PsoBest CVderm

German Psoriasis Registry PsoBest

· access to data · options for analytics · value generation

Data and Analyses in the German Psoriasis Registry PsoBest

Many patients, broad coverage of care, real-world evidence. As a supporting company of PsoBest, you have exclusive access to data from routine psoriasis care in Germany, with all its facets.

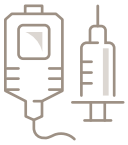
The PsoBest registry observes adult patients with moderate to severe psoriasis. Patients are registered at the start of naïve systemic treatment and followed for up to 10 years regardless of the further course of treatment. Data are collected via standardized questionnaires in dermatological practices and clinics as well as via postal patient interviews. In PsoBest, clinical parameters (e.g. the Psoriasis Area and Severity Index (PASI)), patient-reported outcomes (e.g., the Dermatologic Quality of Life Index (DLQI)), drug-specific treatment and safety data are documented.

How to use the following lists ...

The following lists are intended to help you to get started with the numerous analyses options in the registry. For a complete analysis approach, please select the medication and patients you are interested in, as well as the type of analysis and its content-related questions. Of course, you can combine the components of the analyses with each other or pick up only individual aspects. Feel free to contact us with a fully developed idea or even if we may still give any advice on the selection.

Pick the drug of interest ...

Biological and biosimilar drugs



Anti-TNFa-Inhibitor	Adalimumab (Humira®) / Adalimumab biosimilars / Certolizumab / Etanercept (Enbrel®) / Etanercept biosimilars / Infliximab (Remicade®) / Infliximab biosimilars / Golimumab
Anti-IL-17-Inhibitor	Bimekizumab / Brodalumab / Ixekizumab / Secukinumab
Anti-IL-23-Inhibitor	Guselkumab / Risankizumab / Tildrakizumab
Anti-IL-12/23-Inhibitor	Ustekinumab

Non-biological systemic drugs

PDE-4 inhibitor	Apremilast
Calcineurine inhibitor	Ciclopsorine
Fumaric acid esters	Fumaderm® / Skilarence®
JAK inhibitor	Tofacitinib / Upadacitinib
Folat acid antagonist	Methotrexate
Dihydroorotate-DH-antagonist	Leflunomid
Retinoids	Acitretin

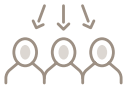
Phototherapy, topical drugs and drug free periods

Phototherapy	UV-A/B / PUVA
Topical drugs	Glucocorticosteroids / vitamin A and D analogues / dithranol / salicylic acid / urea

Choose your approach ...

- ○ Descriptive analysis
- ○ Comparative analysis
- ○ Predictive analysis
- ○ Associative (corr. expl. structure)
- ○ Nested cohort/registry study
- ○ Health economic analysis
- ○ Health service analysis

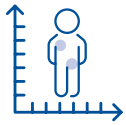
Select your patients by ...



- ○ Treatment at inclusion
- ○ Treatment gaps
- ○ Switch to treatment
- ○ Subgroups/cohorts
- ○ Observation time

Set your focus ...

Baseline I: standard · Get first insight on what patients we are talking about.



Personal data	Age, gender
Patient characteristics	Weight, height, BMI, waist and hip circumference, waist-hip ratio (WHR)
Psoriasis history	Duration of illness, age at onset, positive family history
Psoriasis type	Plaque type, guttate, nail involvement, intertriginous, pustular, psoriatic arthritis
Clinical severity	PASI, BSA, PGA

Baseline II: extended · If you want to know more background.

Comorbidity	Grouped by classes, e.g. cardiovascular diseases, CNS, metabolic diseases ...
Addiction	Consumption of alcohol and tobacco and other drug abuse
Pregnancy	Pregnancy and breastfeeding, child wish

Baseline III: health care setting · Understand the frame of health care in our patients.

Setting	Outpatient or office-based care
Region and insurance	Health insurance district/region/infrastructural type (e.g. rural, urban), health insurance
Quality of care	Percieved quality of care

Baseline IV: patient burden and needs · Get deep insights in the patient‘s perspective.

Burden of disease	Treatment burden, patient assesment of activity of Pso
Comorbidity	Total comorbidity burden (# comorbidity groups (score in development))
Topology	Prevalence of and severity in specific body regions (grid scheme of 1044 single micro-areas)
Patient needs	Patient needs questionnaire
Quality of life	DLQI, EQ-5D VAS, SF-12 (assessed 2015-2021), DLQI single items
Anxiety and depression	HADS (assessed 2015-2021)

Baseline V: pretreatment · On patient history.

