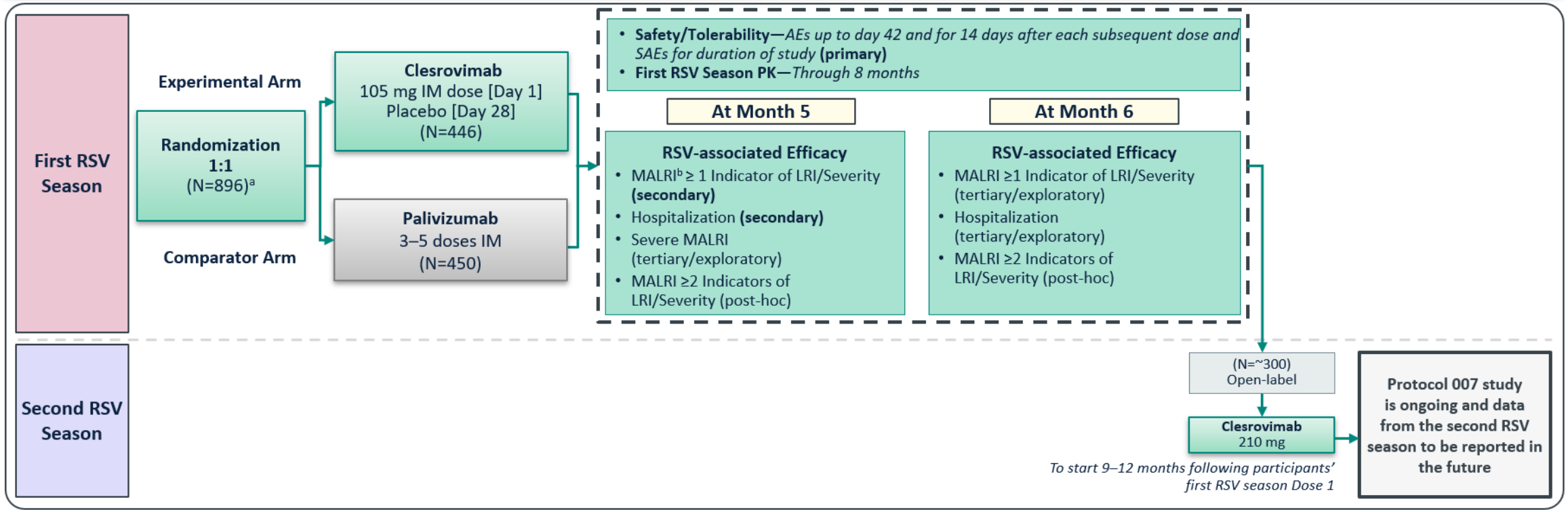
Protocol 007 SMART Study Design

Phase 3, multicenter, randomized, partially blinded, palivizumab-controlled trial conducted with active surveillance over 2 RSV seasons

Objective: Safety, pharmacokinetics and RSV-associated endpoint incidence rates of clesrovimab in infants and children at increased risk for severe RSV disease



a. N=Number of randomized infants, dosed with clesrovimab or palivizumab; b. MALRI is defined as the presence of the following in a clinical setting: 1) cough or difficulty breathing; AND 2) 1 or more of wheezing, chest wall in-drawing/retraction, rales/crackles, hypoxemia, tachypnea, or dehydration; AND 3) RSV-positive reverse transcriptase polymerase chain reaction (RT-PCR) nasopharyngeal sample; AE=Adverse Event; IM=Intramuscular; MALRI=Medically-Attended Lower Respiratory Tract Infection; PK=Pharmacokinetics; RSV=Respiratory Syncytial Virus; SAE=Serious Adverse Event.

Sinha A. Safety and Efficacy of Clesrovimab. CDC, ACIP Presentation Slides Oct 23-24, 2024 Meeting 02-RSV-Mat-Peds-Sinha-508.pdf (cdc.gov)