BLOOD CANCER 201: MOVING BEYOND THE BASICS OF DISEASE, TREATMENT, AND THE ROLE OF THE HCP

November 10, 2021

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Treatment guidelines are constantly evolving.
For the most current treatment guidelines, please refer to the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) at: https://www.nccn.org/guidelines/category_1.
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At the time of this presentation, there were treatments noted to be in trials and pending FDA approval that may have since been FDA approved. A list of FDA approved treatments to treat blood cancers can be accessed at: https://www.LLS.org/Drugs.

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WELCOME AND INTRODUCTIONS

Caroline Kornhauser, MPH

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LEARNING OBJECTIVES

- **Explain the role of genomics and molecular profiling in the diagnosis, prognostication, treatment, and monitoring of blood cancer.**
- **Describe the psychosocial impact of different blood cancer diagnoses.**
- **Explore treatment options for blood cancer patients including precision medicine, cellular therapy, and clinical trials.**
- **List resources for patients with blood cancers and how to access them.**

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SPEAKERS

Laura Romundstad, MSN, RN, CRNP, AOCNP

Lynn Steele, LSW, OSW-C

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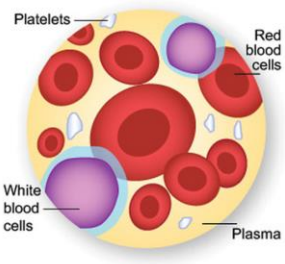
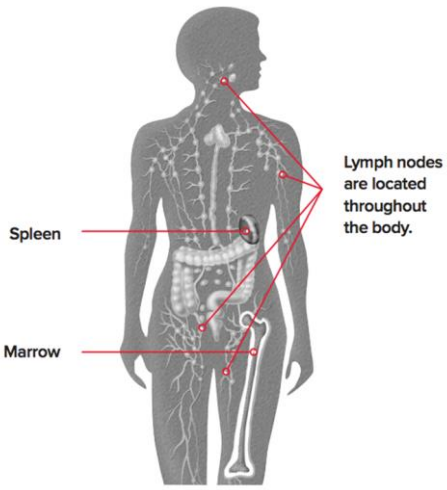
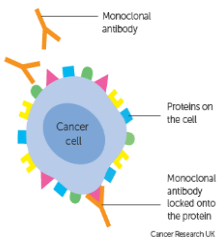
REMEMBER THE BASICS







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BUT FIRST WE MUST KNOW…

All cancer is genetic.

A) True

B) False

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BUT FIRST WE MUST KNOW…

All cancer is genetic.

A) True

B) False

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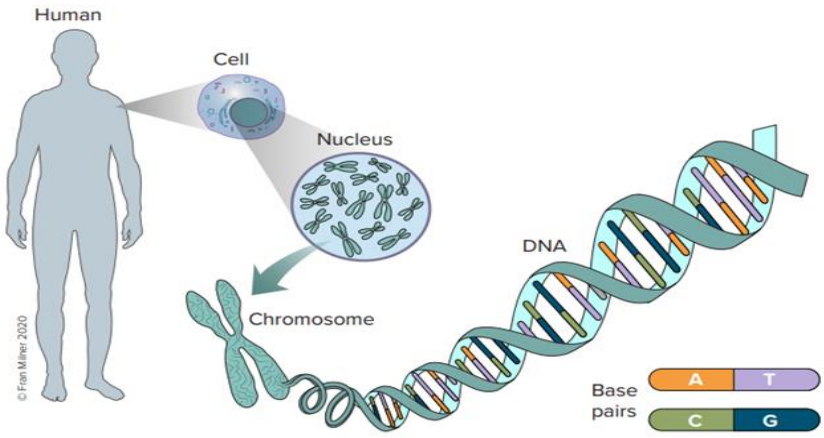
LET'S START AT THE VERY BEGINNING



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https://www.ncbi.nlm.nih.gov/books/NBK115558/

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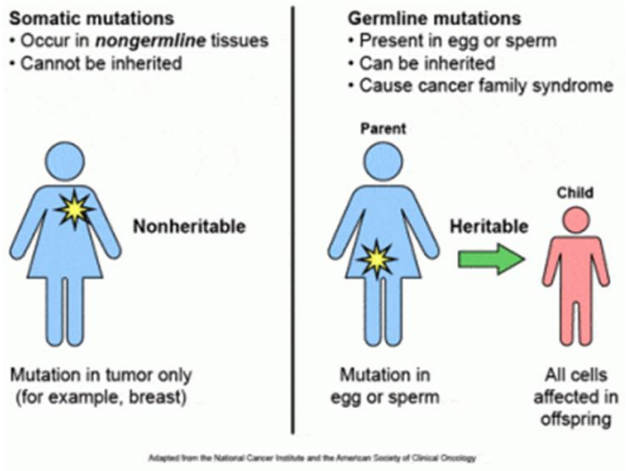
GERMLINE & SOMATIC MUTATIONS

- All cancer is genetic
- 90% of cancers are caused by **somatic mutations** (error happens after conception)
- 10% of cancers are caused by **germline mutations** (error happens in the egg or sperm)



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https://positivebioscience.com/somatic-mutations-vs-germline-mutations/

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WHAT ARE THE DIFFERENCES IN GENETICS & GENOMICS

Genetics (YOU)	Genomics (YOUR TUMOR/CANCER)
Genetics can help identify your risk of developing cancer	Genomics can help guide your treatment once you have cancer
Genetic testing detects **hereditary** (from your parents) alterations in DNA that can be passed from one generation to the next through genes	Genomic testing detects **acquired** (over the course of your life) alterations in DNA; 90% of cancer is acquired
Harmful variants in some genes are known to be associated with an increased risk of developing cancer (contributes to about 5-10% of all cancers) (NIH, 2019)	Once you have cancer, the activity and interaction of certain genes in your tumor tissue influences the behavior of your tumor, including how likely it is to grow or spread
Once you know your genetic risk for cancer, you can take steps to lower that risk (i.e., lifestyle changes)	Once you have the personalized information from the genomic testing, you and your doctor can decide what treatment you need

https://www.genome.gov/about-genomics/fact-sheets/Genetics-vs-Genomics

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BIOMARKER TESTING OR MOLECULAR PROFILING

WHAT HAPPENS NEXT?

