

Surveillance of Drug Resistance in Tuberculosis

A User's Guide to the Software: SDRTB4

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1. Summary Points

- This document presents SDRTB4, the 4th version of the software for *Surveillance of Drug Resistance in Tuberculosis* developed by the World Health Organization.
- Previous versions, SDRTB1, SDRTB2 and SDRTB3 introduced in December 1994, July 1996, and January 2002 respectively, were developed using DOS versions of EpiInfo (freeware for public health from the US CDC and from WHO).
- Though still a "DOS program", SDRTB3 is fully Y2K compatible and can still run under all current versions of Windows.
- SDRTB4 now provides a new option for most users who will prefer to move on to software which uses the now standard Windows interface.
- The data entry screens and layouts for summary drug resistance reports in SDRTB4 resemble those from previous versions. Users of older versions should thus experience a smooth transition to this new release.
- SDRTB4 has been developed using FileMaker Pro™ and is made available through WHO as a *compiled run-time* application which can be legally distributed at no cost.
- An option in SDRTB4 allows data from its FileMaker Pro (.FP5 format) files to be exported to dBase (.DBF format) files which in turn can be imported into, manipulated and further analyzed by EpiInfo, by commonly available programs such as Excel and Access, or by commercial statistical software packages such as SAS, SPSS or STATA.
- Suggestions for improvement in the programme may be brought to the attention of WHO/CSR/DRS (see particulars page 6).

2. Introduction

In 1994 the Tuberculosis unit of WHO in collaboration with the International Union against Tuberculosis and Lung Diseases (IUATLD) developed guidelines to assist national tuberculosis programmes in establishing policies for surveillance of resistance of *M. tuberculosis* to antimycobacterial drugs. Guidelines were initially prepared in the document WHO/TB/94.178 and later in WHO/TB/96.216 *Guidelines for Surveillance of Drug Resistance in Tuberculosis: 1997*. Results of the WHO / IUATLD project with collaborating countries, has resulted in several publications concerning TB drug resistance in the world including summaries published in the New England Journal of Medicine in the issues of 4 June, 1998 and 17 April 2001 as well as in WHO's own reports on *Anti-Tuberculosis Drug Resistance in the World* which are available on the World-Wide-Web (www.who.int/gtb/publications/dritw/index.htm).

This document is a "User's Guide" for SDRTB4, the fourth implementation of the SDRTB system.

3. What's new in Version 4?

The overall presentation and function of SDRTB4 has not changed since SDRTB3 so that transition to this version should not be difficult. The most important new features are:

- **Interface:** as mentioned above, this has changed from EpiInfo's older DOS interface to a standard modern Windows interface
- **Sub-set summaries:** SDRTB4 now allows users to produce summary drug-resistance tables not only for "all the cases" in a participating country's data set but for also many *pre-programmed* as well *any user-defined* "subsets of cases" of interest. For example, it is now possible to examine patterns of drug-resistance for any age and sex subgroups, for patients infected with HIV, or for those with a history of incarceration, or prior hospitalization or treatment for TB
- **File Format:** previous versions stored data in EpiInfo for DOS **.REC** files. However SDRTB4 data are kept in FileMaker Pro **.FP5** files. To facilitate detailed statistical analyses (beyond the basic summary tables produced by SDRTB4 itself), SDRTB4 includes an **Export option** which creates a dBase-III **.DBF** version of the user's data set. The DBF files in turn can be read or imported into standard analytical or statistical software such as EpiInfo, Excel, SPSS, SAS, STATA.

4. Installing SDRTB4: For convenience the SDRTB4 system, which consists of many files, is distributed as a single "compressed" self-extracting file called:

SDRTB4 SETUP.EXE.

The file size is approximately 3.0 megabytes. Whether you have downloaded this file over the internet or have received it on a CD, the installation steps are identical.

Step 1: Using your Windows Explorer, click on the file SDRTB4 SETUP.EXE. A dialog box will open offering to Unzip all the compressed files to a folder called c:\sdrtb4.

Step 2: Click "Unzip" to start the installation process. The SDRTB4 files will then be unzipped and copied to the folder c:\sdrtb4. There are about 20 files in all. (See section 6 below for a full listing and details about each of these files.)

Step 3: A dialog box will open saying the files have been unzipped successfully. Click "OK" to acknowledge the message and close the box.

Step 4: Click "Close" to end the installation process.

5. A word about files

After you have completed the four installation steps outlined above you folder c:\sdrtb4 will contain approximately 20 files. (You may wish to verify this using the Windows Explorer). Table 1 lists these and provides a brief explanatory comment about each file or group of files.

Table 1: The SDRTB4 files

File	Comment
SDRTB4 EXE	This EXE file is the "actual program which makes the SDRTB4 system work. To start SDRTB4 you can either: <ul style="list-style-type: none"> Click on this file, or Create a desktop shortcut to this file. (See section 6 below)
ANALYSIS.EXE	These two files are actually from EpiInfo for DOS. (They are not essential to the function of SDRTB4 but provide users with extra tools for optional additional analyses. See further details below.)
EGAVGA.BGI	
FM_USR DLL	These DLL files are "system files" (dynamic link library files) which are "called" by the EXE file but which users never access directly. These files are really of no practical concern to users but they should never be moved or deleted
FMCOR10 DLL	
FMINT10 DLL	
FMGFX10 DLL	
FMWFC10 DLL	
FMQTE10 DLL	
FMML10 DLL	
FMOLE10 DLL	
FMFC10 DLL	
FMNSV14 DLL	
FMENG10 DLL	
FMCON10 DLL	
CLLNGENU DLL	
CLPROOF DLL	
MFC42 DLL	
MSVCRT DLL	
CTL3D32 DLL	
FMPRT50 HLP	A FileMaker Help file. Not used by SDRTB4 per se.
SDRMAN.DOC & SDRMAN.PDF	Copies of this manual in WORD .DOC format and in PDF format (Acrobat reader required for viewing.) [The DOC file may be best for printing and reading, the PDF version for on-screen viewing.]
SDRTB4_USR	This file with the USR extension is the actual SDRTB4 "database file", i.e. the file which contains the records users enter with information about resistance to TB drugs. Since this contains your actual data, this is one which MUST be regularly backed up to a diskette or other backup medium.

Although all the DLL files are essential from a technical point of view, users do not need to deal with these in any way. The only files you need to know about are:

SDRTB4.EXE: if you want the convenience of being able to click an icon on your Windows desktop to start the SDRTB4 system, just create a shortcut to this file.

SDRTB4.USR: This file will contain all your data. As such this is the file which you must faithfully backup.

ANALYSIS.EXE and **EGAVGA.BGI:** These files come from CDC's EpiInfo for DOS. They are not essential in any way to the functioning of SDRTB4. They are included for convenience because they can be used for *ad hoc* statistical analyses data from SDRTB4 which has been EXPORTED to a DBF file. ANALYSIS.EXE does the actual analyses. EGAVGA.BGI is included because it allows ANALYSIS.EXE to produce graphics. Detailed explanations are given below in Annex

6. Creating a shortcut

As mentioned above, for convenience in starting the SDRTB4 system, it is useful to create a shortcut to the file c:\sdrtb4\sdrtb4.exe. This can be done in several ways, for example:

- in Explorer by right clicking on the SDRTB4.EXE FILE => Send to => Desktop (create shortcut),

OR

- by right clicking on an empty spot on your desktop => New => Shortcut

At this point you should have installed SDRTB4 on your hard drive and created a shortcut which can start the program. Consultation with a colleague experienced with PCs can help in case you have had any difficulty with these steps.

7. A word about screen resolution

Most modern PC monitors and PC graphics cards can be set to display at different resolutions such as:

- 640 x 480 (fewer pixels displayed => "lower resolution")
- 800 x 600
- 1024 x 768
- 1280 x 1024
- 1600 x 1200 (more pixels displayed => "higher resolution")

A setting of 640x480 is too low to display the complete SDRTB4 screens and should be avoided. Resolutions of 1280x1024 or higher should also work but at those resolutions the size of the type on the data entry screens will become very small and difficult to read. Therefore most users will probably find it best to work at 800x600 or 1024x768.

