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ORIGINAL ARTICLE

Baseline characteristics of atopic eczema patients enrolled in seven European registries united in the TREatment of ATopic eczema (TREAT) registry taskforce

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Abstract

Background: The TREAT Registry Taskforce is a collaborative effort of international registries aiming to provide real-world data on the long-term efficacy, cost-effectiveness and safety of systemic treatments and phototherapy for atopic eczema (AE).

Objectives: This study seeks to present a comprehensive overview of the demographics, prior systemic treatments, clinical characteristics and disease severity and burden at baseline among patients enrolled in seven TREAT registries. Moreover, the aim is to gain insight into the differences between the registries and to explore the current prescribing practices of various therapies for patients with AE across Europe.

Methods: Data from June 2016 to 31 October 2022, were collected from seven observational cohorts: A-STAR (UK/Ireland), AtopyReg (Italy), Biobadatop (Spain), SCRATCH (Denmark), SwedAD (Sweden), TREATgermany (Germany) and TREAT NL/BE (Netherlands/Belgium).

Results: The analysis included 5337 patients, with a mean age of 39.1 years (6.3% paediatric, 54.4% male). Of these, 84.1% had previously received systemic treatments, primarily systemic corticosteroids (58.8%) and ciclosporin (39.0%), while 30.1% had undergone phototherapy. At enrolment, dupilumab was the most prescribed treatment (75.0%), followed by ciclosporin (7.8%) and Janus Kinase inhibitors (5.9%); only 1.7% started phototherapy. Baseline assessments showed that most patients had moderate (41.9%) to severe (30.1%) AE, with an average Eczema Area and Severity Index (EASI) score of 17.6. The Patient-Oriented Eczema Measure (POEM) score averaged

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17.2, indicating severe disease impact. The Dermatology Life Quality Index (DLQI) score averaged 13.4, and the Numerical Rating Scale (NRS) for itch was 6.4.
Conclusions: This pooled analysis from the TREAT Registry Taskforce highlights the variability and similarities in data collection across national registries, providing significant insights into the baseline characteristics of the patient population. It establishes a robust foundation for future analyses of key effectiveness and safety outcomes.

KEYWORDS
atopic dermatitis, atopic eczema, baseline, demographics, disease burden, disease severity, patient-reported outcomes, phototherapy, real-world data, registry, systemic immunomodulating treatment

INTRODUCTION

Atopic eczema (AE), or atopic dermatitis, is a chronic inflammatory skin disease that affects both children and adults and significantly impacts quality of life.[1–4] While topical therapy is the first-line treatment for most patients, those with moderate-to-severe AE often require phototherapy or systemic immunomodulatory therapy to achieve disease control.[5,6] Since 2017, the therapeutic landscape has expanded with the EMA approval of biologics (e.g. dupilumab, tralokinumab) and JAK inhibitors (e.g. baricitinib, upadacitinib, abrocitinib).[7–12] Before this, ciclosporin was the only approved systemic treatment, although off-label use of methotrexate, oral corticosteroids and phototherapy was common.[5,13,14] Evidence on the long-term safety, effectiveness and cost-effectiveness for most systemic immunomodulating treatments prescribed for AE in a real-world setting is sparse.[15,16] The TREatment of ATopic eczema (TREAT) Registry Taskforce therefore aims to generate reliable real-world data on long-term effectiveness and safety of systemic immunomodulatory treatments and phototherapy in AE patients across country borders.[17] To achieve this, a network of independent, prospective, multi-centre registries across Europe was created and a core dataset aligned with the Harmonizing Outcome Measures for Eczema (HOME) recommendations was created to harmonize data collection.[18–20] Currently, eight independent registries from 10 countries participate: the TREAT NL/BE registry (the Netherlands and Belgium), the A-STAR registry (The UK-Irish Atopic Eczema Systemic Therapy Register; United Kingdom and Ireland), TREATgermany registry (Germany), Biobadatop registry (Spain), SCRATCH registry (Severe and ChRonic Atopic dermatitis Treatment CoHort, Denmark), SwedAD registry (Sweden), AtopyReg registry (Italy) and FIRST registry (French atopIc deRmatitiS cohorT, France; unable to participate in this in analysis). While several single-country studies have been published, no cross-border pooled analysis has been performed.[21–31]

A recent mapping exercise confirmed a high degree of overlap in collected data, supporting the feasibility of pooled analyses.[32] This current study builds on that foundation, presenting the first pooled baseline analysis of seven registries

Why was the study undertaken?

- The TREAT Registry Taskforce was established to generate real-world evidence on the long-term effectiveness and safety of systemic immunomodulatory treatments and phototherapy for atopic eczema (AE).
- This study aimed to demonstrate the feasibility of pooling data across multiple national registries, providing a comprehensive overview of baseline patient characteristics, treatment patterns and disease burden in AE.

What does this study add?

- This study presents pooled baseline data from 5337 patients across seven European registries, demonstrating the ability to combine real-world data after the establishment of a harmonized core dataset.
- Findings reveal notable variations in prescribing patterns, with dupilumab being the most frequently prescribed systemic therapy at enrollment but subject to reimbursement restrictions in many countries.
- The study highlights both similarities and challenges in data harmonization, showing that pooled analyses across registries are feasible but require continued standardization efforts.

What are the implications of this study for clinical care?

- The findings of this study emphasize the need to account for differences in treatment access and prior medication use when interpreting real-world data.
- Given the large proportion of patients starting dupilumab at baseline, the study provides a strong foundation for generating robust real-world safety data on this biologic in the coming years.

- This study lays the groundwork for future large-scale analyses by the TREAT Registry Taskforce on treatment effectiveness, safety and long-term outcomes in AE, demonstrating the feasibility of cross-border pooled analyses essential for informing clinical guidelines and optimizing care across Europe.

to examine patient demographics, treatment patterns, disease severity and burden of disease. It also explores between-registry differences and the feasibility of conducting future collaborative studies across Europe.

