

DOLON

A collaborative approach to optimising managed entry agreements for innovative therapies

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Confidential

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Disclaimers

- The Value-Based Negotiation Framework has been originally developed by Amanda Whittal, Claudio Jommi, Gérard De Pourville, David Taylor, Lieven Annemans, Lies Schoonaert, Sebastian Vermeersch, Adam Hutchings and Julien Patris with the financial support of Alnymam Pharmaceuticals
- The Value-Based Negotiation Framework mock-up negotiations have been conducted by Dolon and Hict, with the support of Alnyam Pharmaceuticals, argenx, Ultragenyx
- The VBNF Experimental Research has been conducted by ESSEC Business School with the financial support of Alnylam

We live at the age of breakthrough innovation and biotech renaissance...

The New York Times Magazine

Suddenly, It Looks Like We're in a Golden Age for Medicine

We may be on the cusp of an era of astonishing innovation — the limits of which aren't even clear yet.




Illustration by Ibrahim Rayintakath

By David Wallace-Wells

June 23, 2023

- Evolving understanding of biology and disease pathophysiology are opening the door to targeted therapeutic approaches
- Cutting-edge technologies are leading to unprecedented, disease-modifying treatments (e.g., cell and gene therapies)
- Emergence of new research and development models and advancements in the field of computational science and artificial intelligence
- New generation of biotech companies with a focus on developing treatments for rare and severe diseases, or high unmet need patient populations

...but access to innovation is increasingly complex and often delayed or not possible at all

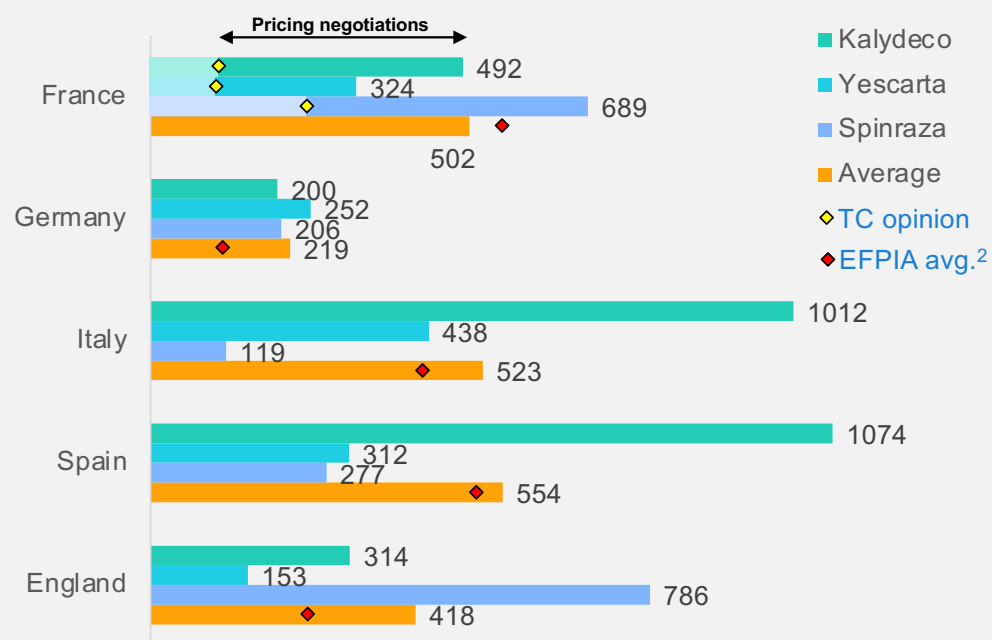
Delayed or endangered time to access

Clinical and budget uncertainties can prolong time to access, or in worst cases prevent access altogether

Lack of alignment between manufacturers and P&R bodies can lead to lengthy pricing negotiations, potentially delaying access significantly

Better structured agreements have the potential to allow faster access for products, by shortening price negotiation processes (often the most time-consuming part of the P&R process)

Examples of delayed time to access for orphan products (days from EMA authorization to price publication*) in EU-51



*Methodological differences between this analysis and the EFPIA study explain the delta observed for Germany. While not explicitly stated, the EFPIA study likely considered an earlier timepoint for end of procedure.

