Special article

The Myositis Clinical Trials Consortium: an international collaborative initiative to promote clinical trials in adult and juvenile myositis

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ABSTRACT

Idiopathic inflammatory myopathies (IIM), or myositis, are a heterogeneous group of systemic autoimmune disorders that are associated with significant morbidity and mortality. Conducting high-quality clinical trials in IIM is challenging due to the rare and variable presentations of disease. To address this challenge, the Myositis Clinical Trials Consortium (MCTC) was formed. MCTC is a collaborative international alliance dedicated to facilitating, promoting, coordinating and conducting clinical trials and related research in IIM. This partnership works to advance the discovery of effective evidence-based treatments for IIM by integrating a diverse group of clinical investigators, research professionals, medical centres, patient groups, and industry partners. The Steering Committee, Core Group, and Paediatric Subcommittee of MCTC are comprised of myositis experts and junior investigators from around the world, representing a diversity of genders, geographies, and subspecialties. MCTC works alongside other current myositis organisations to complement existing work by concentrating on the operationalisation of clinical trials. Our pilot Myositis Investigators' Information Survey gathered responses from 173 myositis investigators globally and found considerable variability in proficiency with outcome measures, geographic disparities in patient recruitment, and a significant disconnect between investigators' routine myositis patient load and clinical trial enrolment. MCTC will meet the need to support and diversify myositis clinical trials by facilitating trial planning, feasibility assessments, site selection, and the training and mentoring of junior investigators/centres to establish their readiness for clinical trial participation. Through experienced leadership, strategic collaborations, and interdisciplinary discussions, MCTC will establish standards for IIM clinical trial design, protocols, and outcome measures in myositis.

Introduction

Pressing challenges in myositis clinical trials

Idiopathic inflammatory myopathies (IIM), or myositis, represent a rare, heterogeneous group of systemic autoimmune rheumatic diseases characterised by muscle weakness and/or inflammatory rashes, as well as a variety of extramuscular organ manifestations involving the lungs, heart, joints, and gastrointestinal tract (1). Despite increasing recognition in recent years, IIM remains a group of rare diseases with considerable unmet needs and substantial associated morbidity and mortality (2).

First-line therapy for IIM nearly always includes high-dose glucocorticoids (GC) in combination with traditional immunosuppressive agents, despite the paucity of randomised controlled trial (RCT) data supporting this approach (3, 4). Many patients respond poorly to these first-line treatments (5) and long-term GC exposure often leads to various adverse effects and complications (6). Currently, there are only three therapies approved by the US Food and Drug Administration (FDA) for IIM: prednisone, adrenocorticotropic hormone (ACTH) gel (7) for dermatomy-

ositis (DM) and polymyositis (PM), and intravenous immunoglobulin (IVIg) for DM (8). Of these, IVIg remains the only treatment approved based on a placebo-controlled RCT (9).

While there has been a sharp increase in the number of RCT evaluating both novel and repurposed treatments against various forms of IIM over the last three years (10), conducting high-quality clinical trials to find effective therapies for IIM presents several challenges unique to rare and heterogeneous diseases, including:

Reducing the competitive landscape for patient recruitment

Currently, most IIM clinical trials are performed at only a small number of institutions globally. Therefore, institutions may be simultaneously conducting multiple competing trials that share similar inclusion and exclusion criteria. This redundancy not only reduces the efficiency of participant recruitment but also complicates patient screening and enrolment. On the other hand, many centres with an otherwise established clinical trial infrastructure are not being approached for myositis clinical trials due to a lack of recognition and limited experience in performing myositis outcome measures. We need to expand the availability for clinical trial inclusion to these unrecognised centres with collaborative support and training from more established experts in the field.

Improving diversity in trial participation

Despite the increase in the number of IIM trials, there remains an underrepresentation of many geographic regions and important minority groups, including Hispanic/Latino, black, and indigenous populations (8). This lack of diversity limits the generalisability of trial results across different demographics. Similarly, some outcome measures employed in myositis trials have not been sufficiently studied or validated in respect to diverse geographic and ethnic populations (10). Limited diversity in myositis clinical trials is frequently attributed to barriers such as language limitations, restricted trial accessibility, the necessity for travel to academic centres, and substantial direct and indirect costs faced by underserved communities.

