

NCCN Request for Proposals (RFP): Quality Improvement in Chronic Lymphocytic Leukemia and Small Lymphocytic Lymphoma (CLL/SLL)

Date Issued: April 10, 2024

1.0 Purpose

The National Comprehensive Cancer Network® (NCCN) and AstraZeneca Pharmaceuticals, LP are collaborating to offer a new grant opportunity seeking proposals for quality improvement initiatives in Chronic Lymphocytic Leukemia and Small Lymphocytic Lymphoma (CLL/SLL). NCCN has received a \$1 Million Dollar research grant from AstraZeneca (hereafter, “Grantor”) to support NCCN Member Institution faculty for the performance of quality improvement initiatives in the management of CLL/SLL. NCCN will serve as the funding organization. Grants are available only to investigators from NCCN Member Institutions.

2.0 Organization Information

National Comprehensive Cancer Network

The National Comprehensive Cancer Network® (NCCN®) is a not-for-profit [alliance of 33 leading cancer centers](#) devoted to patient care, research, and education. NCCN is dedicated to improving and facilitating quality, effective, efficient, and equitable cancer care so patients can live better lives. Through the leadership and expertise of clinical professionals at [NCCN Member Institutions](#), NCCN develops resources that present valuable information to the numerous stakeholders in the health care delivery system. By defining and advancing high-quality cancer care, NCCN promotes the importance of continuous quality improvement and recognizes the significance of creating clinical practice guidelines appropriate for use by patients, clinicians, and other health care decision-makers around the world.

AstraZeneca in Oncology

AstraZeneca is leading a revolution in oncology with the ambition to provide cures for cancer in every form, following the science to understand cancer and all its complexities to discover, develop and deliver life-changing medicines to patients.

The Company's focus is on some of the most challenging cancers. It is through persistent innovation that AstraZeneca has built one of the most diverse portfolios and pipelines in the industry, with the potential to catalyze changes in the practice of medicine and transform the patient experience. AstraZeneca has the vision to redefine cancer care and, one day, eliminate cancer as a cause of death.

AstraZeneca

AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development, and commercialization of prescription medicines in Oncology, Rare Diseases, and BioPharmaceuticals, including Cardiovascular, Renal & Metabolism, and Respiratory & Immunology. Based in Cambridge, UK, AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide.

3.0. Background

Chronic Lymphocytic Leukemia and Small Lymphocytic Lymphoma (CLL/SLL) are clonal disorders characterized by the growth and accumulation of monoclonal CD5+ B lymphocytes accumulating in the blood, bone marrow, lymph nodes, and spleen. CLL and SLL are different manifestations of the same

disease and are managed similarly (Tsimberidou et al., 2007). A subtype of indolent, non-Hodgkin's lymphoma/leukemia, CLL/SLL is the most diagnosed leukemia in the US and Europe, with an estimated 20,000 new cases in 2022, accounting for 20% of all B-cell lymphoma/leukemias (Siegel et al., 2022). With a 5-year survival rate of 88%, CLL/SLL affects older individuals, and the clinical course is variable. Despite survival improvements in younger individuals with CLL/SLL, only modest improvements have occurred in older adults (Duchesneau et al., 2023; Molica et al., 2024; Wierda et al., 2024). Like other cancers, racial and economic disparities in the treatment of CLL remain (Kittai et al., 2023).

The treatment of CLL/SLL has evolved with improvements in the last decade owing to a better understanding of the underlying biology of the disease. Targeted therapies with Bruton's tyrosine kinase (BTK) inhibitors and BCL-2 inhibitors have emerged as effective chemotherapy-free options with predictable side effect profiles and are becoming the new standard of care for patients with previously untreated or relapsed/refractory CLL/SLL (Al-Sawaf et al., 2023; Ghia et al., 2023; Mato et al., 2023; Shadman et al., 2023; Sharman et al., 2022). When given effective treatments for CLL/SLL, and when side effects are appropriately managed, many patients are no longer dying of the disease but rather of other acute and chronic conditions (Wierda et al., 2024). A baseline understanding of an individual's prognostic factors, such as IgHV mutational status, cytogenetic abnormalities by karyotype and FISH, and molecular genetic studies can aid treatment selection and monitoring. Undetectable minimal residual disease (MRD) at the end of treatment is emerging as an essential predictor of progression-free and overall survival for patients treated with fixed-duration BCL-2 inhibitor-based treatment. However, this comprehensive disease characterization, novel targeted therapy, and treatment monitoring have not been widely adapted in general oncology practice.

