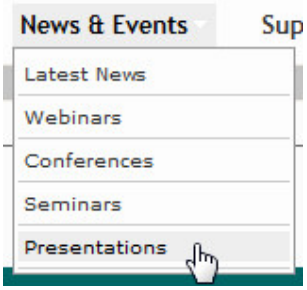
Goals for this presentation

- 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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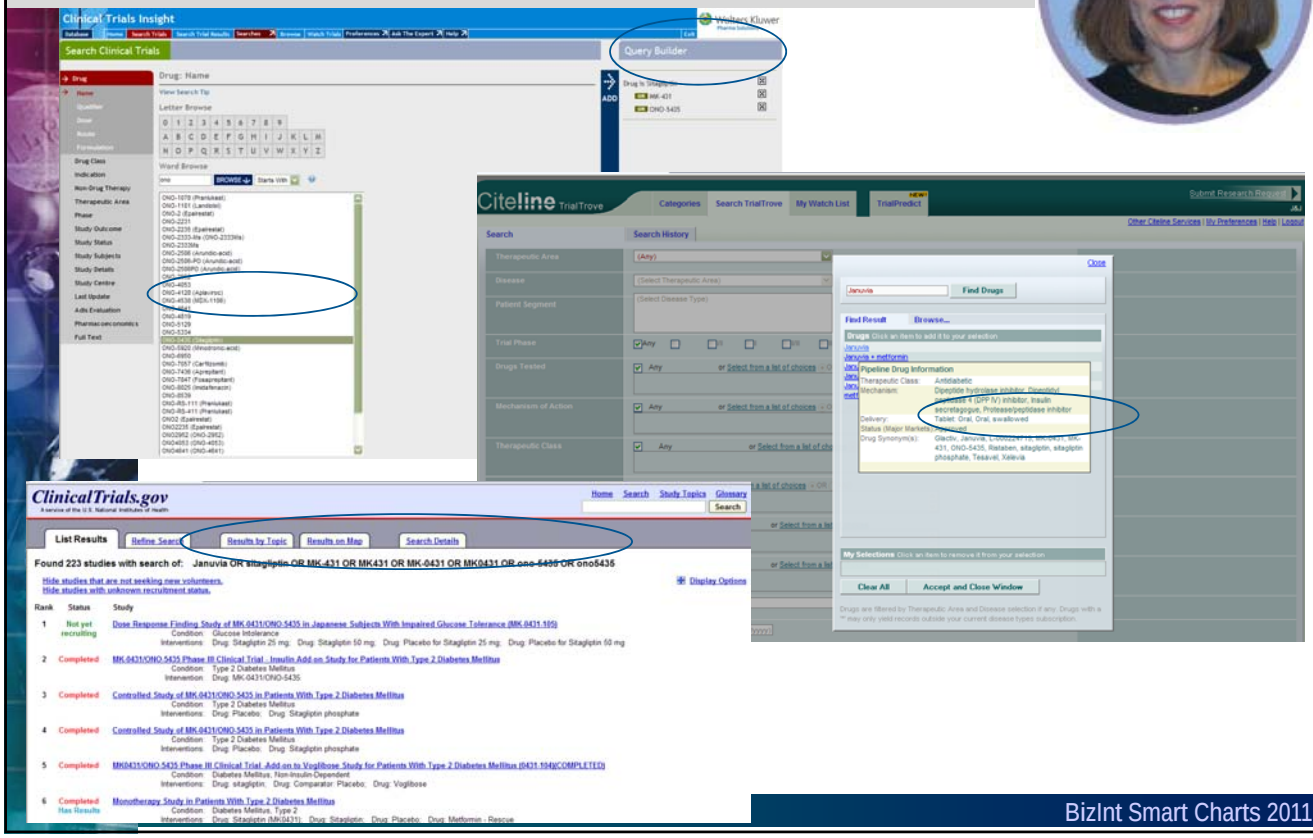
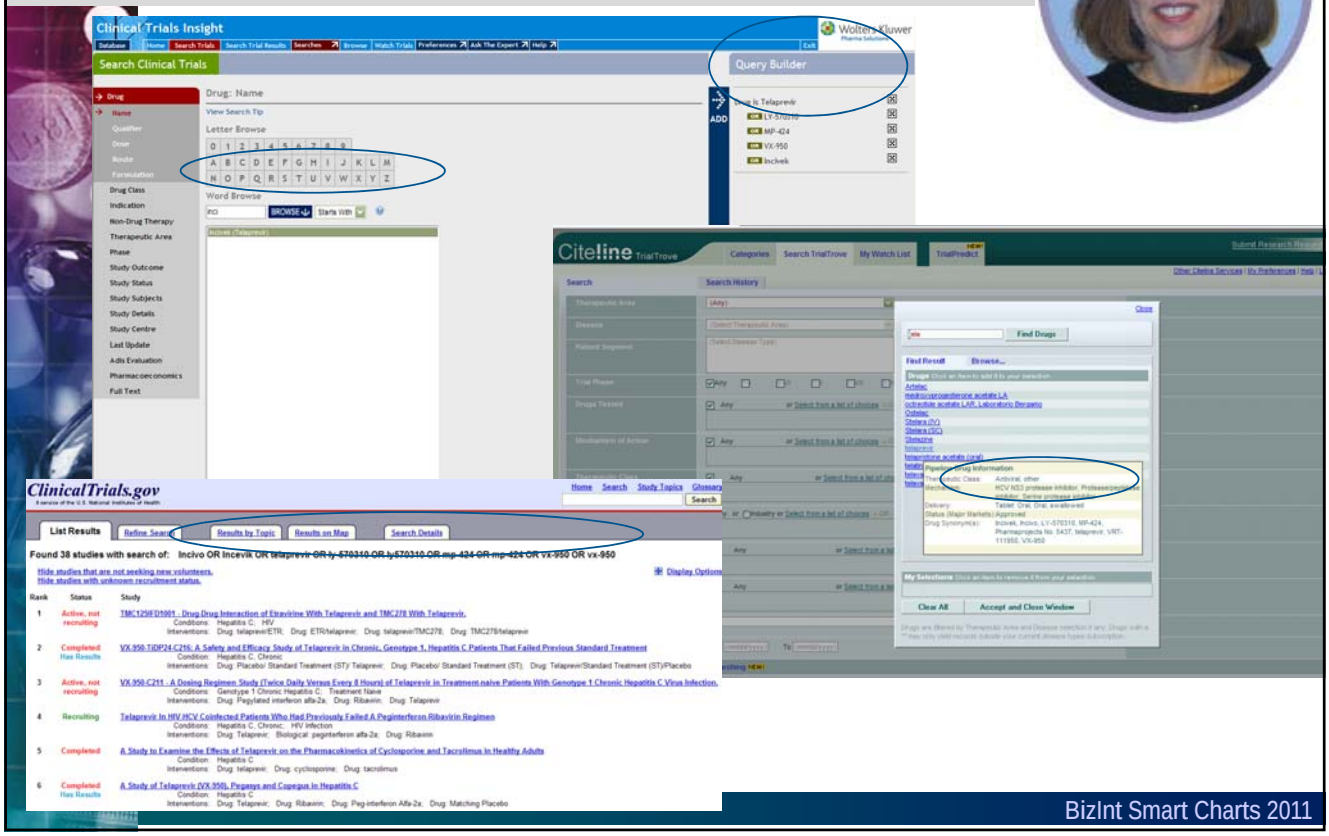
Januvia – search methodology



