

# Forecasting ViV TAVI in Korea (2025-2035)

A Demography-Anchored Monte Carlo Simulation to estimate clinical demand for Valve-in-Valve procedures, correcting for post-COVID anomalies and population aging.

---

**CORE METHODOLOGY**

Risk-based Index Projection × Stochastic Survival

**DATA SOURCES**

HIRA Registry (2015-2024) & Ministry of Interior Pop. Stats

**CONFIGURATION**

n\_runs: 100 | jitter: 5-10%

**STATUS**

- Results Validated (Nov 2024)



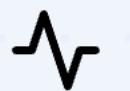
# Background & Original Goal

## Original Goal

Replicate the methodology proposed by **Genereux et al.** and **Ohno et al.** to predict ViV surges.

## Original Methodology

- Linear extrapolation of TAVI/SAVR rates.
- Speculative "Penetration Curves" (assuming 60-80% uptake).
- Applied to US and Japanese registries.



## Genereux/Ohno Model

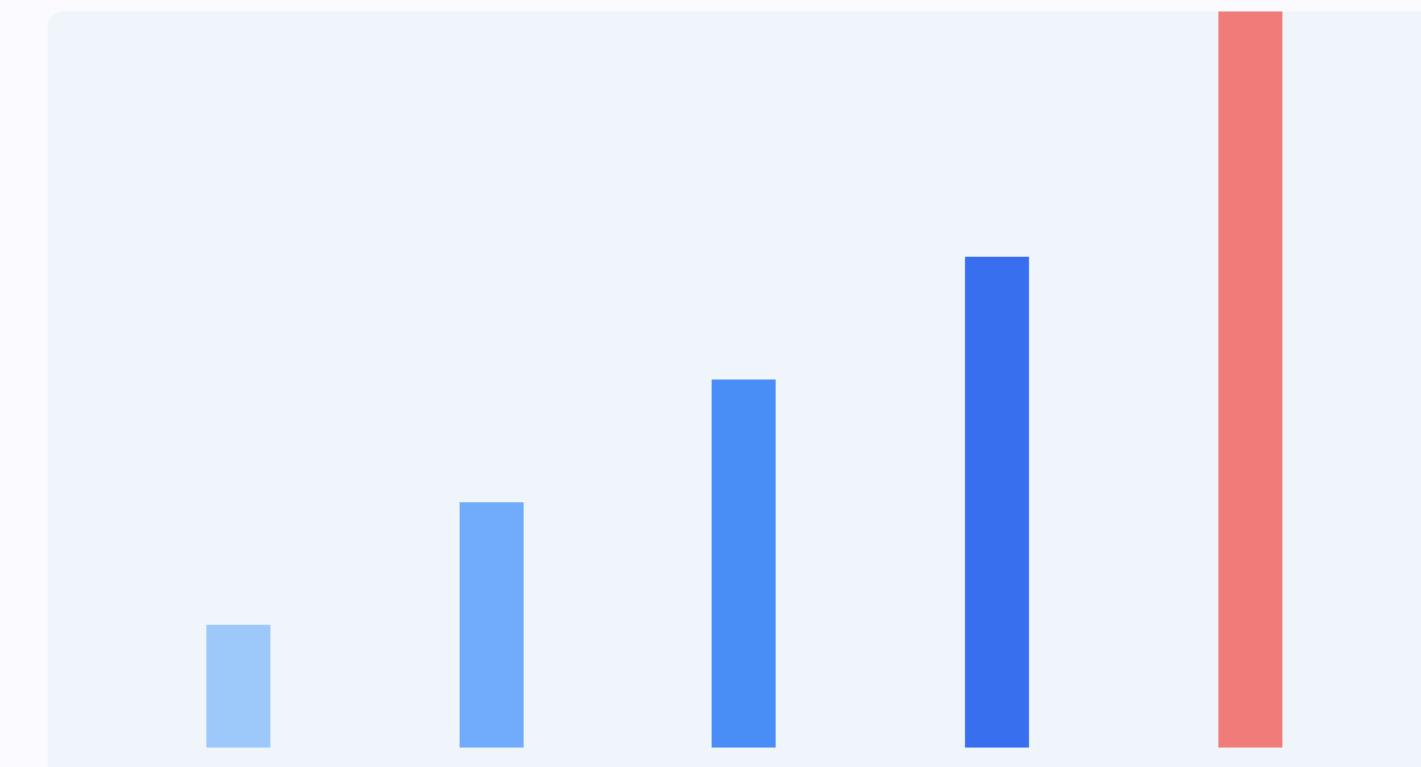
*Image of previous study showing massive/exponential growth.*

# Context: The Original Goal

Our initial objective was to replicate the methodology proposed by **Genereux et al.** and **Ohno et al.**

## The "Standard" Methodology:

- Use US/Japan Registry Data (2015-2023).
- Assume linear growth for TAVI/SAVR.
- Apply a **speculative penetration curve** (e.g., 60% market capture).



