CLOSED STUDIES FOR DIABETES MELLITUS TYPE 2

Title	Completed	Not yet recruiting/ Not open	No longer recruiting	Investigator	Sponsor	Eligibility			Total Enroll	Start	End	Adult/Child	Objective
						Gender	Age	Race	n > 200				
DRUG TREATMENT OF GLYCEMIA													
Comparison of the Effect on Glycemic Control of Biphasic Insulin Aspart 70/30 Versus Insulin Glargine in Combination With Metformin in Subjects With Type 2 Diabetes			√	Braceras, Rogelio	Novo Nordisk	Both	18+	N/S	348	January-05	N/S	Adult	To test whether Biphasic Insulin Aspart 70/30 twice a day with Metformin improves glycemic control vs. once daily Insulin Glargine with Metformin in subjects with Type 2 Diabetes who are inadequately controlled on basal insulin plus oral anti-diabetic therapy
A Phase 3, Randomized, Double-Blind, Active Controlled, Multicenter Trial to Evaluate the Safety and Efficacy of Muraglitazar (BMS-298585) Compared to Pioglitazone in Subjects With Type 2 Diabetes Who Have Inadequate Glycemic Control **(International)**	√			Bristol Myers Squibb	Bristol Myers Squibb	Both	18 to 70	N/S	1,440	August-05	N/S	Adult	To compare Muraglitazar and Pioglitazone in patients with Type 2 Diabetes.
A Phase III, Multicenter, Randomized, Double-Blind Clinical Trial to Study the Safety and Efficacy of the Addition of Sitagliptin (MK0431) to Patients With Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control on Insulin Therapy (Alone or In Combination With Metformin)				Merck	Merck	Both	21+	N/S	600	December-06	N/S	Adult	To determine the safety and efficacy of sitagliptin in patients with Type 2 Diabetes Mellitus who have inadequate glycemic control on insulin or insulin/metformin combination therapy.
A Multicenter, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of the Initial Therapy With Coadministration of Sitagliptin and Pioglitazone in Patients With Type 2 Diabetes Mellitus				Merck	Merck	Both	18+	N/S	450	December-06	N/S	Adult	To evaluate the safety and efficacy of the initial combination therapy with sitagliptin and pioglitazone in patients with type 2 diabetes mellitus not on treatment with insulin or oral antihyperglycemic therapy
Study of Metformin HCL in Patients With Type 2 Diabetes Intensively Treated With Insulin: a Treatment Strategy for Insulin Resistance in Type 2 Diabetes Mellitus: a Randomized Controlled Trial **(Netherlands)**	√			Kooy, Adriaan	Bethesda General Hospital, Hoogeveen	Both	30 to 80	N/S	400	January-98	February-06	Adult	To investigate the effects of metformin HCL in patients with type 2 diabetes mellitus intensively treated with insulin on the quality of the metabolic control of diabetes, the daily dose of insulin, the lipid profile, the blood pressure, the incidence / progression of microvascular and macrovascular complications, and on the qualify of life (Diabetes Health Profile).
Dose-Finding, Efficacy, and Safety of AZ 242 (Tesaglitazar) in Subjects With Type 2 Diabetes **(International)**	√			Astra Zeneca	Astra Zeneca	Both	30 to 50	N/S	500	April-02	N/S	Adult	This is a 12-week randomized, double-blind, multi-center, active-controlled (open-label pioglitazone) and placebo-controlled study of tesaglitazar (0.1, 0.5, 1, 2, and 3 mg) in patients with type 2 diabetes, not adequately controlled on diet and lifestyle advice alone during the run-in period.
A Parallel-Group, Multi-Centre, Active-Controlled (Glibenclamide) Long-Term Extension Study to Evaluate the Safety and Tolerability of Oral Tesaglitazar Therapy in Patients With Type 2 Diabetes **(Europe)**			√	Astra Zeneca	Astra Zeneca	Both	18+	N/S	400	October-05	N/S	Adult	To monitor the safety and tolerability of oral tesaglitazar compared with glibenclamide in patients with type 2 diabetes for up to 100 weeks of treatment.
South Danish Diabetes Study: A Prospective Randomised Multi-Centre Study for the Evaluation of the Optimal Pharmacological Antidiabetic Treatment of Type 2 Diabetes Mellitus **(Denmark)**			√	Gram, Jeppe	Odense University Hospital	Both	30 to 70	N/S	400	March-03	N/S	Adult	To investigate whether insulin aspart with meals is better than a standard treatment with insulin NPH at bedtime, evaluated by HbA1c.
A 24-Week Randomised, Double-Blind, Multi-Centre, Placebo-Controlled Study to Evaluate the Efficacy, Safety and Tolerability of Tesaglitazar Therapy When Added to the Therapy of Patients With Type 2 Diabetes Poorly Controlled on Insulin	√			Astra Zeneca	Asta Zeneca	Both	18+	N/S	370	August-04	N/S	Adult	To study tesaglitazar in patients with type 2 diabetes who are not adequately controlled on insulin (along or in combination with one or more oral antidiabetic agents in addition to diet and lifestyle advice).
A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Fixed-Dose (Rimonabant 20 mg) Multicenter Study of Long-Term Glycemic Control With Rimonabant in Treatment-naïve Patients With Type 2 Diabetes	√			Sanofi-Aventis	Sanofi-Aventis	Both	18+	N/S	264	March-05	N/S	Adult	Effect on HbA1c over 6 months in drug-naive patients with type 2 diabetes.
A Multicenter, Randomized, Placebo-Controlled, Double-Blind, Parallel-Group, Fixed-Dose Study Evaluating the Effect of One Dose of Rimonabant (20 Mg/Day) on Glycemic Control in Type 2 Diabetic Patients Inadequately Controlled With Insulin **(International)**			√	Sanofi-Aventis	Sanofi-Aventis	Both	18+	N/S	300	January-06	N/S	Adult	Effect on HbA1c over 48 weeks in insulin-treated patients with type 2 diabetes.
A Randomized, Double-Blind, Placebo-Control, Clinical Evaluation of Insulin Plus Rosiglitazone Compared to Insulin Plus Placebo for 24 Weeks in Subjects With Type 2 Diabetes Mellitus Who Are Inadequately Controlled On Insulin **(China)**			√	GlaxoSmithKline	GlaxoSmithKline	Both	18 to 70	N/S	256	September-05	N/S	Adult	To demonstrate that addition of rosiglitazone (4mg) to insulin in Type 2 diabetes mellitus subjects who have not achieved glycemic goals on insulin injections alone is efficacious in terms of improving glycemic control.
A Multi-Center, Double-Blind, Parallel-Group, Randomized, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Tolerability of Denagliptin in Subjects With Type 2 Diabetes Mellitus			√ **(Suspended)**	GlaxoSmithKline	GlaxoSmithKline	Both	18 to 75	N/S	450	May-06	N/S	Adult	To evaluate the effectiveness, safety, and tolerability of 2 doses of GW823093, compared to placebo, taken once daily in patients with Type 2 diabetes mellitus.

CLOSED STUDIES FOR DIABETES MELLITUS TYPE 2

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						Gender	Age	Race	n > 200				
Multicentre Double Blind Placebo Controlled Parallel Group Dose Ranging Study of ATL-962 to Assess Weight Loss, Safety and Tolerability in Obese Patients With Type II Diabetes Being Treated With Metformin, in Comparison With Orlistat **(Europe)**	√			Kopelman, Peter	Alizyme	Both	18 to 65	N/S	600	December-04	N/S	Adult	To investigate whether ATL-962 induces weight loss in diabetic patients and whether its safety and tolerability profile is superior to that of orlistat in such patients.
A Randomized, Double-Blind, Multicenter Study Comparing the Glycemic Control Characteristics of Carvedilol and Metoprolol in Hypertensive Patients With Type II Diabetes Mellitus			√	GlaxoSmithKline	GlaxoSmithKline	Both	30 to 80	N/S	1,210	May-01	N/S	Adult	To evaluate the effect of two different antihypertensive medications in the drug class of beta-blockers on control of glucose in Type II diabetic patients with high blood pressure.
A 24 Week, Randomised, Double Blind, Parallel Study to Compare the Change in HbA1c With AVANDAMET* (8.0 Mg / 2.0 g) Plus Insulin to Placebo Plus Insulin, in Subjects With Type 2 Diabetes Starting Insulin Therapy **(Europe)**			√	GlaxoSmithKline	GlaxoSmithKline	Both	18 to 70	N/S	272	October-03	N/S	Adult	To test the safety and efficacy (how well it works) of AVANDAMET in combination with insulin in improving the control of blood sugar when compared with taking insulin on its own.
AVANDAMET Compared to Metformin Evaluation Trial (ACME): A 48-Week Randomized, Open-Label, Multicenter Study to Compare the Efficacy and Tolerability of AVANDAMET to Metformin Monotherapy in Subjects With Type 2 Diabetes Mellitus Who Are Not Achieving Glycemic Control on Submaximal Metformin **(Canada)**			√	GlaxoSmithKline	GlaxoSmithKline	Both	18 to 75	N/S	600	April-03	N/S	Adult	To compare AVANDAMET vs. Metformin monotherapy for blood glucose control in patients with Type 2 Diabetes Mellitus.
A Randomised, Open-Label, Parallel Group Study to Evaluate the Management of Rosiglitazone-Related Fluid Retention by Investigating the Effect of Diuretics on Plasma Volume in Subjects With Type 2 Diabetes Mellitus Treated for Twelve Weeks With Rosiglitazone 4mg Bd in Addition to Background Anti-Diabetic Agents **(Europe)**	√			GlaxoSmithKline	GlaxoSmithKline	Both	35 to 80	N/S	388	October-02	N/S	Adult	To examine the effect of different diuretics on fluid retention in diabetics treated with rosiglitazone.
A Randomised, Multi-Centre, Phase IV, Double-Blind, Parallel Group Study Comparing the Effects of 52 Weeks Administration of AVANDAMET and Metformin Plus Sulphonylurea on Change in HbA1c From Baseline in Overweight Type 2 Diabetics Poorly Controlled on Metformin **(Europe)**	√			GlaxoSmithKline	GlaxoSmithKline	Both	18 to 75	N/S	544	May-04	N/S	Adult	To compare the effects of Avandamet (rosiglitazone maleate/metformin) treatment and metformin plus sulphonylurea treatment in overweight people with type 2 diabetes.
A Multicenter, Randomized, Double-Blind, Double-Dummy, Parallel-Group, Placebo-Controlled, Study To Evaluate Efficacy, Safety And Tolerability Of Oral GW677954 Capsules (2.5, 5, 10, 15 And 20 Mg Once A Day) As A Monotherapy (Diet and/or Exercise Treated) Or As An Add-On To Metformin For 16 Weeks Duration In Subjects With Type 2 Diabetes Mellitus **(International)**			√	GlaxoSmithKline	GlaxoSmithKline	Both	18 to 70	N/S	448	September-05	N/S	Adult	To evaluate the efficacy, safety and tolerability of a range of doses of GW677954 compared with placebo over sixteen weeks of treatment in subjects with T2DM (Type 2 Diabetes Mellitus).
A Multicenter, Randomized, Double-Blind, Parallel-Group, Placebo-Control, Clinical Evaluation of Insulin Plus Rosiglitazone (2mg and 4mg) Compared to Insulin Plus Placebo for 24 Weeks in Subjects With Type 2 Diabetes Mellitus Who Are Inadequately Controlled on Insulin			√	GlaxoSmithKline	GlaxoSmithKline	Both	18 to 70	N/S	630	November-02	N/S	Adult	To compare the effects of adding the drug rosiglitazone (2mg and 4mg) or placebo to insulin in patients with Type 2 diabetes mellitus (non-insulin-dependent) who have not achieved their blood glucose goal using insulin alone. This study requires a total of seven visits during 28 weeks.
A 24-Week Randomized, Double-Blind Study to Evaluate the Efficacy, Safety and Tolerability of AVANDIA (8mg Once Daily) in Combination With Glyburide in African American and Hispanic Patients With Type 2 Diabetes Mellitus Who Are Inadequately Controlled on Glyburide Monotherapy **(US and Puerto Rico)**				GlaxoSmithKline	GlaxoSmithKline	Both	21+	African American or Hispanic	245	July-00	N/S	Adult	To evaluate the safety and efficacy of AVANDIA (rosiglitazone) (8mg once daily) in African American and Hispanic patients with type 2 diabetes mellitus.
A Randomized, Double-Blind Study to Compare the Durability of Glucose Lowering and Preservation of Pancreatic Beta-Cell Function of Rosiglitazone Monotherapy Compared to Metformin or Glyburide/Glibenclamide in Patients With Drug-Naive, Recently Diagnosed Type 2 Diabetes Mellitus **(International)**	√			GlaxoSmithKline	GlaxoSmithKline	Both	30 to 75	N/S	4,100	April-00	N/S	Adult	To compare and evaluate the effects of long-term treatment of monotherapy with rosiglitazone, metformin and glyburide/glibenclamide on the improvement and maintenance of glycemic control in patients with recently diagnosed type 2 diabetes mellitus.
A Randomized, Double-Blind Study of the Effect of the DPP-IV Inhibitor RO0730699 on HbA1c and Safety in Patients With Type 2 Diabetes Treated With a Stable Dose of Metformin **(International)**	√			Hoffman LaRoche	Hoffman LaRoche	Both	18 to 75	N/S	Enrollment # not specified	N/S	N/S	Adult	To assess the efficacy, safety and tolerability of DPP-IV Inhibitor in patients with type 2 diabetes receiving a stable dose of metformin.
A Randomized, Double-Blind, Double-Dummy, Placebo-Controlled 26-Week Dose-Response Study of Rivoglitazone HCl (CS-011) With Active Comparator (Pioglitazone HCl) in Subjects With Type 2 Diabetes			√	Daiichi Sankyo Inc	Daiichi Sankyo Inc	Both	18 to 75	N/S	441	December-04	N/S	Adult	To evaluate the effects of monotherapy with rivoglitazone, an insulin sensitizer, on glycemic control in newly identified type 2 diabetics or diabetics not adequately treated with other antidiabetic agents.

