Data Access and Use

Leadership, Policies and Processes

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Introduction

DataDerm was launched in 2016 with the vision to serve as the premier registry to facilitate patient care, research, and teaching in dermatology. As of the end of 2021, DataDerm has data from more than 1,600 practices representing more than 5,300 clinicians, 13 million unique patients and 46 million patient visits. For its first five years of existence, DataDerm data were mainly used to calculate quality measure results and facilitate member participation in the Merit-based Incentive Payment System (MIPS). However, with responsible management and oversight, these data can now be used to support the specialty of dermatology through data-driven scientific research, advocacy, and ongoing improvement of patient care and outcomes. The launch of DataDerm's data analytics area aligns with the Academy's efforts to promote the use of DataDerm as a tool for developing beneficial scientific information for the specialty. This document aims to provide a detailed description of DataDerm's data analytics area, including its leadership, policies and processes for data access and use.

Data Governance Task Force

Mission

The Data Governance Task Force (DGTF) is charged with overseeing DataDerm's data analytics area, which includes the overall management of the data, development of data reports, and implementation of established policies and processes for data access, dissemination and use by various stakeholder groups. The Data Governance Task Force makes recommendations to the DataDerm Oversight Committee on these topics.

Objectives

The DGTF plays a crucial role in ensuring that DataDerm data is used ethically and in a way that upholds the confidentiality and privacy of clinicians and patients.

The DGTF oversees DataDerm's approach to:

- Ensuring the confidentiality and protection of clinician and patient data within DataDerm
- Maintaining the data and ensuring its reliability and quality
- Increasing the accessibility of DataDerm data to AAD members and other appropriate stakeholders
- Providing a mechanism for review and approval of ad hoc queries of the data
- Enforcing policies and processes to ensure the responsible use of DataDerm data

Organizational Structure

The DGTF comprises 6-8 members and reports to the AAD's DataDerm Oversight Committee (DOC). The DGTF chair will provide regular updates on Task Force activities to the DOC and is required to obtain DOC's approval on new initiatives. The Task Force is supported by its staff liaison, the Associate Director, Registry Operations, Informatics, and Analysis, with support from the DataDerm Physician Advisor, Data Analyst, and Sr. Data Analyst.

Data Analytics Partner

In Spring 2021, AAD launched a collaboration with OM1, [https://www.om1.com/], a real-world outcomes and technology company. The AAD-OM1 collaboration allows AAD to leverage DataDerm data to provide broader research insights through the ability to link to other data sources such as claims data and access to advanced analytics capabilities. Should a request be deemed beyond the scope of DataDerm analytics staff, AAD will facilitate discussion with OM1.

Data Management and Quality

To manage DataDerm data and improve its overall quality, the DGTF, assigned staff, and the physician advisor oversee various efforts, including:

- Data cleaning: Reviewing data for anomalies, inconsistencies, and patterns that may indicate outliers
- Reviewing data for completeness and providing recommendations to improve data quality
- Identifying trends, gaps, and other patterns in the data

All analyses for DataDerm's data analytics area are performed using a de-identified dataset in compliance with all applicable statutes and regulations, under federal and state laws, including but not limited to the privacy and security regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and any other applicable statutes or regulations concerning patient privacy and data security. The Academy is not permitted to identify or contact the individuals to whom the data pertain.

Data Access and Use

	Data Access	Examples of Data Use
DataDerm participant – Individual clinician	Individual clinician's data with PHI	• Quality improvement • Informing other referring physicians • Counseling patients and families • Collaborative decision making with other physicians • Individual research • MIPS submission
DataDerm participant – Group practice	Upon receiving permission from individual clinicians to report as part of a group, all individual clinicians' data with PHI	• Quality improvement • Comparative analysis and stimulating educational opportunities between different clinicians in same practice • MIPS submission
AAD staff, AAD Councils Committees and Task Forces (CCTFs), and member leaders	Aggregate data report(s) and/or table(s) No patient- or clinician-identifiable data; no individual patient-level data	• Ensuring timely MIPS submission to the Centers for Medicare & Medicaid Services (CMS) • Presentations to AAD Board of Directors or other governing bodies • Developing additional reports for participating clinicians, practices, and other entities • Providing background information for advocacy efforts • Other AAD initiatives and publications
Non-commercial or non-profit entities (e.g., other healthcare providers, hospitals, academic institutions, etc.)	Aggregate data report(s) and/or table(s) No patient- or clinician-identifiable data; no individual patient-level data	• Scholarly activities, care delivery science, educational opportunities, studies on patterns of practices, etc. • Support research investigations • Presentations or publications • Grant submissions
Government or regulatory entities	No patient-identifiable data and no clinician-identifiable data without consent	• MIPS submission to CMS • Supporting audits or implementing policy changes
Industry and other commercial entities (e.g., payers)	Aggregate data report(s) and/or table(s) No patient- or clinician-identifiable data; no individual patient-level data	• Research on practice patterns, leading to development of decision making, tracking outcomes of newly implemented products, therapies, and procedures while monitoring safety and effectiveness of products

Data Requests

This section addresses the management of ad hoc data queries ("data requests"), specifically describing data access, data request submission and review, data use policies and related areas.

