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CANCER TREATMENT

How to Make Informed Choices about Standard Care and Clinical Trials

In this program you will learn

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- How to gather information to help you make treatment decisions
- Questions to ask about the benefits and risks of any treatment
- How new blood cancer treatments are developed
- Myths and facts about clinical trials
- How to locate clinical trials that may be right for you
- How LLS can help

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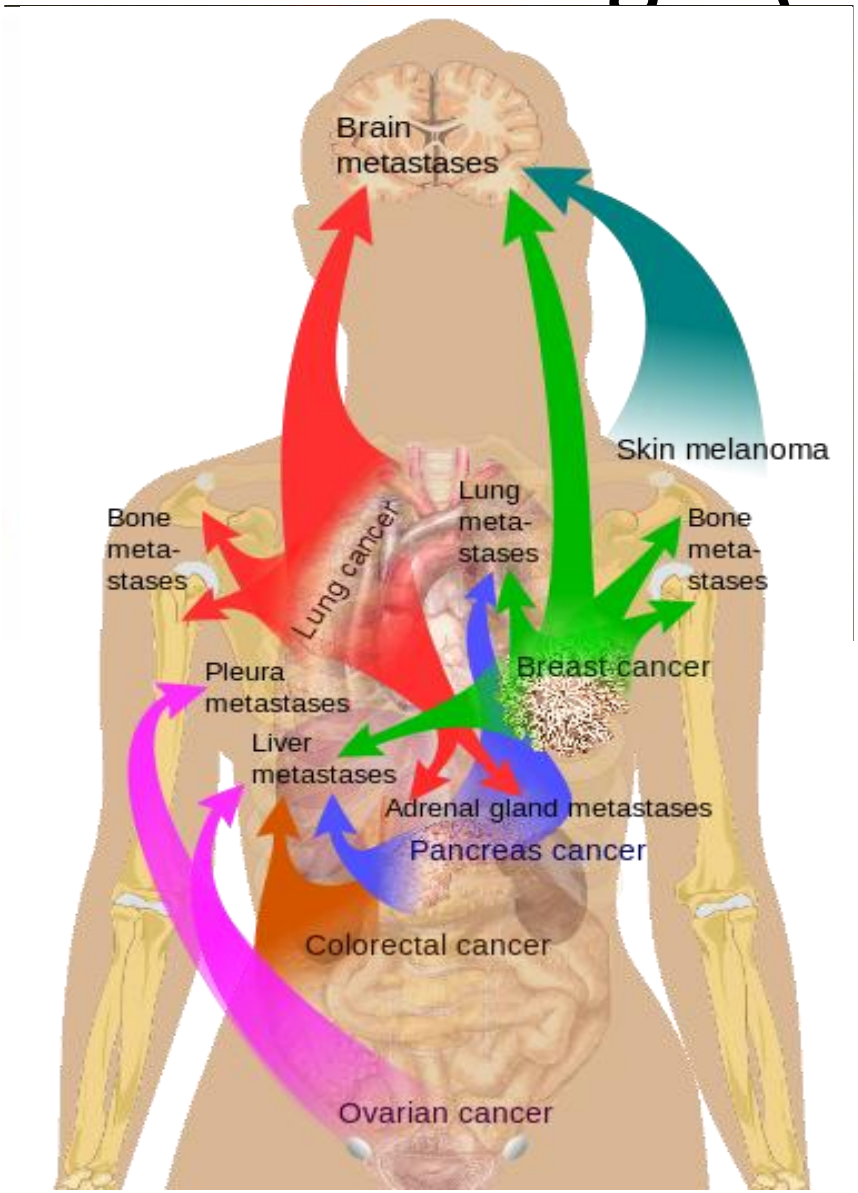
Northern Ohio

Blood Cancer Conference

Saturday October 3, 2015

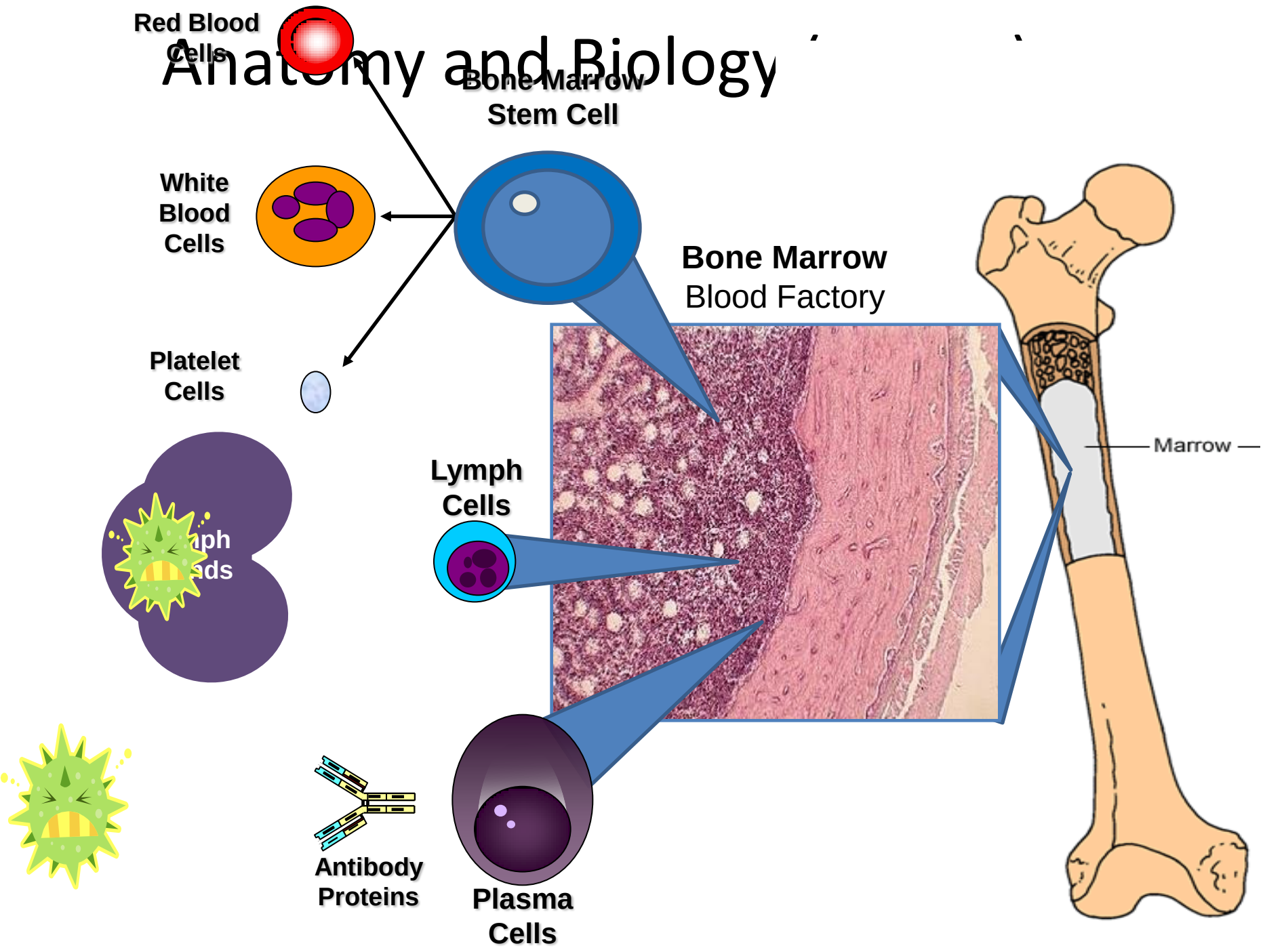
Definitions: what is a hematologic (Blood) caner?

