CLL Society Ed Forum: The Right Tests at the Right Time

October 15, 2021

11:00 AM PT, 12:00 PM MT,
1:00 PM CT, 2:00 PM ET

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Agenda and Speakers

2:00 PM ET	Welcome and Introductions	Patricia & Brian Koffman
2:05 PM	CLL Diagnosis and Early Management	Ryan Jacobs, MD
2:30 PM	Patient Journey	Tammi Garrett
2:35 PM	**Test Before Treat™**, Disease Burden Monitoring, the Role of MRD	Brian Hill, MD, PhD
3:00 PM	Patient Journey	David Klausmeyer
3:05 PM	CLL Society Resources and **Test Before Treat™**	Patricia Koffman
3:15 PM	Audience Q&A	All Speakers
4:00 PM	Program Close	Brian Koffman, MDCM (retired), MS Ed

Patricia Koffman
Co-Founder &
Communications Director
CLL Society

Ryan Jacobs, MD
Hematologist/Oncologist
Levine Cancer Institute and
Atrium Health

Tammi Garrett
Patient Advocate

Brian Koffman, MDCM (retired), MS Ed
Co-Founder, EVP and
Chief Medical Officer,
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Brian Hill, MD, PhD
Hematologist/Oncologist
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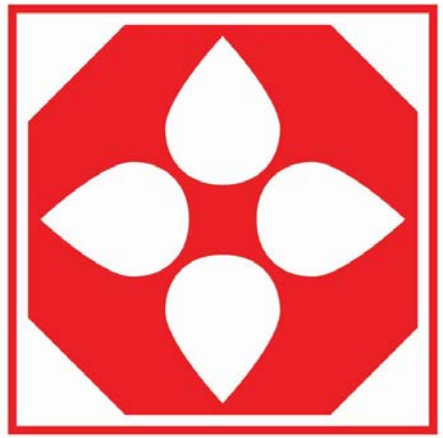
David Klausmeyer
Patient Advocate



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CLL Diagnosis and Early Management

Ryan Jacobs, MD
Levine Cancer Institute
and Atrium Health

Agenda

- Explain CLL
- Diagnostic Tests, Imaging, and Biopsies
- Address myths about disease and treatment

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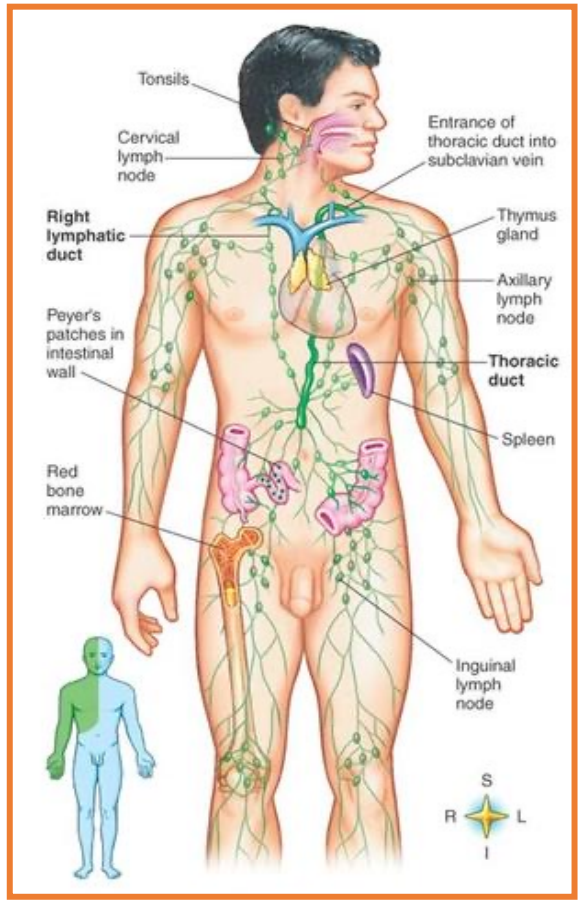
Explain CLL

The Lymphatic System



Lymph nodes

Lymphocytes

Cancer

Spleen

Bone marrow

Blood

Definition of CLL
IWCLL—2008

- CLL = Chronic Lymphocytic Leukemia
- Small clones of mature B-cells
- At least 5000/μL B-cells
- Co-express CD5 and CD23

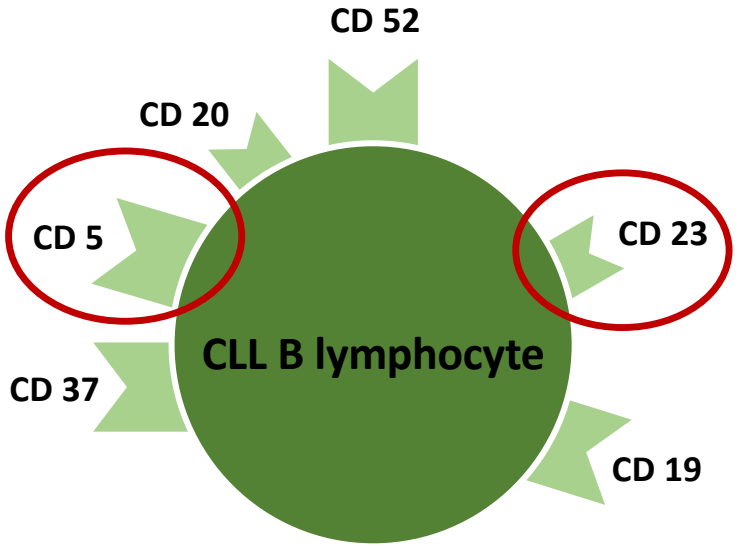
- For diagnosis, we need “The Flow Test”
  - Also called peripheral blood flow cytometry or immunophenotype

IWCLL = International Workshop on Chronic Lymphocytic Leukemia; NCI = National Cancer Institute

Hallek M et al; NCI-IWCLL. *Blood.* 2008;111:5446-5456.

Cell-Surface Markers

CLL = chronic lymphocytic leukemia; CD = cluster designation (antigenic marker on helper/inducer T-cells)



What is SLL?

- SLL = Small Lymphocytic Lymphoma
- Leukemic portion of the disease is either small or absent
- Patients generally present enlarged lymph nodes

- For diagnosis, we need a lymph node biopsy

What Do We Do at Initial Presentation?

- All patients undergo:
  - History and physical
  - CBC with differential
  - CMP
  - Quantitative immunoglobulins
  - Infectious serology*
  - Peripheral blood-flow cytometry
  - +/– CT scan CAP*
  - +/– Bone marrow biopsy*

*** in select cases**

CBC = complete blood count; CMP = complete metabolic profile; CT = computed tomography; CAP = chest, abdomen, pelvis

What Do We Do at Initial Presentation?
(continued)

- Prognostic markers
  - Interphase FISH
  - Conventional karyotyping
  - IGHV mutational analysis
  - Tp53 mutational analysis
  - β_2 microglobulin
  - LDH

Does the Patient Need a PET/CT Scan?

- Depends on symptoms
- Routine CT scans are not required
- Limited role of PET scan

PET = positron emission tomography

Does the Patient Need a Bone Marrow Biopsy?

- Depends on blood counts

- Not every patient needs a bone marrow biopsy

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Address Myths about Disease and Treatment

Myth: Since CLL Is “Chronic,” It Is Good

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Wrong

Chronic has nothing to do with prognosis

Chronic denotes the stage of cell development

So, Is Stage of the Cancer Important in CLL?

- Rai (stages 0–4) and Binet (stages A and B) staging systems have been used for a long time (Stages 0–4)

- Standard prognostic workup is more helpful in making treatment decisions

- American Cancer Society. How is chronic lymphocytic leukemia staged? (www.cancer.org/cancer/chronic-lymphocytic-leukemia/detection-diagnosis-staging/staging.html)

Myth: “Doc I’ve Got Cancer! I Need Treatment”

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Wrong

Maybe…let’s talk

Timing of Therapy

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- Worsening or steroid-resistant anemia and/or thrombocytopenia
- Spleen >6cm below the left costal margin or progressive or symptomatic lymphadenopathy
- Lymph nodes ≥10 cm in longest diameter or progressive or symptomatic lymphadenopathy

Hallek M et al; NCI-IWCLL. *Blood.* 2008;111:5446-5456

Timing of Therapy (continued)

- Constitutional symptoms—how do you feel?
  - Unintentional weight loss of >10% within the previous 6 months
  - Significant fatigue (ECOG PS 2 or worse)
  - Fevers >100.5°F for ≥2 weeks without other evidence of infection
  - Night sweats for >1 month without evidence of infection

ECOG = Eastern Cooperative Oncology Group; PS = performance status

Hallek M et al; NCI-IWCLL. *Blood.* 2008;111:5446-5456.

