Is a Clinical Trial Right for You?

May 16, 2022

11 AM PT, 12 PM MT
1 PM CT, 2 PM ET
Pre-Event Notes

• The audience is muted
• Please direct your questions to CLL Society staff and speakers using the Q&A function (located at the bottom of your screen) at any time throughout the presentation
• Questions can only be seen by staff and speakers. We will do our best to answer as many questions as possible
• Please complete the short survey emailed after the event. Your response will help CLL Society plan future events
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CLL Patient Advocate

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Welcome  
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Director of Scientific Affairs and Research  
CLL Society

Moderator  
Brian Koffman, MDCM (retired)  
MS Ed  
Executive Vice President and Chief Medical Officer  
CLL Society
Poll Questions
Clinical Trials Basics

Adrian Wiestner, MD/PhD

May 16, 2022
Learning Objectives

- Clinical trial: why, how, what?
- Protecting your safety
- Your rights
- Your team
- Is a clinical trial right for me?
The NIH Clinical Center

The NIH Clinical Center is the nation's largest hospital devoted entirely to clinical research.

- More than 9,700 new patients (2018)
- ~800 nurses
- ~1,300 physicians, dentists, and PhD researchers

https://clinicalcenter.nih.gov/
Clinical Trials: Why, How, What?

Clinical Trials

Volunteer Participation
Clinical Trials: Why, How, What?

Clinical Trials are Conducted in Phases

**Phase 1**
- Safety
- Dose of drug
- Signs of activity

**Phase 2**
- Drug activity
- Safety

**Phase 3**
- Compare the new to standard
- Head-to-head comparisons

FDA approval
Looking Out for My Safety

• Information → understanding → Informed Consent
• Voluntary participation: you have the right to leave at any time
• Questions you might ask:
  • What is the purpose of the study?
  • Why is this a good option for me?
  • What are my other options?
  • What are the risks? How are others doing in the study?
  • What is required of me: time and procedures?
Looking Out for My Safety

Independent oversight:

a. Food and Drug Administration (FDA)
b. Institutional Review Board (IRB)
c. Data and Safety Monitoring Board (DSMB)

- More testing than in standard practice
- Close monitoring by your study team
Get to Know Your Team

- Principal Investigator
  - Primarily responsible

- Study coordinator

- Clinical staff

- Research nurse

- Data managers
- Protocol navigators
- Clinical monitors
Can I / Should I Participate?

• Eligibility:
  ✓ disease type
  ✓ need for treatment
  ✓ overall health
  ✓ current medications

• My decision
  ✓ Am I comfortable with my team?
  ✓ Will the study benefit me?
  ✓ Will it benefit others?

80-year-old volunteer: “It’s important to me to participate in clinical trials so that maybe something can be learned or developed.”
Resources to help decide:

• Home oncologist, primary care physician
• Patient organizations
Studies to Generate Knowledge

Vaccination
Recombinant zoster vaccine (RZV)
2 doses: 0 and 3 months

Patients with CLL
• Treatment naïve
  or
• Receiving Bruton tyrosine kinase inhibitor (BTKi)

Antibody response
Cellular response

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<th>BTKi</th>
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P = .0002
P = .0072

Pleyer et al, Blood Adv. 2021
Diversity in Clinical Trials

Participants in clinical trials should represent the patients that will use the medical products. This is often not the case. Racial and ethnic minority groups are underrepresented. This is a concern because people of different ages, races, and ethnicities may react differently to certain medical products.

If you think a clinical trial may be right for you, talk to your health care provider.

https://www.fda.gov/consumers/minority-health-and-health-equity/clinical-trial-diversity
Clinical Trials

- Develop the medicines of tomorrow
- Your safety is priority
- You volunteer based on risks and benefits
- You give informed consent
- You can quit anytime
- Look for resources to help you decide
- Diversity of participants yields equitable health information
Practical Issues for Patients Considering a Clinical Trial

Kaitlin Kennard, BSN, RN
May 16, 2022
Learning Objectives

• Basics
  • Randomization
  • Placebos
  • Blinding

• Close Monitoring
  • Side effects
  • Drug interactions
  • Effectiveness

• Additional Considerations
  • Costs
  • Lifestyle
  • COVID-19
Will I be a guinea pig?

• Are you the first to get a drug?

• Is the drug safe?

• Are you an active participant in decision making?

Unlike a guinea pig you have **autonomy**!
Randomized Trials

- Standard of Care Arm vs. Investigational Arm

- Randomized: You may not get to choose

- Both good options

- Goal is to learn if the investigational drug is better than the standard of care
Placebos & Blinding

What is a Placebo?

- A medication with no therapeutic effect (a sugar pill)
- Rare in clinical trials for cancer
- Cannot be used if there is an effective alternative

What is Blinding?

- Participant does not know which treatment they are receiving
Monitoring
Side Effects

• Known
• Potential
• Unexpected

• Frequency
• Severity
• Treatment
Drug Interactions can increase or decrease the potency of the treatment

Your study team needs to know about…

• Prescription medications
• Over the counter medications
• As needed medications (i.e. Tylenol, Tums, etc.)
• Supplements
• Medical cannabis
• Topicals
Increased Monitoring

Most trials will require more frequent visits and assessments than standard of care treatment

- Provider appointments
- Blood work
- Biopsies (bone marrow & lymph node)
- CT scans or other imaging
Additional Considerations
Costs

• Study drug may be provided for free

• A clinical trial does not pay for everything

Standard of care tests ↓ Billed to insurance or patient
Research-related tests ↓ Paid for by the trial
Lifestyle Considerations

- Is a caregiver required?
- Are there required hospitalizations?
- Are there driving restrictions?
- Dietary restrictions?
- How far are you traveling?
- Will you be able to work?
COVID-19 Considerations

- Vaccines & Evusheld
- Immunosuppression
- COVID treatments
- Treatment Delays
• There are medical, financial, and lifestyle factors to weigh when considering a trial

• Participating in a clinical trial can have significant advantages
  • Access
  • Cost
  • High Quality Care

Thank you to the CLL Society, all of our patients and families, and our clinical trial participants!
Poll Questions
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.

If you’re question was not answered, please feel free to email asktheexpert@cllsociety.org

Join us on June 28th for our upcoming webinar on BTK Inhibitors

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