










ORIGINAL ARTICLE

Mapping exercise and status update of eight established registries within the TREATment of Atopic eczema Registry Taskforce

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Abstract

Background: The TREATment of ATopic eczema (TREAT) Registry Taskforce is a collaborative international network of registries collecting data of atopic eczema (AE) patients receiving systemic and phototherapy with the common goal to provide long-term real-world data on the effectiveness, safety and cost-effectiveness of therapies. A core dataset, consisting of domains and domain items with corresponding measurement instruments, has been developed to harmonize data collection.

Objectives: We aimed to give an overview of the status and characteristics of the eight established TREAT registries, and to perform a mapping exercise to examine the degree of overlap and pooling ability between the national registry datasets. This will allow us to determine which research questions can be answered in the future by pooling data.

Methods: All eight registries were asked to share their dataset and information on the current status and characteristics. The overlap between the core dataset and each registry dataset was identified (according to the domains, domain items and measurement instruments of the TREAT core dataset).

Results and conclusions: A total of 4702 participants have been recruited in the eight registries as of 1st of May 2022. Of the 69 core dataset domain items, data pooling was possible for 69 domain item outcomes in TREAT NL (the Netherlands), 61 items in A-STAR (UK and Ireland), 38 items in TREATgermany (Germany), 36 items in FIRST (France), 33 items in AtopyReg (Italy), 29 items in Biobadatop (Spain), 28 items in SCRATCH (Denmark) and 20 items in SwedAD (Sweden). Pooled analyses across all registries can be performed on multiple important domain items, covering the main aims of analysing data on the (cost-)effectiveness and safety of AE therapies. These results will facilitate future comparative or joint analyses.

INTRODUCTION

Atopic eczema (AE, syn. 'atopic dermatitis'), is a chronic inflammatory skin condition that affects up to 20% of children and adolescents and up to 10% of adults.^{1,2} Patients with moderate-to-severe AE may require systemic immunomodulating medication or photo(chemo)therapy, when topical treatments, including corticosteroids and emollients, prove insufficient for symptom control. A recent survey among 238 dermatologists from 30 European countries conducted by the TREATment of ATopic eczema (TREAT) Registry Taskforce has shown that these therapies are frequently prescribed off-label in both children and adults.³ Currently, the European Medicines Agency has approved ciclosporin, tralokinumab, baricitinib, upadacitinib and abrocitinib or adults and dupilumab for both adults and children from the age of 6 years for the treatment of AE. Although there is some evidence on the short-term effectiveness of systemic immunomodulating therapies and phototherapy prescribed in patients with moderate-to-severe AE, a clear knowledge gap about the long-term safety, effectiveness and cost-effectiveness of these therapies remains.

The TREAT Registry Taskforce is a collaborative international network of registries collecting data of AE patients

receiving systemic and phototherapy.⁴ Patients included are followed during treatment and after treatment discontinuation. The registries established within the TREAT Registry Taskforce have the common goal to provide long-term comparative real-world data on the effectiveness, safety and cost-effectiveness of AE therapies. These data are currently lacking for many commonly prescribed systemic treatments.^{5,6} Previous work of the TREAT Registry Taskforce has been to develop a core dataset, consisting of domains and domain items with corresponding measurement instruments, to be captured in AE research registries, to harmonize data collection.^{7,8} The aim of developing this core dataset was to increase the interoperability, direct comparability and pooling of data, and to reduce heterogeneity in data collection across country borders. The TREAT core dataset is aligned with the Harmonizing Outcome Measures for Eczema (HOME) recommendations (www.homeforeczema.org). The HOME initiative developed a consensus-based core outcome set for clinical trials and is developing one for clinical practice. Heterogeneity of outcomes used in disease registries has been demonstrated to hinder comparing results and pooling of data between centres and countries. A need to harmonize outcomes has been identified within similar collaborative initiatives for other diseases,

for instance the Psonet initiative (an European surveillance network to monitor the long-term effectiveness and safety of systemic agents in the treatment of psoriasis).⁹

The TREAT core dataset consists of 19 core domains and 69 domain items, counting 49 baseline items and 20 follow-up items (defining ‘what to measure’).⁷ As a final step in the harmonization process, the outcome measurement instruments, consisting of a total of 118 measurement instruments for all 69 domain items, and follow-up frequency and visit window were determined (defining ‘how to measure’ and ‘when to measure’).⁸ All affiliated TREAT registries are encouraged to collect data in accordance with this core dataset.

Several registries from different countries have joined the TREAT Registry Taskforce over the past years, currently including the A-STAR registry (The UK-Irish Atopic Eczema Systemic Therapy Register; United Kingdom and Ireland), Biobadatop registry (Spain), TREATgermany registry (Germany), TREAT NL registry (the Netherlands and Belgium), SCRATCH registry (Severe and ChRonic Atopic dermatitis Treatment CoHort, Denmark), FIRST registry (French atopIc deRmatitiS cohort, France), AtopyReg registry (Italy) and SwedAD registry (Sweden). These registries concern prospective observational cohorts and offer a platform to conduct cross-border research. A framework to conduct studies within the taskforce has been published previously.¹⁰

Despite the use of a core dataset, differences in data collection are expected due to several reasons, including the use of different data entry platforms. Potential differences may also arise due to variability in interpretation of the core dataset and the selection of (optional) core dataset items (in the context of feasibility). Furthermore, patient in- and exclusion criteria may differ per country, for example, due to discrepancies in treatment reimbursement and differences in prescribing practices.

