

# Navigating the Transition from Provisional to Full Approval

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Australian Government

Department of Health, Disability and Ageing  
Therapeutic Goods Administration

# Transition – Grand Rounds

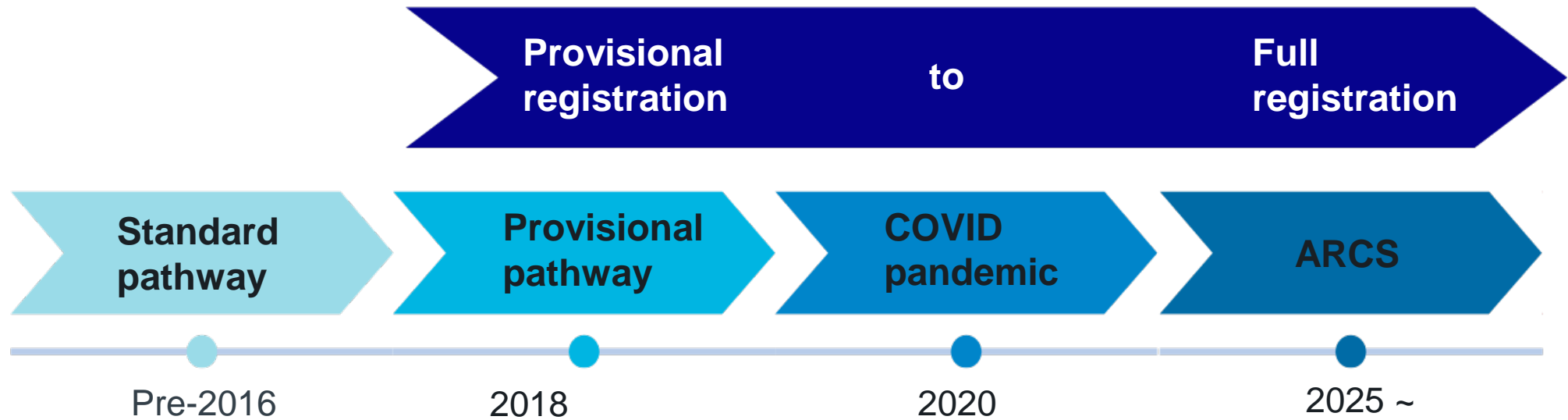
**Why**

**When**

**How**



# Registration Transition



## Knowledge check:

Q: Why is it necessary to transition from provisional registration to full registration?

# Why

Early availability  
of Medicine

to

Confirmation  
Data

## Provisional registration:

- whether, based on **preliminary clinical data**, the **safety and efficacy** of the medicine for the purposes for which it is to be used have been satisfactorily established; and
- whether the **quality** of the medicine for the purposes for which it is to be used has been satisfactorily established;
- whether...the Secretary is satisfied with the applicant's plan to submit comprehensive clinical data on the safety and efficacy of the medicine before the end of the 6 years that would start on the day that registration would commence;

