World Health Organization

HIV DRUG RESISTANCE

USERS MANUAL

HIV DRUG RESISTANCE SURVEYS: TOOL FOR DATA ENTRY

DECEMBER 2017

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ACRONYMS AND ABBREVIATIONS

ADR	Acquired hiv drug resistance
ART	Antiretroviral therapy
ARV	Antiretroviral drug
AUQ	Above upper limit of quantification
BLQ	Below lower limit of quantification
HIV	Human immunodeficiency virus
IRQ	In range of quantification
ISO	International organization for standardization
PDR	Pre-treatment hiv drug resistance
PMTCT	Prevention of mother to child transmission
PEP	Post-exposure prophylaxis
PREP	Pre-exposure prophylaxis
SNA	Sequencing not attempted
SUC	Successfully sequenced
UNK	Unknown
UNS	Unsuccessfully sequenced
WHO	World health organization

1. INTRODUCTION

Nationally representative surveillance of pre-treatment HIV drug resistance (PDR) in populations initiating antiretroviral therapy (ART) is critical to inform the selection of effective first-line ART, as well as appropriate regimens for pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP). Similarly, nationally representative surveillance of acquired HIV drug resistance (ADR) among populations failing ART provides critical information to assess programme efforts to maximize viral suppression, to inform selection and management of second-line therapies and to gauge the extent to which patients are switching therapies unnecessarily. The World Health Organization (WHO) recommends that countries routinely conduct national surveys of PDR and ADR.

To facilitate data collection at sites participating in PDR and ADR surveys, WHO has developed Excel-based Site-level Entry Tools. In addition, to support the management, analysis and reporting of national data, WHO has developed National Data Consolidator Tools for PDR and ADR surveys. These tools aggregate data from multiple Site-level Data Entry Tools into one national file. This manual provides instructions for using the PDR and ADR Site-level Data Entry Tools and the PDR and ADR National Data Consolidator Tools. These tools may be downloaded at the following website: http://www.who.int/hiv/topics/drugresistance/en/.

The intended audience for this manual is site-level data managers charged with collecting data for PDR and ADR surveys and national-level data managers and HIV drug resistance (HIVDR) technical working groups implementing HIVDR surveillance.

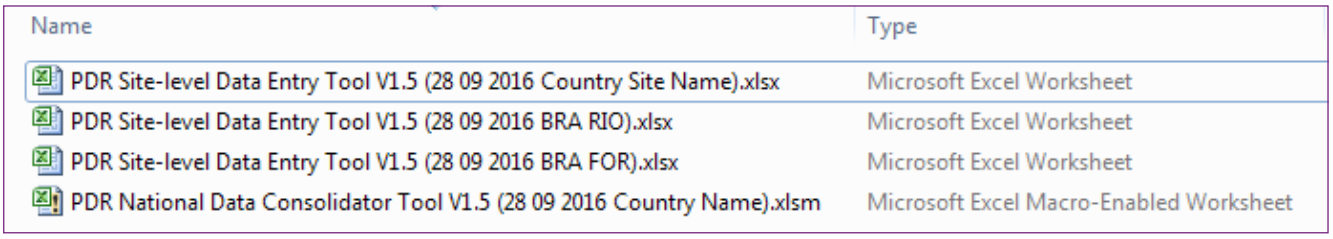
This instruction manual is divided into five sections:

- Section 1 is this introduction to the manual;
- Section 2 provides instructions for the PDR Survey Site-level Data Entry Tool;
- Section 3 provides instructions for the PDR National Data Consolidator Tool;
- Section 4 provides instructions for the ADR Survey Site-level Data Entry Tool;
- Section 5 provides instructions for the ADR National Data Consolidator Tool.

2. PDR SITE-LEVEL DATA ENTRY TOOL

This tool has been designed to capture individual-level data at ART sites participating in national surveys of PDR. Use of this tool standardizes data collection processes across all sites and helps find data entry anomalies in real time, before data are saved. Its use along with the National Data Consolidator Tool facilitates aggregation of data at the national-level into a single master Excel file. This national-level file can be used for in-country analysis, and it can be uploaded into the WHO HIVDR database for quality assurance, storage, and global reporting.

Site-level Data Entry Tools are for illustrative purposes only.

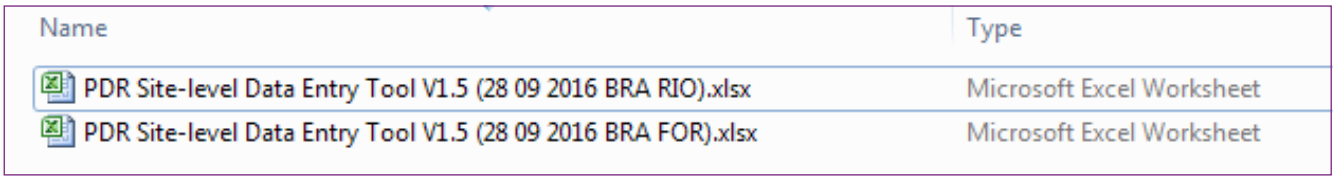


2.1 Before getting started [1]

2.1.1 Naming site-level data entry files (naming convention)

Each Site-level Data Entry File must have a unique file name. Unique file names make it possible to consolidate multiple site-level files into a single national file.

The recommended naming convention is:
PDR Site-level Data Entry Tool Vx.x (date –dd mm yyyy + three-letter ISO country code + three-letter site name code).xlsx. The chart below shows examples.



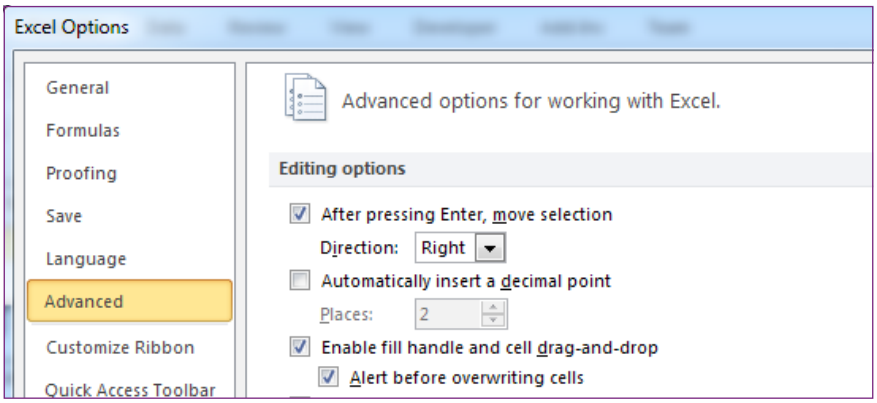
2.1.2 Columns with data validation fields

Warning: Do not cut or paste data in columns with data validation fields. If you do so, the drop-down menus, validation options and formatting will be erased. This will cause problems with consolidating data at the national level. Never change a column format. Columns containing date information have been formatted as text in order to accommodate regional differences in date formatting and character lengths (in the case of partial dates).

2.1.3 Move the cursor to the right (optional)

This is an optional setting that may speed up entry of participant-level data. The screen shot below shows how to change the settings to make the cursor move right ("next column") instead of down ("next row") after entering data in a cell.

To change the settings, click on File, Options, Advanced; go to "Editing options"; and select direction "Right" below the words "After pressing Enter, move selection".



2.2 Worksheet descriptions

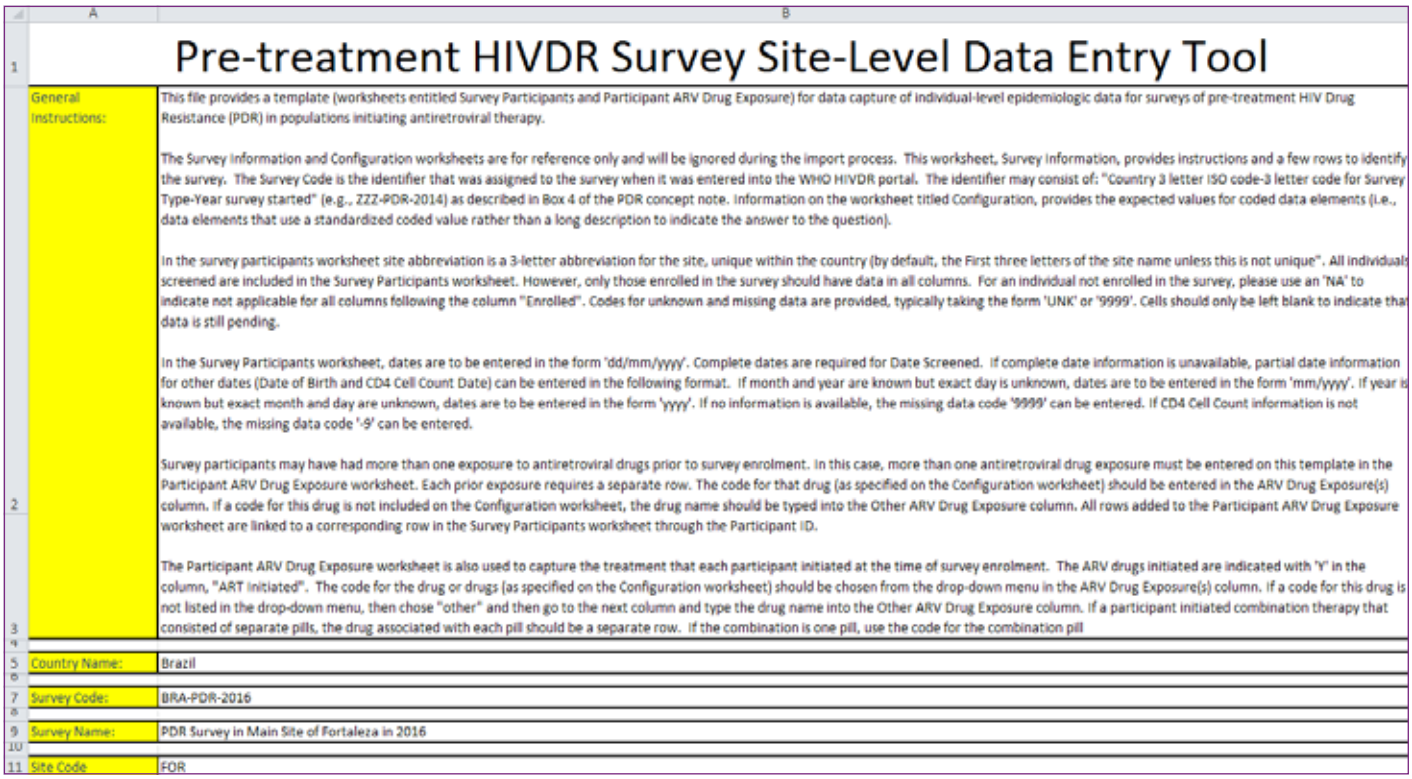
The PDR Site-level Data Entry Tool consists of four worksheets:

- The Survey Information worksheet has general instruction on how to enter data and captures meta-data about the survey;
- The Configuration worksheet contains references and descriptions of data used in the survey;
- The Survey Participants worksheet captures participants' data such as date of birth, CD4 cell count, gender, date screened, etc.;
- The Participant ARV Drug Exposure worksheet captures data related to ARV Drug Exposures and ARV Drugs Initiated amongst enrolled participants.

1. The date validation rules in this tool work correctly when the Regional Settings format is set to English (United Kingdom). To change the Regional Settings go to Control Panel->Region and Language->Formats, choose from "Format" dropdown box "English (United Kingdom)" and click the Apply button.

2.2.1 Survey information worksheet

This worksheet contains general instructions. It also requests that the user provide specific information about the survey so that it can be easily identified – Country Name, Survey Code, Survey Name and Site Code). To illustrate this concept, we use as an example a PDR survey started in 2016 at the "Fortaleza Main Site", located in Fortaleza, Brazil. In this example the "Survey Code" is the ISO standard 3-letter country code[1] ("BRA"), Survey Type (PDR) and year of survey (2016). The "Site Code" is the three-letter site name FOR" (first three letters of the site name[2],)



	A	B
1	Pre-treatment HIVDR Survey Site-Level Data Entry Tool	
2	General Instructions:	This file provides a template (worksheets entitled Survey Participants and Participant ARV Drug Exposure) for data capture of individual-level epidemiologic data for surveys of pre-treatment HIV Drug Resistance (PDR) in populations initiating antiretroviral therapy. The Survey Information and Configuration worksheets are for reference only and will be ignored during the import process. This worksheet, Survey Information, provides instructions and a few rows to identify the survey. The Survey Code is the identifier that was assigned to the survey when it was entered into the WHO HIVDR portal. The identifier may consist of: "Country 3 letter ISO code-3 letter code for Survey Type-Year survey started" (e.g., ZZZ-PDR-2014) as described in Box 4 of the PDR concept note. Information on the worksheet titled Configuration, provides the expected values for coded data elements (i.e., data elements that use a standardized coded value rather than a long description to indicate the answer to the question). In the survey participants worksheet site abbreviation is a 3-letter abbreviation for the site, unique within the country (by default, the First three letters of the site name unless this is not unique". All individuals screened are included in the Survey Participants worksheet. However, only those enrolled in the survey should have data in all columns. For an individual not enrolled in the survey, please use an 'NA' to indicate not applicable for all columns following the column "Enrolled". Codes for unknown and missing data are provided, typically taking the form 'UNK' or '9999'. Cells should only be left blank to indicate that data is still pending. In the Survey Participants worksheet, dates are to be entered in the form 'dd/mm/yyyy'. Complete dates are required for Date Screened. If complete date information is unavailable, partial date information for other dates (Date of Birth and CD4 Cell Count Date) can be entered in the following format. If month and year are known but exact day is unknown, dates are to be entered in the form 'mm/yyyy'. If year is known but exact month and day are unknown, dates are to be entered in the form 'yyyy'. If no information is available, the missing data code '9999' can be entered. If CD4 Cell Count information is not available, the missing data code '-9' can be entered. Survey participants may have had more than one exposure to antiretroviral drugs prior to survey enrolment. In this case, more than one antiretroviral drug exposure must be entered on this template in the Participant ARV Drug Exposure worksheet. Each prior exposure requires a separate row. The code for that drug (as specified on the Configuration worksheet) should be entered in the ARV Drug Exposure(s) column. If a code for this drug is not included on the Configuration worksheet, the drug name should be typed into the Other ARV Drug Exposure column. All rows added to the Participant ARV Drug Exposure worksheet are linked to a corresponding row in the Survey Participants worksheet through the Participant ID. The Participant ARV Drug Exposure worksheet is also used to capture the treatment that each participant initiated at the time of survey enrolment. The ARV drugs initiated are indicated with 'Y' in the column, "ART Initiated". The code for the drug or drugs (as specified on the Configuration worksheet) should be chosen from the drop-down menu in the ARV Drug Exposure(s) column. If a code for this drug is not listed in the drop-down menu, then chose "other" and then go to the next column and type the drug name into the Other ARV Drug Exposure column. If a participant initiated combination therapy that consisted of separate pills, the drug associated with each pill should be a separate row. If the combination is one pill, use the code for the combination pill
3		
4		
5	Country Name:	Brazil
6		
7	Survey Code:	BRA-PDR-2016
8		
9	Survey Name:	PDR Survey in Main Site of Fortaleza in 2016
10		
11	Site Code	FOR

2.2.2 Configuration worksheet

This worksheet defines the codes and abbreviations used in the survey. Below is an example of the information provided on the configuration worksheet. In this example Gender is defined as: Female "F", Male "M", Transgender "T" or Unknown "U". It is advisable to review all codes, labels and descriptions in the configuration worksheet before using the tool.

1	Data Element: Gender		
2	CODE	Label	DESCRIPTION
3	F	Female	Indicates that the participant is female
4	M	Male	Indicates that the participant is male
5	T	Transgender	Indicates that the participant's current gender is different from their birth gender
6	U	Unknown	Indicates that the participant's gender is not known

1. http://www.worldatlas.com/aatlas/ctycodes.htm

2. The recommended convention for assigning the Site Code is use of the first three letters of the site's name. If, however, the names of more than one site in a country begin with the same first three letters, the first site created should be assigned those first three letters as its Site Code. The second to the tenth sites with the same first three letters should be assigned the first two letters followed by an integer from 1 to 9. Sites created after the first 10 should use the first letter followed by integers from 11 to 99. The country HIVDR survey coordinator must be contacted in cases of any doubt concerning the Site Code. This modified alphanumeric convention is used only in situations where more than one site has the same first three letters in their names. To minimize cases where the first three letters of the site names are the same, it is suggested to avoid using common words like clinic, centre, hospital, etc. as the first word in a site name.

2.2.3 Survey participants worksheet

This worksheet is for data about all screened and enrolled participants.

