ProDERM study design definitions

- **Responders:** Patients with a total improvement score (TIS) ≥ 20 at Week 16 and no prior confirmed deterioration up to and including Week 16
- **Non-responders:** Patients discontinuing from the study and patients with no response
- **Confirmed deterioration:** any of the following (compared with baseline)
  - Physician's Global Disease Activity visual analogue scale worsening ≥ 2 cm and Manual Muscle Testing (MMT-8) worsening ≥ 20% on 2 consecutive visits

    OR
  - Global extramuscular activity worsening ≥ 2 cm on the Myositis Disease Activity Assessment Tool (MDAAT) visual analogue scale on 2 consecutive visits

    OR
  - Any 3 of 5 core set measurements (excluding enzymes) worsening by ≥ 30% on 2 consecutive visits