5.4.2 OpenClinica eCRF Specifications

OpenClinica provides a template to users for CRF design. This section explains each of the fields in the template and how those fields are either dependent or independent of each other. Best practices are provided as well as some examples of how the CRF Template can be used effectively.

Definitions and acronyms

- CRF Case Report Form, created in OpenClinica by uploading a CRF definition based on the CRF Template Excel file.
- Dynamics Skip Patterns/Skip Logic created using Rules and based on variables in the CRF template.
- Group - A mechanism for logically associating items within a CRF. Items within the same group may repeat together within a CRF.
- Item A variable within a CRF.
- OIDs Object Identifiers uniquely identify a study object such as a CRF, CRF Version, Item Group, or Item and are used to link objects to one another. OIDs for a given class of object are unique within an instance of OpenClinica, with the exception of Rule OIDs, which are only guaranteed to be unique within a study.
- Rules OpenClinicas mechanism to carry out cross form or cross field edit checks, skip logic and inserting data across CRFs. Rules are declared in XML and executed by the OpenClinica Rules Engine. Rules are declared external to the CRF Template but dependent on the variables defined in one or more CRFs.
- SCD Simple Conditional Display. A way of defining skip logic within the CRF Template, without the use of Rules.
- Section A mechanism for organizing items within a CRF for layout purposes. All items in a given section appear on the same page in a CRF. Multiple sections are displayed as tabs within the CRF.
- Tokens A means of displaying a Study Object value for use in a URL (e.g. in a parameterized link) or for use in other scripts (e.g. jquery). Tokens can also be used in Left Item Text, Right Item Text, Header, and/or Subheader to pass item values. The supported tokens are:

  ${studySubject} - Passes the current Subject ID

  ${studySubjectOID} - Passes the OID for the current Subject

  ${studyName} - Passes the current Study Name

  ${eventName} - Passes the current Event Name

  ${eventOrdinal} - For repeating Events, passes the Event repeat number (e.g., 2 for the second repeat)

  ${crfName} - Passes the CRF Name

  ${crfVersion} - Passes the CRF Version

  ${item[item_name]} - Passes the Item value

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Not valid unless obtained from the OpenClinica document management system on the day of use.

5.4.2.1 CRF Template - General Constraints

The OpenClinica CRF Template can only be edited and saved as a Microsoft Excel 2003.xls file. OpenOffice spreadsheets and later versions of Microsoft Excel can not be used reliably and may not be successful when uploaded to OpenClinica version 3.1.X.

The CRF Template is used to define the CRF on a client machine with MS Excel. Once the required information has been provided in the template, it must be uploaded to OpenClinica through the Add CRF page. Only certain privileged users are allowed access to this page.

During the upload process, a validation of the CRF design is performed. Errors that are caught at this stage will trigger messages to the user informing him of the error and changes necessary to fix the error.

5.4.2.2 Scope of CRFs and Items

A CRF (with its associated versions, groups, and items) is defined globally within an instance of OpenClinica and may be used in one or more studies. The groups and items defined within a particular CRF exist within the scope of the CRF only (though they will have globally unique OIDs). The CRF Physical Exam may have an item with ITEM_NAME blood_pressure and the CRF Vital Signs can have an item also named blood_pressure. OpenClinica treats these items as separate entities and they will have separate OIDs. Response sets also exist within the scope of the CRF only.

A CRF definition may be shared across OpenClinica instances by loading the CRF template spreadsheet into each instance. Each instance of OpenClinica generates OIDs at CRF upload time and those OIDs must be unique within that instance. Therefore the OIDs for the same CRF and items may be different across OpenClinica instances.

5.4.2.3 CRF Versioning

OpenClinica supports multiple CRF versions being in use at the same time. To create a new version, a user must keep the CRF_NAME field the same as the original, but update the CRF_VERSION field with a new value. This new version is uploaded by selecting the Create New CRF Version icon instead of adding a CRF through the Build Study module. The user does have the ability to overwrite a CRF Version if needed, however the CRF Version cannot have been assigned or used in any event definitions prior to the attempt to remove it.

When a new CRF Version is added, any item with the same ITEM_NAME as an item in a previous version of the CRF is treated as the same variable and will have the same OID, DESCRIPTION, and DATA_TYPE. The value of ITEM_NAME is case-sensitive, so items with ITEM_NAMEs 'ItemA' and 'itema' will be considered as different items by OpenClinica.

For Enterprise customers interested in using Datamart:

Please note that Datamart treats items in case-insensitive manner. Please make all ITEM_NAMES case-insensitive if you plan to use Datamart. Special characters and Postgres reserved words should not be used as item names.

New items that did not exist in prior CRF versions will be added and an appropriate OID generated.

Item metadata vs Item form metadata

Items in a CRF have two types of attributes. Item metadata attributes describe core intrinsic properties of the item. These properties are independent of the CRF Version and cannot change across CRF Versions. These properties include:

ITEM_NAME

DESCRIPTION

DATA_TYPE

GROUP_LABEL

Response Sets (see discussion below)

The properties ITEM_NAME, DATA_TYPE, and RESPONSE_LABEL cannot be changed after the CRF is created.

Item form metadata attributes describe the items representation or behavior on a CRF and may have a different value in each version of a CRF. Most of the attributes in the Items Worksheet in the CRF Template fall into this category.

