

## Challenges and Success with Win-Win Negotiations

Canadian Integrated Lifecycle Drug Development, Access, and Management Model for Rare Disease Populations



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# A Win-Win-Win-Win agreement can mean **compromise & trade-offs**



## pCPA's CONSIDERATIONS

Magnitude & certainty of clinical benefit

Budget Impact (& Level of Certainty)

Cost per Patient & Variability

Criteria & Adjudication

Cost-effectiveness & Equity

Unmet Need & Disease Severity



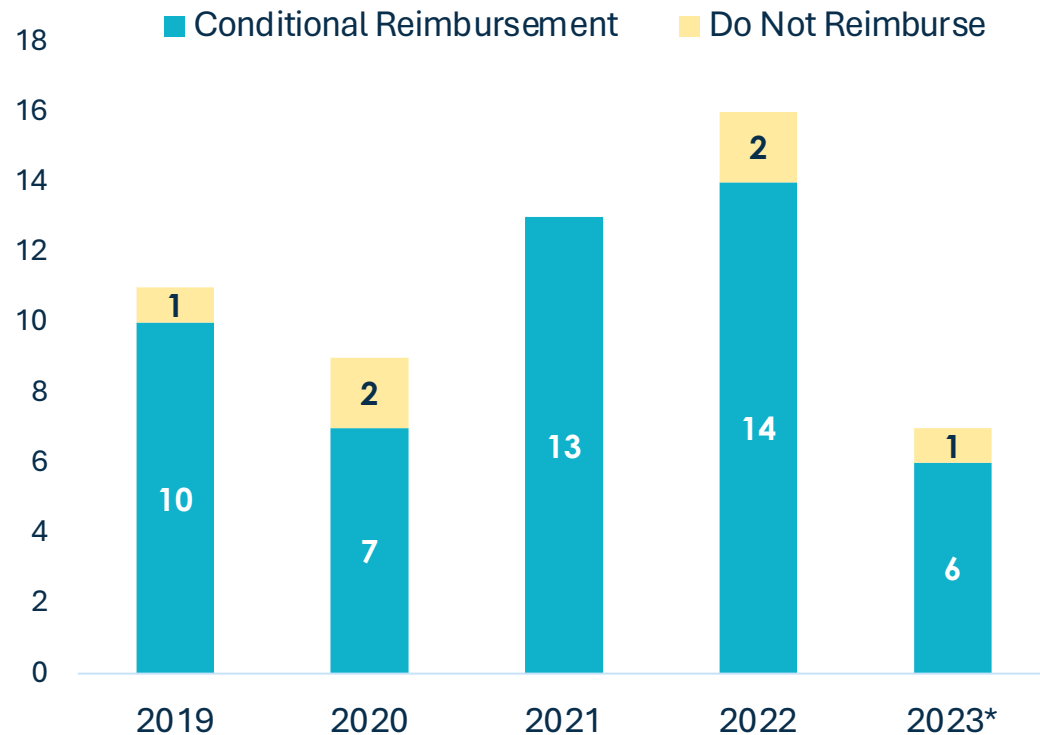


Drugs for Rare Diseases  
(DRD) LANDSCAPE & TRENDS

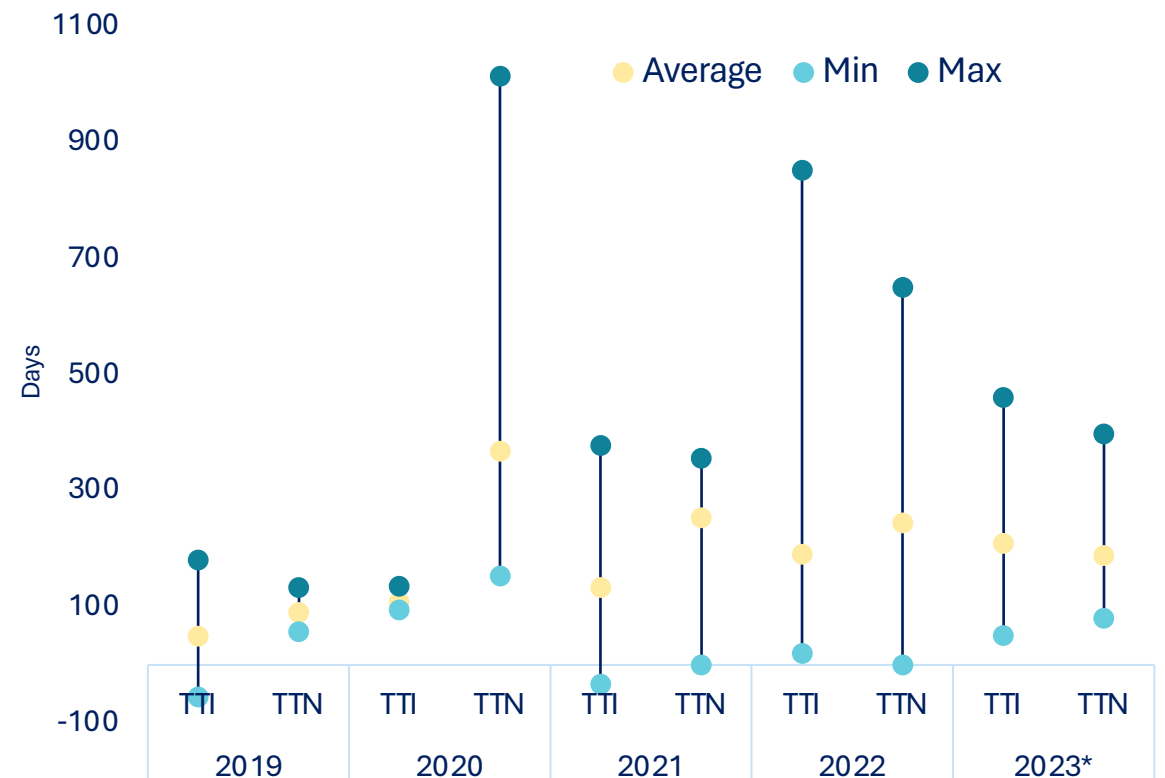
# What do the data say? DRD negotiations can be exceptionally fast or slow

- CADTH has reviewed **57 DRDs since 2019**, with **50** receiving **positive** reimbursement recommendations
- pCPA's average **Time to Initiate (TTI)** for DRDs is **~5 months** and average **Time to Negotiate (TTN)** **~8 months**, but both are heavily skewed by outliers

### Volume of DRDs Reviewed by CADTH



### Time to Initiate & Negotiate DRDs



Source: MORSE market access database; \*2023 data as of November 17<sup>th</sup>

TTI = Time to Initiate, calculated as the # of days between final CADTH recommendation and pCPA engagement letter;

TTN = Time to Negotiate, calculated as the # of days between pCPA engagement letter and LOI or Close Letter

DRD: Drugs for Rare Diseases



# Why can't DRD negotiations be quicker?

We have not agreed on how to prioritize and manage the risks



**Negotiations on average are slower for DRDs**

**Likely due to file complexity and less willingness to close files without LOI when no other alternatives are available**



**Risk mitigation and budgetary measures are important in the context of high uncertainty of DRDs**

**In Canada, such risk mitigation must be developed during each negotiation, with no established framework**



**DRDs with high ICERs still reach LOIs**

**However, poor cost-effectiveness is an indicator of clinical uncertainty as well as high treatment costs that create difficult decisions for payers**





**NEGOTIATION STRATEGIES &  
RECOMMENDATIONS**

# Optimizing pCPA Negotiations: Best Practices

Address payer perspectives in offers, ensuring realistic expectations and maintain a trusting relationship