Systemic pretreatment	All prior systemic antipsoriatics incl. duration (single level and pooled)
Phototherapie	Prior UV-A/B, PUVA treatment incl. duration
Topical pretreatment	Only if last treatment before inclusion in registry

Baseline VI: psoriasis arthritis · What about joints in detail?

PsA diagnosis	Diagnosis (ensured/algorithmic); clarification of diagnosis planned (e.g. radiology)
PsA symptoms	Pain, swelling, morning stiffness, enthesitis, dactylitis
PsA locations	Number/location of swollen/tender joints (body silhouette)
PsA activity	Physician assesment of PsA activity, patient assesment of PsA activity and pain

Health economics: costs · Insights into direct, indirect and intangible costs.

Socio-economics	Occupation, insurance, family background/household
Education	Degree of education
Health care utilization	Number of visits to physicians (e.g. general practitioner, rheumatologist) in the past 12 months
Inpatient care	Hospital stays in the past year
Drug utilization	Antipsoriatic drug consumption
Indirect costs	Days off work
Cost of illness	Comprehensive analysis of psoriasis-related costs

Health services research: health care · Can health care be improved?

Satisfaction	Satisfaction with health care as outcome

Outcomes I: drug survival + treatment ways · Explore the many facets of treatment descisions.

Pretreatments	All prior systemic antipsoriatics incl. duration (single level and pooled)
Treatment switches	Treatment switch in the course of registry (single level and pooled)
Subsequent treatment	Treatment after switch (single level and pooled)
Drug survival rate	Period of treatment from start to stop; retention rates
Reason for discontinuation of drugs	Reasons: Skin clearance, onset of contraindication, safety issues, lack/loss of efficacy, other

Outcomes II: clinical outcomes · Comprehensive view on the course of disease and the effects of drug treatment.

Drug use	Dosage and application
PASI	Absolute/relative course and reduction, PASI-75/90/100, any other threshold
BSA	Absolute/relative course and reduction, any threshold
PGA	Absolute/relative course and reduction, any threshold
Topology	Course of severity in specific body regions (grid scheme of 1044 single micro-areas) including special areas
Phenotype	Change in phenotype

Outcomes III: patient reported outcomes · Understand the patients view along the course of treatment.

Patient needs	Shift of patient needs (annual measurement)
DLQI	Proportion reaching DLQI 0/1, any other threshold MCID
PBI	Total PBI, partial PBI by item of each visit
Further PRO outcomes	EQ-5D VAS, single items on satisfaction, HADS, SF-12 (both assessed 2015–2021)

Safety I: adverse events · All about drug safety.

Adverse events	Events/100 patient years, % patients affected; causality (MedDRA)
Events of special interest (specify)	Events/100 patient years, % patients affected; causality
Serious adverse events	Events/100 patient years, % patients affected; outcomes, causality

Safety II: comorbidity · A focus on conditions emerging from drug treatment and course of disease.

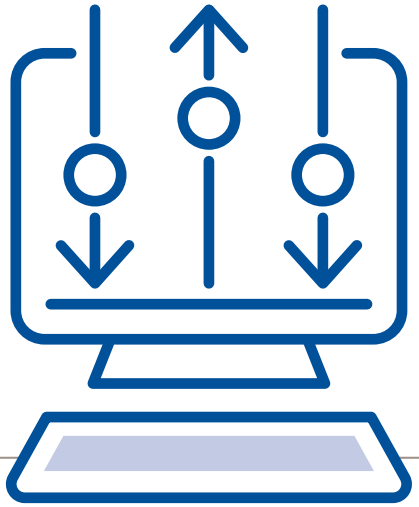
Incidence	Onset of (psoriasis-related) comorbidity: rate, time to event, predictors

Value generation by the German National Psoriasis Registry PsoBest

PsoBest ensures the continuous recording of short- and long-term outcomes of systemic therapies in *plaque-type psoriasis* and *psoriatic arthritis* in Germany. This results in the following functions and benefits of PsoBest:

