Package: ODS (via r-universe)

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Title Statistical Methods for Outcome-Dependent Sampling Designs

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Description Outcome-dependent sampling (ODS) schemes are cost-effective ways to enhance study efficiency. In ODS designs, one observes the exposure/covariates with a probability that depends on the outcome variable. Popular ODS designs include case-control for binary outcome, case-cohort for time-to-event outcome, and continuous outcome ODS design (Zhou et al. 2002) <doi:10.1111/j.0006-341X.2002.00413.x>. Because ODS data has biased sampling nature, standard statistical analysis such as linear regression will lead to biases estimates of the population parameters. This package implements four statistical methods related to ODS designs: (1) An empirical likelihood method analyzing the primary continuous outcome with respect to exposure variables in continuous ODS design (Zhou et al., 2002). (2) A partial linear model analyzing the primary outcome in continuous ODS design (Zhou, Qin and Longnecker, 2011) <doi:10.1111/j.1541-0420.2010.01500.x>. (3) Analyze a secondary outcome in continuous ODS design (Pan et al. 2018) <doi:10.1002/sim.7672>. (4) An estimated likelihood method analyzing a secondary outcome in case-cohort data (Pan et al. 2017) <doi:10.1111/biom.12838>.

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Contents

Bfct *power basis functions of a spline of given degree*

Description

`Bfct` returns the power basis functions of a spline of given degree.

Usage

```
Bfct(x, degree, knots, der)
```

Arguments

`x`	n by 1 matrix of the independent variable
`degree`	the order of spline
`knots`	the knots location
`der`	the der-order derivative. The default is 0

Value

n by (1+degree+nknots) matrix corresponding to the truncated power spline basis with knots and specified degree.

Examples

```
library(ODS)

x <- matrix(c(1,2,3,4,5),ncol=1)
degree <- 2
knots <- c(1,3,4)

Bfct(x, degree, knots)
```

`casecohort_data_secondary`
Data example for the secondary analysis in case-cohort design

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Description

Data example for the secondary analysis in case-cohort design

Usage

```
casecohort_data_secondary
```

Format

A data frame with 1000 rows and 15 columns:

subj_ind An indicator variable for each subject: 1 = SRS, 2 = supplemental cases, 0 = NVsample

T observation time for failure outcome

Delta event indicator

Y2 a continuous secondary outcome

X expensive exposure

Z11 first covariate in the linear regression model

Z12 second covariate in the linear regression model

Z13 third covariate in the linear regression model

Z14 fourth covariate in the linear regression model

Z21 first covariate in the Cox model

Z22 second covariate in the Cox model

Z23 third covariate in the Cox model

Z31 first covariate that is related to the conditional distribution of X given other covariates

Z32 second covariate that is related to the conditional distribution

Z33 thid covariate that is related to the conditional distribution

Source

A simulated data set

Estimate_PLMODS *Partial linear model for ODS data*

Description

Estimate_PLMODS computes the estimate of parameters in a partial linear model in the setting of outcome-dependent sampling. See details in Zhou, Qin and Longnecker (2011).

Usage

```
Estimate_PLMODS(X, Y, Z, n_f, eta00, q_s, Cpt, mu_Y, sig_Y, degree, nknots,
  tol, iter)
```

Arguments

X n by 1 matrix of the observed exposure variable

Y n by 1 matrix of the observed outcome variable

Z n by p matrix of the other covariates

n_f n_f = c(n0, n1, n2), where n0 is the SRS sample size, n1 is the size of the supplemental sample chosen from (-infty, mu_Y-a*sig_Y), n2 is the size of the supplemental sample chosen from (mu_Y+a*sig_Y, +infty).

eta00 a column matrix. eta00 = (theta^T pi^T v^T sig0_sq)^T where theta=(alpha^T, gamma^T)^T. We refer to Zhou, Qin and Longnecker (2011) for details of these notations.

q_s smoothing parameter

Cpt cut point a

mu_Y mean of Y in the population

sig_Y standard deviation of Y in the population

degree degree of the truncated power spline basis, default value is 2

nknots number of knots of the truncated power spline basis, default value is 10

tol convergence criteria, the default value is 1e-6

iter maximum iteration number, the default value is 30

Details

We assume that in the population, the primary outcome variable Y follows the following partial linear model:

$$E(Y|X, Z) = g(X) + Z^T\gamma$$

where X is the expensive exposure, Z are other covariates. In ODS design, a simple random sample is taken from the full cohort, then two supplemental samples are taken from two tails of Y, i.e. (-Infty, mu_Y - a*sig_Y) and (mu_Y + a*sig_Y, +Infty). Because ODS data has biased sampling nature, naive regression analysis will yield biased estimates of the population parameters. Zhou, Qin and Longnecker (2011) describes a semiparametric empirical likelihood estimator for estimating the parameters in the partial linear model.

