KEY POINTS

- Existing outcome measures for Idiopathic inflammatory myopathy (IIM) focus primarily on muscle involvement, overlooking a specific measure of skin activity or severity, particularly in cutaneous-predominant dermatomyositis (DM) patients.
- The development of composite outcome measures like Dermatomyositis Outcomes for Muscle and Skin (DMOMS) addresses the need for comprehensive assessment, enhancing trial efficacy and inclusivity.
- Clinical trials often exclude amyopathic DM patients, hindering drug development and treatment accessibility for this significant subgroup.
- Refinement of classification criteria and adoption of comprehensive outcome measures hold promise for improving research and treatment strategies for all individuals with IIM.

of DM without muscle involvement [6]. These criteria have improved the specificity and sensitivity of IIM diagnoses and have been validated by numerous studies [7–10]. However, recent clinical trials have still opted to use the Bohan and Peter criteria for patient enrollment, consequently limiting the scope of patients who can participate and in turn qualify for therapies [11]. Clinically amyopathic DM (CADM) is a subset of DM patients without muscle involvement and represents roughly 20% of all DM diagnoses [12]. Per the Bohan and Peter criteria, CADM patients do not qualify for DM diagnosis, but per the EULAR/ACR criteria, around 73.7% of CADM patients are accurately classified [13]. In an era of intense research and promising drug development for myositis, we must find a way to ensure that all patients suffering from IIM can benefit from advancements in the field by carefully considering trial design, specifically outcome measures.

Challenges in assessing disease activity in muscle

The International Myositis Assessment and Clinical Studies Group (IMACS) has comprised a list of specific myositis outcome measures that are recommended for use in clinical trials to assess changes in disease activity. These measures are also known as "core set measures" (CSMs), and include the Manual Muscle Test-8 (MMT-8), a measure of strength in eight muscles tested bilaterally (lower scores indicate weaker muscles), physician's global assessment (PhGA) of disease activity (0 represents no evidence of disease activity and 10 is extremely active or severe disease activity), patient's global assessment (PtGA) of disease activity (assessed on the same scale as used for the PhGA of disease activity); the Health Assessment Questionnaire (HAQ, in which total scores range in increments of 0.125 from 0 [no disability] to 3 [complete disability]), Extramuscular activity (higher scores reflecting more disease activity in the extramuscular organs affected by myositis), and serum muscle-enzyme levels (creatine kinase, alanine and aspartate aminotransferase, lactate dehydrogenase, and aldolase). Despite the emphasis on muscle involvement for almost all IIM outcome measures, there are many shortcomings in terms of applicability to patients. For instance, muscle enzymes are typically tracked as a marker of disease activity and are included in many outcome measures, however enzyme levels are insensitive and not always increased in IIM, especially early in the disease course [14,15,16▪]. The MMT has been classically used to assess IIM muscle involvement, but muscles damage from scarring and fibrosis could negatively impact scores and not accurately represent current disease activity. The MMT is also insensitive to changes in muscle strength and endurance, the latter of which can be a hallmark of IIM, particularly in cases where patients have high baseline strength or only minimal muscle weakness [17]. In addition, MMT results are influenced by patient effort, which can be quite variable. The Myositis Functional Index-2 (FI-2) is another assessment that seeks to quantify muscle endurance for individual muscle groups and has been shown to capture other aspects of muscle function that are not well represented by the MMT. An updated version of the FI-2, namely the FI-3, was developed to further streamline the FI-2. However, because each muscle strength task of the FI-2 and FI-3 has been validated individually, only 1 or 2 muscles group can be assessed in a trial at once [18].

Most recently in 2016 the EULAR/ACR approved the "Total Improvement Score" (TIS), a composite number representing a combination of CSMs. The individual CSMs of the TIS include the PhGA, PtGa/PhGa, MMT, HAQ, serum muscle enzyme level, and extramuscular global assessment (EMGA). These CSMs are weighted differently in terms of importance in defining change in disease activity to create the composite TIS score on a scale from 0 to 100, weighting muscle symptoms more heavily [19]. Additionally, these CSMs each have their own weaknesses. For example, the HAQ is dependent on patient compliance, and it also has a significant floor effect, whereby patients with some disability can still have a normal HAQ score. The EMGA serves to be representative of extra-muscular findings, grouping together disease activity in the skin, joints, and lungs. As a result, the TIS only indirectly