Response sets

The item properties beginning with RESPONSE_ on the Items worksheet together define a response set in a CRF. The response set is a coded list of allowable values for the item. The response set is given a name (RESPONSE_LABEL) that allows it to be re-used within the CRF if desired, and the set itself is made up of a list of coded values (RESPONSE_VALUES_OR_CALCULATIONS) with corresponding text labels (RESPONSE_OPTIONS_TEXT). Each item in the list of coded values should meet the constraints defined by the item DATA_TYPE and WIDTH_DECIMAL.

Response sets are intended for use in items that utilize a form input control (INPUT_TYPE) that allows the user to select from a constrained list.

* Note that the RESPONSE_VALUES_OR_CALCULATIONS attribute can also be used in a separate context to create calculated/derived items.

Versioning of response sets should not change the mapping RESPONSE_OPTIONS_TEXT -

RESPONSE_VALUES_OR_CALCULATIONS, but it can delete or add new (_OPTIONS_TEXT - RESPONSE_VALUES_OR_CALCULATIONS) pair to existing set of values. For example, an item is a single-select and its RESPONSE_OPTIONS_TEXT defined as Absent,Mild,Moderate,Severe,Life-threatening while

RESPONSE_VALUES_OR_CALCULATIONS defined as 1,2,3,4,5. In another version of CRF it is possible to drop or add several values, but you cannot redefine mapping by setting Absent to have value other than 1.

5.4.2.4 CRF Template Properties

The CRF Template contains five worksheets. Four of the worksheets are intended for input by the user creating the CRF while the fifth worksheet provides instructions about each of the fields of the Template. When a user selects a cell in a column, a tooltip will popup explaining whether the field is Required or not, and other useful instructive text to help the user understand what the field is for.

In some cases HTML elements like Bold (<b>), Italics (<i>), Line Breaks (<br>), etc. can be used. In the cases where HTML elements are supported, they are designated as such in CRF Template Elements.

In OpenClinica 3.3, Tokens, were introduced. These are available for use in Left or Right Item Text, Header, or Subheader. They can be used to display the Study Object value for use in a URL (as in a Parameterized Link) or for use in other scripts (e.g., jquery). The supported tokens are:

${studySubject}

${studyName}

${eventName}

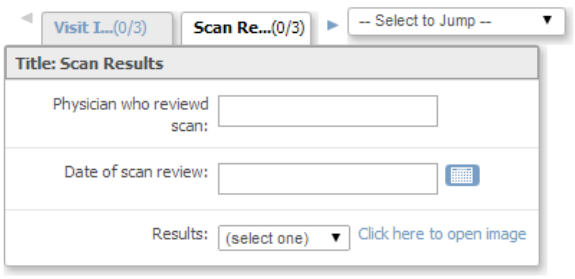
${eventOrdinal}

${crfName}

${crfVersion}

${item[item_name]}

Following is an example of a CRF that passes these tokens to a URL to bring up an image:



When the user clicks on the "Click here to open image" link, based on the following Right Item Text the CRF template, the imaging system (in this case www.example.com) is accessed and passes the

values for studyName, eventName, crfName, and the SCAN_DATE item for the current Study, Event, and CRF.

Right Item Text:

Click here to open image

5.4.2.5 CRF Template Elements

Definitions, restrictions and when to use the OpenClinica CRF Template Elements

- CRF Worksheet
- Sections Worksheet
- Groups Worksheet
- Items Worksheet

OpenClinica CRF Design Template v3.5
This worksheet contains important additional information, tips, and best practices to help you better design your OpenClinica CRFs.

Note:
Each CRF version should be defined in its own Excel file.