Enhancing access to trial participation

Traditional trial models require in-person evaluations by investigators, limiting recruitment to the geographic catchment area around current trial centres. Advances in trial designs/assessments (11), including decentralised recruitment and remote data collection (12, 13), and expansion of the number of centres performing IIM clinical trials are needed to improve access for larger numbers of patients with diverse ethnic and geographic backgrounds. These changes will both improve the robustness and generalisability of trial findings as well as enhance equity in clinical trial access.

Addressing disease and pathogenic heterogeneity

IIM represents a clinically heterogeneous and pathologically diverse group of disorders, unified by related clinical manifestations and outcomes. Addressing the various IIM subtypes, heterogeneous organ involvement, and multiple myositis-specific autoantibody subgroups poses challenges for clinical trials in IIM. These challenges necessitate trials that leverage the expertise of a comprehensive group of stakeholders, including investigators from diverse clinical backgrounds and subspecialties, clinical research professionals, patient partners/organisations, and industry collaborators. This holistic approach enhances the capacity to conduct clinical trials targeting specific IIM subtypes, autoantibody subgroups, or under-represented organ domains, such as myositis-associated interstitial lung disease (ILD) or isolated cutaneous manifestations.

Disease classification and outcome measures

The 2017 European Alliance of Associations for Rheumatology (EULAR) / American College of Rheumatology (ACR) classification criteria for IIM (14) have several shortcomings and are currently undergoing revisions to reflect recent advances in our understanding of myositis-specific/associated autoantibodies and disease pathologies (15). Similarly, the EULAR/ACR Myositis Response Criteria (MRC) using six myositis core set measures and total improvement scores (16) have notable limitations in terms of subjectivity and dependency on expertise and training. More robust, objective, and meaningful IIM outcomes are being developed, including validated patient-reported outcome measures (17). Moreover, an urgent need to develop criteria for remission and low disease activity has arisen due to the transformative potential of CD19 chimeric antigen receptor (CAR) T-cell (18) and bi-specific T-cell engager therapies (19) in myositis. These efforts require integration into the landscape of IIM clinical trials, with active collaboration from investigators, patients, and the therapeutics industry alike.

These challenges underscore the critical need for an international, collaborative framework to enhance the scope, efficiency, and applicability of clinical trials in myositis. The Scleroderma Clinical Trials Consortium (20) and the Vasculitis Clinical Research Consortium (21), dedicated to facilitating clinical trials and related research for their respective diseases, serve as excellent examples of how large, well-coordinated research networks benefit rare autoimmune diseases research. In this context, we have developed the Myositis Clinical Trials Consortium (MCTC) with the mission of fostering, facilitating, and conducting collaborative clinical trials and related research to find effective treatments for IIM.

What is MCTC?

MCTC is a robust, non-profit international network comprised of a diverse group of clinical investigators, clinical research professionals, medical centres, patient partners and organisations, and industry stakeholders allied to advance the efforts and spectrum of IIM clinical trials and related research across the globe. The mission of MCTC is straightforward yet ambitious: to facilitate rigorous and collaborative research initiatives in the landscape of IIM

clinical trials which can, in turn, help develop and/or discover effective treatment modalities for various forms of myositis, ultimately enhancing patient outcomes and quality of life.

Development of MCTC

MCTC was established under the leadership of global key opinion leaders in the field of myositis. In addition to input from myositis experts in multiple key disciplines (Fig. 1), MCTC utilises active collaborations with specialists in juvenile myositis, who now participate in the MCTC Paediatric Subcommittee. Engagement efforts also integrate clinical research professionals, myositis patient support organisations and their affiliated patient partners, and global industry representatives. Feedback from all these groups has been a key feature of the Steering Committee, Paediatric Subcommittee, and industry roundtable activities conducted by MCTC since its inception.

MCTC core goals

The primary goal of MCTC is to facilitate, coordinate, and conduct clinical trials and related research in IIM. Our secondary goals are structured to support this primary aim, and include:

- Facilitation of clinical trial planning, including study feasibility and site selection;
- Training of junior investigators/centres in classification and outcome measures, and expediting the clinical trial readiness of newer myositis research centres;
- Provision of preliminary analysis, feasibility assessments, grant support, collaboration, and other support for participating members;
- Establishment of collaborative clinical trials and studies among various participating centres;
- Generation of interdisciplinary discussion and consensus on standards for myositis clinical trial design, protocols, guidelines, ethics, and outcomes;
- Development of a multi-centre prospective observational myositis clinical trial registry with data collection at individual centres for future myositis clinical trials and related research.

