

BizInt Smart Charts

for Drug Pipelines

3.4

Create Clinical Trials reports from these databases...

■ Citeline TrialTrove

You can export search results from Citeline TrialTrove using the “Export” button in TrialTrove to create a **.ttcd** file. The file will either be automatically imported into BizInt Smart Charts or you can import it using the File | Import command in BizInt Smart Charts for Drug Pipelines.

■ Adis Clinical Trials Insight (CTI)

You can export search results from Adis Clinical Trials Insight on the Adis Insight website. Conduct your search, select the records you want to export, and click the “Results Chart” button to create an **.ard** file. The file will either be automatically imported into BizInt Smart Charts or you can import it using the File | Import command in BizInt Smart Charts for Drug Pipelines.

■ ClinicalTrials.gov

Support for ClinicalTrials.gov was added in November 2009 (Version 3.3.17). Do your search on ClinicalTrials.gov and from the List Results window, scroll down and select Download Options at the bottom of the page. Select the value for all of the found studies, and under Download Content, select the radio button for Download Full Studies as XML (see below). Save the **.zip** file on your PC and use File | Import or drag and drop the file into BizInt Smart Charts.

Hide Download Options

Number of Studies: 39 Found Studies

Download Content: Download Full Studies as XML

Download Select Study Fields:

Which Fields: 2 Shown

Which Format: Plain Text

Download Zip File Zip readers

More details on creating reports from these databases can be found on our website, under Support | Creating Reports from Databases and Hosts.

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BizInt Smart Charts for Drug Pipelines supports three clinical trials databases (more details at left):

- Citeline TrialTrove
- Adis Clinical Trials Insight (CTI)
- ClinicalTrials.gov

All of the standard BizInt Smart Charts features work with these databases including the ability to change the visible columns after creating your report, sort, view the backing record, or even view the current record on the publisher website (View | Record on Publisher Website).

Combining and Updating Clinical Trial Reports

BizInt Smart Charts reports created from these three sources can be combined into a single chart file using the File | Combine command. Similar fields are grouped together, but there are many fields in these databases which don't have good matches to the other files.

Currently, clinical trial reports cannot be combined with drug pipeline reports.

You can use the File | Update command to see what has changed between two reports, with new rows marked and changed cells highlighted (see *sample updated chart on back*).

Generate Common Trial ID

Version 3.4.2 introduces a Tools | Generate Common Trial ID command which matches trial IDs between records and assigns a common value. You can sort on this value to group records. Note that if an NCT ID is present, that will be chosen as the Common Trial ID (see *sample combined chart on back*).

Using BizInt Smart Charts Reference Rows, you can create a report with a single line for each trial, selecting information from your databases of choice.



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Clinical Trial Reports – sample charts

ClinicalTrials.gov: Dasatinib trials (Oct 09 Updated in March 2010)									
Trial Title	Row Status	Drugs	Sponsor(s)	Brief Summary	Overall Status	Primary Outcome	Enrollment		
1 Study of BMS-354825 in Patients With Chronic Myeloid Leukemia Who Are Either Resistant or Intolerant to Imatinib	Updated	dasatinib	Bristol-Myers Squibb	The purpose of this study is to see what effect an investigational drug dasatinib (BMS-354825) has on subjects who are in chronic phase Philadelphia chromosome chronic myeloid leukemia (Ph+CML), who are either resistant to high dose imatinib mesylate (Gleevec) or not tolerant of imatinib. [CONT.]	Completed	Number of Imatinib-Resistant Participants With Major Cytogenetic Response (MCyR)	387 (Actual)		
2 Dasatinib in Polycythemia Vera	Updated	Dasatinib	Weill Medical College of Cornell University Bristol-Myers Squibb	The purpose for conducting this research study is to determine the feasibility of using dasatinib as a treatment for polycythemia vera and to determine the optimum treatment regimen.	Completed	To evaluate the effect of dasatinib on the platelet count and the stabilization of hematocrit when restored by phlebotomy to normal range (HCT <45% for men, <42% for women). To determine change in performance status and development of side effects and complications in patients treated under this protocol. [Safety Issue]	24 (Anticipated)		
3 Study of Ipilimumab and Dasatinib Combination Therapy in Patients With Chronic or Accelerated Chronic Myeloid Leukemia	Updated		Bristol-Myers Squibb	The purpose of the study is to assess the safety of ipilimumab and dasatinib combination therapy in patients with CML.	Withdrawn	To evaluate the safety of ipilimumab in combination with dasatinib in CML patients with a loss of previously achieved major molecular response or a loss of previously achieved cytogenetic response to dasatinib. [Safety Issue]	30 (Anticipated)		
4 Dasatinib Combination for Chronic Lymphocytic Leukemia (CLL) With Refractory Disease	Added	Dasatinib	Academisch Medisch Centrum - Universiteit van Amsterdam (AMC-UVA)	Patients with chemo refractory CLL have a poor prognosis. 2 independent mechanisms are attributed to the development of chemoresistance in CLL. The first is a shift in the balance between pro- and anti-apoptotic regulators. The second mechanism is based on acquired mutations resulting in a dysfunctional p53 response. Recent studies indicate that the tyrosine kinase inhibitor dasatinib acts synergistically with both purine analogues and alkylating agents [CONT.]	Recruiting	response rate and response quality	35 (Anticipated)		
5 Dasatinib, Bevacizumab, Paclitaxel in Patients With Advanced Malignancies	Added	Dasatinib Bevacizumab Paclitaxel	M.D. Anderson Cancer Center	The goal of this clinical research study is to find the highest tolerable dose of the combination of dasatinib, bevacizumab, and paclitaxel that can be	Recruiting	Maximum Tolerated Dose (MTD) [Safety Issue]	60 (Anticipated)		