- There are several different genomic tests that may be ordered depending on the diagnosis
- Some testing will be repeated at specific times & at relapse to see how the cancer is behaving
- Further genomic testing may be indicated based on results of previous testing

https://www.cancercenter.com/treatment-options/precision-medicine/advanced-genomic-testing

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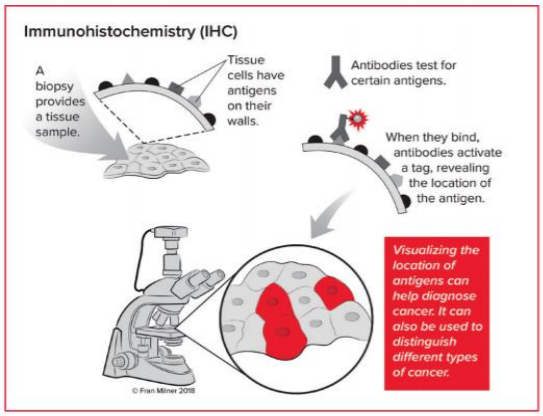
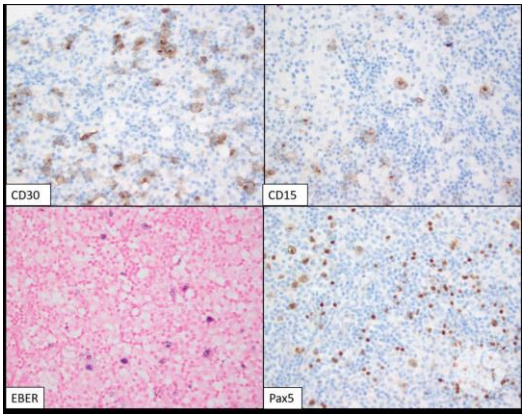
IMMUNOHISTOCHEMISTRY (IHC)



https://www.lls.org/leukemia/acute-lymphoblastic-leukemia/diagnosis



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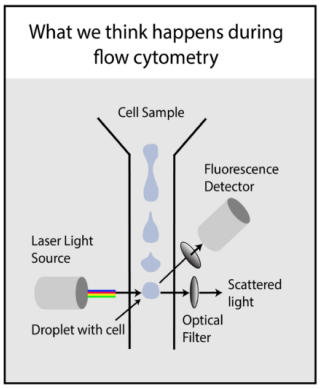
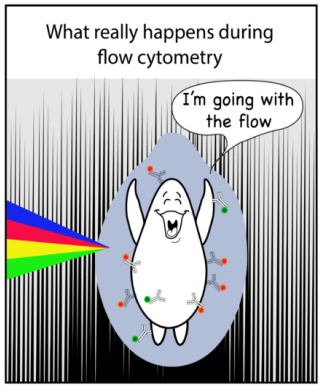
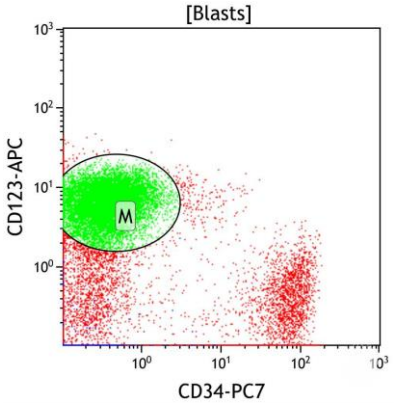
FLOW CYTOMETRY





https://cellcartoons.net



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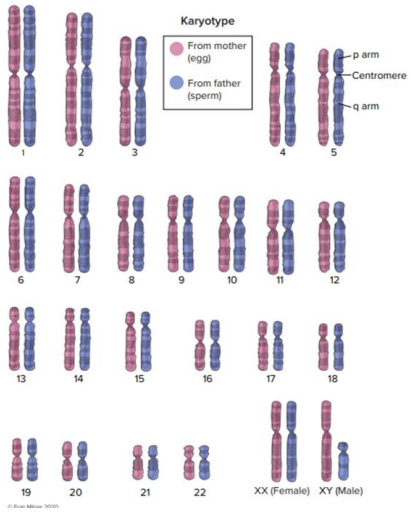
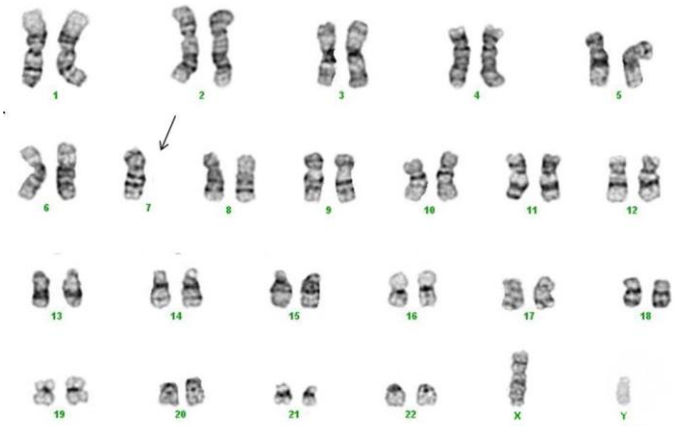
CYTOGENETICS





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https://www.ncbi.nlm.nih.gov/books/NBK115558/