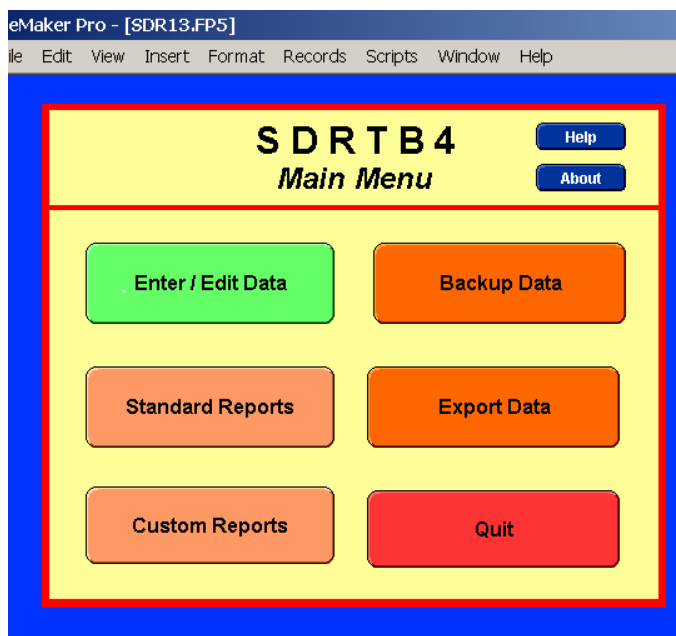
Screen resolutions can be set by right-clicking with your mouse on any empty spot on your Windows desktop, then selecting the tab called “Settings”, and adjusting the resolution by means of the slider. A little experimentation with your own PC system will help you decide what is best for you.

8. Quick tour part 1: Data Entry

When you start SDRTB4 you see a screen which looks like this:



At the bottom of the screen is a green button labeled “Go to the Main Menu”. Most navigation in SDRTB4 is done by clicking on rectangular buttons with rounded corners which resemble this one. When you click on this button you will come to the Main Menu which looks like this:



There is currently no on-line help available. This document, distributed both in Word and in PDF file formats, serves in-lieu of a help file. Clicking on “About” gives some basic information about SDRTB4 and explains that questions about the WHO/IUATLD Global

Project on Anti-Tuberculosis Drug Resistance, or requests for a copy of SDRTB4 can be directed to:

World Health Organization
HTM/STB/THD
Ch-1211 Geneva 27
Switzerland

Contact person:
Abigail Wright
Email: wrighta@who.int
Telephone: +41 22 791 2485
Fax: +41 22 791 4666

From the Main Menu, clicking on “Enter/Edit Data” takes you to a screen which looks like this:

The screenshot shows a FileMaker Pro window titled "FileMaker Pro - [SDR13.FP5]". The menu bar includes File, Edit, View, Insert, Format, Records, Scripts, Window, and Help. The main window has a blue header with the text "Surveillance of Drug Resistance in Tuberculosis" and "[Entry screen 1 of 4]". Below the header is a light blue area with the title "Form 1: Intake, Interview and Shipment". To the right of the title are two red boxes: "First Entered 01/04/2003" and "Last modified 01/04/2003". The form contains several input fields: "Country", "Country Code", "Diagnostic Center", "Center Code", "Pt. Identification No.", "Date Registered", "Sex", "Age", "Country of Origin", and "Age Group". The "Year Registered" field is a red box with a white input field. Below these fields is a "Remarks" text area. At the bottom of the form is a blue navigation bar with buttons: "Go to =>", "Screen 1", "Screen 2", "Screen 3", "Screen 4", "A new record", "Back to Main Menu", "<<< Entry screens for this record >>>", and "Delete this record". On the left side of the window, there is a sidebar with a record list showing "444" records, "Records: 444", and "Unsorted".

Note that two of the fields (Date “First Entered” and date “Last Modified” will already automatically be completed for you. (If these dates are ever found not to be correct you will need to reset your PC’s system clock-calendar.) For the most part (but not always) fields such as this which appear against a solid red background will be completed by the system and NOT by the person doing data entry.

Each record consists of four data entry screens which should be familiar to users of previous versions of the SDRTB software. They are also quite similar in layout and design to standard forms used by WHO’s collaborators in the surveillance of drug resistance in tuberculosis project. The four completed screens for a single (fictitious) record are shown below:

Data Entry Screen 1:

FileMaker Pro - [SDR13.FP5]
File Edit View Insert Format Records Scripts Window Help

Enter1
442
Records: 443
Unsorted

Surveillance of Drug Resistance in Tuberculosis [Entry screen 1 of 4]

Form 1: Intake, Interview and Shipment First Entered 10/15/2001
Last modified 01/04/2003

Country LESOTHO Country Code LES
Diagnostic Center FRANCISTOWN Center Code FRA122

Part A: Patient Information

Pt. Identification No. 111222 Date Registered 04-04-2001 2001 Year Registered
Sex F Age 52
Country of Origin Togo Age Group 45-54

Remarks This patient had been treated for TB in Togo in 1993. She is now sick again in Botswana.

Go to => Screen 1 Screen 2 Screen 3 Screen 4 A new record Back to Main Menu
<<<< Entry screens for this record >>>> Delete this record

Note that several fields were completed automatically by the system:

- as soon as the user entered 04-04-2001 as the “Date registered”, the system put 2001 in the field labeled “Year registered”. (This data is in a variable which will make it easier later to analyze data by whole calendar year.)
- as soon as the user indicated that the Age of the patient was 62, the system indicated that the patient therefore fell into the Age Group 45-54. (This data is in a variable called AgeGp which can facilitate analyses of drug resistance patterns according to standard age categories.)

Data entry tips:

- when you are entering data, you can move from one field to the next by pressing the TAB key.
- You can move back one field by pressing: SHIFT + TAB
- You can also move from one field to any other on the screen simply by clicking in the field with your mouse
- Date fields will accept either a "/" (slash) or a "-" (dash) in between the numbers representing the day, the month and the year respectively. Thus you may enter either "12/10/2001" or 12-10-2001".
- As some PCs are configured to show dates in dd/mm/yyyy format, and others in mm/dd/yyyy format, you may get a message when you start SDRTB4 asking whether you wish to use the "default date format for your PC". You should answer "Yes" or "Ok".
- Some fields allow only pre-set answers. For example, when you move the cursor to SEX, a "pick list" will pop-up with the choices M, F, and U (for Male, Female and Unknown). Likewise, in the field asking whether the patient reports that he or she has previously been treated for TB, the "pick list" shows the answers: "No", "Yes" and

"Unsure". In most cases you can just click on the choice which applies to the patient. (Once in a while, if clicking does not work, you may need to make your selection with the arrow keys which let you move up and down through the choices on the pick-list". To close the pick-list you can also press the ESCAPE key.

- Finally, note also the message **[Entry Screen 1 of 4]** at the top of the screen. There is a corresponding messages on each of the four entry screens so you will always know just where you are in the data entry process.

Data Entry Screen 2

FileMaker Pro - [SDR13.FP5]
File Edit View Insert Format Records Scripts Window Help

Enter2
442
Records: 443
Unsorted

Surveillance of Drug Resistance in Tuberculosis [Entry screen 2 of 4]

Part B: Positive Sputum Smear

Date(s) of most recent positive sputum smear(s) : Date of specimen 1 => 10/02/2001
Date of Specimen 2 => 10/03/2001
(if applicable)

Part C: History given by the patient

Previous treatment for TB according to the patient? YES
Previous number of treatment months according to patient? 4
Outcome of treatment according to the patient? CURED

Previous TB hospitalization according to patient? YES
Previous incarceration according to the patient? YES

HIV tested according to patient? YES
HIV test result according to patient ? POSITIVE

Go to => Screen 1 Screen 2 Screen 3 Screen 4 A new record Back to Main Menu
<<<< Entry screens for this record >>>> Delete this record

This screen is straightforward and includes information about the patient's sputum smears and from the history given by the patient concerning prior treatment for TB and prior testing for HIV.