Provide prompt responses to negotiation leads and develop clear, concise, and rationale-backed proposals

Once negotiations have started respect the process by communicating with the appropriate individuals

1

HTA Importance

Payer Relations

3

Openness

Clear Strategy

5

Proactive Awareness

Respect

2

4

6

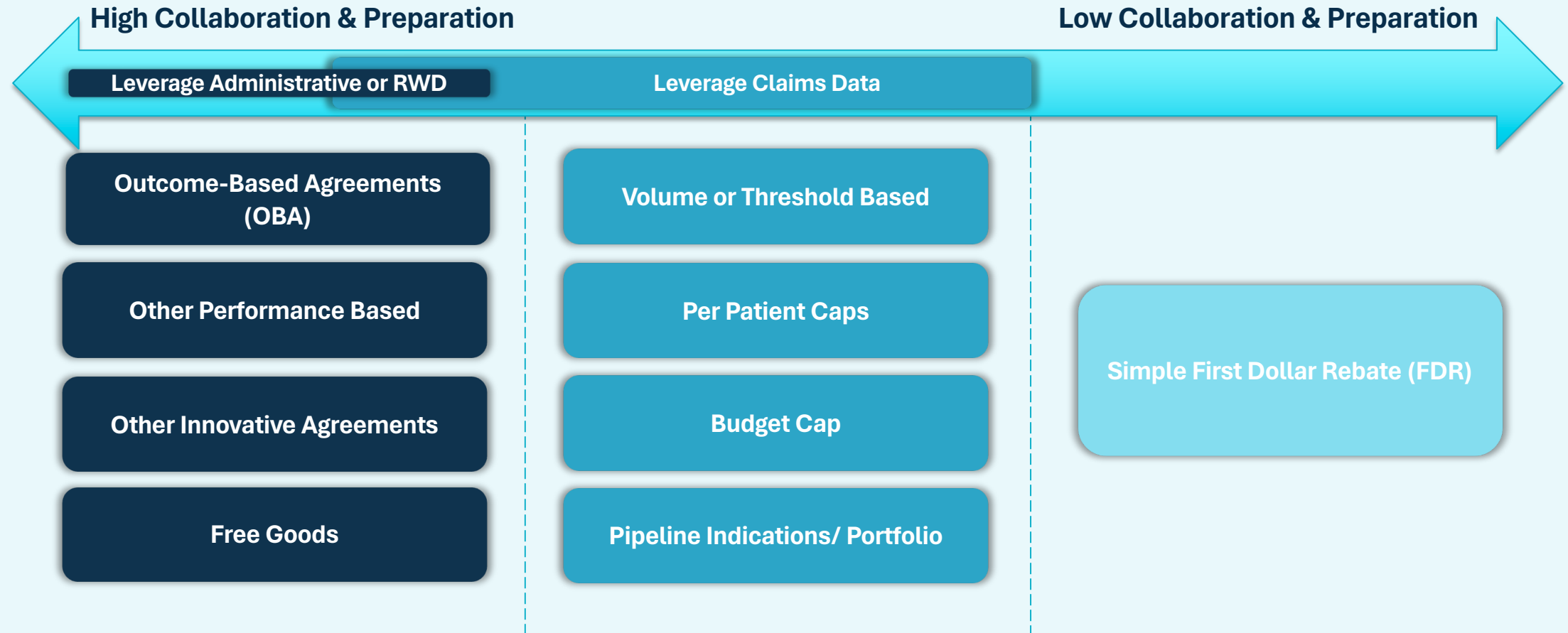
Understand the significance of HTA recommendations on negotiations, especially key uncertainties highlighted

Be transparent with what the organization will and will not do in the Canadian context

Establish routine meetings with lead jurisdictions to stay informed about landscape advancements and policy initiatives



Be prepared to put forward an agreement structure that **addresses payer concerns** and **anticipate that additional time may be required** to collaborate and reach unique solutions







Thank you!



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