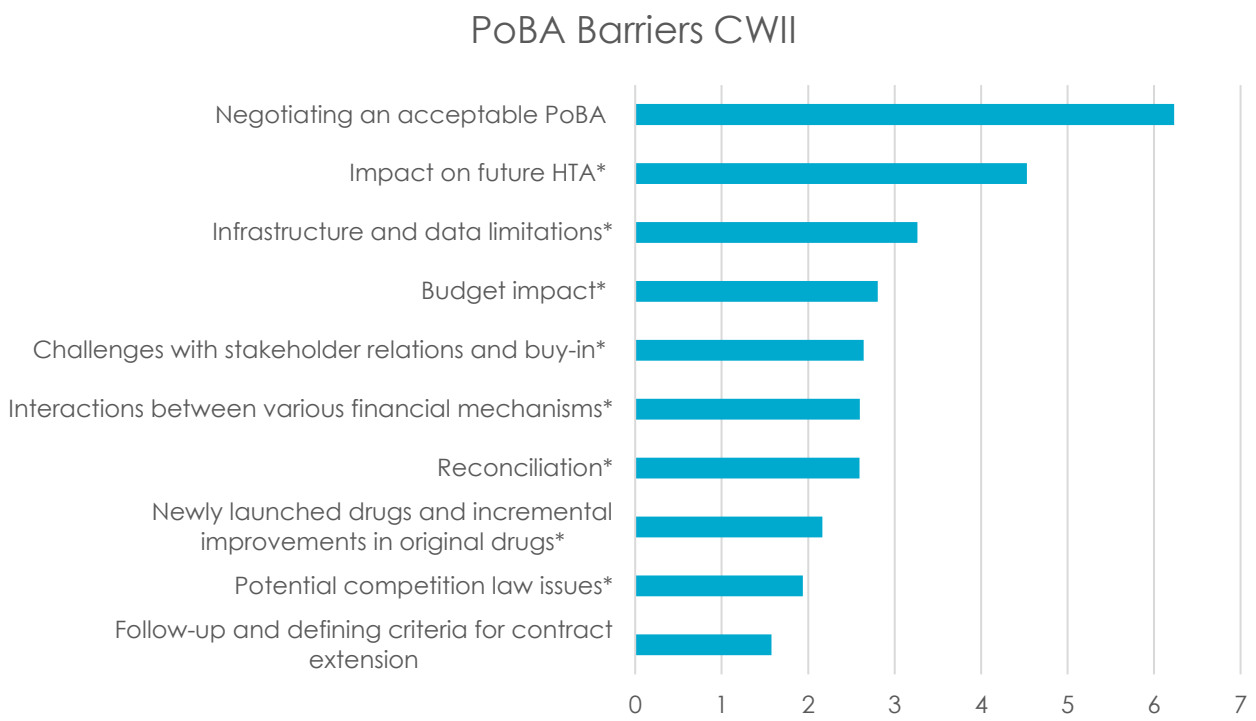


Figure 19. PoBA barriers CWII



* Indicates a change in position relative to the order of means

During discussion, participants generally agreed with the overall ranking and scores, opting not to re-rank the barriers.

Stakeholder-Specific Insights

Table 32. Top three PoBA barriers for each stakeholder type

Stakeholder Type	Most Difficult Barrier	2nd Most Difficult Barrier	3rd Most Difficult Barrier
Academics	Negotiating an acceptable PoBA (87.5)	Impact on future HTA (67.5)	Challenges with stakeholder relations and buy-in (67.5)
Industry	Negotiating an acceptable PoBA (100)	Challenges with stakeholder relations and buy-in (100)	Infrastructure and data limitations (75)
Patient	Negotiating an acceptable PoBA (70)	Impact on future HTA (70)	Infrastructure and data limitations (60)
Payer	Negotiating an acceptable PoBA (75)	Infrastructure and data limitations (75)	Potential competition law issues (70)

Mean scores assigned by stakeholders in parentheses

Table 32 displays the top three barriers for each stakeholder group in the NG. The results of each stakeholder group were generally similar to the group's collective results. In most cases where stakeholder-specific rankings diverged from the overall group's rankings, these differences were not consistent with the pre-NG survey data, indicating that the generalisability of these results to the broader stakeholder populations is limited.

Phased Approach

Table 33. PoBA barriers and implementation phases

	Phase 1	Phase 2	Phase 3	Phase 4
Negotiating an acceptable PoBA	6.23			
Infrastructure and data limitations		3.26	3.26	
Challenges with stakeholder relations and buy-in	2.64			
Budget impact	2.81			
Impact on future HTA			4.53	
Potential competition law issues	1.94	1.94		
Newly launched drugs and incremental improvements in original drugs			2.16	
Interactions between various financial mechanisms			2.60	2.60
Reconciliation				2.59
Follow-up and defining criteria for contract extension				1.58

Numbers correspond to each item's CWII. Green indicates a CWII above 5, yellow indicates a CWII between 3.0 and 5.0, and red indicates a CWII below 3. Phase 1: Inception & Design, Phase 2: Adoption, Phase 3: Sustainment & Maintenance, Phase 4: Wrapping Up & Closing

Table 33 presents the CWII of the PoBA barriers, along with the phases of implementation that each barrier affects. Like FBRSAs, barrier CWIIs are low for PoBAs, with *negotiating an acceptable PoBA* being the only barrier with a CWII above 5. This highlights the shared perception that the design of the agreement is highly difficult. Despite low CWIIs, it is Phase 1 that is most impacted by barriers; this could reflect little country-level experience in comparison to other payment models.

3.2.5.2. Enablers

Figure 20 presents the raw and normalised scores of the NG discussion on PoBA enablers, and **Figure 21** displays the CWIIs for each enabler.

The most highly ranked enablers were *early dialogue between stakeholders*, *budget predictability and affordability*, and *enhanced financial planning and collaboration*. The strongest consensus was generated around *budget predictability and affordability*, followed by *early dialogue between stakeholders*. However, the CWIIs were generally low, reflecting high variability in participants' scores.

Figure 20. PoBAs enablers means and standard deviations

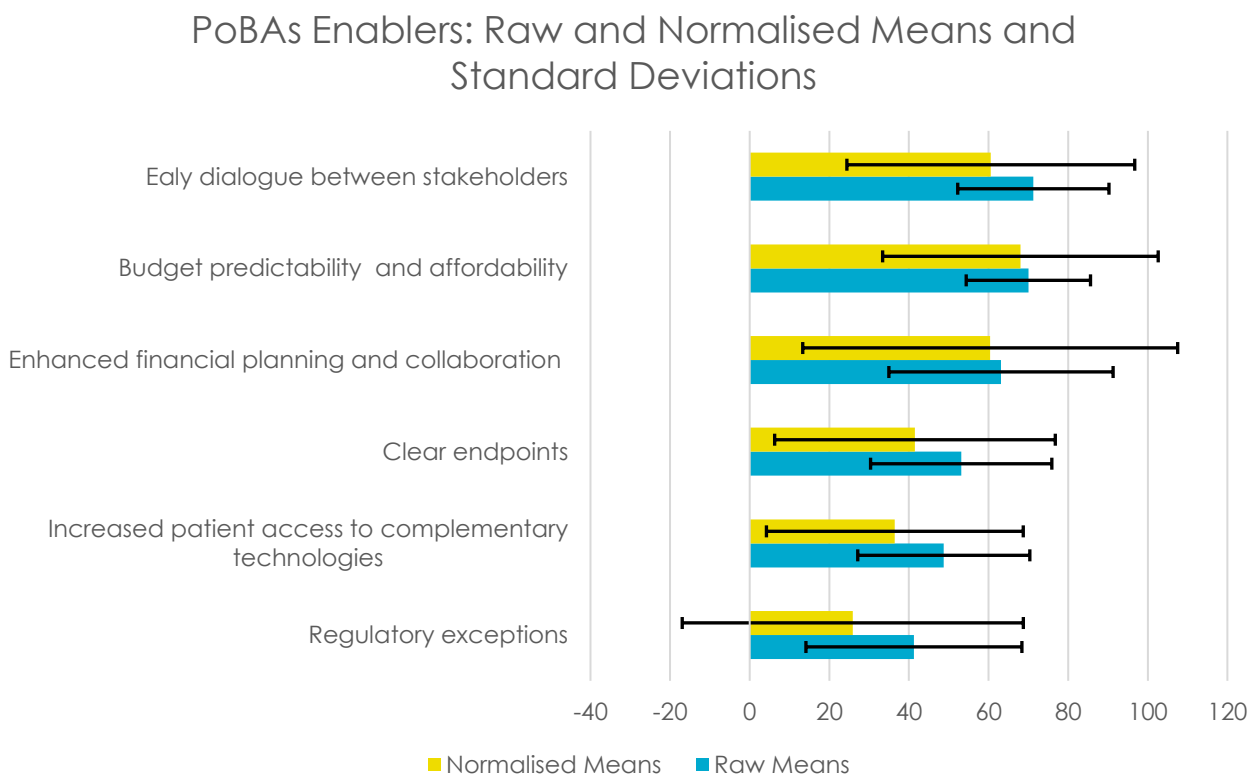
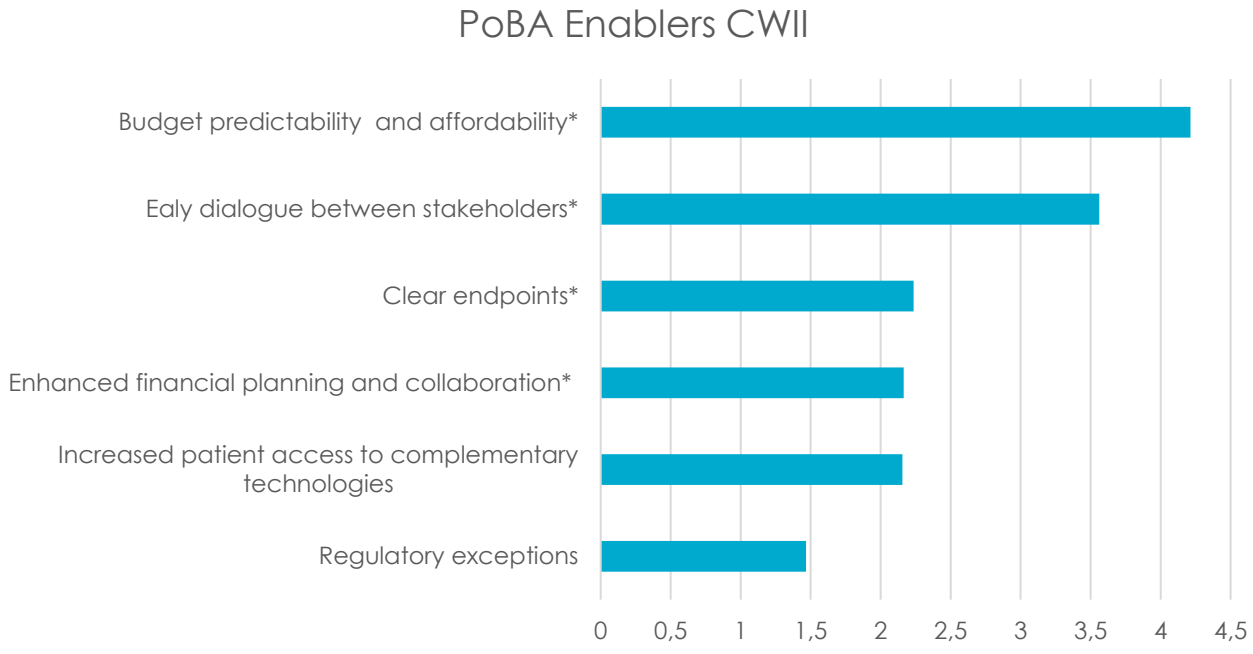


Figure 21. PoBA enablers CWII



* Indicates a change in position relative to the order of means

Incentives for implementing PoBAs were a key point of discussion, particularly with regards to *increased patient access to complementary technologies* and its dynamics with cost-savings. A Spanish academic suggested that patient access

ought to be the purpose of implementing agreements like PoBAs. However, an industry representative highlighted that in his recent experience, payers prioritise cost-savings over patient access with respect to IPMs. To this, an English payer responded that PoBAs are almost always suggested by industry as a means of bundling a non-cost-effective drug with a cost-effective one to make the bundle cost-effective on the whole. Overall, the group had divergent views on which incentives enable PoBA use and implementation, yet participants agreed with the group's overall rankings and scores and chose not to re-score and re-rank the enablers.

