South Africa

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STAR–Sharing of PrEP participant data with the WHO

Study Documentation

November 18, 2020

Metadata Production

Metadata Producer(s)	Africa Health Research Institute (AHRI)
Identification	DDI.AHRI.STAR.WHO.PrEP.Data

Table of Contents

STAR–Sharing of PrEP participant data with the WHO

Overview

Identification	AHRI.STAR.WHO.PrEP.Data
Version	V1.0.0

Abstract

Background

In 2015, WHO published a recommendation on the use of antiretroviral medications for PrEP as an additional prevention choice for individuals at substantial HIV risk. WHO subsequently published modular implementation guidance (a tool) in 2017 to assist countries with introducing PrEP into their health systems. Since the publication of the WHO recommendation and the implementation tool, further positive clinical research findings from studies in men who have sex with men on the use of event-driven ('on-demand') dosing have been published. Key population groups such as men who have sex with men and transgender women are at particularly high risk of HIV globally, and may benefit from a shorter PrEP regimen (4 pills in total taken before and after a sexual exposure, rather than daily dosing.

PrEP is a comparatively new intervention, and data on related toxicities such as renal toxicity among healthy individuals has been limited but is growing. WHO would like to review the evidence on renal function relating to ARVs used in PrEP in order to inform an update to the clinical module on the frequency of creatinine monitoring required.

The results from these literature and clinical data reviews will used to update WHO PrEP clinical guidance and will be included in updated ARV guidelines to be published in 2020. WHO is conducting a systematic review of the available evidence on renal function related to PrEP use. However, the evidence is limited and the number of publications that present results by age or over time are few. Since studies and programs implementing PrEP routinely screen for renal function using creatinine screening, WHO is now requesting de-identified individual patient data from Principal Investigators and PrEP programs that contain the information needed but are not yet published, in order to conduct pooled analyses and generate evidence for updated guidance.

Purpose of analyses

The purpose of this analysis is to review the data on creatinine clearance and screening frequency among PrEP users to inform WHO PrEP clinical guidance for the frequency of creatinine screening.

Unit of Analysis	Data collected by peer-navigators will be summarised by cluster (peer-navigator pair).

Scope & Coverage

Keywords	HIV-Self testing, peer outreach work, HIV prevention, PrEP, ART
Topics	HIV-1; Incidence; Phylogeny; Epidemics; Population Surveillance; Rural Population; HIV Infections; Africa
Time Period(s)	2019-2020
Countries	South Africa

Geographic Coverage

Demographic surveillance area of the Africa Health Research Institute.

Universe

The study population include 24 pairs of area (Ward/izigodi) based peer navigators working with over 2000 young people particularly young women aged 18-24 years. More than 2000 young people (males and females) will be reached during the trial in the 21 wards representing the study area.

Producers & Sponsors

Primary Investigator(s)	Dr Maryam, Shahmanesh, Africa Health Research Institute
	Pillay, Deenan, Africa Health Research Institute

Other Producer(s)	Africa Health Research Institute (AHRI)
Funding Agency/ies	South African Medical Research Council (SAMRC) , Genotyping funding source
Other Acknowledgment(s)	Wilkinson, Eduan , Cleaned, aligned and help analyse the sequence data , KwaZulu-Natal Research Innovation Sequencing Platform

Sampling

Sampling Procedure

Since the study is a cluster randomised control trial with three arms where all areas in the southern Population Intervention Platform (PIP) were included, no formal sampling was done. We estimated that ~500 age eligible 18-24 years olds will be enrolled per peer navigator team catchment area, of whom we anticipate at least 200, 18-24-year-old females will be handed a coupon (so cluster size at least 200). We calculated the sample size calculation using the primary outcome, the rate of linkage after 3 months among women ages 18-24 years. Using our existing data on uptake of HIV testing in the DREAMS interventions as well as our data on uptake of testing and linkage to HIV care in the demographic surveillance rounds of, we estimate that 1 woman will link per 7 months of peer educators outreach work time in the standard of care. With 7 peer educator pairs (or clusters) per arm and a cluster coefficient of variation (k) of 0.25, we have 80% power to detect a 100% increase in rate from 1 woman to 2 women per 7 months of follow-up, and 90% power to detect a 150% increase from 1 woman to 2.5 women per 7 months of follow-up. We have chosen policy and clinically relevant increases in linkage to care. Assuming additional clustering of the outcome within peer educators and increasing the coefficient of variation (k) to 0.35, we have 80% power to detect a 150% increase in rate from 1 woman to 2.5 women per 7 months of follow-up. All sample size calculations assume two-tailed statistical tests with alpha=0.05.