	A	B	C	D	E	F	G	H	I	J	K	L
1	Site Code	Participant ID	Prior Drug(s) Exposure (Y/N/U)	Date Screened	Enrolled (Y/N)	Gender	Date of Birth	Age	CD4 Cell Count	CD4 Cell Count Date	Genotyping Successful	Lab Specimen Code
2	FOR	BRA-PDR-2016-FOR-0001	Y	11/11/2016	Y	M	1990	26	500	11/2015	SUC	
3	FOR	BRA-PDR-2016-FOR-0002	Y	11/12/2016	Y	F	10/10/1992	24	100	2015	SNA	
4	FOR	BRA-PDR-2016-FOR-0003	Y	10/10/2016	Y	T	12/1990	26	200	12/12/2015	UNS	

2.2.3.1 Site code

Enter the site code in column A. Data entered in this column will be compared with the site code entered in the Survey Information worksheet. If the site codes are not identical, the cell in the "Site Code" column will be highlighted in red, signalling a need to resolve this anomaly.

	A	B	C	D	E	F	G	H	I	J	K	L
1	Site Code	Participant ID	Prior Drug(s) Exposure (Y/N/U)	Date Screened	Enrolled (Y/N)	Gender	Date of Birth	Age	CD4 Cell Count	CD4 Cell Count Date	Genotyping Successful	Lab Specimen Code
2	FRT	BRA-PDR-2016-FOR-0001	Y	11/11/2016	Y	M	1990	26	500	11/2015	SUC	
3	FOR	BRA-PDR-2016-FOR-0002	Y	11/12/2016	Y	F	10/10/1992	24	100	2015	SNA	
4	FOR	BRA-PDR-2016-FOR-0003	Y	10/10/2016	Y	T	12/1990	26	200	12/12/2015	UNS	

2.2.3.2 Participant ID

The "Participant ID" entered in column B must be unique. Any attempt to write a duplicate "Participant ID" is not allowed and will be highlighted in red. If a cell is highlighted, re-enter the correct "Participant ID", and cell highlighting will be removed. To avoid duplicate entries in the HIVDR database, the "Participant ID" should follow this format: three-letter ISO country code – three-letter survey type – four digit year – three-letter site name – four-digit unique number. For more information on "Participant ID", refer to the WHO concept notes on PDR and ADR.[1,2]

	A	B	C	D	E	F	G	H	I	J	K	L
1	Site Code	Participant ID	Prior Drug(s) Exposure (Y/N/U)	Date Screened	Enrolled (Y/N)	Gender	Date of Birth	Age	CD4 Cell Count	CD4 Cell Count Date	Genotyping Successful	Lab Specimen Code
2	FOR	BRA-PDR-2016-FOR-0001	Y	11/11/2016	Y	M	1990	26	500	11/2015	SUC	
3	FOR	BRA-PDR-2016-FOR-0002	Y	11/12/2016	Y	F	10/10/1992	24	100	2015	SNA	
4	FOR	BRA-PDR-2016-FOR-0003	Y	10/10/2016	Y	T	12/1990	26	200	12/12/2015	UNS	

2.2.3.3 Prior drug(s) exposure (Y/N/U)

Column C captures information on "Prior drug(s) exposure (Y/N/U)" and has a drop-down menu with three options: Yes "Y", No "N", and Unknown "U". "Prior drug(s) exposure" refers only to prior ARV drug exposures. Only capital letters are permitted in this column; a user cannot enter lower-case letters.

	A	B	C	D	E	F	G	H	I	J	K	L
1	Site Code	Participant ID	Prior Drug(s) Exposure (Y/N/U)	Date Screened	Enrolled (Y/N)	Gender	Date of Birth	Age	CD4 Cell Count	CD4 Cell Count Date	Genotyping Successful	Lab Specimen Code
2	FOR	BRA-PDR-2016-FOR-0001	Y	/11/2016	Y	M	1990	26	500	11/2015	SUC	
3	FOR	BRA-PDR-2016-FOR-0002	Y			F	10/10/1992	24	100	2015	SNA	
4	FOR	BRA-PDR-2016-FOR-0003	N			T	12/1990	26	200	12/12/2015	UNS	
5			U									

Exposure (Y/N/U)
ether the participant
has previously received ARV drug(s)

1. Surveillance of HIV drug resistance in adults initiating antiretroviral therapy (pre-treatment HIV drug resistance). Geneva: World Health Organization; 2014 (http://www.who.int/hiv/pub/drugresistance/pretreatment_drugresistance/en/, accessed 28 November 2016)

2. Surveillance of HIV drug resistance in adults receiving ART. Geneva: World Health Organization; 2014 (http://www.who.int/hiv/pub/drugresistance/acquired_drugresistance/en/, accessed 28 November 2016).

2.2.3.4 Date screened

In Column D, the date must be in the day/month/year format like this: dd/mm/yyyy. If an invalid date is entered, the cell will be highlighted in red (as shown below) and must be corrected.

	A	B	C	D	E	F	G	H	I	J	K	L
1	Site Code	Participant ID	Prior Drug(s) Exposure (Y/N/U)	Date Screened	Enrolled (Y/N)	Gender	Date of Birth	Age	CD4 Cell Count	CD4 Cell Count Date	Genotyping Successful	Lab Specimen Code
2	FOR	BRA-PDR-2016-FOR-0001	Y	11.11.2016	Y	M	1990	26	500	11/2015	SUC	
3	FOR	BRA-PDR-2016-FOR-0002	Y	11-12-2016	Y	F	10/10/1992	24	100	2015	SNA	
4	FOR	BRA-PDR-2016-FOR-0003	Y	10/10/2016	Y	T	12/1990	26	200	12/12/2015	UNS	

Warning: Do not change the format in this column from "text" to "date" format. If the data format is changed from "text" to "date", an error will occur during merging of data by the Data Consolidator Tool as shown below.

	A	B	C	D	E	F	G	H	I	J	K	L
1	Site Code	Participant ID	Prior Drug(s) Exposure (Y/N/U)	Date Screened	Enrolled (Y/N)	Gender	Date of Birth	Age	CD4 Cell Count	CD4 Cell Count Date	Genotyping Successful	Lab Specimen Code
2	FOR	BRA-PDR-2016-FOR-0001	Y	39845	Y	M	1990	26	500	39844	SUC	
3	FOR	BRA-PDR-2016-FOR-0002	Y	39853	Y	F	10/10/1992	24	100	39843	SNA	
4	FOR	BRA-PDR-2016-FOR-0003	Y	39856	Y	T	12/1990	26	200	39849	UNS	
5	RIO	BRA-PDR-2016-RIO-0001	Y	39863	Y	M	1990	26	500	39854	SUC	
6	RIO	BRA-PDR-2016-RIO-0002	N	39872	N	F	1992	24	100	39816	SNA	
7	RIO	BRA-PDR-2016-RIO-0003	Y	39884	Y	F	1990	26	200	9999	UNS	
8												

2.2.3.5 Enrolled (Y/N)

Column E captures whether the participant is enrolled into the survey. Enrolment information is entered using a drop-down menu with two options: Yes "Y" or No "N".

	A	B	C	D	E	F	G	H	I	J	K	L
1	Site Code	Participant ID	Prior Drug(s) Exposure (Y/N/U)	Date Screened	Enrolled (Y/N)	Gender	Date of Birth	Age	CD4 Cell Count	CD4 Cell Count Date	Genotyping Successful	Lab Specimen Code
2	FOR	BRA-PDR-2016-FOR-0001	Y	11/11/2016	Y		1990	26	500	11/2015	SUC	
3	FOR	BRA-PDR-2016-FOR-0002	Y	11/12/2016	Y		10/10/1992	24	100	2015	SNA	
4	FOR	BRA-PDR-2016-FOR-0003	Y	10/10/2016	Y		12/1990	26	200	12/12/2015	UNS	
5					N							

indicates whether the patient is

2.2.3.6 Gender

Column F captures a participant's gender. Gender is entered using a drop-down menu with four options: Female "F", Male "M", Transgender "T" and Unknown "U".

	A	B	C	D	E	F	G	H	I	J	K	L
1	Site Code	Participant ID	Prior Drug(s) Exposure (Y/N/U)	Date Screened	Enrolled (Y/N)	Gender	Date of Birth	Age	CD4 Cell Count	CD4 Cell Count Date	Genotyping Successful	Lab Specimen Code
2	FOR	BRA-PDR-2016-FOR-0001	Y	11/11/2016	Y	M	90	26	500	11/2015	SUC	
3	FOR	BRA-PDR-2016-FOR-0002	Y	11/12/2016	Y		/10/1992	24	100	2015	SNA	
4	FOR	BRA-PDR-2016-FOR-0003	Y	10/10/2016	Y		/1990	26	200	12/12/2015	UNS	
5						F						
						U						
						T						

2.2.3.7 Date of birth

Column G, "Date of birth", captures a participant's date of birth. This column follows the same "dd/mm/yyyy" data format as column D, "Date screened"; however, "Date of birth" may be partial (containing only year or month and year). If the month and year of birth are known, but the day of the month is unknown, a partial date of birth is entered in the form "mm/yyyy". If year of birth is known but month and day are unknown, a partial date of birth is entered in the form "yyyy". If no information on date of birth is available, the missing data code "9999" is entered. If an invalid date is entered, the cell will be highlighted in red (as shown below) and must be corrected.

	A	B	C	D	E	F	G	H	I	J	K	L
1	Site Code	Participant ID	Prior Drug(s) Exposure (Y/N/U)	Date Screened	Enrolled (Y/N)	Gender	Date of Birth	Age	CD4 Cell Count	CD4 Cell Count Date	Genotyping Successful	Lab Specimen Code
2	FOR	BRA-PDR-2016-FOR-0001	Y	11/11/2016	Y	M	13/13/1990	26	500	11/2015	SUC	
3	FOR	BRA-PDR-2016-FOR-0002	Y	11/12/2016	Y	F	10/10/199a	24	100	2015	SNA	
4	FOR	BRA-PDR-2016-FOR-0003	Y	10/10/2016	Y	T	9999	26	200	12/12/2015	UNS	

2.2.3.8 Age

Column H captures a participant's age and permits any integer from 1 to 110. If date of birth is provided, the "Age" column can be left blank; however, a participant's age must be entered when date of birth is not recorded in column G. If Date of Birth or Age are not entered the Date of Birth will be highlighted in red.

C	D	E	F	G	H	I	J	K
Prior Drug(s) Exposure (Y/N/U)	Date Screened	Enrolled (Y/N)	Gender	Date of Birth	Age	CD4 Cell Count	CD4 Cell Count Date	Genotyping Successful
Y	11/11/2016	Y	M	1990	26	500	11/2015	SUC
Y	11/12/2016	Y	F	10/10/1992	24	100	2015	SNA
Y	10/10/2016	Y	T	12/1990	26	200	12/12/2015	UNS

2.2.3.9 CD4 cell count

Column I captures a participant's CD4 cell count and permits numeric data. If CD4 cell count Information is unavailable, the missing data code "-9" is entered. Do not leave this field empty if CD4 cell count is unavailable.

C	D	E	F	G	H	I	J	K
Prior Drug(s) Exposure (Y/N/U)	Date Screened	Enrolled (Y/N)	Gender	Date of Birth	Age	CD4 Cell Count	CD4 Cell Count Date	Genotyping Successful
Y	11/11/2016	Y	M	1990	26	500	11/2015	SUC
Y	11/12/2016	Y	F	10/10/1992	24	100	2015	SNA
Y	10/10/2016	Y	T	12/1990	26	200	12/12/2015	UNS

2.2.3.10 CD4 cell count date

Column J captures the date of a participant's CD4 cell count test. Column J follows the same "dd/mm/yyyy" date format as columns D ("Date screened") and G ("Date of birth"). Like Column G, Column J allows partial dates (containing only year or month and year). If month and year are known but the exact day of the month is unknown, dates are entered in the form "mm/yyyy". If year is known but exact month and day are unknown, dates are entered in the form "yyyy". If no information is available, the missing data code "9999" is entered. If an invalid date or code is entered, the cell will be highlighted in red (as shown below) and the date must be corrected.

F	G	H	I	J	K	L
Gender	Date of Birth	Age	CD4 Cell Count	CD4 Cell Count Date	Genotyping Successful	Lab Specimen Code
M	1990	26	500	13/2015	SUC	
F	10/10/1992	24	100	8888	SNA	
T	12/1990	26	200	12/12/2015	UNS	

2.2.3.11 Genotyping successful

Column K, "Genotyping Successful", contains a drop-down menu with four options: Successfully Sequenced "SUC", Unsuccessfully Sequenced "UNS", Sequencing Not Attempted "SNA", and Unknown "UNK". **During implementation of a PDR survey, it is unlikely that a participating site will know this information at the time of data entry. Therefore, it is anticipated that participating sites will leave this column blank and that this information will be entered at the national level prior to consolidation into a single file.**

D	E	F	G	H	I	J	K	L
Date Screened	Enrolled (Y/N)	Gender	Date of Birth	Age	CD4 Cell Count	CD4 Cell Count Date	Genotyping Successful	Lab Specimen Code
11/11/2016	Y	M	1990	26	500	11/2015	SUC	
11/12/2016	Y	F	10/10/1992	24	100	2015	SUC	
10/10/2016	Y	T	12/1990	26	200	12/12/2015	UNS	
							SNA	
							UNK	

2.2.3.12 Lab specimen code

Some HIVDR testing laboratories may assign a "Lab Specimen Code" to participants' specimens rather than using the "Participant ID" as the specimen unique identifier. In this case, Column L, "Lab specimen code", captures the unique identifier assigned to a participant's specimen by the genotyping lab, if different from the "Participant ID". Column L is left blank if the "Participant ID" is used by the genotyping lab as the unique specimen identifier or if no specimen was taken. This column does not allow duplicate entries. Any cell with duplicate entry will be highlighted in red and must be corrected. **During PDR survey implementation, it is unlikely that participating sites will know this information at the time of data entry. Therefore, "Lab Specimen Code" usually will be entered at the national level prior to consolidation of data into a single file.**

D	E	F	G	H	I	J	K	L
Date Screened	Enrolled (Y/N)	Gender	Date of Birth	Age	CD4 Cell Count	CD4 Cell Count Date	Genotyping Successful	Lab Specimen Code
11/11/2016	Y	M	1990	26	500	11/2015	SUC	L051
11/12/2016	Y	F	10/10/1992	24	100	2015	SNA	L051
10/10/2016	Y	T	12/1990	26	200	12/12/2015	UNS	L052

2.2.4 Participant antiretroviral drug exposure worksheet

This worksheet captures information on participants' antiretroviral (ARV) drug exposure(s) **and** the treatment regimen initiated by a participant at the time of survey enrolment.

If a participant has been previously exposed to ARV drugs on more than one occasion, each prior drug exposure is entered on a **separate row**. If the prior ARV drug exposure was to one or more drugs dispensed as single pills, each drug requires a separate row. If the prior ARV drug exposure was to drugs dispensed as a fixed-dose combination, the drug combination is entered in a **single row.**

If, at the time of the survey enrolment, a participant is initiating an ART regimen dispensed as a fixed-dose combination, the regimen is entered in a **single row**. If, however, the regimen initiated is not dispensed as a fixed-dose combination (that is, two or more pills were dispensed), each individual drug or drug combination is entered on a **separate row.**

Because information on both prior ARV drug exposures and the ART regimen initiated at time of survey enrolment are entered into the same column (Column E), it is essential to differentiate prior ARV drug exposure(s) from drugs initiated at the time of the survey. This distinction is made in Column B, "ART initiated (Y/N)", and is discussed in Section 2.2.4.2.

	A	B	C	D	E	F
1	Participant ID	ART Initiated (Y/N)	Type of Prior ARV Drug Exposure	Type of PMTCT Exposure	ARV Drug Exposure(s)	Other ARV Drug Exposure
2	BRA-PDR-2016-FOR-0001	N	ART		STB elvitegravir + cobicistat + tenofovir + emtricitabine	
3	BRA-PDR-2016-FOR-0001	Y			TRI nevirapine + stavudine + lamivudine	
4	BRA-PDR-2016-FOR-0002	N	PREP		MVC maraviroc	
5	BRA-PDR-2016-FOR-0002	Y			ABC abacavir	
6	BRA-PDR-2016-FOR-0003	N	PEP		IDV indinavir	
7	BRA-PDR-2016-FOR-0003	Y			OTH Other Drugs not listed above	Genvoya

2.2.4.1 Participant ID

Column A captures a participant's survey ID. Column A has a dynamic drop-down menu, which provides choices of "Participant IDs" from those entered in the "Survey Participants" worksheet.

