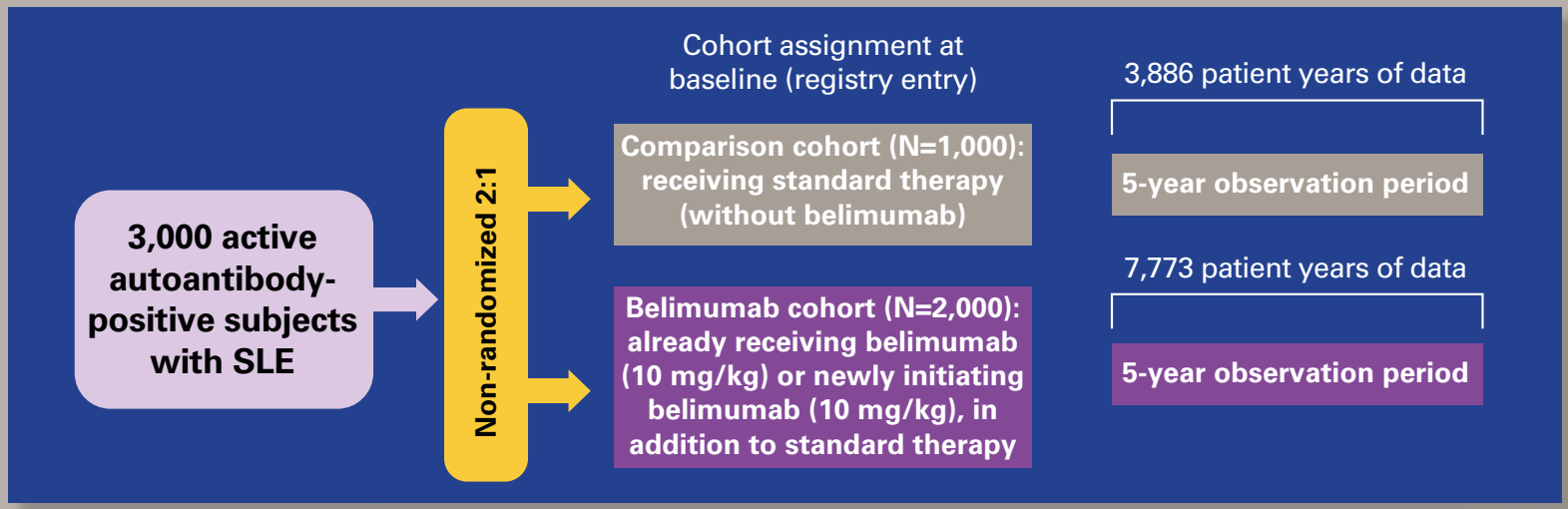
SABLE SLE Registry

A 5-Year Prospective Observational Registry to Assess Adverse Events of Interest and Effectiveness in Adults With Active, Autoantibody-Positive SLE Treated With or Without Benlysta® (belimumab) (SABLE)



Patient inclusion criteria

- Males or females age 18 years or older and have a clinical diagnosis of active SLE
- Current or history of autoantibody-positive SLE
- Provide written informed consent and comply with the study data collection procedures
- Must be treated with SLE therapy including Benlysta® and/or immunosuppressants (e.g. azathioprine, methotrexate, cyclophosphamide, mycophenolate, and biologics)

Patient exclusion criteria

- Treatment with an investigational drug within one year of enrollment
- Currently enrolled in a placebo-controlled belimumab clinical trial or a continuation protocol where belimumab is used as an investigational agent
- Patients who have a history of Benlysta® exposure, but are not currently receiving Benlysta®
- Patients only receiving an anti-malarial for SLE
- Patients only receiving steroids for SLE

Study endpoints

- Primary (safety) endpoints
  - Mortality
  - Malignancies including non-melanoma skin cancers
  - Serious infections, opportunistic infections, and other infections of interest
  - Selected serious psychiatric events
- Other (effectiveness) endpoints
  - SLICC/ACR damage index, SLEDAI 2000, and severe flares
  - Concomitant SLE medications (including steroids) and hospitalization
  - Fatigue (FACIT-Fatigue) and quality of life (SF-12 V2)

Note: patients will continue their usual SLE care (belimumab and other therapies) from their physician. Patients may switch between the study groups (belimumab or non-belimumab comparison cohort) during the 5-year observation period, as part of usual care.

Enrollment through December 2016

For information about participating as a clinical site or referring a potential patient, please contact:
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ClinicalTrials.gov identifier: NCT01729455