

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

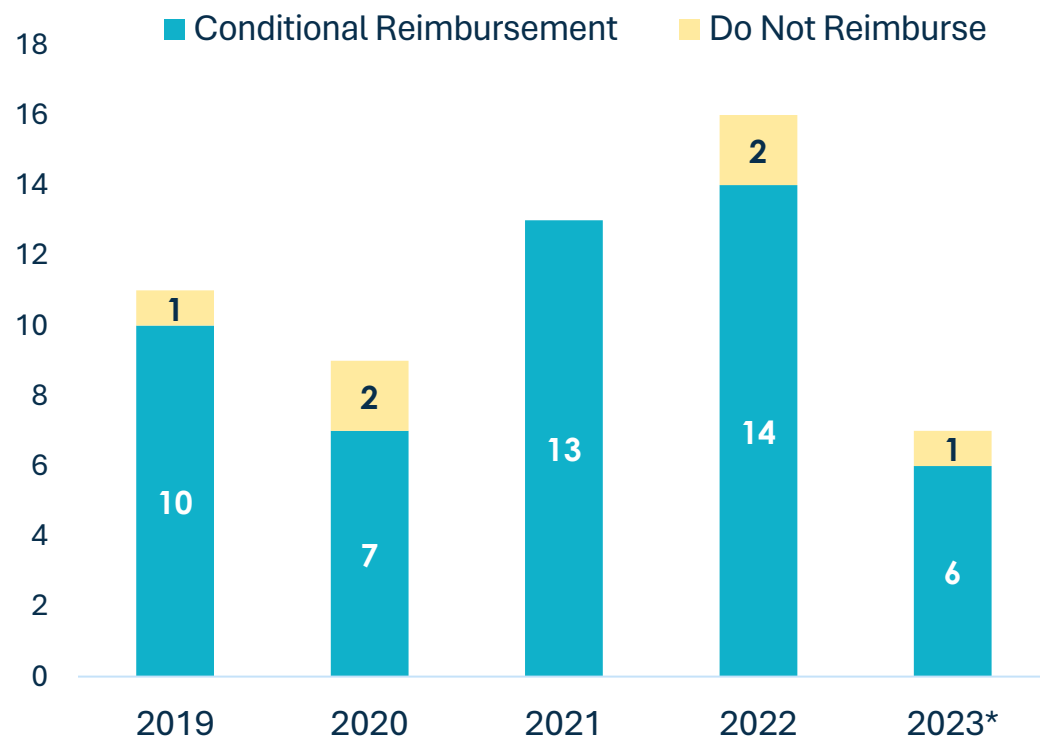
Unmet Need & Disease Severity



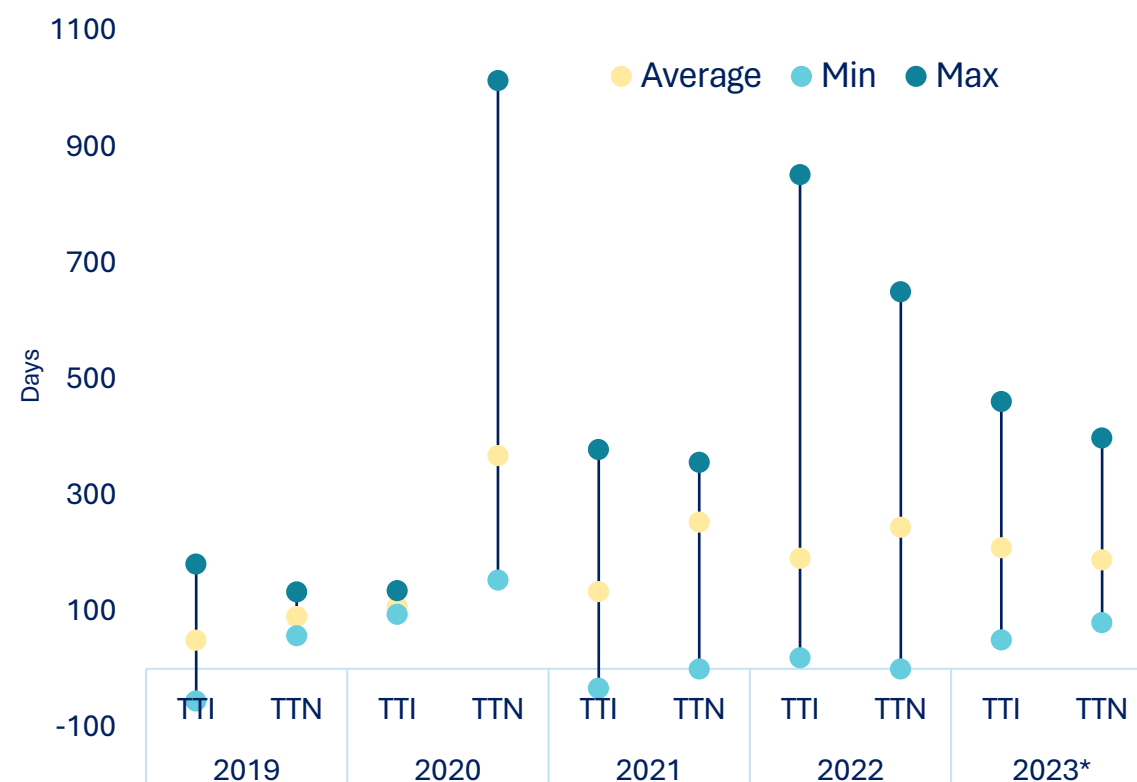
What do the data say? DRD negotiations can be exceptionally fast or slow