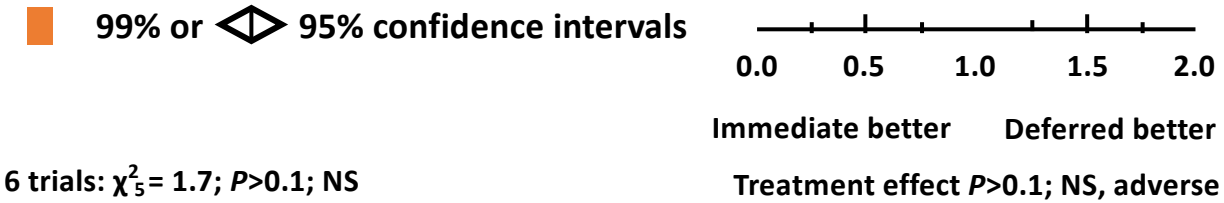
Don’t Treat

- Hypogammaglobulinemia
- Monoclonal or oligoclonal paraproteinemia
- **Elevated leukocyte count**

Hallek M et al; NCI-IWCLL. *Blood.* 2008;111:5446-5456.

Early Treatment Does Not Improve Survival

Start Year	Study Name	Treat-ment	Deaths/Patients		Immediate Deaths		Ratio of annual death rates
			Allocated Immediate	Allocated Deferred	Obs. –Exp.	Variance of Obs-Exp	Immediate | Deferred
1976	CALGB	Chl	7/22	9/25	–0.5	2.7	
1978	MRC-CLL-1	Chl	31/37	32/41	3.7	15.1	
1980	FRE-CLL-80	Chl	175/300	169/307	10.1	85.6	
1984	MRC-CLL-2	Chl	76/121	73/118	5.2	36.6	
1985	FRE-CLL-85	Chl+P	122/457	126/462	–2.0	62.0	
1988	PETHEMA	Chl+P	21/77	21/81	0.5	10.4	
Total			**432/1014 (42.6%)**	**430/1034 (41.6%)**	**16.9**	**212.3**	**1.08 (SD = 0.07)**



Heterogeneity between 6 trials: $\chi^2_5 = 1.7$; $P>0.1$; NS

Treatment effect $P>0.1$; NS, adverse

Chl = chlorambucil; P = prednisone/prednisolone; Obs = observed; Exp = expected; NS = not significant

CLL Trialists' Collaborative Group. *J Natl Cancer Inst.* 1999;91:861-868.

Myth: Patients with CLL Die of Their Cancer

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Wrong

Maybe…let's talk

Infectious Complications

- Infections are the leading cause of death in CLL
- Most common infections are of the sinus, throat, and chest
- Infection generally results from low immunoglobulin levels and defective immune system

- Intravenous immunoglobulins (IVIg) can help in some patients

How To Prevent Infections

- Pneumococcal vaccine
  - 1ST PREVNAR 13 once in consultation with HCP. Consider PREVNAR 20 which is now approved.
  - 2ND PNEUMOVAX 23 (usually 1 yr. after PREVNAR, but can be given as soon as 8 weeks later in the immunocompromised)
- Flu vaccine every year (high dose?)
- COVID-19 Vaccine
  - Do I need a booster?
- Avoid live-virus vaccines, including those for:
  - Shingles (the older live vaccine, ZOSTAVAX, is no longer available in the USA since 2020. Now SHINGRIX is a non-live option and is recommended for the immune compromised)
  - Nasal flu
  - Oral polio (Not used in USA since 2000 because polio has been eliminated in the USA)
  - Yellow fever
  - Oral Typhoid (discontinued due to reduced demand with pandemic, non-live typhoid shot OK)

Other Common Questions

- How did I get this?
- Does my family need to be screened?
- What can I do to help this from getting worse?
  - How should I change my diet/lifestyle?

Testing Summary

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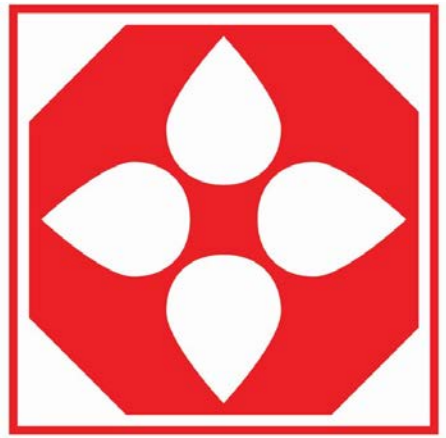
- Mandatory testing for all CLL/SLL patients
  - History and physical
  - CBC with differential
  - CMP
  - Quantitative immunoglobulins
  - Peripheral blood-flow cytometry (needed to confirm diagnosis)
- Optional Testing (decide on a case-by-case basis)
  - CT scan of the chest, abdomen and pelvis
  - Bone marrow biopsy
  - Infectious serology
- SLL usually needs a lymph node biopsy with flow cytometry to confirm diagnosis



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Smart Patients Get Smart Care™

Treatment Decisions: Predictive Tests, Disease Monitoring, and the Role of MRD

Brian Hill, MD, PhD
Cleveland Clinic Taussig Cancer Institute
October, 2021

MRD Slides Compliments of Dr. John Pagel

Learning Objectives

- Prognostic/predictive tests
- When do we need to repeat testing?
- BMB (bone marrow biopsy) and/or imaging needed before treatment?
- Disease Monitoring
  - CBC, tumor markers
  - Role of imaging
  - When is imaging and/or BMB (bone marrow biopsy) needed?
- Role and timing of Minimal Residual Disease (MRD) testing

Overview: Predictive/Prognostic Testing

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- Appropriate testing before treatment is important as these tests may determine which therapies will work and which will not.
- **Prognostic markers** help predict the likely outcome of cancer for a group.
- **Predictive markers** help predict the likelihood of benefiting from any particular therapy.
- CLL is very heterogeneous or variable in how it behaves.

Overview: Predictive/Prognostic Testing

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- Your particular “brand” of CLL will determine its ability to resist certain therapies and its sensitivity to others will be critical in tailoring the appropriate therapy.
- Some prognostic and predictive factors can change over time.
- You need to be retested before starting treatment, even if you were tested at diagnosis or after the last treatment.

What Do We Do Before Treatment?

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- Prognostic markers
  - Interphase FISH (fluorescence *in situ* hybridization)
  - Conventional karyotyping
  - IGHV mutational analysis
  - TP53 mutational analysis (genetic sequencing)
  - β_2 macroglobulin (B2M)
  - LDH
- NEW: Combined reporting at diagnosis can provided both prognostic information and enable future MRD monitoring

FISH (Fluorescence In Situ Hybridization)

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Normal pattern

Karotype: What is the Role Today?

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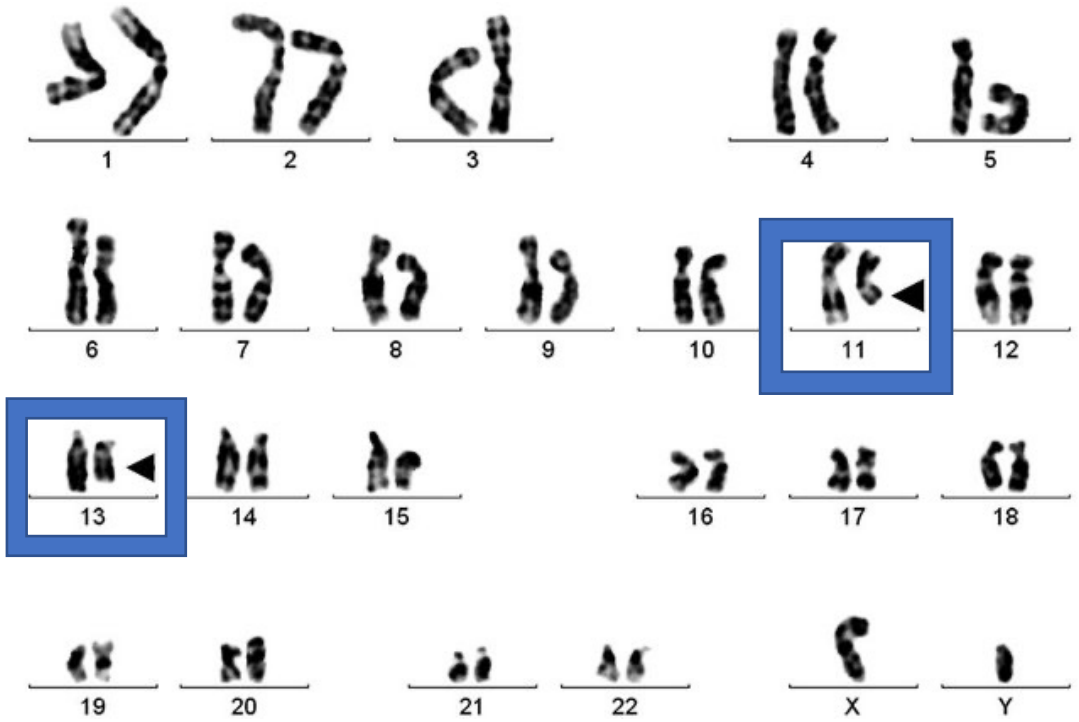

11q and 13 q deletion

Next Generation Sequencing (NGS) TP53

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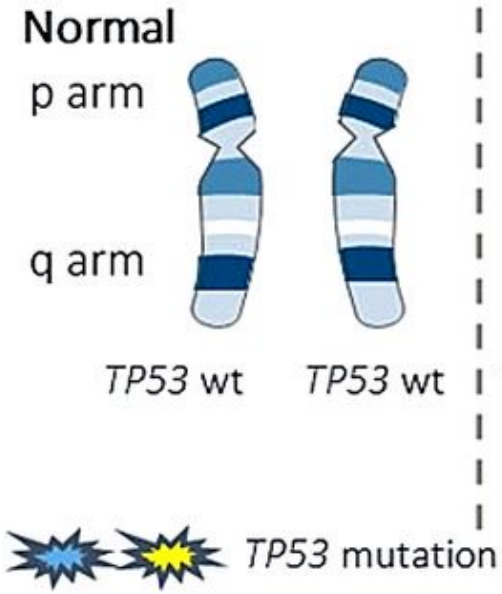

IGHV Mutational Analysis

(**I**mmuno**g**lobulin **H**eavy Chain **V**ariable Segment)

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- It is important to test **IgVH** (also called **IgHV**, both are correct) mutation status
- IgVH mutation status almost never changes over time.
- It is important because we know that more patients with
  - "Mutated" = **Favorable**
  - "Unmutated" = **Unfavorable**
- Patients who have mutated IgVH have better outcomes with traditional chemotherapy treatments.
- With the newer targeted therapies such as ibrutinib, acalabrutinib, and venetoclax, IgVH mutation status has little predictive value.

