Accelerate CMC post approval changes

The story of a regulatory reliance pilot

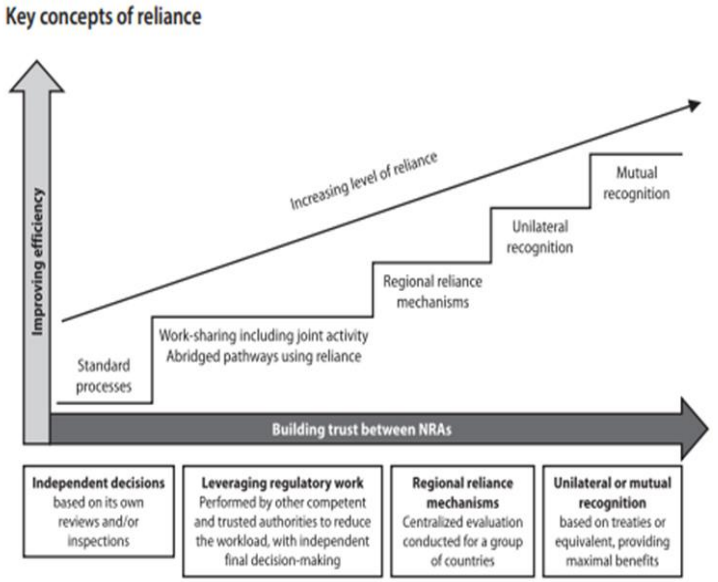
sanofi

Reliance: A key enabler…

…To equal access

…To timely access

…To supply continuity



Source: Good reliance practices in regulatory decision-making for medical products : WHO TRS 1033, Annex 10

Post Approval Change Vaccine Reliance Pilot

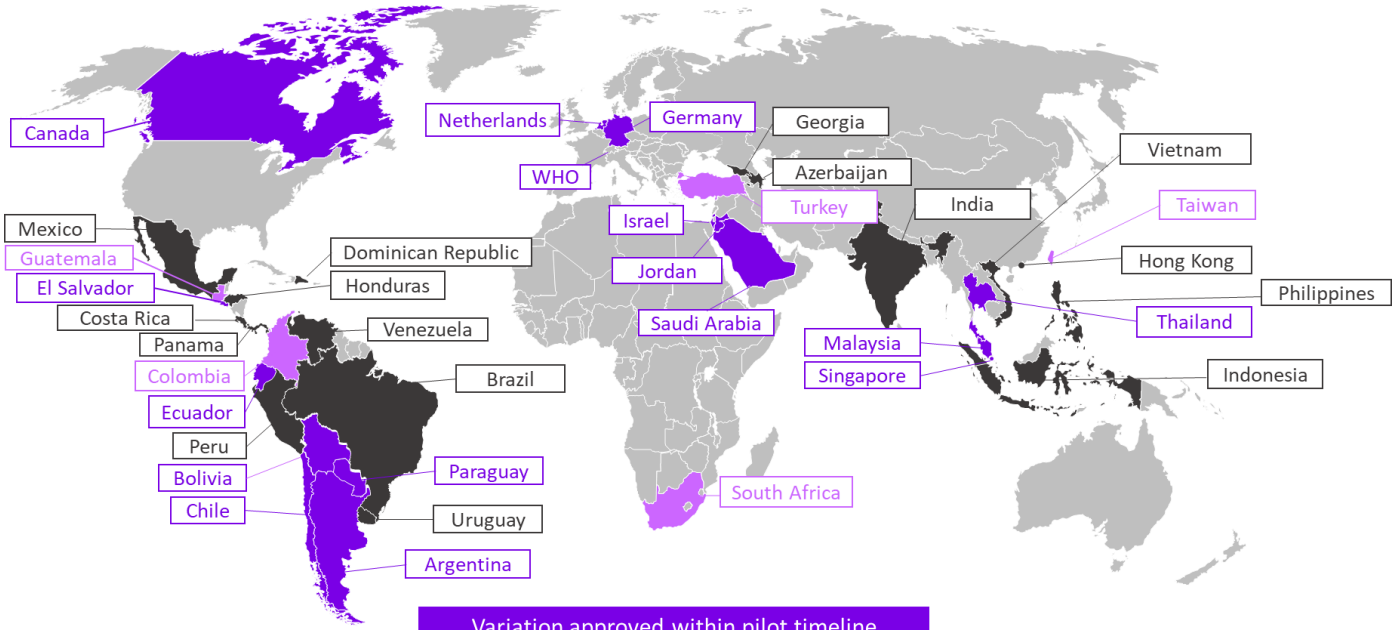
Transfer of a legacy WHO prequalified vaccine Filling & Packaging activities

