The advantages of eClinRO assessments when migrated and implemented according to best practices include:

- Best practices for electronic migration of COAs have mostly focused on patient-reported outcome (PRO) measures.
- Critical Path Institute’s ePRO Consortium and PRO Consortium developed consensus-defined best practice recommendations for electronic migration and implementation of clinician-reported outcome (ClinRO) assessments.

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Table 1. Evaluation of Measurement Comparability for ClinRO and eClinRO Assessments: Level of Modification and Supporting Evidence

<table>
<thead>
<tr>
<th>Classification</th>
<th>Rationale</th>
<th>Level of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>The strategies for the transformation and utility factor to change interpretation of responses</td>
<td>Evidence Supporting the Adequacy of Migration to the Electronic Data Collection Mode</td>
</tr>
<tr>
<td>II</td>
<td>The strategies for the best and worst case to change interpretation of responses</td>
<td>Evidence Supporting the Adequacy of Migration to the Electronic Data Collection Mode</td>
</tr>
</tbody>
</table>

The panel recommended coordinating implementation and training to optimize the benefits of eClinRO assessments in the clinical trial setting. The content from investigator training materials and eClinRO assessments should be complementary.

The implementation of an eClinRO assessment in clinical trials involves four phases in the run up to the first patient enrolling date (First Patient First Visit, see Figure 1):

1. **Preparation**: ClinRO assessment selection, clinician training materials and internal review.
   - ClinRO assessment migration: Validated ClinRO assessment is programmed electronically.
   - Internal clinician training: ClinRO assessment training.

2. **Roll Out**: Develop data entry requirements and training.
   - Develop data entry requirements: Review ClinRO assessment and data entry requirements.
   - Develop clinician training: ClinRO assessment training.

3. **Deployment**: Instructional testing of eClinRO device and ClinRO assessment migration and implementation for the study.
   - Instructional testing: Test ClinRO assessment migration to ensure data quality and usability.

4. **First Patient First Visit**: ClinRO assessment data entry.

The figure on page 4 shows the common elements of electronic migration of ClinRO assessments across three levels of complexity. The specific elements are:

- **Level 1**: Minimal changes to ClinRO assessment (i.e., paper to electronic migration).
- **Level 2**: Moderate changes to ClinRO assessment (i.e., paper to electronic migration with additional training).
- **Level 3**: Major changes to ClinRO assessment (i.e., significant changes to ClinRO assessment).

The table on page 6 outlines the evaluation of measurement comparability for ClinRO and eClinRO assessments: level of modification and supporting evidence.

Figure 1: eClinRO Study Lifecycle

- Preparatory tasks:
  - ClinRO assessment selection.
  - ClinRO assessment migration.
  - Internal clinician training.

- Roll out tasks:
  - Develop data entry requirements.
  - Develop clinician training.

- Deployment tasks:
  - Instructional testing of eClinRO device.
  - ClinRO assessment data entry.

- First patient first visit tasks:
  - ClinRO assessment data entry.

The figure on page 5 shows the key considerations for electronic implementation of ClinRO assessments.

- **Best Practice Recommendations**:
  - ClinRO assessment selection.
  - ClinRO assessment migration.
  - Internal clinician training.

- **Ethics/IRB documentation**:
  - Author/copyright holder review, as needed.
  - Confirm study configuration according to SOE.

- **Language implementation**:

- **Training**:
  - ClinRO assessment training.

- **Life Cycle**:
  - ClinRO assessment migration.
  - ClinRO assessment data entry.

Figure 2: Common Elements of Electronic Migration of ClinRO Assessments: Low to High Complexity

- **Low Complexity**:
  - Original ClinRO assessment.

- **Medium Complexity**:
  - Original ClinRO assessment.

- **High Complexity**:
  - Original ClinRO assessment.

The figure on page 5 shows the key considerations for electronic implementation of ClinRO assessments.

- **Best Practice Recommendations**:
  - ClinRO assessment selection.
  - ClinRO assessment migration.
  - Internal clinician training.

- **Ethics/IRB documentation**:
  - Author/copyright holder review, as needed.
  - Confirm study configuration according to SOE.

- **Language implementation**:

- **Training**:
  - ClinRO assessment training.

- **Life Cycle**:
  - ClinRO assessment migration.
  - ClinRO assessment data entry.