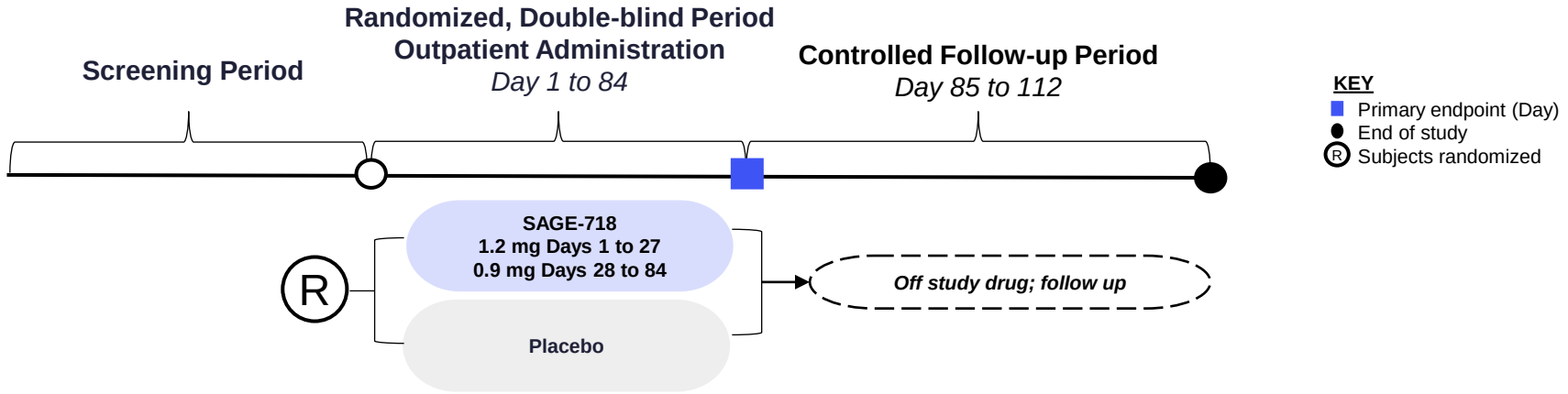
Sage Therapeutics®

SAGE-718 DIMENSION Study Design

DIMENSION Study - SAGE-718

Placebo-controlled study in patients with early Huntington's disease



STUDY OVERVIEW

Status	Enrolling	**Primary Endpoint**	• Change from baseline in Composite score of the Huntington's Disease Cognitive Assessment Battery (HD-CAB)
Indication	Huntington's Disease Cognitive Impairment	**Key Secondary Endpoint**	• UHDRS Independence Scale

Phase	Phase 2	**Inclusion Criteria**	• Be at least 25 years old but no older than 65 years of age at Screening
			• Meet all the following criteria for HD:
			  • Genetically confirmed disease with huntingtin gene CAG expansion ≥36
			  • UHDRS-Total Functional Capacity (TFC) score >6 and <13
			  • No features of juvenile HD
			• Score <26 on the Montreal Cognitive Assessment (MoCA) at screening
			• Be willing to invite a study partner, if available, who is reliable, competent, and at least 18 years of age to participate in the study
			• Be ambulatory (use of assistance devices such as a walker or cane is acceptable; individuals requiring a wheelchair are excluded), able to travel to the study center, and, as judged by the investigator, is likely to be able to continue to travel to the study center to complete study visits for the duration of the study

Arms	Double-blind, randomized: 1:1 • SAGE-718, placebo		
Dosing Regimen	1.2 mg oral daily from days 1 to 27; 0.9 mg oral daily from days 28 to 84	**Exclusion Criteria**	• Have participated in a previous clinical study of SAGE-718, have participated in a previous gene therapy study, or have received study treatment in any other drug, biologic, or device trial within 180 days or 5 half-lives (whichever is longer), unless the patient participated solely in the placebo arm of the study • Have a diagnosis of an ongoing neurodegenerative condition other than HD, including but not limited to, Alzheimer's Disease, vascular dementia, dementia with Lewy bodies, or Parkinson's Disease