OPEN STUDIES FOR DIABETES MELIITUS TYPE 2

Title	Type	Investigator	Sponsor	Eligibility			Total Enroll	Start	End	Adult/Child	Objective
				Gender	Age	Race	n > 200				
DRUG TREATMENT OF GLYCEMIA											
A Randomized, Parallel Group, Double-Blind, Multi-Center Study Comparing the Efficacy and Safety of AVANDAMET and Metformin After 80 Weeks of Treatment **(International)**	2	GlaxoSmithKline	GlaxoSmithKline	Both	18 to 75	N/S	588	October-06	N/S	Adult	To evaluate the longer-term glycemic effect of two medicines approved for initial treatment of type 2 diabetes.
A Double Blind, Randomized, Placebo-Controlled, Parallel Study to Evaluate the Efficacy and Safety of Androgel, as an Adjunct to Hypoglycemic Therapy, in the Treatment of Hypogonadal and Low Testosterone Men With Type 2 Diabetes	2	Batchelor, Alicia	Solvay Pharmaceuticals	Male	30 to 80	N/S	Enrollment # not specified	October-04	N/S	Adult	To investigate how well Androgel, when tested against placebo gel, helps to control blood sugar levels in males with type 2 diabetes who have low testosterone (the main male hormone) blood levels and are taking oral diabetic medicines alone or in combination with insulin.
A 13-Week Multinational, Randomized, Double-Blind, Placebo-Controlled, Dose-Response Trial Assessing the Safety, Tolerability and Efficacy of AVE0010 in Metformin-Treated Subjects With Type 2 Diabetes Mellitus **(International)**	2	Sanofi-Aventis	Sanofi-Aventis	Both	30 to 75	N/S	500	February-06	March-07	Adult	To evaluate the dose-response relationship of AVE0010 administered once daily and twice daily with chronic dosing in metformin-treated subjects with type 2 diabetes.
The Effect of Salsalate Treatment on Insulin Sensitivity and Insulin Secretion in Obese Non-Diabetic Individuals	2	Bogardus, Clifton	NIDDK	Both	18 to 45	N/S	426	March-03	N/S	Adult	To determine whether reducing subclinical inflammation lessens insulin resistance in healthy, obese volunteers.
Phase 2/3, Randomized, Double-Blind, Placebo- and Active Comparator-Controlled, Parallel, Multicenter Study to Determine Safety and Efficacy of Metaglidasen in Treatment of Type 2 Diabetes Suboptimally Controlled on Insulin	2	Soldano-Noble, Catherine	Metabolex	Both	18 to 75	N/S	400	May-06	N/S	Adult	This is a multicenter, randomized, double-blind, placebo- and active comparator-controlled phase 2/3 study of three dose levels of MBX-102 (200, 400, 600 mg) given orally to patients with type 2 diabetes receiving concomitant therapy with insulin.
A Phase 3, Double-Blind, Randomized, Placebo-Controlled Study to Determine the Efficacy, Safety, and Tolerability of AD-4833-536 in the Treatment of Subjects With Type 2 Diabetes and Hypertension **(International)**	2	Rossi, Carlos	Takeda Global Research & Development Center, Inc.	Both	18+	N/S	780	June-06	August-08	Adult	To evaluate the safety, efficacy and tolerability of AD-4833-536 in subjects with type 2 diabetes and hypertension.
A Randomised Trial of the Cost Effectiveness of Screening and Intensive Multi-Factorial Intervention for Type 2 Diabetes **(Europe)**	2	Davies, Melanie	University Hospitals, Leicester	Both	25 to 75	White European 40-75 yrs; Asian, Black, or Chinese 25-75 yrs	14,500	August-04	October-11	Adult	To test whether screening for diabetes is feasible in a South Asian population and to measure the benefits of early detection and intensive treatment.
Evaluation of the Effects of Oral Anti-Hyperglycemic Agents, Multiple Daily Injections or Continuous Subcutaneous Insulin Infusion on Glycemic Control, B-Cell Function and the Remission Rate in Newly-Diagnosed Type 2 Diabetic Patients **(China)**	2	Li, Yanbing	Sun Yat-sen University	Both	25 to 70	N/S	441	September-04	December-06	Adult	To investigate and evaluate the effects of different interventions (oral anti-hyperglycemic agents, multiple daily injections and continuous subcutaneous insulin infusion) on glycemic control, B-cell function and the remission rate in newly-diagnosed type 2 diabetic patients.
A Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Dose-Response, Multicentre, Multinational Study Evaluating the Efficacy and Safety of AVE2268 Administered Either Twice Daily (Breakfast and Lunch) at a Dose of 300, 600 and 1200 mg or Once Daily (Breakfast) at a Dose of 1200 mg, in Patients With Type 2 Diabetes Treated With Metformin and Not Adequately Controlled **(Europe)**	2	Souhami, Elisabeth	Sanofi-Aventis	Both	18 to 74	N/S	300	July-06	N/S	Adult	To assess the effects of several doses of AVE2268 on Mean Plasma Glucose.
Clinical Evaluation of Rosiglitazone Malate (BRL49653C) in Patients With Type 2 Diabetes Mellitus (Monotherapy) - Double-Blind Comparative Study of Rosiglitazone Maleate vs. Pioglitazone Hydrochloride and Placebo **(Japan)**	2	GlaxoSmithKline	GlaxoSmithKline	Both	20 to 75	N/S	350	December-05	N/S	Adult	To compare the efficacy and safety of BRL49653C versus pioglitazone and placebo.
A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Determine the Efficacy and Safety of SYR-322 When Used in Combination With Insulin in Subjects With Type 2 Diabetes **(International)**	2	Takeda Global Research & Development Center, Inc.	Takeda Global Research & Development Center, Inc	Both	18 to 80	N/S	300	January-06	N/S	Adult	To evaluate the efficacy and safety of SYR-322 in combination with placebo or insulin in subjects with type 2 diabetes mellitus and inadequate glycemic control using insulin alone (with or without metformin).
A Multi-Center, Open Label, Extension Study to Evaluate the Long-Term Safety and Tolerability of GK Activator (2) in Type 2 Diabetic Patients From Studies BM18248 or BM18249 **(International)**	2	Hoffman-LaRoche	Hoffman-LaRoche	Both	30 to 75 Years	N/S	100-500	March-06	N/S	Adult	To evaluate the long-term safety and tolerability of GK Activator (2) at doses ranging from 25mg - 100mg po bid, administered alone or in combination with metformin, in patients with type 2 diabetes.