Data Entry Screen 3:

Surveillance of Drug Resistance in Tuberculosis [Entry screen 3 of 4]

Part D: Medical Record

Prior Treatment for TB

Was the pt. previously registered for TB treatment according to the record? **NO**

If yes, what was the outcome according to the record?

Prior HIV testing?

HIV tested according to the record? **YES**

HIV test date according to the record? **04/06/1997**

HIV test result according to the record? **POSITIVE**

Date Form 1 Completed **10/16/2001**

Part E: Shipment of samples

Cetylpyridinium bromide/chloride added: **YES**

Date sample shipped **10/18/2001**

Go to => **Screen 1** **Screen 2** **Screen 3** **Screen 4** **A new record** **Back to Main Menu**

<<<< **Entry screens for this record** >>>> **Delete this record**

This screen includes, at the top, information from the patient's medical record, and at the bottom information about the shipment of sputum samples to the mycobacteriology reference laboratory.

Data Entry Screen 4:

Surveillance of Drug Resistance in Tuberculosis [Entry screen 4 of 4]

Form 2: Results Of Bacteriologic Examination

Laboratory Information

Date shipped to laboratory	10/18/2001	Date received in laboratory	10/22/2001	Laboratory specimen No:	LA41928
----------------------------	------------	-----------------------------	------------	-------------------------	---------

B. Identification

Identification Sample A **M. TUBERCULOSIS**

Identification Sample B **M. TUBERCULOSIS**

YES

M. TB Complex Confirmed

C. Susceptibility of M. tuberculosis

Isoniazid (INH)	RESIST	Resistance Summary
Rifampicin	SUSCEP	
Ethambutol	SUSCEP	
Streptomycin	RESIST	

Resistance Summary

Pattern **HS**

Number **2**

Form 2 completion date **10/20/2001**

Go to => **Screen 1** **Screen 2** **Screen 3** **Screen 4** **A new record** **Back to Main Menu**

<<<< **Entry screens for this record** >>>> **Delete this record**

This screen contains laboratory information including information about drug susceptibility testing. Six of the data entry fields are shown against a red background; four of these are automatically completed by the system.

- “Date shipped to laboratory” is entered automatically. This is just the date previously entered by the user at the bottom of the previous screen.
- “M. TB Complex Confirmed” is entered automatically. Here the field contains a “YES” because either *M. tuberculosis*, *M. bovis*, or *M. africanum* was identified in at least one of the two specimens.
- In the box Resistance Summary, the field “Pattern” has been automatically completed with “HS”. This reflects the fact that the data entry person indicated that the patient’s bacilli were resistant to INH and to Streptomycin. The variable RESPATT (for RESistance PATTern) can provide a powerful way to analyse summary results.
- Finally, and again in the box labeled Resistance Summary, the field “Number” shows “2” indicating that this patient’s bacilli are resistant to two (2) of the drugs tested. This variable is called RESNUM and is also useful for analysis of overall results where one may be interested in seeing how many patients have mono-, double-, triple- or quadruple-resistance.

Note further that at the bottom of each of the four data entry screens are buttons which allow the user to move back and forth from screen to screen, as well as to **Add a new record**, and **Delete the current Record**.

Finally, note the little rolodex-like icon at the top left of the screen. The rolodex (a mechanical roller with 1-card for each entry) is the metaphor used by FileMaker Pro. This icon and the numbers around it let you easily see how many records there are in your data set (here 443) and which record you are on (here 442). The rolodex also allows you to navigate through your data set:

- clicking on the top card of the roller moves you one record backward
- clicking on the bottom card of the roller moves you one record forward
- moving the slider (to the right of the roller) up or down lets you move quickly through dozens or hundreds of records. As you move the slider, the number just under the rolodex changes to show just what record number you are on.

When you have finished entering or editing one or more records, you exit data entry mode by clicking on the button labeled **Back to Main Menu**.

9. Quick Tour Part 2: Standard Drug Resistance Reports

SDRTB4 provides two approaches to producing summary drug resistance reports. These are accessed respectively through the Main Menu buttons labeled “Standard Reports” and “Custom Reports” .

Standard Reports:

If you click on the *Standard Reports* button, you come to a screen which looks like this:

Age Group	Males	Females	Both Sexes	HIV infection			
				No evidence of HIV infection	HIV+ per medical record	HIV+ per patient's history	HIV+ per medical record &/or patient's history
00-14	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				
15-24	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				
25-34	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
35-44	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
45-54	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
55-64	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
65-99	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
All ages	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Subset selection by broad demographic (age - sex) categories

Subset selection according to variables possibly indicating increased risk for drug resistant tuberculosis

[Back to Main Menu](#)

On the left is a box with $8 \times 3 = 24$ small buttons. These correspond to all combinations of broad age-sex categories. Clicking on the appropriate button will generate a summary drug-resistance report just for patients in the selected category. The pale grey buttons are used for reports either for males or females of a particular age-group. For example, clicking on the third button from the top on the left hand column will produce a report just for males who are 25-34 years of age. The light blue buttons at bottom and right will produce a report for all males, all females, or all patients (of either sex) in any particular age group. Finally, the larger dark-blue button on the bottom-right will produce a report for “All TB cases” (i.e. TB patients of either sex and from any-age group). Note that these reports will include only those patients confirmed to have disease due to *M. tuberculosis*. Patients found to have disease due to non-tuberculous mycobacteria are NOT included in these reports.

On the right of the screen is another box with 16 different buttons. These will produce reports for the subset of patients described by the corresponding row and column labels. For example, clicking on the white button in the upper left-hand corner will produce a summary drug resistance report just for patients who:

- have no evidence of HIV infection (the corresponding column heading)
- have no history of previous TB hospitalization or incarceration

The color gradations (from white, to yellow, to red) represent the increased (theoretical) risk of drug resistance in persons with such risk factors as prior treatment for TB, a history of incarceration, and HIV infection. (Of course in different countries and/or in different circumstances, these “theoretical” risk factors may or may not actually be predictors of rates of drug resistance.)

SDRTB4 Drug resistance reports all look like this:

Surveillance of Drug Resistance in Tuberculosis: LESOTHO

SDRTB4 Summary of antituberculosis resistance as of: 08/12/2003

For: All Males & All Females (00 to 99 years of age)

[Previous Menu](#)

[Line Listing](#)

[Print this Summary](#)

	New Cases		Previously Treated Cases	
	N	Pct	N	Pct
Total Tested	359	100.0%	80	100.0%
Fully Sensitive	281	78.3%	50	62.5%
Any Resistance	78	21.7%	30	37.5%
Mono Resistance				
H	20	5.6%	6	7.5%
R	1	0.3%	1	1.3%
E	1	0.3%	3	3.8%
S	5	1.4%	3	3.8%
H+R Resistance				
HR	5	1.4%	1	1.3%
HRE	3	0.8%	0	0.0%
HRS	6	1.7%	2	2.5%
HRES	7	1.9%	1	1.3%
H other Resistance				
HE	2	0.6%	2	2.5%
HS	10	2.8%	5	6.3%
HES	4	1.1%	2	2.5%
R other Resistance				
RE	4	1.1%	2	2.5%
RS	4	1.1%	2	2.5%
RES	4	1.1%	0	0.0%
Other Multiresistance				
ES	2	0.6%	0	0.0%
Any H Resistance	57	15.9%	19	23.8%
Any R Resistance	34	9.5%	9	11.3%

Notes:

