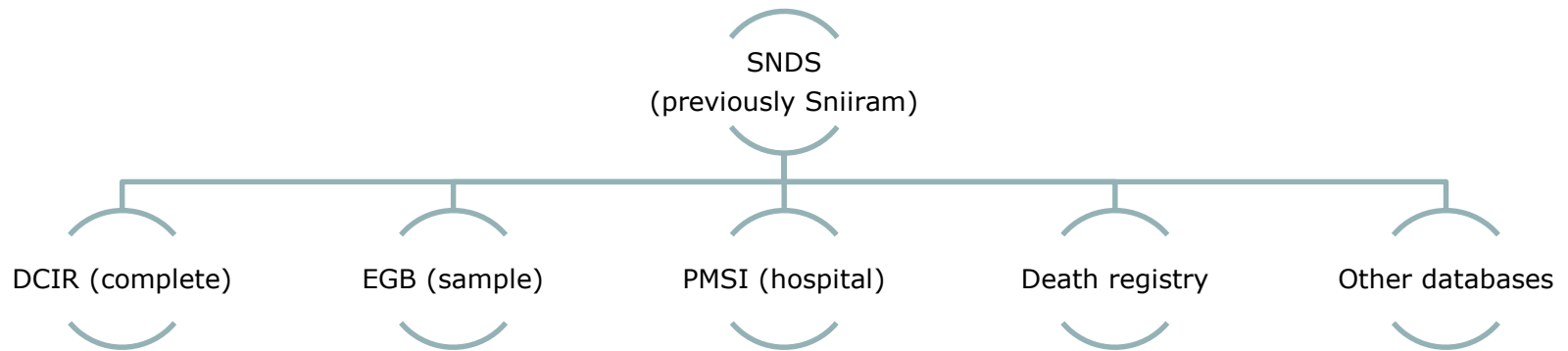


Short overview of the French health insurance database and how it can be used for Real World Evidence studies

Overall organization



- SNDS (système national des données de santé): national health data system
- Sniir-AM: (Système national d'information inter-régime de l'assurance maladie)
- DCIR (datamart de consommation inter-régimes): complete in-patient database
- EGB (Echantillon généraliste des bénéficiaires): permanent representative sample
- PMSI (hospital discharge database)
- Cepi-DC: death registry

SNDS

- Inter-scheme consumption data (données de consommation inter-régimes [DCIR])
- 3 main schemes and other minor schemes, 69 million people, amounting to 99% of the total French population
 - **General scheme including salaried employees of the private sector and their dependents (i.e. about 76% of the population living in France)**
 - **In addition local mutualist sections, e.g. civil servants**
 - **Self-employed workers scheme**
 - **Agricultural scheme**

DCIR

- Data are collected prospectively at the local level, and then transmitted to the National Health Insurance Fund for Salaried Workers (Caisse nationale de l'assurance maladie des travailleurs salariés [CNAMTS]) that hosts all the data in a huge digital warehouse
- A claims database: data used for billing and reimbursement of:
 - **outpatient health care consumption**
 - **→ not first developed for research**
- Beneficiaries are identified in SNDS by a pseudonymised identifier
 - **Same identifier lifelong**
- Past 10 years on demand