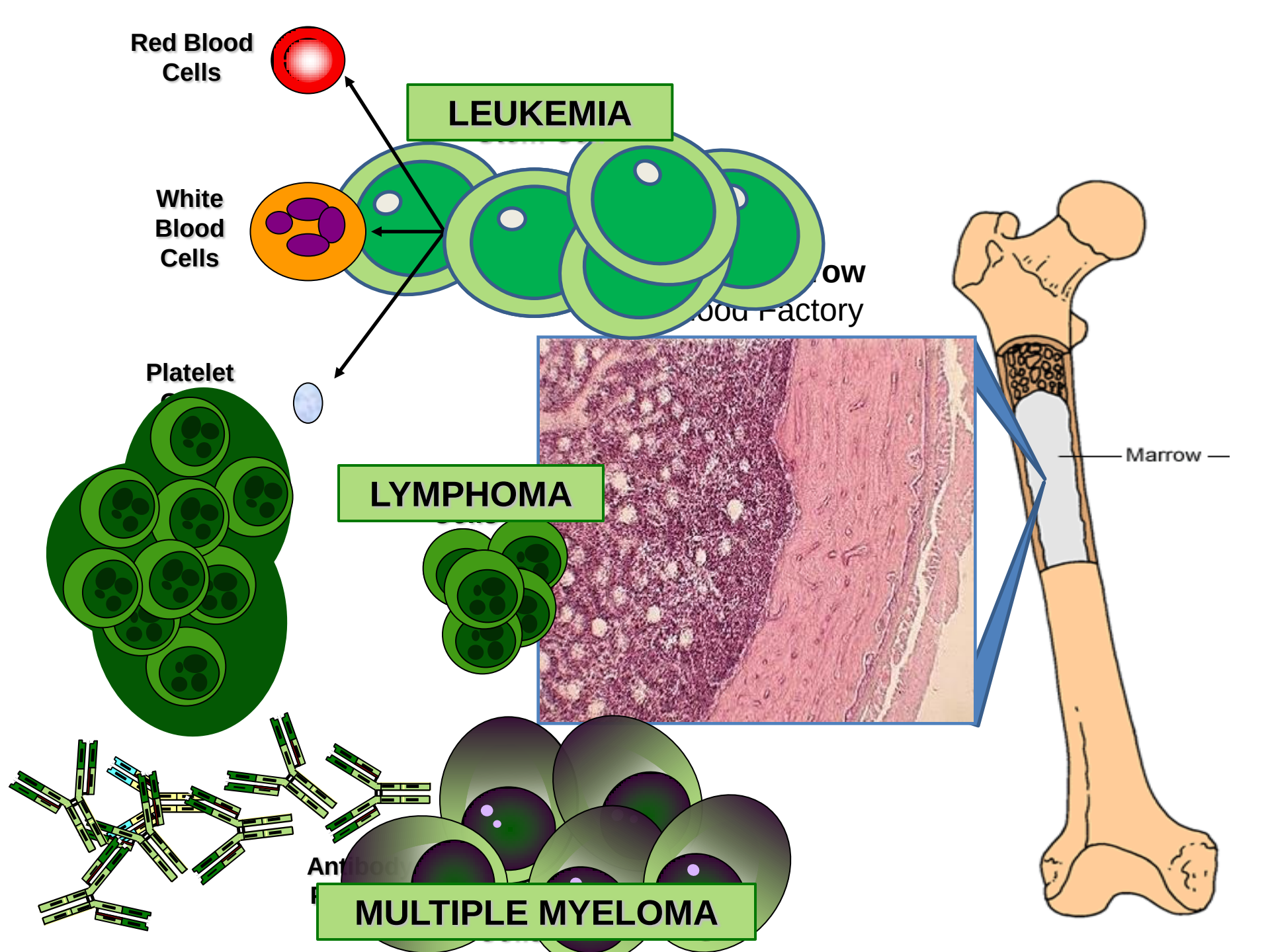


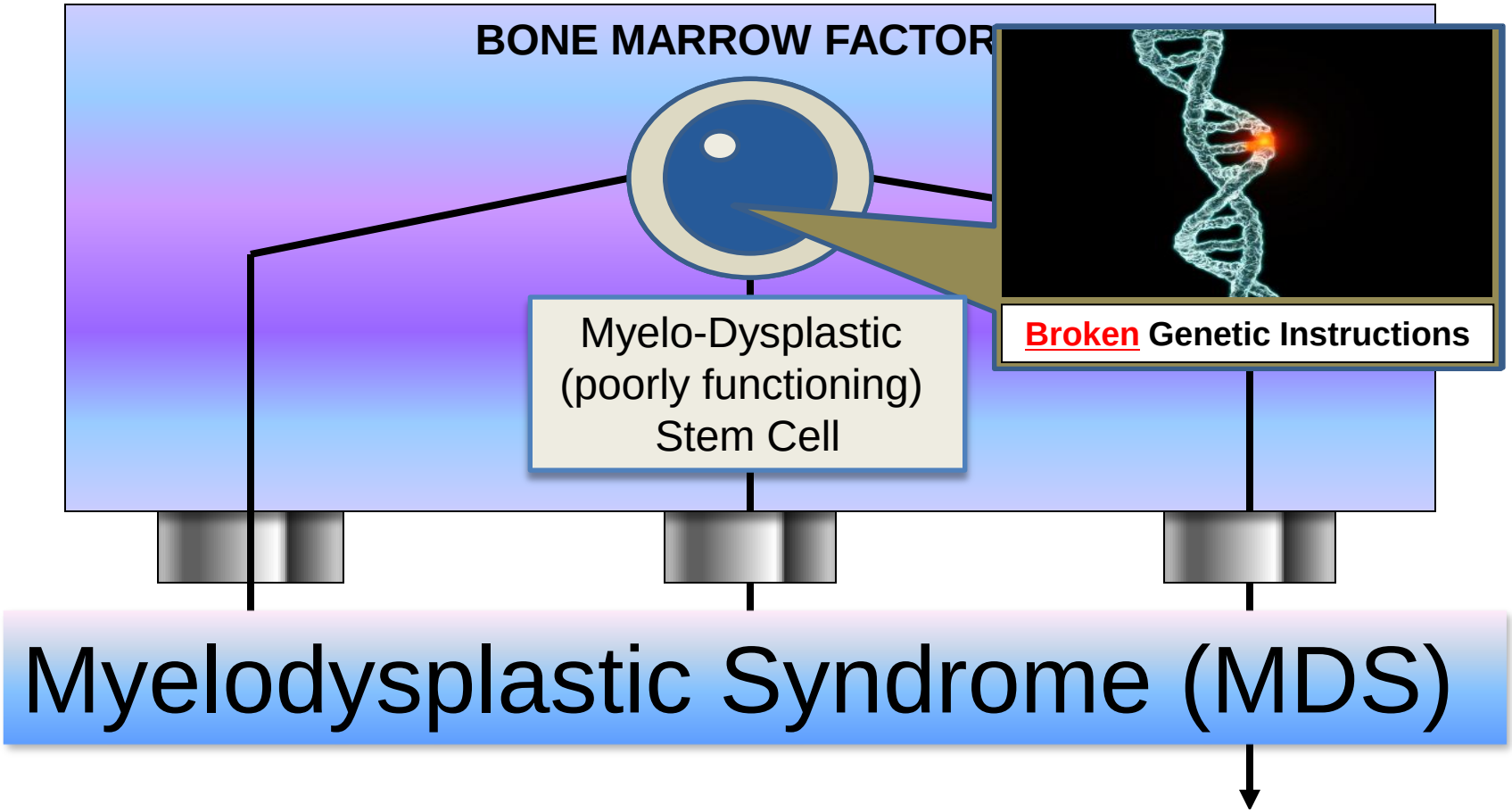
- Is it "bone cancer"?
  - **NO**
  - Bone cancer is a very rare cancer of the bone called **Sarcoma**.
- Is it "cancer that has gone to the bones?"
  - **NO**
  - Other cancers that have gone to the bone are called **"Metastatic cancer to the bone"**.
- Is it "cancer of the blood cells produced by the marrow inside the bone?"

YES

Anatomy and Biology




Red Blood Cells
LEUKEMIA
White Blood Cells
Platelet
LYMPHOMA
Marrow
MULTIPLE MYELOMA



Dysplastic Red Blood Cells

Dysplastic White Blood Cells

Dysplastic Platelets

The Common Blood Cancers

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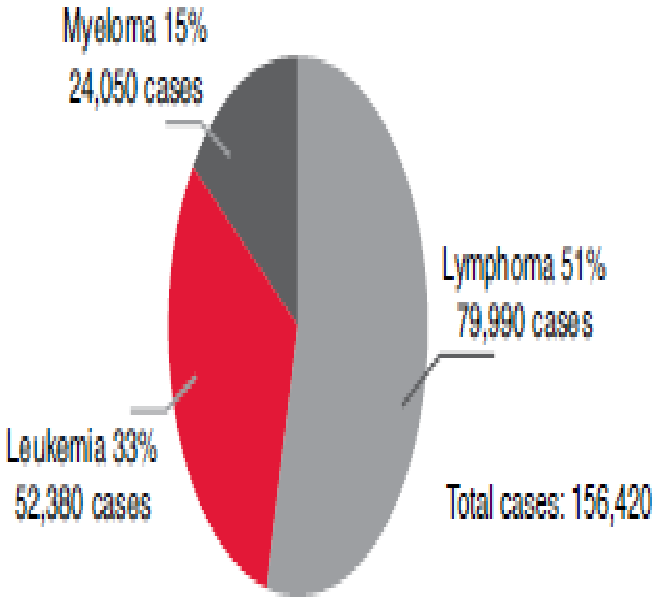
- A total of 156,420 people in the US were diagnosed with leukemia, lymphoma or myeloma in 2014.
- Every 3 minutes one person in the US is diagnosed with a blood cancer.
- Over 1 million people in the US are living with, or are in remission from, leukemia, lymphoma or myeloma.

