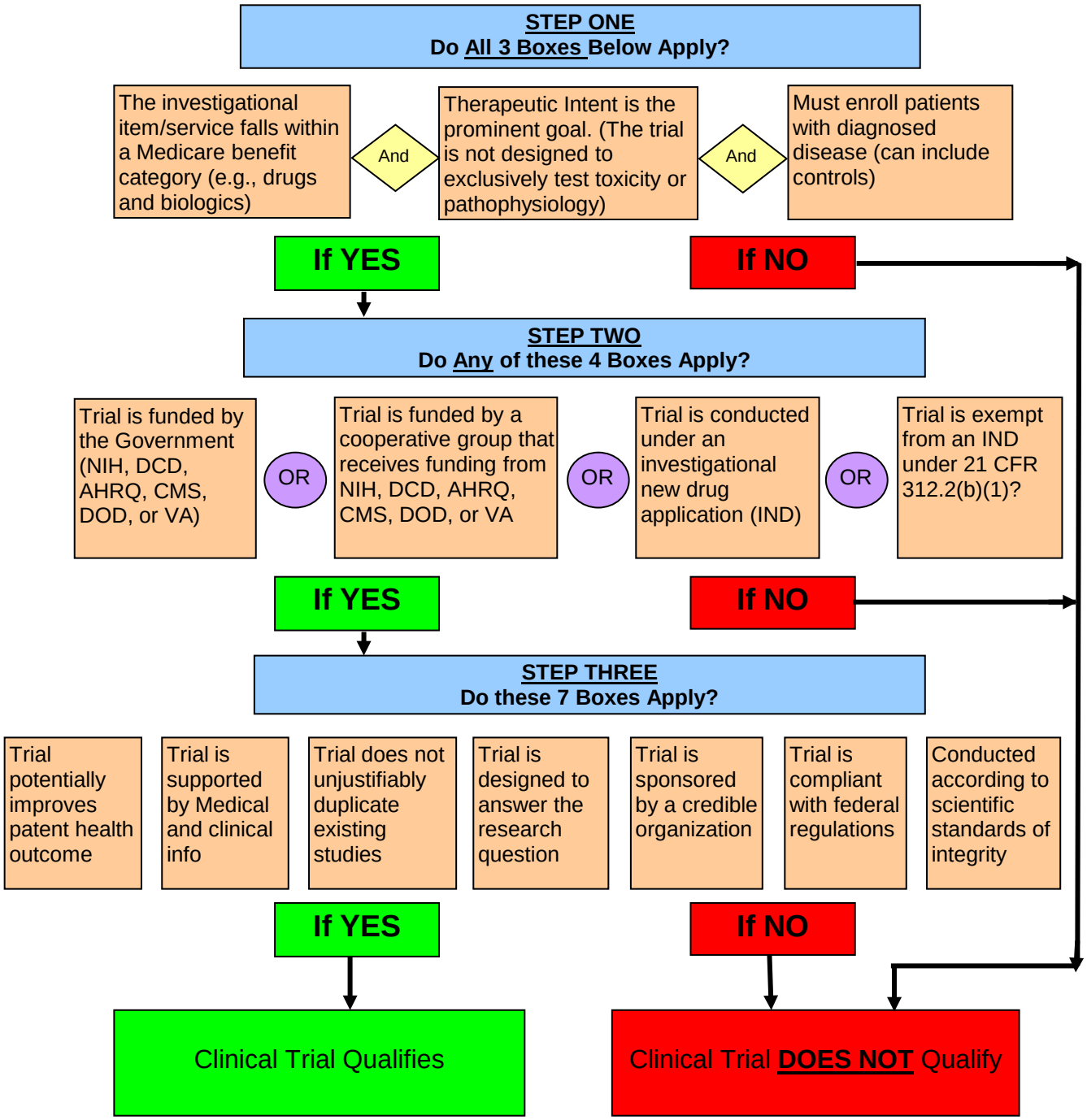Does the Clinical Trial meet the NCD qualifying criteria for Medicare Coverage?