

Outline of Validation Study Methodology for Assessing the Accuracy of Technologies/Methods Measuring Patient Anatomy

- Identify Surgery Requirements
 - Measurement metrics (what need to be measured, e.g. the diameter of the hip socket)
 - Performance criteria (how good the measurements should be achieved, e.g. accuracy, precision, etc.)
 - Other likely factors such as measurement time, risks, etc.
 - ...
- Choices of Technologies/Methods
 - Selection strategy
 - Inclusion criteria
 - Exclusion criteria
 - Selection procedures
 - Abstract for collection
 - Detail reading for selecting
- Sample Size Estimation
 - Find Sample size recommendation from similar studies to make distinct statistical analysis
- Data Collection
 - Design repeatable, reliable, reproducible and consistent measurement procedures
 - Method-based measurement procedure design
 - Manual measurements procedure design
 - Measurement procedures per trial
 - Repeated trials
- Quality Evaluation
 - Reliability Assessment
 - Stability and test-retest (e.g. different days, environments)
 - Alternate form (e.g. vary different variables of interests)
 - Internal consistency (e.g. comparing subscale of the test)
 - ...
 - Validity Assessment
 - Contents (e.g. overall measurement objectives)
 - Criteria (e.g. more accurate or precise than manual)
 - Construct (e.g. if the technologies/software follows its key mathematical theories)
 - ...