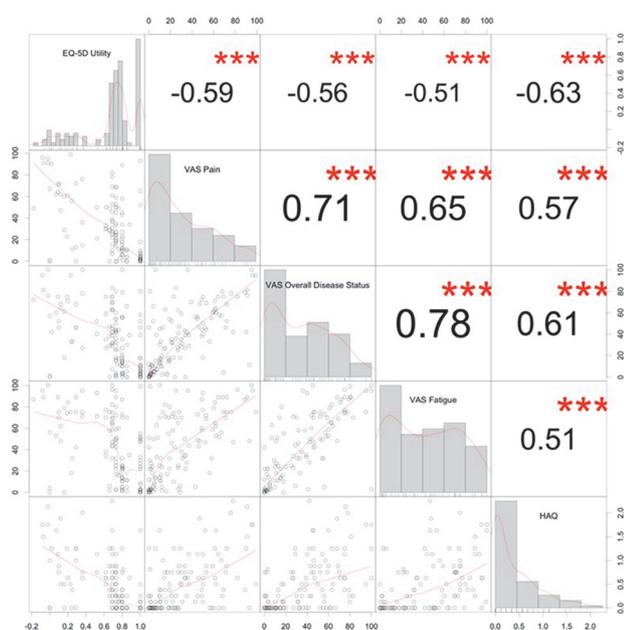


Abstract PO.7.159 Table 1 Mixed-effects regressions for EQ-5D and VAS overall disease status and association with other PROs

	EQ-5D-3L		VAS Overall Disease Status	
	Estimate	<i>p</i>	Estimate	<i>p</i>
VAS Pain	-0.003	<0.001	0.563	<0.001
VAS Fatigue	-0.001	<0.001	0.279	<0.001
HAQ	-0.202	<0.001	4.881	<0.001
Respondents (Observations)	310 (1894)		310 (1918)	
Marginal R ² / Conditional R ²	0.542 / 0.690		0.772 / 0.810	

Models include all symptom or domain measures, as well as age and sex, as fixed effects, and patient as a random intercept. EQ-5D scores are anchored at 1 (perfect health) and 0 (dead). HAQ scores range from 0 (no difficulty) to 3 (unable to do). VAS of pain, fatigue, and overall disease status range from 0 (no impairment) to 100 (complete impairment).



Abstract PO.7.159 Figure 1 Correlation matrix for PROs at the first recorded visit after enrolment in the KLURING registry

HRQoL), the Health Assessment Questionnaire (HAQ) (assessing functional ability), and visual analogue scales (VAS) to assess pain, fatigue, and subjective overall disease status.

Associations between PROs were examined using Spearman's correlations. Mixed-effects regression models were used to assess associations between symptom-specific measures (pain, fatigue, and HAQ) and overall health (VAS disease status and EQ-5D).

Results Fatigue, pain, and functional ability were significantly associated with EQ-5D scores (table 1). Correlation plots suggest that limited impairment on symptom measures are associated with better EQ-5D, but greater impairment was not clearly associated with worse EQ-5D (figure 1). Symptom measures were significantly associated with VAS disease status, and correlations were stronger with disease status than with the EQ-5D. In addition, symptom measures explained more of the variance in subjective disease status than with EQ-5D (R^2 0.77 vs. 0.54). VAS disease status was correlated with the EQ-5D, however the plot showed little association in poorer health states.

Conclusions Fatigue, pain, and functional ability were significant predictors of disease status, indicating that these may be factors influencing HRQoL in SLE. However, objective HRQoL scales may be inadequate indicators of SLE burden, as symptom-specific measures were not as strong predictors of EQ-5D. Subjective disease status was not clearly associated with objective health status across the spectrum of health states, and therefore the overall association may not be clinically meaningful. PROs that capture facets of HRQoL impacting SLE patients may be better indicators of disease status to consider when attempting to optimise HRQoL undertreatment.

PO.7.160 ENLIGHT-LN: A PROSPECTIVE OBSERVATIONAL REGISTRY OF PATIENTS TREATED WITH VOCLOSPORIN FOR LUPUS NEPHRITIS IN THE UNITED STATES

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10.1136/lupus-2022-elm2022.180

Purpose Voclosporin, a novel calcineurin inhibitor, was approved in January 2021 in the United States for the treatment of adult patients with active lupus nephritis in combination with background immunosuppressive therapy. Voclosporin has a favorable metabolic profile and a consistent dose-concentration relationship, eliminating the need for therapeutic drug monitoring associated with other calcineurin inhibitors. Pivotal Phase 2 and Phase 3 studies showed that the addition of voclosporin to mycophenolate mofetil (MMF) and low-dose steroids significantly increased complete renal response (CRR) rates in patients with lupus nephritis at approximately one year of treatment (48 weeks in AURA-LV, 52 weeks in AURORA 1).

Here we describe an actively enrolling prospective observational registry, designed to characterize the real world effectiveness profile and utilization patterns of voclosporin in the United States.

