



# Fit-for-Purpose Data in Value Assessment in Japan: How Best to Leverage Real-World Evidence (RWE) and Qualitative Value Elements to Optimize Decision Analysis

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**Speakers:**

- Christoph Glaetzer, , Dipl. Kfm., Chief Value and Access Officer, Janssen (Johnson & Johnson Innovative Medicine), United States
- Ataru Igarashi, PhD Associate Director, Tokyo Univ. Facul. of Pharm. Dept. of Health Economics & Outcomes Research, Japan
- Sven Demiya, Sr. Principal MBA, MSc, PhD, IQVIA GK, Japan

# What's the RWE role in Value Assessment?

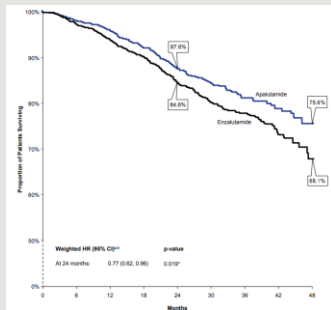


## Confirm

Confirm data from RCTs where there are limitations such as time horizons (e.g., long-term OS data)

For Example:

OS observed in the apalutamide cohort of the RWE study is consistent with that of the Phase 3 TITAN study

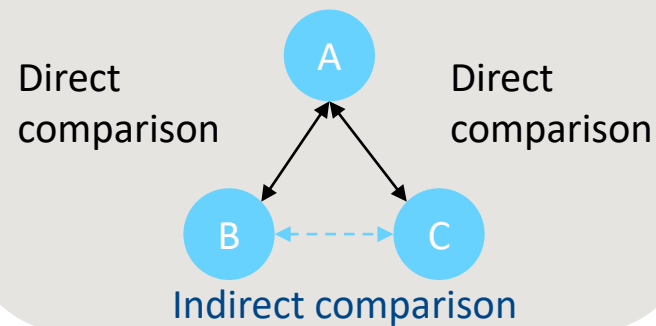


## Complement

Complement RCT data, for example with a comparison to a preferred local comparator

For Example:

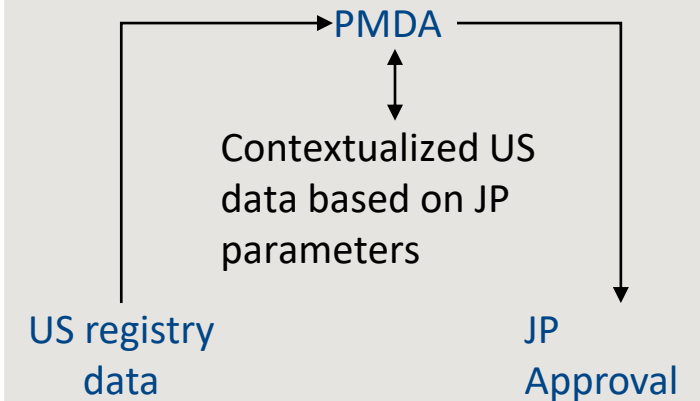
An Indirect Treatment Comparison (ITC) showed Cilta-cel was more effective than the comparator<sup>1,2,3</sup>



## Contextualize

Translate global data into the local context

For Example:



1. [https://c2h.niph.go.jp/results/C2H2113/C2H2113\\_Summary\\_Eng.pdf](https://c2h.niph.go.jp/results/C2H2113/C2H2113_Summary_Eng.pdf)  
2. Current Medical Research and Opinion, 39(1), 81–89. <https://doi.org/10.1080/03007995.2022.2139052>  
3. Adv Ther. 2025 Aug 6. doi: 10.1007/s12325-025-03308-2. Epub ahead of print. PMID: 40768190.

