Software for
Business Intelligence
BizInt Smart Charts

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 Merkel Cell Carcinoma (MCC) trial data from ClinicalTrials.gov and Citeline Trialtrove.

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. Finally, 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: MCC Trials Chart

	Trial Title	Common Trial ID	Database	Sponsor(s)	Phase	Overall Status	Last Changed Date
19.1	Prospective Randomized Trial of an Adjuvant Therapy of Completely Resected Merkel Cell Carcinoma (MCC) With Immune Checkpoint Blocking Antibodies (Nivolumab, Opdivo®; Ipilimumab (Yervoy®) Every 3 Weeks for 12 Weeks Versus Observation	NCT02196961	ClinicalTrials.Gov	Prof. Dr. med. Dirk Schadendorf Bristol-Myers Squibb	Phase 2	Recruiting	2017-08-28
19.2	Prospective Randomized Trial of an Adjuvant Therapy of Completely Resected Merkel Cell Carcinoma (MCC) With Immune Checkpoint Blocking Antibodies (Nivolumab, Opdivo; Ipilimumab (Yervoy) Every 3 Weeks for 12 Weeks Versus Observation	NCT02196961	Citeline TrialTrove	Bristol-Myers Squibb (Other Hospital/Academic/ Medical Center)	II	Open	2019-02-07
20.1	A Phase II Study of MK-3475 in Patients With Advanced Merkel Cell Carcinoma (MCC)	NCT02267603	ClinicalTrials.Gov	National Cancer Institute (NCI)	Phase 2	Active, not recruiting	2019-03-01
20.2	A Phase II Study of MK-3475 in Patients With Advanced Merkel Cell Carcinoma (MCC)	NCT02267603	Citeline TrialTrove	Merck & Co. National Institutes of Health/National Cancer Institute	II	Completed	2019-03-04
21.1	Traitement Des Carcinomes à Cellules de Merkel inopérables et/ou métastatiques Par Analogue de la Somatostatine - Etude Nationale Multicentrique Mono-bras de Phase II.	NCT02351128	ClinicalTrials.Gov	University Hospital, Grenoble	Phase 2	Completed	2017-10-17
21.2	Treatment of Inoperable and / or Metastatic Merkel Cell Carcinoma by Analogous Somatostatin National Multice... Phase II Study	NCT02351128	Citeline TrialTrove	(Other Hospital/Academic/ Medical Center)	II	Completed	2019-03-01

Merkel Cell Carcinoma Trial Landscape

	Trial Title	Common Trial ID	Database	Sponsor(s)	Phase	Overall Status	Last Changed Date
1.	Temporary Authorization for Use (ATU) to Avelumab for Treatment of Adult Patients With Metastatic Merkel Cell Carcinoma (mMCC)	NCT03089658	1.1 NCT | link 1.2 TROVE | link	Merck KGaA, Darmstadt, Germany Pfizer	III	Completed	2019-03-05
	1.1 NCT			1.1 NCT	1.2 TROVE	1.2 TROVE	1.2 TROVE
2.	A Multicenter, Randomized, Double-Blinded, Placebo-Controlled, Phase 3 Trial of Adjuvant Avelumab (Anti-PDL-1 Antibody) in Merkel Cell Carcinoma Patients With Clinically Detected Lymph Node Metastases	NCT03271372	2.1 NCT | link 2.2 TROVE | link	University of Washington National Cancer Institute (NCI)	Phase 3	Open	2019-02-28
	2.1 NCT			2.1 NCT	2.1 NCT	2.2 TROVE	2.2 TROVE
3.	A Phase III Randomized Trial Comparing Adjuvant MK-3475 (Pembrolizumab) to Standard of Care Observation in Completely Resected Merkel Cell Carcinoma	NCT03712605	3.1 NCT | link 3.2 TROVE | link	National Cancer Institute (NCI)	Phase 3	Open	2019-03-15
	3.1 NCT			3.1 NCT	3.1 NCT	3.2 TROVE	3.2 TROVE

Software for
Business Intelligence
BizInt Smart Charts

Create Clinical Trial Landscape Reports

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

1. **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.

2. **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.

3. 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.*

4. **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**.

5. **Analyze overlap between databases**: Right-click on the Common Trial ID column and select **Tools | Statistics**.
   Select "Separate lines" and click OK. Save the .csv file (e.g. "trial stats.csv") and click OK.
   The statistics file will open in Excel. Sort the statistics on Count (largest to smallest) to view the results of the Identify Common Trial ID too. This step is optional, but will help you understand the data.

6. **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
   • remove/hide the following columns: Drugs, Primary Outcome, Secondary Outcome, Enrollment, Condition

7. Check that you now have the following columns: Trial Title, Common Trial ID, Database, Sponsors, Phase, Overall Status, Change Date.

8. **Save your preferred view as a template:** Use **File | Save as Template** and name your template.
   T*his 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**.

9. **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, hide row 13 (NCT00540566) since there is no phase information.*

10. 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

11. 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.*
    Right-click on the Overall Status column and select **Edit Column Rule**. Select "Use Database Ranking" and under "Database Ranking for this column", drag Citeline Trialtrove above ClinicalTrials.gov, and click OK.
    TrialTrove's Overall Status will now be used if there is a TrialTrove record for the group.

14. 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 row 19 and 28 to see the effect of these rules.*

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 overriden 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 "Merkel Cell Carcinoma 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 MCC 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.