MCTC focuses on advancing clinical trials in myositis, fostering international and multidisciplinary collaborations, and supporting junior clinical investigators across the globe to ensure their readiness for future myositis clinical trials. MCTC will serve as a pivotal international platform for myositis investigator and site information, thereby playing a crucial role in facilitating clinical trials globally regardless of whether they are pragmatic, investigator-initiated, or industry-sponsored. This proactive and inclusive approach positions MCTC uniquely in the landscape of IIM clinical research, offering improved expediency for therapeutic advances in this challenging group of diseases.

Operational framework of MCTC

MCTC is a collaborative initiative of myositis physicians (investigators) and non-physician healthcare professionals, clinical research coordinators (CRCs) and other research professionals, pharmaceuticals/industry partners, as well as myositis patient partners and patient support organisations (Fig. 1A). MCTC operates through a structured framework designed to optimise efficiency, which is divided into several key groups: the Steering Committee, the Core Group, various Working Groups, and the Paediatric Subcommittee, each serving distinct yet interconnected functions.

Steering Committee

The Steering Committee is the governing body of the MCTC, responsible for setting the strategic direction and overall policy of the consortium (Fig. 1A). This committee is composed of global myositis experts and representatives from patient advocacy groups. Thirty-eight selected reputed senior and mid-career myositis investigators from around the world were recruited to form the initial Steering Committee of MCTC. The primary role of the Steering Committee is to oversee the development and execution of the consortium's agenda, ensuring that it aligns with the MCTC core goals and its paramount mandate to advance myositis clinical trials.

Core Group

The Core Group acts as the operational backbone of the MCTC, handling the implementation, management, and coordination of consortium activities (Fig. 1A). Example activities include communication between the consortium members, organisation of meetings and workshops, and dissemination of research findings and other initiatives. The Core Group is also responsible for operationalising and executing initiatives/projects approved by the Steering Committee and providing updates and feedback to the Steering Committee and general membership. The Core Group primarily comprises early-career investigators/research professionals and trainees dedicated to pursuing careers in myositis. Similar to the Steering Committee, a premium is placed on ensuring a diversity of geographic location, clinical focus, and professional background amongst the group. The involvement of these junior members facilitates interaction and mentoring from prominent international myositis experts, thus generating upcoming MCTC leaders to ensure the sustainability of the consortium in the future. The current Core Group comprises 19 early/mid-career investigators and fellows dedicated to myositis research, 2 Steering Committee members (RA and PG), 1 clinical research coordinator, 1 clinical trial project director, and 1 data manager.

Working Groups

Working Groups are specialised task-oriented and project-based teams within MCTC formed to address challenges or opportunities identified by the Steering Committee. Each Working Group will be led by experts in relevant fields working collaboratively to achieve defined objectives. Examples of the tasks of the Working Groups include developing new clinical trial protocols, creating patient recruitment strategies, standardising data collection methods, and exploring innovative treatment modalities for diverse disease manifestations within the myositis disease spectrum, such as cancer-associated myositis and predominant skin or lung IIM manifestations.

