MOVR DATA GOVERNANCE POLICY

Policy Provision	Description / Obligation
MOVR Background	About ten years ago, MDA recognized that there was a significant data shortage in the neuromuscular disease space and started crafting strategic approaches to accelerate data collection and its use by researchers, clinicians, and drug developers. One strategy that was identified was to leverage the MDA Care Center Network, which is comprised of over 150 care centers and 2,400 clinical providers across the United States, as a source for efficiently capturing clinical data and growing a longitudinal dataset. Specifically, each year, over 90,000 medical visits are conducted and over 60,000 individuals living with a neuromuscular disease receive expert care at these centers. This network also serves as a hub of neuromuscular research activity with over 20,000 individuals participating in clinical trials and natural history studies. Capturing such a dataset would provide valuable **knowledge** on disease progression for drug development as well as for real-world data in regulatory submissions and post-approval processes. The US Neuromuscular Disease Registry (USNDR) served as MDA's pilot registry. The USNDR actively collected clinic-entered data across four diseases (amyotrophic lateral sclerosis, Becker muscular dystrophy, Duchenne muscular dystrophy, and spinal muscular atrophy), at 26 care centers from 2013 to 2018. The success of USNDR, including collecting data from approximately 2,700 participants and using these data in an EU regulatory submission, inspired MDA to partner with IQVIA, a leader in human data science technology, to create MOVR. The USNDR dataset was directly transferred into MOVR, and three new diseases were added: Facioscapulohumeral muscular dystrophy, Limb-girdle muscular dystrophy, and Pompe disease. MOVR represents the first data hub that aggregates clinical and genetic data across multiple neuromuscular diseases. The core data elements captured across all diseases, include: • Demographics – disease type, enrollment date, gender, DOB, race, ethnicity, insurance, education, and employment • Diagnosis – date and age at diagnosis, clinical diagnosis, muscle biopsy, body regions first affected, family history, molecular and DNA results, and gross and developmental motor milestones • Encounter – encounter date, height and weight, clinical trial participation, surgical history, falls and hospitalizations, medications, mobility, assistive devices, disease progression, spinal conditions and neuroimaging, nutritional and GI therapies, pulmonary and cardiology care, and multidisciplinary care

	• Discontinuation – date of withdrawal, reason for study withdrawal, date of death, and cause of death MOVR data are entered by clinical research staff from the information available in participants' medical records. Data are entered from the initial study enrollment visit through follow-up visits until the participant withdraws from the study, is lost to follow-up, or becomes deceased. The Encounter data is captured at each visit and is the foundation of the longitudinal dataset. Individuals living with neuromuscular diseases and their families are at the heart of MDA's mission. MOVR was created to ensure that these individuals are seen and counted and remain at the forefront of developing life-changing therapies. MDA is committed to ensuring that participant data captured by MOVR can inform and improve standards of care and support research that leads to therapeutic development for neuromuscular diseases while maintaining the integrity and privacy of participant data.
Purpose	This Policy is to establish the rules and regulations regarding governance of MOVR Data, data use, publications, and acknowledgement of fees.
Scope	This document establishes the policy for data governance related to MOVR including MOVR background, acronyms and definitions, MDA's roles, and responsibilities, authorized and non-authorized uses of MOVR Data, prohibited uses of MOVR data, ownership of MOVR Data, MOVR Data requests, access and use agreement for MOVR Data, publication guidelines, and fees associated with use of MOVR Data. This Policy applies to all interactions between MDA and any entity seeking to access and use MOVR Data.
Acronyms & Definitions	• **Agreement:** The specific Data Access, Use, and Distribution Agreement entered into between MDA and an Approved Requestor. • **Authorized Uses:** Approved data usage as defined in this Policy • **Approved Requestor:** Each Requestor whose Data Request Form has been approved and with whom an Agreement has been executed. • **Data Request Form:** A formal process for submitting, tracking, and evaluating MOVR Data requests • **Data Access, Use and Distribution Agreement:** To be executed by Requestor prior to receiving MOVR Data for Secondary Research. The agreement specifies the type of permitted access, use, and guidelines on data publication and distribution.