37 COUNTRIES IMPACTED

FROM 4 YEARS to 6 MONTHS
Regulatory approvals x 8 time faster

21 countries participated in the Pilot

57 % **of participation**



Success factors (1/2)

1 Standard dossier

submitted in all countries based on EU CTD dossier content and Health Canada / WHO requirements

1 Set of requirements

For all countries : some local requirements will NOT be met, based on scientific rationale

1 Timeline

Unique timing for all countries after approval granted by Health Canada as the Responsible NRA

Success factors (2/2)

1 Language

Same language : English for all NRAs except administrative local documents

1 Q&A tool & document

1 tool & 1 Q&A document sent to all NRAs creating transparency

1 Report

Health Canada assessement report and Q&A shared with all NRAs as Sanofi authorises to share confidential and unredacted information

Ø GMP Inspection

Reliance on the GMP certificate of the French site issued routinely by ANSM

Ø Testing

Testing considered as not necessary by Health Canada for this type of change

Key barriers encountered to engage NRAs (1/2)

Misalignment of Reliance Principles	No reliance principles or principles not aligned with pilot in local regulations
New Registration required	Alternate site requires new registration
Grace Period	Fixed grace period of 6/12 months after approval of dossier instead of 18 months required by Sanofi

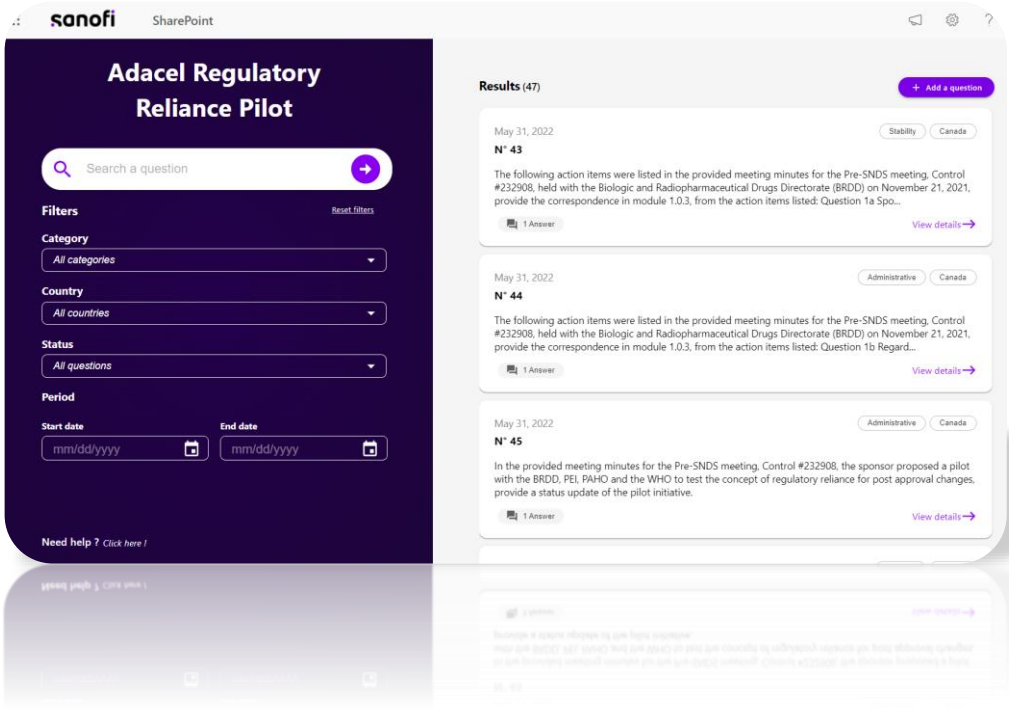
Documentation requested

- GMP documentation
- Additional Module 3 information not part of Standard Dossier
- Legalized CPP
- Extract of GMP Inspection Report
- Shipping conditions
- Dossier translated

Key barriers encountered to engage NRAs (2/2)

1 Manufacturing Site	Only 1 site authorized in the license to manufacture the vaccine
1 Batch Release site	Only 1 site authorized in the license to release the vaccine
Sovereignty	Join the pilot only if the NRA is the reference NRA
Difficulties to connect with NRAs	NRAs not available due to Covid pandemic & outbreaks
Ressources change	New agency Director decided to leave the pilot

