

# A Plain Language Summary looking at how long side effects last after treatment with axitinib is stopped in people with advanced renal cell carcinoma

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## Summary

Axitinib is a medication that stops cancer cell growth by depriving the cancer cell of the nutrients and oxygen that it needs. Axitinib is used to treat advanced renal cell carcinoma (RCC), which is a type of kidney cancer that has spread within or beyond the kidney.

Axitinib has been approved for the treatment of RCC as either a first treatment option or a second treatment option. It is used as a first treatment option for RCC when combined with a medication that reactivates the immune system (immunotherapy), either avelumab or pembrolizumab. If the advanced RCC starts growing again it can be used as a second treatment option where it is taken by itself. It is essential to conduct studies to assess how well the drug works and whether it has any side effects in order to understand whether it is safe to give to people.


This summary reports the combined results of 5 studies and looks at how long side effects last after treatment is temporarily stopped. Researchers found that side effects generally got better in 3 days or less after people stopped taking axitinib on its own. The time it took for side effects to get better was generally shorter than for other similar drugs or combinations of axitinib and immunotherapy.


The results of individual studies may vary from these 5 combined study results. Three of the 5 studies were ongoing at the time of this analysis and the final outcomes of those studies may differ from those described in this summary.

The purpose of this plain language summary is to help you understand the findings from recent research. Health professionals should make treatment decisions based on all available evidence.


How to say (double click sound icon to play sound)...

