

Notice of Special Interest: Building Consensus for Autoimmune Disease-Related Common Data Elements

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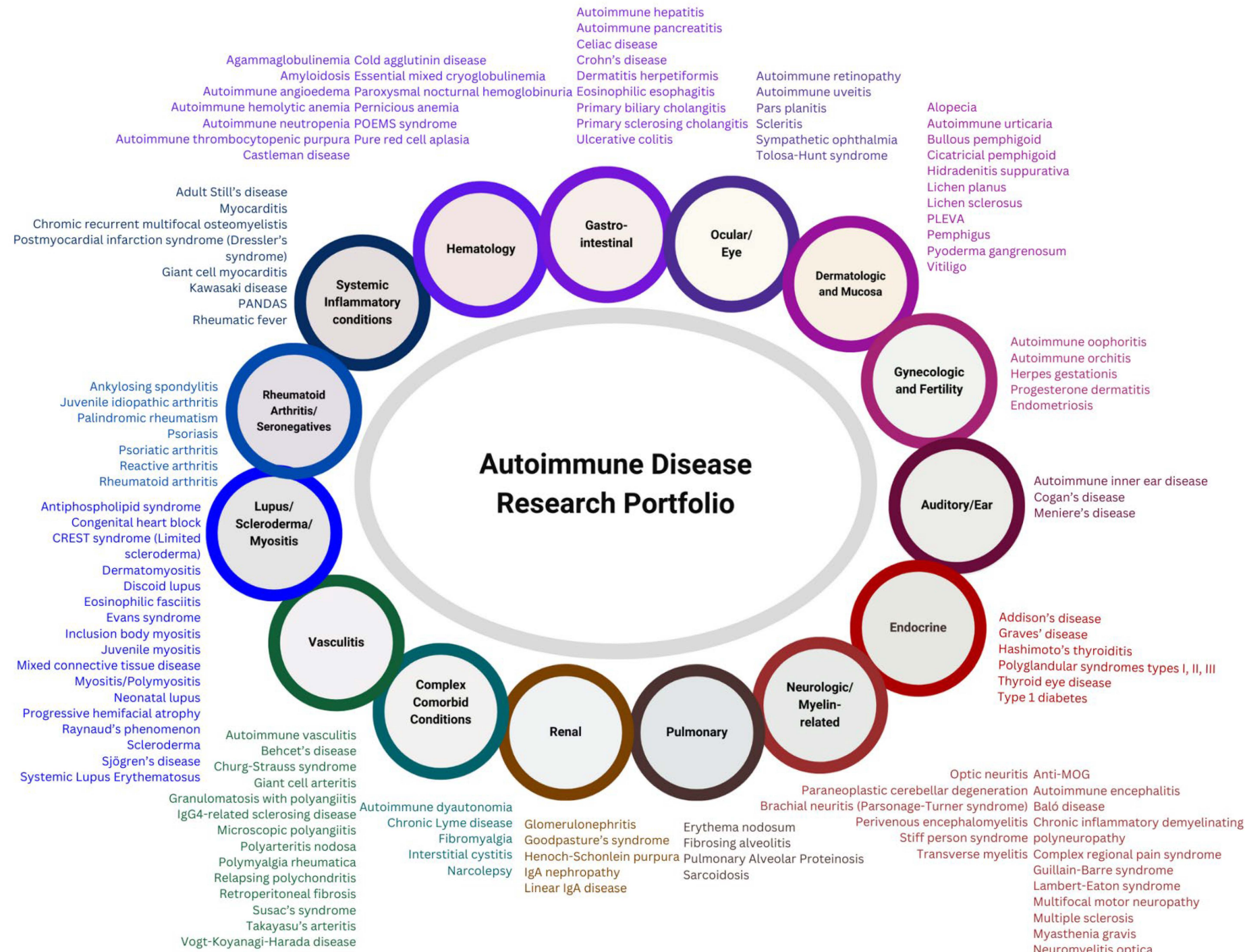
Notice of Special Interest: Common Data Elements for Autoimmune Disease Research

- **Concept Clearance:** New
- **Title:** Building Consensus for Autoimmune Disease-Related Common Data Elements
- **Objective/Purpose:** To highlight interest in receiving applications to stimulate development of NIH-endorsed common data elements applicable to autoimmune diseases through convening members of the scientific, clinical, patient, and advocate community to inform discussions
- **Funds Available and Anticipated Number of Awards:** Subject to availability of funds and Institute, Center and Office collaboration
- **Award Project Period:** 1 year
- **Committee Action:** Vote for approval of the concept of Building Consensus for Autoimmune Disease-Related Common Data Elements

AUTOIMMUNE DISEASES

- Autoimmune diseases affect 7-8% of population
- Approximately 23.5 million Americans affected by autoimmune diseases
- Nearly 80% of people with autoimmune diseases are women
- Four times more women than men are affected by autoimmune diseases

Exact prevalence of autoimmune disease in the US is unknown due to lack of longitudinal data repositories



NIH Endorsed Common Data Elements

- A **Common Data Element** (CDE) is a standardized, precisely defined question, paired with a set of allowable responses, used systematically across different sites, studies, or clinical trials to ensure consistent data collection.
- Multiple CDEs (from one or more Collections) can be curated into **Forms**. Forms in the NIH Repository might be original or might recreate the format of real-world data collection instruments or case report forms.
- NIH has endorsed collections of CDEs that meet established criteria. **NIH-endorsed CDEs** are designated with a gold ribbon.
- The purpose of this endorsement is to facilitate data-sharing and harmonize CDE across datasets, so that data sharing according to the 2023 [NIH Data Management and Sharing Policy](#) by making data from different studies more interoperable.



