Asthma management in France and the United Kingdom

1. Objective

To compare asthma management between patients in the United Kingdom (UK) and in France, more particularly regarding at-risk treatment patterns.

2. Data source

2.1. For France:

EGB database (1/97th random sample of the national French claims data)

2.2. For the UK:

OPCR database (EHRs enriched with PROs)

3. Study design

Two successive cohorts of persistent asthma patients will be defined in 2007-2008, then in 2013-2014.

4. Inclusion / exclusion criteria

4.1. 2007/2008 cohort

▪ Inclusion criteria / entry in the cohort

- French patients: aged 6 to 40 years with at least 3 dispensations of respiratory drug (R03 ATC code except R03DX05, R03AC18, R03BB04, R03BB01, R03AK03 and R03AK04) in 2007 at 3 different dates will qualify to enter the cohort. The date of entry in the cohort will be the date of the 3rd dispensation (entry date).

- UK patients: aged 6 to 40 years with a diagnosis of asthma recorded in the database in 2007. *Patients older than 40 will be described as well in a complementary analysis, but they will not be compared to French patients.*

▪ Exclusion criteria

They will be applied during the 12 months preceding entry date:

. For all patients:

- Any use of Omalizumab
- Chronic use of oral corticosteroids: > 4 packaging dispensed over 12 months
- COPD (previous hospital admission and/or long-term disease status): J41, J42, J44 and J96.1 ICD-10 codes + dispensing/prescription of tiotropium + dispensing/prescription of indacaterol
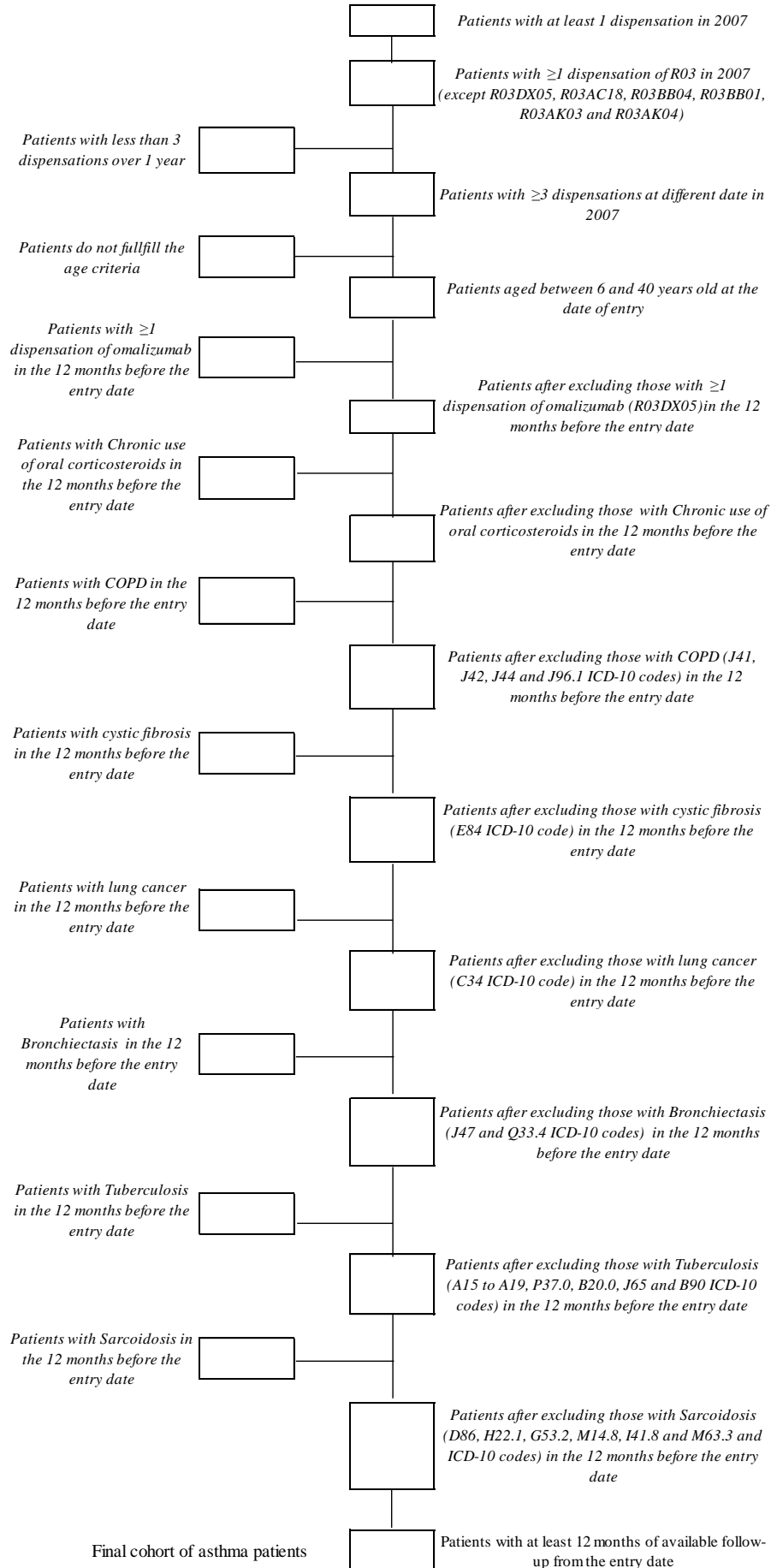
In France, long-term-disease (LTD) status is specific for patients suffering from severe chronic conditions, in need of expensive, long-term therapy. For these patients, the National Health Care Systems pays directly 100% of all healthcare expenses related to the specific LTD, so waiving any co-payment. Diagnoses (ICD-10) are documented for LTD and hospitalization.

