

# **PREDICTIVE: Predictable Results and Experience in Diabetes through Intensification and Control to Target: An International Variability Evaluation - Longitudinal Study on Diabetic Patients Treated with Detemir Insulin**

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| General                                                                                                                  |                                                                                                                                                   |
|--------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|
| Identification                                                                                                           |                                                                                                                                                   |
| Detailed name                                                                                                            | Longitudinal Study on Diabetic Patients Treated with Detemir Insulin                                                                              |
| Sign or acronym                                                                                                          | PREDICTIVE: Predictable Results and Experience in Diabetes through Intensification and Control to Target: An International Variability Evaluation |
| CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation | CNIL                                                                                                                                              |
| General Aspects                                                                                                          |                                                                                                                                                   |
| Medical area                                                                                                             | Endocrinology and metabolism                                                                                                                      |
| Health determinants                                                                                                      | Genetic                                                                                                                                           |
| Keywords                                                                                                                 | analogue, detemir insulin, efficacy, tolerance                                                                                                    |
| Scientific investigator(s) (Contact)                                                                                     |                                                                                                                                                   |
| Name of the director                                                                                                     | Marre                                                                                                                                             |
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| Unit                                                                                                                     | Unité 695 : Déterminants génétiques du diabète de type 2 et de ses complications vasculaires                                                      |

Organization Inserm

## Collaborations

## Funding

Funding status Private

Details - Novo Nordisk A/S.

## Governance of the database

Sponsor(s) or organisation(s) responsible Institut National de la Santé et de la Recherche Médicale - Inserm

Organisation status Public

## Additional contact

## Main features

## Type of database

Type of database Study databases

Study databases (details) Longitudinal study (except cohorts)

Database recruitment is carried out by an intermediary A selection of health care professionals

Database recruitment is made on the basis of: Another treatment or procedure

Database recruitment is carried out as part of an interventional study No

Additional information regarding sample selection. At the discretion of the treating physician.

## Database objective

Main objective To investigate the effect of using determir insulin in normal clinical practice.

Inclusion criteria

- Male and female;
- Adult;
- Diabetic (type 1 and 2);
- Treated with determir insulin.

## Population type

|                                              |                                                                                                                                                     |
|----------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|
| Age                                          | Adulthood (19 to 24 years)<br>Adulthood (25 to 44 years)<br>Adulthood (45 to 64 years)<br>Elderly (65 to 79 years)<br>Great age (80 years and more) |
| Population covered                           | Sick population                                                                                                                                     |
| Gender                                       | Male<br>Woman                                                                                                                                       |
| Geography area                               | International                                                                                                                                       |
| Detail of the geography area                 | Europe (Austria, Denmark, France, Germany, Ireland, Turkey, United Kingdom).                                                                        |
| Data collection                              |                                                                                                                                                     |
| Dates                                        |                                                                                                                                                     |
| Date of first collection (YYYY or MM/YYYY)   | 2006                                                                                                                                                |
| Size of the database                         |                                                                                                                                                     |
| Size of the database (number of individuals) | [1000-10 000[ individuals                                                                                                                           |
| Details of the number of individuals         | 19,911 (Europe): - France (1,772): - 643 patients with type 1 diabetes - 1,129 patients with type 2 diabetes.                                       |
| Data                                         |                                                                                                                                                     |
| Database activity                            | Data collection completed                                                                                                                           |
| Type of data collected                       | Clinical data<br>Biological data                                                                                                                    |
| Clinical data (detail)                       | Direct physical measures                                                                                                                            |
| Details of collected clinical data           | --                                                                                                                                                  |
| Biological data (detail)                     | Glycaemic control                                                                                                                                   |
| Presence of a biobank                        | No                                                                                                                                                  |
| Health parameters studied                    | Health event/morbidity                                                                                                                              |
| Procedures                                   |                                                                                                                                                     |
| Participant monitoring                       | Yes                                                                                                                                                 |

|                                                                                       |                                                                                         |
|---------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| Details on monitoring of participants                                                 | Visits at baseline, 12 weeks, 26 weeks and 52 weeks.                                    |
| Links to administrative sources                                                       | No                                                                                      |
| Promotion and access                                                                  |                                                                                         |
| Promotion                                                                             |                                                                                         |
| Link to the document                                                                  | <a href="http://tinyurl.com/Pubmed-PREDICTIVE">http://tinyurl.com/Pubmed-PREDICTIVE</a> |
| Description                                                                           | List of publications in Pubmed                                                          |
| Access                                                                                |                                                                                         |
| Terms of data access (charter for data provision, format of data, availability delay) | Contact the scientist in charge.                                                        |
| Access to aggregated data                                                             | Access on specific project only                                                         |
| Access to individual data                                                             | Access on specific project only                                                         |