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Title	Type	Investigator	Sponsor	Eligibility			Total Enroll	Start	End	Adult/Child	Objective
				Gender	Age	Race	n > 200				
Liraglutide Effect and Action in Diabetes (LEAD-2): Effect on Glycaemic Control After Once Daily Administration of Liraglutide in Combination With Metformin Versus Metformin Monotherapy Versus Metformin and Glimepiride Combination Therapy in Subjects With Type 2 Diabetes **(Europe)**	2	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 adding to existing metformin therapy and to compare it with the effects of metformin monotherapy and combination therapy of metformin and glimepiride. Conducted in Europe, Oceania, Africa, Asia and South America.
Effect on Glycemic Control of Liraglutide in Combination With Rosiglitazone Plus Metformin Versus Rosiglitazone Plus Metformin in Subjects With Type 2 Diabetes.	2	Novo Nordisk	Novo Nordisk	Both	18 to 80	N/S	492	May-06	N/S	Adult	To show the effect of treatment with liraglutide when added to existing rosiglitazone and metformin combination therapy and to compare it with the effects of therapy with rosiglitazone and metformin alone.
A Phase 3, Open-Label, Three-Group Parallel Study to Evaluate the Efficacy and Safety of Human Insulin Inhalation Powder (HIIP) in Patients With Type 2 Diabetes Treated With Once-Daily Insulin Glargine	2	Eli Lilly	Eli Lilly	Both	18+	N/S	510	August-06	January-08	Adult	To evaluate the efficacy and safety of Human Insulin Inhalation Powder [also known as AIR® Inhaled Insulin][AIR® is a registered trademark of Alkermes,Inc.] in patients with Type 2 diabetes who are currently being treated with once daily insulin glargine injections.
Safety and Efficacy of Exenatide Taken Before Lunch and Before Dinner Compared With Before Breakfast and Before Dinner in Patients With Type 2 Diabetes Using Oral Antidiabetic Therapy **(Europe)**	2	Lilly Clinical Trials Support Center	Amylin Pharmaceuticals	Both	18 to 75	N/S	400	September-06	N/S	Adult	To compare the effects of twice-daily (before lunch and before dinner) exenatide plus oral antidiabetic (OAD) agents and twice-daily (before breakfast and before dinner) exenatide plus OAD with respect to glycemic control (HbA1c) in patients with type 2 diabetes
An Open Label Study Comparing Exenatide With Basal Insulin in Achieving an HbA1c of ≤ 7.4% With Minimum Weight Gain, in Type 2 Diabetes Patients Who Are Not Achieving Adequate HbA1c Control on Oral Anti Diabetic Therapies Alone **(United Kingdom)**	2	Lilly Clinical Trials Support Center	Amylin Pharmaceuticals	Both	30 to 74	N/S	234	June-06	N/S	Adult	To compare the effects of twice daily exenatide plus oral antidiabetic agents (OADs) and once-daily insulin glargine plus OADs with respect to glycemic control, as measured by hemoglobin A1c, with minimum weight gain, in patients with uncontrolled type 2 diabetes on OADs.
Comparison of Two Approaches to Basal-Bolus Insulin Therapy in Patients With Type 2 Diabetes and Inadequate Glycemic Control on Oral Therapy: Comparison of Premixed Insulin Lispro Mid Mixture With Separate Basal and Bolus Insulin Injections **(Europe)**	2	Eli Lilly	Eli Lilly	Both	30 to 80	N/S	502	August-06	April-08	Adult	To study patients with type 2 diabetes who are not controlled on two or more oral antihyperglycemic agents comparing adding insulin lispro mid mixture to the oral antihyperglycemic agents to adding insulin glargine to the oral antihyperglycemic agents.
Effect of Insulin Detemir on Blood Glucose Control in Subjects With Type 2 Diabetes **(China)**	2	Lijun, Han	Novo Nordisk	Both	18+	N/S	250	September-06	N/S	Adult	To compare the effect on glycemic control in subjects with type 2 diabetes of insulin detemir or NPH-insulin given once daily at bedtime as add-on to oral anti-diabetic drug(s).
A Randomized, Double-Blind Study to Investigate the Effect of R1439 on Glycemic Control in Patients With Type 2 Diabetes Mellitus **(International Trial)**	2	Hoffman-LaRoche	Hoffman-LaRoche	Both	18 to 75	N/S	100-500	N/S	N/S	Adult	To assess the efficacy, safety, tolerability and pharmacokinetics of R1439 therapy in patients with Type 2 diabetes
Avandia™ + Amaryl™ or Avandamet™ Compared With Metformin (AVALANCHE™ Study)**(Canada)**	2	Josse, Robert	Canadian Heart Research Centre	Both	18 to 75	N/S	381	September-05	N/S	Adult	To demonstrate that the either combination arm of rosiglitazone plus metformin (AvandametTM) or the other combination arm of AvandiaTM + AmarylTM will provide greater glycemic control while avoiding the side-effects associated with the use of maximal dose metformin.
The Role of Acute Combined Peroxisome Proliferator-Activated Receptors (PPAR) Alpha and Gamma Stimulation on Insulin Action in Humans	2	Stangarone, Angela	Albert Einstein College of Medicine	Both	18 to 65	N/S	Enrollment # not specified	N/S	N/S	Adult	To study natural oils as potential therapies for type 2 diabetes.
A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Determine the Efficacy and Safety of SYR-322 When Used in Combination With Metformin in Subjects With Type 2 Diabetes **(International Trial)**	2	Takeda Global Research & Development Center, Inc.	Takeda Global Research & Development Center, Inc.	Both	18 to 80	N/S	500	January-06	N/S	Adult	To evaluate the efficacy and safety of SYR-322 in combination with placebo or metformin in subjects with type 2 diabetes mellitus and inadequate glycemic control using metformin alone.
A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Determine the Efficacy and Safety of SYR-322 Compared With Placebo in Subjects With Type 2 Diabetes **(International Trial)**	2	Takeda Global Research & Development Center, Inc.	Takeda Global Research & Development Center, Inc.	Both	18 to 80	N/S	325	January-06	N/S	Adult	To evaluate the efficacy and safety of SYR-322 in combination with placebo in subjects with type 2 diabetes mellitus and inadequate glycemic control.
A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Determine the Efficacy and Safety of SYR-322 When Used in Combination With a Sulfonylurea in Subjects With Type 2 Diabetes **(International Trial)**	2	Takeda Global Research & Development Center, Inc.	Takeda Global Research and Development Center, Inc.	Both	18 to 80	N/S	500	January-06	N/S	Adult	To evaluate the efficacy and safety of SYR-322 in combination with placebo or sulfonylurea in subjects with type 2 diabetes mellitus and inadequate glycemic control using sulfonylurea alone.

