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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

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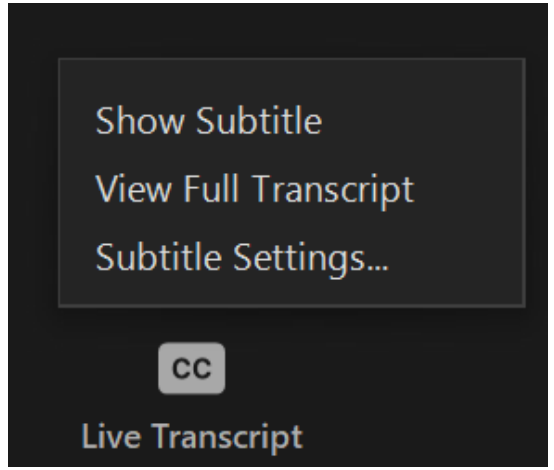
- The audience is muted
- Please direct your questions to CLL Society staff and speakers using the Q&A function (located at the bottom of your screen) at any time throughout the presentation
- Questions can only be seen by staff and speakers. We will do our best to answer as many questions as possible
- Please complete the short survey emailed after the event. Your response will help CLL Society plan future events
- The virtual event is being recorded and will be available on our website
- Closed captions are available. If you want to turn them on or off, go to Live Transcript and Show Subtitle or Hide Subtitle



This program was made possible by grant support from

Speakers

Christina Rodriguez Fuller
CLL Patient Advocate

Adrian Wiestner, MD, PhD
Senior Investigator
Laboratory of Lymphoid Malignancies
National Heart, Lung, and Blood Institute (NHLBI)
National Institutes of Health (NIH)

Kaitlin Kennard, BSN, RN
Clinical Research Nurse
Lymphoma Research Program
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CLL Society Staff

Welcome
Robyn Brumble, MSN, RN
Director of Scientific Affairs and Research
CLL Society

Moderator
Brian Koffman, MDCM (retired) MS Ed
Executive Vice President and Chief Medical Officer
CLL Society

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Poll Questions

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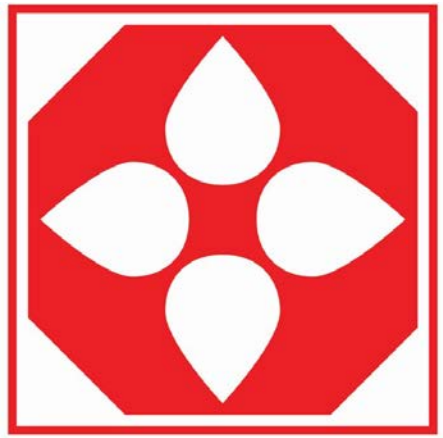

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Clinical Trials Basics

Adrian Wiestner, MD/PhD

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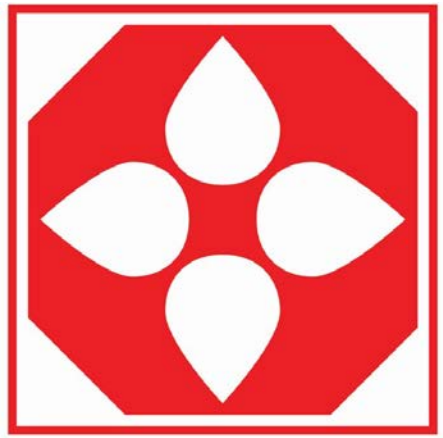

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Learning Objectives

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

The NIH Clinical Center

https://clinicalcenter.nih.gov/

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

Clinical Trials: Why, How, What ?

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Clinical Trials

Volunteer Participation

Clinical Trials: Why, How, What ?

