Use of Digital Methods to Collect Real-World Data in Participants with Psoriatic Arthritis Treated with the IL-23 Inhibitor Guselkumab or IL-17 Inhibitors: Baseline Characteristics from the eDaily PsABIOnd Sub-study

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Key Takeaways

- **Despite challenges with eDaily enrolment, high eDiary and ePRO completion rates (76-88%) were observed among participants**
- **A considerable proportion of participants self-reported negatively-impacted QoL although mild levels of skin disease were observed at baseline**
- **Baseline participant-reported pain scores from PsABIOnd and eDiary (inverted scales) were consistent**
- **Participants had multi-domain PsA with considerable fatigue levels and sleep disturbance**
- **eDaily will capture between-visit patient health status, and could thereby enhance health economic assessment of PsA impact and treatment decision-making in the future**

Background

Psoriatic arthritis (PsA) is a chronic, heterogenous inflammatory disease involving joint arthritis and skin psoriasis with negative impact on physical function and health-related quality of life (HRQoL)[1]

PsA manifestations can fluctuate over time, with an unpredictable, often progressive clinical disease course[2]

- Recent treatment options include interleukin (IL)-17 inhibitors (i) and the IL-23i guselkumab (GUS)
- Patients are seen every ~3-6 months in routine practice resulting in missed clinical insights between visits

Employment of digital methods to enable more frequent data collection on patient status offers an opportunity to further the understanding of PsA and its impact on patient health/burden that may influence patient care[3]

Objectives

To report baseline characteristics among participants enrolled in an eHealth study aiming to characterize PsA impact through the use of electronic devices that capture self-reported PsA symptom levels and patient-reported outcome (PRO) measures with higher frequency than clinical practice

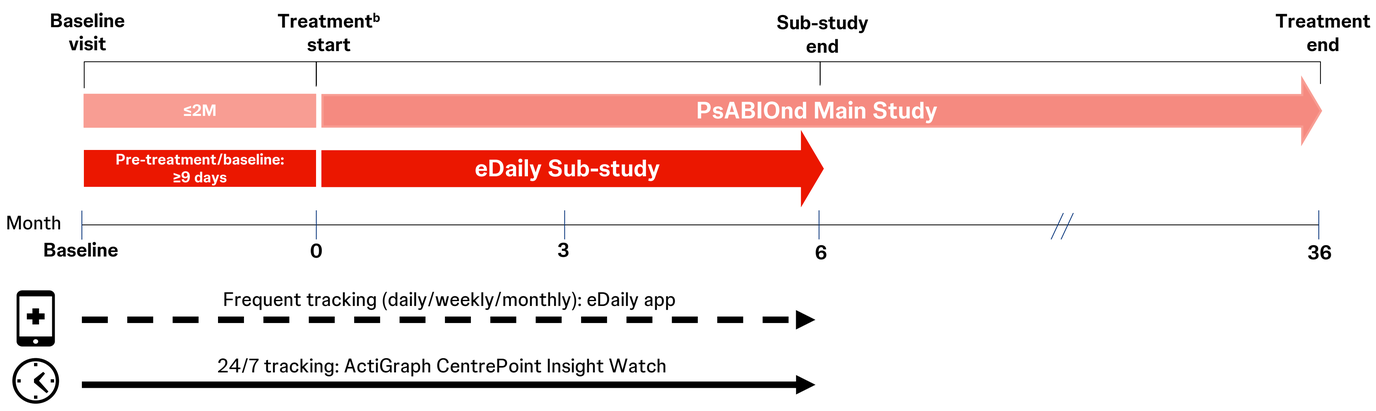
Methods

PsABIOnd (NCT05049798)[4]

- Ongoing, international, prospective observational study with 1,314 enrolled participants across 20 countries
- Adults with confirmed diagnosis of PsA initiating GUS or an IL-17i[a] as a first-to-fourth line biologic therapy per standard of care
- To assess long-term persistence, effectiveness, and safety of treatment

eDaily, an eHealth sub-study in PsABIOnd[4]

- Ongoing study of 27 participants enrolled in 5 European countries (Germany, Spain, Italy, France, and the UK)
- Employs:
  - Smart phone eDaily app including eDiary, ePROs, PsA flares, joint pain map
  - Medical-grade, wearable ActiGraph CentrePoint Insight Watch[5] for continuous monitoring of physical activity and sleep
- To evaluate associations between data collected across eDaily digital methods and ePROs in PsABIOnd main study



[a]Secukinumab, ixekizumab, brodalumab, bimekizumab, or netakimab. [b]After baseline assessment, study visit time points include month 3 (±3 months), month 6 (± 3 months), then every 6 months (±3 months) and at the 'end of treatment' (+1 month) or 'start of treatment' visit (if 2 months have passed since the 'end of treatment' visit). **ePRO**=Electronic patient-reported outcome.

