

# MANAGING AND MONITORING Ph+ CML.

“It’s really important  
for me to find out if  
my disease is under  
control.”

Daniela, actual patient.  
Read her story on page 8.

# UNDERSTANDING Ph+ CML AND YOUR RESULTS.

When you find out that you have Philadelphia chromosome–positive chronic myeloid leukemia (Ph+ CML), it can be overwhelming. All kinds of questions come to mind. Especially when you hear the word “leukemia.”

Thankfully, Ph+ CML has become more manageable over the years with the help of medication. Of course, your doctor plays a key role in your treatment—and so do you.

**This guide is designed to help you do your part in managing Ph+ CML.**  
**You’ll learn about:**

- The basics of Ph+ CML
- The importance of taking your medication as prescribed
- The role of blood tests in tracking your progress
- The goals, or treatment milestones, your doctor may discuss with you

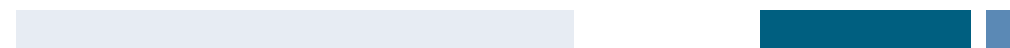
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The information on the following pages can help you understand if your blood is responding to treatment. This way you can speak up at your appointments and have a more productive conversation with your doctor.

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Be sure to discuss any questions you may have with your doctor. The information in this guide can help you know what to ask, so you can become your own advocate for your treatment. You can also visit [www.cmlbasics.com](http://www.cmlbasics.com) to learn more.

# ABOUT Ph+ CML.



Getting diagnosed with Philadelphia chromosome–positive chronic myeloid leukemia (Ph+ CML) comes out of the blue for many people. Oftentimes, there are no symptoms. Your doctor may have identified Ph+ CML as the result of a routine blood test that showed an unusually high white blood cell count.

## ABOUT CHRONIC MYELOID LEUKEMIA (CML)

CML is a cancer that occurs when the blood-forming cells of the bone marrow make too many white blood cells. Bone marrow is a sponge-like tissue in the center of most bones.

## THE PHASES OF Ph+ CML

Doctors categorize Ph+ CML into 3 groups called “phases.” These include chronic phase, accelerated phase, and blast phase.

Most adults are diagnosed in chronic phase, which is the first phase of Ph+ CML. Most people in chronic phase respond to treatment. If Ph+ CML in chronic phase is left untreated, the disease will progress to the accelerated phase.

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## MEDICATION HAS HELPED MAKE Ph+ CML MANAGEABLE

Since 2001, medications have helped make living with Ph+ CML manageable for many people. Here’s some background information that you may find helpful.

Approximately  
**8500**

Number of new cases  
of CML expected to  
be diagnosed in 2020



**50,000+**

Number of people in the United  
States living with CML as of 2016

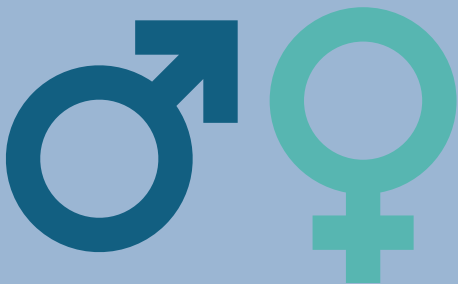


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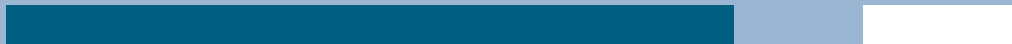
# AFFECTS MEN & WOMEN

CML affects both men and women and is slightly more common among men



More than  
**95%**

Percentage of people with CML who have Ph+ CML



## WHAT CAUSES Ph+ CML?

Ph+ CML is typically the result of a change in chromosomes in the body. In Ph+ CML, pieces from chromosomes 9 and 22 (each cell in the human body typically has 23 chromosome pairs) break off and trade places.

When this change happens, it can create a new abnormal chromosome called the Philadelphia (Ph) chromosome. This can create a defective gene called *BCR-ABL1*, which produces an abnormal protein called BCR-ABL.

# WHAT HAPPENS INSIDE YOUR BODY WITH Ph+ CML?

The BCR-ABL protein triggers the bone marrow to start making too many immature white blood cells, which grow abnormally. Your doctor may call these leukemic cells.

