Prescribing Patterns of Dupilumab for Atopic Dermatitis

1. Milestones

Milestone	Planned/Estimated Date
Release of protocol to OHDSI community	**02/11/2021**
Deadline for feedback acceptance from OHDSI community	**5/15/2021**
Finalization of protocol and feedback from the OHDSI community	**5/15/2021**
Start of Analysis	**6/1/2021**
Presentation of Results	**TBD**
Manuscript Submission	**TBD**

2. Revision History – Amendments and Updates

Version	**Date**	**Author(s)**	**Comments**
0.0	7/1/20	Schilling Wetzel Dellavalle Sivesind Branda Silverberg	Initial protocol

3. Objective

The primary objective of this study is to characterize prescribing patterns of dupilumab for atopic dermatitis and to describe variation by patient characteristics.

4. Specific Aims

The Specific Aims are to:

1. Describe cohort of atopic dermatitis patients by patient characteristics.
2. Describe prevalence of dupilumab prescribed for atopic dermatitis by patient characteristics.
3. For individuals newly diagnosed with atopic dermatitis, describe the time between first

diagnosis of atopic dermatitis and the start date of dupilumab.

We hypothesize prevalence of dupilumab use will vary by patient characteristics, specifically race and age. We hypothesize black patients will have a longer interval between diagnosis of AD and initiation of dupilumab.

5. Rationale:

Atopic dermatitis (AD) is a common chronic inflammatory disease. In the United States, the prevalence of AD in children is approximately 10-13% and in adults is approximately 7%.[1-4] Patients with severe disease experience a decrease in quality of life and worse mental health.[1,5] AD is associated with high healthcare resource utilization and healthcare costs from outpatient visits, pharmacy utilization, emergency department visits, and hospitalizations. These costs parallel disease severity.[6-8] Effectively treating patients with greater disease severity has both clinical and economic implications.

Treatment with a systemic immunomodulating agent is indicated when disease is considered moderate-to-severe or has significant psychosocial impact.[9] A variety of systemic agents including cyclosporine, azathioprine, methotrexate, mycophenolate mofetil, and systemic steroids are used in practice without strict guidelines or recommendations to guide treatment choice.[9,10] In March 2017, dupilumab became the first biologic drug approved for atopic dermatitis in adults; it now has indications for both pediatric and adult populations, having been approved for treatment of AD in children six years or older since May 2020. Its mechanism of action is via inhibition of interleukins (IL)-4 and IL-13, both key mediators in the inflammatory cascade in AD. Compared with the aforementioned systemic immunomodulating agents, dupilumab may be more effective as a long-term/maintenance therapy and has the advantage of an overall better side effect profile, with no required drug-specific laboratory monitoring.[10] Access, however, may be limited by its novelty and cost.

The disease burden of AD disproportionately affects non-Hispanic black patients. In children with AD, the prevalence in black children is greater than 15%, versus approximately 10% in white children.[2] Environment, socioeconomic status, race, and genetics are associated with this disparity.[4,11] Loss of function mutations in the filaggrin gene are associated with an increased risk of developing AD and having persistent disease. Filaggrin mutations are less common in black patients compared to white patients.[12,13] However, regardless of filaggrin mutation status, black children with AD are more likely to have persistent disease than are white children.[12] Additionally, black patients have lower ceramide/cholesterol ratios, an attenuated Th1 and Th17 immunophenotype, and higher serum IgE levels.[14,15] Despite more severe disease and increased healthcare utilization, black patients are less likely to receive outpatient dermatology care.[3,16-18] Previous research has shown black patients with psoriasis are less likely than white patients to receive biologic treatment, independent of demographic/socioeconomic factors and comorbidities.[19,20] Previous research has demonstrated racial disparities in access to newer therapies for atopic dermatitis: in a 2020 study, patients who identified as Black were found to be less likely to receive prescriptions for dupilumab.[21] However, this was a single site study and did not attempt to confirm relevant diagnoses. Expansion upon the work of Bell et al.[21], particularly the characterization of dupilumab use by

race and other patient demographics, is therefore warranted. Further data on prescribing patterns of dupilumab for AD are needed in order to ensure health equity and inform best practice guidelines.

6. Research methods

6.1 Study Design

This study was designed collectively by consensus among the authors following periodic conferencing between June 1, 2020 and April 23, 2021.