Worksheet	Field	Required	Field Description and Instructions	Can vary by CRF Version	Restrictions	When to use	Allowable Values
CRF			This worksheet should have no more than one row				
	CRF_NAME	Yes	Defines the name of the CRF as it will be displayed in the OpenClinica user interface. When a user is assigning CRFs to an event definition, they will be viewing this name. A user performing data entry will identify the form by this name. Best Practice: Include a short study identifier as part of your CRF name so that it is unique within your database instance. The first 12 characters of your CRF_NAME should be unique.	No	Alpha-numeric characters are allowed 255 characters max UNIQUE	If the field is blank, the CRF will be rejected at upload time.	Text
	VERSION	Yes, but does not display in Participate forms	Defines the version of the CRF as it will be displayed in the OpenClinica user interface. You cannot reuse a version number for the same CRF that has already been assigned to an Event Definition. If a particular CRF version has not been used in an Event Definition, you may overwrite the CRF version.	Yes	Alpha-numeric characters are allowed 255 characters max UNIQUE	If this is a new version of a CRF that already exists, the CRF_NAME must match the CRF_NAME of the pre-existing CRF in OpenClinica. A new version of a CRF would be needed due to a protocol change, adding or removing an Item from a CRF, or changing some of the questions.	Text
	VERSION_DESCRIPTION	Yes	This field is used for informational purposes to keep track of what this version of the CRF was created for.	Yes	Alpha-numeric characters are allowed 4000 characters max NOT UNIQUE	This information appears as part of the CRF Metadata when the user clicks on View (original). This information is not displayed during data entry.	Text
	REVISION_NOTES	Yes	This field is used to keep track of the revisions you made to this particular CRF.	Yes	Alpha-numeric characters are allowed 255 characters max	This information appears as part of the CRF Metadata when the user clicks on View (original). This information is not displayed during data entry. If this is the first version of the CRF, you can simply state this is a brand new form. Going forward, as you make changes and update the versions you can provide information on what is different between the first version and each subsequent version.	Text
Sections							
	SECTION_LABEL	Yes, but does not display in Participate form.	Must be unique in the worksheet and contain no spaces. The SECTION_LABEL is referenced in the Items Worksheet to associate Items with the appropriate section of the CRF. When the CRF is accessed for data entry, each Section will be a page. The Items defined with the corresponding SECTION_LABEL will be shown on that single page. This field is not displayed as part of the CRF but can be seen on the CRF Metadata page.	No (added or removed only)	No spaces 255 characters max UNIQUE	This value will be used in the Items Worksheet to define where the Items will appear during data entry. A CRF must have at least one Section.	Alphanumeric text, no spaces
	SECTION_TITLE	Yes, but does not display in Participate form.	The value in this field will be displayed at the top of each page when a user is performing data entry, as well as in the tabs and drop down list used to navigate between Sections in a CRF. It does not have to be unique but should be a readable value that makes sense to people entering data. An example would be 'Inclusion Criteria'	Yes	All characters allowed 2000 characters max	This field must be used at all times. If a CRF does not have a value for SECTION_TITLE the form will be rejected at upload time. Long Section Titles may not display well.	Text
	SUBTITLE	No	A sub-title shown under the Section title.	Yes	All characters allowed 2000 characters max	HTML elements are supported for this field.	Text
	INSTRUCTIONS	No	Instructions at the top of the Section (under the subtitle) that explains to the data entry person what to do on this section of the form.	Yes	All characters allowed 2000 characters max	HTML elements are supported for this field. This field should be used if there are particular data entry instructions that should be conveyed or followed to users.	Text
	PAGE_NUMBER	No	Note: Page_Number is a feature that will not be available in future versions of OpenClinica and should not be used. The page number on which the section begins. If using paper source documents and have a multi-page CRF, put in the printed page number.	Yes	All characters allowed 5 characters max	OpenClinica version 3.3 and above: Do not use. OpenClinica versions prior to 3.3: For the most part, this field is only used in studies collecting data on multi-page paper forms and then having the data keyed in at a central location performing double data entry.	Text
	PARENT_SECTION	No	Note: Parent_Section is a feature that will not be available in future versions of OpenClinica and should not be used. Sections can be sub-sections of ones that have been previously defined. Provide the parent section for this sub-section in this field.	Yes	255 characters max Must equal a valid SECTION_TITLE	OpenClinica version 3.3 and above: Do not use. OpenClinica versions prior to 3.3: This field does not have any effect in the User Interface. It does not affect data being exported. This will be deprecated after version 3.1.3.	Text
Groups							
	GROUP_LABEL	Yes	Must be unique in the worksheet and contain no spaces. GROUP_LABEL is referenced in the Items Worksheet to associate Items with the appropriate Item group in the CRF. The GROUP_LABEL value will be used to generate the GROUP OID to be used in Rules, Data Import, and Export. The field is not displayed as part of the CRF but can be seen on the CRF Metadata page. Best Practice: Each Item on the CRF should be associated with a Group_Label. The first five characters of Group_Label should be unique within your database instance.	No (added or removed only)	Alpha-numeric No spaces 255 characters max UNIQUE	This field should be used in order to logically group Items together. Item Groups may be used to define repeating Items in the CRF, or for logical grouping of NON-REPEATING Items for easier data analysis once data has been exported from OpenClinica. If you don't provide a Group_Label, all Items in the CRF will be part of a single group called UNGROUPED. This is not recommended.	Text