ClinicalTrials.gov + Citeline TrialTrove - Dasatinib									
Trial Title	Common Trial ID	Database	Trial Identifier	Drugs	Sponsor(s)	Brief Summary	Overall Status	Primary Outcome	
27 BMS-354825 or Imatinib Mesylate in Treating Patients With Chronic Phase Chronic Myelogenous Leukemia That Did Not Respond to Previous Imatinib Mesylate	NCT00112775	ClinicalTrials.Gov	CDR0000428457 UCLA-0501047-01 BMS-CA180017 EUDRACT-2004-004450-96 NCT00112775	dasatinib imatinib mesylate	Jonsson Comprehensive Cancer Center National Cancer Institute (NCI)	RATIONALE: BMS-354825 and imatinib mesylate may stop the growth of cancer cells by blocking some of the enzymes needed for cell growth. PURPOSE: This randomized phase II trial is studying BMS-354825 to see how well it works compared to imatinib mesylate in treating patients with chronic phase chronic myelogenous leukemia that did not respond to previous imatinib mesylate.	Active, not recruiting	Major cytogenetic response (MCyR) rate at 12 weeks	
28 A Randomized Multi-Center Open Label Study of BMS-354825 vs Imatinib Mesylate (Gleevec mg/d in Subjects With Chronic Phase Philadelphia Chromosome-Positive Chronic Myeloid Leukemia Who Have Disease That is Resistant to Imatinib at a Dose of 400-600 mg/d.	NCT00112775	Citeline TrialTrove	BMS-CA180017 CA180-017 EUDRACT-2004-004450-96, EUDRACT-CA180-017 NCT00103844 NCT00112775 START-R TrialTroveID-024263 UCLA-0501047-01	dasatinib	BMS Jonsson Comprehensive Cancer Center, UCLA NCI Novartis Wyeth		Completed		
29 A Phase II Study to Determine the Activity of BMS-354825 in Subjects with Chronic Phase Philadelphia Chromosome-Positive Chronic Myeloid Leukemia who Have Disease That is Resistant to High Dose Imatinib Mesylate (Gleevec) or who are Intolerant of Imatinib	NCT00112801	Citeline TrialTrove	BMS-CA180013 CA180-013 EUDRACT-2004-002601-69 NCT00101660 NCT00112801 START-C TrialTroveID-025002 UCLA IRB # 05-01-012 UCLA-0501012-01	dasatinib	BMS Jonsson Comprehensive Cancer Center, UCLA NCI		Completed		
30 BMS-354825 in Treating Patients With Chronic Phase Chronic Myelogenous Leukemia That Did Not Respond to Previous Imatinib Mesylate	NCT00112801	ClinicalTrials.Gov	CDR0000428447 UCLA-0501012-01 BMS-CA180013 EUDRACT-2004-002601-69 NCT00112801	dasatinib	Jonsson Comprehensive Cancer Center National Cancer Institute (NCI)	RATIONALE: BMS-354825 may stop the growth of cancer cells by blocking some of the enzymes needed for cell growth. PURPOSE: This phase II trial is studying how well BMS-354825 works in treating patients with chronic phase chronic myelogenous leukemia that did not respond to previous imatinib mesylate.	Active, not recruiting		

Questions or suggestions?

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