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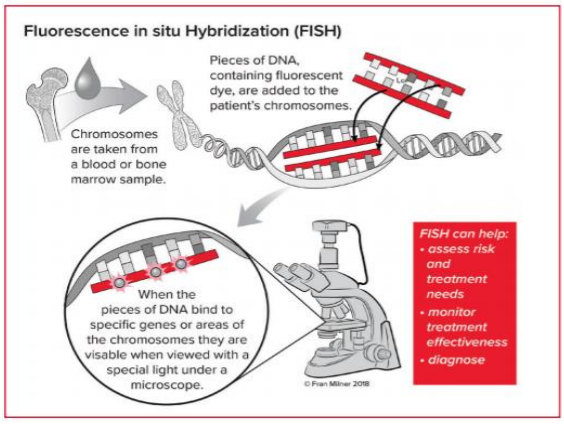
FLUORESCENCE IN SITU HYBRIDIZATION (FISH)



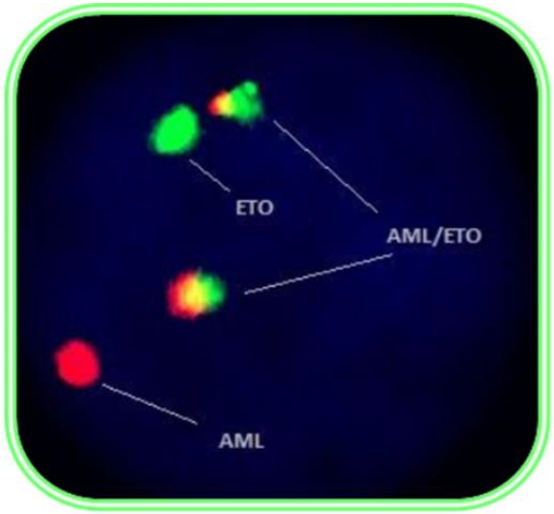


Figure 6. FISH analysis showing AML1/ETO (red and green) fusion signals.

https://www.researchgate.net/figure/FISH-analysis-showing-AML1-ETO-red-and-green-fusion-signals_fig5_312043849

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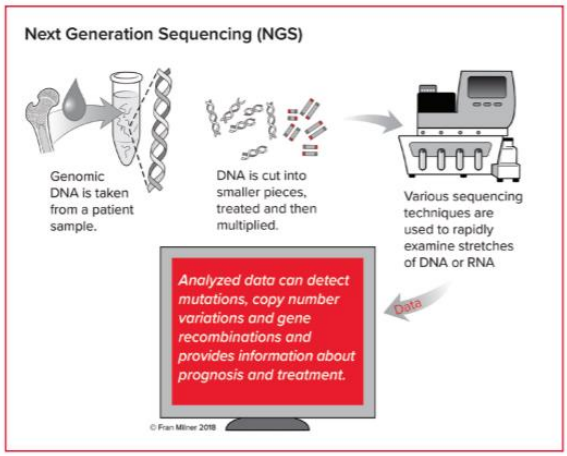
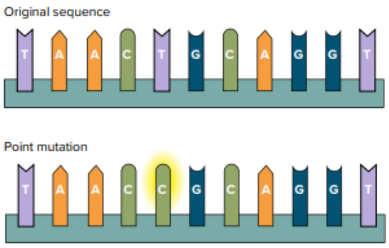
NEXT GENERATION SEQUENCING





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https://www.lls.org/leukemia/acute-lymphoblastic-leukemia/diagnosis

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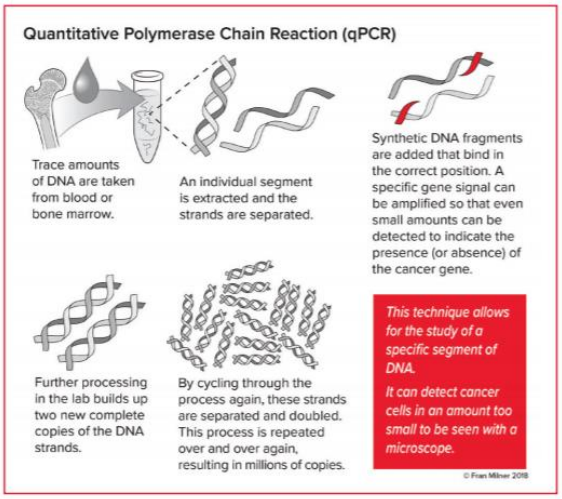
POLYMERASE CHAIN REACTION (PCR) TESTING



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https://www.lls.org/patient-education-videos/lab-tests

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BIOMARKER TESTING FOR BLOOD CANCER MONITORING

Measurable/Minimal Residual Disease

Acute Lymphoblastic Leukemia	Acute Myeloid Leukemia	Multiple Myeloma	Chronic Myeloid Leukemia
• Standard clinical practice • Used to predict outcomes and guide therapy	• More complicated as disease may not be stable over time	• Prognostic value is established, but not enough evidence to alter treatment based on MRD	• Testing is easier since disease driven by well-characterized genetic abnormality • Testing is necessary to gauge response, inform prognosis, and alter treatment

