

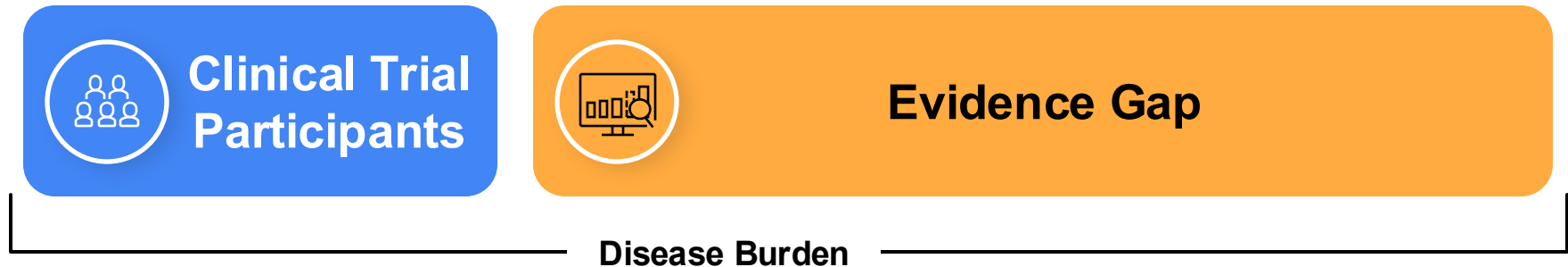
# **Inclusive Clinical Trials: *Why Diversity is a Competitive Advantage for Biotechs***

Awny Farajallah, MD, FACP | Chief Medical Officer, Takeda



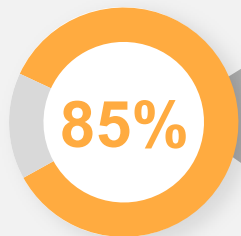
**Do our trials truly reflect the  
patients who will use  
our medicines?**

# The gap between disease burden and trial representation is where risk lives.

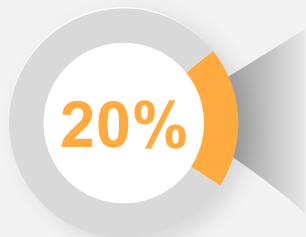


*Evidence Gap = Scientific + Regulatory + Commercial Risk*

# Medicines serve diverse populations. Trials often do not.



About 85% of psoriasis clinical trial participants in the U.S. have been recorded as **White**, despite the disease affecting people of all races and ethnicities, often more severely in patients with skin of color.



Black patients make up over 20% of multiple myeloma cases in the U.S., yet their median enrollment across myeloma clinical trials is 4-5%.



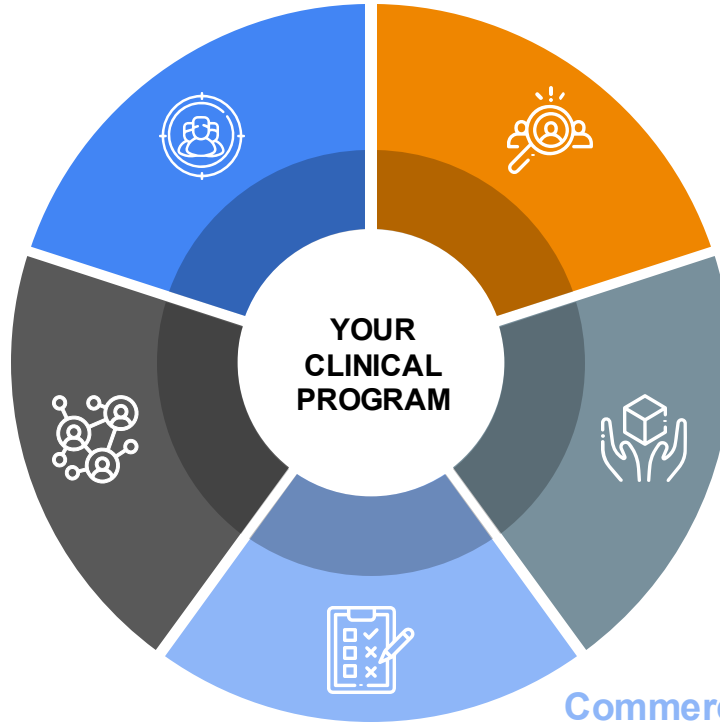
**Trial diversity is no longer optional.  
The forces shaping that reality are  
only accelerating.**

## HTAs & Payers:

Reimbursement bodies are asking if the data reflects the patients they cover. Narrow populations narrow access decisions.

## Patients & Advocacy Groups:

When communities are excluded, it affects trust, recruitment pipelines for future trials, company reputation and physician relationships.



## FDA:

Diversity Action Plans are required for Phase 3 and pivotal trials; non-compliance draws scrutiny to your entire submission.

## BD & Partners:

Partners evaluate the strength of your data package. Demographic gaps are data gaps affecting valuation and deal structure.

