SUPPLY CHAIN POST-APPROVAL CHANGE:

Global Complexity Contributing to Delayed Patient Benefit

International Federation of Pharmaceutical Manufacturers & Associations

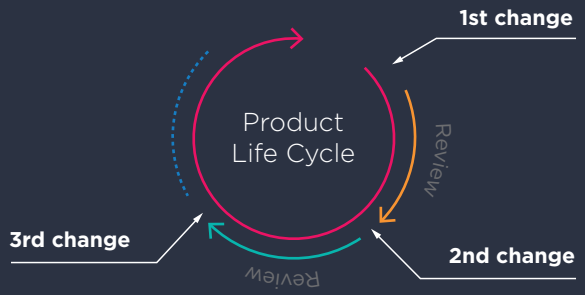
IFPMA

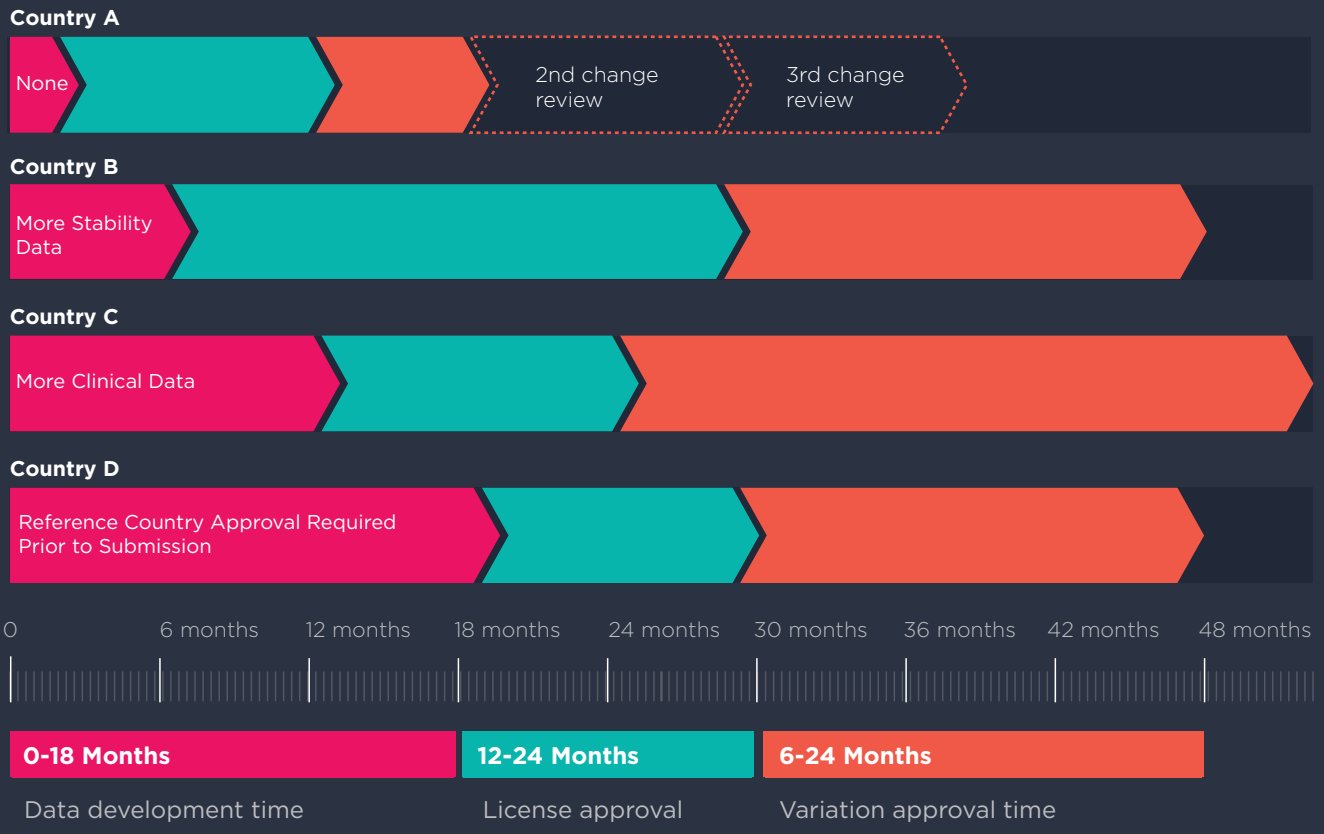
When it comes to licensing a **Medicinal Product** at country level, it will be subject to changes

100 COUNTRIES → 1ST POST-APPROVAL CHANGE →

Hard to step up to the challenge as:

1. change could trigger 0.5-2 year delay
2. changes could trigger 1-4 year delay
3. changes could trigger 1.5-6 year delay





⚠ CHALLENGES:

Unsustainable inventory fragmentation

18m => Fastest timeline for licensure +1 post-approval change

5.5y => Longest timeline for licensure + 1 post approval change

+years => Multiple changes will lead to different product versions

✓ SOLUTIONS:

Important for countries to reach convergence on:

1. Data license requirements

2. Timelines for review

3. Inspection requirements

4. Product testing requirements