Stakeholder-Specific Insights

Table 34. Top three PoBA enablers for each stakeholder type

Stakeholder Type	Most Important Enabler	2nd Most Important Enabler	3rd Most Important Enabler
Academics	Budget predictability (70)	Enhanced financial planning and collaboration (67.5)	Clear endpoints (67.5)
Industry	Early dialogue between stakeholders (100)	Budget predictability (75)	Clear endpoints (75)
Patient	Budget predictability (70)	Enhanced financial planning and collaboration (70)	Increased patient access to complementary technologies (50)
Payer	Ealy dialogue between stakeholders (85)	Enhanced financial planning and collaboration (82.5)	Budget predictability (67.5)

Mean scores assigned by stakeholders in parentheses

Table 34 presents the three barriers scored as the most difficult by each stakeholder group during the NG. Broadly, these stakeholder-specific rankings aligned with the overall group results, as each group's top selections included at least two of the three enablers most highly scored by the full group. Where variations occurred between individual stakeholder groups and the overall group, these were not reflected in the pre-NG survey, indicating that such differences were not likely to be a meaningful divergence in stakeholder perspectives.

Phased Approach

Table 35. PoBA enablers and implementation phases

	Phase 1	Phase 2	Phase 3	Phase 4
Ealy dialogue between stakeholders	3.56			
Budget predictability and affordability	4.21			
Enhanced financial planning and collaboration	2.16			
Clear endpoints				2.24
Increased patient access to complementary technologies	2.156			
Regulatory exceptions	1.47	1.47		

Numbers correspond to each item's CWII. Green indicates a CWII above 5, yellow indicates a CWII between 3.0 and 5.0, and red indicates a CWII below 3. Phase 1: Inception & Design, Phase 2: Adoption, Phase 3: Sustainment & Maintenance, Phase 4: Wrapping Up & Closing

Table 35 highlights the enablers considered for PoBAs, indicating their CWIIs and the phases of implementation that each enabler facilitates. The PoBA barriers and enablers are similar in that their CWIIs are relatively low—reflecting both low means and a lack of consensus—but the enablers have an outsized impact on Phase 1. This finding thus also suggests that PoBAs necessitate more initial investments, which is consistent with the contents of the discussion, wherein participants discussed the incentives and reasons for adopting PoBAs at length.

3.2.5.3. Summary of PoBA Insights

The barriers identified as being the most difficult to overcome were *negotiating an acceptable PoBA*, *infrastructure and data limitations*, and *challenges with stakeholder relations and buy-in*. The enablers with the highest average scores were *early dialogue between stakeholders*, *budget predictability and affordability*, and *enhanced financial planning and collaboration*.

While *negotiating an acceptable design* and *infrastructure limitations* appeared as particularly difficult barriers across several IPMs, *challenges with stakeholder relations and buy-in* was uniquely considered to be one of the most difficult barriers for PoBAs. *Early dialogue between stakeholders* being identified as the most important enabler lends support to the idea that stakeholder relations are fundamental to PoBA success. This barrier-enabler duo reflects insights from the discussion wherein NG participants suggested that stakeholder relations are especially critical for PoBAs because they are less frequently used in practice, thereby necessitating earlier conversations and planning compared to the other payment models.

The phased analysis revealed that, although all PoBA's barriers had relatively low CWIIs, Phase 1 is likely to be the most impacted, potentially reflecting limited country-level experience with the design and implementation of PoBAs. Likewise,

Phase 1 is likely to be the most affected by the enablers, given the number of enablers affecting PoBA inception and design. Taken together, these insights suggest that initial effort and investment in the implementation process ought to be targeted towards catalysing these enablers and overcoming the initial barriers that unduly affect Phase 1, as, with these enablers unlocked and barriers overcome, successful implementation should be more feasible.

3.2.6. Cross-IPM Insights

To highlight the commonalities and differences across IPMs identified in this research, **Table 36** and **Table 37** present the barriers and enablers with the highest raw mean scores for each IPM, respectively.

Table 36. Most difficult barriers to overcome for each IPM, with mean scores presented in parentheses.

OBAs	IBP	IaAPs	FBRSAs	PoBAs
Lack of infrastructure for data collection and monitoring (**82.14**)	Infrastructure and data limitations (**85**)	Legal and regulatory hurdles (**81.43**)	Negotiating an acceptable FRSA design (**71.25**)	Negotiating an acceptable PoBA (**83.75**)
Negotiating an acceptable OBA design (**71.43**)	Legal and regulatory barriers (**80**)	Complex financial management (**76.43**)	Infrastructure and data limitations (**70**)	Infrastructure and data limitations (**67.5**)
Burden on clinical staff (**66.43**)	Designing an optimal model (**63.57**)	Negotiating an acceptable model (**74.29**)	Financial sustainability and planning (**55.63**)	Challenges with stakeholder relations and buy-in (**64.38**)

Table 37. Most important enablers for each IPM, with mean scores presented in parentheses.

OBAs	IBP	IaAPs	FBRSAs	PoBAs
Sufficient infrastructure and funding (**92.86**)	Established data infrastructure and monitoring systems (**85.71**)	Agreed conditions of termination of the agreement in the technology fails during the	Sufficient infrastructure (**89.38**)	Early dialogue between stakeholders (**71.25**)

		amortization period (**85.71**)		
Clear legal and regulatory guidelines (**83.57**)	Change in legal framework to allow IBP (**85.71**)	Existing infrastructure (**79.29**)	Simplicity/ease of implementation (**76.25**)	Budget predictability and affordability (**70**)
Data accuracy and optimisation to achieve OBA's goals (**79.29**)	Rational design and application of IBP (**68.57**)	Pre-existing experience or frameworks to guide implementation (**77.86**)	Capacity to reduce financial uncertainty (**75**)	Enhanced financial planning and collaboration (**63.13**)

Our analysis revealed several cross-cutting themes across IPMs. Among the barriers, data infrastructure limitations ranked among the three most difficult barriers for four of the five IPMS. Negotiating an acceptable model design, and legal and regulatory hurdles, also emerged across several IPMs. Thus, these barriers can be viewed as those that affect IPM implementation more broadly. On the enablers, existing data infrastructure and supportive legal or regulatory environments were among the most important factors identified across several IPMs. In addition, enablers addressing the barrier of negotiating an acceptable design—such as rational IPM design and application and pre-existing knowledge or frameworks—were also observed across multiple IPMs. Overall, the enablers that cut across several IPMs tend to mirror the generalisable barriers, underscoring the heightened importance of these key themes.

Areas that affect several IPMs provide targetable objectives for flexible policy interventions aimed at increasing and enabling a more efficient implementation and use of IPMs. Infrastructure, for instance, emerged as a key enabler and barrier for several IPMs; this suggests that policymakers looking to operationalise various IPMs could strategically invest in infrastructure that can be used across all these models.

Points of divergence also emerged across IPMs, underscoring how certain issues are more relevant for certain IPM types. For instance, *burden on clinical staff* and *data accuracy and optimization* were top barriers and enablers uniquely for OBAs, reflecting the inherent trade-off between imposing additional work on staff and collecting meaningful patient outcome data. In contrast, *complex financial management* as a top barrier and *agreed conditions of termination* as a critical enabler for IaAPs underscore the distinct financial risks inherent in this model. These findings reflect stakeholder concerns about aligning payment schedules with fiscal years and mitigating late payment risks, while emphasizing the need for clear exit

strategies to avoid prolonged commitments to technologies that may fail or become obsolete.

For FBRSAs, *simplicity/ease of implementation* emerged as a unique top enabler, suggesting this model may be easier to implement than other IPMs. Stakeholder relationships were identified as both a critical enabler and difficult barrier for PoBAs. Stakeholders in the NG attributed this to the model's infrequent use in European countries, meaning successful implementation requires advanced planning and collaboration due to limited prior experience. IBP was unique in that all its top barriers and enablers exactly reflect the three general barriers and enablers emerged across all other IPMs, with the three enablers exactly mirroring the three barriers not only in content but also in ranking.

3.2.7. Policy Recommendations

Both NGs concluded with discussions about policies that could support the use of IPMs. This section highlights the key insights that were generated from that discussion.

Policies should be aimed at cross-cutting themes across IPMs

Given that many of the most difficult barriers and most important enablers overlapped across IPMs, the policy discussions in each NG focused largely on cross-cutting themes. Indeed, across both NGs, participants agreed that policymakers should prioritise enablers and barriers that cut across multiple IPMs—such as data infrastructure, pre-existing frameworks, and accommodating legal environments.

Policy interventions should reflect the critical enablers

A key theme was that many relevant policy recommendations are embedded in the enablers, such as the need to invest in data infrastructure and to adapt legal frameworks to accommodate IPMs.

Legal environments were described as both a primary enabler and a major barrier, with participants agreeing on its critical role: Without an enabling legal environment, IPMs cannot be operationalised. Likewise, infrastructure and data limitations also appeared on the barrier- and enabler-side for several IPMs. Participants noted that investment in health data infrastructure is critical for enabling the successful implementation of IPMs. However, some noted that this will involve growing pains, as data sharing remains a significant concern and source of additional barriers.

One industry representative emphasized the time required to implement these reforms, arguing that pragmatic, short-term solutions are needed in the interim. He offered alternatives like cloud-based platforms and third-party data providers—

such as Lyfegen—where proper data infrastructure does not yet exist, as well as the use of credit notes and alternative invoicing mechanisms where legal constraints might hinder instalment payments.

HTA should play a role in supporting IPM implementation

In the second NG, a Spanish academic pointed to the important role that HTA agencies can play in informing the use of IPMs. He argued that HTA processes should be strengthened and used to identify areas of uncertainty, and where uncertainties exist, IPMs can be used to meaningfully address them.

Knowledge exchange networks are key to implementing IPMs in countries with less experience

In both NGs, stakeholders also underscored the need for knowledge sharing. Pre-existing experience and implementation frameworks emerged as consistent enablers across the IPMs. Participants suggested that in settings where direct experience with IPMs is limited, building knowledge through best practice exchange and shared frameworks can substitute for experience in the early stages of IPM adoption. Even where experience exists, comprehensive commercial frameworks offering multiple IPM options—clearly outlining when each is appropriate—would promote more consistent, appropriate and efficient IPM implementation and use.

4. Discussion

Our results highlight barriers and enablers that are unique to specific IPMs, as well as those that apply to all the IPMs under consideration. Barriers related to infrastructure limitations, challenges negotiating acceptable designs, and legal or regulatory constraints were consistently ranked among the top three concerns. Notably, the most significant enablers often mirrored these barriers—for instance, having sufficient infrastructure or a supportive legal environment. In cases where specific barriers and enablers were unique to a given IPM, these distinctions can offer insight into the particularities of that IPM.

Broadly, stakeholders participating in the NG showed strong alignment on the most frequently identified barriers and enablers. Where divergences did occur, data from the pre-NG survey often reinforced the NG consensus, suggesting that observed differences may have stemmed from the small number of NG participants rather than fundamental disagreements. However, exceptions among the identified barriers may point to potential roadblocks or conflicting interests that could hinder implementation. Likewise, the analysis of phase-specific insights reveals where IPM implementation may be especially likely to stall, therefore highlighting potential areas for investment and policy action.

As previously noted, several cross-cutting barriers and enablers appeared across several IPMs. Excluding IaAPs, infrastructure and data limitations was either the highest or second-highest barrier for each IPM. Likewise, this factor was identified as the top enabler for all IPMs except IaAPs and PoBAs. Similarly, legal and regulatory barriers—along with accommodating legal environments as its enabling counterpart—appeared in the top three for two of the IPMs. Additionally, negotiating an acceptable design also appeared in the top three barriers for each IPM.

The consistent appearance of these barriers and enablers across IPMs highlights key areas for policy interventions: specifically, investing in infrastructure and adapting legal environments to make them more conducive to implementing these IPMs. Specific enablers that emerged as counterparts to the challenge of negotiating acceptable designs included the *rational design and application of IBP*, as well as the *presence of pre-existing frameworks for IaAPs*. Additionally, knowledge sharing was highlighted as a critical policy intervention in both NGs, with the potential to support the Inception & Design phase (i.e., Phase 1) of implementation by addressing design-related challenges. Since these themes emerged across various IPMs, policies addressing these barriers and supporting their enablers should be implemented flexibly to enable more effective and efficient IPM implementation across different types.

Barriers and enablers specific to certain IPMs reveal unique characteristics of those models. For example, *burden on clinical staff* and *data accuracy and optimisation* emerged as top-scored barriers and enablers for OBAs, highlighting the trade-off between imposing additional work on healthcare professionals and collecting accurate, meaningful data on patient outcomes. In the case of IaAPs, the inclusion of *complex financial management* and *agreed conditions of termination* among the top three barriers and enablers underscores the unique accounting difficulties associated with this payment model and the need for risk mitigation strategies as a result of its complex payment timeline. Likewise, the identification of *simplicity/ease of implementation* and *capacity to reduce financial uncertainty* emerging as key enablers for FBRSAs suggests that this model may be considered more straightforward to implement relative to other IPM options. Conversely, points related to stakeholder relations—on both the barriers and enabler sides—for PoBAs suggest that they might require earlier conversations and collaboration due to countries' limited experiences implementing such models.