PATIENTS AND METHODS

Study design and population

The current analysis includes data on all patients that were included between the date of first inclusion (varying between registries) and October 31st 2022 in seven out of eight established registries in the TREAT registry Taskforce. The French FIRST registry was excluded due to its early development phase. The registries that have joined the TREAT Registry Taskforce are ongoing, prospective, observational cohorts including patients with AE who are commencing on or switching to another systemic immunomodulatory treatment and/or phototherapy as well as topical therapies. No wash-out period was implemented. Written informed consent was obtained from the patient (or parents/legal guardian) (oral in SwedAD). Table 1 presents a brief summary of the inclusion criteria. A detailed overview of the inclusion and exclusion criteria of the different TREAT registries can be found in another publication.[32]

Data collection and outcome measures

For this study, only a selection of the domain items of the core dataset were analysed. Baseline sociodemographic data (sex, age and level of education) was requested from each registry. According to the core dataset, educational status is measured using the International Standard Classification of Education (ISCED).[33] However, not all registries use the ISCED as a tool to measure level of education.[32] In order to be able to pool data between registries that used other classification systems, the ISCED levels were merged into three categories: lower education (ISCED 0–2), intermediate education (ISCED 3–4) and tertiary education (ISCED 5–8). Other baseline

TABLE 1 Inclusion criteria.

Registry name, country	Inclusion criteria
TREAT NL/BE, the Netherlands and Belgium	• Age: all • Treatment: initiating phototherapy or any type of systemic immunomodulating therapy • AE severity: all
A-STAR, United Kingdom and Ireland	• Age: all • Treatment: initiating phototherapy or any type of systemic immunomodulating therapy • AE severity: all
TREATgermany, Germany	• Age: ≥18 years ○ Children and adolescents are included in TREATkids—a separate part of TREATgermany. • Treatment: initiating topical treatment, phototherapy or any type of systemic immunomodulating therapy • AE severity: ○ Moderate-to-severe AE • Objective SCORAD >20, or; • Currently anti-inflammatory systemic treatment for AE, or; • Previous anti-inflammatory systemic treatment for AE within past 24 months
Biobadatop, Spain	• Age: all • Treatment: first time use of systemic immunomodulating therapy • AE severity: all
SCRATCH, Denmark	• Age: all • Treatment: initiating advanced systemic therapy • AE severity: moderate-to-severe AE
SwedAD, Sweden	• Age: all • Treatment: initiating phototherapy or any type of systemic immunomodulating therapy • AE severity: all
AtopyReg, Italy	• Age: ≥18 years • Treatment: initiating phototherapy or any type of systemic immunomodulating therapy • AE severity: ○ Moderate-to-severe AE • EASI ≥16 • EASI <16 but with at least one of the following conditions: Localization in at least one of the following 'critical' sites: face, hands, genitalia; DLQI > 10; Itch VAS > 7; Sleep VAS > 7

TABLE 2 Number of participating centres and included patients between the date of first inclusion and 31 October 2022.

	TREAT NL/BE, the Netherlands and Belgium	A-STAR, United Kingdom and Ireland	TREATgermany, Germany	Biobadatop, Spain	SCRATCH, Denmark	SwedAD, Sweden	AtopyReg, Italy	
Month and year of first inclusion	**Nov 2017**	**Oct 2018**	**Jun 2016**	**Apr 2020**	**Oct 2017**	**Sep 2019**	**Jun 2020**	**All registries**
Number of inclusions	617	394	1587	256	460	850	1173	**5337**
Number of participating centres	9	24	65	8	5	39	25	**175**
n (%) academic centers	4 (44.44)	20 (83.33)	17 (26.15)	8 (100)	5 (100)	12 (30.77)	25 (100)	91 (52.00)
n (%) inclusions in academic centers	584 (94.65)	374 (94.92)	1041 (65.60)	256 (100)	460 (100)	637 (74.94)	1173 (100)	4525 (84.79)
n (%) non-academic centers	5 (55.56)	4 (16.67)	48 (73.85)	0 (0.00)	0 (0.00)	27 (69.23)	0 (0.00)	84 (48.00)
n (%) inclusions in non-academic centers	33 (5.35)	20 (5.08)	546 (34.40)	0 (0.00)	0 (0.00)	213 (25.06)	0 (0.00)	812 (15.21)

Note: The bold value indicates $p < 0.01$ is considered significant (differs significant between groups).

characteristics included AE treatment before enrolment into the registry and AE treatment started at enrolment into the registry, physician-reported disease severity and patient-reported disease severity and burden of disease.

For baseline physician-reported outcomes, we collected validated Investigator Global Assessment scale for Atopic Dermatitis (vIGA-AD) (number of patients per category: clear, almost clear, mild, moderate, severe) and Eczema Area and Severity Index (EASI) scores (mean [standard deviation (SD)] and number of patients per category: mild [>0 to <6], moderate [6 to <23], severe [23 to 72]).[34,35] Biobadatop (ES), SCRATCH (DK) and SwedAD (SE) did not collect vIGA-AD. For patient-reported outcomes (PROs), the Patient-Oriented Eczema Measure (POEM) (mean [SD] and number of patients per category: clear or almost clear [0–2], mild [3–7], moderate [8–16], severe [17–24], very severe [25–28]), quality of life measured with the Dermatology Life Quality Index (DLQI) (adults), Children's Dermatology Life Quality Index (CDLQI) (children) or Infants' Dermatitis Quality of Life Index (IDQOL) (infants) (scale 0–30) (mean [SD]) and Numerical Rating Scale (NRS) peak pruritus (scale 0–10) over the past 24 h (mean [SD]) were collected.[36–40] SCRATCH (DK) used the NRS peak pruritus over the past 72 h instead of 24 h, and Biobadatop used VAS pruritus over the past 24 h instead of NRS pruritus.

Statistical analyses

Descriptive statistics (means, SDs, frequencies and percentages) were used for continuous and categorical variables. Analyses were conducted using IBM SPSS (v26), Microsoft Excel (v16.54) and R Studio. A sampling procedure based on registry-specific means and SDs was applied to simulate patient-level data for *p*-value generation. Differences between registries were assessed using ANOVA for continuous variables and chi-squared tests for categorical data.

RESULTS

Table 2 shows the number of participating academic and non-academic centres and included patients between the date of first inclusion and 31 October 2022 in the seven different registries.

Baseline socio-demographics

Baseline socio-demographics of patients included in the registries are summarized in Table 3. Between June 2016 and 31 October 2022, a total of 5337 patients were enrolled in the seven TREAT registries, ranging from 256 (Biobadatop, ES) to 1587 (TREATgermany, DE) patients per registry. Patients had a mean (SD) age of 39.1 years (17.8) ($p < 0.01$),

TABLE 3 Baseline socio-demographics.