	A	B	C	D	E	F
1	Participant ID	ART Initiated (Y/N)	Type of Prior ARV Drug Exposure	Type of PMTCT Exposure	ARV Drug Exposure(s)	Other ARV Drug Exposure
2	BRA-PDR-2016-FOR-0001				STB elvitegravir + cobicistat + tenofovir + emtricitabine	
3					TRI nevirapine + stavudine + lamivudine	
4					MVC maraviroc	
5					ABC abacavir	
6	BRA-PDR-2016-FOR-0003				IDV indinavir	
7	BRA-PDR-2016-FOR-0003				OTH Other Drugs not listed above	Genvoya
8						

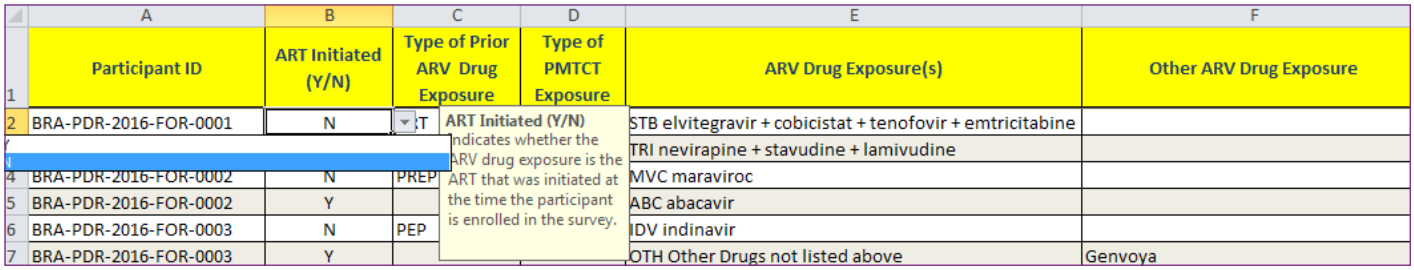
BRA-PDR-2016-FOR-0001
BRA-PDR-2016-FOR-0002
BRA-PDR-2016-FOR-0003

Participant ID

the survey
y the
ow the
survey type-year survey started-3 letter abbreviation for the site-4 digit consecutive unique number assigned to the participant

2.2.4.2 ART initiated (Y/N)

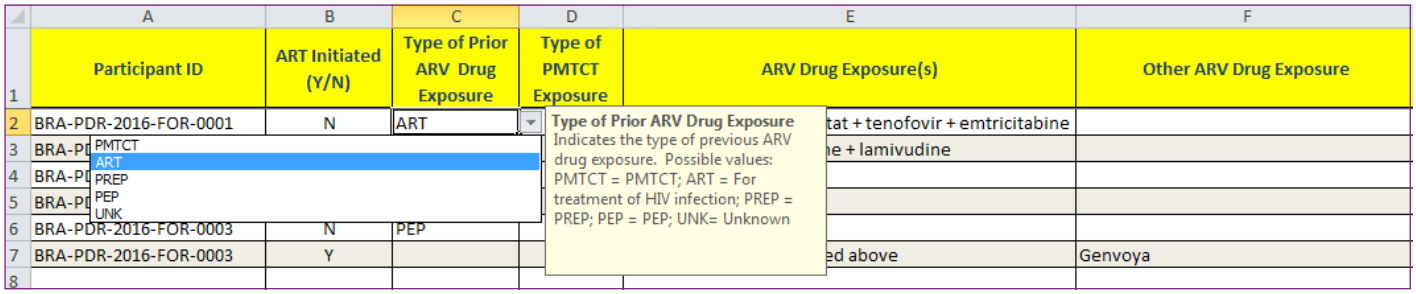
The information captured in Column B, "ART Initiated (Y/N)", denotes whether the ARV drug or drug combination entered in Column E was initiated at the time of survey enrolment. Column B has a drop-down menu with Yes "Y" and No "N" options. If the ARV drug(s) specified in column E are being initiated by the participant at the time of the survey, enter a 'Y' in Column B. If the ARV drug(s) specified in Column E are from an exposure prior to survey enrolment, an "N" is entered in Column B.



	A	B	C	D	E	F
1	Participant ID	ART Initiated (Y/N)	Type of Prior ARV Drug Exposure	Type of PMTCT Exposure	ARV Drug Exposure(s)	Other ARV Drug Exposure
2	BRA-PDR-2016-FOR-0001	N			STB elvitegravir + cobicistat + tenofovir + emtricitabine	
3					TRI nevirapine + stavudine + lamivudine	
4	BRA-PDR-2016-FOR-0002	N	PREP		MVC maraviroc	
5	BRA-PDR-2016-FOR-0002	Y			ABC abacavir	
6	BRA-PDR-2016-FOR-0003	N	PEP		IDV indinavir	
7	BRA-PDR-2016-FOR-0003	Y			OTH Other Drugs not listed above	Genvoya

2.2.4.3 Type of prior ARV drug exposure

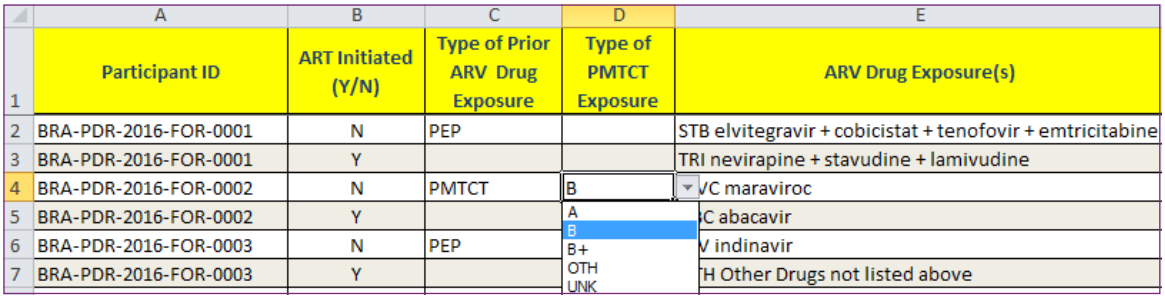
Column C captures the type of **prior ARV** drug exposure for participants with prior exposure(s). Column C has a drop-down menu with options for prevention of mother-to-child transmission "PMTCT", antiretroviral therapy "ART", pre-exposure prophylaxis "PREP", post-exposure prophylaxis "PEP", and unknown "UNK". In rows capturing ARV drugs initiated at time of survey enrolment, this column is left blank.



	A	B	C	D	E	F
1	Participant ID	ART Initiated (Y/N)	Type of Prior ARV Drug Exposure	Type of PMTCT Exposure	ARV Drug Exposure(s)	Other ARV Drug Exposure
2	BRA-PDR-2016-FOR-0001	N	ART		tat + tenofovir + emtricitabine	
3	BRA-P				e + lamivudine	
4	BRA-P					
5	BRA-P					
6	BRA-PDR-2016-FOR-0003	N	PEP			
7	BRA-PDR-2016-FOR-0003	Y			ed above	Genvoya
8						

2.2.4.4 Type of PMTCT exposure

Column D defines the type of prior PMTCT exposure. Column D has a drop-down menu with options "A", "B", "B+", Other "OTH", and Unknown "UNK".

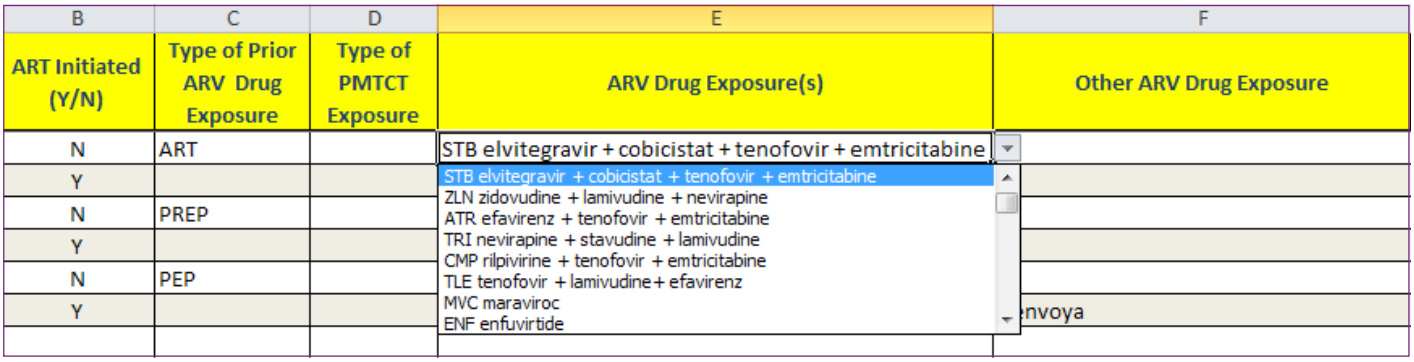


	A	B	C	D	E
1	Participant ID	ART Initiated (Y/N)	Type of Prior ARV Drug Exposure	Type of PMTCT Exposure	ARV Drug Exposure(s)
2	BRA-PDR-2016-FOR-0001	N	PEP		STB elvitegravir + cobicistat + tenofovir + emtricitabine
3	BRA-PDR-2016-FOR-0001	Y			TRI nevirapine + stavudine + lamivudine
4	BRA-PDR-2016-FOR-0002	N	PMTCT	B	VC maraviroc
5	BRA-PDR-2016-FOR-0002	Y			C abacavir
6	BRA-PDR-2016-FOR-0003	N	PEP		V indinavir
7	BRA-PDR-2016-FOR-0003	Y			H Other Drugs not listed above

2.2.4.5 ARV drug exposure(s)

Column E captures the drugs to which the survey participant was previously exposed or the drugs that the participant initiated at the time of survey enrolment. Column E has a drop-down menu with three-letter drug codes and their description. If a three-letter drug code corresponding to the drug or fixed-dose combination to which a participant was exposed or initiates at time of survey enrolment does not exist, choose "Other" and enter the name of the drug or fixed-dose combination in column F, "Other ARV drug exposure". If a participant initiated (or was previously exposed to) combination therapy that consisted of separate pills (that is, not a fixed-dose combination), enter each drug on a separate row. If a co-formulated regimen (or drug) was initiated, use the code for the combination pill.

At the national level, when the National Data Consolidator Tool consolidates multiple Site-level Data Entry Tools into one file, drug descriptions will be replaced automatically by the three-letter drug code.



B	C	D	E	F
ART Initiated (Y/N)	Type of Prior ARV Drug Exposure	Type of PMTCT Exposure	ARV Drug Exposure(s)	Other ARV Drug Exposure
N	ART		STB elvitegravir + cobicistat + tenofovir + emtricitabine	
Y			STB elvitegravir + cobicistat + tenofovir + emtricitabine	
N	PREP		ZLN zidovudine + lamivudine + nevirapine	
Y			ATR efavirenz + tenofovir + emtricitabine	
N	PEP		TRI nevirapine + stavudine + lamivudine	
Y			CMP rilpivirine + tenofovir + emtricitabine	
			TLE tenofovir + lamivudine + efavirenz	
			MVC maraviroc	nvoya
			ENF enfuvirtide	

2.2.4.6 Other ARV drug exposure

Column F is a free-text column that captures ARV drug exposures for which codes do not exist on the Configuration Worksheet. Column F is used only when "Other" has been selected in Column E, "ARV Drug Exposure(s)".

B	C	D	E	F
ART Initiated (Y/N)	Type of Prior ARV Drug Exposure	Type of PMTCT Exposure	ARV Drug Exposure(s)	Other ARV Drug Exposure
N	ART		STB elvitegravir + cobicistat + tenofovir + emtricitabine	
Y			TRI nevirapine + stavudine + lamivudine	
N	PREP		MVC maraviroc	
Y			ABC abacavir	
N	PEP		IDV indinavir	
Y			OTH Other Drugs not listed above	Genvoya

3. PDR NATIONAL-LEVEL TEMPLATE: DATA CONSOLIDATOR TOOL

The Data Consolidator Tool aggregates data from all sites participating in national surveys of PDR into a single national template. The Tool is designed to simplify the work of the person gathering these site-level files for consolidation into such a national master file. The Tool is designed to work only in Windows Operating System. The output of the National Data Consolidator Tool can be used for analysis or for upload into the WHO HIVDR database. The tool uses a three-step process to aggregate participant-level data from multiple site Data Entry Tools into one master file. The three steps are: 1) Select Files, 2) Copy "Survey Participants", and 3) Copy "Participant ARV Drug Exposure". The Data Consolidator Tool is automatically cleared of previously uploaded content after each use.

This section guides the user through the steps needed to extract site-level data and consolidate it into a single national EXCEL file containing data from all PDR survey sites.

Before consolidating site-level data entry files, the national data manager must ensure that required information regarding genotyping has been entered into column K, "Genotyping Successful", of every Site-level Data Entry Tool. In addition, if the genotyping laboratory has used an identifier other than the "Participant ID" in the required format, the national data manager must complete Column L, Lab Specimen Code, in each site-level Data Entry Tool.

Warning: The recommended convention for Site Code identification is use of the first three letters of the site's name. However, if the names of more than one site in a country have the same first three letters, the first site created should use the first three letters as its Site Code, the second to the tenth site created should use the first two letters followed by an integer from 1-9. The eleventh to the hundredth should use the first letter followed by integers from 11-99.

3.1 Before getting started

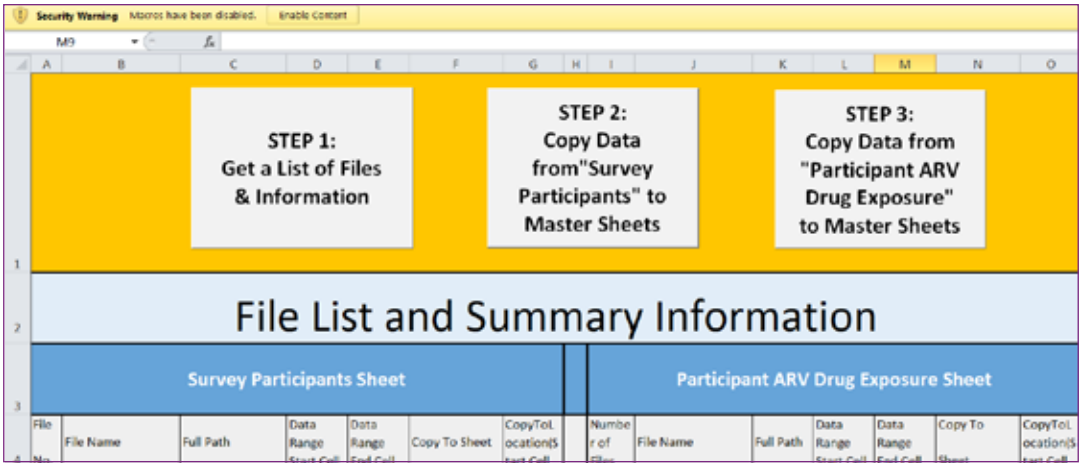
3.1.1 Naming national data consolidator file (naming convention)

It is important that each National Consolidator file have a unique name. The file should be labelled using the following convention: PDR National Data Consolidator Tool Vx.x (dd mm yyyy + three-letter country ISO code).xlsm. An example is provided below.

3.1.2 Enable macros

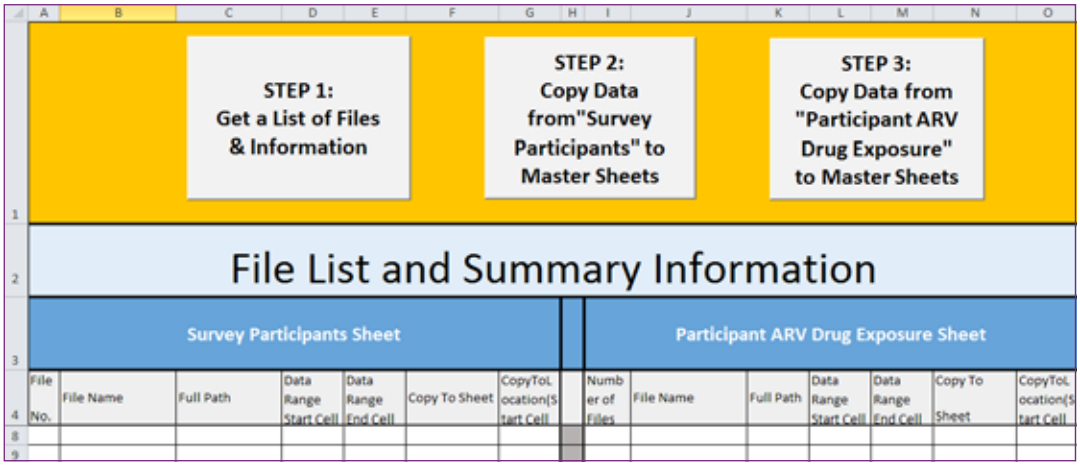
.xlsm is a type of format that allows macros to work in EXCEL. In the case of the National Data Consolidator Tool, a Visual Basic for Applications (VBA) code merges the worksheets from participating ART sites into one national file.

When opening the National Data Consolidator Tool, click on "Enable Content" to enable macros, if prompted to do so. Click on "Enable Content" to activate macros, or "Enable Macros" in case of a security notice.