Barriers and enablers related to legal environments appeared to have a particularly high impact on IBP and IaAPs—though they were also the second-highest scored enabler for OBA. Indeed, this theme emerged as the top barrier for IaAPs and as the second-highest barrier and enabler for IBP, suggesting its

criticality for these IPMs. Insights from the survey and NGs suggest that this was a key concern for participants because the use of IBP and IaAPs are restricted in some countries due to legal limitations.

Recurring barriers and enablers also lend insights into the phases of implementation where bottlenecks are likely to occur. Since *negotiating an optimal design* and *legal and regulatory environments* occur during the Inception & Design phase of IPM implementation (i.e., Phase 1), this suggests an initial struggle to adopt an IPM that both addresses the underlying access issue and fits within a country's legal context. Infrastructure challenges, conversely, are more likely to appear in Phases 2 and 3 as the IPM is operationalised. This implies that successful IPM adoption requires different types of expertise and resources in each phase.

The phase analysis also demonstrated that enablers tend to have the most significant impact on Phase 1 of implementation. Indeed, the only IPMs for which this was not the case were OBAs—where enabler impact was spread evenly across phases—and IBP—where Phases 2 and 3 were the most affected. Even for these IPMs, however, the enabler considered most pivotal was sufficient infrastructure; though, this affects Phases 2 and 3, infrastructure is often planned in the early phases of implementation or prior to implementation altogether. Thus, these results suggest that, across IPMs, actors must make upfront investments in order to harness the enablers deemed most important.

A participant in the NG on FBRSAs observed that enablers can be separated into 'hows' and 'whys,' where enablers considered 'hows' tend to facilitate the actual implementation of the IPM, and those considered 'whys' motivate use of the IPM. The participant who made this observation noted that the 'hows' tend to receive the highest scores of importance. This observation appears to be true across all the IPMs—not just FBRSAs. In **Table 37**, which summarises the top three enablers for each IPM, only three of the nine enablers are 'whys': *simplicity/ease of implementation* and *capacity to reduce financial uncertainty* for FBRSAs, and *budget predictability and affordability* for PoBAs. This suggests that, while incentives can drive interest in using IPMs, stakeholders ultimately prioritise the mechanics of implementation. That is, only after a country builds capacity to use a given IPM can the benefits be realised. Thus, policy aimed to increase adoption of IPMs ought to be more focused on harnessing the 'how' enablers rather than the 'whys.'

In terms of stakeholder-specific insights, three areas of divergence appeared: for IaAPs barriers, payers identified *financial sustainability* as a top difficulty; for OBA enablers, academics *highlighted early stakeholder engagement and buy-in* as critically important, while payers identified *willing and well-trained staff* and *pre-*

existing frameworks, experience, and leadership as two of the most important enablers. As previously mentioned, these results were supported by the pre-NG survey, which included a larger sample of respondents from each stakeholder group, suggesting that these differences were more likely due to varying perceptions between stakeholder groups rather than sample size limitations.

Financial sustainability as a critical barrier for payers highlights a potential roadblock for IaAPs, as payers—due to their role in assessing value for money—are particularly concerned about the budget impact of this type of model. This could point to the enhanced importance of enablers like negotiating the model's design, which could address this concern. The academic-specific enabler of *early stakeholder engagement* may reflect differences in priorities between those who study IPMs from a holistic perspective—primarily involved in the early implementation stages—and those engaged throughout the IPM implementation lifecycle, experiencing barriers and enablers in real-world practice within their own silos. This was also reflected in payers' emphasis on *pre-existing frameworks, experience, and leadership* and *willing and well-trained staff*, showing their priorities might be shaped by the operational intricacies they observe in implementing payment models. However, in most cases, the stakeholder-specific results from the NG and the pre-NG survey were largely consistent with the overall groups' results.

Across all the IPMs, we observed generally high variation in the scores assigned to each barrier and enabler. For the IPMs where re-ranking occurred, we generally observed a decrease in SDs—though this result was always non-significant. For both NGs, participants viewed the end results of the rankings and expressed satisfaction with the scores and relative rankings. Thus, even where high variability in scores existed, experts verbally agreed with the outputs. Moreover, the consistency observed between the results of the NG and the pre-NG survey provided additional confidence in the final NG scores.

Though we found that the results of the survey and NG mostly aligned, we did observe some differences. For instance, in some cases, we found dissimilarities in the ordering of the top three barriers or enablers and even in the items considered to be in the top three. With these differences in mind, we consider the NG to have captured a more robust view of stakeholders' perceptions of the barriers and enablers. Though the survey had more respondents, the 'sample size limitation' of the NG was a result of creating an optimal group size—one that was large enough to capture the relevant stakeholder perspectives, but small enough to allow everyone the opportunity to express their views in discussion. Moreover, the creation of these groups allowed us to be more intentional with representation of stakeholder types and country experiences. In addition, the NG better captured

the strength of importance/difficulty of each item, where the survey did not. In the survey, participants identified barriers/enablers they believed to be most relevant, but the NG's scoring exercise demonstrated how participants viewed each item relative to the other ones under consideration. This also allowed us to understand the level of consensus around each item—something that we were unable to do with the survey. Finally, the NG added additional value to this research by facilitating discussion around the barriers and enablers; this meant that we could understand the motivation behind participants' scores, and it also prompted participants to think critically about whether the items they initially viewed as relevant were deserving of their highest scores. As such, we view the NG as having provided additional richness and insight beyond what the survey could. A potential limitation of this paper is that we could not control whether participants changed their final scores to intentionally manipulate the aggregate results of the group. In general, scores that changed after re-ranking were typically in response to discussion points. However, one expert in the first NG changed his scores dramatically on many occasions—even without discussion taking places on those enablers and barriers. As his motivation for changing the scores was not revealed, we cannot understand what drove these changes but generally interpreted it as a response to viewing the group's aggregate scores rather than an attempt to drive up/down the overall results.

The number of participants in both NG discussions (i.e., sample size) may be a limitation of the study that could have affected the results. We aimed to have approximately eight participants in each NG, but this came at the expense of having a small number of representatives within each stakeholder group, making it difficult to extrapolate the insights generated by stakeholder groups to their larger populations. Even so, where possible, we compared these insights to the results of the pre-NG survey to understand more generalizable takeaways between each group. Perhaps more importantly, the limited number of participants meant less diversity in the countries that are represented in our results—particularly in the NG results. As such, the results should be interpreted given the context of the experts who participated in the NG; however, we did ask experts to consider barriers and enablers more generally and not solely in the context of their own countries to account for this lack of representation.

In any case, the main goal of the mNGT was to build consensus and align stakeholders' views on the most challenging barriers and most important enablers. Despite the acknowledged limitations, the consistency between the overall NG results and the pre-NG survey—as well as participants' agreement with the final rankings and scores—suggests that we achieved the primary objective of the research.

5. Conclusions and recommendations

This research identified stakeholders' perceptions of key barriers and enablers to IPM implementation, highlighting those viewed as most challenging and most important. It captured both cross-cutting and IPM-specific barriers and enablers across five IPM types, which represent the broader IPM landscape. Infrastructure, legal frameworks, and difficulties in negotiating model design consistently emerged as critical barriers, while their corresponding enablers were considered essential for success. These findings point to clear priorities for policy action, particularly in upfront infrastructure investment and regulatory adaptation.

Differences across IPM models revealed important nuances, helping to identify IPM-specific areas for action and optimisation. For example, OBAs involved a trade-off between the need for robust data collection infrastructure and the clinical workload such data collection may impose. The implementation of IBP and IaAPs was shown to strongly depend on enabling legal environments, while PoBAs require effective stakeholder communication for successful adoption. FBRSAs appeared to be the most straightforward model to implement. Observed commonalities and divergences among stakeholder groups—along with analysis of which implementation phases were most affected by each barrier and enabler—offered further insight into the operational and strategic concerns shaping implementation and likely influencing its success.

Despite some limitations, alignment between the NG results and the broader pre-NG survey indicates consensus on the most pressing barriers and enablers. Overall, the study provides a foundation for more targeted and flexible policymaking to support effective and sustainable IPM adoption and underscores the value of addressing common implementation hurdles through international cooperation to enable an effective and sustainable IPM adoption across Europe.

References

1. Manders, E. A., van den Berg, S., de Visser, S. J. & Hollak, C. E. M. Drug pricing models, no 'one-size-fits-all' approach: a systematic review and critical evaluation of pricing models in an evolving pharmaceutical landscape. *Eur J Health Econ* **26**, 683–696 (2025).
2. Hollis, A. Sustainable Financing of Innovative Therapies: A Review of Approaches. *PharmacoEconomics* **34**, 971–980 (2016).
3. Lee Mendoza, R. Incentives and disincentives to drug innovation: evidence from recent literature. *Journal of Medical Economics* **22**, 713–721 (2019).
4. Tordrup, D., van den Ham, H. A., Glanville, J. & Mantel-Teeuwisse, A. K. Systematic reviews of ten pharmaceutical pricing policies – a research protocol. *J of Pharm Policy and Pract* **13**, 22 (2020).
5. Moreno, S. G. & Epstein, D. The price of innovation - the role of drug pricing in financing pharmaceutical innovation. A conceptual framework. *Journal of Market Access & Health Policy* **7**, 1583536 (2019).
6. Bell, E., Berdud, M., Cookson, G. & Besley, S. *Delivering the Triple Win: A Value-Based Approach to Pricing*. https://www.ohe.org/publications/delivering-triple-win-value-based-approach-pricing/ (2023).
7. Vogler, S. *et al.* How Can Pricing and Reimbursement Policies Improve Affordable Access to Medicines? Lessons Learned from European Countries. *Appl Health Econ Health Policy* **15**, 307–321 (2017).
8. Balderrama, F., Schwartz, L. J. & Longo, C. J. When are Pharmaceuticals Priced Fairly? An Alternative Risk-Sharing Model for Pharmaceutical Pricing. *Health Care Anal* **28**, 121–136 (2020).
9. Fuller, R. L. & Goldfield, N. Paying for On-Patent Pharmaceuticals: Limit Prices and the Emerging Role of a Pay for Outcomes Approach. *The Journal of Ambulatory Care Management* **39**, 143 (2016).

10. Wenzl, M. & Chapman, S. *Performance-Based Managed Entry Agreements for New Medicines in OECD Countries and EU Member States: How They Work and Possible Improvements Going Forward*. vol. 115 https://www.oecd-ilibrary.org/social-issues-migration-health/performance-based-managed-entry-agreements-for-new-medicines-in-oecd-countries-and-eu-member-states_6e5e4c0f-en (2019).

11. McElwee, F., Cole, A., Kaliappan, G., Masters, A. & Steuten, L. Alternative Payment Models for Innovative Medicines: A Framework for Effective Implementation. *Appl Health Econ Health Policy* **23**, 535–549 (2025).

12. Piatkiewicz, T. J., Traulsen, J. M. & Holm-Larsen, T. Risk-Sharing Agreements in the EU: A Systematic Review of Major Trends. *PharmacoEconomics Open* **2**, 109–123 (2018).

13. Thanimalai, S., Choon, W. Y. & Lee, K. K.-C. Stakeholder views of managed entry agreements: A literature review of national studies. *Health Policy Open* **2**, 100032 (2021).

14. Hlávka, J. P., Tysinger, B., Yu, J. C. & Lakdawalla, D. N. Access to Disease-Modifying Alzheimer's Therapies: Addressing Possible Challenges Using Innovative Payment Models. *Value Health* **25**, 1828–1836 (2022).

15. Hampson, G. & Steuten, L. Netflix and pill: is there a role for volume-delinked subscription-style payments beyond antimicrobials?'. *Expert Review of Pharmacoeconomics & Outcomes Research* **24**, 1–3 (2024).

16. Ciulla, M. *et al.* Healthcare Systems across Europe and the US: The Managed Entry Agreements Experience. *Healthcare (Basel)* **11**, 447 (2023).

17. Preckler, V. & Espín, J. The Role of Indication-Based Pricing in Future Pricing and Reimbursement Policies: A Systematic Review. *Value in Health* **25**, 666–675 (2022).

18. Brekke, K. R., Dalen, D. M. & Straume, O. R. Paying for pharmaceuticals: uniform pricing versus two-part tariffs. *Journal of Health Economics* **83**, 102613 (2022).

19. Cole, A., Neri, M. & Cookson, G. *Payment Models for Multi-Indication Therapies - OHE*. https://www.ohe.org/publications/payment-models-multi-indication-therapies/ (2021).

20. HI-PRIX HORIZON. Pay for Innovation Observatory. (2023).

21. Whittal, A. *et al.* Facilitating More Efficient Negotiations for Innovative Therapies: A Value-Based Negotiation Framework. *International Journal of Technology Assessment in Health Care* **38**, e23 (2022).

