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”

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](https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm208727.htm)
Electronic PRO

Site

Database

Sponsor

CRA

Site

Home
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
Common issues faced using ePRO

Supply Issues

Possible disruption in data transmission

Lack of Training

Maintenance and Help Desk
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

<table>
<thead>
<tr>
<th>Solution</th>
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**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
<table>
<thead>
<tr>
<th>Get involved during the hands-on user training</th>
<th>Check for valid user access in advanced</th>
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<tbody>
<tr>
<td>Check for connectivity during SIV</td>
<td>Provide patients adequate trainings</td>
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<tr>
<td>Review report to identify trends / issues that may need to be addressed</td>
<td>Do not be afraid to ask questions when in doubt</td>
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