Instructions for Using 'seqDesign' and Generating Output Tables and Figures Describing Operating Characteristics of the Trial Design

Step 1. Specify per-arm sample sizes in the placebo and vaccine arm, average VE scenarios (the length of each component of `aveVElist` equals the number of vaccine arms in a given scenario), the annual incidence in the placebo arm, the type of estimand, the logical value for whether lagged non-efficacy monitoring should be applied (and, if TRUE, the time lag in weeks for this monitoring), and the output directory:

```
N.pla <- 1900
N.vax <- 1700
aveVElist <- list(-2, -1.5, -1, -0.5, 0, 0.1, 0.2, 0.3, 0.4, 0.5, 0.6, 0.7, 0.8, c(0,0), c(0.4,0),
                  c(0.4,0.4), c(0.4,0.2), c(0.4,0.3), c(0.5,0.3), c(0.5,0.4), c(0.6,0.3), c(0.6,0.4))
infRate <- 0.04
estimand <- "cuminc"
laggedMonitoring <- TRUE
lagTime <- 26
outDir <- "./"
```

Step 2. Simulate data-sets (for each component of `aveVElist`), apply the monitoring procedures, and extract results needed for generating output tables and figures:

```
for (i in 1:length(aveVElist)){
  simTrial(N=c(N.pla, rep(N.vax, length(aveVElist[[i]]))), aveVE=c(0, aveVElist[[i]]),
           VEmodel="half", vePeriods=c(1,27,79), enrollPeriod=78, enrollPartial=13,
           enrollPartialRelRate=0.5, dropoutRate=0.05, infecRate=infRate, fuTime=156,
           visitSchedule=c(0, (13/3)*(1:4), seq(13*6/3, 156, by=13*2/3)),
           missVaccProb=c(0,0.05,0.1,0.15), VEcutoffWeek=26, nTrials=1000,
           blockSize=NULL, stage1=78, saveDir=outDir, randomSeed=9)

  monitorTrial(dataFile=
                 paste0("simTrial_nPlac=",N.pla,"_nVacc=",
                        paste(rep(N.vax, length(aveVElist[[i]])), collapse="_"),
                        "_aveVE=",paste(aveVElist[[i]], collapse="_"),"_infRate=",infRate,".RData"),
               stage1=78, stage2=156, harmMonitorRange=c(10,100), alphaPerTest=NULL,
               nonEffStartMethod="FKG", nonEffInterval=20, lowerVEnoneff=0, upperVEnoneff=0.4,
               stage1VE=0, lowerVEuncPower=0, highVE=0.6, alphaNoneff=0.05, alphaStage1=0.05,
               alphaUncPower=0.05, alphaHigh=0.05, estimand=estimand,
               laggedMonitoring=laggedMonitoring, lagTime=lagTime, saveDir=outDir)

  censTrial(dataFile=
              paste0("simTrial_nPlac=",N.pla, "_nVacc=",
                     paste(rep(N.vax, length(aveVElist[[i]])), collapse="_"),"_aveVE=",
                     paste(aveVElist[[i]], collapse="_"),"_infRate=",infRate,".RData"),
            monitorFile=
              paste0("monitorTrial_nPlac=", N.pla, "_nVacc=",
                     paste(rep(N.vax, length(aveVElist[[i]])), collapse="_"),"_aveVE=",
                     paste(aveVElist[[i]], collapse="_"),"_infRate=",infRate,"_",estimand,".RData"),
            stage1=78, stage2=156, saveDir=outDir)
```

```
  if (i %in% 17:22){
    rankTrial(censFile=
                paste0("trialDataCens_nPlac=",N.pla,"_nVacc=",
                       paste(rep(N.vax, length(aveVElist[[i]])), collapse="_"),"_aveVE=",
                       paste(aveVElist[[i]], collapse="_"),"_infRate=",infRate,"_",estimand,".RData"),
              idxHighestVE=1, headHead=matrix(1:2, nrow=1, ncol=2), lowerVE=0, stage1=78, stage2=156,
              alpha=0.05, saveDir=outDir)
  }
}

VEpowerPP(dataList=
            as.list(paste0("trialDataCens_nPlac=", N.pla, "_nVacc=", N.vax, "_aveVE=",
                           do.call("c", aveVElist[5:13]), "_infRate=",infRate,"_",estimand,".RData")),
          lowerVEuncPower=0, alphaUncPower=0.05, VEcutoffWeek=26, stage1=78,
          outName=paste0("VEpwPP_nPlac=", N.pla, "_nVacc=", N.vax, "_infRate=",infRate,".RData"),
          saveDir=outDir)
```

Step 3. Look up the vignette titled "seqDesign's Report Template" by, e.g., calling

```
browseVignettes(package="seqDesign")
```

The vignette's source contains .Rnw template code for generating the report, and the vignette's PDF is the compiled template code (note that it is a static PDF because the .Rnw source requires seqDesign's .RData output files to be compiled and those are not part of the package, the user generates them in Step 2). Update the user-specified constants in the first R chunk and compile the PDF report. Note that other changes in table/figure captions, legends and labels might be needed to reflect the specified trial design.