**Avelumab:** a-VEL-yoo-mab 


**Axitinib:** AK-sih-TIH-nib 


**Pembrolizumab:** pem-bro-LIZ-zoo-mab 

**Renal cell carcinoma:** REE-nul sel

KAR-sih-NOH-muh 

**Sorafenib:** saw-AH-feh-nib 

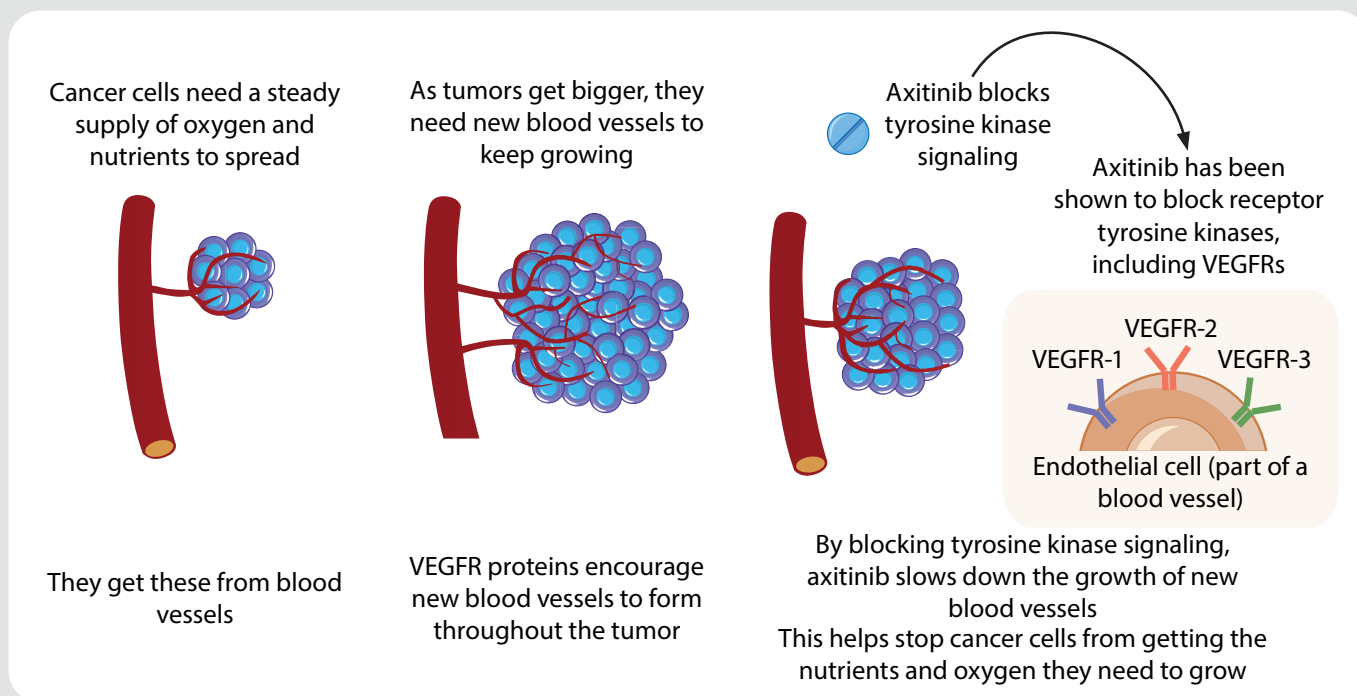
**Sunitinib:** soo-NIH-tih-nib 

**Tyrosine kinase inhibitor:** TY-ruh-seen  
KY-nays in-HIH-bih-ter 

## What did this study look at?

- Renal cell carcinoma (RCC for short) is a type of cancer that forms a tumor in one of the kidneys:
  - Advanced RCC is cancer that has spread either within or beyond the kidney
- Axitinib is a tyrosine kinase inhibitor (TKI for short)
- Tyrosine kinases are proteins in the body that control how cells grow and divide
- In cancer, tyrosine kinase proteins are more active than normal, which helps the cancer cells grow

Axitinib works by blocking vascular endothelial growth factor receptors (VEGFR for short). This slows down the growth of new blood vessels and helps stop cancer cells from getting the nutrients and oxygen they need to grow.

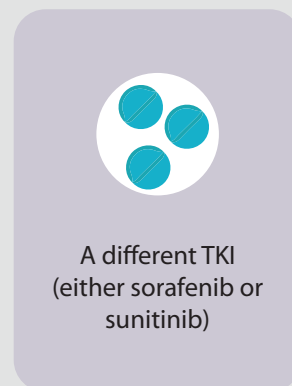
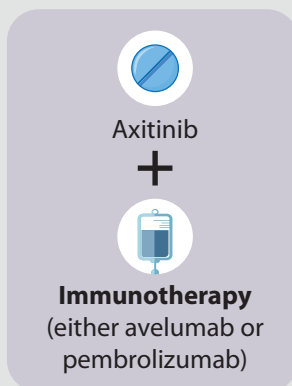


**Side effect:** A side effect is a physical or mental change (expected or unexpected) that may or may not be caused by a medicine or treatment you take.

**Immunotherapy:** Immunotherapy is a type of cancer treatment that helps the person's own immune system find and kill cancer cells.

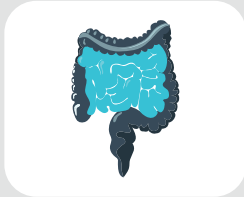
- In this study, the researchers wanted to investigate how long **side effects** last after treatment is temporarily stopped
- Researchers looked at five different clinical studies and combined the results

People who had advanced RCC and took one of the following treatments:



The study evaluated five common side effects in people taking axitinib:

