



BizInt Smart Charts

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

Pharma-Bio-Med 2011 - Venice, Italy – 21 Nov 2011

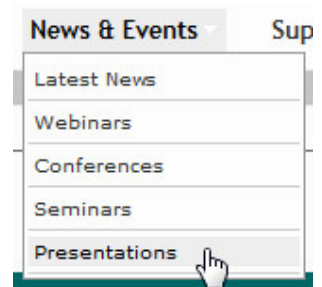
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Jennifer Friend-Huizer,
Manager, Global Business Intelligence,
Janssen Global Services (J&J)



Goals for this presentation

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

Slides will be 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)
- Searches performed in April, July, Sept 2011
- Searched two compounds:
 - Januvia** (diabetes, launched,)
 - Teleprevir** (hepatitis-C, late phase 3/launched)

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Januvia – search methodology



ClinicalTrials.gov Search Results:

Found 223 studies with search of: **Januvia OR sitagliptin OR MK-431 OR MK431 OR MK-6431 OR MK6431 OR ooo-6430 OR ooo6436**

Rank	Status	Study
1	Not yet recruiting	Dose-Response Finding Study of MK-6431/OHO-5435 in Japanese Subjects With Impaired Glucose Tolerance (MK-6431-10) Condition: Glucose Intolerance Interventions: Drug: Sitagliptin 20 mg; Drug: Sitagliptin 50 mg; Drug: Placebo for Sitagliptin 25 mg; Drug: Placebo for Sitagliptin 50 mg
2	Completed	MK-6431/OHO-5435 Phase III Clinical Trial - Insulin Add-on Study for Patients With Type 2 Diabetes Mellitus Condition: Type 2 Diabetes Mellitus Intervention: Drug: MK-6431/OHO-5435
3	Completed	Controlled Study of MK-6431/OHO-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-6431/OHO-5435 in Patients With Type 2 Diabetes Mellitus Condition: Type 2 Diabetes Mellitus Interventions: Drug: Placebo; Drug: Sitagliptin phosphate
5	Completed	MK-6431/OHO-5435 Phase III Clinical Trial - Add-on to Voglibose Study for Patients With Type 2 Diabetes Mellitus (MK-6431-10) COMPLETE Condition: Diabetes Mellitus, Non-Insulin Dependent Interventions: Drug: sitagliptin; Drug: Comparator Placebo; Drug: Voglibose
6	Completed Has Results	Monotherapy Study in Patients With Type 2 Diabetes Mellitus Condition: Diabetes Mellitus, Type 2 Interventions: Drug: Sitagliptin MK-6431; Drug: Sitagliptin; Drug: Placebo; Drug: Metformin; Drug:

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Telaprevir – search methodology



The image displays two screenshots of clinical trial search engines. The top screenshot shows the 'ClinicalTrials.gov' search interface. The 'Query Builder' is active, showing a list of drugs including Telaprevir, VX-950, and Incevik. A 'Letter Browse' grid is visible, with the letters 'A' through 'Z' circled. The bottom screenshot shows the 'Citeline' search interface. A 'Find Drugs' window is open, displaying a list of drugs including Telaprevir, VX-950, and Incevik. A 'Find First' button is circled. Below the screenshots, a list of search results is shown, including study titles and conditions.

ClinicalTrials.gov Search Results:

Found 38 studies with search of: Incevik OR Incevik OR telaprevir OR vx-950 OR vx-950 OR vx-950 OR vx-950 OR vx-950

Rank	Status	Study
1	Active, not recruiting	TMC125E D1981 - Drug-Drug Interaction of Efavirenz With Telaprevir and TMC278 With Telaprevir
2	Completed	VX-950-TD024-C26: A Safety and Efficacy Study of Telaprevir in Chronic Genotype 1 Hepatitis C Patients That Failed Previous Standard Treatment
3	Active, not recruiting	VX-950-C211 - A Dosing Regimen Study (Twice Daily Versus Every 8 Hours) of Telaprevir in Treatment-naïve Patients With Genotype 1 Chronic Hepatitis C Virus Infection
4	Recruiting	Telaprevir in HIV/HCV Coinfected Patients Who Had Previously Failed A Peginterferon/Sibavirin Regimen
5	Completed	A Study to Examine the Effects of Telaprevir on the Pharmacokinetics of Cyclosporine and Tacrolimus in Healthy Adults
6	Completed	A Study of Telaprevir (VX-950), Pegasys and Coartem in Hepatitis C

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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)	

