samon - the software

January 12, 2015
Randomized study with outcome measurements taken at fixed time-points

Monotone missing data pattern

Interest is in a comparison of treatment arm means at the last scheduled time-point

Outcomes are coded as positive integers

Missing values are coded as -1

Rows indicate individuals and columns indicate time-points

Data at the first time-point (the baseline) is never missing
### Background

#### Subject

```
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```
Case Study: Chronic Schizophrenia

- RIS-INT-3 (Marder and Meibach, 1994, Chouinard et al., 1993) was a multi-center study designed to assess the effectiveness and adverse experiences of four fixed doses of risperidone compared to haloperidol and placebo in the treatment of chronic schizophrenia.

- At selection, patients were required to have a PANSS (Positive and Negative Syndrome Scale) score between 60 and 120.
Prior to randomization, there was a single-blind, one-week washout phase during which all anti-psychotic medications were to be discontinued. If acute psychotic symptoms occurred, patients were randomized to a double-blind treatment phase, scheduled to last 8 weeks.

Patients were randomized to one of 6 treatment groups: risperidone 2, 6, 10 or 16 mg, haloperidol 20 mg, or placebo.

Dose titration occurred during the first week of the double-blind phase.
■ Patients scheduled for 5 post-baseline assessments at weeks 1, 2, 4, 6, and 8 of the double-blind phase.

■ Primary efficiency variable: PANSS score

■ 521 patients randomized to receive placebo ($n = 88$), haloperidol 20 mg ($n = 87$), risperidone 2 mg ($n = 87$), risperidone 6 mg ($n = 86$), risperidone 10 mg ($n = 86$), or risperidone 16 mg ($n = 87$).

■ Here we compare placebo (treatment 1) with risperidone 6 mg (treatment 2).

■ Data distributed with samon are simulated from this trial (they are not the original data).
What is the difference in the mean PANSS scores at week 8 between risperidone at a dose of 6mg versus placebo in the counterfactual world in which all patients were followed to that week?
R interface to underlying C code provided by the samon library

The library function loads the library, typically:

```r
library(samon, lib.loc="location of library")
```

This will also let you load the datasets:

```r
data(samonPANSS1)
data(samonPANSS2)
```
<table>
<thead>
<tr>
<th>function</th>
<th>description</th>
</tr>
</thead>
<tbody>
<tr>
<td>samon</td>
<td>The main function. Takes data, estimates optimal $\sigma_P$ and $\sigma_Q$, produces (one-step IF) estimate for the input data and for pairs of parametric bootstrap samples.</td>
</tr>
<tr>
<td>samonCombine</td>
<td>Combines the outputs from samon into one samonMat object. Takes a list of filenames and combines them.</td>
</tr>
<tr>
<td>samonDiff</td>
<td>Takes two samonMat objects and produces a samonMat object for the difference in influence function estimates</td>
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<tr>
<td>samonBiasCorrection</td>
<td>Takes a samonMat object and produces corrected influence estimates</td>
</tr>
<tr>
<td>samonXBiasCorrection</td>
<td>Takes two samonMat objects (one from each treatment groups and for each pair of alphas produces an estimate of the difference in Influence function estimates.</td>
</tr>
</tbody>
</table>
```r
> library(samon,
+    lib.loc="../../../Rver0.1/samlib")
> data("samonPANSS1")
>
> print(samonPANSS1)

