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Case study: Reliance pilot to improve management of Post-Approval Changes (PAC) during the lifecycle of a vaccine

PANDRH Webinar Nov 17, 2022

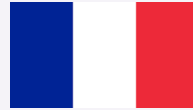
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T. Gastineau

Global Quality Head of Innovation, Culture & Engagement

PAC Reliance Pilot of a Vaccine

Transfer of a legacy WHO prequalified vaccine Filling & Packaging activities



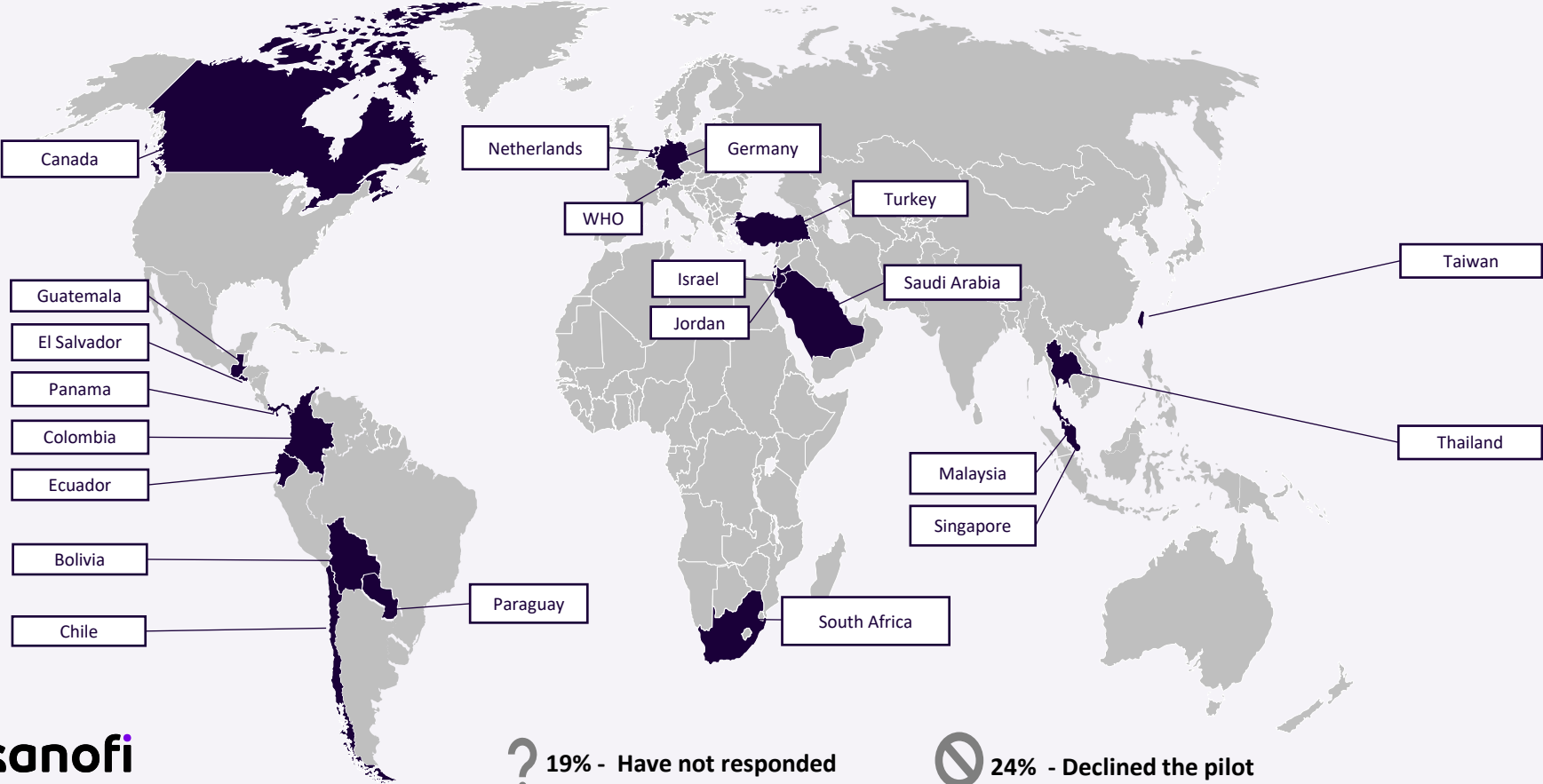
37 COUNTRIES IMPACTED



Regulatory approvals :

