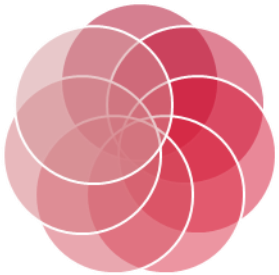
Think Beyond.

# LESSONS LEARNED

from **20** years and **21** studies on

## Psoriasis



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# PSORIASIS

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## Epidemiology

- Drastic variations in global prevalence: 0.9 – 8.5 % with strong geographic impact [1]
- No clear gender effect
- Two age periods with increased incidence: 30-39 and 50-69 years

Cohort studies hint at an **increasing incidence** between the early 1970s and late 1990s [2]

## Risk factors

(for development and worsening of psoriasis)

### Genetic

First degree relatives, e.g. HLA-Cw6, HLA-B17

### Environmental

Smoking(both current and former)

Obesity

Drugs (e.g. Lithium, beta-blockers, antimalerials, NSAID, tetracyclines)

Infections

Alcohol abuse

[1] Parisi R et al., J Invest Dermatol. 2013 Feb;133(2):377-85. Epub 2012 Sep 27; [2] Icen M et al., J Am Acad Dermatol. 2009;60(3):394

# PSORIASIS

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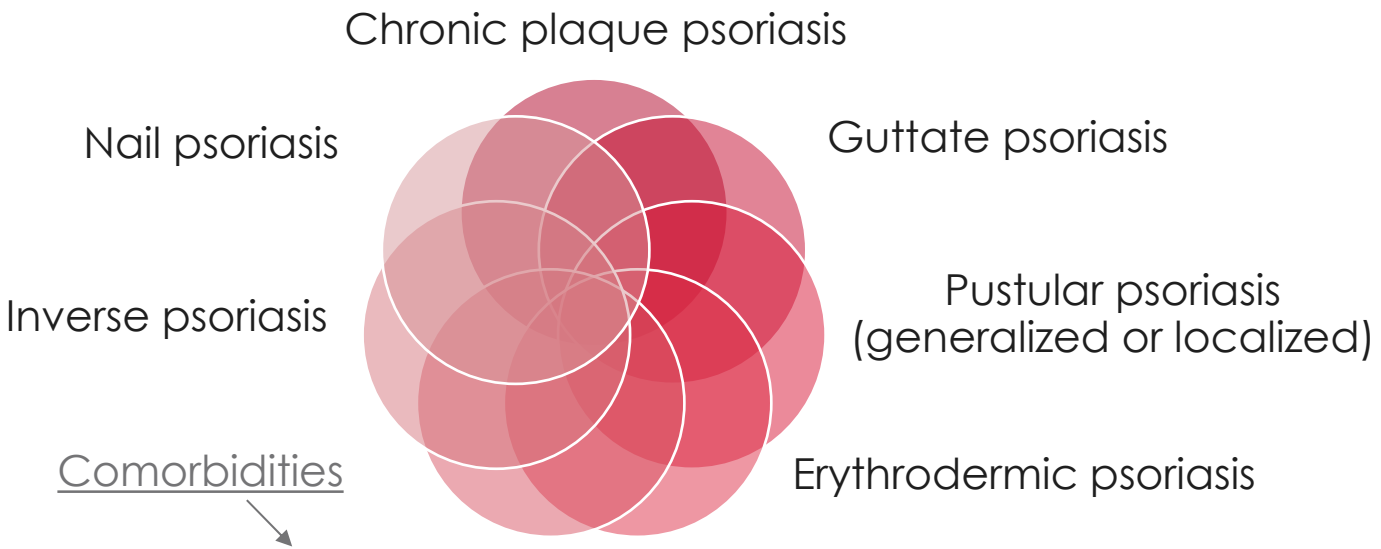
## Multi-faceted clinical presentation: independent nosologies, frequent comorbidities



# LEARNINGS: PATIENT POPULATION

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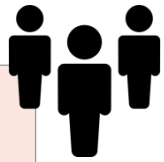
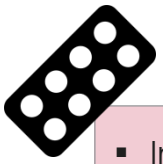


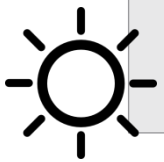
- Consider baseline-**severity** and psoriatic **comorbidities** → if necessary pre-define **subgroups** and consider impact on power and sample size

- Precisely define **forbidden medications** also based on their potency and their formulation (e.g. eye drops can also be considered topical corticosteroids)
- Consider **impact of each medication** and its prohibition on study conduct and patient compliance
- Remember that certain cosmetics may contain ingredients with **antipsoriatic properties**
- Clearly define what products patients actually can use (e.g. bland emollients etc.)

- In pre-treated patients consider need for **washout periods**



- In all patients consider concomitant medication can have impact on **disease activity** (e.g. calcium channel blockers) – patients should be on stable regimen at least for **4 weeks prior to randomisation**



- Limitation of **exposure to sun light** necessary – include this information also in ICF

- Consider **stratification of randomisation** according to body weight, smoking status and/or geographical region (e.g. sun light exposure )

# LEARNINGS: ENDPOINTS

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- Caution to be used when relating **absolute** outcome effect sizes to previously **categorically** collected baseline data (e.g. reflecting disease severity)

- When monitoring target lesion(s) or lesion scores: precisely define the **target lesion(s)** (e.g. always the same lesion(s)? lesion characteristics?)

- Clearly define **rebound** and how it should be documented (efficacy or safety?)

- Define *a priori* how worsening of psoriasis should be documented (i.e. **efficacy or safety** endpoint?)

- Make sure to **maintain blinding** – e.g. by additional blinding for laboratory assessments that can hint at the anti-inflammatory efficacy (e.g. CRP)

- For scores based on objective assessments – facilitate **standardised rating** by providing guidance to the investigators (e.g. online trainings, FAQs)

Choose Passion!

Think Beyond.

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