FRESH QOLA - Cross-cultural Validation of Systemic Lupus Activity (SLAQ) and Lupus Quality of Life (Lupus QOL) Questionnaires in French

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General		
Identification		
Detailed name	Cross-cultural Validation of Systemic Lupus Activity (SLAQ) and Lupus Quality of Life (Lupus QOL) Questionnaires in French	
Sign or acronym	FRESH QOLA	
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL: 28/01/2009	
General Aspects		
Medical area	Immunology	
Health determinants	Occupation Social and psychosocial factors	
Keywords	Advancement, translation, French, quality of life, questionnaire	
Scientific investigator(s) (Contact)		
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Collaborations

Funding

Funding status Private

Details LUPUS FRANCE

Governance of the database

Sponsor(s) or organisation(s)

responsible

CHU Dijon

Organisation status Public

Additional contact

Main features

Type of database

Type of database Study databases

Study databases (details)

Longitudinal study (except cohorts)

Database recruitment is carried

out by an intermediary

A selection of health institutions and services

Database recruitment is carried out as part of an interventional study

No

Additional information regarding sample selection.

Prospective

sample selection.	
Database objective	
Main objective	General objective: To translate and validate the Systemic Lupus Activity questionnaire and the Lupus Quality of Life into French
Inclusion criteria	- Patients fulfilling ACR 1997 criteria for systemic lupus erythematosus classification; - patients that understand written and spoken French; - patients between 18 and 75 years of age; - patients who received oral and written information regarding research.
Population type	
Age	Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years) Elderly (65 to 79 years)
Population covered	Sick population
Gender	Male Woman
Geography area	Regional
French regions covered by the database	Alsace Champagne-Ardenne Lorraine Bourgogne Franche-Comté
Detail of the geography area	Multicentric cohort throughout the Eastern Region of France (6 centres)
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	02/2009
Date of last collection (YYYY or MM/YYYY)	01/2010
Size of the database	

Size of the database (number of < 500 individuals

individuals)	
Details of the number of individuals	13
Data	
Database activity	Current data collection
Type of data collected	Clinical data Declarative data
Clinical data (detail)	Direct physical measures Medical registration
Declarative data (detail)	Paper self-questionnaire Face to face interview
Presence of a biobank	No
Health parameters studied	Quality of life/health perception
Procedures	
Data collection method	Self-administered questionnaire: from a paper questionnaire (manual input) with double data entry Interview: from a paper questionnaire (manual input) with double data entry Clinical Examinations: handwritten (manual input) with double data entry
Participant monitoring	Yes
Details on monitoring of participants	Follow-up duration: 6 months
Links to administrative sources	No
Promotion and access	
Promotion	
Link to the document	http://tinyurl.com/Hal-FRESH-QOLA
Description	List of publications in HAL
Link to the document	http://tinyurl.com/Pubmed-FRESH-QOLA
Description	List of publications in Pubmed
Access	
Terms of data access (charter	To be decided if data may be used by academic

for data provision, format of data, availability delay)	teams Data may not be used by industrial teams
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only