Simplified architecture of SNDS

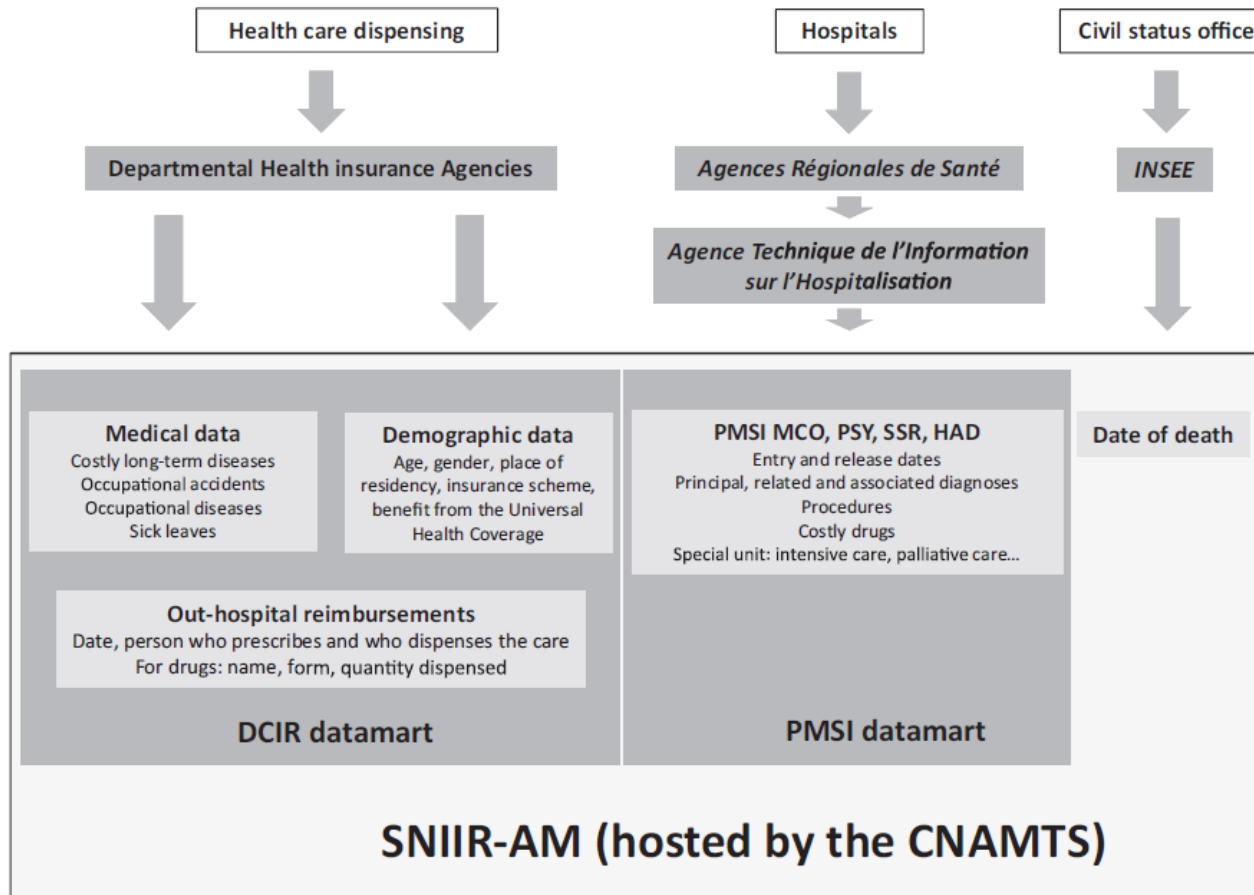


Fig. 1. Simplified architecture of the French National Health Insurance Information System. CNAMTS: *Caisse nationale de l'assurance Maladie des travailleurs salariés* (National Health Insurance Fund for Salaried Workers); DCIR: *données de consommation inter-régimes* (Inter-Scheme Consumption Data); HAD: *hospitalisation à domicile* (Home Hospitalization); INSEE: *Institut national des statistiques et des études économiques* (National Institute of Statistics and Economic Studies); MCO: *médecine, chirurgie, obstétrique* (Medicine, Surgery, Obstetrics); PMSI: *programme de médicalisation des systèmes d'information* (Program for the Medicalization of Information Systems); PSY: psychiatry; SNIIR-AM: *Système national d'information inter-régime de l'assurance maladie* (National Health Insurance Information System); SSR: *services de suite et de réadaptation* (after-care and rehabilitation).

Source: 1

DCIR (complete DB) strengths

- number of people
- extensive coverage
- starts in 2005
- accurate description and quantification of drug exposure, no recall bias
- individual data on patients
- Specifically appropriate for:
 - **signal detection or long-term follow up**
 - **rare disease**
 - **linkage of outside sources**

DCIR limitations

■ Lack of information

- **Socioeconomic characteristics**
- **Type of employment, employment status**
- **Risk factors**
- **Disease severity and stage**
- **Results of clinical examinations**
- **Laboratory (biology) test results**
- **Over-the-counter drugs not recorded**
- **Whether drugs have been taken**
- **Reasons for diagnosis of medical or paramedical consultations**
- **Drugs dispensed during acute or long ward, apart from costly drugs on the excess list**
-

■ Complexity

- **An extraction of the SNDS has several dozen of tables , hundreds of variables**

EGB (sample)

- 1/97th random sample of total beneficiaries of national healthcare insurance, and their dependents, in terms of age and sex
- started in 2005
- about 780,000 people
- Each quarter,
 - adds neonates, newcomers of schemes included in the EGB, foreigners arriving in France
 - leaves: deceased persons, persons who leave schemes, foreigners leaving France
- Appropriate for:
 - feasibility and algorithm testing
 - long-term research on more frequent diseases.