- Cystic fibrosis (previous hospital admission and/or long-term disease status): E84 ICD-10 code
- Lung cancer (previous hospital admission and/or long-term disease status): C34 ICD-10 code
- Bronchiectasis (previous hospital admission and/or long-term disease status): J47 and Q33.4 ICD-10 codes
- Tuberculosis (previous hospital admission and/or long-term disease status): A15 to A19, P37.0, B20.0, J65 and B90 ICD-10 codes
- Sarcoidosis (previous hospital admission and/or long-term disease status): D86, H22.1, G53.2, M14.8, I41.8 and M63.3 and ICD-10 codes
- Patients with less than 12 months of available follow-up from the entry date

. For UK patients:

- Patients with no asthma prescriptions recorded in the 12 months before entry date

Flowchart selection of cohort in 2007

Patients with at least 1 dispensation in 2007

Patients with ≥1 dispensation of R03 in 2007 (except R03DX05, R03AC18, R03BB04, R03BB01, R03AK03 and R03AK04)

Patients with less than 3 dispensations over 1 year

Patients with ≥3 dispensations at different date in 2007

Patients do not fullfill the age criteria

Patients aged between 6 and 40 years old at the date of entry

Patients with ≥1 dispensation of omalizumab in the 12 months before the entry date

Patients after excluding those with ≥1 dispensation of omalizumab (R03DX05)in the 12 months before the entry date

Patients with Chronic use of oral corticosteroids in the 12 months before the entry date

Patients after excluding those with Chronic use of oral corticosteroids in the 12 months before the entry date

Patients with COPD in the 12 months before the entry date

Patients after excluding those with COPD (J41, J42, J44 and J96.1 ICD-10 codes) in the 12 months before the entry date

Patients with cystic fibrosis in the 12 months before the entry date

Patients after excluding those with cystic fibrosis (E84 ICD-10 code) in the 12 months before the entry date

Patients with lung cancer in the 12 months before the entry date

Patients after excluding those with lung cancer (C34 ICD-10 code) in the 12 months before the entry date

Patients with Bronchiectasis in the 12 months before the entry date

Patients after excluding those with Bronchiectasis (J47 and Q33.4 ICD-10 codes) in the 12 months before the entry date

Patients with Tuberculosis in the 12 months before the entry date

Patients after excluding those with Tuberculosis (A15 to A19, P37.0, B20.0, J65 and B90 ICD-10 codes) in the 12 months before the entry date

Patients with Sarcoidosis in the 12 months before the entry date

Patients after excluding those with Sarcoidosis (D86, H22.1, G53.2, M14.8, I41.8 and M63.3 and ICD-10 codes) in the 12 months before the entry date