Diarrhea



Loose and watery stool

Fatigue



Tiredness or a lack of energy

Hypertension



High blood pressure

Nausea



Feeling like you may throw up

Hand-foot syndrome



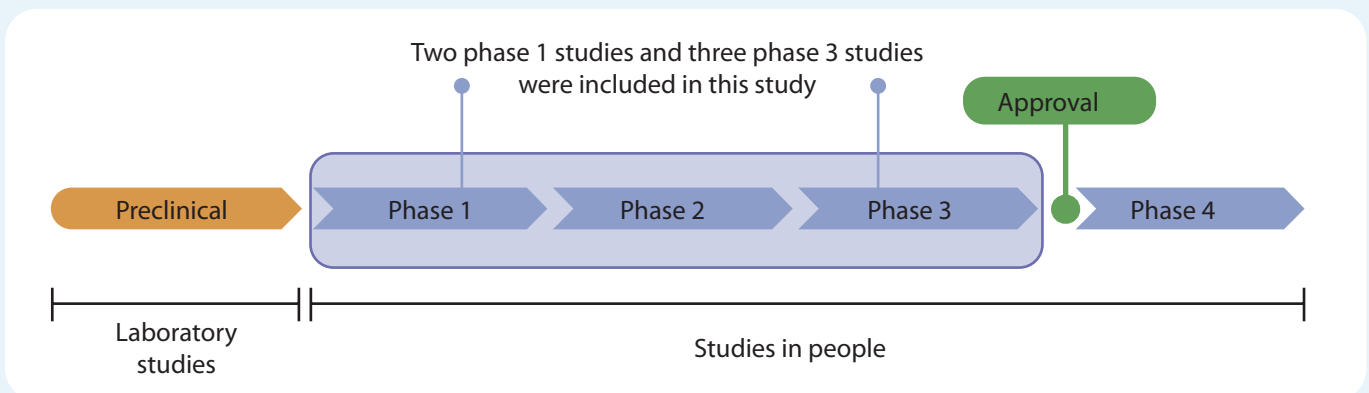
Redness, swelling or blistering on the palms of the hands and soles of the feet

- When a side effect caused people to stop taking treatment, either temporarily or permanently, the researchers calculated the **time to resolution** for that side effect

**Time to resolution:** The period between the first day the treatment was interrupted to the day the side effect was reported as having resolved.

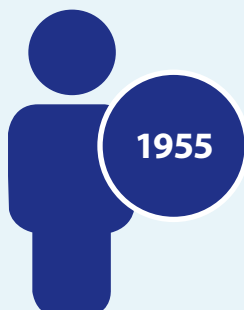
## What types of information were included in this study?

- This study combined information from two phase 1 and three phase 3 trials:
  - A phase 1 study is usually the first time a treatment is tested on people. They aim to confirm that the treatment is safe and to find the most effective dose
  - Phase 3 studies involve a larger group of people. They aim to compare the new treatment with the current standard treatment



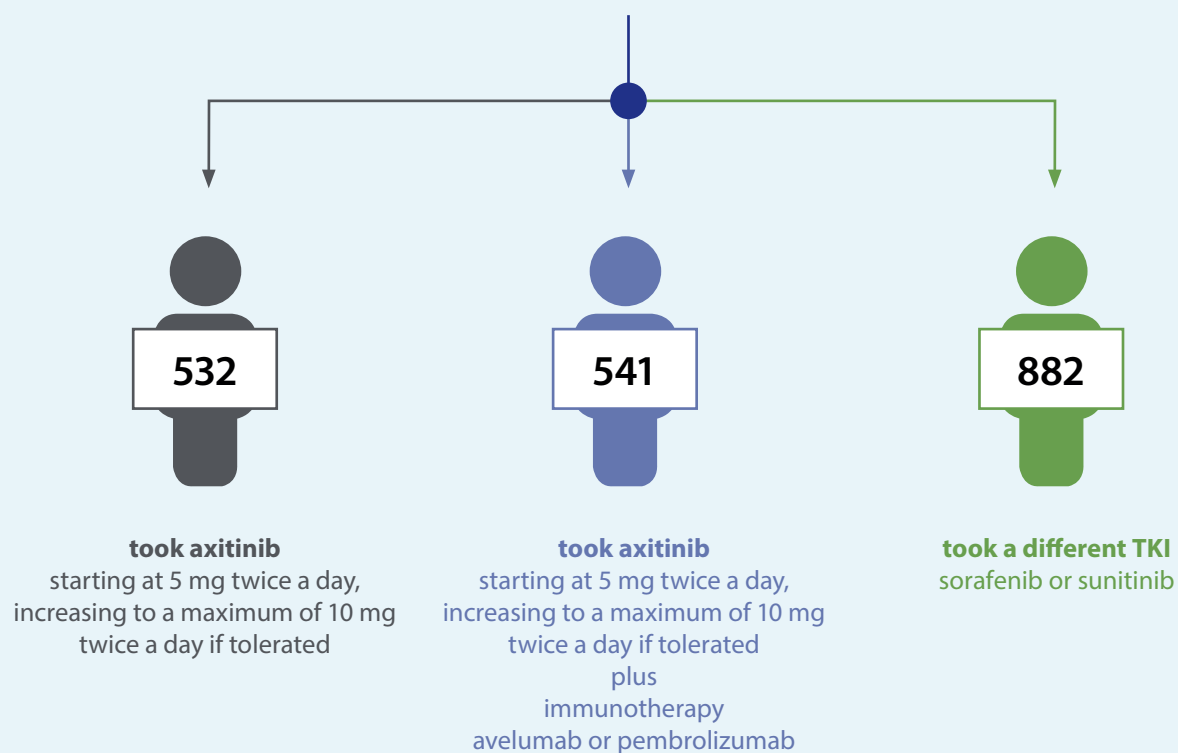
- Once a new treatment has completed phase 1–3 clinical trials, it must be reviewed and approved by a country's medical regulatory agency before it can be used in the clinic. The evidence must show that the benefits outweigh its known potential risks for the people it is intended to treat
  - Axitinib is approved as the first treatment option for people with advanced RCC when combined with avelumab or pembrolizumab. It is approved as the second treatment option when it is taken as the only cancer drug