Baseline socio-demographics	TREAT NL/BE, the Netherlands and Belgium	A-STAR, United Kingdom and Ireland	TREATgermany, Germany	Biobadatop, Spain	SCRATCH, Denmark	SwedAD, Sweden	AtopyReg, Italy	All registries	*p*-value
Sex									
n (%) patients per category	**617**	**394**	**1587**	**256**	**460**	**850**	**1173**	**5337**	<0.05
Male	331 (53.65)	232 (58.88)	886 (55.83)	139 (54.30)	274 (59.57)	446 (52.47)	602 (51.32)	2910 (54.53)	
Female	286 (46.35)	162 (41.12)	701 (44.17)	117 (45.70)	186 (40.43)	404 (47.53)	571 (48.68)	2427 (45.47)	
Other	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	
Age									
Mean (SD)	35.59 (16.28)	26.06 (15.70)	40.30 (14.80)	32.60 (16.20)	40.05 (16.60)	41.20 (18.60)	43.00 (20.68)	39.12 (17.84)	<0.01
Adult patients	577 (93.52)	258 (65.48)	1587 (100)	207 (80.86)	425 (92.39)	775 (91.18)	1173 (100)	5002 (93.72)	
Paediatric patients	40 (6.48)	136 (34.52)	0 (0.00)[a]	49 (19.14)	35 (7.61)	75 (8.82)	0 (0.00)	335 (6.28)	
Level of education									
n (%) patients per category	**473**	**383**	**1562**	**n/a**	**295**	**433**	**899**	**4048**	<0.01
Lower education	84 (17.76)	83 (21.67)	203 (13.00)	n/a	46 (15.59)	38 (8.78)	185 (20.58)	640 (15.81)	
Intermediate education	220 (46.51)	147 (38.38)	972 (62.23)	n/a	83 (28.14)	198 (45.27)	480 (53.39)	2103 (51.95)	
Tertiary education	169 (35.73)	153 (39.95)	387 (24.78)	n/a	166 (56.27)	197 (45.50)	234 (26.03)	1305 (32.24)	

Note: The bold value indicates $p < 0.01$ is considered significant (differs significant between groups).

Abbreviations: n/a, not available.

[a]Children and adolescents are included in TREATkids – a separate part of TREATgermany.

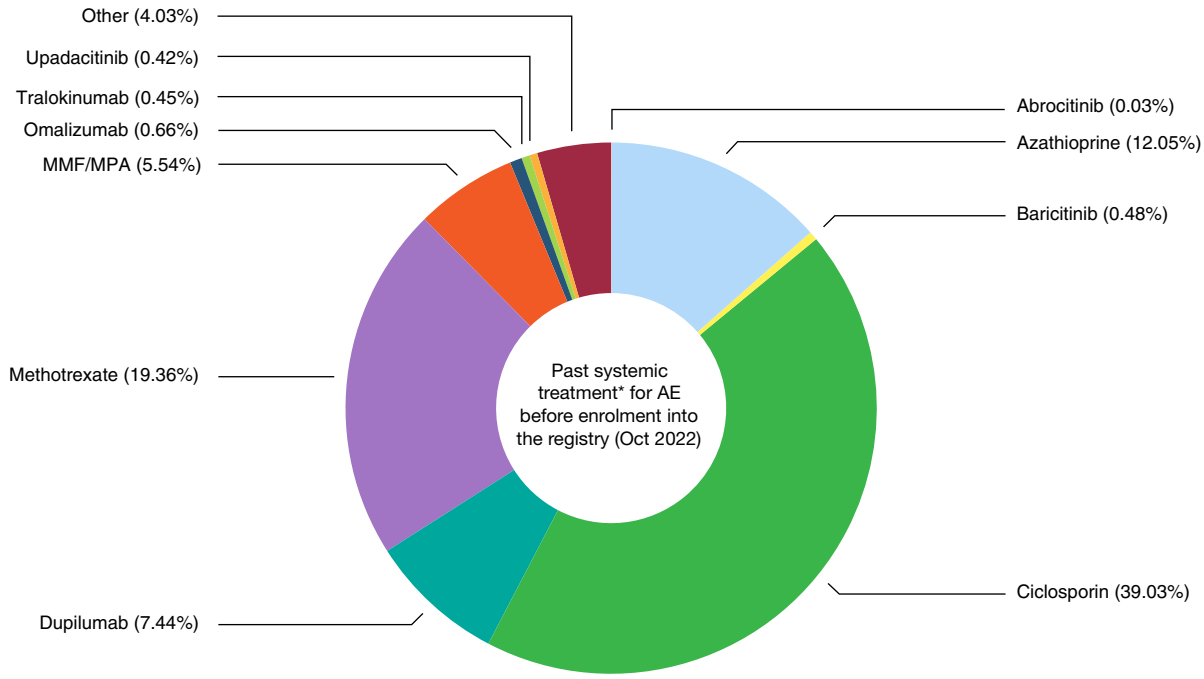

FIGURE 1 Past systemic treatment for atopic eczema (AE). In total, 3775 patients had previous systemic treatment, with potential for 0 or >1 treatment per patient. *Any systemic treatment besides systemic corticosteroids. SwedAD registry does not collect data on past systemic treatment.