OPEN STUDIES FOR DIABETES MELIITUS TYPE 2

Title	Type	Investigator	Sponsor	Eligibility			Total Enroll	Start	End	Adult/Child	Objective
				Gender	Age	Race	n > 200				
A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Determine the Efficacy and Safety of SYR-322 When Used in Combination With Pioglitazone in Subjects With Type 2 Diabetes **(International Trial)**	2	Takeda Global Research & Development Center, Inc.	Takeda Global Research and Development Center, Inc.	Both	18 to 80	N/S	500	January-06	N/S	Adult	To evaluate the efficacy and safety of SYR-322 in combination with placebo or pioglitazone (with or without metformin or a sulfonylurea) in subjects with type 2 diabetes mellitus and inadequate glycemic control using pioglitazone alone (with or without metformin or a sulfonylurea).
A Long-Term, Open-Label Extension Study to Investigate the Long-Term Safety of SYR110322 (SYR-322) in Subjects With Type 2 Diabetes **(International Trial)**	2	Takeda Global Research & Development Center, Inc.	Takeda Global Research and Development Center, Inc.	Both	18 to 80	N/S	1,300	March-06	N/S	Adult	To evaluate the safety of SYR-322 administered alone or in combination with a sulfonylurea, metformin, a thiazolidinedione, or insulin by evaluating AEs, clinical laboratory parameters, electrocardiogram (ECG) readings, vital sign measurements, oral temperature, physical examinations, and hypoglycemic events.
A Randomized, Open-Label, Multicenter, Comparator-Controlled Study to Examine the Effects of Exenatide Long-Acting Release on Glucose Control (HbA1c) and Safety in Subjects With Type 2 Diabetes Mellitus Managed With Diet Modification and Exercise and/or Oral Antidiabetic Medications **(USA and Canada)**	2	Amylin Pharmaceuticals	Amylin Pharmaceuticals	Both	16+	N/S	300	March-06	N/S	Young Adult to Adult	To examine the effects of Exenatide Long Acting Release (LAR) on glucose control and safety in subjects with type 2 diabetes mellitus managed with diet modification and exercise and/or oral antidiabetic medications.
Safety and Efficacy of Biphasic Insulin Aspart 70/30 (NovoLogÂ® Mix 70/30) vs. Exenatide (ByettaTM) in Subjects With Type 2 Diabetes Mellitus Not Achieving Glycemic Targets on Metformin and a Sulfonylurea.	2	Braceras, Rogelio	Novo Nordisk	Both	18 to 80	N/S	540	March-06	N/S	Adult	To compare A1C reduction achieved in patients receiving biphasic insulin aspart 70/30 once or twice daily to patients receiving exenatide twice daily.
Safety and Efficacy of Exenatide in Patients With Type 2 Diabetes Using Metformin or Sulfonylureas and Metformin **(Europe)**	2	Malone, James	Amylin Pharmaceuticals	Both	21 to 75	N/S	480	January-06	N/S	Adult	To compare the effects of twice-daily exenatide plus oral antidiabetic (OAD) agents and twice-daily placebo plus OAD with respect to glycemic control.
A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Determine the Efficacy and Safety of the Combination of SYR-322 and Pioglitazone HCl (ACTOS) in Subjects With Type 2 Diabetes **(International)**	2	Vandernoot, Nancy	Takeda Global Research and Development Center, Inc.	Both	18 to 80	N/S	1,440	April-06	N/S	Adult	To evaluate the effect of the combination of SYR-322 with pioglitazone HCl as compared with pioglitazone HCl alone in subjects with type 2 diabetes mellitus who have experienced inadequate glycemic control using metformin alone.
A Phase 3, Open-Label, Parallel Group Treatment Concordance Study to Compare Insulin Use and Its Effect on Glycemic Control in Patients With Type 2 Diabetes Mellitus: Two Populations With Different Insulin Treatment Options **(International)**	2	Eli Lilly	Eli Lilly	Both	18+	N/S	1,000	June-06	December-08	Adult	To compare insulin use and its effect on glucose control and other outcomes in patients with Type 2 diabetes who together with their healthcare provider manage their disease by discussing and agreeing on the diabetes treatment chosen from a selection of available treatment options.
Double-Blind Trial of Miglitol in Type 2 Diabetic Patients Treated With Biguanide **(Japan)**	2	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 evaluate the clinical efficacy and safety of Miglitol in patients with Type 2 Diabetes Mellitus treated with Biguanide.
Open Trial of Miglitol in Type 2 Diabetic Patients Treated With Biguanide **(Japan)**	2	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 evaluate the clinical efficacy and safety of Miglitol in patients with Type 2 Diabetes Mellitus treated with Biguanide.
A Phase III Randomized, Placebo-Controlled Clinical Trial to Study the Safety and Efficacy of the Addition of Sitagliptin (MK0431) in Patients With Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control on Combination Therapy With Metformin and a PPARg Agonist **(International)**	2	Merck	Merck	Both	18 to 78	N/S	Enrollment # not specified	June-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 metformin/PPARg agonist combination therapy.
Long Term Treatment With Exenatide Versus Glimepiride in Patients With Type 2 Diabetes Pretreated With Metformin (EUREXA: **European Exenatide Study**)	2	Amylin Pharmaceuticals	Amylin Pharmaceuticals	Both	18 to 85	N/S	1,054	September-06	N/S	Adult	To assess the effects of twice-daily subcutaneous injection exenatide versus treatment with sulfonylurea (glimepiride) on long-term glycemic control and beta-cell function.
Safety and Efficacy of Exenatide as Monotherapy in Drug Naive Patients With Type 2 Diabetes **(International)**	2	Lilly Clinical Trials Support Center	Amylin Pharmaceuticals	Both	18+	N/S	258	September-06	N/S	Adult	To compare the effects of twice-daily exenatide and twice-daily placebo with respect to glycemic control in drug-naive patients with type 2 diabetes treated with diet and exercise.
A Phase 3, Open-Label, Parallel-Group Study to Compare Two Dosing Algorithms for Preprandial Human Insulin Inhalation Powder (HIIP) in Insulin-Naïve Patients With Type 2 Diabetes Mellitus **(International)**	2	Eli Lilly	Eli Lilly	Both	18+	N/S	360	October-06	February-08	Adult	To compare the efficacy of two treatment regimens (Algorithm A versus Algorithm B) in insulin-naïve patients with type 2 diabetes not optimally controlled by one or more oral antihyperglycemic medications.