<table>
<thead>
<tr>
<th>V1</th>
<th>V2</th>
<th>V3</th>
<th>V4</th>
<th>V5</th>
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<td>70</td>
<td>53</td>
<td>85</td>
<td>-1</td>
<td>-1</td>
</tr>
</tbody>
</table>
```
The `samonDataCheck` function can be used to check and describe data to ensure it is in samon canonical form.

- The function takes a dataframe or matrix as its sole argument:
  
  ```r
  samonDataCheck(samonPANSS1)
  ```

- Prints a small report on the data and returns a list with some useful objects. We will ignore this.
> # Check treatment 1 data
> chk1 <- samonDataCheck( samonPANSS1 )

Samon Data Check:
--------------------------------
Number of time-points:  6
Number of subjects:     88
Minimum value:          44
Maximum value:          153

No Samon problems found
### Missing Patterns:

<table>
<thead>
<tr>
<th>Pattern</th>
<th>N</th>
<th>proportion</th>
</tr>
</thead>
<tbody>
<tr>
<td>*______</td>
<td>8</td>
<td>0.0909</td>
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<tr>
<td>**______</td>
<td>10</td>
<td>0.1136</td>
</tr>
<tr>
<td>***_____</td>
<td>25</td>
<td>0.2841</td>
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<td>*****__</td>
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<td>******</td>
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</tbody>
</table>
samonDataCheck

> # Check treatment 2 data
> chk2 <- samonDataCheck( samonPANSS2 )

Samon Data Check:
--------------------------------
Number of time-points: 6
Number of subjects: 86
Minimum value: 37
Maximum value: 135

No Samon problems found
### Missing Patterns:

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>proportion</th>
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</thead>
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<td>0.0465</td>
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<tr>
<td>***_____</td>
<td>9</td>
<td>0.1047</td>
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<tr>
<td>****___</td>
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<td>*****__</td>
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<td>0.0233</td>
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<tr>
<td>******</td>
<td>51</td>
<td>0.5930</td>
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</table>
Treatment 1

Mean PANSS by last observation

Time-point

50 60 70 80 90 100 110
Consider each treatment group separately.

Let $K$ denote the number of time-points after baseline and $n$ denote the number of individuals in a treatment group.

- $R_{t,j}$ indicates if individual $j$ is on study at time-point $t$, $1 \leq j \leq n$ and $0 \leq t \leq K$. That is $R_{t,j} = 1$ if individual $j$ is on study at time $t$ and $R_{t,j} = 0$ otherwise.

- If $R_{t,j} = 1$ then $Y_{t,j}$ denotes individual $j$’s outcome at time $t$. 
We sometimes wish to refer to the condition of being on-study without specifying which individual is involved. In this case we drop the subscript $j$, so that, for example, $\text{Prob}(R_t = 1)$ refers to the probability of being on study at time-point $t$.

In a similar fashion $Y_t$ denotes an outcome value at time $t$. 
The data in a treatment group are partitioned as follows. Given $N_P$ the number of partitions, the first partition $Prn_1$ is formed from individuals $1, 2, \ldots, [n/N_P]$, where the bracket notation, $[x]$, denotes the greatest integer less than or equal to $x$. If $2 < n \mid N_P$ the next $[n/N_P]$ set of individuals are assigned to partion $Prn_2$, otherwise the next $[n/N_P] + 1$ set of individuals are assigned to partion $Prn_2$. This process is continued until the whole treatment group is partitioned into $N_P$ partitions.
The probability of continuing on study, \( P \)

For a partition \( Prn_s, s = 1, 2, \ldots N_P \), the probability of staying on study at time \( t \) given that an individual is on study at time \( t - 1 \) and has outcome \( Y_{t-1} \) at time \( t - 1 \) is denoted by \( P_s( R_t = 1 \mid R_{t-1} = 1, Y_{t-1} ) \). Invoking a first order Markov assumption we model this probability as follows:

\[
P_s( R_t = 1 \mid R_{t-1} = 1, Y_{t-1} ) = \sum_{j=1}^{N} I(j \notin Prn_s) R_{t-1,j} K(Y_{t-1,j}, Y_{t-1}, \sigma) \sum_{j=1}^{N} I(j \notin Prn_s) K(Y_{t-1,j}, Y_{t-1}, \sigma)
\]

where we take the kernel \( K \), to be normal

\[
K(Y_{t-1,j}, Y_{t-1}, \sigma) = \frac{1}{\sqrt{2\pi\sigma}} e^{-\frac{1}{2}\left(\frac{Y_{t-1,j} - Y_{t-1}}{\sigma}\right)^2}
\]
The loss function

We choose an optimal $\sigma_P$ by minimizing the loss function $L_P$, which up to a constant is

$$L_P(\sigma) = \sum_{t=2}^{N_t} \sum_{j=1}^{n} R_{t-1,j} \left( R_{t,j} - P_{-j}(R_{t,j} = 1 \mid Y_{t-1,j}) \right)^2$$

where $P_{-j}$ is the probability distribution derived from the data after removing the partition to which $j$ belongs.
The functions samonevalP and samonevalQ can be used to compute the loss function for a range of \( \sigma \).

Takes five arguments:

```r
samonevalP(
    mat = samonPANSS1,
    Npart = 10,
    LowSigmaP = 0.1,
    HighSigmaP = 100,
    IncrementSigmaP = 0.1
)
```

returns a two column matrix, the first column containing \( \sigma_P \) and the second the corresponding loss function value.
> library(samon,
+       lib.loc="../../ ../../Rver0.1/samlib")
> data("samonPANSS1")
> data("samonPANSS2")
>
> ResultsP1 <- samonevalP(
+     mat       = samonPANSS1,
+     Npart     = 10,
+     
+     IncrementSigmaP = 0.1,
+     LowSigmaP   = 0.1,
+     HighSigmaP  = 100.0
+   )
> ResultsP2 <- samonevalP(  
+   mat = samonPANSS2,  
+   Npart = 10,  
+   IncrementSigmaP = 0.1,  
+   LowSigmaP = 0.1,  
+   HighSigmaP = 100.0  
+  )  
> ResultsP <- cbind(ResultsP1,ResultsP2)  
> PQPlot(ResultsP,  
+   "P.pdf", 4.2, 4.2,  
+   "Loss function (P)",  
+   c(0,100), c(3,7), c(45,7.0) )
Loss function ($Q$)

- Treatment 1
- Treatment 2
The samon function can be used to find the optimal values of $\sigma_P$ and $\sigma_Q$. Arguments include:

- **mat**: data matrix
- **Npart**: Number of partitions
- **InitialSigmaP**: initial value for $\sigma_P$
- **LowSigmaP**: lower bound
- **HighSigmaP**: upper bound
- **InitialSigmaQ**: initial value for $\sigma_Q$
- **LowSigmaQ**: lower bound
- **HighSigmaQ**: upper bound
# Example1.R
# Finding optimal Sigma_p and Sigma_q.
# ----------------------------------------
library(samon, lib.loc="../../samlib")
data("samonPANSS1")

samonResults <- samon(
  mat = samonPANSS1,
  Npart = 10,
  InitialSigmaP = 10.0,
  LowSigmaP = 0.001,
  HighSigmaP = 50.0,
  InitialSigmaQ = 8.0,
  LowSigmaQ = 0.001,
  HighSigmaQ = 50.0,
  nametype = "PQ" )

# print the output
print(samonResults)
> print(samonResults)
  ResultType1 ResultType2 Sample
 [1,]    0       1      0
 [2,]    0       2      0

  Converged Iterations Estimate LossMin
 [1,]    0   18 15.451858  5.398571
 [2,]    0   14  8.399289  3.618053

  inputLB  inputUB  inputInitial
 [1,]   0.001     50       10
 [2,]   0.001     50        8
>

Frame: 39 of 62
Within samon the sensitivity bias function is the cumulative function of the beta distribution, a flexible function with bounded support. This together with the sensitivity analysis parameter $\alpha$ provides the mechanism by which we measure the sensitivity of the results to informative drop-out.

$\alpha = 0$ is missing at random

$\alpha$ quantifies the influence of $Y_{t+1}$ on the decision to drop-out between $t$ and $t + 1$. 
Sensitivity Analysis

- The cumulative beta function is defined on the interval $(0,1)$ and in order to use it as the sensitivity bias function we need to map the range of our data into $(0,1)$.
- In the case of PANSS data there are theoretical limits in that PANSS scores range between 30 and 210.
- Clinical practice gives a range of values over which a change in PANSS noticeable effect. This translates to parameters for the cumulative beta function $\zeta_1$ and $\zeta_2$.
- Another strategy might be to fit a beta distribution to the data (after suitable transformation) to determine $\zeta_1$ and $\zeta_2$. 
# Example2_partA.R
# Produce one-step influence function estimates
# ----------------------------------------------
library(samon, lib.loc="../..//samlib")
data(samonPANSS1)

Results1 <- samon(
    mat = samonPANSS1,
    Npart = 10,

    # initial value, lower and upper
    # bounds for sigmaP
    InitialSigmaP = 10.0,
    LowSigmaP = 0.001,
    HighSigmaP = 50.0,

    # initial value, lower and upper
    # bounds for sigmaQ
    InitialSigmaQ = 8.0,
    LowSigmaQ = 0.001,
    HighSigmaQ = 50.0,
LowAlpha = -10,  # alphas
HighAlpha = 10,
IncrementAlpha = 1,

lb = 30,  # parameters for
ub = 210,  # cumulative
zeta1 = 4.0,  # beta distribution
zeta2 = 7.0,
nametype = "Alpha" )

print(Results1)
saveRDS(Results1,"Results1.rds")
```r
> print(Results1[ Results1[,2] == 3,
+           c( 6, 7, 8, 9, 10)])