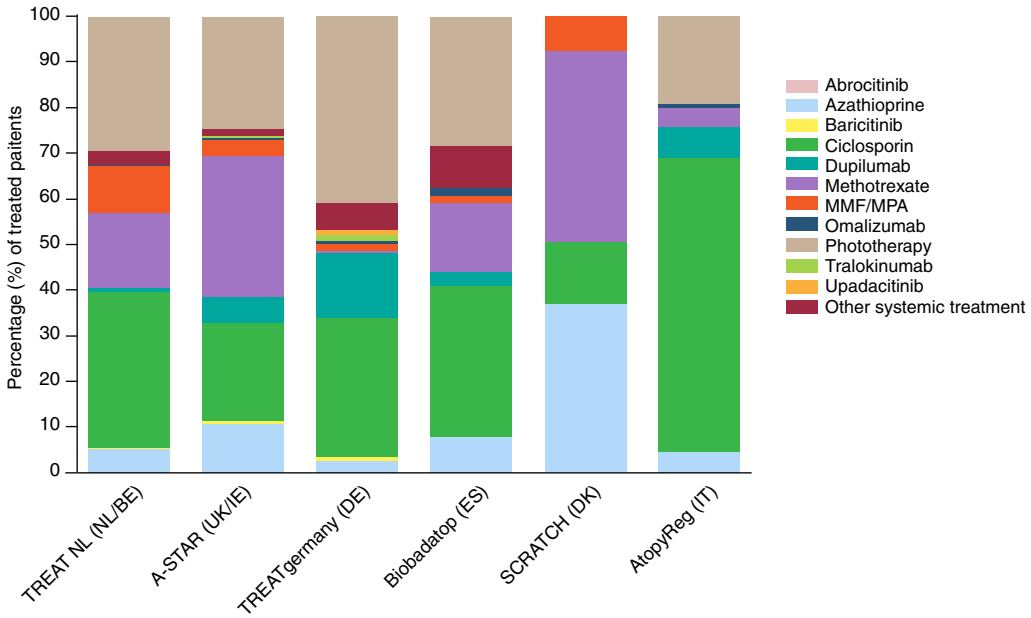

FIGURE 2 Percentage of patients treated with various systemic treatments or phototherapy before enrolment in the registries. Each bar represents a registry (100%), with segments showing the proportion of patients exposed to each treatment. Total number of treatments = 4591. MMF/MPA, mycophenolate mofetil or mycophenolic acid. *Any systemic treatment besides systemic corticosteroids. SwedAD (SE) does not collect data on past systemic treatment. SwedAD (SE) and SCRATCH (DK) do not collect data on past treatment with phototherapy.

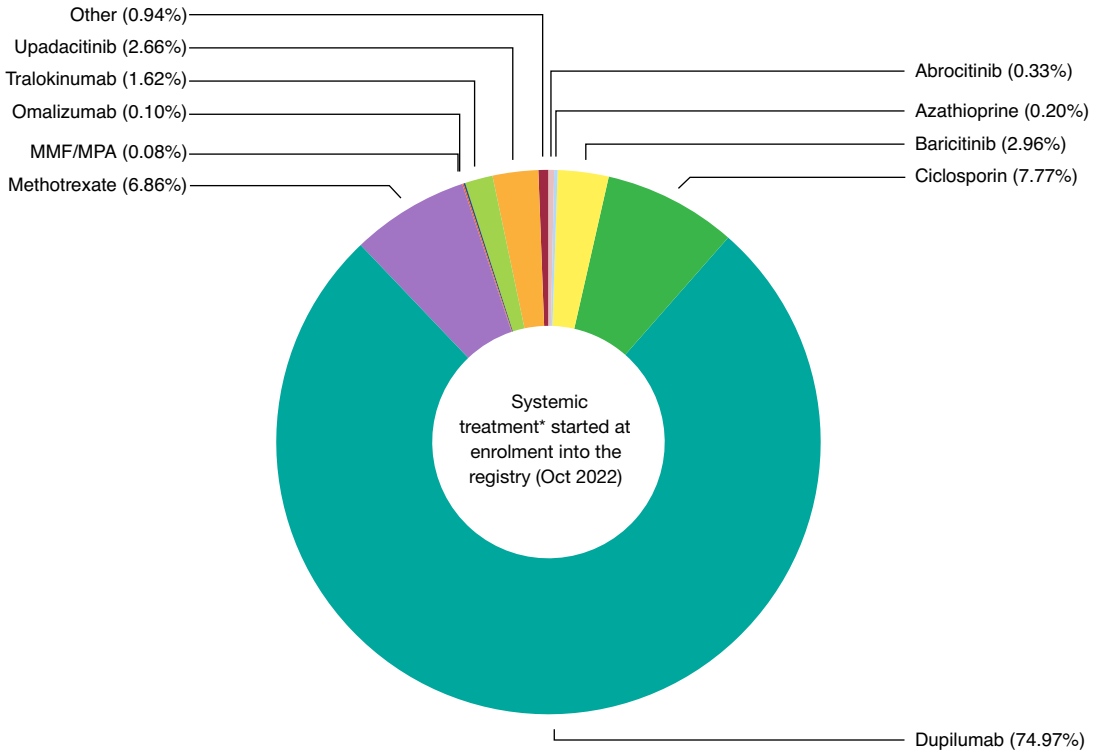

FIGURE 3 Systemic treatment started at enrolment into the registries. In total, 3952 patients started a specific systemic treatment, with potential for 0 or >1 treatment per patient. MMF/MPA, mycophenolate mofetil or mycophenolic acid. *Any systemic treatment besides systemic corticosteroids. SCRATCH (DK) does not include patients on conventional systemic treatments.

ranging from 26.0 years in A-STAR (UK/IE) to 43.0 years in AtopyReg (IT). Five registries included children, with a total number of 335 (6.3%) paediatric patients. A slight majority of patients were male (54.4%), and this male predominance is seen in all registries ($p < 0.05$). 15.8% of patients had followed lower education (ISCED 0–2), 52.0% intermediate education (ISCED 3–4) and 32.2% tertiary education (ISCED 5–8) ($p < 0.01$). Biobadatop (ES) did not collect data on the level of education. Differences can be seen regarding education level between countries, for instance, the majority (56.3%) of the patients in SCRATCH (DK) have tertiary education levels, while in other registries this was not the case.

Past treatments before enrolment into the registry

A complete overview of the past AE treatments patients received before their enrolment into the registries is shown in Figures 1 and 2, and Table S1. Due to the fact that systemic corticosteroids are typically administered as short-term courses to manage flares, the number of patients treated with systemic corticosteroids in the past is not shown in the figures.

3775 (84.1%) patients were treated with any type of systemic treatment before they were enrolled into the registry. Noteworthy, SwedAD (SE) did not collect data on past AE treatment. Patients with prior exposure to systemic medications underwent a cumulative total of 5598 systemic treatment courses, reflecting an average of 1.5 previous systemic treatments per patient. The majority of patients received (short courses of) systemic corticosteroids (58.8%) as a past treatment for their AE, ranging from 25.3% (A-STAR [UK/IE]) to 59.7% (AtopyReg [IT]) of patients. Ciclosporin, methotrexate, azathioprine and mycophenolate mofetil (MMF) or mycophenolic acid (MPA) were administered to 39.0%, 19.4%, 12.1% and 5.5% of patients, respectively. However, substantial differences in the proportions of patients having received certain systemic treatments for their AE in the past exist between the registries ($p < 0.01$). For example, in SCRATCH (DK), the majority of patients previously received azathioprine (66.1%), while this percentage is considerably lower in most other registries. Moreover, in TREAT NL/BE (NL/BE), 20.0% of patients received previous treatment with MMF/MPA, while this number is much lower in the other registries. In total, 7.4% of patients received past treatment with dupilumab before enrolment. Past treatments before enrolment with other biologicals (tralokinumab and omalizumab), JAKi (baricitinib, upadacitinib and abrocitinib) and other treatments were only prescribed to a small proportion of patients in the current analysis.