Final cohort of asthma patients

Patients with at least 12 months of available follow-up from the entry date

4.2. 2013/2014 cohort

Inclusion and exclusion criteria will be similar to those presented for the 2007/2008 cohort, but during the 2013/2014 period:
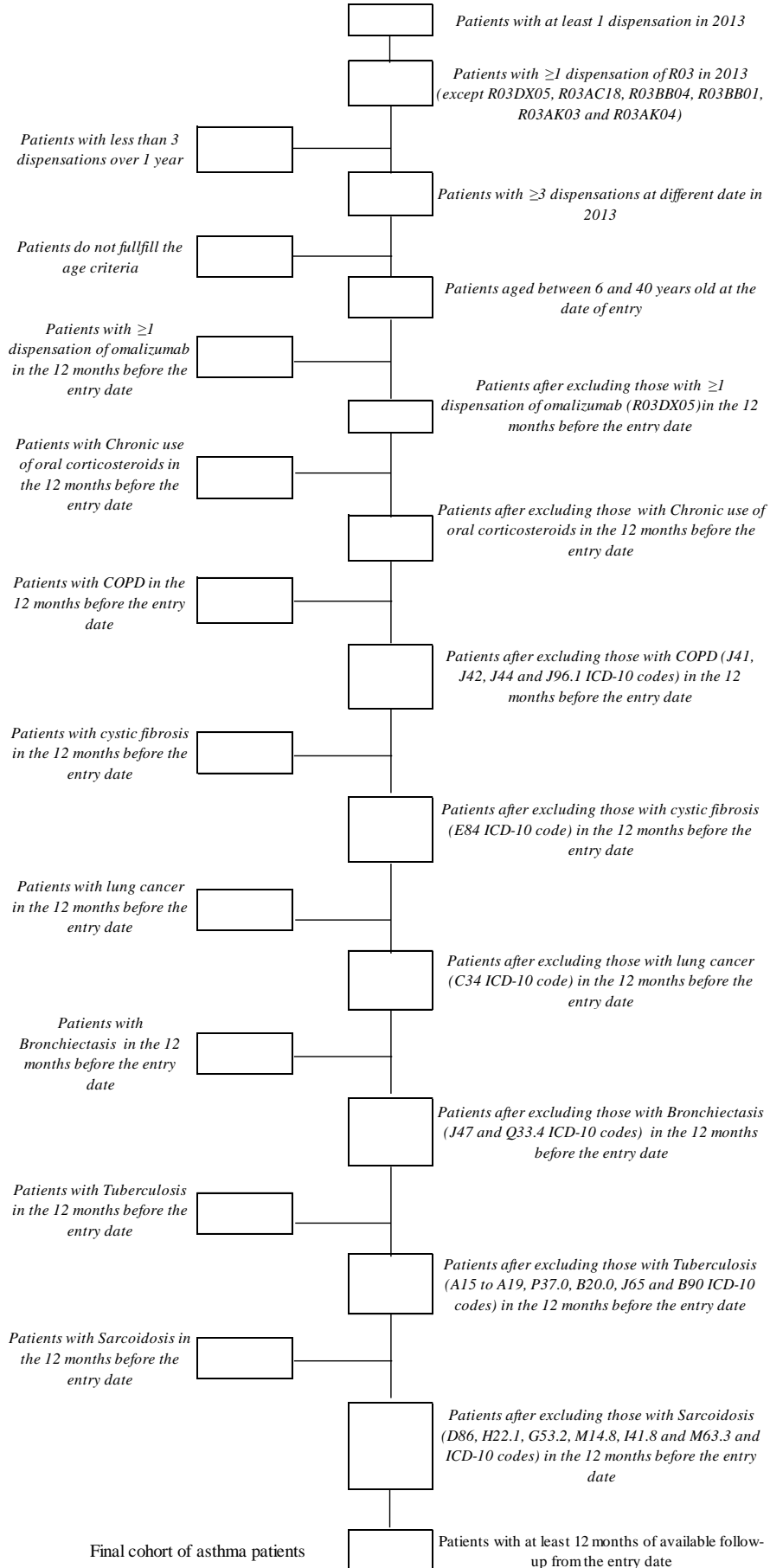
- **Inclusion criteria / entry in the cohort**

- French patients: aged 6 to 40 years with at least 3 dispensations of respiratory drug (R03 ATC code except R03DX05, R03AC18, R03BB04, R03BB01, R03AK03 and R03AK04) in 2013 at 3 different dates will qualify to enter the cohort. The date of entry in the cohort will be the date of the 3rd dispensation (entry date=T0).

- UK patients: aged 6 to 40 years with a diagnosis of asthma recorded in the database in 2013. *Patients older than 40 will be described as well in a complementary analysis, but they will not be compared to French patients.*

- **Exclusion criteria**
The same criteria will be applied during the 12 months preceding entry date.