Therefore, we aimed to give an overview of the status and characteristics of the established TREAT registries and to perform a mapping exercise. The main objective was to examine the data pooling ability between the registries by evaluating the degree of overlap between the registry datasets. Ultimately, this will allow us to determine which research questions can be answered in the future by pooling data and how such joint analyses can be approached.

METHODS

The following eight established registries in the TREAT registry Taskforce were included in this study: the A-STAR, TREAT NL, TREATgermany, Biobadatop, SCRATCH, FIRST, SwedAD and AtopyReg.

Status and characteristics of the registries

To investigate the current status and a description of the characteristics of each registry, we requested the following information (as of 1st of May 2022): status of recruitment,

month and year of first patient inclusion, number of recruited patients, number of participating centres, countries involved in each registry, website address, data capture platform/modality, funding sources, language of the database and included therapies (conventional systemic therapies, biologicals, phototherapy and other systemic therapies). In addition, we requested the inclusion and exclusion criteria of each registry. Furthermore, information was collected on the follow-up frequency and visit windows for follow-up, to allow comparison with the defined ‘when to measure’. The results were compiled descriptively in tables.

Mapping exercise

All registries were asked to share their dataset (e.g. the (electronic) case report forms ([e]CRFs) used) for the purpose of the mapping exercise. If more than one CRF was used for different timepoints within one registry, multiple CRFs were received. The use of the core dataset and the overlap between the core dataset and the registry dataset was identified according to the domains ($n = 19$), domain items ($n = 69$; ‘what to measure’) and measurement instruments ($n = 118$; ‘how to measure’) of the TREAT core dataset.⁸ We scored positive (1) if the dataset item was completely in accordance with the core dataset, negative (0) if the item was not captured and partially positive (2) if the item was only partly corresponding. The mapping exercise was conducted as follows:

- **Core dataset domain items (‘what to measure’, $n = 69$):** we scored the presence of core dataset domain items in each registry dataset.
- **Core dataset measurement instruments (‘how to measure’, $n = 118$):** we scored the use of core dataset instruments in each registry dataset, of which usually more are included per domain item (for example: the core dataset domain item ‘how diagnosis AE is established’ is measured by two measurement instruments: (1) ‘clinically Y/N’ and (2) ‘histopathology Y/N’). We considered an instrument partially positive (2) if at least one part or category of the core dataset instrument was used (for example: if the answer categories for topical treatment in a registry were: ‘<30 g | 30–60 g | >60 g’; instead of the predefined categories in the core dataset: ‘<30 g | 30–60 g | 60–100 g | >100 g’, this instrument would be scored partially positive (2)).
- **Pooling ability of domain item outcomes:** the ability to pool outcomes of the domain items was scored positive (1) if pooling of at least one of the corresponding measurement instruments was deemed possible (for example, when a registry collects data on the domain item ‘how diagnosis AE is established’ using the measurement instrument ‘clinically Y/N’, but not ‘histopathology Y/N’, data pooling on the domain item ‘how diagnosis AE is established’ was scored positive). Otherwise, pooling ability of the domain items was scored negative (0). We considered the pooling ability of domain item outcomes

TABLE 1 Description and status of the TREAT registries, as of 1st of May 2022

Registry name, country		TREAT NL, the Netherlands and Belgium		TREAT Germany, Germany		Biobadatop, Spain		SCRATCH, Denmark		FIRST, France		SwedAD, Sweden		AtopyReg, Italy	
A-STAR, United Kingdom and Ireland	Recruiting	October 2018	283	1.484	198	493	57	637	953	Recruiting	September 2019	June 2020	Recruiting	Recruiting	
Month and year of first inclusion															
N included patients (May 1, 2022)			597	1.484	198	493	57	637	953						
N participating centres			7	57	10	6	1	39	12						
Countries involved	United Kingdom and Ireland	The Netherlands and Belgium	Germany	Spain	Denmark	France	France	Sweden	Italy						
Website	astar-register.org	www.treatregister.nl	www.treatgermany.org	aedy.es/investigacion/proyectos-de-investigacion/	naed.zitelab.eu/	-	www.swedad.nu	www.atopyreg2.it							
Data capture modality	A-STAR (eCRF)	Castor (eCRF)	REDCap (eCRF)	RedCap (eCRF)	Zitelabs own software and platform (eCRF)	Epiconcept (Healthcare data host), Voozanoo 4 Software (eCRF)	Carmona, dermareg (eCRF)	Patient chart (eCRF)							
Language of database	English	English	German	Spanish	Danish	French	Swedish	Italian							
Funding	Government, pharma, charity	Government, pharma, academic support	Pharma	Pharma	Pharma	Academic support	Government, pharma	Pharma, academic support							
Conventional systemic therapies included															
Methotrexate	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Ciclosporin	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Azathioprine	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Mycophenolate mofetil/acid	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Systemic corticosteroids	Yes	Yes	Yes	Yes	No	No	No	No	No	No	No	No	No	No	Yes
Biologicals included															
Dupilumab	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Omalizumab	Yes	Yes	Yes	Yes	No	Yes	Yes	No	No	Yes	No	Yes	Yes	Yes	Yes
Baricitinib	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Tralokinumab	Yes	Yes	Yes	No	Yes	Yes	Yes	No	No	Yes	No	No	No	No	No
Upadacitinib	Yes	Yes	Yes	No	Yes	Yes	Yes	No	No	Yes	No	No	No	No	No
Abrocitinib	Yes	Yes	Yes	No	Yes	Yes	Yes	No	No	Yes	No	No	No	No	No
Phototherapy included															
BB-UVB	No	Yes	Yes	Yes	No	No	No	No	No	No	No	No	No	No	No
NB-UVB	No	Yes	Yes	Yes	No	No	No	No	No	No	No	No	No	No	Yes