Given advancements in survival for patients with CLL/SLL, more attention should be focused on health-related quality of life (HRQoL), addressing disparities, and identifying best practices in CLL/SLL management (Sharman et al., 2023). Gaps exist in baseline disease characterization, optimal treatment selection and disease monitoring, ongoing patient management, quality of life, and racial disparity. Thus, this RFP aims to develop innovative quality improvement projects to advance patient care and outcomes in CLL/SLL. This RFP seeks projects that could be quickly implemented, disseminated, and scaled to improve care delivery to this patient population after funding completion.

4.0. Aims and Eligibility

Aim:	Develop innovative quality improvement projects to advance patient care and outcomes in CLL/SLL. It is hoped proposals submitted in response to this RFP will be scalable and sustainable after funding completion, with potential for widespread dissemination and implementation.
Geographic Scope:	United States

<p>Eligibility Criteria: Investigators from the following organizations may apply</p>	<ul style="list-style-type: none"> • NCCN Member Institutions. • Collaboration between NCCN Member Institutions is strongly encouraged in order to foster the interactive sharing of knowledge and expertise, and to utilize the combined clinical strengths of members, particularly in the case of uncommon tumors. Although the submitting investigator must be from an NCCN Member Institution, participating co-investigators do not need to be at an NCCN Member Institution. This can also include cross-institutional collaboration for the conduct of correlative studies. • Proposal submissions from Junior Faculty are encouraged. • Trainees may participate as a sub-investigator under the appropriate mentorship from a PI from a NCCN Member Institution.
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5.0. Requirements

<p>Clinical Area:</p>	<p>Chronic Lymphocytic Leukemia and Small Lymphocytic Lymphoma (CLL/SLL)</p>
<p>Target Audience:</p>	<p>The intent of this Request for Proposal (RFP) is to support proposals that seek to improve the quality of care of patients with CLL/SLL.</p>
<p>Funding Considerations:</p>	<ul style="list-style-type: none"> • A total of \$1 Million Dollars is available for the funding of all projects. • <u>Please see Section 7.0 for details on maximum per project funding amounts.</u> • The intent is to fund individual projects capped at \$250,000 (direct and indirect costs) although smaller, lower-cost projects are encouraged. Funding greater than \$250,000 will be considered for exceptional proposals with detailed budget justification. • Maximum indirect (overhead) rate is 25% and <i>must</i> be included in total grant request amount. • Direct funding will include all costs including investigators' salaries. For example, \$80,000 direct costs and \$20,000 indirect costs for a total grant of \$100,000. Any funds in excess of the limits stipulated in this section for direct funding will require detailed justification and review. • Salaries are capped at the current NIH salary cap. • No travel or publication costs will be covered. • Applicants are required to disclose additional sources of funding for this project and demonstrate that funding does not overlap. • The decision relative to funding is deferred to the members of the Scientific Review Committee (SRC) as chosen by NCCN and is independent of Grantor.