CLOSED STUDIES FOR DIABETES MELLITUS TYPE 2

Title	Completed	Not yet recruiting/ Not open	No longer recruiting	Investigator	Sponsor	Eligibility			Total Enroll	Start	End	Adult/Child	Objective
						Gender	Age	Race	n > 200				
A Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of the Efficacy and Safety of WelChol® in Type 2 Diabetics With Inadequate Glycemic Control on Metformin Monotherapy or Metformin Therapy in Combination With Other Oral Anti-Diabetic Agents **(US, Mexico and Peru)**			√	Daiichi Sankyo Inc	Daiichi Sankyo Inc	Both	18 to 75	N/S	300	June-04	N/S	Adult	To see how safe and effective and tolerable the use of colesevelam hydrochloride is for type 2 diabetes when added to metformin alone or in combination with other anti-diabetic drugs.
A Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of the Efficacy and Safety of WelChol® in Type 2 Diabetics With Inadequate Glycemic Control on Sulfonylurea Monotherapy or Sulfonylurea Therapy in Combination With Other Oral Anti-Diabetic Agents **(US, Mexico and Peru)**			√	Daiichi Sankyo Inc	Daiichi Sankyo Inc	Both	18 to 75	N/S	400	June-04	N/S	Adult	To see how safe and effective and tolerable the use of colesevelam hydrochloride is for type 2 diabetes when added to sulfonylurea alone or in combination with other anti-diabetic drugs.
A Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of the Efficacy and Safety of WelChol® in Type 2 Diabetes With Inadequate Glycemic Control on Insulin Therapy Alone or Insulin Therapy Combination With Other Oral Anti-Diabetic Agents **(US, Mexico and Peru)**			√	Daiichi Sankyo Inc	Daiichi Sankyo Inc	Both	18 to 75	N/S	260	June-04	N/S	Adult	To see how safe and effective and tolerable the use of WelChol® is for type 2 diabetes when added to insulin alone or in combination with other anti-diabetic drugs.
A Multi-Center, 52-Week, Open-Label Extension Study (From Studies WEL-301, WEL-302, and WEL-303) to Evaluate the Long-Term Safety and Tolerability of WelChol® in Type 2 Diabetic Patients **(US, Mexico and Peru)**			√	Daiichi Sankyo Inc	Daiichi Sankyo Inc	Both	18 to 75	N/S	780	December-04	N/S	Adult	To evaluate the long term safety and tolerability of colesevelam hydrochloride in patients with type 2 diabetes .
Effect of Liraglutide on Glycaemic Control in Japanese Subjects With Type 2 Diabetes **(Japan)**			√	Rasmussen, Mads Hagihara, Izumi	Novo Nordisk	Both	20 to 75	Japanese	200	January-05	N/S	Adult	To evaluate the effect of treatment with liraglutide or placebo on blood glucose control after 14 weeks in Japanese subjects with type 2 diabetes.
Comparison of the Effect on Glycemic Control of Biphasic Insulin Aspart 70/30, Biphasic Insulin Aspart 50/50, and Biphasic Insulin Aspart 30/70 All in Combination With Metformin in Subjects With Type 2 Diabetes (the INTENSIMIX Trial) **(Europe)**	√			Krüger. Malene	Novo Nordisk	Both	18+	N/S	600	April-05	N/S	Adult	To compare the effect on glycemic control in subjects with type 2 diabetes of three different premixed insulin analogues given in combination with an oral anti-diabetic drug.
A Phase 3, Randomized, Double-Blind, Active-Controlled, Multicenter Trial to Evaluate the Safety and Efficacy of BMS-298585 in Combination With Metformin Compared to Pioglitazone in Combination With Metformin in Type 2 Diabetics With Inadequate Glycemic Control on Metformin Alone **(International)**	√			Bristol Myers Squibb	Bristol Myers Squibb	Both	18 to 70	N/S	1,159	October-03	N/S	Adult	To evaluate if type 2 diabetics who have inadequate glycemic control on metformin alone, have a similar, or not inferior, glycemic response when treated with the combination of muraglitazar and metformin compared to pioglitazone and metformin.
A 24-Week Randomised, Double-Blind, Parallel-Group, Multi-Centre, Placebo-Controlled Study to Evaluate the Efficacy, Safety and Tolerability of Tesaglitazar Therapy When Added to the Therapy of Patients With Type 2 Diabetes Poorly Controlled on Sulphonylurea Alone **(Europe)**			√	Astra Zeneca	Astra Zeneca	Both	18+	N/S	555	July-04	N/S	Adult	This is a 24-week randomized double-blind, parallel-group, multi-center, placebo-controlled study of tesaglitazar (0.5 mg and 1 mg) given as add-on therapy to sulphonylurea in patients with type 2 diabetes, not adequately controlled on optimized sulphonylurea treatment and on diet/lifestyle advice during the titration and run-in period.
A 24-Week Randomised, Double-Blind, Parallel-Group, Multi-Centre, Placebo-Controlled Study to Evaluate the Efficacy, Safety and Tolerability of Tesaglitazar Therapy When Added to the Therapy of Patients With Type 2 Diabetes Poorly Controlled on Metformin Alone **(Europe)**	√			Astra Zeneca	Astra Zeneca	Both	18+	N/S	555	July-06	N/S	Adult	This is a 24-week randomized double-blind, parallel-group, multi-center, placebo-controlled study of tesaglitazar (0.5 mg and 1 mg) given as add-on therapy to metformin in patients with type 2 diabetes, not adequately controlled on optimized metformin treatment and on diet/lifestyle advice during the titration and run-in period.
A 24-Week Randomized, Double-Blind, Parallel-Group, Multi-Centre, Placebo-Controlled Study to Evaluate the Efficacy, Safety and Tolerability of Tesaglitazar Therapy When Administered as Monotherapy to Drug-Naïve Patients With Type 2 Diabetes **(Europe)**			√	Astra Zeneca	Astra Zeneca	Both	18+	N/S	475	April-05	N/S	Adult	This is a 24-week randomized, double-blind, parallel-group, multi-center, placebo-controlled study of tesaglitazar (0.5 and 1 mg) in patients with type 2 diabetes, not adequately controlled on diet and lifestyle advice alone during the run-in period.
An Open-Label, Multi-Centre and Long-Term Extension Study to Evaluate the Safety and Tolerability of Oral Tesaglitazar 1 Mg in Patients With Type 2 Diabetes Mellitus **(International)**			√	Astra Zeneca	Astra Zeneca	Both	18+	N/S	2,000	March-05	N/S	Adult	This is a 107-week open-label, multi-center long-term extension study from GALLANT studies 2/22, 5, 7, 8 and 14 to monitor the safety and tolerability of oral tesaglitazar 1 mg in patients with type 2 diabetes during up to 104 weeks of treatment.
A 52-Week Randomized, Double-Blind, Parallel-Group, Multi-Centre, Active-Controlled (Glibenclamide) Study to Evaluate the Efficacy, Safety and Tolerability of Tesaglitazar Therapy When Administered to Patients With Type 2 Diabetes **(Europe)**			√	Astra Zeneca	Asta Zeneca	Both	18+	N/S	580	September-04	N/S	Adult	This is a 52-week randomized, double-blind, parallel-group, multi-center, active-controlled (glibenclamide) study of tesaglitazar in patients with type 2 diabetes, not adequately controlled on diet and lifestyle advice alone during the run-in period.

CLOSED STUDIES FOR DIABETES MELLITUS TYPE 2

Title	Completed	Not yet recruiting/ Not open	No longer recruiting	Investigator	Sponsor	Eligibility			Total Enroll	Start	End	Adult/Child	Objective
						Gender	Age	Race	n > 200				
A 24-Week Randomised, Double-Blind, Parallel-Group, Multi-Centre, Active-Controlled (Metformin or Metformin Combined With Fenofibrate) Study to Evaluate the Lipid Metabolic Effects, Safety and Tolerability of Tesaglitazar Therapy in Patients With Type 2 Diabetes and Low HDL-Cholesterol on a Fixed Background Therapy With a Statin **(Europe)**			√	Astra Zeneca	Asta Zeneca	Both	18+	N/S	1,000	March-05	N/S	Adult	To determine the lipid metabolic effects, safety, and tolerability of tesaglitazar compared with metformin and metformin in combination with fenofibrate in patients with type 2 diabetes and low high-density lipoprotein cholesterol (HDL-C).
A Randomized, Double-Blind, Multicentre, Placebo-Controlled Study to Evaluate the Efficacy, Dose-Response and Safety of Tesaglitazar Therapy in Japanese Subjects With Type 2 Diabetes **(Japan)**	√			Astra Zeneca	Asta Zeneca	Both	30 to 80	Japanese	250	May-04	N/S	Adult	To determine the effect on glucose and lipids, safety, and tolerability of four doses of tesaglitazar (0.25, 0.5, 0.75 and 1 mg) compared with placebo in patients with type 2 diabetes.
A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Phase 2 Trial to Evaluate the Safety and Efficacy of BMS-512148 as Monotherapy in Subjects With Type 2 Diabetes Mellitus Who Are Treatment Naive And Have Inadequate Glycemic Control on Diet and Exercise **(International)**			√	Bristol Myers Squibb	Bristol Myers Squibb	Both	18 to 79	N/S	385	December-05	N/S	Adult	To learn if BMS-512148 is effective in controlling blood sugar levels as determined by HbA1c and fasting plasma glucose in patients who have been diagnosed with Type 2 diabetes.
A Randomized, Double-Blind Study to Determine the Effect of GK Activator (2) on Efficacy (HbA1c), Safety, Tolerability and Pharmacokinetics in Patients With Type 2 Diabetes Mellitus **(International)**			√	Hoffman LaRoche	Hoffman LaRoche	Both	30 to 75	N/S	100-500	November-05	N/S	Adult	To evaluate the efficacy, safety, tolerability, and pharmacokinetics of oral GK Activator (2), compared to placebo, in patients with type 2 diabetes mellitus.
A Randomized Double-Blind Study to Determine the Effect of GK Activator (2) on Efficacy (HbA1c), Safety, Tolerability and Pharmacokinetics in Patients With Type 2 Diabetes Mellitus Treated With a Stable Dose of Metformin **(International)**			√	Hoffman LaRoche	Hoffman LaRoche	Both	30 to 75	N/S	100-500	November-05	N/S	Adult	To evaluate the efficacy, safety, tolerability, and pharmacokinetics of GK Activator (2) in combination with metformin, compared to that of placebo (metformin monotherapy), in patients with type 2 diabetes mellitus.
Liraglutide Effect and Action in Diabetes (LEAD-1): Effect on Glycaemic Control After Once Daily Administration of Liraglutide in Combination With Glimepiride Versus Glimepiride Monotherapy Versus Glimepiride and Rosiglitazone Combination Therapy in Subjects With Type 2 Diabetes **(Europe)**			√	Zdravkovic, Milan	Novo Nordisk	Both	18 to 80	N/S	1,026	May-06	N/S	Adult	To show the effect of treatment with liraglutide when added to existing glimepiride therapy and to compare this to both glimepiride monotherapy and to rosiglitazone as add-on therapy to glimepiride.
Liraglutide Effect and Action in Diabetes (LEAD-5): Effect on Glycaemic Control After Once Daily Administration of Liraglutide in Combination With Glimepiride and Metformin Versus Glimepiride and Metformin Combination Therapy, and Versus Insulin Glargine Added to Glimepiride and Metformin Combination Therapy in Subjects With Type 2 Diabetes. A Six-Month Randomised, Double-Blind, Parallel-Group, Multi-Centre, Multi-National Trial With an Open-Label Treat-to-Target Insulin Glargine Control Arm **(Africa, Asia, Europe and South America)**			√	Zdravkovic, Milan	Novo Nordisk	Both	18 to 80	N/S	570	May-06	N/S	Adult	To show the effect of treatment with liraglutide added to existing glimepiride and metformin combination therapy and to compare it with the effects of insulin glargine added to combination therapy of glimepiride and metformin.
An Open Label Study to Determine the Effect on Fasting Glucose Levels, and Safety, of Increasing Doses of GK Activator(2) in Patients With Type 2 Diabetes Not Optimally Controlled With One Previous Oral Antihyperglycemic Agent **(International)**			√	Hoffman LaRoche	Hoffman LaRoche	Both	18 to 75	N/S	100-500	July-06	N/S	Adult	To assess the efficacy, safety and tolerability of increasing doses of GK Activator (2) in patients with type 2 diabetes whose condition has not been optimally controlled with one previous oral antihyperglycemic agent.
A Long Term, Open Label, Randomised Study in Patients With Type 2 Diabetes, Comparing the Combination of Rosiglitazone and Either Metformin or Sulphonylurea With Metformin Plus Sulphonylurea on Cardiovascular Endpoints and Glycaemia **(Europe)**			√	GlaxoSmithKline	GlaxoSmithKline	Both	40 to 75	N/S	4,452	April-01	N/S	Adult	This study is a phase 3b, multicentre, randomised, open label, parallel group study. A 4-week run-in period will be followed by a median of 6 years of treatment with study medication in addition to continuation of background glucose lowering therapy. Patients inadequately controlled on background metformin will be randomised to receive, in addition to metformin, either rosiglitazone or an Su (glibenclamide, gliclazide or glimepiride) in a ratio of 1:1. Patients inadequately controlled on background Su will be randomised to receive, in addition to Su, either rosiglitazone or metformin in a ratio of 1:1. Equal numbers of patients receiving background metformin and Su at entry will be entered into the study.
Safety and Efficacy of Exenatide in Patients With Type 2 Diabetes Using Thiazolidinediones or Thiazolidinediones and Metformin **(International)**	√			Malone, James	Amylin Pharmaceuticals	Both	21 to 75	N/S	280	May-04	N/S	Adult	Tocompare the effects of twice-daily exenatide plus oral antidiabetic (OAD) agents and twice-daily placebo plus OAD with respect to glycemic control, as measured by hemoglobin A1c (HbA1c), in patients with type 2 diabetes who experience inadequate glycemic control with OAD alone.

