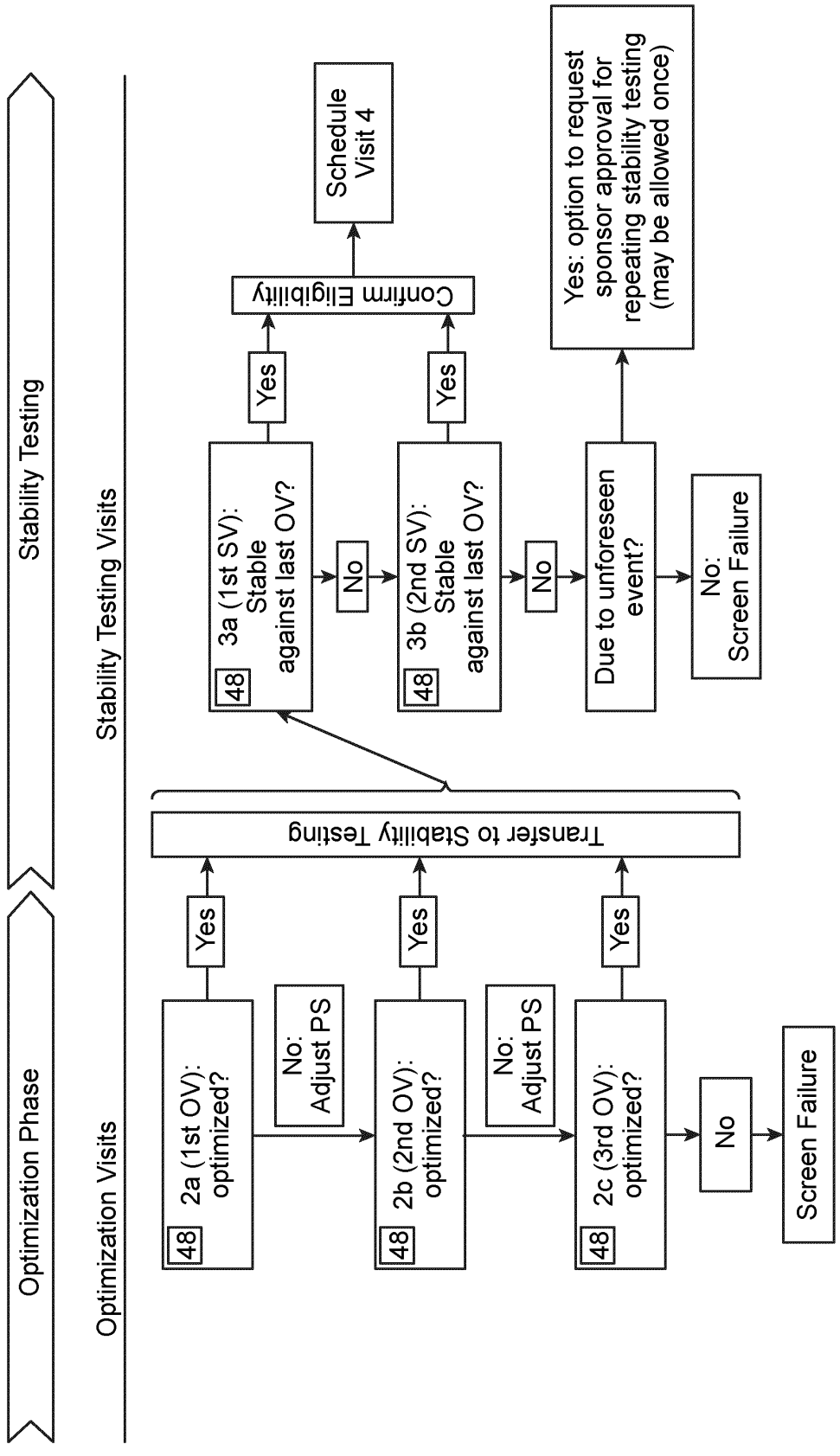

Optimization Phase
Stability Testing
Optimization Visits
Stability Testing Visits
48 2a (1st OV): optimized?
Yes
No: Adjust PS
48 2b (2nd OV): optimized?
Yes
No: Adjust PS
48 2c (3rd OV): optimized?
Yes
No
Screen Failure
Transfer to Stability Testing
48 3a (1st SV): Stable against last OV?
Yes
No
48 3b (2nd SV): Stable against last OV?
Yes
No
Due to unforeseen event?
Yes: option to request sponsor approval for repeating stability testing (may be allowed once)
No: Screen Failure
Confirm Eligibility
Schedule Visit 4