## Who took part in this study?



1955 adults with advanced RCC were included in the study

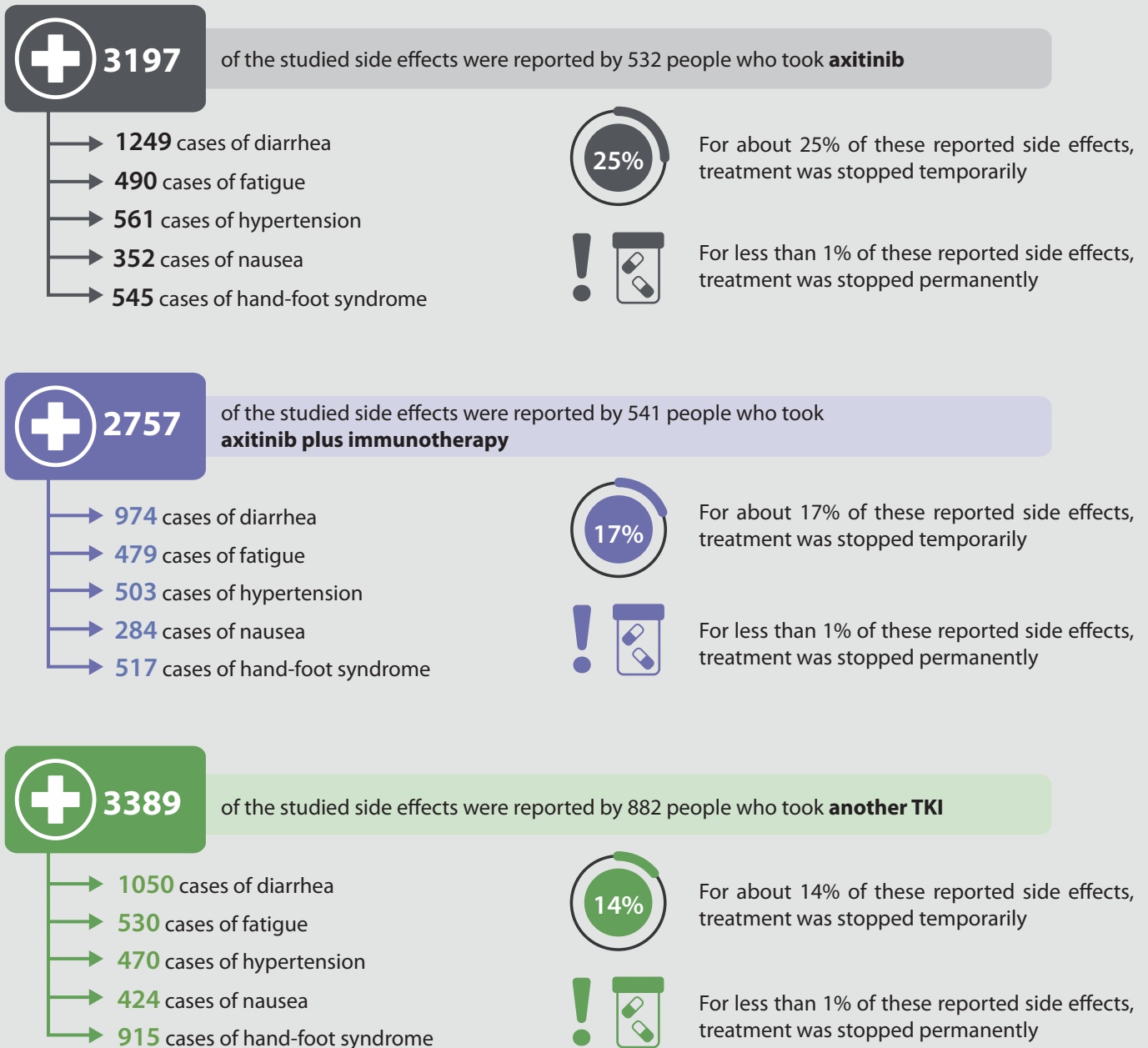
They had not received another treatment for advanced RCC, or they had finished their previous treatment more than 2 weeks ago