	GROUP_LAYOUT	Yes	REQUIRED. GRID formats associated Items into a table and allows rows to be added as needed. NON-REPEATING puts Items into a named, logical grouping (useful for Show/Hide functionality). Defines the type of Item Group (GRID or NON-REPEATING). If left blank will default to NON-REPEATING. A layout of GRID means the Items defined as part of the Item Group will be displayed in a table where each Item is represented as a column, and users can add rows of data to the table as needed during data entry. In Participate, Grids do not display as tables but allow Participants to add repeating records as needed. When viewed in OpenClinica these records will display as a table. If NON-REPEATING is chosen, the fields will be logically grouped together in the CRF metadata, but cannot repeat, and are displayed using the standard OpenClinica CRF layout. Logically associating Items as a NON-REPEATING Group can be used with Rules to implement show and hide logic.	Yes	GRID, NON-REPEATING (Blank)	This field should be used to define the Item Groups as GRID (repeating) or NON-REPEATING. NON-REPEATING: Item Groups can span multiple Sections of the CRF. Grouping is not a positional limitation but rather a logical association of Items. GRID: Item Groups must appear in the same Section and must be placed together in the Items Worksheet. Definition of a repeating Item Group activates the use of the attributes GROUP_HEADER, GROUP_REPEAT_NUMBER and GROUP_REPEAT_MAX.	GRID, NON-REPEATING, Blank
	GROUP_HEADER	No, If used, will not be displayed in Participate.	The value is displayed above the GRID when a user is performing data entry. Used only when the GROUP_LAYOUT is equal to GRID.	Yes	All characters allowed 255 characters max	Only use when the layout is set to GRID. This value is like a title for the group. An example of a GROUP_HEADER would be Medications Log. The field can be left blank if you do not want a title or header. If the Layout is set to NON-REPEATING, the value will be ignored and not displayed during data entry.	Text
	GROUP_REPEAT_NUM	No	Used only when the GROUP_LAYOUT is equal to GRID. Specifies the default initial number of repeats to be displayed on the form. If left blank, only one row will be displayed by default.	Yes	Integer Should be left blank for non GRID layout	This field should be used to specify how many rows of data should exist for the Item Group upon initiation of data entry, or in printing of a blank CRF from OpenClinica. If three rows of information, specify the number 3 in the field. When a user accesses the CRF, the row is repeated 3 times by default. A user will be allowed to add more rows up to the GROUP_REPEAT_MAX and even remove some of the rows displayed by default.	A number (e.g. 1, 2, 3).
	GROUP_REPEAT_MAX	No	Used only when the GROUP_LAYOUT is equal to GRID. This represents the total number of repeats a user will be allowed to add in the Item Group. When left blank, the default number of repeats is 40, but you can specify more than 40 if necessary.	Yes	Integer There is no max value Should be left blank for non GRID layout	This field should be used to restrict users to a certain number of repeats for the GRID. However, this restriction works only if data are entered through OpenClinica Web UI. If data are imported using Task-> Import Data option or through web services, all rows of data in the import file will be allowed to import, even if the rows of data in the import exceed the GROUP_REPEAT_MAX. If GROUP_REPEAT_MAX is less than GROUP_REPEAT_NUMBER, the Group will have the GROUP_REPEAT_MAX number of rows on initial data entry displayed, and no additional rows can be added.	A number
	GROUP_DISPLAY_STATUS	No	Used in conjunction with Rules. If set to HIDE, the Item Group will not appear in the CRF when a user is entering data until certain criteria are met. This criteria is specified in a Rule using the ShowAction. If left blank, the Group defaults to SHOW.	Yes	Blank, SHOW, HIDE	If set to SHOW, all Items in the Group are displayed in the CRF. If set to HIDE, this can be used with a Rule to conditionally display an entire Group of Items. If left blank, the default is SHOW.	Hide, Show or leave blank
Items							
	ITEM_NAME	Yes	The unique label or variable name for the data element. The field is not displayed as part of the CRF but can be viewed as part of the CRF and Item Metadata, and is shown in the Discrepancy Notes and Rules modules. This field is case-sensitive. Items with names item1 and Item1 will be treated as different Items. This can cause issues with many data analysis tools and should be avoided in most cases. For Enterprise customers interested in using Datamart: Please note that Datamart treat Items in case-insensitive manner. Please treat all ITEM_NAMES as case-insensitive. Also for use with Datamart, Postgres has a list of reserved words and special characters, which should not be used as Item Names. For a complete list, please see http://www.postgresql.org/docs/8.4/static/sql-keywords-appendix.html Best Practice: The first five characters of Item_Name should be unique within your instance. If you are using SAS, Item_Name is truncated to eight characters.	No (added or removed only)	English No spaces 255 characters max Case-sensitive UNIQUE	This field should be used at all times. ITEM_NAME will be used to form the OID and the variable name when exporting data from OpenClinica. Brevity is recommended for the value as it will be used to generate the unique OC OID. Re-use of the name ITEM_NAME across CRF Versions indicates the variable is the same Item. Once created, an Item Name cannot be modified within the CRF. See CRF Versioning and Scope of CRFs and Items in this document for more detail.	Alphanumeric text, no spaces
	DESCRIPTION_LABEL	Yes	The description or definition of the Item. Should give an explanation of the data element and the value(s) it captures. It is not shown on the CRF but is in the data dictionary.	No	Required All characters allowed 4000 characters max	This field must be used at all times. Provide a description that will help explain what the variable means and what values it is collecting. For example, if the variable were looking to collect height, the DESCRIPTION_LABEL would be This variable collects the height of the subject. It captures the value in inches. This field should not be changed in any subsequent versions of the CRF. If you do change it and you are the owner of the CRF the DESCRIPTION_LABEL attribute for this Item will be changed for all versions of the CRF.	
