

Elissa Baldwin: Hello everyone and welcome to *LLS COVID Antibody Research Study: Your Questions Answered*. My name is Elissa Baldwin with the Patient Education team at The Leukemia & Lymphoma Society, and I will be your moderator today. We will have a brief question and answer session after the presentation and our guest will answer commonly asked questions about the LLS study. Special thanks to Dr. Larry Saltzman for sharing his time and expertise with us today. Before we begin, Our Chief Medical Officer, Dr. Gwen Nichols would like to welcome you to this important program.

Dr. Gwen Nichols: Hello, I'm Dr. Gwen Nichols, the Chief Medical Officer of The Leukemia & Lymphoma Society. I'd like to welcome all the patients, caregivers, and healthcare professionals listening to this informative question and answer session.

At LLS, we hear from blood cancer patients and caregivers each day about the profound effects the pandemic has had on their cancer care, on their daily lives, including questions about COVID-19 vaccination and how well the vaccines may work in people who have blood cancer. We understand that you're experiencing a lot of uncertainty about the impact of on your cancer care and may have many, many questions about when and if you should get vaccinated.

In February 2021, LLS began to collect data of COVID 19 in our patient registry. We understood that COVID antibody research needed to be done, and so, in February this study began and over the ensuing months, we have over 3500 patients that have had blood drawing and taking part in this study. And our registry now is over 8000 patients.

We will be sharing some of these results with you today. The study is ongoing and will be continuing not only to understand safety and efficacy of the vaccines, but soon some information about whether other parts of the immune system, besides antibodies, are important for your ability to respond to the vaccine. And this is especially important for patients who don't make normal amounts of antibodies.

Blood cancer patients, we know, are among those at increased risk of developing more severe illness and even of dying from COVID-19, so we encourage blood cancer patients to get vaccinated, unless your health care provider says you have a medical contraindication to do so.

Because the vaccines may not work fully in blood cancer patients, we also recommend continuing to follow all prevention measures as an extra layer of protection.

Our motto is “Get Vaccinated and Act Unvaccinated”. By acting unvaccinated, we mean cancer patients and their caregivers, who have been fully vaccinated against COVID-19 should continue to take preventative measures - wearing a mask handwashing, avoiding crowded indoor spaces. You need to control your environment.

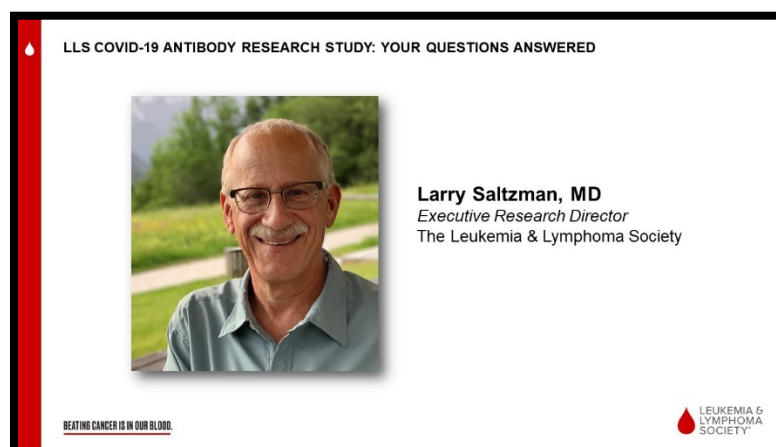
If you are a blood cancer patient or caregiver who is hesitant about the vaccines and are waiting for more vaccine data, we really want you to pay attention to this program to get many of your questions answered. Please also consult with your doctor about the vaccines. At LLS, our top priority is to keep blood cancer patients safe.

Today, you'll have the opportunity to hear from our Executive Research Director, Dr. Larry Saltzman. He's the primary investigator of this COVID antibody research study. We look forward to sharing the results of our study and our ongoing research. Thank you for joining us today.

Elissa Baldwin: Thank you, Dr. Nichols for your remarks to start off our program today, and thank you to our viewers for watching as you continue to face your or your loved one's blood cancer diagnosis during a pandemic and beyond. These past 18 months have been so difficult for the blood cancer community. As an acute myeloid leukemia survivor myself, I can understand the deep concerns and fears of patients and caregivers.

Like many of you watching today, I signed up for the new LLS Patient Registry and then the COVID-19 vaccine study. Cancer patients generally weren't included in the clinical trials, which created real concern for the blood cancer community and how we would react to the vaccines. Would we have adverse reactions? Would they be effective for immunocompromised community? Were we going to be protected against this highly transmissible disease?

These questions needed to be answered and LLS took on the challenge. Since we started the Patient Registry, over 8000 participants have signed up and many of them also participated in the vaccine study. Today we're excited to have Dr Saltzman with us to explain the results in more detail.

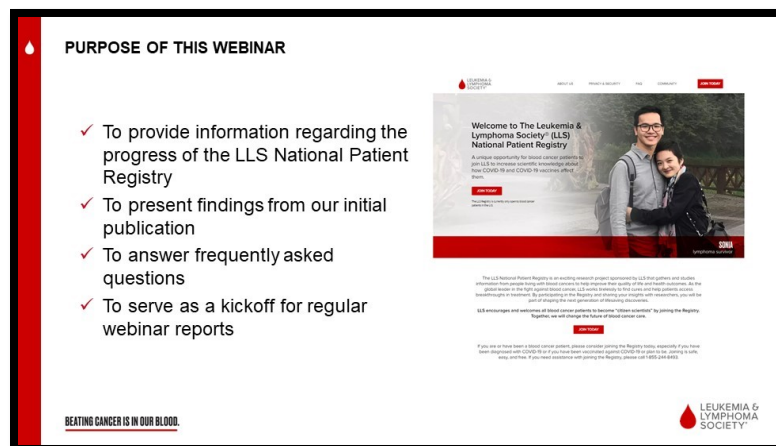


I'm now pleased to introduce Dr. Larry Saltzman. Dr. Saltzman is a chronic lymphocytic leukemia, or CLL, survivor, board certified family physician, and now the Executive Research Director for LLS. Diagnosed with an aggressive form of CLL in 2010, Dr. Saltzman went through multiple treatments, including CAR T-cell therapy. He retired from active clinical practice and was soon retained by LLS, utilizing his clinical and IT experience to help build the national registry of blood cancer patients, searching for patterns of care to produce better outcomes, with less side effects. With Dr. Gwen Nichols, he leads the COVID-19 vaccine study and is excited to share the results with you today.

Dr. Saltzman, I am now privileged to turn the program over to you.



Dr Larry Saltzman: Thank you Elissa and Dr. Nichols for the introduction.



The purpose of this webinar is to provide information regarding the progress of our LLS national patient registry. We will present findings from our initial publication, we will attempt to answer frequently asked questions and have this serve as a kickoff for regular webinar reports.




LARRY SALTZMAN, MD
LLS Executive Research Director


- ✓ Family Physician
- ✓ Health IT company founder
- ✓ Chronic Lymphocytic Leukemia Patient (Diagnosed 2010)
- ✓ Principal Investigator for the LLS National Patient Registry



I'm Dr. Larry Saltzman. As mentioned, I'm a Family Physician, I founded a health IT company in big data. I am a chronic lymphocytic leukemia patient, surviving since 2010 and I am the principal investigator for our LLS national patient registry.



Treatments include:
Bendamustine & Rituximab - 2013
Ibrutinib – 2015, 2016-2019
Right Colon Removal - 2015
Venetoclax – 2016-2019
Chemo x3 2019
CAR T Therapy – Dec 2019
IVIG – 2020-2021



BEATING CANCER IS IN OUR BLOOD.

This is meaningful to me because, through my treatments for CLL, I have been on almost every combination of therapy, that one might be concerned with including Bendamustine and Rituxan®, ibrutinib, Venetoclax, surgery to remove my colon, with regard to a lymphoma obstruction. In preparation for my CAR T-cell therapy, I had three rounds of different chemotherapies and currently I am taking IBIG on a monthly basis.

THE LLS NATIONAL PATIENT REGISTRY

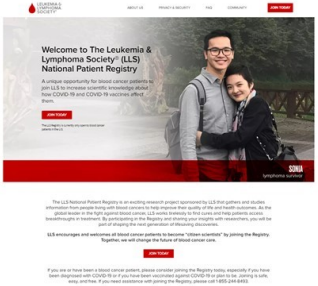
- ✓ A means to collect medical records to compare for outcomes
- ✓ Research study supported by Institutional Review Board Consent
- ✓ Registered with ClinicalTrials.org
- ✓ Now providing a unique opportunity for blood cancer patients to join LLS and increase scientific knowledge about how COVID and COVID vaccines affect them



The LLS national patient registry is a means to collect medical records to compare outcomes. It's a research study, supported by an institutional review board consenting process. We are registered with clinicaltrials.gov and it provides a unique opportunity for blood cancer patients to join LLS and increase our scientific knowledge about how COVID and COVID vaccines affect all of us.

THE LLS NATIONAL PATIENT REGISTRY


- ✓ An "observational" study – not a means to evaluate new treatments or medications
- ✓ Important for booster questions
- ✓ LLS is not a clinical provider
- ✓ LLS cannot give medical advice
- ✓ LLS can collect Patient Reported Outcomes
- ✓ Akin to the to Framingham cardiac study



This is an observational study, which means it's not a means to evaluate new treatments or medications. It's observational. We are looking at booster questions to inform our constituents about that. It's important to point out that LLS is not a medical provider and therefore we cannot give specific clinical or medical advice, based on a particular question or person's problems. LLS can collect patient reported outcomes and we do that, via surveys, and this is akin to what's called the Framingham Cardiac Study.