IGHV Mutational Analysis

(**I**mmuno**g**lobulin **H**eavy Chain **V**ariable Segment)

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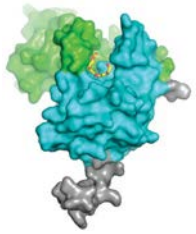
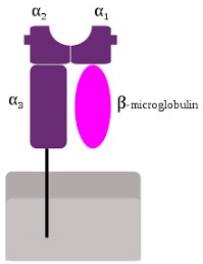
- New NGS test that identifies both:
  - IGHV mutation status
  - Unique sequences in the cell clone that can be used later to test for Measurable (Minimal) Residual Disease (MRD) that can be helpful in monitoring disease

Traditional/Inexpensive Tests for Prognosis

- LDH 
- B2M 

- These are proteins that are found in many cells including CLL.
- Simple inexpensive tests that monitor disease burden and activity.

SUMMARY: TEST BEFORE TREAT™

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Test Before Treat

- **FISH and TP53 Mutation**

  Advise against chemotherapy if 17p deletion and/or TP53 mutation

- **IgVH mutation status**

  Generally advise against chemotherapy if unmutated

Proper Testing is Not Being Done

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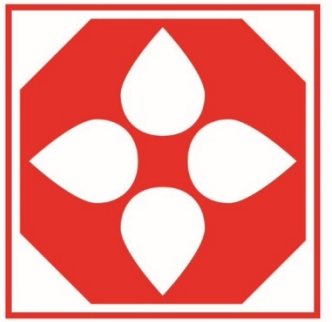
- **Testing**
  - **InformCLL** 2015-18 examined the data on 840 pts
  - Among all 840 patients,
    - only 31% had FISH testing
    - 11% had testing performed for *TP53* mutation
    - 11% had testing for IGHV mutational status
  - In the 381 relapsed/ refractory pts
    - Only 26% had testing for FISH
    - 9% for *TP53*
    - 10% for IGHV

Prognostic Testing and Treatment Approaches in Patients with Chronic Lymphocytic Leukemia: Clinical Experience from an Interim Analysis of the informCLL™ Real-World Registry : Anthony R. Mato, et al

What Else Needs to Be Done Before Starting Treatment?



- Physical exam
  - General health
  - Lymph nodes
  - Spleen and liver size
- Routine Labs
- Tests for other illnesses (comorbidities) that could impact therapy
  - Cardiac, renal, respiratory, psychological
- Imaging?
  - CT scan?
  - PET Scan- Almost never unless another problem is suspected
- Bone Marrow Biopsy (BMB)?

Disease Monitoring: Assessing Disease Burden is Fundamental to Guiding Therapy

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- Disease burden in CLL is assessed in all patients and in a variety of ways
- Measuring disease burden is crucial to:

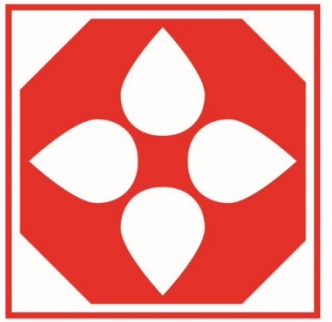
Assess treatment efficacy

Monitor disease remission

Detect early relapse

- Serial assessment over time is required to monitor disease burden changes

How is Disease Burden Monitored



- Physical Exam
- CBC, CMP, B2M, LDH
- Imaging?

Response criteria

- **Complete response** or **Complete Remission (CR)**:
- In a clinical trial, the confirmation of a CR usually requires a bone marrow biopsy that shows no CLL

Disease Burden Assessment in CLL is Done in a Variety of Ways

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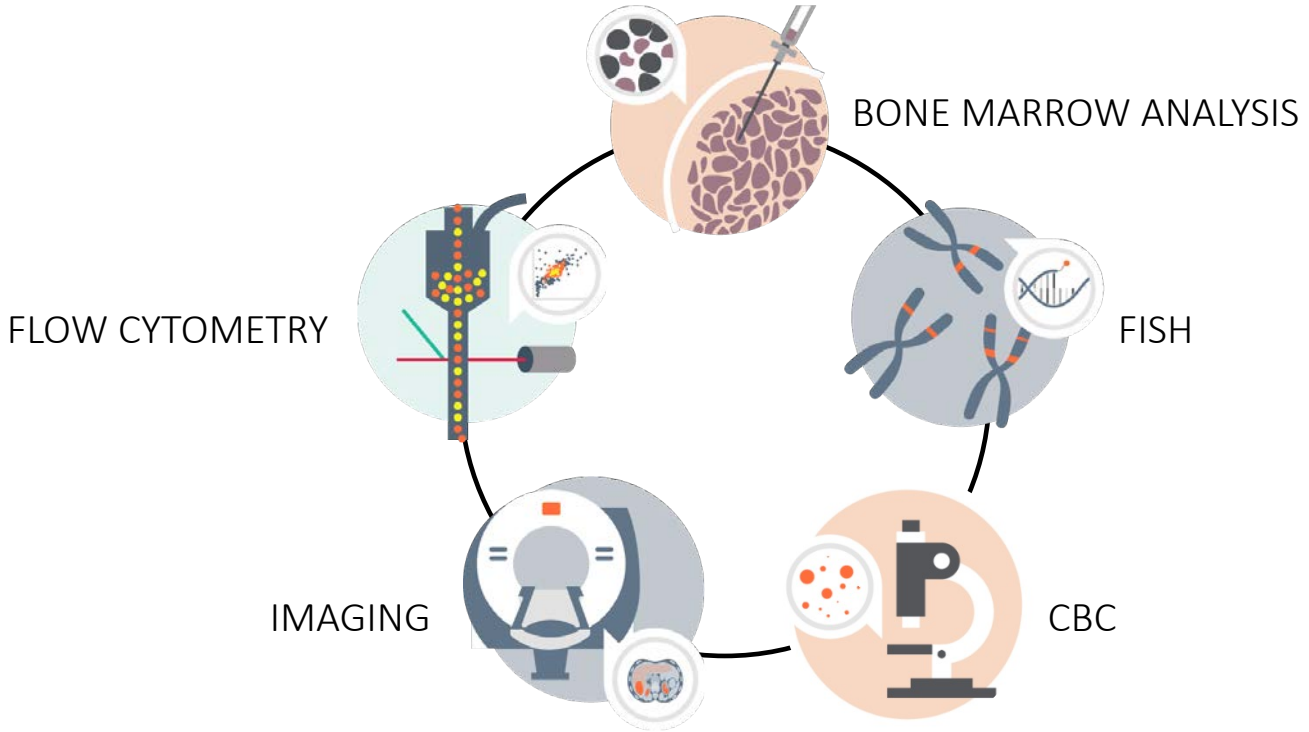
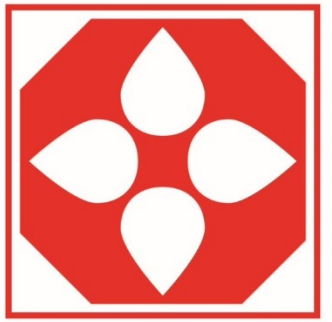
Standard tools used in CLL to assess disease burden, inform staging and evaluate risk:



Many of these testing paradigms have been used empirically to inform decisions

NCCN Clinical Practice Guidelines in Oncology: NCCN Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia. Version 2.2020. Hallek M, et al. Blood. 2018;131(25):2745-2760.

Measurable (minimal) Residual Disease



- **Undetectable Measurable (or minimal) Residual Disease (uMRD):**
- This is associated with the longest durations of response
- Flow Cytometry can be used to find a single CLL cell hiding among 10,000 cells in the blood or bone marrow
- NGS or next generation sequencing can find 1 cancer cell in 1,000,000
- uMRD does not mean there is no cancer. It may be there, but below our best detection level.
- It is possible to be uMRD and not be in a complete remission (CR) if your nodes are still enlarged. This happens when enlarged nodes don’t shrink back to normal size but are cancer free.

