

Principal Investigator

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General Information

Key Personnel (in addition to PI):

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First Name: Anjana

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Are external grants or funds being used to support this research?: No external grants or funds are being used to support this research.

How did you learn about the YODA Project?: Other

Conflict of Interest

https://yoda.yale.edu/system/files/as_coi_signed.pdf

https://yoda.yale.edu/system/files/jt_coi_signed.pdf

Certification

Certification: All information is complete; I (PI) am responsible for the research; data will not be used to support litigious/commercial aims.

Data Use Agreement Training: As the Principal Investigator of this study, I certify that I have completed the YODA Project Data Use Agreement Training

1. [NCT02203032 - CNT01959PSO3003 - A Phase 3, Multicenter, Randomized, Double-blind Study to Evaluate the Efficacy and Safety of Guselkumab for the Treatment of Subjects With Moderate to Severe Plaque-type Psoriasis and an Inadequate Response to Ustekinumab](#)

What type of data are you looking for?: Individual Participant-Level Data, which includes Full CSR and all supporting documentation

Research Proposal

Project Title

Clinical Trial Diversity for Common Dermatologic Diseases: A Systematic Review

Narrative Summary:

Existing literature supports that responses to drugs and therapeutics differ between population subgroups. Despite federal efforts, emerging data suggest that clinical trials suffer from under-reporting of demographic data and under-representation of minorities. But there is limited literature in dermatology. We aim to describe the demographic composition of dermatologic clinical trial participants in the U.S. for common skin conditions (psoriasis, atopic dermatitis and acne vulgaris) reported between 2014 and 2019. We conducted a systematic review of literature and among international studies we are reaching out to pharmaceutical companies to request data on the participant pool from the US.

Scientific Abstract:

Background: Existing literature supports that responses to drugs and therapeutics differ between population subgroups. Emerging data suggest that clinical trials suffer from under-reporting of demographic data and under-representation of minorities. Literature on diversity of dermatologic clinical trials is limited, warranting further research. **Objective:** The study aims to describe the demographic composition of dermatologic clinical trial participants in the U.S. for psoriasis, atopic dermatitis and acne vulgaris reported between 2014 and 2019. **Study design:** A systematic review of literature on psoriasis, atopic dermatitis and acne vulgaris phase 3 clinical trials published between 2014 and 2019. Data will be compiled from two sources?for studies conducted exclusively in the US, demographic data reported in the published articles and among international studies, descriptive analysis and summary for each clinical trial requested from study sponsors. Final data includes descriptive summaries from each clinical trial obtained from different sources. **Participants:** Dermatologic clinical trial participants, specifically from psoriasis, atopic dermatitis and acne vulgaris trials reported between 2014 and 2019 and enrolled in the US. **Main Outcome Measures:** Participant enrollment in the US measured by mean/median age of the participant pool and proportion by sex and race/ethnicity. **Statistical Analysis:** Collective data will be weighted for the total population across the clinical trials and descriptive data analysis using weighted study population will be conducted.

Brief Project Background and Statement of Project Significance:

The US population is rapidly diversifying, and according to the US Census Bureau's 2014 National Projections report, more than half of the US population is projected to be represented by minority groups by 2044 (L. Colby & Ortman, 2015). Existing literature supports that responses to and adverse events due to drugs, including dermatologic drugs (Taylor, 2002), can differ between population subgroups (Conforti et al., 2018; Ramamoorthy, Pacanowski, Bull, & Zhang, 2015). NIH and FDA policies and guidelines call for adequate inclusion of women and minorities in clinical trials and other clinical research (Health, 2001, 2017). However, despite federal efforts, emerging data suggest that clinical trials, including for dermatologic conditions, suffer from under-reporting of demographic data and under-representation of minorities (Charrow, Xia, Joyce, & Mostaghimi, 2017; Chen, Lara, Dang, Paterniti, & Kelly, 2014). There is limited literature on the diversity of clinical trials in dermatology, thus, additional and more detailed studies describing the current composition of dermatologic clinical trial populations are warranted.

Specific Aims of the Project:

The purpose of this study is to describe, in detail, the demographic composition (specifically age, gender, and race/ethnicity) of dermatologic clinical trial participants in the U.S. for common skin conditions (psoriasis, atopic dermatitis and acne vulgaris) reported between 2014 and 2019. We hypothesize that there is under-representation of racial/ethnic minorities among all clinical trials for psoriasis, atopic dermatitis, and acne vulgaris in the U.S.

What is the purpose of the analysis being proposed? Please select all that apply.

Preliminary research to be used as part of a grant proposal

Other

Research Methods

Data Source and Inclusion/Exclusion Criteria to be used to define the patient sample for your study:

We conducted a systematic review of literature published between 2014 and 2019 on phase 3 clinical trials on psoriasis, atopic dermatitis and acne vulgaris. In addition, among trials that were conducted internationally, we plan to reach out to pharmaceutical companies that sponsored the trial to request demographic data on the participant pool from the USA.

Inclusion criteria:

1. Clinical trials on psoriasis, atopic dermatitis or acne vulgaris
2. Clinical trials reported or published between 2014 and 2019
3. Clinical trials conducted in the US
4. Phase 3 clinical trials

Exclusion criteria:

Non-human trials

Main Outcome Measure and how it will be categorized/defined for your study:

Study enrollment: mean/median age, and counts and percentages by sex and race/ethnicity among participants enrolled in the US alone.

Main Predictor/Independent Variable and how it will be categorized/defined for your study:

Age, sex (male, female), race (white, black, Asian, other), and ethnicity (Hispanic, non-Hispanic) of participants enrolled in the USA.

Statistical Analysis Plan:

Data will be collected from two sources- data from published articles and descriptive summaries generated on the data sharing platforms. For studies conducted exclusively in the US, demographic data reported in the published articles were collected. And among international studies, descriptive analysis will be conducted for each clinical trial on the data sharing platforms and a descriptive summary for each clinical trial will be generated. Participants with missing data in these clinical trial will be included in the analysis and will be categorized under other/unknown in the descriptive summary. Final data will include descriptive summaries from each clinical trial obtained from different sources. The collective data from the two sources will be weighted for the total population across the clinical trials and descriptive data analysis using weighted study population will be conducted. The demographic factors age, gender and race/ethnicity will be described.

Software Used:

STATA

Project Timeline:

Timeline: Now - 06/30/2020

Analysis completion date: 06/30/2020

Manuscript preparation and publication timeline: TBD

Date results reported to YODA: 06/30/2020

Dissemination Plan:

We plan to use the findings of this study as preliminary data for an NIH grant proposal and to publish our results in the Journal of American Academy of Dermatology.

Bibliography:

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