

# Using Electronic Patient-Reported Outcomes (ePRO) in Clinical Trials: Lessons Learnt

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# What is Patient-Reported Outcome (ePRO)

**“any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else”**

*US Food and Drug Administration: Guidance for Industry Patient-reported outcome measures: Use in medical product development to support labeling claims. US: Department of Health and Human Services Food and Drug Administration; December, 2009.*

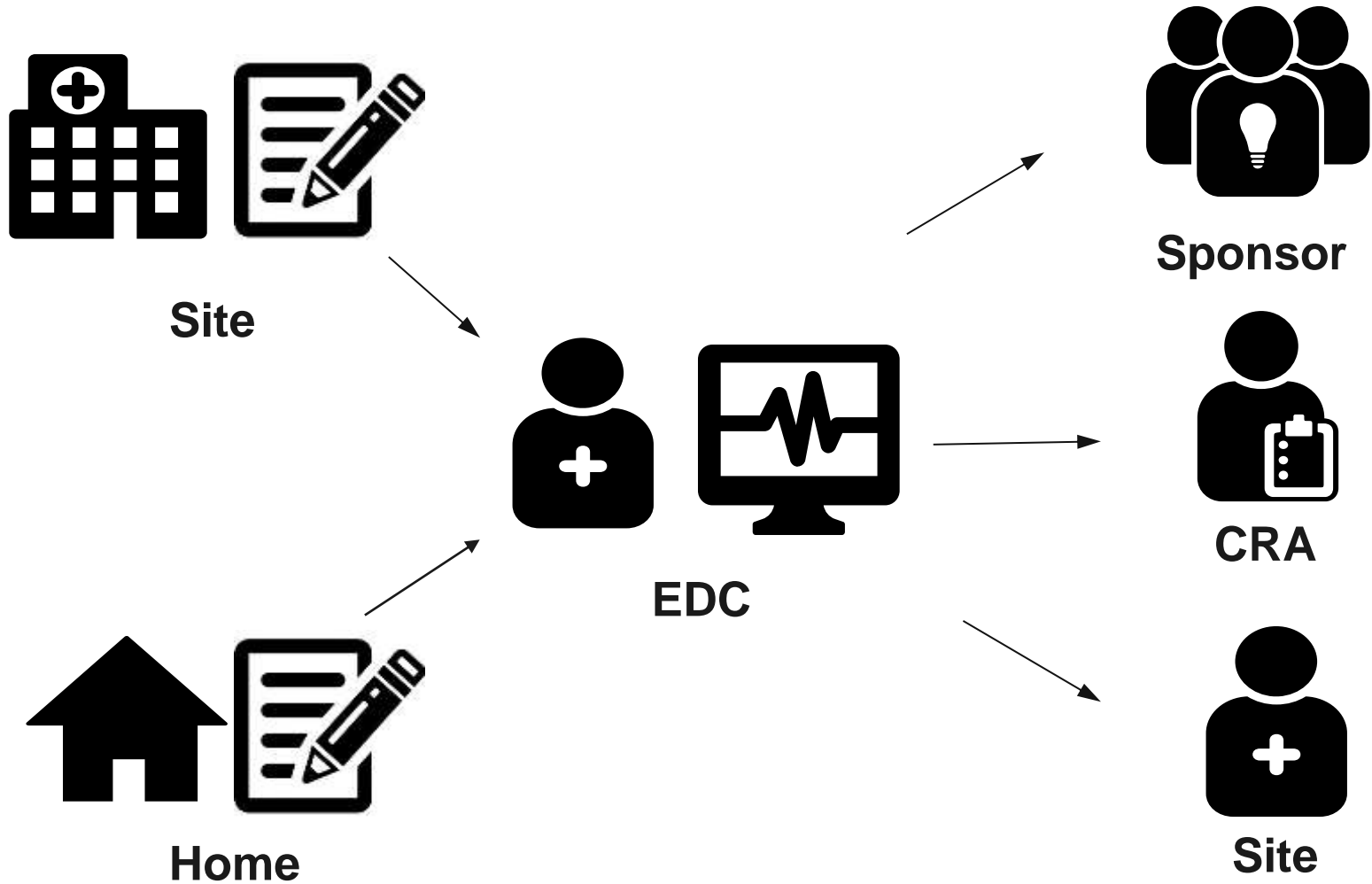


