SUPPLY CHAIN POST-APPROVAL CHANGE:
Global Complexity Contributing to Delayed Patient Benefit

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

1st change

Product Life Cycle

Review

2nd change

3rd change

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

1ST POST-APPROVAL CHANGE

Country A
None
2nd change review
3rd change review

Country B
More Stability Data

Country C
More Clinical Data

Country D
Reference Country Approval Required Prior to Submission

0-18 Months
Data development time

12-24 Months
License approval

6-24 Months
Variation approval time