CLOSED STUDIES FOR DIABETES MELLITUS TYPE 2

Title	Completed	Not yet recruiting/ Not open	No longer recruiting	Investigator	Sponsor	Eligibility			Total Enroll	Start	End	Adult/Child	Objective
						Gender	Age	Race	n > 200				
A Multicenter, Randomized, Double-Blind Factorial Study of the Co-Administration of MK0431 and Metformin in Patients With Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control			√	Merck	Merck	Both	18 to 78	N/S	1,050	April-05	N/S	Adult	To determine the safety and effectiveness of an investigational drug in patients with Type 2 Diabetes Mellitus (a specific type of diabetes).
Efficacy and Safety Comparison of Insulin Detemir and Insulin Glargine Plus Insulin Aspart in Patients With Type 2 Diabetes **(International)**				Koenen, Christoph	Novo Nordisk	Both	18+	N/S	600	March-05	N/S	Adult	To determine if the use of insulin detemir in combination with insulin aspart is safe and at least as effective as insulin glargine in combination with insulin aspart for the control of blood glucose in patients with Type 2 diabetes.
A Phase 3B, Multicenter, Open-Label Study Investigating the Clinical Utility and Safety of Pramlintide in Subjects With Type 1 and Type 2 Diabetes Mellitus Who Have Not Achieved Glycemic Targets With Insulin Therapy	√			Porter, Lisa	Amylin Pharmaceuticals	Both	18+	N/S	400	April-03	N/S	Adult	To investigate the clinical utility and safety of pramlintide treatment in subjects with type 1 and type 2 diabetes who are failing to achieve the desired level of glycemic control using insulin
MK0431 Late Phase II Double-Blind Dose-Response Study - Type 2 Diabetes Mellitus **(Japan)**			√	Merck	Merck	Both	20 to 75	N/S	350	July-05	N/S	Adult	To determine the efficacy and safety of an investigational drug in patients with type 2 diabetes mellitus.
A Study to Assess the Efficacy and Tolerability of MK-0478 (Muraglitazar, Also, BMS 298585) Coadministered With Insulin in Patients With Type 2 Diabetes **(International)**			√ **(Terminated)**	Merck	Merck	Both	18 to 70	N/S	600	October-05	N/S	Adult	To evaluate the effectiveness and tolerability of an investigational drug in patients with type 2 diabetes (a specific type of diabetes) who are not currently treated with insulin.
Safety and Efficacy of Insulin Glargine Versus Biphasic Insulin Aspart 30/70 or Biphasic Insulin Aspart 30/70 in Combination With Metformin in Subjects With Type 2 Diabetes **(Asia)**			√	Tuna, Sebnem	Novo Nordisk	Both	35+	N/S	242	September-04	N/S	Adult	To compare the glyacemic control of Insulin glargine versus Biphasic Insulin Aspart 30/70 or Biphasic Insulin Aspart 30/70 in combination with metformin in subjects with Type 2 Diabetes.
Nateglinide: a Double Blind Add-on Study With Pioglitazone for Type 2 Diabetic Patients **(Japan)**			√	Astellas Pharma	Astellas Pharma	Both	20+	N/S	Enrollment # not specified	N/S	N/S	Adult	To investigate the superiority of nateglinide over placebo for inadequately controlled type 2 diabetic patients with pioglitazone treatment.
Double-Blind Trial of Miglitol in Type 2 Diabetic Patients With Insulin Treatment **(Japan)**	√			Sanwa Kagaku Kenkyusho Co., Ltd.	Sanwa Kagaku Kenkyusho Co., Ltd.	Both	20+	N/S	Enrollment # not specified	N/S	N/S	Adult	To evaluate the clinical efficacy and safety of Miglitol in patients with Type 2 Diabetes Mellitus with treated insulin.
Effects of Miglitol on Daily Plasma Glucose in type2 Diabetes Treated With Insulin **(Japan)**	√			Sanwa Kagaku Kenkyusho Co., Ltd.	Sanwa Kagaku Kenkyusho Co., Ltd.	Both	20 to 74	N/S	Enrollment # not specified	N/S	N/S	Adult	To evaluate the effect of miglitol on daily plasma glucose in type 2 diabetic patients treated with insulin
Complaints Associated With Use of Pre-Filled Pen B When Used by Patients With Type 2 Diabetes on Twice-Daily Insulin Therapy **(International)**	√			Eli Lillly & Co	Eli Lilly & Co	Both	25 to 75	N/S	370	September-05	June-06	Adult	To collect complaint data on the Pre-filled Pen B when used by persons with type 2 diabetes to self-administer insulin in take-home situations for 2 months.
A Randomized, Double-Blind, Placebo-Controlled, Multicenter Study Evaluating the Efficacy and Safety of Adding Symlin® to Lantus® (Insulin Glargine) in Subjects With Type 2 Diabetes Who Are Not Achieving Glycemic Targets	√			Porter, Lisa	Amylin Pharmaceuticals	Both	18 to 75	N/S	200	October-05	N/S	Adult	To evaluate the efficacy and safety of adding Symlin to an established regimen of insulin glargine in subjects with type 2 diabetes who are not achieving glycemic targets.
Impact of a Self-Adjusted Titration Guideline in Subjects With Type 2 Diabetes Mellitus: A Treat-to-Target of the Efficacy and Safety of Levemir® (Insulin Detemir [rDNA Origin] Injection) **(USA and Puerto Rico)**			√	Novo Nordisk	Novo Nordisk	Both	18+	N/S	5,000	October-05	N/S	Adult	To compare the safety and efficacy in subjects with type 2 diabetes using either self titration or physician guided titration according to the local standard of care.
Comparison of Efficacy and Safety of Insulin Detemir and Insulin Glargine as Add-on to Current Oral Antidiabetic Drugs in Subjects With Type 2 Diabetes **(International)**	√			Novo Nordisk	Novo Nordisk	Both	18+	N/S	548	March-03	N/S	Adult	To test if Insulin Detemir as add-on to current Oral Antidiabetic Drug treatment is at least as effective as Insulin Glargine as add-on to current Oral Antidiabetic Drug treatment in reducing HbA1c in patients with Type 2 Diabetes.
A Multicenter, Double-Blind, Randomized, Placebo-Controlled Study of MK0431 in Patients With Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control			√	Merck	Merck	Both	18+	N/S	500	March-06	N/S	Adult	To determine the safety and efficacy of an investigational drug in patients with type 2 diabetes mellitus.
44-Week, Parallel, Open, Randomized, Multinational, Multi-Center Clinical Trial to Compare Efficacy and Safety of the Combination Therapy of an Oral Anti-Diabetic Drug Treatment With Either HOE901 Insulin Once Daily or Lispro Insulin Analogue at Mealtime in Type 2 Diabetes Mellitus Patients Poorly Controlled With Oral Anti-Diabetic Drug Treatment	√			Pilorget, Valérie	Sanofi-Aventis	Both	18 to 75	N/S	Enrollment # not specified	N/S	N/S	Adult	To compare efficacy of oral antidiabetics (OAD) combination therapy with either HOE901 insulin analogue once daily or Lispro insulin analogue at mealtime in terms of change in HbA1c (baseline to endpoint).
Pioglitazone Versus Rosiglitazone in Subjects With Type 2 Diabetes Mellitus and Dyslipidemia				Perez, Alfonso	Takeda Global Research & Development Center, Inc.	Both	35+	N/S	706	September-00	November-04	Adult	Pioglitazone HCl and rosiglitazone will be evaluated and compared for their lipid-altering potential, as measured by the fasting triglyceride levels, in subjects with type 2 diabetes mellitus and dyslipidemia.

CLOSED STUDIES FOR DIABETES MELLITUS TYPE 2

Title	Completed	Not yet recruiting/ Not open	No longer recruiting	Investigator	Sponsor	Eligibility			Total Enroll	Start	End	Adult/Child	Objective
						Gender	Age	Race	n > 200				
Insulin Glargine v Rosiglitazone as Add-on Therapy in Patients Failing Sulfonylurea and Metformin Combination Therapy	√			Barch, Karen	Sanofi-Aventis	Both	18 to 80	N/S	220	January-01	September-02	Adult	To compare the glycemic control, as measured by HbA1C, between insulin glargine and rosiglitazone add-on therapies in patients who fail oral combination of a sulfonylurea and metformin.
A Randomized, Double-Blind, Placebo-Controlled Trial to Assess Safety and Tolerability During Treatment of Type 2 Diabetes With Usual Diabetes Therapy and Either Cycloset or Placebo			√	Gaziano, Michael	VeroScience	Both	30 to 80	N/S	3,000	July-04	April-07	Adult	To test the hypothesis that the rate of all-cause severe adverse events for those recieving usual drug therapy for diabetes management plus Cycloset is not greater than that for usual drug therapy plus placebo by more than an acceptable margin.
Double-Blind Study of Miglitol in Japanese With type2 Diabetes **(Japan)**	√			Sanwa Kagaku Kenkyusho Co., Ltd.	Sanwa Kagaku Kenkyusho Co., Ltd.	Both	20 to 69	N/S	Enrollment # not specified	N/S	N/S	Adult	To investigate the efficacy and safety of miglitol in Japanese patients with type 2 diabetes that is insufficiently controlled diet alone.
A Phase III, Multicenter, Randomized, Double-Blind Clinical Trial to Study the Safety and Efficacy of the Addition of Sitagliptin (MK0431) to Patients With Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control on Insulin Therapy (Alone or In Combination With Metformin)		√		Merck	Merck	Both	21+	N/S	600	December-06	N/S	Adult	To determine the safety and efficacy of sitagliptin in patients with Type 2 Diabetes Mellitus who have inadequate glycemic control on insulin or insulin/metformin combination therapy.
A Multicenter, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of the Initial Therapy With Coadministration of Sitagliptin and Pioglitazone in Patients With Type 2 Diabetes Mellitus		√		Merck	Merck	Both	18+	N/S	450	December-06	N/S	Adult	To evaluate the safety and efficacy of the initial combination therapy with sitagliptin and pioglitazone in patients with type 2 diabetes mellitus not on treatment with insulin or oral antihyperglycemic therapy.
Efficacy and Safety of Insulin Glulisine Given as a Single Injection at Breakfast + Insulin Glargine+OAD (Oral Antidiabetic Drug) Vs Insulin Glulisine Given as a Single Injection at Main Meal+Insulin Glargine+OAD in Type 2 Diabetic Patients for Which Glycemic Control is Suboptimal Using Insulin Glargine+ OAD Alone **(Germany)**			√	Landgraf, Wolfgang	Sanofi-Aventis	Both	18+	N/S	348	July-04	N/S	Adult	To compare efficacy of Insulin glulisine, once a day at breakfast vs. Insulin glulisine given once a day at main meal in combination with insulin glargine + OAD in terms of change in HbA1c, from baseline to endpoint for the individual patient.
Effect of Pioglitazone on Ambulatory Blood Pressure **(Germany)**		√		Schmieder, Roland	University of Erlangen-Nürnberg	Male	18 to 75	N/S	Enrollment # not specified	N/S	N/S	Adult	The anti-diabetic pioglitazone has been found to reduce casual blood pressure. To date no data are available looking at this effect in detail. Especially, ambulatory blood pressure has not yet been utilized to confirm the hypothesis that pioglitazone has blood pressure lowering effects.
10-Week, Open, National, Multicenter Clinical Trial to Evaluate the Safety of Insulin Glargine in Type 2 Diabetes Mellitus Patients, on Intensified Conventional Therapy (ICT) **(Germany)**	√			Landgraf, Wolfgang	Sanofi-Aventis	Both	18 to 75	N/S	480	October-03	N/S	Adult	Difference in frequency of subjects with conventionally detected hypoglycemia by the subject [at least one measurement smaller/equal 60mg/dl documented in the 8-point profile in the case record form (CRF) or documentation of symptomatic hypoglycemia in the CRF through Visits 8/9] compared to CGMS detected blood glucose values smaller/equal 60mg/dl during CGMS measurements (at least one measurement through Visits 8/9) after eight weeks of treatment with insulin glargine.
A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of the Efficacy and Safety of Topiramate in the Treatment of Obese, Type 2 Diabetic Patients Treated With Metformin			√	Johnson & Johnson Pharmaceutical Research & Development, L.L.C.	Johnson & Johnson Pharmaceutical Research & Development, L.L.C.	Both	18 to 75	N/S	838	August-00	N/S	Adult	To compare the efficacy (in terms of weight and hemoglobin type A1c [HbA1c]) and safety of topiramate (96 milligrams[mg] or 192 mg daily) with placebo in the treatment of obesity in Type 2 diabetic patients receiving metformin.
Study Of Subjects With Type II Diabetes Mellitus Who Are Inadequately Controlled On Insulin	√			GlaxoSmithKline	GlaxoSmithKline	Both	18 to 70	N/S	Enrollment # not specified	N/S	N/S	Adult	To compare the effects of adding the drug rosiglitazone (2mg and 4mg) or placebo to insulin in patients with Type 2 diabetes mellitus (non-insulin-dependent) who have not achieved their blood glucose goal using insulin alone.
A 12-Week, Parallel-Group, Double-Blind, Randomized, Placebo-Controlled, Multicenter, Dose Ranging Study to Evaluate the Efficacy, Safety and Tolerability of GW823093, Administered Orally, Once Daily, as Monotherapy in Subjects With Type 2 Diabetes Mellitus Followed by a 12-Week Active Treatment Extension **(International)**	√			GlaxoSmithKline	GlaxoSmithKline	Both	18 to 75	N/S	366	N/S	N/S	Adult	To investigate the safety and efficacy of several dosages of a potential new oral medicine for Type II diabetes mellitus.