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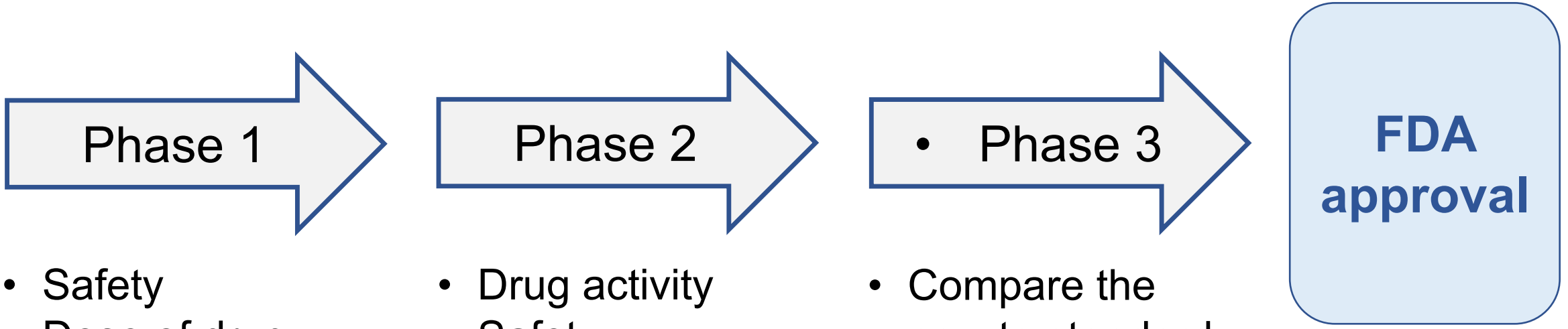
Clinical Trials are Conducted in Phases



- Safety
- Dose of drug
- Signs of activity

- Drug activity
- Safety

- Compare the new to standard
- Head-to-head comparisons

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

Study coordinator

Clinical staff

Principal Investigator - Primarily responsible

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?