Data Collection

Data Collection Dates	start 2019-03-15 end 2020-06-30

Accessibility

Access Conditions

The representative of the Receiving Organization agrees to comply with the following conditions:

1. Access to the restricted data will be limited to the Lead Researcher and other members of the research team listed in this request.
2. Copies of the restricted data or any data created on the basis of the original data will not be copied or made available to anyone other than those mentioned in this Data Access Agreement, unless formally authorized by the Data Archive.
3. The data will only be processed for the stated statistical and research purpose. They will be used for solely for reporting of aggregated information, and not for investigation of specific individuals or organizations. Data will not in any way be used for any administrative, proprietary or law enforcement purposes.
4. The Lead Researcher must state if it is their intention to match the restricted microdata with any other micro-dataset. If any matching is to take place, details must be provided of the datasets to be matched and of the reasons for the matching. Any datasets created as a result of matching will be considered to be restricted and must comply with the terms of this Data Access Agreement.
5. The Lead Researcher undertakes that no attempt will be made to identify any individual person, family, business, enterprise or organization. If such a unique disclosure is made inadvertently, no use will be made of the identity of any person or establishment discovered and full details will be reported to the Data Archive. The identification will not be revealed to any other person not included in the Data Access Agreement.
6. The Lead Researcher will implement security measures to prevent unauthorized access to licensed microdata acquired from the Data Archive. The microdata must be destroyed upon the completion of this research, unless the Data Archive obtains satisfactory guarantee that the data can be secured and provides written authorization to the Receiving Organization to retain them. Destruction of the microdata will be confirmed in writing by the Lead Researcher to the Data Archive.

7. Any books, articles, conference papers, theses, dissertations, reports, or other publications that employ data obtained from the Data Archive will cite the source of data in accordance with the citation requirement provided with the dataset.

8. An electronic copy of all reports and publications based on the requested data will be sent to the Data Archive.

9. The original collector of the data, the Data Archive, and the relevant funding agencies bear no responsibility for use of the data or for interpretations or inferences based upon such uses.

10. This agreement will come into force on the date that approval is given for access to the restricted dataset and remain in force until the completion date of the project or an earlier date if the project is completed ahead of time.

11. If there are any changes to the project specification, security arrangements, personnel or organization detailed in this application form, it is the responsibility of the Lead Researcher to seek the agreement of the Data Archive to these changes. Where there is a change to the employer organization of the Lead Researcher this will involve a new application being made and termination of the original project.

12. Breaches of the agreement will be taken seriously and the Data Archive will take action against those responsible for the lapse if willful or accidental. Failure to comply with the directions of the Data Archive will be deemed to be a major breach of the agreement and may involve recourse to legal proceedings. The Data Archive will maintain and share with partner data archives a register of those individuals and organizations which are responsible for breaching the terms of the Data Access Agreement and will impose sanctions on release of future data to these parties.

Citation Requirements
Shahmanesh, M., & Deenan, P. (2020). STAR–Sharing of PrEP participant data with the WHO [Data set]. Africa Health Research Institute (AHRI). https://doi.org/10.23664/AHRI.STAR.WHO.PREP.DATA

Files Description

Dataset contains 2 file(s)

AHRI.STAR.WHO.IndividualPatientData_v1	
# Cases	318
# Variable(s)	80

AHRI.STAR.WHO.StudyData_v1	
# Cases	1
# Variable(s)	7

Variables List

Dataset contains 87 variable(s)

