

**Objectives:** Long-term observation of systemic antipsoriatic treatment in Germany (biologics and non-biologics) with special focus on long-term effectiveness and safety in routine care as well as on specific patient benefit.

**Performance:** Starting with the first application of a conventional systematic or biological agent, PsoBest documents the long-term course of patients with moderate to severe psoriasis. Thus, patients who receive systemic or biological agents with market approval after 2005 can be included in PsoBest. The designated observation time per patient is ten years, disregarding the therapies being taken or therapy-free periods within this observational time.

**Design:** Multi-centre, prospective, national, non-interventional patient registry

**Participants:** Patients with plaque-type psoriasis (Pso) or psoriatic arthritis (PsA), age  $\geq 18$  years, being administered a specific systemic drug for the first time, written informed consent to participate, sufficient language skills (German) are able to be included. Patients diagnosed with pure forms of psoriasis inversa or psoriasis pustulosa are excluded. Participation in clinical trials at the day of admission to the registry is not allowed, while participation in a clinical trial during the registry time is.

**Visits:** Visits are carried out every 3 months alternating as dermatology office visits ( $n = 22$ ) and as direct mail to participants by CVderm ( $n = 19$ ). Observation time is currently 10 years.



Follow-ups with physician appointments (A) and participant contacts by mail (P)

**Main criteria:** Clinical course (PASI), quality of life (DLQI), patient benefit (PBI), side effects.

**Organisation:** Begin of the registry was 01.09.2007, first participant was registered 01.12.2007. All German dermatology offices can participate and include appropriate patients in the registry. After site registration all material needed is provided by CVderm, including case report forms. Forms filled out, have to be send to CVderm by fax or mail. New sites and participants can be registered any time.

**Inclusion:** For every new PsoBest participant, these steps are necessary:

- Patient information, obtain informed consent form including GDPR and send to CVderm.
- Fill out CRF (dermatologist and patient) and send both forms to CVderm.
- Fix appointment for follow-up visit.

**Monitoring:** Participating registry sites are visited by the CVderm at their own request and according to a fixed schedule. The objectives of the visits are to advise on the implementation as well as the quality control of the documentation within PsoBest. The visit is reimbursed to the dermatologist at € 80.

**Payment:** The dermatologist will receive an honorary of € 45 for each protocol-compliant, completed and returned visit documentation, for the inclusion visit of € 84.

**Ethics:** The positive vote of the ethics committee of the Ärztekammer Hamburg from 24.07.2007 is available for the psoriasis registry PsoBest. 2 Amendments were evaluated on 07.05.2015 and 20.07.2022.

**Lead:** The psoriasis register PsoBest is carried out by the CVderm at the University Medical Center Hamburg-Eppendorf (Head: Prof. Dr. Augustin) on behalf of the DDG and the BVDD. The project is accompanied by a scientific advisory board to which the presidents and other members of both associations belong.

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