

Creating Clinical Trial Landscape Reports

This workshop shows how to build a clinical trials landscape report using the key features of BizInt Smart Charts. The sample data we'll be using is Covid-19 trial data from ClinicalTrials.gov, the EU CTR, and the WHO's ICTRP.

With BizInt Smart Charts Drug Development Suite you can import data from key commercial and trial registry databases and combine the data to create a single chart. The Identify Common Trial ID tool automatically identifies records from different databases covering the same trial. You can also review the combined data and begin to customize the chart for your landscape report by hiding irrelevant records and choosing the most relevant aspects to include as columns. You can use Reference Rows to create a single row for each trial, selecting the most accurate and up-to-date from each group of records.

Combined: COVID-19 clinical trial landscape										
	Trial Title	Common Trial ID	Database	Drugs	Sponsor(s)	Phase	Study Type	Overall Status	Countries	Last Changed Date
110.1	Lessening Organ Dysfunction With Vitamin C (LOVIT)	NCT03680274	ClinicalTrials.Gov	Vitamin C	Université de Sherbrooke Lotte & John Hecht Memorial Foundation Université de Sherbrooke	Phase 3	Interventional	Recruiting	Canada	2020-04-08
110.2	Lessening Organ Dysfunction With Vitamin C (LOVIT)	NCT03680274	WHO ICTRP	Drug: Vitamin C;Other: Control	Université de Sherbrooke	Phase 3	Interventional	Recruiting	Canada	
111.1	A Phase III Randomized Placebo-Controlled Study to Examine the Efficacy and Safety of DAS181 for the Treatment of Lower Respiratory Tract Parainfluenza Infection in Immunocompromised Subjects	NCT03808922	ClinicalTrials.Gov	DAS181 Placebo DAS181 COVID-19 DAS181 OL	Ansun Biopharma, Inc.	Phase 3	Interventional	Recruiting	Australia Korea, Republic of Taiwan United States	2020-03-31
111.2	A Phase III Randomized Placebo-Controlled Study to Examine the Efficacy and Safety of DAS181 for the Treatment of Lower Respiratory Tract Parainfluenza Infection in Immunocompromised Subjects	NCT03808922	WHO ICTRP	Drug: DAS181;Drug: Placebo;Drug: DAS181 COVID-19;Drug: DAS181 OL	Ansun Biopharma, Inc.	Phase 3	Interventional	Recruiting	United States Australia Korea, Republic of Taiwan	
112.1	Efficacy and Safety of Darunavir and Cobicistat for Treatment of COVID-19	NCT04252274	ClinicalTrials.Gov	Darunavir and Cobicistat	Shanghai Public Health Clinical Center	Phase 3	Interventional	Recruiting	China	2020-04-09
112.2	Efficacy and Safety of Darunavir and Cobicistat for Treatment of COVID-19	NCT04252274	WHO ICTRP	Drug: Darunavir and Cobicistat	Shanghai Public Health Clinical Center	Phase 3	Interventional	Recruiting	China	
113.1	A Phase 3 Randomized, Double-blind, Placebo-controlled Multicenter Study to Evaluate the Efficacy and Safety of Remdesivir in Hospitalized Adult Patients With Mild and Moderate COVID-19.	NCT04252664	ClinicalTrials.Gov	Remdesivir Remdesivir placebo	Capital Medical University Chinese Academy of Medical Sciences	Phase 3	Interventional	Suspended	China	2020-04-13
113.2	A Phase 3 Randomized, Double-blind, Placebo-controlled Multicenter Study to Evaluate the Efficacy and Safety of Remdesivir in Hospitalized Adult Patients With Mild and Moderate 2019-nCoV Respiratory Disease.	NCT04252664	WHO ICTRP	Drug: Remdesivir placebo;Drug: Remdesivir	Capital Medical University	Phase 3	Interventional	Recruiting	China	