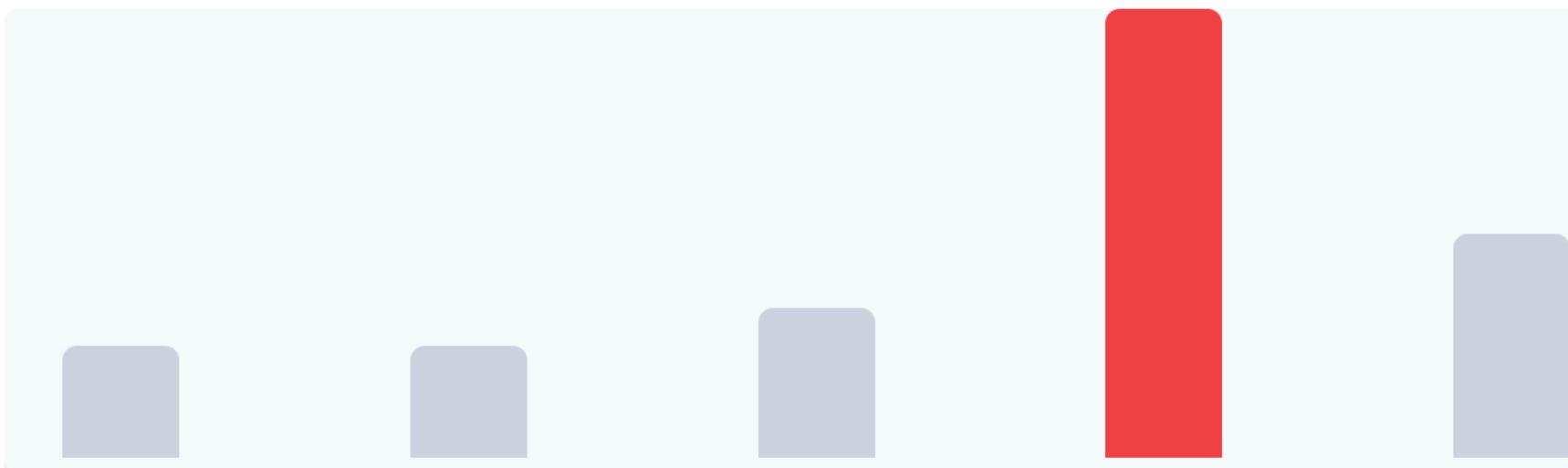
*Representative Chart: Aggressive Linear Extrapolation*

# Why the Original Approach Failed

## 1. The 2023 Data Spike

Korean registry data showed a massive, anomalous spike in 2023 procedures.

Backlog?



Linear extrapolation from 2023 creates infinite unrealistic growth.

## 2. The JACC Critique

*"Extrapolations... potentially introducing bias... significant adjustments were made... clinical factors and patient characteristics were not accounted for."*

We cannot blindly apply US/Japan growth rates to Korea's unique aging demographic.

# Research Context & The Pivot

Background

## A The "Standard" Model

Based on **Genereux et al. (USA)** and **Ohno et al. (Japan)**.

### METHODOLOGY:

- **Input:** Historical TAVI/SAVR volumes.
- **Projection:** Linear regression ( $y = mx + c$ ).
- **Constraint:** **Speculative Penetration** (e.g., "ViV will capture 60% of market").

"Predicts 7-9 fold increase by extrapolating past growth trends."

CRITICAL FLAW

## B Why it failed in Korea

### 1. The 2023 "Backlog Spike"

Korean data shows a massive outlier in 2023 (post-COVID recovery).  
Linear extrapolation from this point creates infinite unrealistic growth.

### 2. The Demographic Disconnect

As noted in the **JACC: Asia** editorial, standard models fail to account for Asian-specific aging velocity.

*"Extrapolations... potentially introducing bias... significant adjustments to data were made..."*

### Conclusion:

We need a model anchored to **Risk & Demography**, not just historical lines.

# The Pivot: A Demography-Anchored Approach

## Old Model

Linear Extrapolation

"Procedures will grow by X% every year"



## New Model (v9)

Risk × Demography

"Given the stable risk profile of a Korean patient, how many failures occur as the population ages?"

# Simulation Architecture (model\_v9)



## Inputs:

- Ministry Pop Stats (2025-2050)
- HIRA Registry (2023-2024)
- Sex/Age-band granularity

## Logic:

- Extrapolate Pop, hold Risk constant
- Index Vol = Risk × Future Pop
- Stochastic Jitter enabled

## Filters:

- Fail Year ≤ Death Year
- Subtract Redo-SAVR
- NO speculative penetration

# The "Demography Anchor"

Replacing linear trends with demographic probability.

`_project_index_by_pop_rate()`

## Step 1: Freeze the Risk

We calculate the probability of a procedure for every age/sex bracket based on 2023-24 actuals.

$$\text{Risk_Constant}_{\text{Per Age Band}} = \frac{\text{Observed_Procedures (2024)}}{\text{Total_Population (2024)}}$$

## Step 2: Apply to Future

We define future volume strictly as a function of the aging population structure.

$$\text{Future_Volume}_{\text{Year Y}} = \text{Risk_Constant} \times \text{Projected_Pop(Y)}$$

# Simulation Architecture

High-level data flow of `model_v9.py`

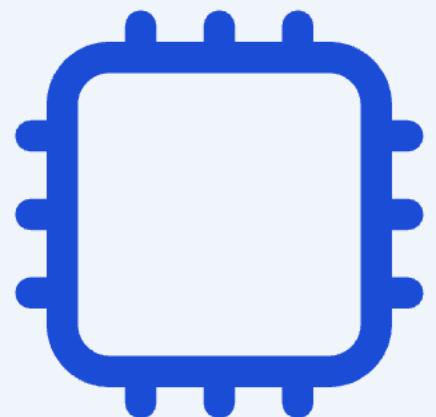
## 1. INPUTS

- Registry Data (2023–24)
- Pop Stats (Ministry)
- Age/Sex Bands

## 2. PRE-COMPUTE

$$\text{Risk} = \text{Obs} / \text{Pop}$$

Generates stable risk profiles per age-band.