	LEFT_ITEM_TEXT	No	Descriptive text that appears to the left of the input on the CRF. Often phrased in the form of a question, or descriptive label for the form field input.	Yes	All characters allowed 2000 characters max	This field should be used as a way of describing the expected input to users entering or reviewing CRF data. The value of LEFT_ITEM_TEXT is displayed to the left of the form input. The text wraps after the first 20 characters. An example question would be What is the subjects height? Or, a simple one word height suffices as well. If the Item is part of a GRID, the LEFT_ITEM_TEXT is displayed as a column header above the field and not be displayed to the left of the Item. HTML elements are allowed; however, only a limited subset of tags is officially supported (bold , italics <i>, underline <u>, superscript <sup>, subscript <sub>, line break , link <a href="">, image <img src="">). Tokens can also be used to substitute Study Object values. These can be used to display the Study Object value for use in a URL or for use in other scripts (e.g. jquery). The supported tokens are: ${studySubject} ${studySubjectOID} ${studyName} ${eventName} ${eventOrdinal} ${crfName} ${crfVersion} ${item[item_name]} For more information please see: https://docs.openclinica.com/3.1/study-setup/build-study/create-case-report-forms-crfs#content-title-5514	
	UNITS	No	Used to define the type of values being collected. It appears to the right of the input field on the CRF.	No	64 characters max	If you are collecting data in inches, this field can specify your units as inches, IN, or in. This field should not be changed in any subsequent versions of the CRF. If you do change it and you are the owner of the CRF and no data have been entered for this Item, the UNITS attribute for this Item will be changed for all versions of the CRF. There are no edit checks associated specifically with units. This will appear as text to right of the input field and will be displayed between parenthesis. If you are exporting to CDISC ODM XML format, this will appear in the metadata as measurement units.	
	RIGHT_ITEM_TEXT	No	Descriptive text that appears to the right of the form input on the CRF, and to the right of any UNITS that are specified too. Often phrased in the form of a question, or supporting instructions for the form field input.	Yes	All characters allowed 2000 characters max	This field can be used as a way of describing the expected input to users entering or for field-specific instructions. The value of RIGHT_ITEM_TEXT is displayed to the right of the form input. The text wraps after the first 20 characters. An example of use of right Item text is If other, please specify. If the Item is part of a GRID, the RIGHT_ITEM_TEXT will be ignored and never displayed. HTML elements are allowed; however, only a limited subset of tags is officially supported (bold , italics <i>, underline <u>, superscript <sup>, subscript <sub>, line break , link <a href="">, image <img src="">). Tokens can also be used to substitute Study Object values. These can be used to display the Study Object value for use in a URL or for use in other scripts (e.g. jquery). The supported tokens are: ${studySubject} ${studySubjectOID} ${studyName} ${eventName} ${eventOrdinal} ${crfName} ${crfVersion} ${item[item_name]} For more information please see: https://docs.openclinica.com/3.1/study-setup/build-study/create-case-report-forms-crfs#content-title-5514	
	SECTION_LABEL	Yes, but does not display in Participate form.	All Items in a given Section are displayed on a single web page when the user is entering data, and appear in the order in which they are entered on this Template. Every Item must be assigned to a Section of the CRF. SECTION_LABEL does not display in Participate.	Yes	Value must exist on the Sections Worksheet	For example, you might want all of the information collected as part of a physical exam such as height, weight, blood pressure, and heart rate should be on the same Section.	A valid SECTION_LABEL as defined in the 'Sections' worksheet
	GROUP_LABEL	Yes, but does not display in Participate form.	Assigns Items to an Item Group. If the Group is GRID the Items need to have the same SECTION_LABEL as all other Items in the Group, and must be consecutively defined in the ITEMS worksheet. Best practice: All Items should be assigned to a GROUP_LABEL. GROUP_LABEL does not display in Participate.	Yes	Value must exist on the Groups Worksheet	GROUP_LABEL should be used to identify whether an Item belongs to an Item Group defined in the GROUPS worksheet. If the Group is a repeating group (GRID layout), each Item in the Group is displayed as a column in the grid. Warning, too many Items in a Group, or use of long LEFT_ITEM_TEXT values, will make the grid extremely wide and force the data entry user to scroll the page to the right to complete data entry. For NON-REPEATING Items, specify a Group Label to be used to logically assemble related Items together for easier data analysis. OpenClinica 3.1.2 and previous versions allowed Items to be moved from one Item Group to another between versions (i.e. UNGROUPED Items could later be grouped). While OpenClinica allowed this functionality, CDISC ODM does not support this type of structure change between different CRF versions. As a result, these types of structural changes could break extracts which contain the affected CRF. A new column has been introduced to View CRF page to allow a user to verify CRF integrity. The new table, called Items gives a list of Items in a CRF where the last two columns (Version(s) and Integrity Check) provide information about which version(s) the Item belongs to and if the Item passes the integrity check (verifying that the Item has not been assigned to more than one Item Group). OpenClinica 3.1.3 and future versions will not allow Items to be assigned to different Item Groups between versions.	Must be the GROUP_LABEL of a section defined in 'Groups' worksheet
	HEADER	No	Contains text that used as a header for a particular Item. Using this field will break up the Items with a distinct line between the header information and the next set of Items. The text is bolded to call greater attention to it.	Yes	All characters allowed 2000 characters max	HTML elements are allowed; however, only a limited subset of tags is officially supported (bold , italics <i>, underline <u>, superscript <sup>, subscript <sub>, line break , link <a href="">, image <img src="">). Tokens can also be used to substitute Study Object values. These can be used to display the Study Object value for use in a URL or for use in other scripts (e.g. jquery). The supported tokens are: ${studySubject} ${studySubjectOID} ${studyName} ${eventName} ${eventOrdinal} ${crfName} ${crfVersion} ${item[item_name]} For more information please see: https://docs.openclinica.com/3.1/study-setup/build-study/create-case-report-forms-crfs#content-title-5514 This field can be used as a replacement for left and right Item text or as a replacement for instructions. It allows a greater number of characters, along with bolding the text, to get the data entry persons attention.	