This study will be a retrospective, observational cohort study. By "retrospective" we mean the study will use data already collected before the start of the study. By "observational" we mean no intervention will take place in the course of this study. By "cohort study" we mean a collection of persons that meet certain criteria.

The analyses will be performed across a network of observational healthcare databases. All databases have been transformed into the OMOP Common Data Model, Version 5. The complete specification for the OMOP Common Data Model, Version 5 is available at: https://github.com/OHDSI/CommonDataModel. The following databases will be included in this analysis following successful feasibility and passing all study diagnostics.

6.2 Participating Organizations and their Data Sources

Information to be collected from participating entities (via form):
Data partners, please fill out the following form to provide institutional and data details:

- Owner (university, claims aggregator, etc.)
- Name of Database
- Type of data (claims, clinical data/electronic medical records)
- Medication information available (insurance claims, pharmacy fulfillments, prescriptions, clinical narrative documentation
- Geographic representation
- Study contact – Name and email

Participating Partners & Data Sources: TBD--Will be completed based on information completed on the form.

6.3 Data Collection

The University of Colorado will serve as the coordinating center (CC) for this study. The CC will share "study packages" (e.g., SQL queries and R code) that have been tested by the CC team prior to distribution to participating data partners. Partners will run the study packages on their own OMOP CDM data and return the extracted data sets to the CC Team. The CC team will complete the final data analysis.

6.4 Data Time Period

3/28/2017 to 3/28/2021
The data time period was chosen by consensus among the authors to capture prescribing patterns for the newest biologic agent, dupilumab, which received FDA approval on 3/28/2017 for the treatment of atopic dermatitis in adults. The data time period will therefore begin on the approval date and include four years of data spanning 03/28/2017 – 03/28/2021.

6.5 Population Cohort Definitions

Study cohorts will be created using ATLAS parameters and code lists.

Target cohort – Patients with atopic dermatitis, age four to 85 years.

- Persons between four and 85 years of age during the study period of treatment that occurs between 3/28/2017 and 3/28/2021. This equates to an earliest birth date of 03/28/1932 and a latest birthdate of 03/28/13.
- The earliest potential start of inclusion for a person would be defined as the start of the 4th year of life (DOB + 4 years) within the data source time period.
- The latest potential end of a person's inclusion in the analysis would be defined as the start of the 85th year of life (DOB + 85 years) within the data source time period.
- Any two occurrences of a diagnosis of atopic dermatitis, as defined within the Atlas parameters, within study time period

Outcome cohort – Prescription for dupilumab for treatment of atopic dermatitis.

6.5.1 Specific Aim 1: Defining and Describing the Study Cohort of Interest

Aim 1 cohort inclusion criteria includes:

- Two diagnoses of atopic dermatitis, with at least one diagnosis of atopic dermatitis occurring within the 4 year study period (= denominator) (see Figure 1).
- The AD cohort will be characterized with respect to number of individuals, age, sex, race/ethnicity, date of first diagnosis of AD, and insurance type

6.5.2 Specific Aim 2: Addressing Prevalence of Drug of Interest (DOI)

Aim 2 cohort inclusion criteria includes:

- Two diagnoses of AD within the study period with at least one DOI prescribing event defined as a prescription for dupilumab within the study period, with at least one diagnosis of atopic dermatitis within the observation period starting 24 months prior to- and ending at the 1st DOI event date, so T = -24 mo to T=0 days where T=0 is dupilumab prescribing (clinical data).
- DUI (dupilumab) Prescribing Prevalence - an eligible dupilumab prescribing event will be identified by the following:
    - DOI is any prescription of dupilumab
    - Must be prescribed for >= 1 day.
    - A DOI event must occur on or after the date of the 1st diagnosis of atopic dermatitis and until the end of the study period.

6.5.3 Specific Aim 3: Assess time between first diagnosis of atopic dermatitis and the start date of dupilumab for those newly diagnosed with AD

Aim 3 cohort inclusion criteria include:

- Individuals who have a single diagnosis of atopic dermatitis occurring within a 24-month lookback period plus the 4 year study period of treatment that occurs between 3/28/2017 and 3/28/2021 will be considered “newly diagnosed” with AD
- At least one dupilumab prescribing event within the study period, occurring after the diagnosis of AD
- Patients with an existing AD diagnosis at the start of the 24-month look-back period will be excluded, as we will be unable to accurately determine how long they have had the diagnosis

