The Jackson Laboratory
Leading the search for tomorrow's cures

THE JACKSON LABORATORY OPEN HOUSE

Welcome to the Clinical Research Team!

In our collaborative study on cancer genomics, we will investigate treatments for melanoma cancer using human tumors and mouse models. On this team, you are stepping into the role of a clinical researcher and will use specific skills and training to recruit patients to our study. Before we dive into our research, let's first explore careers in clinical research and learn about what clinical researchers do to contribute to a project like this one.

Careers in Clinical Research

We are the clinical research team for this project. You are now a member of a collaborative group of professionals who work directly or indirectly with patients.

Here's an example of a real clinical research team: there's a study coordinator, a medical doctor, and a laboratory technician.

1. The **study coordinator** manages the research study. They help to identify which people should participate in the study. They have a bachelor's degree and could have advanced degrees or certificates to gain expertise and responsibilities in their career.
2. The **medical doctor** in this case is an oncologist. They evaluate the health of the patients and lead medical care and treatments. They have a bachelor's degree and a medical degree, plus specific training in their specialty field of cancer called oncology.
3. The **laboratory technician** works with the samples collected from the people participating in the study. They perform lab tests and experiments. They often have an associate's degree and could have advanced degrees or certificates to gain expertise and responsibilities in their career.

As you can see the clinical research team relies on people with all kinds of training and experiences. You can explore these careers further with the resources on our Virtual Open House website.

Your Role as a Clinical Researcher

As clinical researchers, an important first part of your team's job is to find an eligible group of patients to participate in clinical research for an experimental melanoma treatment (see **Figure 1**).

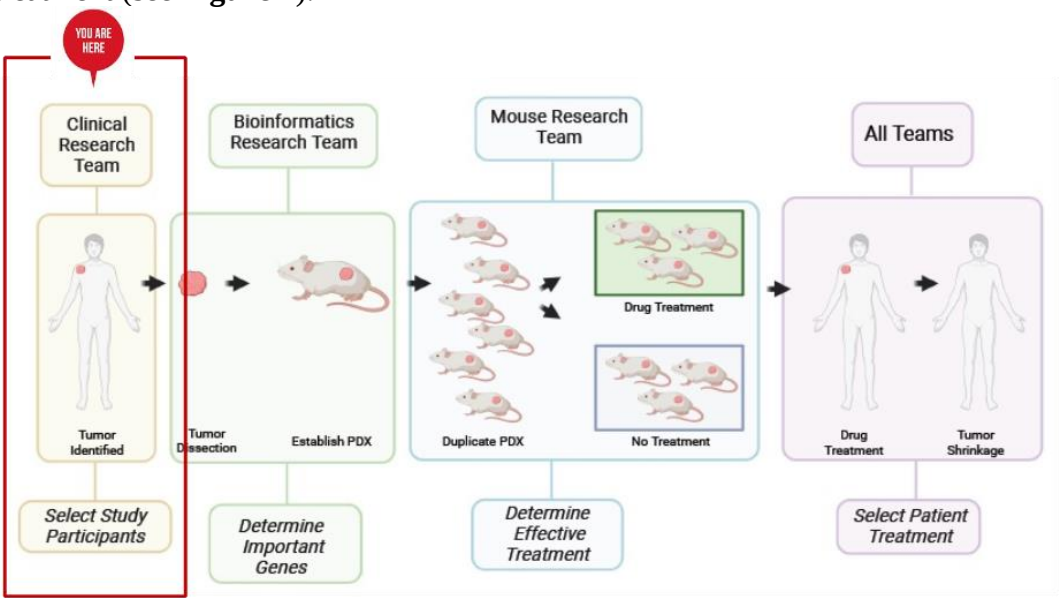


Figure 1. The clinical research team finds eligible patients to participate in the study. In collaboration with the mouse and bioinformatics research teams, the clinical research team plays an important role in this cancer genomics study identifying and recruiting specific patients to participate in the research project.