Estimated New Cases of Leukemia, Lymphoma, and Myeloma, 2014*



- In general, the likelihood of dying from most types of leukemia, lymphoma or myeloma decreased from 2000 to 2010 (the most recent data available).

State Incidence rates: New Patients

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Estimated New Cases of Blood Cancers by Site, by State, 2013				
State	Leukemia	Non-Hodgkin Lymphoma	Myeloma	Hodgkin Lymphoma
United States	48,610	69,740	22,350	9,290
Michigan	1,750	2,530	770	320
Ohio	1,770	2,840	820	380
Illinois	2,020	2,840	930	400
Wisconsin	1,050	1,400	430	180

Improved Survival

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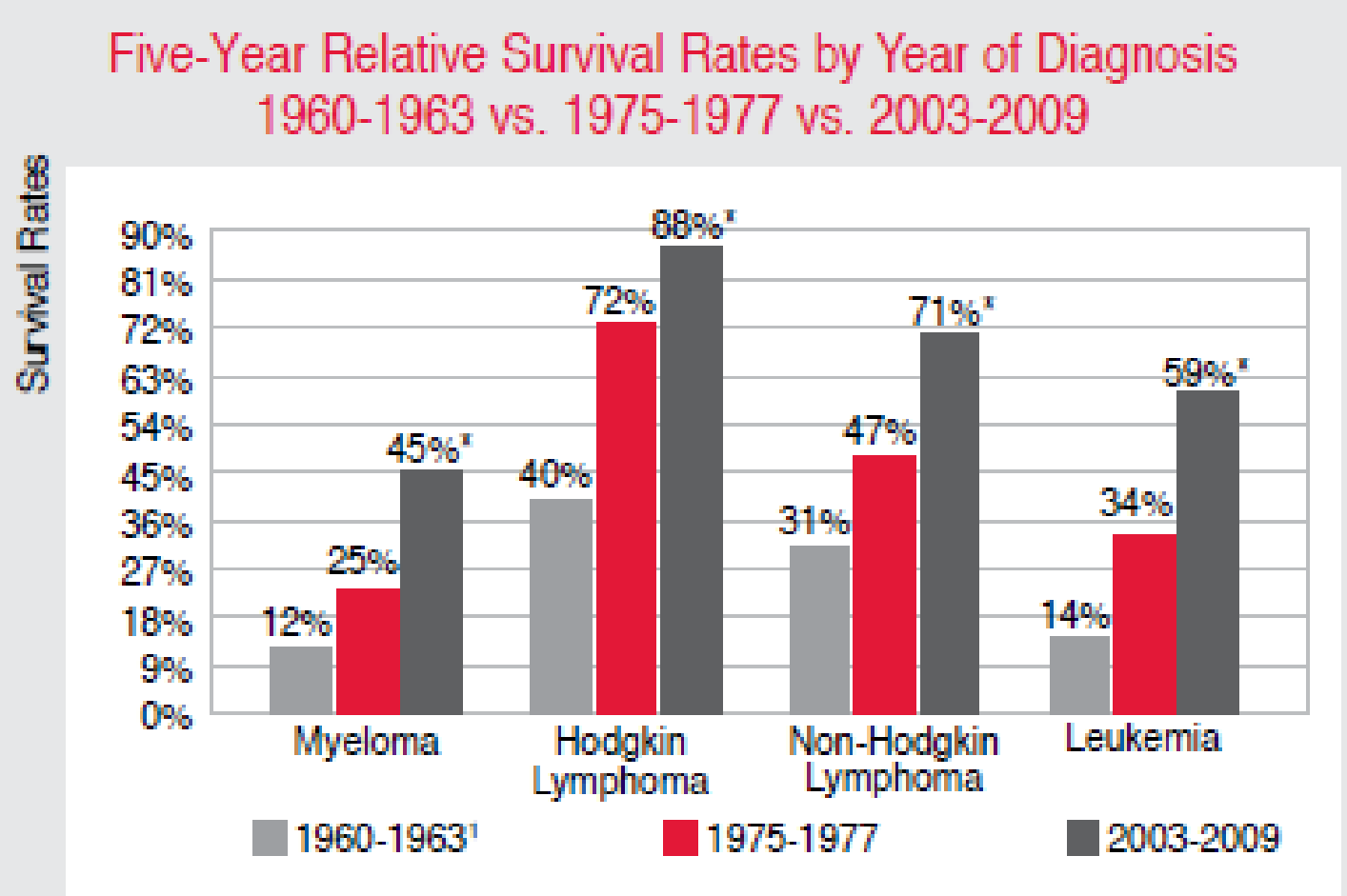

Figure 1. Source: *SEER (Surveillance, Epidemiology and End Results) Cancer Statistics Review, 1975-2010*. National Cancer Institute; 2013.

Steps to make an informed treatment decision

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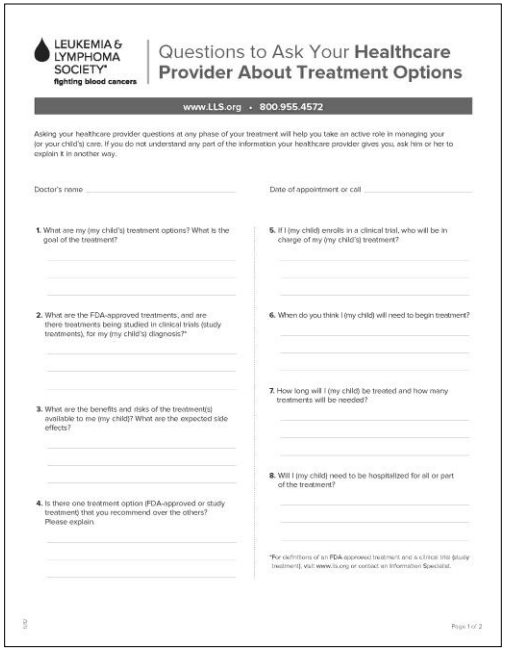
Diagnosis and Treatment

- **Ask your doctor for your specific diagnosis and write it down**
  - **Your specific diagnosis is important in determining treatment**
- Gather information about all your treatment options
  - Ask your doctor to explain the treatment options

•Refer to *Questions to Ask Your Healthcare Provider About Treatment Options* when you meet with your doctor - www.LLS.org/whattoask



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Questions to Ask Your **Healthcare Provider About Treatment Options**

www.LLS.org • 800.955.4572

Asking your healthcare provider questions at any phase of your treatment will help you take an active role in managing your (or your child's) care. If you do not understand any part of the information your healthcare provider gives you, ask him or her to explain it in another way.

Doctor's name _____ Date of appointment or call _____

1. What are my (my child's) treatment options? What is the goal of the treatment?

2. What are the FDA-approved treatments, and are there treatments being studied in clinical trials (study treatments), for my (my child's) diagnosis?*

3. What are the benefits and risks of the treatment(s) available to me (my child)? What are the expected side effects?

4. Is there one treatment option (FDA-approved or study treatment) that you recommend over the others? Please explain

5. If I (my child) enrolls in a clinical trial, who will be in charge of my (my child's) treatment?

6. When do you think I (my child) will need to begin treatment?

7. How long will I (my child) be treated and how many treatments will be needed?

8. Will I (my child) need to be hospitalized for all or part of the treatment?

*For definitions of an FDA-approved treatment and a clinical trial (study treatment), visit www.lls.org or contact an Information Specialist.

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Steps to make an informed treatment decision

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- **Ask your doctor**
  - What is the goal of treatment?
  - Is my cancer curable?
  - What are the options for my treatment?

- **Ask yourself**
  - What are my personal goals for treatment?
    - Your goals are an important part of your treatment decision process.
  - Do I have the information I need to make an informed decision?