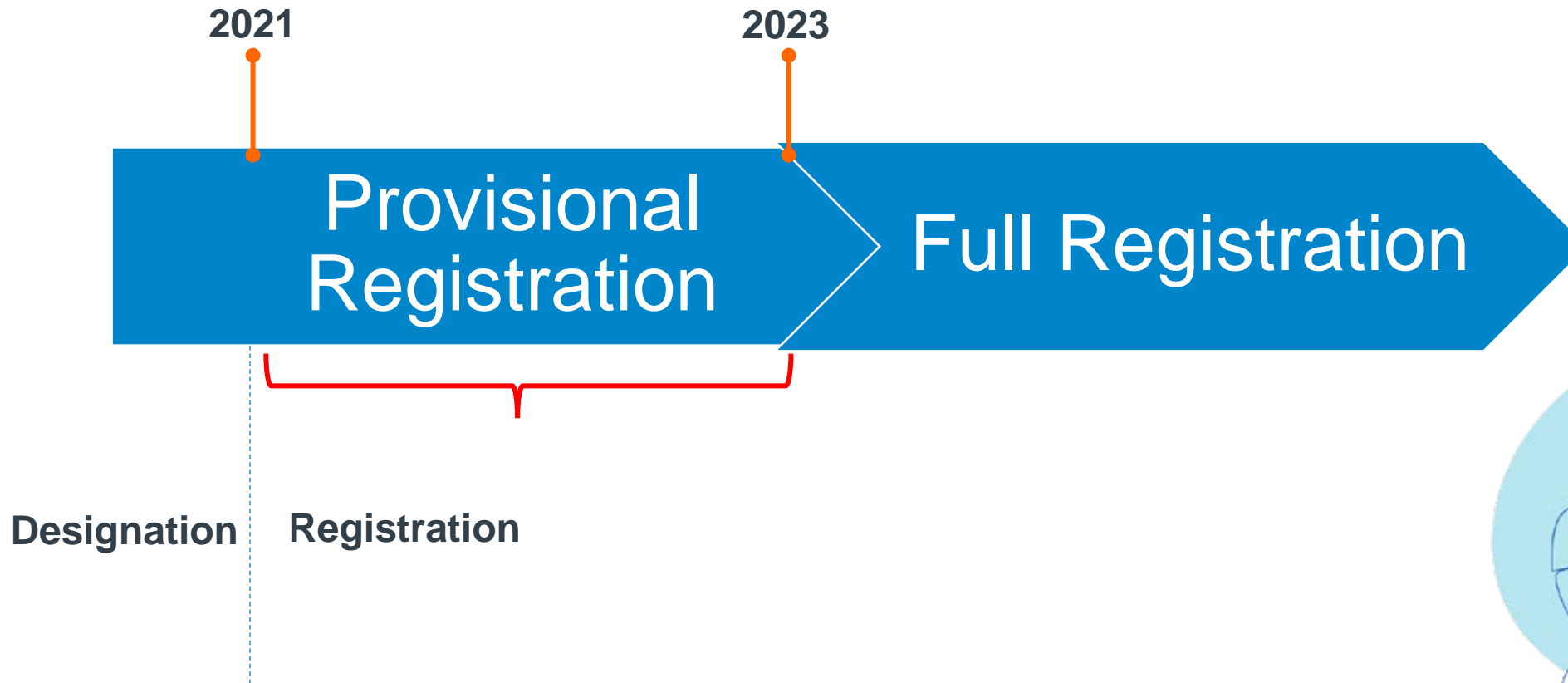
## Full registration:

- whether the **quality, safety and efficacy** of the goods for the purposes for which they are to be used have been satisfactorily established



# Case study 1

COVID Vaccine X  
(Original strain)

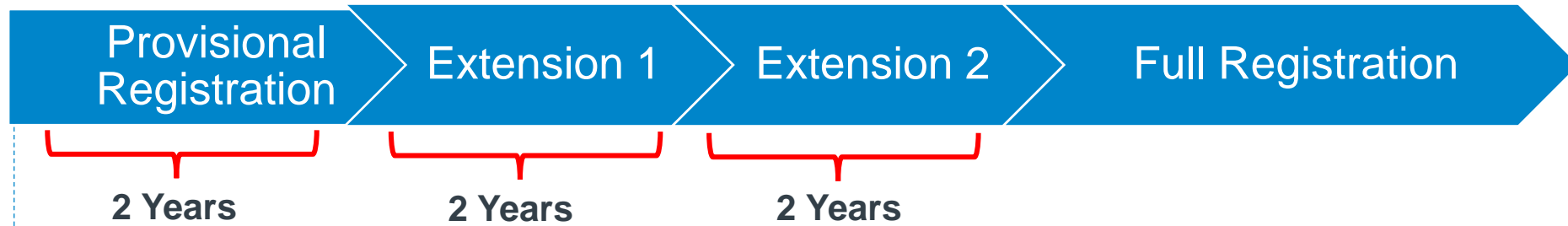




## Knowledge check:

Q: When can the application to transition from provisional registration to full registration be submitted?