Telaprevir – search methodology



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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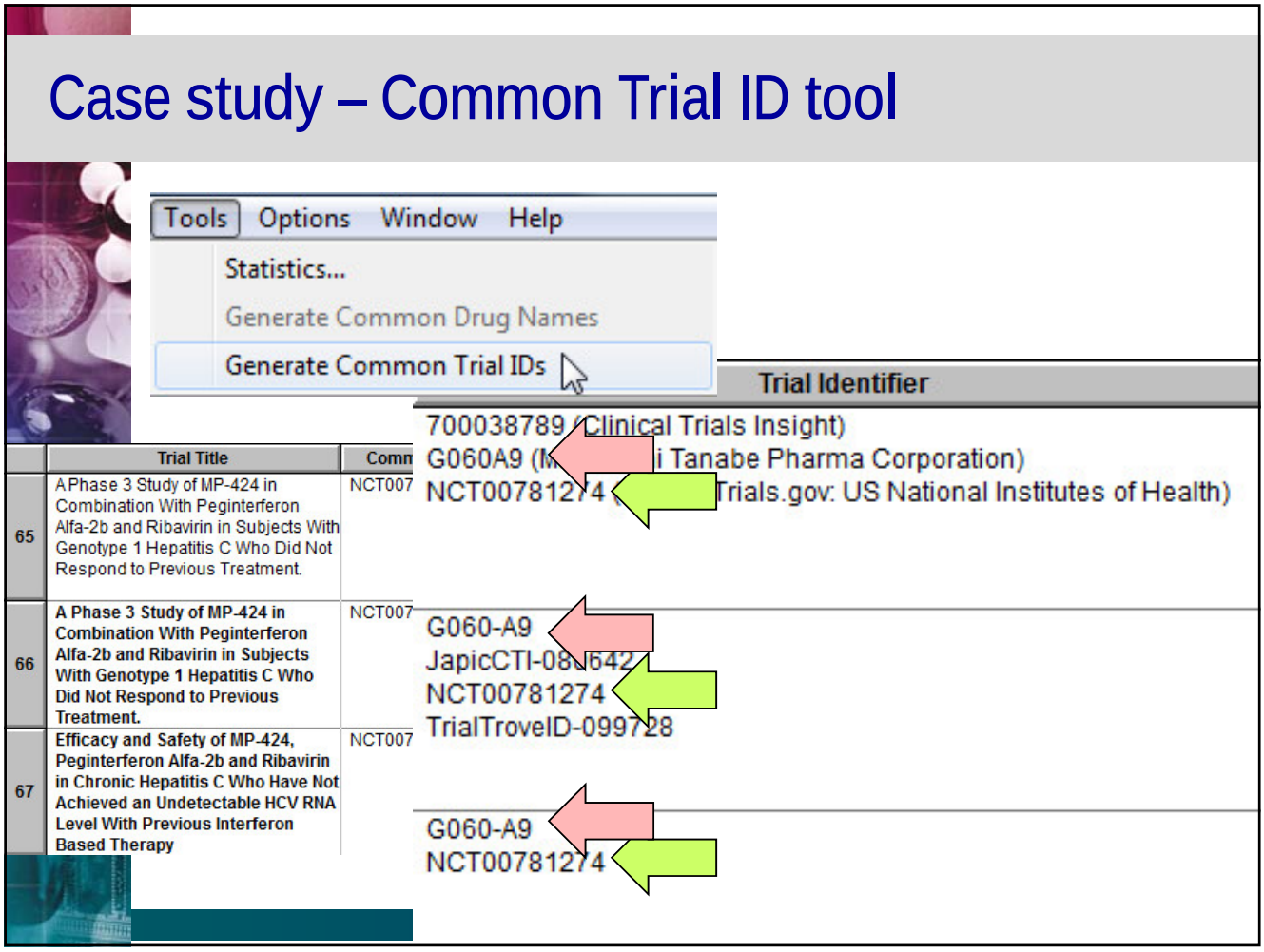
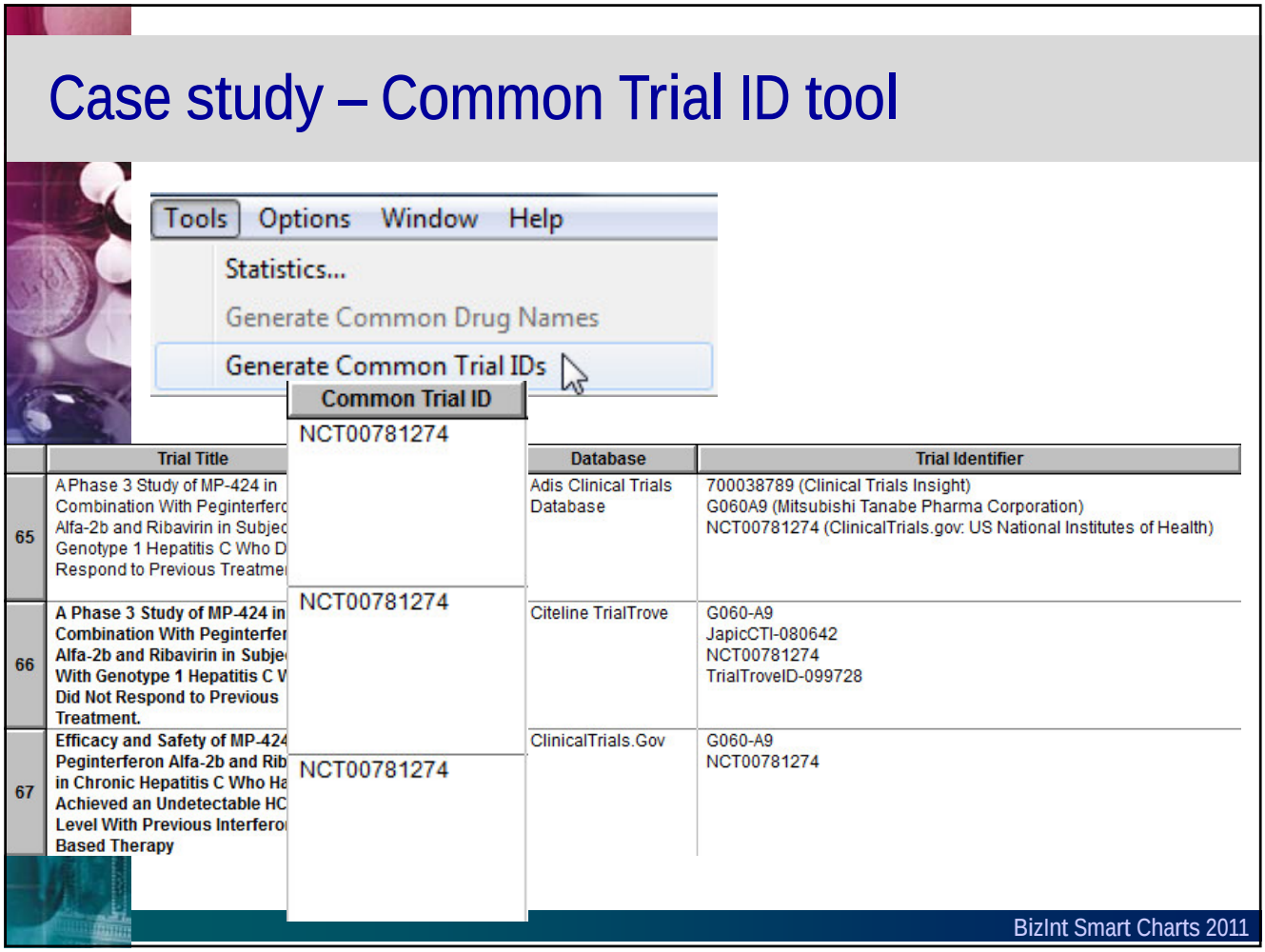
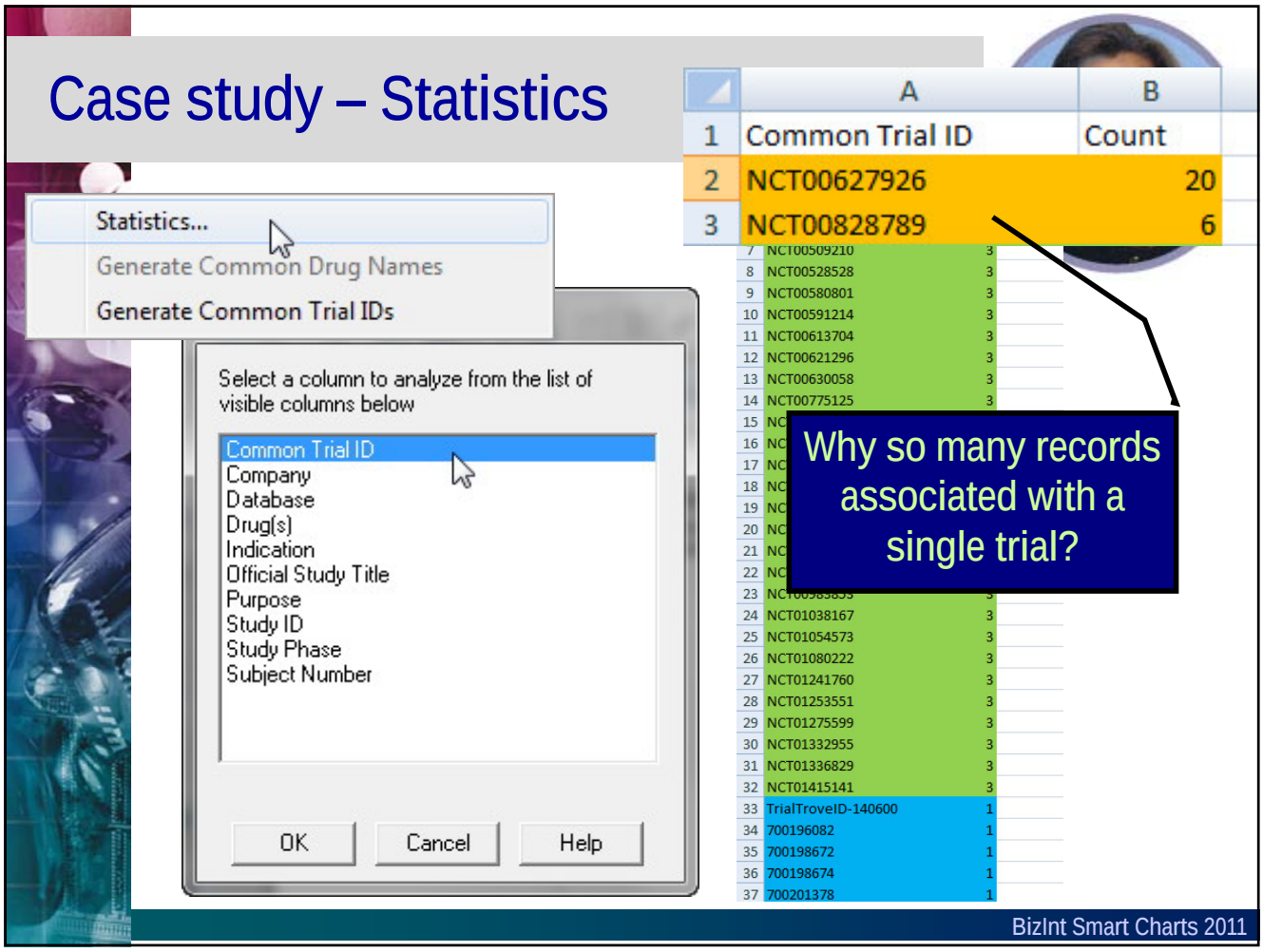
Case study – Common Trial ID tool