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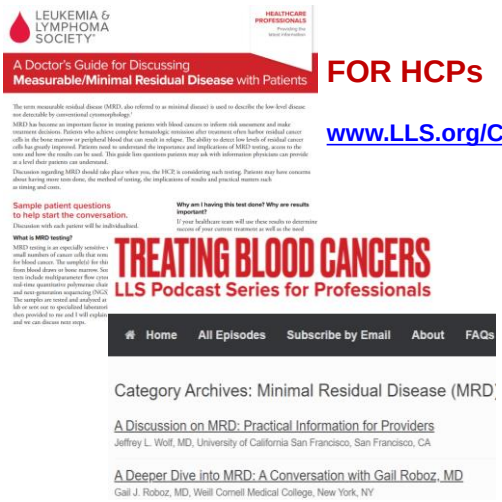
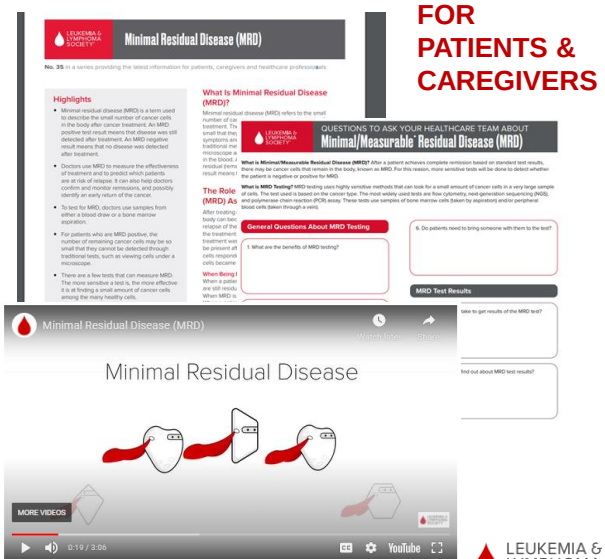
MRD RESOURCES



FOR HCPs

www.LLS.org/CE

Podcast: treatingbloodcancers.org



FOR PATIENTS & CAREGIVERS

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WHICH PATIENTS NEED MOLECULAR PROFILING OR BIOMARKER TESTING?

A. **Patients with relapsed AML**

B. **Patients with newly diagnosed CLL**

C. **Patients with multiple myeloma**

D. **All of them!**

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WHICH PATIENTS NEED MOLECULAR PROFILING OR BIOMARKER TESTING?

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D. **All of them!**

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IMPORTANCE OF BIOMARKER TESTING

- Understand underlying genomic drivers of cancer
- Guides surgical and treatment decisions
- Guides which therapies NOT to take
- Determines eligibility and access to clinical trials

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NCCN GUIDELINES VERSION 6.2023 DIFFUSE LARGE B-CELL LYMPHOMA

ADDITIONAL DIAGNOSTIC TESTING[a,b]

ESSENTIAL:
- Adequate immunophenotyping to establish diagnosis and germinal center B-cell (GCB) versus non-GCB origin[c]
  - IHC panel: CD20, CD3, CD5, CD10, CD21, CD45, BCL2, BCL6, Ki-67, IRF4/MUM1, MYC with or without
  - Cell surface marker analysis by flow cytometry with peripheral blood and/or biopsy specimen: kappa/lambda, CD45, CD3, CD5, CD19, CD10, CD20
- Karyotype or FISH for *MYC*; FISH for *BCL2*, *BCL6* rearrangements if *MYC* positive

USEFUL UNDER CERTAIN CIRCUMSTANCES:
- Additional immunohistochemical studies to establish lymphoma subtype
  - IHC panel: cyclin D1, kappa/lambda, CD30, CD138, anaplastic lymphoma kinase (ALK), human herpesvirus-8 (HHV8), SOX11
- Epstein-Barr virus (EBV)-encoded RNA (EBER) in situ hybridization (EBER-ISH)
- Karyotype or FISH for *IRF4/MUM1* rearrangements[d]

SUBTYPES

Subtypes included:
- DLBCL, not otherwise specified (NOS)[e] (includes germinal center and non-germinal center)
- DLBCL coexistent with FL of any grade
- DLBCL coexistent with EMZL of stomach
- DLBCL coexistent with EMZL of nongastric sites
- FL grade 3[f]
- Intravascular LBCL
- DLBCL associated with chronic inflammation
- EBV-positive DLBCL, NOS
- T-cell-/histiocyte-rich LBCL
- LBCL with *IRF4/MUM1* rearrangement
- Double expressor DLBCL
- Fibrin-associated LBCL
- ALK-positive LBCL; see BCEL-B 1 of 3.
- Mediastinal gray zone lymphoma (MGZL); see BCEL-B 2 of 3.
- Primary mediastinal large B-cell lymphoma (PMBL); see PMBL-1.
- HGBL; see HGBL-1.
- HGBL, NOS; see HGBL-1.
- Primary cutaneous DLBCL, leg type; see BCEL-B 3 of 3.

→ See Workup (BCEL-2)

Subtypes *not* included:
- Primary cutaneous marginal zone lymphoma (PCMZL) and primary cutaneous follicle center lymphoma (PCFCL) (See NCCN Guidelines for Primary Cutaneous B-Cell Lymphomas)
- Primary DLBCL of the CNS (See NCCN Guidelines for CNS)
- DLBCL arising from CLL (Richter's transformation) (See NCCN Guidelines for CLL/SLL)
- LBCL with 11q aberration [ICC]; HGBL with 11q aberrations [WHO] (BURK-1)

[a] See Special Considerations for Adolescent and Young Adult Patients (AYA) with B-Cell Lymphomas (NHODG-B 5 of 5).
[b] See International Prognostic Index (BCEL-A).
[c] Typical immunophenotype: CD20+, CD45+, CD3-; additional markers are used for subclassification.
[d] LBCL with *IRF4/MUM1* rearrangement are usually DLBCL but occasionally are purely FL grade 3b (ICC/FLBL [WHO]) and often DLBCL with FL grade 3b. Patients typically present with Waldeyer's ring involvement and are often children/young adults. These lymphomas are locally aggressive but respond well to chemotherapy ± RT. They do not have a *BCL2* rearrangement and should not be treated as low-grade FL.
[e] Germinal center (or follicle center) phenotype is not equivalent to FL and can occur in DLBCL and BL. Morphology is required to establish diagnosis.
[f] FL, grade 3b (ICC)/FLBL (WHO) is commonly treated as DLBCL. The management of FL, grade 3a is controversial and treatment should be individualized.

Note: All recommendations are category 2A unless otherwise indicated.
Clinical Trials: NCCN believes that the best management of any patient with cancer is in a clinical trial. Participation in clinical trials is especially encouraged.