Information was collected for the following side effects: diarrhea, fatigue, hypertension, nausea, hand-foot syndrome

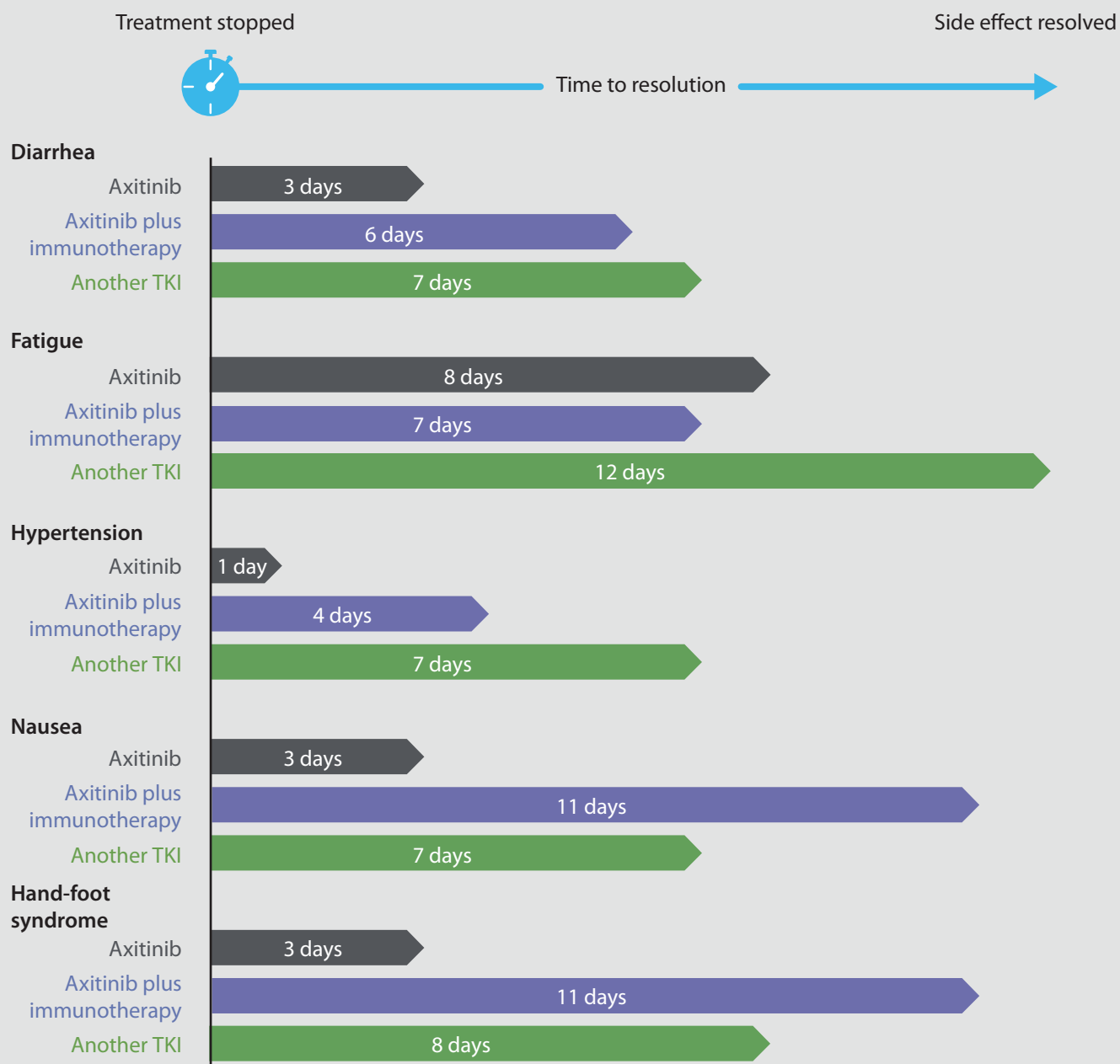
## What were the results of the study?