## 3. MC ENGINE

- 100 Runs
- Durability vs Survival
- Jitter/Uncertainty

## 4. OUTPUTS

- ViV Candidates
- Realized Volume
- Visualization (PNG)

# Step 1 & 2: Anchoring to Demography

## The Logic:

Instead of extrapolating procedure counts, we calculate the **Risk Profile**. We assume the risk per person remains stable, but the population structure shifts.

```
# Python Pseudocode
def compute_risk_scores(obs, pop):
    for age_band in bands:
        risk = observed_count / total_pop
        # e.g. Men, 75-79
    return risk_profile
```

## Visualizing the Anchor

2024

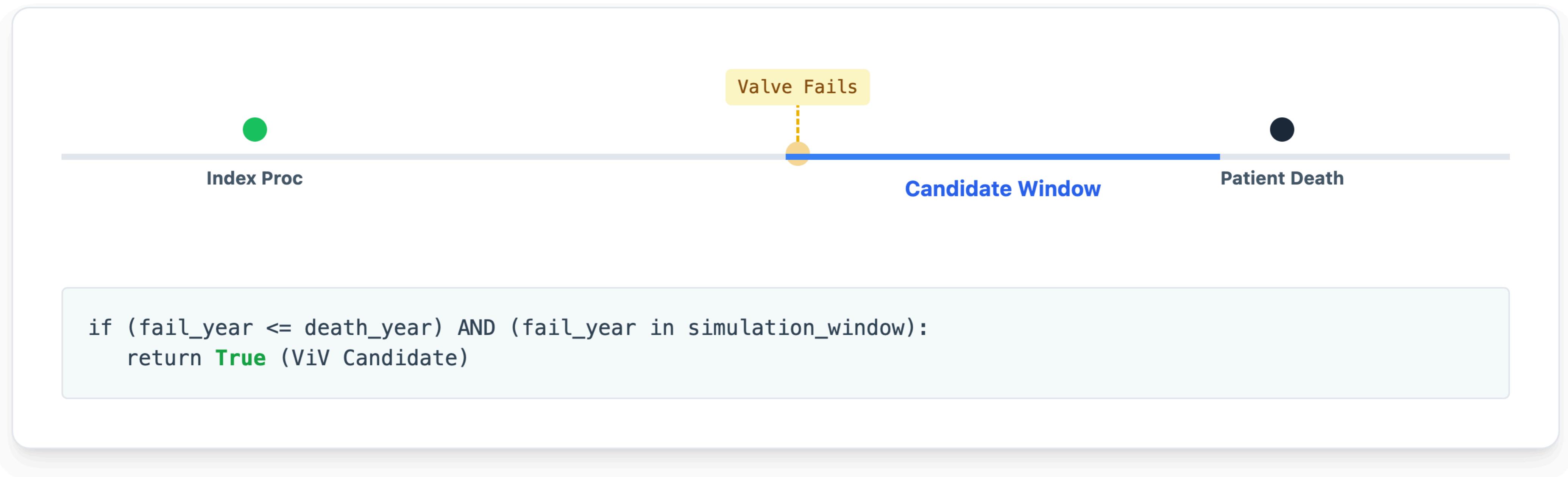


2035



## Step 3: The "Race" (Monte Carlo)

For every simulated patient in every run, we define "ViV Eligibility" based on a race between two events.



# ⚙️ Simulation Logic: The "Race"

Inside the Monte Carlo Engine, every simulated patient runs a "Race" between two curves:

## A Durability Sampling

Sampled from bimodal distributions (TAVI vs SAVR)

