QIBA is currently using two types of *claim statements*

- Cross-sectional: measurement at a single time point
- Longitudinal: change in measurement over two time points

Patient-Centric

- The claim language is patient-centric, describing the quantitative interpretation of the measurements for the individual patient (or feature of a patient).

Example of Cross-Sectional Claim

For an ADC measurement of X mm^2/s in solid tumors greater than 1 cm in diameter or twice the slice thickness (whichever is greater), a 95% confidence interval for the true ADC value is X $\pm$ 5 $\times 10^{-10} mm^2/s$.

Example of a Longitudinal Claim
(two-parts)

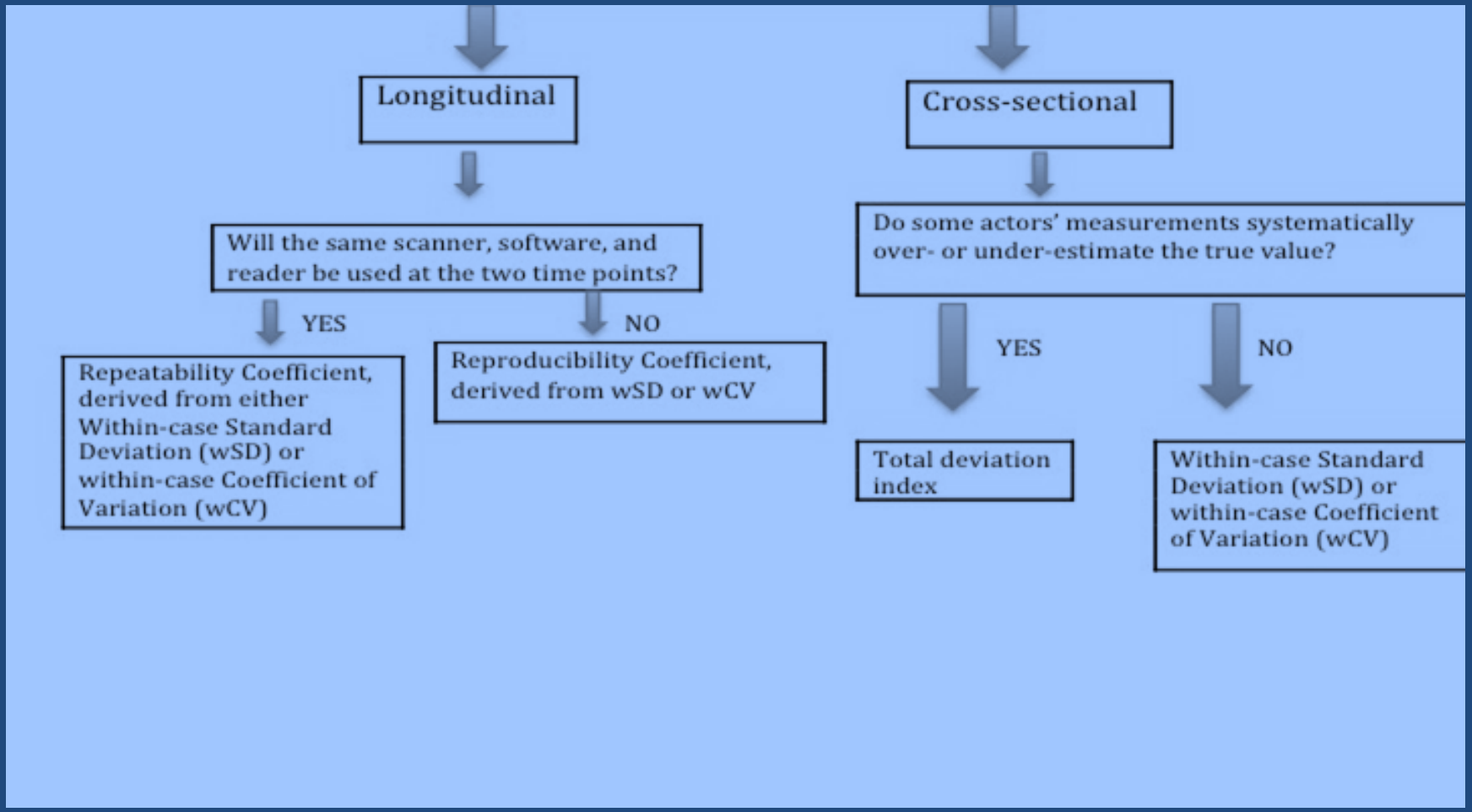
- *A measured change in tumor volume of* D% *indicates that a true change in the tumor's volume has occurred with 95% confidence if* D>25%.
- *If Y_1 and Y_2 are the volume measurements (in mm^3) at the two time points, then the 95% confidence interval for the true change is*