- Separate resistance summaries (with separate percent resistant calculations) are given for:
 - New Cases [on the left of the report]
 - Previously treated cases [on the right of the report]
- this particular report was produced by clicking on the larger dark blue button labeled “All TB cases”. This is reflected in the title which reads “All males and all females: 00 to 99 years of age”. However by clicking on other buttons, you could have obtained a similar report for different age-sex subsets of patients.
- Three blue buttons appear at the top of the screen As indicated, these allow you to:
 - Return to the previous menu
 - Produce a line listing (see discussion below)
 - Print the resistance summary (The buttons which appear on the screen will not appear on the printed report).
- If you clicking on the line listing button would give a screen like this:

FileMaker Pro - [Sdr13.fp5]

File Edit View Insert Format Records Scripts Window Help

08/12/2003 Line listing of selected variables for record subset of interest : LESOTHO

Print Line Listing Standard Reports Menu Custom Reports Menu Main Menu

PTNUMB	DATEREG	SEX	AGE	ORIGIN	PRIORTMT	INCARPT	HOSPPT	HIVPOSPR	LABNUMB	TB	RESPATT
940460	11/11/1994	M	36	LESOTHO	NO	YES	NO	NO	LA34667	YES	ALL OK
940468	11/11/1994	M	60	LESOTHO	NO	YES	YES	YES	LA34684	YES	HRES
940467	11/11/1994	F	37	LESOTHO	NO	NO		YES	LA34601	YES	ALL OK
940466	11/11/1994	M	44	LESOTHO	NO	NO		NO	LA34618	YES	ALL OK
940465	11/11/1994	M	28	LESOTHO	YES	YES	YES	NO	LA34635	YES	ALL OK
940464	11/11/1994	F	30	LESOTHO	NO	NO	YES	NO	LA34662	YES	ALL OK
940462	11/11/1994	M	33	LESOTHO	YES	YES	NO	NO	LA34669	YES	ALL OK
940461	11/11/1994	F	33	LESOTHO	NO	NO	NO	NO	LA34686	YES	H
940460	11/11/1994	M	47	LESOTHO	YES	ASDF	UNSURE	NO	LA34703	YES	H
940448	10/17/2001	U	12	LESOTHO	YES	YES	NO	YES	111222	YES	RE
940446	11/11/1994	M	51	LESOTHO	NO	NO		NO	LA34737	YES	HRES
940433	11/11/1994	F	29	LESOTHO	NO	YES		NO	LA34754	YES	H
940420	11/11/1994	F	30	LESOTHO	NO	NO		NO	LA34771	YES	H
940412	11/11/1994	M	24	LESOTHO	YES	NO		NO	LA34788	YES	ALL OK
940401	11/11/1994	F	45	LESOTHO	NO	YES		NO	LA34805	YES	ALL OK
940395	11/11/1994	M	2	LESOTHO	YES	NO		NO	LA34822	YES	RS
940393	11/11/1994	M	3	LESOTHO	YES	NO		NO	LA34839	YES	ALL OK
940390	11/11/1994	F	25	LESOTHO	NO	YES		NO	LA34856	YES	ALL OK
940388	11/11/1994	F	26	LESOTHO	NO	NO		NO	LA34873	YES	ALL OK
940385	11/11/1994	M	36	LESOTHO	YES	YES		NO	LA34890	YES	ALL OK
940310	10/17/1994	F	15	LESOTHO	NO	NO		NO	LA34907	YES	H
940309	10/17/1994	F	4	LESOTHO	YES	YES		NO	LA34924	YES	H
940308	10/17/1994	M	24	LESOTHO	NO	NO		NO	LA34941	YES	ALL OK
940307	10/17/1994	M	31	LESOTHO	NO	NO		NO	LA34958	YES	ALL OK
940306	10/17/1994	M	42	LESOTHO	NO	YES		NO	LA34975	YES	ALL OK
940305	10/17/1994	M	30	LESOTHO	NO	NO	YES	YES	LA34992	YES	ALL OK
940304	10/17/1994	M	56	LESOTHO	NO	NO	YES	YES	LA35009	YES	ALL OK
940303	10/17/1994	M	44	LESOTHO	NO	NO		YES	LA35026	YES	ALL OK
940302	10/17/1994	M	52	LESOTHO	YES	NO		YES	LA35043	YES	ALL OK
940301	10/17/1994	F	30	LESOTHO	NO	NO		NO	LA35060	YES	ALL OK
940300	10/17/1994	M	5	LESOTHO	NO	NO		NO	LA35077	YES	HRES
940299	10/17/1994	M	6	LESOTHO	NO	NO		NO	LA35094	YES	HRS
940296	10/17/1994	M	37	LESOTHO	NO	NO		NO	LA35111	YES	ALL OK
940295	10/17/1994	M	38	LESOTHO	NO	NO		NO	LA35128	YES	S
940294	10/17/1994	M	68	LESOTHO	YES	NO		NO	LA35146	YES	HS
940292	10/17/1994	M	65	LESOTHO	YES	NO		NO	LA35162	YES	ALL OK
940283	10/17/1994	F	22	LESOTHO	NO	NO		NO	LA35179	YES	S

100% Browse

Start FileMaker Pro - [Sdr1... Microsoft Word - SDR4MA...

This listing includes one line for each patient whose data are summarized in the report. In this case the listing includes all patients in the data set. However, if you had asked for a summary report just for males 35-44, then this line listing would have included only males 35-44 years of age. The line listing does not include all the variables in the data set, but does include:

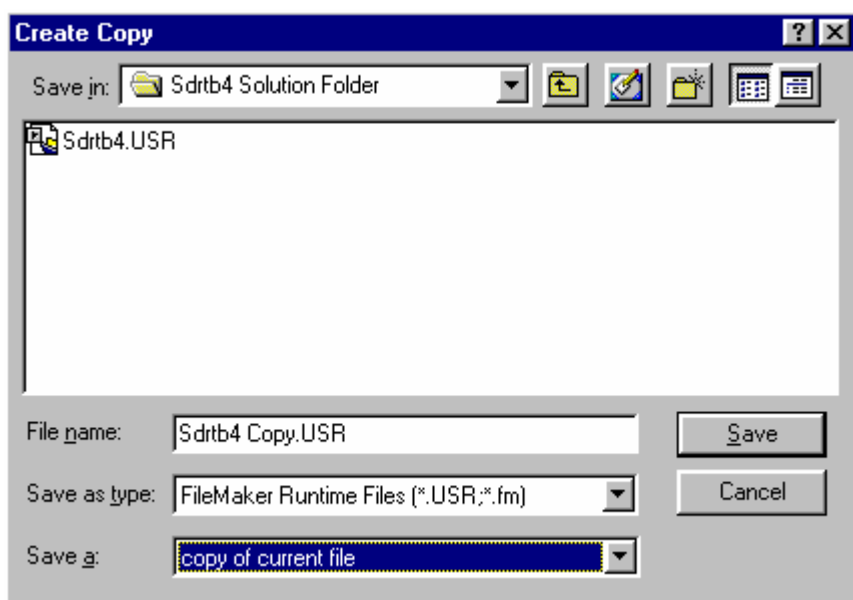
- The patient number
- Date the patient was registered
- Sex
- Age
- Origin
- Prior treatment (Yes or No)
- History of prior incarceration (Yes or No)
- Previous hospitalization for TB (Yes or No)
- Any indication that the patient is HIV positive whether by patient's history OR from the medical record (Yes or No)
- The patient's laboratory number
- Whether the patient's culture(s) confirmed that he has tuberculosis (Yes or No)
- The drug resistance pattern (RESPATT), e.g.
 - ALLOK = no resistance observed
 - H = resistance to INH
 - HRE = resistance to INH, rifampin and ethambutol
 - HS = resistance to INH and streptomycin

These line listings can be used in a number of ways. For example they can be used to identify individual patients of particular interest (e.g. those with MDR-TB) whose actual patient records could then be reviewed in more detail. The line listing, like the drug resistance summary, can also be printed, and other buttons on the screen allow you to navigate back to other menus.