Trial Title	Common Trial ID	Database	Drugs	Sponsor(s)	Phase	Study Type	Overall Status	Countries	Last Changed Date
				Manitoba University of Alberta					
Hydroxychloroquine Treatment for Severe COVID-19 Respiratory Disease: Randomised Clinical Trial (HYDRA Trial)	NCT04315896	129.1 NCT link 129.2 ICTRP link	Hydroxychloroquine Placebo oral tablet	National Institute of Respiratory Diseases, Mexico Sanofi	Phase 3	Interventional	Not yet recruiting		2020-03-18
Multi-centre, Adaptive, Randomized Trial of the Safety and Efficacy of Treatments of COVID-19 in Hospitalized Adults	NCT04315948	130.1 NCT link 130.2 ICTRP link 130.3 EUDRACT link	Remdesivir Lopinavir/ritonavir Interferon Beta-1A Hydroxychloroquine	Institut National de la Santé Et de la Recherche Médicale, France	Phase 3	Interventional	Recruiting	France	2020-03-23
A Randomized, Double-blind, Placebo-controlled, Multi-site, Phase III Study to Evaluate the Safety and Efficacy of CD24Fc in COVID-19 Treatment	NCT04317040	131.1 NCT link 131.2 ICTRP link	CD24Fc Placebo	Oncimmune, Inc.	Phase 3	Interventional	Not yet recruiting	United States	2020-03-19
Chemoprophylaxis With Hydroxychloroquine in Healthcare Personnel in Contact With COVID-19 Patients: A Randomized Controlled Trial (PHYDRA Trial)	NCT04318015	132.1 NCT link 132.2 ICTRP link	Hydroxychloroquine Placebo oral tablet	National Institute of Respiratory Diseases, Mexico Sanofi	Phase 3	Interventional	Not yet recruiting		2020-03-19
An Clinic Trial of Recombinant Human Interferon Alpha Nasal Drops to Prevent Coronavirus Disease 2019 in Medical Staff in Epidemic Area	NCT04320238	133.1 NCT link 133.2 ICTRP link	recombinant human interferon Alpha-1b thymosin alpha 1	Shanghai Jiao Tong University School of Medicine	Phase 3	Interventional	Recruiting	China	2020-03-30

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BIZINT SMART CHARTS DRUG DEVELOPMENT SUITE - IMPORT, COMBINE, IDENTIFY & REVIEW

- Import data:** Use [File | Import](#) to import the sample data for each database. (Or, drag the sample data into the BizInt Smart Charts window.)
Click OK to create the chart and choose the Summary of Key Data (for CT.gov) or Summary Chart (for Trialtrove) depending on the database) as the initial chart template and click OK.
The choice of chart template is optional, but these choices work well for this workshop.
- Combine data:** Use [File | Combine](#) to combine the two charts, choosing the CT.gov chart as your key chart.
Choose the first radio button option and type in “MCC Trials Chart” for new chart title. Select Finish, and a new combined chart will appear.
- Select [Tools | Identify Common Trial ID](#). *This tool matches clinical trial ID’s between trial records. If an NCT number is present for a related set of records, it will be chosen as the Common Trial ID.*
- Bring grouped records together:** Right-click on the Common Trial ID column and select [Sort...](#)
Check the box for “Alternate row shading when sort key changes” at the bottom of the panel. Click [Sort](#).
- Display key information:** *Which fields do you want in your trial landscape?* Select [View | Columns](#) to choose key columns and set the order. For this workshop, you should:
 - add the Phase column and move it after Sponsors.
 - add the Study Type column and move it after Phase.
 - add the Countries column and move it after Overall Status.
 - add the Funding Class column after Countries.
 - remove/hide the following columns: Brief Summary, Primary Outcome, Secondary Outcome, Enrollment, Condition
- Check that you now have the following columns: Trial Title, Common Trial ID, Database, Drugs, Sponsor(s), Phase, Study Type, Overall Status, Countries, Funding Class, Last Changed Date.
- Save your preferred view as a template:** Use [File | Save as Template](#) and name your template.
This template can be used with any combined chart with data from more than one trial database. You can apply a standard template and then customize it for a particular project using [View | Columns](#).
- Right-click on the Study Type column and choose Sort and add Study Type to the top of the Sort Order. Then click the Descending button to sort in descending order.
- Review and curate your chart:** *BizInt Smart Charts provides tools to review and curate your data.*
 - You can view the “Smart Charts record” by double-clicking on a row.
 - To view the record on the publisher’s site, right-click on a CT.gov row (e.g. row 7) and choose [Record on Publisher Website](#). *This will open up the ClinicalTrials.gov record in a browser window.*
 - If after review, a record appears in your chart that you don’t want to include in your report, right-click on that row and choose [Hide Row](#). *In this workshop, use Shift+click to select all trials with an observational study type and then use ctrl+H to hide the rows. You will need to click Yes to confirm you wish to hide all selected rows.*
- Save the .cht file and select [File | Send to Reference Rows](#) to open the chart in BizInt Smart Charts Reference Rows.