# Why the need for Patient-Reported Outcome?

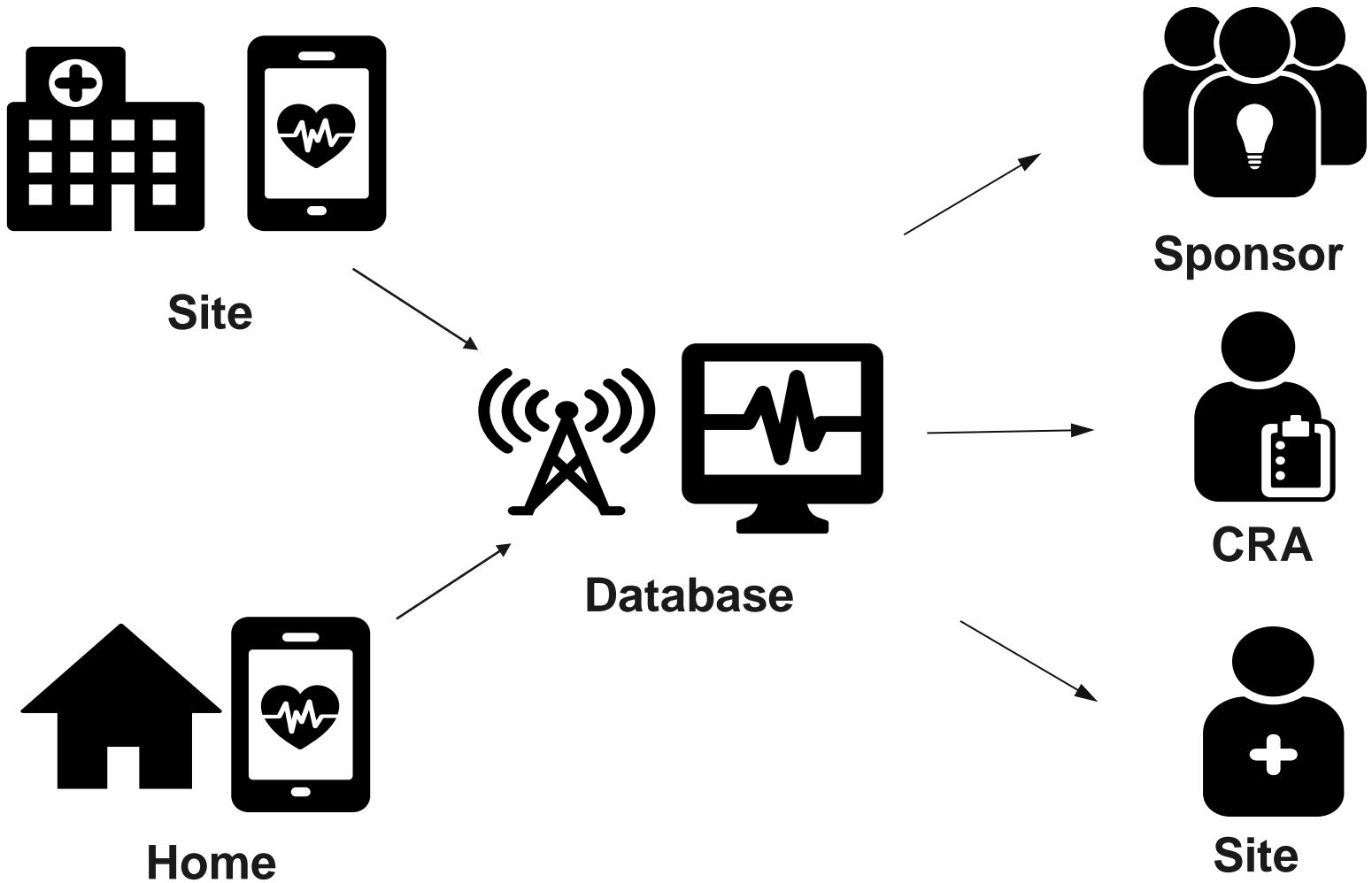
- Patients are at the center of healthcare
- PROs are increasingly playing a part in drug and medical device process
- Importance of PROs in Clinical Trials:
  - > Demonstrate drug efficacy
  - > Evaluate the treatment benefit or risk of new medical products
  - > Comparison of treatment
- Importance of PROs is evidenced by the FDA's issuance of [Guidance for Industry Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims](#)



