



BizInt Smart Charts

Managing Data and Providing
Competitive Insights from Clinical Trials
Using BizInt Smart Charts

PHTD Spring Meeting, Baltimore MD, 19 March 2012

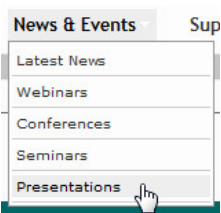
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Manager, Global Commercial Analytics Operations,
Janssen Global Services (J&J)

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Goals for this presentation

- Conduct a case study of trials for two drugs using three clinical trials databases.
- Conduct a case study for one disease.
- Evaluate using tools in BizInt Smart Charts.
- Discuss how clinical trials databases are used for competitive intelligence.

Slides are at www.bizcharts.com
News & Events – Presentations



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Case study - methodology

- Searched three clinical trials databases:
ClinicalTrials.gov (CT.gov)
Citeline TrialTrove (TT)
Adis Clinical Trials Insight (CTI)
- Searched two *compounds* in April, July, Sept 2011 and February 2012:
Januvia (diabetes, launched,)
Teleprevir (hepatitis-C, launched in 2011)
- Searched one *disease* in February 2012:
Hepatitis C (phase III only)

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Januvia – search methodology

The screenshot shows the ClinicalTrials.gov search results page. The search criteria are: Januvia OR sitagliptin OR MK-431 OR MK431 OR MK-0431 OR MK0431 OR ono-5435 OR ono5435. The results are sorted by rank, with 5 studies listed. The first study is 'Dose Response Finding Study of MK-0431/ONO-5435 in Japanese Subjects With Impaired Glucose Tolerance (MK-0431-105)', which is 'Not yet recruiting'. The other four studies are 'Completed'.

Rank	Status	Study
1	Not yet recruiting	Dose Response Finding Study of MK-0431/ONO-5435 in Japanese Subjects With Impaired Glucose Tolerance (MK-0431-105) Condition: Glucose Intolerance Interventions: Drug: Sitagliptin 25 mg; Drug: Sitagliptin 50 mg; Drug: Placebo for Sitagliptin 25 mg; Drug: Placebo for Sitagliptin 50 mg
2	Completed	MK-0431/ONO-5435 Phase III Clinical Trial - Insulin Add-on Study for Patients With Type 2 Diabetes Mellitus Condition: Type 2 Diabetes Mellitus Intervention: Drug: MK-0431/ONO-5435
3	Completed	Controlled Study of MK-0431/ONO-5435 in Patients With Type 2 Diabetes Mellitus Condition: Type 2 Diabetes Mellitus Interventions: Drug: Placebo; Drug: Sitagliptin phosphate
4	Completed	Controlled Study of MK-0431/ONO-5435 in Patients With Type 2 Diabetes Mellitus Condition: Type 2 Diabetes Mellitus Interventions: Drug: Placebo; Drug: Sitagliptin phosphate
5	Completed	MK0431/ONO-5435 Phase III Clinical Trial - Add-on to Voglibose Study for Patients With Type 2 Diabetes Mellitus (0431-104)(COMPLETED) Condition: Diabetes Mellitus, Non-Insulin-Dependent Interventions: Drug: sitagliptin; Drug: Comparator: Placebo; Drug: Voglibose

Januvia – search methodology

The screenshot shows the Citeline TrialTrove search interface. On the left, there are various filters for search criteria: Therapeutic Area (Any), Disease (Select Therapeutic Area), Patient Segment (Select Disease Type), Trial Phase (Any, I, II, III), Drugs Tested (Any, or Select from a list of choices), Mechanism of Action (Any, or Select from a list of choices), Therapeutic Class (Any, or Select from a list of choices), Sponsorship (Any, Industry, or Select from a list of choices), Location (Any, or Select from a list of choices), Protocol ID / Trial Identifier (Any, or Select from a list of choices), and Investigator / Contact.

A search results window is open, displaying the search term "Januvia" and a "Find Drugs" button. Below this, there is a "Find Result" section with a "Browse..." link. The main content of the window is titled "Januvia + metformin" and includes the following information:

- Pipeline Drug Information**
- Therapeutic Class:** Antidiabetic
- Mechanism:** Dipeptide hydrolase inhibitor, Dipeptidyl peptidase 4 (DPP IV) inhibitor, Insulin secretagogue, Protease/peptidase inhibitor
- Delivery:** Tablet, Oral, swallowed
- Status (Major Markets):** Approved
- Drug Synonym(s):** Glactiv, Januvia, L-000224715, MK-0431, MK-431, ONO-5435, Ristaben, sitagliptin, sitagliptin phosphate, Tesavel, Xalevia

At the bottom of the window, there is a "My Selections" section with a "Clear All" button and an "Accept and Close Window" button. A small note at the bottom states: "Drugs are filtered by Therapeutic Area and Disease selection if any. Drugs with a * may only yield records outside your current disease types subscription."

Januvia – search methodology

The screenshot shows the Clinical Trials Insight search interface. On the left, there are various filters for search criteria: Drug, Name, Qualifier, Dose, Route, Formulation, Drug Class, Indication, Non-Drug Therapy, Therapeutic Area, Phase, Study Outcome, Study Status, Study Subjects, Study Details, Study Centre, Last Update, Adis Evaluation, Pharmacoeconomics, and Full Text.

The main content of the window is titled "Drug: Name" and includes a "View Search Tip" section. Below this, there is a "Letter Browse" section with a grid of letters (A-Z) and a "Word Browse" section with a search box containing "ona" and a "BROWSE" button. The search results are displayed in a list format, showing various drug names and their corresponding IDs:

- ONO-1070 (Pranlukast)
- ONO-1101 (Landsiol)
- ONO-2 (Epalrestat)
- ONO-2211
- ONO-2235 (Epalrestat)
- ONO-2333-3jy (ONO-2333Ma)
- ONO-2333jite
- ONO-2506 (Arundic-acid)
- ONO-2506-PO (Arundic-acid)
- ONO-2506PO (Arundic-acid)
- ONO-2952
- ONO-4052
- ONO-4128 (Aralivinc)
- ONO-4528 (NOV-1106)
- ONO-4641
- ONO-4819
- ONO-5129
- ONO-5334
- ONO-5334 (Cefadiazin)
- ONO-4820 (Mendotronic-acid)
- ONO-4950
- ONO-7067 (Carfilzomib)
- ONO-7436 (Aprepitant)
- ONO-7847 (Fosaprepitant)
- ONO-8026 (midaltenacon)
- ONO-8539
- ONO-RG-111 (Pranlukast)
- ONO-KC-411 (Pranlukast)
- ONO02 (Epalrestat)
- ONO2225 (Epalrestat)
- ONO2562 (ONO-2562)
- ONO4553 (ONO-4553)

On the right side of the window, there is a "Query Builder" section with a "Drug Is Sitagliptin" filter and an "ADD" button. Below this, there are two search results listed: "MK-431" and "ONO-5435". At the bottom of the window, there are buttons for "ADVANCED", "SAVE SEARCH", and "CLEAR".