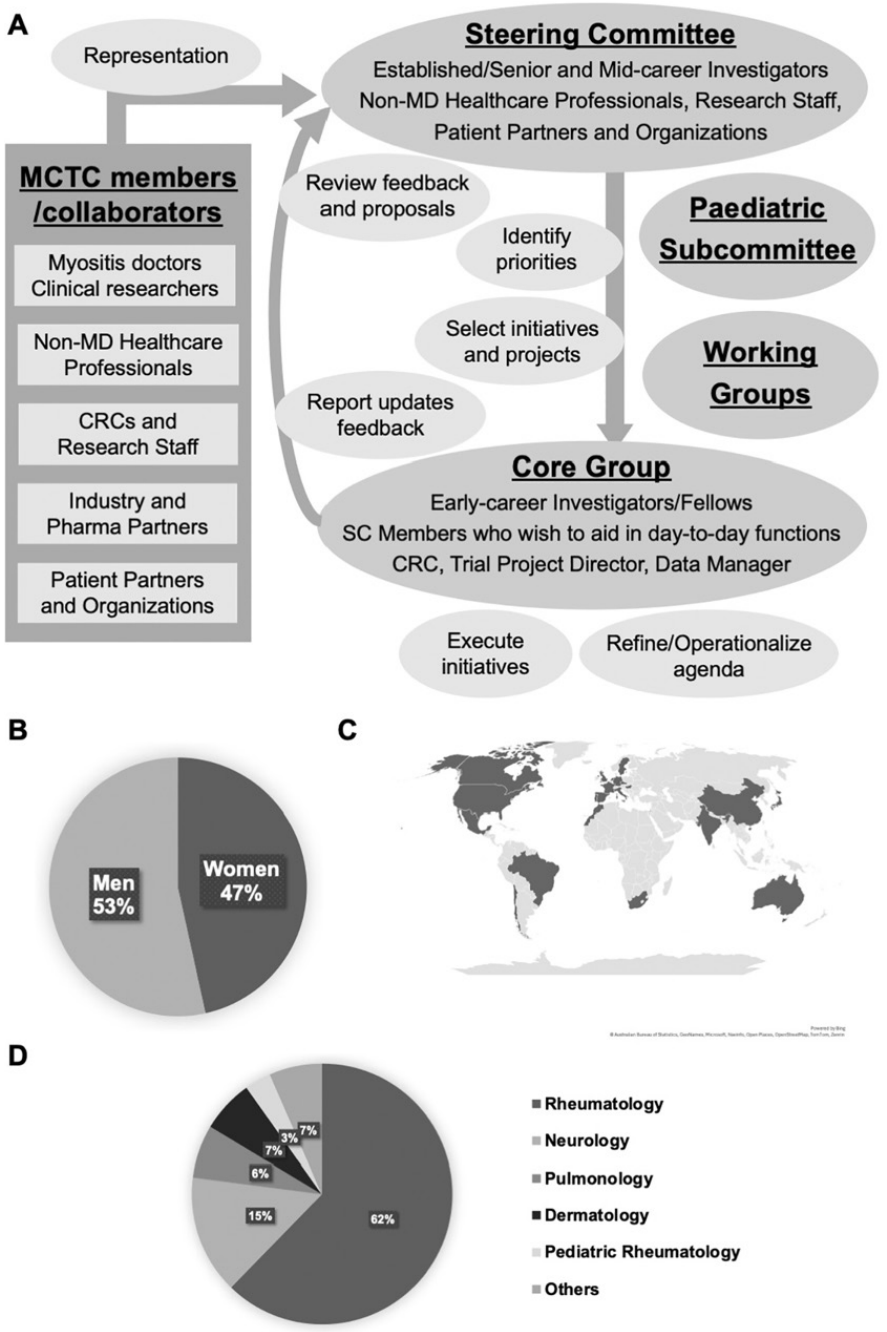

Fig. 1. A: MCTC organisational framework designed to optimise inclusivity and efficiency. Deliberate emphasis was made to promote diversity of **(B)** gender representation, **(C)** geographic distribution, and **(D)** medical subspecialties amongst the MCTC Steering Committee and Core Group members.
CRC: clinical research coordinators; MCTC: Myositis Clinical Trials Consortium; MD: medical doctors.

Paediatric Subcommittee

MCTC has organised an initial Paediatric Subcommittee comprised of a Steering Committee member and 6 other paediatric rheumatologists to focus on advancing clinical trials in the field of juvenile myositis. This Subcommittee advises the Steering Committee on optimal methods of facilitating this work in collaboration with existing paediatric research networks and advocacy organisations.

The operational format of MCTC leverages expertise from diverse fields, and ensures a high level of organisation and accountability, thereby facilitating effective communication and collaboration among members spread across different geographical locations. Both the Steering Committee and Core Group emphasise diversity in gender (Fig. 1B), geography (Fig. 1C), and subspecialty (Fig. 1D). The future structure and rotation scheme for the Steering Committee and Core Group of MCTC are currently being developed, with plans for positions to potentially rotate every 2–3 years. This rotation will be determined through a voting process involving both the current Steering Committee and Core Group members and the general membership, ensuring dynamic leadership and fresh perspectives in guiding the activities of the consortium. This approach is designed to maintain a vibrant and effective leadership cycle, fostering continuous innovation and responsiveness within MCTC.