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Case study – search results



Januvia	April 2011	July 2011	Sept 2011
CT.gov	202 trials	221 trials	223 trials
Citeline TT	276 trials	303 trials	311 trials
Adis CTI	219 trials	257 trials	280 trials

Teleprevir	April 2011	July 2011	Sept 2011
CT.gov	36 trials	37 trials	38 trials
Citeline TT	45 trials	48 trials	65 trials
Adis CTI	37 trials	42 trials	43 trials

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Case study – Common Trial ID tool

The screenshot shows the 'Tools' menu of the Common Trial ID tool. The 'Generate Common Trial IDs' option is selected. Below the menu is a table with three columns: 'Trial Title', 'Common ID', and 'Trial Identifier'. The table contains three rows of data, with red and green arrows pointing to specific identifiers in the 'Common ID' column.

	Trial Title	Common 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 (Janssen Pharmaceutica NV, 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-081642 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 displays the 'Common Trial ID' tool interface. At the top, there is a menu bar with 'Tools', 'Options', 'Window', and 'Help'. The 'Tools' menu is open, showing options: 'Statistics...', 'Generate Common Drug Names', and 'Generate Common Trial IDs', with the latter being selected. Below the menu, a table lists trial information. A pop-up window titled 'Common Trial ID' shows the value 'NCT00781274' for each row.

	Trial Title	Common Trial ID	Database	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	Adis Clinical Trials Database	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	Citeline TrialTrove	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 Achieved an Undetectable HCV 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

OK Cancel Help

	A	B
1	Common Trial ID	Count
2	NCT00627926	20
3	NCT00828789	6
7	NCT00509210	3
8	NCT00528528	3
9	NCT00580801	3
10	NCT00591214	3
11	NCT00613704	3
12	NCT00621296	3
13	NCT00630058	3
14	NCT00775125	3
15	NC	
16	NC	
17	NC	
18	NC	
19	NC	
20	NC	
21	NC	
22	NC	
23	NCT00588855	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	700198672	1
36	700198674	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 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.