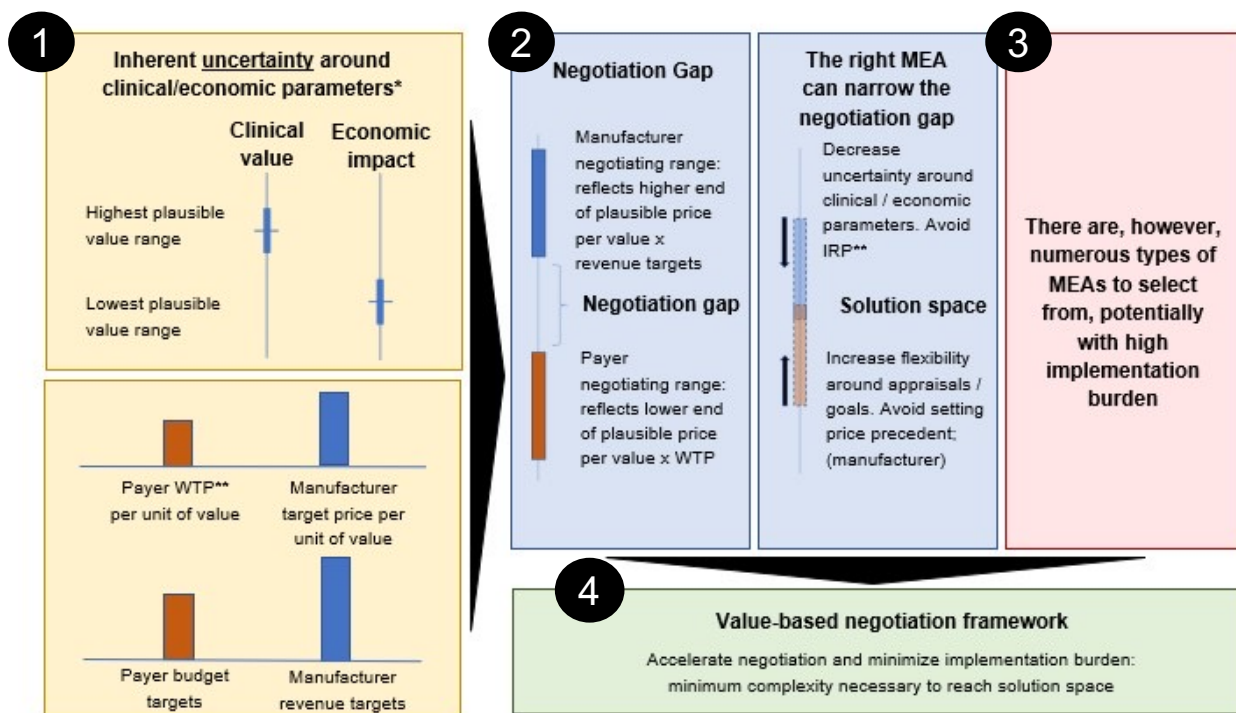
1. Dolon analysis based on data available from EMA ([https://www.ema.europa.eu/en/medicines/download-medicine-data#european-public-assessment-reports-\(epar\)-section](https://www.ema.europa.eu/en/medicines/download-medicine-data#european-public-assessment-reports-(epar)-section)), Legifrance (<https://www.legifrance.gouv.fr>), G-BA (<https://www.g-ba.de/bewertungsverfahren/nutzenbewertung/>), Gazzetta Ufficiale (<https://www.gazzettaufficiale.it/>), BotPlus (<https://botolusweb.portalfarma.com/>), NICE (<https://www.nice.org.uk/guidance>)

2. EFPIA Patient W.A.I.T. Indicator 2018 survey, <https://www.efpia.eu/media/412747/efpia-patient-wait-indicator-study-2018-results-030419.pdf>

A collaborative, pragmatic and transparent approach based on a common language could help address this issue by facilitating more efficient negotiations and agreements



The 'value-based negotiation framework' (VBNF) aims to provide a structured framework to address uncertainties, while balancing payer/manufacture contexts and constraints



*Figures not intended to represent actual quantification of uncertainty
 **WTP= Willingness to pay; IRP = International reference pricing

- 1. Inherent uncertainty** around clinical and economic parameters
- 2. Negotiation gaps** due to asymmetric information & conflicting goals
- 3. Wide variety of MEA mechanisms** that could potentially help, all with different resource requirements
- 4. But breadth of MEA options, MEA complexity and asymmetric impact** of MEA can make negotiations inherently complex

The VBNF can help navigate these options in a faster, more transparent way

The VBNF aims to better structure negotiations of MEAs for innovative therapies in a pragmatic way

Goals of the framework

- ✓ Help identify cases when MEAs are appropriate to use



- ✓ Support identification of priority P&R risks & contract terms to address these risks



- ✓ Accelerate negotiations by offering a structured approach & a common language