Value

Parameter estimates and standard errors for the partial linear model:

$$E(Y|X,Z) = g(X) + Z^T\gamma$$

where the unknown smooth function g is approximated by a spline function with fixed knots. The results contain the following components:

`alpha`	spline coefficient
`gam`	other linear regression coefficients
`std_gam`	standard error of gam
`cov_mtxa`	covariance matrix of alpha
`step`	numbers of iteration requied to acheive convergence
`pi0`	estimated notation pi
`v0`	estimated notation vtheta
`sig0_sq0`	estimated variance of error

Examples

```
library(ODS)
# take the example data from the ODS package
# please see the documentation for details about the data set ods_data

nknots = 10
degree = 2

# get the initial value of the parameters from standard linear regression based on SRS data #
dataSRS = ods_data[1:200,]
YS = dataSRS[,1]
XS = dataSRS[,2]
ZS = dataSRS[,3:5]

knots = quantileknots(XS, nknots, 0)
# the power basis spline function
MS = Bfct(as.matrix(XS), degree, knots)
DS = cbind(MS, ZS)
theta00 = as.numeric(lm(YS ~ DS -1)$coefficients)
sig0_sq00 = var(YS - DS %*% theta00)
pi00 = c(0.15, 0.15)
v00 = c(0, 0)
eta00 = matrix(c(theta00, pi00, v00, sig0_sq00), ncol=1)
mu_Y = mean(YS)
sig_Y = sd(YS)

Y = matrix(ods_data[,1])
X = matrix(ods_data[,2])
Z = matrix(ods_data[,3:5], nrow=400)

# In this ODS data, the supplemental samples are taken from (-Infty, mu_Y-a*sig_Y) #
# and (mu_Y+a*sig_Y, +Infty), where a=1 #
n_f = c(200, 100, 100)
Cpt = 1

# GCV selection to find the optimal smoothing parameter #
q_s1 = logspace(-6, 7, 10)
gcv1 = rep(0, 10)

for (j in 1:10) {

  result = Estimate_PLMODS(X,Y,Z,n_f,eta00,q_s1[j],Cpt,mu_Y,sig_Y)
 etajj = matrix(c(result$alpha, result$gam, result$pi0, result$v0, result$sig0_sq0), ncol=1)
  gcv1[j] = gcv_ODS(X,Y,Z,n_f,etajj,q_s1[j],Cpt,mu_Y,sig_Y)
}

b = which(gcv1 == min(gcv1))
q_s = q_s1[b]
q_s

# Estimation of the partial linear model in the setting of outcome-dependent sampling #
result = Estimate_PLMODS(X, Y, Z, n_f, eta00, q_s, Cpt, mu_Y, sig_Y)
result
```

gcv_ODS *Generalized cross-validation for ODS data*

Description

gcv_ODS calculates the generalized cross-validation (GCV) for selecting the smoothing parameter in the setting of outcome-dependent sampling. The details can be seen in Zhou, Qin and Longnecker (2011) and its supplementary materials.

Usage

```
gcv_ODS(X, Y, Z, n_f, eta, q_s, Cpt, mu_Y, sig_Y, degree, nknots)
```

Arguments

X	n by 1 matrix of the observed exposure variable
Y	n by 1 matrix of the observed outcome variable
Z	n by p matrix of the other covariates
n_f	n_f = c(n0, n1, n2), where n0 is the SRS sample size, n1 is the size of the supplemental sample chosen from (-infty, mu_Y-a*sig_Y), n2 is the size of the supplemental sample chosen from (mu_Y+a*sig_Y, +infty).
eta	a column matrix. eta = (theta^T pi^T v^T sig0_sq)^T where theta=(alpha^T, gamma^T)^T. We refer to Zhou, Qin and Longnecker (2011) for details of these notations.

