

# POPCORN - Measurement of the changes in hepatitis B immunization coverage in infants, and the acceptability thereof, before reimbursement, then during the three years after reimbursement of InfanrixHexa® in France, among the general population

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## General

### Identification

|               |                                                                                                                                                                                                                                           |
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| Detailed name | Measurement of the changes in hepatitis B immunization coverage in infants, and the acceptability thereof, before reimbursement, then during the three years after reimbursement of InfanrixHexa® in France, among the general population |
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|                 |         |
|-----------------|---------|
| Sign or acronym | POPCORN |
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| CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation | -- |
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### General Aspects

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| Medical area | Infectious diseases |
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| Pathology (details) | Vaccine |
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| Keywords | infants, vaccine |
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### Scientific investigator(s) (Contact)

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| Unit | Laboratoire GSK |
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### Collaborations

| Funding                                                                |                                                                                                                                                                                                                                                                                             |
|------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Funding status                                                         | Private                                                                                                                                                                                                                                                                                     |
| 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)                                              | Repeated cross-sectional studies (except case control studies)                                                                                                                                                                                                                              |
| Database recruitment is carried out by an intermediary                 | A population file                                                                                                                                                                                                                                                                           |
| Database recruitment is 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.                     | Set of patients aged 2 years or younger in the general French population. Study conducted in the general population that will cover samples of homes with children aged 27 months or less, selected via the quota method.                                                                   |
| Database objective                                                     |                                                                                                                                                                                                                                                                                             |
| Main objective                                                         | Measure, in the general population, the variation in the proportion of infants (less than 27 months) vaccinated against hepatitis B according to the recommended plan between the initial measure and the measures repeated 1, 2 and 3 years after obtaining reimbursement of InfanrixHexa® |
| Inclusion criteria                                                     | ? Child aged 12 to 15 months or 24 to 27 months included at the time of the study,<br>? For whom a parent or legal guardian accepts to respond to the interview,                                                                                                                            |

? Resident of metropolitan France.

| Population type                              |                                                               |
|----------------------------------------------|---------------------------------------------------------------|
| Age                                          | Infant (28 days to 2 years)<br>Early childhood (2 to 5 years) |
| Population covered                           | General population                                            |
| Gender                                       | Male<br>Woman                                                 |
| 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)    | 2012                                                          |
| Size of the database                         |                                                               |
| Size of the database (number of individuals) | [1000-10 000[ individuals                                     |
| Details of the number of individuals         | 1200 every 4 years                                            |
| Data                                         |                                                               |
| Database activity                            | Data collection completed                                     |
| Type of data collected                       | Declarative data                                              |
| Declarative data (detail)                    | Face to face interview                                        |
| Presence of a biobank                        | No                                                            |
| Health parameters studied                    | Health care consumption and services<br>Others                |
| Care consumption (detail)                    | Medicines consumption                                         |
| Other (detail)                               | Acceptability of a prevention measure by vaccination          |

## Procedures

|                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
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| Data collection method | The interviews, face-to-face, will be conducted by survey takers who will have received training beforehand in the principles of sample surveys and in the specifics of this survey (in particular the vaccinal plan of the infant). They will go to the main domicile of the households. During the face-to-face interviews, the survey takers will perform the acceptability interviews with the parent in charge of the health of the children and then will proceed with taking information from the vaccinations booklet. In the event the vaccinations booklet is not accessible, the survey takers will suggest another time to return to the household. They will use the CAPI system (Computer Assisted Personal Interview) which allows for controlled key-entry of the data. |
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| Participant monitoring | No |
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|---------------------------------|----|
| Links to administrative sources | No |
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## Promotion and access

### Promotion

### Access

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|---------------------------------------------------------------------------------------|--------------------------------------|
| Terms of data access (charter for data provision, format of data, availability delay) | abstract (RICAI 2010)<br>publication |
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| Access to aggregated data | Access on specific project only |
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| Access to individual data | Access on specific project only |
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