Take an active role in making treatment decisions for yourself

Steps to make an informed treatment decision

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Ask Questions, Seek a Second Opinion

- Bring a family member, friend or other advocate to take notes and for support
- Ask who on the cancer care team can answer additional or follow up questions
- Seek a second opinion for diagnosis and/or treatment

Personal Medical Records

- Establish a file and keep it with you for reference
  - Specific diagnosis, including the subtype
  - Laboratory reports
  - Radiology reports
  - Current medications you are taking (including vitamin supplements)
  - Past and current treatments you have had for cancer
  - Medical history
  - List of your healthcare providers and contact information/business cards

Standard Treatment

- A “standard treatment” is the most widely accepted treatment for a specific diagnosis
  - The “standard” is based on information gathered by clinical trial research done previously
  - The National Comprehensive Cancer Network (NCCN) guidelines serves as a database for the standard of care for many types of cancer (nccn.org)
  - For some blood cancers, the standard treatment may only be somewhat effective
    - In these instances, you may want to consider a clinical trial

Clinical Trials

- Cancer clinical trials are
  - Carefully controlled research studies
  - Conducted by doctors to improve the care and treatment of cancer patients
- The aim of a clinical trial is to
  - Study a new therapy or a new use for an already approved therapy
  - Compare a new treatment with a standard treatment to find out which one works better and/or has fewer side effects

Steps to make an informed treatment decision

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Clinical Trials

- Ask about therapies being studied in a clinical trial
  - Ask if a clinical trial might be right for you
  - Ask about benefits and risks of both standard treatment and treatment in the clinical trial and how they differ
- Ask about side effects of each treatment option and how these will be managed
- Consent forms are written documents that have all of the information of a clinical trial written down for patients to review

Having more information will help you make decisions and manage challenges

Clinical trial study design or protocol

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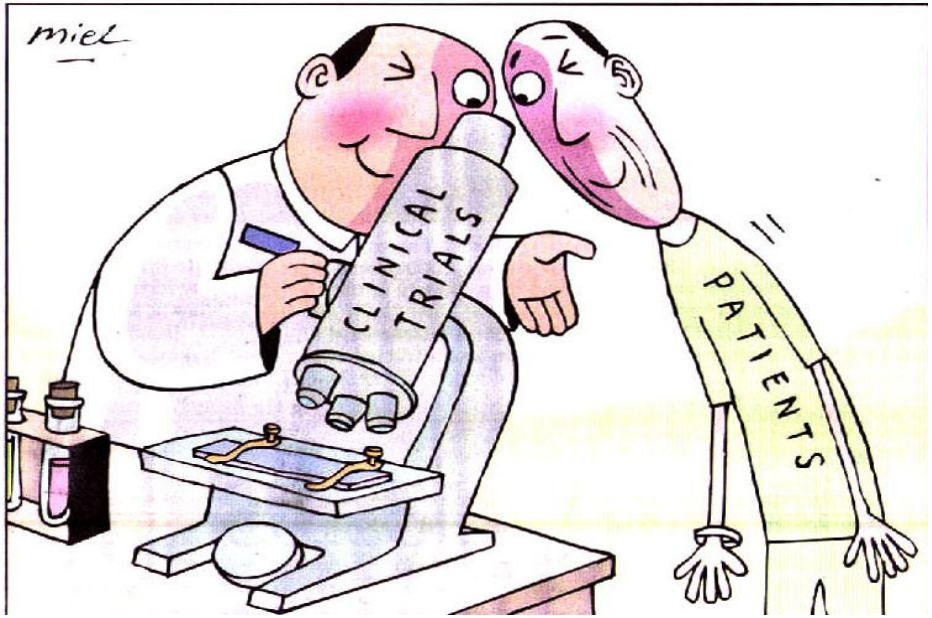
- **Each cancer clinical trial has a written detailed study design called a *protocol* that includes:**
  - Why the clinical trial is needed
  - Purpose of the clinical trial
  - What drug or drug(s) are being tested, with a treatment and follow-up schedule
  - Safety measures throughout the clinical trial program
  - How outcomes will be measured
  - Who is eligible for the clinical trial
  - How the clinical trial will be organized, one site or multiple sites
    - If the clinical trial is a multi-site trial, all participating physicians must follow the same protocol

Where does the standard of care come from?

Clinical Trials!



How Medical Care Advances:

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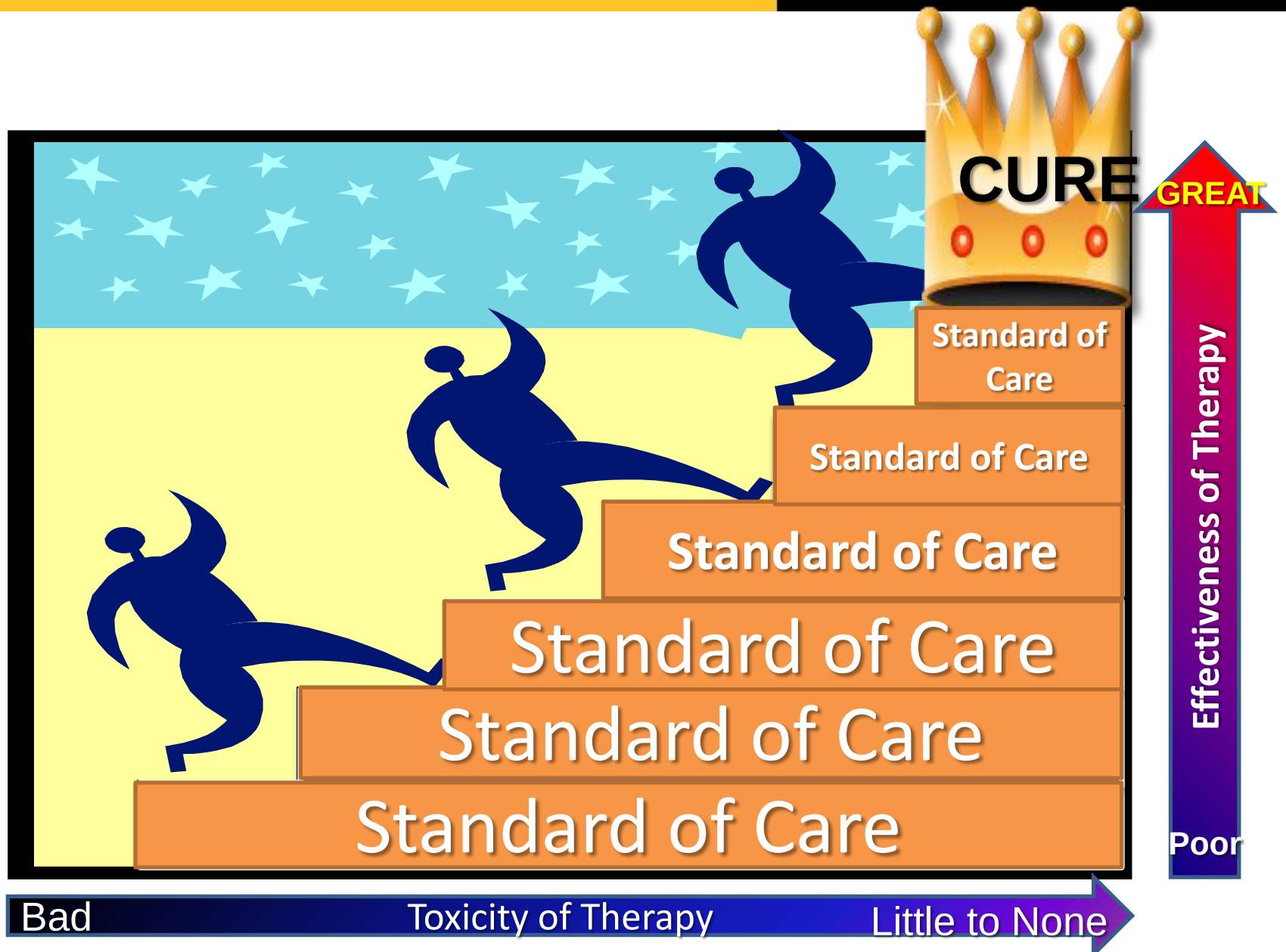

Clinical trials:
A key step in drug development

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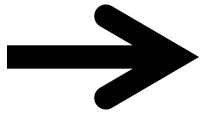
Initial development of new drug in lab



Drug studied in lab and animals

Food and Drug Administration (FDA) approves the new drug for human clinical trials

The drug can now be studied in people in carefully controlled clinical trials

Types of clinical trials

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Phase 1: **investigates for *safety and side effects*, dosage and best way to give treatment–includes 20 or more people**