Clinical Trial Databases - Strengths

Strength	Adis CTI	TrialTrove	CT.gov
Additional research support	√	√	
Full indication coverage	√	limited	√
Mechanism of Action search	√	√	Only if in text
Results and Links to completed trial details	√	√	
Trial Alerts/Saved Searches	√	√	
Comprehensive advanced searching	√ (ROA, Endpoints, Dose, Formulation, etc)	√ (some)	
Pricing structure	Moderately priced as add on to ADIS RDI	Purchased by Disease –reasonable if only need a few, but very costly to purchase all diseases	Free

Case study – Drug search results

Januvia	April 2011	July 2011	Sept 2011	Feb 2012
CT.gov	202 trials	221 trials	223 trials	241 trials
Citeline TT	276 trials	303 trials	311 trials	344 trials
Adis CTI	219 trials	257 trials	280 trials	315 trials
Teleprevir	April 2011	July 2011	Sept 2011	Feb 2012
CT.gov	36 trials	37 trials	38 trials	55 trials
Citeline TT	45 trials	48 trials	65 trials	87 trials
Adis CTI	37 trials	42 trials	43 trials	65 trials
Hepatitis C – Phase III				Feb 2012
CT.gov				194 trials
Citeline TT				381 trials
Adis CTI				205 trials

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Case study – Update changes

Januvia	April 2011	July 2011	Sept 2011	Feb 2012
Unchanged	initial	310 records	597 records	368 records
Updated	initial	384 records	179 records	444 records
Added	initial	87 records	38 records	88 records

Teleprevir	April 2011	July 2011	Sept 2011	Feb 2012
Unchanged	initial	54 records	73 records	63 records
Updated	initial	64 records	54 records	81 records
Added	initial	9 records	19 records	63 records

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Case study – Hepatitis C search results

Hepatitis C – Phase III	March 2012	
CT.gov	195 trials	
Citeline TT	386 trials	(90 ongoing/planned; 276 Completed)
Adis CTI	211 trials	
Adis CTI Results	412 records	(Published trials – trials could have several publications)

- Adis CTI has two search options: Trials and Trials Results
 - When reviewing single trials from TT, several records found were in Adis Trials Results, which was not searched for this exercise.
 - Trial Trove contains more foreign language trial publications

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Case study – Common Trial ID tool

The screenshot shows the 'Tools' menu with 'Generate Common Trial IDs' highlighted. Below the menu is a table with three rows of trial data. Red and green arrows point to specific trial identifiers in the table.

	Trial Title	Common Trial ID	Trial Identifier
65	A Phase 3 Study of MP-424 in Combination With Peginterferon Alfa-2b and Ribavirin in Subjects With Genotype 1 Hepatitis C Who Did Not Respond to Previous Treatment.	NCT00781274	700038789 (Clinical Trials Insight) G060A9 (Mitsubishi Tanabe Pharma Corporation) NCT00781274 (ClinicalTrials.gov: US National Institutes of Health)
66	A Phase 3 Study of MP-424 in Combination With Peginterferon Alfa-2b and Ribavirin in Subjects With Genotype 1 Hepatitis C Who Did Not Respond to Previous Treatment.	NCT00781274	G060-A9 JapicCTI-080642 NCT00781274 TrialTroveID-099728
67	Efficacy and Safety of MP-424, Peginterferon Alfa-2b and Ribavirin in Chronic Hepatitis C Who Have Not Achieved an Undetectable HCV RNA Level With Previous Interferon Based Therapy	NCT00781274	G060-A9 NCT00781274

Case study – Common Trial ID tool

The screenshot shows the 'Tools' menu with 'Generate Common Trial IDs' highlighted. Below the menu is a detailed view of the trial identifier NCT00781274, showing its mapping to various databases and trial identifiers.

Trial Title	Common Trial ID	Database	Trial Identifier
A Phase 3 Study of MP-424 in Combination With Peginterferon Alfa-2b and Ribavirin in Subjects With Genotype 1 Hepatitis C Who Did Not Respond to Previous Treatment.	NCT00781274	Adis Clinical Trials Database	700038789 (Clinical Trials Insight) G060A9 (Mitsubishi Tanabe Pharma Corporation) NCT00781274 (ClinicalTrials.gov: US National Institutes of Health)
A Phase 3 Study of MP-424 in Combination With Peginterferon Alfa-2b and Ribavirin in Subjects With Genotype 1 Hepatitis C Who Did Not Respond to Previous Treatment.	NCT00781274	Citeline TrialTrove	G060-A9 JapicCTI-080642 NCT00781274 TrialTroveID-099728
Efficacy and Safety of MP-424, Peginterferon Alfa-2b and Ribavirin in Chronic Hepatitis C Who Have Not Achieved an Undetectable HCV RNA Level With Previous Interferon Based Therapy	NCT00781274	ClinicalTrials.Gov	G060-A9 NCT00781274

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Case study – Statistics

Statistics...
Generate Common Drug Names
Generate Common Trial IDs

Select a column to analyze from the list of visible columns below

- Common Trial ID
- Company
- Database
- Drug(s)
- Indication
- Official Study Title
- Purpose
- Study ID
- Study Phase
- Subject Number

	A	B
1	Common Trial ID	Count
2	NCT00627926	20
3	NCT00828789	6
7	NCT0059210	3
8	NCT00528528	3
9	NCT00508001	3
10	NCT00591214	3
11	NCT00613704	3
12	NCT00621296	3
13	NCT00630058	3
14	NCT00775125	3
15	NG	3
16	NG	3
17	NG	3
18	NG	3
19	NG	3
20	NG	3
21	NG	3
22	NG	3
23	NCT00585855	3
24	NCT01038167	3
25	NCT01054573	3
26	NCT01080222	3
27	NCT01241760	3
28	NCT01253551	3
29	NCT01275599	3
30	NCT01332955	3
31	NCT01336829	3
32	NCT01415141	3
33	TrialTroveID-140600	1
34	700196082	1
35	700196672	1
36	700196674	1
37	700201378	1

Why so many records associated with a single trial?

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Case study – Common Trial ID tool

	Trial Title	Common Trial ID	Database	Trial Identifier
68	VX-950-TIDP24-C134: A Phase I, Open-Label, Single-Sequence Drug-Drug Interaction Trial in Subjects on Stable Methadone Maintenance Therapy, to Investigate the Potential Interaction Between Telaprevir 750 mg Every 8 Hours and Methadone, at Steady-State.	NCT00828789	Adis Clinical Trials Database	700046859 (Clinical Trials Insight) CR015931 (Tibotec Pharmaceuticals) NCT00933283 (ClinicalTrials.gov: US National Institutes of Health) VX950TIDP24C134 (Vertex Pharmaceuticals)
69	A Phase I, Open-Label, Randomized, Crossover Trial in 20 Healthy Subjects to Investigate the Pharmacokinetic Interactions Between the Combination of Efavirenz and Tenofovir Disoproxil Fumarate and Different Dosages of Telaprevir.	NCT00828789	Adis Clinical Trials Database	700041033 (Clinical Trials Insight) CR015790 (Johnson and Johnson Pharmaceutical Research and Development) NCT00828789 (ClinicalTrials.gov: US National Institutes of Health) VX950TIDP24C134 (Vertex Pharmaceuticals)
70	A Phase I, Open-Label, Single-Sequence Drug-Drug Interaction Trial in Subjects on Stable Methadone Maintenance Therapy, to Investigate the Potential Interaction Between Telaprevir 750 mg Every 8 Hours and Methadone, at Steady-State.			CR015931 NCT00933283 TrialTroveID-111628 VX-950-C135 VX-950-TIDP24-C135
71	A Phase I, Open-Label, Randomized, Crossover Trial in 20 Healthy Subjects to Investigate the Pharmacokinetic Interactions Between the Combination of Efavirenz and Tenofovir Disoproxil Fumarate and Different Dosages of Telaprevir.			CR015790 NCT00828789 TrialTroveID-103679 VX-950-C134 VX-950-TIDP24-C134
72	VX-950-TIDP24-C134: Drug-drug Interaction Trial Between Combination of Efavirenz and Tenofovir Disoproxil Fumarate and Different Dosages of Telaprevir on Healthy Volunteer	NCT00828789	ClinicalTrials.Gov	CR015790 NCT00828789
73	VX-950-TIDP24-C135: Drug-drug Interaction Trial Between Telaprevir and Methadone.	NCT00828789	ClinicalTrials.Gov	CR015931 NCT00933283

Incorrect VX trial ID results in two trials being grouped in error.