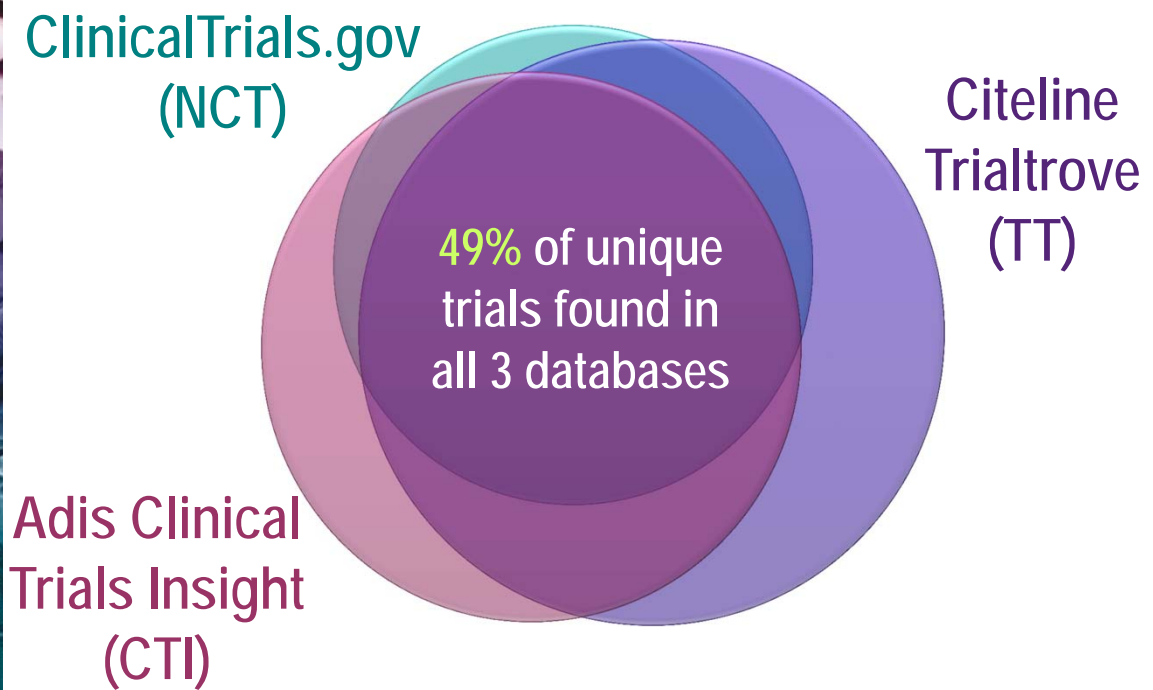
Case study – Common Trial ID tool

	Trial Title	Common Trial ID	CiteID	Trial Identifier
25	A Randomized Study of Stopping Treatment at 24 Weeks or Continuing Treatment to 48 Weeks in Treatment-Naive 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	CiteID	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 Inhibition for Viral Evaluation 2 (PROVE2) trial.	NCT00535847	CiteID	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	CiteID	VX08-950-111 VX08-950-112 NCT00372385 NCT00916474 PROVE 2 TrialTroveID-048351
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 Inhibition for Viral Evaluation 1 (PROVE1) Trial.	NCT00535847	CiteID	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 Inhibition of Viral Evaluation 3 (PROVE3).	NCT00535847	CiteID	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 TrialTroveID-076900
30	A Phase 3 Study of 2 Dose Regimens of Telaprevir in Combination With Peginterferon Alfa-2a (Pegasys) and Ribavirin (Copegus) in Treatment-Naive Subjects With Genotype 1 Chronic Hepatitis C.	NCT00535847	CiteID	VX06-950-107 VX08-950-112

Phase IV trial ID included for all prior related trials.

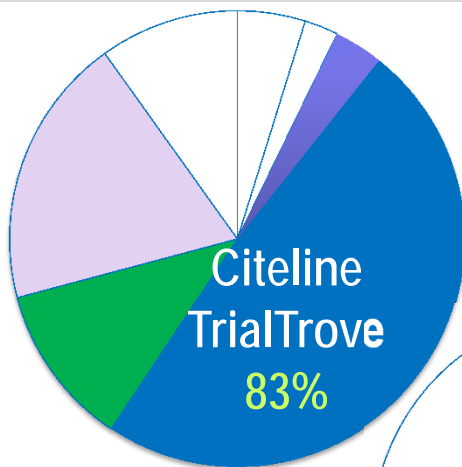
Vertex ADVANCE
VX07-950-108
VX07950108
VX08-950-112

Januvia – Overlap between databases

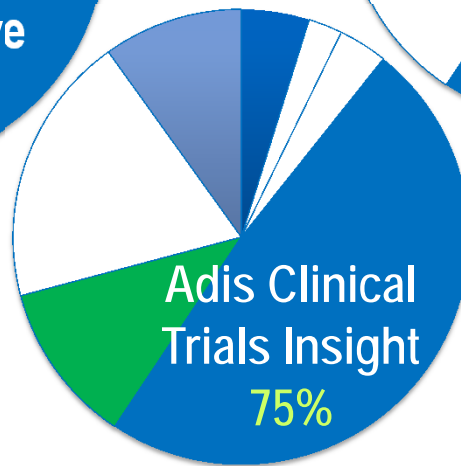
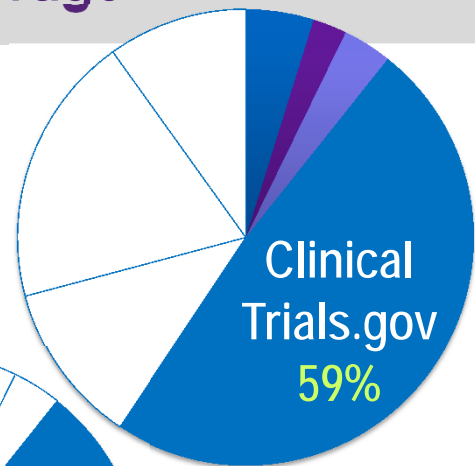


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Januvia trials – Database coverage



*Percentage of
unique trials
retrieved from
each database.*



49% of unique
trials found in all
3 databases.

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Januvia – evaluation



- 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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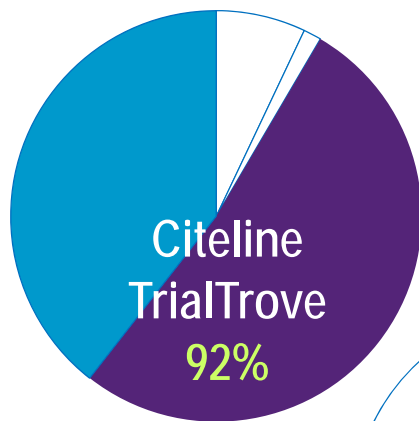
Januvia – evaluation (cont.)