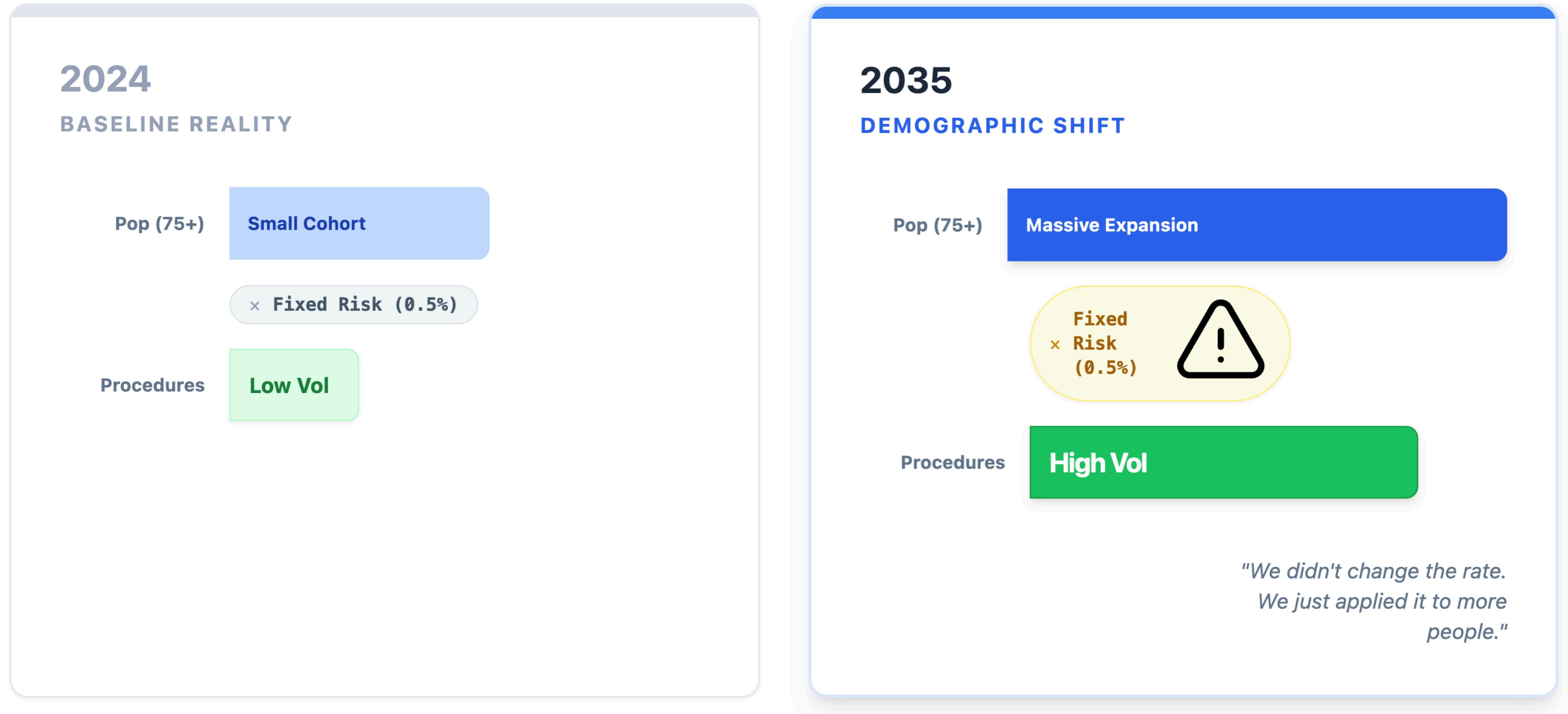
## B Survival Sampling

Actuarial curves adjusted for risk category

```
if (fail_year <= death_year) {  
    candidate = true;  
}
```



# Visualizing the Mechanism



# MC Engine: Setup & Uncertainty

Technical configuration of the `ViVSimulator` class.

## `sim_config.yaml`

```
n_runs: 100  
rng_seed: 2025  
window: 2022-2050
```

*"We simulate the entire future timeline 100 times to build Confidence Intervals."*

## JITTER Parameter Uncertainty

To account for biological variance and model uncertainty, we apply multiplicative Gaussian noise (Jitter) to global parameters **per run**.

**±7.5%**

DURABILITY SD

`rng.normal(1.0, 0.075)`

**±5.0%**

SURVIVAL SD

`rng.normal(1.0, 0.05)`

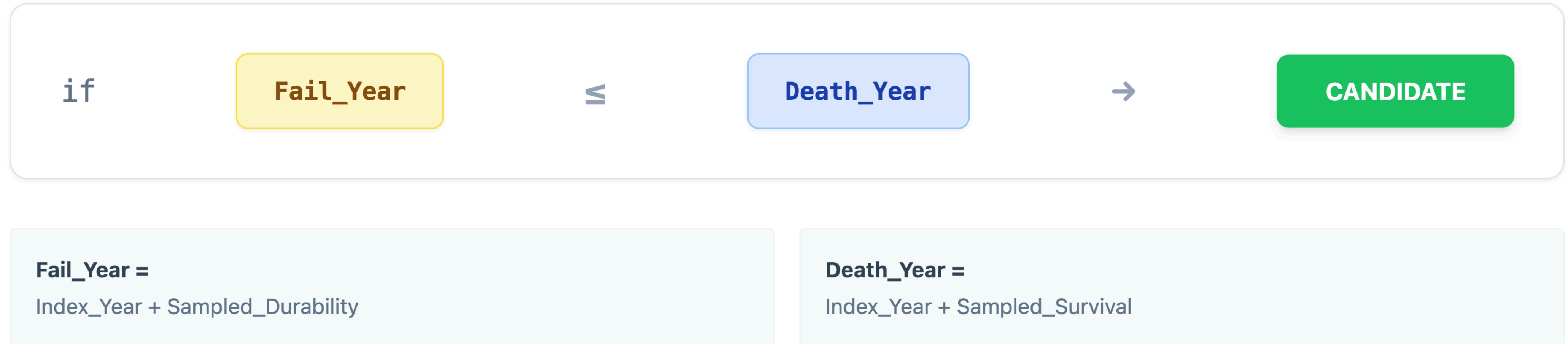
**±10.0%**

PENETRATION SD

`rng.normal(1.0, 0.10)`

# The Core Logic: "The Race"

A patient only becomes a candidate if their valve fails **while they are still alive**.