File AHRI.STAR.WHO.IndividualPatientData_v1

#	Name	Label	Type	Format	Valid	Invalid	Question
1	SurveyRe ..	SurveyRecord	continuous	numeric.0	318	0	-
2	dob	dob	discrete	character-8	318	0	-
3	gender	gender	discrete	numeric.0	318	0	-
4	race	race	discrete	numeric.0	318	0	-
5	height	height	continuous	numeric.2	275	43	-
6	weight	weight	continuous	numeric.2	271	47	-
7	bmi	bmi	continuous	numeric.2	268	50	-
8	kp	kp	continuous	numeric.0	318	0	-
9	comorbid	comorbid	discrete	numeric.0	3	315	-
10	comorbid ..	comorbid_spec	discrete	character-6	1	0	-
11	medication	medication	discrete	numeric.0	318	0	-
12	steroids	steroids	discrete	numeric.0	318	0	-
13	fam_hist	fam_hist	discrete	numeric.0	318	0	-
14	dt_prep_1	dt_prep_1	discrete	character-8	318	0	-
15	dt_prep_2	dt_prep_2	discrete	character-8	141	0	-
16	dt_prep_3	dt_prep_3	discrete	character-8	51	0	-
17	dt_prep_4	dt_prep_4	discrete	character-8	27	0	-
18	dt_prep_5	dt_prep_5	discrete	character-8	12	0	-
19	dt_prep_6	dt_prep_6	continuous	numeric.0	9	309	-
20	dt_prep_7	dt_prep_7	discrete	numeric.0	1	317	-
21	dt_creat_1	dt_creat_1	discrete	character-8	315	0	-
22	creat_1	creat_1	discrete	character-5	315	0	-
23	serumcre ..	serumcreat_1	discrete	numeric.0	318	0	-
24	crcl_1	crcl_1	discrete	numeric.0	318	0	-
25	crcl_1_c ..	crcl_1_comp	discrete	numeric.0	318	0	-
26	dt_creat_2	dt_creat_2	discrete	character-8	135	0	-
27	creat_2	creat_2	discrete	character-5	135	0	-
28	serumcre ..	serumcreat_2	discrete	numeric.0	318	0	-
29	crcl_2	crcl_2	discrete	numeric.0	318	0	-
30	crcl_2_c ..	crcl_2_comp	discrete	numeric.0	318	0	-
31	dt_creat_3	dt_creat_3	discrete	character-8	48	0	-
32	creat_3	creat_3	discrete	character-5	48	0	-
33	serumcre ..	serumcreat_3	discrete	numeric.0	318	0	-
34	crcl_3	crcl_3	discrete	numeric.0	318	0	-
35	crcl_3_c ..	crcl_3_comp	discrete	numeric.0	318	0	-
36	dt_creat_4	dt_creat_4	discrete	character-8	26	0	-

File AHRI.STAR.WHO.IndividualPatientData_v1

#	Name	Label	Type	Format	Valid	Invalid	Question
37	creat_4	creat_4	discrete	character-5	26	0	-
38	serumcre ..	serumcreat_4	discrete	numeric.0	318	0	-
39	crcl_4	crcl_4	discrete	numeric.0	318	0	-
40	crcl_4_c ..	crcl_4_comp	discrete	numeric.0	318	0	-
41	dt_creat_5	dt_creat_5	discrete	character-8	8	0	-
42	creat_5	creat_5	discrete	character-5	8	0	-
43	serumcre ..	serumcreat_5	discrete	numeric.0	318	0	-
44	crcl_5	crcl_5	discrete	numeric.0	318	0	-
45	crcl_5_c ..	crcl_5_comp	discrete	numeric.0	318	0	-
46	dt_creat_6	dt_creat_6	continuous	numeric.0	6	312	-
47	creat_6	creat_6	discrete	character-5	6	0	-
48	serumcre ..	serumcreat_6	discrete	numeric.0	318	0	-
49	crcl_6	crcl_6	discrete	numeric.0	318	0	-
50	crcl_6_c ..	crcl_6_comp	discrete	numeric.0	318	0	-
51	dt_creat_7	dt_creat_7	discrete	numeric.0	0	318	-
52	creat_7	creat_7	discrete	numeric.0	0	318	-
53	serumcre ..	serumcreat_7	discrete	numeric.0	318	0	-
54	crcl_7	crcl_7	discrete	numeric.0	318	0	-
55	crcl_7_c ..	crcl_7_comp	discrete	numeric.0	318	0	-
56	dt_adver ..	dt_adverse_1	continuous	numeric.0	3	315	-
57	adverse_ ..	adverse_1_spec	discrete	character-39	3	0	-
58	adverse_1	adverse_1	discrete	numeric.0	3	315	-
59	pregnant ..	pregnant_prep1	discrete	numeric.0	118	200	-
60	pregnant ..	pregnant_prep2	discrete	numeric.0	23	295	-
61	pregnant ..	pregnant_prep3	discrete	numeric.0	8	310	-
62	pregnant ..	pregnant_prep4	discrete	numeric.0	2	316	-
63	pregnant ..	pregnant_prep5	discrete	numeric.0	3	315	-
64	pregnant ..	pregnant_prep6	discrete	numeric.0	1	317	-
65	pregnant ..	pregnant_prep7	discrete	numeric.0	1	317	-
66	pregnant ..	pregnant_creat1	discrete	numeric.0	118	200	-
67	pregnant ..	pregnant_creat2	discrete	numeric.0	23	295	-
68	pregnant ..	pregnant_creat3	discrete	numeric.0	8	310	-
69	pregnant ..	pregnant_creat4	discrete	numeric.0	2	316	-
70	pregnant ..	pregnant_creat5	discrete	numeric.0	3	315	-
71	pregnant ..	pregnant_creat6	discrete	numeric.0	1	317	-
72	pregnant ..	pregnant_creat7	discrete	numeric.0	1	317	-
73	disconti ..	discontinue	discrete	numeric.0	3	315	-
74	dt_disco ..	dt_discontinue	discrete	character-8	1	0	-
75	restart	restart	discrete	numeric.0	318	0	-