10. Backing up your data

As is the case with any software system which maintains an important data set, keeping a backup of your SDRTB.USR file (your "data" file) is essential. You can prepare backups in two ways: either from "within SDRTB4" by using the system's "Backup Data" option , or from "outside SDRTB4", by using the Windows Explorer or other backup utility.

Option 1: One of the large orange buttons on the Main Menu screen is labeled *Backup Data*. When you press this button, a dialog box named "Create Copy" will open and will look something like this.



You can use this system to make a backup copy of your data set to the drive and folder of your choice. Usually you can accept the default File name proposed which is "SDRTB4 Copy.USR", though you could give the backup a different name if you wished. The file type here should be .USR. (The USR file is in fact just a standard FileMaker Pro .FP5 file with a .USR extension as created when the system is compiled for run time use and distribution). Finally, you have several choices user the *Save As* option:

- You can save an exact copy of the current SDRTB4.USRfile (always a safe choice)
- You can save what the dialog box calls a "compressed copy ". Note that "compressed" here does not refer to a Zip or other truly compressed file format. "Compressed" in this context simply refers to the fact that after heavy use FileMaker files may get "bloated" with unused space which can be "recovered" by "compression" (something like squeezing air from a plastic bag) which makes the file size a bit smaller. File bloat occurs mostly with files where there is a great deal of record deletion as well as data entry, which will probably not often be the case with the

SDRTB4 system so this option may not be that important for routine SDRTB4 use. In any case, the so-called "compressed" file is still in fact a normal FileMaker .USR (.FP5) file. You can experiment with this option to see if your backup copy is significantly smaller than your original, which might for example, make it easier to save the file to a floppy disk.

- The final Save As option in this dialog box is to make a "clone (no records)". In this case your copy will have the file structure, data entry screens, buttons etc, but will not have any records. Most SDRTB4 users will probably not need this options, though it might be used in special circumstances, for example in a training or classroom situation where a student might enter 10 practice records, but then want to make a clean new file (with no records) which could then be renamed SDRTB4.USR and be clean and ready for the next student.

Option 2: The other option is simply to back up SDRTB4.USR, using your Windows Explorer to make a copy to a floppy diskette, to your network drive, to a Zip drive, or some other backup media. If your file becomes very large you may want to make a compressed version (e.g. a Zip file) before you make your copy. The exact option you choose will depend on the file size, the configuration of your PC, and what other compression or backup utility software you may have and are familiar with. The important thing though is to always maintain a back up your SDRTB4.USR data file.

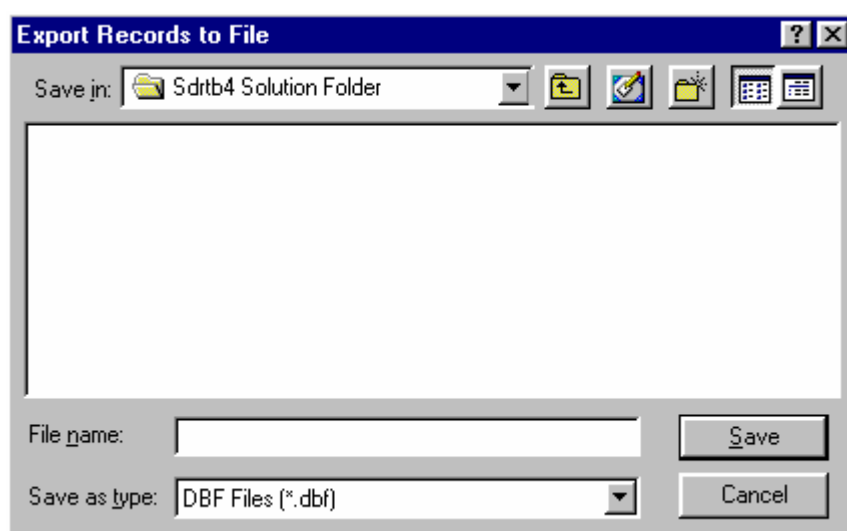
11. Exporting SDRTB4 data

As you have seen above, SDRTB4 allows you to perform two basic functions:

- enter and edit data
- produce standard summary drug resistance reports and line listings

These functions suffice for many routine purposes. However, you or your colleagues may also wish to perform additional more detailed statistical analyses which are beyond the capabilities of FileMaker and SDRTB4. Thus, you may need to "export" your data in a format which can be used by statistical software such as SAS, SPSS, Stata (commercial software) or the DOS or Windows versions of EpiInfo (freeware for public health).

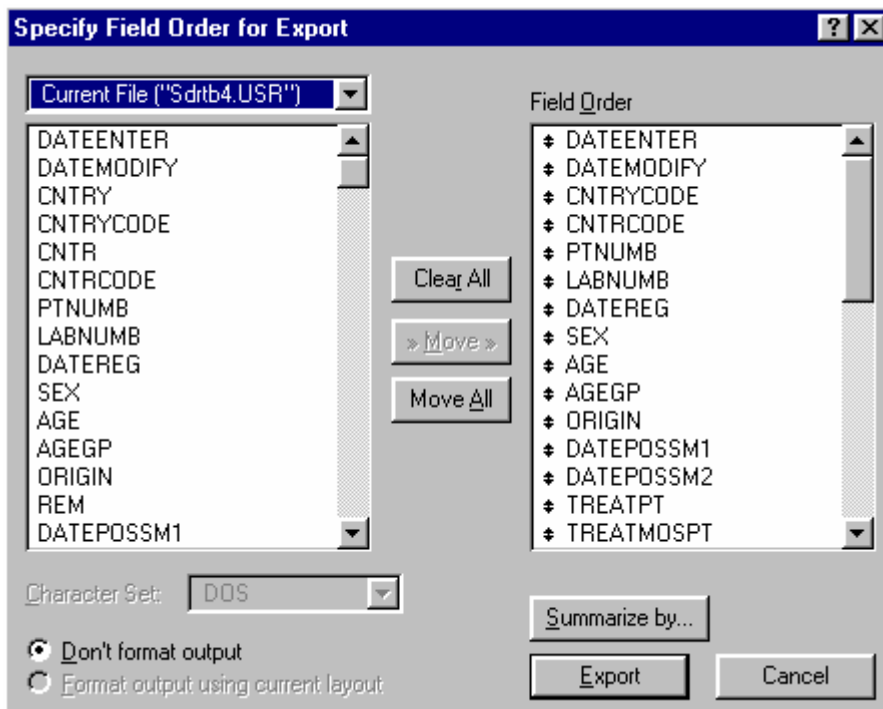
You can "export" your data form the SDRTB4 Main Menu by clicking on the Orange Button labeled "Export Data". You will then see a dialog box which looks like something this:



Note that you can:

- Indicate the drive and folder to which you wish to export your data (don't forget where you export to!)
- Pick a file name for your exported data (for example, you could call the file SDRTB4EXP indicating that it contains EXPorted data from SDRTB4.)
- Finally, you can use the *Save as type* option to indicate the file format to which you wish to export your data. By default this is set to the DBF file format. DBF files are the native format used by earlier versions of dBase and Foxpro, but in recent years the DBF format has become a standard format which can be read by almost all database, spreadsheet and statistical software packages as well as by all versions of EpiInfo. For most purposes you can thus accept the DBF format as your default, though, depending on the software you might be using for further analysis, prefer to export to another format such as "comma delimited" or "tab delimited".

After you have completed the dialog box, click on SAVE, and you will see the following dialog box:



Here you can select just which SDRTB4 variables you wish to export. The SDRB4 variables are listed in the box on the left. The variables you will be exporting are listed on the right. By default SDRTB4 already has placed 37 variables on the right hand panel. These includes all the raw data entered into individual patient records (e.g. age), as well as several important derived variables (age group). Included already are all the variables needed for more detailed analyses of drug resistance patters. You should probably NOT be tempted to move all of the SDRTB4 variables from the left panel over to the right even though you can do that with the click of a mouse (on the button "Move All"). One additional variable you may want to move over to the right is PRIORTMT which indicates whether or not the patient has been treated for TB either according to the medical record OR by his/her own history. Other variables on the left panel are generally not useful. The point is that SDRTB4 contains numerous "internal variables" which would actually not be helpful in any epidemiologic analysis as they are just used "internally by the SDRTB4 software to help prepare summary drug resistance tables.