Case study – Common Trial ID tool





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-Seque Drug-Drug Interaction Trial in Subjec Methadone Maintenance Therapy, to the Potential Interaction Between Te mg Every 8 Hours and Methadone, a Steady-State.**			CR015931 NCT00933283 TrialTrovelD-111628 VX-950-C135 VX-950-TiDP24-C135
71	**A Phase I, Open-Label, Randomized Trial in 20 Healthy Subjects to Invest Pharmacokinetic Interactions Betw Combination of Efavirenz and Tenofovir Disoproxil Fumarate and Different Dosages of Telaprevir.**			CR015790 NCT00828789 TrialTrovelD-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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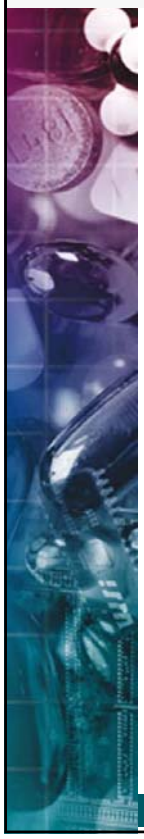
Case study – Common Trial ID tool



	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-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	Citeli	EudraCT 2008-003836-39 EudraCT No: 2009-011464-11 EXTEND ILLUMINATE NCT00758043 NCT00916474 TrialTroveID-081922 VX08-950-111 VX08-950-112
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	Citeli	
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	Citeli	NCT00372385 NCT00916474 PROVE 2 TrialTroveID-048351 VX05-950-104EU VX08-950-112
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	Citeli	EudraCT No: 2009-01 EXTEND 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 VX06-950-107 VX08-950-112
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	Citeli	
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	Citeli	

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

Phase IV trial ID included for all prior related trials.

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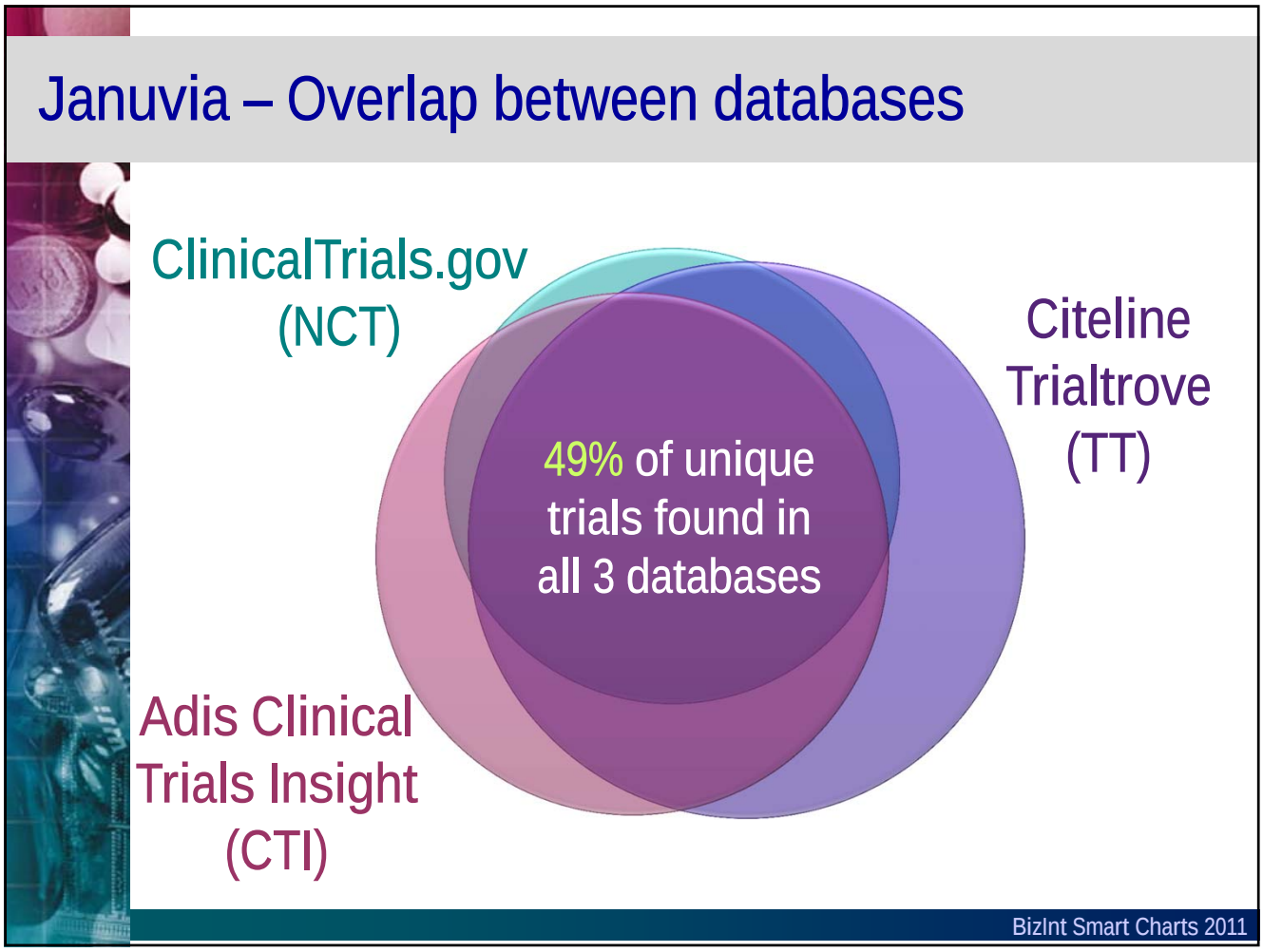