### How many of the side effects that were studied were reported?



Some people may have no side effects, while others may have more than one side effect.

**What was the time to resolution for each studied side effect?**



- Except for fatigue, the time to resolution for each of the studied side effects was shorter for people taking axitinib than for people taking axitinib plus immunotherapy
- For all studied side effects, the time to resolution was shorter for people taking axitinib than for people taking another TKI

## What were the main conclusions/implications reported by the researchers?

- The side effects of diarrhea, hypertension, nausea, and hand-foot syndrome resolved in 3 days or less for people taking axitinib
- Side effects generally got better more quickly for axitinib than for axitinib plus immunotherapy or another TKI
- These results help doctors to understand when a side effect is caused by axitinib so they can take action to manage it

## What are the limitations of this study?

The clinical trials in this study took place at different times. How doctors may have treated the studied side effects may have changed over time. This may have affected how long side effects took to get better.

## How to use this summary to help people with RCC and doctors talk about this research

Question for people with RCC to doctor: how important is this research to my care?

Question from doctor to people with RCC: does this research affect what matters most to you in your treatment?

## Are there any plans for further studies?

This analysis is complete.  
There are no plans for further analyses.

## Who sponsored this study?

Pfizer Inc.  
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Phone (United States): +1 800-879-3477

## Additional information

The full title of this article is: Time to Resolution of Axitinib-Related Adverse Events After Treatment Interruption in Patients With Advanced Renal Cell Carcinoma

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You can access the full article for free: <https://www.sciencedirect.com/science/article/pii/S1558767321000823>

For more information on clinical studies in general, please visit:

- <https://www.clinicaltrials.gov/ct2/about-studies/learn>
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### Disclaimer

When reading this summary, it is important to understand the following:

- This summary reports the combined results of five studies. The results of individual studies may vary from these combined study results. Health professionals should make treatment decisions based on all available evidence
- This summary reports results partly based on three ongoing studies. The final outcomes of those studies may differ from those described in this summary

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### Financial & competing interests disclosure

Full author disclosure information can be found in the original article. Rosemary E Teresi is an employee of, and owns stock or stock options in, Pfizer

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