When you have Ph+ CML:

- Leukemic cells start to grow and divide
- These cells build up in the bone marrow and spread to the rest of the blood
- This overload of leukemic cells can crowd out healthy red blood cells and platelets
- This can cause health problems, including anemia, bruising easily, and a greater risk of infections

## DOING YOUR PART TO MANAGE Ph+ CML


A key goal in treating Ph+ CML is to reduce the amount of leukemic cells in your body. Medication can help lower the amount of leukemia in your blood. That's why it's important to take your medication as prescribed.

The following pages provide an overview of blood tests your doctor may require and help explain what your results mean.

MEET DANIELA,  
LIVING WITH Ph+ CML IN CHRONIC PHASE SINCE 2012

“I went to a CML support group about 6 months into my treatment. Everyone was older than me and they were all okay. They were involved with all kinds of projects and they were living normal lives, and they left me with the message after that first meeting that I was going to be fine.

“Today, I am part of a program where I talk with other patients over the phone all over the country. Once I felt my health was under control, I really wanted to help other people who were at the beginning stage of their diagnosis. I felt like they needed to hear they were going to be okay from the start. I feel if I can relay that message to other people as early as possible, it would help them out.”



To watch Daniela's story and the stories of others with Ph+ CML, visit the YouTube channel at [www.youtube.com/livingwithcml](https://www.youtube.com/livingwithcml)

“I’m young for a CML patient.”

Daniela, actual patient





# TESTS YOUR DOCTOR MAY ORDER.

Going for blood and bone marrow tests is a key part of your treatment. Your results can help your doctor see if you are responding to your medication. It can also inform your doctor's next steps—such as adjusting your dose or considering another treatment option.

## SETTING TREATMENT GOALS

It's a good idea to work with your doctor to set treatment goals for Ph+ CML. While every patient is different, your goals may include:

- Getting your blood cell counts back to normal
- Reducing the number of leukemic cells in your body
- Getting the amount of the BCR-ABL protein down to a level that is undetectable
- Keeping Ph+ CML in chronic phase from progressing to the next, more serious accelerated phase. Most patients are diagnosed in chronic phase

**COMPLETE BLOOD COUNT (CBC):** It's important for your doctor to know your blood counts. When you have Ph+ CML, the number of white blood cells is usually higher than normal—in some cases, extremely high. Your red blood cells may be lower than normal. Your platelets may be higher or lower than normal.

**CYTOGENETIC TEST:** In this test, a small sample of bone marrow is removed. It is then analyzed under a microscope to see the number of cells with the Ph chromosome.

**FLUORESCENCE IN SITU HYBRIDIZATION (FISH) TEST:** A standard cytogenetic test may not detect all the CML cells in the blood. That's why your doctor may order a FISH test, which uses fluorescent dyes and a fluorescent microscope to measure the number of cells with the Ph chromosome.

**STANDARDIZED POLYMERASE CHAIN REACTION (PCR OR MOLECULAR) TEST:** PCR testing is sensitive enough to detect even the smallest amount of leukemic cells. For details about the PCR test, see page 14.

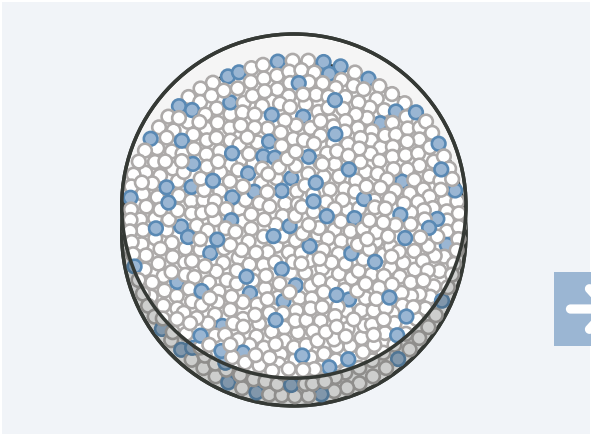
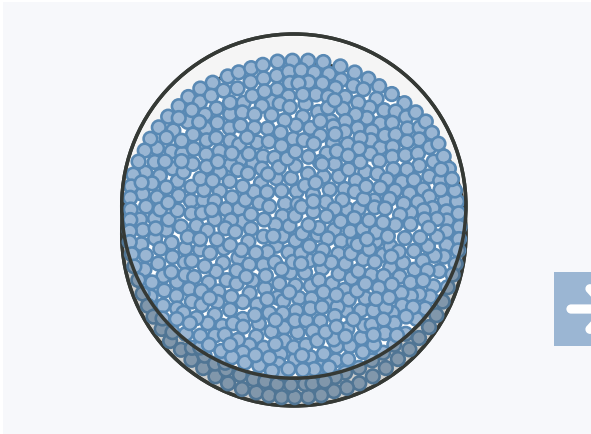
Be sure to discuss the results of your tests with your doctor. On the following pages, you'll get an understanding of what your results mean. This may help you and your doctor have a more productive conversation.