TABLE 1 (Continued)

Registry name, country		TREAT NL, the Netherlands and Belgium	TREAT Germany, Germany	Biobadatop, Spain	SCRATCH, Denmark	FIRST, France	SwedAD, Sweden	AtopyReg, Italy
A-STAR, United Kingdom and Ireland								
UVA	No	Yes	Yes	Yes	No	No	No	No
UVA1	No	Yes	Yes	Yes	No	No	No	Yes
UVAB	No	Yes	Yes	Yes	No	No	No	No
PUVA	No	Yes	Yes	Yes	No	No	No	Yes

Other systemic therapies included (so far)

Montelukast, Apheresis (plasmapheresis)

Abbreviations: A-STAR, The UK-Irish Atopic Eczema Systemic Therapy Register; FIRST, French atopic dermatitis cohort; TREAT, Treatment of Atopic eczema; SCRATCH, Severe and Chronic Atopic Dermatitis Treatment Cohort.

as the main outcome of interest, because ultimately this will provide information on which cross-border analyses can be performed.

Uncertainties in data collection were resolved through discussion or e-mail correspondence with the corresponding registry investigators. Analyses were performed by using descriptive statistics to summarize the results, using Microsoft Excel version 16.54.

RESULTS

Status and characteristics of the registries

The status and characteristics of the registries are summarized in Table 1. All eight registries are currently recruiting. In total 4702 participants have been recruited to the eight registries, ranging from 57 to 1484 participants per registry (as of 1st of May 2022). The therapies included in the registries are methotrexate (in seven of the registries ($n = 7$)), ciclosporin ($n = 7$), azathioprine ($n = 7$), mycophenolate mofetil/mycophenolic acid ($n = 7$), systemic corticosteroids ($n = 5$), dupilumab ($n = 8$), omalizumab ($n = 6$), baricitinib ($n = 8$) and phototherapy ($n = 4$). Three registries also include patients on drugs that are or were investigational at the time like tralokinumab, upadacitinib or abrocitinib, and one registry includes patients treated with montelukast and apheresis (plasmapheresis). Each registry is a separate entity. Funding sources comprise governmental and pharmaceutical as well as charity support, academic support or a combination of these. The in- and exclusion criteria of each registry are shown in Table 2.

In context of the defined 'when to measure', the follow-up frequency and visit windows of all TREAT registries are shown in Table 3. Although the taskforce had reached consensus on the follow-up frequency and visit window to be applied, differences still exist between the registries. A baseline visit is conducted in all registries, but not all registries have specified a follow-up frequency and visit window. When specified, the first follow-up visit after inclusion ranges from 4 weeks to 12 months after baseline. The next follow-up visits during treatment are scheduled ranging from every 3 to (at least) every 12 months. The follow-up frequency after treatment discontinuation varies from no follow-up at all to at least every 6 months. Five registries have the option for extra visits, for example, in case of switch of therapy or disease flares. If specified, the visit window ranges from 2 weeks to 1 month.

Mapping exercise

The complete results of the mapping exercise with the assessment of the presence of core dataset domain items and measurement instruments, and the pooling ability of measurement instruments and domain items can be found in Table S1.

