The CDISC ODM Viewer
Version 1.6
User Manual

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Introduction

The CDISC ODM Viewer allows to inspect ODM files in a very user-friendly way. Instead of viewing the (ugly) XML, the content of the ODM file is displayed as a set of tables in HTML format. These tables are hyperlinked, so that context information about an item in such a table can immediately be obtained.

Furthermore, the user can create subsets of clinical data to inspect. For example, the user can select the first 10 subjects of a specific site, or a specific investigator. Also selections at the study event, the form, subform (ItemGroup) and even question (ItemDef) level can be made.

New in version 1.6

At start up, the user can choose by having the ItemGroups in the clinical data be displayed with the name only (value of the "Name" attribute in the corresponding ItemGroupDef) or with a combination of the name and the OID. The latter is useful when different ItemGroups have identical names.

New in version 1.5

Improved handling of inheritance of AuditRecords, Signatures, and Annotations. Options to also display audit records, signatures and annotations to be inherited from the Form, StudyEvent and SubjectData level have been added. See the section "Inheritance of AuditRecords, Signatures and Annotations".

New in version 1.4

Version 1.4 now also supports v.1.3.1 of the CDISC ODM standard.
Also a technology change has been made: v.1.4 now uses VTD-XML for searching through the ODM document and creating susbsets of data. The choice for VTD-XML means a lower memory footprint and faster response of the software in the case of large datasets.

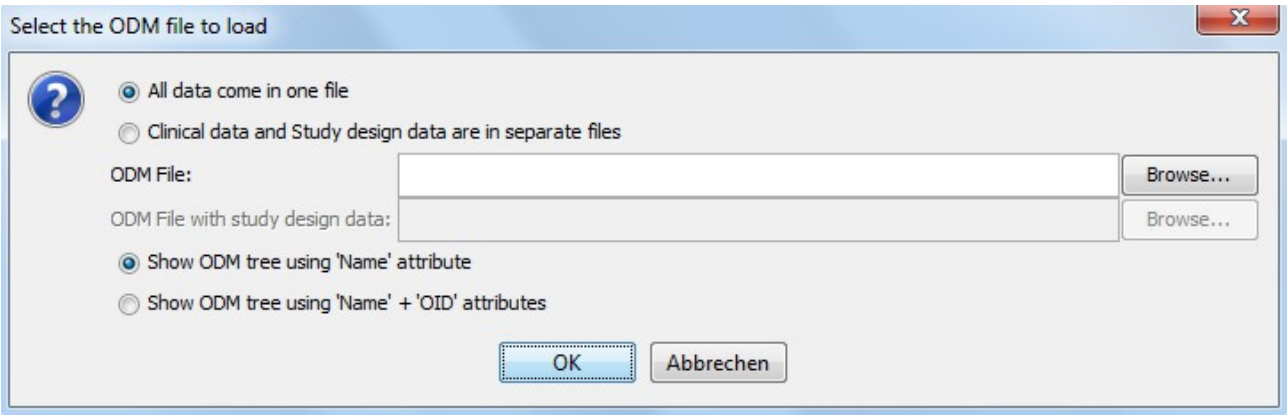
New in version 1.3

New in this version is that one can create sets of audit records. These can then be displayed in different ways, and simple statistics can be derived. This makes it very easy to find out for which data point(s) the most audit records have been created, or for (or by) which investigator.

Starting the software and basic features

Please read the installation manual first, even when you have just copied the software from a CD, or unzipped it from a download from the XML4Pharma website.

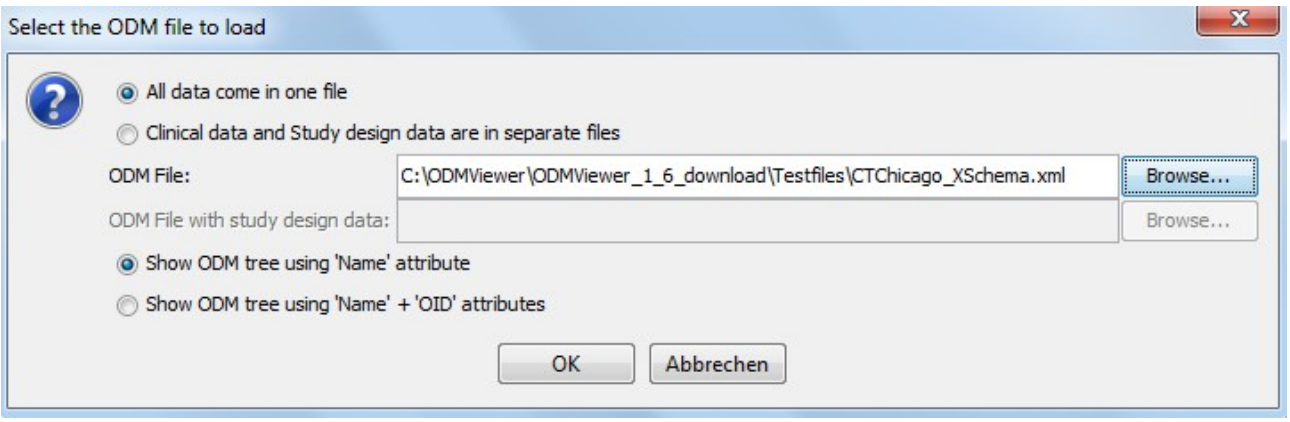
The software can be started by double-clicking the "ODMViewer.bat" file icon (MS Windows), or by executing the shell script "ODMViewer.sh" (Linux). If the installation was done correctly, the software starts up with an almost empty screen, and then presents a file chooser, allowing to select an ODM file:



One can either select to load a file that has everything in it, i.e. metadata and data, or to load separate files, one with the clinical data, and one with the metadata. The latter has been done as not all EDC vendors repeat the metadata in the provided files with the clinical data.

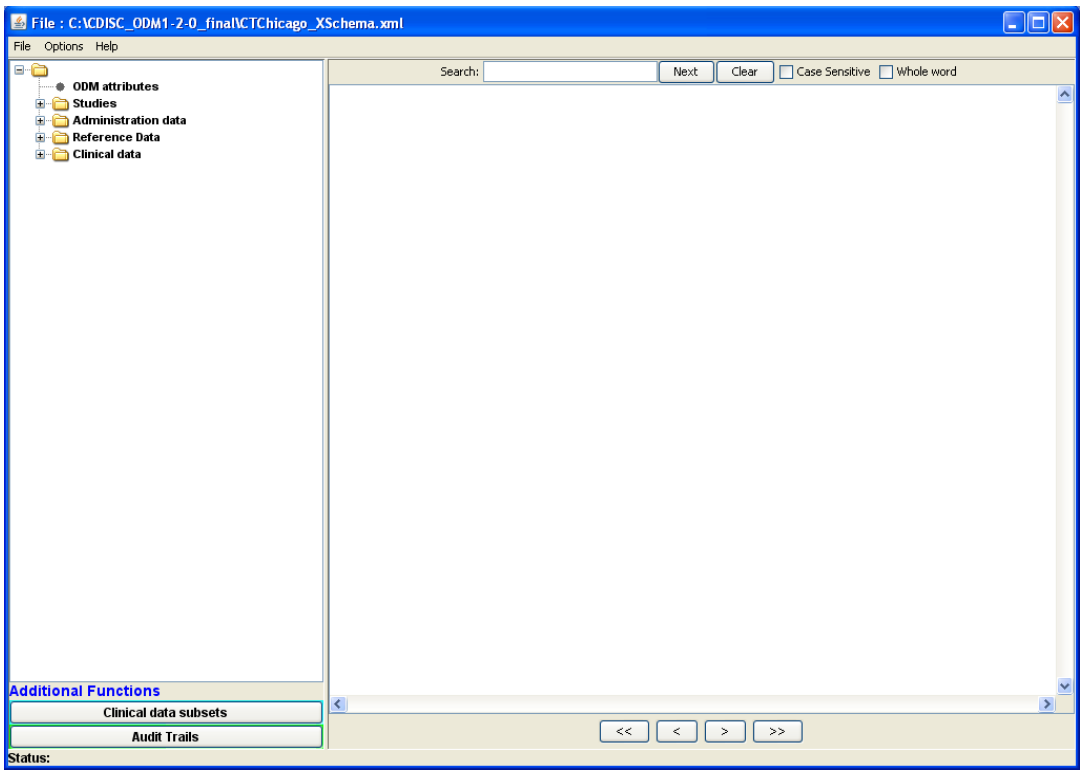
Also you can choose between having the ItemGroups in the tree for clinical data be displayed using the value of the "Name" attribute (from the corresponding ItemGroupDef), or using a combination of both the "Name" and "OID". The latter is usually more user friendly (as long as the "Name" attribute contains a good and short description). The latter should be selected when the values of the "Name" attribute are not unique, as otherwise the system will not be able to decide which ItemGroup is exactly meant.

For this tutorial, we now select a single file that "has all of it":

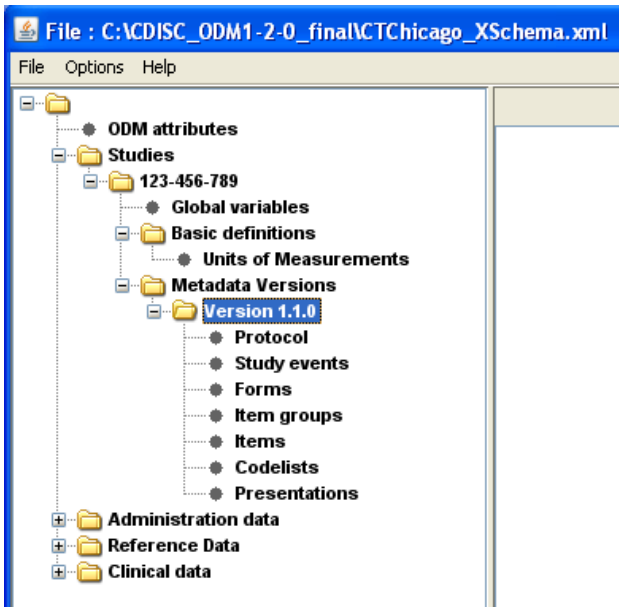


Remark that the ODMViewer can work with ODM files version 1.2 and 1.3/1.3.1.

Once the file loaded, the screen will look like:



On the left side of the screen, a tree view of objects is shown. The tree can be expanded by clicking on one of the "+" icons, or collapsed by clicking on one of the "-" icons.
The right side of the screen will display the HTML tables that are produced when information is requested for specific parts of the study, of for specific subsets of clinical data.
Fully expanding the "Studies" tree in our case gives the following tree view:



When clicking on one of the leaf elements of the tree (having a gray symbol), information related to the item that was clicked is gathered (for a short time, the right side of the screen will show a "Working" message), and displayed as HTML.
For example, if the "Protocol" leaf node is clicked, the right side of the screen shows us the following information:

top

Protocol: Study Events for Study 123-456-789 - MetaDataVersion v1.1.0

Study Events

Study Event Name	Study Event OID	Order Number	Mandatory ?
Pre-treatment	SE.VISIT0	1	Yes
Post-treatment	SE.VISIT1	2	Yes
Study Events for MetaDataVersion v1.1.0			

Back to top

It shows us that two visits (study events) have been planned, and that both are mandatory.

Similar, when the "Study events" leaf node is clicked, the following information is displayed (incomplete view):

top

Study Events - Study 123-456-789 - MetaData Version v1.1.0

Name	OID	Repeating ?	Type	Category
Pre-treatment	SE.VISIT0	No	Scheduled	PreTreatment
Post-treatment	SE.VISIT1	No	Scheduled	PostTreatment
Study Events				

Back to top

Study Event: Pre-treatment

Forms:

Form Name	Form OID	Order Number	Mandatory ?
Demography	FORM.DEMOG	1	No
Treatment Assignment	FORM.DRUGPHRM	2	No
Pharmacokinetics	FORM.PHARMVIT	3	No
Physical Exam	FORM.VITPHYEX	4	No

For each of the study events (visits) it shows us the forms that are used, and whether these are mandatory or not.

In the same way, one can inspect all defined forms, all defined subforms (ItemGroup's), all defined questions (Items), codelists, method definitions and condition definitions.

Following internal hyperlinks

One has probably already remarked that some pieces of text are underlined and in blue, and maybe even that these correspond to hyperlinks (as our tables are HTML tables).
There will be two types of hyperlinks: internal hyperlinks, i.e. when clicked a jump will be made to a place within the same document, and external hyperlinks, which will pop up a new window with a new document. We will see that for the latter, the hyperlinking can be switched on or off.