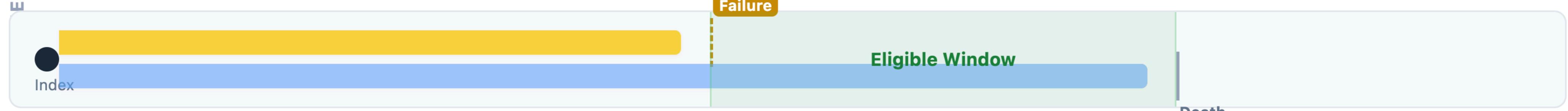


# Simulation Scenarios

Visualizing `run_once()` outcomes

EVENT A

ViV Candidate



EVENT B

Non-Candidate



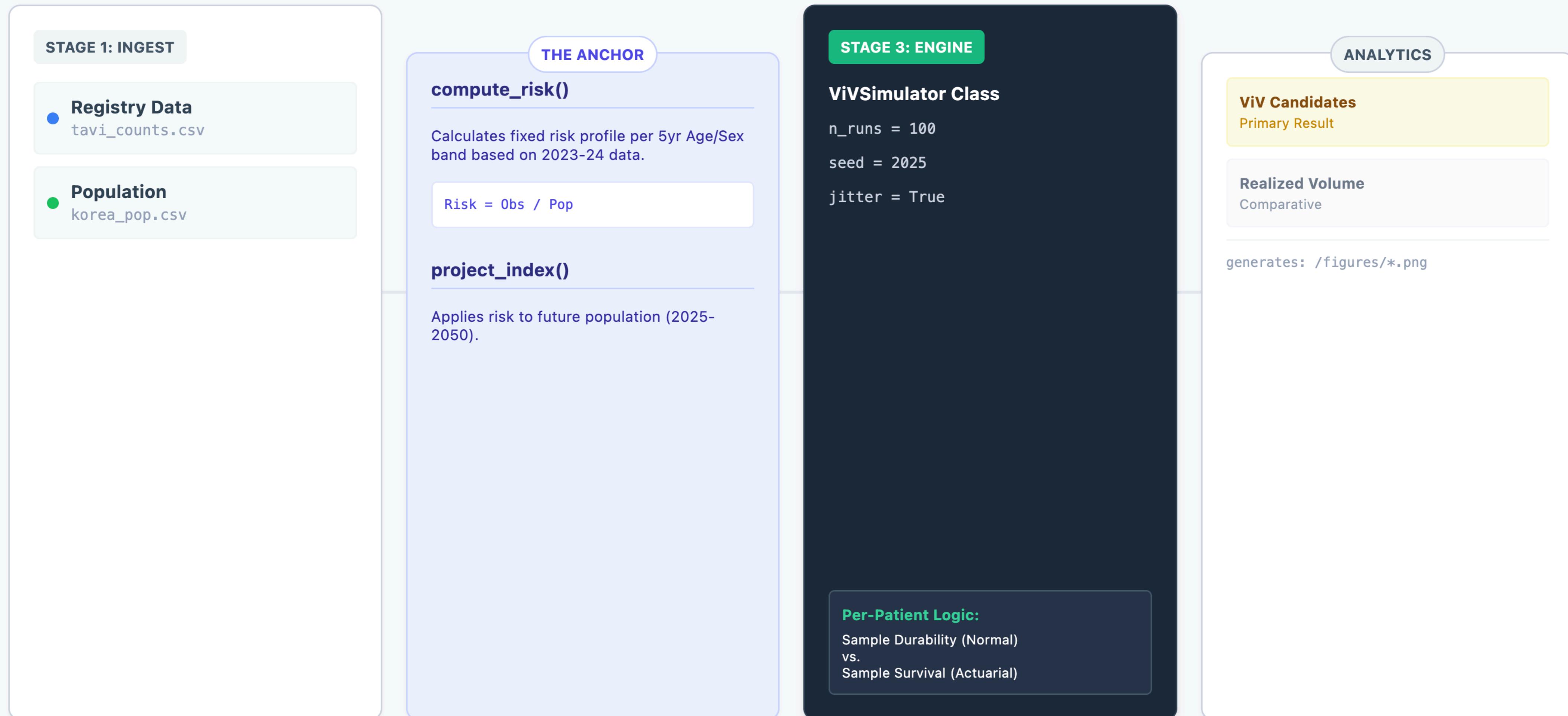
# Technical Architecture

Pipeline implementation: model\_v9.py

Input: CSV

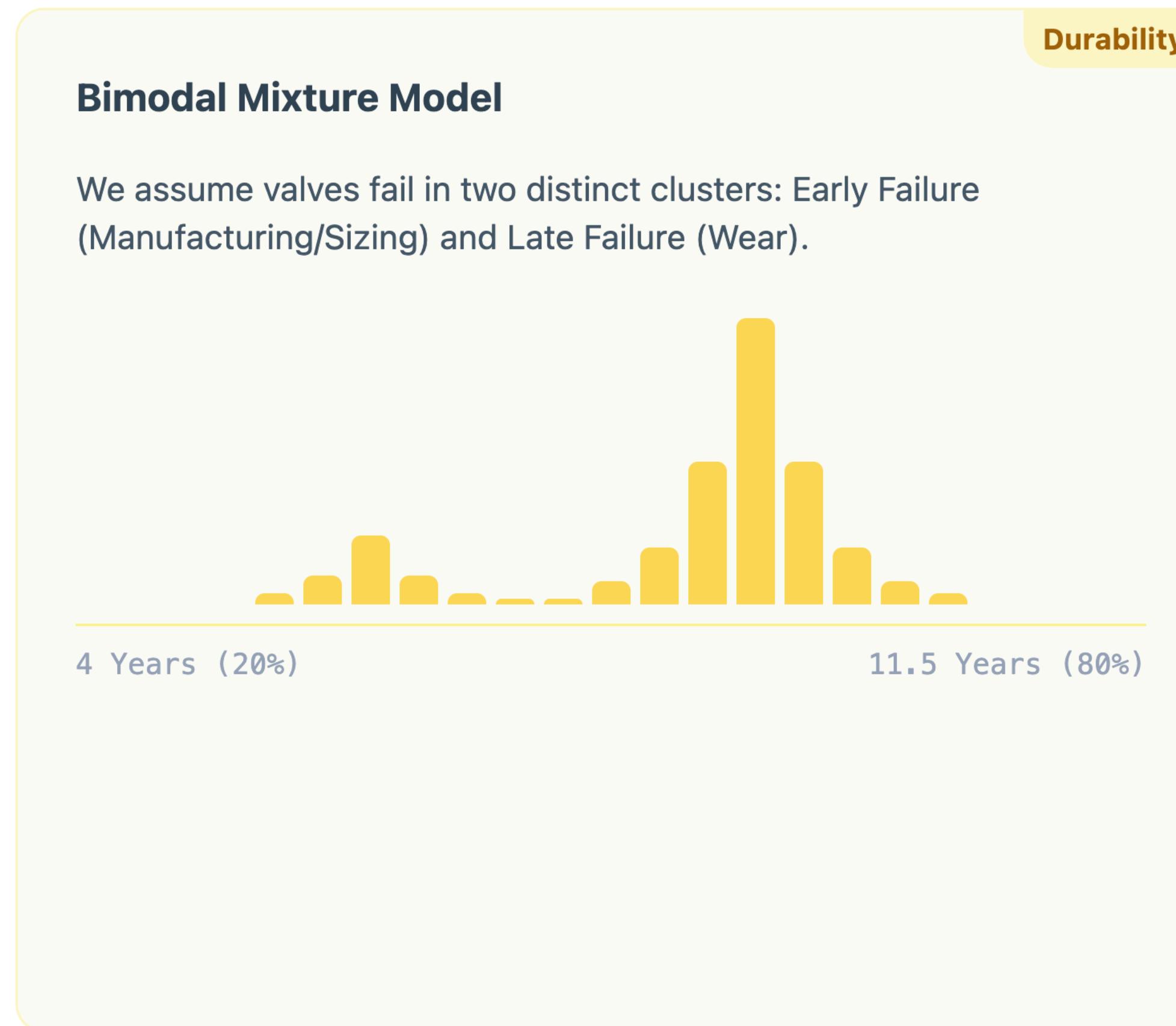
Process: Pandas/NumPy

Output: Matplotlib



# MC Engine: Sampling Distributions

Inside the loop, every patient is assigned a distinct biological pathway.

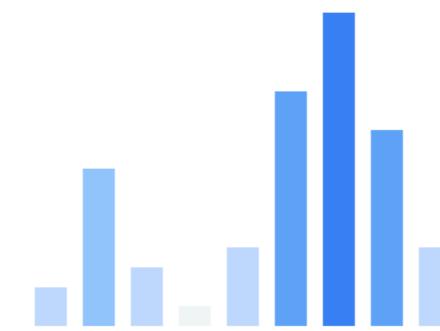


# Simulation Engine: Stochastic Sampling

Inside `run_once()`, we generate unique pathways for every index patient.

## 1. Valve Durability

Bi-modal distribution (Early vs Late failure)



TAVI: Mean 4.0yr (20%)  
& Mean 11.5yr (80%)

## 2. Patient Survival

Actuarial curves + Risk modifiers

Base Survival:

Log-Normal

Age Hazard:

