

Accelerate CMC post approval changes

The story of a regulatory
reliance pilot

sanofi



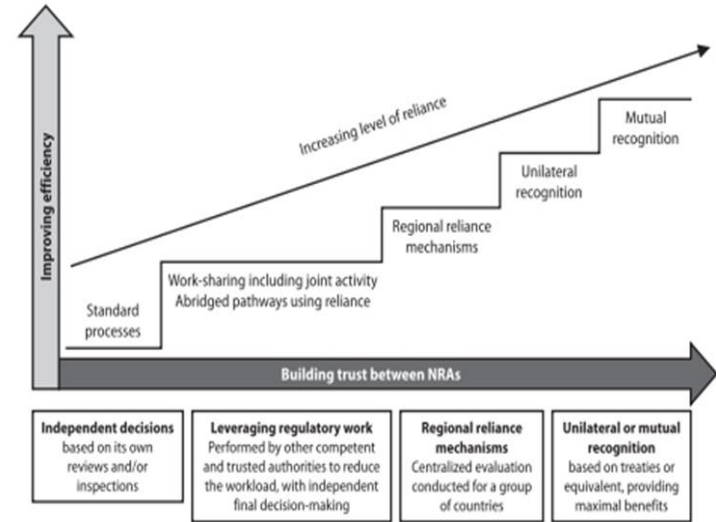
Reliance: A key enabler...

...To equal access

...To timely access

...To supply continuity

Key concepts of reliance



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**

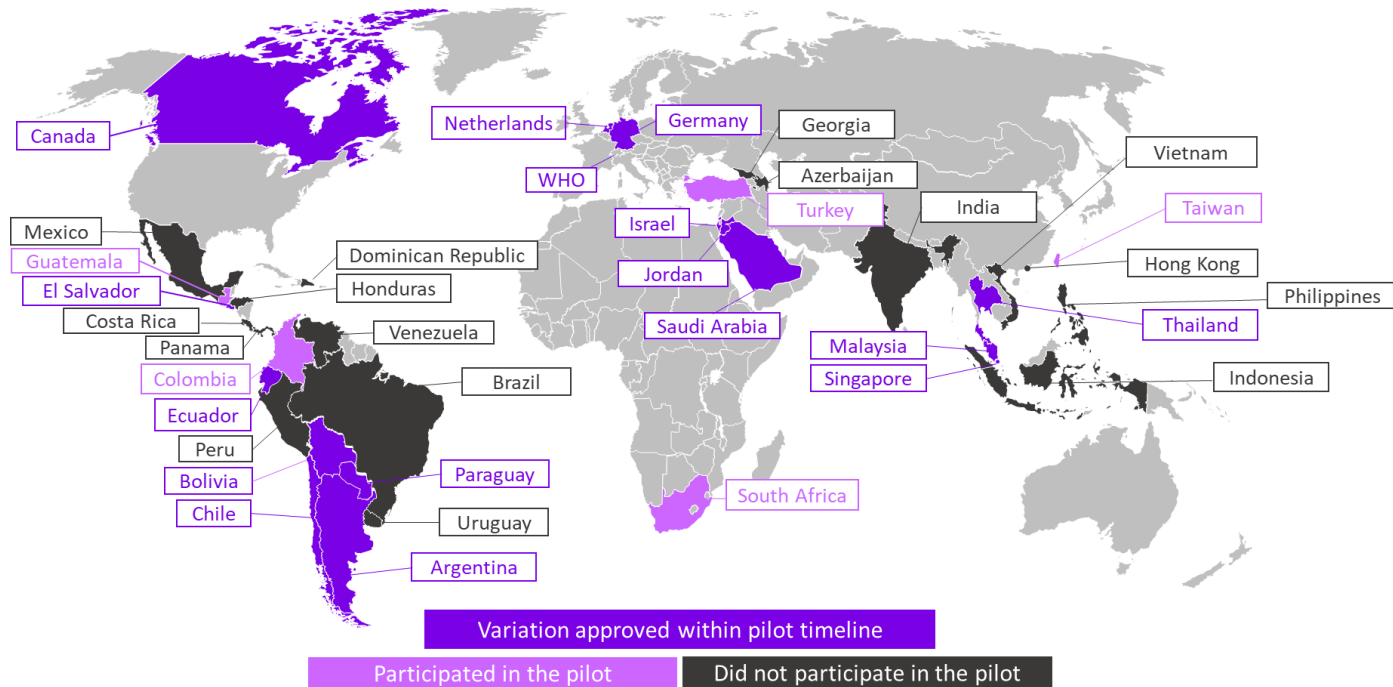


FROM 4 YEARS to 6 MONTHS
Regulatory approvals x 8 time faster



21 countries participated in the Pilot

57 % of participation



Success factors (1/2)