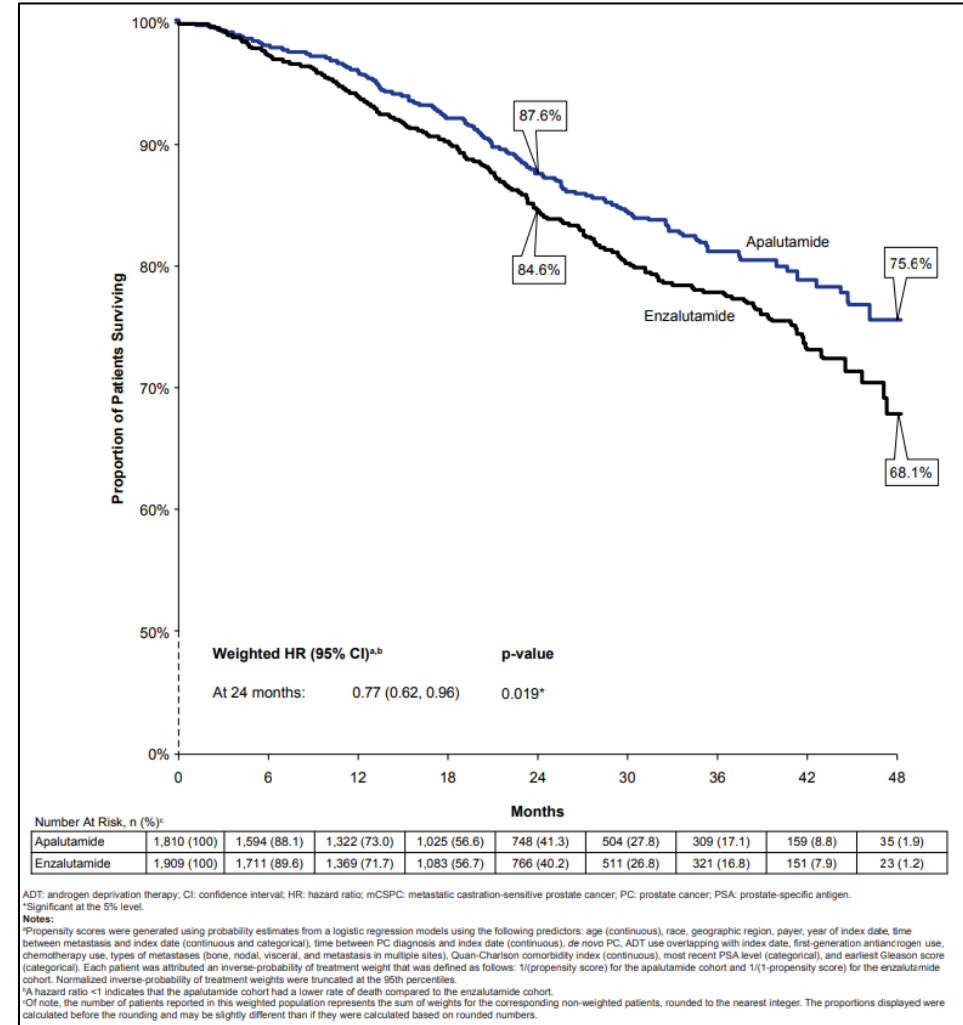
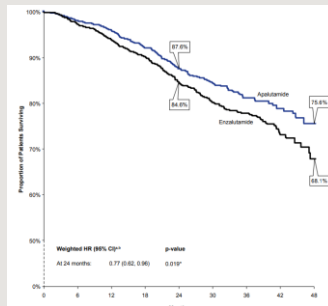
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<https://www.jnjmedicalconnect.com/media/attestation/congresses/oncology/2024/ecop/realworld-headtohead-analysis-of-overall-survival-in-patients-with-metastatic-castrationsensitive-pr.pdf>

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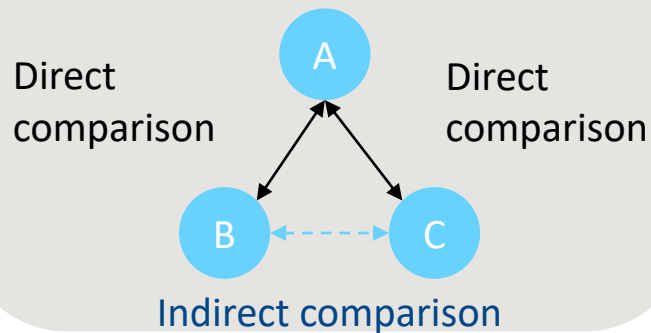