# MILESTONES THAT MATTER.

Here is a brief overview of an ideal response to treatment for Ph+ CML. The illustrations can help you picture how the number of leukemic cells may come down over time with treatment. The blue dots represent the number of *BCR-ABL1* cells in the body.

Every patient is different. Not all patients will reach these treatment milestones or reach them at the same point in time.



**At diagnosis: Baseline**  
100% leukemic cells

When you were diagnosed with Ph+ CML, it's likely that blood tests showed a high level of blood cells with an abnormal gene called *BCR-ABL1*.

While the amount of *BCR-ABL1* in the body is different for everyone at the time of diagnosis, your doctor will use these initial results as a baseline. For most patients, the baseline is set at 100%. This means that almost all the cells in your blood are leukemic cells.

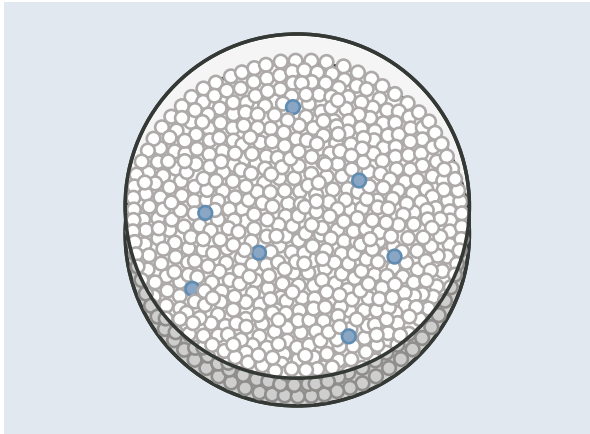
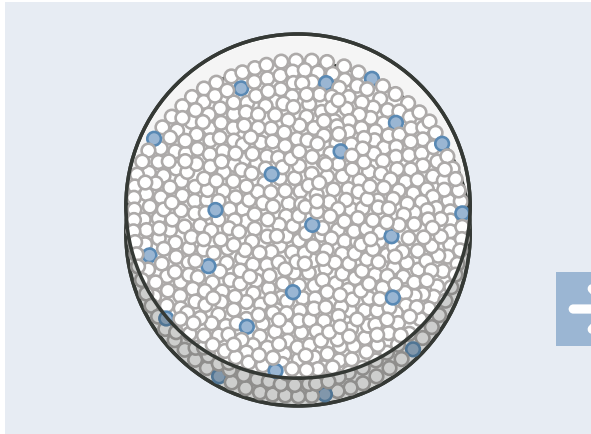
**At 3 months: Complete Hematologic Response (CHR)**  
Leukemic cells reduced by 90% vs baseline

To see how you are responding to treatment, you may have a test called a complete blood count (CBC). This measures the number of red blood cells, white blood cells, and platelets in your blood.

The goal is to see your blood counts return to normal. Your doctor may call this a CHR. Many people achieve a CHR within 3 months of starting medication for Ph+ CML.

CHR means the amount of *BCR-ABL1* in your body has been reduced by 90% compared to baseline.

The *BCR-ABL1* levels cited on these pages are based on a standardized scale called the International Scale.



**At 12 months: Complete Cytogenetic Response (CCyR)**  
Leukemic cells reduced by 99% vs baseline

Your doctor may use a cytogenetic test or a FISH test to measure the number of Ph+ cells in your bone marrow. If either of these tests show there are no Ph+ cells in the bone marrow, your doctor may say that you have a CCyR.

CCyR means the amount of *BCR-ABL1* in your body has been reduced by 99% compared to baseline.