Current Assessments and Analyses

- Data from 07-February-2023 to 08-January-2024 were included
- Baseline characteristics from PsABIOnd were analysed descriptively, pooling treatment groups
- eDiary ratings and ePRO assessments were collected during the pre-treatment/baseline period and summarized descriptively

Data source		Assessment
PsABIOnd		Baseline demographic and clinical characteristics
eDaily app	eDiary	Daily self-reported ratings (scale 0-100) of: •Mood (100=best mood) •Pain (100=no pain) •Fatigue (100=no fatigue) •Skin (100=clear skin) •Morning stiffness duration/severity (100=no stiffness)
	ePROs	Weekly self-reported assessments of: •Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue (scale 0-52, 52=no fatigue) •Medical Outcomes Study Sleep Scale (MOS-SS; scale 0-100, 100=highest level of each attribute)

Actigraphy was not in scope for this analysis

Results

eDaily participants were characterized by moderate-to-severe joint disease activity and multi-domain disease at baseline

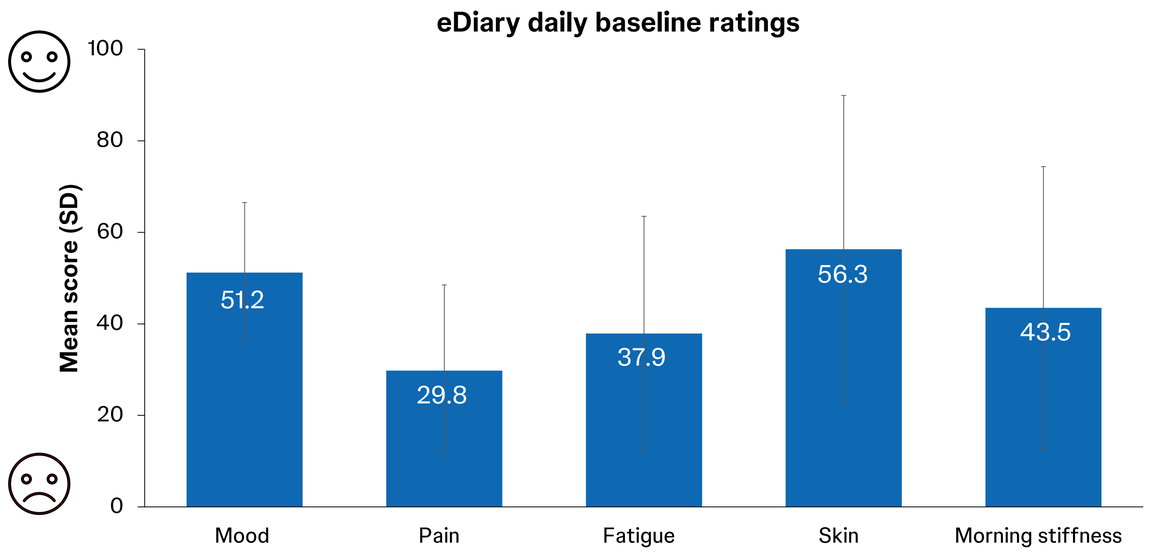
- Majority of participants (62.5%) had mild skin disease (BSA <3%)
- Participants reported considerable levels of pain