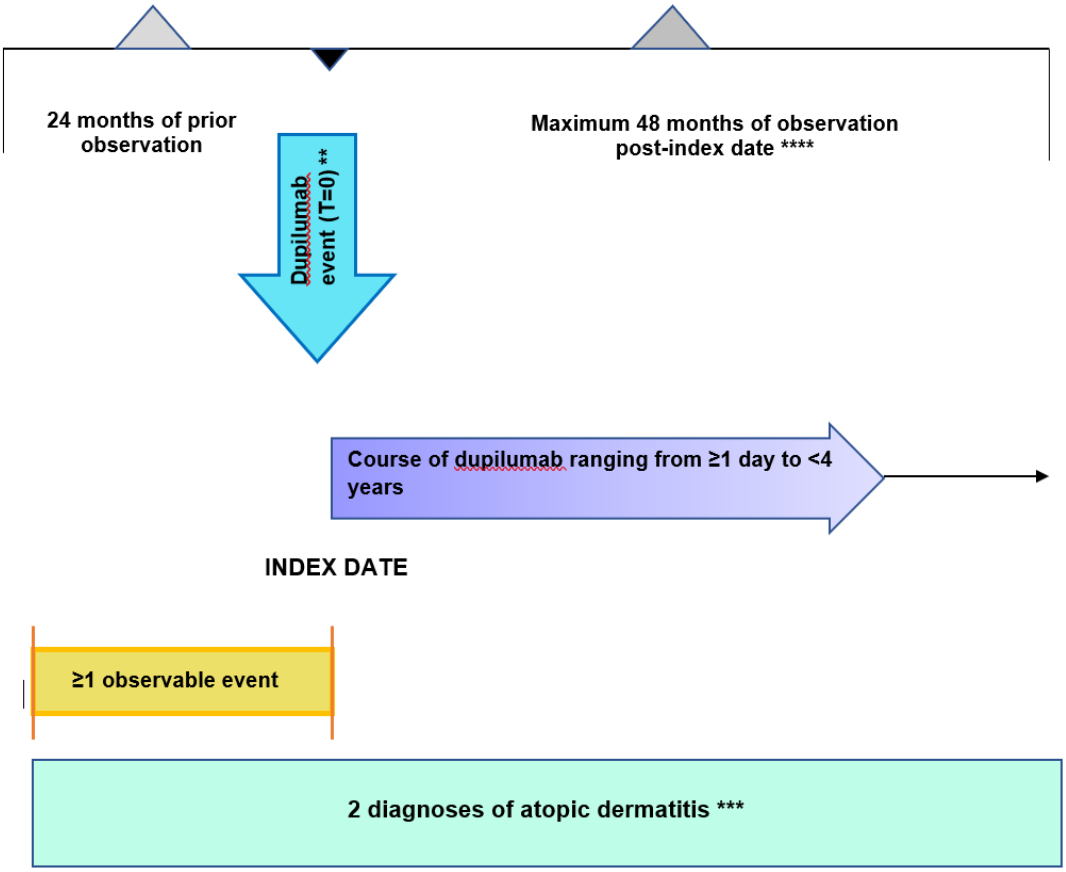
Potential limitations:

- If the DOI prescribing event cannot be specifically associated with a diagnosis of atopic dermatitis, people who have AD but are on dupilumab for a reason other than AD (e.g., asthma, chronic rhinosinusitis) may be included (numerator problem)
- We may miss people who have atopic dermatitis but are misclassified by diagnosis (e.g., “dermatitis unspecified,” “lichen simplex chronicus,” “prurigo nodularis”) (denominator problem).
- Without observation of patients’ full medical histories, it is possible that prior diagnoses of atopic dermatitis and associated courses of treatment for AD could be missed

- Patients who received dupilumab as a manufacturer sample may be missed.
- Dupilumab is indicated for moderate-severe atopic dermatitis; disease severity will not be captured by disease coding, therefore, some patients in the AD cohort may have a severity level for which dupilumab is not indicated

Once a person is admitted to the cohort, the length of time of observation following the index date, and therefore information on subsequent dupilumab prescriptions, will continue until the period of the individual's observation (maximum 4 years) ends or the study period end date of 03/28/2020, whichever occurs first.
We will collect data on the latest date of an observable event (ie, visit, procedure, any prescribing event or measurement) so we can describe the length of each person's observable period.

