Supplemental Information

SUPPLEMENTAL TABLE 7 Trial Information Definitions Derived From ClinicalTrials.gov[20,21]

Recruitment status	
Completed	The clinical study has ended normally, and participants are no longer being examined or treated.
Terminated	The study has stopped recruiting or enrolling participants early and will not start again. Participants are no longer being examined or treated.
Withdrawn	The study stopped early, before enrolling its first participant.
Suspended	The study has stopped recruiting or enrolling participants early but may start again.
Recruiting	The clinical study is currently recruiting participants.
Enrolling by invitation	A study that selects its participants from a population, or group of people, decided on in advance by the researchers. These studies are not open to everyone who meets the eligibility criteria but only to people in that particular population who are specifically invited to participate.
Not yet recruiting	The clinical study has not started recruiting participants.
Active, not recruiting	The study is ongoing (ie, participants are receiving an intervention or being examined), but potential participants are not currently being recruited or enrolled.
Funding type	Describes the organization that provides funding or support for the clinical study. Support may include providing facilities, expertise, or financial resources. Organizations listed as sponsors and collaborators for a study are considered the funders of the study.
Academic	Includes any entity that is a university, school, or college; a hospital or member of a health system that has university affiliation; or an institute that offers training courses or degree programs.
Government	Includes the National Institutes of Health, other US federal agencies (eg, the FDA, Centers for Disease Control and Prevention, US Department of Veterans Affairs), and non–US government agencies.
Industry	Includes all pharmaceutical and device companies.
Other	Includes individuals and community-based organizations.
Primary completion date	The date that the last participant in a clinical study was examined or received an intervention and that data for the primary outcome measure were collected. Whether the clinical study ended according to the protocol or was terminated does not affect this date.
Trial phase	
Phase 0	Exploratory study involving limited human exposure to the drug, with no therapeutic or diagnostic goals (eg, screening studies, microdose studies).
Phase 1	Studies that are usually conducted with healthy volunteers and that emphasize safety. The goal is to find out what the drug's most frequent and serious adverse events are and, often, how the drug is metabolized and excreted.
Phase 2	Studies that gather preliminary data on effectiveness (whether the drug works in people who have a certain disease or condition). For example, participants receiving the drug may be compared with similar participants receiving a different treatment, usually an inactive substance (called a placebo) or a different drug. Safety continues to be evaluated, and short-term adverse events are studied.
Phase 3	Studies that gather more information about safety and effectiveness by studying different populations and different dosages and by using the drug in combination with other drugs.
Phase 4	Studies occurring after the FDA has approved a drug for marketing. These including postmarket requirement and commitment studies that are required of or agreed to by the sponsor. These studies gather additional information about a drug's safety, efficacy, or optimal use.
Trial design	
Open label	Describes a clinical trial in which masking is not used. This means that all parties involved with the trial know which participants have been assigned to which interventions.
Single-blind masking	A type of masking in which 1 party involved with the clinical trial, either the investigator or participant, does not know which participants have been assigned which interventions.
Double-blind masking	A type of masking in which ≥2 parties involved with the clinical trial do not know which participants have been assigned which interventions. Typically, this includes the investigator and participant.