



# CLINICAL TRIALS & BLOOD CANCERS: SEARCHING FOR CURES



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## WELCOMING REMARKS

CLINICAL TRIALS & BLOOD CANCERS: SEARCHING FOR CURES



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*Rye Brook, NY*





## WELCOMING REMARKS

CLINICAL TRIALS & BLOOD CANCERS: SEARCHING FOR CURES



**Leah Szumita, MS, RN, ACNS-BC**  
 Director, Clinical Trial Support Center  
 The Leukemia & Lymphoma Society  
 Rye Brook, NY

3



3



## PRESENTATION

CLINICAL TRIALS & BLOOD CANCERS: SEARCHING FOR CURES



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4



4



## DISCLOSURES

### CLINICAL TRIALS & BLOOD CANCERS: SEARCHING FOR CURES

Updated 3/2023	
Research Support	BMS, Curis
Consultancy	AbbVie, Acrotech, Astellas, AZ, BMS, Caribou, CRISPR, Diiachi Sankyo, Fate Therapeutics, Genentech, Genmab, Ipsen, Janssen, Kite, Loxo, Miltenyi, Morphosys, Nurix, Pharmacyclics, Regeneron, Sanofi, Seagen, Takeda
Employment	NONE
Stock/Equity	NONE
Speakers Bureau	NONE

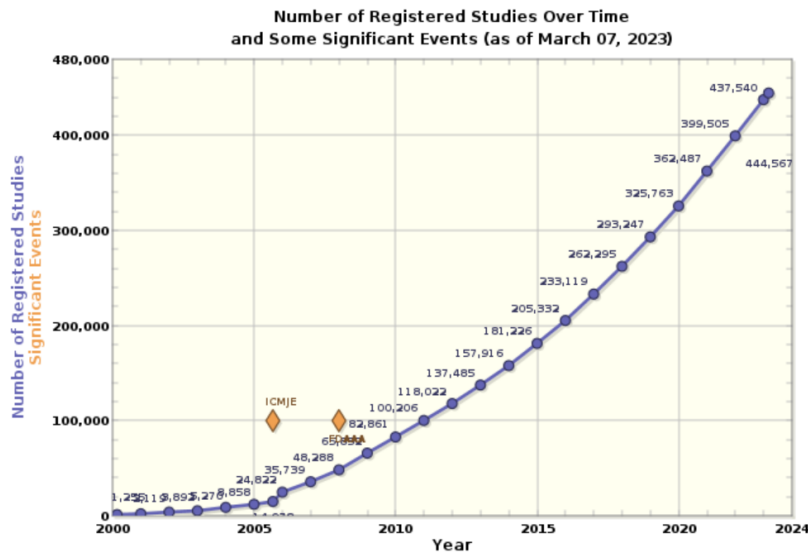
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## THE RISE OF CLINICAL RESEARCH

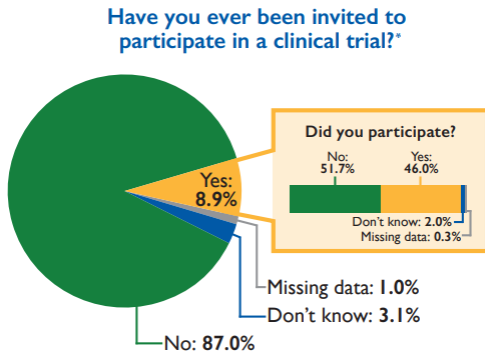


6 [www.clinicaltrials.gov](http://www.clinicaltrials.gov)



6

## THE MYSTERY OF CLINICAL RESEARCH



- 41% of US public never heard of a clinical trial
- In the USA, only ≈4% patients participate in cancer clinical trials
- **How can we improve this?**
  - Education
  - Partnerships
  - Understanding and Eliminating Barriers

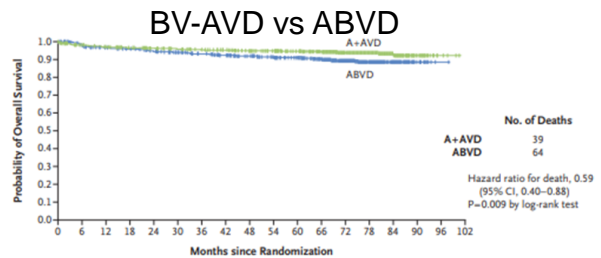
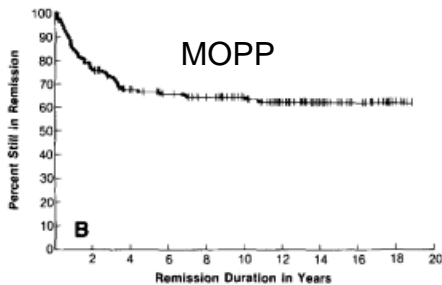
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## WHY CLINICAL TRIALS MATTER

- Virtually every cancer treatment available today is the direct result of clinical research