MRD is Another Way to Evaluate Disease Burden

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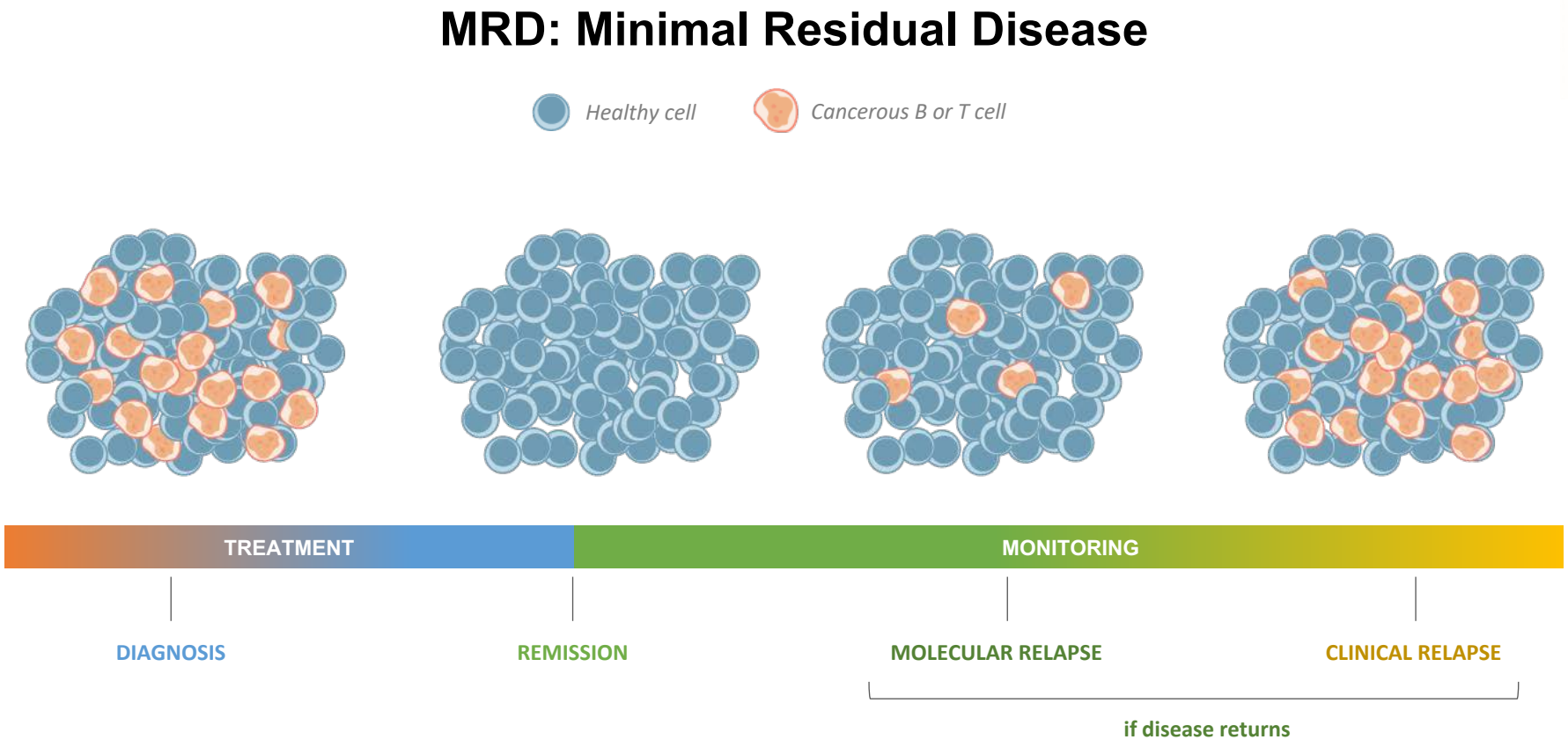

Several MRD Assessment Technologies Are Now Used Regularly in Trials and in Clinical Practice

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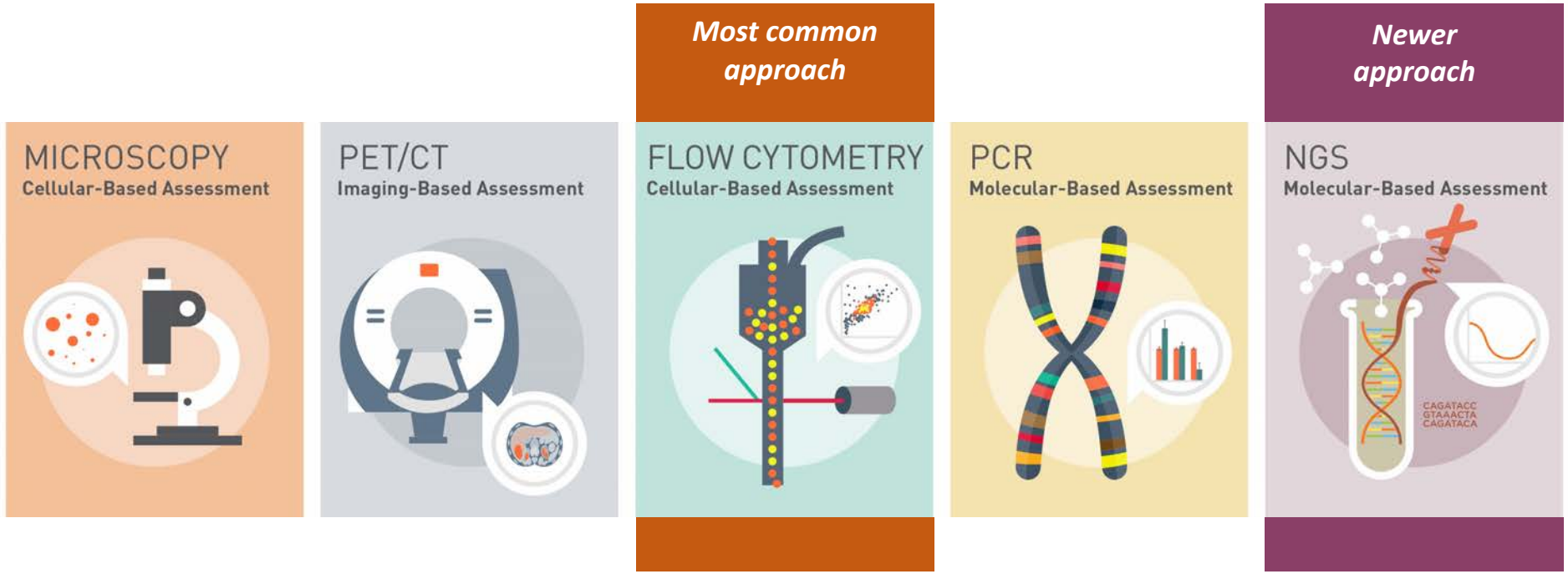
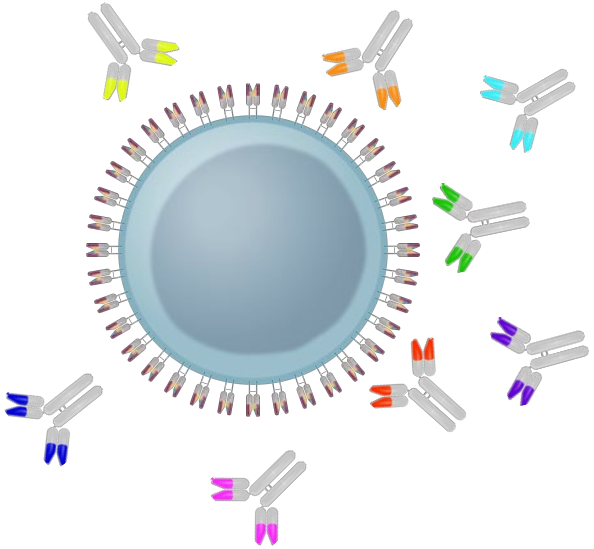
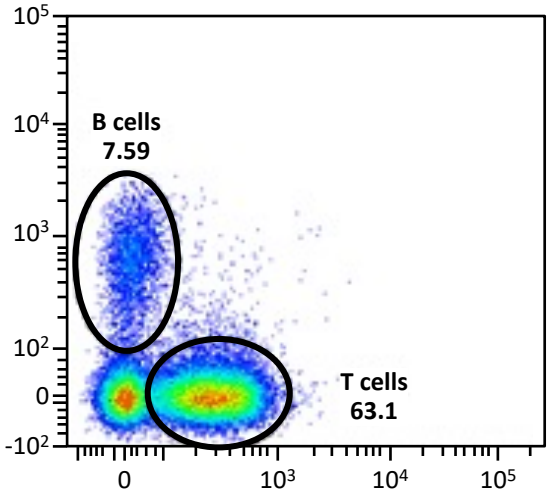


Flow Cytometry

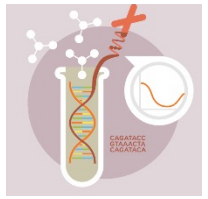
Assesses cell surface proteins using antibodies conjugated to fluorescent molecules

- Antibodies are conjugated to fluorescent molecules and mixed with cells
  - If molecule of interest is present, antibody binds
- Characteristics of cells are analyzed as they pass through the cytometer
  - Different colors represent distinct cell surface proteins being assessed
  - Results enable understanding of the phenotype of cells within a sample





