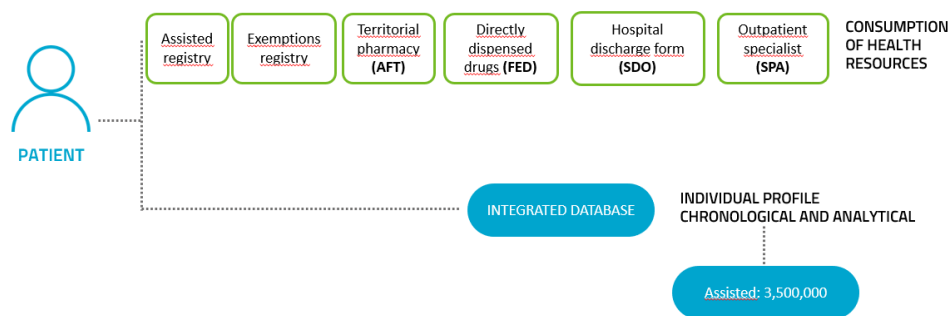


## Section 1. Methodology of the study

Authors: L. Degli Esposti, C. Veronesi, V. Perrone  
CliCon S.r.L. Health Economics & Outcomes Research

A retrospective observational study was conducted on the services provided by the National Health Service to patients diagnosed with psoriasis and undergoing biological therapy. Data were extracted from the current administrative flows of a sample of institutions distributed on the Italian national territory, for a total of about 3.5 million patients (Fig 1).



*Fig. 1 Databases queried for analysis purposes*

All patients with a diagnosis of psoriasis identified by: i) the presence of at least one hospitalization having as discharge diagnosis code (main and secondary) ICD-9-CM 696; ii) the presence of an active exemption code for psoriasis (code 045.696.1), iii) the presence of at least one prescription of topical antipsoriatic drugs (ATC code: D05A) were identified during the period between January 1, 2013 and October 31, 2019 (inclusion period).

Among subjects identified with a diagnosis of psoriasis, only patients aged  $\geq 18$  years who were found to be treated with a biologic drug indicated for the treatment of psoriasis subsequent to the diagnosis of psoriasis during the inclusion period were included. The first prescription of a biological drug during the inclusion period was defined as the index date.

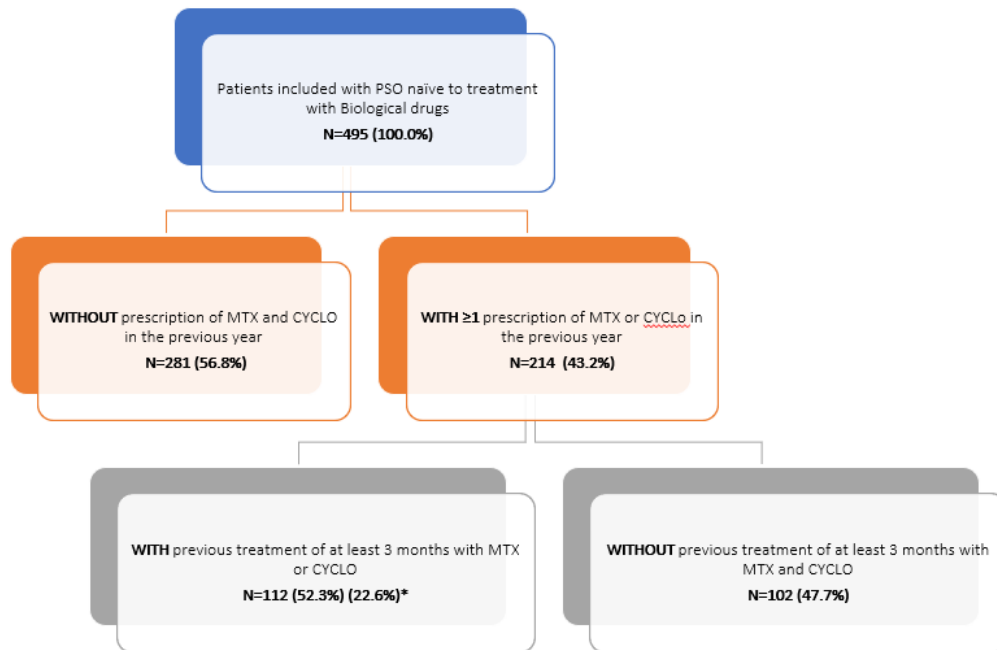
Excluded from the analysis were patients younger than 18 years of age, those treated with a biological drug in the 12 months preceding the index date, and patients with a concomitant diagnosis of: rheumatoid arthritis (ICD-9 code: 714 or exemption code 006); ankylosing spondylitis (ICD-9 code: 720.0 or exemption code 054), psoriatic arthritis (ICD-9 code: 696.0 or exemption code 045.696.0), Crohn's disease (ICD-9 code: 555 or exemption code 009.555), ulcerative colitis (ICD-9 code: 556 or exemption code 009.556); and patients treated with systemic corticosteroids (ATC code H02) in the 12 months preceding the index date (criterion for identification of a possible diagnosis of psoriatic arthritis).

Patients with psoriasis and started on treatment with biologic drugs (naïve patients) were classified according to the presence/absence of prescriptions for Methotrexate (ATC codes: L01BA01,

L04AX03) or Cyclosporine (ATC code: L04AD01), assessed during the 12 months preceding the first biologic prescription (ANALYSIS 1) and during the entire available period preceding the first biologic prescription (ANALYSIS 2).

## Section 2. Results of the study

In the first analysis, 495 patients with psoriasis naïve to treatment with biological drugs were included, of whom 281 (56.8%) had not received prior treatment with Methotrexate or Cyclosporine in the 12 months preceding the index date (Fig. 2); 43.2% (N=214) had been treated with Methotrexate or Cyclosporine in the year preceding the start of biological therapy, and of these 52.3% (N=112) had received conventional treatment for a period of at least 3 months. Compared to the total population included (N=495), 22.6% of patients had prior treatment with Methotrexate or Cyclosporine of at least 3 months in the year prior to the start of biological treatment (Fig.2).



*\*Percentage calculated from 495 patients with PSO*

*MTX: Methotrexate; CYCLO: Cyclosporine*

*Fig. 2 Evaluation 12 months pre index date. Stratification by presence of previous treatment with methotrexate/cyclosporine and by duration of treatment*

Analyzing the entire available period prior to the index date (analysis 2), of the 468 patients included, 37.4% (N=175) had no conventional treatment with Methotrexate or Cyclosporine prior to the initiation of biologic therapy; 62.6% (N=293) had been treated with Methotrexate or Cyclosporine during the entire period prior to the initiation of biologic therapy, and of these, 29.7% (N=87) had received conventional treatment for a period of at least 3 months. Compared to the total population included (N=468), only 18.6% of patients had been prescribed conventional therapy for at least 3 months, during the entire period prior to the index date.