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.

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* 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
    o   Test-retest Repeatability (Repeatability Coefficient)
    o   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.