CLOSED STUDIES FOR DIABETES MELLITUS TYPE 2

Title	Completed	Not yet recruiting/ Not open	No longer recruiting	Investigator	Sponsor	Eligibility			Total Enroll	Start	End	Adult/Child	Objective
						Gender	Age	Race	n > 200				
A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Assess the Safety and Efficacy of Topiramate in the Treatment of Obese, Type 2 Diabetic Patients on a Controlled Diet			√	Johnson & Johnson Pharmaceutical Research & Development, L.L.C	Johnson & Johnson Pharmaceutical Research & Development, L.L.C	Both	18 to 75	N/S	600	January-01	N/S	Adult	To determine the efficacy and safety of topiramate compared with placebo in obese, Type 2 diabetic patients on a controlled diet.
A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study of the Efficacy and Safety of Topiramate in the Treatment of Obese, Type 2 Diabetic Patients Inadequately Controlled on Sulfonylurea Therapy			√	Johnson & Johnson Pharmaceutical Research & Development, L.L.C	Johnson & Johnson Pharmaceutical Research & Development, L.L.C	Both	18 to 75	N/S	580	N/S	N/S	Adult	To compare the effectiveness and safety of topiramate with placebo in the treatment of obesity and Type 2 diabetes mellitus in patients who have failed on sulfonylurea therapy.
An Evaluation of an Oral Antidiabetic Agent for the Treatment of Type 2 Diabetes	√			Eli Lillly & Co	Eli Lilly & Co	Both	18 to 70	N/S	Enrollment # not specified	N/S	N/S	Adult	To determine if an investigational drug is safe and efficacious for poorly controlled type 2 diabetes mellitus.
Safety and Efficacy of INGAP-Peptide in Patients With Type 2 Diabetes (creation of new B cells)	√			Procter & Gamble Pharmaceuticals	Procter & Gamble Pharmaceuticals	Both	35 to 70	N/S	Enrollment # not specified	N/S	N/S	Adult	INGAP-Peptide is being tested to attempt to create new beta cells in the pancreas, and to improve the ability to produce insulin in type 2 diabetic patients.
Efficacy and Safety of Vildagliptin in Combination With Pioglitazone in Patients With Type 2 Diabetes	√			Novartis	Novartis	Both	18 to 80	N/S	345	May-04	N/S	Adult	To assess the safety and effectiveness of vildagliptin, an unapproved drug, in lowering overall blood glucose levels when added to pioglitazone in people with type 2 diabetes not at target blood glucose levels on either pioglitazone or rosiglitazone alone.
Efficacy and Safety of Vildagliptin Compared to Metformin in Drug Naive Patients With Type 2 Diabetes **(Germany)**	√			Novartis	Novartis	Both	18 to 75	N/S	780	January-04	N/S	Adult	To assess the safety and effectiveness of vildagliptin, an unapproved drug, compared to metformin in lowering overall blood glucose levels in people with type 2 diabetes who have not been previously treated with drug therapy to lower their blood sugar.
Efficacy and Safety of Vildagliptin in Combination With Metformin in Patients With Type 2 Diabetes	√			Novartis	Novartis	Both	18 to 78	N/S	345	May-04	N/S	Adult	To assess the safety and effectiveness of two doses of vildagliptin, an unapproved drug, when added to metformin in people with type 2 diabetes who are not at target blood glucose levels on metformin alone.
A Clinical Study to Assess the Efficacy and Safety of Three Doses of Vildagliptin in Patients With Type 2 Diabetes	√			Novartis	Novartis	Both	18 to 80	N/S	577	April-04	N/S	Adult	To assess the safety and effectiveness of three doses of vildagliptin, an unapproved drug, compared to placebo in lowering overall blood glucose levels in people with type 2 diabetes who have not been previously treated with drug therapy to lower their blood sugar.
Efficacy and Safety of Vildagliptin in Combination With Insulin in Patients With Type 2 Diabetes **(Germany)**	√			Novartis	Novartis	Both	18 to 80	N/S	296	May-04	N/S	Adult	To assess the safety and effectiveness of vildagliptin, an unapproved drug, in lowering overall blood glucose levels when added to insulin in people with type 2 diabetes who are not at target blood glucose levels on insulin alone.
Efficacy and Safety of Vildagliptin Compared to Rosiglitazone in Drug Naive Patients With Type 2 Diabetes **(NJ and Germany)**	√			Novartis	Novartis	Both	18 to 80	N/S	705	May-06	N/S	Adult	To assess the safety and effectiveness of vildagliptin, an unapproved drug, compared to rosiglitazone in lowering overall blood glucose levels in people with type 2 diabetes who have not previously been treated with drug therapy to lower their blood sugar.
Efficacy and Safety of Vildagliptin in Combination With Glimepiride in Patients With Type 2 Diabetes	√			Novartis	Novartis	Both	18 to 80	N/S	345	May-04	N/S	Adult	To assess the safety and effectiveness of two doses of vildagliptin, an unapproved drug, in lowering overall blood glucose levels when added to glimepiride in people with type 2 diabetes not at target blood glucose levels on a sulfonylurea alone.

CLOSED STUDIES FOR DIABETES MELLITUS TYPE 2

Title	Completed	Not yet recruiting/ Not open	No longer recruiting	Investigator	Sponsor	Eligibility			Total Enroll	Start	End	Adult/Child	Objective
						Gender	Age	Race	n > 200				
Efficacy and Safety of Vildagliptin in Patients With Type 2 Diabetes With HbA1c 9-11% **(Switzerland)**	√			Novartis	Novartis	Both	18+	N/S	250	March-04	N/S	Adult	To assess the safety and effectiveness of two doses of vildagliptin, an unapproved drug, in lowering overall blood glucose levels in people with type 2 diabetes who had not previously been treated with drug therapy to lower their blood sugar and whose blood sugar levels were in a specified range.
Efficacy and Safety of Vildagliptin Compared to Placebo in Patients With Type 2 Diabetes and Mild Hyperglycemia **(Switzerland and Germany)**	√			Novartis	Novartis	Both	18+	N/S	300	October-04	N/S	Adult	To assess the safety and effectiveness of vildagliptin, an unapproved drug, compared to placebo in lowering overall blood glucose levels in people with type 2 diabetes who have not been previously treated with drug therapy to lower their blood sugar and whose blood glucose levels are close to normal.
Efficacy and Safety of a Standard Titration Algorithm Coupled With a Conventional Dietary Intervention or Intensive Dietary Intervention Versus a Standard Titration Algorithm, Alone, in Patients With Type 2 Diabetes Initiating Biphasic Insulin Analogue Therapy			√	Braceras, Rogelio	Novo Nordisk	Both	18+	N/S	6,000	July-04	N/S	Adult	To compare the effectiveness and safety of a biphasic insulin aspart standard titration regimen when coupled with dietary intervention to standard titration without dietary intervention.
Efficacy and Safety of Vildagliptin Compared to Gliclazide in Drug Naive Patients With Type 2 Diabetes **(Switzerland and Germany)**			√	Novartis	Novartis	Both	18+	N/S	800	January-05	N/S	Adult	To assess the safety and effectiveness of vildagliptin, an unapproved drug, compared to gliclazide in lowering overall blood glucose levels in people with type 2 diabetes who have not been previously treated with drug therapy to lower their blood sugar.
Vildagliptin Compared to Gliclazide in Combination With Metformin in Patients With Type 2 Diabetes **(Switzerland and Germany)**			√	Novartis	Novartis	Both	18 to 78	N/S	588	January-05	N/S	Adult	To assess the safety and effectiveness of vildagliptin, an unapproved drug, compared to that of gliclazide in lowering overall blood glucose levels when added to metformin in people with type 2 diabetes not at target blood glucose levels on metformin alone.
Vildagliptin Compared to Glimepiride in Combination With Metformin in Patients With Type 2 Diabetes **(NJ and Germany)**			√	Novartis	Novartis	Both	18 to 73	N/S	3,000	March-05	N/S	Adult	To assess the long term safety and effectiveness of vildagliptin, an unapproved drug, compared to that of glimepiride in lowering overall blood glucose levels when added to metformin in people with type 2 diabetes not at target blood glucose levels on metformin alone.
Efficacy and Safety of Vildagliptin Compared to Acarbose in Drug Naive Patients With Type 2 Diabetes **(Switzerland)**			√	Novartis	Novartis	Both	18+	N/S	660	April-05	N/S	Adult	To assess the safety and effectiveness of vildagliptin, an unapproved drug, compared to acarbose in lowering overall blood glucose levels in people with type 2 diabetes who have not been previously treated with drug therapy to lower their blood sugar.
Efficacy and Safety of Three Doses of Vildagliptin in Drug Naive Patients With Type 2 Diabetes	√			Novartis	Novartis	Both	18 to 80	N/S	344	June-05	N/S	Adult	To assess the long term safety and effectiveness of three doses of vildagliptin, an unapproved drug, compared to placebo in lowering overall blood glucose levels in people with type 2 diabetes who have not previously been treated with drug therapy to lower their blood sugar.

CLOSED STUDIES FOR DIABETES MELLITUS TYPE 2

Title	Completed	Not yet recruiting/ Not open	No longer recruiting	Investigator	Sponsor	Eligibility			Total Enroll	Start	End	Adult/Child	Objective
						Gender	Age	Race	n > 200				
Extension to a Study on the Efficacy and Safety of Vildagliptin in Combination With Metformin in Patients With Type 2 Diabetes	√			Novartis	Novartis	Both	18 to 78	N/S	280	November-04	N/S	Adult	This is a 28-week extension to a study to assess the safety and effectiveness of vildagliptin, an unapproved drug, in lowering overall blood glucose levels when added to metformin in people with type 2 diabetes who are not at target blood glucose levels on metformin alone. The purpose of the extension study is to gather data on the long-term safety and effectiveness of vildagliptin in people with type 2 diabetes.
Extension to a Study to Assess the Efficacy and Safety of Three Doses of Vildagliptin in Patients With Type 2 Diabetes	√			Novartis	Novartis	Both	18 to 80	N/S	280	October-04	N/S	Adult	This is a 28-week extension to a study of the safety and effectiveness of three doses of vildagliptin, an unapproved drug, compared to placebo in lowering overall blood glucose levels in people with type 2 diabetes who have not been previously treated with drug therapy to lower their blood sugar. The purpose of the extension study is to gather long-term safety and efficacy data for vildagliptin in people with type 2 diabetes.
Extension to a Study on the Efficacy and Safety of Vildagliptin in Combination With Pioglitazone in Patients With Type 2 Diabetes	√			Novartis	Novartis	Both	18 to 80	N/S	345	November-04	N/S	Adult	This is a 28-week extension to a study to assess the safety and effectiveness of vildagliptin, an unapproved drug, in lowering overall blood glucose levels when added to pioglitazone in people with type 2 diabetes not at target blood glucose levels on pioglitazone or rosiglitazone alone. The purpose of the extension study is to gather data on the long-term safety and effectiveness of vildagliptin in people with type 2 diabetes.
Extension to a Study on the Efficacy and Safety of Vildagliptin Compared to Metformin in Drug Naive Patients With Type 2 Diabetes **(NJ and Germany)**	√			Novartis	Novartis	Both	18 to 78	N/S	530	January-05	N/S	Adult	This is a 52-week extension to a study to assess the safety and effectiveness of vildagliptin, an unapproved drug, compared to metformin in lowering overall blood glucose levels in people with type 2 diabetes who have not been previously treated with drug therapy to lower their blood sugar. The purpose of the extension study is to gather data on the long-term safety and effectiveness of vildagliptin in people with type 2 diabetes.
Extension to a Study on the Efficacy and Safety of Vildagliptin in Combination With Glimepiride in Patients With Type 2 Diabetes	√			Novartis	Novartis	Both	18 to 80	N/S	345	November-04	N/S	Adult	This is a 28-week extension to a study to assess the safety and effectiveness of vildagliptin, an unapproved drug, in lowering overall blood glucose levels when added to glimepiride in people with type 2 diabetes not at target blood glucose levels on a sulfonylurea alone. The purpose of the extension study is to gather data on the long-term safety and effectiveness of vildagliptin in people with type 2 diabetes.
Extension to a Study on the Efficacy and Safety of Vildagliptin in Combination With Insulin in Patients With Type 2 Diabetes **(NJ and Germany)**	√			Novartis	Novartis	Both	18 to 80	N/S	200	January-05	N/S	Adult	This is a 28-week extension to a study to assess the safety and effectiveness of vildagliptin, an unapproved drug, in lowering overall blood glucose levels when added to insulin in people with type 2 diabetes who are not at target blood glucose levels on insulin alone. The purpose of the extension study is to gather data on the long-term safety and effectiveness of vildagliptin in people with type 2 diabetes.