When the leaf node “Forms” is clicked, the following is displayed (partial view):

top

Forms - Study 123-456-789 - MetaData Version v1.1.0

Name	OID	Repeating ?
Adverse Events	FORM.AE	No
Concom Meds	FORM.CONMED	No
Demography	FORM.DEMOG	No
Treatment Assignment	FORM.DRUGPHRM	No
Pharmacokinetics	FORM.PHARMVIT	No
Physical Exam	FORM.VITPHYEX	No
Forms		

It gives us a list of the available forms for this study.
Now, if more information about a specific form is wanted, one can either scroll down to the section with the details for that form, or more simply, use the hyperlink to that form. For example, when clicking on “Treatment Assignment”, the system jumps to that table, so that we see:

Search: Next Clear Case Sensitive Whole word

Form: Treatment Assignment

Item Groups:

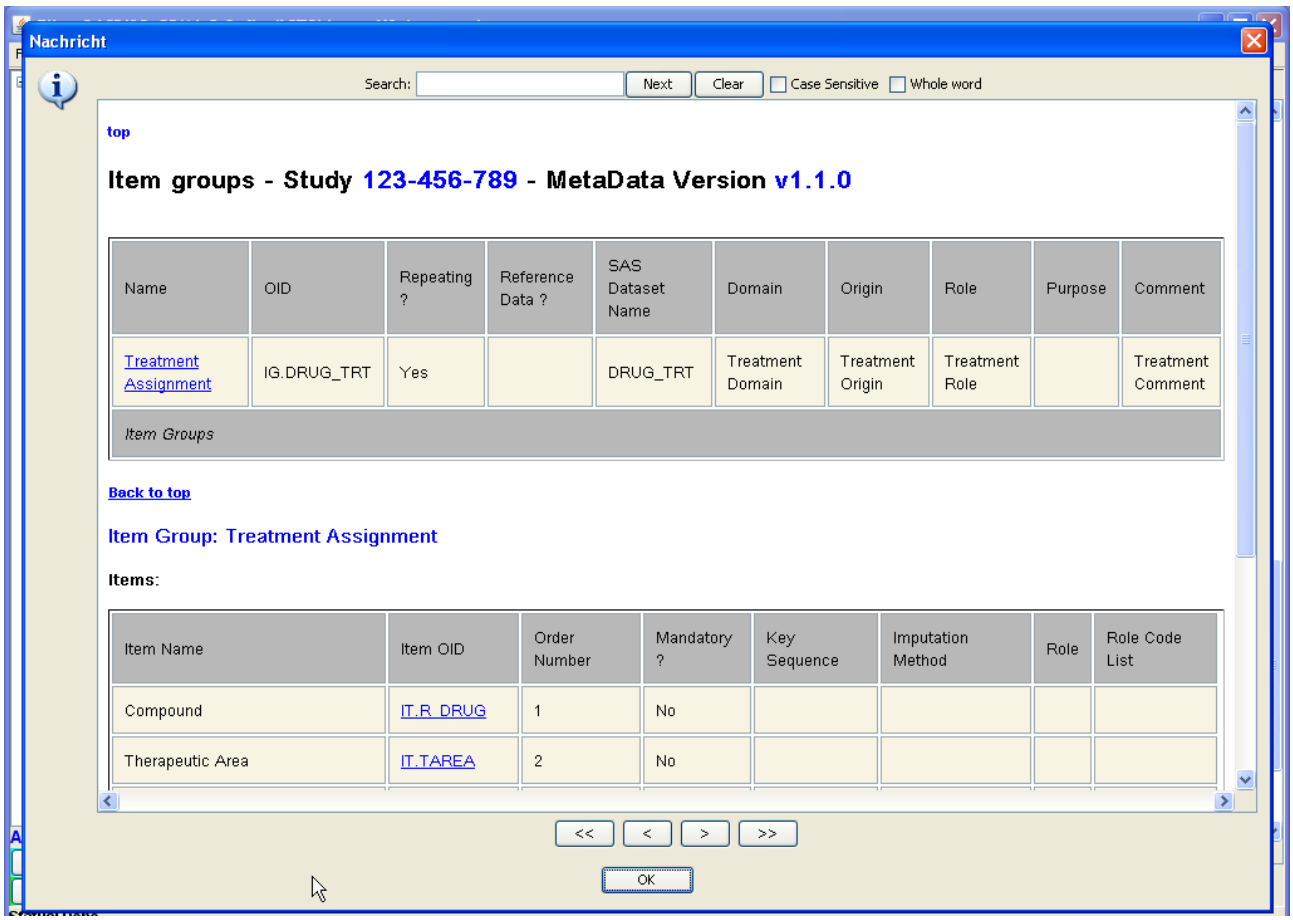
Item Group Name	Item Group OID	Order Number	Mandatory ?
Treatment Assignment	IG.DRUG_TRT	1	No
Item Groups for Form Treatment Assignment			

Back to top

Clicking the link “Back to top” brings us back to the top of the document.

Following external (deep) hyperlinks

The details for the form “Treatment Assignment” shows us that there is only one ItemGroup (subform), and that it is mandatory.
We do also see that there is a hyperlink on “IG.DRUG_TRT” (which is the OID for that ItemGroup). As we do only have a list of Forms here, and not of ItemGroups, this is an external hyperlink, meaning that when it is clicked, a **new window** shows up with the details for that specific ItemGroup.
So, if we click the “IG.DRUG_TRT” link, we obtain (in a new window):



Within this window, we can again follow internal hyperlinks (leading us to specific sections within the document) or follow external hyperlinks (opening new windows).
The new window can be closed by clicking the “OK” button.

Scrolling back to previous positions

When following hyperlinks, it is very handsome to be able to go back to the place from where the hyperlink was followed. In a normal browser (such as IE), this is done by clicking the “Back” button. In IE however, this does not always work correctly. This has been one of the major complaints of FDA reviewers when inspecting CDISC files (like define.xml) for which stylesheets exist.

Our ODM Viewer however has a much more intelligent mechanism to be able to return to a previous “halt” position, whether the last position was obtained by following a hyperlink, or by scrolling.

In the previous image, one sees four buttons near the bottom: there is a “back” button (<), a “forward” button (>), a “first” button “<<”, and a “last” button “>>”.
The “back” button allows to return to the previous scroll position (i.e. where the scrolling was halted the last time). The “forward” button allows to return to a position that was reached before the “back” button was used. Furthermore, the “first” and “last” buttons allow to return to the scrolling positions that was at the beginning (typically the top of the document), and the last position that was reached before a series of “back” actions was performed.

For example, click the “Codelists” leaf node in the tree on the left side of the main window. This gives us a description of all the codelists used in the study:

top

Codelists - Study 123-456-789 - MetaData Version v1.1.0

Name	OID	Data Type	SAS Format Name	External ?
AE Action Taken, Study Drug	CL.AEACTTR	text	AEACTTR	No
AE Action Taken, Other	CL.AECONTR	text	AECONTR	No
AE Outcome	CL.AEOUT	text	AEOUT	No
AE Relationship to Study Drug	CL.AEREL	text	AEREL	No
AE Severity	CL.AESEV	text	AESEV	No
Assigned Study Drug	CL.DRUGTRTF	integer	DRUGTRTF	No
Record Status, Internal	CL.F_STATU	text	F_STATU	No

Now follow the hyperlink for the codelist "Record Status, Internal" and start playing around with the four buttons. Also notice that when manually scrolling (using the mouse), the position where the scrolling is halted is remembered, so that one can go back to it using the "back" button.

Searching within a displayed document

When information is displayed as an HTML document, one can search in that document, by using the "Search" toolbar at the top:

Search: [ ] Next Clear ☐ Case Sensitive ☐ Whole word

We can make the search for a word (or sets of words) case-sensitive, or allow only "whole words". For example, in case we are in the window that displays all codelists, we can search for a codelist that contains gender or sex information. As we do not know whether we need to search for "Gender" or for "Sex", we search for "female":

Search: female Next Clear ☐ Case Sensitive ☐ Whole word

We click the "next" button, and the system jumps to the first occurrence of the word "female" (in this case case-insensitive, as we did not check "Case Sensitive":

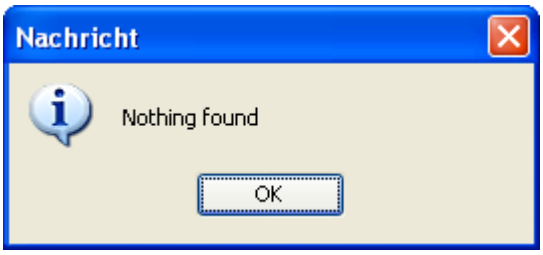
Back to top

CodeList: Gender

Coded Value	Decoded Value and Language
F	Female | Language: en
M	Male | Language: en
Coded values for Codelist Gender	

Back to top

The hit is highlighted (in yellow).
If we click the “next” button again, we obtain a message:



indicating that this was the only occurrence of the word “female” in our document.
The “clear” button can then be used to clear all highlighting, and to return to the top of the document.

Inspecting administrative data

Sofar, we have only inspected study design data (under “Study”).
Similarly, in case the ODM file that we loaded contains a section “AdminData”, we can inspect the administrative data for a specific study, by clicking one of the nodes “Users”, “Locations”, and “Signature defs”

This is for example our (very small, as this is a demo study) list of users:

top

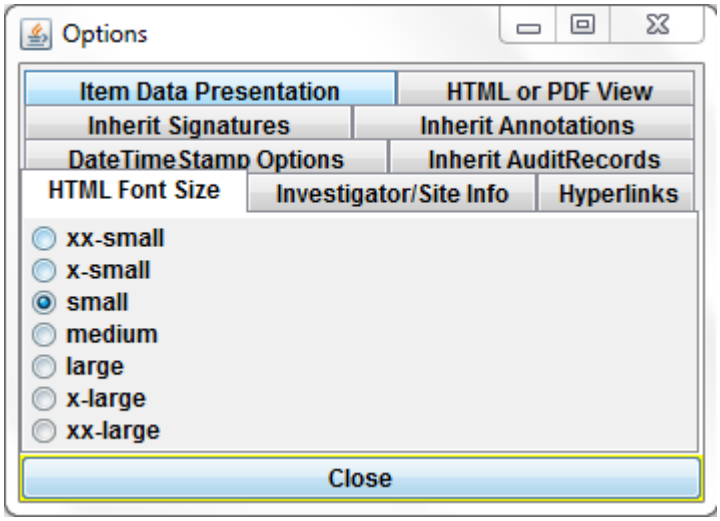
Users - Study 123-456-789

OID	User Type	Login Name	Full Name	First Name	Last Name	Organization	Ad
USR.cdisc001	Other		Shirley Williams	Shirley	Williams	CDISC	
USR.inv001	Investigator		John Smith, M.D.	John	Smith	Roswell Park	
USR.inv002	Investigator		Jane Doe, M.D.	Jane	Doe	Fred Hutchinson	
Users							

Remark that in CDISC ODM, users can be as well investigators, as well as monitors, data management personnel, i.e. any person who can enter or change or monitor data information in the ODM.