Collaborations with existing myositis networks and patient support organisations

MCTC will collaborate with existing myositis networks including but not limited to the International Myositis Assessment and Clinical Studies Group (IMACS) (22), the International Myositis Society (iMyoS) (23), MYONET (24), and the Myositis International Health and Research Collaborative Alliance (MIHRA) (25). MCTC values and respects the foundational work of these organisations, and our focus is distinctively on the practical aspects of clinical trial execution. MCTC works in cooperation with these established myositis organisations, ensuring that its efforts complement rather than duplicate or replace existing work by concentrating on the operationalisation and management of clinical trials, thereby bridging the gap between academic research, real-world practice, and industry. This approach ensures that the MCTC adds unique value to the myositis research community by enhancing the efficiency and effectiveness of IIM clinical trials.

MCTC will also offer close collaboration with myositis patient support organisations, such as The Myositis Association (TMA), Myositis Support and Understanding (MSU), and other patient support groups globally. Representatives of these patient support organisations will also serve as Steering Committee members on a rotating basis. Our Paediatric Subcommittee will col-

Table I. Characteristics of myositis investigators responding to the pilot Investigator Survey.

		Investigators (n=173)
Primary affiliation, n (%)		
	Centre	44 (25.4)
	Practice	5 (2.9)
	Clinic	13 (7.5)
	University	95 (54.9)
	Institute	15 (8.7)
Medical specialties, n (%)		
	Adult	152 (87.9)
	Paediatric	2 (1.2)
	Both	14 (8.1)
	Rheumatology	130 (75.1)
	Neurology / Neuromuscular	21 (12.1)
	Pulmonology	19 (11.0)
	Dermatology	7 (4.0)
	Other	6 (3.5)
Board-certified or board-eligible in specialty of practice, n (%)		160 (92.5)
Completed additional training program focused on myositis, n (%)		41 (23.7)
Years of clinical research experience, median [IQR], years		10 [5–20]
Number of total peer-review publications in PubMed, median [IQR]		29 [8–76]
Previous experience in myositis research, n (%)		113 (65.3)
Years of clinical research experience in myositis, median [IQR] (years)		5 [0–10]
Number of clinical research studies on myositis conducted or participated within the last five years, median [IQR]		2 [0–5]
Number of interventional/drug clinical trials on myositis conducted or participated within the last five years, median [IQR]		0 [0–2]

IQR: interquartile range.

laborate with juvenile myositis working groups of prominent paediatric rheumatology societies. These include the Childhood Arthritis and Rheumatology Research Alliance (CARRA), the Paediatric Rheumatology European Society (PReS), the Paediatric Rheumatology International Trials Organization (PRINTO), and the Paediatric Rheumatology Collaborative Study Group (PRCSG). Additionally, we partner with juvenile myositis patient support groups such as Cure JM to enhance our efforts to address this important IIM subtype.

We advocate that effective collaboration among the organisations working in the arena of IIM is the key to enhancing clinical trials in myositis, especially given current inefficiencies in the clinical research landscape for these rare diseases (10). The global representation of MCTC offers a substantial advantage in encouraging collaborations with existing myositis networks and patient support organisations around the world.

Transparent and active collaboration with industry in the MCTC: enhancing engagement and efficacy

The medical therapeutics industry currently encompasses an undeniably prominent role in the development of IIM treatments and clinical trials. As such, active investigator-industry partnerships built on aligning clinical trial research with unmet patient needs, enhancing transparency, and streamlining logistical processes are required to expedite bringing novel and repurposed evidence-based interventions to IIM patients. MCTC will work as an unbiased dynamic forum to facilitate these vital alliances worldwide through roundtables and other engagement, thereby amplifying the landscape of innovative industry-sponsored/investigator-initiated IIM trials and clinical research funding considerations. MCTC will also lead efforts in maintaining uniformly high standards for ethical and transparent industry interactions in IIM clinical research, improving patients' trust in these collaborations.

MCTC moreover has the potential to act as a neutral yet unified cohesive platform that could facilitate regulated access to vast high-quality clinical and laboratory data as well as biospecimens obtained in industry-sponsored trials. Effective utilisation of these trial data would deepen our understanding of the patient populations involved in clinical trials compared to those seen in daily clinical practice ("non-study" populations) and offer valuable insights into future clinical and basic research in IIM. Just as importantly, the MCTC communication network will allow effective, unbiased dissemination of trial findings to academic and medical communities, regulatory bodies, patient advocacy groups, and other stakeholders, ultimately enhancing research visibility to drive faster adoption of IIM trial findings into routine clinical care.