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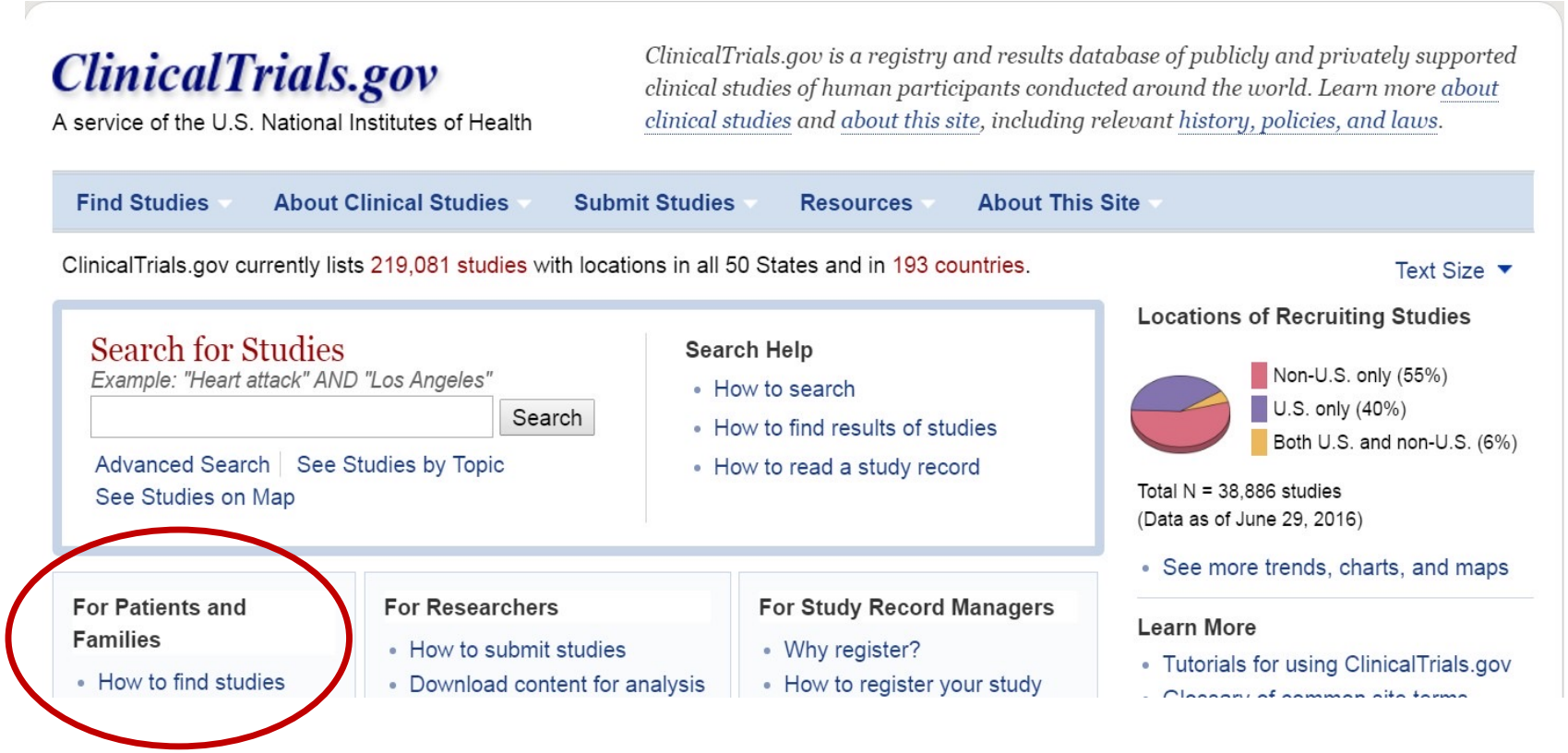
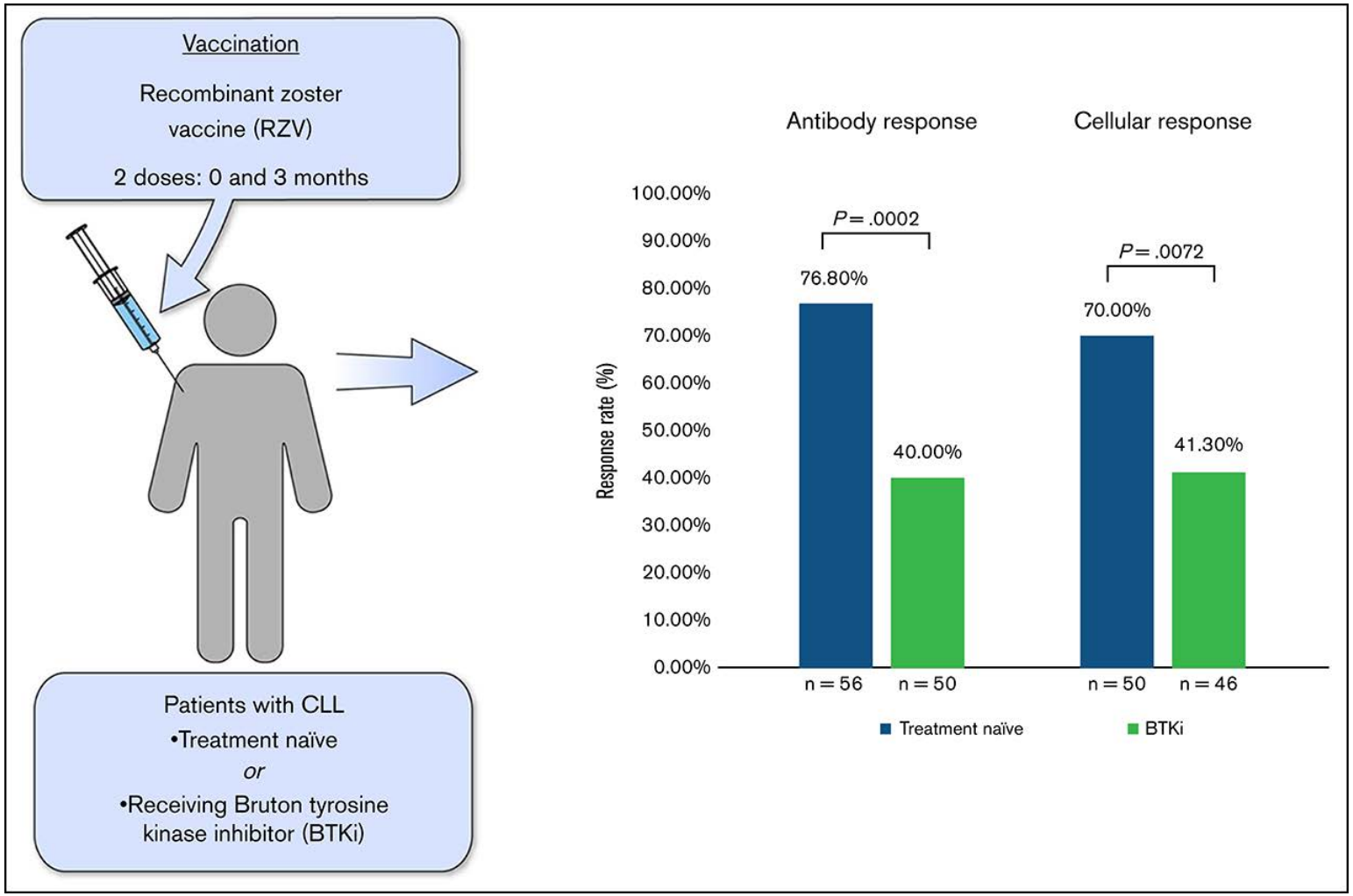
80-year-old volunteer:
“It’s important to me to participate in clinical trials so that maybe something can be learned or developed.”