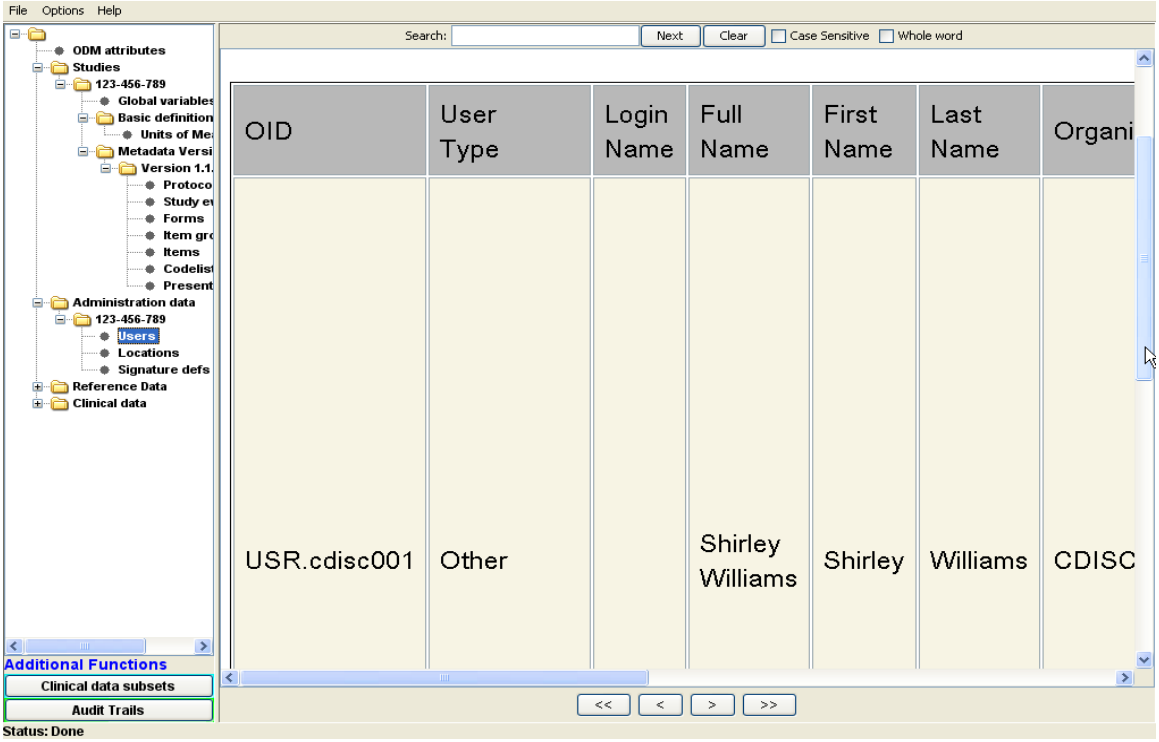
Changing the font size

The ODM Viewer allows to change/set some settings, one being the font size whith which the information is displayed.
In order to do so, use the menu “Options”, followed by “Settings”. A small window, with some tabbed panels is displayed, for example:



The default font size is “small”. People with a visual handicap can e.g. set the font size to “x-large”.

The new settings become valid once the “close” button is clicked. The result after setting the font size to “x-large” is:

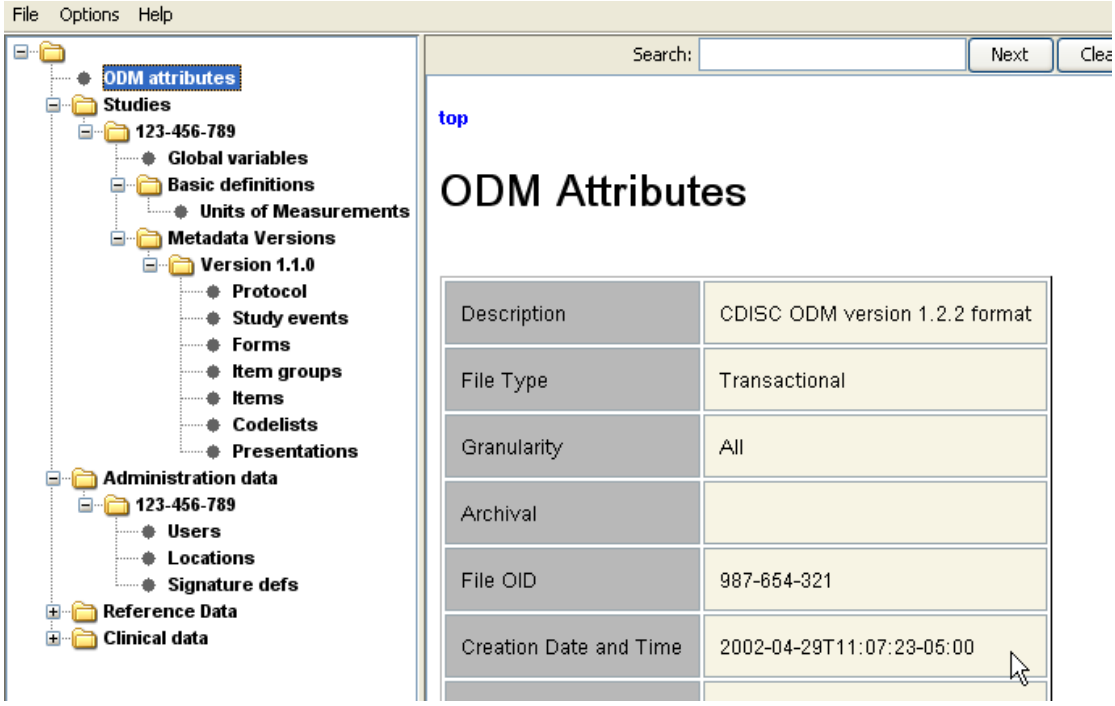


Some other simple options

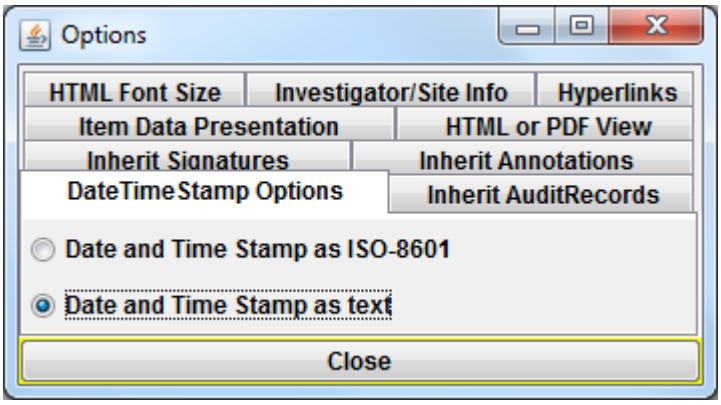
The system has a lot of options, some of them only being of importance when doing advanced work, such as when working with subsets of clinical data, or when working with audit records.

Others are generally applicable, such as the “DateTimeStamp Options”.
The ODM (and XML in general) uses ISO-8601 to store dates, times, and datetimes.
Although ISO-8601 is very easy to learn (and we encourage to do so), some users feel more confortable with inspecting a date- or datetimestamp as plain text.
The tab “DateTimeStamp Options” allows you to switch between the two presentations.

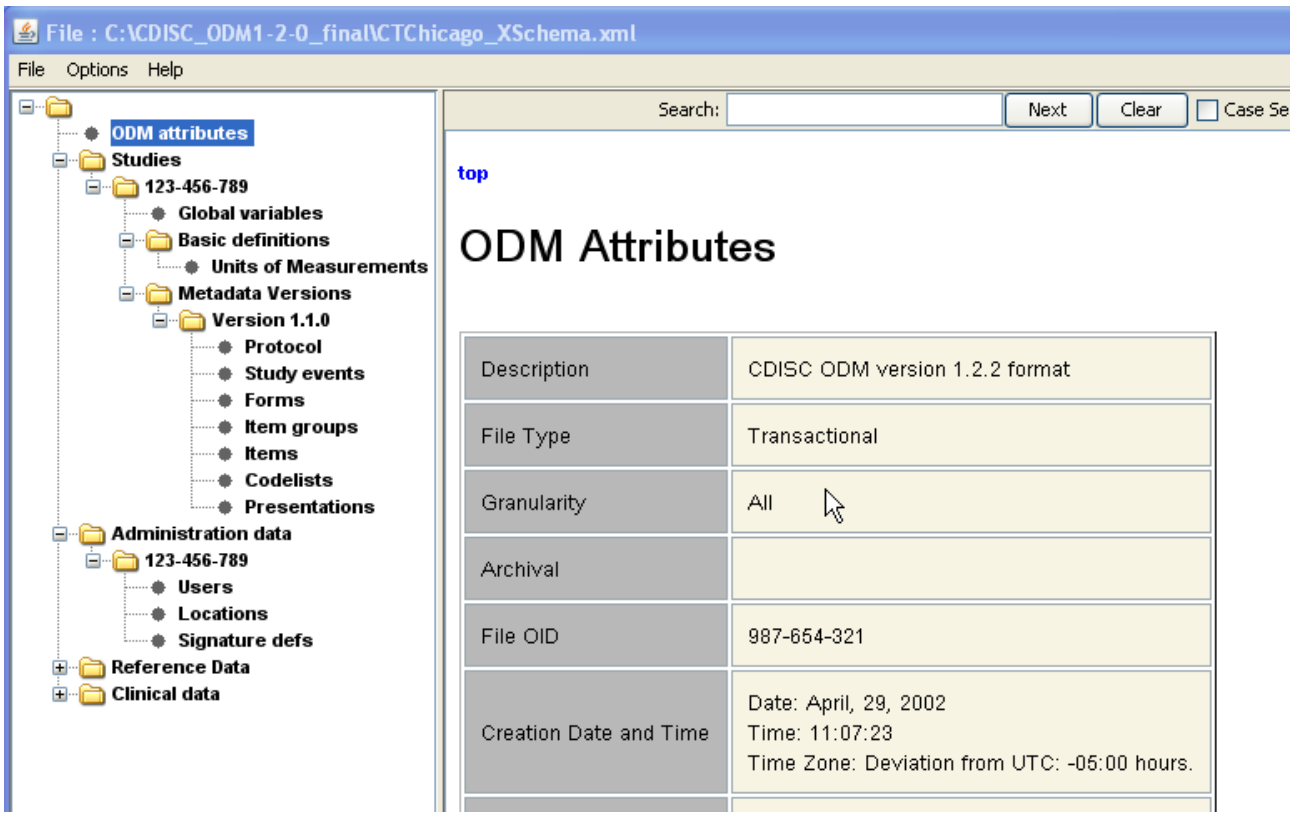
For example, in the tree on the left, click on “ODM Attributes” (near the top). The following is displayed:



One sees that the value of the “Creation Date and Time” of the file is given in ISO-8601 format, as it is given in the ODM file itself.
Using the menu “Options” and going to the tab “DateTimeStamp Options”, and selecting “Date and Time Stamp as text”,



and clicking the “Close” button, the screen is refreshed and the same information is now displayed as:



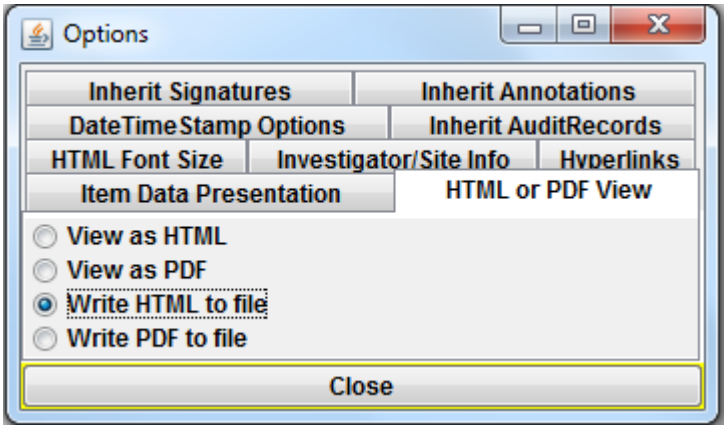
which might be considered as being more human-readable.

Saving the generated HTML

Essentially, everything that is displayed on the right side of the screen is HTML (later we will see that one can also generate PDF). The HTML displayed can be saved to file using the menu "File – Save HTML". A filechooser then pops up, allowing to choose a file location to where the HTML can be written.

Remark that the HTML written to file is essentially XHTML, which has the advantage of being well-formed, well-standardized, and portable between different browsers.