Phase 2: **determines *effectiveness* and safety–typically includes fewer than 100 (may include up to 300) people**

Phase 3: **looks at effectiveness, side effects and safety *in comparison with other standard treatments*–includes 100s to 1000s of people**

Drug receives FDA approval, it's available to everyone, and it might become standard practice

Phase 4: **gathers more information after FDA approval**

Randomized clinical trials (Phase 3): Getting assigned to a group

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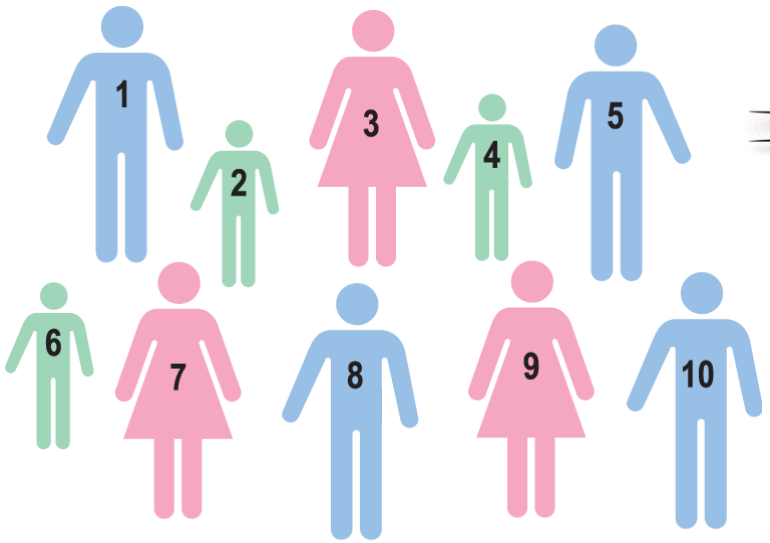
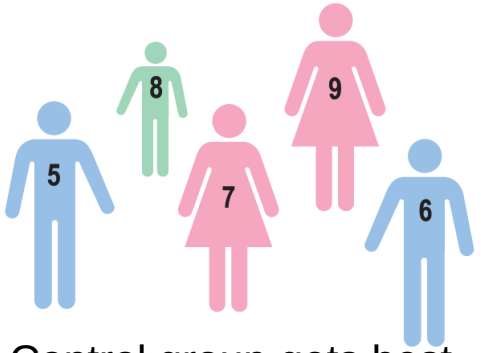
Many cancer clinical trials are “randomized” to enable doctors to compare **new treatments** with **standard treatments**.

Patients are divided into different groups at random:

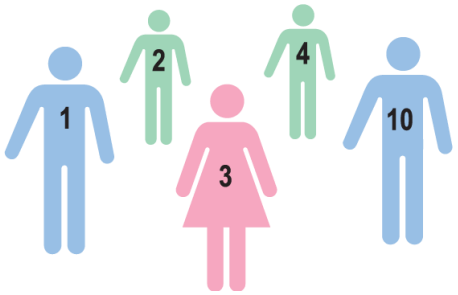
- “**Control group” receives the best standard treatment available**
- **“Treatment group” receives the treatment under study**



Randomization



Control group gets best available treatment



Investigational or study group gets study drug

Increasing Number of Clinical Trials

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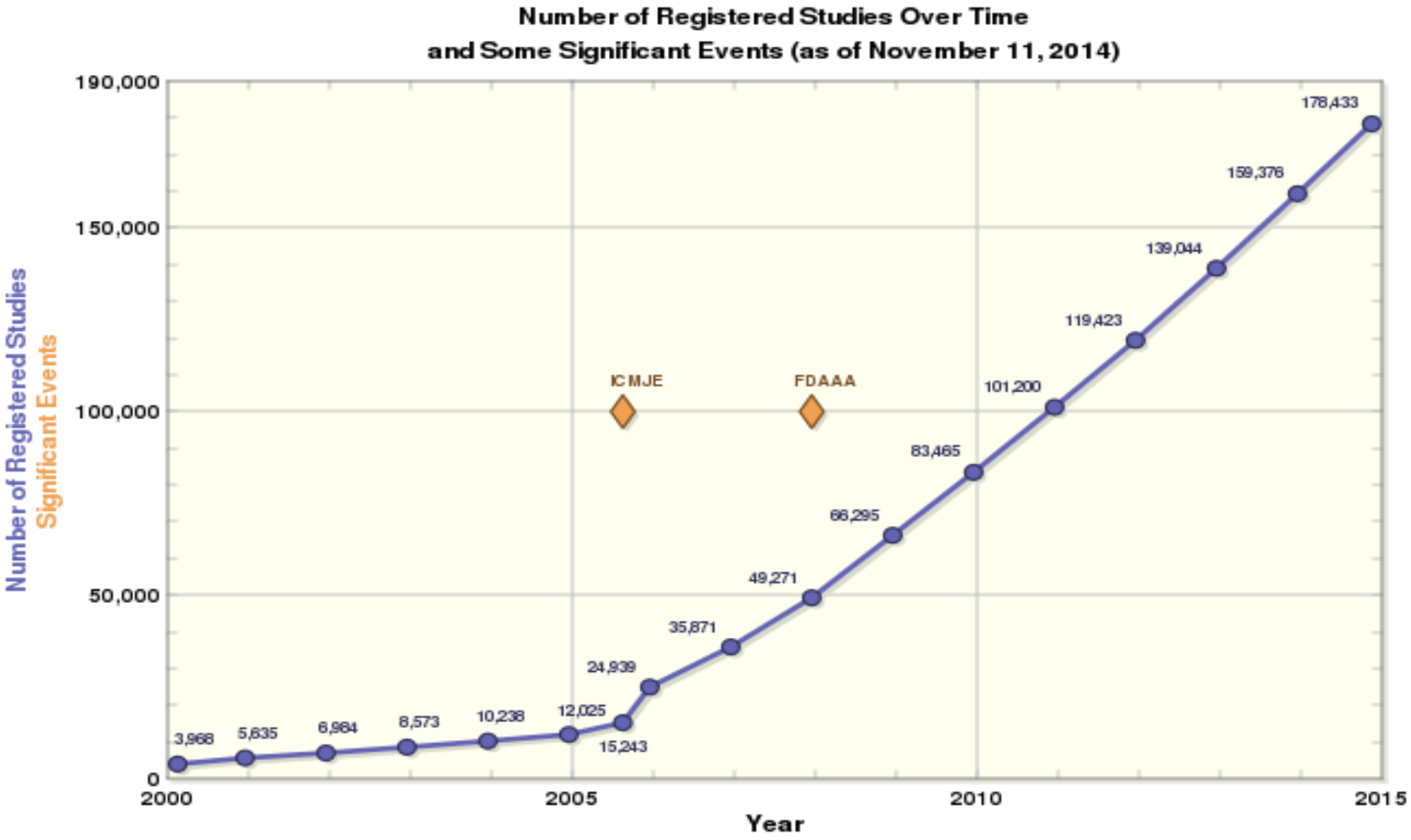

Source: http://ClinicalTrials.gov

Have all the clinical trials *REALLY* done *anything, for anyone????*

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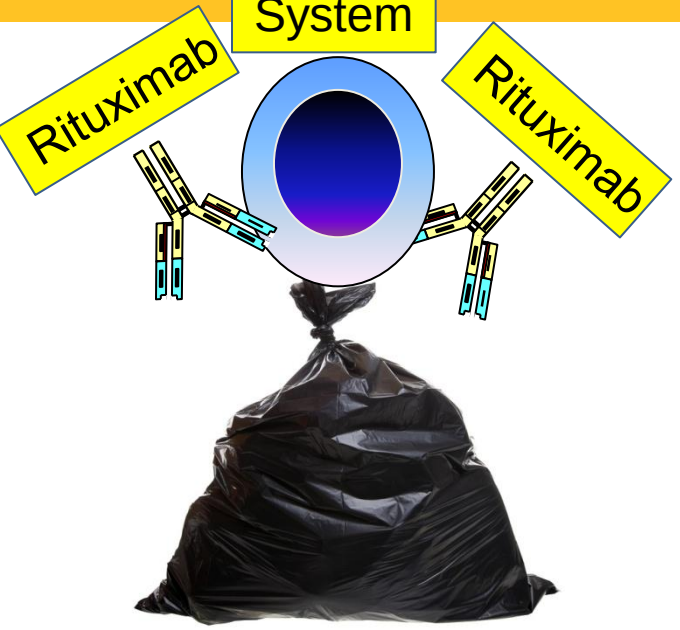
What do Clinical Trials do? **SAVE LIVES**