File AHRI.STAR.WHO.IndividualPatientData_v1

#	Name	Label	Type	Format	Valid	Invalid	Question
76	restart_..	restart_adv	discrete	numeric.0	318	0	-
77	exit	exit	discrete	numeric.0	318	0	-
78	exit_spec	exit_spec	discrete	character-23	108	0	-
79	dt_exit	dt_exit	discrete	character-8	224	0	-
80	notes	notes	discrete	numeric.0	0	318	-

File AHRI.STAR.WHO.StudyData_v1

#	Name	Label	Type	Format	Valid	Invalid	Question
1	country	country	discrete	character-12	1	0	-
2	design	design	discrete	numeric.0	1	0	-
3	start_d	start_d	discrete	numeric.0	1	0	-
4	end_d	end_d	discrete	numeric.0	1	0	-
5	source_d ..	source_data	discrete	numeric.0	1	0	-
6	total_n	total_n	discrete	numeric.0	1	0	-
7	crscreen_n	crscreen_n	discrete	numeric.0	1	0	-

Variables Description

Dataset contains 87 variable(s)

File : AHRI.STAR.WHO.IndividualPatientData_v1

SurveyRecord: SurveyRecord

Information	[Type= continuous] [Format=numeric] [Range= 7-575] [Missing=*]
Statistics [NW/ W]	[Valid=318 /-] [Invalid=0 /-] [Mean=276.594 /-] [StdDev=156.26 /-]

dob: dob

Information	[Type= discrete] [Format=character] [Missing=*]
Statistics [NW/ W]	[Valid=318 /-] [Invalid=0 /-]

gender: gender

Information	[Type= discrete] [Format=numeric] [Range= 0-1] [Missing=*]
Statistics [NW/ W]	[Valid=318 /-] [Invalid=0 /-]

race: race

Information	[Type= discrete] [Format=numeric] [Range= 99-99] [Missing=*]
Statistics [NW/ W]	[Valid=318 /-] [Invalid=0 /-]

height: height

Information	[Type= continuous] [Format=numeric] [Range= 53.5-246] [Missing=*]
Statistics [NW/ W]	[Valid=275 /-] [Invalid=43 /-] [Mean=163.284 /-] [StdDev=15.984 /-]

weight: weight

Information	[Type= continuous] [Format=numeric] [Range= 39.2-184] [Missing=*]
Statistics [NW/ W]	[Valid=271 /-] [Invalid=47 /-] [Mean=68.969 /-] [StdDev=18.807 /-]

bmi: bmi

Information	[Type= continuous] [Format=numeric] [Range= 8.2-370.2] [Missing=*]
Statistics [NW/ W]	[Valid=268 /-] [Invalid=50 /-] [Mean=28.54 /-] [StdDev=31.663 /-]