- 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 17th

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
and no category caps**



**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**



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

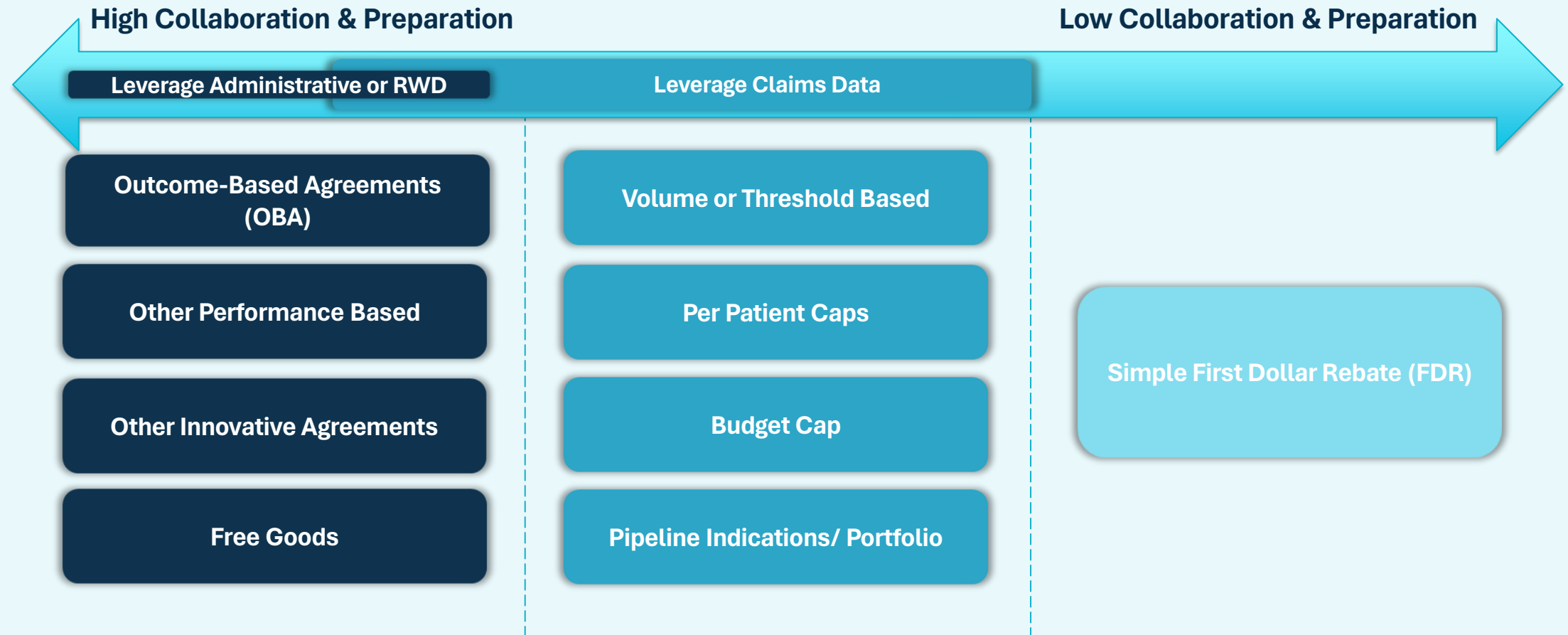
Once negotiations have started respect the process by communicating with the appropriate individuals

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HTA Importance

Payer Relations

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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