Lympho ituxan® (Rituximab)



No LYMPHOMA Cell

Rituximab added to CHOP chemotherapy:
80% Complete Responses

2011 ~600,000 NHL or CLL Survivors

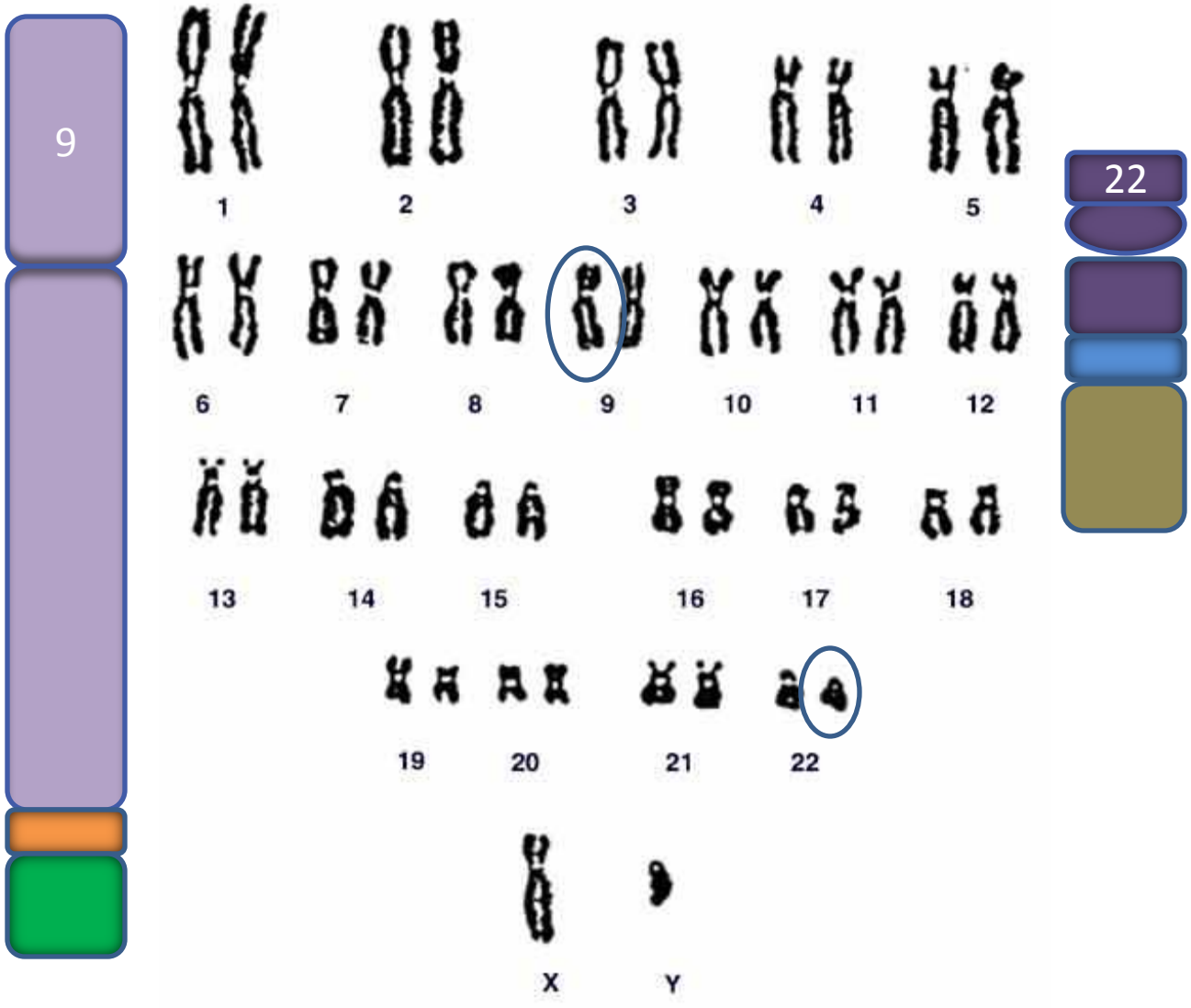
1996
Phase III Multicenter Study Initiated
~166 Patients Enrolled

1993
Phase II Trial Initiated
~37 Patients Enrolled

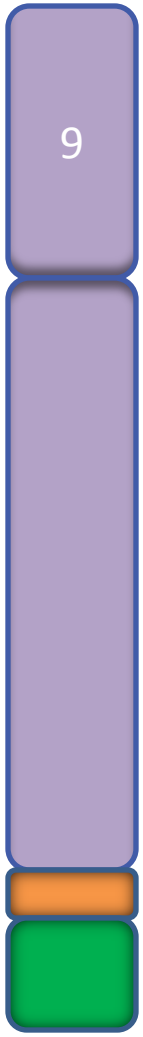
1993
Phase 1 Trial Initiated
~20 Patients Enrolled

1991
First anti-CD20 Antibodies Produced

Standard of care in the 1980's was chemotherapy (CHOP) alone
Complete Responses in only 40%



Your cells each contain 23 pairs of chromosomes that are made of DNA and hold the instructions for every cell in your body.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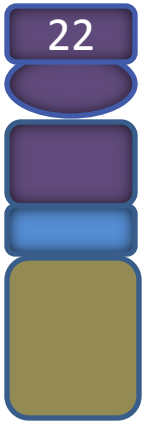
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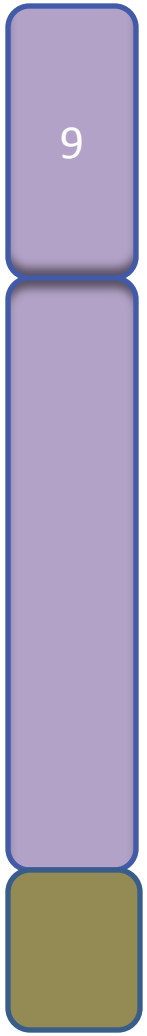
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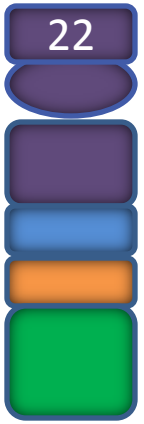
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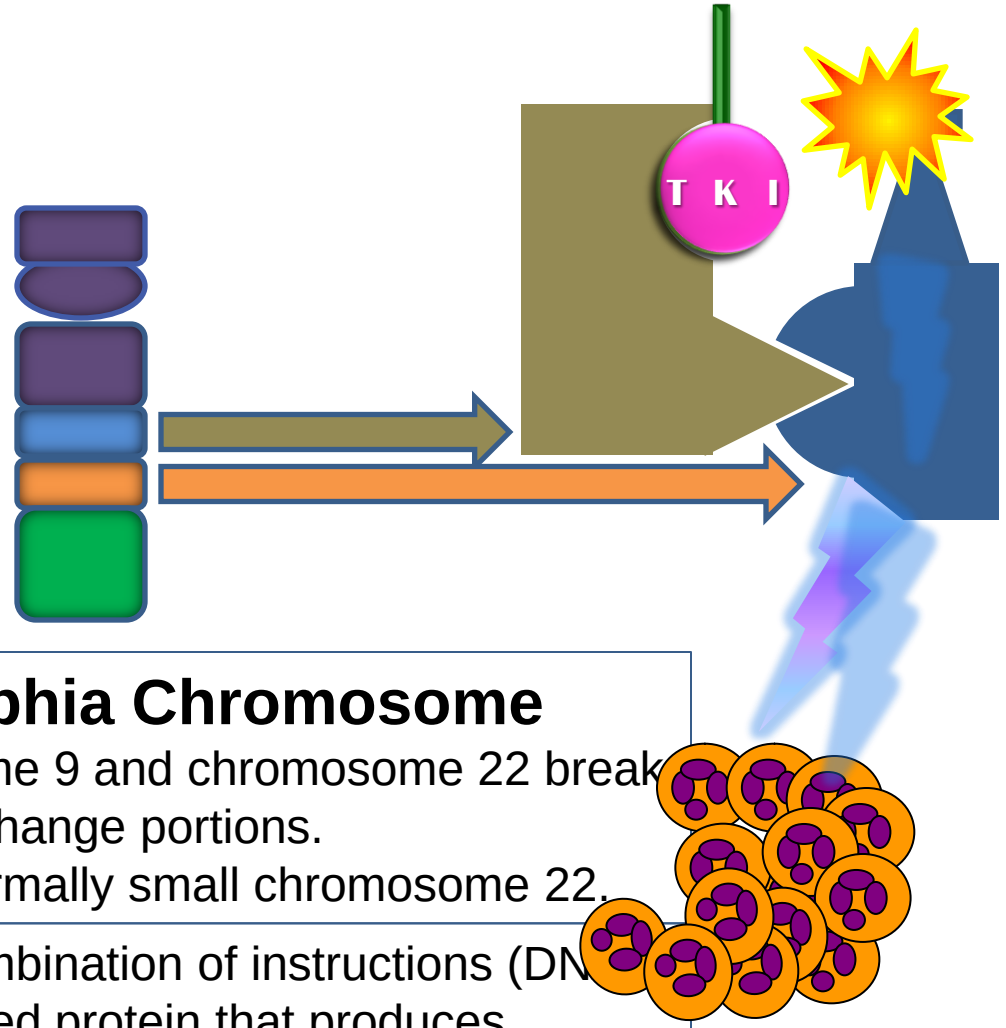

The Philadelphia Chromosome

Forms when chromosome 9 and chromosome 22 break and exchange portions.
This creates an abnormally small chromosome 22.