The HTML can also be saved to file by using the menu "Options – Settings" and then selecting the tab "HTML View or PDF View":



When the radiobutton "Write HTML to file" is selected, and the "Close" button is used, a

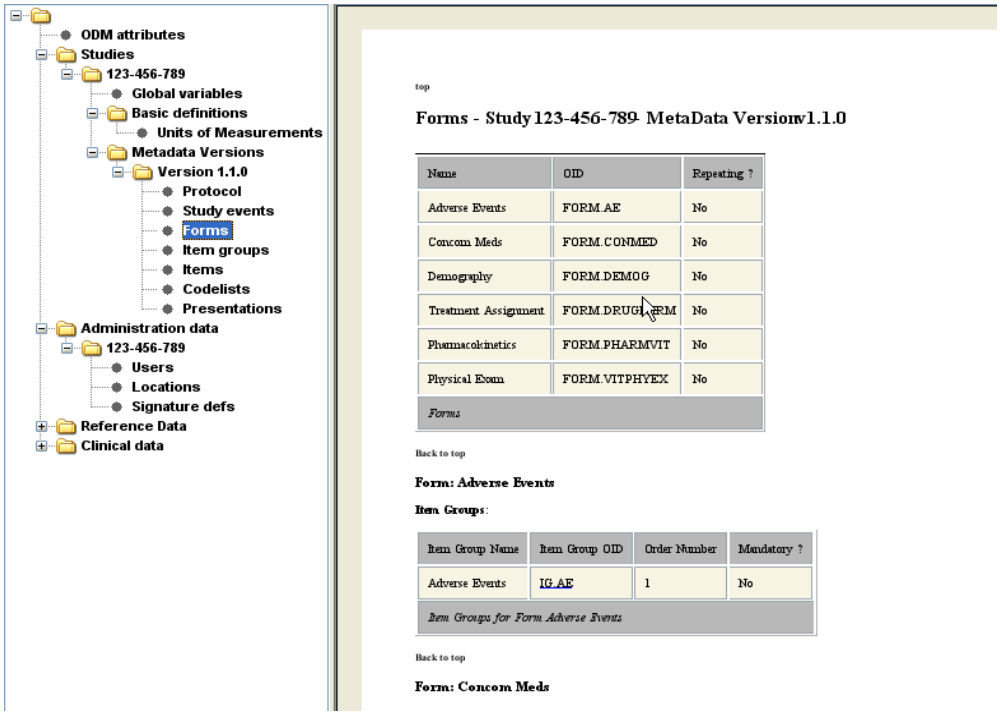
filechooser again pops up allowing to save the HTML to disc.

Generating PDF

Saving the generated HTML file can be very useful for inspecting information from the ODM off-line, or e.g. in reporting. Another way to achieve something similar is to transform the HTML into PDF. This feature has the advantage that PDF can easily be ported and can be printed.
As PDF is essentially a "paper" format (i.e. it has pages), there are however a number of disadvantages:

- tables can be broken over pages
- hyperlinks will not work within the browser (but internal hyperlinks will work when saving to file)
- information that is far on the right and that does not fit on the paper may be lost.

Let us take the view "ODM Attributes" again.
If we use "Options – Settings" and then take the tab "HTML or PDF View" and choose for "PDF View", the result is:



I.e. PDF is generated from the HTML, and is displayed.
Remark that (currently) the hyperlinks in the PDF <u>in the browser</u> will not work[1].

We can now save the generated PDF as a file, either by using the menu "File – Save PDF" (which has become available when switching to PDF) or by using the menu "Options – Settings", then choosing the tab "HTML or PDF View" and then select "Write PDF to File".

The PDF file that is generated has an A4 format with Landscape orientation. The internal hyperlinks will work when displayed in Adobe Acrobat Viewer.

1 This is a feature we are working on for a next version.

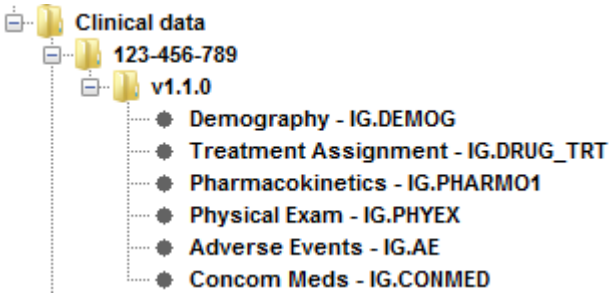
Inspecting clinical information

Let us now inspect some clinical information.

In the ODM Viewer, clinical information is organized per ItemGroup (subform) per MetaDataVersion[2], per Study. This has been done in order to be able to compare clinical information between subjects. So when one fully expands the node “Clinical data” one e.g. obtains:

Listing all the ItemGroups within “MetaDataVersion” “v.1.1.0” within “Study” “123-456-789”.

When at programm startup the option “Show ODM tree using 'Name' + 'OID' attributes” was selected, the tree will look like:



Showing as well the “Name” as the “OID” of each ItemGroup for which there are clinical data.

If we want e.g. to inspect all demographic data, click the “Demography” leaf node. The following is displayed:

2 For a complete description of the concept of MetaDataVersions, please read the ODM specification, which can be downloaded from the CDISC website.

top

Clinical Data - Study 123-456-789
MetaDataVersion v1.1.0
Item Group Demography

Item Group: Demography
Repeat Key: 1
Transaction Type: Insert

SubjectKey: 001
Study Event: Pre-treatment
Form: Demography
Investigator: John Smith, M.D.
Site: Roswell Park

Item OID	Item Name	Item Value	Transaction Type	is null?	Measurement Unit Reference	Audit Record	Signature	Annotations
IT.R_DRUG	Compound	SDP				Yes		
IT.TAREA	Therapeutic Area	Oncology						Yes
IT.PNO	Protocol Number	143-02					Yes	

I.e. for each subject, a single table (as the information has only be captured a single time) is displayed with all information that is within the ODM element “ItemGroupData”. Also here, internal hyperlinks are provided.
If for example, the data point “IT.R_DRUG” (name is “Compound”) has an audit record attached, than this will be marked in the column “Audit Record” and an hyperlink is provided. When clicking it, the system jumps to the audit record details, i.e.:

AuditRecord for Item 'Compound'

User	John Smith, M.D.
Location	Roswell Park
Date and Time Stamp	Date: February, 04, 2002 Time: 14:01:32 Time Zone: Deviation from UTC: -05:00 hours.
Reason for Change	J.A. AuditRecord at ItemData level
Source ID	46902604
Edit Point	
Imputation Method Used ?	

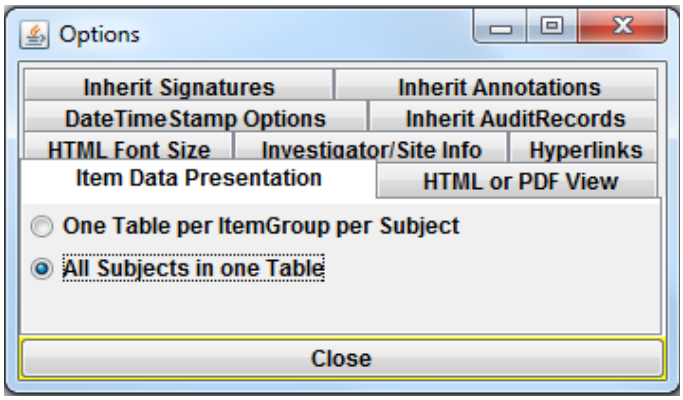
Similarly, one can also see the details of the associated annotations and signatures.

Remark that by default, only audit records, signatures and annotations that have been added at the ItemGroupData and ItemData level are displayed. In order to also see the audit records, signatures and annotations at the FormData, StudyEventData and SubjectData level, one should check the option “AuditRecords ARE inherited” in the “Options” panel called from the “Options” menu (and similarly for signatures and annotations). See the section “Inheritance of AuditRecords, Signatures and Annotations”.

As explained, we have one table per subject for the demographics.
However, it would also be great if we could get one table for all subjects, allowing us to directly compare the demographic data of all subjects.

In order to do so, use the menu “Options – Settings” and select the tab “ItemData Presentation”.
There are two possibilities:

- One table per ItemGroup per Subject
- All Subjects in one table



Select the second option (“All Subjects in one Table”) and click the “Close” button.

The tables are reorganized, and the new view of the same data is now:

top

Clinical Data - Study 123-456-789
MetaDataVersion v1.1.0
Item Group Demography

Subject	StudyEvent (and RepeatKey)	Form (and RepeatKey)	ItemGroup RepeatKey	Transaction Type	Compound	Therapeutic Area	Protocol Number	Country	Record status, 5 levels, internal use
001	Pre-treatment	Demography	1	Insert	SDP	Oncology	143-02	United States	Source verified, queried
002	Pre-treatment	Demography	1	Insert	SDP	Oncology	143-02	United States	Source verified, not queried
003	Pre-treatment	Demography	1	Insert	SDP	Oncology	143-02	United States	Source verified, not queried
									Source

allowing us to directly compare the demographic data between subjects.

The disadvantage of this view on the data however is that it does not show us the “additional” information, such as audit records, annotations, and signatures.

Later we will see how we can inspect the audit records and compare them between subjects, create subsets of audit trails, and even get some simple statistics.

The right side of the table is:

Protocol Number	Country	Record status, 5 levels, internal use	Height	Weight	Gender	Date of Birth	Ethnic Group
143-02	United States	Source verified, queried	73	204 (Pound)	NOT IN CODELIST !	1960-04-03	Caucasian
143-02	United States	Source verified, not queried	64	153 (Pound)	Female	1947-02-14	Black
143-02	United States	Source verified, not queried	65	122 (Pound)	Female	1972-12-01	Asian

There is some interesting information here. For the weight, it is also displayed which units of measurement were used (this information comes from the “MeasurementUnitRef” element that is under “ItemData”), as in the study design, it was described that the weight could either be captured as pounds or as kilograms.
Also have a look at the first row, column “Gender”. It says “NOT IN CODELIST !).
The reason is that an invalid coded value was given in the ODM export from the database. So this means there is a data management issue here.

Now, click the leaf node “Physical Exam” in the tree on the left side of the screen. This is a pretty large table, as the physical examination has been repeated several times during a visit (it is a “repeating” ItemGroup), and has been executed in every visit. The results is:

Clinical Data - Study 123-456-789
MetaDataVersion v1.1.0
Item Group Physical Exam

Subject	StudyEvent (and RepeatKey)	Form (and RepeatKey)	ItemGroup RepeatKey	Transaction Type	Compound	Therapeutic Area	Protocol Number	Country	Record status, 5 levels, internal use	Physical Exam Body System	Norr Don
001	Pre-treatment	Physical Exam	1	Insert	SDP	Oncology	143-02	United States	Source verified, queried	Head, Neck and Thyroid	Norr
001	Pre-treatment	Physical Exam	2	Insert	SDP	Oncology	143-02	United States	Source verified, queried	Eyes, Ears, Nose and Throat	Norr
001	Pre-treatment	Physical Exam	3	Insert	SDP	Oncology	143-02	United States	Source verified, queried	Chest	Norr
001	Pre-treatment	Physical Exam	4	Insert	SDP	Oncology	143-02	United States	Source verified, queried	Lungs	Abn
001	Pre-treatment	Physical Exam	5	Insert	SDP	Oncology	143-02	United States	Source verified, queried	Heart	Abn
001	Pre-treatment	Physical	6	Insert	SDP	Oncology	143-02	United	Source verified,	Lymph Nodes	Abn

with the right part of the table being:

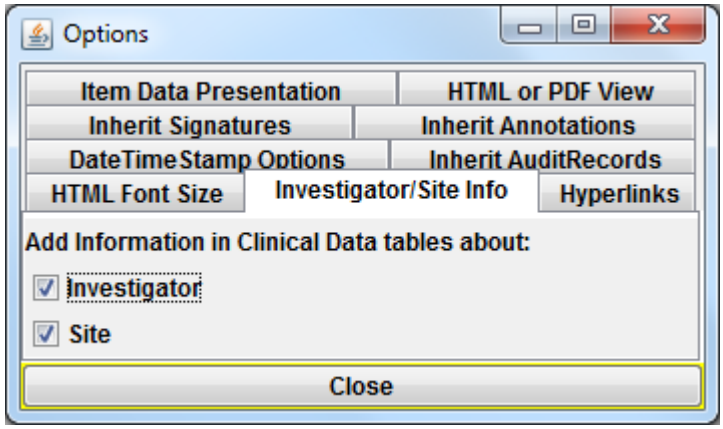
ion	Compound	Therapeutic Area	Protocol Number	Country	Record status, 5 levels, internal use	Physical Exam Body System	Normal/Abnormal/Not Done	Comment	*Investigator*	*Site*
	SDP	Oncology	143-02	United States	Source verified, queried	Head, Neck and Thyroid	Normal		*John Smith, M.D.*	*Roswell Park*
	SDP	Oncology	143-02	United States	Source verified, queried	Eyes, Ears, Nose and Throat	Normal		*John Smith, M.D.*	*Roswell Park*
	SDP	Oncology	143-02	United States	Source verified, queried	Chest	Normal		*John Smith, M.D.*	*Roswell Park*
	SDP	Oncology	143-02	United States	Source verified, queried	Lungs	Abnormal	MILD WHEEZING	*John Smith, M.D.*	*Roswell Park*
	SDP	Oncology	143-02	United States	Source verified, queried	Heart	Abnormal	TACHYCARDIA	*John Smith, M.D.*	*Roswell Park*
	SDP	Oncology	143-02	United	Source verified,	Lymph Nodes	Abnormal	SLIGHTLY	*John*	*Roswell*

One sees that in the last two columns, also the investigator and site information is given (from the "SiteRef" and "InvestigatorRef" elements that come under "SubjectData").