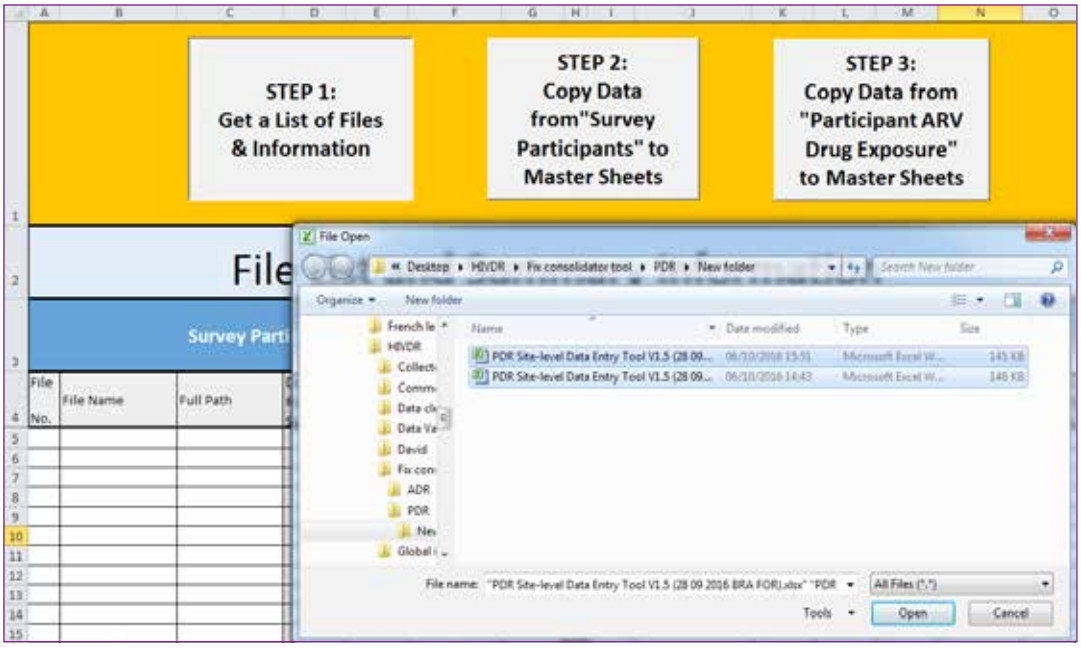
3.2 "List" worksheet

The purpose of the "List" worksheet is to aid in the identification and selection of national PDR survey files from multiple ART sites for consolidation into one master file by the national data manager.

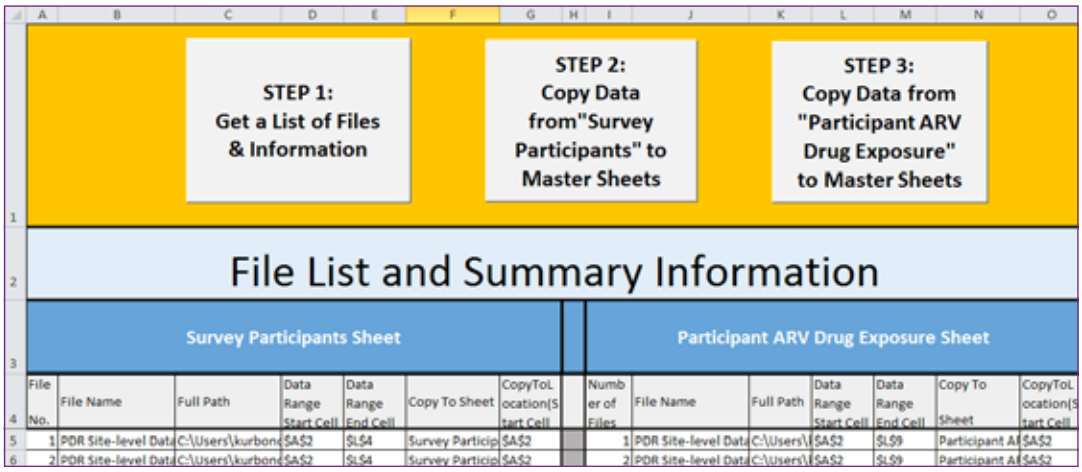


3.2.1 STEP 1

Click on "STEP 1". This will direct the user to a Windows Explorer dialogue box that prompts the user to select the location and files for import. Once all files have been selected, the "List" worksheet automatically creates a list of the selected files and summary information. The list shows the number of files selected, the file names, their location in the computer, the worksheets of interests and their data range (start cell to end cell). Simultaneous selection of multiple files is required in the opened Windows Explorer dialogue box. Before merging Site-level data, close files which are being consolidated (Site-level Data Entry Tool).



The information obtained in "STEP 1" is used in "STEP 2" to tell the tool which files, worksheets and range of data to copy and where to paste the information.



Warning: If the "STEP 1" button is clicked a second time, it will automatically clear all contents in order to avoid duplicated data.

File List and Summary Information

Survey Participants Sheet							Participant ARV Drug Exposure Sheet						
File No.	File Name	Full Path	Data Range Start Cell	Data Range End Cell	Copy To Sheet	CopyToLocation(Start Cell	Number of Files	File Name	Full Path	Data Range Start Cell	Data Range End Cell	Copy To Sheet	CopyToLocation(Start Cell

3.3 Survey participants worksheet

The Survey Participants Worksheet is blank before any site-level data are added. Once completed, this worksheet will become the National Master Consolidated Repository for storing all participant-level survey data.

	A	B	C	D	E	F	G	H	I	J	K	L
1	Site Code	Participant ID	Prior Drug(s) Exposure (Y/N/U)	Date Screened	Enrolled (Y/N)	Gender	Date of Birth	Age	CD4 Cell Count	CD4 Cell Count Date	Genotyping Successful	Lab Specimen Code
2												
3												
4												
5												
6												

3.3.1 STEP 2

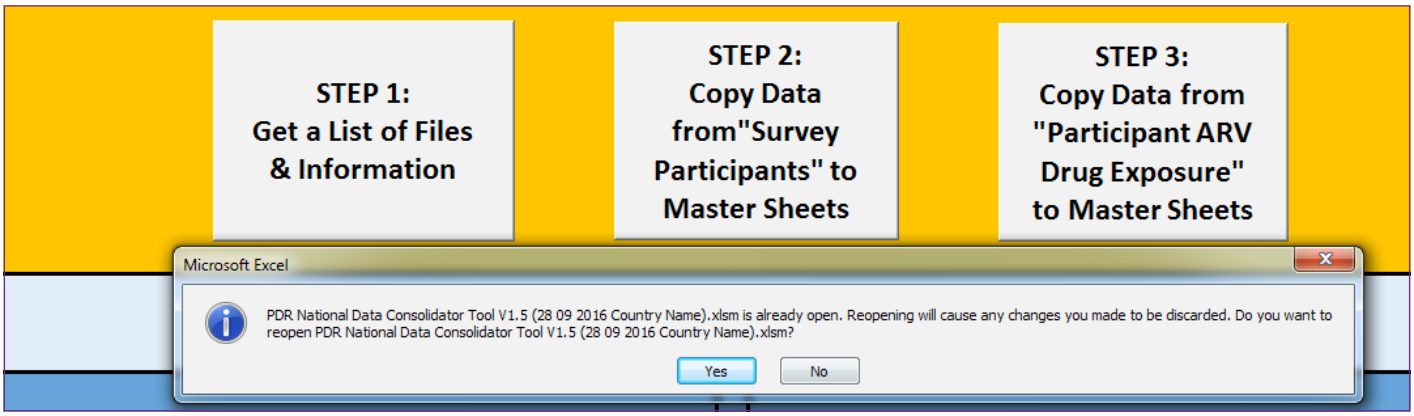
Click on the "STEP 2" button in the "List" worksheet. All data from "Survey Participants" worksheets from the selected files will be copied and pasted into the Consolidator Master "Survey Participants" worksheet.

	A	B	C	D	E	F	G	H	I	J	K	L
1	Site Code	Participant ID	Prior Drug(s) Exposure (Y/N/U)	Date Screened	Enrolled (Y/N)	Gender	Date of Birth	Age	CD4 Cell Count	CD4 Cell Count Date	Genotyping Successful	Lab Specimen Code
2	FOR	BRA-PDR-2016-FOR-0001	Y	11/11/2016	Y	M	1990	26	500	11/2015	SUC	
3	FOR	BRA-PDR-2016-FOR-0002	Y	11/12/2016	Y	F	10/10/1992	24	100	2015	SNA	
4	FOR	BRA-PDR-2016-FOR-0003	Y	10/10/2016	Y	T	12/1990	26	200	12/12/201	UNS	
5	RIO	BRA-PDR-2016-RIO-0001	Y	11/11/2016	Y	M	1990	26	500	11/2015	SUC	
6	RIO	BRA-PDR-2016-RIO-0002	N	11/12/2016	N	F	1992	24	100	2005	SNA	
7	RIO	BRA-PDR-2016-RIO-0003	Y	10/10/2016	Y	F	1990	26	200	2015	UNS	
8												

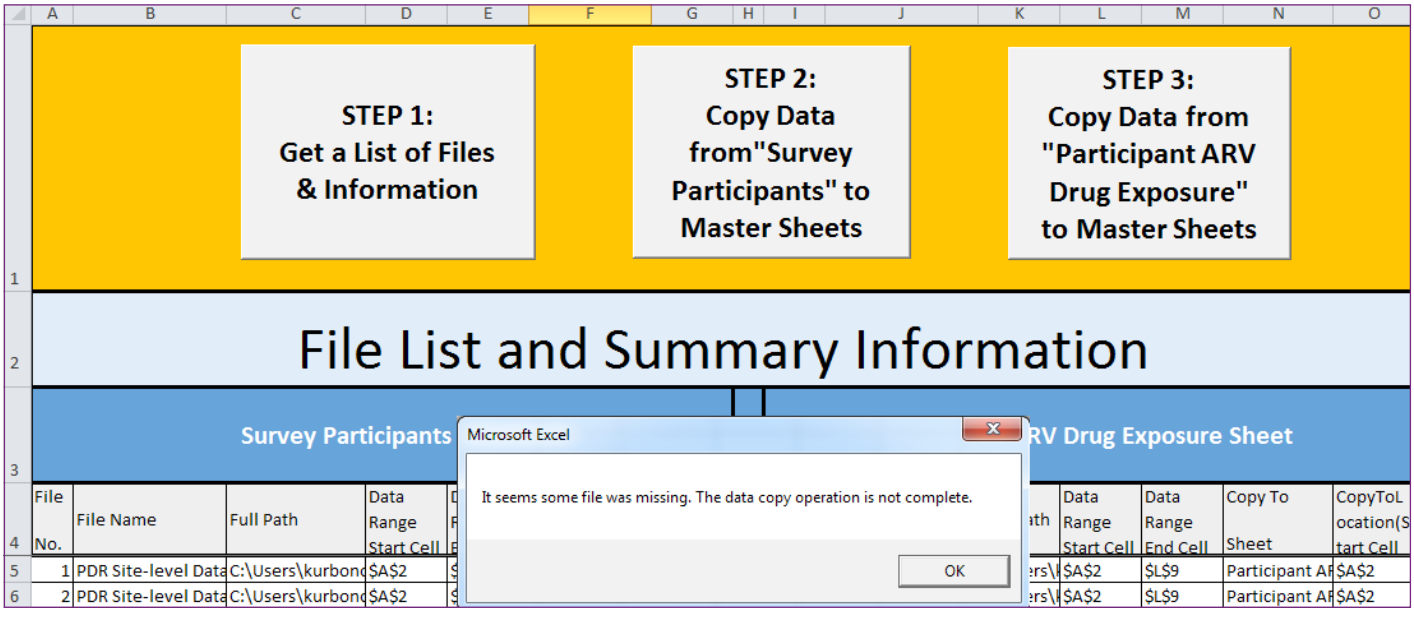
Warning: Never change column formats containing date information from "text" format to "date" format in any site-level or national-level file. As shown below, date information would be lost.

	A	B	C	D	E	F	G	H	I	J	K	L
1	Site Code	Participant ID	Prior Drug(s) Exposure (Y/N/U)	Date Screened	Enrolled (Y/N)	Gender	Date of Birth	Age	CD4 Cell Count	CD4 Cell Count Date	Genotyping Successful	Lab Specimen Code
2	FOR	BRA-PDR-2016-FOR-0001	Y	39845	Y	M	1990	26	500	39884	SUC	
3	FOR	BRA-PDR-2016-FOR-0002	Y	39853	Y	F	10/10/1992	24	100	39883	SNA	
4	FOR	BRA-PDR-2016-FOR-0003	Y	39853	Y	T	12/1990	26	200	39849	UNS	
5	RIO	BRA-PDR-2016-RIO-0001	Y	39863	Y	M	1990	26	500	39854	SUC	
6	RIO	BRA-PDR-2016-RIO-0002	N	39872	N	F	1992	24	100	39816	SNA	
7	RIO	BRA-PDR-2016-RIO-0003	Y	39884	Y	F	1990	26	200	39883	UNS	

Warning: Make sure all selected files are closed before importing. All site-level data entry files must be closed during consolidation at the national level; otherwise, the message shown below will appear.



If this happens, click "No" to continue. The message shown below will appear.

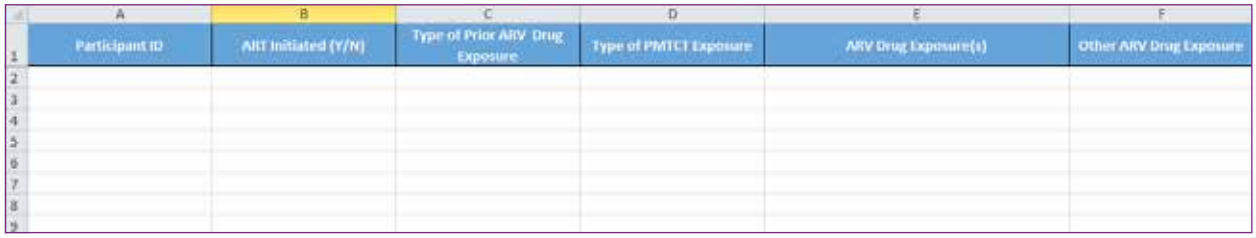


To continue, close all open files and reinitiate STEP 1.

Warning: If a file with the same name already exists, the file will be overwritten.

3.4 Participant ARV drug exposure worksheet

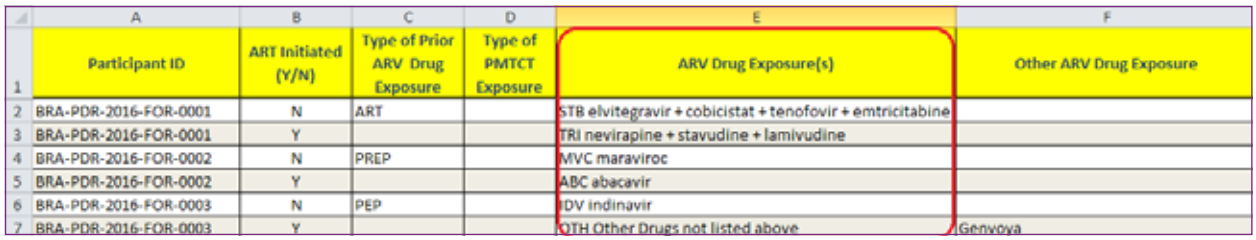
The "Participant ARV Drug Exposure" worksheet is blank before any site-level data are added. This worksheet will be the National Master Consolidated Repository for storing all participant-level "ARV drug exposure(s)" data.



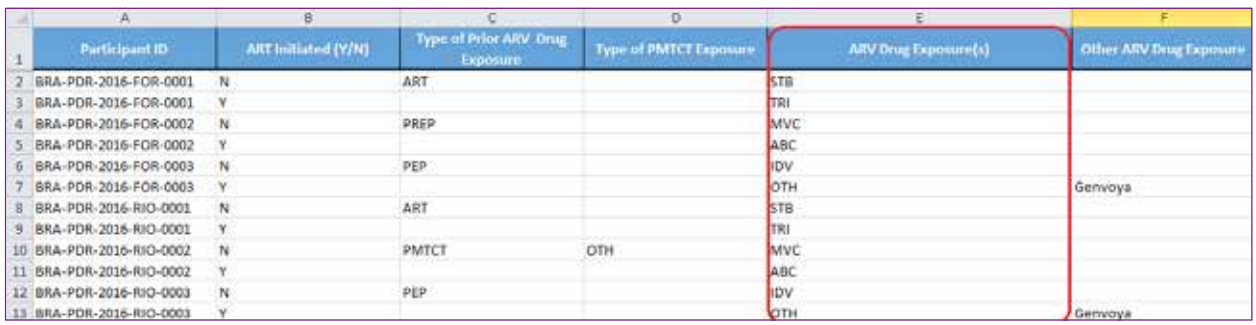
	A	B	C	D	E	F
1	Participant ID	ART Initiated (Y/N)	Type of Prior ARV Drug Exposure	Type of PMTCT Exposure	ARV Drug Exposure(s)	Other ARV Drug Exposure
2						
3						
4						
5						
6						
7						
8						
9						

3.4.1 STEP 3

Click on the "STEP 3" button in the "List" worksheet. All data from the "Participant ARV drug exposure" worksheets from the selected files will be copied and pasted into the Consolidator Master "Participant ARV drug exposure" worksheet. The ARV drug description that was entered into site-level data collection tools is converted automatically to a three-letter ARV Drug Code.