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<th>Var Estimate</th>
<th>IF</th>
<th>Var IF</th>
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<td>73.6086</td>
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<td>6.0467</td>
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<td>75.085</td>
<td>0.097727</td>
<td>74.4928</td>
<td>5.9872</td>
</tr>
</tbody>
</table>
# Example2_partC.R
# Retrieve the estimates and plot them
# -------------------------------------------------
Results1 <- readRDS("Results1.rds")
Results2 <- readRDS("Results2.rds")

# Select the IF results from the results matrices
Trt1Results <- Results1[ Results1[,2] == 3, ]
Trt2Results <- Results2[ Results2[,2] == 3, ]

pdf(file="Example2.pdf", height=5.5, width=5)
par(mar=c(4,4,2,2))

plot.new()
plot.window( xlim = c(-5, 5), ylim = c( 60, 100 ))
lines( x = Trt1Results[,6], y = Trt1Results[,9],
   lwd=2, col = "#CC8866FF")
lines( x = Trt2Results[,6], y = Trt2Results[,9],
   lwd=2, col = "#6688CCFF")

axis(1); axis(2)

legend( -4.4, 98,
       legend = c("treatment 1", "treatment 2"),
       xjust=0, yjust=1,
       lty = c("solid","solid"), lwd=c(5,5),
       col=c("#CC8866FF","#6688CCFF"))

title( xlab = expression(alpha),
       ylab = "Influence function PANSS estimates")
box()
dev.off()
Influence function PANSS estimates

- Treatment 1
- Treatment 2
- Use double bootstrap to compute bias corrected IF estimates and standard errors.
- Using the optimal $\sigma_P$ and $\sigma_Q$ the original data is used to create a sample, sampleA say. Optimal $\sigma_P$ and $\sigma_Q$ and then found for sampleA and in turn a new sample is created, sampleB. The two samples sampleA and sampleB are a single sample pair of the original data.
- The one-step IF estimate is created for each alpha for both sampleA and sampleB.
- samon is used to generate multiple sample pairs.
# Example3_1a.R
# Produce influence function estimates and 500 pairs of bootstrap estimates for treatment 1.
# ----------------------------------------------
library(samon, lib.loc="../../samlib")
data("samonPANSS1")

Results1a <- samon(
    mat = samonPANSS1,
    Npart = 10,
    InitialSigmaP = 10.0,
    LowSigmaP = 0.001,
    HighSigmaP = 50.0,
    InitialSigmaQ = 8.0,
    LowSigmaQ = 0.001,
    HighSigmaQ = 50.0,
LowAlpha = -5,          # alphas
HighAlpha = 5,
IncrementAlpha = 0.5,

lb = 30,              # parameters to
ub = 210,            # cumulative
zeta1 = 4.0,         # beta distribution
zeta2 = 7.0,

NBootstrapPairs = 500,  # number of bootstrap
seed0 = 826847827 )

# save results for latter use
saveRDS(Results1a, "Results1a.rds")
<table>
<thead>
<tr>
<th>function</th>
<th>description</th>
</tr>
</thead>
<tbody>
<tr>
<td>samonCombine</td>
<td>combines the outputs from samon into one samonMat object. The results are stored in rds files. samon-Combine takes a list of such files and combines them.</td>
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<td>Takes two samonMat objects and produces a samonMat object for the difference in influence function estimates</td>
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<tr>
<td>samonBiasCorrection</td>
<td>Takes a samonMat object and produces corrected influence estimates</td>
</tr>
<tr>
<td>samonXBiasCorrection</td>
<td>Takes two samonMat objects (one from each treatment groups and for each pair of alphas produces an estimate of the difference in Influence function estimates.</td>
</tr>
</tbody>
</table>
# Example3_plots.R
#
# Results have previously been stored in rds files
# treatment 1:  Results3a.rds,  Results3b.rds
# treatment 2:  Results3c.rds,  Results3d.rds
#
# 1. put the results together
# 2. create a difference object
# 3. create bias corrected estimates
# 4. plot some results
# --------------------------------------------------
library(samon,lib.loc="../..../samlib")

filenames1 <- c("Results1a.rds", "Results1b.rds")
filenames2 <- c("Results2a.rds", "Results2b.rds")

trt1Results <- samonCombine( filenames1 )
trt2Results <- samonCombine( filenames2 )