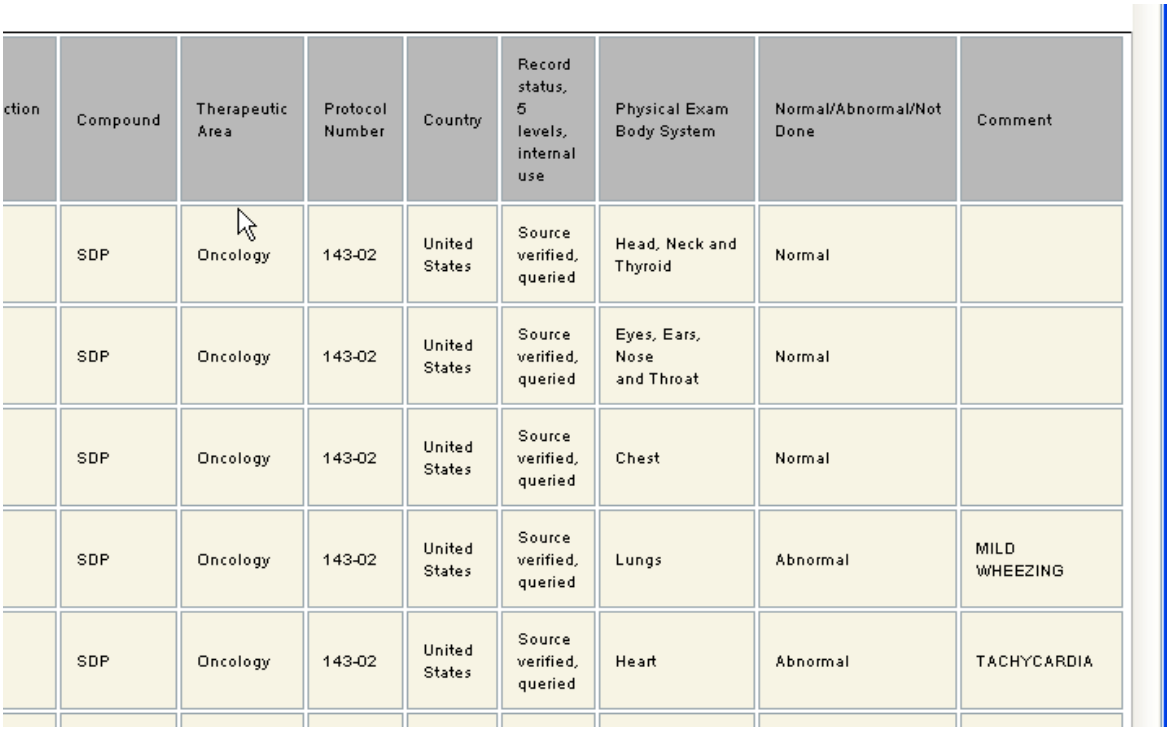
Some people now prefer <u>not</u> to see this site and investigator information, so there is an option to

hide it.

Use the menu “Options – Settings” and select the tab “Investigator/Site Info”:



Unchecking the boxes “Investigator” and “Site” allows us to hide the information in the tables. For example, if we uncheck both, the right side of our table becomes:

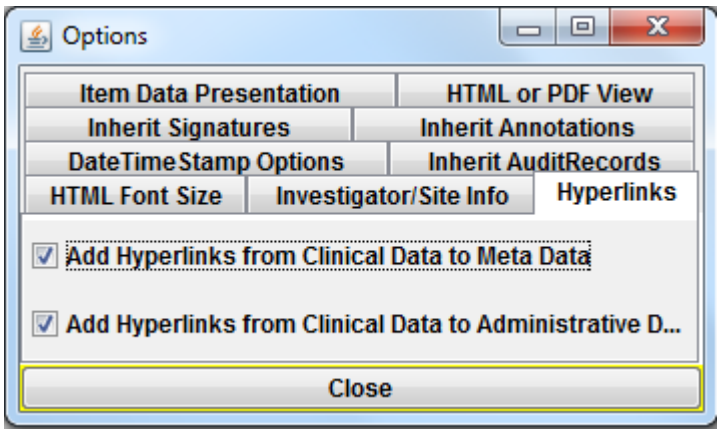


ction	Compound	Therapeutic Area	Protocol Number	Country	Record status, 5 levels, internal use	Physical Exam Body System	Normal/Abnormal/Not Done	Comment
	SDP	Oncology	143-02	United States	Source verified, queried	Head, Neck and Thyroid	Normal	
	SDP	Oncology	143-02	United States	Source verified, queried	Eyes, Ears, Nose and Throat	Normal	
	SDP	Oncology	143-02	United States	Source verified, queried	Chest	Normal	
	SDP	Oncology	143-02	United States	Source verified, queried	Lungs	Abnormal	MILD WHEEZING
	SDP	Oncology	143-02	United States	Source verified, queried	Heart	Abnormal	TACHYCARDIA

Obtaining meta-information of clinical data

Often, when inspecting data points, we would like to see the meta-information of that data point again. For example, when inspecting the demographic data, we would like to know how exactly the data point for “Weight” was defined.

In order to obtain meta-information for clinical data, we need to change an optional setting.
Use the menu “Options – Settings” and select the tab “Hyperlinks”:



There are two checkboxes: one for adding hyperlinks from clinical data to metadata, and one for adding hyperlinks from clinical data to administrative data. The former allows to link to information about the definitions of forms, questions, codelists etc. from within tables with clinical data. The latter allows to add hyperlinks to base data of investigators, auditors, sites, and other locations.
If we do check both checkboxes (setting them to "true"), and then click the "Close" button, the window with the tables refreshes and we get:

Country	Record status, 5 levels, internal use	Height	Weight	Gender	Date of Birth	Ethnic Group	Height Units	Weight Units	Investigator	Site
United States	Source verified, queried	73	204 (Pound)	NOT IN CODELIST !	1960-04-03	Caucasian	in	lb	John Smith, M.D.	Roswell Park
United States	Source verified, not queried	64	153 (Pound)	Female	1947-02-14	Black	in	lb	John Smith, M.D.	Roswell Park
United States	Source verified, not queried	65	122 (Pound)	Female	1972-12-01	Asian	in	lb	John Smith, M.D.	Roswell Park
United States	Source verified, not queried	69	185 (Pound)	Male	1948-06-19	Caucasian	in	lb	John Smith, M.D.	Roswell Park
United States	Source verified, not queried	71	244 (Pound)	Male	1963-08-20	Black	in	lb	John Smith, M.D.	Roswell Park

Suddenly (although the table data are the same), a large number of hyperlinks are added. For example, when we now click on the "Weight" column heading, a new window pops up, giving us all metadata information about the definition of the data item "Weight":

top

Items - Study 123-456-789 - MetaData Version v1.1.0

Name	OID	Data Type	Length	Significant Digits	SAS Field Name	SDS Variable Name	Origin	Comment	Code List
Weight	IT.WT	float	4		WT				
Items									

Back to top

Item: Weight

Measurement Units:

Measurement Unit
Pound
Kilogram

In the main window, of we click on the "Pound" cell data, a new window pops up with the definition of the unit of measurement "Pound".

Similarly, if we want to know more background information about the investigator "John Smith" we click the hyperlink, and a new window pops up with the information:

top

Users - Study 123-456-789

OID	User Type	Login Name	Full Name	First Name	Last Name	Organization
USR.inv001	Investigator		John Smith, M.D.	John	Smith	Roswell Park
Users						

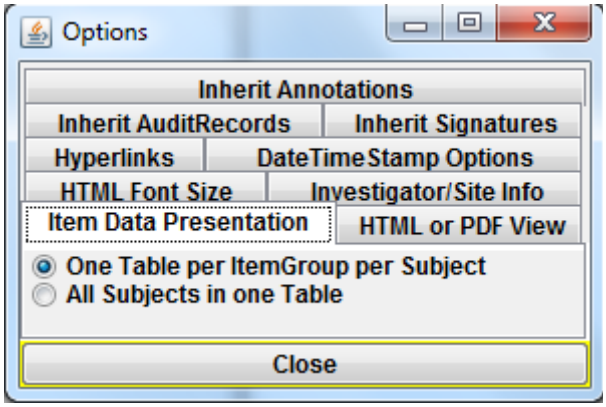
Back to top

So, with the hyperlinking for clinical data on, we can obtain a lot of meta information about the information. This of course only works when such meta information is available in the same file. If it is not, clicking the link will not lead to any action.

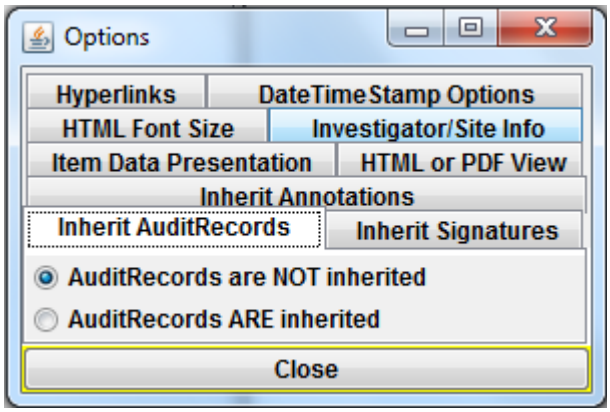
Inheritance of AuditRecords, Signatures and Annotations

When inspecting data points in the "One table per ItemGroup per Subject" mode, only the audit records, signatures and annotations that have been added at the "ItemGroupData" and "ItemData" will be displayed by default. This has been done to avoid that an overwhelming amount of information is displayed on the screen.

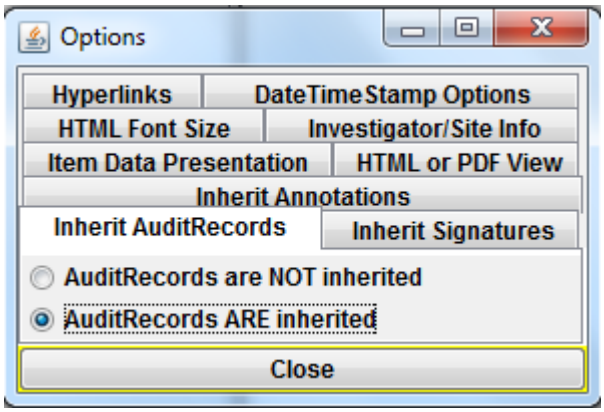
If one also would like to see audit information that has been added at the "SubjectData", "StudyEventData" and "FormData" level in the ODM file, and that can be regarded as being "inherited", one should set this using the "Options - Settings" menu:



One also sees that there is a tab “Inherit AuditRecords”. When selected, one gets:



The default is “AuditRecords are NOT inherited”. Now select “AuditRecords ARE inherited”:



and click the “Close” button.

One then gets e.g. for “Demographics”:

Back to top

Audit Record for this Item Group:

User	John Smith, M.D.
Location	Roswell Park
Date and Time Stamp	3002-02-04T14:01:32-05:00
Reason for Change	J.A. AuditRecord at ItemGroupData level
Source ID	46902604
Edit Point	
Imputation Method Used ?	

Back to top

Audit Record for this Item Group inherited from SubjectData:

User	John Smith, M.D.
Location	Roswell Park
Date and Time Stamp	3002-02-04T14:01:32-05:00

with the second part also displaying audit information “inherited” from higher levels such as “SubjectData”, “StudyEventData” and “FormData”.