**At 18 months: Major Molecular Response (MMR)**  
Leukemic cells reduced by 99.9% vs baseline

As the number of leukemic cells in your blood go down, you may need a test that can detect even the smallest amount of Ph+ cells. This is called a PCR test or a molecular test.

Based on your results, your doctor can see if you have achieved a MMR. MMR means the amount of *BCR-ABL1* in your body has been reduced by 99.9% compared to baseline.



# ABOUT PCR TESTING.

Early on in your treatment, certain blood tests may be more important than others. As the number of leukemic cells in the body come down, your doctor may order a blood test that can detect even the smallest amount of leukemic cells: the PCR test.

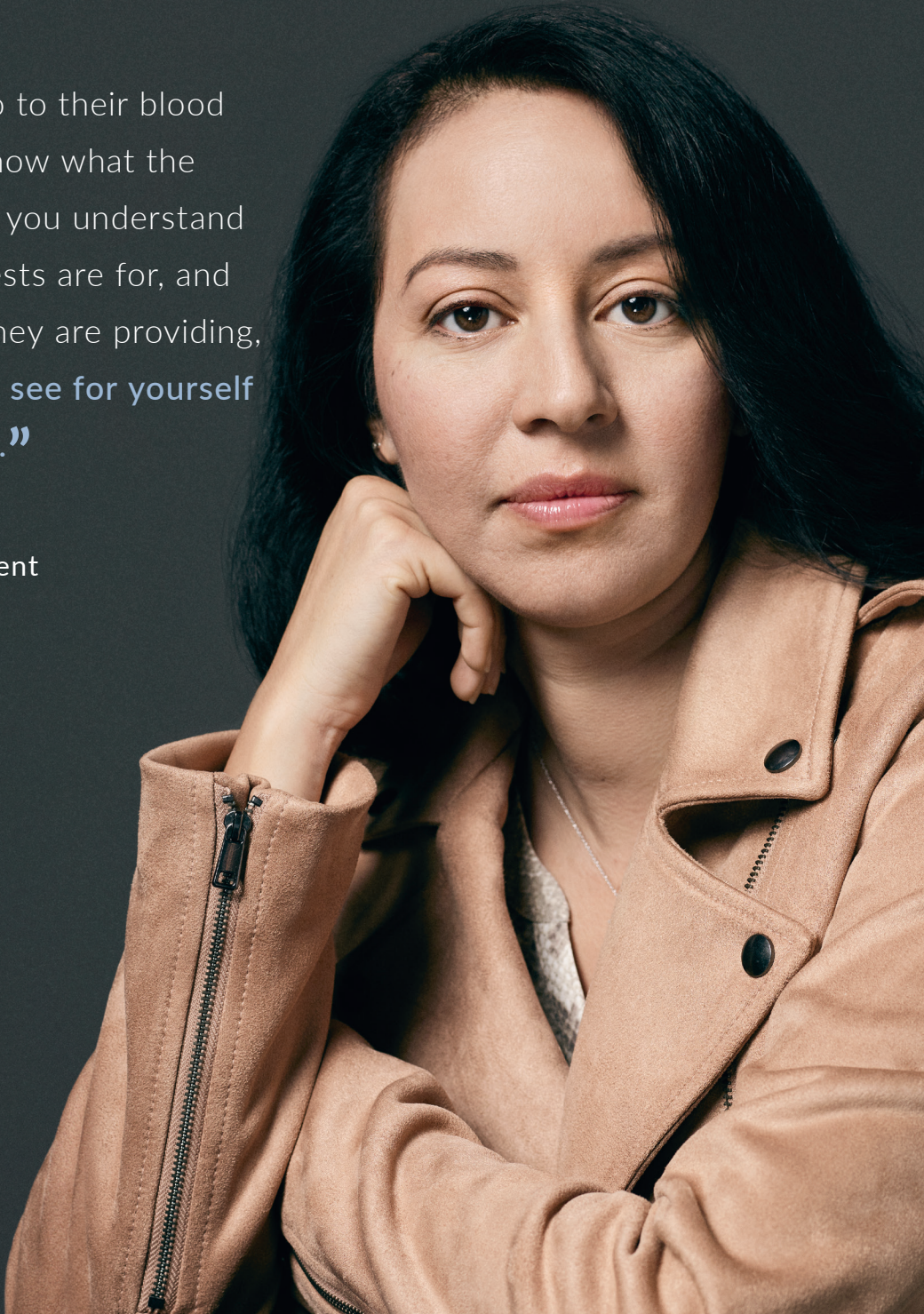
With PCR, it is possible to identify  
**1 cancer cell within 100,000 to 1 million normal cells**

## THE ROLE OF THE PCR TEST

The PCR test can measure the amount of the BCR-ABL protein in the blood from the highest levels to the very lowest. Your PCR number says a lot about your response to treatment and your progress in reaching your goals.