A total of 1212 (30.6%) patients received any type of phototherapy prior to enrolment ($p < 0.01$). However, two registries (SCRATCH [DK], SwedAD [SE]) did not collect data on treatment history with phototherapy. Of the registries collecting data on past topical treatment, most

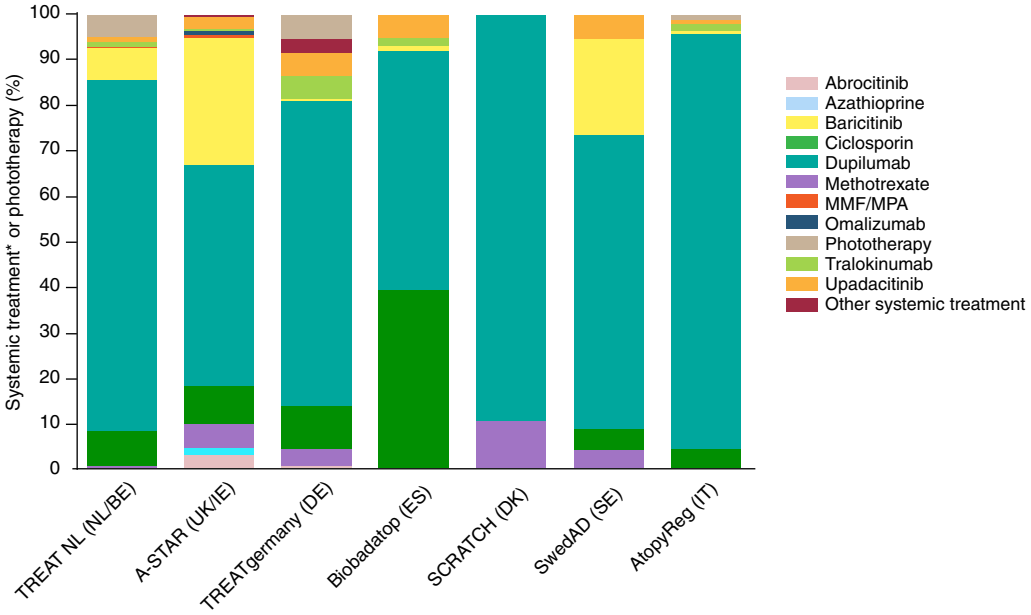

FIGURE 4 Systemic treatment or phototherapy started at enrolment into each registry. Total number of treatments = 3960. MMF/MPA, mycophenolate mofetil or mycophenolic acid. *Any systemic treatment besides systemic corticosteroids. SCRATCH (DK) does not include patients initiating conventional systemic treatments. Biobadatop (ES), SCRATCH (DK) and SwedAD (SE) do not include patients initiating phototherapy.

patients had some form of topical therapy before enrolment. TREATgermany collects data on topical treatment only for the past year prior to inclusion.

Treatments started at enrolment into the registries

Table S2 depicts an overview of the AE treatments that were initiated when patients were enrolled into the registries. The percentage of patients who started a particular systemic treatment (any treatment besides systemic corticosteroids) or phototherapy in the registries are shown in Figures 3 and 4.

In this analysis, dupilumab was the most frequently prescribed drug at enrolment in all registries (75.0%). Less frequently prescribed therapies at baseline were ciclosporin (7.8%), methotrexate (6.9%), baricitinib (3.0%) and upadactitinib (2.7%). However, SCRATCH (DK) did not include patients starting systemic treatment other than biologicals or JAKi. Noticeable inter-register differences were observed ($p < 0.01$). For instance, a substantial proportion of patients started methotrexate treatment at enrolment into A-STAR (UK/IE) and SwedAD (SE) (26.7% and 21.2% of patients, respectively), whereas this number is considerably lower in the other registries. At the time of enrolment in Biobadatop (ES), the prescription rate of ciclosporin was notably higher (38.3%) compared to the other registries. Phototherapy was infrequently initiated at baseline in a total of 82 (1.7%) patients, although three registries (Biobadatop, SCRATCH and SwedAD) do not include patients initiating phototherapy. Finally, a large proportion of patients were prescribed (concomitant) topical treatment at the time of enrolment.

AE severity and disease burden at the time of enrolment into the registry

A complete overview of the AE severity and disease burden at the time of enrolment into the registry using physician- and patient-reported outcomes is shown in Table 4. Based on the vIGA-AD, which is a global assessment for clinical signs, most patients were suffering from moderate (41.9%) or severe (30.1%) AE, varying across registries ($p < 0.01$). The combined mean (SD) EASI score was 17.4 (12.1) at baseline and the majority of patients were categorized as having moderate (44.8%) to severe (35.4%) disease; however, substantial differences exist between registries ($p < 0.01$). As for patient-reported outcomes, the combined mean (SD) POEM score of all patients included in the registries was 17.2 (7.7), corresponding with severe eczema. Most patients were suffering from moderate (28.3%) to severe (38.0%) eczema, and 18.9% even from very severe eczema at the time of enrolment. POEM scores varied between the registries ($p < 0.01$). Figure 5 shows disease severity at baseline across all registries, measured with vIGA-AD, EASI and POEM. The combined mean (SD) DLQI score was 13.5 (8.4) at baseline, varying across registries ranging from 11.5 (TREATgermany [DE]) to 17.0 (AtopyReg [IT]) ($p < 0.01$). Combined mean (SD) CDLQI and IDLQI scores at baseline were 12.1 (7.2) and 22 (6.7), respectively ($p < 0.01$). Combined mean (SD) NRS pruritus (past

TABLE 4 Atopic eczema severity and disease burden at the time of enrolment into the registry.