BIZINT SMART CHARTS REFERENCE ROWS - PREPARE YOUR LANDSCAPE REPORT

- In the wizard, click Next and then click Finish on the second panel. *You could change Database Rankings and select*

column rules in the wizard, but it's not required.

12. **View Reference Rows in the Selection View:** Note that the row numbering has changed to reflect each group of records with the same Common Trial ID. *Scroll down to group 19 to see a Reference Row with a record from both databases.*
13. **Set rules and review selections:** *You can set rules for individual columns.*
Now apply the "Most Recently Updated" rule to the Overall Status column and to the Last Changed Date column, so you can easily identify the most recently updated record. *Overall Status will now be shown from the most recently updated record for each trial. Look at NCT04257656 to see the effect of these rules.*
14. **Get the most complete list of countries:** Right-click in the Countries column and choose **Edit Column Rule**. Choose "Summarize Unique Values" as the Selection Rule and click OK to apply.
15. **Review and make changes as necessary:** To change the selected cell, right click on the desired cell and choose "Select this cell." A purple check will appear indicating that you have overridden the rules. *You can also click in a cell to edit the text, and use copy/paste to change the text in cells.*
16. **Sort your Report:** Right-click in the Phase column and choose **Sort**. Drag Phase above Common Trial ID. Click the Descending button and then click **Sort**.
In Reference Rows, each trial will appear once in your chart. And, sorting will now be by trial (i.e. group of related records for a trial) rather than by record, with Phase 3 trials at the top of the chart.
17. **Set links for NCT numbers:** Right-click in the Common Trial ID column and select Column Properties. In the panel, select the "Link NCT numbers to ClinicalTrials.gov in HTML exp" option. *If the Common Trial ID is an NCT number, a link to the ClinicalTrials.gov record will be automatically created in exported reports.*
18. **Title your report:** Double-click on the title to rename it "COVID-19 clinical trial landscape." Then, go to **Options | Chart title style...** and select the "Single" radio button and click OK. *This option prevents the word "Combined" from appearing in multi-database report titles.*
19. **Export to create your custom landscape report:** You can choose from multiple formats to share your landscape report. Go to **File | Export** and choose the first option: HTML, chart and records. You can choose whether to include all records or only the first from each group.

USE STATISTICS FOR QUICK INSIGHTS

One powerful features of BizInt Smart Charts that might get missed is **Statistics** – the ability to run simple statistics on any standard column in your chart (not subtables) It is most powerful in Reference Rows where the statistics will be on a per trial rather than per record basis. To run statistics on a column, right click on the column and choose Statistics.

20. **See where trials are happening:** Right-click in the Countries column, choose **Statistics** and click OK. Then click OK to accept the default options. Enter a filename for your new statistics as a .csv file. *Your file should open in your default spreadsheet application, generally Microsoft Excel. You can then sort the list and generate visualizations from this data.*
21. **Who is sponsoring trials:** Repeat the same approach with the Funding Class column. Right-click on the Funding Class column and choose **Statistics** again. *For more detail, we should use the Sponsor(s) column, which we will want to cleanup with VP-SCE.*