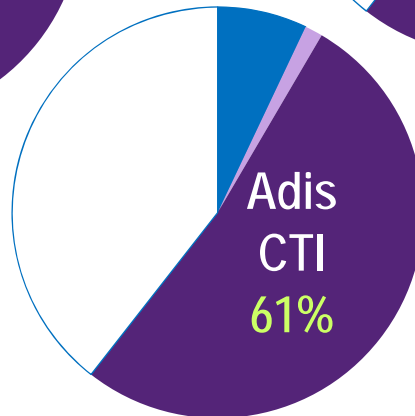
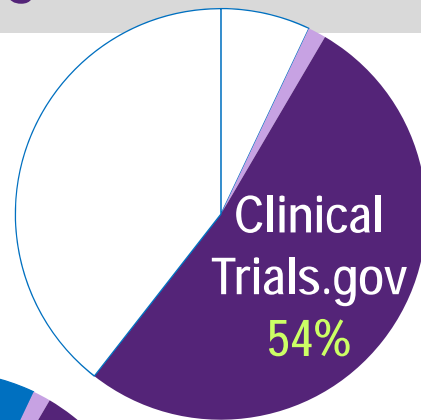
- Of the 9 trials found only CT.gov, 2 did not have Januvia in the record. The 7 others are legitimate trials but were not retrieved from TT or CTI.
- One trial only in Adis was a new observational trial of 500 patients in Japan – source from University Hospital Medical Information Network - Japan.
-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

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Telaprevir – Database coverage



Percentage of unique trials retrieved from each database.



52% of unique trials found in all 3 databases.

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Telaprevir – some evaluation



- 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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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.

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Januvia: updated clinical trial reports with changes		Row Status	Patient Population			
Januvia (TrialTrove) April 2011 updated S		Added	Japanese subjects with impaired glucose tolerance who have inadequate glycemic control using diet and exercise therapy.			
Trial Title		Added	Trial Phase	Trial Status	Disease	Patients with type 2 diabetes during ramadan fasting.
1	A Phase II, Randomized, Placebo-Controlled, Parallel-group, Double-Blind, Dose Response Finding Clinical Trial to Study the Efficacy and Safety of MK-0431/ONO-5435 in Japanese Subjects With Impaired Glucose Tolerance Who Have Inadequate Glycemic Control on Diet/Exercise Therapy.	Added	II	Planned	Type 2 Diabetes	Patients with type II diabetes receiving a de novo prescription (for the first time or within less than 8 weeks) for bitherapy with or without Januvia/Xelevia or any other treatment regimen including Januvia/Xelevia by general practitioners in private practice under real life conditions without any additional treatment or monitoring procedures.
2	An Open-Label, Randomized Naturalistic Study Evaluate the Incidence of Hypoglycemia Compared Sitagliptin With Sulfonylurea Treatment in Patients With Type 2 Diabetes During Ramadan Fasting.	Added	III	Closed	Type 2 Diabetes	Diabetic patients treated with metformin monotherapy in Austria.
3	Observational Study of the Treatment and Follow-up of Patients With Type II Diabetes Receiving Bitherapy With or Without Januvia/Xelevia.	Added	IV	Closed	Type 2 Diabetes	Patients with type 2 diabetes mellitus who have inadequate glycemic (blood sugar) control (age = 56 +/- 7 yrs [mean +/- SD], BMI = 29.9 +/- 4.2 kg/m ² , HbA1c = 7.4 +/- 0.8%) and age- and BMI-matched controls (n = 7).
4	Efficacy and Tolerability of Sitagliptin in Type 2 Diabetic Patients Inadequately Controlled with Metformin. A Prospective Observational Study Austrian Primary Care.	Updated	IV	Completed	Type 2 Diabetes	Japanese patients with type 2 diabetes mellitus.
5	A Randomized, Placebo-Controlled Study to Evaluate the Safety, Efficacy and Mechanism of Action of MK0431/Sitagliptin in Patients With Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control.	Updated	I	Completed	Type 2 Diabetes	Nondiabetic mild to moderate hypertensive patients on stable treatment with antihypertensive agent(s) were enrolled.
6	An open-label, 3-period crossover study of voglibose on the pharmacokinetics and pharmacodynamics of sitagliptin in Japanese subjects.	Updated	II	Completed	Type 2 Diabetes	Patients with T2 DM with inadequate glycemic control on metformin.
7	A study to evaluate the effect of sitagliptin, a dipeptidyl peptidase-4 inhibitor, on blood pressure in nondiabetic patients with mild to moderate hypertension.	Updated	II	Completed	Hypertension	Patients With Type 2 Diabetes Mellitus With Inadequate Glycemic Control.
8	A Multicenter, Randomized, Open-Label Study to Assess the Efficacy and Safety of Sitagliptin Added to the Regimen of Patients With T2 DM With Inadequate Glycemic Control on Metformin.	Updated	III	Completed	Type 2 Diabetes	
9	A Multicenter, Double-Blind, Randomized Study Evaluate the Safety and Efficacy of Sitagliptin Compared With Metformin in Patients With Type 2 Diabetes Mellitus With Inadequate Glycemic Control.	Updated	III	Completed	Type 2 Diabetes	