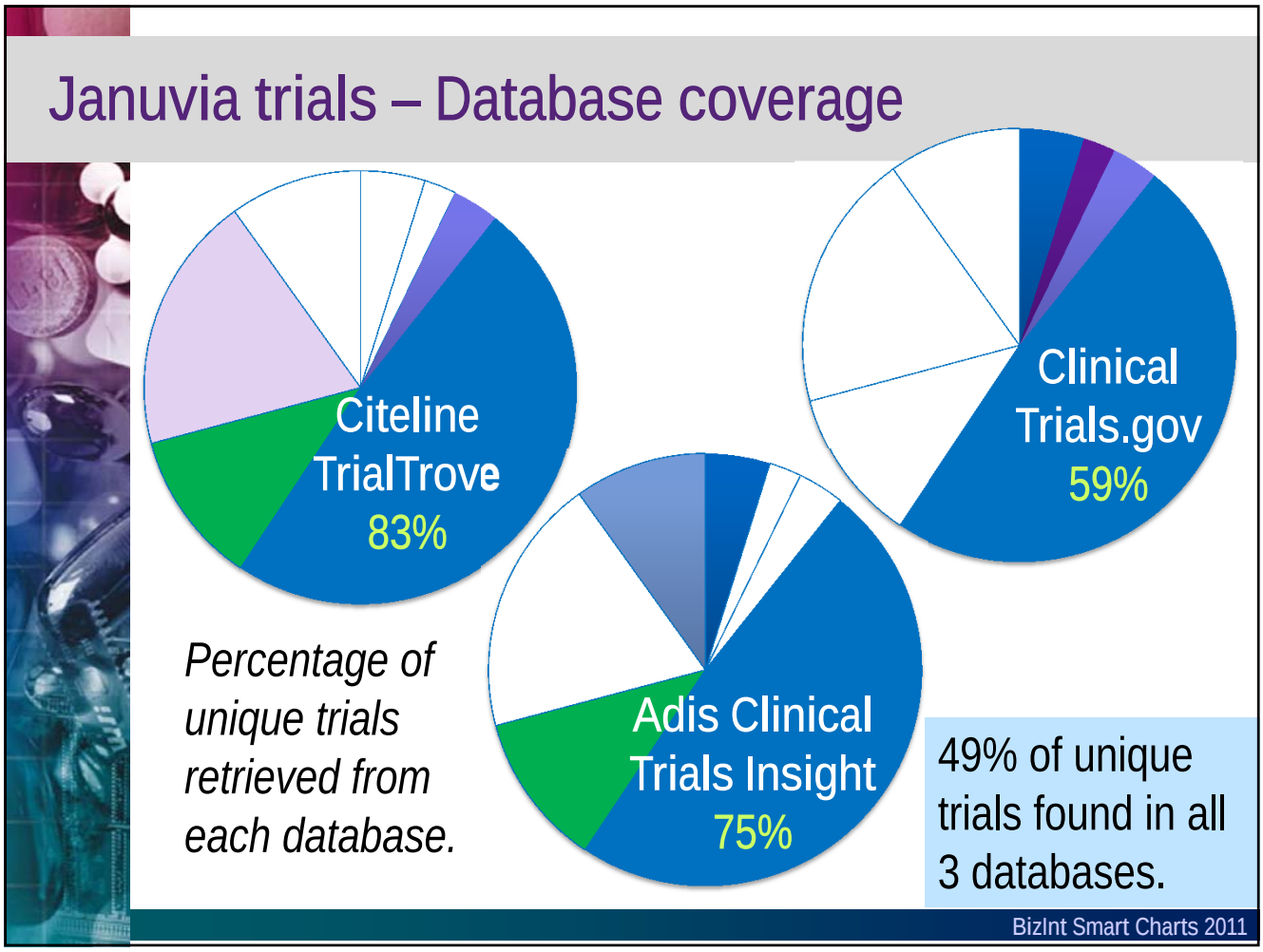

Januvia – evaluation

- 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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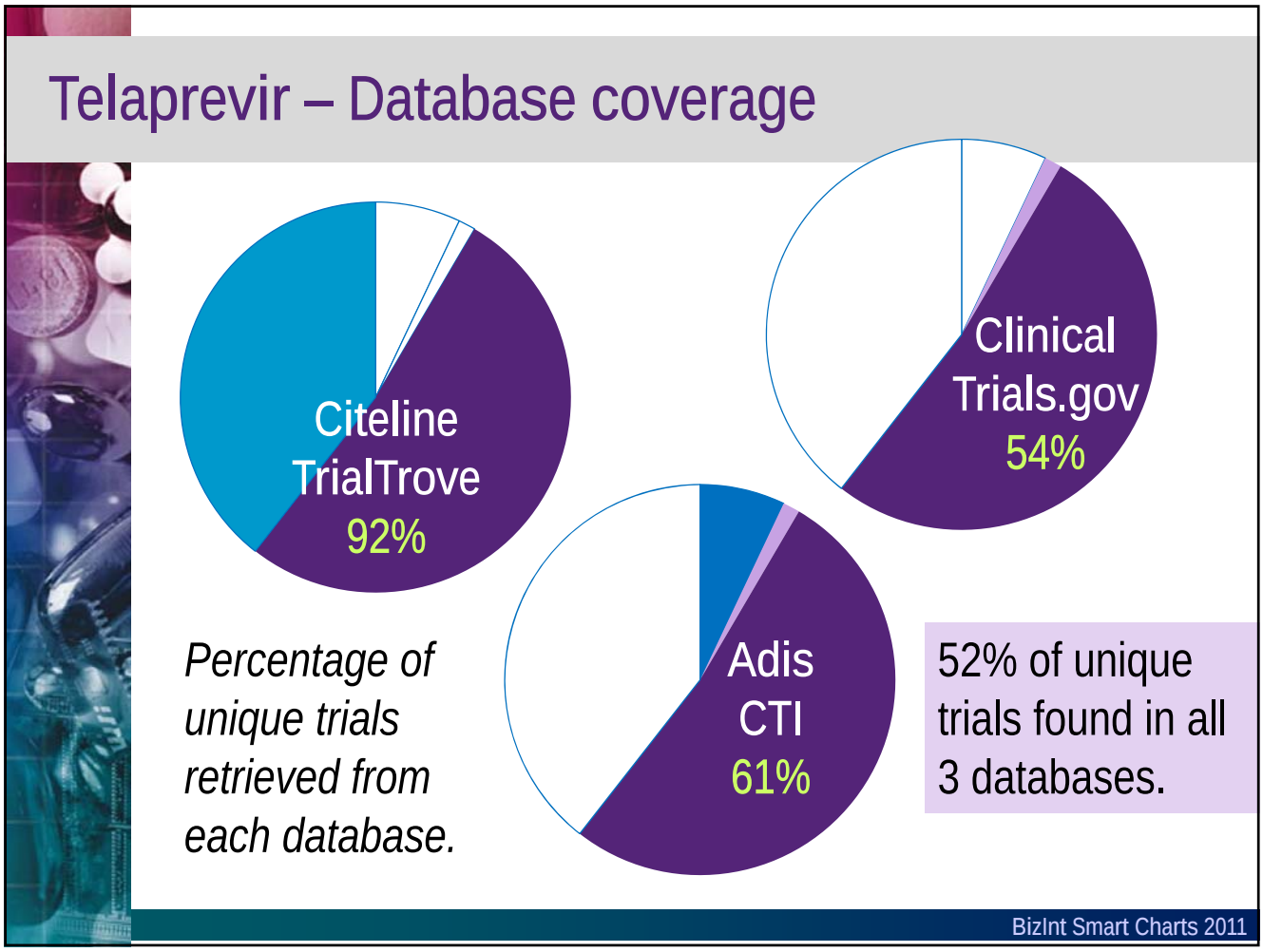

Telaprevir – some evaluation

- 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: up reports with cha

Januvia (TrialTrove) April 2011 updated S

	Trial Title	Row Status	Trial Phase	Trial Status	Disease		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 Subj With Impaired Glucose Tolerance Who Have Inadequate Glycemic Control on Diet/Exercise Therapy.	Added	II	Planned	Type 2 Diabetes	Merc Dohr	Japanese subjects with impaired glucose tolerance who have inadequate glycemic control using diet and exercise therapy.
2	An Open-Label, Randomized Naturalistic Study Evaluate the Incidence of Hypoglycemia Compa Sitagliptin With Sulfonylurea Treatment in Patie With Type 2 Diabetes During Ramadan Fasting.	Added	III	Closed	Type 2 Diabetes	Merc	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	Merc Dohr	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 Austrian Primary Care.	Updated	IV	Completed	Type 2 Diabetes	Merc Dohr	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 Ty Diabetes Mellitus Who Have Inadequate Glycen Control.	Updated	I	Completed	Type 2 Diabetes	Merc	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	II	Completed	Type 2 Diabetes	Merc Phar	Japanese patients with type 2 diabetes mellitus.