Transparency in the Q&A



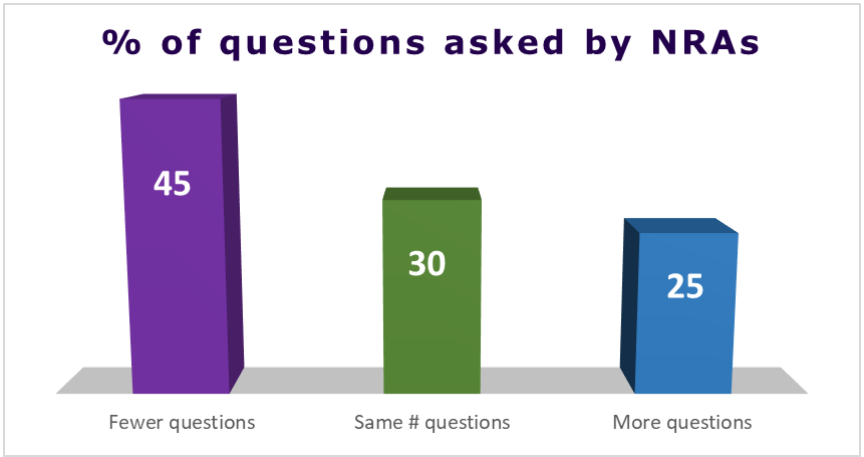
49 QUESTIONS FROM 11 COUNTRIES

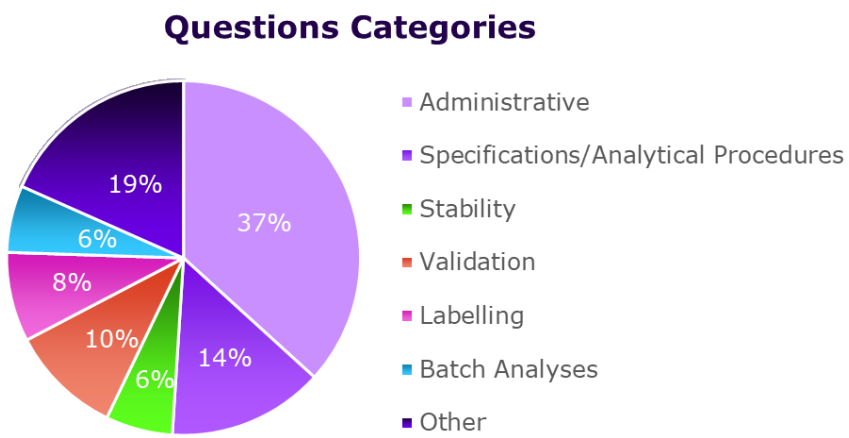
36 questions during the Q&A period from 8 countries

Approval Status & Q&A

APPROVALS

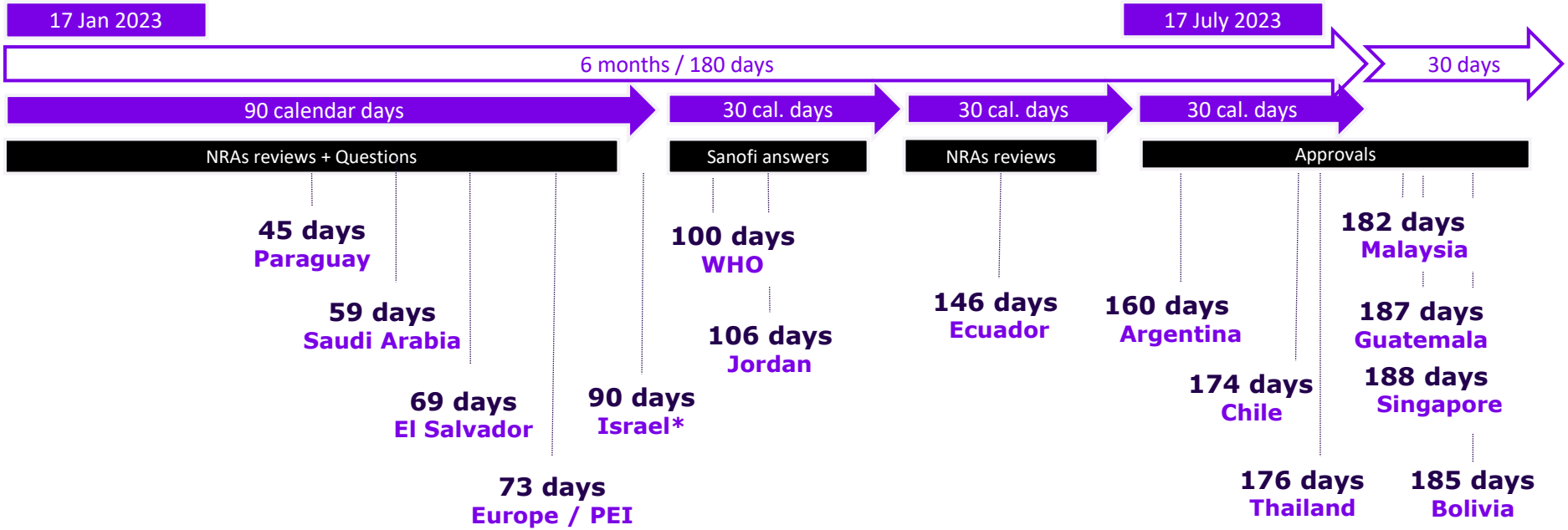
- **7 without questions**
- **9 with questions**