kp: kp

Information	[Type= continuous] [Format=numeric] [Range= 1-99] [Missing=*]
Statistics [NW/ W]	[Valid=318 /-] [Invalid=0 /-] [Mean=4.393 /-] [StdDev=5.686 /-]

comorbid: comorbid

Information	[Type= discrete] [Format=numeric] [Range= 2-4] [Missing=*]
Statistics [NW/ W]	[Valid=3 /-] [Invalid=315 /-]

comorbid_spec: comorbid_spec

Information	[Type= discrete] [Format=character] [Missing=*]
Statistics [NW/ W]	[Valid=1 /-] [Invalid=0 /-]

medication: medication

Information	[Type= discrete] [Format=numeric] [Range= 99-99] [Missing=*]
Statistics [NW/ W]	[Valid=318 /-] [Invalid=0 /-]

steroids: steroids

Information	[Type= discrete] [Format=numeric] [Range= 99-99] [Missing=*]
Statistics [NW/ W]	[Valid=318 /-] [Invalid=0 /-]

fam_hist: fam_hist

Information	[Type= discrete] [Format=numeric] [Range= 99-99] [Missing=*]

File : AHRI.STAR.WHO.IndividualPatientData_v1

fam_hist: fam_hist

Statistics [NW/ W]	[Valid=318 /-] [Invalid=0 /-]

dt_prep_1: dt_prep_1

Information	[Type= discrete] [Format=character] [Missing=*]
Statistics [NW/ W]	[Valid=318 /-] [Invalid=0 /-]

dt_prep_2: dt_prep_2

Information	[Type= discrete] [Format=character] [Missing=*]
Statistics [NW/ W]	[Valid=141 /-] [Invalid=0 /-]

dt_prep_3: dt_prep_3

Information	[Type= discrete] [Format=character] [Missing=*]
Statistics [NW/ W]	[Valid=51 /-] [Invalid=0 /-]

dt_prep_4: dt_prep_4

Information	[Type= discrete] [Format=character] [Missing=*]
Statistics [NW/ W]	[Valid=27 /-] [Invalid=0 /-]

dt_prep_5: dt_prep_5

Information	[Type= discrete] [Format=character] [Missing=*]
Statistics [NW/ W]	[Valid=12 /-] [Invalid=0 /-]

dt_prep_6: dt_prep_6

Information	[Type= continuous] [Format=numeric] [Range= 14052020-31082020] [Missing=*]
Statistics [NW/ W]	[Valid=9 /-] [Invalid=309 /-] [Mean=23408686.667 /-] [StdDev=6712331.935 /-]

dt_prep_7: dt_prep_7

Information	[Type= discrete] [Format=numeric] [Range= 14082020-14082020] [Missing=*]
Statistics [NW/ W]	[Valid=1 /-] [Invalid=317 /-]

dt_creat_1: dt_creat_1

Information	[Type= discrete] [Format=character] [Missing=*]
Statistics [NW/ W]	[Valid=315 /-] [Invalid=0 /-]

creat_1: creat_1

Information	[Type= discrete] [Format=character] [Missing=*]
Statistics [NW/ W]	[Valid=315 /-] [Invalid=0 /-]

serumcreat_1: serumcreat_1

Information	[Type= discrete] [Format=numeric] [Range= 9999-9999] [Missing=*]
Statistics [NW/ W]	[Valid=318 /-] [Invalid=0 /-]

crcl_1: crcl_1

Information	[Type= discrete] [Format=numeric] [Range= 9999-9999] [Missing=*]
Statistics [NW/ W]	[Valid=318 /-] [Invalid=0 /-]

crcl_1_comp: crcl_1_comp

Information	[Type= discrete] [Format=numeric] [Range= 9999-9999] [Missing=*]
Statistics [NW/ W]	[Valid=318 /-] [Invalid=0 /-]