<p>Area of interest/emphasis:</p>	<p>This Request for Proposal (RFP) intends to support proposals <u>to improve patient care and outcomes in CLL/SLL.</u></p> <p>Proposals in the following topic areas of emphasis identified for this RFP include the following and are strongly encouraged:</p> <p>1. Best practices surrounding CLL/SLL diagnosis, molecular profiling, treatment, and disease monitoring.</p> <ul style="list-style-type: none"> • Decision support related to optimizing genetic/biomarker testing, interpretation, and treatment selection. • Support oncology providers in choosing and delivering therapy in CLL/SLL aligned with patient priorities (e.g., decentralized monitoring of ramp-up or methods to include pharmacy management to personalize standard therapy). • Identify best practices to support patients during active surveillance and watchful waiting (including, but not limited to, integrating resources such as social work, support groups, and standardized patient and caregiver education). • Optimizing delivery of comprehensive care for the unique needs of CLL/SLL patients (i.e., social work support, nutrition, mental health counseling options, adherence to oral drugs, shared decision making, and AE management). • Mitigating financial toxicity associated with receipt of comprehensive care for patients with CLL/SLL. <p>2. Innovative ways to enhance access to care for disparate populations.</p> <ul style="list-style-type: none"> • Interventions to overcome barriers to clinical trial enrollment and participation. • Inclusion of ancillary staff and organizations to connect CLL/SLL patients and caregivers to resources to assist in mitigating physical or financial barriers to treatment. • Explore HRQoL at various stages of treatment and best tools to measure patient-reported outcomes. • Optimize patient adherence to treatment and/or ongoing disease monitoring. <p>3. Integrate technology tools for decision support</p> <ul style="list-style-type: none"> • Pilot novel, multidisciplinary delivery of care with a focus on technology (i.e., identification of ways to reduce ER visits or novel use of telemedicine to improve access to multidisciplinary care for CLL/SLL patients). • Educational tools for patients and/or providers. • Create well-functioning academic and community partnerships in care management of CLL/SLL patients.
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	<ul style="list-style-type: none"> Optimizing delivery of care to patients in underserved geographical areas/rural areas through technology.
<p>Areas excluded or considered out of scope:</p>	<p>Proposals in the following topic areas will be considered out-of-scope for this RFP:</p> <ul style="list-style-type: none"> Proposals not relevant to CLL/SLL disease setting. Clinical therapeutic interventional trials and specific drug/drug-based interventions. Translational, correlative, or basic science studies. Proposals duplicative of completed, ongoing, or planned studies will not be considered.
<p>Study Time Frames for Approved Studies:</p>	<ul style="list-style-type: none"> Commencement (defined as activation at the institution): Within 6 months unless IRB approval is required. If IRB approval is required by the Institution, activation must commence no later than 10 months after Institution is provided with notice of funding approval by NCCN. Period of Performance: Two years Reporting and Dissemination of Results in manuscript form: Within 9 months of study completion. *Please note that manuscript must be submitted to NCCN and Grantor for review prior to submission for publication consideration. Studies will be funded as described in Section 7.0 and should be designed with subject numbers commensurate with study time frames and funding. Studies that do not meet the time frame requirements for completion may have funds rescinded and will be required to return any and all unused funds previously disbursed.
<p>Selection Criteria:</p>	<p>Applications will be evaluated on the basis of:</p> <ul style="list-style-type: none"> Knowledge of and experience with the area; Capability of carrying out the work; Collaboration if appropriate; Scalability and sustainability; Potential effect and expected outcomes of the project; and Dissemination strategies. <p><i>The GRANTOR has the ability to reject any study with safety issues or if it is an already studied concept.</i></p>

Key Dates:	<ul style="list-style-type: none"> • RFP release date: April 10, 2024 • Proposal Submission Deadline (8 weeks): June 5, 2024 - Please note the deadline is 5:00 pm Eastern Time • Anticipated Grant Award Notification Date: July 17, 2024
Questions:	<ul style="list-style-type: none"> • If you have questions regarding this RFP, please direct them in writing to Nicole Zion, Clinical Research Manager, at zion@nccn.org with the subject “2024 NCCN-AZ CLL/SLL RFP”.

6.0 Review and Approval Process

The NCCN Request for Proposals Development Team (RFPDT) has developed a Request for Proposals (RFP) with a formalized review procedure to accept applications and select the proposals of highest scientific merit. The NCCN RFPDT has overseen the development of the RFP and a NCCN Scientific Review Committee composed of this group will perform the review of applications. All reviews, evaluations and award decisions are independent of Grantor.

Applicants will be notified via email with the information regarding submission and/or funding status by the dates noted above.

Proposals duplicative of completed, ongoing, or planned studies will not be considered. If you wish for additional information or have questions, please e-mail Zion@nccn.org or call Nicole Zion at 215-690-0230.

Studies that have safety issues, are already well-funded concepts, or are not consistent with the strategy for investigation as written in this RFP will not be reviewed by the SRC.

7.0 Funding

NCCN and its member institutions have an agreement to include a maximum of 25% indirect costs for trials funded by the NCCN. Direct funding will include all costs including investigators’ salaries. For example, \$80,000 direct costs and \$20,000 indirect costs for a total grant of \$100,000. Any funds in excess of the limits stipulated in this section for direct funding will require detailed justification and review.

NCCN shall make Funding disbursements to Institutions for each approved study as follows:

- Thirty percent (30%) of total award after commencement of Study.
- Twenty-five percent (25%) after 50% completion of Study.
- Twenty-five percent (25%) after 100% completion of Study.
- Twenty percent (20%) after submission of a final report or manuscript for publication.

The goal is to have rapid submission of a manuscript so as to have the data available to the wider scientific community.

Studies that do not meet the time frame requirements as stipulated in Section 5.0 will have funds rescinded and will be required to return any and all unused funds previously disbursed.