1 STANDARD DOSSIER

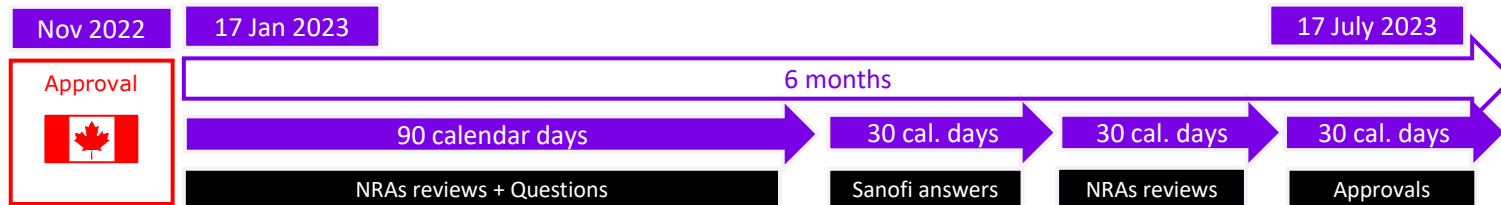
submitted in all countries
based on EU CTD dossier
content and Health Canada /
WHO requirements

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 assessment 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

sanofi | SharePoint

Adacel Regulatory Reliance Pilot

Search a question

Filters [Reset filters](#)

Category
All categories

Country
All countries

Status
All questions

Period
Start date: mm/dd/yyyy End date: mm/dd/yyyy

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Results (47) [Add a question](#)

May 31, 2022 [Stability](#) [Canada](#)
N° 43
The following action items were listed in the provided meeting minutes for the Pre-SNDS meeting, Control #232908, held with the Biologic and Radiopharmaceutical Drugs Directorate (BRDD) on November 21, 2021, provide the correspondence in module 1.0.3, from the action items listed: Question 1a Spo...
1 Answer [View details](#)

May 31, 2022 [Administrative](#) [Canada](#)
N° 44
The following action items were listed in the provided meeting minutes for the Pre-SNDS meeting, Control #232908, held with the Biologic and Radiopharmaceutical Drugs Directorate (BRDD) on November 21, 2021, provide the correspondence in module 1.0.3, from the action items listed: Question 1b Regard...
1 Answer [View details](#)

May 31, 2022 [Administrative](#) [Canada](#)
N° 45
In the provided meeting minutes for the Pre-SNDS meeting, Control #232908, the sponsor proposed a pilot with the BRDD, PEI, PAHO and the WHO to test the concept of regulatory reliance for post approval changes, provide a status update of the pilot initiative.
1 Answer [View details](#)