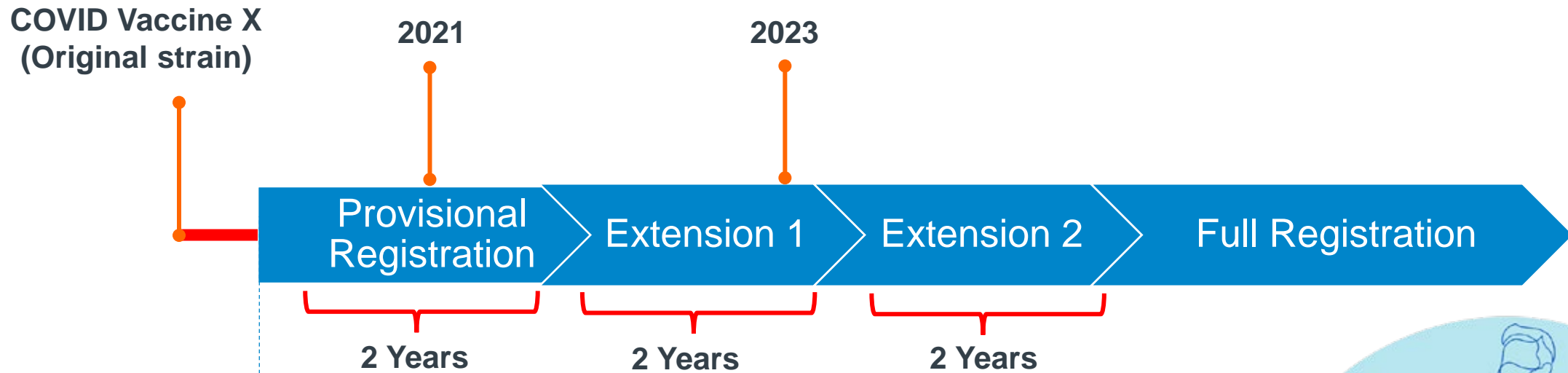
# When



Designation Registration



# Case study 1

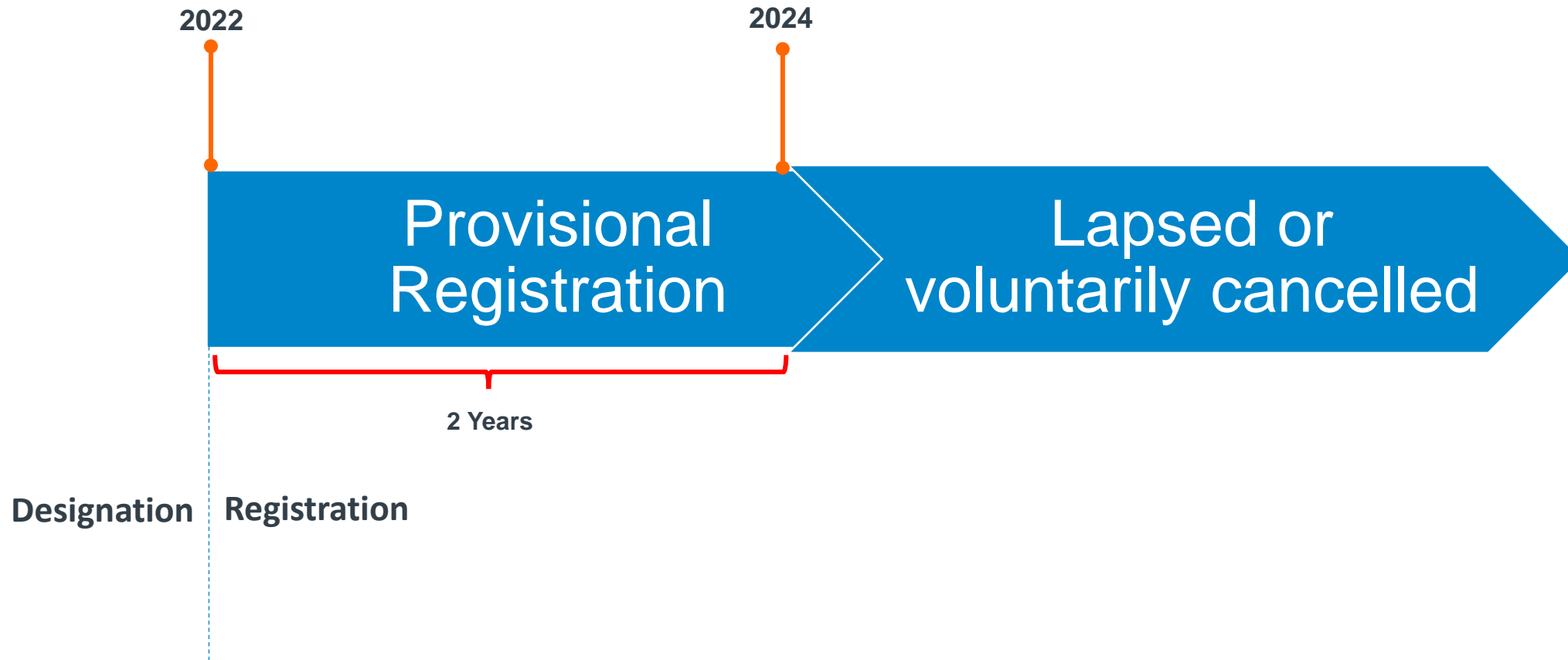