	SUBHEADER	No	This field can contain text that will be used underneath the HEADER, or independently of a HEADER being provided. The text will be separated by a line and have a grey background.	Yes	All characters allowed 240 characters max	HTML elements are allowed; however, only a limited subset of tags is officially supported (bold , italics <i></i>, underline <u></u>, superscript , subscript , line break , link <a href="">, image <img src="">). Tokens can also be used to substitute Study Object values. These can be used to display the Study Object value for use in a URL or for use in other scripts (e.g. jquery). The supported tokens are: ${studySubject} ${studySubjectOID} ${studyName} ${eventName} ${eventOrdinal} ${crfName} ${crfVersion} ${item[item_name]} For more information please see: https://docs.openclinica.com/3.1/study-setup/build-study/create-case-report-forms-crfs#content-title-5514 This field can be used as a replacement or augmentation for left and right item text or as a replacement/augmentation for section/group instructions. It allows a greater number of characters, along with providing a grey background to the text in order to get the data entry users attention.	
	PARENT_ITEM	No	DO NOT USE. This will not be supported in future versions of OpenClinica and should not be used. Historically, this field could contain an ITEM_NAME that immediately preceded this Item, and was in the same Section. This would cause the child Item to be indented underneath the ITEM_NAME specified.	Yes	Value for ITEM_NAME must already exist in the CRF and immediately precede the current ITEM Only one level of indention is allowed.	Do not use Parent_Item in OpenClinica version 3.3 and above. In OpenClinica versions prior to version 3.3, this can only be used with NON-REPEATING Items and must be a valid ITEM_NAME. It is used strictly for visual purposes in the user interface when people are entering data. Use of this field is not recommended. It will be deprecated in a future release.	
	COLUMN_NUMBER	No, If used, will not be displayed in Participate.	Data entry screens are set up by columns. By default a blank value will put the Item in column 1. To have NON-REPEATING Items show up on a horizontal plane next to each other, specify column numbers greater than 1.	Yes	Integer	This is to be used with only NON-REPEATING Items and controls the display of multiple Items on a single row. If you set the column to 3 for an Item, the previous two Items in the worksheet should have COLUMN_NUMBERS of 1 and 2. Otherwise, your Item will be displayed in the first column. Use of COLUMN_NUMBERS greater than 3 is not recommended due to typical screen width limitations.	
	PAGE_NUMBER	No	DO NOT USE. This will not be supported in future versions of OpenClinica and should not be used.	Yes	Alpha-numeric 5 characters max	Note: Page_Number will not be available in future versions of OpenClinica, so it is recommended that you do not use it.	
	QUESTION_NUMBER	No, If used, will not be displayed in Participate.	This field is used to specify an identifier for each Item on the Items worksheet. It appears to the extreme left of the LEFT_ITEM_TEXT. If LEFT_ITEM_TEXT was left blank, to the left of the form input.	Yes	Alpha-numeric 20 characters max	Used to display question numbers on a CRF.	
	RESPONSE_TYPE	Yes	The type of input display you would like to use for a given Item on the CRF. It is different from DATA_TYPE. RESPONSE_TYPE reflects the display; DATA_TYPE defines how it is stored in the database.	Yes	Option must be selected from the drop down box: -text -textarea -single-select -radio -multi-select -checkbox -calculation -group-calculation -file -instant calculation	Text: a rectangular box to enter information on a single line (3999 character limit) Textarea: a multi-line box for entering information (3999 character limit) Radio and Single-Select only allow one option to be chosen for an Item. Radio buttons cannot be deselected in the user interface once an option has been chosen. Multi-Select and Checkbox allow multiple options to be selected at once. File allows a file to be uploaded and attached to the CRF by the data entry person. Any file type is acceptable. (10MB size limit) Calculation and Group-Calculation are used to derive values. Calculations allow for the execution of arithmetic expressions and support some basic functions. The calculations use values from previous fields within the same CRF as variables. The calculated field cannot be directly edited by the data entry person and will appear grayed out. Group-calculation allows the user to find a value based on the values in a column of a GRID (e.g. sum). The group-calculation should not be contained in a repeating group, rather the variable that is being used in the calculation should be in a GRID while the calculated field itself is NON-REPEATING. The values of calculated fields are generated when the user saves the Section of the form. Forced reason for change (when turned on) is not enforced for calculated fields. Instant-calculation (introduced in 3.1.3) is used to populate a destination field with date/time information when content of a trigger field is changed. The trigger field must precede the instant-calculation field. This is a client side action, it is executed by triggering an on change function defined by the CRF designer in the RESPONSE_VALUES_OR_CALCULATIONS field in the CRF template. The on change function takes arguments of an Item Name (trigger item) and value. The Item Name indicates the name of trigger field. The value indicates what date format should be used (two variables may be used: _CURRENT_DATE - the current server date, _CURRENT_DATE_TIME - current server date and time). Please note that instant-calculation field can be used in a GRID only if its trigger field is on the same row of the GRID. The trigger field for an instant-calculation field can be of any response type.	
	RESPONSE_LABEL	Yes	Create a custom label associated with a response set. This label must be defined once and may be reused by other Items with the same responses (e.g. Yes, No) and values.	No	80 characters max Must be alphanumeric	In order to facilitate the creation of a CRF, unnecessary duplication of RESPONSE_OPTIONS_TEXT and RESPONSE_VALUES_OR_CALCULATIONS values can be mitigated by the RESPONSE_LABEL. If the same options and values are going to be used for multiple Items like Yes, No and 1,2, provide the information once and enter a unique response label. This label can be used throughout the rest of the Items worksheet so other Items will use the exact same options and values. If a RESPONSE_LABEL is reused within a CRF, the RESPONSE_OPTIONS_TEXT and RESPONSE_VALUES_OR_CALCULATIONS must be left blank or exactly match the values of the original RESPONSE_LABEL in the CRF.	Alphanumeric text, no spaces