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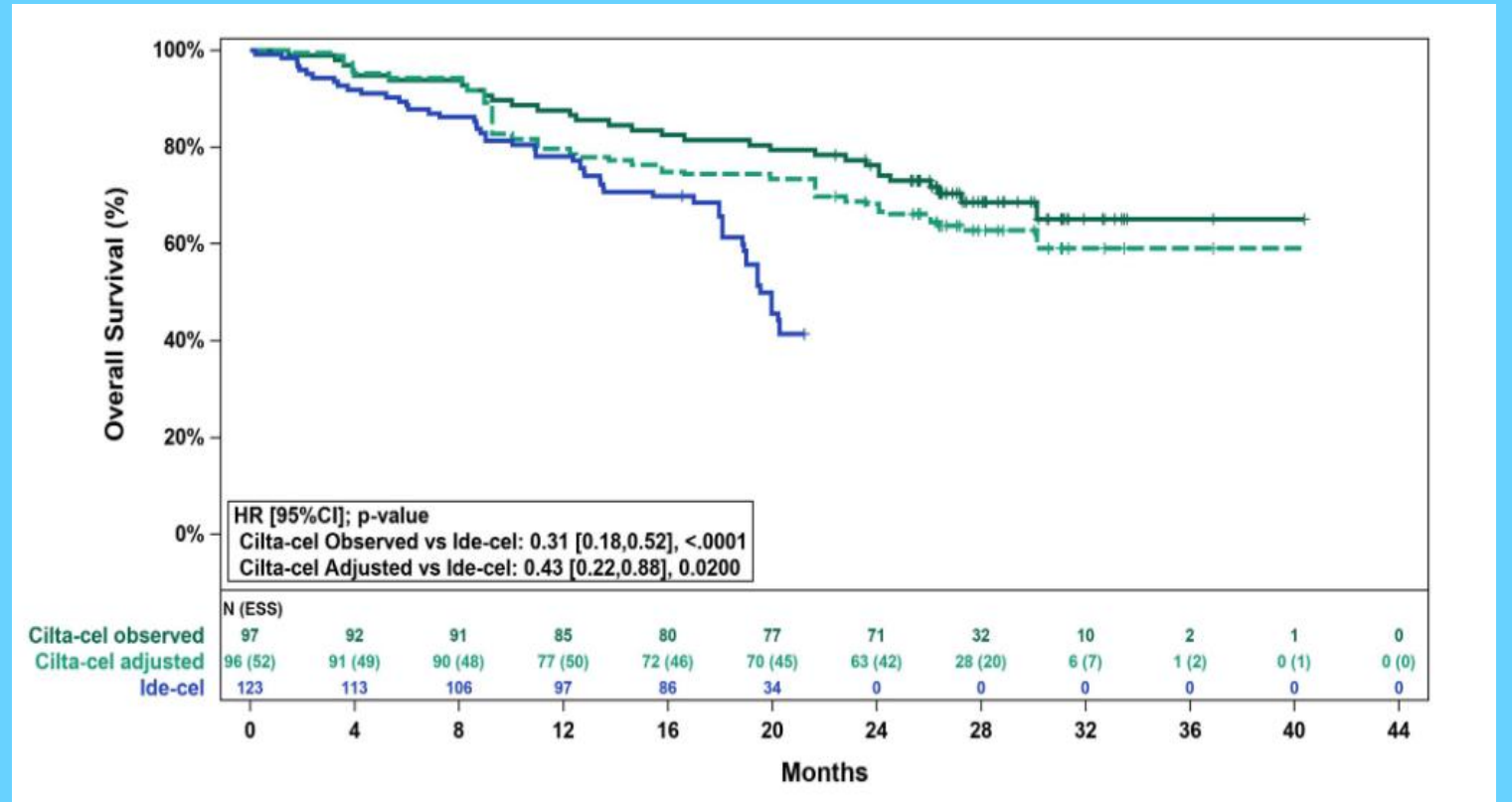
For Example:

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## Comparison of cell therapies from single arm studies