$$(Y_2-Y_1) \pm 1.96 \times \mathrm{sqrt}\{ [Y_1 x 0.09]^2 + [Y_2 x 0.09]^2 \}.$$

Steps in Determining Performance Value used in Claim

Steps	Description
1	Choose appropriate statistical metric
2	Determine characteristics which degrade performance and their relative frequency
3	Identify plausible set of performance values
4	Consider clinical requirements
5	Consider sample size for testing compliance
6	Choose performance value

Longitudinal or Cross-sectional?



Cross-sectional claim

- Example 1 (Constant SD): *"For an ADC measurement of X mm^2/s in solid tumors greater than 1 cm in diameter or twice the slice thickness (whichever is greater), a 95% confidence interval for the true ADC value is X $\pm$ 5 $\times 10^{-10} mm^2/s$."*

Cross-sectional claim

- Example 2 (Constant wCV): *"For a measured lung tumor volume of Y mm^3, a 95% confidence interval for the true volume is Y ± (1.96* **x** *Y* **x** *0.14)."*
- For some QIB measurements, such as tumor volumes, the precision varies with the magnitude of the measurement. In these cases, precision is often quantified by the wCV (wSD/Y).

Cross-sectional Claim

- Example 3 (Look-up Table for wCV): *"For a measured lung nodule volume of Y mm^3, a 95% confidence interval for the true volume is Y ± (1.96* **x** *Y* **x** *wCV)."*
- For some QIB measurements, such as tumor nodules, not only does the precision vary with the magnitude of the measurement, but we cannot assume that the wCV is constant.

Longitudinal Claim

- Example 1 (Constant RC): *"A measured decrease in Perc15 of 18 HU or more without volume adjustment indicates that a true increase in the extent of emphysema has occurred with 95% confidence. For a measured change of Δ HU in Perc15 without volume adjustment, a 95% confidence interval for the true change is [Δ -18 HU, Δ +18 HU]."*
- Note that "18" is the Repeatability Coefficient

