Conformance Assessment

Introduction

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From the QI BA WIKI:

Conformance

• Conformance to a Profile involves each Actor conforming to all the specifications assigned to it in the Profile.

Assessment Procedures

• Conformance to most requirements is assessed by direct observation. Some requirements specify that a particular Assessment Procedure must be used. The assessment procedure defines how a test is run. The original requirement defines the pass/fail mark.
Three parallel activities related to validating our Profile claims:

- Achieve “Claim Confirmed” Stage
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Achieve “Claim Confirmed” Stage

To independently validate that the claims are achievable and generalizable
Three parallel activities related to validating our Profile claims:

1. Achieve “Claim Confirmed” Stage
   - To independently validate that the claims are achievable and generalizable

2. Assess individual actors’ conformance
   - To validate that an individual actor conforms to its role in the biomarker production chain

3. Assess site’s Conformance
   - To validate that an individual actor conforms to its role in the biomarker production chain
Three parallel activities related to validating our Profile claims:

- **Achieve “Claim Confirmed” Stage**: To independently validate that the claims are achievable and generalizable.
- **Assess individual actors’ conformance**: To validate that an individual actor conforms to its role in the biomarker production chain.
- **Assess site’s Conformance**: To activate a site for a clinical trial by verifying that it can generate measurements that meet the claim.

**How do we assess conformance?**

- For “Claim Confirmed” and “Site Conformance”, the focus is on the final product, i.e. the measurement is correct, and not how we got there.

- For “Actors’ Conformance”, the focus is on individual actors’ roles and their contribution to the bias and imprecision of the measurements.
How do we assess conformance?

• NOTE: For many of our claims, we cannot validate the claim itself, but rather we must validate the assumptions underlying it.

• EXAMPLE: Our longitudinal claims provide a cutoff for defining a real change with 95% confidence
  • We can’t validate the cutoff
  • We can validate the wCV that was used to calculate the cutoff.

What do we need to assess?

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<tr>
<th>Statistical Metric/Property</th>
<th>How?</th>
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<tbody>
<tr>
<td>Repeatability</td>
<td>Test-retest study</td>
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<tr>
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<td>Reproducibility</td>
<td>scanners (need test-retest) readers, image analysis software (No test-retest)</td>
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Reproducibility allows expansion of longitudinal claims and assessment of standardization for clinical trials.