22. Neumann, P. J., Chambers, J. D., Simon, F. & Meckley, L. M. Risk-Sharing Arrangements That Link Payment For Drugs To Health Outcomes Are Proving Hard To Implement. *Health Affairs* **30**, 2329–2337 (2011).

23. Michelsen, S., Nachi, S., Van Dyck, W., Simoens, S. & Huys, I. Barriers and Opportunities for Implementation of Outcome-Based Spread Payments for High-Cost, One-Shot Curative Therapies. *Front. Pharmacol.* **11**, 594446 (2020).

24. Hofer, M. *et al. Within-Country Performance of Novel Payment/Pricing Schemes: Costs and Benefits of Implementation*. (2025).

25. McMillan, S. S., King, M. & Tully, M. P. How to use the nominal group and Delphi techniques. *Int J Clin Pharm* **38**, 655–662 (2016).

26. Hofer, M. *et al. Within-Country Performance of Novel Payment/Pricing Schemes: Costs and Benefits of Implementation*. (n.d.).

27. Spark Therapeutics. Spark Therapeutics Announces First-of-their-kind Programs to Improve Patient Access to LUXTURNA™ (voretigene neparvovec-rzyl), a One-time Gene Therapy Treatment – Spark Therapeutics. https://sparktx.com/press_releases/spark-therapeutics-announces-first-of-their-kind-programs-to-improve-patient-access-to-luxturna-voretigene-neparvovec-rzyl-a-one-time-gene-therapy-treatment/.

28. Novartis. AveXis receives EC approval and activates "Day One" access program for Zolgensma®, the only gene therapy for spinal muscular atrophy (SMA). *Novartis*

https://www.novartis.com/news/media-releases/avexis-receives-ec-approval-and-activates-day-one-access-program-zolgensma-only-gene-therapy-spinal-muscular-atrophy-sma (2020).

29. Novartis. AveXis Announces Innovative Zolgensma® Gene Therapy Access Programs for US Payers and Families. *Novartis* https://www.novartis.com/news/media-releases/avexis-announces-innovative-zolgensma-gene-therapy-access-programs-us-payers-and-families (2019).

30. Jørgensen, J., Hanna, E. & Kefalas, P. Outcomes-based reimbursement for gene therapies in practice: the experience of recently launched CAR-T cell therapies in major European countries. *Journal of Market Access & Health Policy* **8**, 1715536 (2020).

31. Fox, J. & Watrous, M. Overcoming Challenges Of Outcomes-Based Contracting For Pharmaceuticals: Early Lessons From The Genentech--Priority Health Pilot. *Health Affairs Forefront* (2017) doi:10.1377/forefront.20170403.059442.

32. Clopes, A. *et al.* Financial consequences of a payment-by-results scheme in Catalonia: gefitinib in advanced EGFR-mutation positive non-small-cell lung cancer. *Journal of Medical Economics* **20**, 1–7 (2017).

33. Moon, S. & Erickson, E. Universal Medicine Access through Lump-Sum Remuneration — Australia's Approach to Hepatitis C. *N Engl J Med* **380**, 607–610 (2019).

34. Folkhälsomyndigheten - Public Health Agency of Sweden. *Tillgänglighet till Vissa Antibiotika – En Pilotstudie Av En Alternativ Ersättningsmodell*. https://www.folkhalsomyndigheten.se/publikationer-och-material/publikationsarkiv/t/tillganglighet-till-vissa-antibiotika-en-pilotstudie-av-en-alternativ-ersattningsmodell/ (2023).

35. Public Health Agency of Sweden. *Availability to Antibiotics of Particular Importance*. https://www.folkhalsomyndigheten.se/publikationer-och-material/publikationsarkiv/a/availability-to-antibiotics-of-particular-importance/ (2023).

36. Agenzia Italiana del Farmaco. *Riclassificazione Del Medicinale per Uso Umano Luxturna Ai Sensi Dell'art.* https://www.aifa.gov.it/documents/20142/961234/Determina_DG-1344-2020_Luxturna.pdf (2020).

37. NICE. *Ranibizumab and Pegaptanib for the Treatment of Age-Related Macular Degeneration: Technology Appraisal Guidance [TA155]*. https://www.nice.org.uk/guidance/ta155/chapter/4-Evidence-and-interpretation (2008).

38. Vertex Pharmaceuticals Incorporated. Vertex Announces Long-Term Reimbursement Agreement with the Republic of Ireland for ORKAMBI® (lumacaftor/ivacaftor), KALYDECO® (ivacaftor) and Future Cystic Fibrosis Medicines. https://investors.vrtx.com/news-releases/news-release-details/vertex-announces-long-term-reimbursement-agreement-republic (2017).

39. Vertex Pharmaceuticals Incorporated. Vertex Announces Access Contract in Denmark for Current and Future Cystic Fibrosis Medicines. https://investors.vrtx.com/news-releases/news-release-details/vertex-announces-access-contract-denmark-current-and-future (2018).

40. Vertex Pharmaceuticals Incorporated. Vertex Announces Agreement with NHS England for Access to All Licensed Cystic Fibrosis Medicines. https://investors.vrtx.com/news-releases/news-release-details/vertex-announces-agreement-nhs-england-access-all-licensed (2019).

41. Vertex Pharmaceuticals Incorporated. Vertex Announces New Portfolio Reimbursement Agreement in Italy Including KAFTRIO®, SYMKEVI® and Additional Indications of ORKAMBI® and KALYDECO® for Eligible Patients With Cystic Fibrosis. https://news.vrtx.com/news-releases/news-release-details/vertex-announces-new-portfolio-reimbursement-agreement-italy (2021).

42. Rawson, J. Portfolio access agreements – Lessons learnt from Vertex Pharma's Orkambi. *Partners4Access* https://partners4access.com/blogs/portfolio-access-agreements-lessons-learnt-from-vertex-pharmas-orkambi/ (2018).

43. Main, B., Csanadi, M. & Ozieranski, P. Pricing strategies, executive committee power and negotiation leverage in New Zealand's containment of public spending on pharmaceuticals. *HEPL* **17**, 348–365 (2022).

44. Caves, K. W. & Singer, H. J. Bundles in the Pharmaceutical Industry: A Case Study of Pediatric Vaccines. *SSRN Journal* (2011) doi:10.2139/ssrn.1908306.

45. Jørgensen, J., Hanna, E. & Kefalas, P. Outcomes-based reimbursement for gene therapies in practice: the experience of recently launched CAR-T cell therapies in major European countries. *J Mark Access Health Policy* **8**, 1715536.

46. Mestre-Ferrandiz, J., Towse, A., Dellamano, R. & Pistollato, M. *Multi-Indication Pricing: Pros, Cons and Applicability to the UK*. https://www.ohe.org/wp-content/uploads/2016/06/418-Multi-indication-pricing_0.pdf (2015).

47. Geography, J. S. in W. Regions Of Europe. *WorldAtlas* https://www.worldatlas.com/articles/the-four-european-regions-as-defined-by-the-united-nations-geoscheme-for-europe.html (2021).

48. OECD (2025). Annual GDP and consumption per capita, US $, current prices, current PPPs. OECD Data Explorer. Available at: https://data-explorer.oecd.org/

49. OECD (2025). Health expenditure and financing. OECD Data Explorer. Available at: https://data-explorer.oecd.org/

Appendix

EU and UK Country Taxonomy

Table 38. EU and UK Country Taxonomy

	Geography	GDP per Capita[48]* ($)	Health expenditure per capita[49]* ($)	Primary Financing System	Health System Reimbursement	IPM Experience**
Austria	Central	73234.80	7275.4	Compulsory Social Insurance	Regional	No Evidence Identified
Belgium	Western	70272.70	6600	Compulsory Social Insurance	National	No Evidence Identified
Bulgaria	Eastern	38098.50	2,677.71	Compulsory Social Insurance	National	Low
Croatia	Southern	43562.53	2814.12	Compulsory Social Insurance	National	No Evidence Identified
Cyprus	Southern	54456.96	4,169.01	Taxation	National	No Evidence Identified
Czechia	Eastern	54143.20	4512.2	Compulsory Social Insurance	National	No Evidence Identified
Denmark	Northern	75999.60	6279.8	Taxation	National	Medium
Estonia	Northern	48567.00	3102.5	Compulsory Social Insurance	National	Medium
Finland	Northern	64458.10	5598.9	Taxation	National	No Evidence Identified
France	Western	60175.70	6629.6	Compulsory Social Insurance	National	Medium
Germany	Central	68613.40	8010.9	Compulsory Social Insurance	National	High
Greece	Southern	40119.90	3015.3	Taxation	National	No Evidence Identified
Hungary	Eastern	45490.70	2840.1	Compulsory Social Insurance	National	No Evidence Identified
Ireland	Northern	126087.90	6046.5	Taxation	National	Medium
Italy	Southern	58044.10	4290.7	Taxation	Regional	High
Latvia	Northern	42194.90	3445.3	Taxation	National	Low

Lithuania	Northern	51570.10	3587.3	Compulsory Social Insurance	National	Low
Luxembourg	Western	142825.60	6436.1	Compulsory Social Insurance	National	No Evidence Identified
Malta	Southern	59978.88	4,880.17	Taxation	National	No Evidence Identified
Netherlands	Western	77766.00	6729.1	Compulsory Social Insurance	National	High
Poland	Eastern	47673.00	2973	Compulsory Social Insurance	National	Low
Portugal	Southern	49221.50	4162.1	Taxation	National	No Evidence Identified
Romania	Eastern	46482.70	2,575.33	Compulsory Social Insurance	National	No Evidence Identified
Slovakia	Eastern	43449.40	2755.9	Compulsory Social Insurance	National	No Evidence Identified
Slovenia	Eastern	54451.40	4113.8	Compulsory Social Insurance	National	No Evidence Identified
Spain	Southern	52759.70	4431.9	Taxation	Regional	High
Sweden	Northern	69570.80	6437.7	Taxation	National	High
United Kingdom	Northern	58390.40	5492.6	Taxation	National	High

*Grey rows indicate the countries that were targeted for contacting survey respondents.*Green - highest third, White - middle third, Orange - lowest 3rd. GDP and health expenditure per capita data are from 2023 (or 2022 where 2023 was not available adjusted to 2023 prices). ** High (at least 3 IPM documented in literature), Medium (1-3 IPM documented in literature), Low (anecdotal evidence of IPM).*

Illustrative Example of Score Normalisation

The formula we used to normalise participants' scores is

$$Normalised\ Score = \frac{(Raw\ Score) - (Minimum\ Score)}{(Maximum\ Score) - (Minimum\ Score)} * 100$$

Table 39. Sample raw scores to illustrate min-max normalisation

Participant	Barrier A	Barrier B	Barrier C	Barrier D
Participant 1	75	80	85	90
Participant 2	20	90	60	85

Table 2 provides an example of individual scoring. To normalise Participant 1's score for Barrier B, we calculate

$$\frac{80 - 75}{90 - 75} * 100 = 33.33$$

Likewise, to generate Participant 2's normalised score for Barrier B, we calculate

$$\frac{90 - 20}{90 - 20} * 100 = 100$$

Therefore, the normalised scores for Participants 1 and 2 across all barriers are as reported in the table below.