FIG. 1

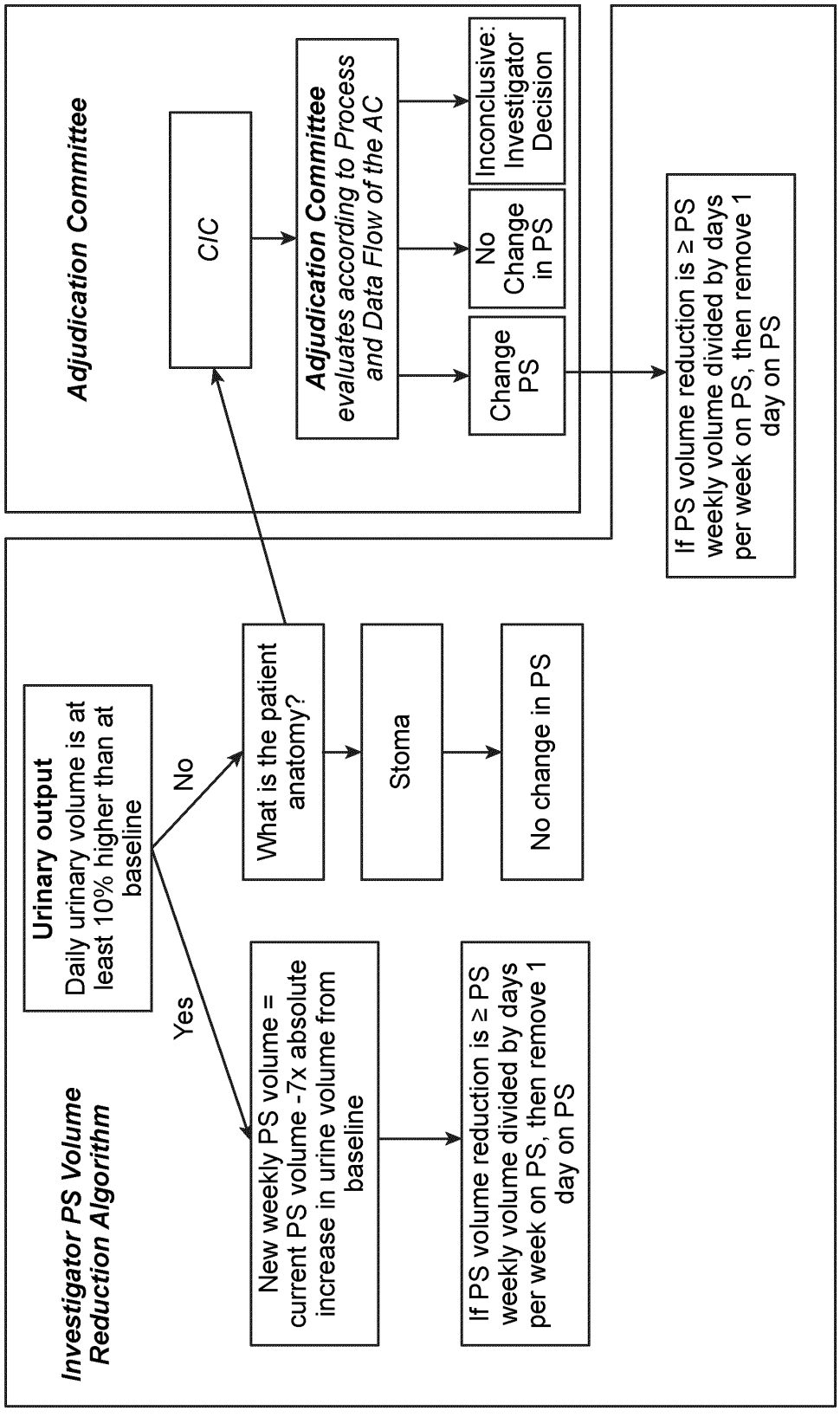

Investigator PS Volume Reduction Algorithm
Urinary output
Daily urinary volume is at least 10% higher than at baseline
Yes
No
New weekly PS volume = current PS volume -7x absolute increase in urine volume from baseline
If PS volume reduction is ≥ PS weekly volume divided by days per week on PS, then remove 1 day on PS
What is the patient anatomy?
Stoma
No change in PS
Adjudication Committee
CIC
Adjudication Committee evaluates according to Process and Data Flow of the AC
Change PS
No Change in PS
Inconclusive: Investigator Decision
If PS volume reduction is ≥ PS weekly volume divided by days per week on PS, then remove 1 day on PS

FIG. 2