

# AVANCE - Observational study of the real-world usage, efficacy and safety of rosiglitazone in Type 2 diabetics

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## Général

### Identification

Nom détaillé Observational study of the real-world usage, efficacy and safety of rosiglitazone in Type 2 diabetics

Sigle ou acronyme AVANCE

Numéro d'enregistrement (ID-RCB ou EUDRACT, CNIL, CPP, etc.) CCTIRS : 05.309

### Thématiques générales

Domaine médical Endocrinology and metabolism

Mots-clés pharmaco-epidémiologY, rosiglitazone

### Responsable(s) scientifique(s)

Nom du responsable Leclerc-Zwirn

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Laboratoire Laboratoire GSK

### Collaborations

### Financements

Financements Private

Précisions Laboratoire GSK

### Gouvernance de la base de données

Organisation(s) responsable(s) ou promoteur Laboratoire GSK

Statut de l'organisation                      Secteur Privé

Contact(s) supplémentaire(s)

## Caractéristiques

Type de base de données

Type de base de données                      Study databases

Base de données issues  
d'enquêtes, précisions                      Longitudinal study (except cohorts)

Origine du recrutement des  
participants                      A selection of health care professionals

Critère de sélection des  
participants                      Medication(s) taken

Le recrutement dans la base de  
données s'effectue dans le  
cadre d'une étude  
interventionnelle                      No

Informations complémentaires  
concernant la constitution de  
l'échantillon                      Physicians are to be randomly selected from the CEGEDIM data base. To take stock of refusals, a pool will be constituted containing three times as many specialists and general practitioners as will eventually be required. Every physician in each pool (specialists and general practitioners) will be randomly attributed a number. Lists will then be compiled in ascending order, using this random number. Physicians will then be successively solicited in the order of appearance of their names on the list until the required number of general practitioners or specialists has been attained. The planned inclusion period is nine months. This duration could nevertheless be extended if there are recruitment problems, or curtailed if enough patients have been recruited.  
During this period, all the Investigating Physicians will be asked to include all patients they see (in consultations or home visits) who start or have recently started (within the previous 30 days) a course of rosiglitazone treatment and who have agreed to take part in the Study, until a maximum number of patients has been reached, namely 4 for the general practitioners and 5 for the specialists. Participating physicians will also be asked to fill out a non-inclusion record for every patient who was in theory eligible but was not included (with the reason for non-inclusion).

## Objectif de la base de données

Objectif principal	To describe the profiles of patients being treated by general practitioners and specialists, compatibility of practice with the SPC, patient compliance, and the safety and efficacy of rosiglitazone in "real-world" conditions of use.
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Critères d'inclusion	<ul style="list-style-type: none"><li>- Type 2 diabetic spontaneously consulting (i.e. independently of the study);</li><li>- Patient who is starting or has recently started (within a month) a course of treatment with Avandia® or Avandamet®;</li><li>- Patient who has given his/her consent to participate.</li></ul>
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## Type de population

Age	Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years) Elderly (65 to 79 years) Great age (80 years and more)
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Population concernée	Sick population
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Sexe	Male Woman
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Champ géographique	National
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Détail du champ géographique	France
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## Collecte

### Dates

Année du premier recueil	2006
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Année du dernier recueil	2009
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## Taille de la base de données

Taille de la base de données (en nombre d'individus)	[1000-10 000[ individuals
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Détail du nombre d'individus	1120
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## Données

Activité de la base	Data collection completed
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Type de données recueillies	Clinical data Declarative data
Données cliniques, précisions	Direct physical measures Medical registration
Données déclaratives, précisions	Paper self-questionnaire Face to face interview
Existence d'une bibliothèque	No
Paramètres de santé étudiés	Health event/morbidity Health event/mortality Health care consumption and services
Consommation de soins, précisions	Medicines consumption
<b>Modalités</b>	
Mode de recueil des données	CRF and self administrated questionnaire
Suivi des participants	Yes
Détail du suivi	Data will be collected at 5 stages : ? At inclusion ? After about 6 months (Follow-Up Visit 1):Up Visit 3) ? After about 12 months (Follow-Up Visit 2) ? After about 18 months (Follow-Up Visit 3) ? After about 24 months (End-of-Study Visit)
Appariement avec des sources administratives	No
<b>Valorisation et accès</b>	
<b>Valorisation et accès</b>	
<b>Accès</b>	
Charte d'accès aux données (convention de mise à disposition, format de données et délais de mise à disposition)	Publication in congress
Accès aux données agrégées	Access on specific project only
Accès aux données individuelles	Access on specific project only