`q_s`	smoothing parameter
`Cpt`	cut point a
`mu_Y`	mean of Y in the population
`sig_Y`	standard deviation of Y in the population
`degree`	degree of the truncated power spline basis, default value is 2
`nknots`	number of knots of the truncated power spline basis, default value is 10

Value

the value of generalized cross-validation score

Examples

```
library(ODS)
# take the example data from the ODS package
# please see the documentation for details about the data set ods_data

nknots = 10
degree = 2

# get the initial value of the parameters from standard linear regression based on SRS data #
dataSRS = ods_data[1:200,]
YS = dataSRS[,1]
XS = dataSRS[,2]
ZS = dataSRS[,3:5]

knots = quantileknots(XS, nknots, 0)
# the power basis spline function
MS = Bfct(as.matrix(XS), degree, knots)
DS = cbind(MS, ZS)
theta00 = as.numeric(lm(YS ~ DS -1)$coefficients)
sig0_sq00 = var(YS - DS %*% theta00)
pi00 = c(0.15, 0.15)
v00 = c(0, 0)
eta00 = matrix(c(theta00, pi00, v00, sig0_sq00), ncol=1)
mu_Y = mean(YS)
sig_Y = sd(YS)

Y = matrix(ods_data[,1])
X = matrix(ods_data[,2])
Z = matrix(ods_data[,3:5], nrow=400)

# In this ODS data, the supplemental samples are taken from (-Infty, mu_Y-a*sig_Y) #
# and (mu_Y+a*sig_Y, +Infty), where a=1 #
n_f = c(200, 100, 100)
Cpt = 1

# GCV selection to find the optimal smoothing parameter #
q_s1 = logspace(-6, 7, 10)
gcv1 = rep(0, 10)
```

```
for (j in 1:10) {

  result = Estimate_PLMODS(X,Y,Z,n_f,eta00,q_s1[j],Cpt,mu_Y,sig_Y)
 etajj = matrix(c(result$alpha, result$gam, result$pi0, result$v0, result$sig0_sq0), ncol=1)
  gcv1[j] = gcv_ODS(X,Y,Z,n_f,etajj,q_s1[j],Cpt,mu_Y,sig_Y)
}

b = which(gcv1 == min(gcv1))
q_s = q_s1[b]

q_s

# Estimation of the partial linear model in the setting of outcome-dependent sampling #
result = Estimate_PLMODS(X, Y, Z, n_f, eta00, q_s, Cpt, mu_Y, sig_Y)
result
```

logspace *Generate logarithmically spaced vector*

Description

logspace generates n logarithmically spaced points between 10^d1 and 10^d2. The utility of this function is equivalent to logspace function in matlab.

Usage

```
logspace(d1, d2, n)
```

Arguments

d1	first bound
d2	second bound
n	number of points

Value

a vector of n logarithmically spaced points between 10^d1 and 10^d2.

Examples

```
logspace(-6,7,30)
```

`odsmle` *MSELE estimator for analyzing the primary outcome in ODS design*

Description

`odsmle` provides a maximum semiparametric empirical likelihood estimator (MSELE) for analyzing the primary outcome Y with respect to expensive exposure and other covariates in ODS design (Zhou et al. 2002).

Usage

```
odsmle(Y, X, beta, sig, pis, a, rs.size, size, strat)
```

Arguments

`Y` vector for the primary response

`X` the design matrix with a column of 1's for the intercept

`beta` starting parameter values for the regression coefficients that relate Y to X.

`sig` starting parameter values for the error variance of the regression.

`pis` starting parameter values for the stratum probabilities (the probability that Y belongs to certain stratum) e.g. pis = c(0.1, 0.8, 0.1).

`a` vector of cutpoints for the primary response (e.g., a = c(-2.5,2))

`rs.size` size of the SRS (simple random sample)

`size` vector of the stratum sizes of the supplemental samples (e.g. size = c(50,0,50) represents that two supplemental samples each of size 50 are taken from the upper and lower tail of Y.)

`strat` vector that indicates the stratum numbers (e.g. strat = c(1,2,3) represents that there are three stratums).