The final step is to click on "Export", and your DBF (or other format) file will be created.

12. SDRTB Data Variables

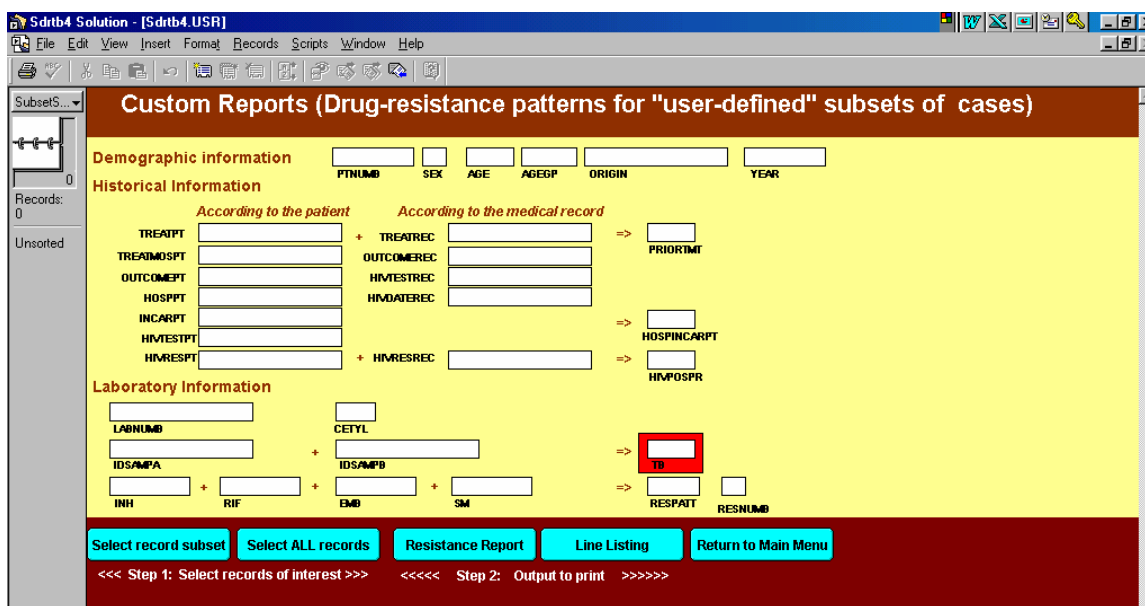
If you have examined the data entry screens and followed the discussion this far, you have already acquired a good general understanding about the basic data variables which are computerized by SDRTB4. This following table gives a complete listing of these variables. This list can be helpful for users who will want to perform additional analyses on data exported to a DBF file (see section 11 above).

DATEENTER	Date record was first entered
DATEMODIFY	Date record was last modified
CNTRYCODE	Country code (usually a 3 letter code)
CNTRCODE	Center code
PTNUMB	Patient number
LABNUMB	Laboratory number
DATEREG	Date registered
SEX	Sex
AGE	Age
AGEGP	Age group (using standard WHO TB age groupings)
ORIGIN	Origin (e.g. for patients diagnosed in one country but who have immigrated from another)
DATEPOSSM1	Date of first positive smear
DATEPOSSM2	Date of second positive smear
TREATPT	Prior treatment according to the patient
TREATMOSPT	Prior treatment in months according to the patient
OUTCOMEPT	Outcome of prior treatment according to the patient
HOSPPT	Previously hospitalization for tuberculosis according to the patient
INCARPT	Previously incarceration in a prison or jail according to the patient
HIVTESTPT	Prior HIV test according to the patient
HIVRESPT	Prior HIV test result according to the patient
TREATREC	Prior treatment according to records
OUTCOMEREC	Outcome of prior treatment according to records
HIVTESTREC	HIV test ever given according to records
HIVDATAREC	HIV test data according to records
HIVRESREC	HIV results according to records
DATEFORM1	Date form1 was completed
CETYL	Whether cetylpyridinium bromide/chloride has been added
DATESHIP	Date sputum specimens were shipped
IDSAMPA	Mycobacterial species isolated, sample A
IDSAMPB	Mycobacterial species isolated, sample B
INH	Susceptibility to INH
RIF	Susceptibility to rifampin
EMB	Susceptibility to ethambutol
SM	Susceptibility to streptomycin
FORM2DATE	Date Form2 was completed
RESPATT	Summarizes the drug-resistance pattern of each patient (e.g. ALLOK, H, R, RE, HRE etc.)
RESNUMB	counts the number of drugs to which each patient's bacilli are resistant (e.g. 0, 1, 2, 3, or 4)
PRIORTMT	Categorizes patients according to whether they have, or have not, according to records OR their own history, received prior treatment for TB

13. Customized Drug-Resistance Reports

You have previously seen (see P. 10) how to produce standard summary drug resistance reports. You will recall that those "standard reports" could be produced either for all records entered into SDRTB4, or for certain pre-defined subsets of patients (e.g. only males of a certain age group, or only for patients known to be infected with HIV who had also been previously hospitalized for tuberculosis.) For most purposes those pre-programmed "standard" reports may suffice. However, you may occasionally wish to examine patterns of drug resistance for subsets of patients which you wish to define even more precisely. For example, you might wish to look at patterns of resistance just for males aged 20-29 who were registered in the year 2002), who were known to be infected with HIV, and whose organisms were shown by the mycobacteriology laboratory to be resistant to at least one drug. Or, you might wish to obtain a line-listing of just this subset of patients so that you could examine their records in more detail for some other purpose. As you might expect, the process of producing such a "custom report" requires more steps than the single-mouse-click which produces a "standard report", However, the process is not very complicated and is explained here step-by-step.

When you select the "Custom Reports" option from the main menu you will come to a screen which looks like this:



The screen looks very much like a "form" which needs to be filled out, and in fact that is just how the process works. By indicating on the form just which patients are of interest for your analysis, you are in effect asking SDRTB4 to select just those patients who meet the criteria you have indicated. The process also requires that the blue buttons at the bottom of the screen be pressed in the proper sequence. The FileMaker "Find" button is also used.

Example: You wish to obtain a line listing and as well as a drug-resistance summary table for patients who meet the following criteria:

- they are females
- they are over 30 years of age
- there is evidence either from the patient's history or from the medical record that they are HIV positive
- the laboratory has found that the isolate of M. TB is resistant to at least one drug

Steps to follow:

Step 1: Begin by clicking on the blue "Select record subset" button.