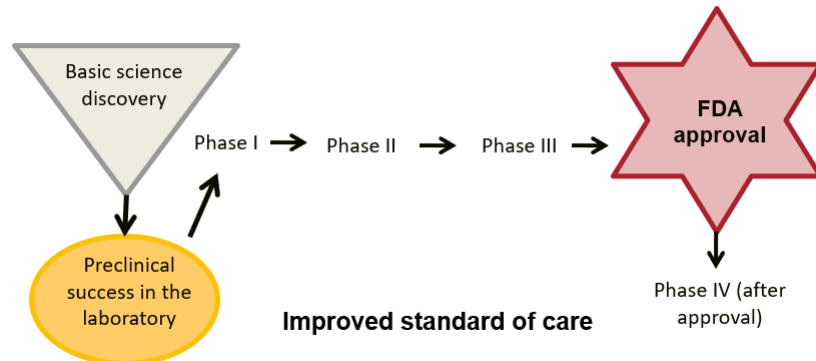
Longo et al. JCO 1986; Ansell et al. NEJM 2022

8



8

## THE JOURNEY OF A DRUG



9

9

## BEFORE YOU START YOUR JOURNEY ON A CLINICAL TRIAL

- Subject safety is the highest priority in clinical trials
- Cancer clinical trials are conducted under rigorous scientific and ethical safeguards
- Many safeguards are in place to ensure patient safety:

Institutional Review Board (IRB)  
 Scientific Review Committee (SRC)  
 Data Safety Monitoring Board (DSMB)



10

10



## YOUR JOURNEY IN A CLINICAL TRIAL: PHASE I

- Phase I
  - Subject who may have failed multiple therapies
    - Healthy volunteers **not** used for cancer research
  - Goal – Identify the maximum tolerated dose
  - Often low subject numbers
  - May be no direct subject benefit but benefit to society

11



11



## YOUR JOURNEY IN A CLINICAL TRIAL: PHASE II

- Determine biologic activity
  - Overall response rate, complete response
- Expand safety & toxicity profile
  - Adverse events over time
- Narrow disease activity
  - Expansion cohorts
- Two-stage design
  - Stage I – exclude drugs with minimal or no activity
  - Stage II – size depends on the precision required
- Randomized phase II trials
  - Pick the winner to move to phase III

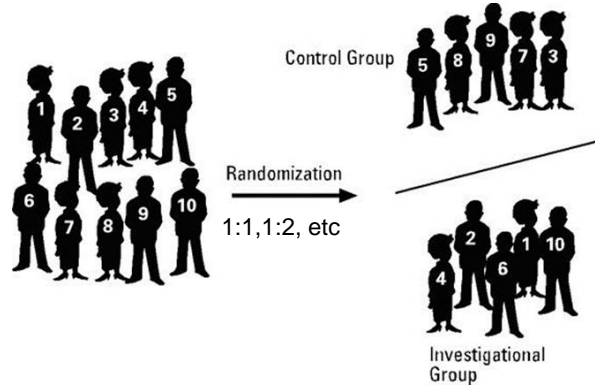
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12

## YOUR JOURNEY IN A CLINICAL TRIAL: PHASE III

### Challenging Standard of Care



- Open label
- Blind
- Double blind

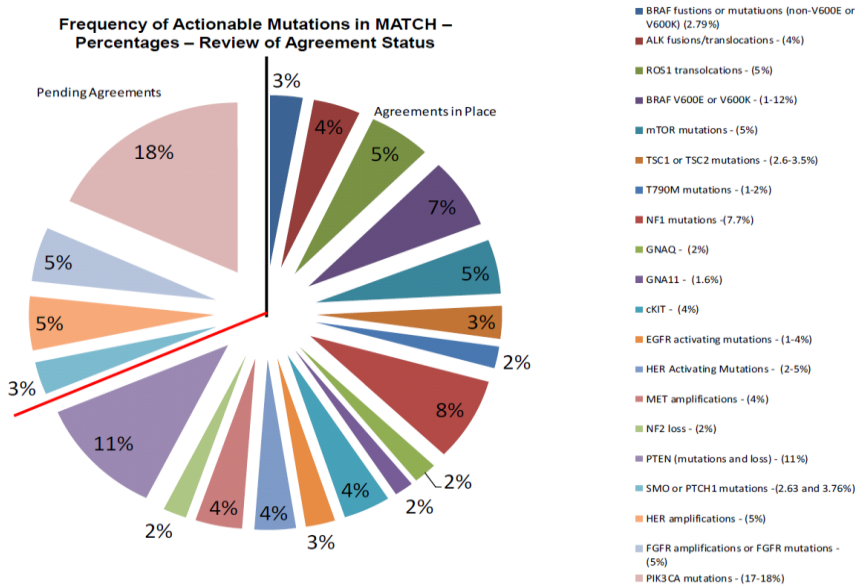
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13

## CANCER TRIALS ARE EVOLVING: RISE OF PERSONALIZED MEDICINE

Frequency of Actionable Mutations in MATCH – Percentages – Review of Agreement Status