Next-Generation Sequencing



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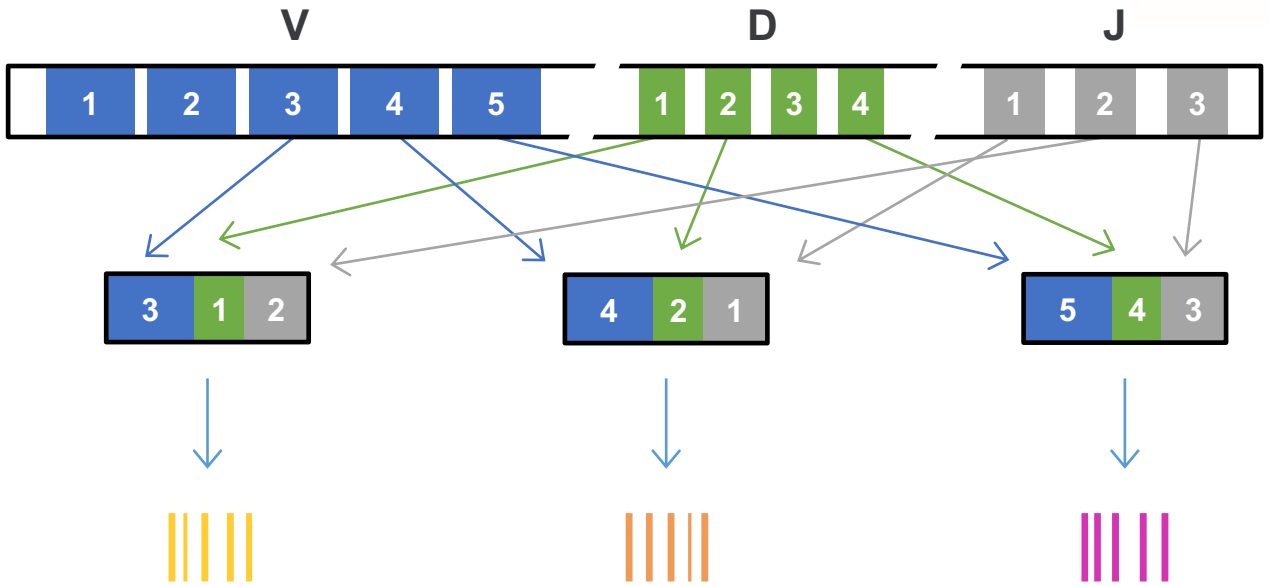
Identifies and counts specific DNA sequences associated with malignant B cells

These cancer-associated B-cell DNA sequences are made up of 3 segments: Variable, Diversity, and Joining

Segments recombine to form unique DNA sequences

These sequences serve as DNA “barcodes” that can used to track malignant B or T cells



Potential diversity (IgH): ~10^{11}

Abbas A, et al. *Cell and Mol Immun*. Philadelphia, PA: Elsevier. 2015:176-177.

Selection of an MRD Assay for Use in Clinical Practice Should Take into Account Several Important Criteria

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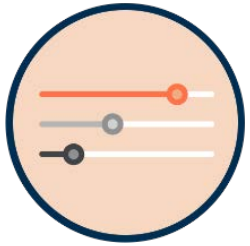
Specificity

Ability to avoid false MRD determinations is critical in the context of new therapies

Standardization

Clinical actionability is linked to the rigor of validation studies conducted for the assay



Sensitivity

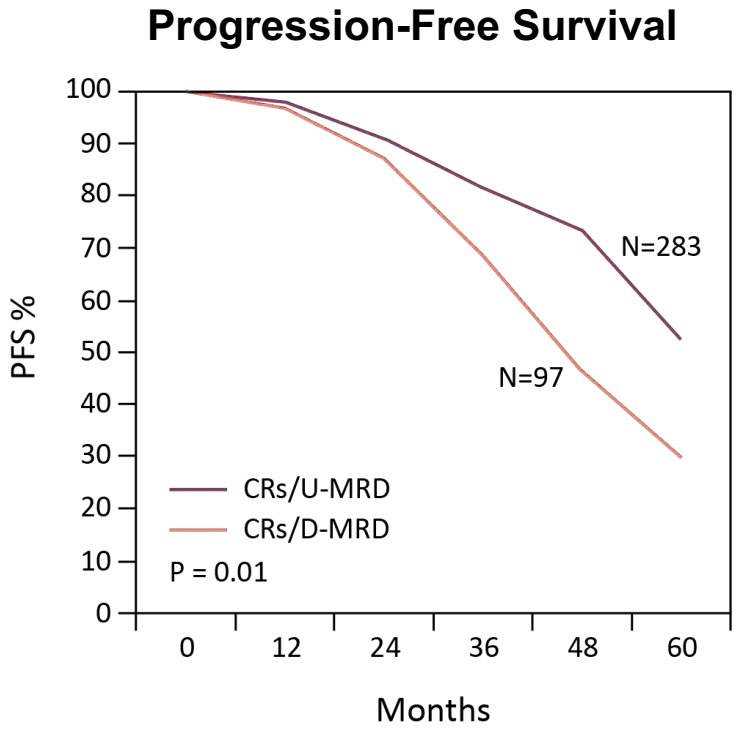
Outcomes continue to improve as patients achieve MRD negativity at lower levels

Patient Impact

Sample types and input volumes required, as well as availability of financial support for testing, are important considerations to patients

MRD Status May Be More Informative Than Conventional Complete Response For CLL Patients

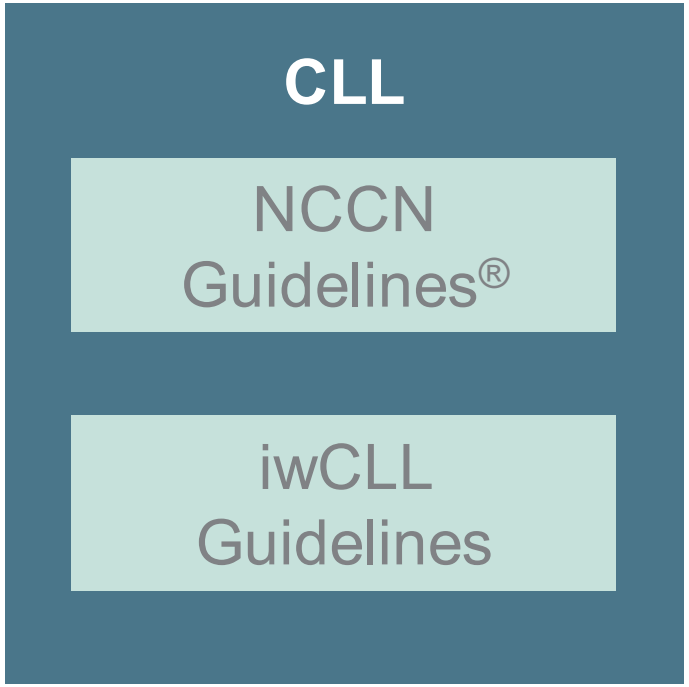
- Patients in CR who achieve undetectable MRD have better outcomes than those who remain MRD positive



Molica S, et al. Clinical Lymphoma, Myeloma & Leukemia. 2019;19(7):423-30.

MRD Assessment Is Recommended in Consensus Guidelines

- Clinical practice guidelines in CLL include MRD as part of response assessment
- According to 2018 iwCLL guidelines, the complete eradication of disease is a desired endpoint in CLL



NCCN Clinical Practice Guidelines in Oncology: NCCN Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia. Version 2.2020.
Hallek M, et al. Blood. 2018;131(25):2745-2760.

Conclusions: Prognostic/Predictive Testing and Disease Monitoring

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Prognostic/Predictive Testing

- Test before treat
- Retest before each subsequent treatment (the exception is IGVH) as CLL evolves over time
- Predictive tests should guide therapy

Disease Monitoring

- Ongoing disease burden assessment is critical in CLL management
- The role of measuring MRD is changing and expanding

Conclusions: MRD

- MRD provides additional insight beyond conventional CLL response assessment
- There are several testing methodologies available to assess MRD
  - Testing method should be selected based on clinical needs, technical and practical considerations (e.g., sensitivity, specificity, standardization)
- Patients who achieve undetectable MRD have improved long-term outcomes
- In the context of patient care, there are several ways in which MRD may be useful to inform CLL management

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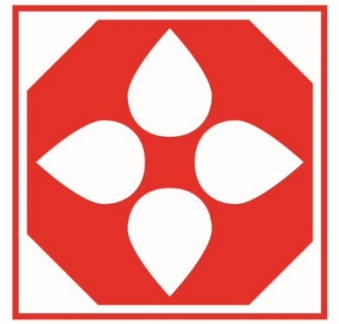

Thank You!