FROM 4 YEARS to 6 MONTHS

57% of countries (21) participate to the Pilot (As of 09 Nov 2022)



Focus on Latin American NRAs (As of 09 Nov 2022)

8 ACCEPTED

- Bolivia
- Chile
- Colombia
- Ecuador
- El Salvador
- Guatemala
- Panama
- Paraguay

6 PENDING

- Argentina
- Brazil
- Costa Rica
- Honduras
- Mexico
- Venezuela

3 DECLINED

- Dominican Republic
- Peru
- Uruguay

Success factors (1/2)

1 STANDARD DOSSIER

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

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1 SET OF REQUIREMENTS

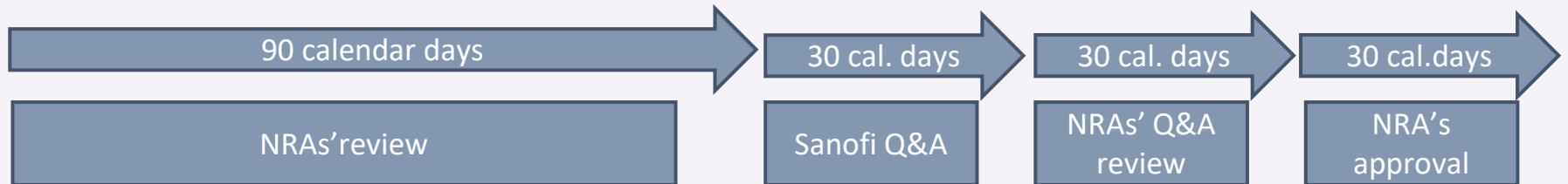
*For all countries : some local
requirements will NOT be met,
based on scientific rationale*

1 TIMELINE

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

1 Q&A DOCUMENT

*Unique Q&A document sent to all
NRAs creating transparency*



Success factors (2/2)