TABLE 2 Inclusion and exclusion criteria of the TREAT registries

Registry name, country	Inclusion criteria	Exclusion criteria
A-STAR, UK and Ireland	<ul style="list-style-type: none"> Paediatric and adult patients with AE of any age who due to the severity of their disease and/or impact on quality of life are commencing on or switching to another systemic immuno-modulatory agent (e.g. CsA, AZA, MTX or biologic treatments); Written informed consent for study participation obtained from the patient or parents/legal guardian, with assent as appropriate by the patient, depending on the level of understanding; Participants consent to participate in long-term follow-up and access to all medical records, including hospital admission records and linkage to data held by NHS bodies or other national providers of healthcare data; Diagnosis of AE in keeping with the U.K. Working Party's Diagnostic Criteria; Willingness to comply with all study requirements; Competent use of English language, according to patient's age (capable of understanding patient questionnaires) 	<ul style="list-style-type: none"> Insufficient understanding of the study by the patient and/or parent/guardian; Patients who are currently participating in a randomized clinical trial
TREAT NL, the Netherlands	<ul style="list-style-type: none"> Patient has a diagnosis of AE, based on the U.K. Working Party's Diagnostic Criteria; Starts with any type of phototherapy (e.g. UVB) or systemic immunomodulating therapy (e.g. CsA, systemic glucocorticosteroids, AZA, MTX, MPA, dupilumab); Has voluntarily signed and dated an informed consent prior to any study related procedure or has a legal representative to do so and is willing to comply with the requirements of this study protocol 	<ul style="list-style-type: none"> Patient uses only (systemic) antibiotics or antihistamines; Patient starts with systemic immunomodulating therapy for another indication than AE; Insufficient understanding of the study by the patient or parent/legal representative
TREATgermany, Germany	<ul style="list-style-type: none"> AD according to the U.K. Working Party's Diagnostic Criteria: moderate-to-severe AE; Age \geq 18 years; Objective SCORAD $>$20 or currently anti-inflammatory systemic treatment for AE or previous anti-inflammatory systemic treatment for AE within past 24 months 	Not defined
Biobatop, Spain	<ul style="list-style-type: none"> Any age; First time use of systemic treatment 	<ul style="list-style-type: none"> Unable to provide consent, current participation in a clinical trial, intention to move in the next 3 months
SCRATCH, Denmark	<ul style="list-style-type: none"> Adults ($>$18 years) with moderate-to-severe AE (one or more of the following EASI $>$16, BSA $>$ 10%, DLQI $>$10 or POEM $>$16), who have not responded adequately to relevant topical treatment and at least one traditional systemic treatment or are not considered to be candidates for traditional systemic treatment Patients aged 12–17 years with moderate-to-severe AE, who have not responded adequately to relevant topical treatment and one traditional systemic treatment or are not considered to be candidates for traditional systemic treatment Patients aged 12–17 years with severe AE, who are candidates for systemic ciclosporin, where there is a need for rapid onset of action of the systemic treatment due to severe flare-up of AE Children (6–11 years) with severe AE after at least one previous traditional systemic treatment 	Not defined
FIRST, France	<ul style="list-style-type: none"> Adult patients \geq18 year old (amendment for inclusion of adolescents and children \geq6 year-old is ongoing); With AD according to the U.K. Working Party's Diagnostic Criteria; Who due to the severity of their disease and/or impact on quality of life are commencing on or switching to a systemic treatment (e.g. CsA, MTX, biologic treatments, JAK inhibitors); With written informed consent for study participation obtained from the patient (consent to participate in long-term follow-up and for access to all medical records, including hospital admission records and linkage to data held by national providers of healthcare data); Willingness to comply with all study requirements including blood samples dedicated to the biological collection 	<ul style="list-style-type: none"> No systemic treatment (other than phototherapy)
SwedAD, Sweden	<ul style="list-style-type: none"> Age \geq5 years; Systemic treatment 	Not defined

TABLE 2 (Continued)

Registry name, country	Inclusion criteria	Exclusion criteria
AtopyReg, Italy	<ul style="list-style-type: none"> • Age: ≥ 18 years • To sign informed consent • Diagnosis of moderate or severe AE made by one dermatologist defined on the basis of the following criteria: <ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • Patient unable to provide informed consent prior to any data collection procedures • data related to the study; • Patient unable to complete the procedures required for the study; • Patient already participating in another registry for the same condition

Of the 69 core dataset domain items, data pooling was possible for 69 items in TREAT NL (the Netherlands), 61 domain items in A-STAR (UK and Ireland), 39 items in TREATgermany (Germany), 36 items in FIRST (France), 34 items in AtopyReg (Italy), 29 items in Biobadatop (Spain), 28 items in SCRATCH (Denmark) and 20 items in SwedAD (Sweden). The specific results on the pooling ability per domain items are displayed in Table 4. This concerns a condensed part of Table S1. In Table 4, it is shown that dataset domain items with the ability to pool data from all eight registry datasets include: ‘date of birth’, ‘date of enrolment into registry’, ‘gender’ (domain: demographics), date of onset of AE (domain: AE diagnosis), ‘systemic therapy’ (domain: current AE treatments), ‘family history of AE or allergic diseases’ (domain: family history of AE or allergic diseases), ‘asthma’, ‘allergic rhinoconjunctivitis’ (domain: allergic co-morbidities), ‘physician-assessed clinical signs’, ‘patient-reported symptoms’, ‘skin-specific quality of life score’ (domain: baseline physician- and patient-reported domains), physician-assessed clinical signs, ‘patient-reported symptoms’, ‘skin-specific quality of life score’ (domain: follow-up physician- and patient-reported domains). The number of domain items that scored positive for pooling ability according to the number of registries can be found in Figure 1.