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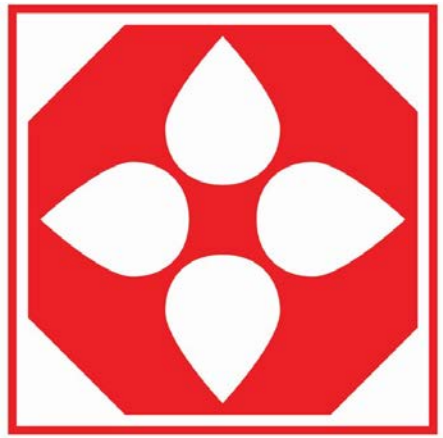

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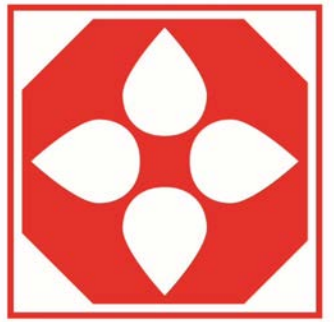
CLL Society Resources and Test Before Treat™

Patricia Koffman

Prognostic & Predictive Testing in CLL



Why test before each and every treatment?

Let’s hear what Dr. Stephen Stilgenbauer has to say!

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TEST before TREAT

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TB4T

SMART PATIENTS GET SMART CARE™

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Are they always being done?

No!

Let’s see what *the Inform Study*
led by Dr. Anthony Mato
revealed

Test Results Are Being Ignored

Sometimes all the right testing is being done…. But the results are ignored

And the patient receives chemotherapy that will absolutely not work for them… anyway!

Let's hear what Dr. Anthony Mato has to say about CLL Society's **Test Before Treat™** campaign

Proper Testing is Not Being Done

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- **Testing**
  - **InformCLL** 2015-18 examined the data on 840 pts
  - Among all 840 patients,
    - only 31% had FISH testing
    - 11% had testing performed for *TP53* mutation
    - 11% had testing for IGHV mutational status
  - In the 381 relapsed/ refractory pts
    - Only 26% had testing for FISH
    - 9% for *TP53*
    - 10% for IGHV

Prognostic Testing and Treatment Approaches in Patients with Chronic Lymphocytic Leukemia: Clinical Experience from an Interim Analysis of the informCLL™ Real-World Registry : Anthony R. Mato, et al

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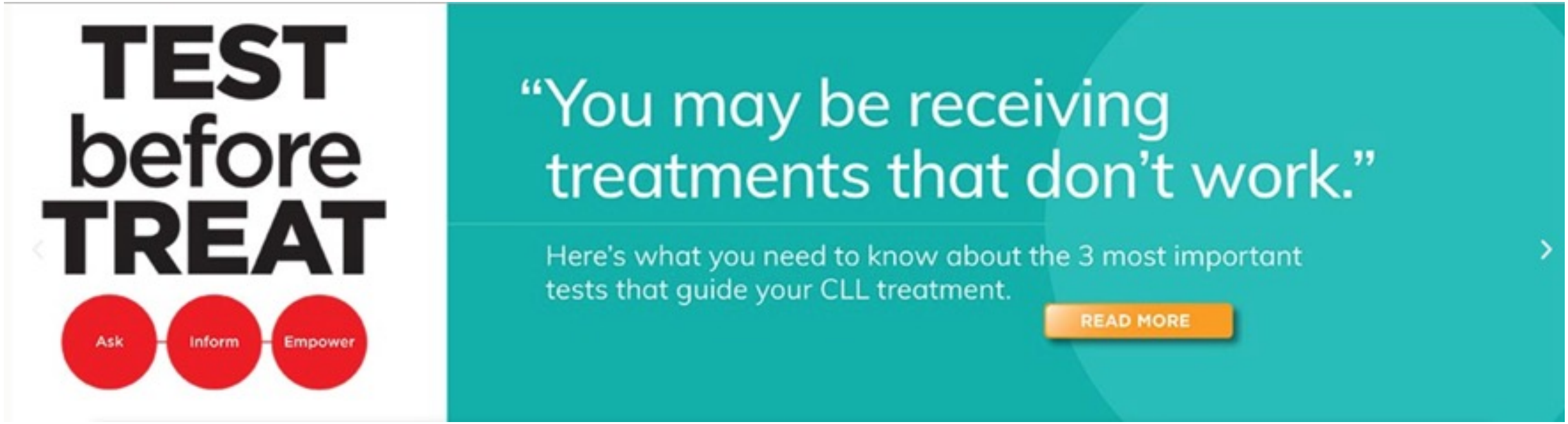
TEST
before
TREAT
Ask
Inform
Empower
"You may be receiving treatments that don't work."
Here's what you need to know about the 3 most important tests that guide your CLL treatment.
READ MORE

Take It With You!

- Print out CLL Society's Test Before Treat™ One-Pager
- Take it with you to your doctor appointments
- Don't leave home with out it!

Test Before Treat

Once we know that our CLL needs treatment, we need to know how to treat it.

Current NCCN and iwCLL guidelines tell us that it is critical to get appropriate predictive testing before the first and every subsequent therapy. Results of these tests give us information about the biology of our disease, which in turn, gives us the ability to make a reasonable prediction as to which therapies offer us the best chance of success.

Simply put, depending on what the tests show, some commonly prescribed CLL therapies likely will work for us and others may not!

While there are many tests that might help CLL patients needing treatment to make their most informed decision, these three tests are essential:

1. **FISH** (Interphase fluorescence in situ hybridization) test looks for common chromosomal abnormalities that predict the likelihood that various CLL treatments will be effective and durable. For example, if FISH testing finds there is a deletion of the short arm of the 17 chromosome or del(17p) we know that traditional chemo-immunotherapy (CIT) such as fludarabine, cyclophosphamide and rituximab (FCR) or the combination of bendamustine and rituximab known as BR, will not be effective and should be avoided.
2. Additionally, it is important to test **IgVH** (also called **IgHV**, both are correct) mutation status. IgVH mutation status almost never changes over time, so it is generally not recommended that it be retested. It is important because we know that patients with a "mutated" IgVH immunoglobulin do much better with FCR based therapies than those who are unmutated. Generally only patients who have mutated IgVH should consider FCR based therapies.
3. The 3rd and newest predictive factor is genetic testing for mutation of the **TP53** gene. TP53 is the gene on the short arm of the 17th chromosome that helps chemo to work and suppress cancer growth. It has been called the "guardian of the genome" because it tries to repair damaged genetic material in the CLL cells and if can't repair what's broken by chemo or any other cause, it signals the cell to commit programmed cell death or apoptosis. You can see how handy TP53 would be in suppressing cancer or helping chemo to work. However, if it's missing as in del(17p) or mutated, and therefore dysfunctional, as discovered by genetic testing, generally chemotherapy will not work and the CLL can be harder to manage.

If you know the status of these 3 tests before your 1st and every subsequent treatment you can best map out your treatment strategy. FISH and TP53 need to be checked and rechecked before the first and any subsequent treatments as they can change over time, usually for the worse. IgVH mutation status is considered stable over time.

Test Before Treat

- **Test FISH and TP53 Mutation before every treatment**
- **Test IgVH mutation status before the 1st treatment**
- **Deletion 17p or del(17p) = NO CHEMOTHERAPY**
- **TP53 mutation = NO CHEMOTHERAPY**
- **IgVH unmutated = NO FCR**
- **IgVH mutated = possible FCR**