Type of studies

- **Enrichment of outside databases**
 - **Clinical studies: social security number (NIR) or probabilist linkage with a 80% to 90% success**
 - **Cohorts, specific registries**
- **Epidemiological study**
 - **Assessment of incidence and prevalence of diseases**
- **Pharmacoepidemiological study**
 - **Adherence/persistence study**
 - **Post-registration studies (PRS) (5)**
 - **Post-marketing authorization safety study**
 - **Drug effectiveness study**
- **Economic study**
- **Care pathway study**
- **...**

Examples

- Follow-up of **proper usage of Duoplavin ® in real life** with EGB data (anti platelet agent). Work in progress.
- **Real life effectiveness of Tecfidera® in multiple sclerosis** with Sniiram data. Work in progress.
- **Retrospective study of patients with Zepatier ® delivery (C hepatitis)**. Work in progress
- Management of pulmonary arterial hypertension in France. Work in progress
- Care pathway and clinical and economical burden of patients suffering from multiple myeloma in France. Work in progress
- **Prevalence and incidence of Sjögren's Syndrome in France: A Claims-based Nationwide Study**. Work in progress

Examples

- Latry P and al. **Adherence with statins in a real-life setting is better when associated cardiovascular risk factors increase:** a cohort study. BMC Cardiovasc Disord. 2011 Jul 26;11:46. doi: 10.1186/1471-2261-11-46.
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- Mathonnet M. **What is the care pathway of patients who undergo thyroid surgery in France and its potential pitfalls?** A national cohort. BMJ Open. 2017 Apr 7;7(4):e013589. doi: 10.1136/bmjopen-2016-013589.
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Approval and access to data

Normal access

- Expert committee+Data protection authority: ca. 9 months

Fast access

- EGB(representative sample)/ ca. three months
- Hospital database: self-declaration one month

Permanent access

- Health authorities and accredited agencies

Access to data

- Need for a “public interest” in the research
- Data available with a remote secured access in a “bubble”
- Non-profit and profit research can apply
- Protocols needed to get approval
- Results made public at the end of the study
- Two specific objectives are explicitly prohibited: the promotion of health products to practitioners and health care institutions and the exclusion of insurance coverage or modifications of health insurance premiums.

Economic model

■ Currently

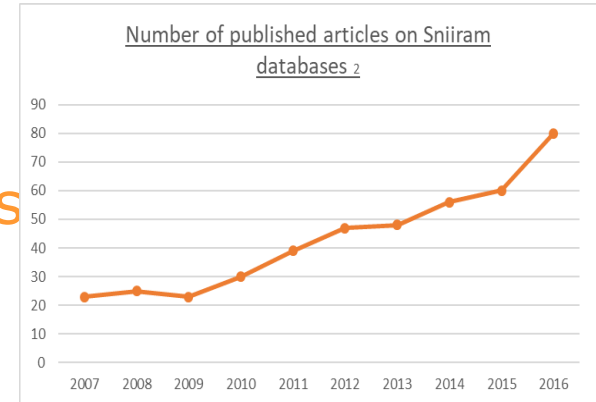
- **EGB/DCIR: 0 € for data**
- **PMSI(hospital): database charged to data researcher**

■ Planned for early 2020

- **Upon request of health authorities**
 - **No change**
- **In other cases**
 - **DCIR (complete database): about 22 k€ per projet**
 - **EGB (representative sample): 23k€ per end-user and yeard**
 - **PMSI (hosipital): about 11k€ per end-user and per year**

Next

- Increased number of publications
- Additional healthdatabases
 - Disabled people database
 - Complementary health insurance
- SNDS→Healthdata hub
 - New registries



Conclusions

- A whole-life, whole-country coverage
- One of the largest healthcare database in the world
- Appropriate for:
 - **(very) rare events: DCIR (complete database)**
 - **More common patterns: EGB (permanent representative sample)**
- Richness of data, with limitations in certain areas
- Reasonable costs and time of access
- Development in progress for more qualitative data

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- 2. P. Tuppin and al, From the système national d'information interrégimes de l'Assurance Maladie (SNIIRAM) to the système national des données de santé (SNDS) in France, *Revue d'Epidémiologie et de Santé Publique* 65S (2017) S149–S167
- 3. A. Palmaro, G. Moulis, F. Despas, J. Dupouy, M. Lapeyre-Mestre. Overview of drug data within French health insurance databases and implications for pharmacoepidemiological studies, *Fundamental and clinical pharmacology* (2016)
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- Performs studies on SNDS data
- Gives training on SNDS data