HR/5yrs

*"Patients compete against their valve: will they die before it fails?"*

## 3. Jitter (Uncertainty)

Standard Deviation applied per run

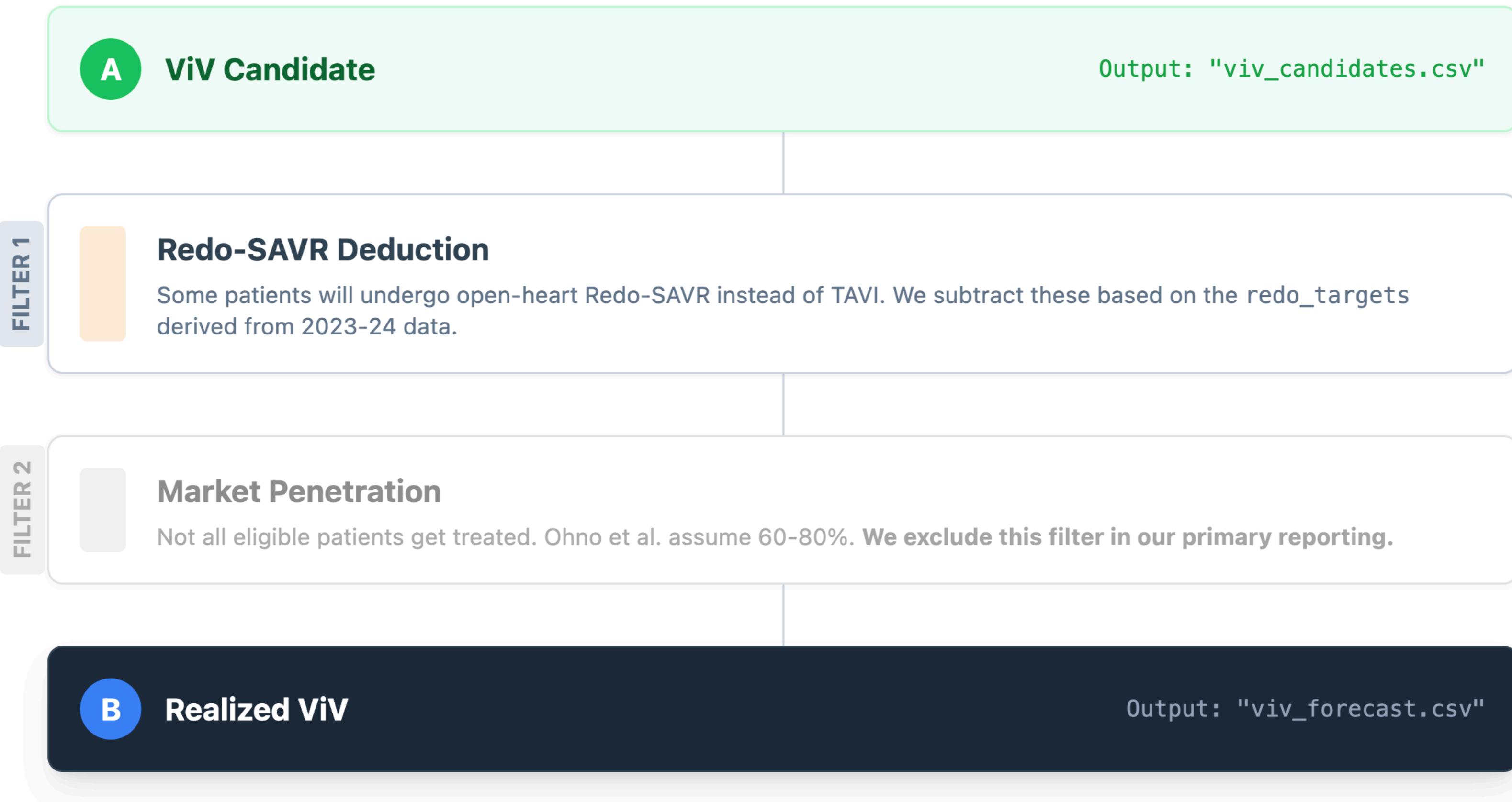
**durability\_pct\_sd:** 7.5%

**survival\_pct\_sd:** 5.0%

**penetration\_pct\_sd:** 10.0%

# Logic Flow: From Candidate to Realized

Once a patient wins "The Race" (becomes a Candidate), we apply clinical filters.

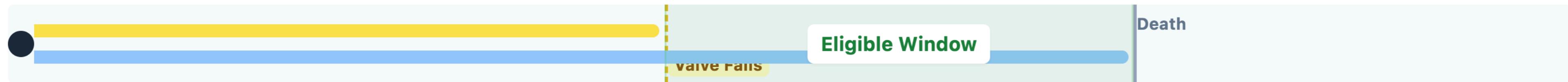


# The Core Logic: "The Race"

For every patient, we calculate two dates. If the valve fails **before** the patient dies (and within our simulation window), they become a candidate.

Index Year

## Scenario A: ViV Candidate

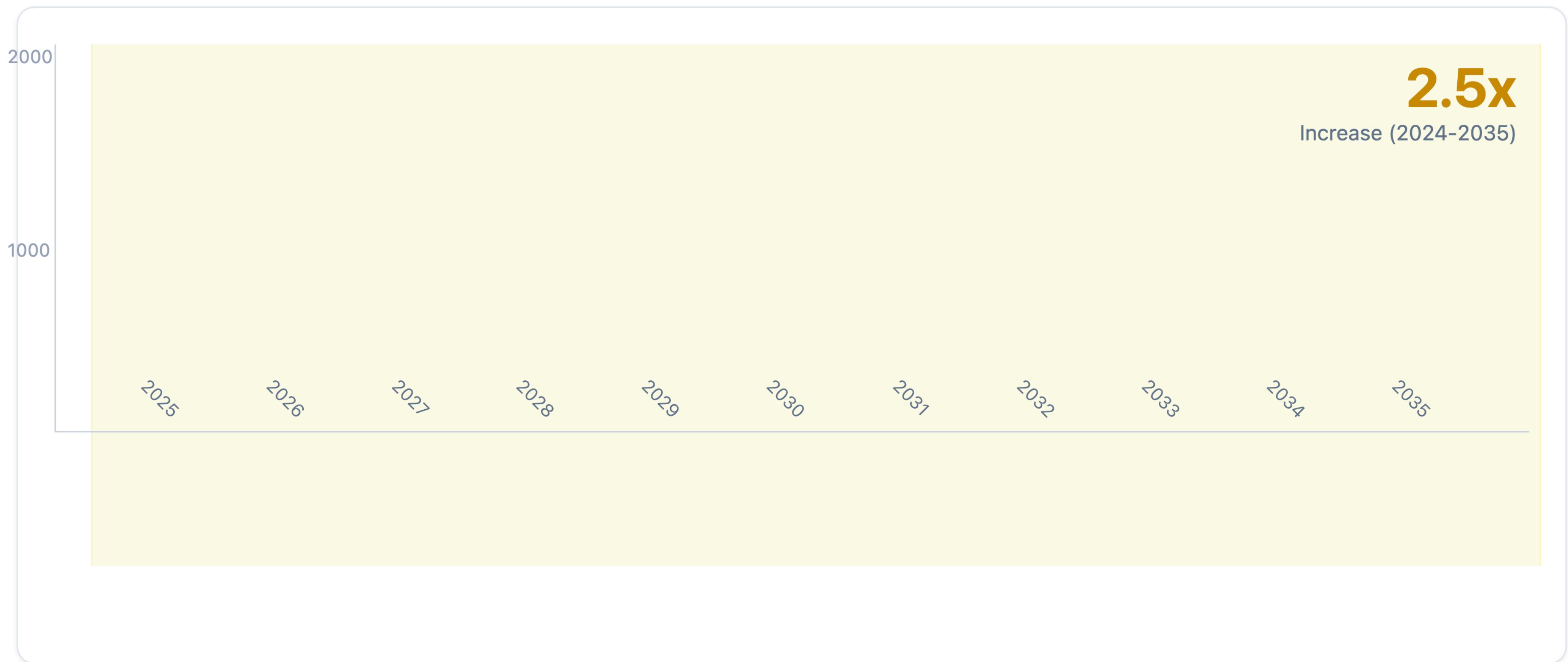


## Scenario B: Death before Failure



# Figure 1: ViV Candidates (2025-2035)

Projected volume of patients alive with failed valves (The Clinical Demand)



