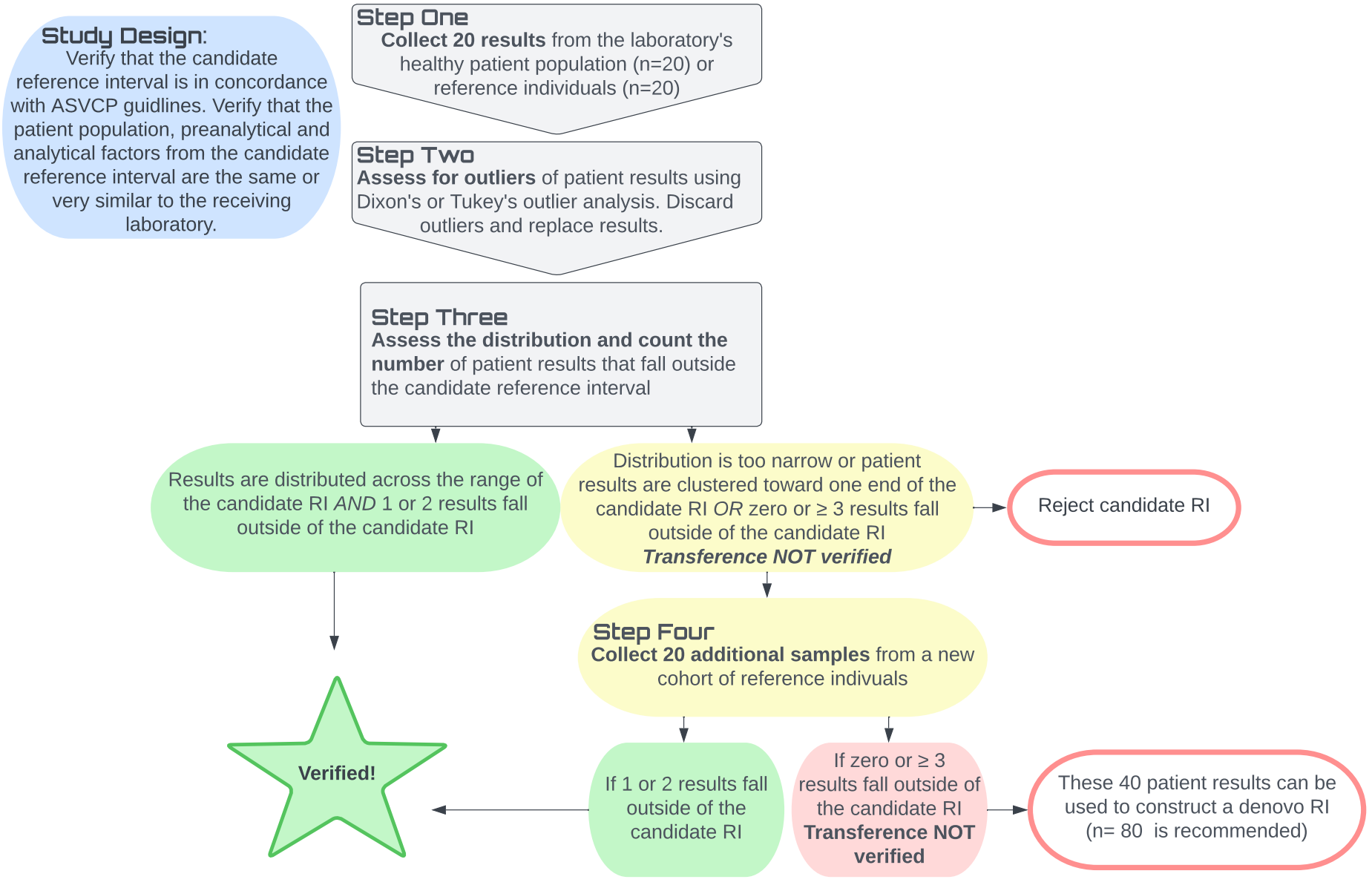
Study Design:
Verify that the candidate reference interval is in concordance with ASVCP guidlines. Verify that the patient population, preanalytical and analytical factors from the candidate reference interval are the same or very similar to the receiving laboratory.
Step One
Collect 20 results from the laboratory's healthy patient population (n=20) or reference individuals (n=20)
Step Two
Assess for outliers of patient results using Dixon's or Tukey's outlier analysis. Discard outliers and replace results.
Step Three
Assess the distribution and count the number of patient results that fall outside the candidate reference interval
Results are distributed across the range of the candidate RI AND 1 or 2 results fall outside of the candidate RI
Distribution is too narrow or patient results are clustered toward one end of the candidate RI OR zero or ≥ 3 results fall outside of the candidate RI
Transference NOT verified
Reject candidate RI
Step Four
Collect 20 additional samples from a new cohort of reference indivuals
Verified!
If 1 or 2 results fall outside of the candidate RI
If zero or ≥ 3 results fall outside of the candidate RI
Transference NOT verified
These 40 patient results can be used to construct a denovo RI (n= 80 is recommended)