Dermatomyositis (DM) is a rare idiopathic inflammatory myopathy with skin involvement. Clinical manifestations may be severe and disabling:
- Painful, itchy skin rash on eyelids, cheeks, nose, back, upper chest, elbows, knees and knuckles
- Sudden or progressive proximal muscle weakness
- Hardened calcium deposits under the skin (calcinosis)
- Difficulty swallowing (dysphagia)
- Interstitial lung disease
- Increased cancer risk

Significant unmet need for new therapies:
- Even with standard of care treatment, ~35% have recurrence after remission or chronic disease course >24 months*
- Steroids and immunomodulatory drugs are commonly used to treat DM, but can introduce chronic toxicities

Prednisone use*
- Prednisone is used to treat a variety of disorders, including endocrine, rheumatic, dermatologic, allergic, ophthalmic, respiratory, hematologic, neoplastic, and nervous system disorders
- Very strict labeling instructions are provided to reduce the risk of harmful side effects associated with use
  - “The lowest possible dose of corticosteroid should be used to control the condition under treatment, and when reduction is possible, the reduction should be gradual”
- Adverse effects (AE) of prednisone include, but are not limited to:
  - Fluid and electrolyte disturbances
  - Musculoskeletal
    - Weakness
    - Myopathy
    - Loss of muscle mass
  - Gastrointestinal
    - Peptic ulcer
    - Pancreatitis
  - Dermatologic
    - Infrared wound healing
    - Freckles
    - Sweating
  - Metabolic
  - Ophthalmic
  - Cataracts
  - Glaucoma
  - Neurological
    - Convulsions
    - Vertigo
    - Headache
    - Diabetes
  - Other
    - Hypersensitivity reaction

Study background:
- Objective of the study was to assess the real-world use of oral prednisone via a closed commercial and Medicare supplemental claims databases to understand the unmet need for new corticosteroid-sparing agents for patients with dermatomyositis
- Statistical analysis was performed on the defined patient cohort using Anaconda Python

METHODS
- MarketScan® database, containing patient-level claims for ~1.46 million patients (2006 – 2014)
- Dataset for the study contains commercial claims, Medicare, and Medicaid
- Patients with DM were defined as having the 710.3 ICD-9 diagnosis code within at least 3 separate months in their history
  - The DM diagnosis code was required to occur 3 times to increase the confidence that this was truly a DM patient population
- Patients with a minimum of 12 months of history before the first use of the DM ICD-9 code, and a max follow-up of 60 months, were included in the analysis (n = 3,238)
- The analysis examined patients who were prescribed prednisone
  - High-dose prednisone ≥10mg/day
  - Low-dose prednisone <10mg/day

CONCLUSIONS
- Approximately half of DM patients were prescribed high or low dose prednisone for 120 days or longer
- The use of high dose prednisone was required to treat DM patients throughout all phases of their illness (pre-diagnosis, at diagnosis, and up to 5 years post-diagnosis)
- One quarter of DM patients were prescribed high dose prednisone for prolonged periods of time
- With high numbers of DM patients on chronic high dose prednisone, the need for medications that have a steroid-sparing effect to reduce the number of patients who could experience harmful steroid-related side effects
- Future analyses should evaluate the incidence of corticosteroid-related adverse events and the limitations of currently used corticosteroid-sparing medications in the DM population