## Figure 2: Comparison vs. Ohno et al.

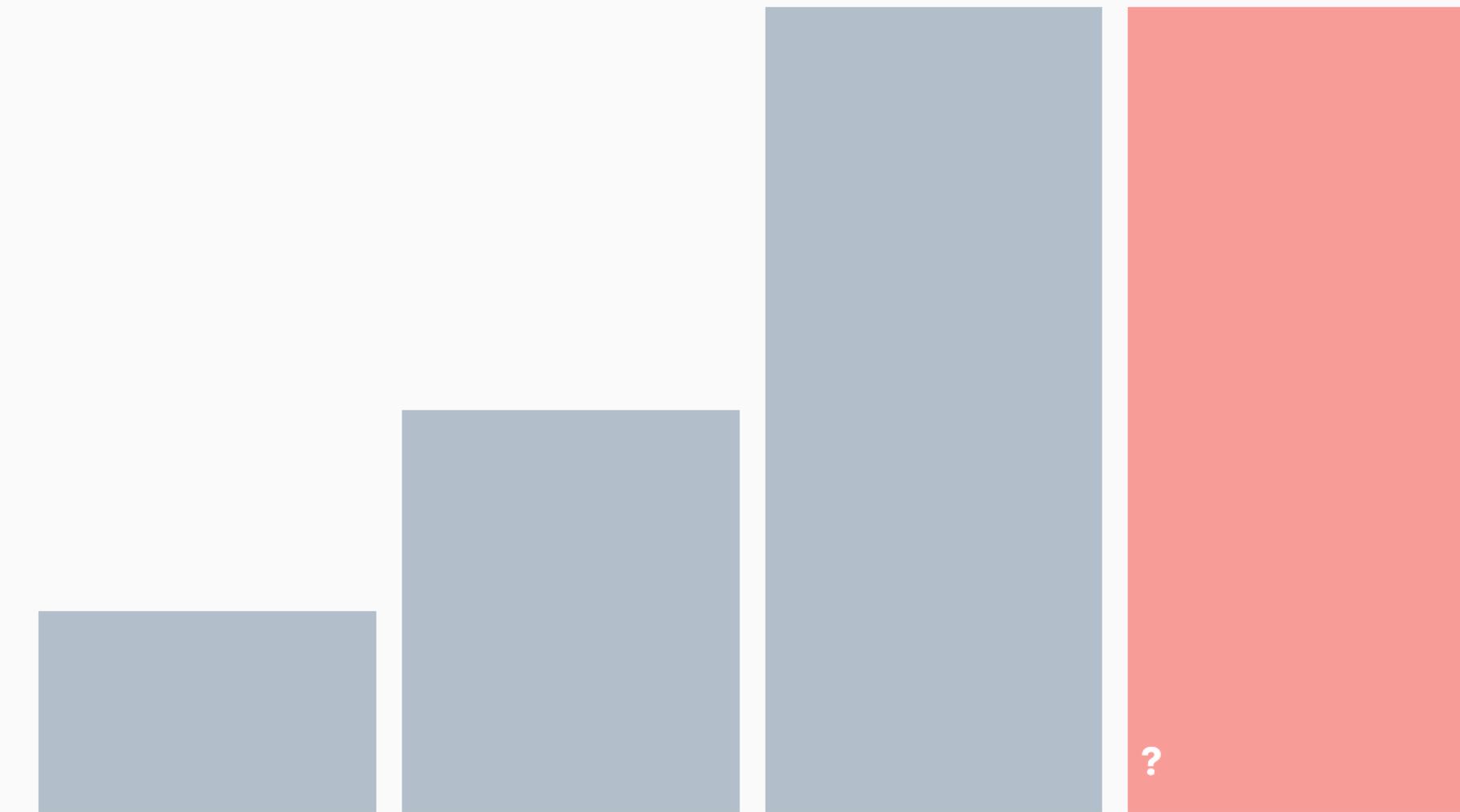
Our Model (Realized)



**~3-fold**

Increase by 2035

Ohno / Genereux (US/Japan)



**7-9 fold**

Predicted Increase

\*Comparisons made applying the same penetration assumptions. Our demographic anchor significantly tempers the "infinite growth" curve.

# Conclusion & Next Steps

## Summary

- ✓ Moved away from linear extrapolation.
- ✓ Anchored prediction to 2023/24 risk profiles.
- ✓ Validated against population aging trends.
- ✓ Established a conservative "demand floor".

## Immediate Action Items

- 1 Run pipeline on Singaporean Data
- 2 Draft Manuscript targeting JACC critique
- 3 Clean & Publicize `model\_v9` Repo

# Definitions

## **ViV Candidate**

A patient who is still alive at the moment their bioprosthetic valve fails.

## **Realized ViV**

A Candidate who actually undergoes the TAVI procedure (Candidate  $\times$  Penetration Rate).

## **Index Procedure**

The very first TAVI or SAVR surgery a patient undergoes.

## **Redo-SAVR**

Open heart surgery to replace a valve (removed from ViV pool).