File : AHRI.STAR.WHO.IndividualPatientData_v1

dt_creat_2: dt_creat_2

Information	[Type= discrete] [Format=character] [Missing=*]
Statistics [NW/ W]	[Valid=135 /-] [Invalid=0 /-]

creat_2: creat_2

Information	[Type= discrete] [Format=character] [Missing=*]
Statistics [NW/ W]	[Valid=135 /-] [Invalid=0 /-]

serumcreat_2: serumcreat_2

Information	[Type= discrete] [Format=numeric] [Range= 9999-9999] [Missing=*]
Statistics [NW/ W]	[Valid=318 /-] [Invalid=0 /-]

crcl_2: crcl_2

Information	[Type= discrete] [Format=numeric] [Range= 9999-9999] [Missing=*]
Statistics [NW/ W]	[Valid=318 /-] [Invalid=0 /-]

crcl_2_comp: crcl_2_comp

Information	[Type= discrete] [Format=numeric] [Range= 9999-9999] [Missing=*]
Statistics [NW/ W]	[Valid=318 /-] [Invalid=0 /-]

dt_creat_3: dt_creat_3

Information	[Type= discrete] [Format=character] [Missing=*]
Statistics [NW/ W]	[Valid=48 /-] [Invalid=0 /-]

creat_3: creat_3

Information	[Type= discrete] [Format=character] [Missing=*]
Statistics [NW/ W]	[Valid=48 /-] [Invalid=0 /-]

serumcreat_3: serumcreat_3

Information	[Type= discrete] [Format=numeric] [Range= 9999-9999] [Missing=*]
Statistics [NW/ W]	[Valid=318 /-] [Invalid=0 /-]

crcl_3: crcl_3

Information	[Type= discrete] [Format=numeric] [Range= 9999-9999] [Missing=*]
Statistics [NW/ W]	[Valid=318 /-] [Invalid=0 /-]

crcl_3_comp: crcl_3_comp

Information	[Type= discrete] [Format=numeric] [Range= 9999-9999] [Missing=*]
Statistics [NW/ W]	[Valid=318 /-] [Invalid=0 /-]

dt_creat_4: dt_creat_4

Information	[Type= discrete] [Format=character] [Missing=*]
Statistics [NW/ W]	[Valid=26 /-] [Invalid=0 /-]

creat_4: creat_4

Information	[Type= discrete] [Format=character] [Missing=*]
Statistics [NW/ W]	[Valid=26 /-] [Invalid=0 /-]

serumcreat_4: serumcreat_4

Information	[Type= discrete] [Format=numeric] [Range= 9999-9999] [Missing=*]

File : AHRI.STAR.WHO.IndividualPatientData_v1

serumcreat_4: serumcreat_4

Statistics [NW/ W]	[Valid=318 /-] [Invalid=0 /-]

crcl_4: crcl_4

Information	[Type= discrete] [Format=numeric] [Range= 9999-9999] [Missing=*]
Statistics [NW/ W]	[Valid=318 /-] [Invalid=0 /-]

crcl_4_comp: crcl_4_comp

Information	[Type= discrete] [Format=numeric] [Range= 9999-9999] [Missing=*]
Statistics [NW/ W]	[Valid=318 /-] [Invalid=0 /-]

dt_creat_5: dt_creat_5

Information	[Type= discrete] [Format=character] [Missing=*]
Statistics [NW/ W]	[Valid=8 /-] [Invalid=0 /-]

creat_5: creat_5

Information	[Type= discrete] [Format=character] [Missing=*]
Statistics [NW/ W]	[Valid=8 /-] [Invalid=0 /-]

serumcreat_5: serumcreat_5

Information	[Type= discrete] [Format=numeric] [Range= 9999-9999] [Missing=*]
Statistics [NW/ W]	[Valid=318 /-] [Invalid=0 /-]

crcl_5: crcl_5

Information	[Type= discrete] [Format=numeric] [Range= 9999-9999] [Missing=*]
Statistics [NW/ W]	[Valid=318 /-] [Invalid=0 /-]

crcl_5_comp: crcl_5_comp

Information	[Type= discrete] [Format=numeric] [Range= 9999-9999] [Missing=*]
Statistics [NW/ W]	[Valid=318 /-] [Invalid=0 /-]

dt_creat_6: dt_creat_6

Information	[Type= continuous] [Format=numeric] [Range= 14052020-31082020] [Missing=*]
Statistics [NW/ W]	[Valid=6 /-] [Invalid=312 /-] [Mean=24235353.333 /-] [StdDev=8336214.169 /-]

creat_6: creat_6

Information	[Type= discrete] [Format=character] [Missing=*]
Statistics [NW/ W]	[Valid=6 /-] [Invalid=0 /-]