1. Continuous pharmacovigilance and readiness to receive 24/7 safety reports on systemic therapeutics with psoriasis approval in Germany, including company follow-ups on reported events.
2. Periodic, semi-annual safety reporting for the supporting pharmaceutical companies as pharmacovigilance report of the corresponding drug and comparator cohorts.
3. Through 1. and 2.: Ensuring optimized patient safety for the systemic therapy of *plaque-type psoriasis* in Germany and creating a basis of trust for patients, prescribing physicians, health insurances and health care policy.
4. Real-world evidence base regarding efficacy, safety, patient benefit in the long-term course of comorbidity, comedication, combination/alternative therapy to optimize the quality of care for patients.
5. Generation of pharmacoeconomic parameters, e.g. cost-benefit for health care policy, health insurances and industry.
6. Knowledge platform on best practice care including standards of indication, application, safety and cost-effectiveness of systemic drugs for German dermatologists.
7. Real-world evidence source for the information of stakeholders (e. g. payers, G-BA, ministries) and the interested public.
8. Participation in the European network of psoriasis registries Psonet including a proactive drug surveillance system and a rapid alert system permitting robust signal detection and validation.
9. Provision of representative, nation-wide data to the pharmaceutical companies on the best practice mode of using systemic therapeutics in psoriasis.
10. Analyzing and obtaining data on the effects of systemic drugs on clinical and patient-reported outcomes.
11. Reporting to pharmaceutical companies on the use patterns of systemic drugs including drug survival over the long-term.

12. Review and reporting on the quality of care for plaque-type psoriasis in Germany.
13. Epidemiological reporting on phenotype, comorbidity and psychosocial determinants of moderate to severe plaque-type psoriasis in Germany.
14. Characterization of drug supply in psoriasis and positioning of all systemic drugs for pharmaceutical companies.
15. Provision of information on drug use for the preparation of dossiers in the risk-benefit assessment by pharmaceutical companies including information on appropriate comparator therapies and on the care of patient profiles.
16. Provision of valid and verified health care information for the benefit assessment of drugs (AMNOG) to pharmaceutical companies, the Federal Joint Committee (G-BA), IQWIG, self-governance and medical specialist groups.
17. Dissemination of PsoBest conclusions to the community for the improvement of quality of routine care for plaque-type psoriasis in Germany with system therapeutics via the regional psoriasis networks, quality circles and other specialist groups.
18. Communication of the appropriate use of antipsoriatic drugs to the Association of Statutory Health Insurance Physicians and controling bodies for proper use of drugs (Prüfeinrichtungen) for the sake of supporting the prescribing dermatologists and providing an innovative, quality-assured drug supply.



List of Variables in PsoBest

		CRF			First year					Annual repetition			
	Data type	Doctor	Patient	Visits month	V1 0	V2 3	V3 6	ZV1 9	V4 12	ZV2 15	V5 18	ZV3 21	V6 24
Inclusion criteria*	D	x			x								
Exclusion criteria*	D	x			x								
Socio-demographic status													
Gender*	D	x			x								
Age*	N	x			x								
Relatives	N		x		x								
Hospitalizations	N		x		x				x				x
Job	N		x		x				x				x
Type of job	C		x		x				x				x
Part-time job [hours]	N		x		x				x				x
Days of illness	N		x		x				x				x
Work days lost	N		x		x				x				x
First diagnosis	T		x		x								
Compliance	C	x	x			x	x	x	x		x		x
Family status	C		x		x				x				x
Size of household	N		x		x				x				x
Graduation	C		x		x								
Health insurance	C		x		x				x				x
Smoking	D		x		x				x				x
Smoking, quantity	N		x		x				x				x
Smoking, no, reasons	V		x		x				x				x
Alcohol	D		x		x				x				x
Kind of alcohol, quantity	C		x		x				x				x
Patient Characteristics													
Size*	N	x			x				x				x
Weight*	N	x			x				x				x
BMI*	N	x			x				x				x
Hip circumference*	N	x			x				x				x
Waist circumference*	N	x			x				x				x
WHR*	N	x			x				x				x
Additional questions on pregnancy	C	x				x	x		x		x		x
Characteristics of psoriasis													
Characteristics of psoriasis*	C	x			x								
Involvement of finger nails*	D	x			x	x	x		x		x		x
Number of nails involved*	N	x			x	x	x		x		x		x
% of finger nail involved*	N	x			x	x	x		x		x		x
Clinical Characteristics													
BSA*	N	x			x	x	x		x		x		x
PASI*	N	x			x	x	x		x		x		x
PGA*	C	x			x	x	x		x		x		x
PGA historical peak activity	C	x			x								
PsA - clarification	C	x			x	x	x		x		x		x
PsA - measures	C	x			x	x	x		x		x		x
PsA - new findings	C	x			x	x	x		x		x		x
PsA - swollen joints	N	x			x	x	x		x		x		x
PsA - pressure-painful joints	N	x			x	x	x		x		x		x
PsA additional question to joint status	C	x			x	x	x		x		x		x
PsA characteristics	N	x			x	x	x		x		x		x
PsA - activity	N	x			x	x	x		x		x		x
Arthralgia	N		x		x								
Confirmed diagnosis of PsA*	N		x		x								
PsA suspected symptoms*	C	x				x	x		x		x		x
Psoriasis lesions, anatomical grids	C		x		x	x	x	x	x		x		x
Global psoriasis assessment*	N		x		x	x	x	x	x		x		x
Quality of life													
Patient benefit index	N		x		x	x	x	x	x		x		x
DLQI	N		x		x	x	x	x	x		x		x
EQ-5D-Skala	N		x		x	x	x	x	x		x		x
EQ-5D	N		x		x			x					
SF-12	N		x		x			x					
General + mental condition	N		x		x			x					
HAQ	N		x		x	x	x		x		x		x
Treatment													
Biologic therapy* (product, dose, duration)	M	x			x	x	x		x		x		x
Non-biologic therapy* (product, dose, duration)	M	x			x	x	x		x		x		x
Indications for treatment*	C	x			x	x	x		x		x		x
Previous treatment* (product, dose, duration)	M	x			x								
Current topical agents	C	x			x	x	x		x		x		x
Change of clinical psoriaisis type*	C	x				x	x		x		x		x
Change of treatment (from V2)*	D	x				x	x		x		x		x
Psoriasis treatment discontinued	D	x				x	x		x		x		x
Reasons for discontinuation	C	x				x	x		x		x		x

