SCENARIO 1

Device 1 (Mature Technology)

- Conventional device design & well-characterized biomaterials
- Extensive post-market evidence
- Device is safe (risk of harm is low)
- Rare/idiosyncratic events unlikely

Mature Device

Suppose **25 similar** devices exist and on the market

- Pre-clinical, clinical, post-market data
- Different registries

Regulatory Questions

How to use the existing information from **this device** to:

- Determine comparative safety and effectiveness on **similar** device types
- Determine the expected performance on a **new** device

SCENARIO 2

Device 2 (New Technology)

- Modern device design & new biomaterials
- Scarce post-market evidence
- Target populations not well-determined
- Device safety is questionable (risk of harm high)
- Rare/idiosyncratic events likely

New Device

Suppose **no other** US device

- New device available outside US
- Other devices (*somewhat* similar) available in US

Regulatory Questions

How can information from **other devices** be re-used to:

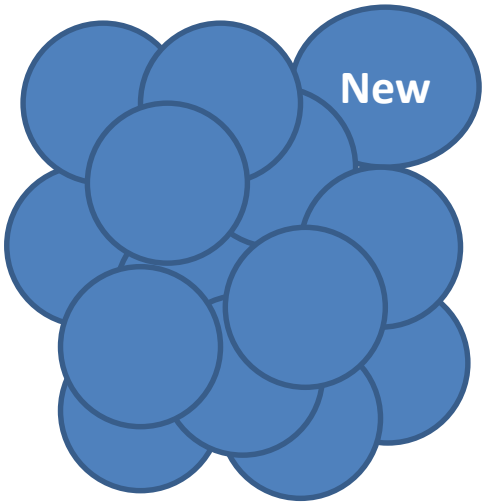
- Predict long-term performance of the **new** device
- Identify (early) device/biomaterial/patient characteristics related to **outlying** performance

INFORMATION AVAILABLE

STRATEGICALLY COORDINATED REGISTRY NETWORK

Mature Device

Existing US Evidence Base

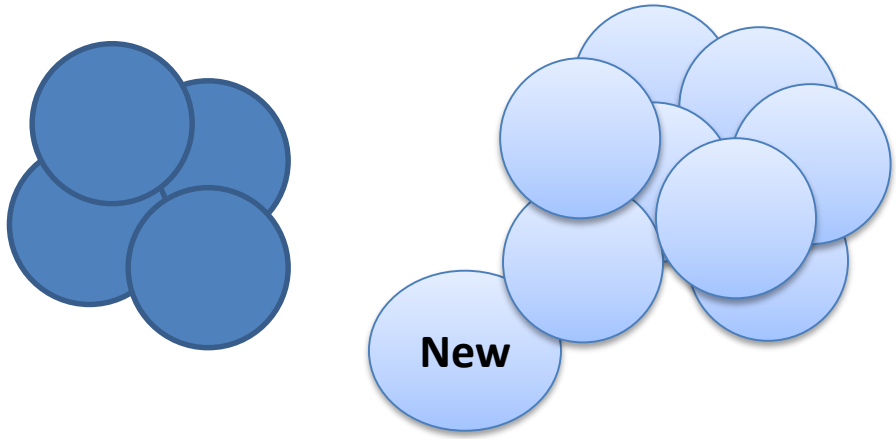


Similarity Scale

New Device

Existing US Evidence Base

Existing Outside US Evidence Base



Similarity Scale