For those not familiar - the town of Framingham, Massachusetts was asked about 60 years ago to allow heart researchers to collect information about them, including their medical treatments and blood. And it was through that observational process that we now know that cardiac disease is worsened by smoking habits, by high cholesterol, and high blood pressure.

Page 5 of 28

 **THE LLS NATIONAL PATIENT REGISTRY – TECHNOLOGY**

- ✓ Technology platform is Ciitizen
- ✓ HIPAA compliant medical record collection
- ✓ No work on the medical provider's part
- ✓ Record requests for updated records on a periodic bases
- ✓ Patient Reported Outcomes (PRO) via survey collection
- ✓ Invitations for ongoing research
- ✓ PHI is stripped from all records
- ✓ LLS approved researchers will study records and results
- ✓ Participants will be asked for consent for entities outside of LLS who are interested in reviewing data


BEATING CANCER IS IN OUR BLOOD.

 LEUKEMIA &
LYMPHOMA
SOCIETY®

This was part of the study and we are trying to do the same for blood cancer patients in an observational manner to look for outcomes that are positive, based on treatments and making sure that side effects are lessened in our treatments. Now the technology for this is run by a company called *Ciitizen* and that's important because we get asked if this is a real company. It is not LLS, it's our technology partner.


The medical record collection is HIPAA compliant there is no work on the medical providers part because we and *Ciitizen* request records and you can be a part of this registry. By only I say only being a blood cancer patient, it is not necessary for you to have had the vaccine or had COVID. We are primarily looking at and for blood cancer patients. Record request for updated records are asked, on a periodic basis.

We do patient reported outcomes via survey collection, so you may receive surveys from us these invitations for ongoing research will be sent. Personal health information is stripped from all of your records and LLS approved researchers will study the records and the results, and if an outside party wants to review our research, you will be asked for consent to send your de-identified records to a third party.

 **THE LLS NATIONAL PATIENT REGISTRY – BASIS OF THE STUDY**

- ✓ Blood cancer patients are among those who are at increased risk of developing more severe illness from the virus that causes COVID-19. This includes higher risk for severe infections and death.
- ✓ Many COVID vaccine trials did not include blood cancer patients, leaving us without important information about how well COVID vaccines work for them.
- ✓ The vaccines may provide less protection to people with some types of blood cancer. Blood cancer treatments, like chemotherapy, can also affect how well vaccines work.

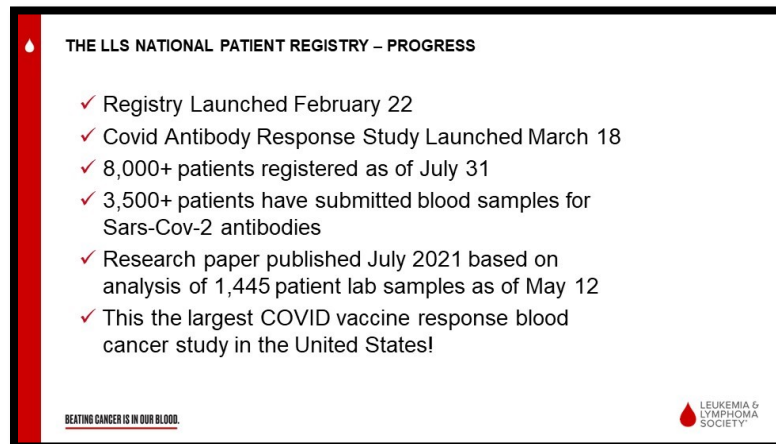
BEATING CANCER IS IN OUR BLOOD.

 LEUKEMIA &
LYMPHOMA
SOCIETY®

Now, for the basis of the study blood cancer patients are among those who are at increased risk of developing a more severe illness from the virus that causes COVID-19. This includes a higher risk for severe infections and death, unfortunately. The initial COVID vaccine trials did not

include blood cancer patients, leaving us without important information about how well COVID vaccines will work for us.

The vaccines may provide less protection to people with some types of blood cancer or various blood cancer treatments like chemotherapy can affect how the vaccines work and I will go over the results of our first study in a few minutes.



THE LLS NATIONAL PATIENT REGISTRY – PROGRESS

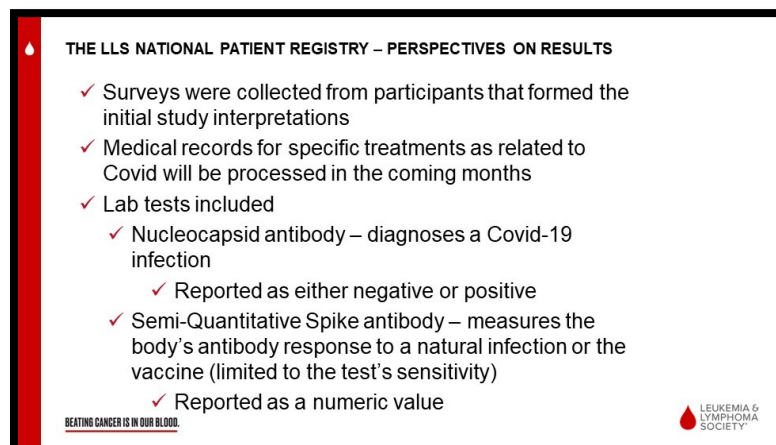
- ✓ Registry Launched February 22
- ✓ Covid Antibody Response Study Launched March 18
- ✓ 8,000+ patients registered as of July 31
- ✓ 3,500+ patients have submitted blood samples for Sars-Cov-2 antibodies
- ✓ Research paper published July 2021 based on analysis of 1,445 patient lab samples as of May 12
- ✓ This the largest COVID vaccine response blood cancer study in the United States!

BEATING CANCER IS IN OUR BLOOD

LEUKEMIA & LYMPHOMA SOCIETY®

The registry itself was launched this year on February 22. Given the COVID vaccine availability, we launched our COVID Antibody Response Study on March 18, just a few months ago. Since then, we've had over 8000 patients register for our project and over 3500 patients have been to our lab partner, LabCorp, and submitted blood samples for SARS-CoV-2 antibodies.

We have published a research paper this past July 2021 in a peer reviewed journal called *Cancer Cell*, based on an analysis of 1445 patients as of May 12, and this is the largest COVID vaccine response cancer study in the United States.



THE LLS NATIONAL PATIENT REGISTRY – PERSPECTIVES ON RESULTS

- ✓ Surveys were collected from participants that formed the initial study interpretations
- ✓ Medical records for specific treatments as related to Covid will be processed in the coming months
- ✓ Lab tests included
 - ✓ Nucleocapsid antibody – diagnoses a Covid-19 infection
 - ✓ Reported as either negative or positive
 - ✓ Semi-Quantitative Spike antibody – measures the body's antibody response to a natural infection or the vaccine (limited to the test's sensitivity)
 - ✓ Reported as a numeric value


BEATING CANCER IS IN OUR BLOOD

LEUKEMIA & LYMPHOMA SOCIETY®


Surveys were collected from participants that form the initial study interpretations. Medical records for specific treatments as related to COVID are going to be processed in the coming months.

And therefore, this study was based on survey results and lab results. The lab tests we included, were a Roche assay. This is worldwide, best, most sensitive assay for COVID

vaccines. We're asking and studying the nucleocapsid antibody response which diagnoses a current or previous COVID infection. This has reported as either negative or positive.

**THE LLS NATIONAL PATIENT REGISTRY – PERSPECTIVES ON RESULTS**


- ✓ Semi-Quantitative Spike antibody
- ✓ Includes a measurement of IgA, IgM, and IgG antibodies
- ✓ Simply stated
 - ✓ Value <0.79 = no response (most of these are reported as <0.40)
 - ✓ Value of >0.8 indicates a response
 - ✓ LabCorp changed the results to indicate a top positive response of <250 now is >2500
 - ✓ A previous response of <250 lies somewhere in the 250-<2500 range.
 - ✓ A previous or current response of up to 250 remains the same

BEATING CANCER IS IN OUR BLOOD.


And then we're asking for a Spike Semi-Quantitative antibody level, which measures the body's antibody response to a natural infection or the vaccine. And since we're studying the vaccine response, this is why we also asked for a nucleocapsid test to differentiate a response from an infection versus the vaccine. And this Antibody Spike Semi-Quantitative test is looking at as a combination of immunoglobulin including IgA, IgM and IgG. The report is a numeric value and that value is limited to the test sensitivity, as will go through again in a minute.

We are looking for a Semi-Quantitative Spike antibodies, including the antibodies as mentioned and simply stated, a Semi-Quantitative Antibody result of less than 0.79 equates to no response. Most people will see these as a value of less than 0.40. Value of greater than 0.8 indicates a response LabCorp has changed the results midstream in the month of May that now indicates a top positive response of greater than 2500. Prior to May, it was greater than 250.

Now, this is more sensitive in the upper range. Anybody who had a test before May and after May, if a result was reported that's between zero and 250, those are comparable apples to apples and those results remain the same.