Similarly, one can use the menu “Options – Settings” followed by checking the item “Signatures ARE inherited” to also display signatures “inherited” from higher levels. For example for “Demographics”:

IT.HTUNITS	Height Units	in			
IT.WTUNITS	Weight Units	lb			
Item Group Demography					

Back to top

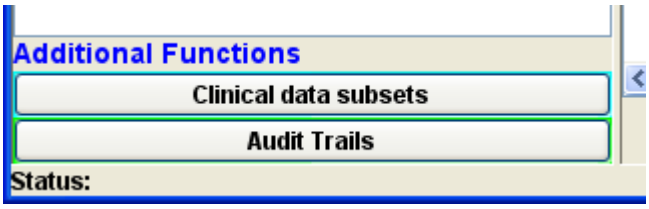
Signature for this Item Group inherited from SubjectData:

User	Shirley Williams
Location	CDISC Headquarters
Signature Reference	Methodology: Electronic Meaning: Signature Meaning Legal Reason: Legal Reason
Date and Time Stamp	2002-02-04T14:01:32-05:00
Cryptographic Binding Manifest (Deprecated in ODM 1.2)	

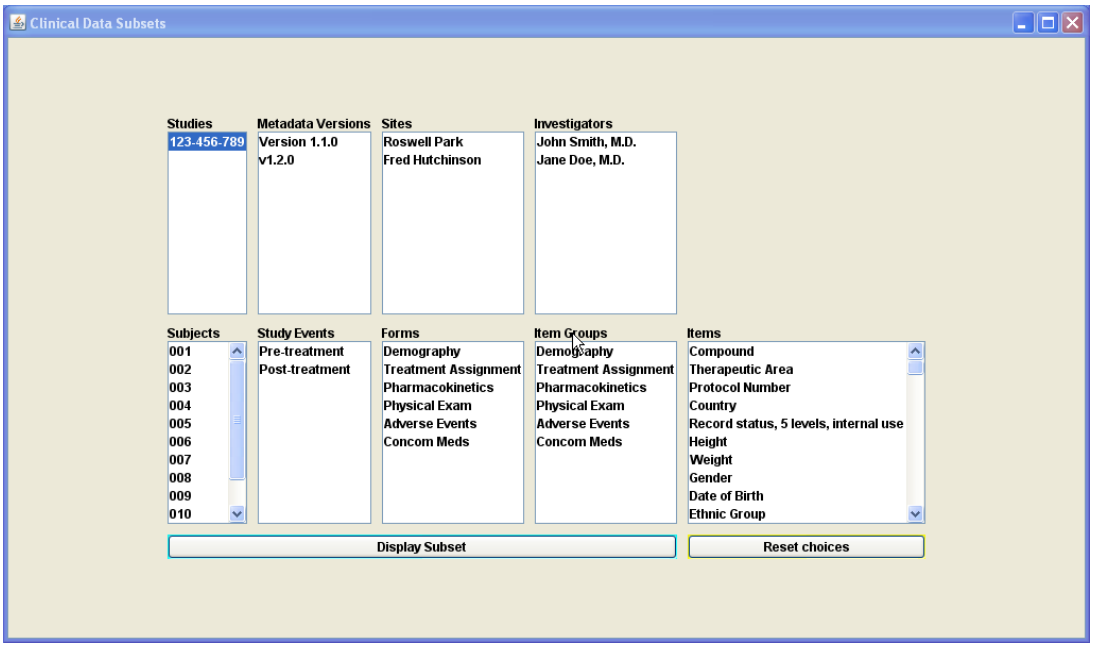
Similarly, one can set “Annotations ARE inherited” using the menu “Options – Settings” to also display “inherited” annotations.

Generating and inspecting clinical data subsets

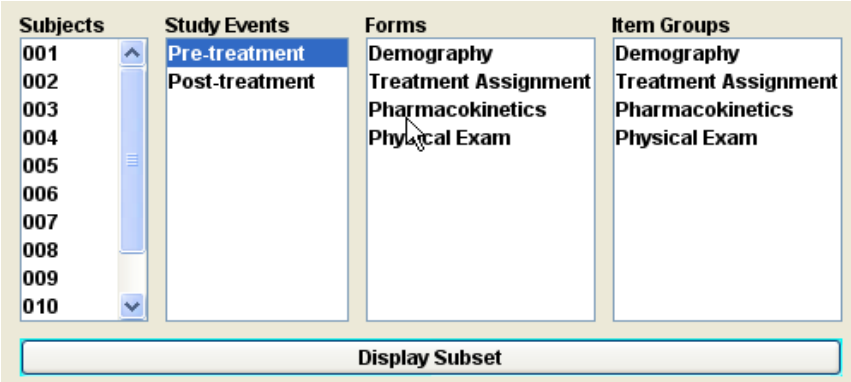
One can also easily create and inspect subsets of clinical data. To do so, use the button “Clinical data subsets” which can be found at the left down side of the main screen.



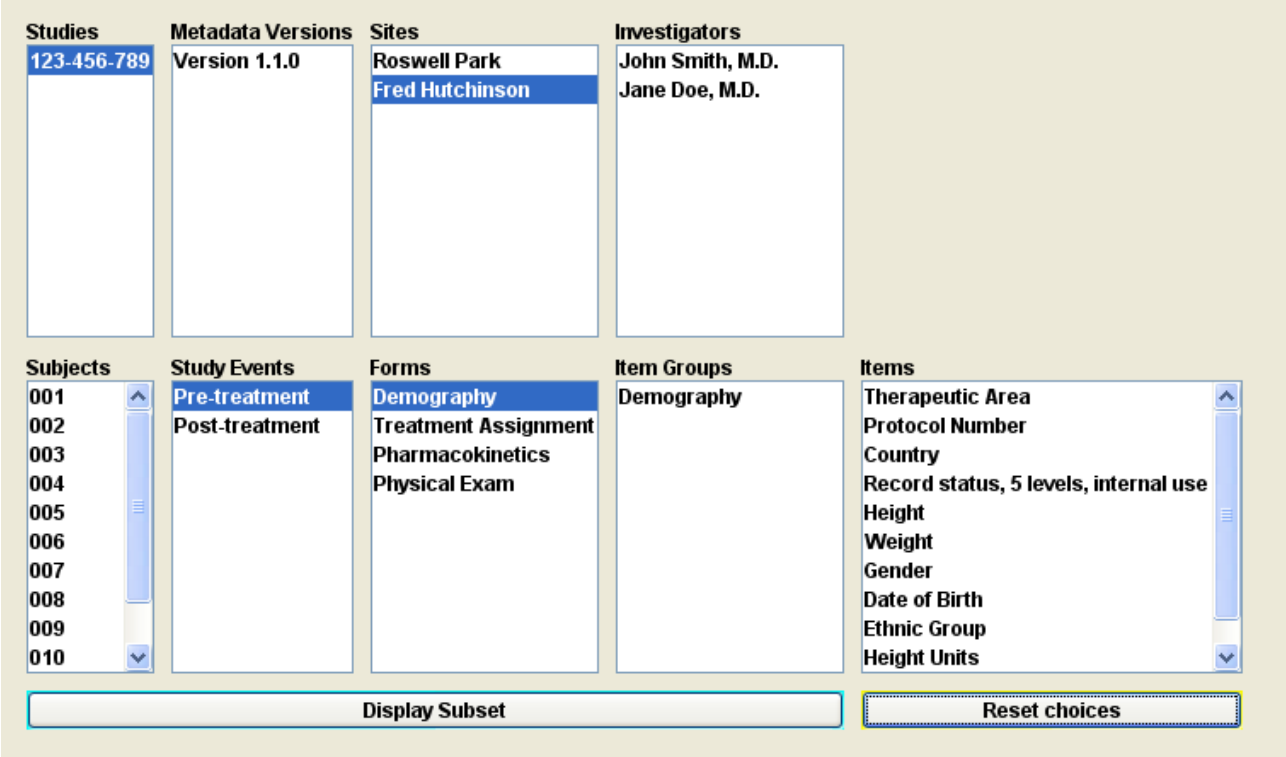
When clicked, the system makes an inventory of all studies, subjects, visits, investigators, sites, etc.. During the inventarisation, the main screen will display the message “Collecting Data”. For large files, this step can take some time, but do not worry, it only needs to be done once.
After that, a new window pops up.



If there is more than one study in the file, the first one will automatically be selected. The user can then select for which version of the metadata the clinical data will need to be displayed, for which sites and investigators, for which subjects, for which visits, etc..
It is important to notice that selecting nothing in a list is the same as selecting everything, so for example, you do not select any subjects from the “Subjects” list, this means “all subjects”.
In order to avoid obtaining empty datasets, some intelligence has been build in. For example, when clicking a specific Study Event (visit), the fields become disabled for a few moments, and after that, <u>only</u> those forms used in that specific visit are displayed in the list of visits.
For example (you can compare with the previous image), when “Pre-treatment” is clicked, the list of forms is updated to:

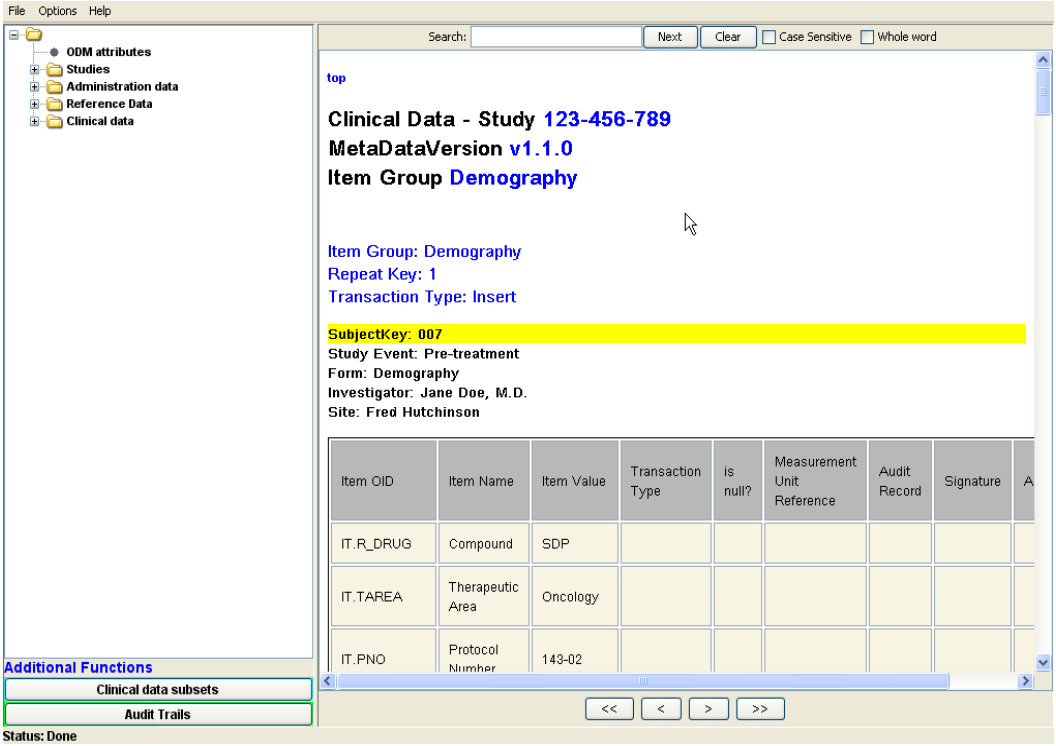


Similarly, if a single form is selected, the list of Item Groups and of Items is automatically updated. Please note that using the “Ctrl” and “Shift” buttons, you can select several entries in a list at the same time.
Suppose we are only interested in the Demographic data of all subjects from Site “Fred Hutchinson”. The following selection then applies:

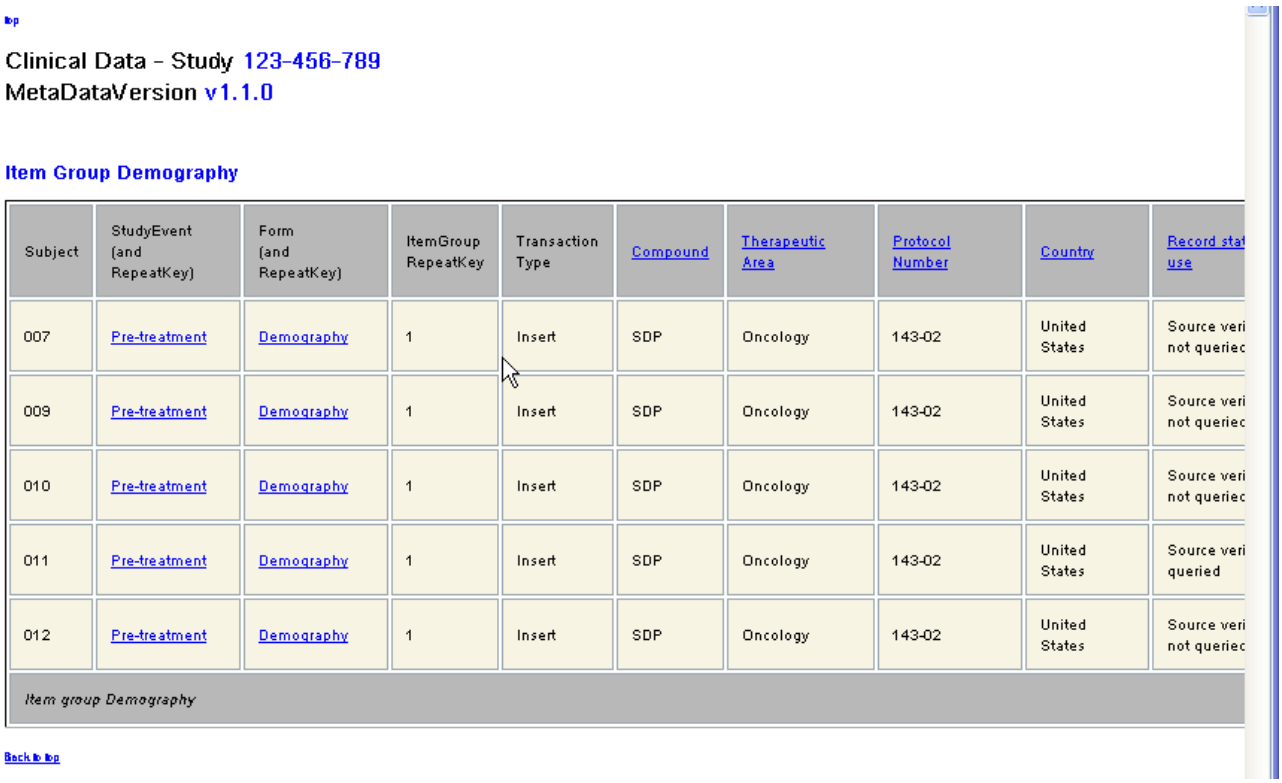


If we are interested in certain data points only, we can even filter further by selecting the items of interest in the “Items” list.

The “Display” subset then excecutes the selection, and the tables are generated and displayed.



One sees that the first subject for this site is “007”.
Also here, we can change the way the tables are displayed, the occurrence of hyperlinks to the metadata, the generation of PDF, etc., by using the “Options – Settings” menu. For example, if we want to more easily compare over subjects, and want hyperlinks to metadata and administrative data, the result after changing these settings is:

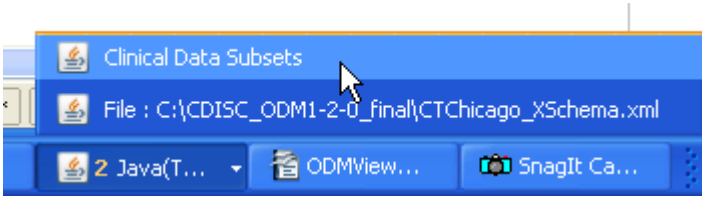


and the right side of the screen:

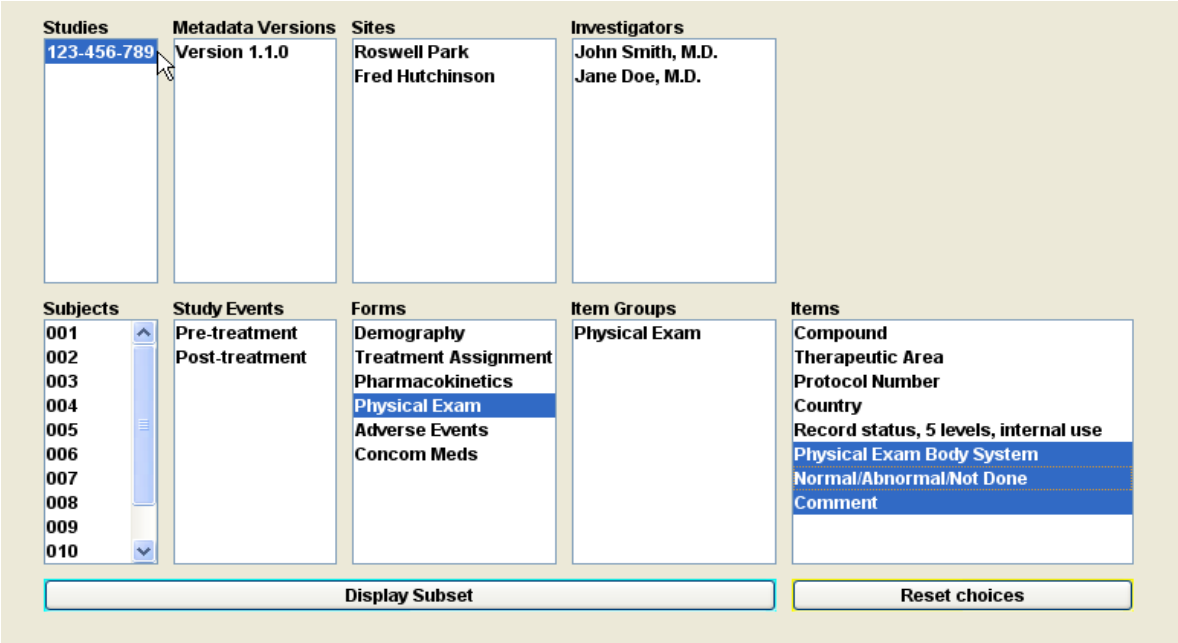
d status, 5 levels, internal	Height	Weight	Gender	Date of Birth	Ethnic Group	Height Units	Weight Units	Investigator	Site
e verified, ieried	72	168	Male	1970-08-09	Caucasian	in	lb	Jane Doe, M.D.	Fred Hutchinson
e verified, ieried	66	171	Male	1954-11-16	Caucasian	in	lb	Jane Doe, M.D.	Fred Hutchinson
e verified, ieried	69	163	Male	1958-09-17	Caucasian	in	lb	Jane Doe, M.D.	Fred Hutchinson
e verified, ed	61	114	Female	1966-11-11	Latino	in	lb	Jane Doe, M.D.	Fred Hutchinson
e verified, ieried	66	193	Female	1949-03-24	Caucasian	in	lb	Jane Doe, M.D.	Fred Hutchinson

The hyperlinked text (in blue, and underlined) can then again be used to obtain meta information about the selection.

We can e.g. do the same for the “physical exam” data. Just select the window with “Clinical Data Subsets” again,



and make a new selection, e.g.



selecting only the data from “Physical Exam” forms in all visits and for all subjects, but only the information on the items “Body System”, “Normal/Abnormal/..” and “Comment”. The result after clicking the “Display Subset” button is (incomplete):

010	Pre-treatment	Physical Exam	9	Insert	Genitalia	Normal		Ja M.
010	Post-treatment	Physical Exam	9	Insert	Genitalia	Normal		Ja M.
011	Pre-treatment	Physical Exam	9	Insert	Genitalia	Normal		Ja M.
012	Pre-treatment	Physical Exam	9	Insert	Genitalia	Normal		Ja M.
012	Post-treatment	Physical Exam	9	Insert	Genitalia	Normal		Ja M.
001	Pre-treatment	Physical Exam	10	Insert	Skin	Abnormal	PET	Jo Sm
002	Pre-treatment	Physical Exam	10	Insert	Skin	Abnormal	PETECHIA	Jo Sm
003	Pre-treatment	Physical Exam	10	Insert	Skin	Abnormal	PETECHIA	Jo Sm
003	Post-treatment	Physical Exam	10	Insert	Skin	Normal		Jo Sm
004	Pre-treatment	Physical Exam	10	Insert	Skin	Abnormal	PETECHIA	Jo Sm

Of course we can also inspect all physical exam data for a single subject, by selecting that subject only in the "Subjects" list. The result is:

Search: Next Clear Case Sensitive Whole word

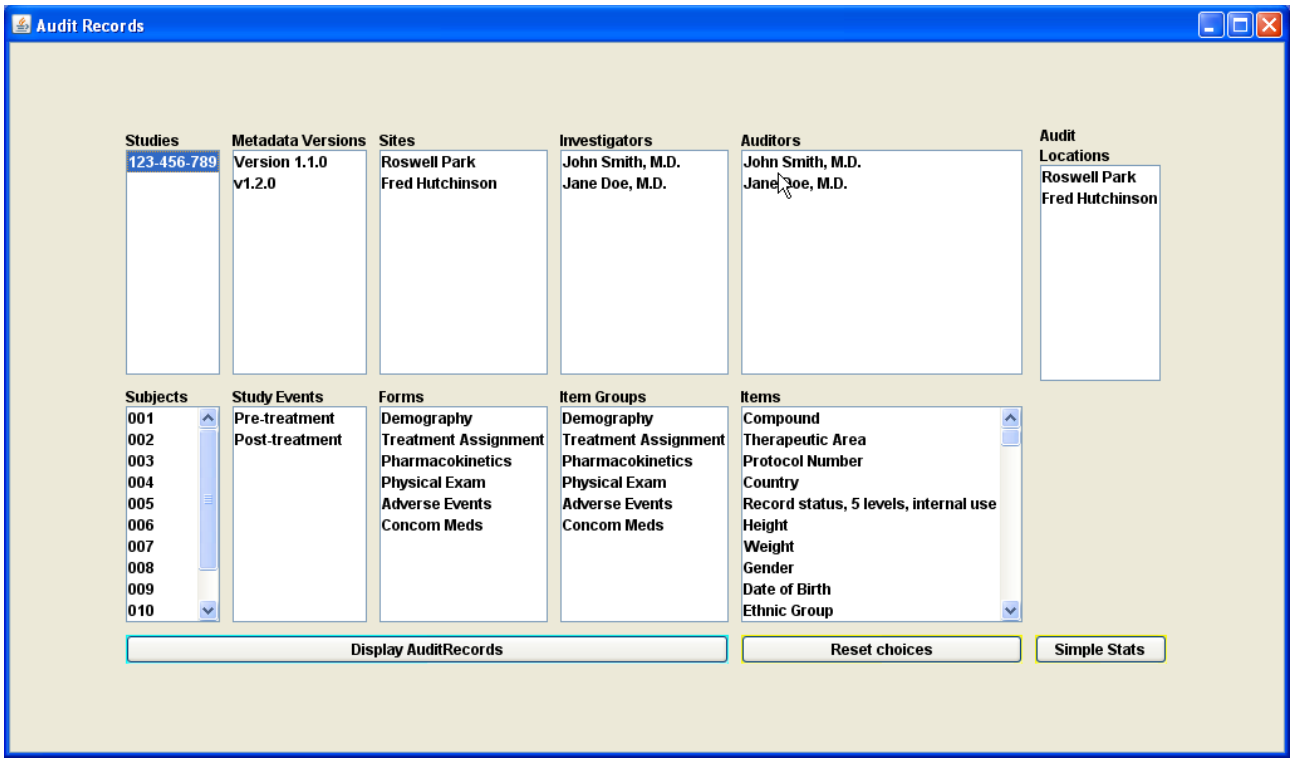
Subject	StudyEvent (and RepeatKey)	Form (and RepeatKey)	ItemGroup RepeatKey	Transaction Type	Physical Exam Body System	Normal/Abnormal/Not Done	Comment	Inve
001	Pre-treatment	Physical Exam	1	Insert	Head, Neck and Thyroid	Normal		Joh Smi
001	Pre-treatment	Physical Exam	2	Insert	Eyes, Ears, Nose and Throat	Normal		Joh Smi
001	Pre-treatment	Physical Exam	3	Insert	Chest	Normal		Joh Smi
001	Pre-treatment	Physical Exam	4	Insert	Lungs	Abnormal	MILD WHEEZING	Joh Smi
001	Pre-treatment	Physical Exam	5	Insert	Heart	Abnormal	TACHYCARDIA	Joh Smi
001	Pre-treatment	Physical Exam	6	Insert	Lymph Nodes	Abnormal	SLIGHTLY ENLARGED-NCS	Joh Smi
001	Pre-treatment	Physical Exam	7	Insert	Abdomen	Normal		Joh Smi
001	Pre-treatment	Physical Exam	8	Insert	Anorectal	Not Done		Joh Smi
001	Pre-treatment	Physical Exam	9	Insert	Genitalia	Normal		Joh Smi
001	Pre-treatment	Physical Exam	10	Insert	Skin	Abnormal	PET	Joh Smi

and again do searches, e.g. on the word “Abnormal”