Figure 1. Prescribed drug of interest course



Inclusion Criteria

*A person should not be prescribed dupilumab (type and days >=1) in this period

**T=0 is dupilumab prescribing date (clinical data) or fulfillment date (claims data)

***A person should have 2 diagnoses of atopic dermatitis with at least 1 diagnosis between the 24-month observation period and the 1st DOI date OR between the index date and the 4-year study period

****Observation will continue until the individual's observation period ends or the maximum observation period of 4 years is reached

6.5.5 Drug of Interest

The Drug of Interest is defined as any prescription of dupilumab, known to be prescribed for atopic dermatitis >= 1 day, represented by the following concept set:

- Dupilumab (subcutaneous injection) 200 mg and 300 mg formulations, identified by National Drug Code associated with generic name and Master Form Code.[9,10,22]
    - Limitations:
        - Dupilumab received as a manufacturer sample will not be captured.

6.5.6. Atopic Dermatitis Diagnosis

- The AD diagnoses used for the broad inclusion cohort are represented by the following concept set.
- Concept set to include ICD10 L20 (AD) and its descendant codes:
    - L20 Atopic Dermatitis
    - L20.0 Besnier's prurigo
    - L20.8 Other atopic dermatitis
    - L20.81 Atopic neurodermatitis
    - L20.82 Flexural eczema
    - L20.84 Intrinsic (allergic) eczema
    - L20.89 Other atopic dermatitis
    - L20.9 Atopic Dermatitis, unspecified

  and ICD10 L30 (eczema and unspecified dermatitis) descendant code:
    - L30.9 Dermatitis, unspecified

- Concept to exclude ICD10 L40 Psoriasis, L26 Exfoliative dermatitis, L27 Dermatitis due to substances taken internally, L28 Lichen simplex chronicus and prurigo, L29 Pruritus, R21 Rash and other nonspecific skin eruption, and their descendant codes

6.5.7 Other Variables of Interest

- Disease severity
    - Hospitalizations for primary diagnosis of AD during study time period
    - Hospital length of stay for primary diagnosis of AD during study time period
    - Clinical data – disease grading by clinician (mild, moderate, severe); Eczema Area and Severity Index, SCORAD, *if available*
- Other conditions (>=30 days prior to DOI start) that may affect treatment choice
    - Pregnancy, lactation, or peripartum condition
- Information on select non-atopic dermatitis diagnoses for which dupilumab has FDA approval and for which a patient might be prescribed dupilumab for >=14 days. Concept sets to include:
    - Asthma: ICD10 J45 and its descendent codes
    - Chronic rhinosinusitis: ICD10 J32.9 (chronic sinusitis) and ICD10 J31.0 (chronic

rhinitis)
    - Allergic rhinitis, unspecified: ICD10 J30.9
    - Nasal polyp/polyposis: ICD10 J33.9
- Date of last observable event (visit, prescribing event) for a given patient.
    - May be coded as days duration from index date to last observable event.

6.7 Outcomes

Reporting of results will adhere to STROBE guidelines for reporting observational studies.[23] Patient demographics will be reported using descriptive statistics with count and percentage for categorical characteristics or mean and standard deviation if normally distributed otherwise median and interquartile range for continuous characteristics.

For Aim 1: Patients with a diagnosis of AD will be categorized by demographic factors (age, gender, race and insurance) as well as the type of AD that was first diagnosed, and will be further categorized by pregnancy, lactation, or peripartum status.

For Aim 2: Patients with a prescription of dupilumab will be categorized by demographic factors (age, gender, race, and insurance). As race is a primary factor of interest (Denominator = # of persons with AD within each race category) we will be characterizing the distribution of dupilumab within race. Within a race category, the prevalence of dupilumab will be captured by first showing the population counts with AD in each race category and the prevalence of those with a qualifying dupilumab prescription. The race category will be assigned as the most recent update of race within OMOP; we will not reassign the race category.

Further analysis will be performed with respect to trends over time in prescription of dupilumab, with possible subgroup analysis for pre-March 2020 and post-March 2020 subgroups, in order to assess impact of COVID-19 on dupilumab prescription continuity--i.e., fewer dupilumab prescription starts or interruptions in prescription fills since start of the COVID-19 pandemic.

For Aim 3. Patients newly diagnosed during the study window or preceding 24-month observation period will be categorized by time between first diagnosis of atopic dermatitis and the start date of dupilumab, amount and duration of dupilumab prescribed.