Table 40. Sample normalised scores to illustrate min-max normalisation

Participant	Barrier A	Barrier B	Barrier C	Barrier D
Participant 1	0	33.33	66.67	100
Participant 2	0	100	57.14	86.67

OBA Long Lists

Barriers

Category	Individual Barriers
Negotiating an acceptable OBA design (e.g., what to measure, how to measure, complexity of design)	Measurement issues (what to measure, when to measure, who measures, and how to measure)
	Negotiation
	Decision-makers not fully understanding clinical complexity
	Protocols for OBAs duplicating available information
	Misalignment between OBA design and problem being addressed
	Complexity of OBP
	Time-intensive & resource intensive to design agreed-upon model
	Limited baseline data to set realistic targets and thresholds
	Using real-world data to understand the actual benefits of medicines for patients and adjusting their prices accordingly.
Lack of infrastructure for data collection and monitoring (registries, reporting mechanisms, etc.)	Lack of proper infrastructure, data gaps, etc.
	Need to standardise monitoring and reporting systems
	Lack of reporting data and follow-up
	Lack of existent infrastructure
	Significant investments in systems and legal work
	Lack of infrastructure or data
	Need for additional resources
	Cost of implementing infrastructure
	Lack of creativity and flexibility in overcoming the lack of infrastructure
Financial sustainability	Financial sustainability
Negative perception of OBAs and lack of trust among stakeholders	Lack of political will
	Unwillingness to establish contracts with long durations
	Negative perceptions of OBAs
	Stakeholders' engagement and trust
	Reluctance to move away from traditional payment models
	Inertia in the system against change
	Feasibility of aligning multiple stakeholders
Uncertainty in results (e.g., inconclusive evidence/findings or	Ensuring consistency among measures and over time
	Disputes on details of outcomes
	Inconsistencies in measuring outcomes
	Missing information needed for final assessment

inconsistent data quality and reporting across sites)	Potential for inconsistencies across HCPs
	Accuracy/quality of clinical data that can be collected
	Managing uncertainty
Financial management challenges (e.g., aligning payment schedules with fiscal years, managing delays)	VAT complicating payment
	Coordinating payment schedules with fiscal year
	Financial planning in the context of systems that don't allow for instalments
	Uncertainty in payments caused by outcome delays or inconclusive outcomes
	Potential for late payments and delayed outcome reporting
External changes (e.g., introduction of new therapeutic alternatives, or changes to healthcare affecting outcomes)	Difficulty establishing causality between intervention and outcomes
	Risk of choosing patients that can provide better outcomes
	Patient adherence
	Market, policy, or clinical practice shifts affecting outcomes
	Potential for new entry and indications
	New evidence is often available by the time the OBA is finished
Burden on clinical staff (educating staff, and administrative burden of data collection and data entry)	Difficulties in documenting outcomes for authorities
	High financial and organisational burden due to continuous monitoring
	Difficulties inputting data
	The vision of additional work without incentives
	Raising awareness for the need of data collection
	Lack of trained staff available to undertake administrative tasks
	Extra burden on clinical and admin teams
	Burden of educating providers and hospitals
	Data quality and governance
Rigid governance requirements (e.g., data confidentiality, independent oversight, etc.)	Confidentiality issues when patient numbers are very small
	Confidentiality hindering learning in the scientific community
	Independent oversight
Legal and regulatory hurdles	Legal and regulatory hurdles
	Fragmented HC system
Lack of leadership or experience to guide implementation	Lack of leadership and experience with the scheme
	Limited technical expertise on negotiating and operationalising IPMs
Legal disputes and inflexible contracting	Legal disputes
	Disputes on details of outcomes
	Unmet outcomes leading to legal disputes
	Inflexible contracting practices

Concern over risk-sharing distribution	Contracts seen as unfairly benefitting companies
	Willingness by industry to take on risks
	Difficulty in agreeing on how to allocate risks between stakeholders
Managing treatment (e.g., caseload, accrediting treatment centres, treatment alternatives)	Accrediting treatment centres
	Case management
	Delays in treatment leading to withdrawal from model due to strict timelines
	Lack of switch (e.g., to biosimilars)
	Frequent deviations on the criteria by prescribers
Reconciliation	Reconciliation
	Will final reconciliation trigger a payment?
Lack of effective mechanisms to wrap up OBA	Interruption of follow-up
	Disagreements about how to assess agreement success
	Open-ended IPMs (i.e., no end date or mechanisms to transition IPM to non-IPM)
	Alignment on data provided through IPM
High transaction costs	High transaction costs
	Impossibility to transfer share of transaction costs
Over-regulation of standardisation of data	Over-regulation of standardisation of data
Communication to all areas of the health system	Communication to all areas of the health system
Difficulties adapting payments/contracts to evolving understanding of therapies	Difficulties adapting payments/contracts to evolving understanding of therapies

Enablers

Categories	Individual Enablers
Sufficient infrastructure and funding (e.g., for data collection and management)	Pre-existing infrastructure
	Existent data registries
	Existence of a registry
	Adequate funding for any data collection and analysis
	Accredited treatment centres
	Efficient data infrastructure
	Automated data collection
	Pharmaceutical laboratory provides an infrastructure for data management
	Existence of feedback loops to allow for payments
	Justification of costs for benefits obtained after analysis of registry data

Data accuracy and optimisation to achieve OBA's goals	Comprehensive evaluation of available data sources and quality before design
Pre-existing frameworks, clinical experience, leadership, and real-world experience to guide implementation	Research on other system's experiences
	Standardised framework and models for OBA implementation
	Case study examination
	Scenario examination
	Agreed framework to follow
	Technical staff who are specialised in running and managing the implementation and follow-up of OBAs
	Step-by-step guides for operationalizing agreements
	Dedicated resources to facilitate organizational transition
	Written agreement outlining roles and responsibilities
	Using the pivotal trial variables
Willing and well-trained staff members (e.g., HCP, administrative staff, etc.)	HCP willingness to participate in the scheme
	Well-trained data collectors
	Well-trained and experienced teams
	Administrative support for the OBA
	Well-trained and experienced teams
	Third-party or dedicated staff to ensure coordination and harmonisation of data collection
	Company paying for any data that is required and ensuring that data is collected
	Need/desire from HCP to be recognized as the best
	Well-trained and experienced teams
	Financial incentives
Early stakeholder engagement and buy-in (e.g., agreement on goals, desire to use OBA to manage uncertainty, etc.)	Early involvement and conversations with major stakeholders
	High-level advocacy within each participating organization
	Frameworks that facilitate joint decision-making among all stakeholders
	Inter-team communication to drive harmonisation
	Desire to manage high upfront costs and long-term clinical uncertainty
	Desire to address unmet medical need
	Reduces financial uncertainty for manufacturers
	Risk-sharing reduces institutional hesitancy
	Political will
	Partnerships with different stakeholders
	Myth-busting
	Provides opportunity to further prove value of the product
	Managing uncertainty

	Previous successful experiences for clinicians and payers
	Collaborative governance
	Increased scientific production
	Pre-planning and midterm discussions
	Temporary nature of OBP can alleviate concerns about long-term complexities and burdens
Safeguards against misuse (e.g., independent third party, solid audit mechanisms)	Independent third party Efficient audit mechanisms and reporting systems Third-party providers (e.g., Lyfegen)
Solid mechanisms to wrap-up and close OBAs	Solid mechanisms to wrap-up and close OBAs once they have met their pre-defined goal
	Arrangements to review OBA progress and to determine when it can end
	Agreed methodologies for final assessment
	Tools to capture and organize lessons learned
Fair pricing	Fair prices
Good communication to communities who will be treated	Good communication to communities who will be treated
	Good communication on progress of scheme
	Data platform should be simple and transparent for all involved
Clear, accommodating legal and regulatory environment	Clear legal and regulatory guidelines
	Regulatory exceptions
Well-designed protocol	Defining the sources of uncertainty that need further evidence from OBA
	Determining how OBA will fill evidence gaps
	Set out conditions and timetable for the OBA
	Certainty about the need for implementation and patients benefit
	Obtaining real-world evidence that complements clinical trial data
	Standardised treatment protocols and designed formularies
	Simple outcomes that can be automatically or easily collected
	Standardized methodologies for identifying and prioritizing relevant outcomes
Clear, flexible contracts	Dispute settlement mechanisms
	Predefined legal mechanisms for adjusting payments based on outcomes
	Clear contracts
Upfront payments	Upfront payments

IBP Long Lists

Barriers

Categories	Individual Barriers
Designing optimal model (e.g., selection of most appropriate implementation model, complexity of design, details of regression model)	Details of regression models, including risk adjustment
	Complexity
	Agreement on regression models issued
	Single Ex-Factory Price (especially if same vial / packaging / presentation) used across several diseases
Lack of stakeholder buy-in or trust (e.g., loss of value surplus due to price discrimination, resistance to adopting new model)	Resistance to adopting new pricing models
	Lack of trust among stakeholders
	Perception of 'high cost' patients
	Loss of value surplus due to price discrimination
	Conceptual discordance between payment per unit sold and the concept of value-based pricing
Infrastructure and data limitations (e.g., billing infrastructure, use-tracking challenges, burden of data collection)	Billing infrastructure
	Burden of data collection
	Use-tracking challenges / data challenges
	Insufficient data infrastructure
	Lack of reliable information on indications for prescribing
	Lack of existing infrastructure for data collection
	Feasibility of using 'units' of products specifically for each indication
Challenges restricting prescription to the relevant authorised indications (i.e. prevention of arbitrage)	Difficulties containing prescription in authorised indications without P&R positive decisions
	Potential for off-label use
	Possibility of arbitrage
	Funding of approved indications that still do not have a P&R decision, or that are still in R&D phase
Legal and regulatory barriers (e.g., VAT complicating rebates, laws limiting use of IBP, lack of ability to use confidential rebates)	VAT complicating the rebate mechanisms
	Legal/regulatory barriers
	Lack of a general possibility to use confidential rebates
	VAT that cannot be refunded/rebated, but there is an expectation via the agreement that this will be covered by the manufacturer
	Discounts and rebates applied to the P&R-decided price that are generalized and massive distort rational approach to the issue
Uncertainty for future interventions (e.g., impact on future interventions and the	Potential for continued innovative entry and new competition
	Impact on future interventions

impact of new competition on product price at indication-level and the feasibility for scheme implementation)	Delays to the HTA process (and access) due to negotiation
	Evaluations of new products when IBP products are used as comparator
	Can make HTA decisions look perverse
	Future interventions for a given indication that do not have multiple indications might not be able to compete with high-indication comparators in an HTA
	Evaluation of new products when IBP products are used as comparator
Potential for price erosion	Potential for price erosion due to international reference pricing
Burden on healthcare system (e.g., administrative, educating HCP, resource requirements)	Administrative burden to manage contracts, payments, and tracking
	Presentation of too much information to HCPs on new indications
	Lack of understanding by physicians on reasons behind restrictions
	Complex models for payment by indication require resources to implement and are error-prone
	Resources required for devising multiple prices for the same drug
	Burden on health system in identifying use of a drug by indication and implementing regular changes to the price of a drug
Data reconciliation and price adjustment challenges (e.g., reconciling usage data with an updated price, unexpected outcomes leading to re-negotiations)	Reconciling usage data with an updated price
	Misallocation of usage within indications distorting blended average price
	Unexpected outcomes leading to re-negotiations
	Allocation of consumption and impact on blended price
	Potential for disputes on data quality
	Post-result negotiations
	Disagreement over consumption across indications
	Disagreement over which rebate or cap to use to calculate and updated price
	Price is unlikely to change except downwards

Enablers

Category	Individual Enablers
Established data infrastructure and monitoring systems (e.g., routine clinical	Pre-existing data collection/monitoring systems
	Reliable routine clinical data used to track use and invoicing
	Information availability

data used for tracking use, pre-existing data collection)	A fully funded, accessible data collection system
	Appropriate data collection methodology
Rational design and application of IBP (e.g., acceptance for weighted IBP, containing the granularity of indications, pre-established regression models, use of proxy data)	Acceptance for weighted IBP
	Containing the granularity of indications to make it more rational
	Pre-established regression models, including all necessary details such as risk adjustment
	Accepting approximations when data is not available
	Allowing grouping indication by disease
	Clear, consistent rules for IBP
	Matching indications to conventional clinical coding
Mechanisms for informed, inclusive implementation (e.g., stakeholder education, multi-stakeholder discussions, information sharing)	Information sharing
	Educating stakeholders on IBP
	Multi-stakeholder discussions
	Myth-busting
	Research on other system's experiences
	Case study examination
	Consultation scenario examination
	Inter-team communications
	Acceptance that the price can go up
	Inform and educate prescribers and clinical management on P&R implications
	HCP training
	Pre-planning and midterm discussions
Patient access	Patient access
Flexibility for use only in certain indications	Allowing payer to recommend IBP for a given indication
Safeguards against misuse (e.g., effective auditing mechanisms, clear arrangements preventing stakeholders from manipulating the system, confidentiality)	Effective auditing mechanisms
	Clear arrangements preventing stakeholder from manipulating the system to their own benefit
	Confidentiality
Transparency and communication	Good communication to communities who will be treated
	Good communication on progress of scheme
	Improved transparency on actual prices (discounts and rebates by indication) for pricing discussions
	A level of transparency on when IBP has been agreed and used in the HTA process
	Explaining to the operational NHS price differences
Conferring benefits onto involved hospitals and clinics	Transparent plan for sharing any savings with hospitals
	Where clinics collect data, feeding that back to the clinics in a useful way
Legal flexibilities	Legal flexibilities

Clear termination guidelines	An endpoint when no more data collection is needed
Relatively easy to segment patient population receiving the treatment	Relatively easy to segment patient population receiving the treatment

IaAPs Long Lists

Barriers

Category	Individual Barriers
Negotiating an acceptable model (e.g., complexity of design, choosing the optimal model, etc.)	Complexity
	Contract details
	Uncertainty of the best model to use
	Agreement on outcomes to measure
	Determining time horizon
	Negotiations in places of uncertainty
Stakeholder relations and trust (e.g., engaging all stakeholder, and lack of trust)	Lack of trust among stakeholders
	Need for involvement of all stakeholders
	Lack of willingness of payers to engage in instalment agreements or to commit to long term agreements when patients can switch between payers
	Uninterested payers when condition is incidence is high
Financial sustainability (e.g., budget impact, risk of high prices being hidden behind deferred payments)	Budget impact over the years regarding previous treatment
	Risk of hiding high prices behind deferred payments and uncertain outcomes
	Financial sustainability
	Financial sustainability for manufacturers
	Extremely high price proposals by companies
Complex financial management (e.g., coordinating payment schedules with fiscal years, dealing with uncertainty in payments or late payments, reconciling data and payments)	Uncertainty in payments or late payments
	Coordinating payment schedules with fiscal years
	Reconciliation of data and payment
	Reconciling discount rates and inflation if those factors were not originally considered in financial planning
	VAT and accounting issues due to periodization of payments
	Uncertainty in payments caused by outcome delays or inconclusive outcomes
Infrastructure and data limitations	Recording of data necessary for proper payments
	Collection of data
	Need for a unified clinical outcome monitoring system