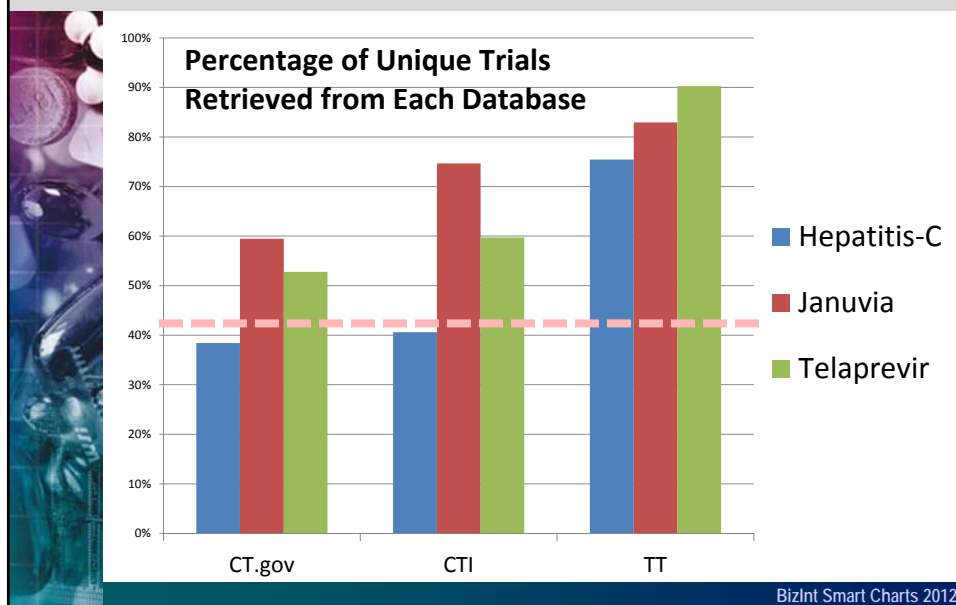
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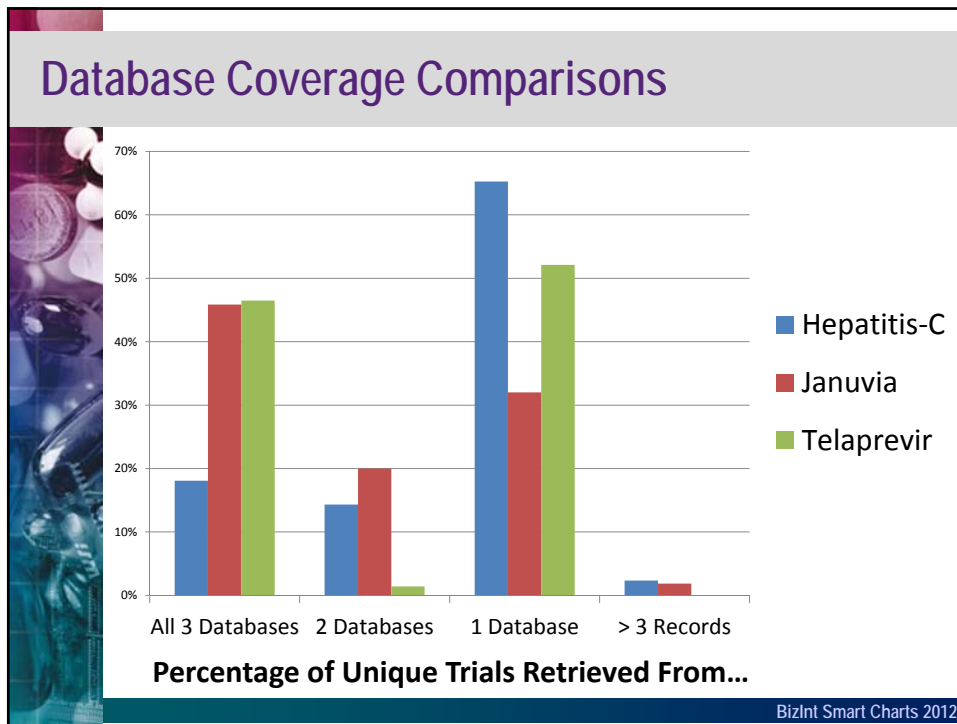
Case study – Common Trial ID tool

Trial Title	Common Trial ID	Trial Identifier
25 A Randomized Study of Stopping Treatment at 24 Weeks or Continuing Treatment to 48 Weeks in Treatment-Naïve Subjects With Genotype 1 Chronic Hepatitis C Who Achieve an Extended Rapid Viral Response (eRVR) While Receiving Telaprevir, Peginterferon Alfa2a (Pegasys) and Ribavirin (Copegus). ILLUMINATE: Illustrating the Effects of Combination Therapy with Telaprevir	NCT00535847	EudraCT 2008-003836-39 EudraCT No: 2009-011464-11 EXTEND ILLUMINATE
26 A Phase 2 Study of VX-950 in Combination With Peginterferon Alfa-2a (Pegasys), With and Without Ribavirin (Copegus) in Subjects With Hepatitis C. The Protease Inhibitor for Viral Evaluation 2 (PROVE2) trial.	NCT00535847	NCT00758043 NCT00916474 TrialTroveID-081922
27 A Phase 2 Rollover Protocol of Telaprevir (VX-950) in Combination With Peginterferon Alfa-2a (Pegasys) and Ribavirin (Copegus) in Subjects Enrolled in the Control Group (Group A) of Study VX06-950-106, VX05-950-104 and VX05-950-104EU Who Did Not Achieve or Maintain an Undetectable HCV RNA Level Through Sustained Viral Response.	NCT00535847	VX08-950-111 VX08-950-112 NCT00372385 NCT00916474
28 A Phase 2 Study of VX-950 in Combination With Peginterferon Alfa-2a (Pegasys), With Ribavirin (Copegus) in Subjects With Genotype 1 Hepatitis C Who Have Not Received Prior Treatment. Protease Inhibitor for Viral Evaluation 1 (PROVE1) Trial.	NCT00535847	PROVE 2 TrialTroveID-048351 VX05-950-104EU VX08-950-112 EudraCT No: 2009-01 EXTEND
29 A Phase 2b Study of Telaprevir (VX-950) in Combination With Peginterferon Alfa-2a (Pegasys), and Ribavirin (Copegus) in Subjects With Genotype 1 Hepatitis C Who Have Not Achieved Sustained Viral Response With a Prior Course of Interferon Based Therapy. Protease Inhibitor for Viral Evaluation 3 (PROVE3).	NCT00535847	NCT00535847 NCT00916474 Prove 107 Roll Over Study of VX05-950-104 Roll Over Study of VX05-950-104EU Roll Over Study of VX06-950-106 Study 107
30 A Phase 3 Study of 2 Dose Regimens of Telaprevir in Combination With Peginterferon Alfa-2a (Pegasys) and Ribavirin (Copegus) in Treatment-Naïve Subjects With Genotype 1 Chronic Hepatitis C.	NCT00535847	TrialTroveID-076900 VX06-950-107 VX08-950-112

Phase IV trial ID included for all prior related trials.