	RESPONSE_OPTIONS_TEXT	No	A comma delimited string of values that will be used as the options to be chosen by a data entry person when they are entering data in a CRF.	Yes (with limitations)	Required for each unique RESPONSE_LABEL 4000 characters max	This field is only used for checkbox, multi-select, radio and single-select fields. This will be the text displayed to the data entry person, which they will choose for each Item. If the options themselves contain commas (,) you must escape the commas with a \	Comma-delimited list of values
	RESPONSE_VALUES_OR_CALCULATIONS	No	If the field is not a calculation or group-calculation, this will be a comma-delimited string of values that will be used as the values saved to the database when a user chooses the corresponding RESPONSE_OPTIONS_TEXT. If this is a calculation or group-calculation field, it will be an expression that takes the inputs of other Items in the Items worksheet that are of INT or REAL data type to calculate a value.	Yes (with limitations)	Required for each unique RESPONSE_LABEL 4000 characters max	For checkbox, multi-select, radio and single-select fields, this will be the values that correspond to a RESPONSE_OPTIONS_TEXT. The number of options and values must match exactly or the CRF will be rejected when it is uploaded into OpenClinica. The following calculations are allowed in this field if the RESPONSE_TYPE is calculation: sum(), avg(), min(), max(), median(), stdev(), pow(), and decode(). Cumulative calculations on a group of repeating Items must be of type group-calculation. Only cumulative calculations on the entire set of repeating items are allowed. The allowed functions are sum(), avg(), min(), max(), median(), and stdev(). For example, in an invoice with a repeating group of line Items, the calculation for a total price would be the group-calculation func: (sum (LINE_ITEM_PRICE)). Instant calculation fields should use this field to define the onchange() function with arguments of an Item Name (the trigger Item) and value.	Comma-delimited list of values
	RESPONSE_LAYOUT	No	The layout of the options for radio and checkbox fields. The options can be HORIZONTAL (left to right) or VERTICAL (top to bottom). In Participate the response layout will automatically adjust to optimize display on the Participant's device.	Yes	Blank, Horizontal, Vertical	Leaving the field blank or selecting Vertical displays the Items in a single column from top to bottom. Choosing Horizontal will put the Items in a single row, left to right. Response Layout will automatically adjust to optimize display on different devices.	Horizontal or Vertical
	DEFAULT_VALUE	No, If used, will not be displayed in Participate.	Default text for RESPONSE_OPTIONS_TEXT Commonly used for response type single select to provide additional instructions for data entry. For example, select one.	Yes	4000 characters max	Use this to specify an instruction (for example: "Select one") that will appear in the input field. For single-select default value does not have to be part of the response set. It will be interpreted as a blank value if the user does not choose anything. Default values can be used for the following RESPONSE_TYPEs: TEXT TEXTAREA SINGLE-SELECT MULTI-SELECT CHECKBOX Note: Be careful in using this field because if the default value corresponds to an option in the response set, it will be saved to the database even if the user does not select it.	ST - Character String INT - Integer REAL - Floating DATE - Date PDATE - Partial Date FILE - File
	DATA_TYPE	Yes	The data type is the format in which the value is stored in the database.	No	Required Option must be selected from the drop down box: -ST -INT -REAL -DATE -PDATE (Not supported in Participate forms) -FILE	ST (String): Any characters can be provided for this data type. INT (Integer): Only numbers with no decimal places are allowed for this data type. REAL: Numbers with decimal places. DATE: Only full dates are allowed for this data type. The default date format the user must provide the value in is DD-MMM-YYYY. PDATE: Partial dates are allowed for this data type. The default date format is DD-MMM-YYYY so users can provide either MMM-YYYY or YYYY values. (Not supported in Participate forms.) FILE: This data type allows files to be attached to the item. It must be used in conjunction with a RESPONSE_TYPE of file. The attached file is saved to the server and a URL is displayed to the user viewing the form. The maximum file size that can be uploaded is 10 megabytes. There is no file type restriction. This field should not be changed in any subsequent versions of the CRF. If you do change it and you are the owner of the CRF and no data have been entered for this Item, the DATA_TYPE attribute for this Item will be changed for all versions of the CRF. If original DATA_TYPE for the Item was DATE, owner of the CRF can change it to PDATE even if data have been submitted for the CRF.	
	WIDTH_DECIMAL	No, If used, has no effect in Participate.	Specify the width (the length of the field) and the number of decimal places to use for the field Has no effect in Participate.	Yes	Not required. If provided must be in the form w(d) as follows: w integer from 1 to 26, or literal w if INT or REAL. If ST, from 1 to 4000 is allowed. d literal d. if the item has DATA_TYPE of REAL, may also be an integer from 1 to 20. d cannot be larger than w	Defines the width (the maximum allowed length of the field) and the number of decimal places to use for the field in the form w(d). The first input defines the width of the field. The second input specifies the number of decimal places for the field, if the item has a DATA_TYPE of REAL. The WIDTH_DECIMAL attribute should only be used for Items with the ST, INT or REAL data types. The width attribute specifies the length of the field treated as a string, so even if the Item is of type INT or REAL, leading/trailing zeroes and decimal points count towards the width. For Items of type REAL, evaluation of the width occurs prior to evaluation of the decimal, so values exceeding the specified or system default width will be rejected even if they could be rounded to a length within the width limit. Examples : DATA_TYPE REAL, WIDTH_DECIMAL 5(1) Allows a maximum of 5 characters with only 1 decimal place. OpenClinica will accept 12345 and 1234., 123.4, or 12.30 but will not accept 012345 or 123456. Inputs such as 12.345 or 1234.5678 or 012345 or 12.300 will be allowed and rounded. REAL w(4) Allows up to OpenClinicas maximum length for an Item of ST, INT, or REAL (26 characters), with any decimal in excess of 1/10000th rounded to the 4th decimal place. REAL 20(d) Allows a maximum length of 20 and decimal length of 4 (the default in OpenClinica). . ST 20(d) or INT 20(d) Allows a maximum length of 20 characters. If the DATA_TYPE of the Item is DATE, PDATE, or FILE, the WIDTH_DECIMAL attribute should be left blank. Please be advised that OpenClinica is not tuned to process very large REAL numbers or numbers with many digits after decimal point. So, numbers like 1234.12345678901234589 may not be validated properly to their format. For more complex scenarios where precision above 20 digits is required, it may be better to use a regular expression to verify the input.	
