

Comparing the efficacy of bosutinib in people with chronic myeloid leukemia who previously received other tyrosine kinase inhibitors

Date of summary: December 2019

Study number: NCT02228382 | Study start date: November 2014 | Estimated study end date: September 2021

The full title of this abstract is: Efficacy of Bosutinib in Imatinib-Resistant vs Dasatinib/Nilotinib-Resistant Chronic Phase Chronic Myeloid Leukemia: Results From the Phase 4 BYOND Study

The study drug is approved to treat the condition under study that is discussed in this summary.

Researchers must look at the results of many types of studies to understand whether a study drug works, how it works, and whether it is safe to prescribe to patients.

This summary reports the results of only one study. The results of this study might be different from the results of other studies that the researchers look at.

More information can be found in the scientific abstract of this study, which you can access here: [View ASH Abstract](#)

Click to find out how to say tricky medical terms ^

- Bosutinib** <boh-SOO-tih-nib>
- Dasatinib** <da-SA-tih-nib>
- Imatinib** <ih-MA-tih-nib>
- Myeloid leukemia** <MY-eh-loyd loo-KEE-mee-ah>
- Nilotinib** <ny-LOH-tih-nib>
- Tyrosine kinase inhibitor** <TY-ruh-seen KY-nays in-HIH-bih-ter>

What did this study look at?

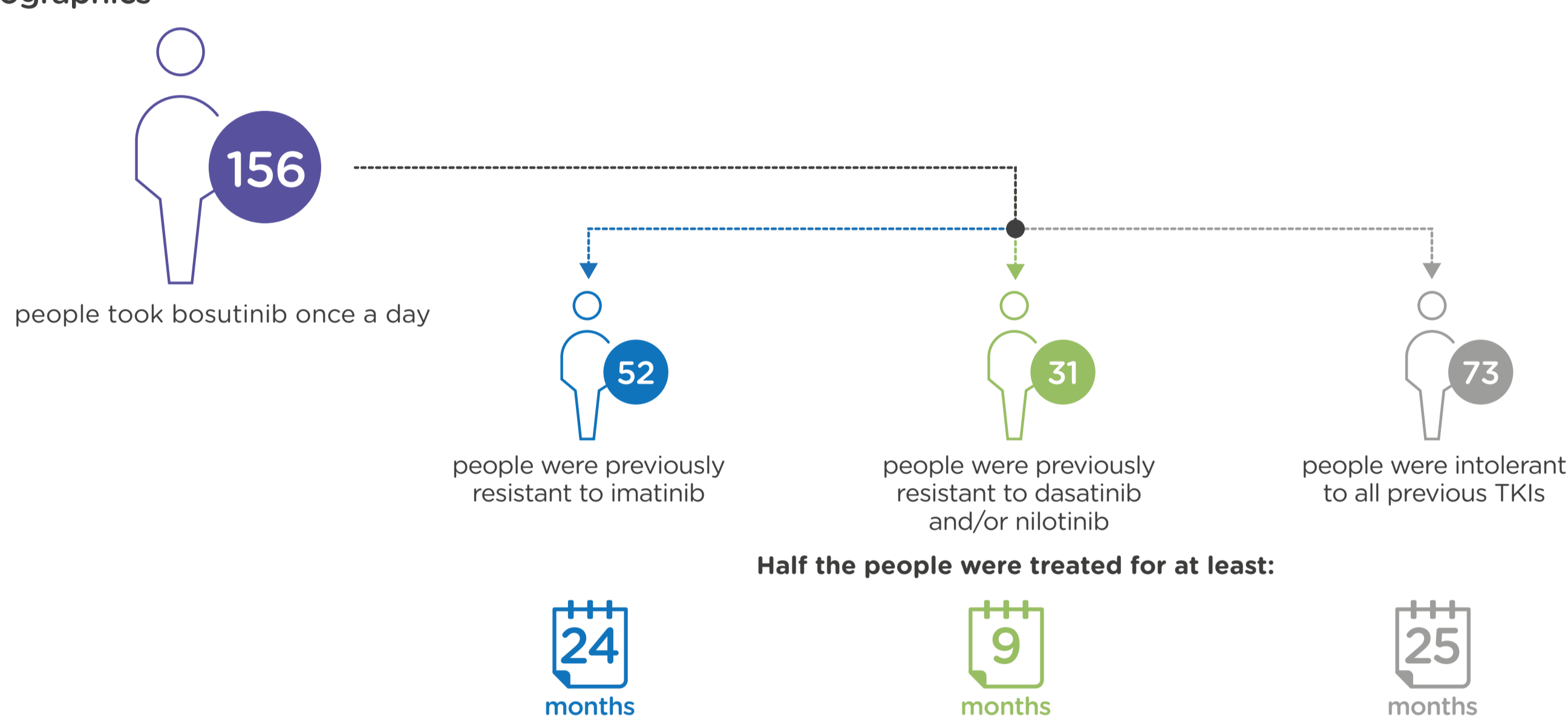
- Chronic myeloid leukemia (CML for short) is a type of cancer that affects white blood cells. It tends to progress slowly over many years.
 - CML is caused by an alteration in a gene called BCR-ABL, which causes the cancer cells to increase in number.
 - Genes are segments of DNA* and are found in structures called chromosomes within each cell of the body. BCR-ABL is found in a chromosome called the Philadelphia chromosome (Ph chromosome for short), which is present in some types of leukemia cancer cells.
- Bosutinib is a type of medicine known as a tyrosine kinase inhibitor (TKI for short).
 - Tyrosine kinases are proteins in the body that control how cells grow and divide.
 - Bosutinib works by blocking tyrosine kinase in the cancer cells, causing them to die.
 - Bosutinib is an approved treatment for people who:
 - have newly diagnosed CML
 - have CML that is no longer responding to treatment with other TKIs or
 - have discontinued prior treatment because they could not tolerate it.
- In this study, people with CML who had already received 1 to 3 previous TKI treatments (such as dasatinib, imatinib, and nilotinib) took bosutinib. These people had CML that was no longer responding to treatment (known as resistance), or they could no longer tolerate their previous TKI treatment (known as intolerance).
- This summary looks at whether the efficacy* of bosutinib differs for:
 - people with resistance to imatinib
 - people with resistance to dasatinib and/or nilotinib, and
 - people who are intolerant to all TKIs.