Januvia: highlighting trials of possible interest

Januvia (TrialTrove) April 2011 updated Sept 2011			Trial Phase	Trial Status	Disease	Investigator	Patient Population
1	A Phase II, Randomized, Placebo-Controlled, Parallel-group, Double-Blind, Dose Response Finding Clinical Trial to Study the Efficacy and Safety of MK-0431/ONO-5435 in Japanese Subjects With Impaired Glucose Tolerance Who Have Inadequate Glycemic Control on Diet/Exercise Therapy.	Added	II	Planned	Type 2 Diabetes	Sharp &	Japanese subjects with impaired glucose tolerance who have inadequate glycemic control using diet and exercise therapy.
2	An Open-Label, Randomized Naturalistic Study to Evaluate the Incidence of Hypoglycemia Comparing Sitagliptin With Sulfonyleurea Treatment in Patients With Type 2 Diabetes During Ramadan Fasting.	Added	III	Closed	Type 2 Diabetes		Patients with type 2 diabetes during ramadan fasting.
3	Observational Study of the Treatment and Follow-up of Patients With Type II Diabetes Receiving Bitherapy With or Without Januvia/Xelevia.	Added	IV	Closed	Type 2 Diabetes	Sharp &	Patients with type II diabetes receiving a de novo prescription (for the first time or within less than 8 weeks) for bitherapy with or without Januvia/Xelevia or any other treatment regimen including Januvia/Xelevia by general practitioners in private practice under real life conditions without any additional treatment or monitoring procedures.
4	Efficacy and Tolerability of Sitagliptin in Type 2 Diabetic Patients Inadequately Controlled with Metformin. A Prospective Observational Study in Austrian Primary Care.	Added	IV	Closed	Type 2 Diabetes	Sharp &	Diabetic patients treated with metformin monotherapy in Austria.
5	A Randomized, Placebo-Controlled Study to Evaluate the Safety, Efficacy and Mechanism of Action of MK0431/Sitagliptin in Patients With Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control.	Updated	IV	Completed	Type 2 Diabetes		Patients with type 2 diabetes mellitus who have inadequate glycemic (blood sugar) control (age = 56 +/- 7 yrs [mean +/- SD], BMI = 29.9 +/- 4.2 kg/m ² , HbA1c = 7.4 +/- 0.8%) and age- and BMI-matched controls (n = 7).
6	An open-label, 3-period crossover study of voglibose on the pharmacokinetics and pharmacodynamics of sitagliptin in Japanese subjects.	Updated	I	Completed	Type 2 Diabetes		Japanese patients with type 2 diabetes mellitus.
7	A study to evaluate the effect of sitagliptin, a dipeptidyl peptidase-4 inhibitor, on blood pressure in nondiabetic patients with mild to moderate hypertension.	Updated					Nondiabetic mild to moderate hypertensive patients on stable treatment with antihypertensive agent(s) were enrolled.
8	A Multicenter, Randomized, Open-Label Study to Assess the Efficacy and Safety of Sitagliptin Added to the Regimen of Patients With T2 DM With Inadequate Glycemic Control on Metformin.	Updated	II	Completed	Type 2 Diabetes		Patients with T2 DM with inadequate glycemic control on metformin.
9	A Multicenter, Double-Blind, Randomized Study to Evaluate the Safety and Efficacy of Sitagliptin Compared With Metformin in Patients With Type 2 Diabetes Mellitus With Inadequate Glycemic Control.	Updated	II	Completed	Hypertension		Patients With Type 2 Diabetes Mellitus With Inadequate Glycemic Control.

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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)

Januvia – how to deal with duplicate records?

