BizInt Smart Charts

Drug Development Suite

VERSION 4

Mini Guide

Creating Trial Reports

New in Version 4

- Support for EU Clinical Trials (EudraCT) and the WHO International Clinical Trials Registry Platform (ICTRP).
- Support for biomedical literature: Embase, Medline, and Biosis on several platforms – Ovid, STN (classic & new) and ProQuest Dialog; plus Medline on PubMed.

BizInt Smart Charts Drug Development Suite helps you create, customize and distribute tabular reports from the leading commercial and public clinical trials databases. You can also create tabular reports from biomedical databases.

Commercial trial databases: Citeline TrialTrove, Adis Clinical Trials Insight, Cortellis Clinical Trials.

Public trials databases: ClinicalTrials.gov, EudraCT, WHO ICTRP

The **Generate Common Trial IDs** tool automatically analyzes trial study IDs to help you identify related trials.

You can distribute reports in several formats—including HTML, Word, PDF and Excel—with links back to records on the publisher platforms.

▶ For more info: www.bizint.com/tips

LOOK INSIDE

to see how you can…

Spend a few minutes with this Mini Guide to understand the key features of BizInt Smart Charts Drug Development Suite.

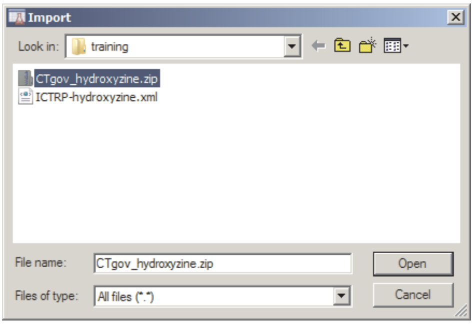
You can use the sample import files **CTgov_hydroxyzine.zip** and **ICTRP-hydroxyzine.xml** located in the **training** folder to follow the steps in this Mini Guide.

Creating your report

The first step to creating your BizInt Smart Charts report is to import the results of your clinical trials search.

You can import search results and transcripts from many different sources into BizInt Smart Charts Drug Development Suite. Information about the currently supported databases and platforms can be found at **"Creating Reports from Databases and Hosts" on the Support section** of our website. Please review this information before exporting search results.

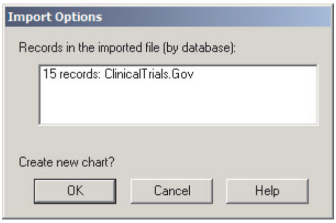
- Use **File | Import** (not **File | Open**) to import files into BizInt Smart Charts. Or, you can drag and drop your file into the BizInt Smart Charts window.
- **For ClinicalTrials.gov:** do not unzip the .zip file and import files individually -- import the .zip file to import all the documents.



Importing your search results

If BizInt Smart Charts is not automatically invoked when you export your search results, select **File | Import** from the menu bar.

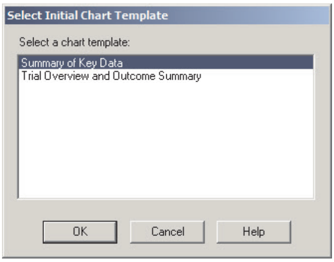
From the Import window, find and select the transcript file that you want to use to create a chart. Use **File | Import**—not **File | Open**—to import search results. Or, you can drag and drop your file into the BizInt Smart Charts window.



A panel will appear showing the number of records in the transcript. If you import a transcript containing records from multiple databases you will see the number of records in each supported database. Records from unsupported databases will not be included in the chart. When you create a chart from multiple databases it is treated as a combined chart (see page 4).

Applying a chart template

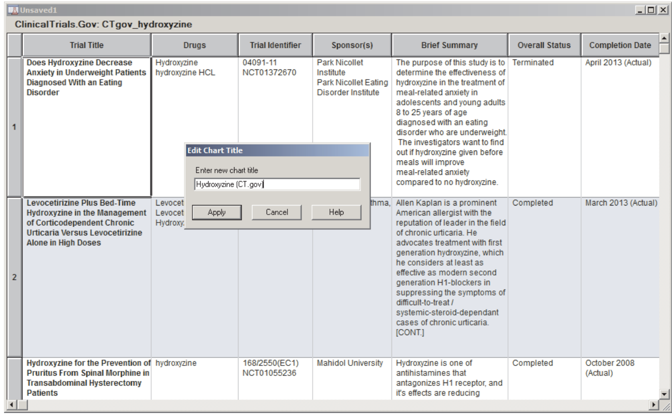
After clicking OK you will be asked to select a chart template. Chart templates define the initial presentation of the report including visible columns. You can change this later, apply a different template, and even create your own templates (see page 6).