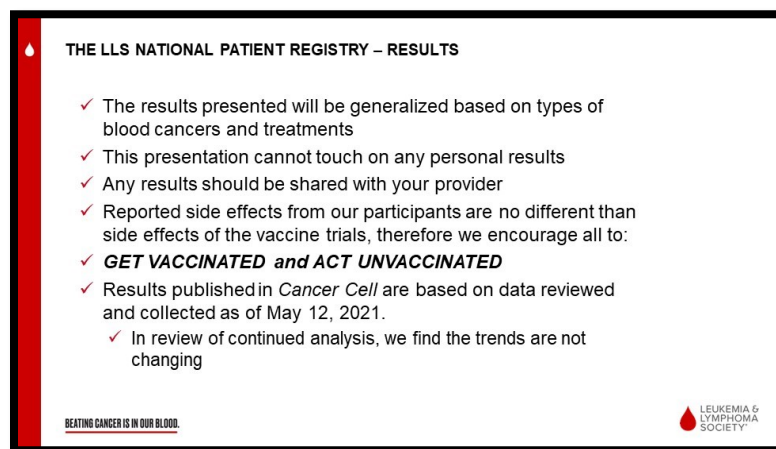
**THE LLS NATIONAL PATIENT REGISTRY – PERSPECTIVES ON RESULTS**

- ✓ How do our responses compare to the "normal-healthy" population?
- ✓ Vaccine trials were based on the lab values of 0->250
- ✓ There are no official reports of what is protective
- ✓ Two values pop out
 - ✓ 200 is the value that is reported to indicate a full response in healthy individuals
 - ✓ 132 is a value that the Red Cross blood banks use to decide if a plasma sample contains enough Covid-19 antibodies to be used for plasma treatments
- ✓ A result of greater than 200 implies a full response. Whether your number is 200 or >2500 there is no data as to which number is better

BEATING CANCER IS IN OUR BLOOD.

There are questions about how our results compared to normal, healthy population, and there are no official reports of what is protective. This is an important question that we get asked, and it's something we cannot answer, specifically. Having said that, two values pop out to us from the clinical trials for the vaccines, one is that, a number value of 200 is the reported number that indicates a full response to the vaccine and healthy individuals. So, when we're asked is my number considered a healthy response - if the value is greater than 200, we would say yes.

If the value is, let's say 132 which is less than 200, we know that that's a value that the Red Cross blood banks use to decide if a plasma sample contains enough COVID-19 antibodies to be used for plasma treatments which are now being given if somebody is diagnosed with COVID. So a result of greater than 200 does imply a full response to the vaccine. Whether your number is 200 or greater than 2500 there is no data and there's no answer to which number is better. We just know that that's the vaccine response number.



THE LLS NATIONAL PATIENT REGISTRY – RESULTS

- ✓ The results presented will be generalized based on types of blood cancers and treatments
- ✓ This presentation cannot touch on any personal results
- ✓ Any results should be shared with your provider
- ✓ Reported side effects from our participants are no different than side effects of the vaccine trials, therefore we encourage all to:
- ✓ **GET VACCINATED and ACT UNVACCINATED**
- ✓ Results published in *Cancer Cell* are based on data reviewed and collected as of May 12, 2021.
 - ✓ In review of continued analysis, we find the trends are not changing

BEATING CANCER IS IN OUR BLOOD

LEUKEMIA & LYMPHOMA SOCIETY®


Now, the results presented will be generalized based on the types of blood cancers and treatments. This presentation cannot touch on any of your personal results. Your results should be shared with your provider because they know your case better than we do.

And reported side effects from our participants, side effects to the vaccine are no different than side effects of the vaccine trials, there were no greater side effects reported and therefore, we stick by our recommendation of get vaccinated. Although we should all act unvaccinated, meaning wear a mask, especially in crowds or indoors.

Social distance and handwashing and any protection that you can give yourself would be best. Now our results again were published in the *Cancer Cell* peer reviewed journal based on data collected as of May 12, 2021. And in reviewing continued analysis, because we're now into August, we find that the trends that we reported are not changing.

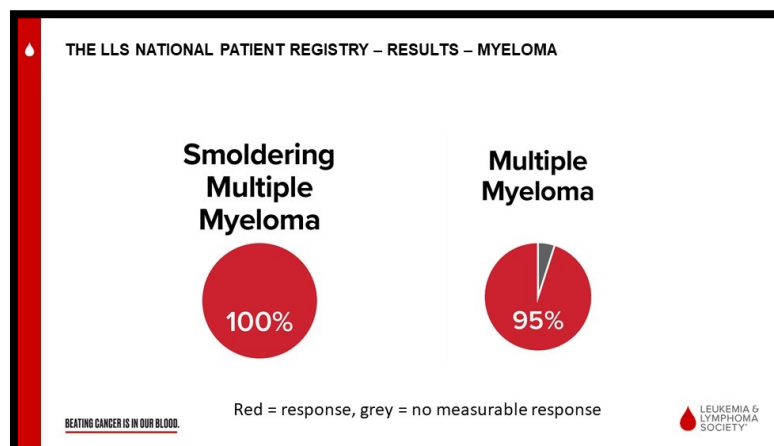
THE LLS NATIONAL PATIENT REGISTRY – RESULTS PAGE

- ✓ Big Picture reviewed 1,445 results
- ✓ 75% of blood cancer patients have adequate antibody response
 - ✓ Additional data shows these trends are persisting
- ✓ For the 25% who are seronegative, these percentages vary by blood cancer type and/or treatment.
- ✓ Our findings were statistically significant and in general are inline with studies published in the UK and Israel as well as smaller studies in the USA.

BEATING CANCER IS IN OUR BLOOD. 

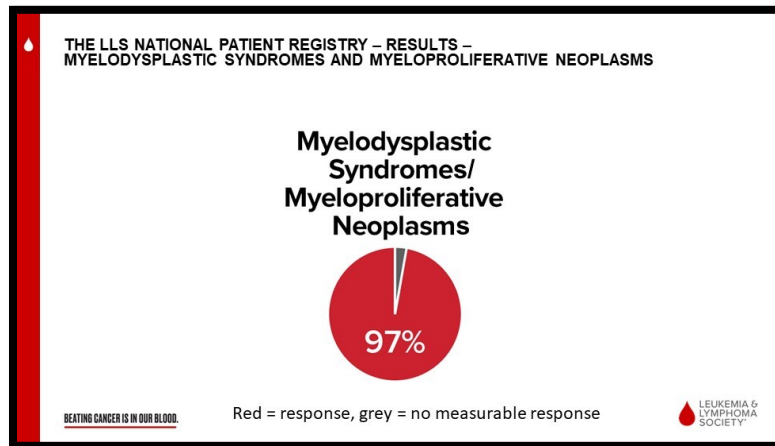
So, the big picture here is that we reviewed again a little over 1400 results and 75% of blood cancer patients have an adequate antibody response. That's important. And additional data again shows these trends are persisting. For the 25% of patients who are zero negative, these percentages vary by the type of blood cancer and/or the type of treatment that has been received in the recent months or years and I'll go through some of this.

Our findings were statistically significant, meaning they were looked at by statistics statisticians and in general are in line with studies published in the UK and Israel as well as smaller studies in the USA. The following results, I'm going to show include all participants, whether they have been treated recently with blood cancer therapies or not. So here we go.

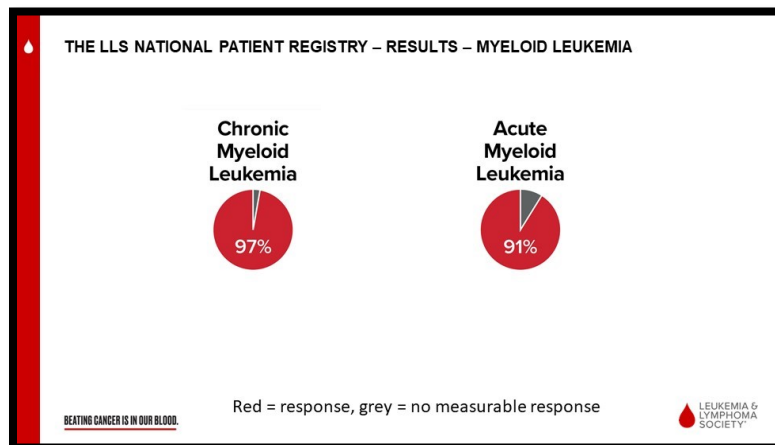


I have showing these based on the type of categories of blood cancer, and as you look at these - the red color indicates, there was a response. The grey color indicates the percentage of non-responders so if a person has a diagnosis of smoldering myeloma and they receive these SARS-CoV-2 to vaccine, any one of them, we're showing that those constituents have 100% response to the vaccine.

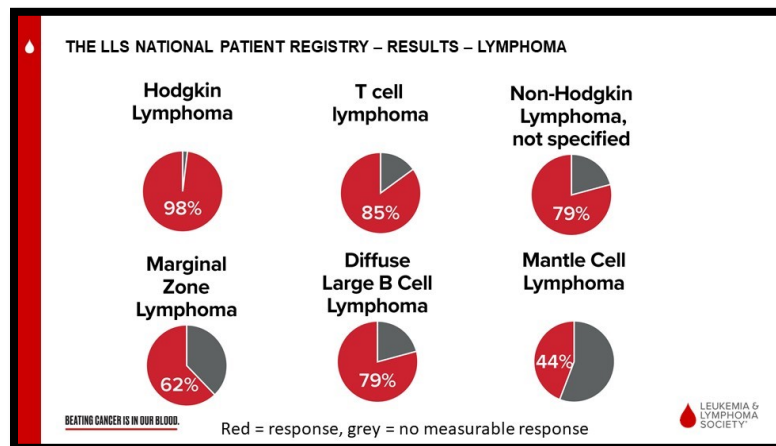
And if you have multiple myeloma, we show that 95% of the people we studied have a response to the vaccine. So these are very compelling numbers.