Observed (unadjusted) and adjusted (base case) Kaplan–Meier plots of OS



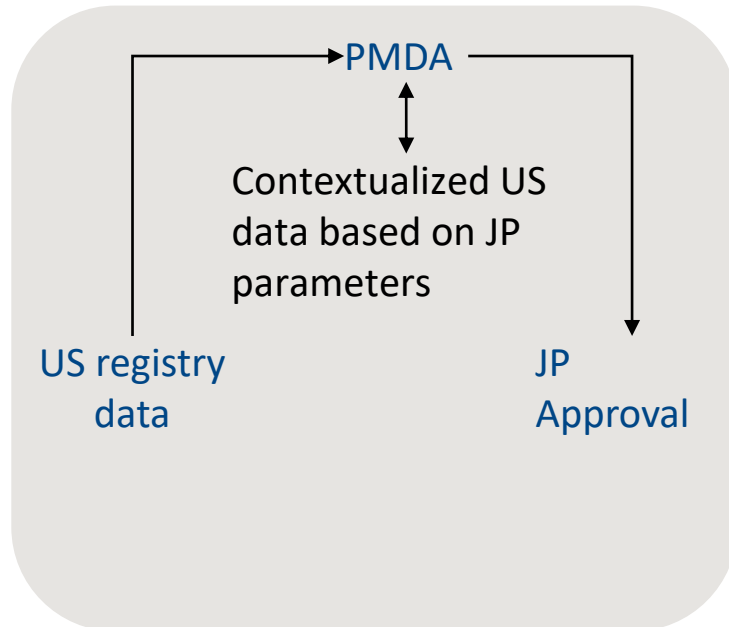
- [https://c2h.niph.go.jp/results/C2H2113/C2H2113\\_Summary\\_Eng.pdf](https://c2h.niph.go.jp/results/C2H2113/C2H2113_Summary_Eng.pdf)
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The Japanese authorities accepted the US TVT Registry data for regulatory approval by :

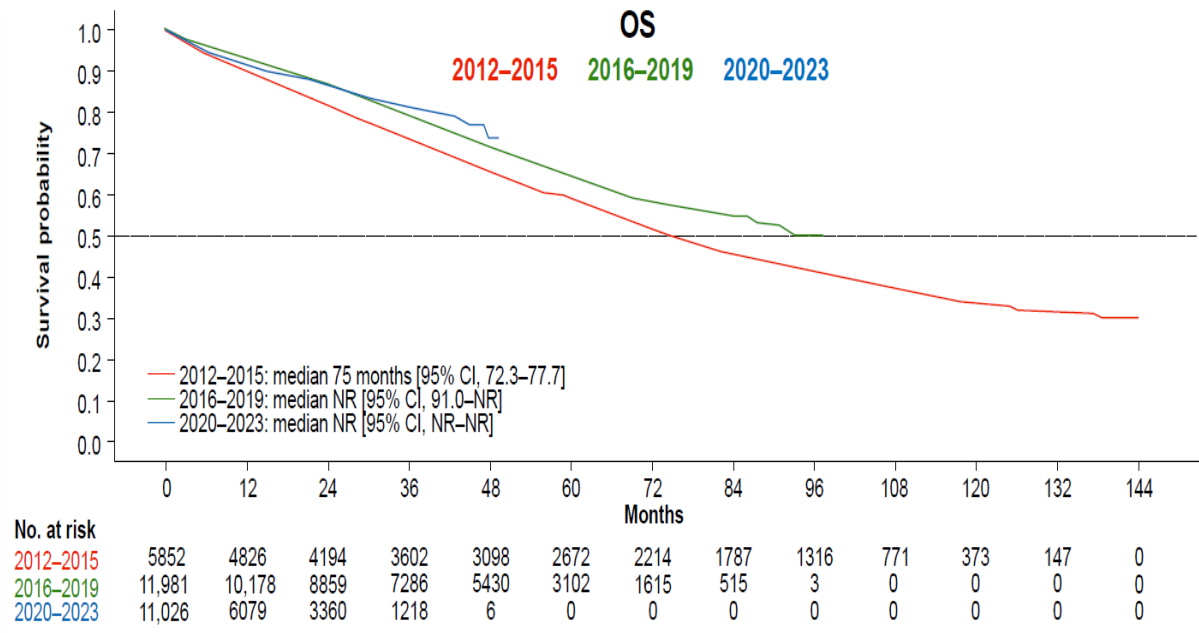
- a) Thoroughly comparing medical environments,
- b) Confirming the technical and diagnostic equivalency,
- c) Supplementing with Japanese-specific data and literature,
- d) Applying safeguards and post-market surveillance, and
- e) following government policies for the use of international registry data—ultimately concluding that the US real-world data was sufficiently relevant and reliable for Japan, with explicit consideration for potentially higher patient age and risk.

