

# EMES - Pragmatic pharmacoeconomic assessment of Sinovial® in the treatment of gonarthrosis

Head :Moore Nicholas, Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen

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## General

### Identification

Detailed name Pragmatic pharmacoeconomic assessment of Sinovial® in the treatment of gonarthrosis

Sign or acronym EMES

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation CCTIRS 03.457, CNIL 903389

### General Aspects

Medical area Rheumatology

Health determinants Iatrogenic

Others (details) Gonarthrosis

Keywords hyaluronic acid viscosupplementation, gonarthrosis, safety, Sinovial®, cost, effectiveness, pharmacoepidemiology, cohort, Department of Pharmacology, Bordeaux

### Scientific investigator(s) (Contact)

Name of the director Moore

Surname Nicholas

Address Bât du Tondu - Case 41 - 146, Rue Léo Saignat - 33076 BORDEAUX Cedex

Phone + 33 (0)5 57 57 46 75

Email nicholas.moore@pharmaco.u-bordeaux2.fr

Unit Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen

|                                                                        |                                                                                                                                                                                                                       |
|------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Organization                                                           | Université Bordeaux                                                                                                                                                                                                   |
| Collaborations                                                         |                                                                                                                                                                                                                       |
| Funding                                                                |                                                                                                                                                                                                                       |
| Funding status                                                         | Mixed                                                                                                                                                                                                                 |
| Details                                                                | Laboratoire Genévrier                                                                                                                                                                                                 |
| Governance of the database                                             |                                                                                                                                                                                                                       |
| Sponsor(s) or organisation(s) responsible                              | Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen                                                                                                                                         |
| 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:                          | Medication(s) taken                                                                                                                                                                                                   |
| Database recruitment is carried out as part of an interventional study | No                                                                                                                                                                                                                    |
| Additional information regarding sample selection.                     | Sample of subjects that have had an injection of Sinovial®. Subjects were identified by rheumatologists and by functional rehabilitation physicians prescribing Sinovial ® (list provided by Laboratories GENEVRIER). |
| Database objective                                                     |                                                                                                                                                                                                                       |
| Main objective                                                         | The objective was to compare the cost of two therapeutic strategies: Sinovial® and other care versus other care alone.                                                                                                |
| Inclusion criteria                                                     | Patient agreed to participate in this study and having signed the consent form; Patient having had a first injection of Sinovial® between 01/01/2003                                                                  |

and 31/03/2003; Patient having never previously received viscosupplementation treatment; Patient aged 20 years and over; Patient affiliated to the general health insurance system for at least 12 months at the time of first injection

| 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                               | National                                                                                                                                            |
| Detail of the geography area                 | Rheumatologists and functional rehabilitation physicians in metropolitan France                                                                     |
| Data collection                              |                                                                                                                                                     |
| Dates                                        |                                                                                                                                                     |
| Date of first collection (YYYY or MM/YYYY)   | 2004                                                                                                                                                |
| Date of last collection (YYYY or MM/YYYY)    | 2005                                                                                                                                                |
| Size of the database                         |                                                                                                                                                     |
| Size of the database (number of individuals) | < 500 individuals                                                                                                                                   |
| Details of the number of individuals         | 408                                                                                                                                                 |
| Data                                         |                                                                                                                                                     |
| Database activity                            | Data collection completed                                                                                                                           |
| Type of data collected                       | Clinical data<br>Declarative data<br>Administrative data                                                                                            |
| Clinical data (detail)                       | Direct physical measures                                                                                                                            |

|                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                 |
|---------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Declarative data (detail)                                                             | Paper self-questionnaire                                                                                                                                                                                                                                                                                                                                                        |
| Administrative data (detail)                                                          | Patient name, first name, date of birth, social security number                                                                                                                                                                                                                                                                                                                 |
| Presence of a biobank                                                                 | No                                                                                                                                                                                                                                                                                                                                                                              |
| Health parameters studied                                                             | Health event/morbidity<br>Health care consumption and services                                                                                                                                                                                                                                                                                                                  |
| Care consumption (detail)                                                             | Medical/paramedical consultation<br>Medicines consumption                                                                                                                                                                                                                                                                                                                       |
| Procedures                                                                            |                                                                                                                                                                                                                                                                                                                                                                                 |
| Data collection method                                                                | Data collection was conducted through two questionnaires (one for the physician and the other for the patient). Further information about care consumed by each patient were also retrieved from the database ERASME (Extraction, Recherche, Analyse pour le Suivi Médico-Economique) database of the CNAM-TS (Caisse Nationale d'Assurance Maladie des Travailleurs Salariés). |
| Participant monitoring                                                                | Yes                                                                                                                                                                                                                                                                                                                                                                             |
| Links to administrative sources                                                       | Yes                                                                                                                                                                                                                                                                                                                                                                             |
| Linked administrative sources (detail)                                                | ERASME database (Extraction, Recherche, Analyse pour le Suivi Médico-Economique) of the CNAM-TS (Caisse Nationale d'Assurance Maladie des Travailleurs Salariés)                                                                                                                                                                                                                |
| Promotion and access                                                                  |                                                                                                                                                                                                                                                                                                                                                                                 |
| Promotion                                                                             |                                                                                                                                                                                                                                                                                                                                                                                 |
| Access                                                                                |                                                                                                                                                                                                                                                                                                                                                                                 |
| Terms of data access (charter for data provision, format of data, availability delay) | A study report was delivered to the pharmaceutical company after validation by the study Scientific Committee. Scientific articles are currently being drafted. Ownership of study data is the subject of an agreement between the University of Bordeaux Segalen and the pharmaceutical company. Terms for third-party access to the database are to be defined.               |
| Access to aggregated data                                                             | Access on specific project only                                                                                                                                                                                                                                                                                                                                                 |
| Access to individual data                                                             | Access on specific project only                                                                                                                                                                                                                                                                                                                                                 |