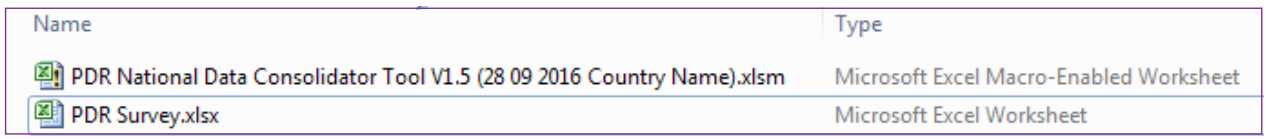


	A	B	C	D	E	F
1	Participant ID	ART Initiated (Y/N)	Type of Prior ARV Drug Exposure	Type of PMTCT Exposure	ARV Drug Exposure(s)	Other ARV Drug Exposure
2	BRA-PDR-2016-FOR-0001	N	ART		STB elvitegravir + cobicistat + tenofovir + emtricitabine	
3	BRA-PDR-2016-FOR-0001	Y			TRI nevirapine + stavudine + lamivudine	
4	BRA-PDR-2016-FOR-0002	N	PREP		MVC maraviroc	
5	BRA-PDR-2016-FOR-0002	Y			ABC abacavir	
6	BRA-PDR-2016-FOR-0003	N	PEP		IDV indinavir	
7	BRA-PDR-2016-FOR-0003	Y			OTH Other Drugs not listed above	Genvoya



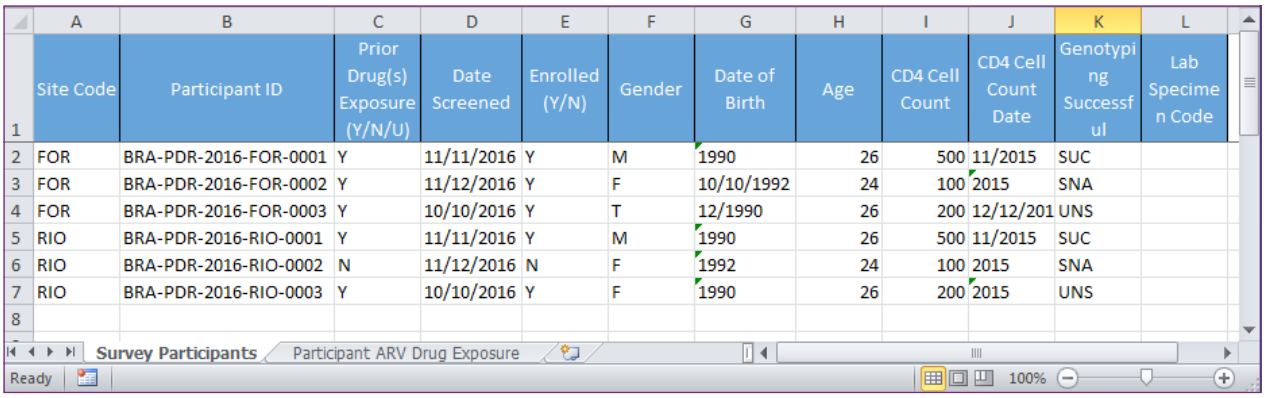
	A	B	C	D	E	F
1	Participant ID	ART Initiated (Y/N)	Type of Prior ARV Drug Exposure	Type of PMTCT Exposure	ARV Drug Exposure(s)	Other ARV Drug Exposure
2	BRA-PDR-2016-FOR-0001	N	ART		STB	
3	BRA-PDR-2016-FOR-0001	Y			TRI	
4	BRA-PDR-2016-FOR-0002	N	PREP		MVC	
5	BRA-PDR-2016-FOR-0002	Y			ABC	
6	BRA-PDR-2016-FOR-0003	N	PEP		IDV	
7	BRA-PDR-2016-FOR-0003	Y			OTH	Genvoya
8	BRA-PDR-2016-RIO-0001	N	ART		STB	
9	BRA-PDR-2016-RIO-0001	Y			TRI	
10	BRA-PDR-2016-RIO-0002	N	PMTCT	OTH	MVC	
11	BRA-PDR-2016-RIO-0002	Y			ABC	
12	BRA-PDR-2016-RIO-0003	N	PEP		IDV	
13	BRA-PDR-2016-RIO-0003	Y			OTH	Genvoya

A "PDR Survey.xlsx" file will be created automatically and saved in the same folder where the National Data Consolidator is located.



Name	Type
PDR National Data Consolidator Tool V1.5 (28 09 2016 Country Name).xlsm	Microsoft Excel Macro-Enabled Worksheet
PDR Survey.xlsx	Microsoft Excel Worksheet

This "PDR Survey.xlsx" file has two worksheets: "Survey participants" and "Participant ARV drug exposure". The "Survey participants" worksheet contains the consolidated participant-level data from all sites selected for consolidation.

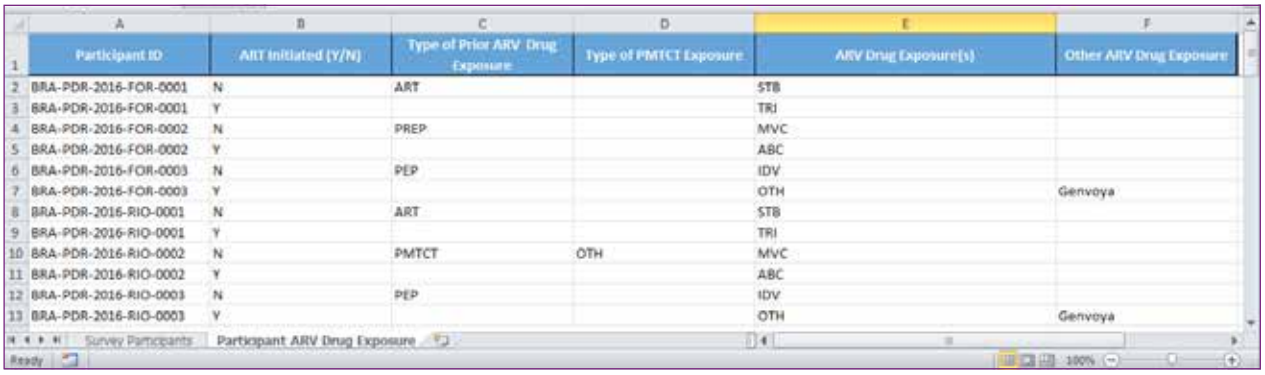


	A	B	C	D	E	F	G	H	I	J	K	L
1	Site Code	Participant ID	Prior Drug(s) Exposure (Y/N/U)	Date Screened	Enrolled (Y/N)	Gender	Date of Birth	Age	CD4 Cell Count	CD4 Cell Count Date	Genotyping Successful	Lab Specimen Code
2	FOR	BRA-PDR-2016-FOR-0001	Y	11/11/2016	Y	M	1990	26	500	11/2015	SUC	
3	FOR	BRA-PDR-2016-FOR-0002	Y	11/12/2016	Y	F	10/10/1992	24	100	2015	SNA	
4	FOR	BRA-PDR-2016-FOR-0003	Y	10/10/2016	Y	T	12/1990	26	200	12/12/201	UNS	
5	RIO	BRA-PDR-2016-RIO-0001	Y	11/11/2016	Y	M	1990	26	500	11/2015	SUC	
6	RIO	BRA-PDR-2016-RIO-0002	N	11/12/2016	N	F	1992	24	100	2015	SNA	
7	RIO	BRA-PDR-2016-RIO-0003	Y	10/10/2016	Y	F	1990	26	200	2015	UNS	
8												

Survey Participants | Participant ARV Drug Exposure

Ready 100%

The "Participant ARV drug exposure" worksheet contains consolidated ARV drug exposure data from all ART selected for consolidation.



	A	B	C	D	E	F
1	Participant ID	ART Initiated (Y/N)	Type of Prior ARV Drug Exposure	Type of PMTCT Exposure	ARV Drug Exposure(s)	Other ARV Drug Exposure
2	BRA-PDR-2016-FOR-0001	N	ART		STB	
3	BRA-PDR-2016-FOR-0001	Y			TRI	
4	BRA-PDR-2016-FOR-0002	N	PREP		MVC	
5	BRA-PDR-2016-FOR-0002	Y			ABC	
6	BRA-PDR-2016-FOR-0003	N	PEP		IDV	
7	BRA-PDR-2016-FOR-0003	Y			OTH	Genvoya
8	BRA-PDR-2016-RIO-0001	N	ART		STB	
9	BRA-PDR-2016-RIO-0001	Y			TRI	
10	BRA-PDR-2016-RIO-0002	N	PMTCT	OTH	MVC	
11	BRA-PDR-2016-RIO-0002	Y			ABC	
12	BRA-PDR-2016-RIO-0003	N	PEP		IDV	
13	BRA-PDR-2016-RIO-0003	Y			OTH	Genvoya

Survey Participants | Participant ARV Drug Exposure

Ready 100%

The final file "PDR Survey.xlsx" should undergo data verification and validation at the national level using standard best practices prior to using the file as a starting point for data analysis or for upload into the WHO HIVDR database for quality assurance and global reporting.

4. ADR SITE-LEVEL DATA ENTRY TOOL

This tool helps accomplish the entry of participant data at ART sites selected to participate in national surveys of ADR performed at either the 12 ± 3 month time point or the >48 month time point. Use of this tool standardizes the data collection process across all sites participating in national ADR surveys and facilitates detection of data entry anomalies in real time before data are saved. Its use in conjunction with the ADR National Data Consolidator Tool facilitates consolidation of data into one master national-level EXCEL file. This national-level master EXCEL file may be used for in-country analyses or may be uploaded into the WHO HIVDR database for global reporting.

4.1 Before getting started

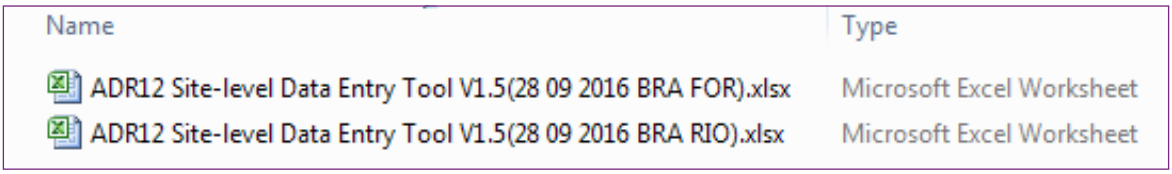
4.1.1 Naming site-level data entry files (naming convention)

Each site-level template must have a unique file name. A unique file name permits consolidation of multiple site-level data entry files into a single national file.

The suggested naming convention for a 12-month ADR time point is: ADR12 Site-level Data Entry Tool Vx.x(date – dd mm yyyy + three-letter ISO country code + three-letter site name code).xlsx

The suggested naming convention for a >48 month ADR time point is: ADR48 Site-level Data Entry Tool Vx.x(date--dd mm yyyy + three-letter ISO country code + three-letter site name code).xlsx

The chart below shows examples.



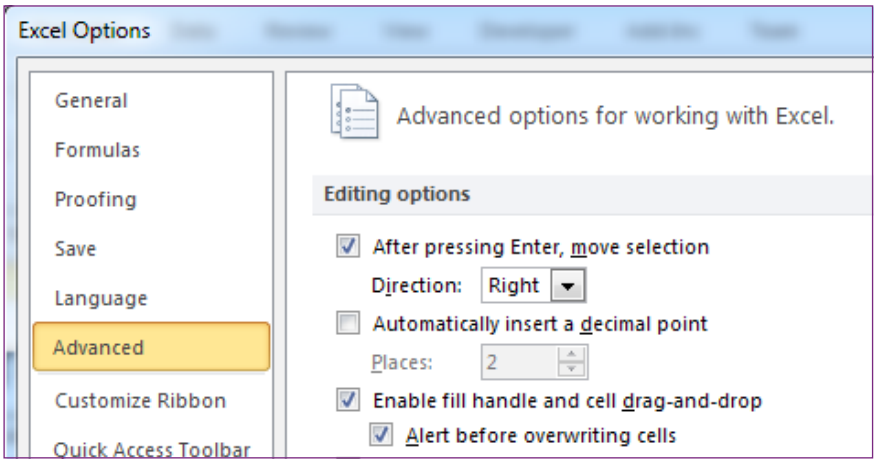
4.1.2 Columns with data validation fields

Warning: Do not cut or paste data in columns with data validation fields. If you do so, the drop-down menus, validation options, and formatting will be erased, causing problems when consolidating data at the national-level. Never change a column format. Columns containing date information have been formatted as text in order to accommodate regional differences in date formatting and date lengths (in the case of partial dates).

4.1.3 Move the cursor to the right (optional)

This is an optional setting that may speed up the process of participant-level data entry. The screen shot below shows how to change the settings to make the cursor move right (next column) instead of down (next row) after entering data into a cell.

To change the settings, click on File, Options, Advanced, go to "Editing options," and select direction "Right" below where it says, "After pressing enter, move selection".



4.2 Worksheets description

The ADR Site-level Data Entry Tool consists of four worksheets:

- The Survey Information worksheet has general instruction on how to enter data and captures meta-data about the survey;
- The Configuration worksheet contains references and descriptions of data used in the survey;
- The Survey Participants worksheet captures participants' data such as date of birth, viral load result, gender, date screened, etc.;
- The Participant ARV Drug worksheet captures the ARV Drugs taken by enrolled participants.

4.2.1 Survey information worksheet

This worksheet contains general instructions. It also requests that the user provide specific information about the survey ("Country", "Survey code", "Survey name", and "Site code") so it can be easily identified. To illustrate this concept we use the Fortaleza Main Site, located in Fortaleza, Brazil. In this example shown below, the "Survey code" is composed of the three-letter country code BRA, followed by the "Survey type" abbreviation ADR12 for the 12-month time point, followed by the year of the survey. The "Site code" is the three-letter abbreviation FOR.[1]

	A	B
1		Acquired HIVDR Survey Site-level Data Entry Tool
2	General Instructions:	This file provides a template (worksheets entitled *Survey Participants* and *Participant ARV Drug Exposure*) for submitting individual-level epidemiologic data to WHO from surveys of acquired HIV Drug Resistance (ADR) in populations receiving antiretroviral therapy for 12 (±3) months and/or ≥ 48 months. It is not recommended as a tool for data capture. A record for the survey, including the information on the *Survey Information* worksheet, must be entered into the WHO HIVDR database portal before the template can be imported. The *Survey Information* and *Configuration* worksheets are for reference only and will be ignored during the import process. This worksheet, *Survey Information*, provides instructions and a few rows to identify the survey. The Survey Code is the identifier that was assigned to the survey when it was entered into the WHO HIVDR portal. The identifier may consist of: "Country 3 letter ISO code-3 letter code for Survey Type-Year survey started" (e.g., ZZZ-ADR-2014) as described in Box 2 of the ADR concept note. Information on the worksheet titled *Configuration*, provides the expected values for coded data elements (i.e., data elements that use a standardized coded value rather than a long description to indicate the answer to the question). All individuals screened are included in the Survey Participants worksheet. However, only those enrolled in the survey should have data in all columns. For an individual not enrolled in the survey, please use an 'NA' to indicate not applicable for all columns following the column "Enrolled". Codes for unknown and missing data are provided, typically taking the form 'UNK' or '9999'. Cells should only be left blank to indicate that data is still pending. In the Survey Participants and Participant Treatment(s) worksheet, dates are to be entered in the form dd/mm/yyyy. Complete dates are required for Date Screened. If complete date information is unavailable, partial date information for other dates (Date of Birth and Date Started) can be entered in the following format. If month and year are known but exact day is unknown, dates are to be entered in the form mm/yyyy. If year is known but exact month and day are unknown, dates are to be entered in the form yyyy. If no information is available, the missing data code '9999' can be entered. For participants enrolled in the survey, viral load information is stored in the Viral Load Result and Viral Load Value columns. First, the result of the viral load test should be entered in Viral Load Result using the codes described in the Configuration worksheet. These codes indicate whether the result is within the range of assay quantitation, below the lower limit of assay quantitation, or above the upper limit of assay quantitation. If the result is unavailable or the test was unsuccessful, the result is unknown. Second, the value of the viral load test should be entered in Viral Load Value. If the viral load result is in range, the result is entered in copies/mL. If the viral load result is below the lower limit, the lower limit of quantitation is entered. If the the viral load result is above the upper limit, the upper limit of quantitation is entered. If the result is unknown, 'NA' is entered for not applicable. Data on antiretroviral treatment history are collected in the *Participant Treatment(s)* worksheet. Separate drugs within a single treatment regimen must be listed as one drug per row (unless they are part of a fixed dose combination). If a participant is on second-line or above, previously used drugs are entered on separate rows. Each ART line (first, second, third) must be specified in separate rows, and the ART line designation is indicated in the ART Line column. Drugs that are used in more than one line (e.g., 3TC used in first-line and second-line treatment) must be re-entered for each ART line (once with the first-line drugs and again with the second-line drugs). The code for that drug (as specified on the *Configuration* worksheet) should be entered in the ARV Drug column. If a code for this drug is not
5	Country:	Brazil
7	Survey Code:	BRA-ADR12-2016
9	Survey Name:	ADR Survey in Main Site of Fortaleza in 2016
11	Site Code:	FOR

1. The recommended convention for assigning Site Code is use of the first three letters of the site's name. If, however, the names of more than one site in a country begin with the same first three letters, the first site created should be assigned those first three letters as its Site Code. The second to the tenth sites with the same first three letters should be assigned the first two letters followed by an integer from 1 to 9. Site codes created after the first 10 should use the first letter followed by an integer from 11 to 99. It is essential that sites participating in surveys liaise with the national HIVDR survey coordinator if any doubt exists about the correct Site Code.