OPEN STUDIES FOR DIABETES MELIITUS TYPE 2

Title	Type	Investigator	Sponsor	Eligibility			Total Enroll	Start	End	Adult/Child	Objective
				Gender	Age	Race	n > 200				
Effect of Liraglutide on Glycaemic Control in Subjects With Type 2 Diabetes **(Japan)**	2	Katayama, Yasuyuki	Novo Nordisk	Both	20+	N/S	378	October-06	N/S	Adult	To compare the effect on glycaemic control of liraglutide, compared to sulfonylurea (SU treatment), as assessed by HbA1C after 24 and 52 weeks in subjects with type 2 diabetes.
A Multicenter, Double-Blind Study to Determine the Efficacy and Safety of SYR-322 Plus Pioglitazone HCl (Actos®), SYR-322 Alone, or Pioglitazone HCl Alone in Subjects With Type 2 Diabetes	2	Takeda Global Research & Development Center, Inc.	Takeda Global Research & Development Center, Inc.	Both	18 to 80	N/S	580	September-06	N/S	Adult	To evaluate the efficacy and safety of SYR-322 plus pioglitazone HCl, SYR-322 alone, or pioglitazone alone in subjects with type 2 diabetes.
Effect of Liraglutide in Combination With Sulfonylurea (SU) on Glycaemic Control in Subjects With Type 2 Diabetes **(Japan)**	2	Katayama, Yasuyuki	Novo Nordisk	Both	20+	N/S	228	October-06	N/S	Adult	To compare the effect on glycaemic control of liraglutide in combination with sulfonylurea agent (SU) compared to SU monotherapy, as assessed by HbA1C after 24 weeks and 52 weeks in subjects with type 2 diabetes. Liraglutide will be compared to placebo, in combination with SU.
Effect of Twice Daily Versus Thrice Daily Repaglinide and Metformin Combination Tablet and Rosiglitazone and Metformin in Fixed Dose Combination on HbA1c in Subjects With Type 2 Diabetes	2	Howard, Campbell	Novo Nordisk	Both	18+	N/S	501	November-06	N/S	Adult	To compare the changes in HbA1c after 26 weeks of repaglinide and metformin fixed dose combination tablet given as twice daily versus three times daily regimens or versus twice daily rosiglitazone and metformin fixed dose combination tablet in subjects with type 2 diabetes currently on monotherapy.
Pulmonary Outcomes Within a 2-Year Period in Subjects With Diabetes Mellitus Treated With Technosphere /Insulin or Usual Antidiabetic Treatment and in Subjects Without Abnormalities in Glucose Control **(International)**	2	Mankind	Mankind	Both	18 to 70	N/S	2,464	June-05	August-08	Adult	Pulmonary Safety in Diabetics with T/I
A Prospective, Multi-Center, Open-Label, Randomized, Controlled Clinical Trial Comparing the Efficacy and Safety in Subjects With Type 2 Diabetes Receiving Subcutaneous Basal Insulin and Prandial Inhyalation of Technosphere /Insulin Versus Subcutaneous Premixed Insulin Therapy Over a 52-Week Treatment Period and a 24-Week Follow-up **(International)**	2	Mankind	Mankind	Both	18 to 70	N/S	621	February-06	June-08	Adult	To determine whether inhaled insulin is safe and effective in the treatment of type 2 diabetes.
A Comparison of Insulin Lispro MM Intensive Mixture Therapy With Progressive Dose-Titration of Insulin Lispro LM or Biphasic Insulin Aspart 30/70 **(Europe)**	2	Eli Lilly	Eli Lilly	Both	30 to 75	N/S	270	October-06	September-09	Adult	To try to achieve optimal metabolic control and explore full therapeutic potential of the strategies.
A 16 Week Randomized, Double-Blind, Parallel Group Study to Evaluate the Efficacy and Safety of a New Medication (GSK523338) to Lower LDL-c and HbA1c in Subjects With Type 2 Diabetes Mellitus **(International)**	2	GlaxoSmithKline	GlaxoSmithKline	Both	18 to 75	N/S	360	August-05	N/S	Adult	To evaluate the effect of medicines for type 2 diabetes and lipids control.
A Multicenter, Double-Blind, Randomized, Parallel-Group Study to Compare the Effect of 12 Weeks Treatment With Vildagliptin (50mg Qd, 50mg Bid, 100mg Qd) to Placebo in Patients With Type 2 Diabetes **(Japan)**	2	Novartis	Novartis	Both	20+	N/S	236	June-06	N/S	Adult	To evaluate the effect of vildagliptin 50mg qd, 50mg bid or 100mg qd compared to placebo in patients with type 2 diabetes.
A Multicenter, Double-Blind, Randomized, Parallel-Group Study to Compare the Effect of 24 Weeks Treatment With Vildagliptin 100 MG QD to Placebo as Add-on Therapy in Patients With Type 2 Diabetes Inadequately Controlled With Metformin Monotherapy **(NJ and Germany)**	2	Novartis	Novartis	Both	18 to 78	N/S	369	May-06	N/S	Adult	To assess the efficacy on HbA1c of 100 mg vildagliptin once daily as compared to placebo as add-on to metformin in patients with type 2 diabetes inadequately controllled with metformin.
A Multicenter, Randomized, Double-Blind, Active-Controlled Study to Compare the Effects of 12 Weeks Treatment With Vildagliptin 50 Mg Bid to Voglibose 0.2 Mg Tid in Patients With Type 2 Diabetes **(Japan)**	2	Novartis	Novartis	Both	20+	N/S	370	August-06	N/S	Adult	To evaluate the efficacy, safety and tolerability of vildagliptin compared to voglibose in patients with type 2 diabetes. Please note this study is not being conducted in the United States.
A Randomized, Double-Blind, Active-Controlled, Multicenter Study to Compare the Effect of 24 Weeks Treatment With a Fixed Combination Therapy of Vildagliptin and Metformin to the Individual Monotherapy Components in Drug Naive Patients With Type 2 Diabetes **(NJ and Germany)**	2	Novartis	Novartis	Both	18 to 78	N/S	1,200	September-06	N/S	Adult	To evaluate the efficacy and safety of a fixed combination of vildagliptin and metformin in lowering blood glucose in patients with type 2 diabetes .
A Multicenter, Randomized, Double-Blind, Active Controlled Study to Compare the Effect of 24 Weeks Treatment With Vildagliptin 100 mg qd or Metformin 1500 mg Daily in Elderly Drug Naive Patients With Type 2 Diabetes **(Europe)**	2	Novartis	Novartis	Both	65+	N/S	850	August-06	N/S	Adult	To demonstrate the efficacy and safety of vildagliptin compared to metformin in elderly drug naive patients with type 2 diabetes.

