

## The Claim Statements

### ***Cross-sectional:***

The small lung tumor screening profile states,

*“A plausible range for the true tumor diameter is the measured tumor diameter  $\pm 1.2\text{mm}$ , with 95% confidence.”*

Consider an example. Suppose that one follows the imaging specifications of the Profile and measures a nodule at 9mm. Because of measurement error in the imaging system we cannot conclude that the true size is 9mm. Rather, taking into account the known measurement error, we can state that there is a 95% probability that the true tumor diameter is between 9-1.2mm and 9+1.2mm, i.e. [7.8mm, 10.2mm]. This is the 95% confidence interval for the tumor diameter.

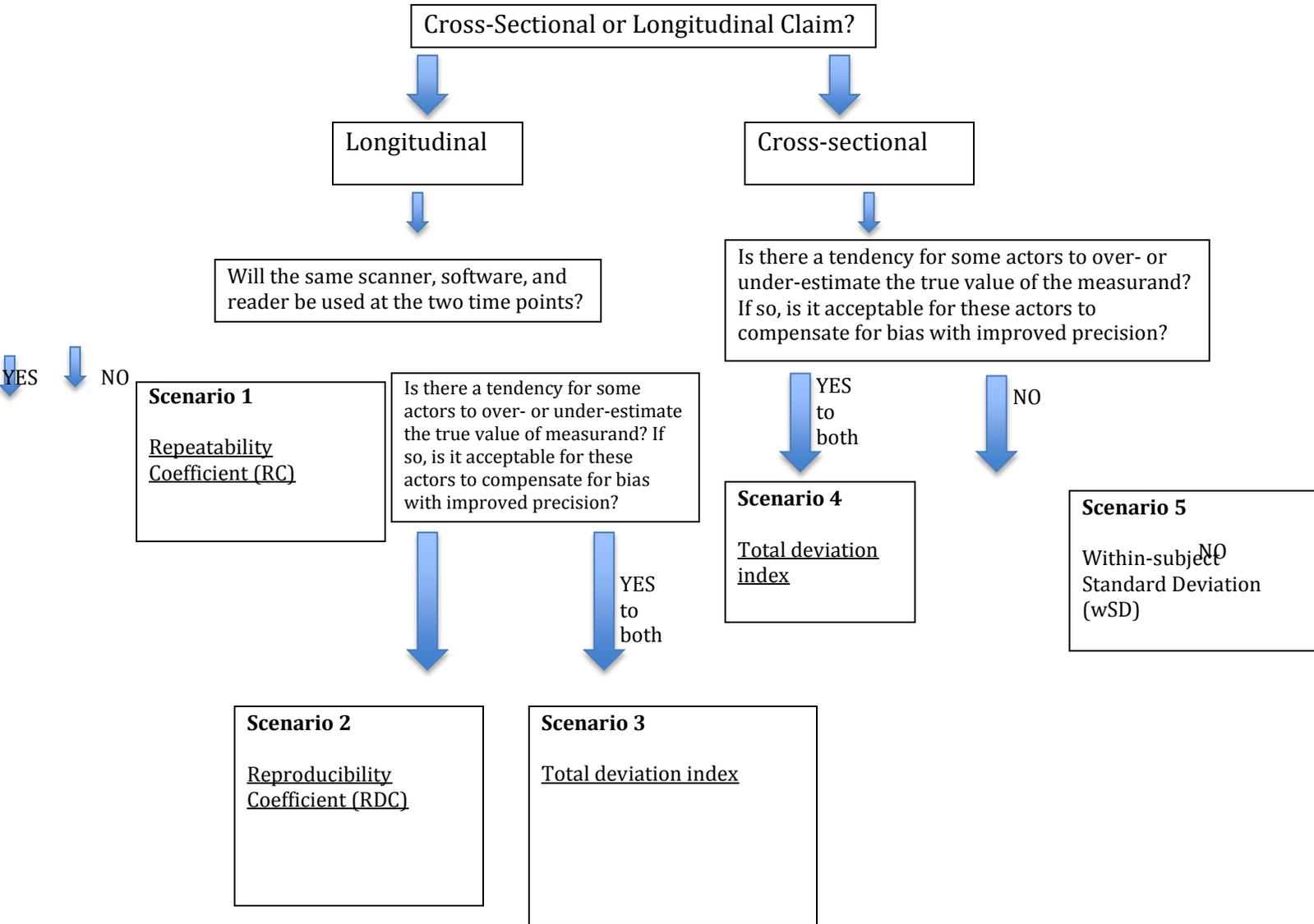
### ***Longitudinal:***

The DCE-MRI claim is

*“A plausible range for the true change in  $T_1$  is the measured change in  $T_1$   $\pm 30\%$ , with 95% confidence”.*

Note that if the change is more than 30%, then we can conclude that a true change has occurred with 95% confidence. The statement also provides a 95% confidence interval for the magnitude of the change.

# Which Performance Metric Should be Used?



# Five Test Scenarios and Minimum Compliance Requirements