Resources to help decide:

- Home oncologist, primary care physician
- Patient organizations



Studies to Generate Knowledge



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 under-represented.

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

This is a concern because people of different ages, races, and ethnicities may react differently to certain medical products.

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

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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

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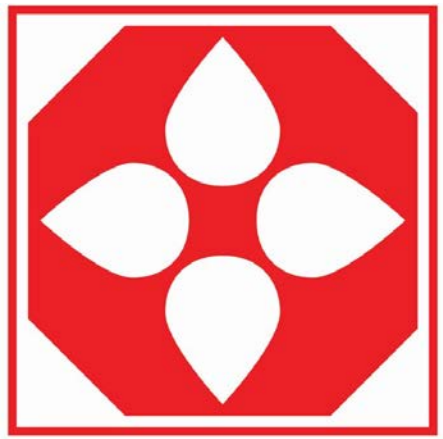
Practical Issues for Patients Considering a Clinical Trial

Kaitlin Kennard, BSN, RN

May 16, 2022



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Learning Objectives

- **Basics**
  - Randomization
  - Placebos
  - Blinding
- **Close Monitoring**
  - Side effects
  - Drug interactions
  - Effectiveness
- **Additional Considerations**
  - Costs
  - Lifestyle
  - COVID-19

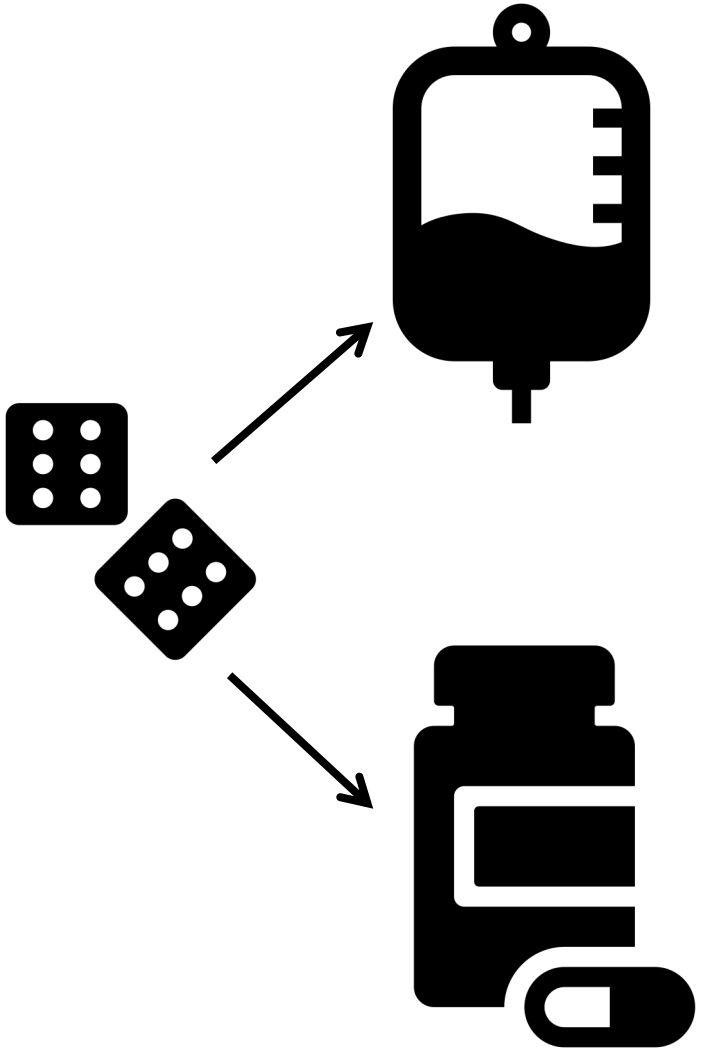
Will I be a guinea pig?