Details

We assume that in the population, the primary outcome variable Y follows the following model:

$$Y = \beta_0 + \beta_1 X + \epsilon,$$

where X are the covariates, and epsilon has variance sig. In ODS design, a simple random sample is taken from the full cohort, then two supplemental samples are taken from two tails of Y, i.e. (-Infty, mu_Y - a*sig_Y) and (mu_Y + a*sig_Y, +Infty). Because ODS data has biased sampling nature, naive regression analysis will yield biased estimates of the population parameters. Zhou et al. (2002) describes a semiparametric empirical likelihood estimator for estimating the parameters in the primary outcome model.

Value

A list which contains the parameter estimates for the primary response model:

$$Y = \beta_0 + \beta_1 X + \epsilon,$$

where epsilon has variance sig. The list contains the following components:

beta	parameter estimates for beta
sig	estimates for sig
pis	estimates for the stratum probabilities
grad	gradient
hess	hessian
converge	whether the algorithm converges: True or False
i	Number of iterations

Examples

```
library(ODS)
# take the example data from the ODS package
# please see the documentation for details about the data set ods_data

Y <- ods_data[,1]
X <- cbind(rep(1,length(Y)), ods_data[,2:5])

# use the simple random sample to get an initial estimate of beta, sig #
# perform an ordinary least squares #
SRS <- ods_data[1:200,]
OLS.srs <- lm(SRS[,1] ~ SRS[,2:5])
OLS.srs.summary <- summary(OLS.srs)

beta <- coefficients(OLS.srs)
sig <- OLS.srs.summary$sigma^2
pis <- c(0.1,0.8,0.1)

# the cut points for this data is Y < 0.162, Y > 2.59.
a <- c(0.162,2.59)
rs.size <- 200
size <- c(100,0,100)
strat <- c(1,2,3)

odsmle(Y,X,beta,sig,pis,a,rs.size,size,strat)
```

ods_data *Data example for analyzing the primary response in ODS design*

Description

Data example for analyzing the primary response in ODS design (zhou et al. 2002)

Usage

```
ods_data
```

Format

A matrix with 400 rows and 5 columns. The first 200 observations are from the simple random sample, while 2 supplemental samples each with size 100 are taken from one standard deviation above the mean and below the mean, i.e. (Y1 < 0.162) and (Y1 > 2.59).

Y1 primary outcome for which the ODS sampling scheme is based on

X expensive exposure

Z1 a simulated covariate

Z2 a simulated covariate

Z3 a simulated covariate

Source

A simulated data set

`ods_data_secondary` *Data example for the secondary analysis in ODS design*

Description

Data example for the secondary analysis in ODS design

Usage

```
ods_data_secondary
```

Format

A matrix with 3000 rows and 7 columns:

subj_ind An indicator variable for each subject: 1 = SRS, 2 = lowerODS, 3 = upperODS, 0 = NVsample

Y1 primary outcome for which the ODS sampling scheme is based on

Y2 a secondary outcome

X expensive exposure

Z1 a simulated covariate

Z2 a simulated covariate

Z3 a simulated covariate

Source

A simulated data set

quantileknots *Create knots at sample quantiles*

Description

quantileknots creates knots at sample quantiles

Usage

```
quantileknots(x, nknots, boundstab)
```

Arguments

x	a vector. The knots are at sample quantiles of x.
nknots	number of knots
boundstab	parameter for boundary stability. The default is 0. If boundstab = 1, then nknots+2 knots are created and the first and last are deleted. This mitigates the extra variability of regression spline estimates near the boundaries.

Value

a vector of knots at sample quantiles of x.

Examples

```
library(ODS)

x <- c(1, 2, 3, 4, 5)
quantileknots(x, 3, 0)
```

se.spmle *standard error for MSELE estimator*

Description

se.spmle calculates the standard error for MSELE estimator in Zhou et al. 2002

Usage

```
se.spmle(y, x, beta, sig, pis, a, N.edf, rhos, strat, size.nc)
```

Arguments

y — vector of the primary response

x — the design matrix with a column of 1's for the intercept

beta — final estimates of the regression coefficients obtained from odsmle

sig — final estimate of the error variance obtained from odsmle

pis — final estimates of the stratum probabilities obtained from odsmle

a — vector of cutpoints for the primary response (e.g., a = c(-2.5,2))

N.edf — should be the size of the SRS (simple random sample)

rhos — which is size/pis, where size is a vector representing the stratum sizes of supplemental samples. e.g. size = c(100, 0, 100), and pis are the final estimates obtained from odsmle.

strat — vector that indicates the stratum numbers of supplemental samples, except that you should only list stratum with size > 0. (e.g. if the supplemental size is c(100, 0, 100), then the strat vector should be c(1,3))

size.nc — total size of the validation sample (SRS plus supplemental samples)

Value

A list which contains the standard error estimates for betas in the model :

$$Y = \beta_0 + \beta_1 X + \epsilon,$$

where epsilon has variance sig.

