Conformance Assessment Introduction

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From the QIBA 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.

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Assess site's Conformance

Three parallel activities related to validating our Profile claims:

Achieve "Claim Confirmed" Stage	Assess individual actors' conformance	Assess site's Conformance
To independently validate that the claims are achievable *and generalizable*	To validate that an individual actor conforms to its role in the biomarker production chain	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?

Statistical Metric/Property	How?
Repeatability	Test-retest study
Linearity	Phantom study
Slope of regression line of measurements vs. ground truth	Phantom study
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Reproducibility	scanners (need test-retest) readers, image analysis software (No test-retest)

Reproducibility allows expansion of longitudinal claims and assessment of standardization for clinical trials.