Normally, this medical team would recruit patients directly from a hospital or clinic. For the purposes of our exercise today we will use data from an online database to select eligible patients. You will work to select the eligible patients for our study based on specific criteria, including type of cancer, patient biological sex, patient age, and tumor type.

Clinical Research Activity

For this lab, use the **Activity Spreadsheet** to keep track of your work and document your findings. If you have already completed another lab, you can continue to use the same spreadsheet for this portion.

We will now go through the steps to identify patients that meet the criteria for our research study. Use your spreadsheet to keep track of your work. We will be working in the "Clinical" tab.

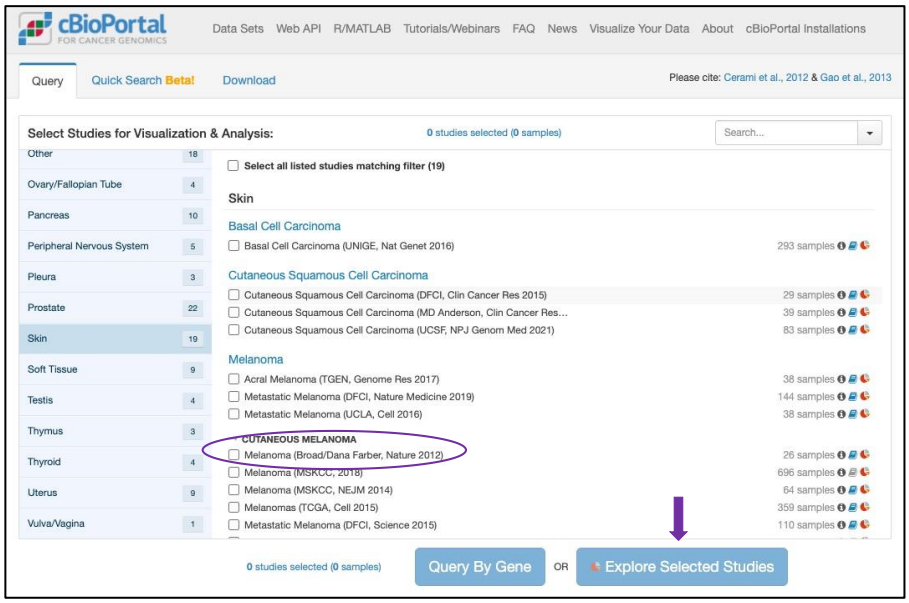
Part 1. Navigating to cBioPortal and Finding Our Study

1. In order to start our clinical research, we first need to locate patients with skin cancer to participate in the study. To do this, we need to navigate to a useful cancer database called the cBioPortal.

2. Once you open this link, you are on the main page of the cBioPortal database. If you scroll down the center box, you will see a very long list. This is a list of studies covering many different types of cancers. The cBioPortal houses a lot of useful information within each of these studies, including data about patients and their cancers, such as the genetics of patients' tumors and patient responses to different treatments.

3. We are interested in skin cancer, so we will navigate to the skin cancer studies. In the menu on the left, click on "Skin."

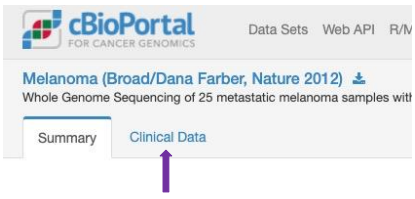
4. In the center box, find the study directly under "Cutaneous Melanoma" called "Melanoma (Broad/Dana Farber, Nature 2012)." To access this study, click the box next to the study and then click the blue button "Explore the Selected Study" or you can also directly access the study using this link.



5. On the main page of the study, you can see a lot of information presented as graphs and tables. There is information about each of the 25 patients that are part of this study, including demographic data such as the age of diagnosis, biological sex, and likely exposure to the sun.