The HOME core outcome set consists of clinical signs (EASI), patient-reported symptoms (POEM and NRS-11 for peak itch over past 24h), quality of life (DLQI (adults), CDLQI (children), IDQoL (infants)) and long-term control (Recap of Atopic Eczema (RECAP) or Atopic Dermatitis Control Test (ADCT)). We found that all eight registries collect data on EASI, POEM, DLQI, CDLQI and IDQoL. NRS-11 peak itch over past 24h was fully or partially collected by five registries. The long-term control item has recently been introduced to the outcome set. Data collection on this item using RECAP and/or ADCT is currently implemented or planned to be implemented by most TREAT registries.

DISCUSSION

The overview of the status and characteristics presented here provides insight into the current AE treatment registries within the TREAT Registry Taskforce. Since inception, the

TREAT Registry Taskforce has aimed to develop an international platform to uniformly collect long-term data on the (cost-)effectiveness and safety of systemic immunomodulating therapies and/or phototherapy in patients with AE. As per May 1, 2022, the established registries participating within the TREAT Registry Taskforce have jointly collected data of over 4700 patients. The registries have already been publishing their first results on patient characteristics, treatment effectiveness and safety individually.^{11,12} The next step is to increase the power of the data of individual countries by pooling data across registries. As described, the TREAT Registry Taskforce has developed a core dataset to be used in all registries and a protocol to enable this cross-border data pooling.^{8,10} The current study has revealed both similarities and differences regarding the degree of core dataset use and pooling ability between registries within the TREAT Registry Taskforce.

Similarities between the registries cover the main aims of collecting data on the effectiveness, safety and cost-effectiveness of AE therapies. Pooled analyses across all registries can be performed on the following domain items: ‘date of birth’, ‘date of enrolment into registry’, ‘gender’, date of onset of AE, ‘systemic therapy’, ‘family history of AE or allergic diseases’, ‘asthma’, ‘allergic rhinoconjunctivitis’, ‘physician-assessed clinical signs’ (e.g. EASI) (baseline and follow-up), ‘patient-reported symptoms’ (e.g. POEM) (baseline and follow-up) and ‘skin-specific quality of life score’ (baseline and follow-up). These items cover important effectiveness outcomes. As for safety, six registries collect data on severe and serious adverse events. Cost-effectiveness analyses can be performed using the generic quality of life score EQ-5D. Data collection on EQ-5D is included in three registries. We found that all HOME core outcomes, except from long-term control, were collected by all eight registries within the TREAT Registry Taskforce. As a result, comparative and pooled analyses on effectiveness and pharmacovigilance are feasible.

Despite the aspired use of an uniform core dataset, differences in data collection were identified. These differences may pose potential challenges in data pooling and synthesis. They may have resulted from various factors, including the use of different data entry platforms per registry. Further, countries may have given their own

TABLE 3 Visit schedule and window of the TREAT registries

Registry name, country	Baseline visit	First follow-up visit after baseline	Follow-up while on treatment	Follow-up after treatment discontinuation	Visit schedule window (aspired maximum deviation (\pm) from visit schedule)	Extra visits (optional)
A-STAR, UK and Ireland	Baseline	4 weeks	3 months	6 months	First follow-up: 2 weeks Thereafter: 1 month	<ul style="list-style-type: none"> Therapy switch (schedule restarts at baseline) Unscheduled visit (e.g. in case of therapy side-effects or disease flare-ups)
TREAT NL, the Netherlands	Baseline	4 weeks	3 months	6 months	1 month	<ul style="list-style-type: none"> (Re)start/switch of therapy (schedule restarts at baseline) Unscheduled visit (e.g. in case of therapy side-effects or disease flare-ups)
TREATGermany, Germany	Baseline	3 months	6 months (3 months if systemic treatment is initiated or changed)	6 months	2 weeks	<ul style="list-style-type: none"> Therapy switch Therapy side-effects Disease flare-ups Extra patient questionnaire (every 2 years)
Biobadatop, Spain	Baseline	3 months	At least every 12 months	At least every 12 months	As indicated by standard clinical practice	<ul style="list-style-type: none"> Second follow-up visit (6 months after baseline)
SCRATCH, Denmark	Baseline	Usually 4 weeks (not specifically defined)	Usually 3–6 months (not specifically defined)	None, follow-up ends after treatment discontinuation	Not defined	Not defined
FIRST, France	Baseline	At least in 12 months	At least every 12 months	At least every 12 months	1 month	Not defined
SwedAD, Sweden	Baseline	Usually 1 month (not specifically defined)	3–6 months (not specifically defined)	3–6 months (not specifically defined)	Not defined	<ul style="list-style-type: none"> Therapy side-effects Therapy switch
AtopyReg, Italy	Baseline	6 months	6 months	6 months	1 month	Not defined