“A lot of people go to their blood tests and don’t know what the numbers mean. If you understand what the blood tests are for, and the information they are providing, then you can also **see for yourself how you’re doing.**”

Daniela, actual patient







# Your doctor may order a PCR test every 3 months

## FREQUENCY OF PCR TESTS

You should ask your doctor about getting a PCR test every 3 months to see if you are responding to treatment. This way, you and your doctor can keep a close eye on your progress.

If you achieve a major molecular response (MMR), you should continue to get a PCR test every 3 months for 2 years and every 3 to 6 months after that.

## HOW YOUR PCR LEVEL MAY CHANGE

As you start on medication, your PCR level may go down significantly over the course of several months or a year or more. Once you reach certain treatment milestones, such as a complete cytogenetic response (CCyR) or a MMR, it is typical for PCR levels to go down at a much slower pace.

If your PCR levels start to rise, be sure to discuss your results with your doctor. It may be time for your doctor to change your dosage or recommend that you switch to a different medication.

## USE THE SAME LAB FOR EVERY PCR TEST

The PCR test is so sensitive that different labs can produce different results. So be sure to go to the same lab for your PCR test each time. You also want to make sure the lab uses what’s called the International Scale to measure your PCR level. It’s a reliable way to measure progress toward your goals.

You can use the following pages to record and track your PCR results.



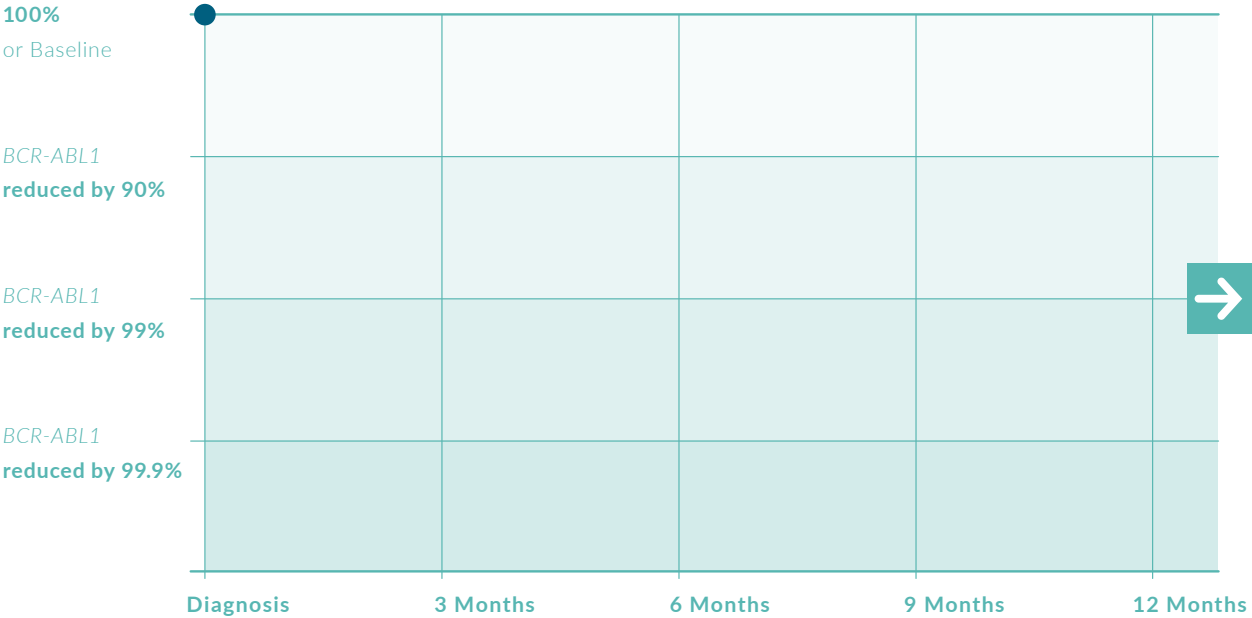
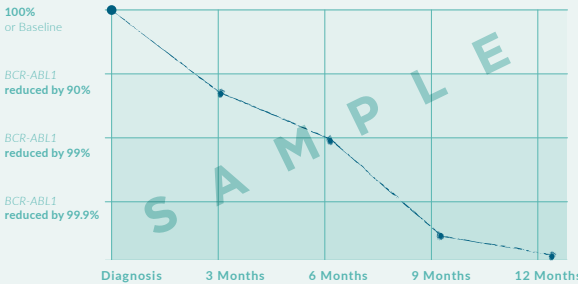
# KEEP TRACK OF YOUR RESULTS.