Database Coverage Comparisons





Januvia – evaluation from April 2011

- 117 trials appear from a single database (72-TT, 37-CTI, 9-CT.gov)
- Many trials that were found in only TT or CTI were from conference abstracts.
- Several trials from only TT or TT/CTI were sourced from UMIN-CTR Clinical Trials (Japanese clinical trial registry for non-profit trials (not industry sponsored). CT.gov does not appear to pick these up.
- Review of a single trial from Adis that included an NCT number showed no instance of sitagliptin in the CT.gov record that was reviewed.

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Januvia – evaluation (cont.)

- Of the 9 trials found only CT.gov, 2 did not have Januvia in the record. The 7 others are legitimate trials but were not retrieved from TT or CTI.
- One trial only in Adis was a new observational trial of 500 patients in Japan – source from University Hospital Medical Information Network - Japan.
- One trial only in TT contained a record from 2009 where it was sourced from the ADA conference.

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Telaprevir – some evaluation from April 2011

- 33 trials appear from a single database (28-TT, 5-CTI, 0-CT.gov)
- Two single trials were matched as same trials from TT and Adis CTI by reviewing title, phase, subject number and drugs
- One of these trials was picked up by a conference abstract and not found in CT.gov
- Another trial was new in Adis CTI and updated in TT, but not in CT.gov

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Hepatitis C Phase III –evaluation

- 338 trials appear from a single database (213-TT, 68-CTI, 57-CT.gov) (277 after manual review)
- Since limited to phase III-several trial from CT.gov did not appear as no phase data in record.
- For this indication, several trials for liver cancer inaccurately indexed for HCV
- Some trials indexed as other types of hepatitis in one database and HCV in another.
- Issue with TT and CTI using too many references for trial ID that link related trials together as one.
- Several trials from Japan and Europe not in CT.gov.

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Telaprevir: Competitive intelligence insights

- Product launched in 2011 – currently 19 phase IV trials, 11 new since Sept update.
- There is one comparative head to head trial being done by BMS for daclatasvir.
- Combination therapies being evaluated for various sub-types of HCV.
- US and EU Registries being evaluated as observational studies – goal for one US registry to enroll 4500 patients.

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Januvia: Competitive intelligence insights

- Review newly added trials –
What is the company currently working on?
- For Example – review all company sponsored trials to look for new indications, post marketing trials, new patient populations.
- Review competitors that are doing head to head trials with drug.
- Of the 87 new trial records added in the July Update, 22 are sponsored by Merck.
- Several ongoing trials are based in Japan.

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Januvia: Competitive intelligence insights

- Trial NCT01260246 is for a different patient population & indication -- NASH (Non-alcoholic Steatohepatitis) in Patients With Type 2 Diabetes.
- Trial started in December 2010 to be completed in 2013
- Primary endpoint to improve liver disease by liver biopsy
- Small trial in Canada – see if other trials with same patient population on larger scale.
- Not sponsored by Merck, so perhaps not looking at add-on indication

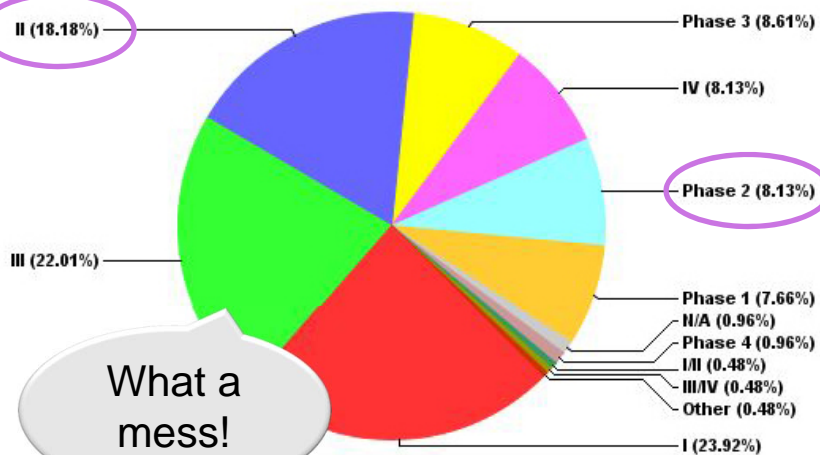
Trial Title	Database	Condition	Start Date	Completion Date	Countries	Sponsor(s)	Brief Summary	Enrollment
654 Sitagliptin for the Treatment of Non-alcoholic Steatohepatitis in Patients With Type 2 Diabetes	ClinicalTrials.Gov	Type 2 Diabetes Nonalcoholic Steatohepatitis	December 2010	November 2013 (Anticipated)	Canada	Lawson Health Research Institute PSI Foundation inc	This is a randomized, double-blind, placebo-controlled trial evaluating the impact of sitagliptin therapy in patients with concomitant type 2 diabetes and non-alcoholic steatohepatitis (NASH) on improving liver disease based on biopsy results. (CONT)	20 (Anticipated)

Some questions we'd like to explore...

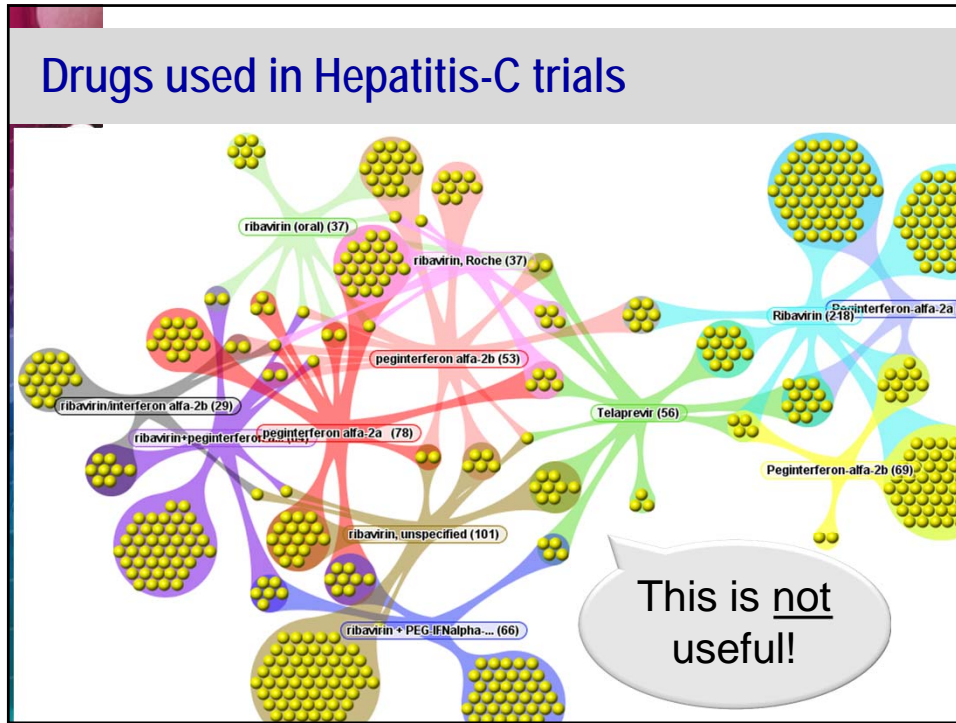
- What **phases** are these trials in?
- What is the **status** of the trials?
- Which **drugs** are being used in these trials, and how are they used together?