[https://www.pmda.go.jp/medical\\_devices/2022/M20221018001/170492000\\_22800BZX00094\\_A100\\_2.pdf](https://www.pmda.go.jp/medical_devices/2022/M20221018001/170492000_22800BZX00094_A100_2.pdf)

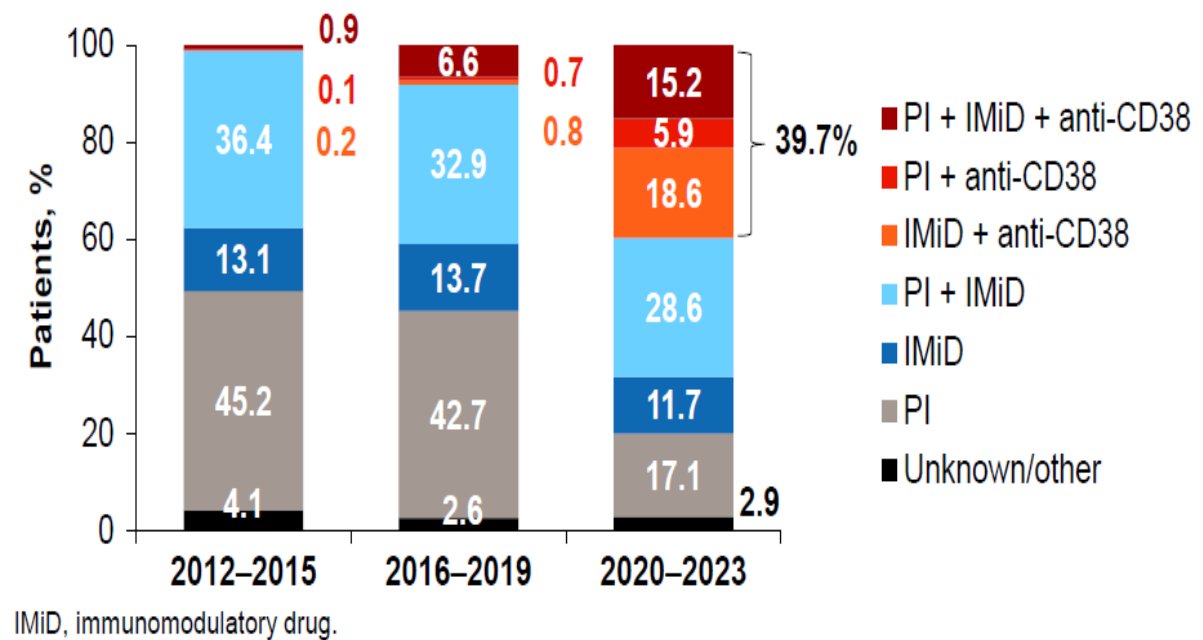
# Considerations

Evolution of Treatment Patterns and Survival Outcomes in European Patients with Multiple Myeloma from 2012-2023 through the Honeur Federated Data Network (2024)

Survival for Multiple Myeloma (MM) patients has increased over the last decade



... coinciding with use of new innovative medicines in front line



“Across all countries, improved frontline TTNT and OS was observed from 2012 to 2023, which coincided with a change in treatment regimens. The observed improvement in outcomes was driven by data from France and Germany, which is likely related to availability of PI-IMiD combinations and the emergence of anti-CD38 therapies for frontline treatment in both countries”<sup>1</sup>.

1. [https://ashpublications.org/blood/article/144/Supplement 1/2388/532426/Evolution-of-Treatment-Patterns-and-Survival](https://ashpublications.org/blood/article/144/Supplement%201/2388/532426/Evolution-of-Treatment-Patterns-and-Survival)