serumcreat_6: serumcreat_6

Information	[Type= discrete] [Format=numeric] [Range= 9999-9999] [Missing=*]
Statistics [NW/ W]	[Valid=318 /-] [Invalid=0 /-]

crcl_6: crcl_6

Information	[Type= discrete] [Format=numeric] [Range= 9999-9999] [Missing=*]
Statistics [NW/ W]	[Valid=318 /-] [Invalid=0 /-]

crcl_6_comp: crcl_6_comp

Information	[Type= discrete] [Format=numeric] [Range= 9999-9999] [Missing=*]
Statistics [NW/ W]	[Valid=318 /-] [Invalid=0 /-]

dt_creat_7: dt_creat_7

Information	[Type= discrete] [Format=numeric] [Missing=*]
Statistics [NW/ W]	[Valid=0 /-] [Invalid=318 /-]

creat_7: creat_7

Information	[Type= discrete] [Format=numeric] [Missing=*]
Statistics [NW/ W]	[Valid=0 /-] [Invalid=318 /-]

serumcreat_7: serumcreat_7

Information	[Type= discrete] [Format=numeric] [Range= 9999-9999] [Missing=*]
Statistics [NW/ W]	[Valid=318 /-] [Invalid=0 /-]

crcl_7: crcl_7

Information	[Type= discrete] [Format=numeric] [Range= 9999-9999] [Missing=*]
Statistics [NW/ W]	[Valid=318 /-] [Invalid=0 /-]

crcl_7_comp: crcl_7_comp

Information	[Type= discrete] [Format=numeric] [Range= 9999-9999] [Missing=*]
Statistics [NW/ W]	[Valid=318 /-] [Invalid=0 /-]

dt_adverse_1: dt_adverse_1

Information	[Type= continuous] [Format=numeric] [Range= 27062019-29032019] [Missing=*]
Statistics [NW/ W]	[Valid=3 /-] [Invalid=315 /-] [Mean=27722019 /-] [StdDev=1134504.297 /-]

adverse_1_spec: adverse_1_spec

Information	[Type= discrete] [Format=character] [Missing=*]
Statistics [NW/ W]	[Valid=3 /-] [Invalid=0 /-]

adverse_1: adverse_1

Information	[Type= discrete] [Format=numeric] [Range= 3-3] [Missing=*]
Statistics [NW/ W]	[Valid=3 /-] [Invalid=315 /-]

pregnant_prep1: pregnant_prep1

Information	[Type= discrete] [Format=numeric] [Range= 2-2] [Missing=*]
Statistics [NW/ W]	[Valid=118 /-] [Invalid=200 /-]

pregnant_prep2: pregnant_prep2

Information	[Type= discrete] [Format=numeric] [Range= 2-2] [Missing=*]
Statistics [NW/ W]	[Valid=23 /-] [Invalid=295 /-]

pregnant_prep3: pregnant_prep3

Information	[Type= discrete] [Format=numeric] [Range= 2-2] [Missing=*]
Statistics [NW/ W]	[Valid=8 /-] [Invalid=310 /-]

pregnant_prep4: pregnant_prep4

Information	[Type= discrete] [Format=numeric] [Range= 2-2] [Missing=*]
Statistics [NW/ W]	[Valid=2 /-] [Invalid=316 /-]

pregnant_prep5: pregnant_prep5

Information	[Type= discrete] [Format=numeric] [Range= 2-2] [Missing=*]
Statistics [NW/ W]	[Valid=3 /-] [Invalid=315 /-]

pregnant_prep6: pregnant_prep6

Information	[Type= discrete] [Format=numeric] [Range= 2-2] [Missing=*]
Statistics [NW/ W]	[Valid=1 /-] [Invalid=317 /-]

pregnant_prep7: pregnant_prep7

Information	[Type= discrete] [Format=numeric] [Range= 2-2] [Missing=*]
Statistics [NW/ W]	[Valid=1 /-] [Invalid=317 /-]

pregnant_creat1: pregnant_creat1

Information	[Type= discrete] [Format=numeric] [Range= 2-2] [Missing=*]
Statistics [NW/ W]	[Valid=118 /-] [Invalid=200 /-]