Examples

```
library(ODS)
# take the example data from the ODS package
# please see the documentation for details about the data set ods_data

Y <- ods_data[,1]
X <- cbind(rep(1,length(Y)), ods_data[,2:5])

# use the simple random sample to get an initial estimate of beta, sig #
# perform an ordinary least squares #
SRS <- ods_data[1:200,]
OLS.srs <- lm(SRS[,1] ~ SRS[,2:5])
OLS.srs.summary <- summary(OLS.srs)

beta <- coefficients(OLS.srs)
sig <- OLS.srs.summary$sigma^2
pis <- c(0.1,0.8,0.1)

# the cut points for this data is Y < 0.162, Y > 2.59.
a <- c(0.162,2.59)
rs.size <- 200
size <- c(100,0,100)
strat <- c(1,2,3)
```

```
# obtain the parameter estimates
ODS.model = odsmle(Y,X,beta,sig,pis,a,rs.size,size,strat)

# calculate the standard error estimate
y <- Y
x <- X
beta <- ODS.model$beta
sig <- ODS.model$sig
pis <- ODS.model$pis
a <- c(0.162,2.59)
N.edf <- rs.size
rhos <- size/pis
strat <- c(1,3)
size.nc <- length(y)

se = se.spmle(y, x, beta, sig, pis, a, N.edf, rhos, strat, size.nc)

# summarize the result
ODS.tvalue <- ODS.model$beta / se
ODS.pvalue <- 2 * pt( - abs(ODS.tvalue), sum(rs.size, size)-2)

ODS.results <- cbind(ODS.model$beta, se, ODS.tvalue, ODS.pvalue)
dimnames(ODS.results)[[2]] <- c("Beta","SEbeta","tvalue","Pr(>|t|)")
row.names(ODS.results) <- c("(Intercept)","X","Z1","Z2","Z3")

ODS.results
```

secondary_casecohort *Secondary analysis in case-cohort data*

Description

secondary_casecohort performs the secondary analysis which describes the association between a continuous secondary outcome and the expensive exposure for case-cohort data.

Usage

```
secondary_casecohort(SRS, CCH, NVsample, Z1.dim, Z2.dim, Z3.dim)
```

Arguments

SRS A data frame for subjects in the simple random sample. The first column is T: observation time for time-to-event outcome. The second column is Delta: the event indicator. The thid column is Y2: the continuous scale secondary outcome. The fourth column is X: the expensive exposure. Starting from the fifth column to the end are Z1, Z2 and Z3. Z1 is the set of covariates that are included in the linear regression model of the secondary outcome. Z2 is the set of covariates that are included in the Cox model (the proportional hazards model which relates the primary failure time to covariates). Z3 is the set of covariates that are related to the conditional distribution of X given other covariates.

`CCH` A data frame for subjects in the case-cohort sample. The case-cohort sample includes the simple random sample (SRS) and the supplemental cases. The data structure is the same as SRS.

`NVsample` A data frame for subjects in the non-validation sample. Subjects in the non-validation sample don't have the expensive exposure X measured. The data structure is the following: The first column is T. The second column is Delta. The thid column is Y2. Starting from the fourth column to the end are Z1, Z2 and Z3.

`Z1.dim` Dimension of Z1.

`Z2.dim` Dimension of Z2.

`Z3.dim` Dimension of Z3. Note here that the algorithm requires Z3 to be discrete and not high-dimensional, because we use the SRS sample to estimate the conditional distribution of X given other covariates.