	• **De-identified Data:** Coded data from which identifiers have been removed using industry standards compatible and in conformance with HIPAA including, where available, a Global Unique Identifier (GUID) • **Protected Health Information:** Clinical information captured by MOVR • **HIPAA:** Health Insurance Portability and Accountability Act of 1996 • **MOVR:** MOVR Data Hub® • **MOVR Data:** De-identified aggregate data collected in connection with MOVR that MDA makes available to Approved Requestor and over which MDA maintains ownership • **MOVR Sites:** MDA Care Centers participating in MOVR • **Non-Authorized Uses:** Data uses expressly not approved under this Policy • **Requestor:** Researchers (MOVR Principal Investigators, academic or government researchers, Life Sciences Companies, etc.) who request access to MOVR Data • **Secondary Research:** Scientific research projects developed and conducted by Requestor
Roles & Responsibilities	MDA is responsible for the following: • Ensure that data privacy and security are maintained in accordance with HIPAA, and all applicable security requirements; • Ensure aggregated data is de-identified through Safe Harbor or Statistical Expert de-identification standards under HIPAA; • Maintain confidentiality of all MOVR Data and related information; • Ensure maintenance of MOVR Data quality; • Alert implicated MOVR Sites of breaches in the data capture system and MOVR Data; • Process MOVR Data requests; and • Enforce this Policy, the Data Access, Use and Distribution Agreement, and Secondary Research scope compliance.
Authorized Data Use	Approved Requestor* shall have the right to utilize MOVR Data only for the Authorized Uses defined below, unless otherwise agreed upon by MDA in writing. Authorized Uses shall include the use of MOVR Data for pre- and post-approval patient, disease, and/or market analytics for Requestor. To further prevent against prohibitive use cases, patient, physician, and site identifiers are removed. Authorized Uses therefore include:

	• Protocol based observational research with the intent to publish in peer- reviewed journals or present at scientific conferences;
	• Protocol feasibility (impact on inclusion/exclusion criteria, attrition, patient distributions, and data availability) to inform study design;
	  ○ Note: does not include operational recruitment of MOVR Sites, physicians, and/or study participants
	• Secondary Research to help facilitate better patient, disease, market understanding;
	• Secondary Research to drive clinical care improvement and reduce barriers to therapy development;
	• Analysis of the limitations of MOVR Data; and
	• Comparative Effectiveness Research ("CER"), defined as the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition, or to improve the delivery of care, but only under the following conditions:
	  ○ Approved Requestor's competitor that is the subject of such research will be made aware that a CER study is being conducted;
	  ○ Results must be made public; and
	  ○ Approved Requestor's competitor must be given courtesy review prior to publication/public announcement of results, provided there is no obligation to provide or take action on feedback from the review.
	
	*All Requestors are required to submit a Data Request Form even if request falls under Authorized Data Use.

Non-Authorized Data Use	Non-Authorized Uses expressly prohibits the use of MOVR Data for:
	• Direct physician or MOVR Site targeting for promotional activities;
	• Direct physician or MOVR Site level analytics for product or brand benchmarking;
	• Direct patient, physician or MOVR Site targeting for the purposes of recruiting for enrollment into clinical trials or observational studies;
	• Non-scientific purposes, such as:
	  ○ Litigation pursuits or sales;
	  ○ Personal gain for purposes inconsistent with the Secondary Research objectives; and
	  ○ Disclosure of MOVR Data in a manner that would violate HIPAA regulations.

Neither Authorized nor Non-Authorized Data Use	Requestor(s) with incomplete or unclear MOVR Data requests must modify their proposal and/or provide additional necessary information.
Prohibited Use	Approved Requestor may not (and may not attempt to) isolate or re-identify any elements contained in MOVR Data, including but not limited to, health plan, health plan members or individual patient identifiers. Approved Requestor may not co-mingle MOVR Data with Approved Requestor's internal or third-party data without the express written consent of MDA. For the avoidance of doubt, Approved Requestor is expressly prohibited from reidentifying in any manner any prescribers that are the subject of MOVR Data, including, but not limited to, linking, or combining MOVR Data with other available data sets for this purpose.
Data Security	Approved Requestor must ensure that MOVR Data is stored securely using software that is compliant with current laws and regulations and is kept up-to-date with all then-current legal or regulatory requirements. Access to MOVR Data is limited to personnel expressly approved on the Data Request Form and appropriate security measures must be in place to avoid unauthorized sharing of MOVR Data. Upon completion of the approved data use or term of use, MOVR Data must be destroyed such that data are irrecoverable. Approved Requestor must certify such destruction on request by MDA. In the event of a breach of security leading to the accidental or unauthorized disclosure of, or access to, MOVR Data, Approved Requestor must immediately (and in any case within 24 hours) notify MDA at mdamovr@mdausa.org and provide all reasonable assistance to MDA in rectifying such accidental or unauthorized disclosure of or access to such MOVR Data.
Data Ownership	Requestor acknowledges that regardless of any analysis, data transformation, or combination of MOVR Data with other data sets, MOVR Data remains the sole and exclusive property of MDA.