	Potential burden on the operational NHS--or other healthcare system--in tracking and collecting those payment regularly over multiple years
	Lack of existing infrastructure that is conducive to payment model
	Difficulty preserving confidentiality of data
Innovation from new or improved drugs	Innovation from new or improved drugs
Legal and regulatory environment	Regulations that limit abilities of payers to engage in these agreements
	Fragmented healthcare systems
	Systems that do not allow or accommodate instalments
Case management	Outcome-based guarantee and payment in the event of patient mobility
	Difficulties inputting patient data in cases of patient mobility
Lack of experience or framework to guide implementation	Lack of experience
	Lack of framework
Budget Impact calculations	Budget Impact calculations
Contractual agreements	Contractual agreements

Enablers

Category	Individual Enablers
Existing infrastructure (e.g., data registries)	Existing infrastructure (e.g., data registries)
	Access to data
	Existence of outcome-based payback
Pre-existing experience or frameworks to guide implementation	Existing expertise/master protocol with local adaptation
	Clear definition of the key variables in the agreement (e.g., total value of the technology, number of years over which amortization is calculated and discount rate used)
	Flexibility to adapt master protocols to the actual available information already in the electronic records of each payer
	Predefined legal framework outlining protocol for late payments and adjusting payments to avoid future legal disputes
	If outcomes-based, clear inclusion criteria for patients and clearcut, hard, undisputable outcomes

	Repository of practical issues for information sharing across countries
Safeguards against misuse (e.g., independent oversight or effective auditing)	Independent third party (or automated system) overseeing implementation
	Effective auditing
	Third party (private) acting as a clearing house
Certainty about the need for implementation	Certainty about the need for implementation
Risk mitigation (i.e. managing high upfront costs and long-term clinical uncertainty, desire to improve odds of reimbursement)	Dilution of the cost over several economic periods
	Desire to manage high upfront costs and long-term clinical uncertainty
	Understanding by manufacturers that reimbursement may be refused unless on an agreement is reached
	Financial uncertainty addressed at the first instalment of the staged payment
	Additional financial mechanisms to mitigate additional risks at population level
	Management of uncertainty
	Re-evaluation of uncertainty
Perceived high unmet need	Perceived high unmet need
	High unmet need
Transparency and fair pricing	Transparency and fair pricing
Conditions of termination of the agreement if the technology fails during the amortization period	Conditions of termination of the agreement if the technology fails during the amortization period
Accommodating legal environment	Accommodating legal environment

FBRSAs Long Lists

Barriers

Category	Individual Barriers
Negotiating an acceptable FBRSA design (e.g., complexity of design, choosing the optimal model and reimbursement amount)	Negotiations
	Choosing the optimal model
	Very subject to the bargaining power of the 2 parties
	Complexity
	Challenges in establishing appropriate rebate triggers or payment thresholds
	Supply guarantee clauses involving financial risks
	Budget is fixed and not adjustable to value-based adjustments
	Use of very conservative hard caps

	Use of treatment in multiple indications with different prices (or not)
	Ability of public payers to coerce manufacturers
	Models based on overall cappings may incentivise irrational use
Infrastructure and data limitations (e.g., data needs, financial data collection challenges, agreeing on monitoring systems, coordinating volume-based agreements with several payers)	Lack of infrastructure
	Coordinating volume-based agreements in settings with several payers
	Financial data collection challenges
	Need for follow-up data
	Difficulties tracking relevant utilization
	Difficulties in monitoring results
	Challenges implementing specialized tracking and payment systems
	Difficulties forecasting consumption/volume
	Data
	Poor data infrastructure
	Difficulty accurately estimating volume of consumption
Lack of stakeholder trust or resistance to adopting a new model	Resistance to adopting this model
	Lack of trust among stakeholders
	Scepticism towards more capitalist approach
	An opaquer, results-oriented and cost-oriented model
	Different payers might delay the acquisition until discount level has changed
	In conflict with value-based pricing
	Involvement of all stakeholders
	Unequal access to data between payers and manufacturers
Financial sustainability and planning	Difficult financial management
	Sufficient budget is needed
	Discordance with existing financial planning processes
	Worries about resources required to manage the agreement
	Models where discounts are paid through product
	Slow uptake of medicines
	Internalised risk: high costs with low volumes
	When patient numbers are higher than expected, company becomes victim of its own success
Challenges for potential market evolution (e.g., evaluating new products using RSA-covered comparator, potential for new entry)	Evaluation of new products when products within agreements are used as comparators
	Entry of a similar product into the healthcare system

Disagreements over final payments or reconciliation	Reconciliation
	Outcomes different from those expected
	Return on financing lower than expected
	Disagreements about financial calculations and amounts owed
Duration of the agreement and potential revision/exit	Contract renewal and extension
	Differing views on appropriate continuation terms
	Duration of the agreement and potential revision / exit
	Limited duration
Lack of motivation	Lack of motivation from clinicians
	Lack of motivation
No existing adaptable framework to use as blueprint	Lack of infrastructure and framework
	Lack of framework
Legal and regulatory limitations	Legal restraints could limit these agreements (e.g., may not be allowed to commit payment in future years)
Rigid contracts	Elements introducing rigidity in the contract create risk

Enablers

Categories	Individual Enablers
Sufficient infrastructure (e.g., utilization databases) and funding	Historical utilization databases
	Large enough budget
	Infrastructure
	Dedicated financial management system
	Real-time financial dashboards
	Dedicated resources for adoption and transition costs.
	Horizon scanning to improve forecasts
	Sophisticated simulation software for scenario testing and risk projection
	Simple methodology for monitoring
Design of FBRSA (e.g., well-designed protocol, alignment on assumptions, clear threshold)	Well-designed program and clear threshold
	Alignment on hypothesis for patients, consumption, etc.
Capacity to reduce financial uncertainty	Reduces uncertainty around volume and usage
	Budget predictability
	Reduced pressure of cost-containment (incentive)
	Helps avoid penalties in case of stock-outs or failure to deliver on time

Fair prices	Fair prices
Safeguards against misuse (e.g., effective auditing mechanisms)	Effective audit mechanisms
Simplicity/ease of implementation (e.g., limited additional data required)	Low cost to implement
	Limited additional data collection required
	Easy adaptation and flexibility
Flexible contract terms	Flexible contract terms and periodic re-negotiations
	Reconciliation of payments in short cycles
	Flexible contract terms
Communication about scheme results, information, and lessons learned	Simple and clear reporting on sales volumes and delivery times
	Financial lessons learned repository
	Real-time information on usage
Framework for implementation	Framework and infrastructure
Stakeholder buy-in	Stakeholder support for such schemes
	Sense of 'good deal'
	Direct impact on the negotiation
Distributes costs across all users	Distributes costs across all users
Maintained vigilance along the years	Maintained vigilance along the years

PoBAs Long Lists

Barriers

Category	Individual Barriers
Negotiating an acceptable PoBA (e.g., complexity of design, choosing the optimal model)	Designing the agreement
	Negotiations
	Complexity
	Difficulties assigning cost to certain products
Infrastructure and data limitations (tracking usage, understanding real prices used)	Keeping the deal under control, regarding data (number of treatments p.e.) and real prices uses
	Tracking consumption across multiple products or indications
Budget impact (e.g., risk of increasing costs and potential burden on healthcare system)	Risk of increasing costs
	Incremental associated costs on the providers' side
	Shifting associated costs onto the providers' side
Reconciliation	Reconciliation
	Risk of missing data
Challenges with stakeholder relations and buy-in (e.g., stakeholder trust and	Lack of incentives for extending public funding of innovative medicines
	Lack of trust among stakeholders

engagement, secrecy concerns, resistance to extending public funding of innovative medicines)	Secrecy concerns (when agreements are made that cover more than one company)
	May require transparency that is uncomfortable for companies
Impact on future HTA (e.g., evaluating new products using covered comparator, aligning HTA and negotiations to prevent delays)	Impact on future HTA evaluations of new medicines
	Alignment of HTA and negotiations to prevent delays to access
Follow-up and defining criteria for contract extension	Follow-up
	End of agreement may require a further HTA review, creating capacity problem
	Unclear exit strategies
Limited patient and physician choice	Limited consumer choice
	Can be seen as a method of "forcing" physicians to specific prescription patterns
External changes affecting the terms of agreement	Newly launched drugs and incremental improvements in original drugs
	New entries competing for market share
Potential competition law issues	Complex competition law barriers
	Legal and regulatory barriers (e.g., anti-competition law)
	Risk of excluding competitors
Defining value and contract terms across multiple medicines	Defining and splitting value across multiple treatments
	Can lead to tricky discussions when approaching bundling agreements
	Particular complexity where the bundle concerns medicines from multiple companies
	Difficulty understanding which medicines will drive revenues/expenditures
	For pipeline deals, uncertainty on the future indication value in general--and relative to current indication value in particular
Interactions between various financial mechanisms	Interactions between various financial mechanisms
Burden on health system	Burden on health systems if agreement requires additional information or action
	High transactional cost
Reduced transparency	Reduced transparency
Limited real-life experience	Limited real-life experience
Different timelines and/or contracts	Different timelines and/or contracts
Impact of negotiations on timeliness of HTA evaluation and speed of patient access	Impact of negotiations on timeliness of HTA evaluation and speed of patient access

Enablers

Category	Individual Enablers
Early dialogue between stakeholders	Early dialogue between stakeholders
Budget predictability (i.e. of costs and revenues) and affordability	Affordability
	Predictability of costs/revenues
Increased patient access to complementary technologies	Increased patient access to complementary technologies
	Products that may not have been assessed as cost-effective can become cost-effective in bundles
Clear end points when patents expire	Clear end points when patents expire
Regulatory exceptions	Regulatory exceptions
Enhanced financial planning and collaboration (e.g., improved methodology of budget impact assessment and transparent shared funding schemes)	Improved methodology of the budget impact assessment
	Transparent shared funding schemes with participation of the national authorities/payer
Capacity building	Capacity building
Data sharing	Data sharing
Transparent and fair support for providers	Transparent and fair support for providers
Good logistic and control practices	Good logistic and control practices
Improved awareness about the value-added of innovative medicines	Improved awareness about the value-added of innovative medicines
Low competition in cases of complicated production and/or low volume	In case of complicated production and / or low volume even without a patent protection, competition will be low

Survey Questionnaire

Pricing and payment models play a central role in balancing the sustainability of health innovation with the sustainability of health care systems. HI-PRIX (Health Innovation Next Generation Payment & Pricing Models) is an EU-funded project that aims to develop policy recommendations that can guide EU member states in applying Innovative Pricing and Payment Models (IPMs) in a variety of contexts (e.g., across technology classes, therapeutic areas, healthcare systems, etc.). As part of this objective, the Office of Health Economics (OHE) is conducting this survey to learn more about various IPMs and the barriers and enablers that can impact their implementation.

As such, this survey will ask you to reflect on the barriers and enablers of implementing five different IPMs. The table below lists these five IPMs and how we define them.

IPM	Description
Outcomes-Based Agreement	Payment is tied to clinical outcomes achieved in real-world practice.
Financial-Based Risk Sharing Agreement	The unit price of the product depends on the volume purchased. These can be implemented at the population-level, such as in a price-volume agreement or volume-delinked subscription model, or on the patient-level, such as in utilization caps.
Portfolio or Bundling Agreement	A 'bundle' or 'portfolio' of two or more medicines are purchased at an agreed 'overall' price.
Instalment Payments or Amortization	Payments are split into several instalments spread over time. Instalments can be risk-sharing. Split payments may or may not be outcomes-based.
Indication-Based Pricing	The price of the medicine depends on the subgroup (or 'indication') in which it is used.

In reference to barriers and enablers, we use the following definitions:

> Barriers - Barriers are obstacles that hinder or prevent the implementation of innovative payment models. While implementation costs are not inherently barriers, they become so when they obstruct adoption. For example, significant time investments or legal expenses may discourage stakeholders from adopting a particular model, or the cost of a new data monitoring system may impede effective implementation.

Enablers – Enablers are factors that facilitate the implementation of innovative payment models. While benefits are not always enablers, they become so when they actively support adoption. For example, if a new payment model aligns with good financial or healthcare management practices, organisations may see it as a responsible and worthwhile approach, increasing the chances of implementation.