- ✓ Adaptable to different country systems



Practical Considerations

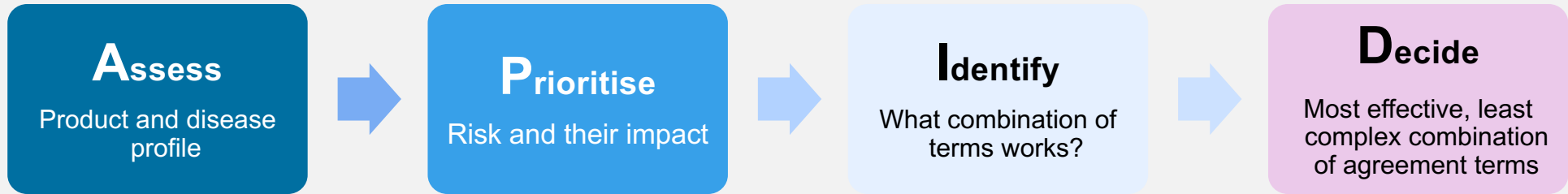
- × Not designed to suggest (more) complex MEAs

- × Does not assess value, price or value for money

- × Does not require changes in P&R legislation

- × Not a MCDA or other decision-making tool

The VBNF aims to bridge the negotiation gap between payers and manufacturers in a timely manner



Disease and product profile template

Matrix 1	Core area	Topic	Key questions - level of evidence per point of innovation sub-topic	Response for consideration - objective
Disease background	Epidemiology	Disease	Incidence	Means on rate of target patient population
		Prevalence	Impact on cost profile over time	
	Patient population characteristics	Age of onset	Impact on willingness to pay	
		Other patient characteristics (e.g. gender, ethnicity, risk factors, genetic mutation)	Impact on clinical uncertainties for specific subgroups	
	Disease manifestation	Disease progression (e.g. acute vs. chronic, effects)	Impact on mortality and life expectancy / prognosis	
		Impact on morbidity	Characterise the disease profile, which sets up for the treatment goals	
	Economic burden of disease	Impact on quality of life	Identify the urgency to treat	
		Direct or indirect costs (e.g. missed school days, productivity)	Present a holistic view of the disease impact that influences the perception of burden of disease rate (e.g. for discussion of patient effect)	
	Diagnostic pathway	Time to diagnosis	Impact on diagnosis rates (e.g. restriction to sub-populations), budget impact	
		Diagnostic method (e.g. biomarker test, clinical differential, diagnosis of exclusion)	Other elements	
Patient care pathway	Availability of clinical guidelines	Qualify how the patient care experience is structured in the health system		
	Treatment capacity in the healthcare system	Helps identify potential changes to the health system brought about by the novel treatment		
Standard of care	Treatment location (e.g. acute vs. ambulatory)	Impact on the extent of unmet medical need		
	Existence of (a) therapeutic options (approved or off-label)			
Product profile description	Technology presentation	Treatment goal (e.g. curative, disease modifying, symptom management, slow progression, slow reversion)	Impact on perception of innovativeness	
	Mechanism of action	Impact on complexity of administration		
Regulatory background	Modes of administration	Impact on cost structure and variability in costs		
	Pharmacology (per label)	Impact on the perception of innovativeness and level of uncertainty		
	Regulatory designations (orphan, PRIME)	Impact on cost of the patient population (current population, extent of future)		
	Time of approval (i.e. conditions, under exceptional circumstances)			
	Current and anticipated additional indications			

Uncertainties matrix

Priorities Legend (P):
 0: not evaluated
 1: no priority
 2: minor priority
 3: moderate priority - itself not sufficient to block reimbursement
 4: major priority - itself blocking reimbursement

Steps:
 1. Identify uncertainties
 2. Connect uncertainties to real world clinical outcomes, budget impact, cost effectiveness
 3. Prioritize using legend

UNCERTAINTIES	Description	Expected influence on real world health outcomes		Expected influence on budget impact/revenue (cost per patient + population)		Expected influence on cost-effectiveness	
		P	P	P	P		
Uncertainties related to the size and characteristics of the population							
Incidence and prevalence							
Size of the target population							
Characteristics of subpopulations and target population, such as age and time since diagnosis							
The spectrum and variations of disease manifestations, such as symptom severity							
Different genotypes or phenotypes							

Solutions matrix

Solutions legend:
Capacity to mitigate risk: to be determined based on expected impact on four key parameters
Feasibility of implementation: considering individual preferences and contexts, to be rated as:
 0: not considered
 1: low
 2: moderate
 3: high

Priority concern	Potential agreement term	Description	Expected impact on real world health outcomes	Expected impact on real cost per patient	Expected impact on budget impact/revenue (cost per patient + population)	Expected impact on cost-effectiveness	Implementation feasibility