Atopic eczema severity and disease burden at the time of enrolment into the registry	TREAT NL/BE, the Netherlands and Belgium	A-STAR, United Kingdom and Ireland	TREATgermany, Germany	Biobadatop, Spain	SCRATCH, Denmark	SwedAD, Sweden	AtopyReg, Italy	All registries	*p*-value
vIGA-AD									
n (%) patients per category:	**374**	**350**	**1580**	**n/a**	**n/a**	**n/a**	**580**	**2884**	<0.01
Clear (0)	0 (0.00)	1 (0.29)	30 (1.90)	n/a	n/a	n/a	22 (3.79)	53 (1.84)	
Almost clear (1)	17 (4.55)	12 (3.43)	125 (7.91)	n/a	n/a	n/a	47 (8.10)	201 (6.97)	
Mild (2)	140 (37.43)	31 (8.86)	227 (14.37)	n/a	n/a	n/a	157 (27.07)	555 (19.24)	
Moderate (3)	133 (35.56)	175 (50.00)	617 (39.05)	n/a	n/a	n/a	283 (48.79)	1208 (41.89)	
Severe (4)	84 (22.46)	131 (37.43)	581 (36.77)	n/a	n/a	n/a	71 (12.24)	867 (30.06)	
n missing or unknown	243	44	7	n/a	n/a	n/a	593	887	
EASI									
n patients	582	366	1575	245	365	785	1171	5089	
Mean (SD)	16.06 (11.23)	20.04 (13.14)	15.40 (12.80)	23.40 (11.90)	18.57 (11.44)	13.10 (11.30)	22.00 (9.64)	17.59 (12.09)	<0.01
n missing or unknown	35	28	12	11	95	65	2	248	
EASI – categories									
n (%) patients per category:	**582**	**366**	**1575**	**245**	**365**	**785**	**1171**	**5089**	<0.01
Clear (0)	7 (1.20)	0 (0.00)	30 (1.90)	1 (0.41)	0 (0.00)	29 (3.69)	0 (0.00)	67 (1.32)	
Mild (>0 to <6)	115 (19.74)	41 (11.20)	377 (23.94)	15 (6.12)	48 (13.15)	232 (29.55)	116 (9.91)	944 (18.55)	
Moderate (6 to <23)	334 (57.42)	203 (55.46)	812 (51.56)	103 (42.04)	203 (55.62)	381 (48.54)	243 (20.75)	2279 (44.78)	
Severe (23–72)	126 (21.64)	122 (33.33)	356 (22.60)	126 (51.43)	114 (31.23)	143 (18.22)	812 (69.34)	1799 (35.35)	
POEM									
n patients	503	371	1560	173	351	755	599	4312	
Mean (SD)	19.30 (6.20)	19.27 (6.97)	16.40 (7.80)	19.70 (6.30)	19.49 (6.25)	16.90 (8.40)	14.60 (8.09)	17.21 (7.72)	*p < 0.01*
n missing or unknown	114	23	27	83	109	95	574	1025	
POEM – categories									
n (%) patients per category	**503**	**371**	**1560**	**173**	**351**	**755**	**599**	**4312**	<0.01
Clear or almost clear (0–2)	9 (1.76)	3 (0.81)	91 (5.83)	1 (0.58)	3 (0.85)	56 (7.42)	17 (2.84)	180 (4.17)	
Mild eczema (3–7)	27 (5.28)	28 (7.55)	156 (10.00)	5 (2.89)	15 (4.27)	84 (11.13)	144 (24.04)	459 (10.64)	
Moderate eczema (8–16)	146 (28.57)	88 (23.72)	471 (30.19)	43 (24.86)	85 (24.22)	178 (23.58)	211 (35.23)	1222 (28.34)	
Severe eczema (17–24)	240 (46.97)	153 (41.24)	571 (36.60)	75 (43.35)	160 (45.58)	272 (36.03)	166 (27.71)	1637 (37.96)	
Very severe eczema (25–28)	81 (15.85)	99 (26.68)	271 (17.37)	49 (28.32)	88 (25.07)	165 (21.85)	61 (10.18)	814 (18.88)	

TABLE 4 (Continued)

Atopic eczema severity and disease burden at the time of enrolment into the registry	TREAT NL/BE, the Netherlands and Belgium	A-STAR, United Kingdom and Ireland	TREATgermany, Germany	Biobadatop, Spain	SCRATCH, Denmark	SwedAD, Sweden	AtopyReg, Italy	All registries	*p*-value
DLQI									
n patients	463	282	1559	164	318	728	1104	4618	
Mean (SD)	11.89 (7.07)	14.96 (8.28)	11.50 (7.90)	14.62 (7.62)	12.86 (7.17)	12.00 (8.10)	17.00 (9.42)	13.35 (8.51)	<0.01
n missing or unknown	132	11	28	72	128	106	69	546	
CLDQI									
n patients	22	98	n/a	20	14	16	n/a	170	
Mean (SD)	9.09 (5.26)	13.48 (7.56)	n/a	9.70 (5.58)	15.07 (5.15)	8.31 (6.24)	n/a	12.11 (7.15)	<0.01
n missing or unknown	0	0	n/a	0	0	0	n/a	0	
IDLQI									
n patients	0	3	n/a	0	0	0	n/a	3	
Mean (SD)	0 (0.00)	22.00 (6.68)	n/a	0 (0.00)	0 (0.00)	0 (0.00)	n/a	22 (6.68)	
n missing or unknown	0	0	n/a	0	0	0	n/a	0	
NRS pruritus past 24 h[a]									
n patients	358	382	394	219	361	691	1064	3469	
Mean (SD)	6.59 (2.21)	6.31 (2.47)	5.00 (3.10)	7.50 (2.10)	7.23 (2.32)	5.30 (3.00)	7.00 (3.20)	6.37 (2.96)	<0.01
n missing or unknown	259	12	1193	37	99	159	109	1868	

Note: The bold value indicates $p < 0.01$ is considered significant (differs significant between groups).

Abbreviations: CDLQI, Children's Dermatology Life Quality Index (children) (scale 0–30); DLQI, Dermatology Life Quality Index (adults) (scale 0–30); EASI, Eczema Area and Severity Index (scale 0–72); IDLQI, Infants' Dermatitis Quality of Life Index (infants) (scale 0–30); n/a, not available; POEM, Patient-Oriented Eczema Measure (scale 0–28); vIGA-AD, Validated Investigator Global Assessment scale for Atopic Dermatitis (scale 0–4).