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Title	Type	Investigator	Sponsor	Eligibility			Total Enroll	Start	End	Adult/Child	Objective
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A Multi-Center, Randomized, Open-Label, Active Controlled, Parallel Arm Study to Compare the Efficacy of 12 Weeks of Treatment With Vildagliptin 100 mg, qd to Thiazolidinedione (TZD) as Add-on Therapy in Patients With Type 2 Diabetes Inadequately Controlled With Metformin Monotherapy in a Community-Based Practice Setting	2	Novartis	Novartis	Both	18 to 80	N/S	8,000	October-06	N/S	Adult	To evaluate, in a primary care setting, the safety and efficacy of vildaglipgtin as add on therapy to metformin relative to TZD added to metformin in patients with type 2 diabetes inadequately controlled by metformin alone.
A Multicenter, Double-Blind, Randomized Parallel-Group, Study to Demonstrate the Effect of 24 Weeks Treatment With Vildagliptin 100 mg qd as Add-on to Metformin 500 mg Bid Compared to Metformin 1000 mg Bid in Patients With Type 2 Diabetes Inadequately Controlled on Metformin 500 mg Bid Monotherapy **(NJ and Germany only)**	2	Novartis	Novartis	Both	18 to 78	N/S	860	October-06	N/S	Adult	To evaluate the efficacy and safety of vildagliptin in combination with metformin 500 mg bid compared to metformin 1000 mg bid in patients with type 2 diabetes.
Treatment Options for Type 2 Diabetes in Adolescents and Youth (TODAY)	2	Kaufman, Francine	NIDDK	Both	10 to 17	N/S	750	May-04	N/S	Child	To compare the efficacy of three treatment arms on time to treatment failure based on glycemic control.
Variable Bolus Regimen 1-2-3 for Type 2 Diabetes Mellitus	2	Barch, Karen	Sanofi-Aventis	Both	18 to 79	N/S	Enrollment # not specified	N/S	N/S	Adult	To show the non-inferiority of insulin glulisine administered with 1 meal versus 2 meals versus 3 daily meals, as measured by the change in hemoglobin A1c (HbA1c), from baseline to study week 24.
Comparison of Three Therapeutic Strategies for Treating Type 2 Diabetes Mellitus Patients Poorly Controlled With Basal Insulin Associated With Oral Antidiabetic Drugs **(Europe)**	2	Pilorget, Valérie	Sanofi-Aventis	Both	18 to 75	N/S	388	December-04	N/S	Adult	To show the non inferiority in terms of efficacy (HbA1c) of insulin glargine plus metformin combined with 1 to 3 bolus of insulin glulisine introduced progressively (Arm 2) compared with insulin glargine plus metformin combined with 3 bolus of insulin glulisine (Arm 1), in type 2 diabetes mellitus patients poorly controlled on basal insulin therapy with oral antidiabetic drugs; and To show the non inferiority in terms of efficacy (HbA1c) of insulin glargine plus metformin combined with 1 to 3 bolus of insulin glulisine introduced progressively (Arm 2) compared with insulin glargine plus metformin and insulin secretagogue (sulfonylurea or glinide) combined with 1 to 3 bolus of insulin glulisine introduced progressively (Arm 3), in type 2 diabetes mellitus patients poorly controlled on basal insulin therapy with oral antidiabetic drugs.
The Durability of Twice-Daily Insulin Lispro Low Mixture Compared to Once-Daily Insulin Glargine When Added to Existing Oral Therapy in Patients With Type 2 Diabetes and Inadequate Glycemic Control **(International)**	2	Eli Lilly	Eli Lilly	Both	30 to 79	N/S	2,000	December-05	June-10	Adult	To compare insulin lispro low mixture [LM] and insulin glargine in combination with the patient's oral diabetes medicines for their ability to control blood sugar in patients with type 2 diabetes and compare insulin lispro LM to insulin glargine with regard to the length of time that the overall blood sugar can be controlled.
A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of CS-917 as Monotherapy for Type 2 Diabetes	2	Geary, Ellen Innerfield, Ron	Daiichi Sankyo Inc.	Both	18 to 70	N/S	400	January-06	N/S	Adult	To compare glucose lowering with CS-917 compared to placebo after 3 months of treatment.
A Multicenter, Randomized, Double Blind, Placebo Controlled, Phase III Trial to Evaluate the Efficacy and Safety of Saxagliptin (BMS477118) in Combination With Thiazolidinedione Therapy in Subjects With Type 2 Diabetes Who Have Inadequate Glycemic Control on Thiazolidinedione Therapy Alone **(International)**	2	Bristol Myers Squibb	Bristol Myers Squibb	Both	18 to 77	N/S	555	March-06	N/S	Adult	To learn whether Saxagliptin added to TZD therapy is more effective than TZD alone as a treatment for Type 2 diabetic subjects who are not sufficiently controlled with TZD alone.
A Randomized, Double-Blind, Placebo-Controlled, Five Parallel Group Study Investigating the Efficacy and Safety of BI 1356 BS (0.5 mg, 2.5 mg and 5.0 mg Administered Orally Once Daily) Over 12 Weeks in Drug Naive and Treated Patients With Type 2 Diabetes With Insufficient Glycemic Control (Study Includes an Open-Label Metformin Treatment Arm) **(International)**	2	Boehringer Ingelheim Pharmaceuticals	Boehringer Ingelheim Pharmaceuticals	Both	21 to 75	N/S	375	April-06	November-07	Adult	To test the efficacy, safety and tolerability of several doses of BI 1356 BS (1, 5, or 10 mg taken once daily) compared to placebo given for 12 weeks together with metformin in patients with type 2 diabetes mellitus who are not at goal with their HbA1c levels.
Trial to Investigate the Efficacy and the Safety of Thrice-Daily NN2000-Mix70 (NovoRapid 70 Mix) Compared to Twice-Daily NN-X14Mix30 (NovoRapid 30 Mix) in Subjects With Type 2 Diabetes Mellitus **(Japan)**	2	Kanai, Michiaki	Novo Nordisk	Both	20+	N/S	284	April-06	N/S	Adult	To study the efficacy and safety of three times a day BIAsp-70 compared to two times a day BIAsp-30 in subjects with type 2 diabetes.