7. Limitations and Caveats

- Race may not be reported or captured by available categories.
- Atopic dermatitis may be coded differently. Broadening the diagnosis inclusion would run the risk of including patients who do not have atopic dermatitis.
- Patients may have received a diagnosis of AD outside the health systems that

are contributing the study data, causing some diagnoses to be missed

· If the DOI prescribing event (e.g., prescription/order) is not directly associated with a diagnosis of atopic dermatitis, we would run the risk of including patients who were prescribed dupilumab for diagnoses other than AD.

· Unclear whether the databases will capture insurance status (or changes in insurance status during the study window), or length of time on any particular insurance type

8. Protection of Human Subjects

· This study will use de-identified data.

· IRB approval: Each participating data site confirmed Institutional Review Board approval for the study or confirmed their analysis did not require approval because it was exempt or was deemed non-human subjects research (e.g., because the database had previously been de-identified).

9. Return of Data Query/Results

We seek deidentified row-level patient data so we may create aggregate overall results: For every patient meeting inclusion criteria, we would seek return of the following information:

Patient demographic table:

- Age at index visit (first prescription for dupilumab for AD)
- Sex/gender -- biologic or other
- Race
- Ethnicity
- Pregnancy status, lactation status, recent delivery status and delivery date
- Insurance type
- Zip code
- AD severity at beginning of study time period
- AD severity at index visit
- Encounter type for all encounters during study time frame
- Dupilumab dose, days supplied for prescription, # of refills for prescription

10. Plans for disseminating and communicating study results

The study results will be posted on the OHDSI website after completion of the study and published in a peer-reviewed scientific journal.

Initial proposal date: TBD

Launch date: TBD

Study closure date: TBD

Results submission: Email

11. Example Text, Figures, and Table shells for eventual publication

This section illustrates example results text, tables and figures that will be generated:

Example results text:

“There were X dupilumab prescriptions among X patients. Median age was X and X% were male (Table 2). The mean duration of therapy was x days. The mean number of prescriptions as part of a course of therapy was x prescriptions. X% of patients were Caucasian and X% Skin of Color.””

“The number of days from AD diagnosis to prescription of dupilumab ranged from X to X among X patients, with a median length of X.”

Table 1: Concept sets (as defined and linked in Atlas)

Concept Set
CU-AMC Atopic dermatitis
CU-AMC Dupilumab
CU-AMC Asthma
CU-AMC Chronic rhinosinusitis
CU-AMC Allergic rhinitis
CU-AMC Nasal polyposis

Table 2: Atopic Dermatitis diagnosis concept set = CU-AMC Atopic Dermatitis; Table 2 lists the ICD-10 Included Source Codes that map to the included concept IDs for the purpose of face validity

Concept ID	**Concept Code**	**Concept Name**	**Class**	**Domain**	**Vocabulary**
45596150	H60.54	Acute eczematoid otitis externa	5-char nonbill code	Non-standard	Condition
45557485	H60.541	Acute eczematoid otitis externa, right ear	6-char billing code	Non-standard	Condition

45557486	H60.542	Acute eczematoid otitis externa, left ear	6-char billing code	Non-standard	Condition
45547951	H60.543	Acute eczematoid otitis externa, bilateral	6-char billing code	Non-standard	Condition
45581716	H60.549	Acute eczematoid otitis externa, unspecified ear	6-char billing code	Non-standard	Condition
1569765	L20	Atopic dermatitis	3-char nonbill code	Non-standard	Condition
35208449	L20.0	Besnier's prurigo	4-char billing code	Non-standard	Condition
1569766	L20.8	Other atopic dermatitis	4-char nonbill code	Non-standard	Condition
45543364	L20.81	Atopic neurodermatitis	5-char billing code	Non-standard	Condition
45552974	L20.82	Flexural eczema	5-char billing code	Non-standard	Condition
45572263	L20.83	Infantile (acute) (chronic) eczema	5-char billing code	Non-standard	Condition
45601213	L20.84	Intrinsic (allergic) eczema	5-char billing code	Non-standard	Condition
45567351	L20.89	Other atopic dermatitis	5-char billing code	Non-standard	Condition
35208450	L20.9	Atopic dermatitis, unspecified	4-char billing code	Non-standard	Condition
1569772	L25	Unspecified contact dermatitis	3-char nonbill code	Non-standard	Condition
35208480	L25.8	Unspecified contact	4-char billing code	Non-standard	Condition

