# 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

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|---|---|
| Medical area | Immunology |
| Health determinants | Occupation<br>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

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|---|---|
| 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 |

## Database objective

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|---|---|
| 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)<br>Adulthood (25 to 44 years)<br>Adulthood (45 to 64 years)<br>Elderly (65 to 79 years) |
| Population covered | Sick population |
| Gender | Male<br>Woman |
| Geography area | Regional |
| French regions covered by the database | Alsace Champagne-Ardenne Lorraine<br>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

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|---|---|
| Size of the database (number of | < 500 individuals |

| | |
|---|---|
| individuals) | |
| Details of the number of individuals | 13 |

### Data

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|---|---|
| Database activity | Current data collection |
| Type of data collected | Clinical data<br>Declarative data |
| Clinical data (detail) | Direct physical measures<br>Medical registration |
| Declarative data (detail) | Paper self-questionnaire<br>Face to face interview |
| Presence of a biobank | No |
| Health parameters studied | Quality of life/health perception |

### Procedures

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|---|---|
| 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

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|---|---|
| Terms of data access (charter | To be decided if data may be used by academic |

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| 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 |