4.2.2 Configuration worksheet

This worksheet defines the codes and acronyms used in the survey. Below is an example of the information provided on the Configuration Worksheet. In this example, Gender is defined in the following way: Female "F", Male "M", Transgender "T" and Unknown "U". Review of all codes, labels and descriptions found in the Configuration Worksheet is advised prior to using the tool.

1	Data Element: Gender		
2	CODE	Label	DESCRIPTION
3	F	Female	Indicates that the participant is female
4	M	Male	Indicates that the participant is male
5	T	Transgender	Indicates that the participant's current gender is different from their birth gender
6	U	Unknown	Indicates that the participant's gender is not known

4.2.3 Survey participants worksheet

This worksheet is used for data about all screened and enrolled participants.

	A	B	C	D	E	F	G	H	I	J	K	L	M
1	Site Code	Participant ID	Date of First ART Initiation	Date Screened	Enrolled (Y/N)	Gender	Date of Birth	Age	Current ART Line	Viral Load Result	Viral Load Value (copies/mL)	Genotyping Successful	Lab Specimen Code
2													
3													
4													
5													
6													

4.2.3.1 Site code

Enter the site code in column A "Site code." Data entered in this column will be compared with the site code entered in the "Survey information" worksheet. If the site codes are not identical, the cell in the "Site code" column will be highlighted in red, signalling a need to resolve this anomaly.

A	B	C	D	E	F	G	H	I
Site Code	Participant ID	Date of First ART Initiation	Date Screened	Enrolled (Y/N)	Gender	Date of Birth	Age	Current ART Line
FRT	BRA-ADR12-2016-FOR-0001	01/01/2015	02/03/2016	Y	M	1990		F
FOR	BRA-ADR12-2016-FOR-0002	01/2015	03/03/2016	Y	F	12/12/1992		S
FOR	BRA-ADR12-2016-FOR-0003	2015	13/02/2016	N	U	10/1987		F

4.2.3.2 Participant ID

The "Participant ID" entered in column B must be unique. Duplicate "Participant IDs" are not allowed and any attempt to enter a duplicate will be highlighted in red. If a cell is highlighted in red, re-enter correct "Participant ID" and cell highlighting will be removed. To avoid duplicate entries in the HIVDR database, the "Participant ID" should follow this format: three-letter ISO country code – five-letter survey type – year – three-letter site name – four-digit consecutive number. For more information on "Participant ID", refer to the WHO concept notes on PDR and ADR.[1,2]

A	B	C	D	E	F	G	H	I
Site Code	Participant ID	Date of First ART Initiation	Date Screened	Enrolled (Y/N)	Gender	Date of Birth	Age	Current ART Line
FOR	BRA-ADR12-2016-FOR-0001	01/01/2015	02/03/2016	Y	M	1990		F
FOR	BRA-ADR12-2016-FOR-0002	01/2015	03/03/2016	Y	F	12/12/1992		S
FOR	BRA-ADR12-2016-FOR-0002	2015	13/02/2016	N	U	10/1987		F

4.2.3.3 Date of first ART initiation

Column C captures information on date of first ART initiation. The column "Date of first ART initiation" is formatted as text and requires data to be entered in the form "dd/mm/yyyy". This column also accepts partial dates containing only year or month and year. If month and year are known but exact day of the month is unknown, dates are entered in the form "mm/yyyy". If year is known but exact month and day are unknown, dates are entered in the form "yyyy". If no information is available, the missing data code "9999" should be entered.

A	B	C	D	E	F	G	H	I
Site Code	Participant ID	Date of First ART Initiation	Date Screened	Enrolled (Y/N)	Gender	Date of Birth	Age	Current ART Line
FOR	BRA-ADR12-2016-FOR-0001	01/01/2015	02/03/2016	Y	M	1990		F
FOR	BRA-ADR12-2016-FOR-0002	01/2015	03/03/2016	Y	F	12/12/1992		S
FOR	BRA-ADR12-2016-FOR-0003	2015	13/02/2016	N	U	10/1987		F

4.2.3.4 Date screened

Column D captures the date a participant is screened for inclusion into the survey. The "Date Screened" column is formatted as text. It requires a complete date in the form "dd/mm/yyyy". Exactly 10 characters are required including two "/" and up to two leading zeroes for single-digit days and months. If dates are entered in an incorrect format the cell will be highlighted in red. Do not use "-" or "." to separate date, month and year in the "Date Screened" column or in any other column requiring a date. A partial date is not allowed in the "Date Screened" column.

A	B	C	D	E	F	G	H	I
Site Code	Participant ID	Date of First ART Initiation	Date Screened	Enrolled (Y/N)	Gender	Date of Birth	Age	Current ART Line
FOR	BRA-ADR12-2016-FOR-0001	01/01/2015	02/03/2016	Y	M	1990		F
FOR	BRA-ADR12-2016-FOR-0002	01/2015	03.03.2016	Y	F	12/12/1992		S
FOR	BRA-ADR12-2016-FOR-0003	2015	13-02-2016	N	U	10/1987		F

1. Surveillance of HIV drug resistance in adults initiating antiretroviral therapy (pre-treatment HIV drug resistance). Geneva: World Health Organization; 2014 (http://www.who.int/hiv/pub/drugresistance/pretreatment_drugresistance/en/, accessed 28 November 2016).
2. Surveillance of HIV drug resistance in adults receiving art. Geneva: World Health Organization; 2014 (http://www.who.int/hiv/pub/drugresistance/acquired_drugresistance/en/, accessed 28 November 2016.

Warning: Do not change the data format in this column from "text" format to "date" format. If the data format is changed from "text" to "date", an error will occur during merging of data by the Data Consolidator Tool as illustrated below. The date must be in the format "dd/mm/yyyy".

	A	B	C	D	E	F	G	H	I	J	K	L	M
1	Site Code	Participant ID	Date of First ART Initiation	Date Screened	Enrolled (Y/N)	Gender	Date of Birth	Age	Current ART Line	Viral Load Result	Viral Load Value (copies/mL)	Genotyping Successful	Lab Specimen Code
2	FOR	BRA-ADR12-2016-CH1-0001	01/01/2015	42384	Y	M	1990		F	IRQ	2000	SUC	
3	FOR	BRA-ADR12-2016-CH1-0002	01/2015	42423	Y	F	12/12/1992		S	IRQ	50	SNA	
4	FOR	BRA-ADR12-2016-CH1-0003	2015	42397	N	U	10/1987		F	IRQ	1000	UNS	

4.2.3.5 Enrolled (Y/N)

Column E captures whether or not the participant is enrolled into the survey. Enrolment information is entered using a drop-down menu with two options: yes "Y" or no "N".

B	C	D	E	F	G	H	I
Participant ID	Date of First ART Initiation	Date Screened	Enrolled (Y/N)	Gender	Date of Birth	Age	Current ART Line
BRA-ADR12-2016-FOR-0001	01/01/2015	02/03/2016	Y				F
BRA-ADR12-2016-FOR-0002	01/2015	03/03/2016	Y		92		S
BRA-ADR12-2016-FOR-0003	2015	13/02/2016	N				F

Y
N

Enrolled
Indicates whether the patient is enrolled in the survey

4.2.3.6 Gender

Column F captures a participant's gender. Gender is entered using a drop-down menu with four options: Female "F", Male "M", Transgender "T" and Unknown "U".

B	C	D	E	F	G	H	I	J
Participant ID	Date of First ART Initiation	Date Screened	Enrolled (Y/N)	Gender	Date of Birth	Age	Current ART Line	Viral Load Result
BRA-ADR12-2016-FOR-0001	01/01/2015	02/03/2016	Y	M			F	IRQ
BRA-ADR12-2016-FOR-0002	01/2015	03/03/2016	Y				S	BLQ
BRA-ADR12-2016-FOR-0003	2015	13/02/2016	N				F	IRQ

F
M
T
U

Gender
Participant's gender. Possible vales are: "F" = Female; "M" = Male; "T" = Transgender; "U" = Unknown

4.2.3.7 Date of birth

Column G captures a participant's date of birth. If the full date of birth is known, it is entered as "dd/mm/yyyy". If only the month and year of birth are known, a partial date of birth is entered in the form "mm/yyyy". If only the year of birth is known, a partial date of birth is entered in the form 'yyyy'.

If no information is available, the missing data code '9999' is entered. If the date is entered incorrectly, the cell will be highlighted in red as shown below and must be corrected.

B	C	D	E	F	G	H	I	J
Participant ID	Date of First ART Initiation	Date Screened	Enrolled (Y/N)	Gender	Date of Birth	Age	Current ART Line	Viral Load Result
BRA-ADR12-2016-FOR-0001	01/01/2015	02/03/2016	Y	M	13/13/1990		F	IRQ
BRA-ADR12-2016-FOR-0002	01/2015	03/03/2016	Y	F	12/12/199b		S	BLQ
BRA-ADR12-2016-FOR-0003	2015	13/02/2016	N	U	10/1987		F	IRQ

4.2.3.8 Age

Column H captures a participant's age and permits an integer from 1 to 110. Age must be entered when date of birth is not provided. If date of birth is provided, the "Age" column can be left blank.

D	E	F	G	H	I	J	K
Date Screened	Enrolled (Y/N)	Gender	Date of Birth	Age	Current ART Line	Viral Load Result	Viral Load Value (copies/mL)
02/03/2016	Y	M		26	F	IRQ	2000
03/03/2016	Y	F		24	S	BLQ	50
13/02/2016	N	U		29	F	IRQ	1000

4.2.3.9 Current ART line

Column I captures the "Current ART Line" classification per national guidelines that a participant is taking at the time of survey enrolment. The user can open a drop-down menu and choose either First Line "F", Second Line "S", Third Line "T", or Unknown "U".

C	D	E	F	G	H	I	J	K
Date of First ART Initiation	Date Screened	Enrolled (Y/N)	Gender	Date of Birth	Age	Current ART Line	Viral Load Result	Viral Load Value (copies/mL)
01/01/2015	02/03/2016	Y	M	1990		F	IRQ	2000
01/2015	03/03/2016	Y	F	12/12/1992		F S T U	BLQ	50
2015	13/02/2016	N	U	10/1987			IRQ	1000

4.2.3.10 Viral load result

Column J captures information about a participant's viral load result. This column has a drop-down menu with four options: In Range "IRQ", Below Lower Limit of Quantification "BLQ", Above Upper Limit of Quantification "AUQ", or Result Not Available "UNK". Data must be in uppercase letters. If this information is unknown at the site level, the participating site should leave the "Viral Load Result" column blank, and it will be entered at the national level prior to consolidation into one national file.

D	E	F	G	H	I	J	K	L
Date Screened	Enrolled (Y/N)	Gender	Date of Birth	Age	Current ART Line	Viral Load Result	Viral Load Value (copies/mL)	Genotyping Successful
02/03/2016	Y	M	1990		F	IRQ	00	SUC
03/03/2016	Y	F	12/12/1992		S		A	SNA
13/02/2016	N	U	10/1987		F		00	UNS

IRQ
BLQ
AUQ
UNK

4.2.3.11 Viral load value (copies/mL)

Column K captures a participant's viral load value (copies/ml) and is formatted as open text. If the viral load result (column J; see 4.2.3.10 above) is in range the viral load result is entered as number of copies/ml. **The tool does not accept log-transformed values.** If the viral load result is below the lower limit of assay detection (information entered into column J), the lower limit of quantitation of the viral load assay used is entered. If the viral load result is above the upper limit, the upper limit of quantitation of the viral load assay used is entered. If the result is unknown, 'NA' is entered for not applicable. If the required information is known at the participating ART site, the site should enter it. If it is unknown at the site level, Viral Load Value should be left blank by the participating site and it will be entered at the national level prior to consolidation into one national file.

D	E	F	G	H	I	J	K	L
Date Screened	Enrolled (Y/N)	Gender	Date of Birth	Age	Current ART Line	Viral Load Result	Viral Load Value (copies/mL)	Genotyping Successful
02/03/2016	Y	M	1990		F	IRQ	2000	SUC
03/03/2016	Y	F	12/12/1992		S	BLQ	NA	SNA
13/02/2016	N	U	10/1987		F	IRQ	1000	UNS

4.2.3.12 Genotyping successful

Column L contains a drop-down menu with four options: Successfully Sequenced "SUC", Unsuccessfully Sequenced "UNS", Sequencing Not Attempted "SNA", and Unknown "UNK". During implementation of an ADR survey, it is unlikely that participating ART sites will know this information at the time of data entry. It is anticipated that this column will be left blank by participating sites and that information about genotyping success will be entered at the national level prior to consolidation into one national file.

D	E	F	G	H	I	J	K	L	M
Date Screened	Enrolled (Y/N)	Gender	Date of Birth	Age	Current ART Line	Viral Load Result	Viral Load Value (copies/mL)	Genotyping Successful	Lab Specimen Code
02/03/2016	Y	M	1990		F	IRQ	2000	SUC	
03/03/2016	Y	F	12/12/1992		S	BLQ	50		
13/02/2016	N	U	10/1987		F	IRQ	1000		

SUC
UNS
SNA
UNK

4.2.3.13 Lab specimen code

Some HIVDR testing laboratories may assign a "Lab Specimen Code" to participants' specimens rather than use the "Participant ID" as the specimen unique identifier. In this case, Column L captures the unique identifier assigned to a participant's specimen by the genotyping lab if different from the "Participant ID". Column L is left blank if the genotyping lab uses the "Participant ID" as the unique specimen identifier or if no specimen was taken. This column does not allow duplicate entries. Any cell with duplicate entry will be highlighted in red and must be corrected. During ADR survey implementation, it is unlikely that participating sites will know this information at the time of data entry. Therefore, it is anticipated that "Lab Specimen Code" will be entered at the national level prior to consolidation of data into a single file.

E	F	G	H	I	J	K	L	M
Enrolled (Y/N)	Gender	Date of Birth	Age	Current ART Line	Viral Load Result	Viral Load Value (copies/mL)	Genotyping Successful	Lab Specimen Code
Y	M	1990		F	IRQ	2000	SUC	T-034
Y	F	12/12/1992		S	BLQ	50	SNA	T-034
N	U	10/1987		F	IRQ	1000	UNS	T-035

4.2.4 Participant antiretroviral drug worksheet

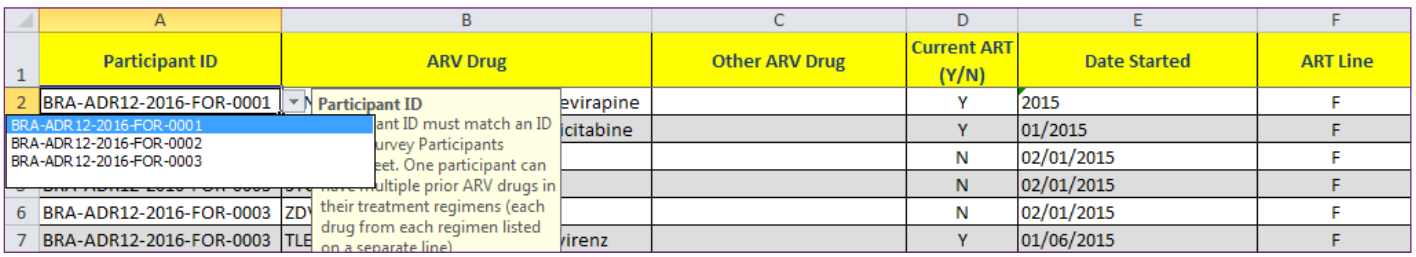
This worksheet is used to capture information on participants' antiretroviral (ARV) drugs. This includes any ART regimen that a participant is taking at the time of survey enrolment and any treatment(s) a participant has taken since the time of ART initiation.

