

# TROPHEE - Benign prostatic hyperplasia: management and medical needs not covered in general practice in France

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## General

### Identification

|               |                                                                                                      |
|---------------|------------------------------------------------------------------------------------------------------|
| Detailed name | Benign prostatic hyperplasia: management and medical needs not covered in general practice in France |
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|                 |         |
|-----------------|---------|
| Sign or acronym | TROPHEE |
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|--------------------------------------------------------------------------------------------------------------------------|----------------|
| CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation | CNIL : 909 315 |
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### General Aspects

|              |                                                       |
|--------------|-------------------------------------------------------|
| Medical area | General practice<br>Urology, andrology and nephrology |
|--------------|-------------------------------------------------------|

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| Health determinants | Iatrogenic |
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| Keywords | adherence, observational, quality of life, satisfaction, sexuality |
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### Scientific investigator(s) (Contact)

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| Name of the director | Leclerc-Zwirn |
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| Unit | Laboratoire GSK |
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### Collaborations

### Funding

|                |         |
|----------------|---------|
| Funding status | Private |
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| Details                                                                | Laboratoire GSK                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Governance of the database                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Sponsor(s) or organisation(s) responsible                              | LABORATOIRE GSK                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Organisation status                                                    | Private                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Additional contact                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Main features                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Type of database                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Type of database                                                       | Study databases                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Study databases (details)                                              | Not-repeated cross-sectional studies (except case control studies)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Database recruitment is carried out by an intermediary                 | A selection of health care professionals                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Database recruitment is carried out as part of an interventional study | No                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Additional information regarding sample selection.                     | <p>The study will only be performed with general practitioners. This choice is justified by the fact that general practitioners represent the source of most prescriptions in BPH. The study will be proposed to approximately 800 general practitioners drawn randomly from the 1,200 GPs in the Thalès observatory. A participation of 180 doctors is expected.</p> <p>During the three month including periode, the participating doctors will systematically and consecutively include each patient who meets all of the eligibility criteria and will then give the patient a self-completed questionnaire.</p> |
| Database objective                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Main objective                                                         | To describe the general practitioner long term management plan for patients with symptoms of BPH in France                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Inclusion criteria                                                     | <p>? Patients over 50 years old</p> <p>? Patients with a diagnosis of BPH for at least 1 year</p> <p>? Patients currently treated with at least one of the treatments for symptoms of BPH</p>                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Population type                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |

|                                              |                                                                                         |
|----------------------------------------------|-----------------------------------------------------------------------------------------|
| Age                                          | Adulthood (45 to 64 years)<br>Elderly (65 to 79 years)<br>Great age (80 years and more) |
| Population covered                           | Sick population                                                                         |
| Gender                                       | Male                                                                                    |
| Geography area                               | National                                                                                |
| Detail of the geography area                 | France                                                                                  |
| Data collection                              |                                                                                         |
| Dates                                        |                                                                                         |
| Date of first collection (YYYY or MM/YYYY)   | 2009                                                                                    |
| Date of last collection (YYYY or MM/YYYY)    | 2010                                                                                    |
| Size of the database                         |                                                                                         |
| Size of the database (number of individuals) | [1000-10 000[ individuals                                                               |
| Details of the number of individuals         | 1098                                                                                    |
| Data                                         |                                                                                         |
| Database activity                            | Data collection completed                                                               |
| Type of data collected                       | Clinical data<br>Declarative data                                                       |
| Clinical data (detail)                       | Direct physical measures<br>Medical registration                                        |
| Declarative data (detail)                    | Paper self-questionnaire                                                                |
| Presence of a biobank                        | No                                                                                      |
| Health parameters studied                    | Quality of life/health perception<br>Others                                             |
| Other (detail)                               | Adherence (MMAS), Satisfaction (TSQM)                                                   |
| Procedures                                   |                                                                                         |

|                                                                                       |                                            |
|---------------------------------------------------------------------------------------|--------------------------------------------|
| Data collection method                                                                | E-CRF and self administrated questionnaire |
| Participant monitoring                                                                | No                                         |
| Links to administrative sources                                                       | No                                         |
| Promotion and access                                                                  |                                            |
| Promotion                                                                             |                                            |
| Access                                                                                |                                            |
| Terms of data access (charter for data provision, format of data, availability delay) | Publication on going                       |
| Access to aggregated data                                                             | Access on specific project only            |
| Access to individual data                                                             | Access on specific project only            |