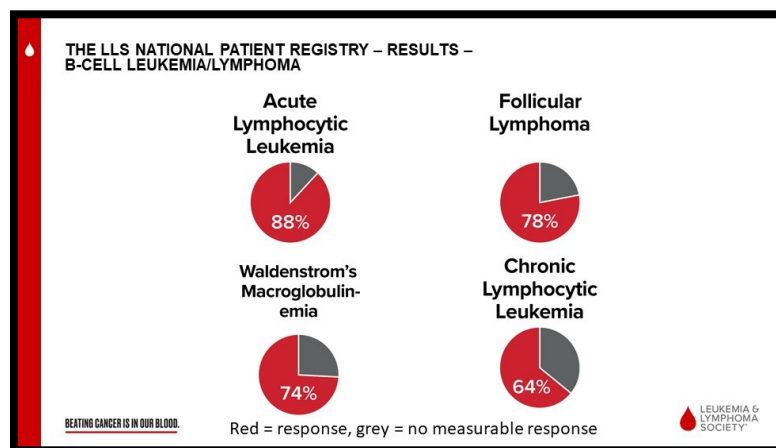
These are the numbers for patients with myelodysplastic or myeloproliferative neoplasms, again 97% of MDS patients or patients who have may have high platelet counts - 97% have a response to the vaccine.



Okay, one more step. Now we're showing myeloid leukemias, these are CML or AML. Again, 97% of CML patients respond to the vaccine. 91% of AML patients respond to the vaccine. Again the grey bar, if you do the subtraction, so 9% of AML patients do not respond and that's probably related to recent treatments that they have been on.



This is the bar graphs or the pie charts, if you will, for lymphoma patients. Again, going from, you know, I guess most comforting, to least comforting. Hodgkin lymphoma patients, 98% responded to the vaccine and as we go down the list, we see T cell lymphoma is that 85%. Non-hodgkin lymphoma, not specified at 79% response, marginal zone lymphoma 62%, diffuse large b-cell lymphoma has 79% response, and mantle cell lymphomas at a 44% response.



As far as the leukemias, especially b-cell leukemias, we find that again for ALL, 88% of patients respond. For follicular lymphoma, 78% of patients respond. Waldenstrom's is a 74% response rate, and CLL, my personal favorite is a 64% response rate again.

Most of the non-responders have some relationship to the treatments they're on, and let me put up this list, so you get an idea of what we're talking about.

THE LLS NATIONAL PATIENT REGISTRY – RESULTS – THERAPIES	
COVID-19 Vaccine Antibody Response among CLL Patients by Type of Treatment	
Treatment within the past 2 years	Percent of patients seronegative
None	17
Obinutuzumab	90
Rituximab, acalabrutinib	85
Rituximab, ibrutinib	77
Multidrug therapy w or w/o cytotoxic chemotherapy	71
Obinutuzumab, ibrutinib	70
Obinutuzumab, acalabrutinib	66
Rituximab	63
Acalabrutinib	55
Ibrutinib	48
Ibrutinib, IVIG	40
IVIG	25

This is just CLL patients and their antibody response based on the treatments they're on. So these are treatments that people have noted for the last two years now. If you look at patients who are not on treatment at all within the last two years, 17% of those patients did not respond to the vaccine and we feel that that may be related to the CLL itself and the fact that a CLL patient's B-cells may not be as efficient as a normal, healthy adult.

Now, where this gets dicey, if you will, is, if you look at the treatment type call Obinutuzumab, which is an anti B-cell treatment. People on Obinutuzumab show that 90% of those patients did not have a response to the vaccine. This is a very powerful anti b-cell treatment and it obviously affects our ability to respond to the vaccine, as does Rituximab in all cases, whether combined with acalabrutinib or ibrutinib.

The serum negative numbers are high at 77 and 85% and even Rituximab on its own 63% of patients are non-responders and the numbers go down from here. So again, this relates to other leukemias and lymphomas. As an example, if there was a follicular lymphoma patient who is on rituximab, then their numbers are going to relate to this table, meaning a majority of those people, if they've been under a rituximab in the last 12 months or more, likely than not will not create antibodies and so we need to all be careful.

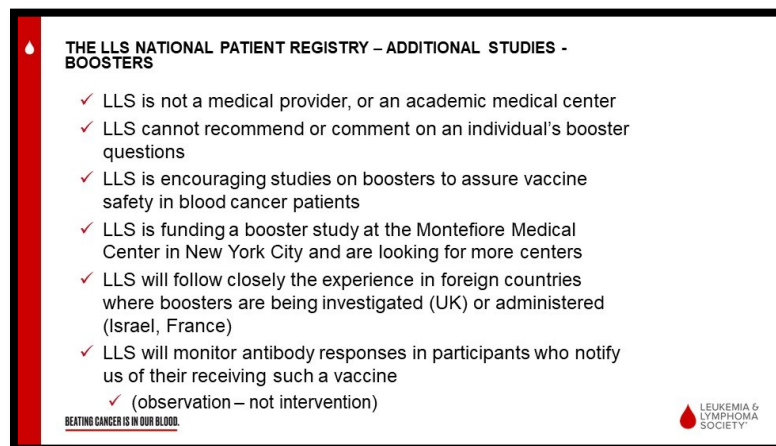
THE LLS NATIONAL PATIENT REGISTRY – ADDITIONAL STUDIES	
✓ T-cell response to Covid-19 vaccines	
✓ Research study where all tests at the lab are de-identified and therefore personal results cannot be returned	
✓ 1100 participants invited	
✓ 700 seronegative – include all blood cancer diagnoses	
✓ 400 seropositive for control groups	
✓ 3-6+ month serology follow up	
✓ To determine serology changes over time	
✓ CAR T observational study	
✓ Booster "observational" study	
✓ LLS is not offering boosters	

Okay, so I'm going to move on now to some additional studies and then we'll get to our frequently asked questions. LLS is currently involved in studying T-cell responses to the

vaccine, because we know that in our human body, there are three components of a response. One is a B-cell response, which is an antibody response managed by B cells.

The second is a T-cell response, which is more of the killer response and very important in managing any infection. And then there is cellular immunity. There are commercial tests to check on the antibodies from B cells which we've been discussing. There are no commercial test to look at T-cell responses. And so LLS is working with a research company and we've invited 1100 participants, 700 who are zero negative and 400 who did make antibodies to act as control groups to study T cells. Now, because these are research studies and they are not EUA (Emergency Use Authorization) approved by the FDA (The Food and Drug Administration), we cannot provide individual results. We can only report by categories of types of blood cancers and/or treatments to blood cancers. And these will take probably three months or so from now to compile these results, so we will stay tuned for that.

We are also asking people who have had vaccines now three to six months ago to do follow up serology to look at changes over time. We are looking specifically at CAR T patients, you're looking at one of them, right now to see what's happened with CAR T treatments. And stay tuned for that and we are in the process of observationally studying participants who report to us that they have had a booster. However, they have been able to receive it.



THE LLS NATIONAL PATIENT REGISTRY - ADDITIONAL STUDIES - BOOSTERS

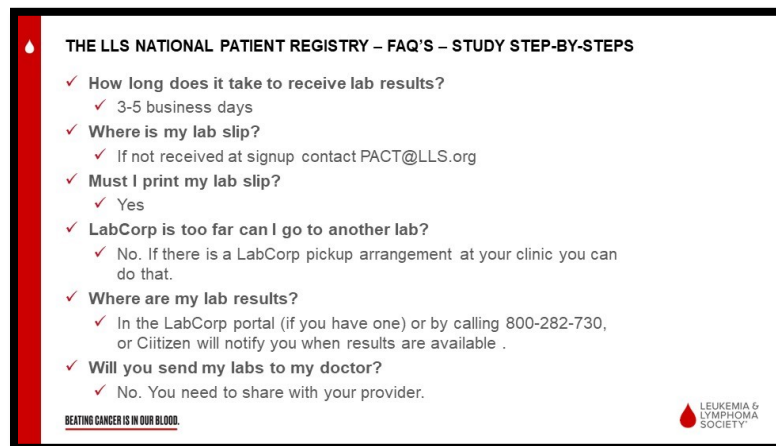
- ✓ LLS is not a medical provider, or an academic medical center
- ✓ LLS cannot recommend or comment on an individual's booster questions
- ✓ LLS is encouraging studies on boosters to assure vaccine safety in blood cancer patients
- ✓ LLS is funding a booster study at the Montefiore Medical Center in New York City and are looking for more centers
- ✓ LLS will follow closely the experience in foreign countries where boosters are being investigated (UK) or administered (Israel, France)
- ✓ LLS will monitor antibody responses in participants who notify us of their receiving such a vaccine
- ✓ (observation – not intervention)

BEATING CANCER IS IN OUR BLOOD.

LEUKEMIA & LYMPHOMA SOCIETY

LLS itself is not offering boosters. You know, again, LLS is not a clinical trial entity. We are only observing. So those who asked us if we can get you a booster the answer to that is, no we can't. And with regard to boosters again, you know we're not a medical provider or an academic medical center, so we cannot really recommend or comment on your individual questions.