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BCEL-1

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Table 3. Myeloma Staging Systems

Stage	Durie-Salmon Staging System	Revised International Staging System (R-ISS)	Survival for R-ISS
I	**All of the following:** ○ Hemoglobin concentration >10 g/dL ○ Serum calcium value normal or ≤12 mg/dL ○ X-ray studies of bone showing normal bone structure (scale 0) or solitary bone plasmacytoma only ○ Low M-component production rate IgG value <5 g/dL IgA value <3 g/dL ○ Urine light chains <4 g/24 hours	○ Serum albumin >3.5 g/dL ○ Serum beta 2 (β_2)-microglobulin <3.5 mg/L ○ No high-risk cytogenetic features ○ Normal serum lactate dehydrogenase level	82%
II	**Neither stage I nor stage III** ○ A – No renal failure (creatinine ≤2 mg/dL) ○ B – Renal failure (creatinine >2 mg/dL)	**Neither stage I nor stage III**	62%
III	**One or more of the following:** ○ Hemoglobin concentration <8.5 g/dL ○ Serum calcium value >12 mg/dL ○ X-ray studies of bone showing >3 lytic bone lesions ○ High M-component production rate IgG value >7 g/dL IgA value >5 g/dL ○ Urine light chains >12 g/24 hours	**Both of the following:** ○ Serum beta 2 (β_2)-microglobulin >5.5 mg/L ○ AND one of the following ○ High-risk cytogenetics t(4;14) t(14;16) del(17p) ○ Elevated serum lactate dehydrogenase level	40%

Key: del, deletion; dL, deciliter; g, gram; Ig, immunoglobulin; L, liter; M-component, monoclonal component; M protein, monoclonal (myeloma) protein; mg, milligram; t, a translocation between chromosomes.

Sources: Rajkumar SV. Multiple myeloma: 2022 update on diagnosis, risk stratification, and management. *American Journal of Hematology.*
Shah, D. Multiple Myeloma Workup. Medscape reference.
Palumbo A, Avete-Loiseau H, Olivia S, et al. Revised international staging system for multiple myeloma: a report from international myeloma working group. *American Society of Clinical Oncology.* See *References* on page 71.

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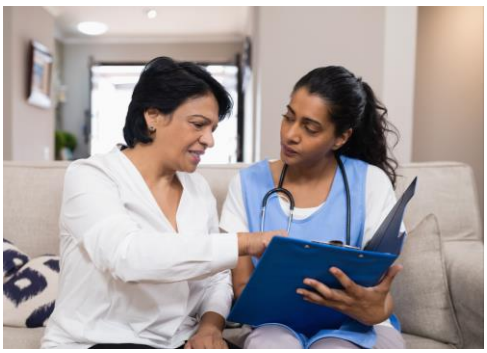
CASE STUDY # 1

- 57-year-old female, employed with employer group insurance
- Chronic Myeloid Leukemia (CML) diagnosis
- Was hospitalized and needs to begin treatment right away
- Wondering about getting a second opinion
- Insurance coverage issues- medication initially denied
- Concerns about coping with chronic nature of CML



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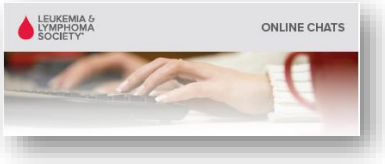
PSYCHOSOCIAL RESOURCES

- Learning about her disease and treatment
- Navigating her healthcare coverage
- Finding peer support
- Developing coping strategies to deal with the chronic nature of her disease



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HOW DO I CHOOSE A TREATMENT CENTER, BLOOD CANCER SPECIALIST, OR GET A SECOND OPINION?

Questions to ask:

- Is care at the treatment center covered by my insurance plan?
- Does my primary care doctor or hematology-oncologist have confidence in this treatment center?
- What type of accreditation does the treatment center have? Do the treatment center and staff have experience treating my specific type of blood cancer?
- Does the center offer the most current treatments available?
- Does the center participate in clinical trials (research studies) related to my diagnosis?
- Are adequate support staff (nurses, social workers, case managers, patient advocates) available?
- Will I see the same support staff members at each visit?
- Is there a pharmacy on the premises or nearby?
- If a stem cell transplant is part of the treatment plan, is this center experienced in performing the type of stem cell transplant I will need?
- Can I speak to other cancer patients who are being treated or were treated at this center?

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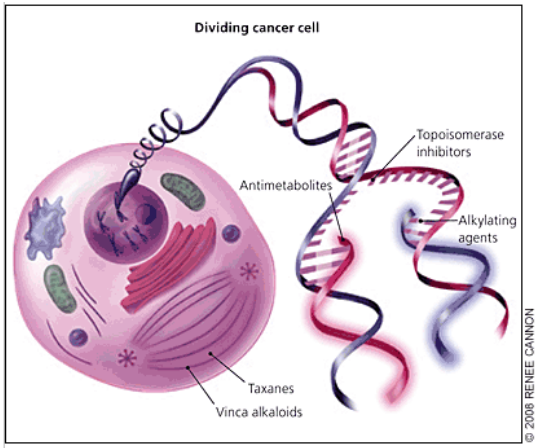
TREATMENT APPROACHES

"Sledge Hammer Approach" with Conventional Chemotherapy

- Can be curative
- Acute side effects
- Long-term side effects that affect quality of life
- Usually IV meds



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https://www.aafp.org/afp/2008/0201/p311.html