Combined: Januvia (CTgov, CTI, TT) 12 Sept 2011

	Trial Title	Database	Phase	Sponsor(s)	Brief Summary	Trial Status
701	Randomized Controlled Study of DPP4 Inhibitor (Sitagliptin) Therapy in the Inpatient Management of Patients With Type 2 Diabetes.	Adis Clinical Trials Database	IV	Merck & Co	This trial will compare the efficacy of sitagliptin [Januvia; Merck and Co] alone or in combination with insulin gargline [Lantus] in hospitalised patients with type 2 diabetes mellitus. Patients will also receive correction doses of rapid-acting insulin-lispro [Humalog] if needed (blood glucose greater than 140 mg/dL). [CONT.]	Active, no longer recruiting
702	Randomized Controlled Study of DPP4 Inhibitor (Sitagliptin) Therapy in the Inpatient Management of Patients With Type 2 Diabetes.	Citeline TrialTrove	IV	Emory University Hospital - Atlanta Merck & Co.	To compare sitagliptin by mouth, insulin (lantus) injection, and the combination of sitagliptin and lantus insulin in controlling blood sugar in hospitalized patients with diabetes.	Planned
703	DPP4 Inhibitor in the Hospital	ClinicalTrials.Gov	Phase 4	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. Glargine (Lantus [®]) insulin injection is the most common treatment of diabetes in the hospital. [CONT.]	Not yet recruiting
704	DPP-IV Inpatient Trial	ClinicalTrials.Gov	Phase 4	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. Lantus insulin injection is the most common treatment of diabetes in the hospital. Sitagliptin is effective in lowering blood glucose, but has not been tested in the hospital [CONT.]	Active, not recruiting

Januvia – Reference Rows – DB Rankings

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:

< Back Next > Finish Cancel

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Januvia – Reference Rows – Column Rules

The image shows two overlapping dialog boxes from the BizInt Smart Charts 2011 application. The background dialog is titled "Cell Selection Rule - Trial Title" and the foreground dialog is titled "Cell Selection Rule - Phase".

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

The "Phase" dialog also features "Move Up" and "Move Down" buttons next to the database ranking list, and "OK" and "Cancel" buttons at the bottom right.

BizInt Smart Charts 2011

Januvia – Reference Rows

Database		Phase	Sponsor(s)	Brief Summary	Mechanism of Action	Update Date
Combined: Januvia (CTgov, CTI, TT) 12						
96.1	DPP4 Inhibitor in the Hospital	ClinicalTrials.Gov	Phase 4	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. Glargine (Lantus®) insulin injection is the most common treatment of diabetes in the hospital. [CONT.]	2011-06-20
96.2	DPP-IV Inpatient Trial	ClinicalTrials.Gov	Phase 4	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. Lantus insulin injection is the most common treatment of diabetes in the hospital. Sitagliptin is effective in lowering blood glucose, but has not been tested in the hospital [CONT.]	2011-06-13
96.3	Randomized Controlled Study of DPP4 Inhibitor (Sitagliptin) Therapy in the Inpatient Management of Patients With Type 2 Diabetes.	Citeline	IV	Emory University Hospital - Atlanta Merck & Co.	To compare sitagliptin by mouth, insulin (lantus) injection, and the combination of sitagliptin and lantus insulin in controlling blood sugar in hospitalized patients with diabetes.	2011-06-24
96.4	Randomized Controlled Study of DPP4 Inhibitor (Sitagliptin) Therapy in the Inpatient Management of Patients With Type 2 Diabetes.	Adis Clinical Databases	IV	Emory University Hospital - Atlanta Merck & Co.	CD26-antigen-inhibitors Ornithine-decarboxylase-stimulants Phosphokinase-stimulants	2011-06-24

BizInt Smart Charts 2011

Januvia - Reference Rows HTML report


Trial Title	Database	Phase	Sponsor(s)	Brief Summary	Trial Status				
96. Randomized Controlled Study of DPP4 Inhibitor (Sitagliptin) Therapy in the Inpatient Management of Patients With Type 2 Diabetes.	96.1 NCT 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				
	96.2 NCT link								
	96.3 TT link								
	96.4 CTI link								
	96.4 CTI	96.3 TT	96.1 NCT	96.2 NCT	96.3 TT				
	97.3 CTI	97.2 TT	97.1 NCT	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.	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	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	2011-08-1	
	98.2 TT link								
	98.3 CTI link								
	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	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	2011-09-0	
	99.2 TT link								
	99.3 CTI link								
	99.3 CTI	99.3 CTI	99.1 NCT	99.2 TT	99.3 CTI	99.2 TT	99.3 CTI	99.3 CTI	

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Reference Rows – terminology variation