PsABIOnd Baseline Parameters		Total (N=17)
Disease characteristics		
	Age, years	51.9 (8.41)
	Male sex	9 (52.9%)
	BMI, kg/m^2	28.1 (6.33)
	Smoking status	15
	Never smoked	3 (20.0%)
	No, but past smoker	7 (46.7%)
	Current smoker	5 (33.3%)
Treatment		
	GUS	7 (41.2%)
	IL-17i	10 (58.8%)
	Biologic-naïve	5 (29.4%)
	Biologic-experienced	12 (70.6%)
Disease parameters		
	BSA	16
	<3%	10 (62.5%)
	3% to 10%	5 (31.3%)
	>10%	1 (6.3%)
	Axial involvement[a]	1 (11.1%)
	cDAPSA (0-154; ModDA 13-27, HDA >27)[b]	30.2 (22.03)
	DAPSA (ModDA 15-28, HDA >28)[a]	28.0 (18.25)
	Swollen joint count (0-66)[b]	6.1 (10.14)
	Tender joint count (0-68)[b]	10.4 (11.76)
	Enthesitis[b]	11 (68.8%)
	Dactylitis	9 (52.9%)
	Nail disease	11 (64.7%)
	Physician global VAS (0-100)[b]	52.2 (15.72)
Patient-reported outcomes		
	Patient global VAS (0-100)	68.6 (18.60)
	Patient pain VAS (0-100)	67.2 (16.91)

Values are mean (SD) or n (%). **cDAPSA**=Clinical Disease Activity Index for Psoriatic Arthritis; **DAPSA**=Disease Activity Index for Psoriatic Arthritis; **HDA**=High disease activity; **ModDA**=Moderate disease activity; **SD**=Standard deviation; **VAS**=Visual analogue scale. [a]N=9; [b]N=16.

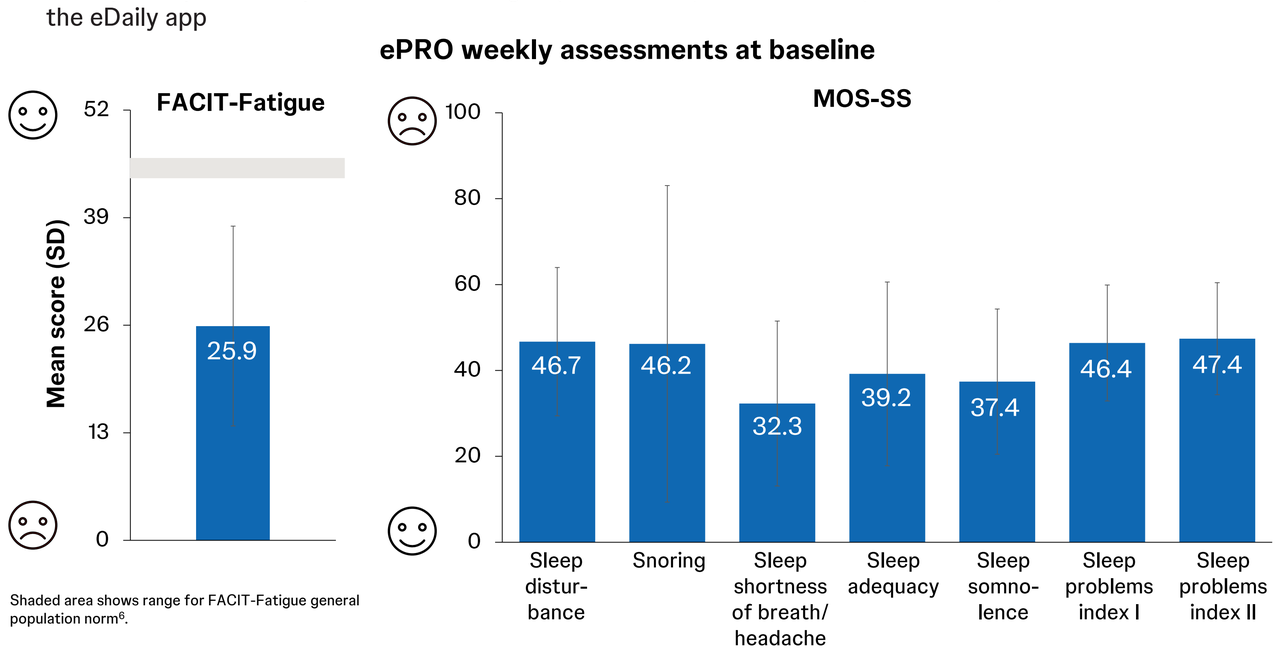
During the eDaily pre-treatment/baseline period, participants had negatively impacted QoL

- Most participants (14-15 out of 17) completed eDiary ratings in the eDaily app



Substantial levels of fatigue and sleep disturbance were observed among participants during the eDaily pre-treatment/baseline period

- Most participants completed FACIT-Fatigue (14 out of 17) and MOS-SS (13 out of 17) assessments in the eDaily app



Shaded area shows range for FACIT-Fatigue general population norm[6].

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