

Welcome to the USCLC Registry Site!

There is a tremendous need to improve the treatment and outcome of patients with cutaneous lymphoma and a collaborative, cooperative, multidisciplinary effort is necessary to do so. This goal necessarily starts with a means of collecting information on patients with all types of cutaneous lymphoma using a standardized lexicon and methodology. The diagnosis, evaluation, staging and response criteria for all types of cutaneous lymphoma have recently been either amended or developed by the United States Consortium for Cutaneous Lymphomas (USCLC) and its international cutaneous lymphoma partners and published or submitted for publication. The USCLC is a dedicated group of physicians of various specialties (dermatologists, oncologists, radiation oncologists and pathologists) who collectively evaluate and treat the majority of cutaneous lymphoma patients in the United States and who have established the creation of a national registry for cutaneous lymphoma as the primary goal for the society. The USCLC Registry is a unique initiative at the grass roots level of patient care that will advance the prognosis, survival and quality of life of patients with all types of cutaneous lymphoma.

Specifically our goals for the USCLC Registry are the following:

- A. Primary: To establish a long term, secure and easily accessible electronic online registry platform for the collection of data on patients with cutaneous lymphoma in the United States and collaborating partner nations
- B. Secondary
 1. To determine the incidence and geographic locations of patients with the various subtypes of cutaneous lymphoma in the US and collaborating partner nations
 2. To determine and validate factors for each type of cutaneous lymphoma that may affect prognosis including those related to:
 - a. Demographic factors
 - b. Staging
 - c. Pathologic, molecular and genetic features of skin, lymph nodes, bone marrow, blood or internal organs
 - d. Radiologic characteristics including various types of imaging
 - e. Blood tumor burden or blood markers of significance
 3. To determine the efficacy and safety of various treatments or interventions (monotherapies or in combination) for patients with each subtype of cutaneous lymphoma as determined by both physicians and patients
 4. To determine the cost-effectiveness of various treatments or interventions used to treat each subtype of cutaneous lymphoma
 5. To enable patients with the various subtypes of cutaneous lymphoma to input data on the effect of their disease and treatment(s) on their and their families' quality of life
 6. To enhance the communication between patients with cutaneous lymphoma and the physicians directing their care
- C. Tertiary
 1. To compare and contrast treatment algorithms between study sites

2. To develop and validate new quality of life metrics for patients with cutaneous lymphoma
3. To develop meaningful outcome measures that are of value to physician and patient alike
4. To provide a platform for clinical trials of patients with cutaneous lymphoma to facilitate collaborative research with other national and international organizations
5. To develop a virtual tissue bank at each site for the purpose of studies on potential biomarkers of each subtype of cutaneous lymphoma with cross reference to Registry data
6. To educate physicians, by their participation in this registry, with best current approaches and treatments of these cutaneous lymphomas and to encourage participation in research studies of same

FAQs

- **What is the platform for the Registry?**

The platform is a secure, cloud-based platform created and maintained by Answers Ahead. Answers Ahead is a company focused on creating secure, cost efficient data management solutions for multi-site studies.

- **Who are the contributors to the Registry?**

The Registry is open to all Active members of the USCLC who are based in the United States (US) and whose dues are current. We are actively working on a plan for our International members. To participate in the Registry, all members must first sign a Registry Site Agreement with the USCLC and have IRB approval at their site for the central IRB approved protocol, informed consent/authorization form (ICAF) and assent forms for minors provided by USCLC to comply with Common Rule and HIPAA requirements for research activities.

- **Who owns the data?**

The data that are submitted by each site are owned by that site, allowing each site to have its own database. The USCLC owns the databases that it creates from the sites' data, as well as the aggregate data, data fields, and data forms used to collect data from the sites.