	MOVR Data and/or research findings may not be shared with or sold to any third parties under any circumstances unless MDA provides prior written consent in each instance.
Data Request Form	Requestor must complete a Data Request Form that contains the following elements: • Name and email of Requestor (and of Principal Investigator if different from Requestor) • Institution or Organization • List of additional users with name and email • Project Name • Brief synopsis of proposed research or study, including goals, expected milestones, and how use of MOVR Data will support these goals • Brief explanation of how the results of the research will be disseminated or used •
Data Access, Use and Distribution Agreement	In addition to complying with the terms of this Policy, all Approved Requestors who receive access to MOVR Data must execute an Agreement. The Agreement contractually obligates the Approved Requestor to: • Use MOVR Data for the research described in the approved Data Request Form only. • List all personnel performing the research and bind them to the same terms and conditions set forth in the Agreement. • Restrict access to MOVR Data to only those personnel named in the Agreement. • Comply with this Policy and all applicable laws and regulations. • Obtain regulatory and/or ethical approvals to perform the research, if required. • Ensure patient privacy and data security. • Not attempt to re-identify study subjects. • Acknowledge MOVR as the source of the data in all publications, abstracts, and presentations (see below in Publication Guidelines). • Submit copies of all publications using MOVR Data to the MOVR Publication Committee for review prior to submission (see below in Publication Guidelines).

	If any information submitted on the Data Request Form changes, including contact information, institution, or personnel working on the project, MDA must be notified immediately. MOVR Data cannot be transferred from one institution to another, or to a different department within the same institution unless expressed written approval from MDA.
Publication Guidelines	MDA encourages Approved Requestor to publish scientific findings in which MOVR Data were used. • MDA strongly recommends that Approved Requestor uses standard guidelines such as, but not limited to, Good Publications Practice, International Committee of Medical Journal Editors and EQUATOR recommendations if planning to publish results derived from MOVR Data. • External publication is only allowed in peer-reviewed channels (e.g., journals, conferences, abstracts, oral and poster presentations) unless written consent is provided by MDA. • Approved Requestor may only publish findings and conclusions related to Approved Requestor's analysis of MOVR Data or a subset thereof, provided Approved Requestor appropriately references MOVR in the manuscript or presentation; it is mandatory to include some variation of the language shown below: ***"This study was conducted using data from the Muscular Dystrophy Association's neuroMuscular ObserVational Research (MOVR) Data Hub®. MOVR is operated through participating MDA Care Centers with the support of participants, MOVR Site PIs, coordinators, and staff."*** • Prior to manuscript, abstract, or oral and poster presentation submission, Approved Requestor must submit a draft to the MOVR Publication Committee for review under MDA's publication guidelines, which are included in the Data Access, Use and Distribution Agreement. ○ MOVR Publication Committee will review only for the acknowledgement of MOVR Data and compliance with the proposed research scope described on the Data Request Form, not for content. Approval can be assumed if no response is given within 2 weeks.

	○ Copies can be sent to mdamovr@mdausa.org.
Fees	Based on the type of Requestor (life sciences/industry, academic researcher, clinician, nonprofit, etc.) and the scope of the request, MDA may require payment of fees to cover the following: • Service fees (e.g., MOVR Data extraction, analysis, full research study, etc.) • MOVR Data access license Fees will be determined following review and discussion of the Data Request Form and how data will be delivered.
Data Request Timelines	MDA will make every effort to meet a request timeline. However, more complex requests may take longer for an approval decision to be made. MOVR Data requests that fall under the Authorized Uses, as outlined in this Policy, will have an average approval time of 10 business days. Other requests outside of the Authorized and Non-Authorized Uses will be reviewed further by the MOVR Research Advisory Committee and may take up to 30-40 business days, depending on the complexity of request.
MOVR Contact Information	General Study: MDAMOVR@mdausa.org