* Efficacy is how well a drug works within a clinical trial.

Who took part in this study?

- 156 people with CML were included in this analysis.
 - Researchers split them into 3 groups, depending on their resistance or intolerance to previous TKIs.
- Researchers monitored most people for around 2 years.

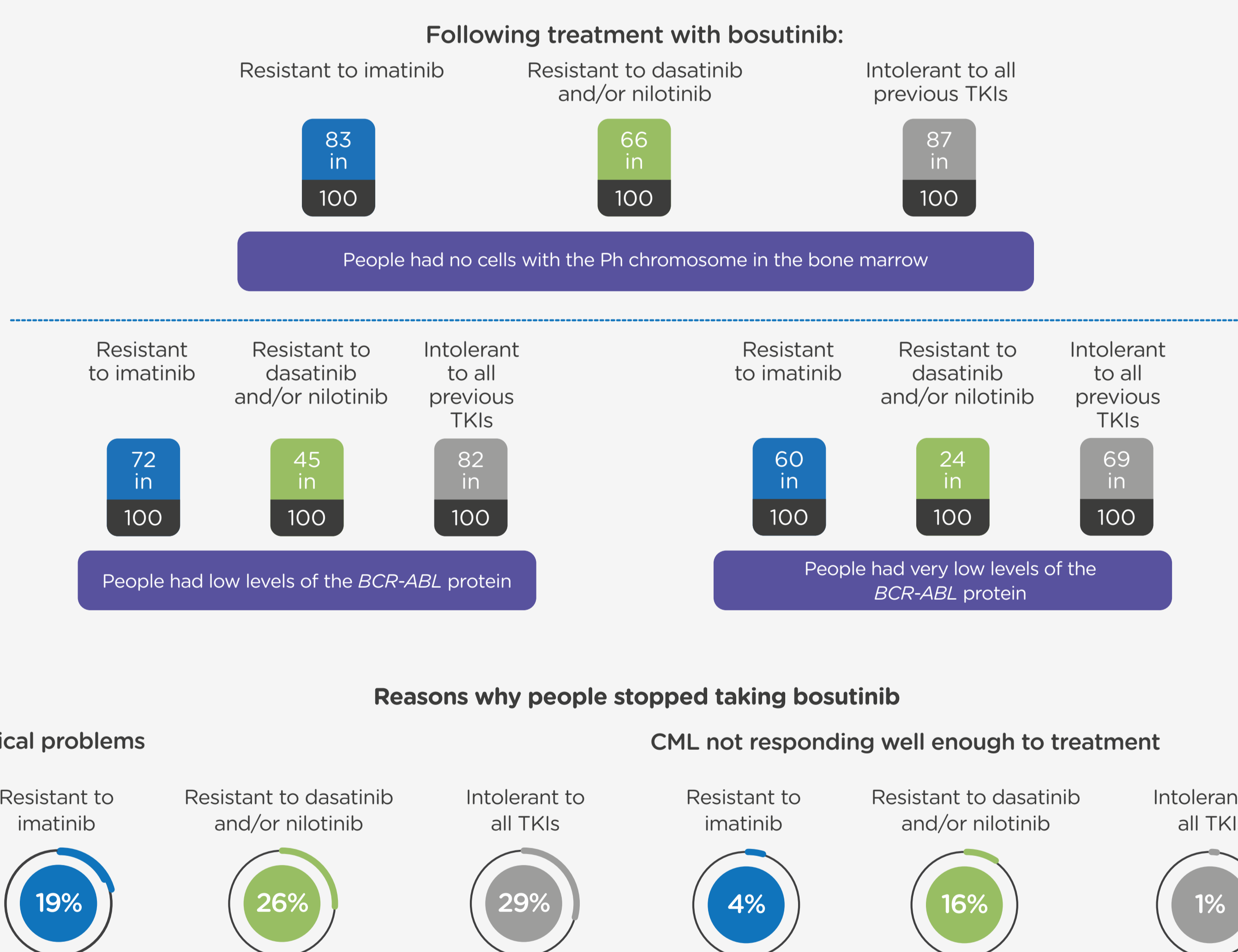
Demographics



What were the results of the study?

- Researchers looked at whether treatment with bosutinib lowered:
 - the proportion of cells with the Ph chromosome in the bone marrow, and
 - the level of the BCR-ABL protein in the blood.
- These tests show how well bosutinib is working.
- Following treatment with bosutinib:
 - Over 65 in 100 people in each group had no cells with the Ph chromosome in the bone marrow.
 - At least 45 in 100 people in each group had low levels of the BCR-ABL protein.
- Overall, the best responses to bosutinib were seen in:
 - people who were resistant to imatinib, and
 - people who were intolerant to all previous TKIs.
- Ten people died during the study. After 2 years, at least 90 in 100 people were still alive in each group.
- The main reason why people stopped taking bosutinib during the study was because of medical problems**.
- A smaller number of people stopped taking bosutinib because their CML was not responding well enough to treatment.

** Medical problems could be caused by reasons not related to the study (for example, caused by an underlying disease or by chance). Or, medical problems could have been caused by a study treatment, or by another medicine the participant was taking."



More results from this study can be found here: [View ASH Abstract](#)

What were the main conclusions reported by the researchers?

- In this study, a high proportion of people who were resistant or intolerant to other TKIs responded to treatment with bosutinib.
 - Responses were similar in people who were resistant to imatinib or intolerant to all previous TKIs.
 - Responses were seen in people who were previously resistant to dasatinib and/or nilotinib, even though they took bosutinib for a shorter length of time.
- These results suggest that bosutinib can be a treatment option for people with CML who are resistant or intolerant to other TKIs.

Who sponsored this study?

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Pfizer would like to thank all of the people who took part in this study.

Further information

Click to show more information on the study and clinical trials in general ^

For more information on this study, please visit:
[View ASH Abstract](#)
<https://clinicaltrials.gov/ct2/show/NCT02228382>

For more information on clinical studies in general, please visit:
<https://www.clinicaltrials.gov/ct2/about-studies/learn>
<http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/what-clinical-trials-are>

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