# the difference trt2 - trt1
diffResults <- samonDiff( trt1Results, trt2Results)
# correct each result
BiasCorrection1 <- samonBiasCorrection(
    trt1Results, -10:10, 1)
BiasCorrection2 <- samonBiasCorrection(
    trt2Results, -10:10, 2)
BiasCorrectionD <- samonBiasCorrection(
    diffResults, -10:10, -1)

samonPlot <- function( Res, file, height, width, ylab, xlim, ylim, legpos) {
    pdf(file=file, height=height, width=width)
    par(mar=c(4,4,2,2))

    # bands for CIs
    polyRes <- rbind( Res[, c(1,4)],
                      Res[ nrow(Res):1, c(1,5)] )

    plot.new()
    plot.window( xlim = xlim, ylim = ylim )
}
lines( x = Res[,1], y = Res[,3], lwd=3, col = "#EE8855FF")
lines( x = Res[,1], y = Res[,2], lwd=3, col = "#888888FF")

legend( legpos[1], legpos[2],
legend = c("Uncorrected", "Bias corrected"),
xjust=0, yjust=1,
lty = c("solid","solid"), lwd=c(5,5),
col=c("#EE8855FF","#888888FF"))

axis(1)
axis(2)

title( xlab = expression(alpha), ylab = ylab)
box()

dev.off()
invisible(return())
# treatment 1
samonPlot(BiasCorrection1[, c(2,3,8,6,7)],
        "Trt1Est.pdf",
        5.5, 6,
        "PANSS estimate (visit 5)",
        c(-10,10), c( 60, 120),
        legpos = c( -9, 119) )

# treatment 2
samonPlot(BiasCorrection2[, c(2,3,8,6,7)],
        "Trt2Est.pdf",
        5.5, 6,
        "PANSS estimate (visit 5)",
        c(-10,10), c( 60, 120),
        legpos = c( -9, 119) )

# and treatment 2 minus treatment 1
samonPlot(BiasCorrectionD[, c(2,3,8,6,7)],
        "TrtDEst.pdf",
        5.5, 6,
        "Difference in PANSS (visit 5)",
Estimated PANSS score at visit 5

Placebo Arm

Active Arm
Estimated PANSS score at visit 5

Difference (active - placebo)
Another useful plot is a surface plot of the difference in the estimated mean value in the two treatment groups given as a function of the two alpha parameters. We use the samonXBiasCorrection function to compute the difference in estimates for each pair of alpha. The plotting is done with the filled.contour function.
# Example3_contourPlot.R
# A contour plot of the difference in estimates.
# -------------------------------------------------
library(samon, lib.loc="../../samlib")

filenames1 <- c("Results1a.rds", "Results1b.rds")
filenames2 <- c("Results2a.rds", "Results2b.rds")

trt1Results <- samonCombine( filenames1 )
trt2Results <- samonCombine( filenames2 )

XRes <- samonXBiasCorrection( trt1Results, 
                              trt2Results, -10:10 )
pdf(file="Example3_contour.pdf", height=5, width=6)
par(mar=c(4,4,2,2))

filled.contour(
x = -10:10,
y = -10:10,
z = matrix(XRes[,3],21,21, byrow=TRUE),
lab = expression(paste(alpha, " (Placebo Arm)")),
lab = expression(paste(alpha, " (Active Arm)")),
nlevels = 8,
color.palette = colorRampPalette(c( "#993404","#D95F0E","#FE9929","#FFD9BE","#FFFFD4"),
 space="rgb"),
plot.axis = ( points(
 XRes[ sign(XRes[,6]) == sign(XRes[,7]),
c(1,2)], pch=15, cex=0.6,
col = c("#44447799"))
 )
dev.off()