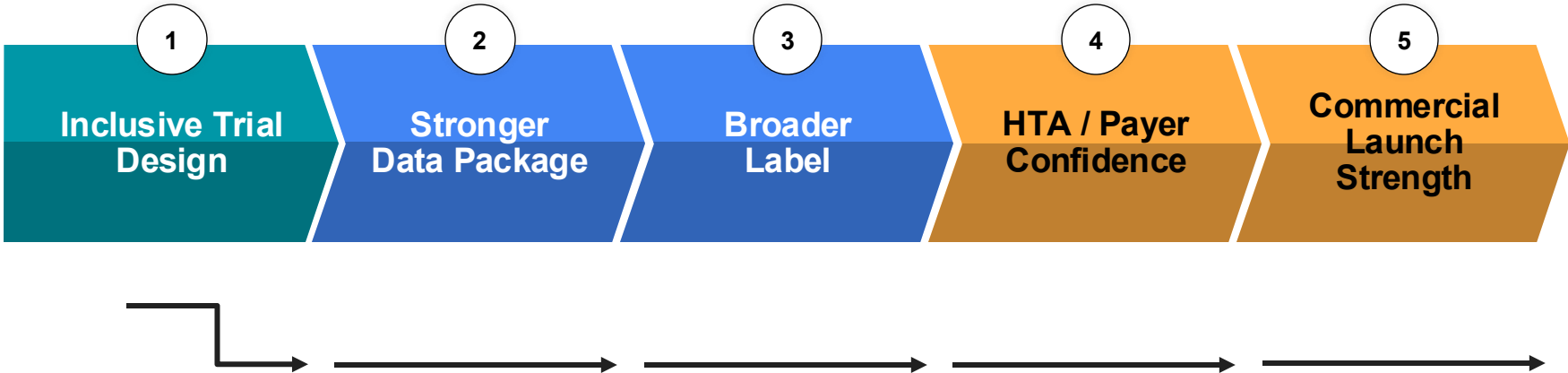
## Commercial Factors:

Enrollment delays, post-marketing commitments, restricted labels and access barriers are the risks of homogenous trials.



Inclusive design is one of the **highest-ROI decisions** in your development plan.

# Inclusive trial design drives downstream value



**What this looks like in practice...**

# Data can find patients. Trust keeps them in the trial.



## DATA

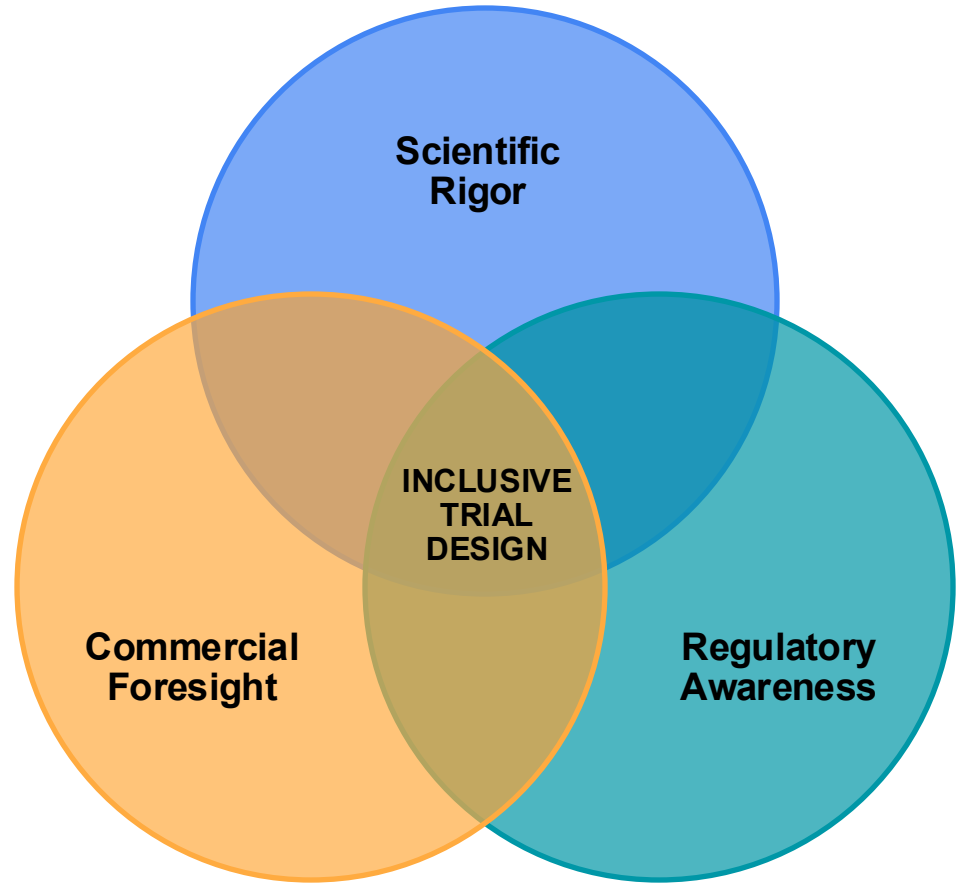
- ✓ Epidemiology
- ✓ Protocol Design
- ✓ Technology
- ✓ AI & Real-World Data

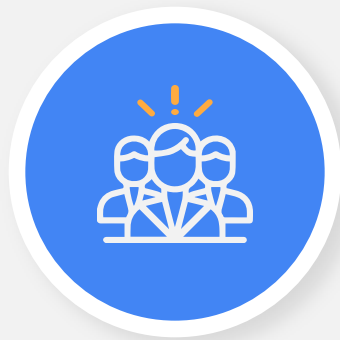
- ✓ Community partnerships
- ✓ Advocacy groups
- ✓ Faith networks
- ✓ Local pharmacies

## TRUST



**Your data  
package tells a  
story to partners.  
Make sure it's the  
right one.**





**Success in drug development is defined not by what gets approved, but by **who gets to benefit.****