OPEN STUDIES FOR DIABETES MELIITUS TYPE 2

Title	Type	Investigator	Sponsor	Eligibility			Total Enroll	Start	End	Adult/Child	Objective
				Gender	Age	Race	n > 200				
A Phase 3, Open-Label, Parallel Group Study to Evaluate the Efficacy and Safety of Human Insulin Inhalation Powder (HIIP) Compared to Preprandial Injectable Insulin in Insulin-Naive Patients With Type 2 Diabetes Mellitus **(International)**	2	Eli Lilly	Eli Lilly	Both	18+	N/S	420	April-06	March-09	Adult	To evaluate the safety and efficacy of the Lilly/Alkermes inhaled insulin system compared to injected pre-meal insulin in non-smoking patients with type 2 diabetes.
A Randomized, Double-Blind, Placebo-Controlled, Five Parallel Group Study Investigating the Efficacy and Safety of BI 1356 BS (0.5 mg, 2.5 mg and 5.0 mg Administered Orally Once Daily) Over 12 Weeks in Drug Naive and Treated Patients With Type 2 Diabetes With Insufficient Glycemic Control (Study Includes an Open-Label Metformin Treatment Arm)	2	Boehringer Ingelheim Pharmaceuticals	Boehringer Ingelheim Pharmaceuticals	Both	21 to 75	N/S	375	May-06	September-07	Adult	To investigate the efficacy, safety, and tolerability of 3 doses of BI 1356 BS compared to placebo over 12 weeks of treatment in patients with type 2 diabetes and insufficient control of thier blood glucose.
Inhaled Pre-Prandial Human Insulin With the AERx® iDMS Versus s.c. Insulin Aspart in Type 2 Diabetes: A 104 Week, Open-Label, Multicenter, Randomised, Trial Followed by a 12 Week Re-Randomised Extension to Investigate Safety and Efficacy **(Europe)**	2	Louise K. Steen	Novo Nordisk	Both	18+	N/S	546	September-06	N/S	Adult	To compare the efficacy (reduction in HbA1c and blood glucose) and pulmonary safety (pulmonary function tests, chest x-rays) of mealtime inhaled insulin with subcutaneous insulin aspart both in combination with insulin detemir in Type 2 Diabetes.
Safety and Efficacy of Inhaled Pre-Prandial Human Insulin Plus Glimepiride Versus Rosiglitazone Plus Glimepiride in Type 2 Diabetes **(Europe)**	2	Bonefeld, Lisbeth	Novo Nordisk	Both	18+	N/S	345	October-06	N/S	Adult	To compare the efficacy of adding inhaled preprandial insulin to glimepiride compared to adding rosiglitazone to glimepiride for the treatment of type 2 diabetes and to verify its safety (hypoglycaemia, pulmonary function, body weight, insulin antibodies and side effects).
Treatment of Early Insulinization With Glargine in Type 2 Diabetes Patients Uncontrolled on Sulfonylurea or Metformin Monotherapy **(China)**	2	Jolain, Bruno	Sanofi-Aventis	Both	18 to 80	N/S	230	June-06	N/S	Adult	To investigate the efficacy of insulin glargine (in terms of change in A1c from baseline to endpoint A1c < 7%) .
Efficacy and Safety of Inhaled Pre-Prandial Human Insulin Plus Metformin Versus Rosiglitazone Plus Metformin in Type 2 Diabetes **(Europe)**	2	Johansen, Pernille	Novo Nordisk	Both	18+	N/S	345	November-06	N/S	Adult	To compare the efficacy of adding inhaled preprandial insulin to metformin compared to adding rosiglitazone to metformin for the treatment of type 2 diabetes and to verify its safety (hypoglycaemia, pulmonary function, body weight, insulin antibodies and side effects).
Insulin Glargine With Step-Wise Addition of Insulin Glulisine or With One Injection of Insulin Glulisine vs a Twice-Daily Premixed Insulin Regimen (Insulin Aspart Mix 70/30) in Adult Subjects With Type-2 Diabetes Failing Dual or Triple Therapy With Oral Agents	2	Barch, Karen	Sanofi-Aventis	Both	30 to 80	N/S	576	May-06	N/S	Adult	Open, controlled, parallel, 1:1 randomized 3-arm study with a run-in phase of 4 weeks and a treatment period of 60 weeks. Subjects will be randomized via central randomization using a dynamic allocation method balancing the study groups according to study site and combination oral hypoglycemic agent use (metformin, TZD, sulfonylurea). All subjects will be instructed to document their food and caloric intake using a diary and to maintain self-monitored blood glucose (SMBG) records. The subject identifies at the study outset the main meal by his/her estimation. Study personnel will confirm on the subsequent profiles that the preprandial or hs glucose tests match the subject's estimation.
A 54 Week Open Randomized Parallel Arm Controlled Study Designed to Assess the Clinical Benefit of the OneTouch Ultra2 System	2	Bevis, Peter	Life Scan	Both	18+	N/S	Enrollment # not specified	October-06	N/S	Adult	To determine whether HbA1c is significantly lower in patients with type 2 diabetes who use the OneTouch Ultra2 system compared to patients who use traditional blood glucose monitoring systems.
A Comparison of Glucovance (Glyburide and Metformin) to Insulin Therapy for the Treatment of Gestational Diabetes and Adult Onset Diabetes in Pregnancy	2	Kipikasa, Joseph	Regional Obstetrical Consultants	Female	18 to 45	N/S	200	September-02	September-08	Adult	To determine if patients will have similar or improved blood glucose control on an oral agent as compared to control on insulin.
Program for the Prevention of Diabetes Mellitus Development in Women Who Had Already Experienced A Gestational Diabetes. Evaluation of the Efficacy of the Life-Style Modification and the Life-Style Modification in Conjunction With Metformin, in the Prevention of Diabetes Mellitus Development in a Population of Women Who Had Expired a Gestational Diabetes - a Multicenter, Randomized, Double Blind Study **(Poland)**	2	Cypryk, Katarzyna	Medical Universtity of Lodz	Female	18 to 50	N/S	300	November-05	N/S	Adult	To compare the efficacy of life style modification and life style modification in conjunction with metformin administration, in a population of women, who had already experienced gestational diabetes.
BEHAVIORAL/LS TREATMENT OF GLYCEMIA											