	A	B	C	D	E	F
1	Participant ID	ARV Drug	Other ARV Drug	Current ART (Y/N)	Date Started	ART Line
2	BRA-ADR12-2016-FOR-0001	ZLN zidovudine + lamivudine + nevirapine		Y	2015	F
3	BRA-ADR12-2016-FOR-0002	ATR efavirenz + tenofovir + emtricitabine		Y	01/2015	F
4	BRA-ADR12-2016-FOR-0003	NVP nevirapine		N	02/01/2015	F
5	BRA-ADR12-2016-FOR-0003	3TC lamivudine		N	02/01/2015	F
6	BRA-ADR12-2016-FOR-0003	ZDV zidovudine		N	02/01/2015	F
7	BRA-ADR12-2016-FOR-0003	TLE tenofovir + lamivudine + efavirenz		Y	01/06/2015	F

If a participant has taken more than one regimen, each regimen is entered on a separate row. If the ARV drug is dispensed as single pills, each ARV drug requires a separate row. If the ARV drug is dispensed as a fixed-dose combination, the drug combination is entered in a single row.

4.2.4.1 Participant ID

Column A captures a participant's survey ID. It has a dynamic drop-down menu that provides choices of "Participant IDs" from those entered on the "Survey Participants" worksheet.



4.2.4.2 ARV drug

Column B captures the drugs that the survey participant is taking at the time of survey enrolment or has taken previously. Column B has a drop-down menu with three-letter drug codes and their description. If a three-letter code corresponding to the drug or fixed-dose combination which a participant is taking or has taken does not exist, choose "Other" and enter the name of the drug or fixed-dose combination in column C, "Other ARV Drug". If a participant is taking (or has previously taken) combination therapy that consisted of separate pills, the drug associated with each pill is entered in a separate row. If a participant is taking (or has previously taken) a co-formulated regimen (or drug), use the code for the combination pill.

	A	B	C	D	E	F
1	Participant ID	ARV Drug	Other ARV Drug	Current ART (Y/N)	Date Started	ART Line
2	BRA-ADR12-2016-FOR-0001	ZLN zidovudine + lamivudine + nevirapine		Y	2015	F
3	BRA-ADR12-2016-FOR-0002			Y	01/2015	F
4	BRA-ADR12-2016-FOR-0003			N	02/01/2015	F
5	BRA-ADR12-2016-FOR-0003			N	02/01/2015	F
6	BRA-ADR12-2016-FOR-0003			N	02/01/2015	F
7	BRA-ADR12-2016-FOR-0003			Y	01/06/2015	F
8						

ZLN zidovudine + lamivudine + nevirapine
ATR efavirenz + tenofovir + emtricitabine
TRI nevirapine + stavudine + lamivudine
CMP rilpivirine + tenofovir + emtricitabine
TLE tenofovir + lamivudine + efavirenz
MVC maraviroc
ENF enfuvirtide
EVG elvitegravir

ARV Drug
For each drug the participant currently or has previously taken, the drug code from the Configuration worksheet is entered. A single row is added if drugs are combined as one pill, and mutliple rows are added if each drug was a separate pill.

4.2.4.3 Other ARV drug

Column C is a free-text column that captures any ARV drug for which codes do not exist on the Configuration Worksheet. Column C is used only when "Other" has been selected in column B, "ARV Drug".

4.2.4.4 Current ART (Y/N)

Column D denotes whether the ARV drug or drug combination entered in Column B and/or Column C is the ART regimen being taken at the time of survey enrolment. This column has a drop-down menu with options Yes "Y" or No "N". If the ARV drug(s) specified in column B and/or Column C are being taken by the participant at the time of the survey, a 'Y' is entered in column D. If the ARV drug(s) specified in Column B and/or Column C are not current ART at the time of the survey, an "N" is entered in Column D. Only uppercase letters are permitted in this column.

B	C	D	E	F
ARV Drug	Other ARV Drug	Current ART (Y/N)	Date Started	ART Line
ZLN zidovudine + lamivudine + nevirapine		Y	1	F
ATR efavirenz + tenofovir + emtricitabine				F
NVP nevirapine		N	02/	F
3TC lamivudine		N	02/	F
ZDV zidovudine		N	02/01/2015	F
TLE tenofovir + lamivudine + efavirenz		Y	01/06/2015	F

Y
N

Current ART
Indicates that the ARV drug is currently taken by participant.

4.2.4.5 Date started

Column E captures the date the participant began the ARV drug. If day, month and year are known, they are entered as "dd/mm/yyyy". If only month and year of the date started are known, a partial date is entered in the form "mm/yyyy". If only the year is known, a partial date is entered in the form 'yyyy'. If no information is available, the missing data code "9999" is entered. If an invalid date is entered, the cell will be highlighted in red (as shown below) and must be corrected. This column is open free text with a minimum of 4 characters and maximum of 10.

B	C	D	E	F
ARV Drug	Other ARV Drug	Current ART (Y/N)	Date Started	ART Line
ZLN zidovudine + lamivudine + nevirapine		Y	8888	F
ATR efavirenz + tenofovir + emtricitabine		Y	aa/2015	F
NVP nevirapine		N	02/01/2015	F
3TC lamivudine		N	02/01/2015	F
ZDV zidovudine		N	02/01/2015	F
TLE tenofovir + lamivudine + efavirenz		Y	01/13/2015	F

4.2.4.6 ART line

Column F captures information on the ART line to which the drug corresponds. "F" = First, "S" = Second, "T" = Third and beyond, "U" = Unknown. Only uppercase letters are allowed in this column.

B	C	D	E	F
ARV Drug	Other ARV Drug	Current ART (Y/N)	Date Started	ART Line
ZLN zidovudine + lamivudine + nevirapine		Y	2015	F
ATR efavirenz + tenofovir + emtricitabine		Y	01/2	
NVP nevirapine		N	02/0	
3TC lamivudine		N	02/0	
ZDV zidovudine		N	02/0	F
TLE tenofovir + lamivudine + efavirenz		Y	01/0	F

ART Line
Indicates which ART line to which the drug corresponds. 'F'=First, 'S'=Second, 'T'=Third and beyond, 'U'=Unknown.

F
S
T
U

5. ADR NATIONAL-LEVEL TEMPLATE: DATA CONSOLIDATOR TOOL

The aim of the Data Consolidator Tool is to simplify the work of the person gathering all site-level files and consolidating them into one national master file. The Data Consolidator Tool is designed to aggregate data from all sites participating in national surveys of ADR into a single national template. The output of the National Data Consolidator Tool can be used for analysis or for upload into the WHO HIVDR database. The tool uses a three-step process to aggregate participant-level data from multiple site Data Entry Tools into one master file. The three steps are: 1) Select Files, 2) Copy "Survey Participants", and 3) Copy "Participant ARV Drug". The Data Consolidator Tool is automatically cleared of previously uploaded content after each use.

Subsequent sections of this document guide the user through the steps needed to extract site-level data and consolidate them into a single national EXCEL file. **Before consolidating site-level data entry files at national level, ensure that "Viral Load Result", "Viral Load Value", and "Genotyping Successful" is entered into every Site-Level Data Entry Tool. Likewise, if "Participant ID" does not match the unique identifier assigned to the participant's specimen by the genotyping lab, the national data manager must complete Column N, Lab Specimen Code, in each Site-level Data Entry Tool.**

Warning: The recommended convention for Site Code is use of the first three letters of the site's name. If, however, the names of more than one site in a country begin with the same first three letters, the first site created should be assigned those first three letters as its Site Code. The second to the tenth sites with the same first three letters should be assigned the first two letters followed by an integer from 1 to 9. Sites created after the first 10 should be assigned the first letter followed by an integer from 11 to 99. This modified alphanumeric convention is used only in situations where the names of more than one site begin with the same first three letters.

5.1 Before getting started

5.1.1 Naming national data consolidator file (naming convention)

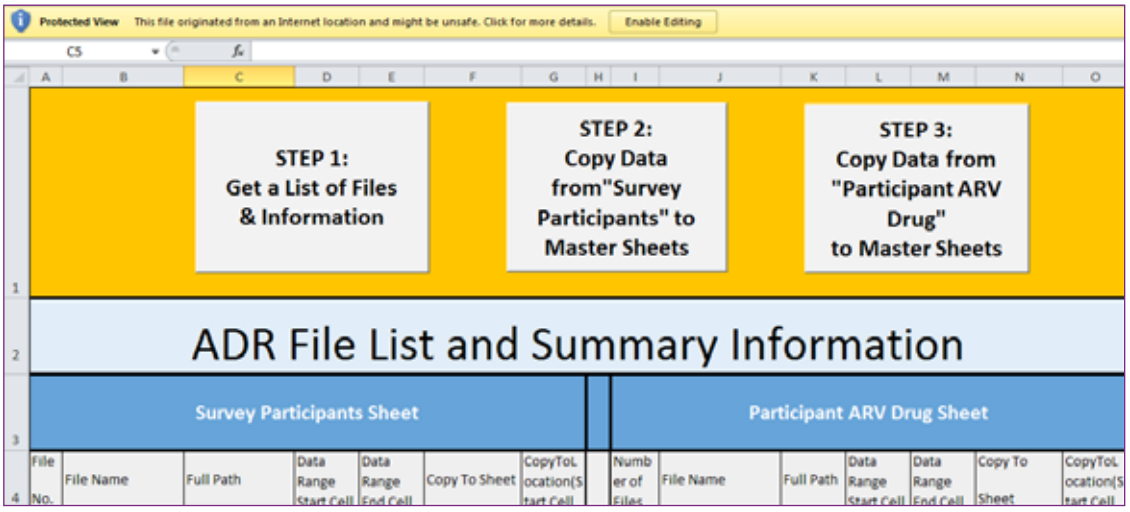
It is important that each file have a unique name. The file should be labelled using the following convention for 12 month time point ADR: ADR12 National Consolidator Tool Vx.x(Date –dd mm yyyy-, + country name(three-letter ISO code).xlsm. An example is provided below.

The file should be labelled using the following convention for >48 month time point ADR: ADR48 National Consolidator Tool Vx.x (Date –dd mm yyyy-, + country name [three-letter ISO code]).xlsm. An example is provided below.

5.1.2 Enable macros

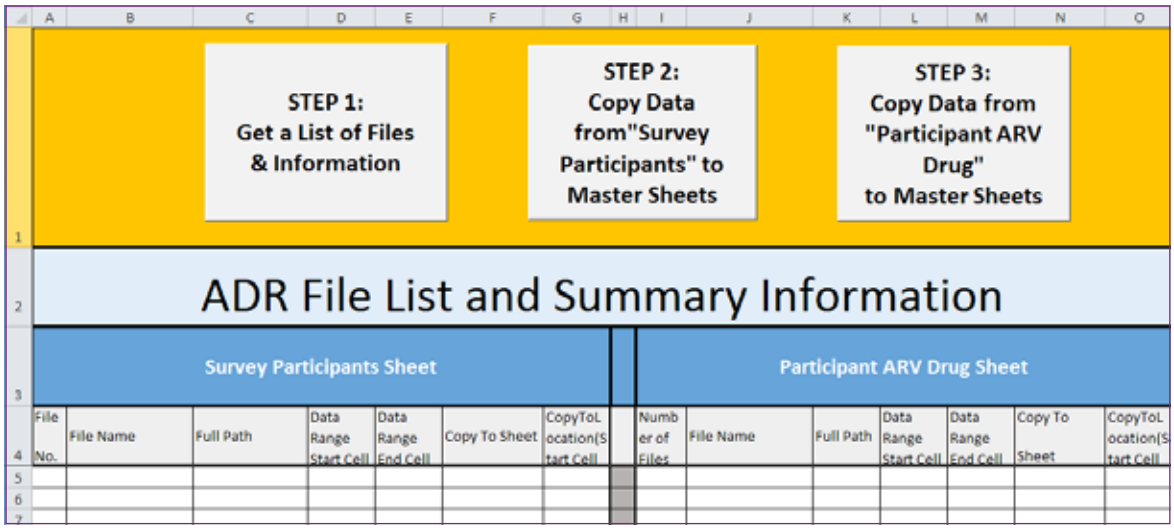
.xlsm is a type of format that allows macros to work in EXCEL. In the case of the National Data Consolidator Tool, a VBA code merges the worksheets from participating ART sites into one national file. Click on "Enable Content" to enable macros if prompted to do so.

When opening the National Data Consolidator Tool, click on "Enable Content" to enable macros if prompted by a security notice.



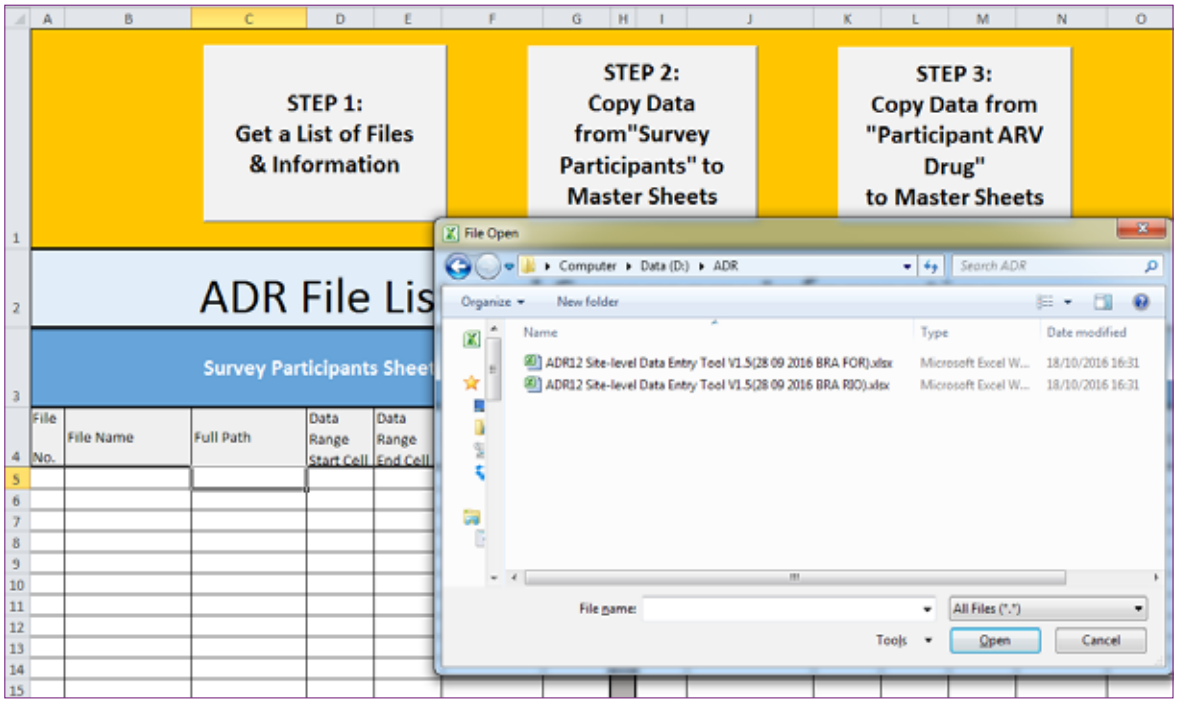
5.2 "List" worksheet

The purpose of the "List" worksheet is to aid in the selection and listing of all national ADR survey files from multiple ART sites for consolidation into one master file by the national data manager.