1 LANGUAGE

Same language : English for all NRAs except administrative local documents

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1 REPORT

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

No GMP INSPECTION

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

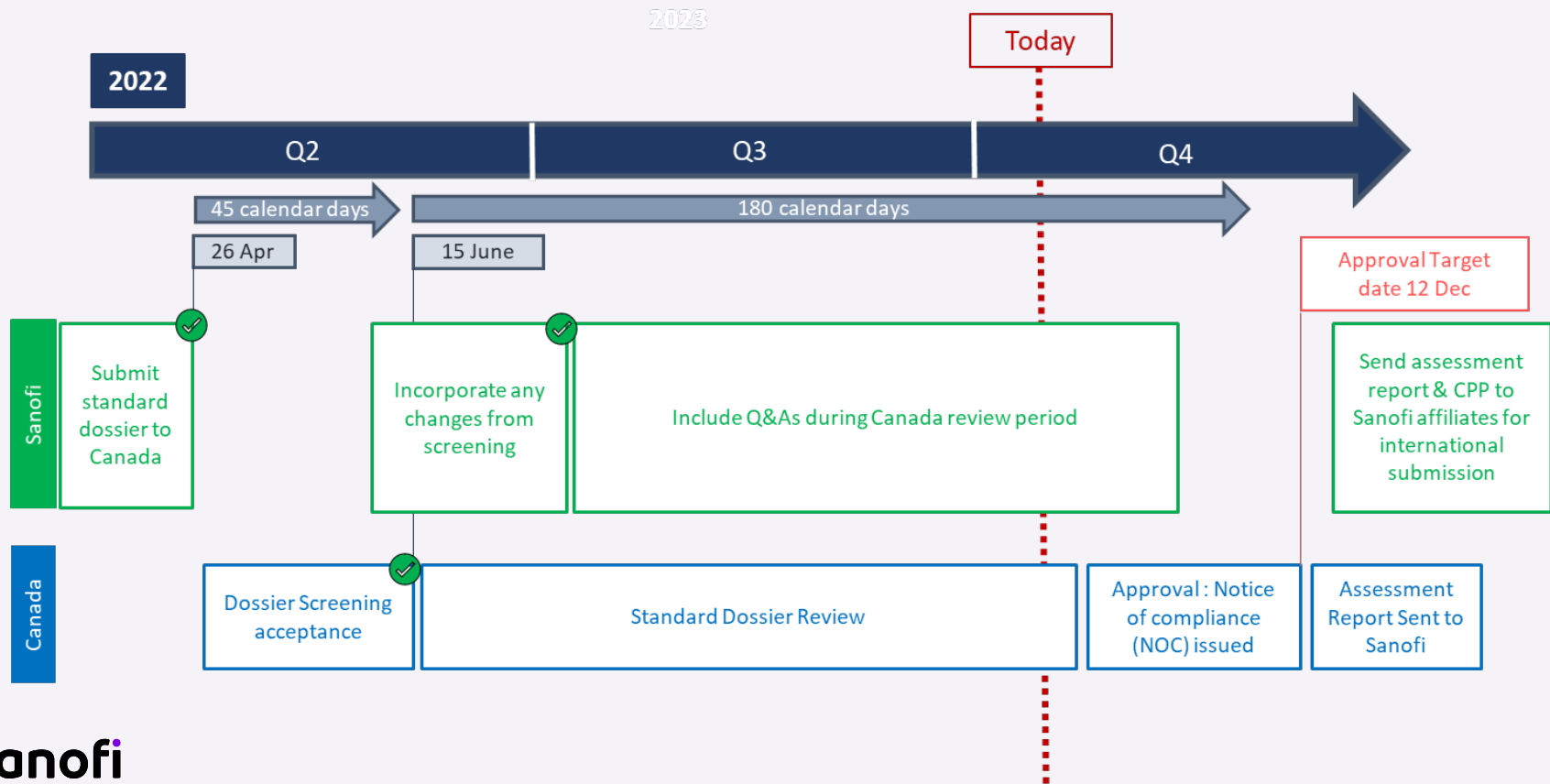
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No TESTING