	VALIDATION	No, If used, has no effect in Participate.	Specify a validation expression to run an edit check on this Item at the point of data entry. Has no effect in Participate, all validation for Participate must be written in Rules.	Yes	1000 characters max	The validation will run when the user hits 'save'. If the user has entered data, which satisfy the validation expression, data will save normally. If the value entered does not meet the requirements of the validation, an error message will appear (i.e., the VALIDATION_ERROR_MESSAGE) and the user will need to correct the value or enter a discrepancy note to continue. The validation should be of the format "expressionType: expression". Must be between 1 and 1000 characters and is an optional field. regexp: This Supports Java-style regular expressions (similar to Perl). For more information, see http://java.sun.com/j2se/1.4.2/docs/api/java/util/regex/Pattern.html Examples: This example requires a three-letter string (all uppercase) regexp: /regular expression/ = regexp: /[A-Z]{3}/ func: Supports built-in library of basic integer functions. Currently supported functions include: (1) greater than - gt(int) or gt(real) (2) less than - lt(int) or lt(real) (3) range - range(int1, int2) or range(real1, real2) (4) gte(int) or gte(real) (5) lte(int) or lte(real) (6) ne(int) or ne(real) (7) eq(int) or eq(real) Examples: This example requires a number between 1 and 10 func: func(args) = func: range(1, 10)	
	VALIDATION_ERROR_MESSAGE	No, If used, has no effect in Participate.	Defines the error message provided on the data entry screen when a user enters data that does not meet the VALIDATION. Has no effect in Participate.	Yes	255 characters max Required if VALIDATION is provided	Must be used when a VALIDATION is specified. The message should be clear to the data entry person as to what the problem is.	
	PHI	Yes	Signifies whether this Item would be considered Protected Health Information	No	Blank, 1, 0	Leaving the field blank or selecting 0 means the Item would not be considered Protected Health Information. This flag does not do anything to mask the data or prevent people from seeing it. The field is used as a label only. When creating a data set, this label will show in the metadata and the user could choose to include this Item in the dataset (create dataset step) or not based on this label. This field should not be changed in any subsequent versions of the CRF. If you do change it and you are an owner of the CRF the PHI attribute for this Item will be changed for all versions of the CRF.	0 or 1
	REQUIRED	Yes	This field indicates whether a value must be entered in order to save the data entered in that Section. In OpenClinica, for REQUIRED fields, users must either enter a value or provide a discrepancy note. In Participate, patients must enter information in required fields to submit data to OpenClinica.	Yes	Blank, 1, 0	This can be used for any RESPONSE_TYPE. Leaving the field blank or selecting 0 means a value is not required. In OpenClinica, if 1 is selected, the data entry person must provide a value or enter a discrepancy note explaining why the field is left blank. In Participate, if 1 is selected, patients must enter information to submit data to OpenClinica.	blank, 0 or 1
	ITEM_DISPLAY_STATUS	No	Used in conjunction with Dynamics in Rules or SIMPLE_CONDITIONAL_DISPLAY. If set to HIDE, the Item will not appear in the CRF when a user is entering data unless certain conditions are met. The conditions for display are specified with a Rule using the ShowAction, or via SIMPLE_CONDITIONAL_DISPLAY. If left blank, the value defaults to SHOW.	Yes	Blank, SHOW, HIDE	If you would like to design skip patterns and dynamic logic for a single Item, set the display status to HIDE. When the form is accessed for data entry, the Item will initially be hidden from view from the user. With Rules, another value can trigger the Group of Items to be shown instead of hidden. Instead of Rules, you can also use the SIMPLE_CONDITIONAL_DISPLAY field to decide when this Item should be shown. SIMPLE_CONDITIONAL_DISPLAY only works with Items set to HIDE.	Hide, Show or leave blank
	SIMPLE_CONDITIONAL_DISPLAY	No, If used, has no effect in Participate.	Does not apply to Participate forms. Contains 3 parts, all separated by a comma: ITEM_NAME, RESPONSE_VALUE, Message. ITEM_NAME - The Item name of the field determining whether this hidden Item becomes shown. RESPONSE_VALUE - The value of the ITEM_NAME that will trigger this hidden Item to be shown Message - A validation message that will be displayed if this Item has a value but should not be shown anymore.	Yes	Comma separated list	Simple Conditional Display works with Items that have a defined response set (radio, checkbox, multi-select and single-select fields). The hidden Item can be of any response type. SIMPLE_CONDITIONAL_DISPLAY (SCD) has an effect only when ITEM_DISPLAY_STATUS (IDS) of the Item is set to HIDE. Several levels of hierarchy of Simple Conditional fields can be nested hierarchically. The Items must be in the same section of the CRF For example, assume there is a SEX Item with response options of Male, Female, and response values of 1,2. If the user chooses Female option, additional questions about pregnancy are asked. If Male is chosen, these questions are hidden. However, if the user chooses Female, fills in pregnancy data and after that gets back to the SEX Item and switches the answer to Male, the Items about pregnancy will remain on the screen (not hidden). The user can delete pregnancy answers and in that case the UI Items will get hidden. Note that the database gets updated only on SAVE. In the above example the system will allow saving inconsistent data (SEX = Male, but pregnancy Items filled), but it is up to a user to create discrepancy fields for them explaining the situation. Note that radio button controls cannot be deselected, meaning there is no way to delete its value once it has been selected.	