CLOSED STUDIES FOR DIABETES MELLITUS TYPE 2

Title	Completed	Not yet recruiting/ Not open	No longer recruiting	Investigator	Sponsor	Eligibility			Total Enroll	Start	End	Adult/Child	Objective
						Gender	Age	Race	n > 200				
Extension to a Study on the Efficacy and Safety of Vildagliptin Compared to Rosiglitazone in Drug Naive Patients With Type 2 Diabetes **(NJ and Germany)**			√	Novartis	Novartis	Both	18 to 80	N/S	530	November-04	N/S	Adult	This is an 80-week extension to a study to assess the safety and effectiveness of vildagliptin, an unapproved drug, compared to rosiglitazone in lowering overall blood glucose levels in people with type 2 diabetes who have not previously been treated with drug therapy to lower their blood sugar. The purpose of the extension study is to gather data on the long-term safety and effectiveness of vildagliptin in people with type 2 diabetes.
A 24-Wk Randomised, Double-Blind, Multi-Centre, Active-Controlled (Pioglitazone) Study to Evaluate the Efficacy, Safety & Tolerability of Tesaglitazar Therapy When Administered to Patients With Type 2 Diabetes **(International)**	√			Asta Zeneca	Astra Zeneca	Both	18+	N/S	1,450	August-04	N/S	Adult	This is a 24-week randomized, double-blind, multi-center, active-controlled (pioglitazone) study of tesaglitazar (0.5 mg and 1 mg) in patients with type 2 diabetes, not adequately controlled on diet and lifestyle advice alone during the run-in period.
A 52-Wk Randomised, Double-Blind, Parallel-Group, Multi-Centre, Active-Controlled (Metformin) Study to Evaluate the Efficacy, Safety & Tolerability of Tesaglitazar Therapy When Administered to Patients With Type 2 Diabetes **(International)**			√	Asta Zeneca	Astra Zeneca	Both	18+	N/S	580	August-04	N/S	Adult	This is a 52-week randomized, double-blind, parallel-group, multi-center, active-controlled (metformin) study of tesaglitazar in patients with type 2 diabetes, not adequately controlled on diet and lifestyle advice alone during the run-in period.
Vildagliptin Compared to Pioglitazone in Combination With Metformin in Patients With Type 2 Diabetes **(NJ and Germany)**			√	Novartis	Novartis	Both	18 to 77	N/S	588	October-05	N/S	Adult	To assess the long-term safety and effectiveness of vildagliptin, an unapproved drug, compared to that of pioglitazone in lowering overall blood glucose levels when added to metformin in people with type 2 diabetes not at target blood glucose levels on metformin alone.
A Clinical Study to Assess the Efficacy and Safety of Vildagliptin in Patients With Type 2 Diabetes **(Europe)**	√			Novartis	Novartis	Both	20 to 75	N/S	344	July-04	N/S	Adult	To assess the safety and effectiveness of a number of doses of vildagliptin, an unapproved drug, in the treatment of people with type 2 diabetes.
A Multicenter, Double-Blind, Randomized, Parallel-Group Study to Compare the Effect of 12 Weeks Treatment With Vildagliptin to Placebo as Add-on Therapy to Sulfonylurea in Patients With Type 2 Diabetes Inadequately Controlled With Sulfonylurea Monotherapy **(Japan)**				Novartis	Novartis	Both	20+	N/S	200	April-06	N/S	Adult	To evaluate the efficacy and safety of vildagliptin as add-on therapy to a sulfonylurea in patients with type 2 diabetes inadequately controlled with sulfonylurea monotherapy.
A Research Study to Assess the Mechanism By Which Glucovance, Metformin, and Glyburide Work To Control Glucose Levels In Patients With Type 2 Diabetes			√	Bristol Myers Squibb	Bristol Myers Squibb	Both	20 to 75	N/S	Enrollment # not specified	N/S	N/S	Adult	To support earlier observations that Glucovance controls glucose levels after a mean, and improves overall glucose control better than metformin or glyburide therapy alone in adults with type 2 diabetes.
Evaluation of the Effect on Glucose Control of AC2993 in Patients With Type 2 Diabetes Mellitus Treated With a Sulfonylurea	√			Amylin Pharmaceuticals	Amylin Pharmaceuticals	Both	16 to 75	N/S	Enrollment # not specified	N/S	N/S	Young Adult to Adult	To assess the effects on glucose control of AC2993 as compared to placebo in patients with type 2 diabetes.
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			√	Merck	Merck	Both	18 to 78	N/S	525	July-04	N/S	Adult	To determine the safety and efficacy of an investigational drug in patients with type 2 diabetes mellitus.
An Open-Label, Multi-Center, Long-Term Extension Study to Evaluate the Safety and Tolerability of Oral Tesaglitazar 0.5mg When Added to Insulin Therapy in Patients With Type 2 Diabetes Mellitus (GALLEX 9)			√	Asta Zeneca	Astra Zeneca	Both	18+	N/S	270	February-05	N/S	Adult	To monitor the safety and tolerability of oral tesaglitazar 0.5 mg and insulin in patients with type 2 diabetes during up to 140 weeks of treatment.
Randomized, Double Blinded, Placebo Controlled, Study to Evaluate Improvements in Glycemic Control, Lipid Levels, Quality of Life and Healthcare Costs After Daily Administration of Chromium Picolinate and Biotin in Patients With T2DM	√			Albarracin, Cesar	Nutrition 21, Inc.	Both	18 to 70	N/S	600	March-03	March-06	Adult	To evaluate the effect of the combination of chromium picolinate (600 µg Cr) + biotin (2 mg) versus placebo on glycosylated hemoglobin (HbA1c), lipid profiles (Total-C, HDL-C, LDL-C, TGs, TG/HDL ratio, etc), and pharmacoeconomic outcomes as measured at the Baseline Visit and 90 days later at the Final Visit. Secondarily, to measure the effect of chromium picolinate (600 µg Cr) + biotin (2 mg) versus placebo on patient quality of life, fasting and post-prandial blood sugar levels, fasting insulin, and anti-hyperglycemic medication usage.

CLOSED STUDIES FOR DIABETES MELLITUS TYPE 2

Title	Completed	Not yet recruiting/ Not open	No longer recruiting	Investigator	Sponsor	Eligibility			Total Enroll	Start	End	Adult/Child	Objective
						Gender	Age	Race	n > 200				
A Double-Blind, Multi-Centre, Active-Controlled (15, 30, and 45 Mg Pioglitazone) Long-Term Extension Study to Evaluate the Safety and Tolerability of Tesaglitazar (0.5 and 1 Mg) in Patients With Type 2 Diabetes Mellitus (GALLEX 6) **(International)**			√	Astra Zeneca	Astra Zeneca	Both	18+	N/S	1,100	March-05	N/S	Adult	To monitor the safety and tolerability of oral tesaglitazar compared with pioglitazone in patients with type 2 diabetes for up to 104 weeks of treatment.
A Research Study to Assess the Mechanism By Which Glucovance, Metformin, and Glyburide Work To Control Glucose Levels In Patients With Type 2 Diabetes			√	Bristol Myers Squibb	Bristol Myers Squibb	Both	20 to 75	N/S	Enrollment # not specified	N/S	N/S	Adult	To support earlier observations that Glucovance controls glucose levels after a mean, and improves overall glucose control better than metformin or glyburide therapy alone in adults with type 2 diabetes.
A Research Study to Determine the Safety and Efficacy of Glucovance Compared to Metformin and Glyburide in Children and Adolescents With Type 2 Diabetes	√			Bristol Myers Squibb	Bristol Myers Squibb	Both	9 to 16	N/S	Enrollment # not specified	N/S	N/S	Child	To see if Glucovance, a medication currently approved for use in adults with type 2 diabetes, can control type 2 diabetes safely and effectively in children 9 to 16 years of age.
Evaluation of the Effect on Glucose Control of AC2993 in Patients With Type 2 Diabetes Mellitus	√			Amylin Pharmaceuticals	Amylin Pharmaceuticals	Both	16 to 75	N/S	Enrollment # not specified	N/S	N/S	Young Adult to Adult	To assess the effects on glucose control of AC2993 as compared to placebo in patients with type 2 diabetes.
Evaluation of the Effect on Glucose Control of AC2993 in Patients With Type 2 Diabetes Mellitus Treated With Metformin	√			Amylin Pharmaceuticals	Amylin Pharmaceuticals	Both	16 to 75	N/S	Enrollment # not specified	N/S	N/S	Young Adult to Adult	To assess the effects on glucose control of AC2993 as compared to placebo in patients with type 2 diabetes.
Evaluation of the Bioavailability of Pramlintide (Type 1 and 2)	√			Amylin Pharmaceuticals	Amylin Pharmaceuticals	Both	18 to 70	N/S	Enrollment # not specified	June-02	N/S	Adult	To examine the bioavailability of pramlintide in normal weight and overweight subjects with type 1 and type 2 diabetes mellitus using insulin.
Evaluation of the Effect of Pramlintide on Satiety and Food Intake (Type 1 and 2) **(Australia)**	√			Amylin Pharmaceuticals	Amylin Pharmaceuticals	Male	18 to 70	N/S	Enrollment # not specified	July-02	N/S	Adult	To evaluate the effect of pramlintide on satiety and food intake in normal-weight and obese non-diabetic subjects and in insulin-treated subjects with type 1 and type 2 diabetes.
Evaluation of the Effect on Glucose Control and the Safety and Tolerability of AC2993 in Patients With Type 2 Diabetes Mellitus	√			Amylin Pharmaceuticals	Amylin Pharmaceuticals	Both	18 to 65	N/S	Enrollment # not specified	N/S	May-03	Adult	To examine the effects on glucose control of AC2993 as compared to placebo in patients with type 2 diabetes.
Effect of AC2993 (Synthetic Exendin-4) Compared With Insulin Glargine in Patients With Type 2 Diabetes Also Using Combination Therapy With Sulfonylurea and Metformin **(International)**	√			Amylin Pharmaceuticals	Amylin Pharmaceuticals	Both	30 to 75	N/S	500	N/S	July-04	Adult	This is a multicenter, comparator-controlled, open-label, randomized, two-arm, parallel trial.
Efficacy of Exenatide (AC2993, Synthetic Exendin-4, LY2148568) Compared With Twice-Daily Biphasic Insulin Aspart in Patients With Type 2 Diabetes Using Sulfonylurea and Metformin **(Europe)**	√			Amylin Pharmaceuticals	Amylin Pharmaceuticals	Both	30 to 75	N/S	Enrollment # not specified	N/S	N/S	Adult	This is a Phase 3, multicenter, open-label, comparator-controlled trial.
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			√	Merck	Merck	Both	18+	N/S	300	July-04	N/S	Adult	To determine the safety and efficacy of an investigational drug in patients with type 2 diabetes mellitus.
A Multicenter, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of MK-0431 Monotherapy in Patients With Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control **(US and Puerto Rico)**			√	Merck	Merck	Both	18 to 75	N/S	600	July-04	N/S	Adult	To determine the safety and efficacy of an investigational drug in patients with type 2 diabetes mellitus.
A Double-Blind, Multicenter Study to Assess the LDL-C Lowering of Combination Tablets Ezetimibe/Simvastatin (10mg/20mg) and Ezetimibe/Simvastatin (10mg/40mg) Compared to Atorvastatin 20 mg in Patients With Type II Diabetes			√	Merck	Merck	Both	18+	N/S	500	February-05	N/S	Adult	To evaluate the cholesterol lowering efficacy of an investigational drug in patients with Type II diabetes (high blood sugar).
A Multicenter, Randomized, Double-Blind Study of MK0431 in Patients With Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control	√			Merck	Merck	Both	18 to 75	N/S	500	October-04	N/S	Adult	To determine the safety and effectiveness of an investigational drug in patients with Type 2 Diabetes Mellitus (a specific type of diabetes).
A Multicenter, Double-Blind, Randomized Study to Evaluate the Safety and Efficacy of the Addition of MK-0431 Compared With Sulfonylurea Therapy in Patients With Type 2 Diabetes With Inadequate Glycemic Control on Metformin Monotherapy			√	Merck	Merck	Both	18 to 78	N/S	1,000	October-04	N/S	Adult	To determine the safety and effectiveness of an investigational drug in patients with type 2 diabetes mellitus (a specific type of diabetes).
A Phase 3, Randomized, Three-Arm, Double-Blind, Active Controlled, Parallel Group, Multicenter Trial to Evaluate the Safety and Efficacy of Muraglitazar in Combination With Metformin Compared to Glimepiride in Combination With Metformin in Subjects Wtih Type 2 Diabetes Who Have Inadequate Glycemic Control on Metformin Therapy Alone	√			Bristol Myers Squibb	Bristol Myers Squibb	Both	18 to 70	N/S	1,752	February-04	N/S	Adult	To learn whether a muraglitazar-metformin combination is at least as effective as a glimepiride-metformin combination to treat type 2 diabetics who are not sufficiently controlled with metformin alone.

