

Request for Proposal: Lupus Landmark Study Clinical Coordination Center and Biorepository Components of the Lupus Nexus

The Lupus Research Alliance (LRA) is soliciting applications to support two of the three components of the Lupus Nexus – a first of its kind in lupus registry, biorepository, and an information exchange platform to accelerate lupus research and clinical translation. This request for proposals (RFP) focuses on the Clinical Coordination Center and the Biorepository. Applicants may apply for one or both components. The third component of the Lupus Nexus, the Data Repository and Analytics Platform, will be the focus of a subsequent RFP. Applicants who apply for one or both components in this RFP will also be eligible to apply to the data/analytics platform RFP.

Introduction

The LRA is the largest global, non-profit, non-governmental funder of lupus research. The organization has invested over \$220M in support of over 525 research projects since its inception in 1999. The LRA is dedicated to accelerating lupus research and translational medicine, shifting the paradigm on how researchers study lupus. In 2018, the LRA established an affiliate organization, Lupus Therapeutics (LT), which is responsible for the coordination, conduct and management of a North American-based clinical trial consortium, the Lupus Clinical Investigators Network (LuCIN). LT through LuCIN is currently conducting 11 Phase I through III clinical trials most of which are industry sponsored.

Lupus is a leading cause of death among young females, and 90% of the affected individuals are women. Currently available treatments lag far behind those for other autoimmune disease and are frequently inadequate to control disease progression and avert long-term complications. A major challenge in understanding and treating lupus is the extreme disease heterogeneity at both the clinical and molecular levels. Lupus heterogeneity appears to be at the core of the many therapeutic failures in the field. This underscores the need for 1) a molecular definition of disease diversity between patients and within patients; and 2) patient stratification by active disease mechanism(s) in clinical research and practice. Recent advances in human immunology as well as rapid technological developments, including advancing computational capabilities, provide an unprecedented opportunity to make major advances in the molecular deconstruction of lupus heterogeneity.

To enable and accelerate these advances, the **LRA is establishing the Lupus Nexus—a lupus registry, biorepository, and an information exchange platform—supported by the Lupus Landmark Study (LLS)—a longitudinal observational study of lupus patients with various disease manifestations** conducted within LuCIN. This study will provide the foundational data for the Lupus Nexus platform.

The Lupus Nexus will transform lupus research and drug development through unprecedented information exchange capabilities. The platform will provide a collaborative solution that is inclusive of diverse patient populations disproportionately affected by lupus, thereby filling an information void in the current research space. The Lupus Nexus will be the leading source in lupus of longitudinal patient data linked with biological samples, catalyzing global collaboration, research innovation, and precision medicine approaches to accelerate lupus drug discovery.

The LRA will be seeking proposals for three core resources to support this strategic initiative:

1. A **Clinical Coordination Center (C3)** which will coordinate with LuCIN clinical site investigators for the implementation, management, and monitoring of the LLS clinical protocol. The center will manage all aspects of the clinical protocol via a clinical trial management system (CTMS); oversee collection and quality control of data and biospecimens via an electronic data capture system (EDC) and source data verification activities; coordinate data flow from clinical sites to the data repository and analytics platform; and coordinate biospecimen management.
2. A **Biorepository** that will receive, manage, store, and make available a diverse range of biospecimens derived from the LLS.
3. A Data Repository and Analytics Platform which will house longitudinal clinical, biospecimen and research data to allow for sharing de-identified data for collaborative analysis. These platform components will be awarded through a subsequent RFP.

RFP Timetable:

Notice of Pending RFP Release:	<i>22 Apr 2022</i>
NDA Executions:	<i>25 Apr-6 May 2022</i>
RFP Issue Date:	<i>9 May 2022</i>
Questions and Requests for Clarifications Due:	<i>20 May 2022</i>
LRA's Responses to Requests for Clarifications:	<i>1 Jun 2022</i>
Proposal Due Date:	<i>24 Jun 2022</i>
First round respondent selection (maximum 8):	<i>8 Jul 2022</i>
Respondent webinars (1-1.5 hours each):	<i>11-15 Jul 2022</i>
Notification of Finalists (maximum 4):	<i>22 Jul 2022</i>
Finalist Presentations:	<i>1-5 Aug 2022</i>
Notification of Provisional Award:	<i>9 Sep 2022</i>
Contract Start Date:	<i>Oct 2022</i>

Contact Information

Requests for an NDA template and other inquiries about this RFP can be submitted to LupusNexus@lupusresearch.org. Emails should reference "Lupus CRO/BR RFP Inquiry" and your organization's name within the subject line.