Saving and titling your report

Use **File | Save** to save your report as a .chc file.
Note: Export your report if you want to view it in other applications (see page 7).

The initial chart title is based on the name of the file you imported. You can change the title by double-clicking on the title or using **View | Title**.

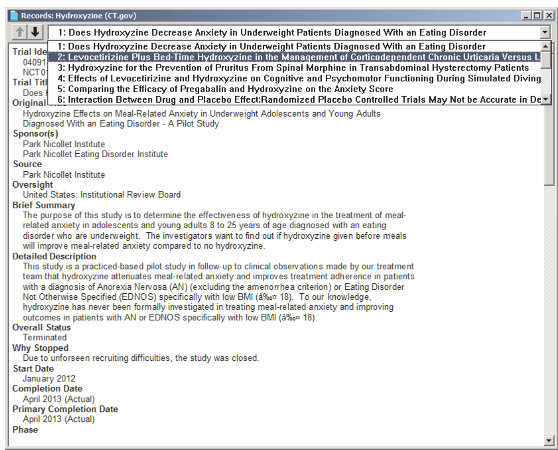


Viewing associated records

Viewing Records

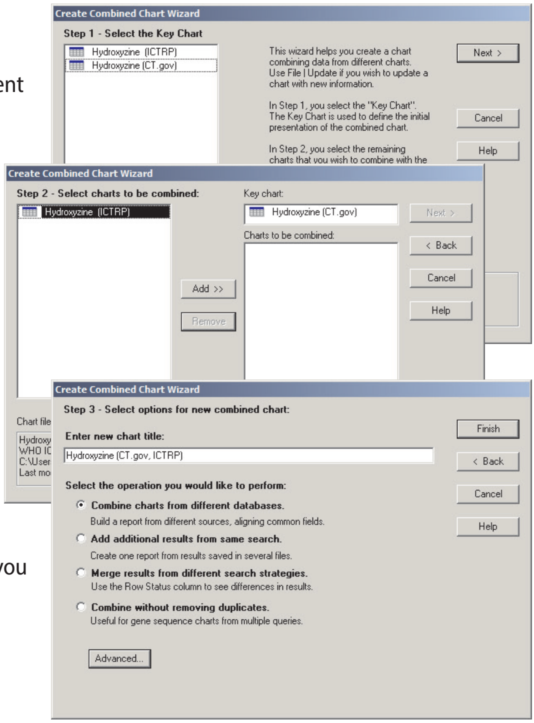
To view the record associated with a row, double-click on the row number button, or select the row and **View | Records**. You can use the arrow buttons or drop-down menu to move between records. Close the Record Viewer or select **View | Chart** to return to the chart.

For most databases you have the option to view the related record on the publisher website by selecting
View | Record on Publisher Website.



BizInt Smart Charts Drug Development Suite Version 4 is compatible with Windows 7, Windows 8, Windows Vista, and Windows XP.

Combining charts



Use **File | Combine** to combine charts from different databases and sources into a single chart.

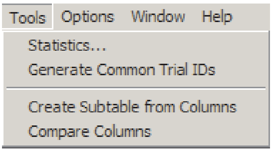
In Step 1, choose the key chart from the list of all open chart files. In Step 2, choose the charts to combine with the key chart.

In Step 3, edit the new chart title and select your combine option. Select "Finish" to create your combined chart.

Each visible row in the original charts will appear in the combined chart; hidden rows will not be included. A Database column indicates the source of each record. Data in columns with similar content are placed into one column.

You can create combined clinical trials charts *or* combined biomedical literature charts, but you cannot combine trials *with* biomedical data.

Identifying Related Records

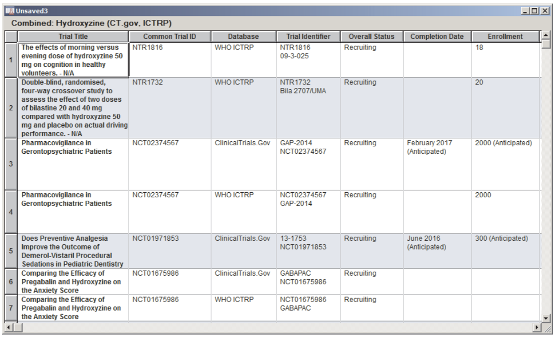


Under the **Tools** menu, use **Generate Common Trial IDs** to help you identify related records in your report.