We are encouraging studies on boosters to assure that there is vaccine safety in blood cancer patients, this is the first question that needs to be answered. We are actively funding a booster study that will launch in the next few weeks at the Montefiore Medical Center in New York City. And we are looking for more center is geographically around the country. We will closely follow the experience in foreign countries where boosters are being investigated or administered. And we will monitor antibody responses in participants who notify us that they have received a booster vaccine. Again, this is observational, not interventional.



Okay, so FAQs. We have compiled many FAQs from you and I'll try and answer them as best as I can. These are what I call, step by step, questions.

How long does it take to receive your antibody lab results? And the answer is three to five business days.

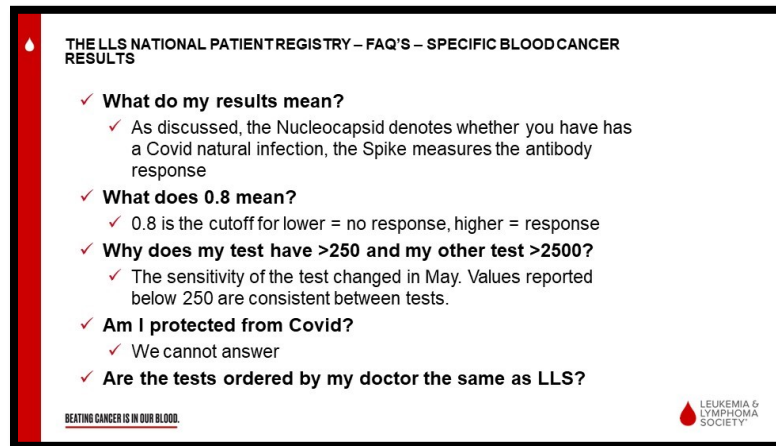
What if I can't find my lab slip to get a blood test? And you will need to take a blood slip to the lab. You can email us at PACT@lls.org and we will send you your lab slip customized for you.

Must I print the lab slip? Yes, LabCorp will not accept the labs that display it on a mobile device, unfortunately. Our participants must bring in a piece of paper.

What if LabCorp is not convenient, can I go to another lab? The answer to there is no. Different labs run different assays and our study needs to compare apples and apples. We do suggest that if your clinic site or lab site has a relationship with LabCorp, they will come and pick up lab samples from that site - that is just fine. You need to bring the requisition slip, the lab slip to your lab, ask them to draw the blood, put it in a little baggie with your lab slip and they have LabCorp pick it up. That will work for us.

Where are my lab results? LabCorp has a portal, just like most providers, and if you have one set up, you can see your results there. Or you can call the LabCorp's toll free number, 800-282-7300 to ask for your results. And in our *Citiizen* technology partner's accounts, we will notify you when the results have been loaded there.

We get asked if we'll send your results to your doctor. The answer, unfortunately, there is no. We do not have a means to mail or fax results to your doctor. We ask that you print them and share them with your doctor in any way that you can.



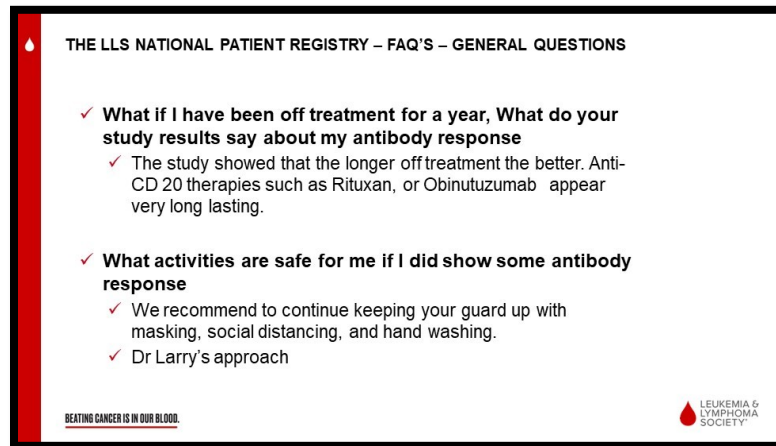
Okay, **what do my results mean?** Well, as I said, the nucleocapsid antibody denotes whether you have had or have a COVID natural infection. And I'll say that the half-life of this test is about 85 days. So, if the test is positive, it doesn't mean you're necessarily infected right now. It may be, as long as three months ago. We won't have the answer specifically to that. The Spike Semi-Quantitative antibody test measures, the antibody response, okay.

We get questions about **what does 0.8 mean** because they have time the lab slip in 0.8 again is the cutoff for no response. If it's lower than 0.8 or a response if it's higher than 0.8.

Why does my lab tests have a greater than 250 and a more recent test may say, greater than 2400/2500? And as I've said, the sensitivity of the test was changed. Having said that, any number below 250 is consistent from one test to another, the higher numbers are just a higher dilution it's called and a bit more sensitive.

Am I protected from COVID depending on my test results? Frankly and honestly, we can't answer their question and, as you all know, there is now a delta variant which seems to be more transmissible. And so it's impossible for us to know what the numbers are that will protect any of us from this virus.

And are the tests ordered by my doctor, the same as LLS? Frankly, if they're ordered at LabCorp with the same test ordering number, then they're the same. But if they're ordered at labs, as an example Quest or a private lab or just in your doctor's office, the answer is probably not the same.




What if I've been off treatment for a year, what do your study results say about my antibody response? As I pointed out with the CLL patients and their treatments, our study, as reported is showing that the longer your off treatment, the better regarding a response to the vaccine. Anti-CD 20 therapies, such as written or been Rituxan or Obinutuzamab appear very long lasting and we would not ever recommend that you stop your treatment for your cancer to wait to get a vaccine. We wouldn't recommend that at all. You need to take care of yourself and you need to take care of your blood cancer.

What activities are safe for me if I did show some antibody response? Again, can't really answer the question. We recommend continue keeping your guard up with masking social distancing and handwashing. Now, as I said, I am a CLL patient. I was treated with CAR T therapy in December of 2019, which is now more than a year and a half ago. My antibody response to the vaccine was negative. I didn't make any antibodies, and again I don't know what my T cell responses. I don't know what my cellular immunity responses. All I know is that, based on the test, they didn't see any antibodies to their sensitivity level of detection.

So what's my approach now? You know, my approach is that I'm not hibernating. But I am not eating indoor at any restaurants. I'm not going indoor to any movie theaters. I'm not going to any bowling alleys. I'm not going to any outdoor concerts or parties where social distancing is a problem. I am visiting with friends and family outdoors and if I'm very close to the friends or family, then we are visiting indoors, assuming we're all protecting ourselves and we're close. I can't tell you exactly what to do, but I think it's best that we all keep our guard up.

THE LLS NATIONAL PATIENT REGISTRY – FAQ'S – BOOSTERS

- ✓ **Do I need a booster shot as a BC patient?**
 - ✓ This has yet to be determined
- ✓ **How can I get a Booster shot?**
 - ✓ There is no clear path as most states keep track of who has had vaccines
 - ✓ If/when Covid-19 vaccines are officially "approved" the avenues will be wider.
- ✓ **How can I enroll in a CT for boosters?**
 - ✓ LLS is not managing a booster clinical trial
 - ✓ When they become available the LLS Information Resource Center will have that information

BEATING CANCER IS IN OUR BLOOD. 

Now, **do I need a booster shot as a blood cancer patient?** Honestly, this is yet to be determined. There's a lot of chatter about it, but we do not have the answer.

How can I get a booster shot? Frankly, there's no clear path to this. Most states keep track of who's had vaccines. And if one presents to a state sponsored site and they enter your demographics, they're likely to know that you've had vaccines already and they're not going to give you a booster.


If and when the COVID 19 vaccines are officially approved, meaning they're not EUA, emergency authorized, then it will be much easier for a doctor to prescribe another shot, a booster, if you will, for any of their patients. And I believe that that's probably coming in the next weeks or very few months from now.

How can I enroll in a clinical trial for boosters? Well again, LLS is not managing a clinical booster trial, we are, we are funding one and we're looking for others. When information on trials become available, the LLS Information Resource Center and our clinical trials team will have that information, so again stay tuned.

THE LLS NATIONAL PATIENT REGISTRY – FAQ'S – VACCINE HESITANCY

- ✓ **Are the side effects from the vaccine worse in blood cancer patients?**
 - ✓ No
- ✓ **Does vaccination lead to relapses of blood cancers?**
 - ✓ No reports in studies
- ✓ **Is the speed of vaccine development mean steps were missed?**
 - ✓ No
- ✓ **When will the FDA fully approve the vaccines?**
 - ✓ Unknown
- ✓ **Based on the treatments that a patient may receive should vaccines be postponed?**
 - ✓ NO

Bottom Line: Get Vaccinated – Act Unvaccinated

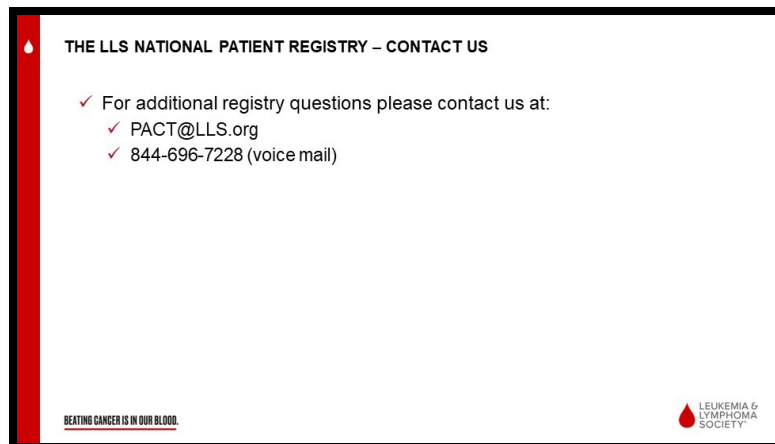
BEATING CANCER IS IN OUR BLOOD. 