MCTC will additionally endeavour to optimise the efficient, equitable selection of research sites (or even target countries in some instances) by recommending member centres that best match the necessary expertise and demographic criteria for the needs of a specific trial. These efforts will enhance trial resource allocation and patient access. MCTC will seek to lessen the administrative burden on member sites by providing logistical support and expert advice to coordinate between sites, manage data collection standards, and ensure regulatory compliance. MCTC will also serve as an essential resource to guide both novice and experienced investigators and industry stakeholders in optimising recruitment strategies and improving the accuracy of disease assessments.

The MCTC commitment to independent, ethical, transparent multi-tiered partnership around shared goals builds trust and credibility with industry partners, fostering long-term relationships that ensure ongoing high-quality, relevant trials focused on addressing unmet needs in IIM treatment.

MCTC surveys and website

The MCTC Core Group developed three sets of surveys to engage potential myositis clinical trial partners:

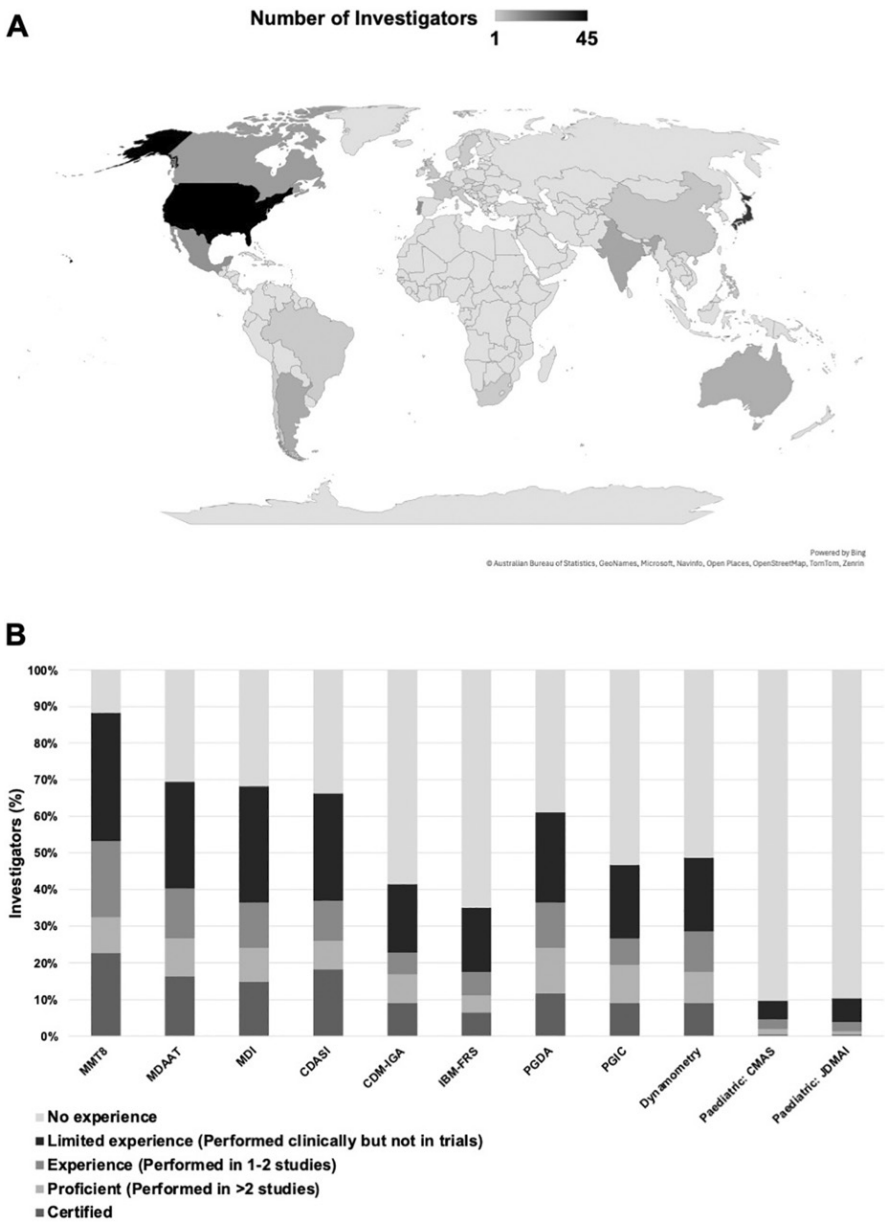

Fig. 2. A: Global distribution of responses to the pilot Investigator Survey highlighting the geographical diversity of MCTC investigators.
:) Significant variability in experience performing myositis outcome measures reported by participating pilot survey investigators.
CDASI: Cutaneous Dermatomyositis Disease Area and Severity Index; CDM-IGA: Cutaneous Dermatomyositis Investigator Global Assessment; CMAS: Childhood Myositis Assessment Scale; IBM-FRS: Inclusion Body Myositis-Functional Rating Scale; JDMAI: Juvenile Dermatomyositis Activity Index; MCTC: Myositis Clinical Trials Consortium; MDAAT: Myositis Disease Activity Assessment Tool; MDI: Myositis Damage Index; MMT-8: Manual Muscle Testing 8; PGDA: Physician reported Global Disease Activity; PGIC: Physician-Global Impression of Change.