TABLE 4 Pooling ability of the TREAT core dataset domain items for each registry

Domain	Domain item	Registry name, country							
		A-STAR, UK and Ireland	TREAT NL, the Netherlands	TREATgermany, Germany	Biobadatop, Spain	SCRATCH, Denmark	FIRST, France	SwedAD, Sweden	AtopyReg, Italy
Demographics	Date of birth	✓	✓	✓	✓	✓	✓	✓	✓
	Date of enrolment into registry	✓	✓	✓	✓	✓	✓	✓	✓
	Gender	✓	✓	✓	✓	✓	✓	✓	✓
	Ethnicity	✓	✓	✓	✓	✓	✓	✓	✓
	Educational status	✓	✓	✓	✓	✓	✓	✓	✓
	Current occupation or education	✓	✓	✓	✓	✓	✓	✓	✓
AE diagnosis	How diagnosis AE is established	✓	✓	✓	✓	✓	✓	✓	✓
	Use of validated diagnostic criteria	✓	✓	✓	✓	✓	✓	✓	✓
	Date of onset AE	✓	✓	✓	✓	✓	✓	✓	✓
Past AE treatments	Phototherapy	✓	✓	✓	✓	✓	✓	✓	✓
	Systemic therapy	✓	✓	✓	✓	✓	✓	✓	✓
	Topical treatments for AE	✓	✓	✓	✓	✓	✓	✓	✓
	Day hospital care treatments for AE (outpatient)	✓	✓	✓	✓	✓	✓	✓	✓
	Hospitalization for AE	✓	✓	✓	✓	✓	✓	✓	✓
Current AE treatments	Phototherapy	✓	✓	✓	✓	✓	✓	✓	✓
	Systemic therapy	✓	✓	✓	✓	✓	✓	✓	✓
	Topical treatments for AE	✓	✓	✓	✓	✓	✓	✓	✓
	Amount of topical creams/ointments used per week	✓	✓	✓	✓	✓	✓	✓	✓
Family history of AE or allergic diseases	Family history of AE or allergic diseases	✓	✓	✓	✓	✓	✓	✓	✓
	Allergic co-morbidities	✓	✓	✓	✓	✓	✓	✓	✓
Allergic co-morbidities	Asthma	✓	✓	✓	✓	✓	✓	✓	✓
	Allergic rhinoconjunctivitis	✓	✓	✓	✓	✓	✓	✓	✓
	Atopic eye disease	✓	✓	✓	✓	✓	✓	✓	✓
	Eosinophilic oesophagitis	✓	✓	✓	✓	✓	✓	✓	✓
	Food allergies	✓	✓	✓	✓	✓	✓	✓	✓
	Contact allergies	✓	✓	✓	✓	✓	✓	✓	✓

(Continues)

TABLE 4 (Continued)

Domain	Domain item	Registry name, country							
		A-STAR, UK and Ireland	TREAT NL, the Netherlands	TREAT Germany	Biobadato, Spain	SCRATCH, Denmark	FIRST, France	SwedAD, Sweden	AtopyReg, Italy
Other past and current co-morbidities	Malignancies	✓	✓	✓	✓	✓	✓	✓	✓
	Serious infections	✓	✓	✓	✓	✓	✓	✓	✓
	Other significant illnesses	✓	✓	✓	✓	✓	✓	✓	✓
Current concomitant medication (i.e. other than specific AE medication)	Antihistamines	✓	✓	✓	✓	✓	✓	✓	✓
	Antibiotics	✓	✓	✓	✓	✓	✓	✓	✓
	Other medication relevant for AE treatment response	✓	✓	✓	✓	✓	✓	✓	✓
	Immunosuppressives for other inflammatory diseases	✓	✓	✓	✓	✓	✓	✓	✓
Baseline general AE questions	Exposures that trigger disease flares	✓	✓	✓	✓	✓	✓	✓	✓
	Episodes of skin infection	✓	✓	✓	✓	✓	✓	✓	✓
	Days lost from usual activities (e.g. work, study)	✓	✓	✓	✓	✓	✓	✓	✓
Baseline physical examination	Fitzpatrick skin type	✓	✓	✓	✓	✓	✓	✓	✓
	Skin examination	✓	✓	✓	✓	✓	✓	✓	✓
Baseline physician- and patient-reported domains	<i>Physician-assessed clinical signs</i>	✓	✓	✓	✓	✓	✓	✓	✓
	Investigator/physician global assessment	✓	✓	✓	✓	✓	✓	✓	✓
	<i>Patient-reported symptoms</i>	✓	✓	✓	✓	✓	✓	✓	✓
	Patient global assessment	✓	✓	✓	✓	✓	✓	✓	✓
	Generic quality of life score	✓	✓	✓	✓	✓	✓	✓	✓
	<i>Skin-specific quality of life score</i>	✓	✓	✓	✓	✓	✓	✓	✓
	Patient-reported satisfaction with AE care received	✓	✓	✓	✓	✓	✓	✓	✓
Baseline investigations	Impact of AE on the family	✓	✓	✓	✓	✓	✓	✓	✓
	Full blood count	✓	✓	✓	✓	✓	✓	✓	✓
	Liver function	✓	✓	✓	✓	✓	✓	✓	✓
	Kidney profile	✓	✓	✓	✓	✓	✓	✓	✓
	Evaluating TPMT level prior to azathioprine use	✓	✓	✓	✓	✓	✓	✓	✓

TABLE 4 (Continued)