CLOSED STUDIES FOR DIABETES MELLITUS TYPE 2

Title	Completed	Not yet recruiting/ Not open	No longer recruiting	Investigator	Sponsor	Eligibility			Total Enroll	Start	End	Adult/Child	Objective
						Gender	Age	Race	n > 200				
Efficacy and Safety Comparison of Insulin Detemir Plus Insulin Aspart Versus Insulin Glargine Plus Insulin Aspart in Type 2 Diabetes **(International)**	√			Clauson, Per	Novo Nordisk	Both	18+	N/S	300	September-04	N/S	Adult	To test whether insulin detemir is a safe and at least as effective alternative to insulin glargine for the control of blood glucose in basal/bolus therapy in patients with type 2 diabetes.
Comparing Intensive and Standard Training for Human Insulin Inhalation Powder (HIIP) **(International)**	√			Eli Lillly & Co	Eli Lilly & Co	Both	18+	N/S	Enrollment # not specified	November-04	N/S	Adult	To compare intensive and standard training for human insulin inhalation powder in patients with type 2 diabetes.
Efficacy and Safety Comparison of Insulin Detemir Morning, Insulin Detemir Evening and NPH Insulin Evening as Add-on to Oral Antidiabetic Drug(s) in Patients With Type 2 Diabetes **(International)**	√			Clauson, Per	Novo Nordisk	Both	18+	N/S	501	N/S	N/S	Adult	To compare the use of Insulin Detemir once a day (morning or evening) to NPH Insulin once a day (evening) when added to treatment with oral antidiabetic drugs in patients with Type 2 diabetes.
A Multicenter, Randomized, Double Blind, Placebo-Controlled 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 Glimeperide Alone or in Combination With Metformin			√	Merck	Merck	Both	18 to 75	N/S	360	April-05	N/S	Adult	To determine the safety and efficacy of an investigational drug in patients with Type 2 diabetes mellitus.
A Comparison of Prandial Insulin Lispro Mixtures Therapy to Glargine Basal-Bolus Therapy With Insulin Lispro on the Overall Glycemic Control of Patients With Type 2 Diabetes Previously Treated With Oral Agents Combined With Insulin Glargine **(US and Puerto Rico)**	√			Eli Lillly & Co	Eli Lilly & Co	Both	30 to 75	N/S	300	April-04	April-06	Adult	To compare Lispro Mixture Therapy (insulin lispro 50/50 given three times daily with meals) to Glargine Basal-Bolus Therapy (insulin glargine daily with the addition of insulin lispro given three times daily with meals). The study is also comparing two different methods for adjusting the dose of insulin.
An Open Label Study to Examine the Long Term Effect on Glucose Control (HbA1c) and Safety and Tolerability of Exenatide Given Two Times a Day to Subjects With Type 2 Diabetes Mellitus			√	Porter, Lisa	Amylin Pharmaceuticals	Both	18 to 70	N/S	400	June-04	N/S	Adult	To assess long term glucose control, as measured by hemoglobin A1c (HbA1c) and to evaluate long term safety and tolerability in subjects with type 2 diabetes mellitus who receive subcutaneously injected exenatide administered twice a day.
A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase 3 Trial to Evaluate the Efficacy and Safety of Saxagliptin (BMS-477118) as Monotherapy in Subjects With Type 2 Diabetes Who Have Inadequate Glycemic Control With Diet and Exercise **(International)**			√	Bristol Myers Squibb	Bristol Myers Squibb	Both	18 to 77	N/S	460	July-05	N/S	Adult	To learn whether Saxagliptin is more effective than placebo as a treatment for type 2 diabetic subjects who are not sufficiently controlled with diet and exercise.
A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase III Trial to Evaluate the Efficacy and Safety of BMS-477118 in Combination With Metformin in Subjects With Type 2 Diabetes Who Have Inadequate Glycemic Control on Metformin Alone **(International)**			√	Bristol Myers Squibb	Bristol Myers Squibb	Both	18 to 77	N/S	720	July-05	N/S	Adult	To learn whether Saxagliptin added to Metformin therapy is more effective than Metformin alone as a treatment for type 2 diabetic subjects who are not sufficiently controlled with Metformin alone.
Insulin Glulisine Administered in a Fixed Bolus Regimen Versus Variable Bolus Regimen Based on Carbohydrate Counting in Adult Subjects With Type 2 Diabetes Receiving Insulin Glargine as Basal Insulin	√			Barch, Karen	Sanofi-Aventis	Both	18 to 70	N/S	281	April-04	October-05	Adult	To compare the change in glycemic control, as measured by hemoglobin A1c (HbA1c) from baseline to study week 24, in subjects receiving insulin glulisine as mealtime insulin following a variable bolus insulin regimen (based on carbohydrate counting) versus a fixed bolus insulin regimen, with insulin glargine as basal insulin in both arms of the study.
Insulin Glulisine Administered Pre-Meal Versus Post-Meal in Adult Subjects With Type 2 Diabetes Mellitus Receiving Insulin Glargine as Basal Insulin			√	Barch, Karen	Sanofi-Aventis	Both	18 to 70	N/S	340	August-04	N/S	Adult	To compare the change in weight from baseline to study week 52 in the per-protocol population of pre-meal insulin glulisine (Apidra) versus post-meal Apidra, in patients receiving insulin glargine (Lantus) as basal insulin.
A Multicentre, Randomised, Double Blind Placebo Controlled Trial Evaluating Atorvastatin in Factorial With Omega-3 Fatty Acids Cardiovascular Risk Reduction in Patients With Type 2 Diabetes: Protocol ID: A2581114 Regulatory Authority Number: 16051/004/A **(United Kingdom)**	√			Pfizer	Pfizer	Both	18+	N/S	N/S	November-04	July-06	Adult	To determine the proportion of people with Type 2 Diabetes are likely to be treated satisfactorily with a fixed dose of a statin that lowers blood cholesterol levels to help reduce the risk of heart disease; to determine the extent that omega-3 fatty acids lower blood triglyceride levels when given with or without a statin; and to determine if there are simple techniques that can help people to take their tablets on a regular basis.

CLOSED STUDIES FOR DIABETES MELLITUS TYPE 2

Title	Completed	Not yet recruiting/ Not open	No longer recruiting	Investigator	Sponsor	Eligibility			Total Enroll	Start	End	Adult/Child	Objective
						Gender	Age	Race	n > 200				
A Double-Blind, Placebo-Controlled, Randomized, Multiple-Dose Study to Evaluate the Safety, Pharmacokinetics, and Pharmacodynamics of BMS-512148 in Diabetic Subjects	√			Bristol Myers Squibb	Bristol Myers Squibb	Both	18 to 70	N/S	Enrollment # not specified	April-05	N/S	Adult	To assess the safety of, exposure to, and biological effects of BMS-512148 in stable Type 2 diabetic subjects.
52-Week, Open, Randomized, Multinational, Multicenter Clinical Trial Comparing Insulin Glulisine in Combination With Insulin Glargine in an Intensified Insulin Regimen to a Two-Injection Conventional Insulin Regimen in Type 2 Diabetes Mellitus Patients With Poor Glycemic Control Pretreated With a Two-Injection Conventional Insulin Therapy **(Europe)**			√	Pilorget, Valérie	Sanofi-Aventis	Both	18 to 75	N/S	268	November-04	N/S	Adult	To demonstrate superior efficacy of an intensified insulin regimen with insulin glulisine and insulin glargine to a two-injection conventional insulin regimen in terms of change in glycated hemoglobin A1c (HbA1c), from baseline to endpoint.
Testing the Usefulness of Lantus When Initiated Prematurely In Patients With Type 2 Diabetes **(Europe)**			√	Pilorget, Valérie	Sanofi-Aventis	Both	40 to 75	N/S	390	April-03	N/S	Adult	To evaluate the efficacy of initiating Lantus in combination with oral antidiabetics drugs compared to oral antidiabetic treatment optimised by enhancing hygienic and dietary measures in type 2 diabetics whose blood glucose control is acceptable but not optimal on maximum oral treatment, based on the number of patients achieving a HbA1c value < 7% at the end of treatment.
Change in HbA1c With Biphasic Insulin Aspart 70/30 in Two Different Treatment Regiments in Subjects With Type 2 Diabetes Inadequately Controlled With Oral Anti-Diabetic Drug Therapy **(Asia)**			√	Hongyu, Qian	Novo Nordisk	Both	18 to 75	N/S	320	July-05	N/S	Adult	To investigate the effectiveness of using Biphasic Insulin Aspart 70/30 in two different treatment regiments for 6 months in subjects with type 2 diabetes, not well controlled on their current oral anti-diabetic drug therapy.
3 Year Efficacy and Safety Comparison of Adding Insulin Detemir, Biphasic Insulin Aspart 30 or Insulin Aspart to Oral Antidiabetic Drug Treatment in Type 2 Diabetes **(Europe)**			√	Teo, Eric	Novo Nordisk	Both	18+	N/S	700	November-04	N/S	Adult	To compare the efficacy (reduction in HbA1c and in blood glucose levels) of insulin detemir, insulin aspart and biphasic insulin aspart 30, when added to current OAD treatment in type 2 diabetes and to verify the safety of use (number and severity of episodes of hypoglycaemia, body weight and side effects).
Long-Term Effects of Insulin Plus Metformin Regimens on the Overall and Postprandial Glycemic Control of Patients With Type 2 Diabetes: A Comparison of Premeal Insulin Lispro Mixtures to Once-Daily Insulin Glargine **(International)**	√			Eli Lillly & Co	Eli Lilly & Co	Both	35 to 75	N/S	320	December-03	September-05	Adult	To show that a prandial insulin regimen, consisting of premeal insulin lispro "mid mixture" (or a combined regimen of insulin lispro "mid mixture" and insulin lispro "low mixture") plus metformin will result in significantly better overall glycemic control (lower HbA1c) at endpoint than once-daily insulin glargine plus metformin.
A Double-Blind, Randomized, Comparator-Controlled Study in Subjects With Type 2 Diabetes Mellitus Comparing the Effects of Pioglitazone HCl Versus Glimepiride on the Rate of Progression of Atherosclerotic Disease as Measured by Carotid Intima-Media Thickness	√			Takeda Global Research & Development Center, Inc.	Takeda Global Research & Development Center, Inc.	Both	45 to 85	N/S	462	August-03	October-06	Adult	To compare the effects of pioglitazone HCl versus glimepiride on the amount of thickening of the carotid artery, a large vessel in the neck.
A Phase 3, Randomized, Double-Blind, Placebo Controlled, Multicenter Trial to Evaluate the Safety and Efficacy of BMS-298585 as Monotherapy in Subjects With Type 2 Diabetes Who Have Inadequate Glycemic Control **(International)**	√			Bristol Myers Squibb	Bristol Myers Squibb	Both	18 to 70	N/S	341	June-03	N/S	Adult	To determine the effect on glycemic control and lipid parameters of the 2.5 and 5 mg. doses of BMS-298585 in drug naive subjects with Type 2 diabetes as an adjunct to diet and exercise.
Evaluation (Safety and Efficacy) of Treatment With Insulin Glargine and Glimepiride in Patients With Type 2 Diabetes Before, During and After the Period of Fasting in Ramadan	√			Sinnassamy, Patrick	Sanofi-Aventis	Both	35+	N/S	450	May-05	N/S	Adult	To compare the number of hypoglycaemic events (severe, symptomatic, asymptomatic, nocturnal) in patients with type 2 diabetes treated with insulin glargine (Lantus®) and glimepiride (Amaryl®), before, during and after the period of fasting in Ramadan.
A Clinical Trial to Study the Efficacy and Safety of Thrice Daily Insulin Aspart Compared to Glibenclamide in Type 2 Diabetes by Comparison of Ability to Control Blood Glucose **(Japan)**			√ **(Terminated)**	Kanai, Michiaki	Novo Nordisk	Both	20+	N/S	336	December-05	N/S	Adult	To study the efficacy and safety of thrice daily Insulin Aspart compared to Glibenclamide in type 2 diabetic patients.
Open Trial of the Safety and Efficacy of Lantus for Insulin Naive Type 2 Diabetes Mellitus Patients or Patients Who Use Insulin Combined With 1 or More Oral Antidiabetic Drugs and Don't Have Good Glycemic Control **(Turkey)**	√			Taylan, Edibe	Sanofi-Aventis	Both	18+	N/S	534	September-04	N/S	Adult	To confirm the efficacy and safety profile of Insulin glargine in daily practice and to improve the physicians' knowledge and experience concerning Insulin glargine.
Pilot Study on Glycaemic Variability in Type 2 Diabetes Mellitus Patients With Basal Insulin and Fixed Combo Oral Antidiabetic Treatment	√			Georges, Paizis	Sanofi-Aventis	Both	45+	N/S	Enrollment # not specified	April-05	N/S	Adult	To evaluate in explorative manner the fasting blood glucose (FBG) coefficient of variability (CV)calculated on SMBG values (SMBG : Self-Monitoring of Blood Glucose).

