declared, Kimmie Hyrich Speakers bureau: Abbvie unrelated to this study, Grant/ research support from: BMS, UCB, and Pfizer, all unrelated to this study, Anja Strangfeld Paid instructor for: AbbVie, MSD, Roche, BMS, Pfizer, outside the submitted work, Grant/research support from: grants from a consortium of 13 companies (among them AbbVie, BMS, Celltrion, Fseniuzki Kabi, Lilly, Mylan, Hexal, MSD, Pfizer, Roche, Samsung, Sanofi-Aventis, and UCB) supporting the German RABBIT register, outside the submitted work, Laure Gossec Consultant of: Abbvie, Biogen, Celgene, Janssen, Lilly, Novartis, Pfizer, Sanofi-Aventis, UCB, unrelated to this study, Grant/research support from: Lilly, Mylan, Pfizer, all unrelated to this study, Loreto Carmona: None declared, Elsa Mateus Grant/ research support from: grants from Abbvie, Novartis, Janssen-Cilag, Lilly Portugal, Sanofi, Grünenthal S.A., MSD, Celgene, Medac, Pharmakerin, GAIPA; and intravenous immunoglobulins (IVIg), however, none of these therapies are randomized clinical trials supporting the efficacy and safety of IVIg in DM.

**Background:** Dermatomyositis (DM) is a rare chronic systemic autoimmune disease with characteristic skin rash and progressive proximal muscle weakness. Current therapies encompass corticosteroids and other immunosuppressants and intravenous immunoglobulins (IVIg), however, none of these therapies are proven by randomized controlled phase 3 studies. There have been no large randomized clinical trials supporting the efficacy and safety of IVIg in DM.

**Objectives:** The ProDERM study aimed to evaluate the efficacy and safety/tolerability of IVIg in DM patients in a double-blind, randomized, placebo-controlled, international multicenter, phase III clinical trial.