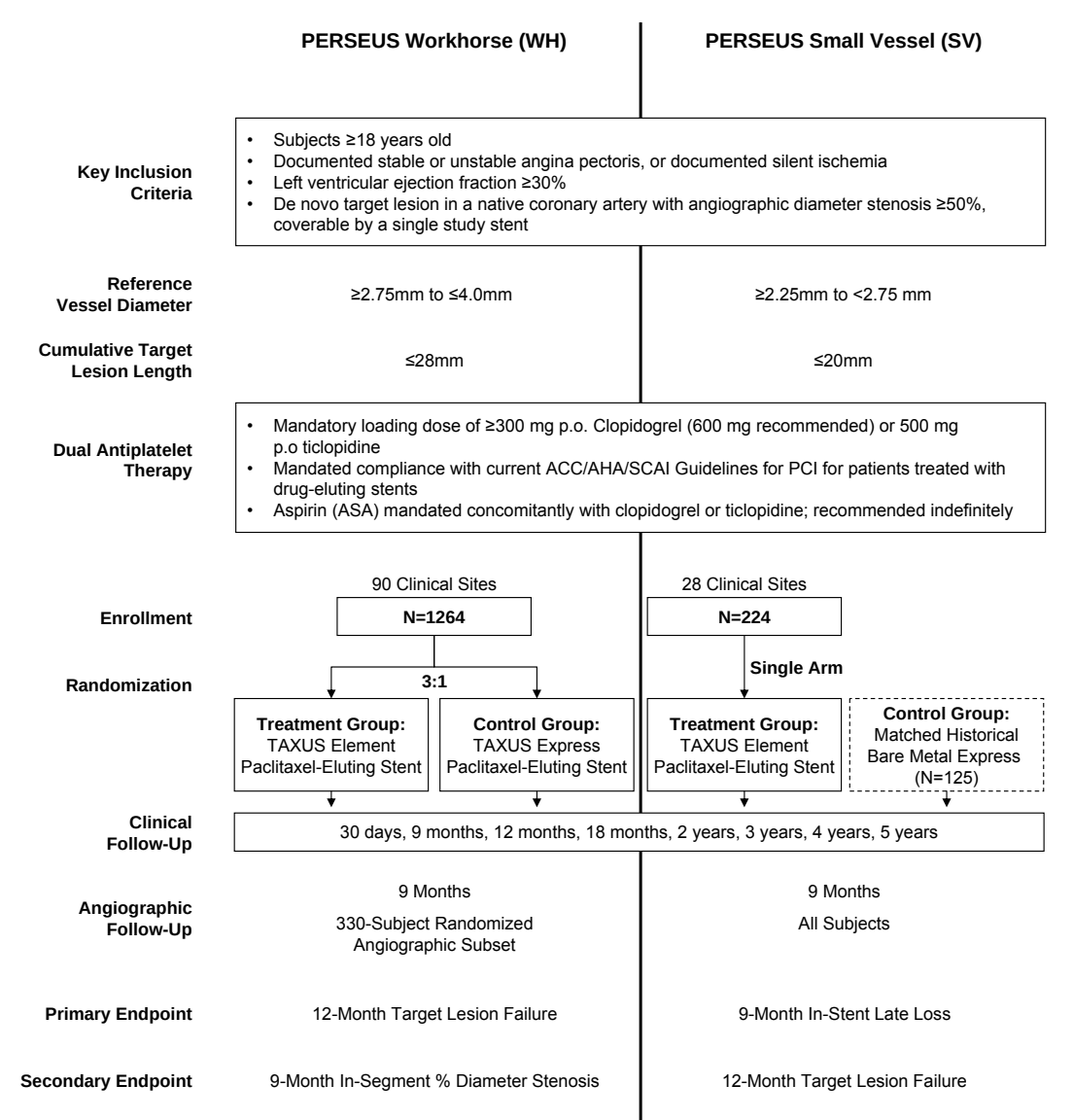
PERSEUS Workhorse (WH)
PERSEUS Small Vessel (SV)
Key Inclusion Criteria
• Subjects ≥18 years old
• Documented stable or unstable angina pectoris, or documented silent ischemia
• Left ventricular ejection fraction ≥30%
• De novo target lesion in a native coronary artery with angiographic diameter stenosis ≥50%, coverable by a single study stent
Reference Vessel Diameter
≥2.75mm to ≤4.0mm
≥2.25mm to <2.75 mm
Cumulative Target Lesion Length
≤28mm
≤20mm
Dual Antiplatelet Therapy
• Mandatory loading dose of ≥300 mg p.o. Clopidogrel (600 mg recommended) or 500 mg p.o ticlopidine
• Mandated compliance with current ACC/AHA/SCAI Guidelines for PCI for patients treated with drug-eluting stents
• Aspirin (ASA) mandated concomitantly with clopidogrel or ticlopidine; recommended indefinitely
Enrollment
90 Clinical Sites
N=1264
28 Clinical Sites
N=224
Randomization
3:1
Single Arm
Treatment Group: TAXUS Element Paclitaxel-Eluting Stent
Control Group: TAXUS Express Paclitaxel-Eluting Stent
Treatment Group: TAXUS Element Paclitaxel-Eluting Stent
Control Group: Matched Historical Bare Metal Express (N=125)
Clinical Follow-Up
30 days, 9 months, 12 months, 18 months, 2 years, 3 years, 4 years, 5 years
Angiographic Follow-Up
9 Months
330-Subject Randomized Angiographic Subset
9 Months
All Subjects
Primary Endpoint
12-Month Target Lesion Failure
9-Month In-Stent Late Loss
Secondary Endpoint
9-Month In-Segment % Diameter Stenosis
12-Month Target Lesion Failure