Flowchart selection of cohort in 2013

Patients with at least 1 dispensation in 2013

Patients with ≥1 dispensation of R03 in 2013 (except R03DX05, R03AC18, R03BB04, R03BB01, R03AK03 and R03AK04)

Patients with less than 3 dispensations over 1 year

Patients with ≥3 dispensations at different date in 2013

Patients do not fullfill the age criteria

Patients aged between 6 and 40 years old at the date of entry

Patients with ≥1 dispensation of omalizumab in the 12 months before the entry date

Patients after excluding those with ≥1 dispensation of omalizumab (R03DX05) in the 12 months before the entry date

Patients with Chronic use of oral corticosteroids in the 12 months before the entry date

Patients after excluding those with Chronic use of oral corticosteroids in the 12 months before the entry date

Patients with COPD in the 12 months before the entry date

Patients after excluding those with COPD (J41, J42, J44 and J96.1 ICD-10 codes) in the 12 months before the entry date

Patients with cystic fibrosis in the 12 months before the entry date

Patients after excluding those with cystic fibrosis (E84 ICD-10 code) in the 12 months before the entry date

Patients with lung cancer in the 12 months before the entry date

Patients after excluding those with lung cancer (C34 ICD-10 code) in the 12 months before the entry date

Patients with Bronchiectasis in the 12 months before the entry date

Patients after excluding those with Bronchiectasis (J47 and Q33.4 ICD-10 codes) in the 12 months before the entry date

Patients with Tuberculosis in the 12 months before the entry date

Patients after excluding those with Tuberculosis (A15 to A19, P37.0, B20.0, J65 and B90 ICD-10 codes) in the 12 months before the entry date

Patients with Sarcoidosis in the 12 months before the entry date

Patients after excluding those with Sarcoidosis (D86, H22.1, G53.2, M14.8, I41.8 and M63.3 and ICD-10 codes) in the 12 months before the entry date

Final cohort of asthma patients

Patients with at least 12 months of available follow-up from the entry date
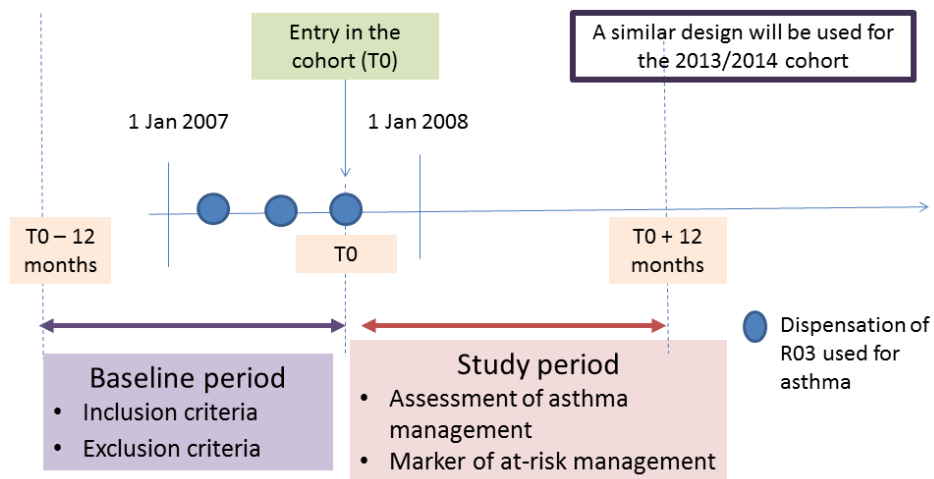
5. Study timelines

Asthma management will be assessed during the 12 months following entry date.

The 12 months preceding entry date will be the baseline period.

Study timelines for the 2007/2008 cohort

6. Analyses

For each country, first in the 2007/2008 period, and next in the 2013/2014 period

6.1. Description of asthma management

1. LABA with no ICs (salmeterol & formoterol)
2. Ratio units dispensed of LABA/ICs ≥2 (unit = canisters or prescriptions in the UK)
3. High use of SABAs (>= 12canisters dispensed/prescribed)

Criteria 1 and 2 will be first computed with all LABAs, then complementary analyses will be performed by focus in specifically on salmeterol then formoterol.

6.2. Comparisons

a. Within country

- Comparison of asthma management in 2007/2008 vs 2013/2014
- Any changes in "at-risk" management markers? More particularly for LABA without ICs,

b. Between countries

In 2013/2014: Differences in management between countries? Differences in prevalence of at risk treatment patterns?