QIBA Claim Template

List Biomarkers/Measurand(s)

Specify: Cross-sectional vs. Longitudinal measurement

State claim in practical terms:

For example for the longitudinal claim: The change in measured __ whatever __ is an unbiased estimate of the true change and can be measured with +xx% precision* with 95% confidence.

* This represents the total variability from all actors (scanner, SWS, and reader, as applicable)

For the cross-sectional claim: The measured __ whatever __ is proportional to the true value and can be measured with +xx% precision* with 95% confidence.

List Indices:

- Bias (Disaggregate indices) [if relevant]
- Precision
  - Test-retest Repeatability (Repeatability Coefficient)
  - Reproducibility (Inter-class Correlation Coefficient; Concordant Correlation Coefficient). Specify conditions, e.g.,
    - Measuring System variability (hardware and software)
    - Site variability
    - Operator variability (Intra- or Inter-reader)

Clinical Context

Comment [NO1]: I think this should all be deleted from this section. Most investigators will not know what RC and RDC mean. These are needed for testing compliance, but I don't think they should be part of the claim.