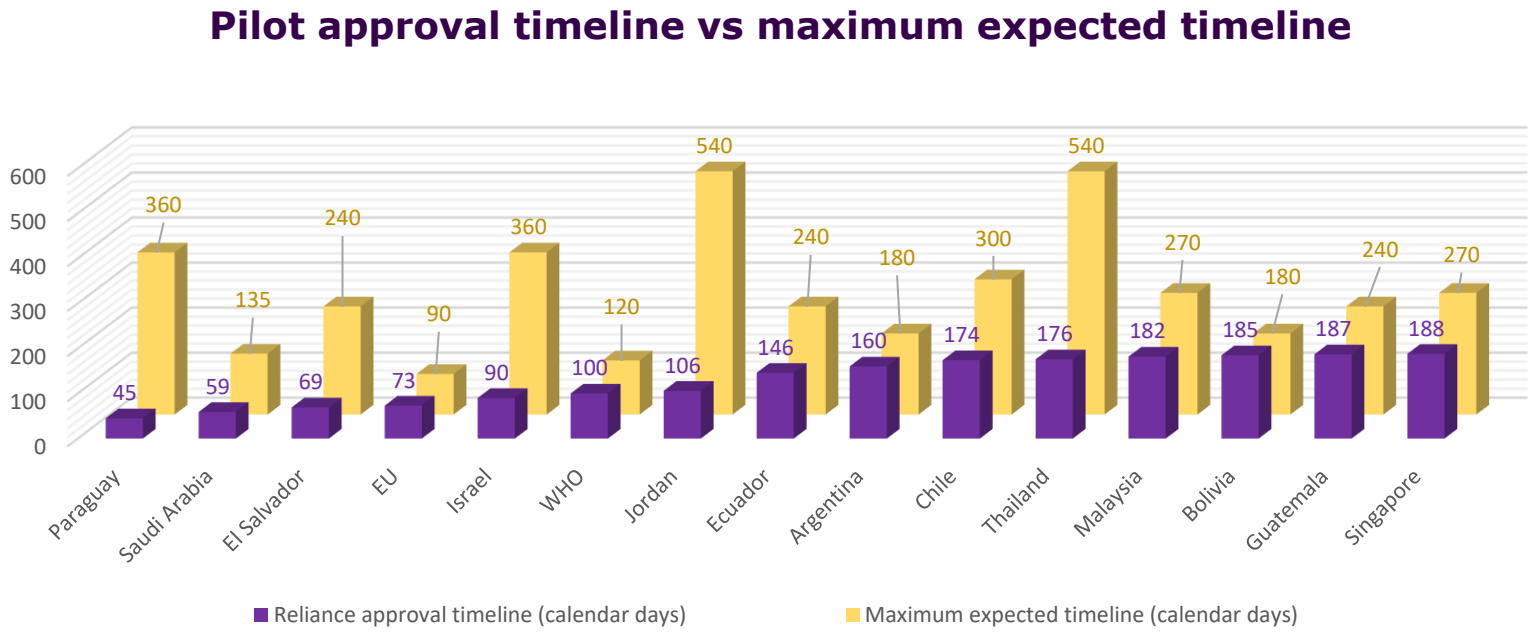
Approval Timelines (1/2)

75 % **of NRAs approved within 6 months** *(+1 month)*



* *Approval modules 2 & 3*

Approval Timelines (2/2)



Lessons Learned (1/3)

⚠ Local regulations and **lack of** global **harmonization** are important barriers:

- Data requirements
- Reporting levels : from limited reporting to new registration
- Inability to have alternate sites/batch release
- Timing for introduction of changes
- Perception of working outside the process

Lessons Learned (2/3)

⚠ **Duplication of data** delaying submission
e.g : Legalized CPP + unredacted assessment report : ↗ 3 months

⚠ **Site registration** requested **in parallel** of reliance variation. Sanofi did not anticipated the risk of delay.

⚠ **Difficulties** to present the pilot

Lessons Learned (3/3)

Appetite for reliance allowed 57 % participation during COVID pandemic & collaboration with



Openess to receive **standard dossier**

Reduced timeline

> Faster approvals than average timeline observed

> Approval within 6 months +/1 month

Next Steps

- Concluding on **# questions received** with/without pilot
- Collecting **feedback** of participating NRAs on pilot and Q&A tool
- **Comparing** timeline, #questions **to countries that did not participate**
- **Communication** : publication, conferences

More to come upon data analysis …

Thank you !

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