Domain	Domain item	Registry name, country								
		A-STAR, UK and Ireland	TREAT NL, the Netherlands	TREATGermany, Germany	Biobadatop, Spain	SCRATCH, Denmark	FIRST, France	SwedAD, Sweden	AtopyReg, Italy	
Baseline management	Main reasons for choosing specific treatment (systemic or phototherapy)	✓	✓	✓						
	Relative contraindication(s) for selected treatment	✓	✓							
Follow-up general AE questions	Days lost from usual activities	✓	✓	✓		✓				
	Change in diagnosis after enrolment	✓	✓							
	Date of death and relation to AE	✓	✓	✓						
Follow-up physical examination	Skin examination	✓	✓			✓			✓	
Follow-up physician- and patient-reported domains	<i>Physician-assessed clinical signs</i>	✓	✓	✓	✓	✓	✓	✓	✓	
	Investigator/physician global assessment	✓	✓	✓		✓		✓	✓	
	<i>Patient-reported symptoms</i>	✓	✓	✓	✓	✓	✓	✓	✓	
	Patient global assessment	✓	✓				✓			
	Generic quality of life score	✓	✓	✓						
	<i>Skin-specific quality of life score</i>	✓	✓	✓	✓	✓	✓	✓	✓	
	Patient-reported satisfaction with AE care received	✓	✓	✓		✓				
	Impact of AE on the family		✓							
	Follow-up investigations	Full blood count	✓	✓						
		Liver function	✓	✓						
Kidney profile		✓	✓							
Follow-up adverse events	Severe adverse events	✓	✓	✓	✓	✓	✓	✓	✓	
	Reason for switching therapy	✓	✓		✓					
Follow-up management	Reason for discontinuation of therapy	✓	✓	✓	✓	✓	✓	✓	✓	
	Total number domain items scored positive on pooling ability	61	69	39	29	28	36	20	34	

Note: The domain items displayed in *italics* are deemed possible to pool across all eight registries.

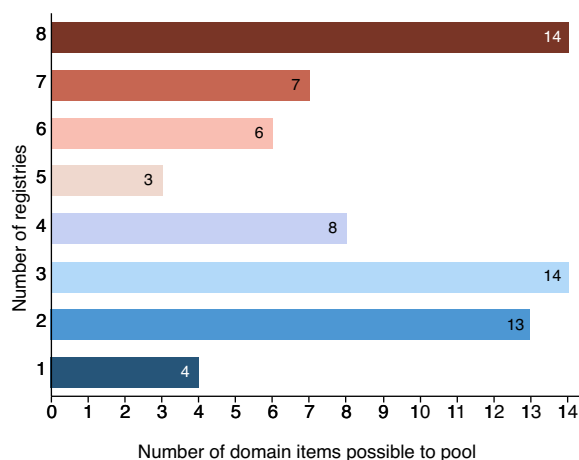


FIGURE 1 Pooling ability of domain item outcomes according to the number of registries. **Dark red bar** – the following 14 domain items are deemed possible to pool across eight registries: ‘date of birth’, ‘date of enrolment into registry’, ‘gender’, ‘date of onset AE’, ‘systemic therapy (current)’, ‘family history of AE or allergic diseases’, ‘asthma’, ‘allergic rhinoconjunctivitis’, ‘physician-assessed clinical signs (baseline and follow-up)’, ‘patient-reported symptoms (baseline and follow-up)’, ‘skin-specific quality of life score (baseline and follow-up)’. **Red bar** – the following seven domain items are deemed possible to pool across seven registries: ‘educational status’, ‘systemic therapy (past)’, ‘phototherapy (current)’, ‘topical treatments for AE (current)’, ‘malignancies’, ‘other significant illnesses’, ‘reason for discontinuation of therapy’. **Pink bar** – the following six domain items are deemed possible to pool across six registries: ‘use of validated diagnostic criteria’, ‘phototherapy (past)’, ‘topical treatments for AE (past)’, ‘atopic eye disease’, ‘food allergies’, ‘severe adverse events’. **Light pink bar** – the following three domain items are deemed possible to pool across five registries: ‘serious infections’, ‘investigator/physician global assessment (baseline and follow-up)’. **Light purple bar** – the following eight domain items are deemed possible to pool across four registries: ‘current occupation or education’, ‘how diagnosis AE is established’, ‘eosinophilic oesophagitis’, ‘antihistamines’, ‘exposures that trigger disease flares’, ‘skin examination (baseline and follow-up)’, ‘days lost from usual activities (follow-up)’. **Light blue bar** – the following 14 domain items are deemed possible to pool across three registries: ‘ethnicity’, ‘contact allergies’, ‘antibiotics’, ‘other medication relevant for AE treatment response’, ‘episodes of skin infection’, ‘Fitzpatrick skin type’, ‘patient global assessment (baseline)’, ‘generic quality of life score (baseline and follow-up)’, ‘patient-reported satisfaction with AE care received (baseline and follow-up)’, ‘main reasons for choosing specific treatment (systemic or phototherapy)’, ‘date of death and relation to AE’, ‘reason for switching therapy’. **Blue bar** – the following 13 domain items are deemed possible to pool across two registries: ‘hospitalisation for AE’, ‘immunosuppressives for other inflammatory diseases’, ‘days lost from usual activities (baseline)’, ‘full blood count (baseline and follow-up)’, ‘liver function (baseline and follow-up)’, ‘kidney profile (baseline and follow-up)’, ‘evaluating TPMT level prior to azathioprine use’, ‘relative contraindication(s) for selected treatment’, ‘change in diagnosis after enrolment’, ‘patient global assessment (follow-up)’. **Dark blue bar** – the following four domain items are registered in one registry: ‘day hospital care treatments for AE (outpatient)’, ‘amount of topical creams/ointments used per week’, ‘impact of AE on the family (baseline and follow-up)’.