# Paper PRO



# Electronic PRO



# Advantages of ePRO



More accurate and complete data



Easy portability i.e. Handheld devices



Improve protocol compliance



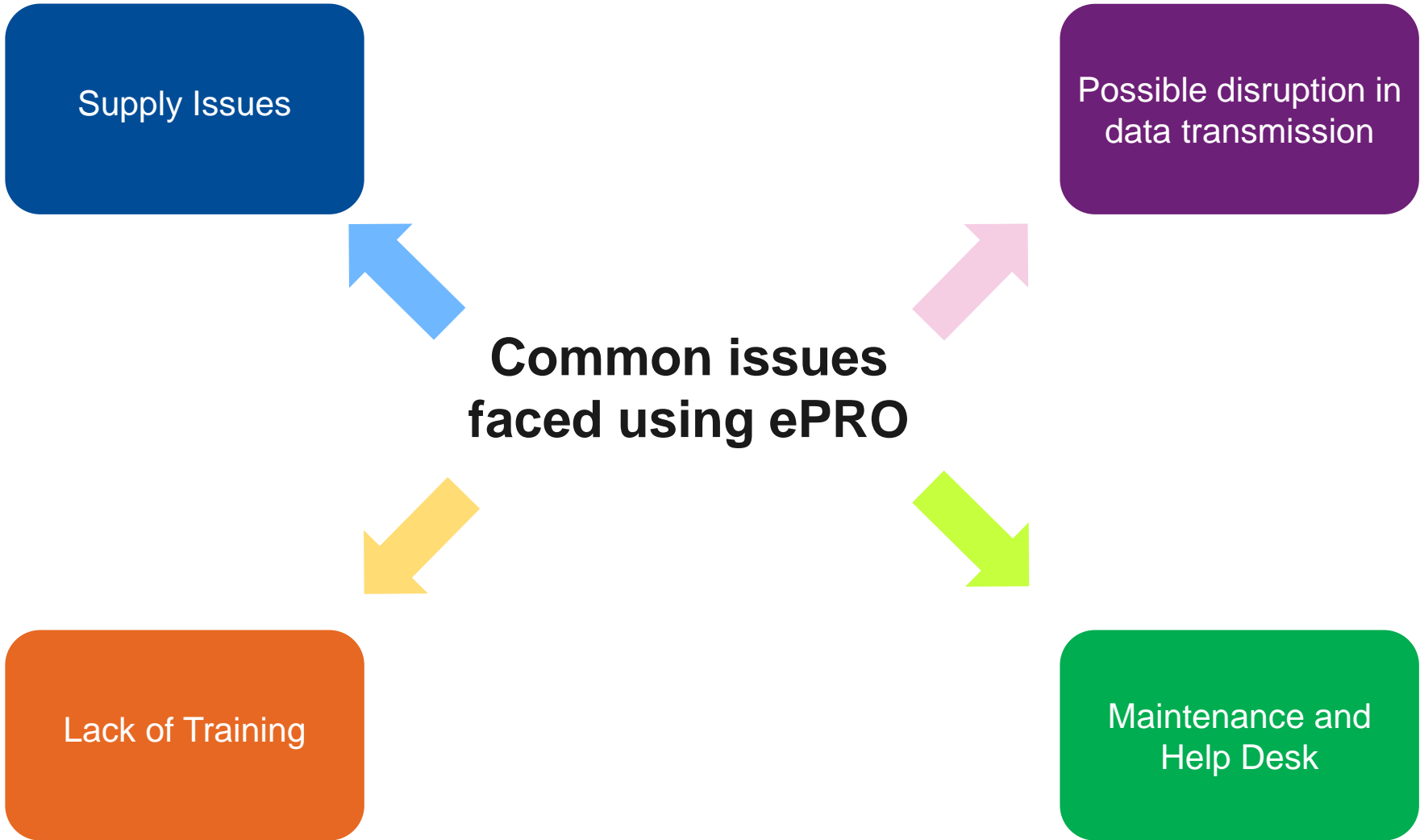
Avoidance of secondary data entry error



Easier to handle skip pattern



Less administrative burden



# Case study #1 – Incorrect language input in ePRO

## Situation

- Subjects are required to complete Patient-Reported Outcomes using home-based electronic PRO (ePRO) device. ePROs are available in English, Singapore Malay and Singapore Simplified Chinese.
- Subjects X and Y are Chinese speaking and do not understand English
- Subjects are to complete ePROs in Singapore Simplified Chinese
- ePROs in Singapore Simplified Chinese were not uploaded to the ePRO devices, HK Traditional Chinese was uploaded instead
  - Subject X completed ePRO in HK Traditional Chinese → HK Traditional Chinese ePRO was not submitted to CIRB for approval
  - Subject Y did not complete ePRO at visit 0 as there were no Singapore Chinese ePROs.



# Case study #1 – Incorrect language input in ePRO

## Solution

### Corrective actions:

- Both events were reported to ethics and sponsor.
- Subject X to return the device to upload the correct Chinese.
- Study coordinator to confirm with subject X that he/she could understand HK Chinese and was able to comprehend the ePRO. This information to be documented in subject X case notes.

### Preventive actions:

- Request sponsor to provide a spare device for training purpose
- Ensure the correct languages are uploaded in the electronic devices prior to first subject in