Now, **what about if you're hesitant to get the vaccine?** Are the side effects from the vaccine worse than blood cancer patients, the answer is no, especially by our study.

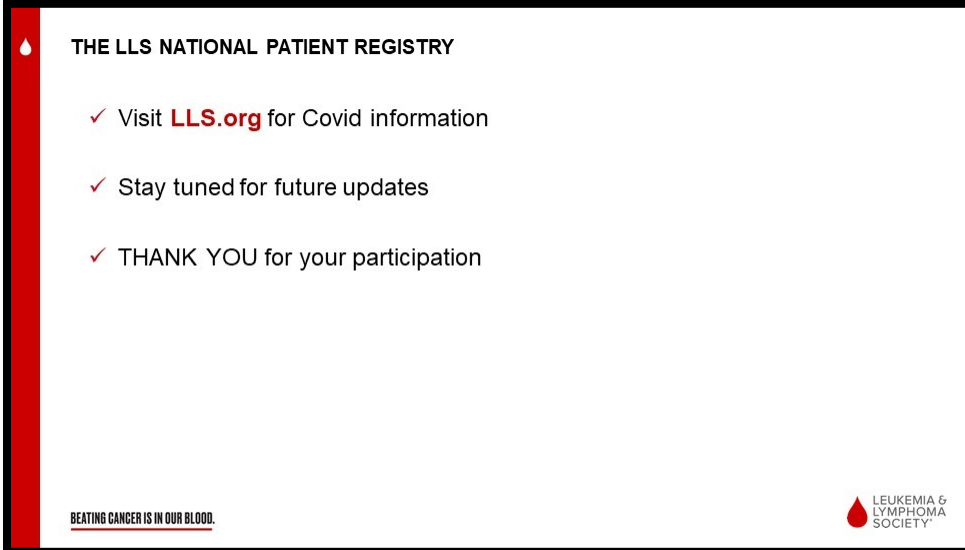
Does the vaccine lead to relapses of blood cancers? Honestly, there are some people who think coincidentally, that they relapsed after they had their vaccine, but this has not been verified or reported in any studies, so we suggest everyone receive a vaccine.

In the speed of the vaccine development - does that mean that steps were missed? And the answer is no. These vaccines were developed over the years, if not decades. The reason they came into approval so rapidly was that COVID was so rampant when they started administering the vaccines, that the numbers of COVID patients in the vaccine trial, who received the vaccine versus the numbers of people who are getting placebo, who then came down with COVID happened very rapidly. And the numbers and 10s of thousands of patients were statistically significant to approve the vaccine.

When will the FDA fully approve the vaccines? Again, a lot of chatter. It's unknown. We anticipate in the coming weeks or months that one or all the vaccines will be finally formally approved. Based on treatments that a patient is receiving should the vaccine be postponed the general answer is no, and the only answer that I can say where this may need to be postponed are for blood cancer patients who are actively and currently having a bone marrow transplant. In that case, the vaccine should be delayed, probably for at least three months. That may be the only case where we suggest a time between treatment and vaccine. Bottom line, again - get vaccinated and please act unvaccinated.



Now for additional questions, we have an email address that is very responsive at PACT@lls.org. we have a toll free number that is a voicemail line. So, if you call 844-696-7228, you will leave a voicemail and we will return your call as soon as we can. Again, the best place to get a response from us regarding our study is that the email address PACT@lls.org.



THE LLS NATIONAL PATIENT REGISTRY

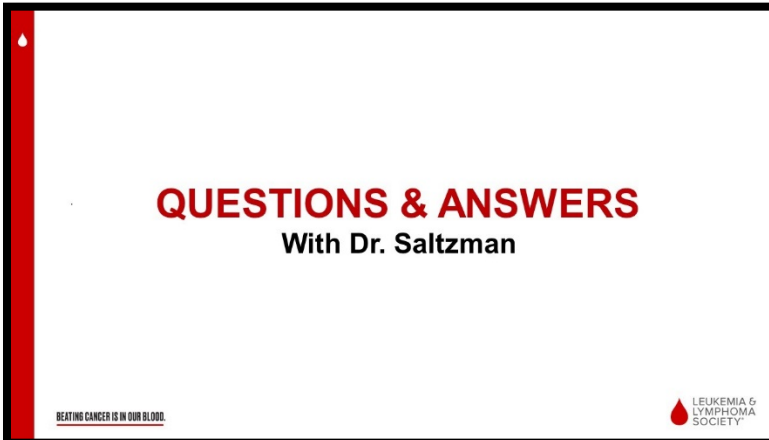
- ✓ Visit **LLS.org** for Covid information
- ✓ Stay tuned for future updates
- ✓ THANK YOU for your participation

BEATING CANCER IS IN OUR BLOOD.

LEUKEMIA & LYMPHOMA SOCIETY®

You may also visit [LLS.org](https://lls.org) for COVID information. And here's a web link. You can search on this on the [LLS.org](https://lls.org) site.

We appreciate your time in listening to this and watching this, and please stay tuned for other updates in the future. We thank you all for your participation. And Elissa, do you have any additional questions for me? Thank you.



QUESTIONS & ANSWERS
With Dr. Saltzman

BEATING CANCER IS IN OUR BLOOD.

LEUKEMIA & LYMPHOMA SOCIETY®

Elissa Baldwin: Thank you, Dr. Saltzman for your very informative presentation. It is time for the question and answer portion of our program. Since the start of the COVID-19 vaccine study, many questions have come into our Information Specialists and LLS Community. We hope Dr. Saltzman answered many of them today, but we have just a few more that we would like to ask. We will start with our first commonly asked question:

If my spike antibody test results show less than 0.4, does that mean I'm basically not vaccinated?

Dr Larry Saltzman: Thank you, Elissa, for that question. And the answer to that is no, you are vaccinated. If a test result comes in at less than 0.4, what it means is that, given the sensitivity of the test, they could not measure any antibodies under that number but, there may be antibodies present. So, you wouldn't think that you're totally at zero, you're just a little less than the sensitivity that's being measured. And having said that, as I commented on, with the vaccine, you may have a T cell response, which is protective and you may have a cellular immunity response. Now what I mean by cellular immunity is, let's give an example.

When I had my second Moderna vaccine. I had a sore arm and I had a fever in response to that immunization and, in my mind, and in my understanding of how our bodies work, that means my body recognized that vaccine from the first vaccine that I received. Meaning, I had a cellular response and should I be exposed to code in the future, I would imagine that that cellular response will be activated again. Now, it doesn't mean that we should take our masks off and go, you know party like it was, you know, a decades past or even currently, it just means that we should all get vaccinated and most likely have some kind of protection, although we don't know exactly what that is.

Elissa Baldwin: Thank you so much for that. For our next question, you kind of briefly went over this, but should I stop my treatment to obtain a vaccine? So, for patients that are currently on some kind of treatment right now.

Dr Larry Saltzman: To very good question and honestly, this is something that you really need to ask your clinician or provider about because, as I said, we had LLS are not clinicians, even though I'm an MD. And we cannot answer these personal questions, having said that. My view, and our view is that unless your doctor says, you should stop treatment, we would want you treated for your blood cancer in any and all cases.

In my case, which I know is personal and I've mentioned already before that I've been on CAR T therapy. At the moment, I seem to be in remission from my blood cancer. Even though, I don't seem to have a B cell antibody response from my vaccines. And you know speaking publicly, I would personally much rather be cancer free and be very careful about my exposure to COVID than be in relapse. And therefore, our answer to this question is, unless your physician advises treatment should be stopped for any number of reasons, we would not recommend that.

Elissa Baldwin: Thank you, and now for our final question of the program: what, if anything, would stop me from getting vaccinated?

Dr Larry Saltzman: Again, another very good question and our general perspective on this is that there's virtually no reason to stop a blood cancer patient from being vaccinated. I guess the question would be what's the right time to do that and, as I mentioned, there is one special case with regard to bone marrow transplants, where there is a period of time where vaccines of any kind or not recommended. And again, you need to talk to your provider.

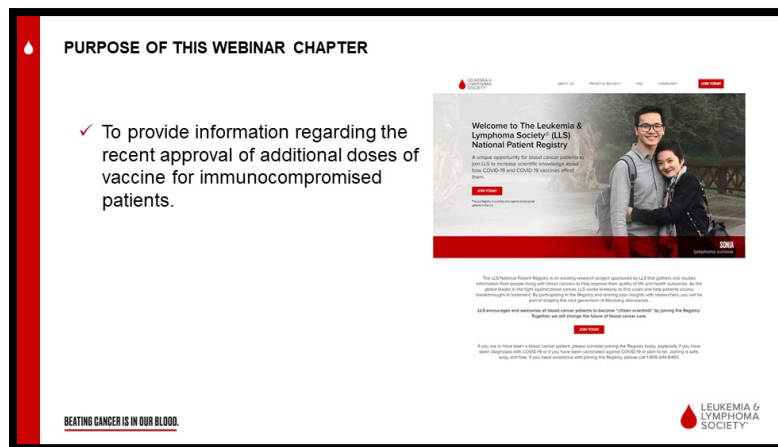
Having said that, no matter what treatment you're on or you've been on in the recent past, or maybe years or decades past, from our perspective, everyone should receive a vaccine.