001	Pre-treatment	Physical Exam	3	Insert	Chest	Normal	
001	Pre-treatment	Physical Exam	4	Insert	Lungs	Abnormal	MILD WHEEZING
001	Pre-treatment	Physical Exam	5	Insert	Heart	Abnormal	TACHYCARDIA
001	Pre-treatment	Physical Exam	6	Insert	Lymph Nodes	Abnormal	SLIGHTLY ENLARGED-NCS
001	Pre-treatment	Physical Exam	7	Insert	Abdomen	Normal	
001	Pre-treatment	Physical Exam	8	Insert	Anorectal	Not Done	
001	Pre-treatment	Physical Exam	9	Insert	Genitalia	Normal	
001	Pre-treatment	Physical Exam	10	Insert	Skin	Abnormal	PET
001	Pre-treatment	Physical Exam	11	Insert	Musculoskeletal	Normal	

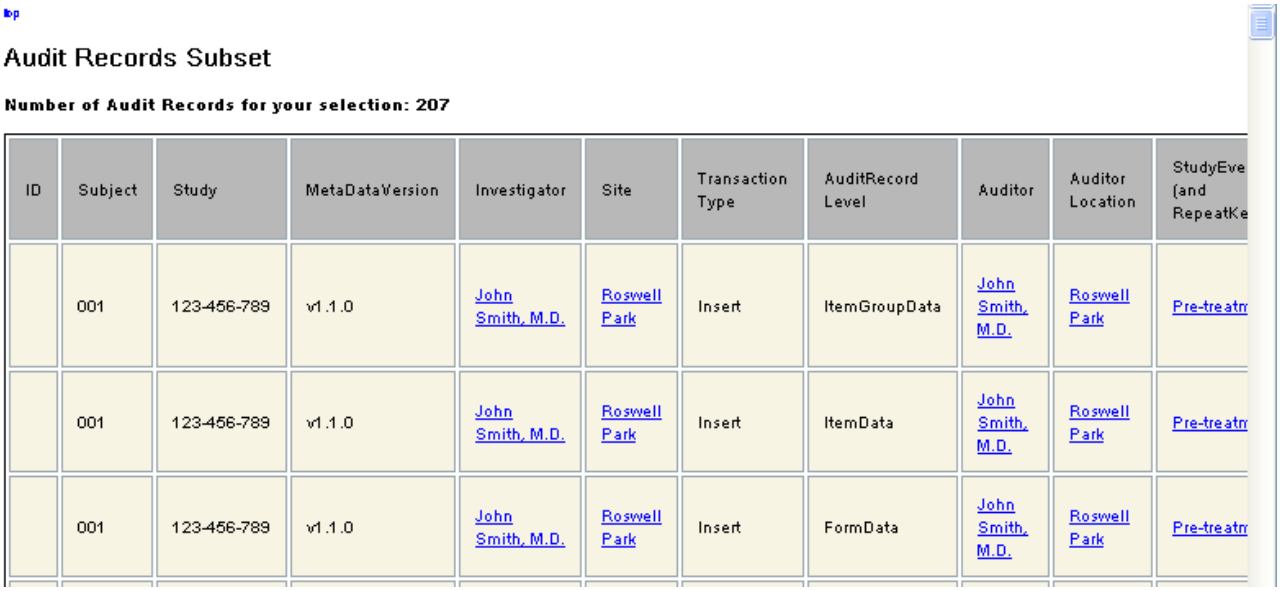
Inspecting audit records

Similarly to creating subsets of clinical data, one can also create subsets of audit records (or inspect them all). In order to do so, use the button “Audit Trails” in left bottom corner.
Again, an inventarisation is made, and soon, a selection screen similar to that for clinical data subsets pops up:



The panel has some extra lists: “Auditors” and “Audit Locations”. These contain the names of those persons (not necessarily investigators) that have added audit records to the system, and their locations (not necessarily sites).

Let us quickly look which audit records have been produced by <u>any</u> auditor, but for data points that come from investigator “John Smith”. The only selection we need to make is in the list for Investigators. The result is obtained after clicking the “Display AuditRecords” button.



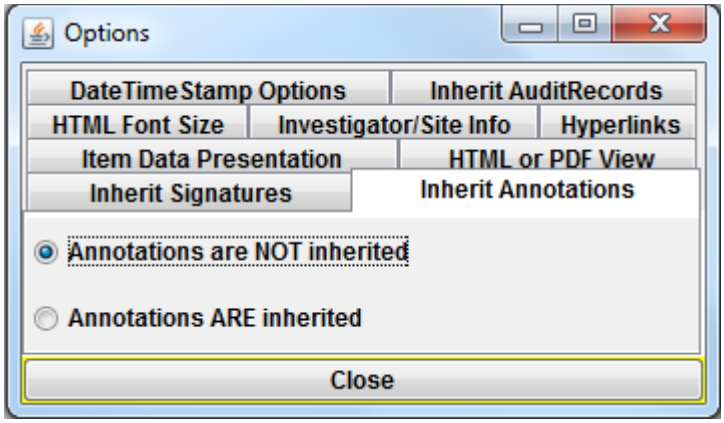
Audit Records Subset

Number of Audit Records for your selection: 207

ID	Subject	Study	MetaDataVersion	Investigator	Site	Transaction Type	AuditRecord Level	Auditor	Auditor Location	StudyEve (and RepeatKe
	001	123-456-789	v1.1.0	John Smith, M.D.	Roswell Park	Insert	ItemGroupData	John Smith, M.D.	Roswell Park	Pre-treatm
	001	123-456-789	v1.1.0	John Smith, M.D.	Roswell Park	Insert	ItemData	John Smith, M.D.	Roswell Park	Pre-treatm
	001	123-456-789	v1.1.0	John Smith, M.D.	Roswell Park	Insert	FormData	John Smith, M.D.	Roswell Park	Pre-treatm

We see that most of the audit records have been created by the investigator himself, at “Insert” time[3]. Others have been added by “Jane Doe”, a fellow Investigator.
As we still have the “hyperlinking to administrative data” on, we can click on the name of the auditor and get all available information about that person.

We see that there is also a column “AuditRecord Level”, for which we can find one of the following values: “SubjectData”, “StudyEventData”, “FormData”, “ItemGroupData” or “ItemData”.
The reason is that audit records can be added at any of these levels, so it is useful information. Somehow, this information does not always show us exactly which data points are involved. For example, if the audit record was added at the “ItemGroup” of “Form” level, no information is shown about exactly which data points the audit record is applicable to.
The reason is that audit records are “inherited”, i.e. if an audit record is available at the FormData level, all underlying “ItemGroupData” “inherit” the audit record, and there, all underlying “ItemData” also “inherit” that audit record.
By default, audit record inheritance is switched off, but one can switch it on using the menu “Options – Settings” and then selecting the tab “Inherit Auditrecords”:



If we change the setting to “AuditRecords ARE inherited”, we notice that the window “Audit Records” disappears. In order to work with the new setting, we need to click the button “Audit Trails” again (as the inventory must be recalculated). Creating a subset for investigator “John Smith” now generates considerably more audit records and we get the following table:

3 I presume this is not very usual

Audit Records Subset

Number of Audit Records for your selection: 264

ID	Subject	Study	MetaDataVersion	Investigator	Site	Transaction Type	AuditRecord Level	Auditor	Auditor Location	StudyEvent (and RepeatKey)	Form (and
	001	123-456-789	v1.1.0	John Smith, M.D.	Roswell Park	Insert	ItemGroupData	John Smith, M.D.	Roswell Park	Pre-treatment	Demo
	001	123-456-789	v1.1.0	John Smith, M.D.	Roswell Park	Insert	ItemData	John Smith, M.D.	Roswell Park	Pre-treatment	Demo
	001	123-456-789	v1.1.0	John Smith, M.D.	Roswell Park	Insert	INHERITED	John Smith, M.D.	Roswell Park	Pre-treatment	Demo
	001	123-456-789	v1.1.0	John Smith, M.D.	Roswell Park	Insert	INHERITED	John Smith, M.D.	Roswell Park	Pre-treatment	Demo
	001	123-456-789	v1.1.0	John Smith, M.D.	Roswell Park	Insert	INHERITED	John Smith, M.D.	Roswell Park	Pre-treatment	Demo

Notice the third to fifth entry where the “AuditRecord Level” says “INHERITED”. When we look at the right side of the table,

tion	AuditRecord Level	Auditor	Auditor Location	StudyEvent (and RepeatKey)	Form (and RepeatKey)	ItemGroup (and RepeatKey)	Item	Item Value	Date and T
	ItemGroupData	John Smith, M.D.	Roswell Park	Pre-treatment	Demography	Demography (1)	Text		3002-02-04
	ItemData	John Smith, M.D.	Roswell Park	Pre-treatment	Demography	Demography (1)	Compound	SDP	2002-02-04
	INHERITED	John Smith, M.D.	Roswell Park	Pre-treatment	Demography	Demography (1)	Compound	SDP	3002-02-04
	INHERITED	John Smith, M.D.	Roswell Park	Pre-treatment	Demography	Demography (1)	Therapeutic Area	ONC	3002-02-04
	INHERITED	John Smith, M.D.	Roswell Park	Pre-treatment	Demography	Demography (1)	Protocol Number	143-02	3002-02-04

we see that there is no “Item Value” for the first row, as the audit record was given at the “ItemGroupData” level. The third to fifth row however exactly show the data points that were comprised in that “ItemGroupData” and thus have inherited the audit record.

Audit record simple statistics

Using the window with selections for audit records, we can also obtain some simple statistics. For example, we would like to know for which investigator the most audit records were created, and for which of the data points.
Let us however first switch to "AuditRecords" are not inherited again.
When we now, without making any selections in the "AuditRecords" panel, click the button "Simple Stats", we obtain the following tables:

Simple Statistics for (selected) Audit Records

Audit Record counts by ItemData point

Total number of Audit Records: 329

ItemData point	Name	Count	Percentage
IT.ABNORM	Normal/Abnormal/Not Done	222	67.48
IT.COMMT1	Comment	51	15.50
IT.DRUG_TRT	Assigned Study Drug Treatment	14	4.26
IT.AE_RELAT	Check If Taken for AE	14	4.26
IT.WTUNITS	Weight Units	13	3.95
IT.MEALTIM	Time of last meal	11	3.34
IT.AECONTRT	Actions taken, other	2	0.61
IT.REF2	Text	1	0.30
IT.R_DRUG	Compound	1	0.30

Audit Record counts by Subject

Total number of Audit Records: 329

Subject	Count	Percentage
005	72	21.88
003	30	9.12
004	30	9.12
009	30	9.12
010	30	9.12
012	30	9.12
001	23	6.99
008	18	5.47
002	17	5.17
006	17	5.17
011	17	5.17

Audit Record counts by Investigator

Total number of Audit Records: 329

Investigator	Name	Count	Percentage
USR.inv001	John Smith, M.D.	207	62.92
USR.inv002	Jane Doe, M.D.	122	37.08

Audit Record counts by Site

Total number of Audit Records: 329

Site	Name	Count	Percentage
LOC.site002	Roswell Park	207	62.92
LOC.site001	Fred Hutchinson	122	37.08

Audit Record counts by Auditor (User)

Total number of Audit Records: 329

Auditor (User)	Name	Count	Percentage
USR.inv001	John Smith, M.D.	189	57.45
USR.inv002	Jane Doe, M.D.	140	42.55

Audit Record counts by Auditor Location

Total number of Audit Records: 329

Auditor Location	Name	Count	Percentage
LOC.site002	Roswell Park	189	57.45
LOC.site001	Fred Hutchinson	140	42.55

Of course, if we had swiched on "Hyperlinks to metadata" and "Hyperlinks to Administrative Data", we could immediately get more metainformation, for example for the last two tables:

Audit Record counts by Auditor (User)

Total number of Audit Records: 329

Auditor (User)	Name	Count	Percentage
USR.inv001	John Smith, M.D.	189	57.45
USR.inv002	Jane Doe, M.D.	140	42.55

Audit Record counts by Auditor Location

Total number of Audit Records: 329

Auditor Location	Name	Count	Percentage
LOC.site002	Roswell Park	189	57.45
LOC.site001	Fred Hutchinson	140	42.55

Please remark that when doing simple statistics, this is always within the scope of the current selection. So if you choose one investigator only from the list of the investigators, you will of course see that 100% of the auditrecords come from data points from that investigator.

Also remark that when you have “Inherit Auditrecords” ON, this changes the statistics.