- **Who may use the data?**

The USCLC Registry Committee determines how the Registry data are used and published. Each site may use its own data for purposes outside that of the USCLC so long as there is IRB approval at their site for any additional research; provided that, to prevent duplication with efforts already planned or undertaken by USCLC, each site will inform USCLC in writing before submitting its data to any other entity or person of the nature and purpose of such submission

- **How is the Registry funded?**

The USCLC Registry is funded through profits from USCLC sponsored meetings and grants from industry, foundations, NIH, and individuals. All grants are made for unrestricted USCLC or USCLC Registry use without any ties to use or direct access to Registry data. The USCLC does

not at this time charge Active US Members an additional fee to use the USCLC Registry Platform.

- **Does the USCLC pay sites to enter data or otherwise financially support regulatory requirements?**

The USCLC is generously paying for the platform and maintenance of the Registry site for all USCLC Active Members. This is up to \$3500 per year per site to start and up to \$3000 per year per site to maintain the platform. There are no additional monies available to pay Members for entering data at this time.

- **Are there any required elements for data entry on each patient?**

Yes, to use the Registry and for the USCLC to continue to pay for the platform costs, the members must enter certain minimal required elements on all patients who are enrolled in the Registry. The required elements are those necessary to accomplish the USCLC's goals and to allow it to compete for national funding. There are many more optional data points that we hope sites will want to enter to further enhance our knowledge of cutaneous lymphomas and options for sites to add data points that they wish to collect that Registry is not otherwise addressing.

- **Is there a related biorepository for patients whose clinical data is in the Registry?**

Yes, two options. First, within the protocol we are using now, it allows for collection of unused tissue from prior biopsies and slides. In addition, there is a virtual biorepository planned and a sample protocol template and ICF will be available soon on the USCLC website. For the latter, each site would obtain IRB approval to collect and store tissue and/or blood at their site from patients already consented to have their clinical data entered into the Registry. Any specific use of the tissue so collected or stored will need additional IRB approval at the site. A USCLC Biorepository Committee will be making recommendations for USCLC projects related to this tissue collection but sites may always determine what they wish to do with that collected at their site and whether they wish to participate in USCLC related projects. The USCLC does not own or determine how a site may use the tissue/blood so collected but it has the potential to create, support or initiate translational research related to the clinical data entered into the Registry.

- **May USCLC members directly transfer their site's data to other research studies?**

Yes, but the databases created by USCLC from the data that sites enter into the Registry may not be transferred or used for other research purposes without approval of the study by the USCLC Registry Committee. Once approved by the USCLC, the site must obtain IRB approval at their site for the new research protocol and informed consent form, and the site to which the data are being transferred must sign a Data Use Agreement with the USCLC.

- **If a site wishes to participate in the PROCLIP study, does it need to enter data into the PROCLIP site and the USCLC Registry separately?**

No, the USCLC has been working with Stanford University, which maintains the platform for the PROCLIP study, to enable transfer of data from the USCLC Registry to Stanford for those sites who have independently also obtained regulatory approval for the PROCLIP study. The USCLC has agreed to pay for the mapping of this data to Stanford specifically for the advanced mycosis fungoides and Sézary syndrome patients which are those exclusively studied in the PROCLIP study. The USCLC has the capability of collecting data directly on all types of cutaneous T and B cell lymphoma and hopes to enable physicians internationally to use the Answers Ahead platform directly for other collaborative projects on cutaneous lymphoma.

- **How do patients participate in the Registry?**

Each site must first have a fully executed consent/authorization form for each patient reviewed by the USCLC before being given a study number for that patient. Patients are queried in the consent form whether they are willing to allow Answers Ahead to communicate with them directly in which case they would be sent a study number by Answers Ahead. If a patient does not agree to sharing his or her email address with Answers Ahead, then his or her physician would instead give the patient information on their study number and about signing up at the patient portal either on the USCLC website or the Cutaneous Lymphoma Foundation website. Answers Ahead would periodically put forms for patients to fill out on the patient portal and patient would be notified by email or their physician of these. Some of the resulting data from patients will be directly communicated to the physician entering clinical data on this patient, some would be given to the patient, and some will be kept separate for purposes of research analysis.