7	A study to evaluate the effect of sitagliptin, a dipeptidyl peptidase-4 inhibitor, on blood pressu in nondiabetic patients with mild to moderate hypertension.	Updated	II	Completed	Hypertension	Merc	Nondiabetic mild to moderate hypertensive patients on stable treatment with antihypertensive agent(s) were enrolled.
8	A Multicenter, Randomized, Open-Label Study t Assess the Efficacy and Safety of Sitagliptin Ad to the Regimen of Patients With T2 DM With Inadequate Glycemic Control on Metformin.	Updated	III	Completed	Type 2 Diabetes	Merc	Patients with T2 DM with inadequate glycemic control on metformin.
9	A Multicenter, Double-Blind, Randomized Study Evaluate the Safety and Efficacy of Sitagliptin Compared With Metformin in Patients With Typ Diabetes Mellitus With Inadequate Glycemic Control.	Updated	III	Completed	Type 2 Diabetes	Merc	Patients With Type 2 Diabetes Mellitus With Inadequate Glycemic Control.

Januvia: highlighting trials of possible interest

Januvia (TrialTrove) April 2011 updated Sept 2011

	Trial Title	Row S	Trial Phase	Trial Status	Disease	p	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 Sulfonylurea 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				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.	Update	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.	Update	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.	Update					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.	Update	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.	Update	II	Completed	Hypertension		Patients With Type 2 Diabetes Mellitus With Inadequate Glycemic Control.