The new (mutated) combination of instructions (DN
lead to an mutated protein that produces
chronic myelogenous leukemia (CML).

What do Clinical Trials do? **SAVE LIVES**
CML: Gleevec (Imatinib mesylate)

5 years post-diagnosis **over 90%** of patients are surviving!

2011 ~26,000 Living with CML

2001
Gleevec receives FDA Approval (1230 total patients)

1999
Phase 2 Trials Initiated ~1100 Patients Enrolled

1998
Phase 1 Trial Initiated ~100 Patients Enrolled

1993
Gleevec First Synthesized

Standard of care in the 1990's donor stem cell transplant
8 years post-diagnosis, fewer than 20% of patients were surviving

What do Clinical Trials do? **SAVE LIVES**
Multiple Myeloma

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# Study Pts	Regimen	Major Response	All Reponses
?	Leeches	0%	0%
344	Melphalan Prednisone (MP)	4%	35%
242	Vincristine Adriamycin Dex (VAD)	6%	63%
99	Thalidomide + Dex	4%	63%
240	Bortezomib + Dex	37%	78%
34	Lenalidomide + Dex	47%	94%
107	Melphalan Prednisone Thalidomide	21%	62%
42	Bortezomib+ Lenalid+Dex	21%	98%
63	Bortezomib+Cytoxan+Dex	67%	90%
53	Carfilzomib+ Lenalid+Dex	78%	98%
34	Carfilzomib+ Cytoxan+ Dex	74%	100%

What do Clinical Trials do? **SAVE LIVES**
Multiple Myeloma

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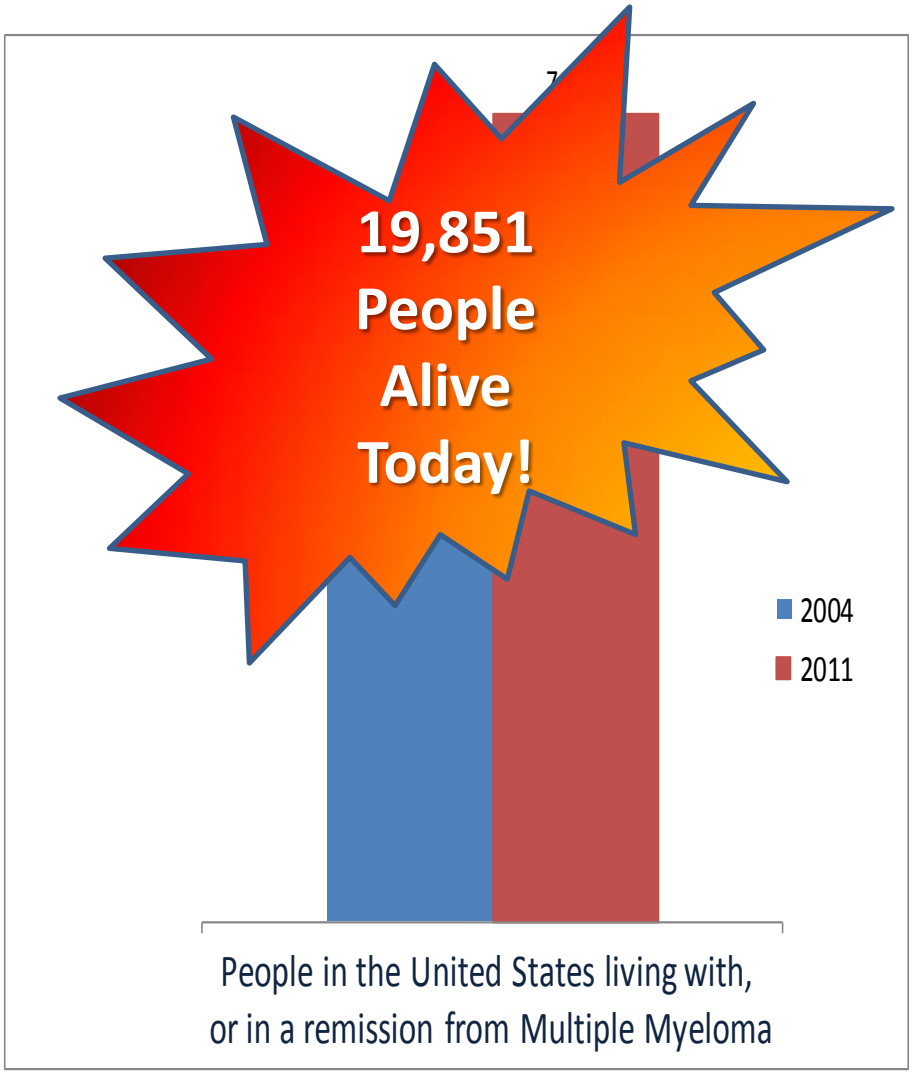
- Myeloma patients diagnosed in the past 10 years have had a **50%** improvement in overall survival.
- Due to the introduction of novel therapies and the use of stem cell transplant.
- **The yearly survival for new patients diagnosed with myeloma are continuing to improve in a non- linear fashion!**




FACT
OR
MYTH
?

What do you think?

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If I enter a clinical trial, there's a good chance that I could receive a placebo

Fact or Myth

Fact: Placebos are rarely used in cancer clinical trials

What do you think?

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A clinical trial is a treatment of last resort

Fact or Myth

Fact: There are clinical trials for people at every stage of disease

What do you think?

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**If I enter a clinical trial,
I'll be a "guinea pig"**

Fact or Myth

Fact: Clinical trials provide patients either the best treatment currently available, or a new and possibly more effective therapy

Clinical trial protocols ensure that patients are closely monitored

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- Patients get a lot of attention and support
- Patients are watched closely by their doctor, as well as other members of their medical team, to ensure their safety

Safety in clinical trials

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- **Sponsor asks outside experts to review merit of study**

- **Institutional Review Board (committee of experts)**
  - Looks at trial's scientific, legal and ethical merit
  - Are risks minimized and reasonable vs. anticipated benefits?
  - Is informed consent process in place and documented? (no coercion or "undue" influence to participate)
  - Does data monitoring include patient safety data?
  - Is there a process to protect privacy of patients?

Safety in clinical trials

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- **Your doctor and the study team must explain**
  - The goals
  - Potential benefits and risks
  - What is expected of you
  - Medical tests you will need

Process of informed consent

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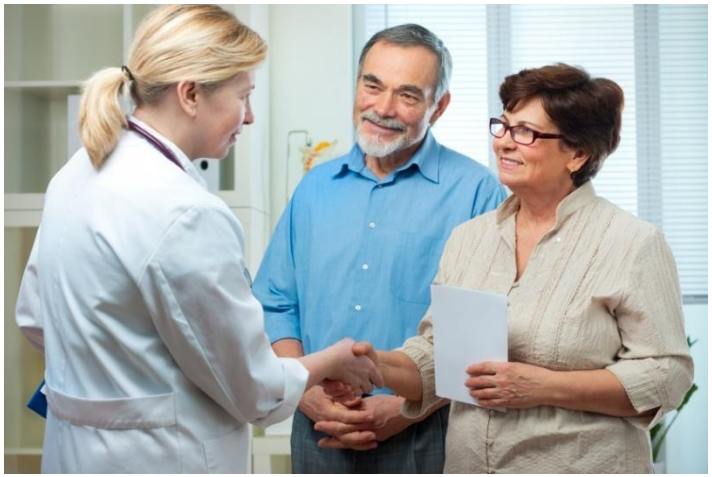
- Your doctor must give you an informed consent document before you enroll in a clinical trial
  - Must be in a language you understand
  - Ask for a language interpreter if needed



- **Bring an advocate**
- **Ask your doctor to explain anything you don't understand**

Take your time in reading and signing the informed consent form. You may take back your consent to participate at any time.