The VBNF demonstrated its potential effectiveness in real-life

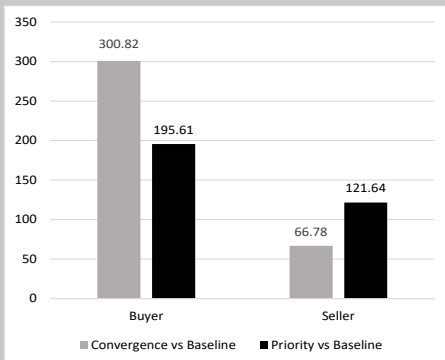
Mock-up negotiations

- 8 Multistakeholder Roundtables with 40 Participants (approx.) from Health Authorities, NGOs, industry
- Live game at various congresses incl. World Evidence, Pricing and Access Congress 2020, ISPOR 2021 and 2022
- Simulations at ESSEC and Solvay Business School

Large scale trial of VBNF based on experimental economics

- 238 participants split between two groups (manufacturers & NHS)
- 119 bilateral negotiations
- 6 variables for negotiations: cost per patient, number of patients (cap), local investment, clinical risk-sharing, time to access, investment in RWE
- Negotiators had different goals (converging on some, diverging on others)
- 3 Arms:
 - (1) No “nudge” or incentives to collaborate
 - (2) Nudge 1: “convergence”: agree on variables with converging interest first
 - (3) Nudge 2: “priority” – information sharing about their goals

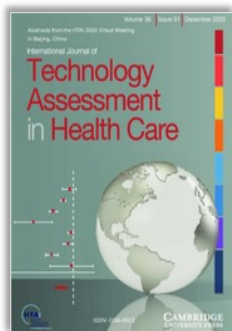
Results: Collaborative & Transparent negotiations increase the effectiveness of negotiations



- Nudging negotiators towards early wins (convergence) or information sharing (priority), created value
- Total value created at dyad level was increasing, concave function in relation to time spent negotiating
- The surplus associated to the two nudges – i.e., ‘advice-based treatments – essentially accrued to the buyer / NHS. The payoff for the seller also increased, but the change was not statistically significant

The VBNF is a practical tool to support faster, more efficient negotiations

1 Published with templates in IJTAHC



International Journal of Technology Assessment in Health Care
www.cambridge.org/thc

Facilitating More Efficient Negotiations for Innovative Therapies: A Value-Based Negotiation Framework

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Commentary

Check this article: WHITTALL A, JOMMI C, De POUVOURVILLE G, TAYLOR D, ANNEMANS L, SCHOONAERT L, VERMEERSCH S, HUTCHINGS A, PATRIS J (2022). Facilitating More Efficient Negotiations for Innovative Therapies: A Value-Based Negotiation Framework. *International Journal of Technology Assessment in Health Care*, 38(1), 423. 1-8. <https://doi.org/10.1017/S0269472722000055>

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Abstract
Objectives: An increasing number of innovative therapies (e.g. gene- and cell-based treatments) have been developed in the past 20 years. Despite the significant clinical potential of these therapies, access delays may arise because of differing perspectives of manufacturers and payers regarding issues such as the value of the product, clinical and financial uncertainties, and sustainability. Managed entry agreements (MEAs) can enable access to treatments that would not be reimbursed by conventional methods because of such concerns. However, although MEA typologies exist, there is currently no structured process to come to agreements on MEAs, which can be difficult to decide upon and implement. To facilitate more structured MEA negotiations, we propose a conceptual 'value-based negotiation framework' with corresponding application tools.

2 Potential effectiveness published in JBEE



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Can attentional nudges improve efficiency of bilateral multi-attribute negotiations?

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ARTICLE INFO

JEL classification: C72, C73, D81, D82

Keywords: Multi-attribute negotiation; Framed experiment; Attentional nudge; Information sharing; Trust

ABSTRACT
This paper reports the results from a lab experiment to simulate negotiation on innovative therapy commercialization. Using a between-subject design, we analyzed the consequences of two light choice interventions (1) guiding negotiations towards early win, and (2) inviting negotiators to share information about their priority goals. In both treatments, the total value created exceeded the control value by approximately 9% of the maximal value that can be created in this experiment. However, it was essentially the buyer who captured the additional value. We found that, conditional on the success of the negotiation, the total value created increased with the time spent negotiating. Negotiator gender had an impact on the negotiation outcome, with women underperforming compared to men.