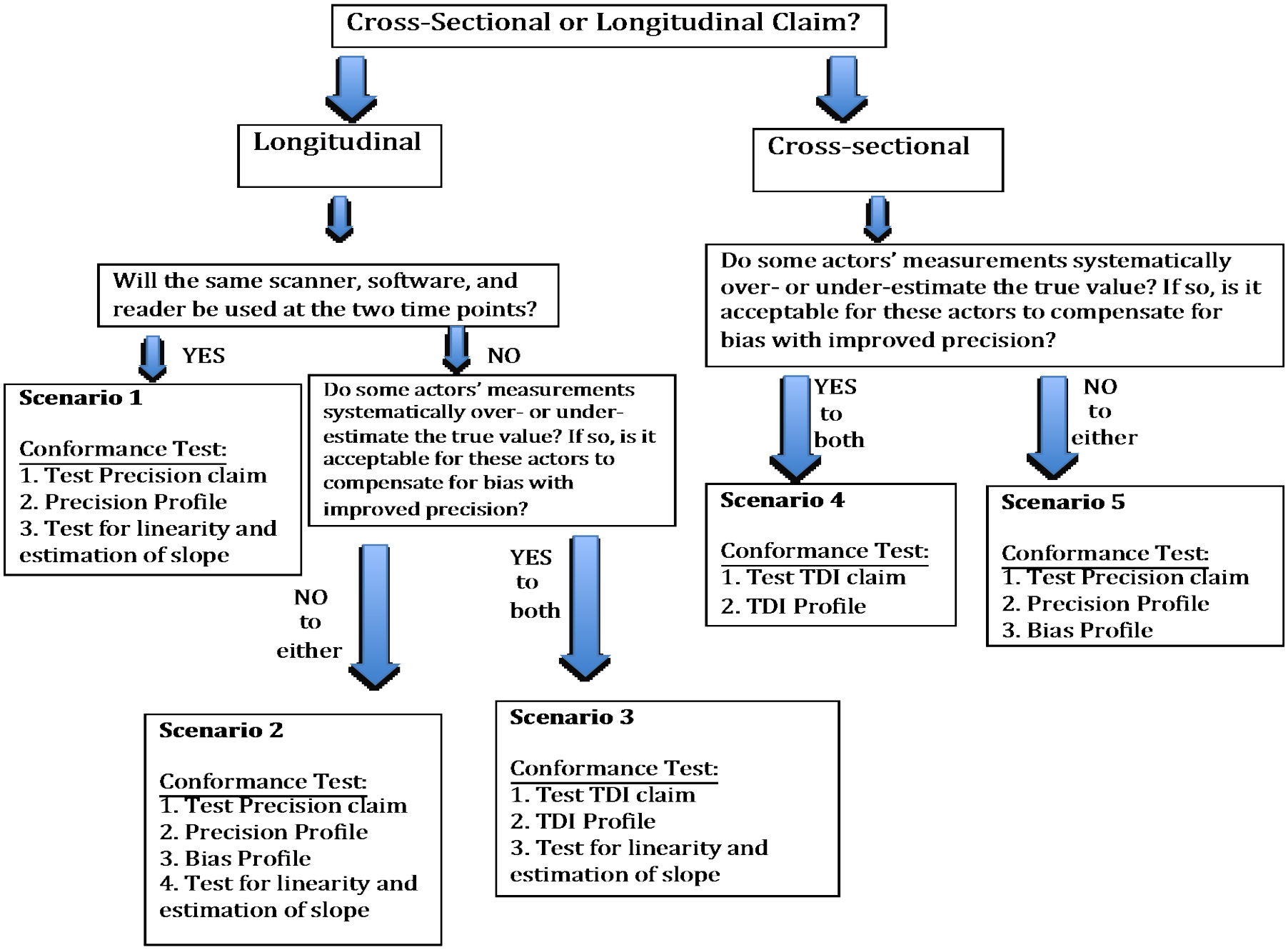
Longitudinal Claim

- Example 2 (Constant wCV): *"A measured change in the tumor's volume of Δ% indicates that a true change has occurred with 95% confidence if Δ% is larger than 38%"* and *"If Y_1 and Y_2 are tumor volume measurements at the two time points, a 95% confidence interval for the true change is*

  $$(Y_2-Y_1) \pm 1.96 \times \sqrt{(Y_1 \times 0.14)^2+(Y_2 \times 0.14)^2}.$$

Longitudinal Claim

- Example 3 (Look-up Table for wCV): *"A measured change in the QIB measurements of Δ% indicates that a true change has occurred with 95% confidence if Δ% is larger than (2.77 x wCV x 100)"* and *"If Y_1 and Y_2 are the QIB measurements at the two time points, a 95% confidence interval for the true change is $(Y_2-Y_1) \pm 1.96 \times \sqrt{(Y_1 \times wCV)^2+(Y_2 \times wCV)^2}$."*


Cross-Sectional or Longitudinal Claim?
Longitudinal
Cross-sectional
Will the same scanner, software, and reader be used at the two time points?
YES
NO
Do some actors' measurements systematically over- or under-estimate the true value? If so, is it acceptable for these actors to compensate for bias with improved precision?
Scenario 1
Conformance Test:
1. Test Precision claim
2. Precision Profile
3. Test for linearity and estimation of slope
NO to either
YES to both
Scenario 2
Conformance Test:
1. Test Precision claim
2. Precision Profile
3. Bias Profile
4. Test for linearity and estimation of slope
Scenario 3
Conformance Test:
1. Test TDI claim
2. TDI Profile
3. Test for linearity and estimation of slope
Do some actors' measurements systematically over- or under-estimate the true value? If so, is it acceptable for these actors to compensate for bias with improved precision?
YES to both
NO to either
Scenario 4
Conformance Test:
1. Test TDI claim
2. TDI Profile
Scenario 5
Conformance Test:
1. Test Precision claim
2. Precision Profile
3. Bias Profile