Part 2. Navigating to Clinical Data Tab

6. Click on the tab "Clinical Data" to reveal a list of all the patients.



Part 3. Identify Eligible Patients for Our Study

7. Your task now is to use this list to identify 10 patients who qualify for the clinical study we will conduct. We want to enroll:
    - *Five women and five men*
    - *Individuals who are <60 years of age*
    - *Individuals who have a "pathological primary tumor stage" of "T3, NOS"*

8. Once you identify a qualifying patient, you need to record some demographic and clinical information about the patient in your spreadsheet, including patient ID number, sex, diagnosis age, mutation count, and primary tumor site.

Conclusions

Now that we have identified ten patients based on our study criteria, we can make some predictions about the results of our study. Our clinical trial will test two different drugs that have been shown to reduce tumor size in some mice in pre-clinical trials.

- Looking at the data you have on your patients, what factors might influence how the patients respond to the two treatments?
- What information about (a) the patients and (b) the drugs might help you make a more informed prediction? How might you get this information?

Awesome work! Our clinical team really made a lot of research progress. We also learned the types of jobs we could have on clinical research teams, which encompass a range of different educational paths and skills. We also learned how to recruit patients for a research study and learned how to navigate a real cancer database, the cBioPortal.

Reminder: Don't forget to check out the conclusions tab of your spreadsheet! Once you complete all three lab segments, you can see a summary of your combined work.

Extension into Ethics

Is working with humans unique? Are there any special considerations when doing research on humans? Can we do any study we want, any time?

Human subject research is very powerful and important. But can be risky to participants if not done properly. There are ethical standards that guide research practices to make sure the studies are performed responsibly, and the person's privacy and safety are upheld.

We'll introduce three case studies about human clinical research. What would you do in these scenarios?

Here is a link to an article about clinical research ethics:
Guiding Principles for Ethical Research (NIH)

Case study 1: Omar the medical scribe

Omar is a medical scribe at a local hospital, working to document doctors' notes during visits with patients in the Oncology department. During lunch one day, his friend Lisa talks about a research study her team is about to begin to test a promising new drug therapy on tumor biopsies taken from melanoma patients. Omar remembers that one of the patients he visited earlier in the day has melanoma and is eligible to participate in Lisa's research study. Omar decides to enroll the patient right away.

Questions to Consider:

- What do you think about Omar's decision to enroll the patient?
- Is it helpful or harmful to the patients, to include them in the research study?
- Thinking about Omar's action, what would you do similarly, or differently?
- Put yourself in the shoes of the patient, what would you want Omar to do?
- What ethics guidelines should be followed in this case, if any?

Case study 2: Boshen the genomic technologist

Boshen is a genomic technologist at a biotech company, working to analyze human samples for genetic mutations. Boshen receives a shipment of 12 patient blood samples from a clinic and is tasked with isolating DNA from the samples. As they examine each tube in the shipment, they see that the tubes are all labeled with each patient's full name and date of birth. Before beginning their lab work, Boshen creates a table to reassign each sample a new label: they record the patient information and reassign each one a number 1-12. Boshen then continues their experiment, labeling each tube with the new numerical code.

Questions to Consider:

- What do you think about Boshen's decision to anonymize the samples?
- Is it helpful or harmful to the patients, to include keep their information private?
- Thinking about Boshen's action, what would you do similarly, or differently?
- Put yourself in the shoes of the patients, what would you want Boshen to do?
- What ethics guidelines should be followed in this case, if any?

Case study 3: Adrienne the cancer patient

Adrienne is a patient with melanoma cancer. During a routine checkup at the clinic, her doctor tells her about his latest research study. She has a lot of questions about the details of the study, but the doctor must see another patient and doesn't have time to discuss the study with her. The doctor assures her she is eligible, and the study will have great benefit to her. Adrienne signs the documents to participate in the study even though she doesn't fully understand what the study will entail.

Questions to Consider:

- What do you think about Adrienne's decision to enroll in the study?
- Is it helpful or harmful to her to enroll?
- Thinking about Adrienne's action, what would you do similarly, or differently?
- Does the doctor have a special responsibility here?
- What ethics guidelines should be followed in this case, if any?