This tool matches clinical trial IDs between records and creates a "Common Trial ID" column. If an NCT ID is present, that will be chosen as the Common Trial ID.

Use the **View | Sort** command on these columns and check the "Alternate row shading when primary sort key changes" box to group related records together in your report.

Use **BizInt Smart Charts Reference Rows** to create a single row summarizing related records (see page 8.)



Unsaved3

Combined: Hydroxyzine (CT.gov, ICTRP)

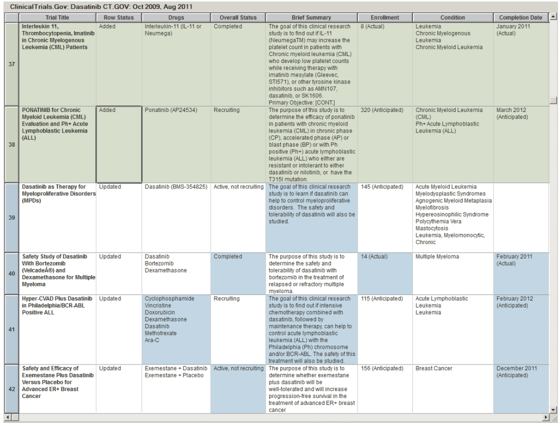
	Trial Title	Common Trial ID	Database	Trial Identifier	Overall Status	Completion Date	Enrollment
1	The effects of morning versus evening dose of hydroxyzine 50 mg on cognition in healthy volunteers. - N/A	NTR1816	WHO ICTRP	NTR1816 09-3-025	Recruiting		18
2	Double-blind, randomised, four-way crossover study to assess the effect of two doses of bilastine 20 and 40 mg compared with hydroxyzine 50 mg and placebo on actual driving performance. - N/A	NTR1732	WHO ICTRP	NTR1732 Bila 2707/UMA	Recruiting		20
3	Pharmacovigilance in Gerontopsychiatric Patients	NCT02374567	ClinicalTrials.Gov	GAP-2014 NCT02374567	Recruiting	February 2017 (Anticipated)	2000 (Anticipated)
4	Pharmacovigilance in Gerontopsychiatric Patients	NCT02374567	WHO ICTRP	NCT02374567 GAP-2014	Recruiting		2000
5	Does Preventive Analgesia Improve the Outcome of Demerol-Vistaril Procedural Sedations in Pediatric Dentistry	NCT01971853	ClinicalTrials.Gov	13-1753 NCT01971853	Recruiting	June 2016 (Anticipated)	300 (Anticipated)
6	Comparing the Efficacy of Pregabalin and Hydroxyzine on the Anxiety Score	NCT01675986	ClinicalTrials.Gov	GABAPAC NCT01675986	Recruiting		
7	Comparing the Efficacy of Pregabalin and Hydroxyzine on the Anxiety Score	NCT01675986	WHO ICTRP	NCT01675986 GABAPAC	Recruiting		

Updating charts

Use **File | Update** to update reports with new information. In Step 1, you select the "older" chart to be updated; in Step 2, select the chart with new information.

A Row Status column appears in the updated chart and updated cells are highlighted in blue.

For more information, see "Combining & Updating Reports" at: www.bizint.com/Tips.

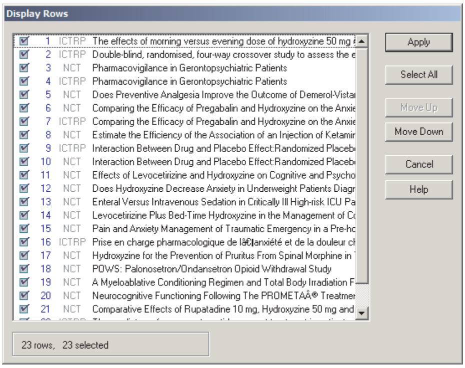


Customizing your report

Hiding and Moving Rows

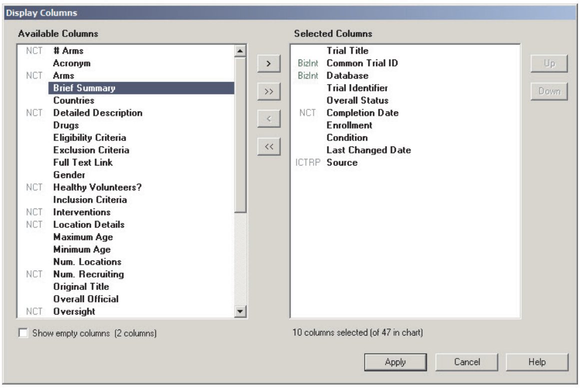
To hide rows, use **Edit | Hide Row** or de-select the rows on the **View | Rows** panel. You can select a range of rows and use Ctrl-H as a shortcut to hide the rows. Hidden rows will not appear in exported or printed reports.