Elissa Baldwin: Thank you so much, Dr. Saltzman for sharing these exciting results with us and providing more information on where the registry in vaccines study will go from here.


SPECIAL BOOSTER UPDATE



Elissa Baldwin: Since the initial recording of this webinar, a 3rd dose of the COVID vaccine was approved for certain immunocompromised individuals. Dr. Saltzman is back to give information about the new FDA authorization and what this means for blood cancer patients.




Dr. Larry Saltzman: The purpose of this webinar chapter is to provide you information regarding the recent approval of additional doses of COVID 19 vaccine for immunocompromised patients.

 **THE LLS NATIONAL PATIENT REGISTRY – BOOSTERS**


- ✓ LLS is not a medical provider, or an academic medical center
- ✓ LLS cannot recommend or comment on an individual's booster questions
- ✓ LLS is encouraging studies on boosters to assure vaccine safety in blood cancer patients
- ✓ LLS is funding a booster study at the Montefiore Medical Center in New York City and are looking for more centers
- ✓ LLS will follow closely the experience in foreign countries where boosters are being investigated (UK) or administered (Israel, France)
- ✓ LLS will monitor antibody responses in participants who notify us of their receiving such a vaccine
 - ✓ (observation – not intervention)

BEATING CANCER IS IN OUR BLOOD

 **LEUKEMIA &
LYMPHOMA
SOCIETY®**


Now, to recap and to make sure we're all on the same page, LLS is not a medical provider or an academic medical center. LLS cannot recommend or comment on an individual's booster questions. LLS is encouraging studies on these boosters to assure vaccine safety in blood cancer patients.

LLS is funding a booster study currently at the Montefiore Medical Center in New York City, and we are looking for more of these centers. LLS will follow closely the experience in foreign countries where boosters are being investigated, such as the United Kingdom or administered in Israel and France, as well as others. LLS will monitor antibody responses in participants who notify us of their receiving such a vaccine. Please note, these are observational studies and not interventional studies.

 **THE LLS NATIONAL PATIENT REGISTRY – FAQ'S – BOOSTERS**

- ✓ **Do I need a booster shot as a Blood Cancer patient?**
 - ✓ The CDC has given guidance that immunocompromised people may receive a 3rd mRNA vaccine dose – essentially a series of 3.
 - ✓ Pfizer for ages 12 and older -- Moderna for ages 16 and older
 - ✓ Active treatment hematologic malignancies
 - ✓ Receipt of CAR-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
 - ✓ Active treatment with high-dose corticosteroids (i.e., ≥20mg prednisone or equivalent per day).
 - ✓ Alkylating agents, antimetabolites, transplant-related immunosuppressive drugs,
 - ✓ Cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory.

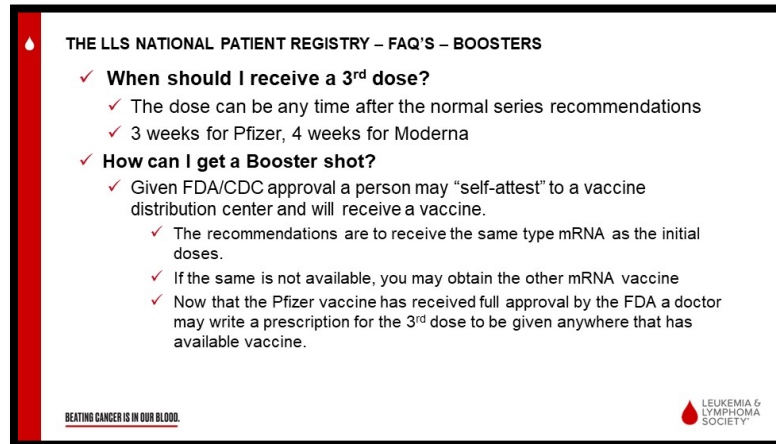
BEATING CANCER IS IN OUR BLOOD

 **LEUKEMIA &
LYMPHOMA
SOCIETY®**

So, here are some of the most frequently asked questions regarding this topic. Do I need a booster shot as a blood cancer patient? The CDC has given guidance that immunocompromised people may receive a third mRNA vaccine dose, essentially becoming a series of three. These are now approved for Pfizer vaccine, ages 12 and older and Moderna vaccine, ages 16 and older.

The CDC has classified these immunocompromised people as the following. People in active treatment for hematologic malignancies. Those who have been in receipt of CAR T-cell or hematopoietic stem cell transplant within two years or taking immunosuppression therapy.

Active treatment with high dose corticosteroids, in other words prednisone and a dose of greater than 20 milligrams or the equivalent each day. Those on what are called alkylating agents, antimetabolites, and transplant-related immunosuppressive drugs. And cancer chemotherapeutic agents classified as severely immunosuppressive, TNF blockers which stands for tumor-necrosis blockers and other biologic agents that are immunosuppressive or immunomodulatory.



THE LLS NATIONAL PATIENT REGISTRY – FAQ’S – BOOSTERS

- ✓ **When should I receive a 3rd dose?**
 - ✓ The dose can be any time after the normal series recommendations
 - ✓ 3 weeks for Pfizer, 4 weeks for Moderna
- ✓ **How can I get a Booster shot?**
 - ✓ Given FDA/CDC approval a person may “self-attest” to a vaccine distribution center and will receive a vaccine.
 - ✓ The recommendations are to receive the same type mRNA as the initial doses.
 - ✓ If the same is not available, you may obtain the other mRNA vaccine
 - ✓ Now that the Pfizer vaccine has received full approval by the FDA a doctor may write a prescription for the 3rd dose to be given anywhere that has available vaccine.

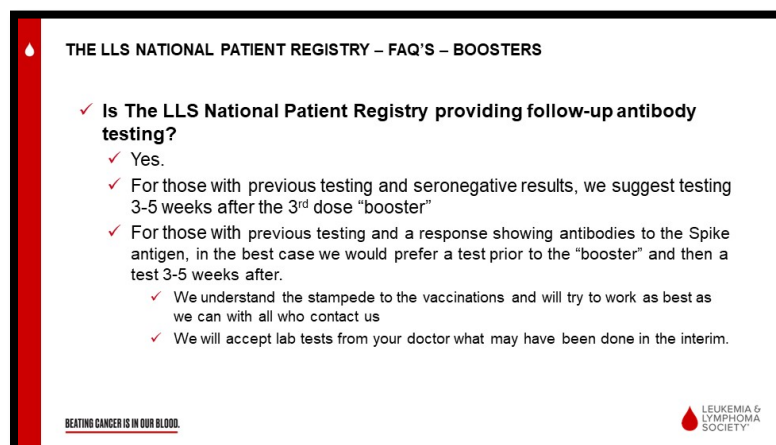
BEATING CANCER IS IN OUR BLOOD.

LEUKEMIA & LYMPHOMA SOCIETY

When should I receive a third booster? This those can be given any time after the normal series recommendation. That means three weeks for Pfizer and four weeks for Moderna. How can I get a booster shot? Given the FDA/CDC approval, a person may self-attest to a vaccine distribution center and therefore will receive a vaccine.

This means a self approval that you have a blood cancer or immunosuppressive diagnosis. The recommendations are to receive the same type of mRNA as the initial doses. However, if the same vaccine is not available, you may obtain the other mRNA vaccine.

Now that the Pfizer vaccine has received full approval by the FDA, and this just occurred yesterday, the 23rd of August, any doctor may write a prescription for the third dose to be given anywhere that has available vaccine.



THE LLS NATIONAL PATIENT REGISTRY – FAQ’S – BOOSTERS

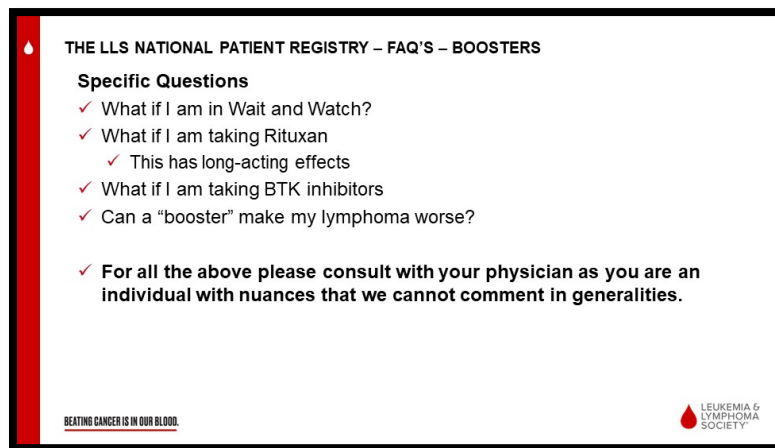
- ✓ **Is The LLS National Patient Registry providing follow-up antibody testing?**
 - ✓ Yes.
 - ✓ For those with previous testing and seronegative results, we suggest testing 3-5 weeks after the 3rd dose “booster”
 - ✓ For those with previous testing and a response showing antibodies to the Spike antigen, in the best case we would prefer a test prior to the “booster” and then a test 3-5 weeks after.
 - ✓ We understand the stampede to the vaccinations and will try to work as best as we can with all who contact us
 - ✓ We will accept lab tests from your doctor what may have been done in the interim.