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		CRF			First year					Annual repetition			
	Data type	Doctor	Patient	Visits month	V1 0	V2 3	V3 6	ZV1 9	V4 12	ZV2 15	V5 18	ZV3 21	V6 24
Quality of care													
Therapeutic burden	N		x		x	x	x	x	x		x		x
Time needed for treatment	N		x		x	x	x	x	x		x		x
Treatment - need for assistance	N		x		x	x	x	x	x		x		x
Time needed for treatment (min.)	N		x		x	x	x	x	x		x		x
Consultations in last 12 month	C		x		x	x	x	x	x		x		x
Assessment of quality of care	N		x		x	x	x	x	x		x		x
Satisfaction with treatment	N		x		x	x	x	x	x		x		x
Comorbidity and its treatment													
Comorbidity, diagnosis*	C	x			x								
Comorbidity, medical treatment *	C	x			x								
Long-term medication*	D	x			x								
Long-term medication/preparation*	V	x			x								
Comorbidity - changes	C	x				x	x		x		x		x
Long-term medication - changes - new	V	x				x	x		x		x		x
Long-term medication - changes - discontinued	V	x				x	x		x		x		x
Pregnancy*	D	x				x	x		x		x		x
Pregnancy outcome	C	x				x	x		x		x		x
Adverse events*	D	x				x	x		x		x		x
Non-serious adverse events													
Event	V	x				x	x		x		x		x
Severity	N	x				x	x		x		x		x
Start	T	x				x	x		x		x		x
End	T	x				x	x		x		x		x
Outcome	N	x				x	x		x		x		x
Action	N	x				x	x		x		x		x
Causality	N	x				x	x		x		x		x
Serious advers events (triggered)													
Reporting Date*	V	x											
Type of report*	D	x											
Patient initials*	V	x											
Date of birth*	T	x											
SAE-event*	V	x											
SAE-symptom-description	V	x											
SAE-classification*	C	x											
SAE-medication*	M	x											
SAE-causality*	C	x											
SAE-comedication	M	x											
SAE-action taken*	C	x											
SAE-Re-exposition*	D	x											
SAE-outcome*	C	x											
SAE-laboratory	D	x											
PSA-diagnosis*	V	x											
Psoriasis since	T	x											
SAE-comorbidities	M	x											
SAE-reporting physician*	V	x											
SAE-speciality*	V	x											
SAE-address*	V	x											
SAE-phone/email*	V	x											
SAE-signature/stamp*	V	x											

* mandatory, D... Dichotomous, N... Numeric, C... Categorical, V... Verbatim, T... Time, M... Multiple types

Contact

For further information please contact the management of the registry at: **info.psobest@uke.de.**

Impressum

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