OPEN STUDIES FOR DIABETES MELIITUS TYPE 2

Title	Type	Investigator	Sponsor	Eligibility			Total Enroll	Start	End	Adult/Child	Objective
				Gender	Age	Race	n > 200				
Project Sugar 2: Health Events Costs in Diabetic Blacks	2	Brancati, Frederick	NIDDK	Both	30+	Blacks only	800	October-00	December-05	Adult	To determine the effects of a NCM/CHW team on metabolic control, on the occurrence of diabetes-related health events, health care utilization, and on direct health care costs. The participants will be African American adults with type 2 diabetes who receive primary care within a managed care organization in inner-city Baltimore.
Optimisation of Insulin Treatment of Type 2 Diabetes Mellitus by Telecare Assistance for Self Monitoring of Blood Glucose (SMBG) **(Italy)**	2	Georges, Paizis	Sanofi-Aventis	Both	35 to 70	N/S	480	September-05	N/S	Adult	To verify the superiority of Telecare program vs. standard SMBG program in terms of mean HbA1c value (- 0,5%) at end-point.
PREVENTION OF TYPE 2 DIABETES											
Diabetes Prevention Program Outcome Study	2	Knowler, William	NIDDK	Both	Age not specified	N/S	220	September-02	N/S	Age not specified	This Diabetes Prevention Program Outcomes Study (DPPOS) is an extension of the Diabetes Prevention Program (DPP), which examined the effects of intensive lifestyle modification and treatment with the drug metformin on diabetes risk. Subjects in the lifestyle modification group of the DPP had a 58% reduced risk of type 2 diabetes; those in the metformin group had a 31% risk reduction. The DPPOS will examine whether this risk reduction can be sustained long-term (up to 10 years) and what impact it has on diabetes-related health problems, such as heart, kidney, and eye disease, and nerve damage.
PREVENTION /TREATMENT OF COMPLICATIONS											
Study of Pitavastatin Vs. Atorvastatin (Following Up-Titration) in Patients With Type II Diabetes Mellitus and Combined Dyslipidemia **(Europe)**	2	Lodhi, A	Kowa Research Europe	Both	18 to 75	N/S	300	November-05	N/S	Adult	The purpose of this study is to compare the efficacy and safety of pitavastatin with that of atorvastatin in patients with type II diabetes mellitus (type II DM) and combined dyslipidemia.
Double-Blind, Follow-On Study of Pitavastatin (4 Mg) Versus Atorvastatin (20 Mg and 40 Mg), With a Single-Blind Extension of Treatment, in Patients With Type II Diabetes Mellitus and Combined Dyslipidemia **(Europe)**	2	Lodhi, A	Kowa Research Europe	Both	Age not specified	N/S	270	May-06	March-08	N/S	This is a sixteen-week double-blind active-controlled follow-on and 28-week single-blind extension study for patients who participated in study NK-104-305.
A Study of Cardiovascular Events iN Diabetes - A Randomized 2x2 Factorial Study of Aspirin Versus Placebo, and of Omega-3 Fatty Acid Supplementation Versus Placebo, for Primary Prevention of Cardiovascular Events in People With Diabetes (ASCEND) **(United Kingdom)**	1	Armitage, Jane	University of Oxford	Both	40+	N/S	10,000	March-05	N/S	Adult	To determine whether 100 mg daily aspirin versus placebo and/or supplementation with 1 gram daily omega-3 fatty acids or placebo prevents “serious vascular events” (i.e. non-fatal heart attack, non-fatal stroke or death from vascular causes) in patients with diabetes who are not known to have occlusive arterial disease and to assess the effects on serious bleeding or other adverse events.
The ADDITION Study: Anglo-Danish-Duch Study of Intensive Treatment and Complication Prevention in Type 2 Diabetic Patients Identified by Screening in Primary Care **(Europe)**	2	Lauritzen, Torsten	University of Aarhus	Both	40 to 69	N/S	3,000	January-01	June-10	Adult	To screen patients for Type 2 diabetes and provide intensive treatment compared to standard treatment.
The LANCET Trial: A Randomized Clinical Trial of Lantus for C-Reactive Protein Reduction in Early Treatment of Type 2 Diabetes	2	Pradhan, Aruna Das	Brigham and Women's Hospital	Both	18 to 79	N/S	800	August-06	April-08	Adult	To determine whether Lantus, a long-acting insulin injection, either alone or in combination with metformin, is effective in reducing C-reactive protein (CRP) in adults with type 2 diabetes.
Targeting Inflammation in Type 2 Diabetes: Clinical Trial Using Salsalate (TINSAL)	2	Goldfine, Allison Shoelson, Steven	NIDDK/ Joslin Diabetes Center	Both	18 to 75	N/S	402	October-06	N/S	Adult	To determine whether salicylates represent a new pharmacological option for diabetes management
Effects of Rosiglitazone on Renal Hemodynamics and Proteinuria of Type 2 Diabetic Patients With Renal Insufficiency Due to Overt Diabetic Nephropathy **(Europe)**	2	Pistrosch, Frank	Dresden University of Technology	Both	40 to 75	N/S	Enrollment # not specified	N/S	N/S	Adult	To evaluate how rosiglitazone does influence the renal plasma flow, the glomerular filtration rate and the degree of proteinuria in type 2 diabetic patients with renal insufficiency due to overt diabetic nephropathy.
The Novel Antihypertensive Goal Of hYpertension With diAbetes — Hypertensive Events and ARb Treatment (NAGOYA-HEART) Study **(Japan)**	2	Murohara, Toyoaki	Nagoya University	Both	30 to 75	Japanese subjects only	Enrollment # not specified	October-04	N/S	Adult	To test whether ARBs or CCBs are superior in treating Japanese diabetic hypertensive patients.
Study for the Effectiveness of Intensive Therapy for Diabetic Nephropathy in Unblinded, Randomized Intergroup Comparison Study **(Japan)**	2	Makino, Hiroshi	Okayama University	Both	20 to 70	N/S	600	November-05	March-12	Adult	To study for the effectiveness of intensive therapy for diabetic nephropathy in unblinded, randomized intergroup comparison study.

