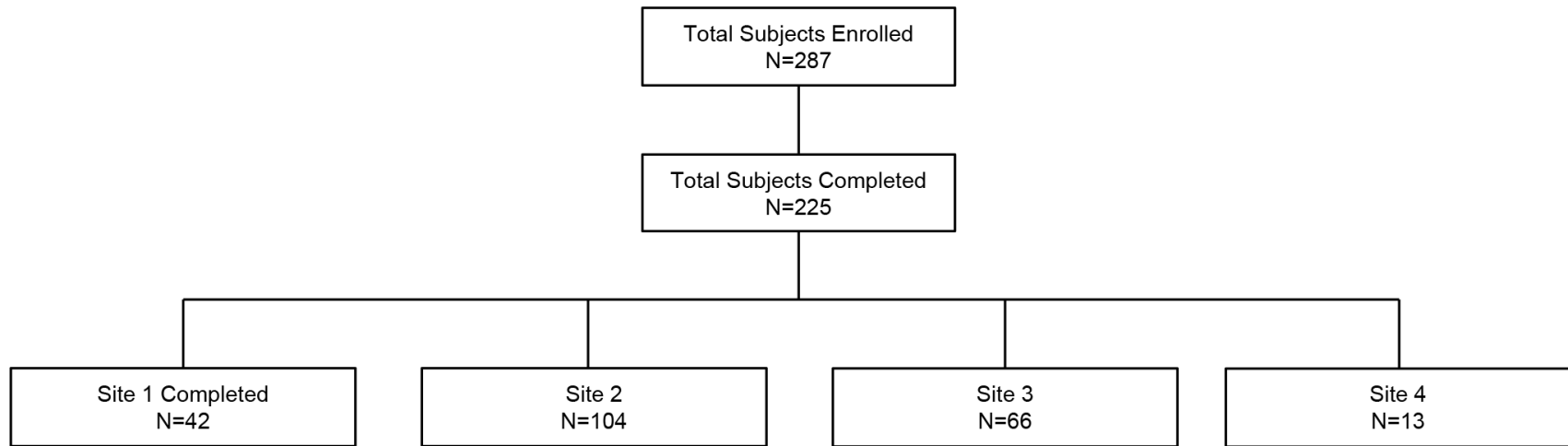


Figure S1—Enrollment flow chart of the multi-center clinical trial included 4 sites.



A total of n=287 subjects were enrolled with a total of n=225 included in the final analysis set.