- 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 **<u>autonomy</u>!**

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



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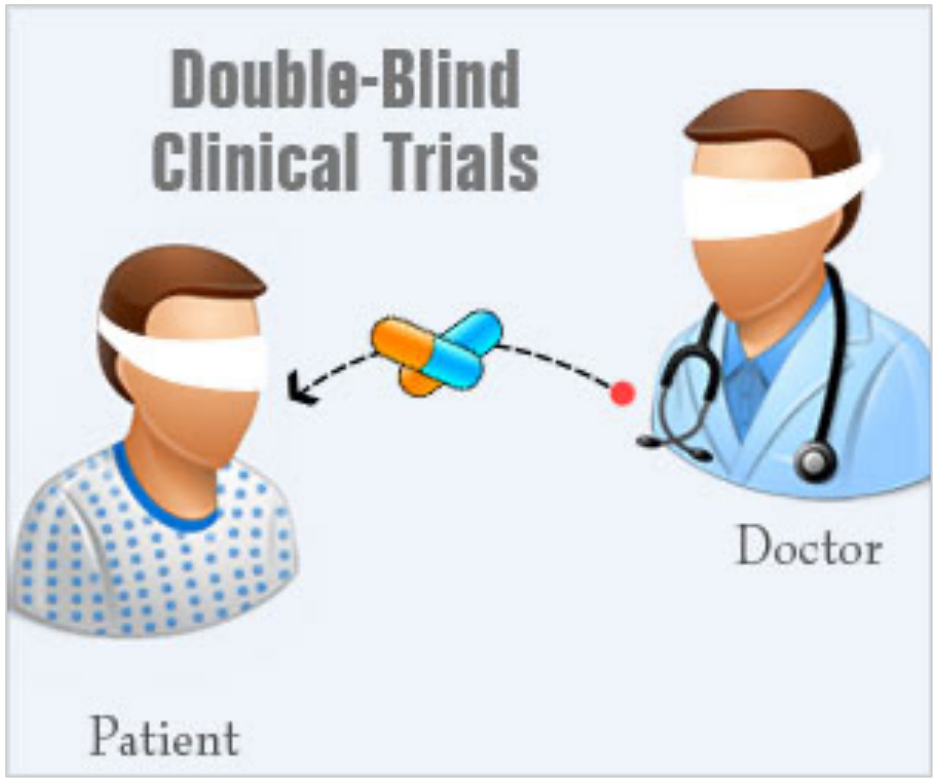
Placebos & Blinding

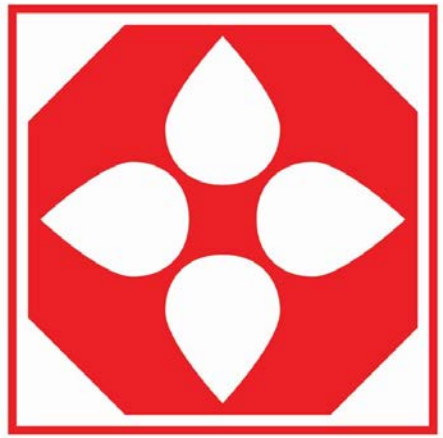


What is a Placebo?

- 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



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Monitoring

Side Effects

- Known
- Frequency

- Potential
- Severity

- Unexpected
- Treatment

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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

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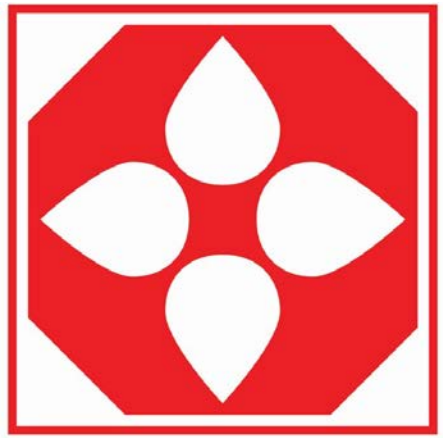
Provider appointments

Blood work

Biopsies (bone marrow & lymph node)

CT scans or other imaging



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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?