8. Proposals

In order to respond to the RFP, investigators will submit a proposal in the format delineated below to NCCN, which will be evaluated by the NCCN Scientific Review Committee (SRC).

Proposals are required to be submitted electronically to the NCCN research portal at https://nccn.envisionpharma.com/ienv_nccn and include letters of support from the governing groups of the institution verifying:

- 1) Office of Sponsored Research approval
- 2) Department Chair/Division approval
- 3) Institutional budgetary review and approval
- 4) Documentation to support feasibility of clinical trials with at least one of the following:
 - Letter from institution's Feasibility Committee if applicable
 - Documentation by previous studies and accrual (if available, publications and abstracts)
- 5) Letter(s) of support from participating institutions including name of PI at participating institution and their feasibility

Letters should be addressed to Crystal S. Denlinger, MD, FACP, CEO, National Comprehensive Cancer Network, 3025 Chemical Road, Suite 100, Plymouth Meeting, PA 19462

Proposals will provide concise documentation of the research plan and should be the equivalent of no more than 10 pages. The proposal is expected to contain sufficient information to allow the reviewers to fully assess the scientific rigor of the proposed study. A full research project plan may be submitted as an attachment, but the required information in iEnvision must also be completed. A robust review of the statistical plan will be conducted.

Proposals should contain detailed information regarding the following areas:

8.1 Study Information

- A. General Information: Title/Type of Support/Subsite(s)
 - Select **"Yes"** for Letter of Intent
 - Select **"AZ02"** for RFPID
 - Select **"Funding"** for Type of Support
- B. Investigators
 - Include academic title and rank
- C. Site Information
 - Primary and Sub-site information as applicable
- D. Concept information
 - Enrollment Target
 - Design (proposals for projects being performed within a larger basket/umbrella study must be clearly identified at time of submission)
 - Phase
 - Study Type
 - Estimated time of completion
 - Overview/Hypothesis/Abstract
 - Background/Rationale

- Overall Goals & Objectives
- Current Assessment of Need in Target Area
- Target Audience
- Project Design and Methods
- Innovation
- Evaluation and Outcomes
- Anticipated Project Timeline
- Organizational Detail
- Detailed Work Plan
- Evaluation Design
- References
- Additional information

E. Outcome/ Oncology analysis

- Tumor Type/Stage
- Body Systems
- Correlative study information
- Budget Justification

F. Planned publications: Journal/Congress/Anticipated Dates

8.2 Requested Funding Information (See iEnvision User Manual for additional instructions)

A. Complete the **NCCN Budget Template** (attached) and submit the **full budget** via the attachments folder.

- Breakdown costs by major cost categories
- Provide justification of major costs with enough detail to demonstrate how funding for major elements in the study will be allocated
- Salaries are capped at the current NIH salary cap
- No travel or publication costs will be covered

B. Complete the remainder of the Funding Page:

- Total direct and indirect costs (see instructions)
- Requested currency (US Dollar)
- Overhead %
- Amount Requested
- Additional sources of funding

8.3 Ancillary Documentation

- A. Current CV of the Principal Investigator
- B. Supportive literature may be provided
- C. Feasibility Letter/Document
- D. Department Chair or Division Letter of Support
- E. Budget Review and Approval Letter
- F. Any additional information to support proposal submission

9. Proposal Submission Process

9.1 Submission

All proposals must be submitted electronically using the directions below and are due by **5:00 PM (Eastern) on June 5, 2024**. No exceptions will be granted.

- A. Please use the link below to register in the system:
https://nccn.envisionpharma.com/ienv_nccn
- B. Select “Register for New Account” in the upper right corner of the page, above the “Log In” button.
- C. Complete all fields (Note: Fields with an asterisk are required)
- D. You will receive a confirmation email. Click on the link in the email to activate your account.
- E. Enter your username and password (Note: Your user name is your email address. Do not copy and paste).
- F. Set up your security questions.
- G. Submit your study under the “**Non-Clinical Research**” Application Type.
 1. Select “**Yes**” for Letter of Intent
 2. Select “**AZ02**” for RFPID
 3. Select “**Funding**” for Type of Support

For technical assistance with the iEnvision system, please contact iEnvision_general_request@envisionpharmagroup.com.

For questions or issues, please e-mail Nicole Zion at zion@nccn.org with the subject line “**2024 NCCN-AZ CLL/SLL RFP**”.