Use **Edit | Move Row** to move rows within the chart or rearrange rows using the **View | Rows** panel.



Changing Columns

To select and rearrange columns, select **View | Columns.** On the left side, you will see all the columns in your chart. Add the columns you wish to display to the "Selected Columns" panel at right. Drag the column name or use the Up/Down buttons to rearrange the order of the columns.

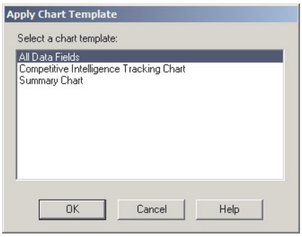


Adding User Columns

To add your own column, select **Edit | Add Column**. A new untitled column appears on the right side of the chart. Double-click on the column title to change the title.

You can change properties of columns using **View | Column Properties.**

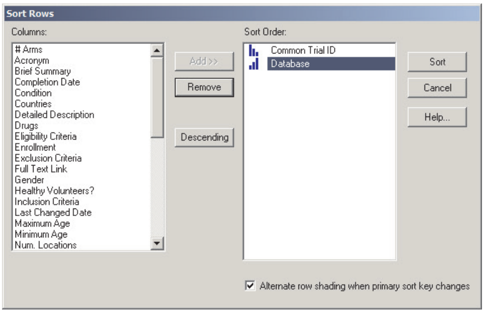
Creating and Applying Chart Templates



You can create your own chart template by creating a chart you like, then saving this template using **File | Save as Template**. To apply a new chart template, select **View | Apply Template**. There are separate templates for each database and for combined charts.

Sorting Rows

To sort the rows, select **View | Sort**. You can sort on multiple columns, in ascending or descending order. Use the check box to control row shading.

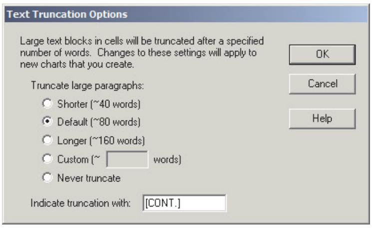


Editing and Highlighting Text

You can edit text in any cell, including subcells. To apply a yellow highlight to cells or rows, use **Text | Highlight Cells** or **Text | Highlight Rows.** Turn highlighting on and off using **View | Enable Highlights.**

You cannot apply a style (e.g. bold, italics, color) to *individual words or phrases* in the chart or records.

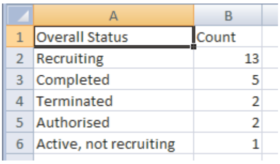
Changing Text Truncation



You can change the text truncation behavior (indicated by [CONT.]) using **Options | Text Truncation in cells.** Changes to these options affect new charts, but not existing charts.

Creating Simple Statistics

To create a count of unique values in a column, select **Tools | Statistics** and select a column (must be visible.) Statistics will be saved in a .csv file for further processing in Excel.



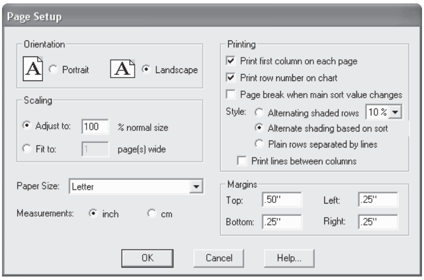
	A	B
1	Overall Status	Count
2	Recruiting	13
3	Completed	5
4	Terminated	2
5	Authorised	2
6	Active, not recruiting	1

Printing reports

You can change the print settings under **File | Page Setup**. Under scaling, you can specify that the chart fits on a specified number of pages in width.

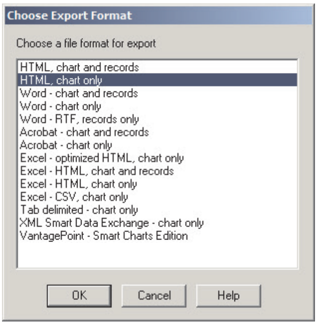
Use **File | Print** to print the chart and records. You can print the current record, all records, or a range of records.