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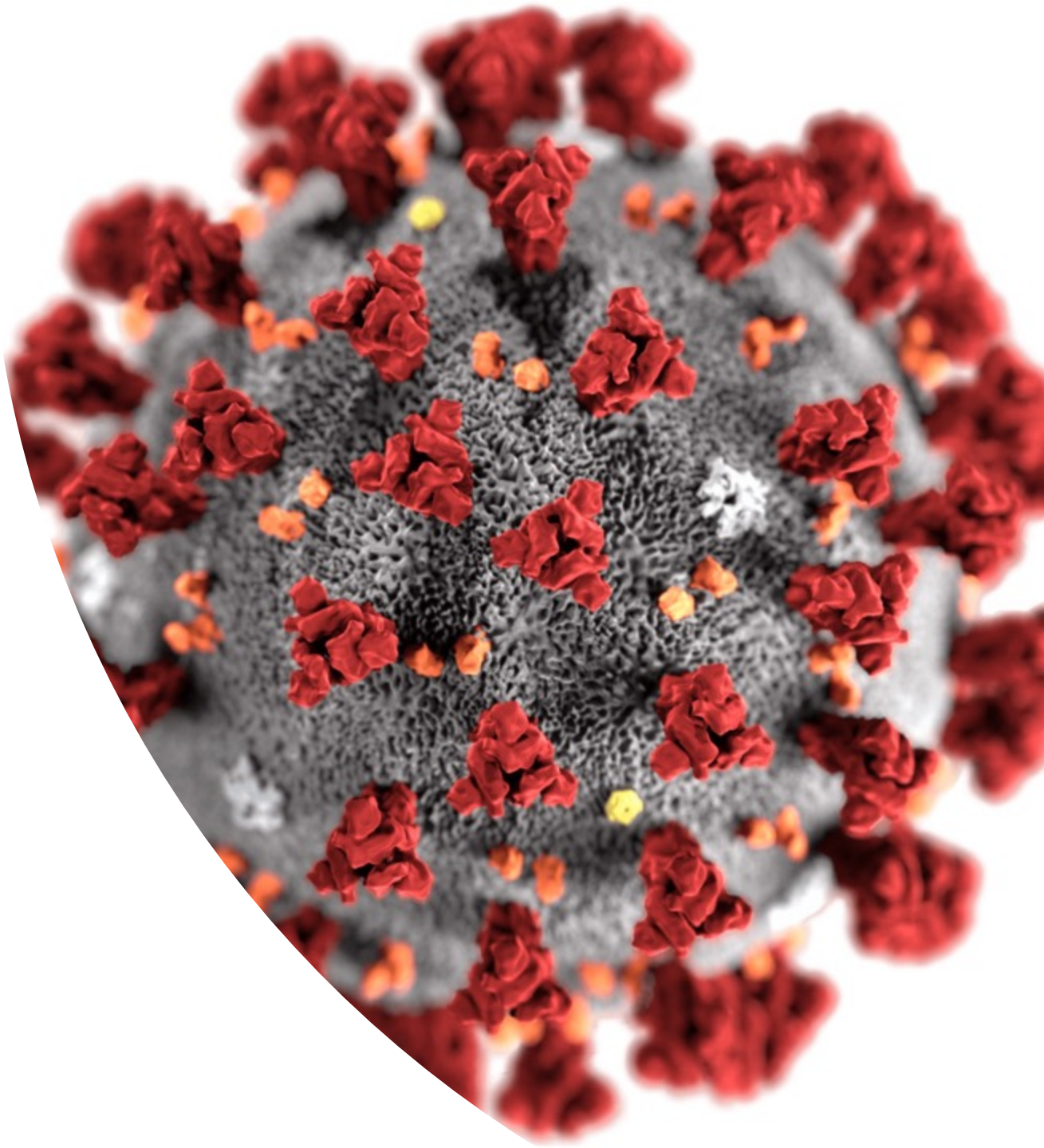
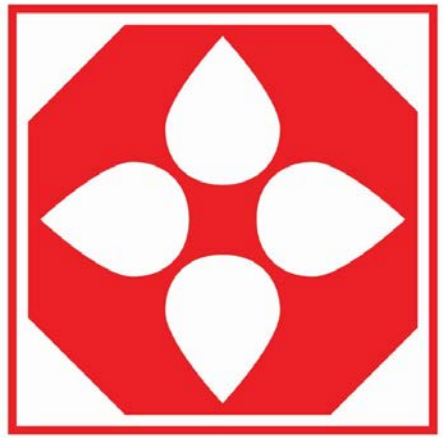
COVID-19 Considerations

- Vaccines & Evusheld
- Immunosuppression
- COVID treatments
- Treatment Delays





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Take Home

- 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

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Audience Questions & Answers

This program was made possible by grant support from

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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