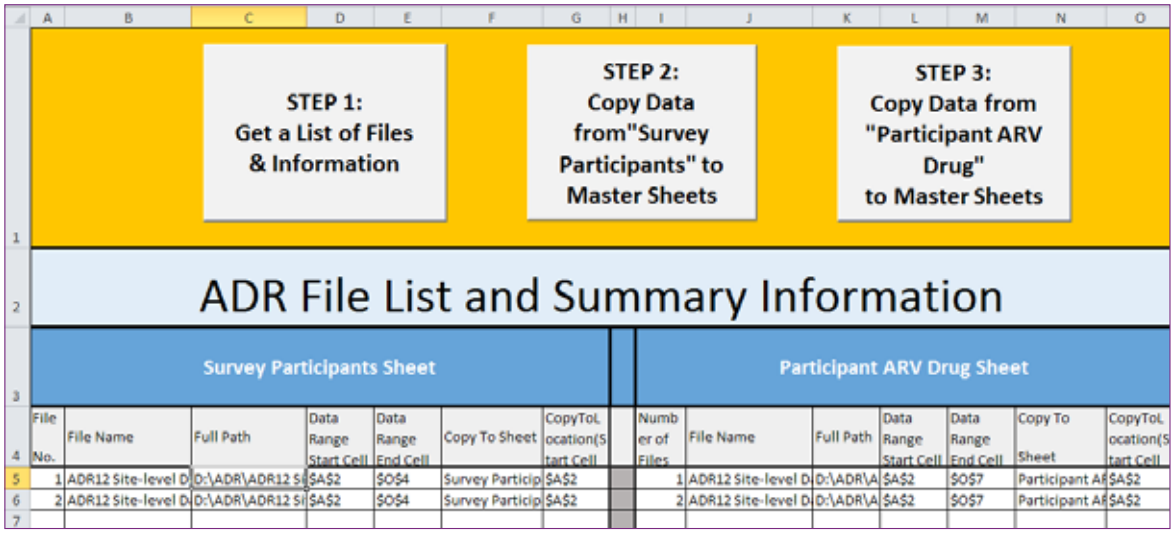


5.2.1 STEP 1

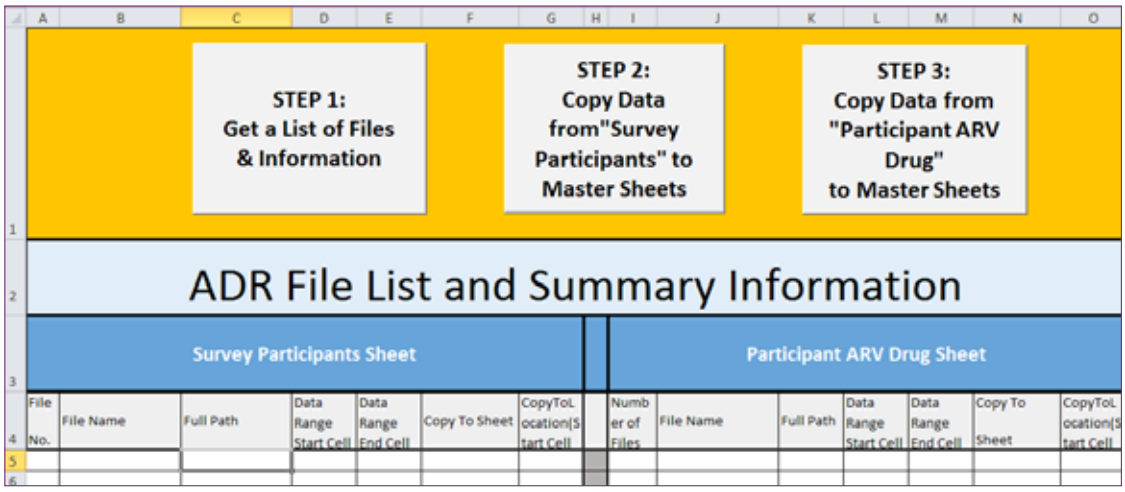
Click on "STEP 1". This will direct the user to a Windows explorer dialogue box that prompts the user to select the location and files for import. Once all files have been selected, the "List" worksheet automatically creates a list of the selected files and summary information. The list shows the number of files selected, the file names, their location in the computer, the worksheets of interests and their data range (start cell to end cell). Simultaneously select multiple files in the opened Windows Explorer dialogue box.



The information obtained in "STEP 1" is used in "STEP 2" to tell the tool which files, worksheets, and range of data to copy and where to paste the information.



Warning: If the "Step 1" button is clicked a second time, it will automatically clear all contents in order to avoid duplicated data.



5.3 Worksheet survey participants

The Survey Participants Worksheet is blank before any site-level data are added. Once completed, this worksheet will become the National Master Consolidated Repository for storing all survey participant-level survey data.

Site Code	Participant ID	Date of First ART Initiation	Date Screened	Enrolled (Y/N)	Gender	Date of Birth	Age	Current ART Line	Viral Load Result	Viral Load Value (copies/mL)	Genotyping Successful	Lab Specimen Code

5.3.1 STEP 2

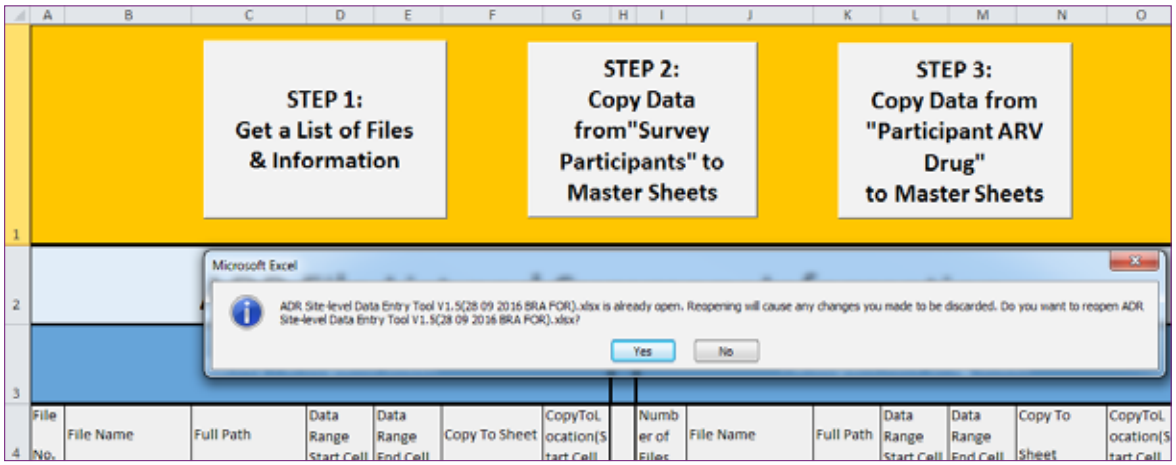
Click on the "STEP 2" button in the "List" worksheet. This will copy and paste all data from "Survey Participants" worksheets from the selected files into the Consolidator Master "Survey Participants" worksheet.

	A	B	C	D	E	F	G	H	I	J	K	L	M
1	Site Code	Participant ID	Date of First ART Initiation	Date Screened	Enrolled (Y/N)	Gender	Date of Birth	Age	Current ART Line	Viral Load Result	Viral Load Value (copies/mL)	Genotyping Successful	Lab Specimen Code
2	FOR	BRA-ADR12-2016-FOR-0001	01/01/2015	02/03/2016	Y	M	1990		F	IRQ	2000	SUC	T-034
3	FOR	BRA-ADR12-2016-FOR-0002	01/2015	03/03/2016	Y	F	12/12/1992		S	BLQ	50	SNA	T-034
4	FOR	BRA-ADR12-2016-FOR-0003	2015	13/02/2016	N	U	10/1987		F	IRQ	1000	UNS	T-035
5	RIO	BRA-ADR12-2016-RIO-0001	01/01/2015	02/03/2016	Y	M	1980	35	F	IRQ	2000	SUC	
6	RIO	BRA-ADR12-2016-RIO-0002	01/01/2015	03/03/2016	Y	F	12/1990	25	S	BLQ	500	SNA	
7	RIO	BRA-ADR12-2016-RIO-0003	02/02/2015	13/02/2016	N	U	1989	27	F	IRQ	1000	UNS	

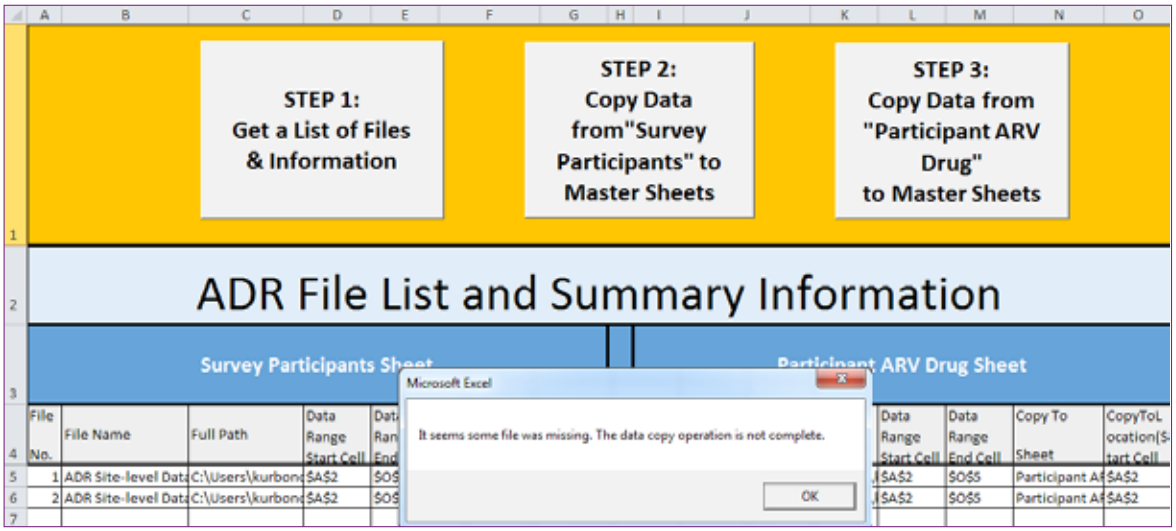
Warning: Never change the format of the column containing date information from "text" to "date" format in any site-level or national-level files. As shown below, date information would be lost.

	A	B	C	D	E	F	G	H	I	J	K	L	M
1	Site Code	Participant ID	Date of First ART Initiation	Date Screened	Enrolled (Y/N)	Gender	Date of Birth	Age	Current ART Line	Viral Load Result	Viral Load Value (copies/mL)	Genotyping Successful	Lab Specimen Code
2	FOR	BRA-ADR12-2016-FOR-0001	01/01/2015	02/03/2016	Y	M	41317		F	IRQ	2000	SUC	T-034
3	FOR	BRA-ADR12-2016-FOR-0002	01/2015	03/03/2016	Y	F	41340		S	BLQ	50	SNA	T-034
4	FOR	BRA-ADR12-2016-FOR-0003	2015	13/02/2016	N	U	41323		F	IRQ	1000	UNS	T-035
5	RIO	BRA-ADR12-2016-RIO-0001	01/01/2015	02/03/2016	Y	M	41347	35	F	IRQ	2000	SUC	
6	RIO	BRA-ADR12-2016-RIO-0002	01/01/2015	03/03/2016	Y	F	41390	25	S	BLQ	500	SNA	
7	RIO	BRA-ADR12-2016-RIO-0003	02/02/2015	13/02/2016	N	U	41374	27	F	IRQ	1000	UNS	

Warning: Make sure all selected files are closed before importing. During consolidation at the national level, all site-level data entry files being consolidated must be closed. Otherwise the message shown below will appear.



To continue, click "No".



To continue, close all open files and reinitiate STEP 1.

Warning: If a file with the same name already exists, the file will be overwritten.

5.4 Participant ARV drug worksheet

The "Participant ARV Drug" worksheet is blank before any site-level data are added. The worksheet will be the National Master Consolidated Repository for storing all participant-level "ARV Drug" data.

	A	B	C	D	E	F
1	Participant ID	ARV Drug	Other ARV Drug	Current ART (Y/N)	Date Started	ART Line
2						
3						
4						
5						
6						
7						

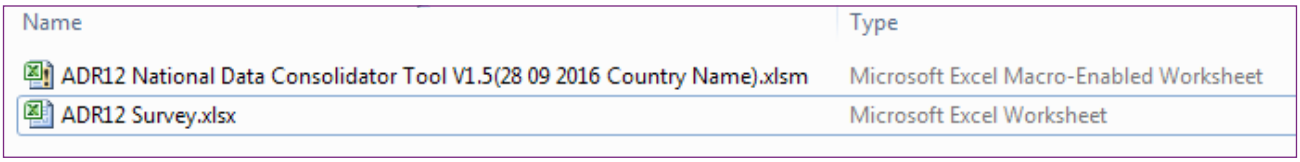
5.4.1 STEP 3

Click on the "STEP 3" button in the "List" worksheet. All data from the "Participant ARV Drug" worksheets from the selected files will be copied and pasted into the Consolidator Master "Participant ARV Drug" worksheet. The ARV Drug description that was entered into site-level data collection tools is converted to a three-letter ARV Drug Code.

	A	B	C	D	E	F
1	Participant ID	ARV Drug	Other ARV Drug	Current ART (Y/N)	Date Started	ART Line
2	BRA-ADR12-2016-FOR-0001	ZLN zidovudine + lamivudine + nevirapine		Y	2015	F
3	BRA-ADR12-2016-FOR-0002	ATR efavirenz + tenofovir + emtricitabine		Y	01/2015	F
4	BRA-ADR12-2016-FOR-0003	NVP nevirapine		N	02/01/2015	F
5	BRA-ADR12-2016-FOR-0003	3TC lamivudine		N	02/01/2015	F
6	BRA-ADR12-2016-FOR-0003	ZDV zidovudine		N	02/01/2015	F
7	BRA-ADR12-2016-FOR-0003	TLE tenofovir + lamivudine + efavirenz		Y	01/06/2015	F

	A	B	C	D	E	F
1	Participant ID	ARV Drug	Other ARV Drug	Current ART (Y/N)	Date Started	ART Line
2	BRA-ADR12-2016-FOR-0001	ZLN		Y	2015	F
3	BRA-ADR12-2016-FOR-0002	ATR		Y	01/2015	F
4	BRA-ADR12-2016-FOR-0003	NVP		N	02/01/2015	F
5	BRA-ADR12-2016-FOR-0003	3TC		N	02/01/2015	F
6	BRA-ADR12-2016-FOR-0003	ZDV		N	02/01/2015	F
7	BRA-ADR12-2016-FOR-0003	TLE		Y	01/06/2015	F
8	BRA-ADR12-2016-RIO-0001	ZLN		Y	2015	F
9	BRA-ADR12-2016-RIO-0002	ATR		Y	01/2015	F
10	BRA-ADR12-2016-RIO-0003	NVP		N	02/01/2015	F
11	BRA-ADR12-2016-RIO-0003	3TC		N	02/01/2015	F
12	BRA-ADR12-2016-RIO-0003	ZDV		N	02/01/2015	F
13	BRA-ADR12-2016-RIO-0003	TLE		Y	01/06/2015	F

An "ADR12 Survey.xlsx" file will be created automatically and saved in the same folder where the National Data Consolidator Tool is located.



This "ADR12 Survey.xlsx" file has two worksheets: "Survey Participants" and "Participant ARV Drug". The "Survey Participants" worksheet contains consolidated participant-level data from all selected sites.

	A	B	C	D	E	F	G	H	I	J	K	L	M
1	Site Code	Participant ID	Date of First ART Initiation	Date Screened	Enrolled (Y/N)	Gender	Date of Birth	Age	Current ART Line	Viral Load Result	Viral Load Value (copies/mL)	Genotyping Successful	Lab Specimen Code
2	FOR	BRA-ADR12-2016-FOR-0001	01/01/2015	02/03/2016	Y	M	41317		F	IRQ	2000	SUC	T-034
3	FOR	BRA-ADR12-2016-FOR-0002	01/2015	03/03/2016	Y	F	41340		S	BLQ	50	SNA	T-034
4	FOR	BRA-ADR12-2016-FOR-0003	2015	13/02/2016	N	U	41323		F	IRQ	1000	UNS	T-035
5	RIO	BRA-ADR12-2016-RIO-0001	01/01/2015	02/03/2016	Y	M	41347	35	F	IRQ	2000	SUC	
6	RIO	BRA-ADR12-2016-RIO-0002	01/01/2015	03/03/2016	Y	F	41390	25	S	BLQ	500	SNA	
7	RIO	BRA-ADR12-2016-RIO-0003	02/02/2015	13/02/2016	N	U	41374	27	F	IRQ	1000	UNS	

The "Participant ARV Drug" worksheet contains consolidated ARV drug data from all selected ART sites.

	A	B	C	D	E	F
1	Participant ID	ARV Drug	Other ARV Drug	Current ART (Y/N)	Date Started	ART Line
2	BRA-ADR12-2016-FOR-0001	ZLN		Y	2015	F
3	BRA-ADR12-2016-FOR-0002	ATR		Y	01/2015	F
4	BRA-ADR12-2016-FOR-0003	NVP		N	02/01/2015	F
5	BRA-ADR12-2016-FOR-0003	3TC		N	02/01/2015	F
6	BRA-ADR12-2016-FOR-0003	ZDV		N	02/01/2015	F
7	BRA-ADR12-2016-FOR-0003	TLE		Y	01/06/2015	F
8	BRA-ADR12-2016-RIO-0001	ZLN		Y	2015	F
9	BRA-ADR12-2016-RIO-0002	ATR		Y	01/2015	F
10	BRA-ADR12-2016-RIO-0003	NVP		N	02/01/2015	F
11	BRA-ADR12-2016-RIO-0003	3TC		N	02/01/2015	F
12	BRA-ADR12-2016-RIO-0003	ZDV		N	02/01/2015	F
13	BRA-ADR12-2016-RIO-0003	TLE		Y	01/06/2015	F

The final file "ADR12 Survey.xlsx" should undergo data verification and validation at the national level using standard best practices prior to using the file for data analysis or for upload into the WHO HIVDR database for quality assurance and global reporting.

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