Methods Patients enrolled in Enlight-LN will receive standard care in accordance with usual clinical practice at each site, with no mandatory visits or assessments required by the protocol. Data will be extracted from patient medical records approximately every 3 months for up to 36 months; collected data will include demographics, disease characteristics, response to therapy, safety, and treatment patterns and

Abstract PO.7.160 Table 1 Enlight-LN registry inclusion and exclusion criteria

Inclusion Criteria	Exclusion Criteria
<ul style="list-style-type: none"> Adults ≥18 years of age Biopsy-confirmed lupus nephritis Initiating or have initiated treatment with voclosporin within the 3 months prior to consent Ability to understand and provide written consent 	<ul style="list-style-type: none"> Off-label use (use of voclosporin outside of the FDA-approved labeling)

FDA, food and drug administration

utilization. The registry will enroll patients who are initiating or who have already initiated treatment with commercial voclosporin within 3 months prior to consent. Patients ≥ 18 years of age with biopsy-confirmed lupus nephritis are eligible (Table 1). Secondary objectives include describing at baseline and during the study period the clinical characteristics, treatment and response patterns of patients treated with voclosporin.

To date, 36 sites in 16 states have been selected to participate in the registry; Enlight-LN is currently enrolling patients.

PO.7.161 CLINICAL AND IMMUNOLOGICAL CHARACTERIZATION OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) PATIENTS IN ESTONIA. A PROSPECTIVE COHORT STUDY OF 40 SLE PATIENTS IN ESTONIA

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10.1136/lupus-2022-elm2022.181

Background SLE is a rare chronic autoimmune disease with polymorphic clinical manifestation and wide-ranging disease course with treatment tactics dependent on disease activity and organ involvement. In 2017, a study to estimate prevalence and incidence of SLE in Estonia was done, but there is no data published to describe the Estonian SLE population. The aim of the present study is to analyze a sample of Estonian SLE patients.

Methods Consecutive outpatient and inpatient patients with rheumatologist diagnosed SLE (≥ 20 years) were enrolled in East-Tallinn Central Hospital. Two study visits were done with 6 months apart to evaluate disease activity, current treatment, organ involvement, immunological findings and comorbidities. In addition, data from medical records were collected: organ involvement and immunological findings at the time of diagnosis and initial treatment. SLE disease activity was measured using SLEDAI 2K (Systemic Lupus Erythematosus Disease Activity Index 2K) score.

Results Among 40 patients (mean age 50 (standard deviation ± 12.4) years, mean disease duration 12 (± 9.9) years, mean SLEDAI 2K at diagnosis 10 (± 3.9)) 92.5% were females. Mean SLEDAI 2K value at entering into the study was 4 (± 3.4) similar to the value after six months 4 (± 4.9). 82.5% of patients received hydroxychloroquine and 75% glyco-corticosteroid treatment, 27.5% of patients were treated with rituximab. During their disease course 90% had joint and 50% skin involvement, 35% had leucopenia, all patients were positive for antinuclear antibody (ANA), 80% were anti-double-stranded DNA antibody (anti-dsDNA) positive and 70% of patients had low complement levels.

Conclusion The first analysis of Estonian SLE patients' clinical and laboratory parameters indicates that the disease is overall well managed in most of the patients. Further studies are in

progress on collected serum and PBMC samples to find immunological causes for poor treatment response.

PO.7.162 EPIDEMIOLOGY OF SYSTEMIC LUPUS ERYTHEMATOSUS IN CENTRAL SWEDEN: A POPULATION-BASED COHORT STUDY FROM THE ÖSTERGÖTLAND COUNTY OVER 14 YEARS

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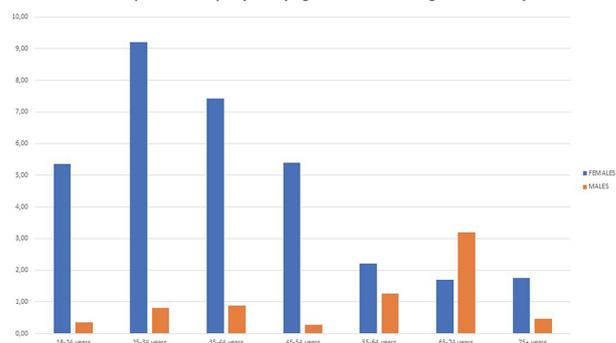
10.1136/lupus-2022-elm2022.182

Purpose We examined variations in incidence and prevalence of systemic lupus erythematosus (SLE) within a geographically defined area of central Sweden over a time period of 14 years. We described longitudinal differences in disease activity measures (e.g., the SLE disease activity index-2000 [SLEDAI-2K] and the Physician's Global Assessment), laboratory measurements and disease manifestations included among the American College of Rheumatology (ACR) criteria.

Methods We identified adults (≥ 18 years) residing in Östergötland County between 2008 and 2021 (mean adult population: 357 000 citizens) with a clinical diagnosis of SLE. Cases were defined as those with an SLE diagnosis set by a rheumatologist combined with fulfillment of the 1982 ACR classification criteria and/or the Fries' diagnostic principle (presence of antinuclear antibodies [ANA] by immunofluorescence microscopy at least once plus involvement of at least two defined organ systems). All subjects were included in the quality and research register 'Clinical Lupus Register in North-Eastern Gothia' (Swedish acronym KLURING). Individuals were followed prospectively until death, December 31, 2021, or emigration. We estimated incidence per 100 000 inhabitants stratified by sex and age. We used linear regression with calendar year of diagnosis as the outcome to assess whether each clinical measurement at diagnosis varied over time.

Results 126 new SLE cases (80% females) were diagnosed during the period 2008–2021, yielding a mean annual incidence of 3.0 per 100 000 inhabitants; higher in females (4.8 per 100 000) than in males (1.2 per 100 000). The mean age at diagnosis was 43.7 (Standard deviation [SD]

Incidence of SLE per 100 000 per year by age and sex in Östergötland County 2008–2021

**Abstract PO.7.162 Figure 1**