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Telaprevir trials – trial phases



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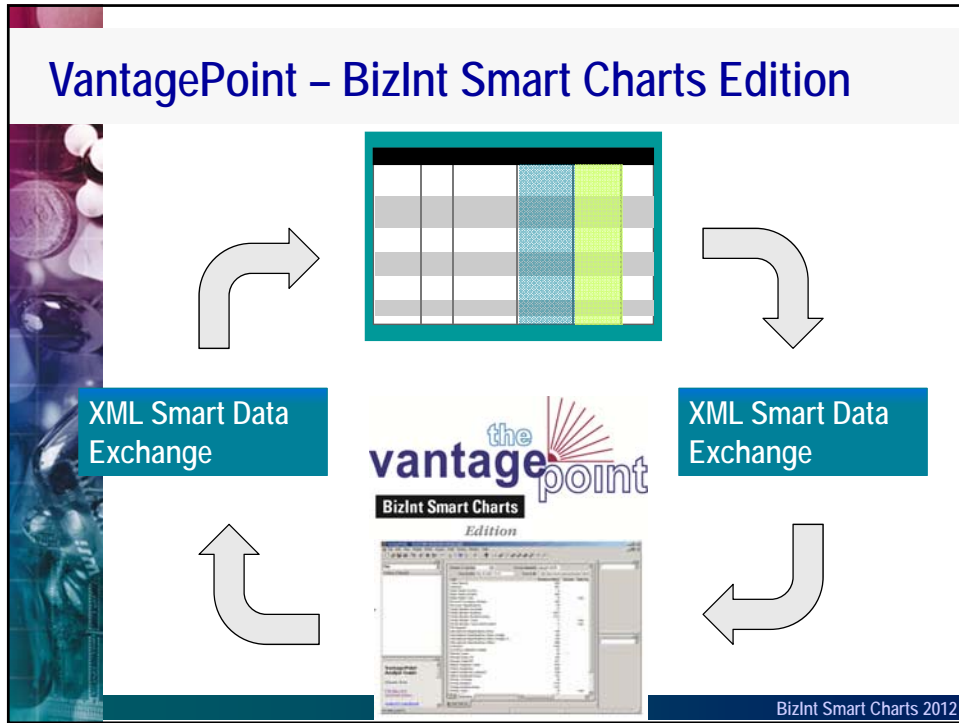
Analysis & Visualization – Two Challenges

	Official Study Title	Database	Common Trial ID	Study ID	Drug(s)	Study Phase	Study Status
469	The Effect of Boceprevir in Russian Participants Diagnosed With Chronic Hepatitis C Genotype 1 (P08160 AM1)	ClinicalTrials.Gov	NCT01425203	P08160 2010-024260-17 NCT01425203	Boceprevir Placebo peginterferon alfa-2b Ribavirin	Phase 3	Recruiting
470	Safety and Efficacy of Boceprevir in Combination With Peginterferon Alfa-2b Plus Ribavirin for Treatment of Chronic Hepatitis C Genotype 1 in Russia: Previously Untreated Patients and Patients Who Failed Prior Treatment With Pegylated-Interferon Plus Ribavirin.	Adis Clinical Trials Database	NCT01425203	700205690 (Clinical Trials Insight) EudraCT2010-024260-17 (European Clinical Trials)	Boceprevir Peginterferon-alfa-2b Ribavirin	III	Recruiting
471	Safety and Efficacy of Boceprevir in Combination With Peginterferon Alfa-2b Plus Ribavirin for Treatment of Chronic Hepatitis C Genotype 1 in Russia: Previously Untreated Patients and Patients Who Failed Prior Treatment With Pegylated-Interferon Plus Ribavirin.	Citeline TrialTrove	NCT01425203	2010-024260-17 NCT01425203 P08160 P08160 AM1 TrialTroveID-152021	boceprevir (capsule) peginterferon alfa-2b ribavirin (oral)	III	Open

2. Multiple Records for the Same Trial

1. Terminology Variation

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Apply Thesaurus to cleanup Phases

The screenshot shows the 'Thesaurus' application window. On the left, there is a table with 12 rows and 2 columns: '# Records' and 'Study Phase'. The 'Study Phase' column has a blue highlight on the 3rd row.

# Records	Study Phase
1	50
2	46
3	38
4	18
5	17
6	17
7	16
8	2
9	2
10	1
11	1
12	1


The main window shows a list of thesaurus files in a table:

Name	Date modified	Type
<input type="checkbox"/> AcadCorpGovIndiv.the	7/19/2011 2:57 PM	THE FI
<input type="checkbox"/> AmericanEnglish.the	7/19/2011 2:57 PM	THE FI
<input type="checkbox"/> BritishEnglish.the	7/19/2011 2:57 PM	THE FI
<input type="checkbox"/> Country.the	7/19/2011 2:57 PM	THE FI
<input type="checkbox"/> IPC7 subclass defs.the	7/19/2011 2:57 PM	THE FI
<input type="checkbox"/> Derwent Classifications (2009).the	7/19/2011 2:57 PM	THE FI
<input type="checkbox"/> DrugDevelopmentPhases.the	11/2/2011 5:57 PM	THE FI
<input type="checkbox"/> DrugDevelopmentPhases_Arabic.the	11/6/2011 2:15 PM	THE FI
<input checked="" type="checkbox"/> DrugDevelopmentPhases_ExcelSort.the	3/10/2012 6:45 PM	THE FI
<input type="checkbox"/> HighestPhase.the	11/2/2011 1:57 PM	THE FI
<input type="checkbox"/> IPC7.the	7/19/2011 2:57 PM	THE FI
<input type="checkbox"/> IPC8 subclass defs.the	12/6/2010 10:45 AM	THE FI
<input type="checkbox"/> IPC8.the	7/19/2011 2:57 PM	THE FI

At the bottom, the 'File name' field contains 'DrugDevelopmentPhases_ExcelSort.the' and the 'Files of type' is set to 'Thesaurus files (*.the)'. The 'Use' button is highlighted.