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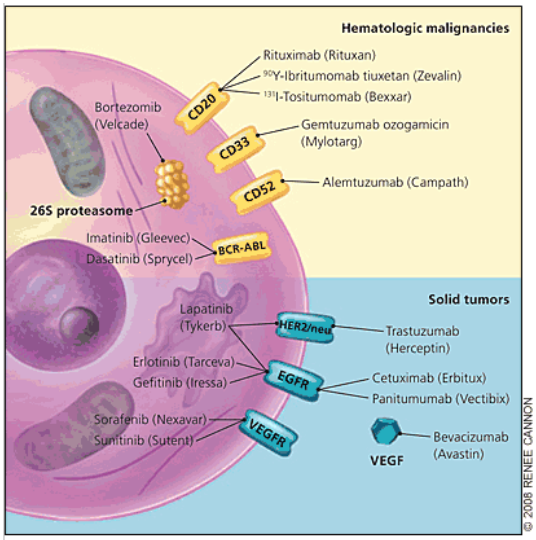
TREATMENT APPROACHES



"Targeted/Pinpoint Approach" with Precision Medicine

- Can be curative
- Fewer side effects both acutely & long term
- Oral or IV meds
- Allows for combinations

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https://www.aafp.org/afp/2008/0201/p311.html

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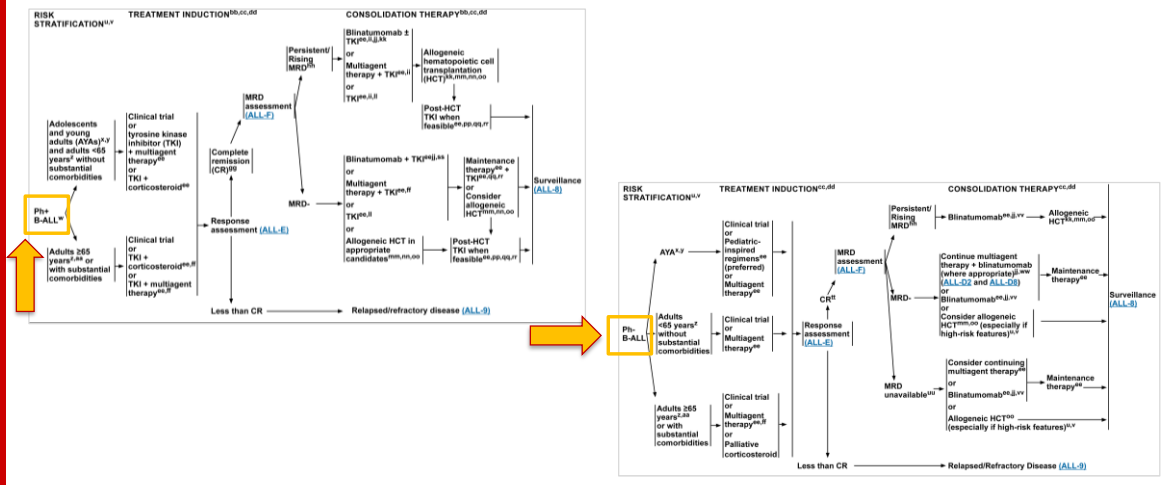
NCCN GUIDELINES VERSION 3.2023 ACUTE LYMPHOBLASTIC LEUKEMIA



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Biomarkers Significant for Study and Treatment of Hematologic Cancers

Chromosome and Gene Abbreviations	Associated Cancer	Treatment Correlation
Philadelphia chromosome t(9;22) (translocation between chromosomes 9+22)	Chronic myeloid leukemia (CML), acute lymphoblastic leukemia (ALL)	Responds to imatinib (Gleevec®), dasatinib (Sprycel®), nilotinib (Tasigna®)
IDH2 *(R140 or R172)*	Acute myeloid leukemia (AML)	Responds to enasidenib (Idhifa®)
JAK2 V617F	Myeloproliferative neoplasms (MPNs): polycythemia vera (PV), myelofibrosis (MF), essential thrombocythemia (ET)**	Responds to ruxolitinib (Jakafi®)
PML-RARA	Acute promyelocytic leukemia (APL)	Responds to all-*trans* retinoic acid (ATRA), arsenic trioxide (Trisenox®)
FLT3-ITD	Acute myeloid leukemia (AML)	Responds to midostaurin (Rydapt®)
ALK rearrangement	Anaplastic large-cell lymphoma (ALCL)	Responds to crizotinib (Xalkori®)*
BRAF V600E	Hairy cell leukemia	Responds to vemurafenib (Zelboraf®)*

*This drug is not FDA approved for this indication.

**Use of ruxolitinib for this diagnosis has not been FDA approved.

Table 1. This table lists some of the biomarkers that are currently known to be significant for the study and treatment of hematologic cancers.

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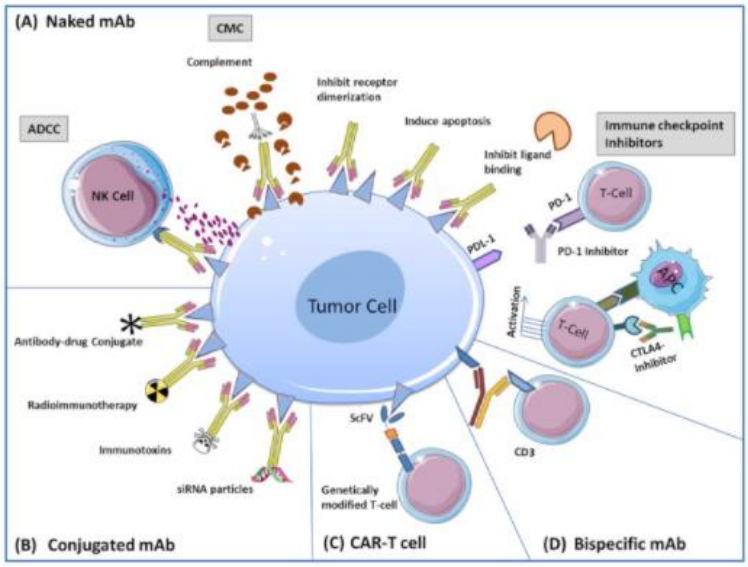

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https://www.exphem.org/article/S0301-472X(17)30656-2/fulltext

