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

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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 post-6 months non-efficacy monitoring should be applied, 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"
post6moMonitor <- TRUE
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=31, 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,
               minCnt=50, minPct=0.33, week1=26, minCnt2=2, week2=52, 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, post6moMonitor=post6moMonitor, VEcutoffWeek=26, 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. Update the user-specified constants in the first R chunk of `seqDesignReportSample.Rnw` in the `extdata` subdirectory and compile the PDF report. The full path to `seqDesignReportSample.Rnw` can be obtained by:

```
system.file("extdata/seqDesignReport.Rnw", package="seqDesign")
```

Note that other changes in table/figure captions, legends and labels might be needed to reflect the specified trial design.

The sample PDF report generated by `seqDesignReportSample.Rnw` can be found in `seqDesignReportSample.pdf` stored in the `inst/doc` subdirectory.