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Apply Thesaurus to cleanup Phases




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	# Records	# Instances	Study Phase		# Records	# Instances	Study Phase (2)
1	50	50	I	1	66	66	1 Phase 1
2	46	46	III	2	1	1	1 Phase 1/2
3	38	38	II	3	55	55	2 Phase 2
4	18	18	Phase 3	4	64	64	3 Phase 3
5	17	17	IV	5	1	1	3 Phase 3/4
6	17	17	Phase 2	6	19	19	4 Phase 4
7	16	16	Phase 1	7	3	3	8 No Development Reported
8	2	2	N/A				
9	2	2	Phase 4				
10	1	1	VII				
11	1	1	III/IV				
12	1	1	Other				

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Apply Thesaurus to cleanup Status




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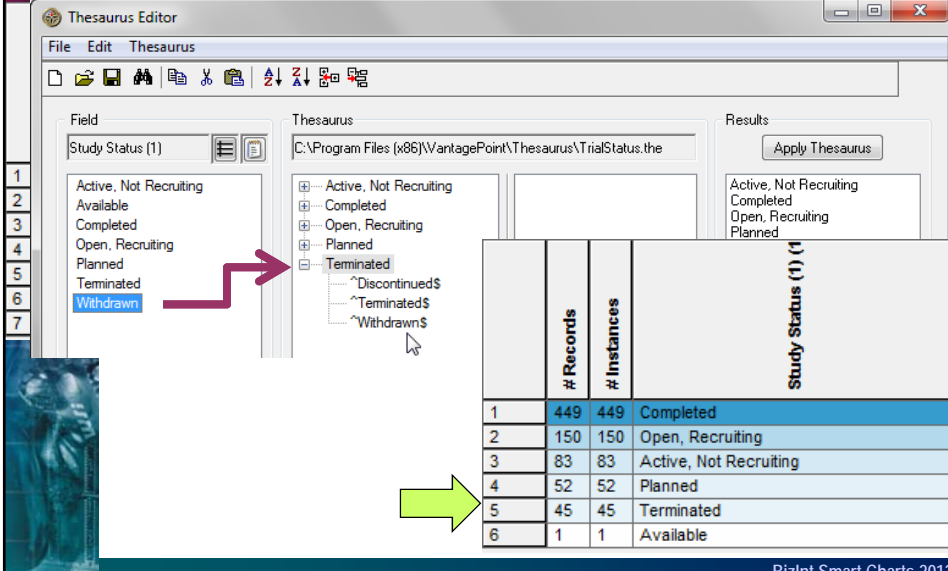
	# Records	# Instances	Study Status		# Records	# Instances	Study Status (1)
1	30	30	Active, no longer recruiting	1	449	449	Completed
2	29	29	Active, not recruiting	2	150	150	Open, Recruiting
3	1	1	Available	3	83	83	Active, Not Recruiting
4	24	24	Closed	4	52	52	Planned
5	449	449	Completed	5	42	42	Terminated
6	12	12	Discontinued	6	3	3	Withdrawn
7	1	1	Enrolling by invitation	7	1	1	Available
8	19	19	Not yet recruiting				
9	40	40	Open				
10	22	22	Planned				
11	11	11	Planning				
12	109	109	Recruiting				
13	30	30	Terminated				
14	3	3	Withdrawn				

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Editing the Trial Status Thesaurus




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	# Records	# Instances	Study Status (1) (1)
1	449	449	Completed
2	150	150	Open, Recruiting
3	83	83	Active, Not Recruiting
4	52	52	Planned
5	45	45	Terminated
6	1	1	Available

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Cleaning up the Drugs field - issues



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	# Records	# Instances	Drug(s)
1	218	218	Ribavirin
2	101	102	ribavirin, unspecified
3	92	92	Peginterferon-alfa-2a
4	78	79	peginterferon alfa-2a
5	69	69	Peginterferon-alfa-2b
6	66	66	ribavirin + PEG-IFNalpha-2a
7	64	65	ribavirin+peginterferon alfa-2
8	56	56	Telaprevir
9	53	53	peginterferon alfa-2b
10	37	37	ribavirin (oral)
11	37	37	ribavirin, Roche
12	29	30	ribavirin/interferon alfa-2b
13	28	29	Amantadine
14	18	18	pegylated interferon alpha-2b, unspecified

Punctuation


Combinations of Drugs

Route of Administration

Descriptors

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Cleaning up the Drugs field - tools



	# Records	# Instances	
1	585	627	Ribavirin
2	287	301	peginterferon
3	154	154	peginterferon
4	64	65	peginterferon
5	64	65	Telaprevir
6	62	68	Interferon alpt
7	30	31	Amantadine
8	30	31	Boceprevir
9	27	27	interferon, Ar
10	22	23	Interferon alfa-2a
11	22	24	placebo
12	20	20	TMC-435
13	15	16	BI 201335
14	14	14	highly active antiretroviral therapy


Cleanup Confirm

Cleanup Sets Detail Window

Item Name	Num Records
peginterferon alfa-2a	296
Pegasys	9
peginterferon alfa-2a	287
peginterferon alfa-2b	155
peginterferon alfa-2b	154
PEGIntron	1

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Import cleaned data as new columns



Drug(s)	Drug(s): (Cleaned)	Study Phase	Study Phase (Excel Sort)	Study Status	Study Status (Cleaned)
Boceprevir Placebo peginterferon alfa-2b Ribavirin	Ribavirin Boceprevir peginterferon alfa-2b placebo	Phase 3	3 Phase 3	Recruiting	Open, Recruiting
Boceprevir Peginterferon-alfa-2b Ribavirin	Ribavirin Boceprevir peginterferon alfa-2b	III	3 Phase 3	Recruiting	Open, Recruiting
boceprevir (capsule) peginterferon alfa-2b ribavirin (oral)	Ribavirin Boceprevir peginterferon alfa-2b	III	3 Phase 3	Open	Open, Recruiting

Now, we need to handle duplicate records...

	Official Study Title	Database	Common Trial ID	Drug(s)	Drug(s): (Cleaned)	Study Phase	Study Phase (Excel Sort)	Study Status	Study Status (Cleaned)
469	The Effect of Boceprevir in Russian Participants Diagnosed With Chronic Hepatitis C Genotype 1 (P08160 AM1)	ClinicalTrials.Gov	NCT01425203	Boceprevir Placebo peginterferon alfa-2b Ribavirin	Ribavirin Boceprevir peginterferon alfa-2b placebo	Phase 3	3 Phase 3	Recruiting	Open, Recruiting
470	Safety and Efficacy of Boceprevir in Combination With Peginterferon Alfa 2b Plus Ribavirin for Treatment of Chronic Hepatitis C Genotype 1 in Russia: Previously Untreated Patients and Patients Who Failed Prior Treatment With Pegylated Interferon Plus Ribavirin.	Adis Clinical Trials Database	NCT01425203	Boceprevir Peginterferon-alfa-2b Ribavirin	Ribavirin Boceprevir peginterferon alfa-2b	III	3 Phase 3	Recruiting	Open, Recruiting
471	Safety and Efficacy of Boceprevir in Combination With Peginterferon Alfa 2b Plus Ribavirin for Treatment of Chronic Hepatitis C Genotype 1 in Russia: Previously Untreated Patients and Patients Who Failed Prior Treatment With Pegylated Interferon Plus Ribavirin.	Citeline TrialTrove	NCT01425203	boceprevir (capsule) peginterferon alfa-2b ribavirin (oral)	Ribavirin Boceprevir peginterferon alfa-2b	III	3 Phase 3	Open	Open, Recruiting
472	Response to Pegylated Interferon and Ribavirin in Chinese Patients With Chronic Hepatitis C Genotypes 1 Versus 2/3 Versus 6.	Citeline TrialTrove	NCT01433887	peginterferon alfa-2a (SC) ribavirin (oral)	Ribavirin peginterferon alfa-2a	III	3 Phase 3	Open	Open, Recruiting
473	Response to Pegylated Interferon and Ribavirin in Chinese Patients With Chronic Hepatitis C Genotypes 1 Versus 2/3 Versus 6	Adis Clinical Trials Database	NCT01433887	Peginterferon-alfa-2a Ribavirin	Ribavirin peginterferon alfa-2b peginterferon alfa-2a	III	3 Phase 3	Recruiting	Open, Recruiting
474	Response to Pegylated Interferon and Ribavirin in Chinese Patients With Chronic Hepatitis C Genotypes 1 Versus 2/3 Versus 6	ClinicalTrials.Gov	NCT01433887	48-weeks course	Ribavirin	Phase 3	3 Phase 3	Recruiting	Open, Recruiting

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Reference Rows™

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Reference Rows – DB Rankings

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Reference Rows™

Create Reference Rows (2 of 3)

Database Ranking
Data in cells will be chosen according to the Database Ranking if no other rule is present or if there is a tie in the rules.