BEATING CANCER IS IN OUR BLOOD.

LEUKEMIA & LYMPHOMA SOCIETY

Now is the LLS national patient registry providing follow up antibody testing? The answer here is yes. For those with previous testing and our sero-negative result, meaning no antibody seen, we suggest testing three to five weeks after the third dose booster. For those with previous testing and a response, showing antibodies to the spike antigen, in the best case, we would prefer test prior to the booster and then a test three to five weeks after. Having said that, we understand that there's been a stampede to the vaccines and we will try to work as best as we can with all who contact us.

We will accept lab tests from your doctor for blood testing that may have been done in the interim, if they have not been done at the LLS LabCorp service centers.



THE LLS NATIONAL PATIENT REGISTRY – FAQ'S – BOOSTERS

Specific Questions

- ✓ What if I am in Wait and Watch?
- ✓ What if I am taking Rituxan
 - ✓ This has long-acting effects
- ✓ What if I am taking BTK inhibitors
- ✓ Can a "booster" make my lymphoma worse?

✓ **For all the above please consult with your physician as you are an individual with nuances that we cannot comment in generalities.**

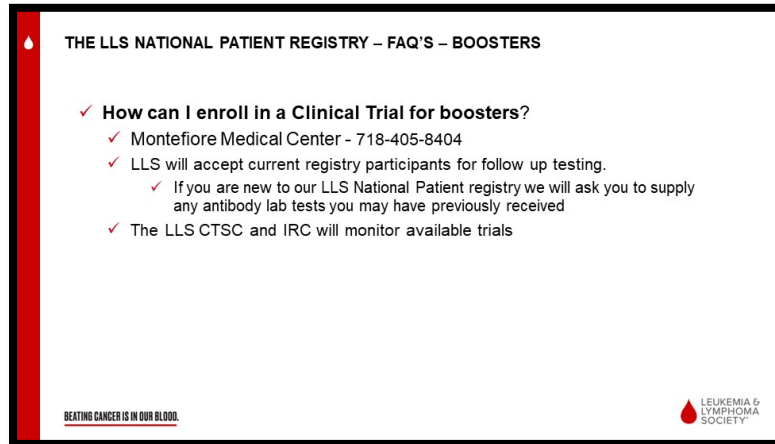
BEATING CANCER IS IN OUR BLOOD

LEUKEMIA & LYMPHOMA SOCIETY®

Here's some specific questions. What if I'm Wait and Watch? What if I'm taking Rituxan®? What if I'm taking BTK inhibitors? And can a booster make my lymphoma worse?

For all the above questions, we suggest you consult with your physician, as you are an individual nuances that we cannot comment in generalities. Having said that, we have seen that Rituxan is a very long lasting drug and the same for any CD20 inhibitors. These have long lasting effects, and we believe their effects may last as long as six to 12 months. So again, please talk to your physician.

If you're on a BTK inhibitor, these are oral drugs that are given on a daily basis to suppress blood cancers. Again, talk to your physician. And our view is that we shouldn't have you stop your cancer treatments, just to take a vaccine. So again, talk to your physician.



THE LLS NATIONAL PATIENT REGISTRY – FAQ'S – BOOSTERS

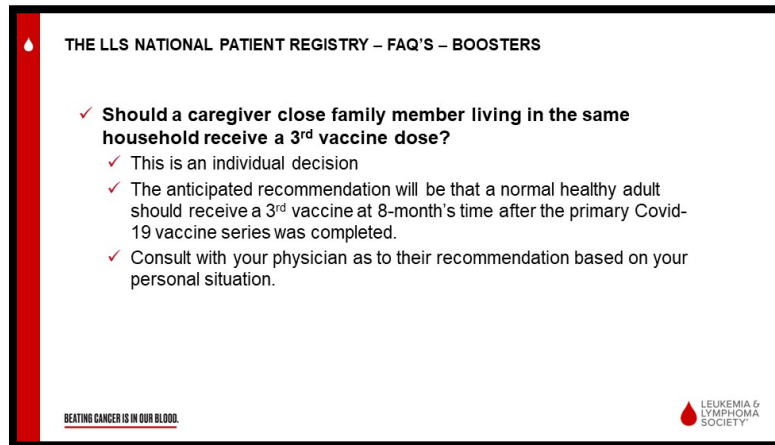
- ✓ **How can I enroll in a Clinical Trial for boosters?**
 - ✓ Montefiore Medical Center - 718-405-8404
 - ✓ LLS will accept current registry participants for follow up testing.
 - ✓ If you are new to our LLS National Patient registry we will ask you to supply any antibody lab tests you may have previously received
 - ✓ The LLS CTSC and IRC will monitor available trials

BEATING CANCER IS IN OUR BLOOD.

LEUKEMIA & LYMPHOMA SOCIETY

Now, how can I enroll in a clinical trial for boosters again? Again, the only center that we know of and LLS is funding is the Montefiore Medical Center in the Bronx in New York. Their phone number is 718-405-8404.

LLS will accept current registry participants for follow up testing. If you are new to our national patient registry, we will ask you to supply any antibody lab tests you may have previously received. And the LLS Clinical Trial Support Center [[LLS.org/CTSC](https://lls.org/CTSC)] and it's Informational Resource Center [[LLS.org/InformationSpecialists](https://lls.org/InformationSpecialists)] will monitor available trials.



THE LLS NATIONAL PATIENT REGISTRY – FAQ'S – BOOSTERS

- ✓ **Should a caregiver close family member living in the same household receive a 3rd vaccine dose?**
 - ✓ This is an individual decision
 - ✓ The anticipated recommendation will be that a normal healthy adult should receive a 3rd vaccine at 8-month's time after the primary Covid-19 vaccine series was completed.
 - ✓ Consult with your physician as to their recommendation based on your personal situation.

BEATING CANCER IS IN OUR BLOOD.

LEUKEMIA & LYMPHOMA SOCIETY


This question comes up frequently- should a caregiver have a close family member living in the same household receive a third vaccine dose? Again, this is an individual decision that you all should consult with your physicians, ask to their recommendations based on your personal situation. The anticipated recommendation will be that a normal, healthy adult should receive a third vaccine at an eight months timeframe after the primary COVID-19 vaccines series was completed.

So you would need to check your calendar for dates, you should talk to your physicians. And again based on the type of vaccine you're looking for, it should become available in September or your provider can now write a prescription for you to get a Pfizer vaccine, if that is the one in your series.

THE LLS NATIONAL PATIENT REGISTRY – CONTACT US

- ✓ For additional registry questions please contact us at:
 - ✓ PACT@LLS.org
 - ✓ 844-696-7228 (voice mail)

BEATING CANCER IS IN OUR BLOOD.


 LEUKEMIA &
LYMPHOMA
SOCIETY®

Now for additional registry questions, please contact us at PACT@LLS.org. We do have a voicemail box: 844-696-7228, where you can leave a message. It is not answered automatically.

THE LLS NATIONAL PATIENT REGISTRY

- ✓ Visit [LLS.org/Coronavirus](https://www.lls.org/Coronavirus) for Covid information
- ✓ Stay tuned for future updates
- ✓ THANK YOU for your participation and attention

BEATING CANCER IS IN OUR BLOOD.

 LEUKEMIA &
LYMPHOMA
SOCIETY®

You can visit [LLS.org](https://www.lls.org) for COVID information. You can search the main website for the term COVID and things will pop up [[LLS.org/Coronavirus](https://www.lls.org/Coronavirus)]. Please stay tuned for future updates. And I thank you so much for your participation and your attention.

LLS EDUCATION & SUPPORT RESOURCES

HOW TO CONTACT US:

To contact us about the Patient Registry or Antibody Study:

-  **Call: (844) 696-7228**
-  **Email: PACT@LLS.org**

Join the Antibody Study or Registry:
[www.LLS.org/Registry](https://www.lls.org/Registry)



The screenshot shows the LLS COVID-19 Antibody Research Study webpage. It features the LLS logo, navigation links (ABOUT US, PRIVACY & SECURITY, FAQ), and a main heading: 'The Leukemia & Lymphoma Society (LLS) COVID-19 Antibody Research Study'. Below this, it states 'Study of COVID-19 Vaccine Response in Blood Cancer Patients. Have any questions on the study?' and includes a red button that says 'Click here to join the COVID-19 Research Study'. A small disclaimer at the bottom reads: 'This study will test your antibody response to the COVID-19. The LLS Registry is currently open to patients who are 18 years of age or older.' The background of the webpage shows a close-up of an elderly woman wearing a blue surgical mask.

BEATING CANCER IS IN OUR BLOOD.

 LEUKEMIA &
LYMPHOMA
SOCIETY®

Elissa Baldwin: If we were not able to answer your question during this program, as Dr. Saltzman mentioned, you can contact The Leukemia & Lymphoma society at 1-844-696-7228 or reach us by email at PACT@LLS.org. You can also still join the antibody study and patient registry by going to LLS.org/Registry.



We also encourage you to please complete the program evaluation which can be found at LLS.org/VaccineEval or by scanning the QR code on your screen with your smartphone. Completing the evaluation will help us to continue to provide the engaging and informative programming that would benefit you the most.