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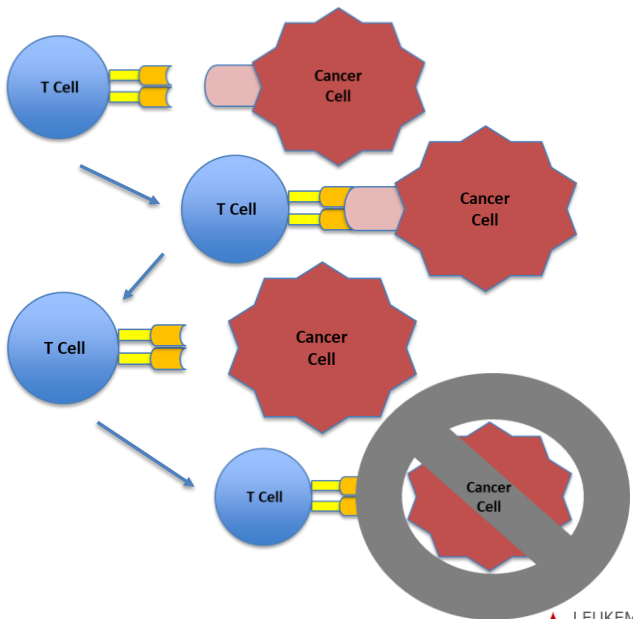
IMMUNOTHERAPY

- **Chimeric Antigen Receptor T-cell Therapy (CAR-T)**: engineering T cells with a receptor that can recognize and attack tumor cells with specific markers on their surface
- Once inside the body the CAR T cell will find the specific target on the cancer cell and attach and kill the cancer cell



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Precision Medicine in Pediatric Cancer: Current Applications and Future Prospects https://www.ncbi.nlm.nih.gov/pubmed/30551569

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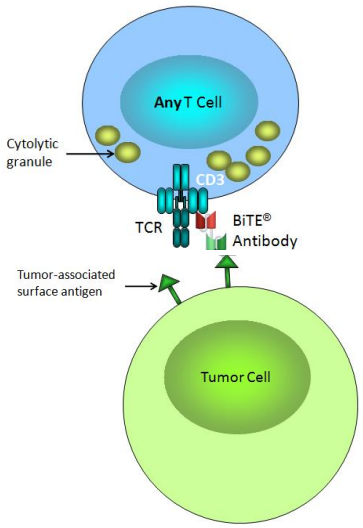
IMMUNOTHERAPY

- **Bispecific T-cell Engager (BiTE)**: this antibody attaches to two targets the T cell and the tumor cell.
  - *Blinatumomab is an example of FDA approved BiTE therapy*
  - *Additional bispecifics being studied in clinical trials*



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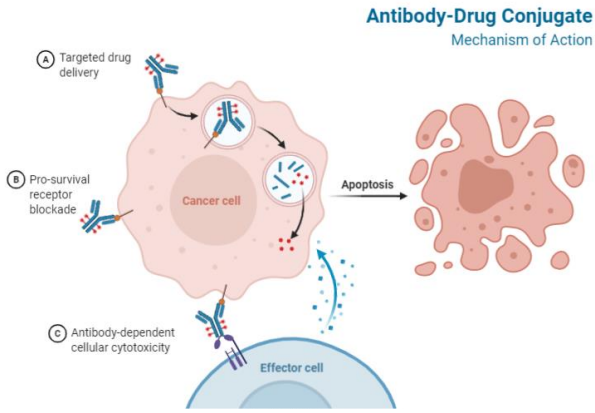
IMMUNOTHERAPY

- **Antibody Drug Conjugate (ADC):** an antibody is linked to a toxic payload (chemotherapy drug) which is released into the tumor once attached
  - *Gemtuzumab for AML, Inotuzumab for ALL, and Brentuximab for HL, are FDA approved ADC therapy*



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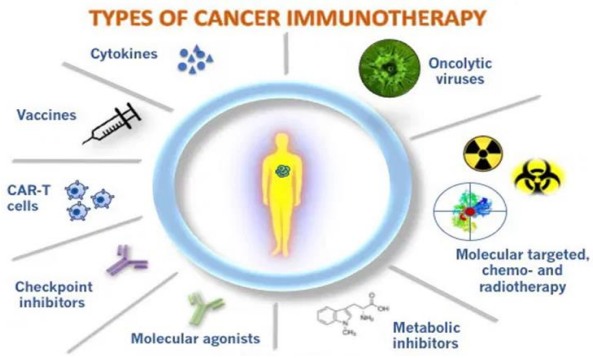
IMMUNOTHERAPY CLINICAL TRIALS FOR BLOOD CANCER PATIENTS



Adult Immunotherapy Trials (911)

- Immunomodulatory (83)
- CAR-T (144)
- Other Cellular Therapy (135)
- BiTE (52)
- Checkpoint Inhibitors (55)
- Gene Therapy (6)

Pediatric Immunotherapy Trials (73)

- Immunomodulatory (1)
- CAR-T (61)
- Other Cellular Therapy (25)
- BiTE (5)
- ADC (6)
- Checkpoint Inhibitors (11)
- Vaccine Therapy (10)
- Other immunotherapy (5)