Rank the databases in your preferred order

ClinicalTrials.Gov	Move Up
Citeline TrialTrove	
Adis Clinical Trials Database	Move Down

Rules Template
Database rankings and rules based on:

Apply...
Save...

< Back Next > Finish Cancel

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Reference Rows – Column Rules

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Reference Rows™

Cell Selection Rule - Trial Title
Choose how Reference Rows will select data for this column.

Selection Rule: Use database ranking
 Match column: Use database ranking
 Earliest Date
 Latest Date
 Most Content (characters)
 Most Content (lines)
 Highest Development Phase
 Most Recently Updated
 Match Column

Database Ranking for this column:
 Adis Clinical Trials Database
 Citeline TrialTrove
 ClinicalTrials.Gov

Cell Selection Rule - Phase
Choose how Reference Rows will select data for this column.

Selection Rule: Most Recently Updated
 Match column: Most Recently Updated
 Earliest Date
 Latest Date
 Most Content (characters)
 Most Content (lines)
 Highest Development Phase
 Most Recently Updated
 Match Column

Database Ranking for this column:
 ClinicalTrials.Gov
 Citeline TrialTrove
 Adis Clinical Trials Database

OK Cancel

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Reference Rows – results of rules

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Reference Rows™

	Official Study Title	Database	Common Trial ID	Drug(s): (Cleaned)	Study Phase (Excel Sort)	Study Status (Cleaned)
263 .1	A Phase 3 Study of MP-424 in Combination With Peginterferon Alfa-2b and Ribavirin in Subjects With Genotype 2 Hepatitis C, Who Relapsed After Previous Treatment. ✓	Adis Clinical Trials Database	NCT01466192 ✓	Ribavirin Telaprevir peginterferon alfa-2b	3 Phase 3	Open, Recruiting
263 .2	A Phase 3 Study of MP-424 in Combination With Peginterferon Alfa-2b and Ribavirin in Subjects With Genotype 2 Hepatitis C, Who Relapsed After Previous Treatment.	Citeline TrialTrove	NCT01466192	Ribavirin Telaprevir peginterferon alfa-2b ✓	3 Phase 3 ✓	Recruiting ←
263 .3	Efficacy and Safety of MP-424, Peginterferon Alfa-2b and Ribavirin in Relapser Genotype 2 Hepatitis C Infected Patients	ClinicalTrials.Gov	NCT01466192	Ribavirin Telaprevir peginterferon alfa-2b	3 Phase 3	Open, Recruiting ✓

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Reference Rows – HTML report

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Reference Rows™

Official Study Title	Database	Common Trial ID	Study Phase (Excel Sort)	Affiliation	Drug(s): (Cleaned)	Subject Number	Study Status (Cleaned)
262. An Open Labelled, Active Controlled, Three Arm, Parallel- Group Study of the Safety and Efficacy of Revenans Administered Alone and in Combination With Standard Interferon Therapy in Patients Chronic HCV Hepatitis	262.1 CTI link 262.2 TT link 262.3 CT.gov link	NCT01463592	3 Phase 3	(Other Hospital/Academic /Medical Center)	Ribavirin Interferon alpha-2b	90	Active, Not Recruiting
263. A Phase 3 Study of MP-424 in Combination With Peginterferon Alfa-2b and Ribavirin in Subjects With Genotype 2 Hepatitis C, Who Relapsed After Previous Treatment.	263.1 CTI link 263.2 TT link 263.3 CT.gov link	NCT01466192	3 Phase 3	Mitsubishi Tanabe Pharma Corporation	Ribavirin Telaprevir peginterferon alfa-2b	100	Open, Recruiting
264. An Open Label,Phase 3 Study of Telaprevir in Combination With Peginterferon Alfa 2a (Pegasy) and Ribavirin (Copegus) in Subjects Coinfected With Genotype 1 Hepatitis C Virus and Human Immunodeficiency Virus Type 1(HCV/HIV-1).	264.1 CTI link 264.2 TT link 264.3 CT.gov link	NCT01467479	3 Phase 3	Vertex Pharmaceuticals	Ribavirin Telaprevir	160	Open, Recruiting

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Reference Rows – export to VantagePoint