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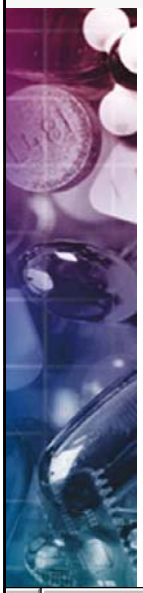
Januvia: Competitive intelligence insights



- 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

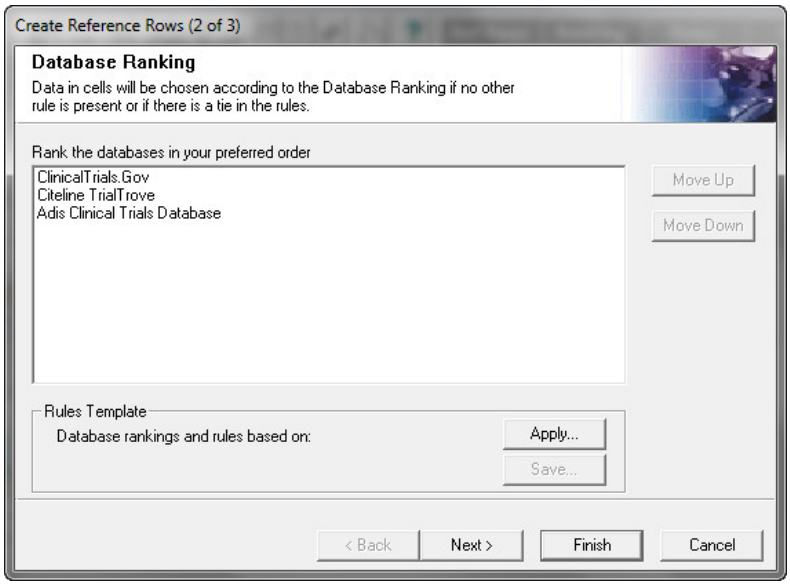
	Trial Title	Database	Condition	Start Date	Completion Date	Countries	Sponsor(s)	Brief Summary	Enrollment
654	**Sitagliptin for the Treatment of Non-alcoholic Steatohepatitis in Patients With Type 2 Diabetes**	ClinicalTrials.Gov	Type 2 Diabetes Nonalcoholic Steatohepatitis	December 2010	November 2013 (Anticipated)	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 (LantusÂ®) 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



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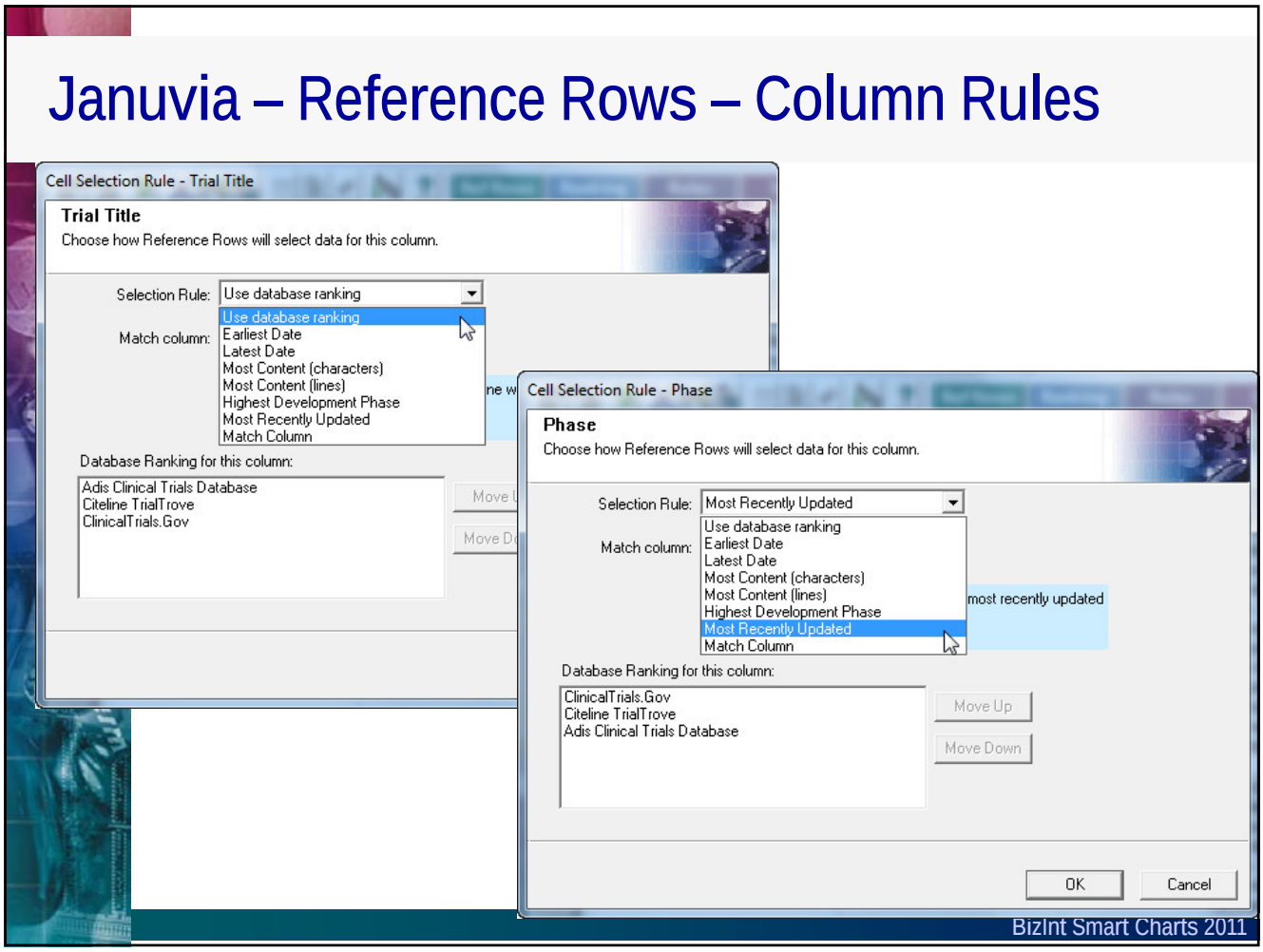
Januvia – Reference Rows – Column Rules