We will ask you to reflect on four different phases of implementation for each IPM. These are listed and defined below.

1. Inception & design: The phase in which stakeholders design and choose the IPM and determine the specific objectives of the IPM. This could include negotiating and agreeing on the IPM.
2. Adoption: The phase in which the IPM is set up. For example, this might include the establishment of necessary infrastructure for collecting data and monitoring outcomes, upskilling staff, accrediting treatment centres, etc.
3. Sustainment & maintenance: The phase involving the ongoing operation of the scheme during which the use of the product is covered under the IPM. This could include ongoing costs resulting from additional data collection on usage or outcomes, for instance.
4. Wrapping up & closing: The phase in which the product is no longer covered under the IPM, but there could be additional work related to the reconciliation of payments, costs, investments, etc.

When answering survey questions asking you to match barriers and enablers to their respective phases, please consider which phase(s) each barrier/enabler affects. For instance, periodic renegotiation clauses, though established in Phase 1, affect Phase 3, as they support the maintenance and sustainment of the IPM and help prevent future contract disputes.

Your input will contribute to a better understanding of innovative payment models. Every response – no matter how comprehensive – will add value to this research. Thank you in advance for your time and contributions.

Section 1: About You

Survey Section	Question	Response Type	Response options (if relevant)
1	Name	Free text	
	Please select the option(s) that best describe(s) the perspective(s) from which you have engaged with an IPM or with the concept of IPMs?	Multiple choice	*a) Payer* *b) HTA* *c) healthcare commissioner* *d) policymaker* *e) regulator* *f) manufacturer* *g) data expert* *h) provider* *i) pharmacist* *j) physician* *k) patient* *l) academic* *m) other (please specify)*
	In which country/countries do you primarily have expertise/experience in?	Multiple choice	Countries respondents selected from: • UK • Austria • Estonia • France • Germany • Lithuania • Poland • Spain • Sweden

			• Pan-European expert • Theoretical experience • Other (please specify)
	Please provide a description of your experience in working with IPMs	Free text	-

Section 2: Outcomes-based agreements

The following tables include barriers/enablers for outcomes-based agreements that we have identified through a series of case studies conducted by the OHE, along with a review of existing literature on outcomes-based agreements.

Phase	Barriers
Phase 1: Inception & Design	• Complexity of OBAs and uncertainty about protocol (e.g., when to measure and what to measure)
Phase 2: Adoption	• Lack of existing infrastructure (e.g., data registries, reporting mechanisms, etc.)
Phase 3: Sustainment & Maintenance	• Inconsistencies in patient care and reporting, making it difficult to standardise outcomes
Phase 4: Wrapping Up & Closing	• Reconciling inflation and discounting (if not initially considered)

Phase	Enablers
Phase 1: Inception & Design	• Early involvement and conversations with major stakeholders
Phase 2: Adoption	• Pre-existing infrastructure (e.g., data registries)
Phase 3: Sustainment & Maintenance	• Well-trained healthcare professionals and clinical teams ensuring accurate data collection
Phase 4: Wrapping Up & Closing	• Efficient audit mechanisms and reporting systems can ensure smooth conclusion of the program

Survey Section	Question	Response Type	Response options (if relevant)
2	How would you rate your level of expertise in outcomes-based agreements?	Multiple choice	a. *No experience (no exposure);* b. *Minimal experience (basic familiarity or some indirect exposure);* c. *Moderate experience (some involvement or practical understanding);* d. *Significant experience (extensive involvement);* e. *Expert (recognized authority in this IPM, extensive experience leading or shaping implementation)*
2.1: Barriers	We have identified several barriers that may hinder the implementation of outcomes-based agreements. The table above provides examples of these barriers, organised by the implementation phase they may impact. In the next questions, we will ask you to review these barriers, confirm their relevance, and suggest any additional ones for each phase. If a barrier applies to multiple phases, please include it in each relevant phase.	[No response; this is just instruction to precede the following questions]	n/a
2.1: Barriers	Phase 1: Inception & Design	Comment Box	
2.1: Barriers	Phase 2: Adoption	Comment Box	

2.1: Barriers	Phase 3: Sustainment & Maintenance	Comment Box	
2.1: Barriers	Phase 4: Wrapping Up & Closing	Comment Box	
2.1: Barriers	Please identify the barrier that is most challenging to overcome for each phase of implementation of outcomes-based agreements. Please provide at least one answer for any phase.	Multiple textboxes	Label 1: Phase 1: Inception & Design Label 2: Phase 2: Adoption Label 3: Phase 3: Sustainment & Maintenance Label 4: Phase 4: Wrapping up & Closing
2.1: Barriers	Of the barriers you have identified AND we have identified, which are the most challenging to overcome and why? Please list up to three from any phase of implementation.	Multiple textboxes	Label 1: Most difficult barrier to overcome Label 2: Second-most difficult barrier to overcome Label 3: Third-most difficult barrier to overcome
2.2: Enablers	We have identified several enablers that may facilitate the implementation of outcomes-based agreements. The table above provides examples of these enablers, organised by the implementation phase they may impact. In the next questions, we will ask you to review these enablers, confirm their relevance, and suggest any additional ones for each phase. If an enabler applies to	[No response; this is just instruction to precede the following questions]	n/a

	multiple phases, please include it in each relevant phase.		
2.2: Enablers	Phase 1: Inception & Design	Comment Box	
2.2: Enablers	Phase 2: Adoption	Comment Box	
2.2: Enablers	Phase 3: Sustainment & Maintenance	Comment Box	
2.2: Enablers	Phase 4: Wrapping Up & Closing	Comment Box	
2.2: Enablers	Please identify the enabler that is most important in facilitating each phase of implementation for outcomes-based agreements. Please provide at least one answer for any phase.	Multiple textboxes	Label 1: Phase 1: Inception & Design Label 2: Phase 2: Adoption Label 3: Phase 3: Sustainment & Maintenance Label 4: Phase 4: Wrapping up & Closing
2.2: Enablers	Of the enablers you have identified AND we have identified, which are the most important and why? Please list up to three from any phase of implementation.	Multiple textboxes	Label 1: Most effective enabler Label 2: Second-most effective barrier Label 3: Third-most effective barrier

Section 3: Financial-based risk-sharing agreements

The following tables include barriers/enablers for financial-based risk-sharing agreements that we have identified through a series of case studies conducted by the OHE, along with a review of existing literature on financial-based risk-sharing agreements.

Phase	Barriers

Phase 1: Inception & Design	• Budget is fixed and not amendable to value-based adjustments (disincentive)
Phase 2: Adoption	• Resistance to adopting a new payment model
Phase 3: Sustainment & Maintenance	• Supply guarantee clauses involving financial risks to stakeholders' plan
Phase 4: Wrapping Up & Closing	• Disagreements over final payments or reconciliations

Phase	**Enablers**
Phase 1: Inception & Design	• Reduces uncertainty around volume and usage (incentive)
Phase 2: Adoption	• Generally low cost to implement
Phase 3: Sustainment & Maintenance	• Flexible contract terms and periodic re-negotiations
Phase 4: Wrapping Up & Closing	• Effective auditing mechanisms

Survey Section	**Question**	**Response Type**	**Response options (if relevant)**
3	How would you rate your level of expertise in financial-based risk-sharing agreements?	Multiple choice	*f. No experience (no exposure);* *g. Minimal experience (basic familiarity or some indirect exposure);* *h. Moderate experience (some involvement or practical understanding);* *i. Significant experience (extensive involvement);* *j. Expert (recognized authority in this IPM, extensive*

			experience leading or shaping implementation)
3.1: Barriers	We have identified several barriers that may hinder the implementation of financial-based risk-sharing agreements. The table above provides examples of these barriers, organised by the implementation phase they may impact. In the next questions, we will ask you to review these barriers, confirm their relevance, and suggest any additional ones for each phase. If a barrier applies to multiple phases, please include it in each relevant phase.	[No response; this is just instruction to precede the following questions]	n/a
3.1: Barriers	Phase 1: Inception & Design	Comment Box	
3.1: Barriers	Phase 2: Adoption	Comment Box	
3.1: Barriers	Phase 3: Sustainment & Maintenance	Comment Box	
3.1: Barriers	Phase 4: Wrapping Up & Closing	Comment Box	
3.1: Barriers	Please identify the barrier that is most challenging to overcome for each phase of implementation of financial-based risk-sharing agreements. Please provide at least one answer for any phase.	Multiple textboxes	Label 1: Phase 1: Inception & Design Label 2: Phase 2: Adoption Label 3: Phase 3: Sustainment & Maintenance Label 4: Phase 4: Wrapping up & Closing

3.1: Barriers	Of the barriers you have identified AND we have identified, which are the most challenging to overcome and why? Please list up to three from any phase of implementation.	Multiple textboxes	Label 1: Most difficult barrier to overcome Label 2: Second-most difficult barrier to overcome Label 3: Third-most difficult barrier to overcome
3.2: Enablers	We have identified several enablers that may facilitate the implementation of financial-based risk-sharing agreements. The table above provides examples of these enablers, organised by the implementation phase they may impact. In the next questions, we will ask you to review these enablers, confirm their relevance, and suggest any additional ones for each phase. If an enabler applies to multiple phases, please include it in each relevant phase.	[No response; this is just instruction to precede the following questions]	n/a
3.2: Enablers	Phase 1: Inception & Design	Comment Box	
3.2: Enablers	Phase 2: Adoption	Comment Box	
3.2: Enablers	Phase 3: Sustainment & Maintenance	Comment Box	
3.2: Enablers	Phase 4: Wrapping Up & Closing	Comment Box	
3.2: Enablers	Please identify the enabler that is most important in facilitating each phase of implementation for financial-based risk-sharing agreements. Please	Multiple textboxes	Label 1: Phase 1: Inception & Design Label 2: Phase 2: Adoption

	provide at least one answer for any phase.		Label 3: Phase 3: Sustainment & Maintenance Label 4: Phase 4: Wrapping up & Closing
3.2: Enablers	Of the enablers you have identified AND we have identified, which are the most important and why? Please list up to three from any phase of implementation.	Multiple textboxes	Label 1: Most effective enabler Label 2: Second-most effective barrier Label 3: Third-most effective barrier

Section 4: Portfolio or bundling agreement

The following tables include barriers/enablers for portfolio or bundling agreements that we have identified through a series of case studies conducted by the OHE, along with a review of existing literature on portfolio or bundling agreements.

Phase	Barriers
Phase 1: Inception & Design	• Complex and lengthy negotiations
Phase 2: Adoption	• Difficulties in defining value across multiple medicines
Phase 3: Sustainment & Maintenance	• Risks of increasing costs due to increasing number of patients or longer treatments
Phase 4: Wrapping Up & Closing	• Disagreements over final payments or reconciliations

Phase	Enablers
Phase 1: Inception & Design	• Predictability of revenue/payments might incentivize involvement
Phase 2: Adoption	• Regulatory exceptions or pathways for bundled medicines
Phase 3: Sustainment & Maintenance	• Access to more than one innovation or health technology

Phase 4: Wrapping Up & Closing	• Clear end point when patents expire

Survey Section	Question	Response Type	Response options (if relevant)
4	How would you rate your level of expertise in portfolio or bundling agreements?	Multiple choice	*k. No experience (no exposure);* *l. Minimal experience (basic familiarity or some indirect exposure);* *m. Moderate experience (some involvement or practical understanding);* *n. Significant experience (extensive involvement);* *o. Expert (recognized authority in this IPM, extensive experience leading or shaping implementation)*
4.1: Barriers	We have identified several barriers that may hinder the implementation of portfolio or bundling agreements. The table above provides examples of these barriers, organised by the implementation phase they may impact. In the next questions, we will ask you to review these barriers, confirm their relevance, and suggest any additional ones for each phase. If a barrier applies to multiple phases, please include it in each relevant phase.	[No response; this is just instruction to precede the following questions]	n/a
4.1: Barriers	Phase 1: Inception & Design	Comment Box	

4.1: Barriers	Phase 2: Adoption	Comment Box	
4.1: Barriers	Phase 3: Sustainment & Maintenance	Comment Box	
4.1: Barriers	Phase 4: Wrapping Up & Closing	Comment Box	
4.1: Barriers	Please identify the barrier that is most challenging to overcome for each phase of implementation of portfolio or bundling agreements. Please provide at least one answer for any phase.	Multiple textboxes	Label 1: Phase 1: Inception & Design Label 2: Phase 2: Adoption Label 3: Phase 3: Sustainment & Maintenance Label 4: Phase 4: Wrapping up & Closing
4.1: Barriers	Of the barriers you have identified AND we have identified, which are the most challenging to overcome and why? Please list up to three from any phase of implementation.	Multiple textboxes	Label 1: Most difficult barrier to overcome Label 2: Second-most difficult barrier to overcome Label 3: Third-most difficult barrier to overcome
4.2: Enablers	We have identified several enablers that may facilitate the implementation of portfolio or bundling agreements. The table above provides examples of these enablers, organised by the implementation phase they may impact. In the next questions, we will ask you to review these enablers, confirm their relevance, and suggest any additional ones for each phase. If an enabler applies to multiple phases, please include it in each relevant phase.	[No response; this is just instruction to precede the following questions]	n/a

4.2: Enablers	Phase 1: Inception & Design	Comment Box	
4.2: Enablers	Phase 2: Adoption	Comment Box	
4.2: Enablers	Phase 3: Sustainment & Maintenance	Comment Box	
4.2: Enablers	Phase 4: Wrapping Up & Closing	Comment Box	
4.2: Enablers	Please identify the enabler that is most important in facilitating each phase of implementation for portfolio or bundling agreements. Please provide at least one answer for any phase.	Multiple textboxes	Label 1: Phase 1: Inception & Design Label 2: Phase 2: Adoption Label 3: Phase 3: Sustainment & Maintenance Label 4: Phase 4: Wrapping up & Closing
4.2: Enablers	Of the enablers you have identified AND we have identified, which are the most important and why? Please list up to three from any phase of implementation.	Multiple textboxes	Label 1: Most effective enabler Label 2: Second-most effective barrier Label 3: Third-most effective barrier

Section 5: Instalment payments or amortizations

The following tables include barriers/enablers for instalment payments or amortizations that we have identified through a series of case studies conducted by the OHE, along with a review of existing literature on instalment payments or amortizations.