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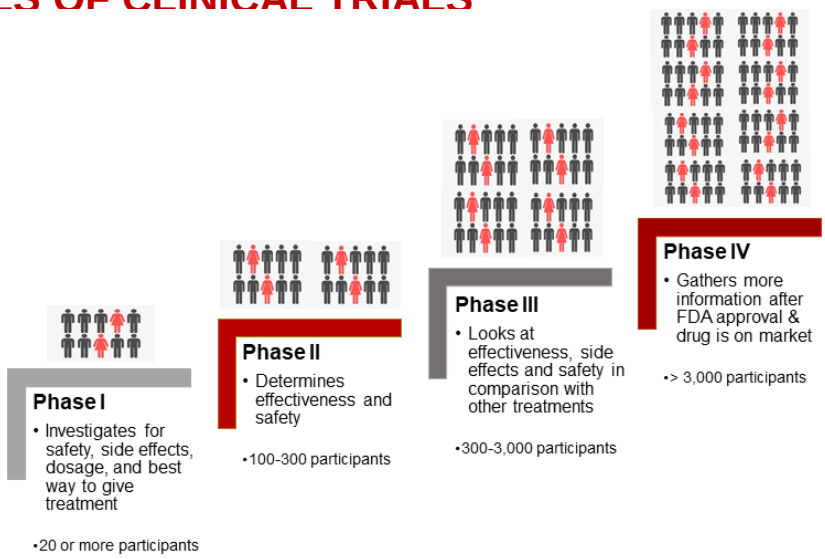
PHASES OF CLINICAL TRIALS



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CLINICAL TRIAL MYTHS

I can only join a clinical trial if I have exhausted all other options	Clinical trials are not safe and I will not benefit from them	I might get a placebo or a sugar pill instead of a real drug if I join a clinical trial	Clinical trials are free
• Clinical trials are available throughout the disease process.	• Drug development is a process that starts in the lab and is regulated by FDA in the US.	• Regulations require patients to know if placebo is a possibility. Placebos are rarely used in serious or life-threatening diseases.	• The drug that is being studied is free. Patient is responsible for standard of care therapy, admission to hospitals, physicians and other associated costs.

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UNDERSTANDING COSTS ASSOCIATED WITH CLINICAL TRIALS

Sponsor	Insurance Carrier (Private, Medicare or Medicaid)	Patient
• Cost of treatment and treatment administration	• Standard of care tests and treatment.	• Co-pays, deductibles, out-of-network costs
• Travel and lodging are sometimes included. This is study specific—you should always ask!!	• Cost of complications of treatment.	• Travel or lodging for patient and/or caregiver.
• Extra tests, interventions or office visits that are required by the trial.	• May or may not cover phase 1 trials.	• Food and other incidentals.
	• May or may not cover trials that take place of out-of-network or out of state.	• Loss of employment income for patient and/or caregiver
		• Child care, pet boarding and home maintenance costs.

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CASE STUDY # 2

- 37-year-old female working presently, but needs a stem cell transplant and will be losing her job and healthcare coverage
- Acute Lymphoblastic Leukemia (ALL) diagnosis
- Single mother
- Financial concerns
- Insurance concerns
- Support resources
- Childcare concerns

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PSYCHOSOCIAL RESOURCES

- Seeking and securing healthcare coverage, is COBRA an option?
- Resources for talking to her child about her diagnosis and treatment
- Financial resources
- Disability – can I apply? Will I be eligible?
- FMLA information
- Utilizing resources from her present healthcare team
- Finding support/family resources

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KEY POINTS TO LEAVE WITH:

- All cancer is genetic, but genetic changes are mostly acquired through your lifetime, few are inherited
- Patients and caregivers benefit from being connected with support and resources prior to diagnosis, throughout treatment, and into survivorship
- Biomarker testing is ESSENTIAL to accurate, complete and thorough diagnosis
- Each patient and caregiver has a unique lived experience and the care we provide should be tailored to their needs - physical, emotional, financial, psychosocial, cultural.
- Precision medicine is changing the way we treat blood cancer.

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BLOOD CANCER 201: MOVING BEYOND THE BASICS OF DISEASE, TREATMENT, AND THE ROLE OF THE HCP

Resources for HCPs

- ❑ Free CME & CE courses: www.LLS.org/CE
- ❑ Fact Sheets for HCPs: www.LLS.org/CE
- ❑ Podcast series for HCPs: www.LLS.org/CE
- ❑ HCP Patient Referral Form: www.LLS.org/HCPreferral
- ❑ LLS Other Helpful Organizations: www.LLS.org/OHO

Clinical Trials and Research

- ❑ Clinical Trials: Learn more about clinical trials: www.LLS.org/ClinicalTrials
- ❑ Research: Focused on finding cures and driving research: www.LLS.org/Research

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Resources for Patients

- Telephone and Web Education Programs: www.LLS.org/Programs & www.LLS.org/Educationvideos
- Free Mobile Apps: *LLS Health Manager:* www.LLS.org/Health-Manager
- Support Resources: www.LLS.org/Support
  - LLS Regions
  - Online Chats
  - One-On-One Nutrition Consultations (PearlPoint)
  - LLS Community (social media platform)
  - Patti Robinson Kaufman First Connection Program (peer-to-peer)
- Financial Assistance
  - Co-Pay Assistance
  - Urgent Need
  - Travel Assistance
  - Referral to Medication Access programs

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FREE GUIDES, BOOKLETS, AND FACT SHEETS

For Patients, Caregivers, and Professionals

www.LLS.org/Booklets

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BLOOD CANCER 201: MOVING BEYOND THE BASICS OF DISEASE, TREATMENT, AND THE ROLE OF THE HCP

Resources for Patients

- **Information Specialists** – Personalized assistance for managing treatment decisions, side effects, and dealing with financial and psychosocial challenges.
- **Clinical Trial Nurse Navigators** – RNs assist patients and healthcare providers explore potential clinical trials and overcome any barriers to clinical trial enrollment.
- **Registered Dieticians** – (LLS) provides PearlPoint Nutrition Services® to patients/caregivers of all cancer types, free nutrition education and one-on-one consultations by phone or email.
- **Reach out** **Monday–Friday, 9 am to 9 pm ET**
  - Phone: (800) 955-4572
  - Live chat: www.LLS.org/InformationSpecialists
  - Email: infocenter@LLS.org

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Q & A

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Thank you for participating.
Please complete the program evaluation

For a list of our CME and CE activities, podcasts and fact sheets, please visit:
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