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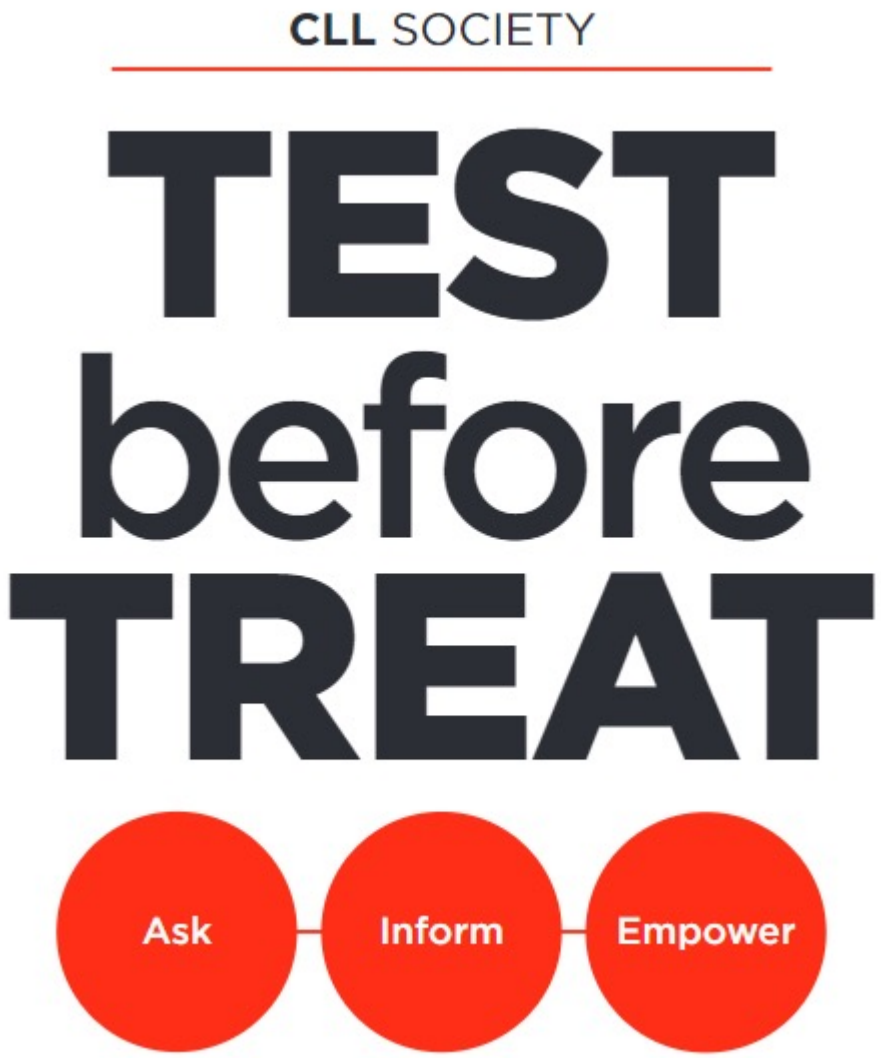
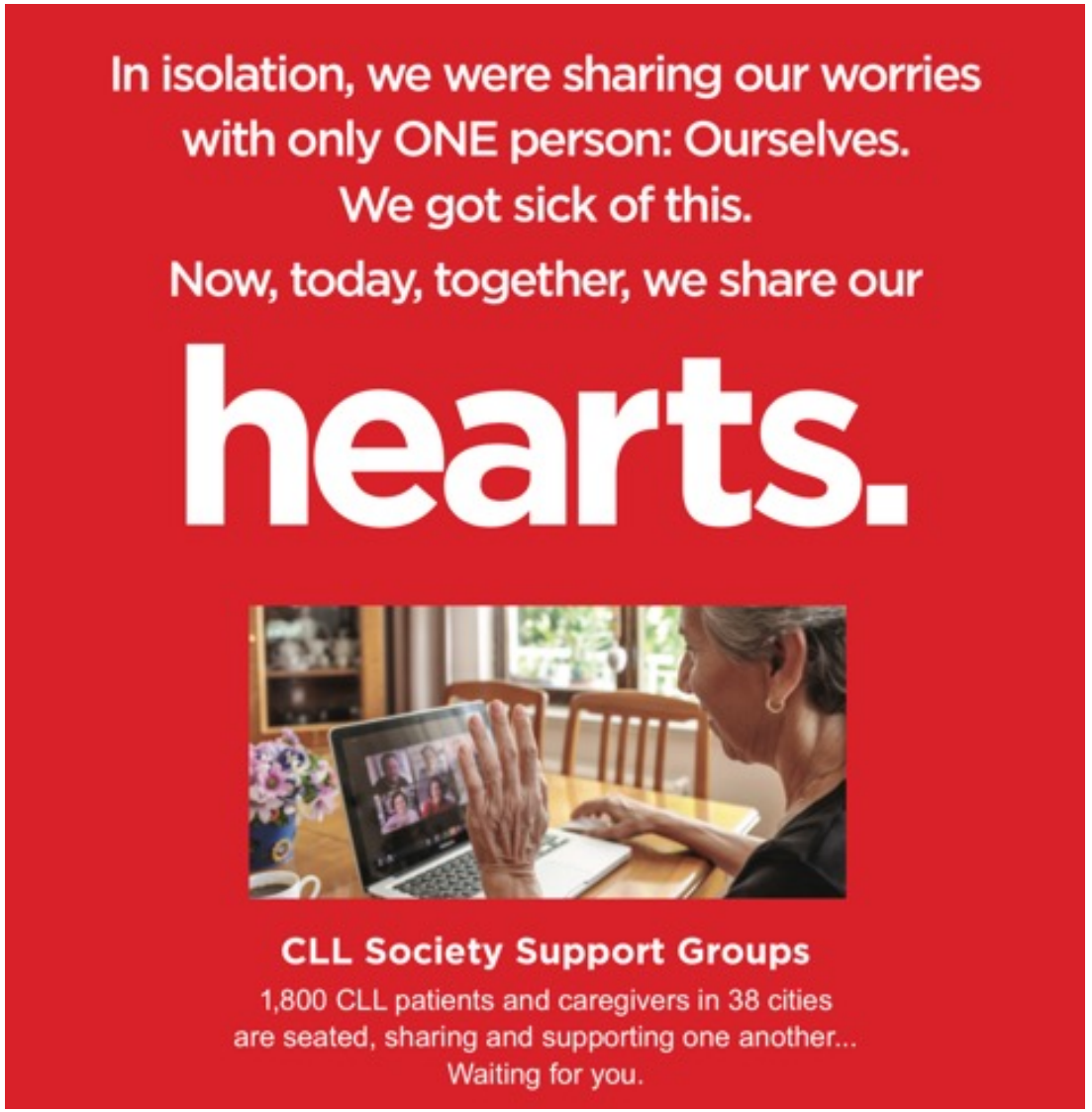


CLL Society Patient & Caregiver Support Groups



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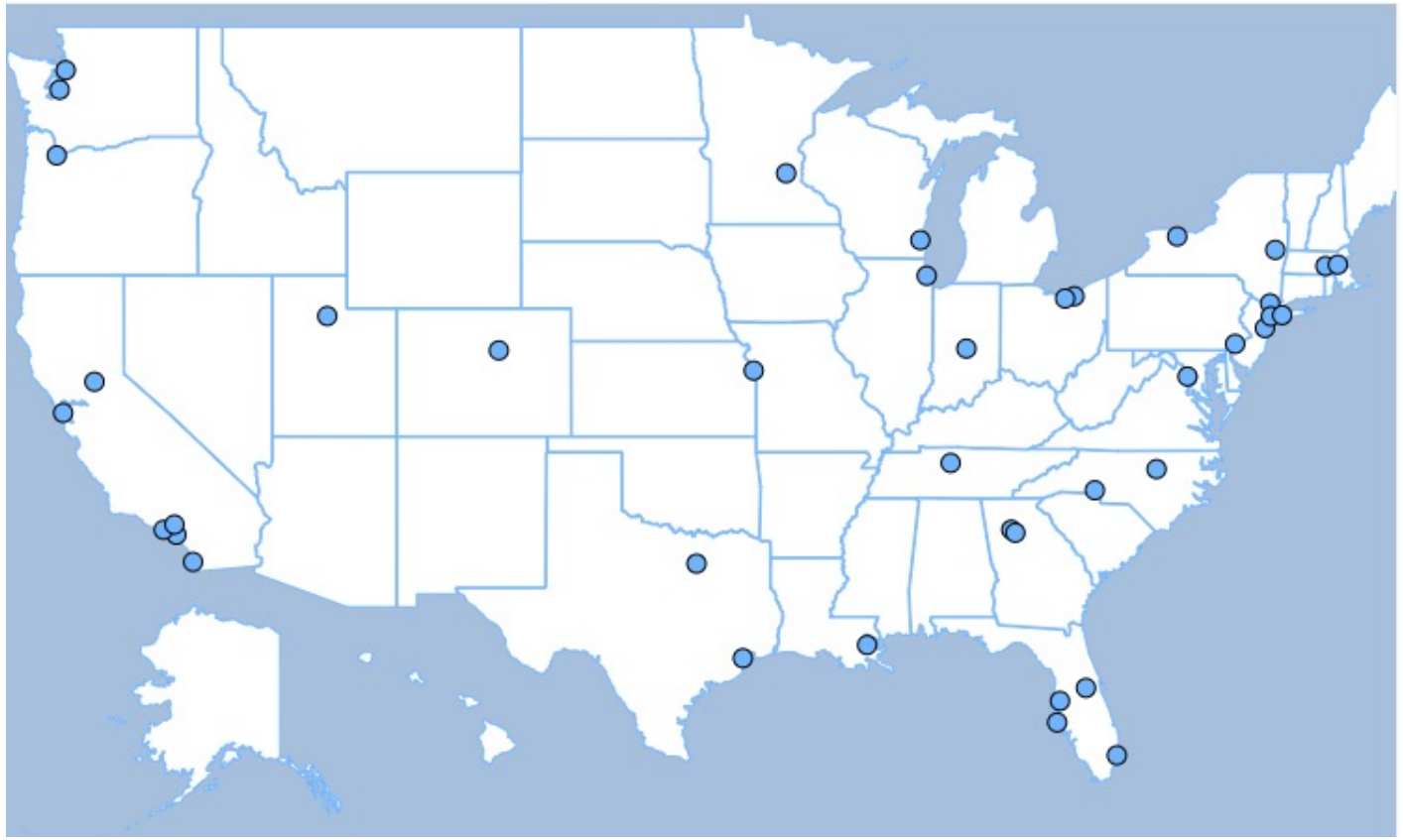
CLL Society Patient & Caregiver Support Groups



- Almost 40 CLL-Specific Support Groups Meet (Virtually) Every Month
- Over 2,000 Support Group Members

Sign-Up Today! Don’t Spend Another Month Alone!

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Awake worrying?
Stop it!
Receive an Online 2nd Opinion Consult with a CLL Expert
CLL Society's Expert Access™ Program
It's free.
You deserve some sleep!