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

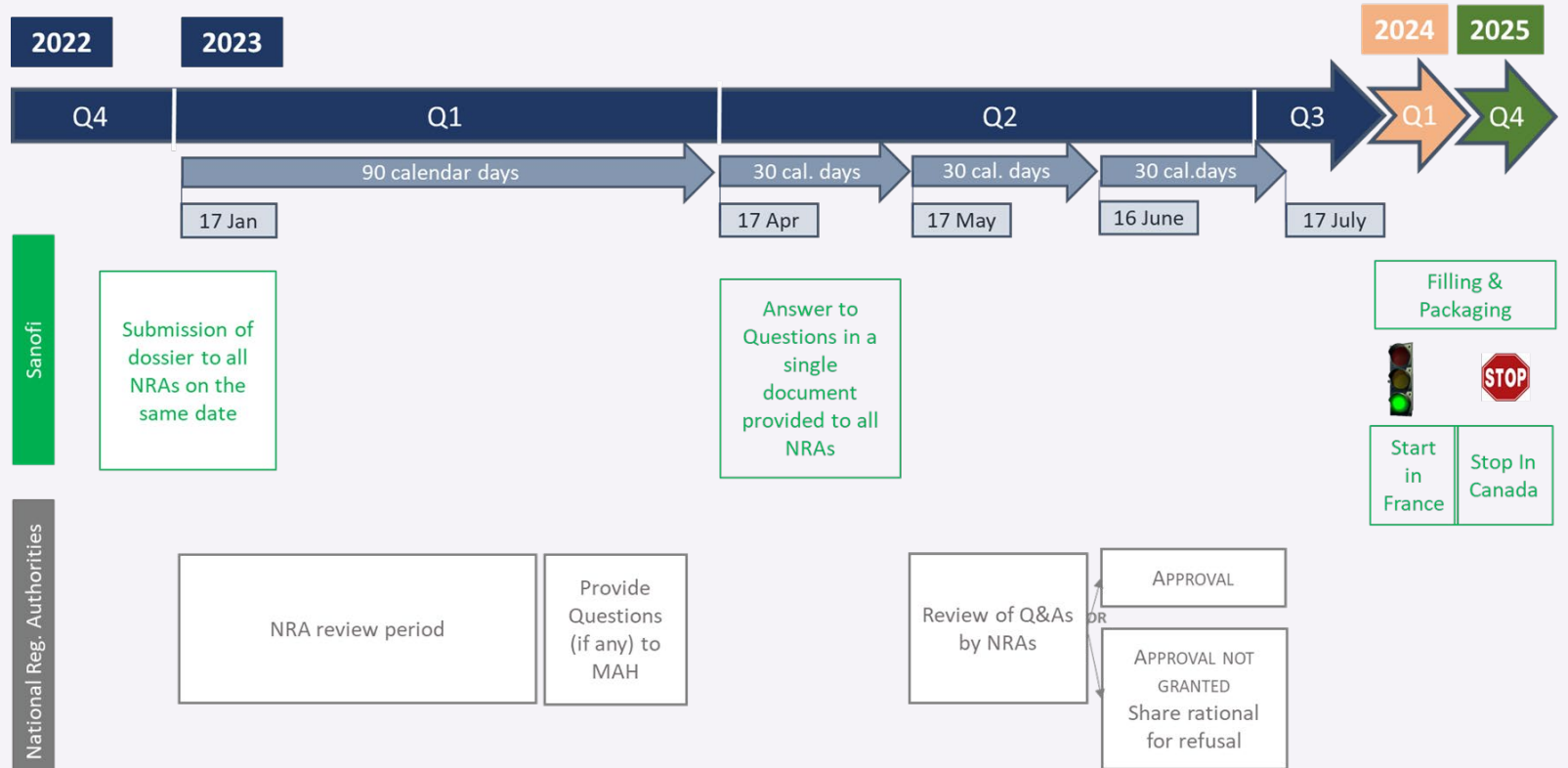
1 timeline for all countries (1/2)

STEP 1 : Submission & Approval in Canada

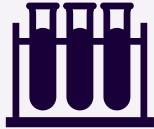


1 timeline for all countries (2/2)

STEP 2 : Submission & Approval in ALL other participating NRAs



Barriers encountered (1/2)



1 BATCH RELEASE SITE

Only 1 site authorized in the license to release the vaccine



1 MANUFACTURING SITE

Only 1 site authorized in the license to manufacture the vaccine



GRACE PERIOD

(time from approval of the Variation to available date of the product)

Fixed grace period of 6/12 months after approval of dossier instead of 18 months required



NEW REGISTRATION REQUIRED

*Several manufacturing sites authorized in the license
BUT alternate site = New Registration*



GMP DOCUMENTATION &/OR INSPECTION

GMP documentation and/or inspection required to add the filling at the French site as no reliance on French authorities' inspection certificate

Barriers encountered (2/2)



DIFFICULTIES TO CONNECT WITH NRAs

NRAs not available due to Covid pandemic & outbreaks



MISALIGNMENT OF RELIANCE PRINCIPLES

*Local Legislation does not contain reliance principles
Local reliance legislation not aligned with the pilot*



ADDITIONAL DOCUMENTATION

Few NRAs joining the pilot requested additional Module 3 documentation that is not part of Standard Dossier



GOVERNMENT CHANGE

Change in government may impact agreement to participate to the pilot

Conclusion

- Challenge to engage NRAs
- Required internal company endeavors
- Great support of external stakeholders



- We welcome NRAs who did not reply yet to still apply (NRAs who first declined are welcome to change their mind !)

Due date: Dec 1st !

Acknowledgment to the Sanofi vaccines active contributors

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-
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Thank you
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