Trial Title	Database	Phase	Sponsor(s)	Brief Summary	Trial Status	Participant 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	IV	University of Oklahoma	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	2011-06-2
	96.2 NCT link							
	96.3 TT link							
	96.4 CTI link							
97. Changes in Bone Turnover With Increased Incretin Hormone Exposure (UAB Diabetes Research and Training Center Pilot and Feasibility Study).	97.1 NCT link	IV	University of Alabama 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	2011-06-2
	97.2 TT link							
	97.3 CTI link							
	97.3 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		artis	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	Patients with type 2 diabetes on metformin therapy.	CD26-antigen-inhibitors	2011-08-1
	98.2 TT link							
	98.3 CTI link							
	97.2 TT							
99. Pharmacogenetics of Ace Inhibitor-Associated Angioedema:Aim 1.	99.1 NCT link	Phase 4	Duke 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	2011-09-0
	99.2 TT link							
	99.3 CTI link							
	99.3 CTI							

XML Smart Data Exchange -

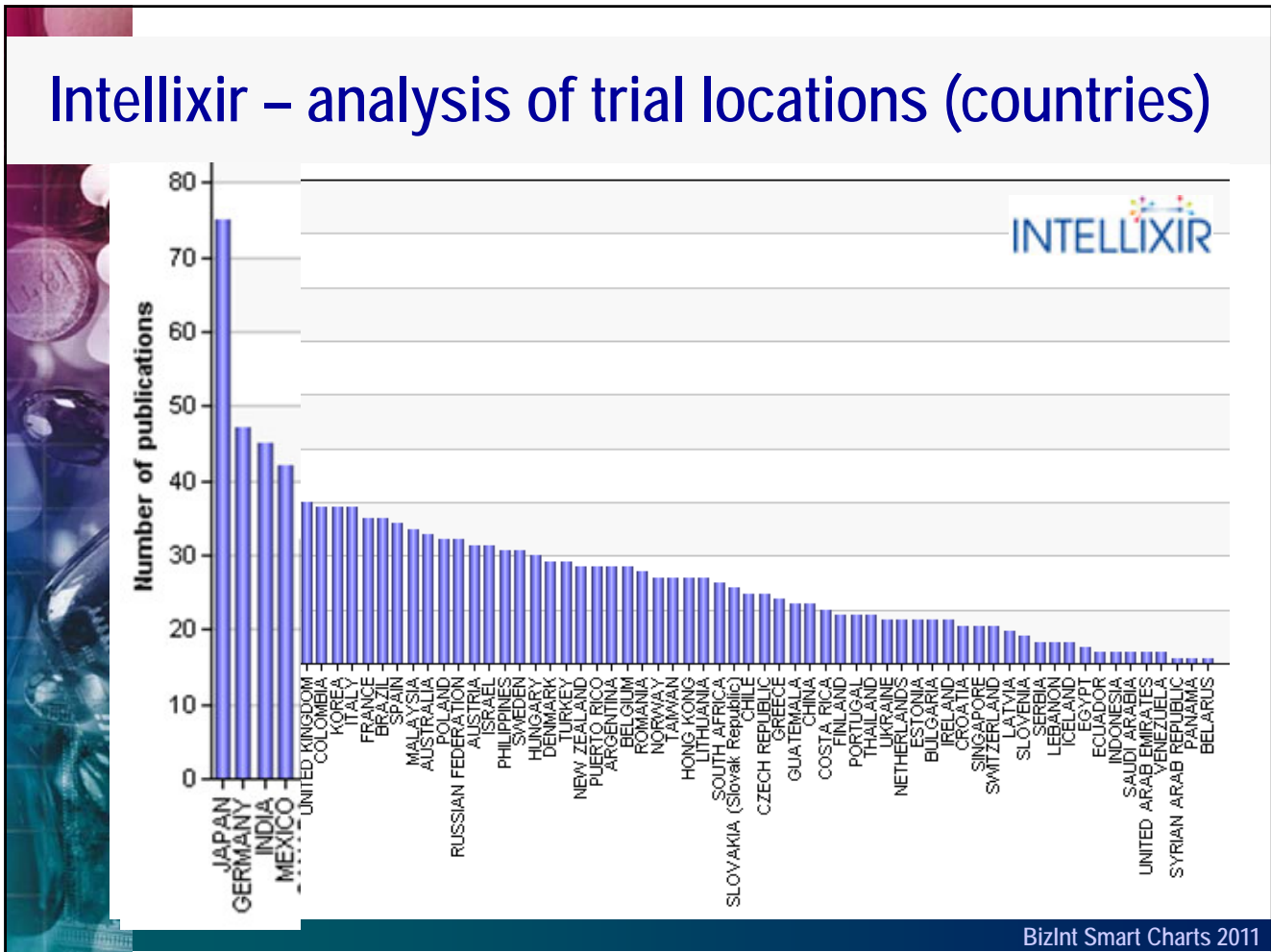


	Trial Title	Database	Phase	Phase (Normalized)	Sponsor(s)	Trial Status	Trial Status (Normalized)
96 .1	DPP4 Inhibitor in the Hospital	ClinicalTrials.Gov	Phase 4	Phase 4 ✓	Emory University Merck ✓	Not yet recruiting	Planned
96 .2	DPP-IV Inpatient Trial	ClinicalTrials.Gov	Phase 4	Phase 4	Emory University Merck	Active, not recruiting	Active, Not Recruiting
96 .3	Randomized Controlled Study of DPP4 Inhibitor (Sitagliptin) Therapy in the Inpatient Management of Patients With Type 2 Diabetes.	Citeline TrialTrove	IV ✓	Phase 4	Emory University Hospital - Atlanta Merck & Co.	Planned ✓	Planned ✓
96 .4	Randomized Controlled Study of DPP4 Inhibitor (Sitagliptin) Therapy in the Inpatient Management of Patients With Type 2 Diabetes. ✓	Adis Clinical Trials Database	IV	Phase 4	Merck & Co	Active, no longer recruiting	Active, Not Recruiting
97 .1	Changes in Bone Turnover With Increased Incretin Hormone Exposure	ClinicalTrials.Gov	Phase 4	Phase 4 ✓	University of Alabama at Birmingham ✓	Recruiting	Open, Recruiting
97 .2	Changes in Bone Turnover With Increased Incretin Hormone Exposure (UAB Diabetes Research and Training Center Pilot and Feasibility Study)	Citeline TrialTrove	IV ✓	Phase 4	University of Alabama, Birmingham	Open ✓	Open, Recruiting ✓