CLOSED STUDIES FOR DIABETES MELLITUS TYPE 2

Title	Completed	Not yet recruiting/ Not open	No longer recruiting	Investigator	Sponsor	Eligibility			Total Enroll	Start	End	Adult/Child	Objective
						Gender	Age	Race	n > 200				
Efficacy and Safety of Insulin Aspart in a Fixed or Flexible Supplementary Insulin Therapy Regimen, With or Without Insulin Detemir in Type 2 Diabetes **(Europe)**			√	Rendschmidt, Til	Novo Nordisk	Both	18+	N/S	320	September-05	N/S	Adult	To compare the efficacy and safety of Insulin Aspart, given in a fixed or in a flexible supplementary insulin therapy, with or without Insulin Detemir plus Metformin, if needed, in subjects with type 2 diabetes.
Effect of Biphasic Insulin Aspart 30 on Glycaemic Control in Subjects With Type 2 Diabetes **(Russian Federation)**	√			Starkova, Ninella	Novo Nordisk	Both	40 to 70	N/S	308	November-03	N/S	Adult	To compare the effect on glycemic control in subjects with type 2 diabetes of three different treatment regimens: biphasic insulin aspart 30 thrice daily, biphasic insulin aspart 30 twice daily in combination with metformin and treatment with oral anti-diabetic drugs.
Evaluation of Efficacy and Safety of HMR1964 Intensive Therapy in Subjects With Type 2 Diabetes Mellitus Not Optimally Controlled With Oral Hypoglycemic Agents (OHA); OHA Therapy Controlled, Open, Randomized, Parallel Group, Comparative (Superiority), 16-Week, Multinational, Multicenter Study **(Japan)**	√			Koyama, Masayoshi	Sanofi-Aventis	Both	20 to 75	N/S	390	December-03	N/S	Adult	To evaluate the superiority in the efficacy of HMR1964 and OHA combination therapy as compared with OHA therapy; to evaluate the superiority in the efficacy of HMR1964 mono-therapy as compared with OHA therapy; and to evaluate the safety of HMR1964.
Liraglutide Effect and Action in Diabetes (LEAD 3): Effect on Glycemic Control of Liraglutide Versus Glimepiride in Type 2 Diabetes **(US and Mexico)**			√	Hale, Paula	Novo Nordisk	Both	18 to 80	N/S	702	February-06	N/S	Adult	To evaluate the effects of treatment with liraglutide versus glimipiride in subjects with type 2 diabetes.
Efficacy And Safety Of Exubera (Inhaled Insulin) Therapy In Subjects With Type 2 Diabetes Mellitus Not Well Controlled With Combination Oral Agents: A Three-Month, Outpatient, Parallel Comparative Trial **(US and Canada)**	√			Pfizer	Pfizer	Both	35 to 80	N/S	345	June-99	September-00	Adult	To assess the impact on glucose control by inhaled insulin alone or added to two oral anti-diabetic agents in patients with type 2 diabetes who are not well controlled on 2 oral anti-diabetic agents.
Insulin Glargine [rDNA Origin] Injection vs Pioglitazone as Add-on Therapy in Patients Failing Monotherapy With Sulfonylurea or Metformin: a Randomized, Open, Parallel Study	√			Barch, Karen	Sanofi-Aventis	Both	18 to 79	N/S	352	December-01	October-06	Adult	To explore the various advantages and possible disadvantages of pioglitazone and insulin glargine when added to monotherapy.
A Six Month, Open-Label Outpatient, Randomized Parallel Group Trial Assessing The Impact Of Dry Powder Inhaled Insulin (Exubera) On Glycemic Control Compared To Insulin Glargine (Lantus) In Patients With Type 2 Diabetes Mellitus Who Are Poorly Controlled On A Combination Of Two Or More Oral Agents		√		Pfizer	Pfizer	Both	30+	N/S	478	December-06	N/S	Adult	To compare efficacy and safety of Exubera vs Lantus in patients with type 2 diabetes mellitus.
A 1-Year, Randomized, Double-Blind, Placebo-Controlled Phase 3 Study To Evaluate The Efficacy And Safety Of CP-945,598 In The Treatment Of Overweight, Oral Agent-Treated Subjects With Type 2 Diabetes Mellitus		√		Pfizer	Pfizer	Both	18 to 70	N/S	900	November-06	N/S	Adult	To determine if CP-945,598 is effective in the treatment of obesity in type 2 diabetic patients.
A Multicentre, Multinational, Randomised, Open Study to Establish the Optimal Method for Initiating and Maintaining Lantus® (Insulin Glargine) Therapy Based on a Comparison of Two Treatment Algorithms to Determine Optimal Metabolic Outcomes, Safety, and Satisfaction in Subjects With Type 2 Diabetes Mellitus	√			Sinnassamy, Patrick	Sanofi-Aventis	Both	18+	N/S	7,376	March-02	N/S	Adult	To determine the optimal treatment algorithm for the clinical use of insulin glargine based on the incidence of severe hypoglycaemia.
BEHAVIORAL/LS TREATMENT OF GLYCEMIA													
A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Fixed-Dose, Multicenter Study of Weight-Reducing Effect and Safety in Obese Patients With Type 2 Diabetes	√			Sanofi-Aventis	Sanofi-Aventis	Both	18 to 70	N/S	370	September-01	March-03	Adult	To assess the effect on weight loss and weight maintenance over a period of one year when prescribed with a hypocaloric diet in obese patients with Type 2 Diabetes.
PREVENTION OF TYPE 2 DIABETES													
Actos Now for Prevention of Diabetes (ACT NOW)			√	DeFronzo, Ralph	Texas Diabetes Institute	Both	18+	N/S	600	January-04	N/S	Adult	To examine whether pioglitazone versus placebo can reduce the conversion rate of impaired glucose tolerance (IGT) to type 2 diabetes mellitus.
PREVENTION /TREATMENT OF COMPLICATIONS													
A Multi-Center, Double Blind, Randomized, Parallel Group Study to Evaluate the Effects of Valsartan on Proteinuria in Hypertensive Subjects With Type 2 Diabetes Mellitus	√			Novartis	Novartis	Both	18+	N/S	369	N/S	N/S	Adult	To determine whether valsartan affects levels of proteinuria in patients with type 2 diabetes and hypertension.
CSP#465 - Glycemic Control and Complications in Diabetes Mellitus Type 2 (VADT) **(US and Puerto Rico)**			√	Dept of Veterans Affairs	Dept of Veterans Affairs	Both	N/S	N/S	1,700	May-00	November-07	Age not specified	To determine whether glycemic control, achieved through intensification of treatment, is effective in preventing clinical macrovascular complications in patients with type 2 DM who are no longer responsive to oral agents alone.

CLOSED STUDIES FOR DIABETES MELLITUS TYPE 2

Title	Completed	Not yet recruiting/ Not open	No longer recruiting	Investigator	Sponsor	Eligibility			Total Enroll	Start	End	Adult/Child	Objective
						Gender	Age	Race	n > 200				
Effect of Different Doses of Olmesartan Medoxomil Compared to Losartan on Proteinuria, Renal Function and Inflammatory Markers in Type 2 Diabetics With Nephropathy **(Europe)**	√			Haller, H	Sankyo Pharma Gmbh	Both	30+	N/S	300	May-03	August-05	Adult	To evaluate several olmesartan dosages compared to losartan on proteinuria, renal function and inflammatory markers in patients with diabetic nephropathy.
Effects of Candesartan Cilexetil (Candesartan) on Diabetic Retinopathy in Type 2 Diabetic Patients With Retinopathy			√	Astra Zeneca	Astra Zeneca	Both	37 to 75	N/S	1,700	August-01	N/S	Adult	To determine whether candesartan, compared to placebo reduces the progression of diabetic retinopathy in normoalbuminuric type 2 diabetic patients with retinopathy.
A Randomized, Double-Blind, Multicenter Study Comparing the Effects of Carvedilol and Metoprolol on Glycemic Control in Hypertensive Patients With Type II Diabetes Mellitus			√	GlaxoSmithKline	GlaxoSmithKline	Both	30 to 80	N/S	1,210	May-01			To evaluate the effect of two different antihypertensive treatments on control of glucose in Type II diabetic patients with high blood pressure.
RAS Rosiglitazone and Atherosclerosis Study: A 1 Year Randomised, Double-Blind, Parallel Group, Placebo Controlled Study to Evaluate the Efficacy of Rosiglitazone on the Progression of Intima-Media Thickness in the Carotid Artery in Subjects With Insulin Resistance Syndrome and/or Type 2 Diabetes Mellitus **(Sweden)**	√			GlaxoSmithKline	GlaxoSmithKline	Both	35 to 80	N/S	556	May-02	N/S	Adult	To investigate the effect of rosiglitazone and placebo on carotid intima media thickness in patients with insulin resistance syndrome and/or type 2 diabetes.
A Multicenter, Randomized, Prospective, Double-Blind Study to Evaluate the Nephroprotective Effect of Delapril Alone or Combined With Manidipine in Patients With Type 2 Diabetes **(Italy and Slovenia)**	√			Ruggenenti, Piero	Mario Negri Institute for Pharmacological Research	Both	40 to 75	N/S	342	February-02	October-08	Adult	To compare the effect of 3 years treatment with the ACEi Delapril (30 mg/day), alone or combined to the CCB Manidipine (10 mg/day), versus conventional (non ACEi, non CCB) therapy on the rate of renal function loss and on the incidence of major cardiovascular events in 342 normo- and micro-albuminuric hypertensive type 2 diabetic patients.
PROspective PioglitAzone Clinical Trial In MacroVascular Events (PROactive)A Macrovascular Outcome Study in Type 2 Diabetic Patients Comparing Pioglitazone With Placebo in Addition to Existing Therapy **(European)**	√			Dormandy, John	Takeda Global Research & Development Center, Inc.	Both	35 to 75	N/S	5,000	May-01	December-05	Adult	To see whether pioglitazone, in addition to its normal role of reducing blood sugar, can delay the time to death, heart attack, acute coronary syndrome, heart bypass surgery, stroke, leg bypass surgery or amputation in patients with type 2 diabetes.
Hyperglycemia and Its Effect After Acute Myocardial Infarction on Cardiovascular Outcomes in Patients With Type 2 Diabetes (HEART2D) **(Europe)**			√	Eli Lillly & Co	Eli Lilly & Co	Both	30+	N/S	1,355	October-02	February-07	Adult	To study patients with type 2 diabetes who have recently had an acute myocardial infarction who receive either premeal insulin lispro and, if necessary, NPH insulin at bedtime or basal insulin or pre-mixed intermediate-acting insulin.
The Irbesartan in Patients With Type 2 Diabetes and Microalbuminuria (IRMA 2)	√			Parving, Hans-Henrik	Steno Diabetes Center	Both	30 to 70	N/S	590	N/S	N/S	Adult	To investigate the renoprotective effect of irbesartan treatment in patients with type 2 diabetes and microalbuminuria (a precursor of diabetic kidney disease).
A Multicenter, Randomized, Double-Blind, Parallel Group, 6-Week Study to Evaluate the Efficacy and Safety of Ezetimibe/Simvastatin Combination Tablet Versus Atorvastatin in Patients With Type 2 Diabetes Mellitus (T2DM) and Hypercholesterolemia			√	Merck	Merck	Both	18 to 79	N/S	1,125	June-05	N/S	Adult	To compare the reduction in cholesterol following treatment with two different marketed drugs, in patients with type 2 diabetes mellitus and hypercholesterolemia.
CSP #465-B - Correlation of Plasma Endothelial Cell (Basic Fibroblast Growth Factor) Activity with Cardiovascular Events in Patients with Diabetes Mellitus Type 2			√	Zimering, Mark	Dept of Veteran Affairs	Both	N/S	N/S	400		November-07	Age not specified	To investigate whether an angiogenic growth factor, basic fibroblast growth factor (bFGF), plays a role in increased CV risk in type 2 diabetes mellitus.
CSP #465-A - Non-Traditional Cardiovascular Risk Factors and Atherosclerosis in Type 2 Diabetes			√	Dept of Veterans Affairs	Dept of Veterans Affairs	Both	N/S	N/S	317	N/S	November-07	Age not specified	MYOCARDIAL INFARCTION: Myocardial infarctions will be determined based on the algorithm supplied at the end of this appendix. All suspected MI will be evaluated in detail by the Endpoints Committee. All supporting documentation, i.e., ECGs, hospital records, laboratory values, etc. needed to confirm or rule out the presence or absence of an MI will be obtained by personnel at the ECG Laboratory. CONGESTIVE HEART FAILURE: Diagnosis of new congestive heart failure (CHF) can be made in the presence of at least two minor manifestations or new onset of pulmonary congestion requiring treatment. Treatment with diuretic, digitalis glycoside, ACE inhibitor, or hospitalization for management of symptoms of CHF would be appropriate