The AAD accepts DataDerm data requests from a variety of stakeholders and reserves the right to deny data requests at the discretion of the DGTF. Data analysis is conducted by the DataDerm analytics team with oversight from the DGTF and physician advisor. The DataDerm dataset is refreshed on a quarterly basis. Data requests will be fulfilled using the most recent data available at the time of analysis unless otherwise specified in the data request form.

Eligibility

DataDerm participants, AAD leadership and CCTFs are eligible to utilize AAD-funded analytic time (i.e., DataDerm staff time required for analysis) for data requests approved by the DGTF, subject to the availability of DataDerm's analytic resources. AAD members not participating in DataDerm, non-commercial or non-profit entities (e.g., other healthcare providers, hospitals, academic institutions, etc.), and other industry or commercial entities may be charged a fee for approved data requests, to be determined. This fee will reflect staff, vendor, and technical resources required to complete the data request. Data requests submitted by DataDerm participants, AAD leadership, and CCTFs will be prioritized. Individuals who hold a leadership position (e.g., board member, elected office, executive committee member, other leadership position) at another registry and/or specialty organization must disclose this outside interest within the Data Request Form. Review and adjudication of disclosed outside interests is under the purview of the DGTF, with escalation (e.g., to the DataDerm Oversight Committee, Executive Committee, other reviewing body) at the discretion of the DGTF chair.

As DataDerm analytic resources are intended to support several stakeholders, any individual researcher may not have more than two active data requests in the queue at a given time. In addition, DGTF members are expected to recuse themselves from all discussions, voting and other activities related to their own requests or those which constitute a conflict of interest as per the AAD's policies pertaining to management of conflicts of interest

Permitted Research and Types of Data Requests

Permitted research using DataDerm data includes, but is not limited to, retrospective observational studies, patterns of care analyses, comparative effectiveness research, and outcomes assessments that will support the Academy's efforts to advance the specialty of dermatology. DataDerm data may not be used or disclosed in such a way as to identify the registry participant or any individual physician or physician group unless appropriate consents or authorizations are submitted in writing by the registry participant to DataDerm.

DataDerm accepts two types of data requests: minor/operational requests and major/research requests. Minor requests include things such as a basic count or straightforward data pull with no advanced analysis or visualization. These requests require minimal DataDerm staff time to complete and do not require iterative rounds of refinement. Major requests include hypothesis-driven projects and projects intended for publication and/or presentation. Major requests require one or more of the following: significant analytic staff time to complete, complex analysis, data visualization, and/or iterative rounds of refinement.

Type	Intended Uses & Required Resources	Fulfillment Time
Minor	• Local quality improvement initiatives • Supplemental information in a presentation, publication, or grant proposal or supplemental data to inform an upcoming major data request • Feasibility studies • No complex analysis or data visualization necessary, a simple data pull, e.g., no risk modeling, univariate/multivariate modeling • Minimal analytic staff time required	2-3 weeks once request is approved
Major	DataDerm data is the primary or majority source of data for: • Publication in a peer-reviewed journal • Abstracts, manuscripts, or other materials intended for presentation at a scientific meeting or conference • Research on practice patterns; support research investigations • More complex analysis and/or iterative refinements required;	Varies

Review Process

The DGTF, its staff liaison, DataDerm's analytics team, and physician advisor participate in the review process. The DGTF Chair has the authority to review and approve minor data requests, as defined above. In instances where the DGTF chair approves a minor request, the DGTF will be informed at their next scheduled meeting or conference call. The DGTF will convene as needed throughout the year to review and approve submitted major data requests and publications/presentations. DGTF members review each data request on individual domains including scientific merit, analytic feasibility, proposal impact and appropriate use of registry data. Data Sharing Agreements are fully executed prior to the commencement of the data request.

Data requests that are operational in nature to support ongoing Academy operations and initiatives (e.g., requests from AAD staff, leadership or CCTFs) do not require DGTF approval for completion. The DGTF will be kept informed and updated on the count and nature of operational requests completed using DataDerm data.

