Create Clinical Trials reports from these databases...

Citeline TrialTrove

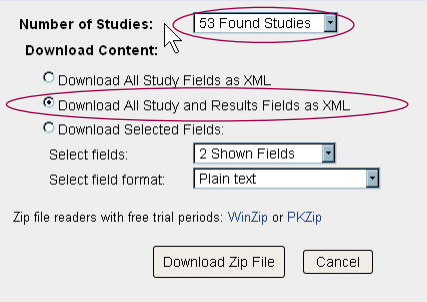
You can export search results from Citeline TrialTrove using the "Export" button in TrialTrove to create a **.ttcd** file. The file will either be automatically imported into BizInt Smart Charts or you can import it using the File | Import command in BizInt Smart Charts for Drug Pipelines.

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

Do your search on ClinicalTrials.gov and From the List Results window, select the Download link (just above the list of results). Under Download Options, select the value for *all* of the found studies. Under Download Content, select the radio button for Download All Study and Results Fields as XML.



Save the **.zip** file on your PC and use File | Import or drag and drop the file into BizInt Smart Charts for Drug Pipelines. *Do not open the .zip file and import files separately!*

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* 3.6

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

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

You can use all the standard BizInt Smart Charts features, including the ability to change the visible columns after creating your report, sort, view the backing record, or 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.

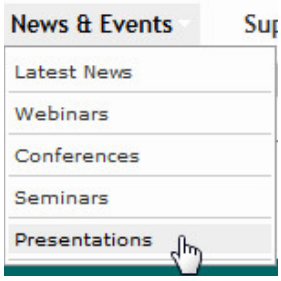
The Tools | Generate Common Trial ID command matches trial IDs between records and assigns a common value. You can sort on this value to group related trials. If an NCT ID is present, that will be chosen as the Common Trial ID.

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

BizInt Smart Charts Reference Rows

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. The reference row is created based on database rankings and rules which you define. *See sample Reference Row chart on back.*

Clinical Trials Case Study: *"Managing Data and Providing Competitive Insights from Clinical Trials Using BizInt Smart Charts"* Diane Webb and Jennifer Friend-Huizer (Janssen Global Services), presented at the SLA PHT Division 2012 Spring Meeting — on our website under Presentations.



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Clinical Trial Reports – sample charts

D:\Export\Trials_Lit_Data\Dasatinib_CTgov_updated.cht

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 analogies 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)

	Trial Title	Database	Phase	Sponsor(s)	Brief Summary	Trial Status	Patient Population	Mechanism of Action	Update Date
96.	Randomized Controlled Study of DPP4 Inhibitor (Sitagliptin) Therapy in the Inpatient Management of Patients With Type 2 Diabetes.	96.1 NCT | link 96.2 NCT | link 96.3 TT | link 96.4 CTI | link	IV	Emory University Merck	High blood glucose levels in hospitalized patients with diabetes are associated with increased risk of medical complications and death. Improved glucose control with insulin injections may improve clinical outcome and prevent some of the hospital complications. [CONT.]	Planned	Patients with Type 2 Diabetes.	CD26-antigen-inhibitors Ornithine-decarboxylase-stimulants Phosphokinase-stimulants	2011-06-24
	96.4 CTI		96.3 TT	96.1 NCT	96.2 NCT	96.3 TT	96.3 TT	96.4 CTI	96.3 TT
97.	Changes in Bone Turnover With Increased Incretin Hormone Exposure (UAB Diabetes Research and Training Center Pilot and Feasibility Study).	97.1 NCT | link 97.2 TT | link 97.3 CTI | link	IV	University of Alabama at Birmingham	This trial will investigate the effects of sitagliptin [Januvia] on bone turnover measures in postmenopausal women with type 2 diabetes mellitus. The primary endpoint is bone turnover measured by osteocalcin, type I collagen cross-linked aminoterminal peptide in urine, bone specific alkaline phosphatase assessed over 8 weeks.	Open	Postmenopausal women with type 2 diabetes.	CD26-antigen-inhibitors	2011-06-23
	97.3 CTI		97.2 TT	97.1 NCT	97.3 CTI	97.2 TT	97.2 TT	97.3 CTI	97.2 TT
98.	Cross-over Study to Assess the Difference in Fasting Plasma Glucose (FPG) Between Vildagliptin (Galvus/Eucreas) and Sitagliptin (Januvia/Janumet) After Two Weeks	98.1 NCT | link 98.2 TT | link 98.3 CTI | link	Phase 4	Novartis	This study is designed to assess the potential difference in Fasting Plasma Glucose (FPG) lowering efficacy between the two DPP-4 inhibitors vildagliptin and sitagliptin, both after a two weeks treatment on top of metformin.	Recruiting	Subjects with type 2 diabetes on metformin monotherapy.	CD26-antigen-inhibitors	2011-08-16
	98.3 CTI		98.1 NCT	98.1 NCT	98.1 NCT	98.1 NCT	98.2 TT	98.3 CTI	98.1 NCT
99.	Pharmacogenetics of Ace Inhibitor-Associated Angioedema:Aim 1.	99.1 NCT | link 99.2 TT | link 99.3 CTI | link	IV	Vanderbilt University	To find out sitagliptin effect in healthy people receiving enalapril, BNP, GLP-1, Bradykinin, substance P for Understanding how these drugs interact in healthy people.	Not yet recruiting	Healthy people.	ACE-inhibitors CD26-antigen-inhibitors	2011-09-01
	99.3 CTI		99.3 CTI	99.1 NCT	99.2 TT	99.3 CTI	99.2 TT	99.3 CTI	99.3 CTI

Questions or suggestions?

Please contact us at:

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Sample updated trials report (top) with new rows highlighted in green and updated cells in blue.

Sample Reference Rows report (bottom) summarizing data from all three trial databases.