

# The smart use of an innovative approach helped Pfizer expand its addressable market

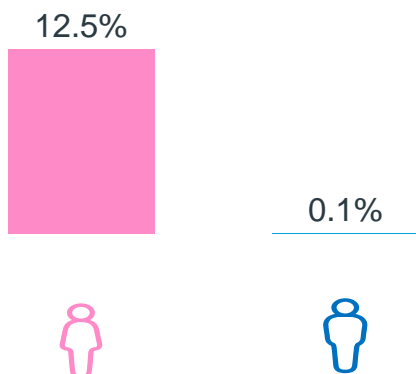
Product Innovation & Registration

RWE based approval

## Business Challenge

Rarity of BC in men limits the feasibility of randomized trials

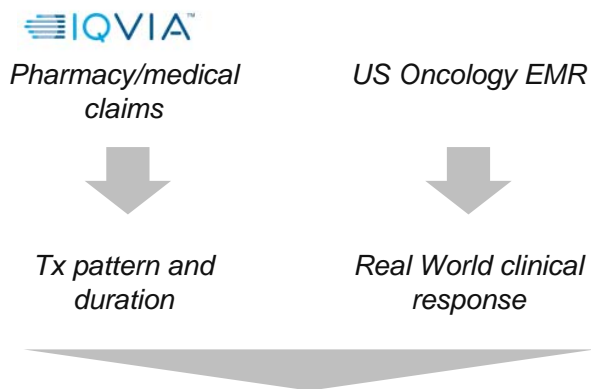
Lifetime risk of developing invasive breast cancer



Women treatment guidelines recommended to men with BC

## Real World Data Driven Solution

RWD was used to describe IBRANCE® (palbociclib) benefits for men with BC



Confirmed clinical benefit from the addition of Ibrance to endocrine therapy

## Results

Evidence generated was accepted by the FDA

“We are **expanding the indication** for Ibrance to include male patients **based upon data from postmarketing reports and electronic health records** showing that the **safety** profile for men treated with Ibrance is consistent with the safety profile in women treated with Ibrance,”

- Richard Pazdur, MD, director of the FDA's Oncology Center of Excellence

Impact

Patient Benefit  
Access to medicines

Cost Saving

N/A

Timing to cost savings realized



Revenue upside

not disclosed

Timing to revenue upside realized