CLOSED STUDIES FOR DIABETES MELLITUS TYPE 2

Title	Completed	Not yet recruiting/ Not open	No longer recruiting	Investigator	Sponsor	Eligibility			Total Enroll	Start	End	Adult/Child	Objective
						Gender	Age	Race	n > 200				
CSP #465C - Fatty Acid Binding Protein 2 (FABP2) Ancillary Proposal **(US and Puerto Rico)**			√	Georgopoulos, Angeliki	Dept of Veterans Affairs	Both	N/S	N/S	874	N/S	November-07	Age not specified	To screen the participants of the CSP# 465 study for the polymorphism and assess a) whether those carrying the polymorphism respond differently to the various treatment modalities and b) whether they develop more cardiovascular events compared to the ones lacking the polymorphism.
CSP #465-D - Markers and Mechanisms of Vascular Disease in Type II Diabetes **(US and Puerto Rico)**			√	Dept of Veterans Affairs	Dept of Veterans Affairs	Both	N/S	N/S	298	N/S	November-07	Age not specified	The unifying theme for the Program Project is that hyperglycemia and insulin resistance alter a number of biological processes which interact in vicious cycles to accelerate atherogenesis and are consequently major underlying risk factors for vascular disease. The overall objectives are to define these unique processes and to elucidate underlying biochemical, metabolic, and genetic determinants of vascular disease complications in diabetes.
Diabetes and Combined Lipid Therapy Regimen (DIACOR) Study: A Randomized, Double-Blind Study of Simvastatin, Fenofibrate, and Combined Fenofibrate and Simvastatin in Patients With Controlled Type II Diabetics Without Evidence of Coronary Disease			√	Muhlestein, Joseph	Intermountain Health Care, Inc.	Both	18+	N/S	300	August-02	December-06	Adult	To determine whether there is a greater percentage of patients achieving a triglyceride level of <200 mg/dL with the combination of simvastatin 20 mg and fenofibrate 160 mg than with either simvastatin 20 mg monotherapy or fenofibrate 160 mg monotherapy.
Japanese Primary Prevention of Atherosclerosis With Aspirin for Diabetes (JPAD) Trial **(Japan)**			√	Ogawa, Hisao Saito, Yoshihiko	Kumamoto University	Both	30 to 85	N/S	2,450	December-02	December-08	Adult	To determine the effects of low-dose aspirin for the primary prevention of vascular events in patients with type 2 diabetes in Japan.
Long-Term Study of Nateglinide+Valsartan to Delay Type II Diabetes Mellitus in People Who Do Not Have It **(Germany)**			√	Novartis	Novartis	Both	50 to 75	N/S	9,150	January-02	January-08	Adult	To test the safety and effectiveness of two drugs, one for diabetes and one for hypertension, in keeping high normal patients from progressing to illness.
A Multi-Center, Double-Blind, Randomized Study Comparing the Efficacy of Combination Therapy of Eprosartan Respectively Ramipril With Low-Dose Hydrochlorothiazide and Moxonidine on Blood Pressure Levels in Patients With Hypertension and Associated Diabetes Mellitus Type 2 **(Europe)**			√	Solvay Pharmaceuticals	Solvay Pharmaceuticals	Both	40 to 80	N/S	440	October-04	N/S	Adult	To demonstrate the superiority of combination of eprosartan/HCTZ versus ramipril/HCTZ.
A Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Renal Protective Effects of Losartan in Patients With Non-Insulin Dependent Diabetes Mellitus and Nephropathy	√			Merck	Merck	Both	31 to 70	N/S	1,513	June-96	N/S	Adult	To evaluate the effect of Losartan in reducing kidney disease in patients with Non-insulin Dependent Diabetes and Nephropathy (kidney damage that usually accompanies late stage Diabetes Mellitus).
Action to Control Cardiovascular Risk in Diabetes (ACCORD) **(US and Canada)**			√	NHLBI	NHLBI	Both	40 to 79	N/S	10,000	September-99	N/S	Adult	To prevent major cardiovascular events (heart attack, stroke, or cardiovascular death) in adults with type 2 diabetes mellitus using intensive glycemic control, intensive blood pressure control, and intensive lipid management.
Bypass Angioplasty Revascularization Investigation in Type 2 Diabetics (BARI 2D)			√	Chaitman, Bernard	NHLBI	Both	25+	N/S	2,800	September-00	June-07	Adult	The primary aim of the BARI 2D trial is to test the following two hypotheses of treatment efficacy in 2800 patients with Type 2 diabetes mellitus and documented stable CAD, in the setting of uniform glycemic control and intensive management of all other risk factors including dyslipidemia, hypertension, smoking, and obesity: Coronary Revascularization Hypothesis: a strategy of initial elective revascularization of choice (surgical or catheter-based) combined with aggressive medical therapy results in lower 5-year mortality compared to a strategy of aggressive medical therapy alone; Method of Glycemic Control Hypothesis: with a target HbA1c level of <7.0%, a strategy of hyperglycemia management directed at insulin sensitization results in lower 5-year mortality compared to a strategy of insulin provision.

CLOSED STUDIES FOR DIABETES MELLITUS TYPE 2

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Chronic Diabetic Painful Neuropathy and Cardiovascular Risk Factors in NIDDM: An Alternative Approach	√			Stevens, Martin	National Center for Complementary and Alternative Medicine	Both	20 to 80	N/S	Enrollment # not specified	September-98	June-04	Age not specified	To determine if Reiki will improve glycemic control and cardiac autonomic function diabetic patients with painful neuropathy.
A Multicenter, International Randomized, 2x2 Factorial Design Study to Evaluate the Effects of Lantus (Insulin Glargine) Versus Standard Care, and of Omega-3 Fatty Acids Versus Placebo, in Reducing Cardiovascular Morbidity and Mortality in High Risk People With Impaired Fasting Glucose (IFG), Impaired Glucose Tolerance (IGT) or Early Type 2 Diabetes Mellitus: The ORIGIN Trial (Outcome Reduction With Initial Glargine Intervention) **(Canada)**			√	Johnston, Peter	Sanofi-Aventis	Both	50+	N/S	12,500	September-03	October-09	Adult	To determine whether insulin glargine-mediated normoglycemia can reduce cardiovascular morbidity and/or mortality in people at high risk for vascular disease with either IFG, IGT or early type 2 diabetes; To determine whether omega-3 fatty acids can reduce cardiovascular mortality in people with IFG, IGT or early type 2 diabetes.
A Randomized, Controlled Study on Calcium Channel Blocker Versus Angiotensin II Antagonists in the Hypertensive Patients With Type 2 Diabetes Mellitus Under the Inadequately Controlled Blood Pressure With Angiotension II Antagonists **(Japan)**			√	Kawamori, Ryuzo	Advanced-J	Both	20+	N/S	300	September-04	March-09	Adult	The antihypertensive effect of the increased dose of angiotensin II receptor blocker (AII antagonist) is compared with that of the additional combined use of amlodipine in hypertensive patients with Type 2 diabetes mellitus, who have been treated with AII antagonist, the antihypertensive effect of which has been inadequate.
ADVANCE - Action in Diabetes and Vascular Disease: Preterax and Diamicron - MR Controlled Evaluation **(International)**			√	Chalmers, John MacMahon, Stephen	The George Institute	Both	55+	N/S	10,000	June-01	June-08	Adult	To provide information on the risks and benefits of routine blood pressure lowering (regardless of blood pressure level), and intensive lowering of blood glucose levels, in patients with Type 2 diabetes at high risk of cardiovascular events.
Cardiolite-406; A Phase IV Open-Label, Randomized, Multi-Center Trial To Evaluate The Ability of Cardiolite Stress MPI to Detect Asymptomatic Restenosis in Diabetic Patients Who Have Undergone Percutaneous Coronary Intervention **(US and Puerto Rico)**			√	Rosenberg, Martin	Bristol Myers Squibb	Both	21+	N/S	400	April-04	N/S	Adult	To determine if patients with diabetes that have undergone previous opening of a heart blockage may have a blockage that is not causing any symptoms that may be detected by imaging with Cardiolite.
Evaluation of Diabetic Retinopathy Progression in Subjects With Type 2 Diabetes Mellitus Treated With Insulin			√	Johnston, Peter	Sanofi-Aventis	Both	30 to 70	N/S	840	June-01	N/S	Adult	To compare the progression of diabetic retinopathy in type 2 diabetic patients with mild-to-moderate diabetic retinopathy treated with insulin glargine vs NPH human insulin.
Prospective, Randomized, Open-Label, Blinded Endpoint, Forced Titration Study to Compare Telmisartan Combined With HCTZ (80mg/12.5mg), to Valsartan Combined With HCTZ (160mg/12.5mg), for the Control of Mild-to-Moderate Hypertension in Obese Patients With Type 2 Diabetes Mellitus Using ABPM **(International)**	√			Boehringer Ingelheim Pharmaceuticals	Boehringer Ingelheim Pharmaceuticals	Both	30+	N/S	846	January-03	September-05	Adult	To demonstrate that, when combined with hydrochlorothiazide (12.5 mg), telmisartan (80 mg) is at least as effective and possibly superior to valsartan (160 mg) in lowering systolic and diastolic BP during the last 6 hours of the 24-hour dosing interval (i.e., the critical morning period) following a 10-week treatment period in hypertensive, overweight/obese Type-2 diabetics.
A Randomised ,Double-Blind ,Parallel-Group Comparison of the Renal and Antihypertensive Effects of Telmisartan and Enalapril in Subjects With Mild to Moderate Hypertension and Concurrent Type II Diabetes Mellitus and Diabetic Nephropathy **(Europe)**	√			Boehringer Ingelheim Pharmaceuticals	Boehringer Ingelheim Pharmaceuticals	Both	35 to 80	N/S	272	July-97	November-04	Adult	To compare the renal consequences of two different approaches to blocking the renin angiotensin system in subjects with hypertension and concurrent Type II diabetes mellitus and diabetic nephropathy.
CS-866DM Phase 3 Clinical Study: A Double-Blind Controlled Trial in Patients With Diabetic Nephropathy and Overt Proteinuria Secondary to Type 2 Diabetes Mellitus **(China and Japan)**			√	Makino, Hirofumi	Sankyo Co. Ltd.	Both	30 to 70	N/S	400	April-03	N/S	Adult	To evaluate the effectiveness and safety of olmesartan versus placebo on the progression of diabetic renal disease.
An Open Label, Multi-Centre, Single Arm Phase IV Study to Evaluate the Antihypertensive Effect of Lacidipine in Mild to Moderate Essential Hypertension Patients With Type 2 Diabetes in Korea **(Korea)**			√	GlaxoSmithKline	GlaxoSmithKline	Both	35 to 75	Korean	257	April-05	N/S	Adult	To evaluate the anti-hypertensive efficacy of lacidipine in hypertensives with Type 2 diabetes and effectiveness on endothelial cell function in Korean population.
Effects of Amlodipine/Benazepril on Albuminuria in Hypertensive Patients With Type 2 Diabetes Mellitus			√	Novartis	Novartis	Both	21 to 85	N/S	888	April-03	N/S	Adult	To evaluate the effects of amlodipine/benazepril in reducing blood pressure and urinary protein in hypertensive subjects with type 2 diabetes mellitus.
A Randomized, Double-Blind Trial Assessing the Efficacy and Safety of Low and Standard Doses of Fenofibrate in Combination With Metformin on the Lipid Profile in Patients With Type 2 Diabetes and Dyslipidemia	√			Gottlieb, Isabelle	Fournier Laboratories Ireland Ltd	Both	20 to 80	N/S	382	January-04	N/S	Adult	To assess the effect of 3-month treatment of low and standard doses of fenofibrate in combination with stable dose of metformin on fasting triglycerides levels in patients with type 2 diabetes and dyslipidemia.

CLOSED STUDIES FOR DIABETES MELLITUS TYPE 2

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A 24-Week Study to Assess Blood Pressure Independent Effects of Valsartan Treatment, Benazepril Treatment and Combination of Both Valsartan and Benazepril Treatment on Urinary Albumin Excretion Rate With Type II Diabetes Mellitus and Microalbuminuria **(Switzerland)**			√	Novartis	Novartis	Both	35 to 75	N/S	240	January-05	N/S	Adult	To evaluate the efficacy of valsartan, benazepril or the combination of both in reduction of microalbuminuria in Type 2 diabetic patients.