Phase	Barriers

Phase 1: Inception & Design	• Financial planning in the context of systems that don't allow for instalments or only allow instalments for a limited number of years
Phase 2: Adoption	• Complexity of IPM design: uncertainty about optimal payment timepoints and quantities
Phase 3: Sustainment & Maintenance	• Potential for late payments
Phase 4: Wrapping Up & Closing	• Coordinating payment schedules with fiscal years

Phase	**Enablers**
Phase 1: Inception & Design	• A desire to manage uncertainty of high upfront costs and long-term clinical uncertainty can incentivise use of instalment payments or amortizations
Phase 2: Adoption	• Existing infrastructure (e.g., automated payment processing)
Phase 3: Sustainment & Maintenance	• Clear, predefined legal framework outlining protocol for late payments and adjusting payments to avoid future legal disputes
Phase 4: Wrapping Up & Closing	• Effective auditing mechanisms

Survey Section	**Question**	**Response Type**	**Response options (if relevant)**
5	How would you rate your level of expertise in financial-based risk-sharing agreements?	Multiple choice	*p. No experience (no exposure);* *q. Minimal experience (basic familiarity or some indirect exposure);* *r. Moderate experience (some involvement or practical understanding);* *s. Significant experience (extensive involvement);* *t. Expert (recognized authority in this IPM, extensive experience leading or shaping implementation)*

5.1: Barriers	We have identified several barriers that may hinder the implementation of instalment payments or amortizations. The table above provides examples of these barriers, organised by the implementation phase they may impact. In the next questions, we will ask you to review these barriers, confirm their relevance, and suggest any additional ones for each phase. If a barrier applies to multiple phases, please include it in each relevant phase.	[No response; this is just instruction to precede the following questions]	n/a
5.1: Barriers	Phase 1: Inception & Design	Comment Box	
5.1: Barriers	Phase 2: Adoption	Comment Box	
5.1: Barriers	Phase 3: Sustainment & Maintenance	Comment Box	
5.1: Barriers	Phase 4: Wrapping Up & Closing	Comment Box	
5.1: Barriers	Please identify the barrier that is most challenging to overcome for each phase of implementation of instalment payments or amortizations. Please provide at least one answer for any phase.	Multiple textboxes	Label 1: Phase 1: Inception & Design Label 2: Phase 2: Adoption Label 3: Phase 3: Sustainment & Maintenance Label 4: Phase 4: Wrapping up & Closing
5.1: Barriers	Of the barriers you have identified AND we have identified, which are	Multiple textboxes	Label 1: Most difficult barrier to overcome

	the most challenging to overcome and why? Please list up to three from any phase of implementation.		Label 2: Second-most difficult barrier to overcome Label 3: Third-most difficult barrier to overcome
5.2: Enablers	We have identified several enablers that may facilitate the implementation of instalment payments or amortizations. The table above provides examples of these enablers, organised by the implementation phase they may impact. In the next questions, we will ask you to review these enablers, confirm their relevance, and suggest any additional ones for each phase. If an enabler applies to multiple phases, please include it in each relevant phase.	[No response; this is just instruction to precede the following questions]	n/a
5.2: Enablers	Phase 1: Inception & Design	Comment Box	
5.2: Enablers	Phase 2: Adoption	Comment Box	
5.2: Enablers	Phase 3: Sustainment & Maintenance	Comment Box	
5.2: Enablers	Phase 4: Wrapping Up & Closing	Comment Box	
5.2: Enablers	Please identify the enabler that is most important in facilitating each phase of implementation for instalment payments or	Multiple textboxes	Label 1: Phase 1: Inception & Design Label 2: Phase 2: Adoption Label 3: Phase 3: Sustainment & Maintenance Label 4: Phase 4: Wrapping up & Closing

	amortizations. Please provide at least one answer for any phase.		
3.2: Enablers	Of the enablers you have identified AND we have identified, which are the most important and why? Please list up to three from any phase of implementation.	Multiple textboxes	Label 1: Most effective enabler Label 2: Second-most effective barrier Label 3: Third-most effective barrier

Section 6: Indication-based pricing

The following tables include barriers/enablers for indication-based pricing that we have identified through a series of case studies conducted by the OHE, along with a review of existing literature on indication-based pricing.

Phase	Barriers
Phase 1: Inception & Design	• Legal/regulatory environment (e.g., rules requiring manufacturers to offer lowest-indication price across all indications)
Phase 2: Adoption	• Challenges in billing infrastructure (e.g. if implemented through rebates)
Phase 3: Sustainment & Maintenance	• Data collection can be a significant burden to the healthcare workers or providing patient care
Phase 4: Wrapping Up & Closing	• Reconciling usage data with an updated price (e.g. where IBP is facilitated through a blended / average weighted price)

Phase	Enablers
Phase 1: Inception & Design	• Educating stakeholders on IBP and multi-stakeholder discussions
Phase 2: Adoption	• Pre-existing data collection/monitoring systems for products at indication level

Phase 3: Sustainment & Maintenance	• Information-sharing among all stakeholders
Phase 4: Wrapping Up & Closing	• Effective auditing mechanisms

Survey Section	Question	Response Type	Response options (if relevant)
6	How would you rate your level of expertise in indication-based pricing?	Multiple choice	u. *No experience (no exposure);* v. *Minimal experience (basic familiarity or some indirect exposure);* w. *Moderate experience (some involvement or practical understanding);* x. *Significant experience (extensive involvement);* y. *Expert (recognized authority in this IPM, extensive experience leading or shaping implementation)*
6.1: Barriers	We have identified several barriers that may hinder the implementation of indication-based pricing. The table above provides examples of these barriers, organised by the implementation phase they may impact. In the next questions, we will ask you to review these barriers, confirm their	[No response; this is just instruction to precede the following questions]	n/a

	relevance, and suggest any additional ones for each phase. If a barrier applies to multiple phases, please include it in each relevant phase.		
6.1: Barriers	Phase 1: Inception & Design	Comment Box	
6.1: Barriers	Phase 2: Adoption	Comment Box	
6.1: Barriers	Phase 3: Sustainment & Maintenance	Comment Box	
6.1: Barriers	Phase 4: Wrapping Up & Closing	Comment Box	
6.1: Barriers	Please identify the barrier that is most challenging to overcome for each phase of implementation of indication-based pricing. Please provide at least one answer for any phase.	Multiple textboxes	Label 1: Phase 1: Inception & Design Label 2: Phase 2: Adoption Label 3: Phase 3: Sustainment & Maintenance Label 4: Phase 4: Wrapping up & Closing
6.1: Barriers	Of the barriers you have identified AND we have identified, which are the most	Multiple textboxes Most difficult barrier to overcome Second-most difficult barrier to overcome Third-most difficult barrier to overcome	Label 1: Most difficult barrier to overcome Label 2: Second-most difficult barrier to overcome Label 3: Third-most difficult barrier to overcome

	challenging to overcome and why? Please list up to three from any phase of implementation.		
6.2: Enablers	We have identified several enablers that may facilitate the implementation of indication-based pricing. The table above provides examples of these enablers, organised by the implementation phase they may impact. In the next questions, we will ask you to review these enablers, confirm their relevance, and suggest any additional ones for each phase. If an enabler applies to multiple phases, please include it in each relevant phase.	[No response; this is just instruction to precede the following questions]	n/a
6.2: Enablers	Phase 1: Inception & Design	Comment Box	

6.2: Enablers	Phase 2: Adoption	Comment Box	
6.2: Enablers	Phase 3: Sustainment & Maintenance	Comment Box	
6.2: Enablers	Phase 4: Wrapping Up & Closing	Comment Box	
6.2: Enablers	Please identify the enabler that is most important in facilitating each phase of implementation for indication-based pricing. Please provide at least one answer for any phase.	Multiple textboxes	Label 1: Phase 1: Inception & Design Label 2: Phase 2: Adoption Label 3: Phase 3: Sustainment & Maintenance Label 4: Phase 4: Wrapping up & Closing
6.2: Enablers	Of the enablers you have identified AND we have identified, which are the most important and why? Please list up to three from any phase of implementation.	Multiple textboxes	Label 1: Most effective enabler Label 2: Second-most effective barrier Label 3: Third-most effective barrier

Section 7: Additional Insights

Survey Section	Question	Response Type	Response options (if relevant)

7.1: Additional IPMs	Do you have experience with any other innovative payment models that were not captured in this survey?	Multiple Choice	Yes No
	Please identify and briefly describe this IPM. If you wish to provide information on multiple additional payment models, please specify which payment you are referring to when you respond to the questions in the remainder of this section.	Free text	
	In the next questions, we will ask you to suggest barriers for this innovative payment model, by implementation phase. If a barrier applies to multiple phases, please include it in each relevant phase.	[No response; this is just instruction to precede the following questions]	n/a
	Phase 1: Inception & Design	Comment Box	
	Phase 2: Adoption	Comment Box	
	Phase 3: Sustainment & Maintenance	Comment Box	
	Phase 4: Wrapping Up & Closing	Comment Box	
	Please identify the barrier that is most challenging to overcome for each phase of implementation for this IPM. Please provide at least one answer for any phase.	Multiple textboxes	Label 1: Phase 1: Inception & Design Label 2: Phase 2: Adoption Label 3: Phase 3: Sustainment & Maintenance Label 4: Phase 4: Wrapping Up & Closing
	Of the barriers you identified, which are the most challenging to overcome and why? Please list up to 3 from any phase of implementation.	Multiple textboxes	Label 1: Most difficult barrier to overcome Label 2: Second-most difficult barrier to overcome

			Label 3: Third-most difficult barrier to overcome
	In the next questions, we will ask you to suggest enablers for this innovative payment model by implementation phase. If an enabler applies to multiple phases, please include it in each relevant phase.	[No response; this is just instruction to precede the following questions]	n/a
	Phase 1: Inception & Design	Comment box	
	Phase 2: Adoption	Comment box	
	Phase 3: Sustainment & Maintenance	Comment box	
	Phase 4: Wrapping Up & Closing	Comment box	
	Please identify the enabler that is most important in facilitating each phase of implementation for this IPM. Please provide at least one answer for any phase.	Multiple textboxes	Label 1: Phase 1: Inception & Design Label 2: Phase 2: Adoption Label 3: Phase 3: Sustainment & Maintenance Label 4: Phase 4: Wrapping Up & Closing
	Of the enablers you have identified, which are the most important and why? Please list up to 3 from any phase of implementation.	Multiple textboxes	Label 1: Most effective enabler Label 2: Second-most effective barrier Label 3: Third-most effective barrier
7.2 Additional comments	Are there any barriers to implementation that affect IPMs more broadly that you would like to note? Please indicate whether this affects a particular phase of implementation.	Free text	-
	Are there any enablers that affect IPMs more broadly that you would like to note? Please indicate whether this	Free text	-

	affects a particular phase of implementation.		
	Is there anything else that you would like to add?	Free text	-
	After this survey, we will conduct a roundtable to build consensus on the barriers and enablers of payment models and gather insights for policy recommendations, using an adapted nominal group technique. A sub-set of survey respondents will be invited to participate. Are you interested in participating in the roundtable?	Multiple Choice	Yes No
	Thank you for taking the time to complete this survey. Your contributions to our research are greatly appreciated.	No response.	