pregnant_creat2: pregnant_creat2

Information	[Type= discrete] [Format=numeric] [Range= 2-2] [Missing=*]
Statistics [NW/ W]	[Valid=23 /-] [Invalid=295 /-]

pregnant_creat3: pregnant_creat3

Information	[Type= discrete] [Format=numeric] [Range= 2-2] [Missing=*]
Statistics [NW/ W]	[Valid=8 /-] [Invalid=310 /-]

pregnant_creat4: pregnant_creat4

Information	[Type= discrete] [Format=numeric] [Range= 2-2] [Missing=*]
Statistics [NW/ W]	[Valid=2 /-] [Invalid=316 /-]

pregnant_creat5: pregnant_creat5

Information	[Type= discrete] [Format=numeric] [Range= 2-2] [Missing=*]
Statistics [NW/ W]	[Valid=3 /-] [Invalid=315 /-]

pregnant_creat6: pregnant_creat6

Information	[Type= discrete] [Format=numeric] [Range= 2-2] [Missing=*]
Statistics [NW/ W]	[Valid=1 /-] [Invalid=317 /-]

pregnant_creat7: pregnant_creat7

Information	[Type= discrete] [Format=numeric] [Range= 2-2] [Missing=*]
Statistics [NW/ W]	[Valid=1 /-] [Invalid=317 /-]

discontinue: discontinue

Information	[Type= discrete] [Format=numeric] [Range= 0-2] [Missing=*]
Statistics [NW/ W]	[Valid=3 /-] [Invalid=315 /-]

dt_discontinue: dt_discontinue

Information	[Type= discrete] [Format=character] [Missing=*]
Statistics [NW/ W]	[Valid=1 /-] [Invalid=0 /-]

restart: restart

Information	[Type= discrete] [Format=numeric] [Range= 99-99] [Missing=*]
Statistics [NW/ W]	[Valid=318 /-] [Invalid=0 /-]

restart_adv: restart_adv

Information	[Type= discrete] [Format=numeric] [Range= 99-99] [Missing=*]
Statistics [NW/ W]	[Valid=318 /-] [Invalid=0 /-]

# **exit: exit**	
Information	[Type= discrete] [Format=numeric] [Range= 0-3] [Missing=*]
Statistics [NW/ W]	[Valid=318 /-] [Invalid=0 /-]

# **exit_spec: exit_spec**	
Information	[Type= discrete] [Format=character] [Missing=*]
Statistics [NW/ W]	[Valid=108 /-] [Invalid=0 /-]

# **dt_exit: dt_exit**	
Information	[Type= discrete] [Format=character] [Missing=*]
Statistics [NW/ W]	[Valid=224 /-] [Invalid=0 /-]

# **notes: notes**	
Information	[Type= discrete] [Format=numeric] [Missing=*]
Statistics [NW/ W]	[Valid=0 /-] [Invalid=318 /-]

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country: country

Information	[Type= discrete] [Format=character] [Missing=*]
Statistics [NW/ W]	[Valid=1 /-] [Invalid=0 /-]

design: design

Information	[Type= discrete] [Format=numeric] [Range= 5-5] [Missing=*]
Statistics [NW/ W]	[Valid=1 /-] [Invalid=0 /-]

start_d: start_d

Information	[Type= discrete] [Format=numeric] [Range= 15032019-15032019] [Missing=*]
Statistics [NW/ W]	[Valid=1 /-] [Invalid=0 /-]

end_d: end_d

Information	[Type= discrete] [Format=numeric] [Range= 20102020-20102020] [Missing=*]
Statistics [NW/ W]	[Valid=1 /-] [Invalid=0 /-]

source_data: source_data

Information	[Type= discrete] [Format=numeric] [Range= 2-2] [Missing=*]
Statistics [NW/ W]	[Valid=1 /-] [Invalid=0 /-]

total_n: total_n

Information	[Type= discrete] [Format=numeric] [Range= 568-568] [Missing=*]
Statistics [NW/ W]	[Valid=1 /-] [Invalid=0 /-]

crscreen_n: crscreen_n

Information	[Type= discrete] [Format=numeric] [Range= 346-346] [Missing=*]
Statistics [NW/ W]	[Valid=1 /-] [Invalid=0 /-]