OPEN STUDIES FOR DIABETES MELIITUS TYPE 2

Title	Type	Investigator	Sponsor	Eligibility			Total Enroll	Start	End	Adult/Child	Objective
				Gender	Age	Race	n > 200				
Effect of Strict Glycemic Control on Improvement of Exercise Capacities (VO2 Peak, Peak Workload After Cardiac Rehabilitation, in Patients With Type 2 Diabetes Mellitus With Coronary Artery Disease **(France)**	2	Vergès, Bruno	Centre Hospitalier Universitaire Dijon	Both	25 to 95	N/S	440	July-05	July-08	Adult	To determine whether strict glycemic control during cardiac rehabilitation may ameliorate the improvement of exercise capacities (VO2 peak, peak workload, ventilatory threshold) in patients with type 2 diabetes with coronary artery disease.
A Phase III, 18 Month, Multicenter, Randomized, Double-Blind, Active-Controlled Clinical Trial to Compare Rosiglitazone Versus Glipizide on the Progression of Atherosclerosis in Subjects With Type 2 Diabetes Mellitus and Cardiovascular Disease (APPROACH) **(International)**	2	GlaxoSmithKline	GlaxoSmithKline	Both	30 to 80	N/S	600	January-05	N/S	Adult	To test the safety and effectiveness of rosiglitazone against a sulfaurea in reducing or slowing the development of atherosclerosis in the blood vessels of the heart.
A Multicenter, Randomized, Open-Label, Parallel-Group, Diabetic Diet–Controlled Study to Evaluate the Efficacy and Safety of Compound α-Keto Acid Tablet in Combination With LPD in Delaying the Progress of Type 2 Diabetic Nephropathy **(China)**	2	Lin, Shantan	Beijing Fresenius Kabi Pharmaceutical Co.	Both	18 to 75	N/S	200	May-06	June-08	Adult	To evaluate the efficacy and safety of compound α-Keto Acid tablet in combination with low protein diet in delaying the progress of nephropathy.
Randomized Olmesartan and Diabetes Microalbuminuria Prevention Study (ROADMAP) **(Germany)**	2	Haller, Hermann	Daiichi Sankyo Inc.	Both	18 to 75	N/S	4,400	October-04	N/S	Adult	This is a study of olmesartan and diabetes microalbuminuria prevention in diabetic patients with at least one additional cardiovascular risk factor and normoalbuminuria prior to randomization.
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 Coronary Atherosclerotic Disease as Measured by Intravascular Ultrasound **(International)**	2	Isaacson, Brigit	Takeda Global Research & Development Center, Inc.	Both	35 to 85	N/S	440	August-03	March-08	Adult	To compare the effect of pioglitazone HCl versus glimepiride on the coronary atheroma volume using IVUS of the coronary arteries after up to 18 months of treatment.
Target Glycemic Control and the Incidence of Documented Symptomatic Hypoglycemia in Insulin naïve Subjects With Type 2 Diabetes Failing on Oral Hypoglycemic Agent(s) and Treated With Insulin Glargine or Insulin Detemir	2	Pilorget, Valérie	Sanofi-Aventis	Both	40 to 75	N/S	910	November-06	N/S	Adult	To demonstrate the non-inferiority of insulin glargine in comparison to insulin detemir in term of percentage of patients who reach the target of HbA1c < 7% at the end of the treatment period and do not experience symptomatic hypoglycemia, confirmed by plasma glucose (PG) <= 56 mg/dL (3.1 mmol/L).
Safety and Efficacy of Orlistat (Xenical, Hoffmann LaRoche) in African American and Caucasian Children and Adolescents With Obesity-Related Comorbid Conditions	2	NICHD	NICHD	Both	7 to 17	All 4 Grandparents must be either all Caucasian or all African American	425	May-98	N/S	Child	To determine the safety, tolerability, and efficacy of Xenical in 12-17 year old severely obese African American and Caucasian children and adolescents who have one or more obesity-related disease (hypertension, hyperlipidemia, sleep apnea, hepatic steatosis, insulin resistance, impaired glucose tolerance, or Type 2 diabetes).
Effect of Low Dose Thiazide Diuretics on New Onset Type 2 Diabetes in Patients With Essential Hypertension **(Japan)**	2	Ueda, Shinichiro	Kyoto University	Both	30 to 79	N/S	1,800	January-04	December-11	Adult	To evaluate the safety (i.e. new onset of diabetes and other metabolic adverse events), efficacy and cost-effectiveness of antihypertensive treatment with low dose diuretics. Exclusion criteria - Patients with Type 2 Diabetes.
Prospective Randomized Controlled Open-Labelled Trial Comparing Effect of Two Haemoglobin Levels (110- 129 g/L and 130 – 149 g/L) on Progression of Chronic Kidney Disease in Patients With Type 2 Diabetes and With Chronic Kidney Disease **(France)**	2	Villar, Emmanuel	Hospices Civils de Lyon	Both	18 to 80	N/S	204	January-04	N/S	Adult	To evaluate the potential benefit of an haemoglobin level of 130 g/L in patients with type 2 diabetes and with a chronic kidney disease defined by a Cockcroft's creatinine clearance of 25 – 60 ml/min.
A Randomized, Double-Blind Trial Comparing the Efficacy and Safety of a Fixed Combination of Fenofibrate and Metformin Vs Rosiglitazone in Patients With Type 2 Diabetes Mellitus and Dyslipidemia **(Europe)**	2	Gottlieb, Isabelle	Fournier Laboratories Ireland Ltd	Both	18 to 75	N/S	600	June-06	N/S	Adult	To show that the efficacy of a fixed combination (FC) of fenofibrate and metformin on glycemic control is not inferior to that of rosiglitazone and the efficacy of FC of fenofibrate and metformin on triglyceride control is superior to that of rosiglitazone.
A Randomized, Double-Blind Study Comparing the Efficacy and Safety of a Fixed Combination of Fenofibrate and Metformin Vs Metformin Alone in Patients With Type 2 Diabetes Mellitus and Dyslipidemia Not Appropriately Controlled With a Statin **(Europe)**	2	Gottlieb, Isabelle	Fournier Laboratories Ireland Ltd	Both	18 to 75	N/S	478	August-06	N/S	Adult	To demonstrate in patients with T2DM and dyslipidemia not appropriately controlled with a statin and receiving metformin, the superiority of a fixed combination of fenofibrate and metformin vs metformin alone on TG and additionally, if the superiority on TG is established, to demonstrate the superiority on HDL-C.

OPEN STUDIES FOR DIABETES MELIITUS TYPE 2

Title	Type	Investigator	Sponsor	Eligibility			Total Enroll	Start	End	Adult/Child	Objective
				Gender	Age	Race	n > 200				
A Prospective, Open Label, Single Arm Study to Evaluate the Safety and Efficacy of an Olmesartan Medoxomil Based Treatment Regimen in Type II Diabetic Patients With Hypertension	2	Schwartz, Helen	Daiichi Sankyo Inc	Both	18+	N/S	200	November-06	N/S	Adult	To examine the ability of olmesartan medoxomil to lower the blood pressure of patients with Type II diabetes and high blood pressure.
The Study Comparing the Incidence of Cardiovascular Events Between High-Dose ARB Monotherapy and Combination Therapy With ARB and Calcium Channel Blocker in Japanese Elderly Hypertensive Patients at High Cardiovascular Risk **(Japan)**	2	Arakawa, Kikuo	OSCAR Study	Both	65 to 84	N/S	1,000	August-05	May-10	Adult	To investigate whether high-dose angiotensin II receptor blocker (ARB) monotherapy or combination therapy with ARB and calcium channel blockers is more effective in reducing the incidence of cardiovascular events in Japanese elderly high-risk hypertensive patients not adequately controlled by standard dose ARB alone.