<https://cde.nlm.nih.gov/home>

Current NIH Endorsed Common Data Elements for Autoimmune Disease Research

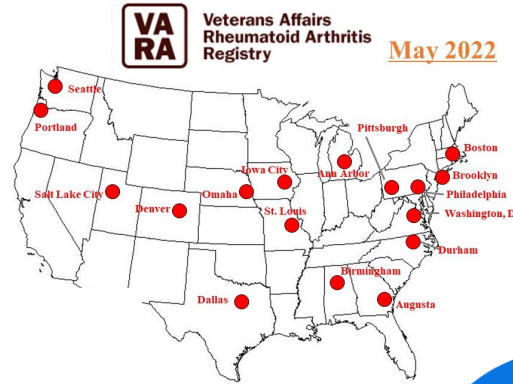
Disease	Number of Currently NIH Endorsed CDE
Multiple Sclerosis	56
Myasthenia Gravis	22
Psoriasis	11
Arthritis	6
Lupus/Scleroderma	4
Type I Diabetes	37
Uveitis	1
Vasculitis	1
Vitiligo	1



<https://www.commondataelements.ninds.nih.gov/Multiple%20Sclerosis>

MANY EXISTING REGISTRIES FOR AUTOIMMUNE RESEARCH

FORWARD
The National Databank for Rheumatic Diseases

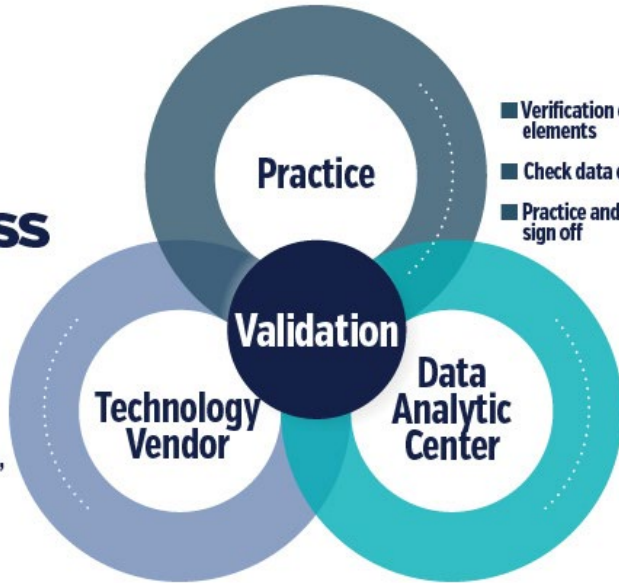



Autoimmune Registry

CARRA 

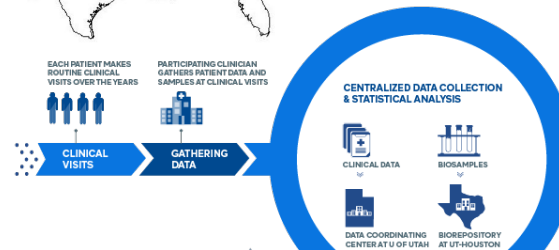
RISE Data Process

- Mapping based on EHR system
- Verify file structure
- Initial data cleaning, scrubbing, and QA



- Verification of data elements
- Check data conversion
- Practice and Vendor sign off

- Check file structure and variables
- Additional data cleaning, scrubbing, and QA
- Advanced data preparation



HEALTH Study
Harnessing Epidemiology to Advance Lupus Treatment and Health

LUMEN Study
Lupus Midwest Network

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California Lupus Epidemiology Study
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NIH National Institutes of Health
Office of Autoimmune Disease Research
Office of Research on Women's Health

Office of Autoimmune Disease Research

Women bear a disproportionate burden of autoimmune disease compared to men. Aligned with content from the 2022 NASEM Report, Congress directed NIH to establish the OADR within ORWH.

P.L. 117-328 Consolidated Appropriations Act of 2023 directed OADR-ORWH to:

1. Coordinate development of multi-Institute and Center (IC) strategic research plan
2. Identify emerging areas of innovation and research opportunity
3. Coordinate and foster collaborative research across ICs
4. Annually evaluate NIH Autoimmune Disease Research (ADR) portfolio
5. Provide resources to support planning, collaboration, and innovation
6. Develop publicly accessible central repository for ADR

P.L. 117-328 Consolidated Appropriations Act of 2023

[Division H--Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2023](#)



<https://nap.nationalacademies.org/catalog/26554/enhancing-nih-research-on-autoimmune-disease>

Office of Autoimmune Disease Research

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- **Areas of Focus:**

High priority topics identified through literature review, internal and external engagement and portfolio analysis

Collaborative approaches encouraged

- **Multi-IC Partnership:** Wide interest across NIH

- **Examples of Priority Topics:**

Myositis

Hidradenitis Suppurativa

Rheumatoid Arthritis

Sarcoidosis

Scleroderma

Systemic Lupus Erythematosus

Uveitis

Vasculitis