the Myositis Investigator (Physician) Member Information Survey, the Myositis Non-investigator (Non-physician) Collaborator Information Survey, and the Myositis Site Information Survey. The MCTC surveys serve to globally identify centres, investigators, and key stakeholders with significant interest in conducting or supporting myositis clinical trials and related studies. More importantly, the surveys help to assess potential targetable opportunities to enhance research experience, patient access, training, site resources, and overall clinical trial readiness of investigators and centres around the world. A secured platform (REDcap) was used for pilot survey development and initial data storage. The planned full survey catalogues will be utilised as a critical tool in feasibility assessment and site selection for future myositis trials.

Myositis investigator member information survey (investigator survey)

The Investigator Survey is designed to generate a registry focused on investigators' research experience and training related to myositis. Information collected from investigators includes their affiliation, medical education, myositis outcome measures training, clinical trial experience, and myositis patient care load. These data both help identify potential investigators for trial involvement and guide training initiatives within MCTC.

The Investigator Survey was piloted from July to October 2024 (14 weeks) to engage clinicians interested in joining MCTC and elucidate current barriers to IIM trial participation. A public link for the survey is available at: https://redcap.link/mctc_investigatorsurvey. A total of 173 clinical investigators of various subspecialties from 23 countries participated in the pilot (Table I). Fig. 2A demonstrates the distribution of participating MCTC investigators by region.

Our results identified notable heterogeneity in experience with validated outcome measures commonly used in IIM clinical trials: In example, nearly half reported no or only limited experience in performing manual muscle testing 8 (MMT-8) (Fig. 2B). The variability in outcome measures experience presents a notable barrier to study entry and potentially increases variability in pooled trial assessments.

The Investigator Survey also identified a substantial discrepancy between routine IIM patient care load and clinical trial enrolment (Fig. 3). Among 144 respondents to questions about patient load, 56.9% had seen over 50 myositis patients in the previous year yet 61.1% had not enrolled any patients in IIM trials over the last three years. Enrolment was highest in Europe and North America compared to other regions. The pilot survey data underscores the vast potential to expand the pool of myositis