Choose Export Format

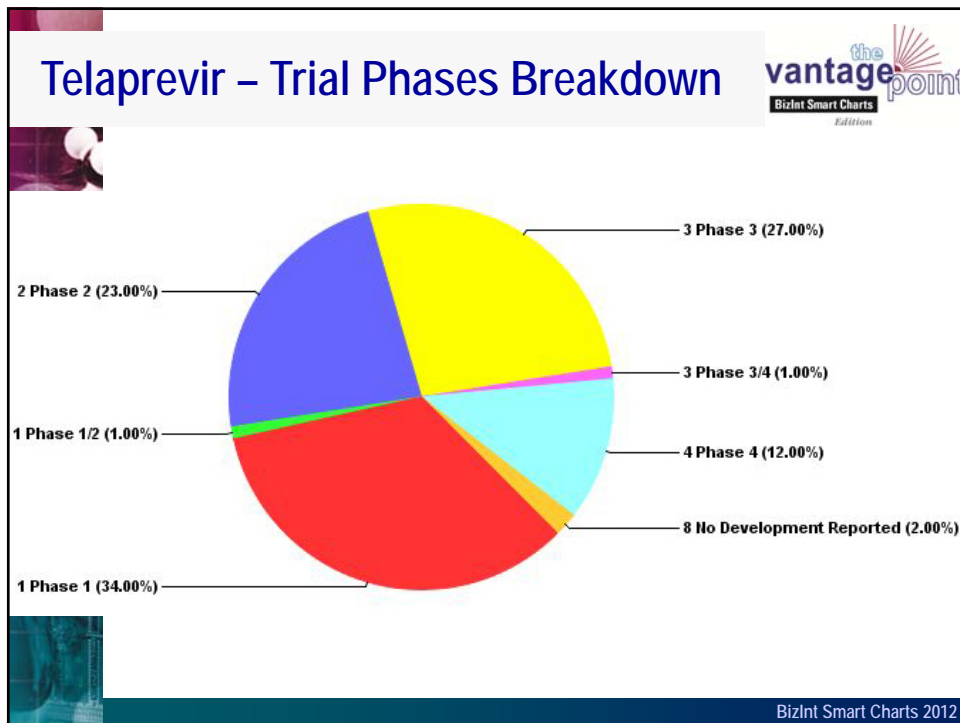
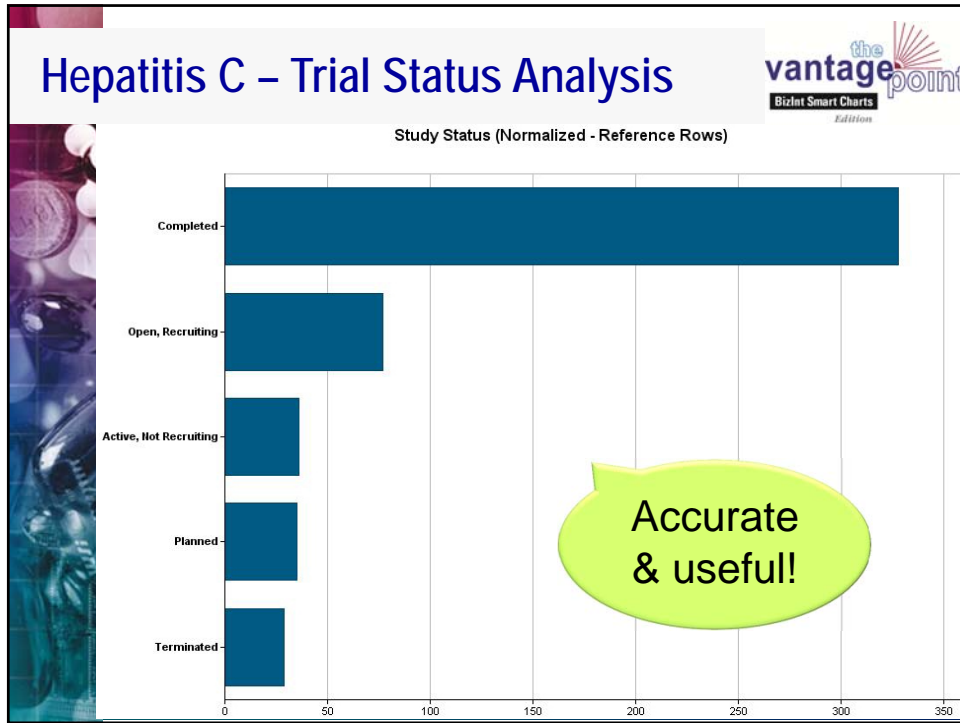
Choose a file format for export

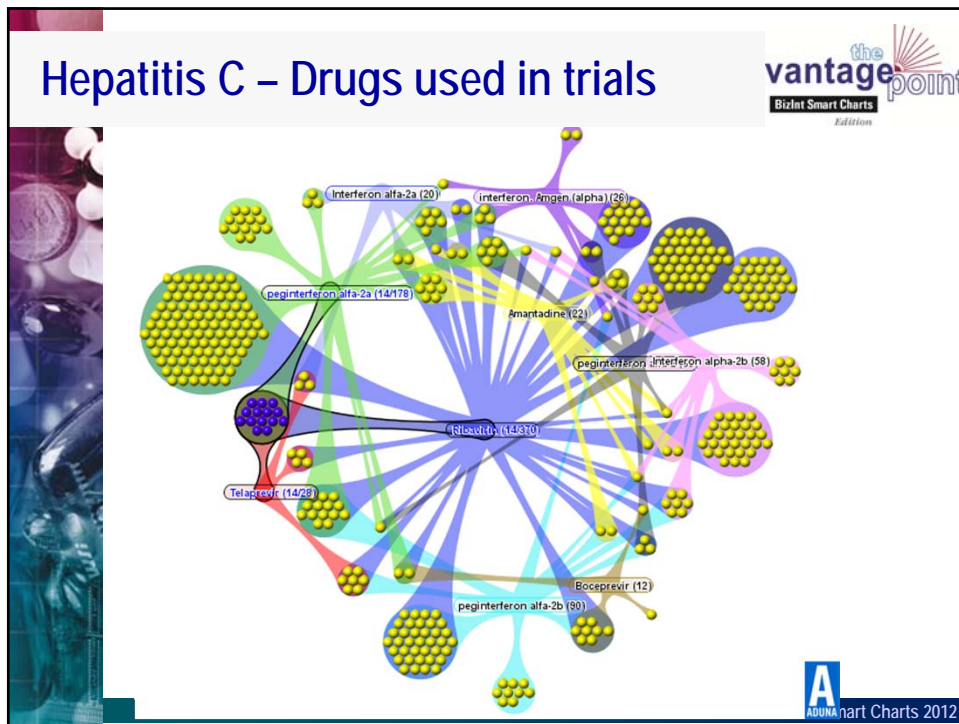
- HTML (chart and records)
- HTML - for Word (chart only)
- HTML - for Word (chart and records)
- HTML - for Excel (chart only)
- HTML - for Excel (chart and records)
- RTF (records only)
- CSV - for Excel (chart only)
- Tab delimited (chart only)
- XML - Smart Data Exchange [BETA] (chart only)**

OK Cancel Help

Official Study Title	Database	Common Trial ID	Study Phase (Excel Sort)	Affiliation	Drug(s): (Cleaned)	Subject Number	Study Status (Cleaned)
262. An Open Labelled, Active Controlled, Three Arm, Parallel- Group Study of the Safety and Efficacy of Revenans Administered Alone and in Combination With Standard Interferon Therapy in Patients Chronic HCV Hepatitis	262.1 CTI link 262.2 TT link 262.3 CT.gov link	NCT01463592	3 Phase 3	(Other Hospital/Academic /Medical Center)	Ribavirin Interferon alpha-2b	90	Active, Not Recruiting
263. A Phase 3 Study of MP-424 in Combination With Peginterferon Alfa-2b and Ribavirin in Subjects With Genotype 2 Hepatitis C, Who Relapsed After Previous Treatment.	263.1 CTI link 263.2 TT link 263.3 CT.gov link	NCT01466192	3 Phase 3	Mitsubishi Tanabe Pharma Corporation	Ribavirin Telaprevir peginterferon alfa-2b	100	Open, Recruiting
264. An Open Label,Phase 3 Study of Telaprevir in Combination With Peginterferon Alfa 2a (Pegasy) and Ribavirin (Copegus) in Subjects Coinfected With Genotype 1 Hepatitis C Virus and Human Immunodeficiency Virus Type 1(HCV/HIV-1).	264.1 CTI link 264.2 TT link 264.3 CT.gov link	NCT01467479	3 Phase 3	Vertex Pharmaceuticals	Ribavirin Telaprevir	160	Open, Recruiting

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Competitive Intelligence Must be Actionable!

Clinical Trial intelligence adds an added level of focus to Pipeline Intelligence.

- Determine key competitor drug trial endpoints.
- Determine when trials may be ending to predict potential product launches.
- Monitor additional indications being sought.
- Determine in which countries trials are being run and for which indications.
- Evaluate dosing and delivery options.

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Concluding Thoughts

- Value in having more than one database.
- Each of the clinical trial databases have indexing inaccuracies.
- Important to review CT databases after major meetings.
- Use of Smart Charts Common Trial ID and Statistics results in less time sorting and more time for analysis.
- Use Reference Rows and VantagePoint to clean up data for meaningful analysis.

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