10.0 Additional Terms and Conditions

- 10.1 IRB requirements (as applicable): If a study requires IRB review and approval, the following applies:

10.1 (a) Draft protocols will be reviewed by NCCN and the Grantor **prior** to IRB review (if applicable). **A copy of the draft protocol must be submitted to NCCN within 4 weeks after the study approval letter.** The protocol must be consistent with the approved proposal and all reviewer comments must be addressed.

10.1 (b) All investigators will submit protocols for IRB review and document approval to NCCN prior to study activation and all collaborators will furnish evidence of IRB approval (if applicable). It is expected that IRB review and approval be completed **within 10 months** following NCCN notification of funding for the project.

- 10.2 Human Biological Specimens (if applicable): If specimens are collected, informed consent and IRB approval must be obtained as appropriate for the study. Compliance with all federal regulations is required.
- 10.3 Serious Adverse Event Reporting (if applicable): All serious adverse events will be reported to NCCN and the Grantor in addition to local regulatory authorities.

- 10.4 Institutional Monitoring (if applicable): All studies will be internally monitored in accordance with appropriate committees (e.g. institutional Data Safety and Monitoring Plan in the case of human studies). As required by institutional policy, a copy of any applicable Data Monitoring Plan for the study must be submitted to NCCN prior to NCCN approval of study activation.
- 10.5 Progress Reports: Investigators will provide interim progress reports to NCCN detailing the progress of studies quarterly, and a final study report or manuscript within 9 months following study completion. These reports will be used administratively for funding purposes. If study progress or accrual lags behind the expected rate, the SRC may be asked for suggestions to improve study progress, or alternatively, to terminate the study and any further funding.
- 10.6 Abstracts and Manuscripts: Abstracts for presentation at scientific meetings and all publications of study results will be submitted to NCCN and Grantor for review related to protection of companies' intellectual property and confidential information **prior to any submission**. Abstracts must be submitted at least 10 days prior to submission and manuscripts at least 30 days prior to submission. Manuscripts must be submitted to NCCN and Grantor for review within 9 months of study completion.
- 10.7 NCCN Multi-Institutional Studies: Collaborative studies between NCCN Member Institutions are encouraged. For these studies, the proposal feasibility section should provide information about data management and statistical analysis.
- 10.8 NCCN institutions and investigators will be responsible for conducting all studies in accordance with the applicable research plan, GCP Guidelines, and all applicable laws and regulations. NCCN institutions and investigators will be responsible for all data collection, statistical analysis, and safety reporting.
- 10.9 Investigators must provide reasonable assurance that submitted studies will be able to reach completion within the time frames specified in Section 5.0.
- 10.10 Final protocols must be consistent with approved proposals. Funds will be rescinded if there are significant changes without prior NCCN approval. There will be no exceptions.
- 10.11 The Principal Investigator (PI) listed on the protocol must be the same PI listed on the proposal submission unless approved by NCCN.
- 10.13 Education Initiatives: Independence remains with respect to the education and practice gap initiatives supported and implemented through the Initiative. Grantor and NCCN acknowledge the Accreditation Council for Continuing Medical Education ("ACCME") Standards for Integrity and Independence in Accredited Continuing Education to ensure the Independence of CME Activities ("ACCME Standards") as a benchmark for independence. All parties, regardless of the offer of Continuing Medical Education ("CME"), will adhere to the ACCME Standards. If the Project is not certified CME for physicians (e.g., other healthcare professional education, quality improvement, etc.) ACCME Standards still apply.

11.0 Study Agreement

A study agreement will be signed between NCCN and each participating institution.

If an institution requires a separate agreement with another pharmaceutical company for a study, that agreement must be fully executed by the time of final agreement execution with NCCN.

All aforementioned points between NCCN and the participating institution must be strictly adhered to.

12.0 Permissions

This RFP does not provide permission and license for the use (including the creation of derivative products) of the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for commercial use.

Funding recipients will need to maintain a separate end-user or other license agreement directly with NCCN for use of the NCCN Guidelines, Compendia, or Chemotherapy Order Templates.

13.0. References

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6. Molica, S., Shanafelt, T. D., Allsup, D., & Giannarelli, D. (2024). Impact of targeted agents on survival of chronic lymphocytic leukemia patients age >65 relative to age- and sex-matched population. *American journal of hematology*, *99*(3), 480–483. <https://doi.org/10.1002/ajh.27182>
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