Healthcare coverage and clinical trials

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- **It is important to find out what will be covered**
  - Some costs may be covered by the sponsor of the study
  - Other costs may be covered by your health insurance plan
- **Costs usually covered by the sponsor at no cost to the patient**
  - Research doctor and nurse time
  - Cost of drug being studied
- **Costs that may not be covered by your private or public health insurance** (costs you may incur with standard treatment or in a clinical trial)
  - Hospitalizations
  - Doctor visits
  - Laboratory tests
  - Drugs not part of the study design
  - Transportation
  - Lodging
  - Meals
- **You may be eligible for assistance from supportive organizations**
  - Contact an LLS Information Specialist for financial assistance resources (e.g., LLS *Co-pay Assistance Program*).

Insurance and financial assistance for standard treatment and clinical trials

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- If you have health insurance, ask your insurance company if they can provide a case manager to work with you on benefit coverage
- If the treatment is not covered by insurance, find out if your treatment center can work with you to access financial assistance
- **Talk to a social worker for other possible assistance**
- Call an LLS Information Specialist at 800-955-4572 who will answer your questions and provide more information
- Review the LLS website at www.LLS.org/finances for information on financial support

Talk to your doctor

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Talk to your doctor about all of your treatment options–
Standard treatment or clinical trials

Ask as many questions as you have, until the answers are clear to you

Clinical trials

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- Are an important option for **everyone**
- Can be for people newly diagnosed, with limited disease or advanced disease
- Are appropriate for people of different age, gender, and race, depending on the purpose and phase of the study
- Take into account all the above factors as well as stage of disease, other treatments used and presence of any other illness

Remember…communication with your healthcare team is important in making treatment decisions about standard treatment or clinical trial treatment

Recap

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- **Before making any treatment decisions, ask questions and gather information**
  - The more information you have, the easier it will be to make decisions and manage challenges

- **Potential benefits of participation in clinical trials**
  - Receive, at minimum, the best treatment available
  - Be among the first to benefit from a new treatment
  - Receive a lot of attention and support, including close monitoring to ensure safety
  - Have access to doctors with extensive experience in the type of cancer you have

Where to learn more

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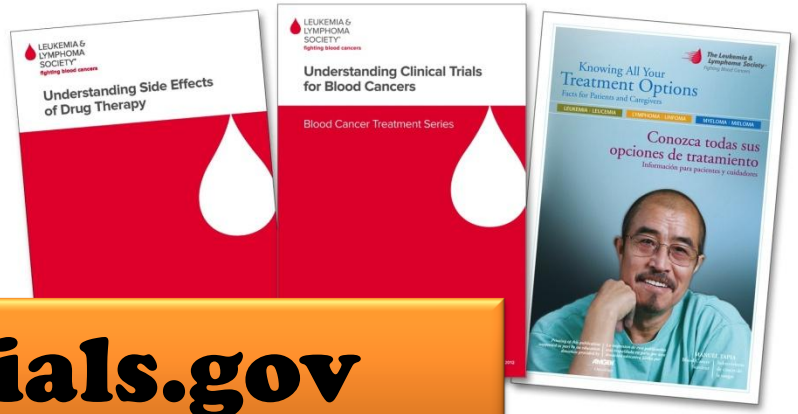
- **If your doctor does not bring up clinical trials as a treatment option, don't hesitate to ask**
- Speak with an LLS Information Specialist to find clinical trials near you
- Refer to LLS booklets and listen to telephone/web education programs on your diagnosis and emerging therapies



ClinicalTrials.gov

Check out these LLS resources

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- www.LLS.org
- Publications www.LLS.org/resourcecenter
- Upcoming telephone/web education programs www.LLS.org/programs
- Past telephone/web education programs www.LLS.org/pastprograms
- Webcasts www.LLS.org/webcasts
- Information Specialists infocenter@LLS.org
- Professionally facilitated *Family Support Groups* www.LLS.org/supportgroups
- Professionally moderated online Chats www.LLS.org/chat
- Peer-to-peer support www.LLS.org/firstconnection
- Financial assistance www.LLS.org/finances
- Your local chapter

For information and to order materials, contact an LLS Information Specialist at (800) 955-4572 or visit www.LLS.org

LLS Support

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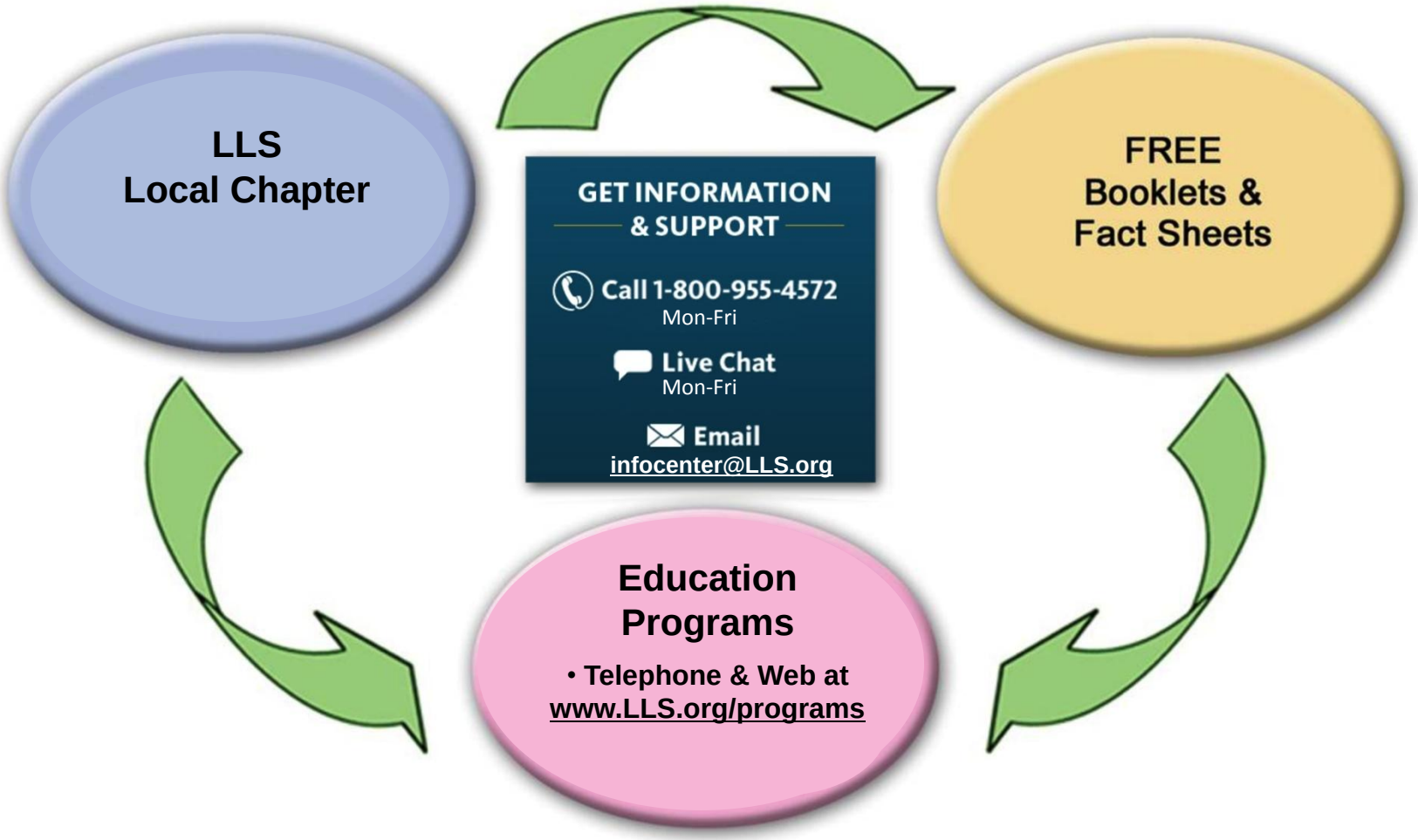

Time for your questions!