Use **File | Print Preview** to preview the appearance of a printed chart.



Distributing reports

To distribute your report, use **File | Export** and choose the appropriate Export Format. Detailed information on export formats is available at:
www.bizint.com/Tips – "Distributing Reports"



Recommended Export Formats

- **HTML** (chart and records, chart only): creates an HTML file which can be viewed in a browser.
- **Word** (chart and records, chart only): creates an HTML file with the chart (and optionally the records and images) which is opened in Microsoft Word. This format is good for reports which will be distributed by email. You can also export the records only as an RTF file.
- **Acrobat** (chart and records, chart only): creates an HTML file which is opened in Adobe Acrobat and can be saved as a PDF. This format is ideal for reports containing images and for printing.
- **Excel - optimized HTML** (chart only): creates an HTML file which preserves most formatting while creating only one row in Excel for each BizInt Smart Charts row. You can also export in .CSV format for analysis in Excel.

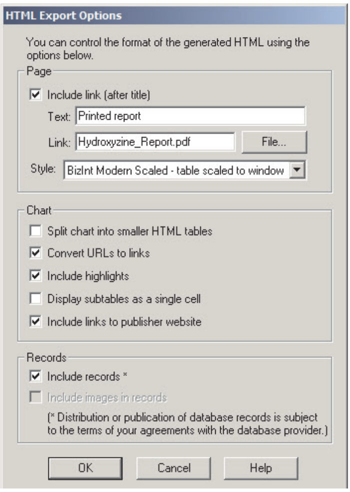
HTML Export Options

You can specify the appearance of your exported HTML using the HTML Export Options panel.

Under "Style", you can select a stylesheet. The "BizInt Modern Scaled" stylesheet will attempt to scale your report to fit the width of the browser window.

One option under "Chart" is to include a link to the full record on the publisher website; "Link" will appear under the row number in the exported HTML.

Under "Records" you can choose to include the records (which will be linked to the record title) and images in the records.



VantagePoint - Smart Charts Edition (VP-SCE)

VantagePoint - Smart Charts Edition (VP-SCE) is a customized version of VantagePoint designed for use with BizInt Smart Charts. It provides tools for data cleanup, filtering and visualization.

Use **Export | VantagePoint - Smart Charts Edition** to send visible columns to VP-SCE for further processing. Cleaned up and filtered data can then be returned to BizInt Smart Charts Drug Development Suite as new columns.

For more information, see: www.bizint.com/vpsce or www.bizint.com/Cookbook

BizInt Smart Charts Reference Rows™

BizInt Smart Charts Reference Rows offers the ability to create a "reference row"— a single row combining information from different sources. Related source records representing the same clinical trial – based on the same Common Trial ID – are presented in a single row.

	Trial Title	Database	Patient Population	Primary Endpoints	Countries	Trial Phase
1.	Study to Determine the Efficacy and Safety of ELS-M11 in Acute Migraine 1.1 NCT	1.1 NCT | *link* 1.2 TROVE | *link*	Subjects with moderate-severe migraine headaches. Subjects, ages 18-65, with a history of episodic migraine for 21 year, meeting ICHD-II w/o aura. 42 randomized patients (mean age 44; 83% female) had a total of 130 headache events 1.2 TROVE	Primary Outcome Measures: Percentage of patients who experience pain relief 2 hours following the first application of ELS-M11 [Time Frame: 2 hours] [Designated as safety issue: No] Pain relief (as defined by a one point decrease on a 4 point pain intensity scale) in subjects experiencing a moderate to severe migraine headache, 2 hours after the initial application of ELS-M11. 1.2 TROVE	United States 1.1 NCT	Phase 1/2 1.1 NCT

BizInt Smart Charts Reference Rows is a separate utility included with BizInt Smart Charts Drug Development Suite. Use **File | Send to Reference Rows** to open your report in BizInt Smart Charts Reference Rows.

For more information on using Reference Rows, see the BizInt Smart Charts Reference Rows Mini Guide or go to **www.bizint.com/tips**

Software for Business Intelligence
BizInt Smart Charts

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QUESTIONS OR SUGGESTIONS?

Please contact us at:

support@bizint.com

1.714.289.1000 (8 am - 5 pm Pacific Time)

www.bizint.com

We are always pleased to hear from you and will do our best to address your issues.