This indicates to SDRTB4 that you want to create your own "subset" of records

Step 2: Enter "F" in the field labeled "SEX"

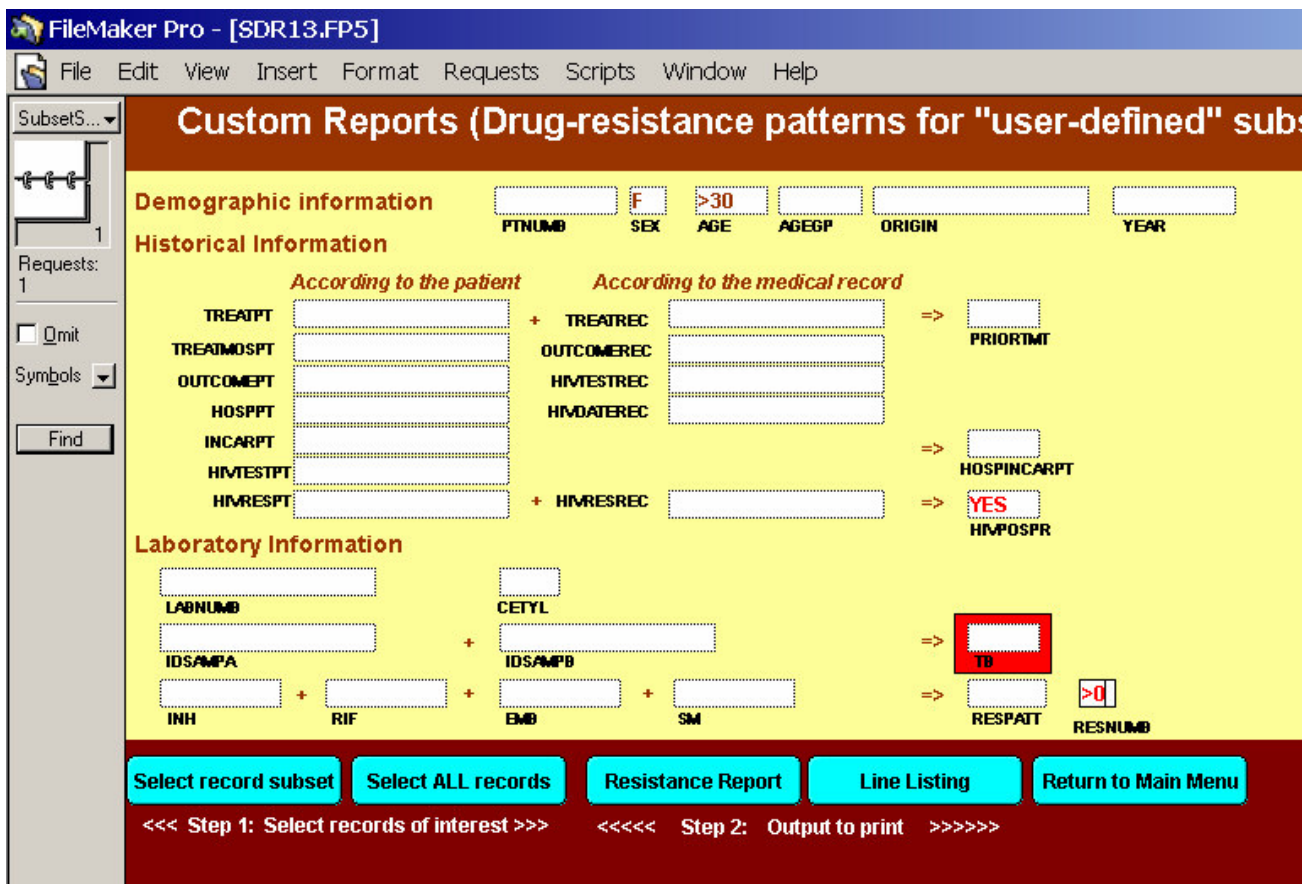
Step 3: Enter ">30" in the field labeled "AGE"

Step 4: Enter "Yes" in the field labeled "HIVPOSPR"

Step 5: Enter ">0" in the field labeled "RESNUMB"

Steps 2-5 have indicated to SDRTB4 the criteria you wish to use to form your "subset" of interest)

Your screen will now look like this:



Looking at this screen-shot note:

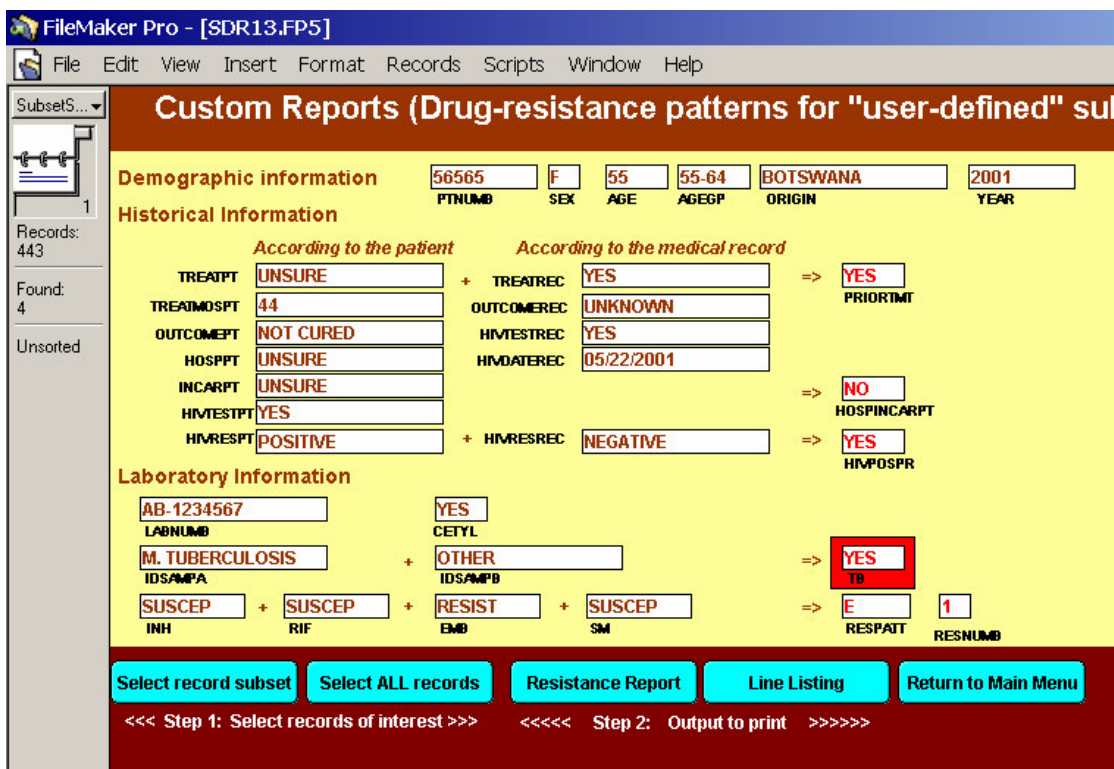
- "F" in the SEX field

- “>30” in the AGE field
- “YES” in the “HIVPOSPR” field
- “>0” in the “RESNUMB” field

Step 6: Click on the “Find” button which has now appeared on the status bar on the left side of the screen.

When you click on “Find”, this tells the program to search all the records in the data file and select just those which match the search criteria you have entered.

After a moment, the screen will look something like this:



Looking at the status pane on the left of the screen we see the icon of the “rolodex” which is the metaphor used by FileMaker. The numbers indicate that there are 443 records currently in the data set, and that 4 of these were found to match the search criteria. The first of the four matched records is shown on the screen. By visual inspection we can see that the patient does meet the four search criteria since she is:

- a female
- 55 years old (i.e. >30 years old)
- is HIV positive either according to her history or according to her medical record. (The details displayed here show that she was positive by “history” but negative by the “medical record”)
- Has an isolate of M. tuberculosis which is resistant to 1 drug (i.e. RESNUM>0), in this case showing resistance to ethambutol.

If we wished, we could visually inspect the other three records which were “found”.

- The “next” found record can be inspected by clicking on the bottom card of the rolodex.
- The previous record can be seen by clicking on the top card of the rolodex.
- It is also possible to move up and down through the rolodex by clicking and dragging the little slider which is visible just to the right of the rolodex cards.

Usually, however, the point here is not to visually inspect each “found record”, but to obtain either a line listing of the “found patients” or a table summarizing their drug resistance status.