14



14

## SAFETY IN A CLINICAL TRIAL

- Inclusion and exclusion criteria
- Dosing (food or no food)
- Compliance (calendars)
- Extra test (blood draws, EKGs)
- Adverse event (toxicity) reporting

15



15

## WHEN IT'S TIME FOR A CLINICAL TRIAL

**Anytime**  
vs.  
**Any Time**



16



16



## HOW TO FIND A CLINICAL TRIAL

 U.S. National Library of Medicine

*ClinicalTrials.gov*

- 215 million pages view
- 145,000 individuals daily



### UNMC Clinical Trials

#### Find Studies

**Browse Studies**  
 By Medical Area  
 By Gender, Phase, or Study Type  
 For Healthy Volunteers  
 or  
**Search**

type keyword such as condition or physician

search

Current Total Studies Count: 408

17



17

## ASK A QUESTION

**CLINICAL TRIALS & BLOOD CANCERS: SEARCHING FOR CURES**

### Ask a question by **phone**:

Press star (\*) 1 on your keypad to ask a question

To remove your question press star (\*) 2 on your keypad

### Ask a question by **web**:

Type your question in the “Ask a question” box under the speaker video window

Due to time constraints, we can only take one question per person.

Once you’ve asked your question, the operator will transfer you back into the audience line.

18



18

## LLS EDUCATION & SUPPORT RESOURCES



19

### HOW TO CONTACT US:

To contact an **Information Specialist** about disease, treatment and support information, resources and clinical trials: [www.LLS.org/InformationSpecialists](http://www.LLS.org/InformationSpecialists)

**Call: (800) 955-4572**

Monday to Friday, 9 a.m. to 9 p.m. ET

**Chat live online: [www.LLS.org/InformationSpecialists](http://www.LLS.org/InformationSpecialists)**

Monday to Friday, 10 a.m. to 7 p.m. ET

**Email: [www.LLS.org/ContactUs](mailto:www.LLS.org/ContactUs)**

All email messages are answered within one business day.

### CLINICAL TRIAL SUPPORT CENTER

Work one-on-one with an LLS Clinical Trial Nurse Navigator who will help you find clinical trials and personally assist you throughout the entire clinical-trial process.  
[www.LLS.org/Navigation](http://www.LLS.org/Navigation)



**NUTRITION CONSULTATIONS**  
Our registered dietitian has expertise in oncology nutrition and provides free one-on-one consultations by phone or email.  
[www.LLS.org/Consult](http://www.LLS.org/Consult)



19

## LLS EDUCATION & SUPPORT RESOURCES



### Online Chats

Online Chats are free, live sessions, moderated by oncology social workers. To register for one of the chats below, or for more information, please visit [www.LLS.org/Chat](http://www.LLS.org/Chat).



### Education Videos

View our free education videos on disease, treatment, and survivorship. To view all patient videos, please visit [www.LLS.org/EducationVideos](http://www.LLS.org/EducationVideos).



### Patient Podcast

*The Bloodline with LLS* is here to remind you that after a diagnosis comes hope. To listen to an episode, please visit [www.TheBloodline.org](http://www.TheBloodline.org).



20

20

## LLS EDUCATION & SUPPORT RESOURCES

LEUKEMIA & LYMPHOMA SOCIETY  
877.557.2672

**Help With Finances**

The Leukemia & Lymphoma Society (LLS) offers financial assistance\* to help individuals with blood cancer.

The **LLS Patient Aid** Program provides financial assistance to blood cancer patients in active treatment. Eligible patients will receive a \$100 stipend. Visit [www.LLS.org/PatientAid](http://www.LLS.org/PatientAid)

The **Urgent Need** Program, established in partnership with Moppie's Love, helps pediatric and young adult blood cancer patients, or adult blood cancer patients who are enrolled in clinical trials, with acute financial need. The program provides a \$500 grant to assist with non-medical expenses, including utilities, rent, mortgage, food, lodging, dental care, child care, elder care, and other essential needs. Visit [www.LLS.org/UrgentNeed](http://www.LLS.org/UrgentNeed)

The **Susan Lang Pay-It-Forward Patient Travel Assistance** Program provides blood cancer patients a \$500 grant to assist with transportation and lodging-related expenses. Visit [www.LLS.org/Travel](http://www.LLS.org/Travel)

The **Co-Pay Assistance** Program offers financial support toward the cost of insurance co-payments and/or insurance premiums for prescription drugs. Visit [www.LLS.org/Copay](http://www.LLS.org/Copay)

\*Funding for LLS's Co-Pay Assistance Program is provided by pharmaceutical companies. Funding for other LLS financial assistance programs is provided by donations from individual donors, companies, and LLS campaigns.

The Leukemia & Lymphoma Society (LLS) offers the following financial assistance programs to help individuals with blood cancers:  
[www.LLS.org/Finances](http://www.LLS.org/Finances)



To order free materials: [www.LLS.org/Booklets](http://www.LLS.org/Booklets)



21

21



# THANK YOU

This program is supported by



We have one goal: A world without blood cancers

22