Designation Registration



# Case study 2

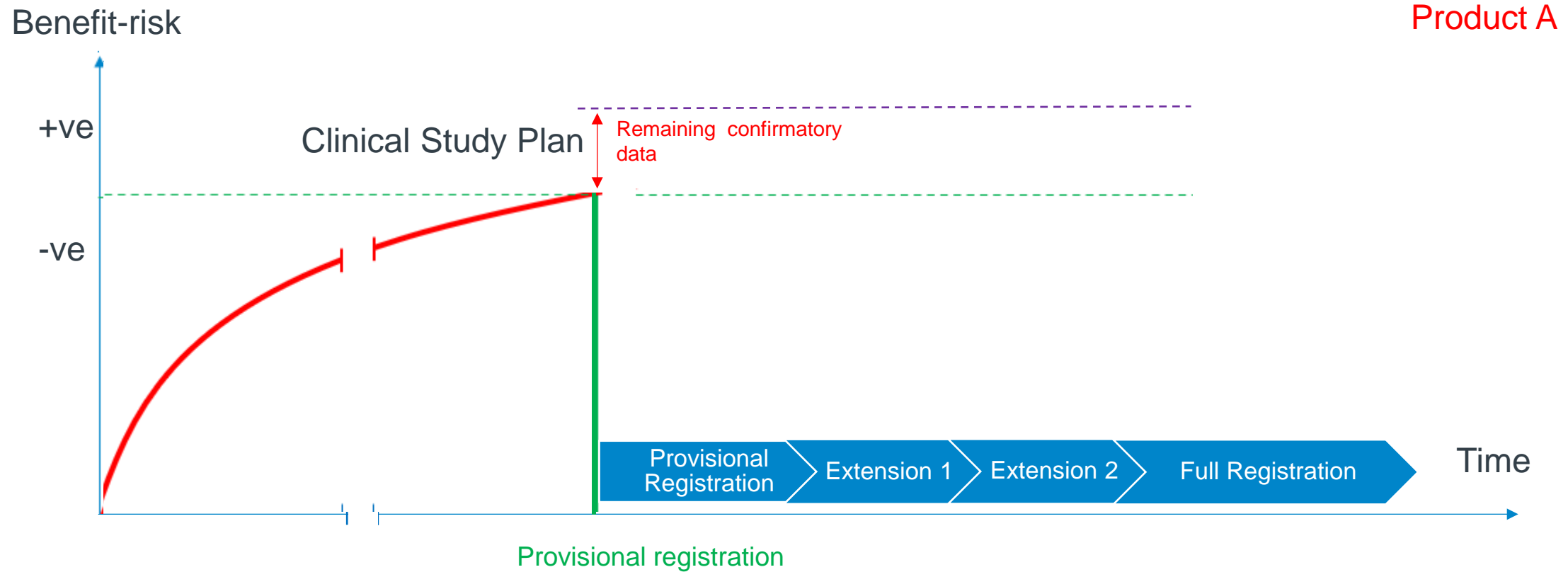
COVID Vaccine Y  
(Bivalent BA1 strain)