		dermatitis due to other agents			
35208481	L25.9	Unspecified contact dermatitis, unspecified cause	4-char billing code	Non-standard	Condition
35208488	L28.0	Lichen simplex chronicus	4-char billing code	Non-standard	Condition
35208497	L30.0	Nummular dermatitis	4-char billing code	Non-standard	Condition
35208498	L30.1	Dyshidrosis (pompholyx)	4-char billing code	Non-standard	Condition
35208500	L30.3	Infective dermatitis	4-char billing code	Non-standard	Condition
1569780	L43	Lichen planus	3-char nonbill code	Non-standard	Condition
35208521	L43.0	Hypertrophic lichen planus	4-char billing code	Non-standard	Condition
35208522	L43.1	Bullous lichen planus	4-char billing code	Non-standard	Condition
35208524	L43.3	Subacute (active) lichen planus	4-char billing code	Non-standard	Condition
35208525	L43.8	Other lichen planus	4-char billing code	Non-standard	Condition
35208526	L43.9	Lichen planus, unspecified	4-char billing code	Non-standard	Condition
35208528	L44.1	Lichen nitidus	4-char billing code	Non-standard	Condition
35208529	L44.2	Lichen striatus	4-char billing code	Non-standard	Condition
35208530	L44.3	Lichen ruber moniliformis	4-char billing code	Non-standard	Condition
35208605	L66.1	Lichen planopilaris	4-char billing code	Non-standard	Condition
35208663	L81.7	Pigmented purpuric	4-char billing code	Non-standard	Condition

		dermatosis			
1569778	L30	Other and unspecified dermatitis	3-char nonbill code	Non-standard	Condition
35208503	L30.8	Other specified dermatitis	4-char billing code	Non-standard	Condition
35208504	L30.9	Dermatitis, unspecified	4-char billing code	Non-standard	Condition

Example Table 3: Databases included and their characteristics

Database	**Location**	**Years of data**	**Owner**

Example Table 4: Study population demographics by data source(s)

	Datasource #1	Datasource #2	Datasource #3, etc.
Age of first AD diagnosis between 4 - 85 years of age	Mean (std) N (%) within age groupings		
Race listed at first AD diagnosis	N (%) within age groupings		
Gender Male Female	N (%)		
Country(ies) of data source US UK Japan etc.	N (%)		
Atopic Dermatitis diagnosis X	N (%)		

X X etc.			
Insurance type Governmental Private None Other	N (%)		

Example Table 5: User prevalence and number of prescriptions of dupilumab by database (prevalence per 1000 persons), ranked by the average user prevalence

	User prevalence					**Prescription prevalence**				
Dupilumab	CPRD	JMDC	Optum	CCAE	Truven	CPRD	JMDC	Optum	CCAE	Truven
Overall										
Male										
Female										
Age 4-15										
16-25										
26-35										
36-45										
etc.										
Caucasian										
Skin of Color										

Example Table 6: Number of qualifying dupilumab prescriptions by database

	Number of prescriptions				
DOI	**Database #1**	**Database #2**	**Database #3**	**Database #4**	**Database #5**

dupilumab					

Example Table 7: Description of duration of dupilumab courses

Sex	**Mean, standard deviation, median and interquartile range of course duration (weeks)**
Overall	
4-15	
16-25	
26-35	
36-45	
46-55	
56-65	
66-75	
76-85	
Male	
4-15	
16-25	
26-35	
36-45	
46-55	
56-65	
66-75	
76-85	
Female	
4-15	
16-25	

26-35	
36-45	
46-55	
56-65	
66-75	
76-85	
Caucasian	
4-15	
16-25	
26-35	
36-45	
46-55	
56-65	
66-75	
76-85	
Skin of Color	
4-15	
16-25	
26-35	
36-45	
46-55	
56-65	
66-75	
76-85	

Example Table 8: Variation in duration of therapy by country

Country	**Duration of therapy (days/months): Mean, standard deviation, median and interquartile range**
United States	
United Kingdom	
Japan	
France	
Germany	
Other	
Other	
Other	

Appendix 1

Please use the below format for adding your institution for this protocol

- Name of Database
- Owner (university, claims aggregator, etc)
- Type of data (claims, clinical data,electronic medical records)
- Medication information (insurance claims, pharmacy fulfillments, prescriptions, clinical narrative documentation)
- Geographic representation

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