Value

A list which contains parameter estimates, estimated standard error for the primary outcome model:

$$\lambda(t) = \lambda_0(t) \exp \gamma_1 Y_2 + \gamma_2 X + \gamma_3 Z2,$$

and the secondary outcome model:

$$Y_2 = \beta_0 + \beta_1 X + \beta_2 Z_1.$$

The list contains the following components:

`gamma_paramEst` parameter estimates for gamma in the primary outcome model

`gamma_stdErr` estimated standard error for gamma in the primary outcome model

`beta_paramEst` parameter estimates for beta in the secondary outcome model

`beta_stdErr` estimated standard error for beta in the secondary outcome model

Examples

```
library(ODS)
# take the example data from the ODS package
# please see the documentation for details about the data set casecohort_data_secondary
data <- casecohort_data_secondary

# obtain SRS, CCH and NVsample from the original cohort data based on subj_ind
SRS <- data[data[,1]==1, 2:ncol(data)]
CCH <- data[data[,1]==1 | data[,1]==2, 2:ncol(data)]
NVsample <- data[data[,1]==0, 2:ncol(data)]

# delete the fourth column (columns for X) from the non-validation sample
NVsample <- NVsample[,-4]

Z1.dim <- 4
```

```
Z2.dim <- 3
Z3.dim <- 3
secondary_casecohort(SRS, CCH, NVsample, Z1.dim, Z2.dim, Z3.dim)
```

secondary_ODS *Secondary analysis in ODS design*

Description

secondary_ODS performs the secondary analysis which describes the association between a continuous scale secondary outcome and the expensive exposure for data obtained with ODS (outcome dependent sampling) design.

Usage

```
secondary_ODS(SRS, lowerODS, upperODS, NVsample, cutpoint, Z.dim)
```

Arguments

SRS A data matrix for subjects in the simple random sample. The first column is Y1: the primary outcome for which the ODS scheme is based on. The second column is Y2: a secondary outcome. The third column is X: the expensive exposure. Starting from the fourth column to the end is Z: other covariates.

lowerODS A data matrix for supplemental samples taken from the lower tail of Y1 (eg. Y1 < a). The data structure is the same as SRS.

upperODS A data matrix for supplemental samples taken from the upper tail of Y1 (eg. Y1 > b). The data structure is the same as SRS.

NVsample A data matrix for subjects in the non-validation sample. Subjects in the non-validation sample don't have the expensive exposure X measured. The data structure is the same as SRS, but the third column (which represents X) has values NA.

cutpoint A vector of length two that represents the cut off points for the ODS design. eg. cutpoint <- c(a,b). In the ODS design, a simple random sample is taken from the full cohort, then two supplemental samples are taken from {Y1 < a} and {Y1 > b}, respectively.

Z.dim Dimension of the covariates Z.

Value

A list which contains parameter estimates, estimated standard error for the primary outcome model:

$$Y_1 = \beta_0 + \beta_1 X + \beta_2 Z,$$

and the secondary outcome model:

$$Y_2 = \gamma_0 + \gamma_1 X + \gamma_2 Z.$$

The list contains the following components:

`beta_paramEst` parameter estimates for beta in the primary outcome model

`beta_stdErr` estimated standard error for beta in the primary outcome model

`gamma_paramEst` parameter estimates for gamma in the secondary outcome model

`gamma_stdErr` estimated standard error for gamma in the secondary outcome model

Examples

```
library(ODS)
# take the example data from the ODS package
# please see the documentation for details about the data set ods_data_secondary
data <- ods_data_secondary

# divide the original cohort data into SRS, lowerODS, upperODS and NVsample
SRS <- data[data[,1]==1,2:ncol(data)]
lowerODS <- data[data[,1]==2,2:ncol(data)]
upperODS <- data[data[,1]==3,2:ncol(data)]
NVsample <- data[data[,1]==0,2:ncol(data)]

# obtain the cut off points for ODS design. For this data, the ODS design
# uses mean plus and minus one standard deviation of Y1 as cut off points.
meanY1 <- mean(data[,2])
sdY1 <- sd(data[,2])
cutpoint <- c(meanY1-sdY1, meanY1+sdY1)

# the data matrix SRS has Y1, Y2, X and Z. Hence the dimension of Z is ncol(SRS)-3.
Z.dim <- ncol(SRS)-3

secondary_ODS(SRS, lowerODS, upperODS, NVsample, cutpoint, Z.dim)
```

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