- **Are USCLC Registry participants able to enter photographs or photomicrographs of biopsy slides into the Registry?**

Yes, but there is an additional fee to the user for this unless specifically part of a USCLC project. Please contact Answers Ahead for further information.

- **Can data be uploaded directly from my EMR into the Registry?**

Not currently but you can cut and paste directly from your EMR to the Registry and we encourage this for pathology and radiologic reports in particular. Answers Ahead is actively working on EMR integration

- **Can I enter data into my EMR from the Registry?**

Yes, you can copy and paste from the Registry to your EMR. We have designated standard information that is collected at each follow-up visit to be collated on one page that can be easily copied and pasted into your clinic note. You may also create your own profile of data that you wish to be able to copy and paste into your clinical note.

- **Are there any specific things I need to do related to Answers Ahead?**

Yes, Answers Ahead requires that all Members entering data into the Registry sign an End User Agreement or “EULA”. The EULA is an agreement between Answers Ahead, LLC, the Registry’s software developer and the user of the Registry which stipulates the terms of each user’s

usage. Simply put, the EULA allows one to use the Registry software in accordance with the rules as set forth in the text of the EULA. It details how the Registry software can and cannot be used and any restrictions imposed (e.g. Registry users are prohibited from making the Registry available to any unauthorized person). Each Registry user will be asked to indicate that they “accept” the terms of the EULA when first accessing the Registry.

- **How do I get started?**

- The first thing to do is to ensure that your USCLC membership is current. Please contact Alyson Conley at alyson@theassociationcompany.com. If you have any doubts about whether your dues have been paid for the current year or go to USCLC.org Members tab.
- Next, you will be able to download the USCLC Site Agreement on the Members side of the USCLC website. This should be signed by your site’s contracts designee and emailed to Dr. Elise Olsen at USCLCregistry@gmail.com. If the contract person at your site has any issues with the Site Agreement, please direct them to Dr. Olsen as well.
- You will also need to have IRB approval for the central protocol, template informed consent form (ICF) and assent form for minors --these are provided for download on the Members side of the USCLC website. Knowing that each site will need to make necessary amendments to the ICF to fulfill their site’s requirements, please send any proposed changes first to Dr. Elise Olsen at USCLCRegistry@gmail.com before submitting to your IRB in order to insure the forms remain consistent with the approved central IRB approved forms.
- Lastly, the EULA of Answers Ahead should be reviewed by your institution if you are an institutional employee to insure there are no problems in you signing. A copy of the EULA is on the USCLC Members side of USCLC.org. Any questions regarding the EULA should be referred to Jeff Schwartz at jeff@answersahead.com.
- Once all has been done, you will be given access to the Registry site with its portal on the Members side of the USCLC website at USCLC.org.

Thank you so much for your interest in participating in the USCLC Registry. Your participation is testimony to your dedication to improving the lives of all your cutaneous lymphoma patients.

All best wishes

Elise A. Olsen, MD
Chairman, USCLC Registry Committee
USCLCRegistry@gmail.com

On behalf of:

USCLC Registry Committee:

Co-Chairman, Madeleine Duvic, MD

Members:

Francine Foss, MD

Larisa Geskin, MD

Joan Guitart, MD

Youn Kim, MD

Lauren Pinter-Brown, MD

Mark Pittelkow, MD

Susan Thornton

Gary Wood, MD

Answers Ahead: Jeff Schwarz

jeff@answersahead.com

USCLC Board of Directors

President: John Zic, MD

Immediate Past President: Elise Olsen, MD

Secretary-Treasurer: Francine Foss, MD

Directors:

Wei Ai, MD

Larisa Geskin, MD

Sam Hwang, MD, PhD

Ellen Kim, MD

Christiane Querfeld, MD

Jasmine Zain, MD

USCLC Association Management

Alyson B. Conley