Januvia – Reference Rows

Combined: Januvia (CTgov, CTI, TT) 12

	Trial Title	Data	Database	Phase	Sponsor(s)	Brief Summary	Mechanism of Action	Update Date
96.1	DPP4 Inhibitor in the Hospital	ClinicalT	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 (LantusÂ®) insulin injection is the most common treatment of diabetes in the hospital. [CONT.]		2011-06-20
96.2	DPP-IV Inpatient Trial	ClinicalT	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						2011-06-24 ✔
96.4	Randomized Controlled Study of ✔ DPP4 Inhibitor (Sitagliptin) Therapy in the Inpatient Management of Patients With Type 2 Diabetes.	Adis Clin Databas	Citeline TrialTrove	IV ✔	[illegible]rsity 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.	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.	96.4 CTI	96.1 NCT | link 96.2 NCT | link 96.3 TT | link 96.4 CTI | link		IV 96.3 TT	Emory University Merck 96.1 NCT		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.] 96.2 NCT		Planned 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 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	2011-08-1	
		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	2011-09-0	
		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	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 | lir 96.2 NCT | lir 96.3 TT | link 96.4 CTI | link	IV	ory University ck	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	ts with Type 2 tes.	CD26-antigen-inhibitors Ornithine-decarboxylase-stimulants Phosphokinase-stimulants	2011-06-2
	96.4 CTI			96.1 NCT	96.2 NCT		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 | lir 97.2 TT | link 97.3 CTI | link	96.3 TT IV	ersity of Alabama irmingham	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.	96.3 TT Open	enopausal women pe 2 diabetes.	CD26-antigen-inhibitors	2011-06-2
	97.3 CTI			97.1 NCT	97.3 CTI		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 | lir 98.2 TT | link 98.3 CTI | 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.	97.2 TT Recruiting	cts with type 2 es on metformin therapy.	CD26-antigen-inhibitors	2011-08-1
	98.3 CTI			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 | lir 99.2 TT | link 99.3 CTI | link	97.2 TT Phase 4	derbilt 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.	98.1 NCT Not yet recruiting	y people.	ACE-inhibitors CD26-antigen-inhibitors	2011-09-0
	99.3 CTI			99.1 NCT	99.2 TT		99.2 TT	99.3 CTI	99.3 CTI

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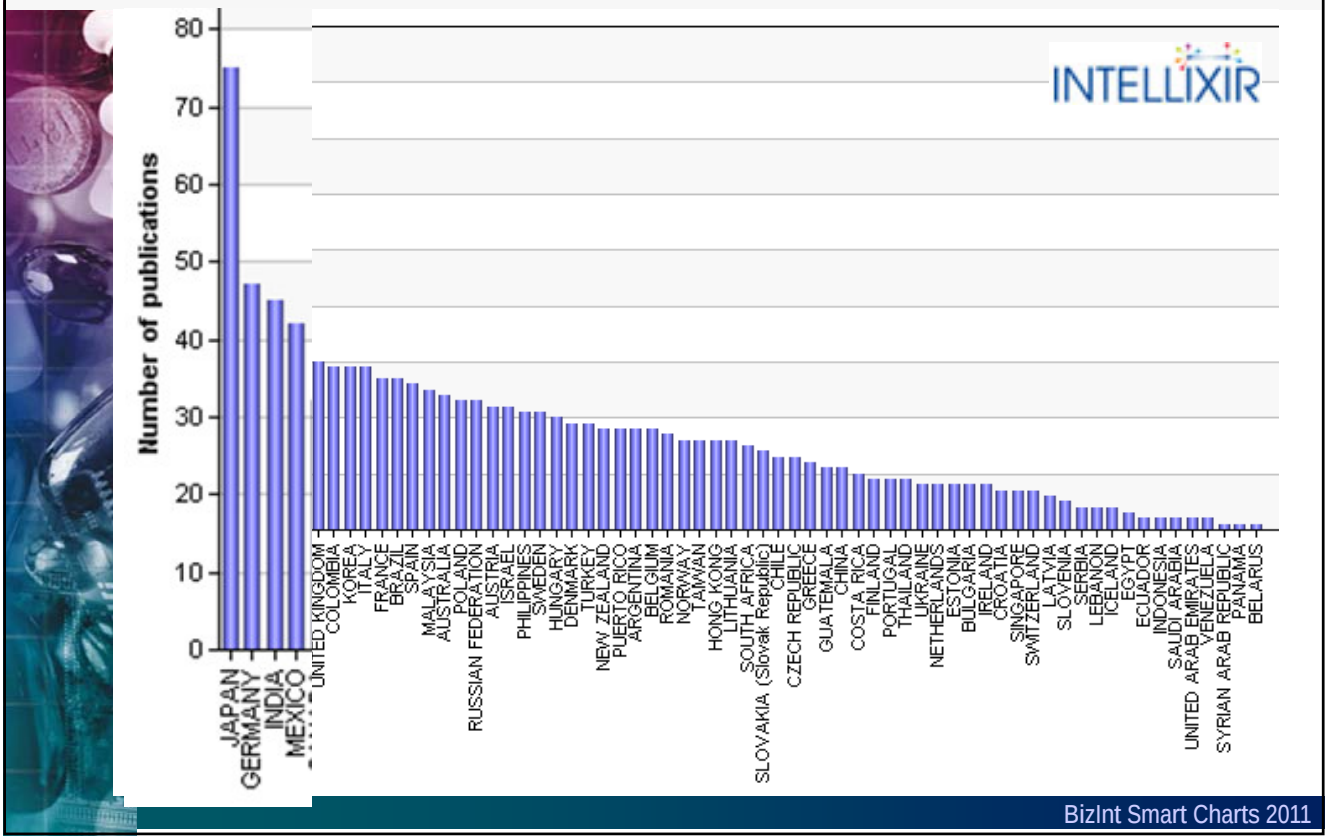
XML Smart Data Exchange - Search Technology the vantage point

	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)	atient 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 | 97.3 CTI |	Phase 4	University of Alabama at Birmingham	Open, Recruiting	ostmenopausal women ith 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 | 98.3 CTI |	Phase 4	Novartis	Open, Recruiting	ubjects with type 2 abetes on metformin onotherapy.	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 | 99.3 CTI |	N/A	Vanderbilt University	Planned	ealthy 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 | 100.3 CTI |	Phase 3	Merck	Completed	atients with type 2 abetes mellitus who ve inadequate glycemic ontrol on pioglitazone erapy.	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 | 101.3 CTI |	Phase 3	Merck	Completed	/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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