interpretation to core dataset items. Also, the high number of domains and domain items included in the core dataset have compromised its feasibility, despite the fact that feasibility aspects were considered in the TREAT core dataset consensus seeking process. This was indicated by the

members ($n = 23$) of the taskforce in a survey, held after finalizing the mapping exercise to clarify the use of the core dataset in their registries. Feasibility was the main reason for not including all core dataset items. Fortunately, the majority of the registries have indicated that they are willing to adapt their registry dataset to overcome potential important differences. We suggest that, in addition to the items that are already being collected by all eight registries, every registry should at least also gather information on safety (i.e. the domain item ‘severe adverse events’) and cost-effectiveness (i.e. the domain items ‘generic quality of life score (baseline and follow-up)’).

For future international analyses, one should not only take differences in registry datasets into consideration, but also differences in prescribing practices (e.g. patient indications), reimbursement restrictions and in- and exclusion criteria, which underlie potential variations in patient populations across the registries. Another factor to consider is that, due to national regulations and preferences, different modalities for data collection (e.g. the data entry platform) and languages are used across countries. Therefore, some challenges for synthesizing data in a network of registries will always remain, leading to potential methodological difficulties. When performing inter-country analyses, these differences should be taken into consideration in the analyses and interpretation of results.

Future perspectives and recommendations

The results of the mapping exercise inform on which data from which registries can be used to answer specific research questions, and therefore, will facilitate comparative or joint analyses across country borders in the future. While considerable differences between the registries exist, comparative and pooled treatment (cost)effectiveness and pharmacovigilance analyses are feasible. This is in particular important and encouraging, as rare but important adverse events (e.g. malignancies) demand investigation in large numbers of patients. Studies within the taskforce will run as investigator-led projects but we are open to project proposals requested by other researchers, clinicians and stakeholders. As a next step, the technical compatibility of the registry data will be assessed in a separate pooling exercise. In addition, we are currently performing an analysis on baseline demographic and clinical characteristics of patients included in all registries.

The present study informs researchers worldwide who are engaged in similar data harmonization processes in international research groups studying other diseases and who are aiming to perform pooled and comparative analyses in the future. In case a centralized data entry platform across registries and countries is impossible, our strong recommendation is to undertake substantial efforts to align and uniform datasets, preferably before inception of the databases. Feasibility should be a major criterion when a core dataset is developed. Finally, we would like to invite and

encourage other national AET treatment registries to join TREAT (treat-registry-taskforce.org).

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CONFLICT OF INTEREST










P.I. Spuls has done consultancies in the past for Sanofi 111017 and AbbVie 041217 (unpaid), received a departmental independent research grants from pharmaceutical industries since December 2019 for the TREAT NL registry, is involved in performing clinical trials with many pharmaceutical industries that manufacture drugs used for the treatment of e.g. psoriasis and atopic dermatitis, for which financial compensation is paid to the department/hospital and, is Chief Investigator (CI) of the systemic and phototherapy atopic eczema registry (TREAT NL) for adults and children and one of the main investigators of the SECURE-AD registry. C. Flohr is 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. L.A.A. Gerbens is one of the main investigators of the TREAT NL registry. She has no further conflicts of interest. A. Chiricozzi is advisory board member, consultant, speaker, investigator in clinical trials for AbbVie, Almirall, Biogen, Fresenius Kabi, Leo Pharma, Lilly, Janssen, Novartis, Sanofi Genzyme and UCB Pharma. M.A. Middelkamp-Hup is consultant for Sanofi and Pfizer and one of the main investigators of the TREAT NL registry. E.K. Johansson received speaker honoraria and/or been a consultant for AbbVie, ACO, Galenica, LEO Pharma, Novartis, and Sanofi-Genzyme. E. Haufe is coordinator of TREATgermany; no further conflicts of interest. J. Schmitt is PI of TREATgermany; institutional funding of IITs from Sanofi, Novartis, Pfizer, ALK; consultancies for Sanofi, Lilly, Novartis, ALK. 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 Newcastle University, research grant funding, funding for lectures and/or travel support from Celgene, Genentech and Sanofi-Genzyme. M. R. Ardern-Jones has acted as a collaborative researcher/consultant/speaker for AbbVie, Pfizer,

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DATA AVAILABILITY STATEMENT

The authors confirm that the data supporting the findings of this study are available within the article and its [Supplementary Materials](#).

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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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