Step 7: To obtain a line listing click on the blue button labeled “Line Listing”. You will then see something like this:

FileMaker Pro - [SDR13.FP5]

File Edit View Insert Format Records Scripts Window Help

05/27/2003 Line listing of selected variables for record subset of interest : LESOTHO

Print Line Listing Standard Reports Menu Custom Reports Menu Main Menu

PTNUMB	DATEREG	SEX	AGE	ORIGIN	PRIORTMT	INCARPT	HOSPPT	HIVOSPR	LABNUMB	TB	RESPATT
56565	02/04/2001	F	55	BOTSWANA	YES	UNSURE	UNSURE	YES	AB-1234567	YES	E
112233	09/07/2001	F	44	BOTSWANA	YES	YES	YES	YES	LA41792	YES	HR
503	03/02/1997	F	65	BOTSWANA	NO	NO	YES	YES	LA41809	YES	HES
111222	04-04-2001	F	52	BOTSWANA	YES	YES	YES	YES	LA41928	NO	HS

The line listing can be visually inspected to make sure that all patients listed do in fact meet the “search criteria”. Here we can see that indeed all four “found patients” were females (see SEX) over 30 years of age (see field AGE), were HIV positive according either to the patient or to the record (see field HIVOSPR), and had M. TB isolates resistant to at least one drug (see field RESPATT).

Note the several options available from the blue buttons on this screen which can:

- print the line listing (assuming your PC is connected to a printer)
- return to the standard reports, custom reports, or main menu

Step 8: If instead of wanting to see a line listing of the “found patients”, we had just wanted to proceed directly to their resistance summary, we would have clicked instead on the blue button titled “resistance report”. SDRTB4 would then have produced a screen which looks like this:

Surveillance of Drug Resistance in Tuberculosis: LESOTHO

SDRTB4 Summary of antituberculosis resistance as of: 05/27/2003

Previous Menu Line Listing Print this Summary

	New Cases		Previously Treated Cases	
	N	Pct	N	Pct
Total Tested	1	100.0%	3	100.0%
Fully Sensitive	0	0.0%	0	0.0%
Any Resistance	1	100.0%	3	100.0%
Mono Resistance				
H	0	0.0%	0	0.0%
R	0	0.0%	0	0.0%
E	0	0.0%	1	33.3%
S	0	0.0%	0	0.0%
H+R Resistance				
HR	0	0.0%	1	33.3%
HRE	0	0.0%	0	0.0%
HRS	0	0.0%	0	0.0%
HRES	0	0.0%	0	0.0%
H other Resistance				
HE	0	0.0%	0	0.0%
HS	0	0.0%	1	33.3%
HES	1	100.0%	0	0.0%
R other Resistance				
RE	0	0.0%	0	0.0%
RS	0	0.0%	0	0.0%
RES	0	0.0%	0	0.0%
Other Multiresistance				
ES	0	0.0%	0	0.0%
Any H Resistance	1	100.0%	2	66.7%
Any R Resistance	0	0.0%	1	33.3%

By visual inspection (always good to do to “double check”) we can see:

- that the report covers just 4 patients (matching the 4 “found” by our search criteria).
- That none of the patients in this summary had fully resistant M. TB isolates, showing at least mono-resistance, and in some cases poly-resistance (again).

Field values to use to produce Custom Reports

(Field labels shown in bold are more likely to be used profitably for "subset of interest" selection.)

Field label as shown on the "Custom Reports" screen	Explanation	Values to enter as criteria for selecting records for a custom report
PTNUMB	Patient number	
SEX	Sex	M F U
AGE	Age	Age as 2 digit number (e.g. 32)
AGEGP	Age group	00-14 15-24 25-34 35-44 45-54 55-64 65-99
ORIGIN	Origin	Country of origin
YEAR	Year	Year patient registered as 4 digit number (e.g. 2002)
TREATPT	Prior treatment according to the patient	NO YES UNSURE
TREATREC	Prior treatment according to the record	NO YES NA
PRIORTMT	Prior treatment either according to the patient OR according to the record	YES NO
TREATMOSPT	Prior treatment in months according to the patient	e.g. 1 or 2 digit number
OUTCOMEREC	Outcome of prior treatment according to the patient's record	CURED COMPLETED DEFAULT FAILURE TRANSFER OUT UNKNOWN
OUTCOMEPT	Outcome of prior treatment according to the patient	CURED NOT CURED UNSURE NOT APPLIC
HIVTESTREC	Prior HIV test results according to the patient's record	NO YES
HOSPPT	Prior hospitalization for TB according to the patient	NO YES UNSURE
HIVDATEREC	Prior HIV test date according to the record	A date
INCARPT	Prior incarceration according to the patient	NO YES UNSURE
HOSPINCARPT	Prior hospitalization OR prior incarceration according to the patient	NO YES
HIVTESTPT	Prior HIV test according to the patient	Yes NO UNSURE
HIVRESPT	Prior HIV test results according to the patient	NEGATIVE POSITIVE UNSURE NOT APPLIC
HIVRESREC	Prior HIV test results according to the medical record	NEGATIVE POSITIVE NOT APPLIC
HIVOSPR	Positive prior HIV results either according to the patient OR according to the record	NO YES
LABNUMB	Laboratory number	Laboratory number
CETYL	Cetylpyridinium bromide added to sample	NO YES
IDSAMPA	Reported lab result for sputum sample A	M. TUBERCULOSIS M. BOVIS M. AFRICANUM NEGATIVE CONTAMINATED OTHER
IDSAMPB	Reported lab result for sputum sample B	M. TUBERCULOSIS M. BOVIS M. AFRICANUM NEGATIVE CONTAMINATED OTHER
TB	Did patient have laboratory confirmed tuberculosis or not (YES if at least one of the two specimens grew either: M. TUBERCULOSIS, M. BOVIS, or M. AFRICANUM)	YES NO
INH	Result of test for susceptibility to INH	SUSCEP RESIST NO RESULT
RIF	Result of test for susceptibility to RIF	SUSCEP RESIST NO RESULT
EMB	Result of test for susceptibility to EMB	SUSCEP RESIST NO RESULT

SM	Result of test for susceptibility to SM	SUSCEP RESIST NO RESULT
RESPATT	Overall resistance pattern	ALL OK H R E S HR HE HS RE ES HRE HRS HES RES HRES
RESNUMB	Overall, no. of drugs (of 4 tested) to which patient's isolate found to be resistant	An integer from 0 to 4 (0, 1,2,3 OR 4)

Annex 1: Primary and Acquired Drug-resistance and WHO standard age groups

In SDRTB1, tables were produced summarizing *overall* drug resistance rates for isoniazid, rifampin, ethambutol and streptomycin. However, it is helpful for TB control programmes to analyze drug resistance rates separately for *patients who have had and have not had prior treatment for TB*. Therefore, all subsequent versions of SDRTB, present summary information concerning drug resistance in relation to a **variable** called **PRIORTMT** (for *prior treatment*). The programme assigns values of YES or NO to PRIORTMT according to information which has already been collected from two questions on the SDRTB data collection form. The two variables are: TREATREC and TREATPT. They indicate respectively whether the patient record indicates prior treatment and whether the patient him/herself (by history) reports having received prior treatment. The algorithm used by the software to assign YES or NO values to PRIORTMT according to TREATREC and TREATPT is presented in the following table:

Decision table used to code the variable PRIORTMT to classify patients as having or NOT having received prior treatment for tuberculosis

		Does the patient give a history of prior treatment for TB? ¹		
		YES	NO	UNSURE
Do available medical records	YES	YES	YES	YES
Indicate the patient has received	NO	YES	NO	NO
Prior treatment for TB? ²	NA ³	YES	NO	NO

In short, under this scheme, patients are classified as having received prior treatment if such treatment is noted (1) by their medical record **AND/OR** (2) by the patient him/herself. Although any classification scheme is subject to some error, this approach appears to be reasonable from an operational point of view.

5. WHO standard age-groups

In SDRTB1 cases of TB were grouped, for purposes of analysis, into 10-year age-groups: 0-9, 10-19, 20-29 etc. All the more recent versions now use the age-groupings more commonly used by TB control programmes in many countries and recommended by WHO. The seven standard age groups now used are shown in the following table:

Group	Ages
1	0-14
2	15-24
3	25-34
4	35-44
5	45-54
6	55-64
7	65+