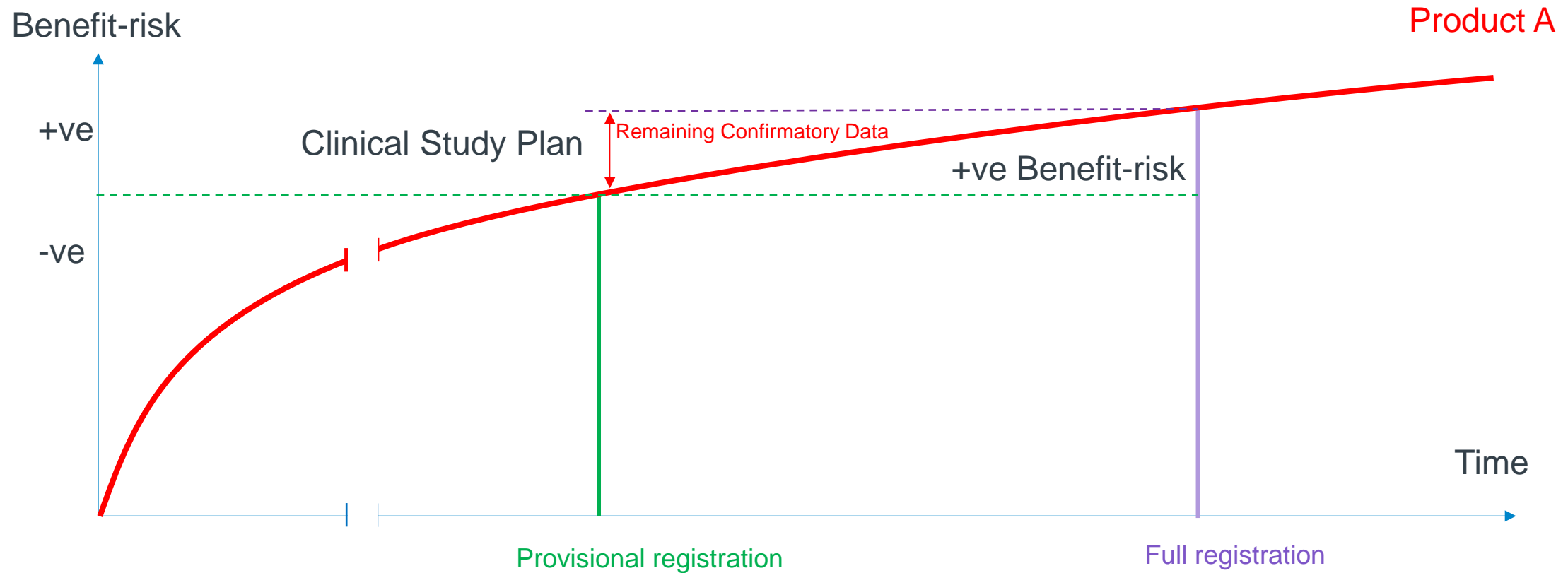
## Knowledge check:

Q: How can you apply for  
Transition from Provisional  
to Full Registration?