- Train and remind the study coordinator that any documents provided to subjects need to be approved by EC

## **Case study #2 – Alarm prompt was not triggered for ePRO completion**

### **Situation**

- Subjects are required to complete Patient-Reported Outcomes using home-based electronic PRO (ePRO) device at home. ePRO device alarm will be triggered 3 days in advanced to remind subject to complete the ePRO
- Subject Z had completed the ePRO at one visit and did not charge the ePRO device
- ePRO device ran out of battery and data was not successfully transferred to the repository
- Subject Z had re-charged the device but the time-stamp in the device was not successfully configured
- Alarm was not prompted to remind completion on the next ePRO → subject Z did not complete the ePRO

## **Case study #2 – Alarm prompt was not triggered for ePRO completion**

### **Solution**

#### **Corrective actions:**

- Incompletion of ePRO at next visit was reported to ethics and sponsor.
- IT ticket was raised to ePRO helpdesk to reset the time-stamp of the device

#### **Preventive actions:**

- Remind subjects to charge their device routinely
- Review device status and ePRO data in repository to ensure subject are compliant

# Take-Home Message for Study Coordinators

Get involved during the hands-on user training

Check for valid user access in advanced

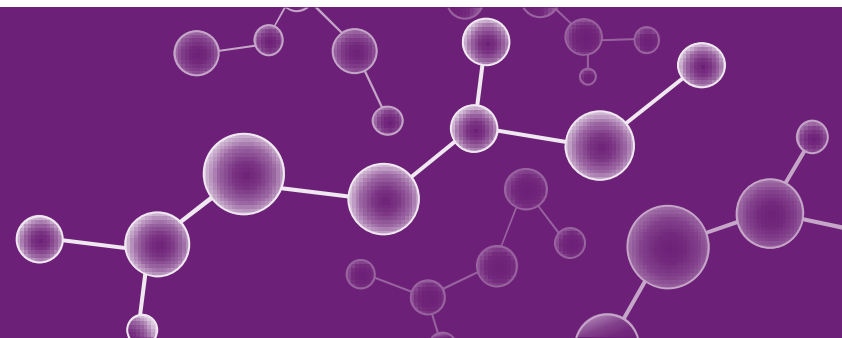
Check for connectivity during SIV

Provide patients adequate trainings

Review report to identify trends / issues that may need to be addressed

Do not be afraid to ask questions when in doubt

*Thank you!*





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