The process for the submission, review, and completion of major data requests is as follows:

1. Requestor submits DataDerm request form and updates their disclosure information on the AAD website (https://disclosures.aad.org)
2. DataDerm analytics staff arrange call to review feasibility of the request and discuss any needed refinements to data request form. Publication plans and authorship expectations will also be discussed in this initial call.
3. Requestor submits revised data request form and any applicable supplementary materials to DGTF for review
4. DGTF reviews submitted request during their next scheduled meeting. If approved, the requestor signs and returns DataDerm Data Sharing Agreement prior to commencement of work on the data request.
5. DataDerm analytics staff work with requestor to provide initial draft data report, as outlined in data request. Additional iterative rounds of refinement may be performed as needed.

a. Additional rounds of refinement must remain within the scope of the original approved data request. If, upon review of the original data report, additional data and/or analyses are found to be necessary, they need to be submitted as a separate request to the DGTF for approval.

6. Once a draft of the data report is provided, it is the responsibility of the requestor to ensure timely feedback on the report. If there is a period >90 consecutive days following delivery of a draft data report where DataDerm staff do not receive any communication from the requestor, the request will be considered closed. To re-initiate work on the project, a new request must be submitted to the DGTF, and the project will be prioritized after other active projects.
7. Requestor must submit all abstracts, manuscripts, presentations, or other materials containing DataDerm data to the DGTF for review **prior to submission.**

Expedited Review

In cases where DataDerm data is being sought for a time-sensitive project, data requestors may seek expedited review by checking the applicable box on the Data Request Form and providing the justification for seeking expedited review, including any relevant deadlines and/or other factors impacting the time-sensitivity of the request. DataDerm staff will share this information with the DGTF chair, who provides approval for expedited reviews. Data requests that are approved for expedited review will follow steps 1-3 as described above. The data request will then be reviewed by the DGTF via email ballot, rather than waiting for the next scheduled DGTF call.

Presentations and/or publications that feature DataDerm data can also be reviewed using the expedited email review process. To seek expedited review, the author should request expedited review in the body of the email where they provide the publication/presentation along with any applicable deadlines and other information relevant to the approval timeline for the content.

Executive Lead and Principal Investigator Appointment

Each data request must have a designated executive lead and principal investigator. These roles may be performed by the same person or by separate people. The executive lead serves as the day-to-day point of contact and is responsible for providing timely responses and feedback to DataDerm communications. The principal investigator serves as the scientific lead for the project and has primary responsibility for the substance of any abstracts, manuscripts, or other scholarly outputs that include DataDerm data. Both the executive lead and principal investigator are responsible for the confidentiality and appropriate use of any DataDerm data received in accordance with the Data Sharing Agreement. Each data request must list all data requesters, co-authors, and stakeholders who will access the data.

Presentations and Publications

The Academy requires all abstracts, manuscripts, and other materials containing DataDerm data to be submitted for review by the DGTF prior to submission for presentation or publication. PowerPoint presentations, abstracts and manuscripts should be submitted at least 30 days prior to submission for publication, where possible.

Publication plans and authorship expectations will be addressed during the initial kickoff call between DataDerm staff and the data requestors. Authorship roles should be determined in accordance with author criteria of the destination peer-reviewed journal. In instances where DataDerm staff do not meet authorship criteria, DataDerm must be included in the acknowledgements section.

Presentations that feature DataDerm data must appropriately acknowledge DataDerm, including an appropriate citation on any slide(s) which feature DataDerm data.

When describing DataDerm in the text of an abstract or manuscript, DataDerm should be described as the clinical data registry of the American Academy of Dermatology. The DataDerm team recommends that authors cite the most recent DataDerm annual report and the results of our 2020 independent audit when referencing DataDerm data:

> Van Beek MJ, Swerlick RA, Mathes B, et al. The 2021 annual report of DataDerm: the database of the American Academy of Dermatology. *J Am Acad Dermatol.* 2021; 86 (5): 1058-1062. Doi: https://doi.org/10.1016/j.jaad.2021.11.029
>
> Van Beek, MJ, Swerlick RA, Mathes B, et al. The completeness and accuracy of DataDerm™: the database of the American Academy of Dermatology (AAD). *J Am Acad Dermatol.* 2021; 86(2): 394-398. Doi: https://doi.org/10.1016/j.jaad.2021.06.024

Major data request investigators are strongly encouraged to seek publication of DataDerm data in the Academy's publications (e.g., Journal of the American Academy of Dermatology (JAAD), Dermatology World, etc.). Abstracts, slide decks (e.g. PowerPoints), manuscripts, or other publications using DataDerm data that include potentially controversial findings may be escalated as necessary (e.g., to the DataDerm Oversight Committee, Executive Committee, Board of Directors, other reviewing body), at the discretion of the DGTF chair. Abstracts, slide decks, manuscripts, or other publications that are intended to represent the position of AAD must be approved by the Board.

If an AAD/A council, committee, task force or work group is interested in obtaining DataDerm data with the intent to publish its work in (JAAD), it must submit a JAAD "From the Academy" Proposal form along with a proposed outline of its manuscript to jaadmanagingeditor@aad.org. Once JAAD approval is received, the council, committee, task force or work group may submit its data request to the DGTF.