# How

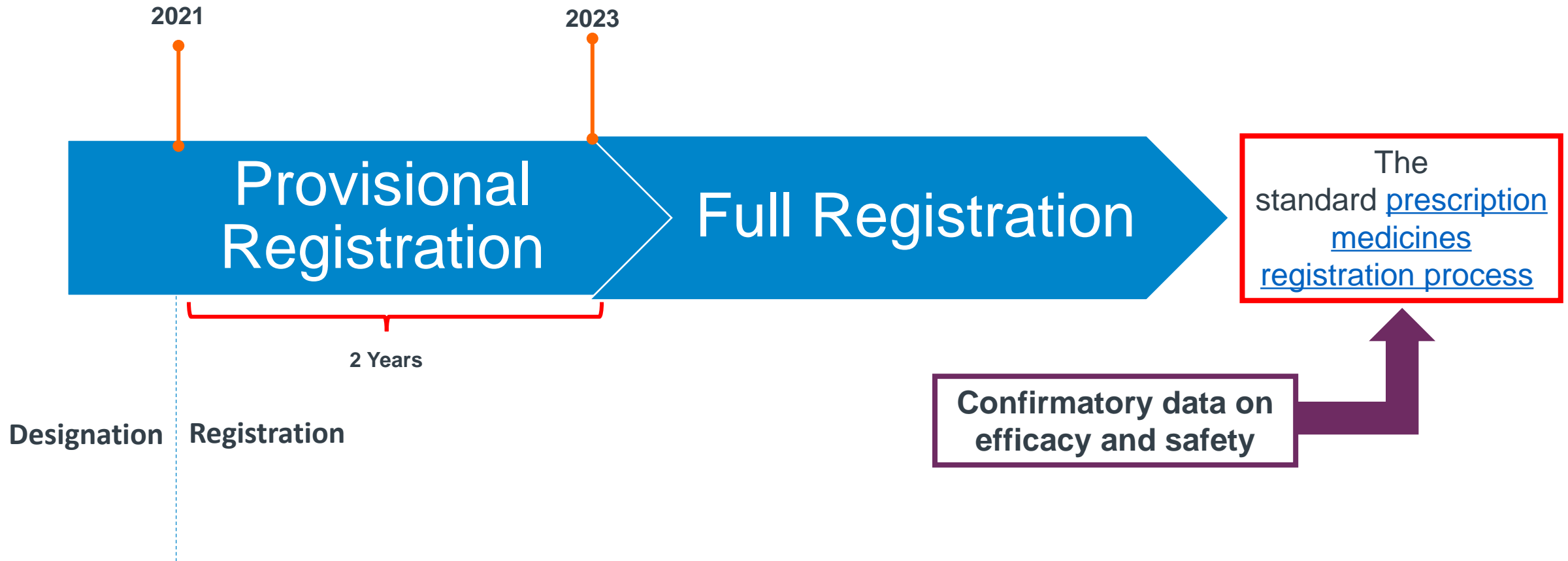


# How- Application Type S

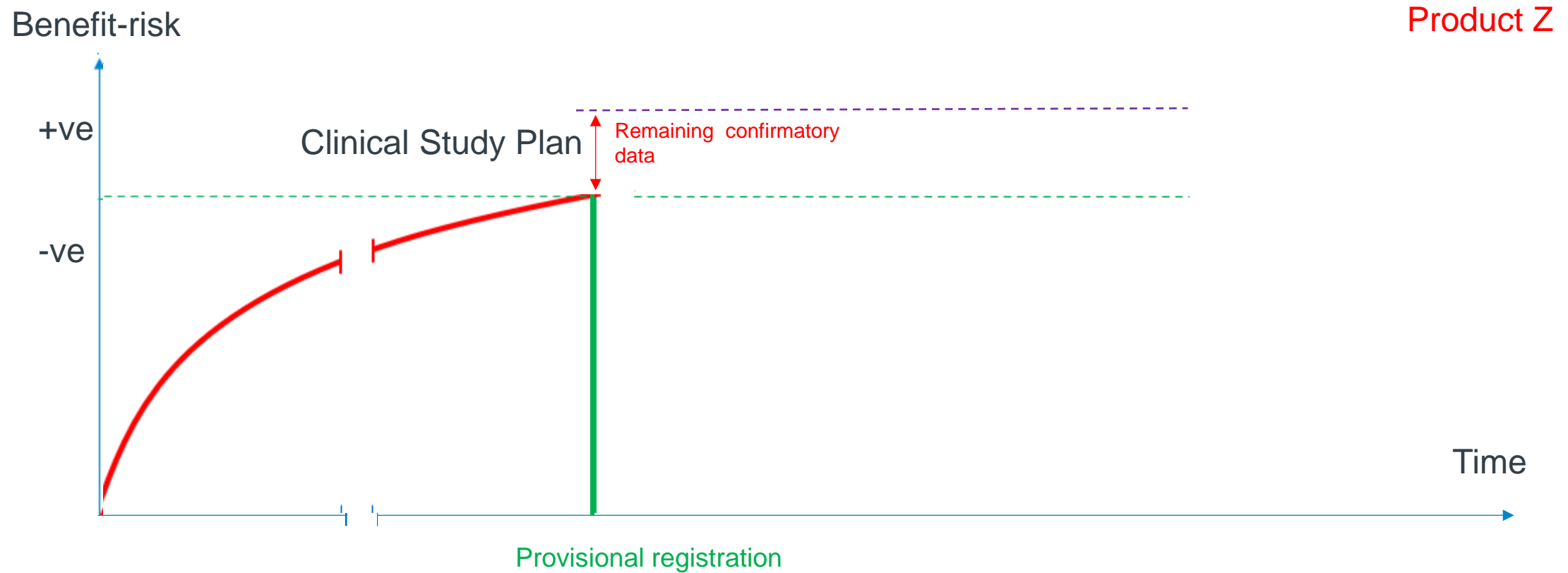


# Case study 1

COVID Vaccine X  
(Original strain)



# Case study 3





# Case study 3- Application Type S withdrawn



# Take away

**Why**

Confirms the early establish benefit

**When**

Within 6 years

**How**

Advance Notice – timely submission –  
comprehensive confirmatory data



# Therapeutic Goods Administration (TGA)

## Exhibition booth No.60

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