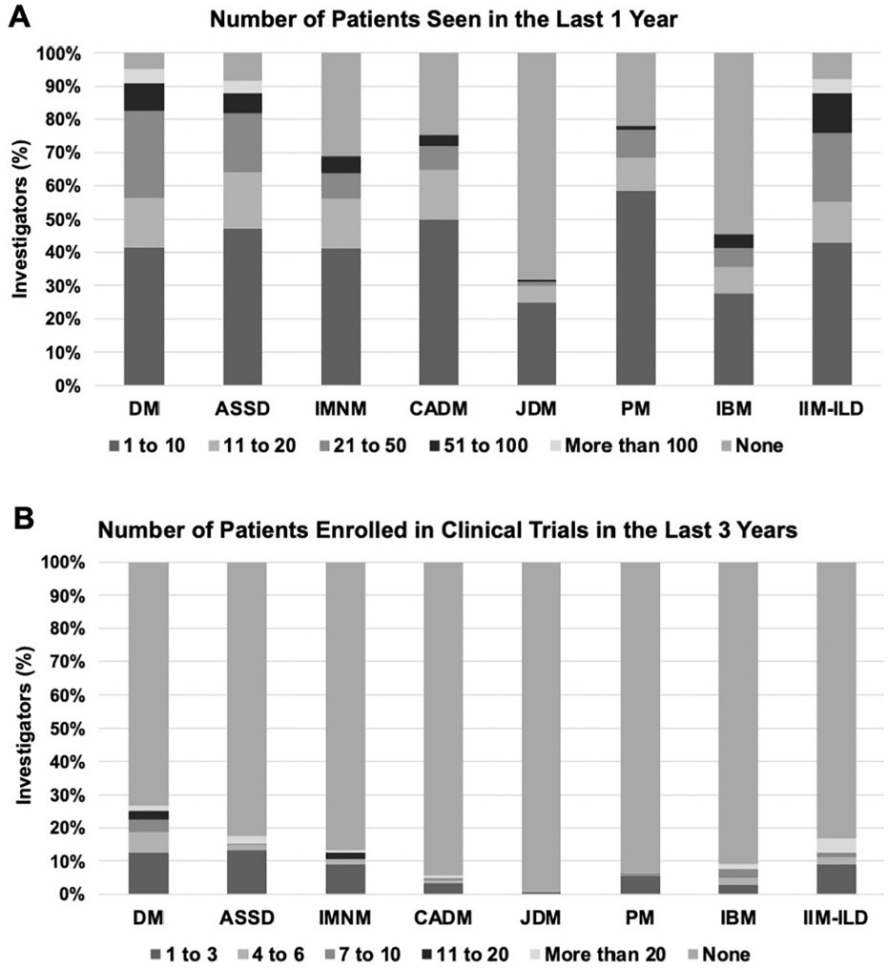

Fig. 3. Significant disparities between reported **(A)** routine myositis clinical care load and **(B)** IIM clinical trial enrolment identified by the pilot Investigator Survey.
ASSD: anti-synthetase syndrome; CADM: clinically amyopathic dermatomyositis; DM: dermatomyositis; IBM: inclusion body myositis; ILD: interstitial lung disease; IMNM: immune-mediated necrotising myopathies; JDM: juvenile dermatomyositis; OM: overlap myositis; PM: polymyositis.

investigators and centres, particularly outside of North America and Europe.

Myositis collaborator information survey (collaborator survey)

MCTC emphasises the crucial roles of non-physician collaborators in advancing myositis trials. The Collaborator Survey is designed to engage non-investigator partners, including but not limited to non-clinician healthcare professionals, patient representatives (members from patient support organisations and patient partners), research coordinators, basic scientists, data scientists, industry leaders, and other interested parties. The public link to the multi-language collaborator survey is available at: https://redcap.link/mctc-collaboratorsurvery.

Myositis site member information survey (site survey)

The site survey is designed to collect information on site infrastructure to expedite myositis clinical trial feasibility assessments and site selection. The survey collects data about sites' experience, subject enrolment processes, study coordinator information, ethical approval timelines, and capability to perform specific investigations and therapeutic interventions relevant to myositis clinical trials.

MCTC website

Our public website (https://myositisclinicaltrialsconsortium.org) offers a ready portal to engage potential investigators/partners and disseminate information regarding MCTC events and initiatives.

Future outlook

MCTC is poised to significantly advance myositis clinical trials worldwide through the development of robust and comprehensive resources and coordination. Central to these advancements are the planned MCTC Site Infrastructure Database and MCTC Patient Registry. The Site Infrastructure Database, enriched with data from the detailed Investigator, Collaborator, and Site Surveys, will serve as a vital tool for mapping the current landscape of myositis research, pinpointing gaps in site resources, and enhancing patient recruitment strategies. Concurrently, the Patient Registry will act as a dynamic platform to aggregate IIM patient data on a global scale and promote collaboration across the international research community. Centralising a source of patient characteristics will substantially improve the effective and efficient execution of large-scale, multinational clinical trials. MCTC further plans to develop unified training and certification programmes for investigators on myositis outcome measures and assessments to improve the quality and consistency of clinical trials. Additionally, our targeted scientific working groups will drive specialised clinical trial research efforts, addressing heterogeneous disease presentation of myositis including skin-predominant disease and myositis-associated ILD.

Conclusion

The notable disparities in myositis clinical trial engagement highlighted by our surveys underscore the need for improved strategies to boost participation, particularly in underrepresented regions. MCTC is dedicated to addressing these issues through its expansive and inclusive global network. In summary, MCTC is poised to markedly improve the myositis clinical trials landscape by providing the essential infrastructure for international collaboration, advancing data collection, and fostering greater inclusivity. This holistic approach will not only expedite and deepen our understanding of treatment options for IIM but also ensure that the benefits of clinical trials reach as broad an audience as possible, thereby enhancing the outcomes of IIM patients globally.

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