97 .3	Changes in Bone Turnover With Increased Incretin Hormone Exposure (UAB Diabetes Research and Training Center Pilot and Feasibility Study). ✓	Adis Clinical Trials Database	IV	Phase 4		Recruiting	Open, Recruiting

Reference Row HTML – with normalized fields

Trial Title	Database	Phase (Normalized)	Sponsor(s)	Trial Status (Normalized)	Patient Population	Mechanism of Action	Update Date
97. Changes in Bone Turnover With Increased Incretin Hormone Exposure (UAB Diabetes Research and Training Center Pilot and Feasibility Study).	97.1 NCT 97.2 TT <i>tr</i> 97.3 CTI <i>ti</i>	Phase 4	University of Alabama at Birmingham	Open, Recruiting	postmenopausal women with type 2 diabetes.	CD26-antigen-inhibitors	2011-06-23
	97.3 CTI		97.1 NCT		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 98.2 TT <i>tr</i> 98.3 CTI <i>ti</i>	Phase 4	Novartis	Open, Recruiting	subjects with type 2 diabetes on metformin monotherapy.	CD26-antigen-inhibitors	2011-08-16
	98.3 CTI		98.1 NCT		98.2 TT	98.3 CTI	98.1 NCT
99. Pharmacogenetics of Ace Inhibitor-Associated Angioedema:Aim 1.	99.1 NCT 99.2 TT <i>tr</i> 99.3 CTI <i>ti</i>	N/A	Vanderbilt University	Planned	healthy people.	ACE-inhibitors CD26-antigen-inhibitors	2011-09-01
	99.3 CTI		99.1 NCT		99.2 TT	99.3 CTI	99.3 CTI
100. A Multicenter, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of the Addition of MK-0431 to Patients With Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control on Pioglitazone Therapy.	100.1 NCT 100.2 TT <i>tr</i> 100.3 CTI <i>ti</i>	Phase 3	Merck	Completed	patients with type 2 diabetes mellitus who have inadequate glycemic control on pioglitazone therapy.	AMP-activated-protein-kinase-stimulants CD26-antigen-inhibitors Gluconeogenesis-inhibitors Peroxisome-proliferator-activated-receptor-gamma-agonists	2011-06-02
	100.3 CTI		100.1 NCT		100.2 TT	100.3 CTI	100.3 CTI
101. A Multicenter, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of the Addition of MK-0431 to Patients With Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control on Metformin Therapy	101.1 NCT 101.2 TT <i>tr</i> 101.3 CTI <i>ti</i>	Phase 3	Merck	Completed	N/A	AMP-activated-protein-kinase-stimulants CD26-antigen-inhibitors Gluconeogenesis-inhibitors Insulinotropin-agonists	2011-06-02
	101.3 CTI		101.1 NCT		101.2 TT	101.3 CTI	101.3 CTI

Intellixir – analysis of trial locations (countries)



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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