[a]SCRATCH (DK) used the NRS peak pruritus over the past 72 h instead of 24 h and Biobadatop used VAS pruritus over the past 24 h instead of NRS pruritus.

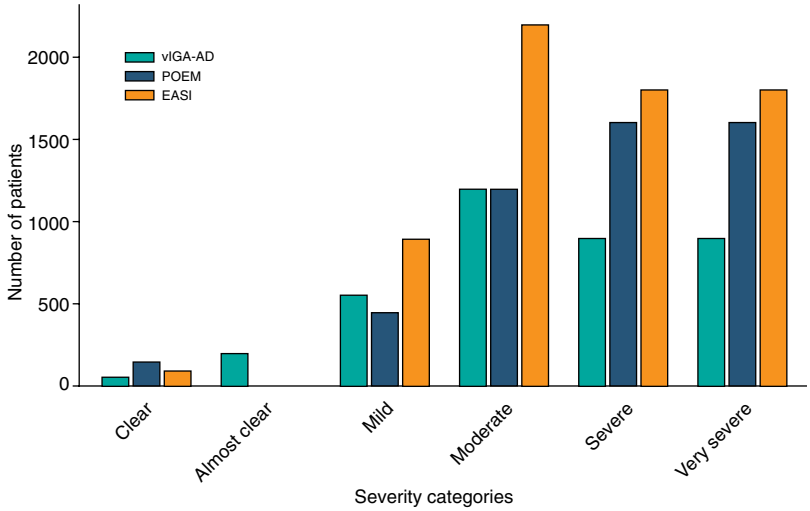

FIGURE 5 Disease severity at baseline across all registries, measured with Validated Investigator Global Assessment scale for Atopic Dermatitis (vIGA-AD), Patient-Oriented Eczema Measure (POEM) and Eczema Area and Severity Index (EASI) score. Biobadatop (Spain), SCRATCH (Denmark) and SwedAD (Sweden) do not collect vIGA-AD.

24 h) was 6.4 (3.0), ranging from 5.0 (TREATgermany [DE]) to 7.5 (Biobadatop [ES]) ($p < 0.01$). NRS pruritus over the past 72 h was used by SCRATCH (DK) and VAS pruritus over the past 24 h was used by Biobadatop (ES).

DISCUSSION

This is the first pooled analysis of baseline data from the TREAT Registry Taskforce, including 5337 patients across seven European registries. Our findings highlight both the feasibility of cross-registry collaboration and the substantial heterogeneity in treatment patterns, severity profiles and patient characteristics across Europe. These differences provide essential context for interpreting future treatment outcomes and assessing real-world use of systemic therapies.

Since dupilumab's EMA approval coincided with the launch of the TREAT Registry Taskforce, it became the predominant treatment at enrolment. However, our baseline data reflect only initial treatment choices, not subsequent switches, meaning current biologic and JAK inhibitor use is likely underestimated. Additionally, in the Netherlands, Belgium, Italy, Spain, Sweden and the United Kingdom, reimbursement policies require patients to try one or two systemic treatments before accessing biologics or JAK inhibitors. Future studies should further explore the impact of insurance frameworks on real-world prescribing behaviours, as differences in coverage, prior authorization requirements and national treatment guidelines may contribute to variability in treatment patterns.

The observed differences in baseline physician-assessed AE severity scores across registries can likely be attributed to variations in inclusion criteria and the real-world, prospective nature of this study. Some registries, such as TREATgermany (DE), SCRATCH (DK) and AtopyReg (IT), exclusively enrol patients with moderate-to-severe AE, whereas others include all patients initiating systemic treatment or phototherapy, regardless of disease severity. These differences in eligibility criteria inherently contribute to variations in baseline severity. Differences in registry inclusion criteria influence the profile of enrolled patients, with some registries representing only moderate-to-severe AE cases, while others include a broader spectrum of disease severity. This means that treatment outcomes and prescribing patterns may not be directly comparable across all registries. Additionally, as this study is based on real-world data without a wash-out period, some patients may have recently discontinued another systemic treatment, resulting in lower disease severity at enrolment. In clinical practice, this reflects real-world treatment adjustments, where patients may switch therapies based on treatment response, side effects or evolving disease burden. These factors may influence the interpretation of baseline disease severity. In future effectiveness analyses, we will account for prior medication use and adjust for these differences to ensure a more precise evaluation of treatment outcomes.

It is noteworthy that, in certain cases, physician evaluations of clinical signs using vIGA-AD and EASI indicate milder AE than some patient-reported outcomes. This phenomenon has also been observed in other prospective observational studies in AE, such as the US-Canadian PROSE registry and the Japanese ADDRESS-J, emphasizing the value of PROs in the management of moderate-to-severe AE.[41,42] Compared to the PROSE registry, a study of adolescent and adult AE patients initiating dupilumab treatment, baseline AE severity and burden measured in patients included in the TREAT registries were generally similar.[41] Disease severity and burden reported by patients

(POEM and DLQI) in our cohort are also comparable to the results from a survey on the burden of illness in adult AE patients from France, Germany, Italy, Spain and the United Kingdom.[43] A significant burden on health and health-related quality of life was reported by patients who participated in this questionnaire, particularly by those with uncontrolled AE. Patients included in the TREAT registries reported a mean POEM of 17.0 (severe) and their disease had a very large effect on their quality of life (mean DLQI 13.5). Moreover, the reported baseline NRS pruritus (past 24 h) ranged from moderate to severe in the registries, a result typically expected for moderate-to-severe AE.[40]

Strengths and limitations

The TREAT Registry Taskforce was established to address questions regarding (cost-)effectiveness and safety of photo- and systemic therapies in AE. This study provides a comprehensive overview of the data collected so far and is crucial for understanding the baseline data and assessing the feasibility of accurately registering and pooling this real-world data. Successful aggregation of such data is a critical step in supporting future research that can pose multiple research questions. This baseline data is considered to be a good representation of a real-world AE population as it is collected from daily practice in 175 centres in nine European countries. Analyses have revealed significant differences across all variables, which is expected given the diverse nature of the registries. These differences are significant by design and reflect the heterogeneity in data collection methodologies and patient populations across the registries. Also, the differences reveal considerable heterogeneity within the patient population as a whole. This heterogeneity underscores the representativeness of our data for the entire population of patients with atopic eczema. The diversity of patients included in the registries enhances the generalizability of our findings and supports the pooling of data from multiple sources. Contrary to concerns about the heterogeneity of the data, we believe that this heterogeneity strengthens the case for data pooling. By including a wide range of patients with varying demographics, treatment characteristics and disease severities, our datasets capture the complexity of atopic eczema in real-world clinical practice. Pooling such heterogeneous data allows for a more comprehensive understanding of the disease and facilitates robust analyses that can inform clinical decision-making and research priorities.