Your blood tests will provide your doctor with results to understand if you are responding to treatment. You may find it helpful to keep track of how you are doing by using the following pages to record your results.

DATE	LAB TEST	RESULTS	CHANGE FROM LAST TEST	NEXT TEST

Work with your doctor to fill out the graph below. Here’s some helpful information:

- The first entry is your baseline and is marked by the large dot at the top left-hand corner of the chart, next to 100%
- Together with your doctor, record the percentage of the decrease in your *BCR-ABL1* based on the results of your PCR test. Your doctor may order this test every 3 months
- As you and your doctor add entries, connect the dots as shown in the sample chart to see how you are responding to treatment. It’s important to know what your numbers mean, so be sure to discuss your results with your doctor





DATE	LAB TEST	RESULTS	CHANGE FROM LAST TEST	NEXT TEST

DATE	LAB TEST	RESULTS	CHANGE FROM LAST TEST	NEXT TEST

DATE	LAB TEST	RESULTS	CHANGE FROM LAST TEST	NEXT TEST

DATE	LAB TEST	RESULTS	CHANGE FROM LAST TEST	NEXT TEST



# HAVING A PRODUCTIVE CONVERSATION WITH YOUR DOCTOR.

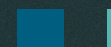
When you have Ph+ CML, it's important to speak up when you go to your doctor's appointments. It's all part of being your own advocate, which includes making sure you're getting the blood tests you need. This way, you and your doctor can see if you are responding to treatment.

Here are a few questions you may want to ask when you visit your doctor:

- What tests do I need for Ph+ CML?
- What do my latest test results mean?
- Do my results show a need to adjust my dosage or switch to another medication?
- How often should I go for blood tests?
- When should I schedule my next doctor's appointment?

“I encourage people to have conversations with their doctors about anything they don't understand. Because **that's how you advocate for yourself.**”

Daniela, actual patient



# RESOURCES YOU MAY FIND HELPFUL.



Sometimes it helps to learn from real people who are living with Ph+ CML. The organizations listed on the next page may be a good source of information, connections, and support.

**Leukemia & Lymphoma Society®**  
[www.LLS.org](http://www.LLS.org)  
1-800-955-4572

**The National CML Society**  
[www.nationalcmlsociety.org](http://www.nationalcmlsociety.org)

**The Max Foundation**  
[www.themaxfoundation.org](http://www.themaxfoundation.org)  
1-888-462-9368

**CancerCare®**  
[www.cancercare.org](http://www.cancercare.org)  
1-800-813-HOPE (1-800-813-4673)

**Leukemia Research Foundation**  
[www.allbloodcancers.org](http://www.allbloodcancers.org)  
1-847-424-0600

**American Cancer Society®**  
[www.cancer.org](http://www.cancer.org)  
1-800-ACS-2345 (1-800-227-2345)

**National Cancer Institute's  
Cancer Information Service**  
[www.cancer.gov/contact](http://www.cancer.gov/contact)  
1-800-4CANCER (1-800-422-6237)

**National Patient Advocate Foundation**  
[www.npaf.org](http://www.npaf.org)  
1-202-465-5013



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To learn more about Ph+ CML, talk with your doctor or visit **[www.cmlbasics.com](http://www.cmlbasics.com)**

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To watch Daniela's story and the stories of others with Ph+ CML, visit the YouTube channel at **[www.youtube.com/livingwithcml](https://www.youtube.com/livingwithcml)**



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