49 QUESTIONS
FROM **11** COUNTRIES

36 questions during the
Q&A period from **8**
countries

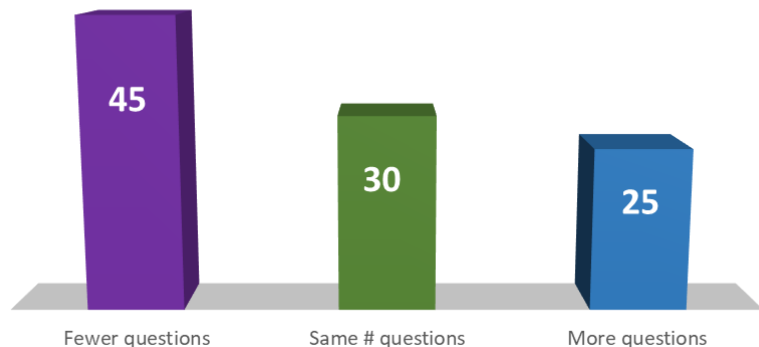
Approval Status & Q&A



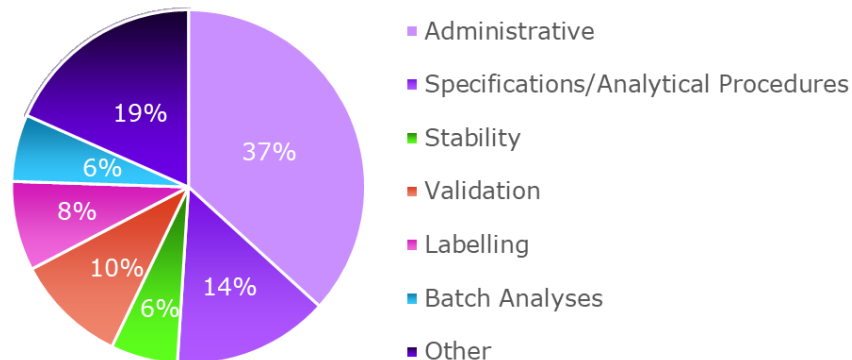
APPROVALS

- 7 without questions
- 9 with questions

% of questions asked by NRAs

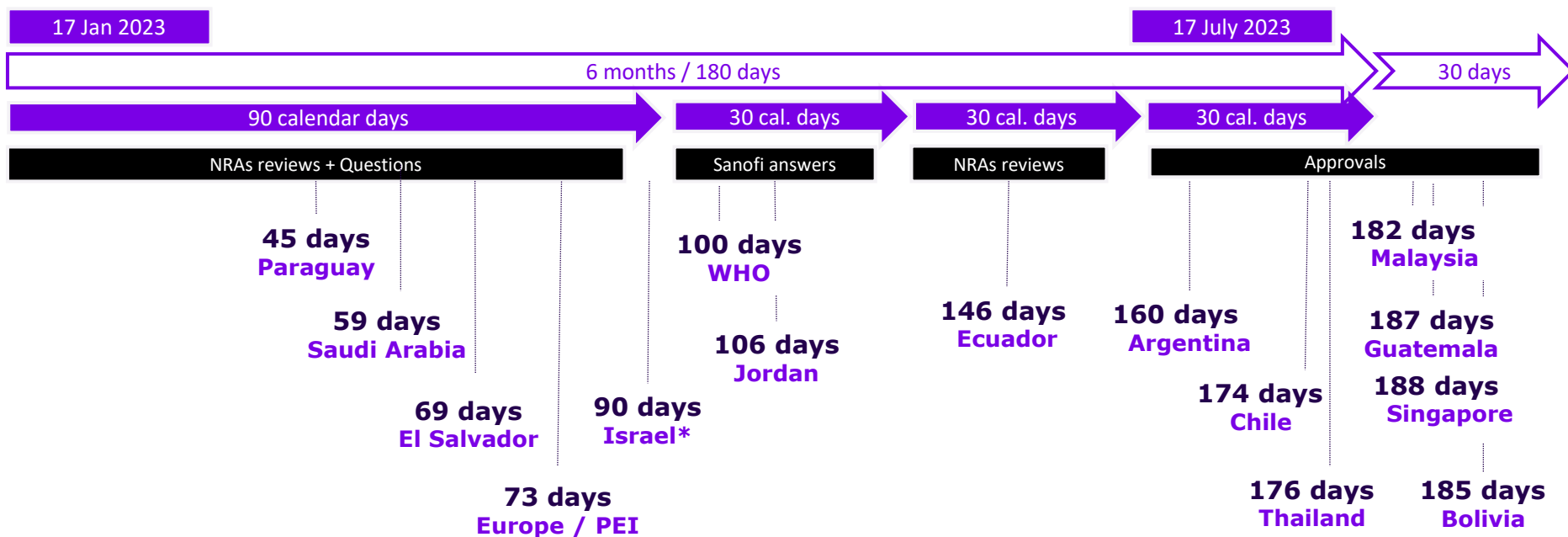


Questions Categories



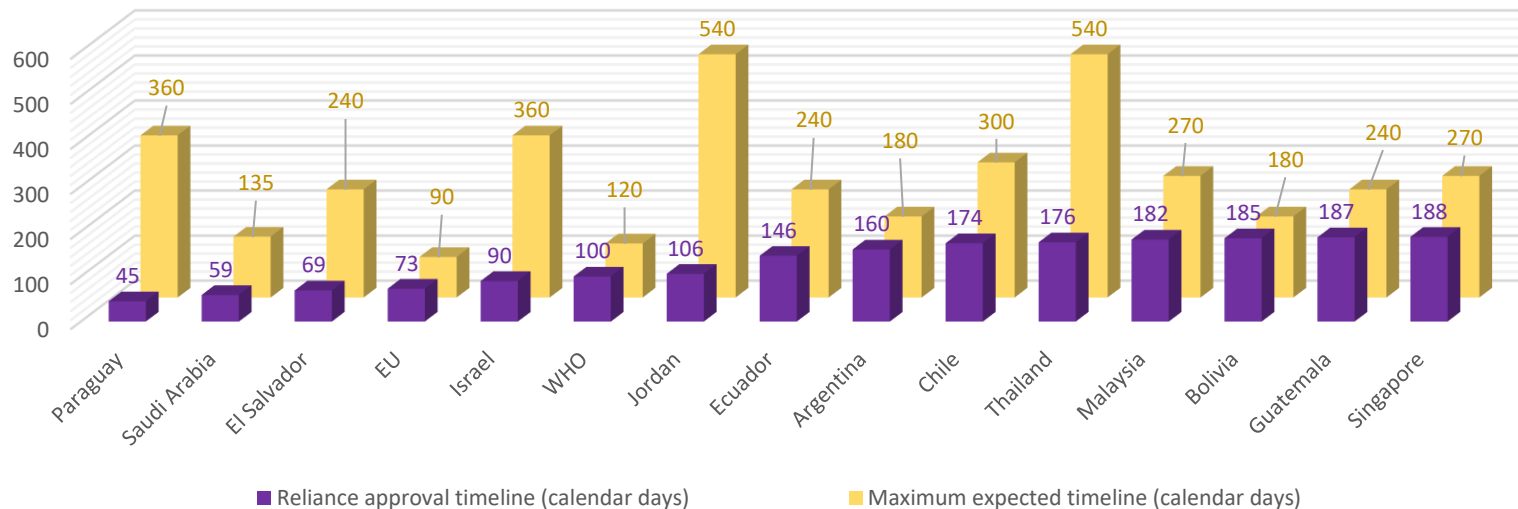
Approval Timelines (1/2)

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



Approval Timelines (2/2)

Pilot approval timeline vs maximum expected timeline



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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