CLL SOCIETY

CLL Society's Expert Access™ Program

NO COST

2nd Opinion Consult

with a CLL expert

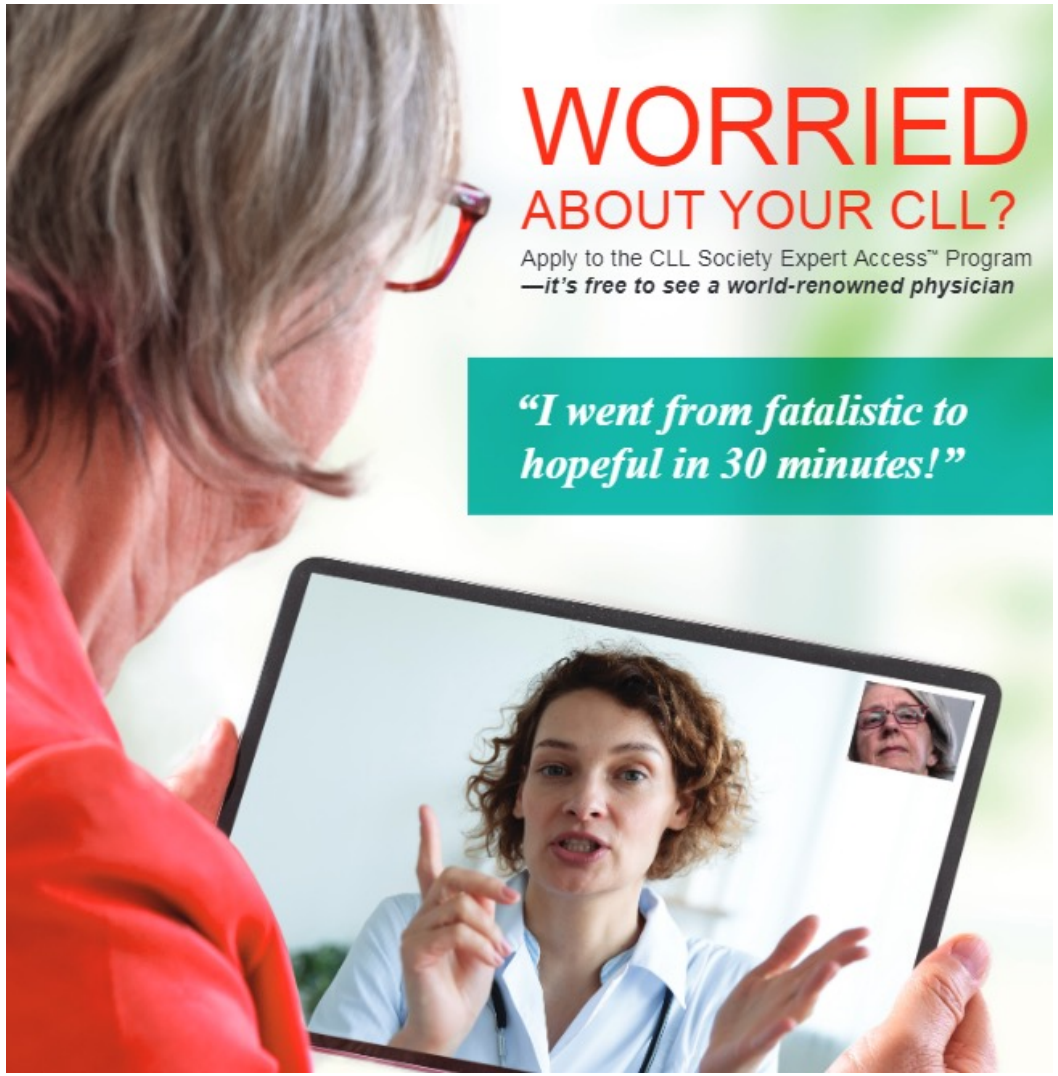
Do you have a diagnosis of CLL?

Live in the United States?

Not currently under the care of a CLL expert?

You Qualify!

CLL Society's Expert Access™ Program



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- Your CLL medical records
- The expert physician will be prepped
- Ask your 3 most critical questions
- You will receive a written summary

CLL Society's Weekly Email

Sign-up for CLL Society's Tuesday weekly emails to stay on-top of:

- Breaking CLL news and research
- Upcoming educational events
- On-demand events covering important subjects
- CLL patient education resources

CLL Society's 130,000 Campaign

We need your help.

Spread the word.


cllsociety.org
130,000 CLL patients are missing out.
expert knowledge
thoughtful guidance
compassionate support
Come home.
Now.
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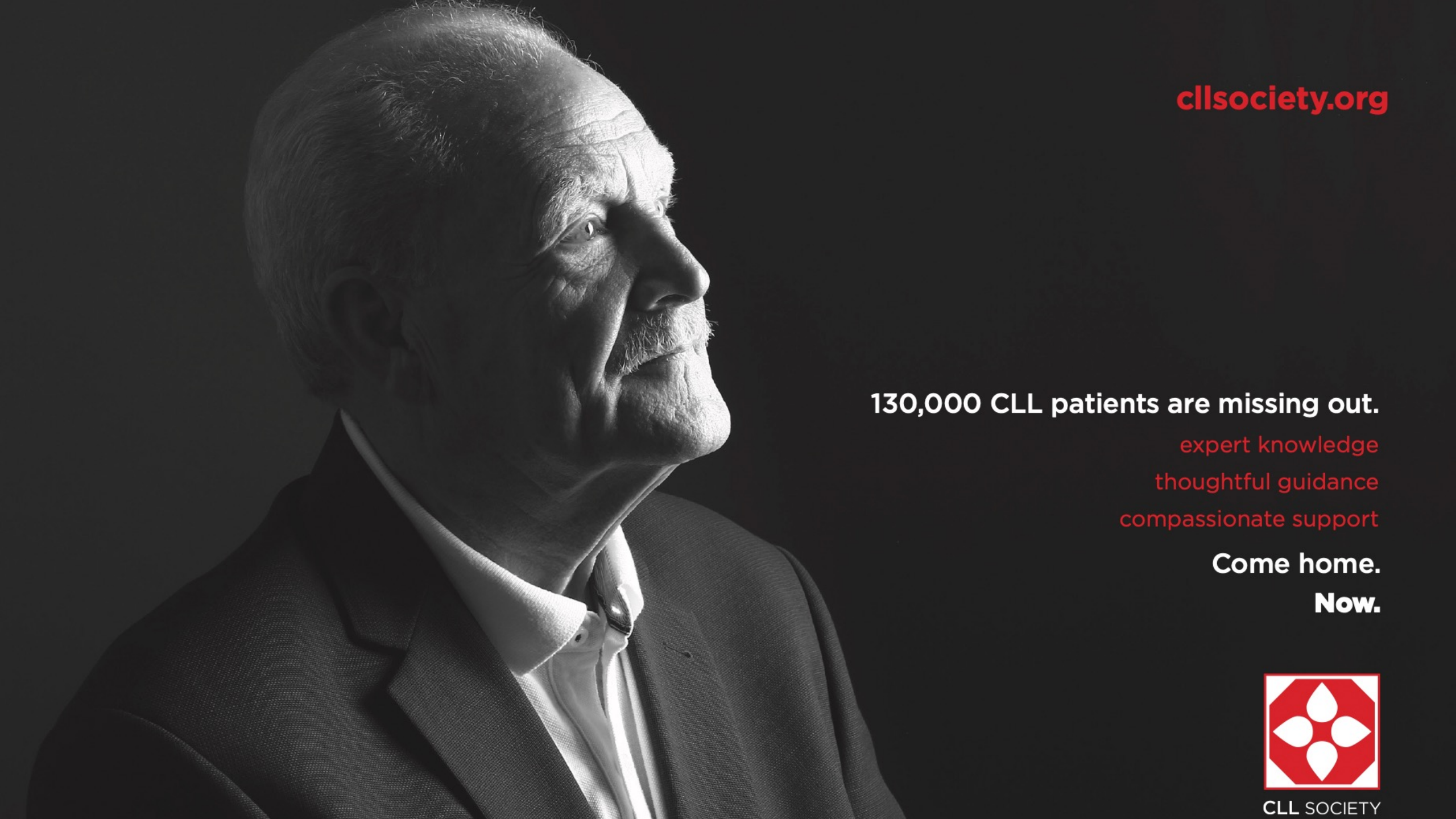
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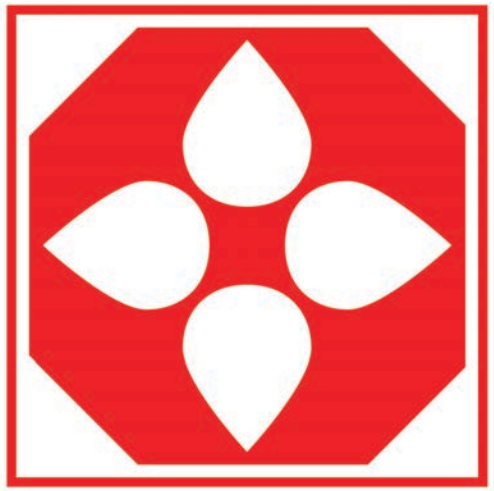

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Spread the Word!

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Audience Questions & Answers

This program was made possible by grant support from

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Thank You for Attending!

Please take a moment to complete our **post-event survey**, your feedback is important to us

Join us on November 1st for our next webinar **Giving Care for the Caregiver**

CLL Society is invested in your long life. Please invest in the long life of the CLL Society by supporting our work

cllsociety.org/donate-to-cll-society/