Our study also has limitations. As charted by our recently published mapping exercise, not all TREAT registries use the core dataset as intended, resulting in missing data.[32] Due to varying eligibility criteria, some registries do not collect data on all the requested systemic immunomodulatory therapies. In addition, registries maintain different inclusion criteria related to disease severity, resulting in differences in baseline AE severity and disease burden scores between registries. Moreover, the treatment landscape for AE has continued to evolve since the data cut-off (October 2022), marked by the introduction of new biologics and increased use of JAK inhibitors. New pooled analyses will capture these developments and evaluate their impact on real-world prescribing practices. Lastly, it is important to consider the potential impact of recruitment bias, as registry studies are susceptible to this type of bias.

Future perspectives

Several single-country studies on treatment effectiveness and other research questions have been conducted by individual TREAT registries.[23,24,44–49] However, it has always been the goal of the TREAT Registry Taskforce to conduct pooled analyses on important safety and (cost)effectiveness outcomes across European countries.[50] With this study, we have taken an important step towards future joint analyses. The ability to conduct cross-border analyses has opened the door to answering many other important research questions, in particular for analyses that require large numbers of patients, such as the investigation of malignancy risks.

Despite the implementation of a core dataset aligned with HOME recommendations, challenges remain in data harmonization due to variability in data completeness, classification systems and registry-specific methodologies. To address these issues, the TREAT Registry Taskforce is implementing Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM) methodology, enabling standardization across different healthcare databases. This can improve data interoperability, making it easier to perform large-scale, multi-database analyses while maintaining consistency across registries. Achieving full data harmonization will require continuous collaboration among registries. Refining data collection methods and adopting interoperable frameworks will be essential for maximizing the potential of real-world data and advancing evidence-based treatment strategies for AE across Europe.

AUTHOR CONTRIBUTIONS

A. H. Musters: conceptualization and design, acquisition and preparation of data, analysis and interpretation of data, drafting the article, revising and editing the article, final approval of the version to be published and corresponding author. **L. A. A. Gerbens**: conceptualization and design, revising and editing the article and final approval of the version to be published. **L. F. van der Gang**: acquisition and preparation of data, analysis and interpretation of data, revising and editing the article and final approval of the version to be published. **M. A. Middelkamp-Hup**: conceptualization and design, revising and editing the article and final approval of the version to be published. **W. Ouwerkerk**: analysis and interpretation of data and final approval of the version to be published. **D. J. Hijnen**: acquisition and preparation of data, revising and editing the

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CONFLICT OF INTEREST STATEMENT

L. A. A. Gerbens: one of the main investigators of the TREAT NL/BE registry. She has no further conflicts of interest. L. F. van der Gang: is a speaker for Abbvie and Sanofi. M. A. Middelkamp-Hup: consultancies for Sanofi and Leo Pharma and one of the main investigators of the TREAT NL/BE registry. D. J. Hijnenis or has been a consultant and/or investigator for Abbvie, Almirall, Astrazeneca, Galderma, Janssen, LEO Pharma, Lilly, Novartis, Pfizer, Sanofi, UCB. C. Flohris Chief Investigator of the UK National Institute for Health Research–funded TREAT (ISRCTN15837754) and SOFTER (ClinicalTrials.gov: NCT03270566) trials and the UK-Irish Atopic Eczema Systemic Therapy Register (A-STAR; ISRCTN11210918) and is a principal investigator in the European Union Horizon 2020–funded BIOMAP Consortium (http://www.biomap-imi.eu/). He is also Chief Investigator of the EU Joint Program Initiative TRANS-FOODS consortium. His department has also received investigator-led funding from Sanofi Genzyme for skin microbiome work. A. Chiricozzi: advisory board member and consultant and has received fees and speaker's honoraria or has participated in clinical trials for AbbVie, Almirall, Bristol Myers Squibb, Leo Pharma, Lilly, Janssen, Novartis, Pfizer and Sanofi Genzyme. L. Stingeni has been principal investigator in clinical trials sponsored by and/or received personal fees from AbbVie, Almirall, Celgene, Eli Lilly, Janssen, Leo Pharma, Novartis and Sanofi Genzyme. P. Calzavara-Pinton has been a consultant for Sanofi, AbbVie, Leo, Cantabria, Pierre Fabre, Galderma, Janssen and Novartis. E. K. Johansson: received speaker honoraria and/or has been a consultant for AbbVie, ACO, Galenica, LEO Pharma, Novartis, Sanofi Genzyme and the Swedish Asthma and Allergy Association. A. Svedbom: received speaker honoraria and/or has been a consultant for AbbVie, BMS, Eli Lilly, ICON, Janssen, Novartis, BMS and UCB. M. Bradley has been principal investigator in clinical trials sponsored by and/or received speaker honoraria and/or been a consultant for Abbvie, ACO, Amgen, LEO Pharma, Pfizer, Novartis and Sanofi Genzyme. L. B. Kobyletzki: Has acted as a collaborative researcher/consultant/speaker for Pfizer, Sanofi, Leo Pharma and Eli Lilly. E. Haufe: coordinator of TREATgermany; no further conflicts of interest. L. Heinrich: research associate of TREATgermany; no further conflicts of interest. J. Schmitt: PI of TREATgermany; institutional funding of IITs from Sanofi, Novartis, Pfizer, ALK; consultancies for Sanofi, Lilly, Novartis, ALK. J. M. Carrascosa served as a consultant and participated in speakers' bureaus for Abbott Laboratories, Janssen Pharmaceuticals Inc., MSD and Pfizer-Wyeth. I. García-Doval: received financial compensation for talks unrelated to atopic dermatitis from UCB and Novartis, and a travel grant from Janssen. N. J. Reynolds has received, through

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DATA AVAILABILITY STATEMENT

The authors confirm that the data supporting the findings of this study are available within the article.

ETHICAL APPROVAL

Procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional or regional) and with the Helsinki Declaration of 1975, as revised in 1983.

ETHICS STATEMENT

All the participants provided informed consent.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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