Summary

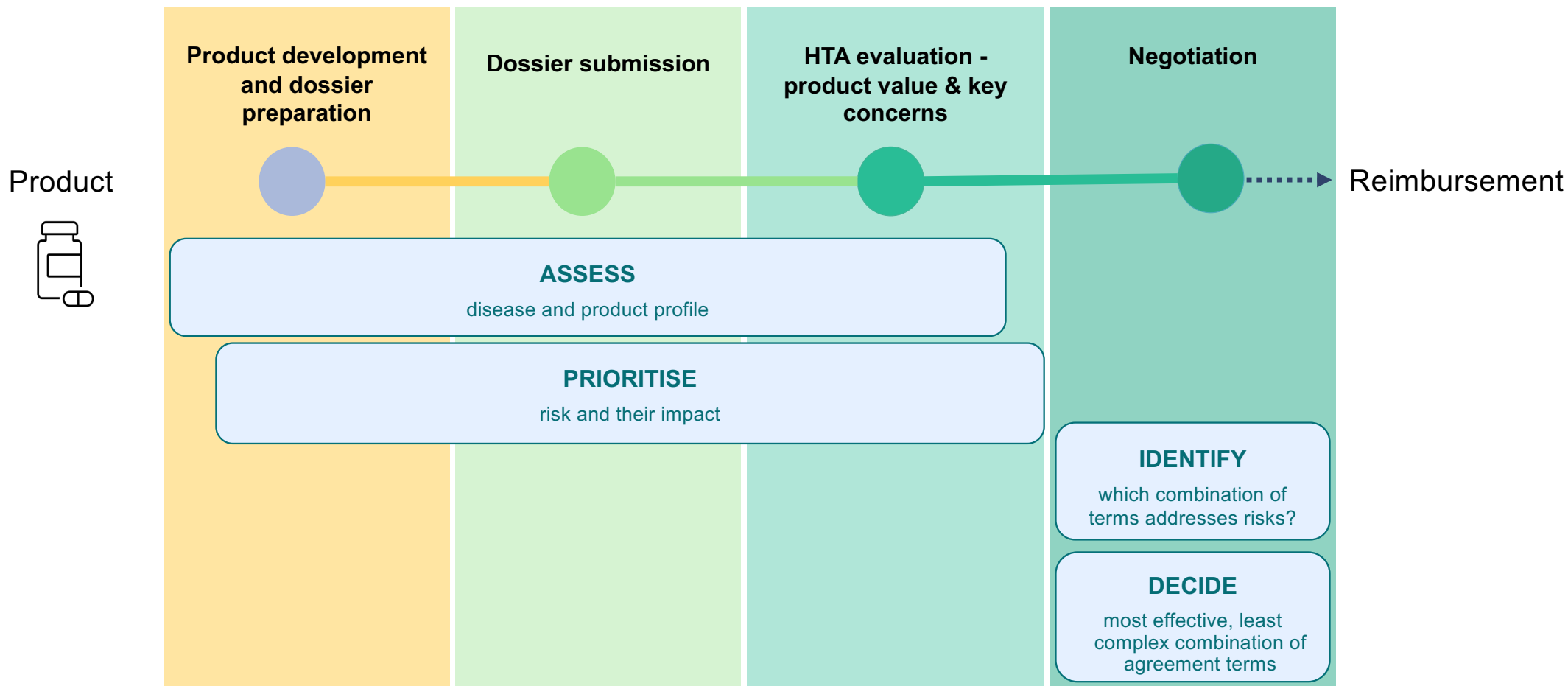
Description of methodology
Conceptual framework
Practical application tools

Summary

Lab experiment to observe and analyze negotiation of a multi-attribute, advanced therapy contract

More integrative outcomes and more trust were achieved when recommending negotiators start the negotiation with convergent criteria / communicate their priorities to the other party

The framework could be used across different stages of the lifecycle and P&R process – creating nudges or processes towards convergence and information sharing



Thank you!

- Lamiraud, K., Patris, J., & Vranceanu, R. (2024). Can attentional nudges improve efficiency of bilateral multi-attribute negotiations?. *Journal of Behavioral and Experimental Economics*, 102205.
- Lamiraud, Karine and Patris, Julien and Vranceanu, Radu, Experimental Evidence on the Value of Time and Structure in Market Negotiations (February 8, 2023). ESSEC Business School Research Paper No.2023_02, Available at SSRN: <https://ssrn.com/abstract=4358819> or <http://dx.doi.org/10.2139/ssrn.4358819>
- Whittal A, Jommi C, De Pouvourville G, et al. Facilitating More Efficient Negotiations for Innovative Therapies: A Value-Based Negotiation Framework. *International Journal of Technology Assessment in Health Care*. 2022;38(1):e23. doi:10.1017/S0266462322000095 available at: [THC 2200009 1..8 \(cambridge.org\)](https://doi.org/10.1017/S0266462322000095)