

ON-TRK website is now live!
on-trk.bayer.com

NEWSLETTER | Issue No. 5

October 2023

ON-TRK: PrOspective Non-interventional study in patients with locally advanced or metastatic TRK fusion cancer treated with larotrectinib



Dear ON-TRK investigators,

2023 has been an incredible year for ON-TRK in terms of enrollment: we now have **95 patients** recruited in the study, almost half of them have been recruited only in 2023. Thank you very much for this performance and your continuous support.



* In comparison to newsletter issue March 2023 (issue #4)

We still rely on your efforts since we only have 14 months to go before the **end of the recruitment period, scheduled on Q4 2024**. Despite the great efforts for the last few months, we are still far from our objective of **300 patients** recruited in the study. We need your continuous vigilance to include any new patient meeting eligibility criteria. In this regard, please don't forget that a patient meeting eligibility criteria can be enrolled only if the initial visit (start of larotrectinib) occurred within **2 months ± 3 days before signing the informed consent**.

Study team Shout out to countries

Finding the patients is probably the biggest challenge in the ON-TRK study. Behind ON-TRK are many collaborators all over the world who are working to initiate the study as soon as possible despite the numerous challenges. Recently, a jump in inclusions has been made and we would like to highlight the countries that have contributed significantly to reach the 95 patients enrolled to date.

China
LPM: Dongwei Li

China joined the ON-TRK study this year. Since the initiation of the first site, 10 patients have been enrolled in the study. We would like to thank Dongwei Li and his team for their efforts.

Republic of Korea
LPM: HyunCheol Lee

Republic of Korea also accounted for a large part of the total number of patients included in the study with 11 patients! Many thanks to HyunCheol Lee for his flawless follow-up on this project.

Austria
LPM: Andreas Nellen

Austria joined the active countries circle with a 1st patient included on Sep 13th in the University of Salzburg. Congratulations to Pr. Greil's team, and our warm thanks to Andreas Nellen for his support.

Patient enrollment More than 30 additional patients enrolled in 6 months!

Country	Planned FPFV	Actual FPFV	Planned total patients	Actual enrolled patients	Planned total sites	Actual active sites
Argentina	30/11/2023		10	0	9	6
Australia	04/12/2023		3	0	2	2
Austria	12/02/2021	13/09/2023	5	1	3	3
Belgium	05/02/2021	09/03/2021	14	6	12	9
Canada	01/06/2020	05/08/2020	6	5	7	6
China	30/04/2023	20/04/2023	30	10	9	7
Finland	13/12/2022	03/02/2023	2	1	1	1
France	30/11/2021	23/11/2021	12	5	13	13
Germany	01/11/2021	01/11/2021	10	5	12	8
Italy	16/12/2022	12/12/2022	25	3	14	13
Korea	19/07/2022	19/07/2022	20	11	13	11
Luxembourg	01/01/2022	05/04/2022	3	2	2	2
Spain	31/12/2023		20	0	18	0
Sweden	20/10/2021	21/10/2021	8	3	5	5
Switzerland	31/03/2021	22/03/2021	16	9	14	10
Taiwan	02/10/2023		10	0	6	5
United States	01/03/2020	03/04/2020	135	34	55	44
Total			329	95	195	145



* The enrolled cohort is not yet documented for 3 patients

ON-TRK website The ON-TRK study website is now live!

After a long period of development, the study team is delighted to announce that the **ON-TRK website has been launched!**

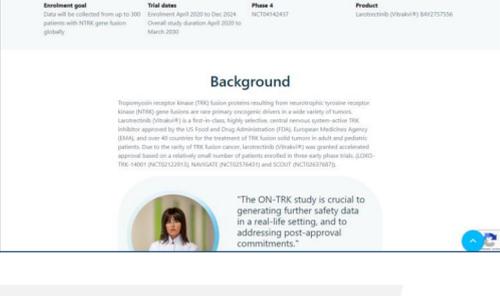
This is a dedicate platform to ON-TRK investigator sites. The content will be regularly updated with country experience, steering committee announcements, investigator meetings feedback, ... This is YOUR website, so we are here to answer your questions and take your suggestions on the content.

This website is a great opportunity to share your journey with the other global experts.

How can ON-TRK study website be accessed? Easy! Type the below URL in your browser's address bar:

www.on-trk.bayer.com

In the pop-up window, click on 'ON-TRK investigator' and enter your 5-digit study site number to gain access. Please don't hesitate to share your experience with your local project manager or by using the contact box at the bottom of the website.



Spain Larotrectinib reimbursed without restrictions



On 24 July 2023, Spain received from the Ministry of Health approval for larotrectinib without restrictions in the following indication:

VITRAKV® (larotrectinib) in monotherapy for the treatment of adult and pediatric patients with solid tumors presenting a neurotrophic tyrosine receptor kinase gene fusion (Neurotrophic Tyrosine Receptor Kinase [NTRK]), with locally advanced, metastatic disease or whose surgical resection is likely to generate high morbidity, and with absence of satisfactory therapeutic options.

A total of 18 sites have been selected during the study feasibility and selection. These sites will be contacted again to confirm their participation. 20 patients are planned to be recruited in Spain.

China Positive impact of investigator meeting in China on enrollment



China held its **initial investigator meeting on 25 June 2023**. Many experts from multi-disciplinary and multi domain were gathered in Shanghai, China. During the meeting, medical background and study rationale were introduced, as well as study overview and execution to the investigators. Then, the investigators had a lively discussion regarding study implementation, such as patient enrolment and recruitment. The conference was successfully concluded.

The meeting provided an opportunity to engage experts and had a significant impact on patient enrolment. Before the meeting, China enrolled 3 patients in 3 months. After the meeting, China enrolled 7 more patients until end of September 2023. It is worth mentioning that 3 patients were enrolled within 1 week after the investigator meeting. With the assistance of the investigator meeting, **10 patients have been enrolled in China in the half year** since the first site was initiated end of March 2023.

ON-TRK faces Testimony from Dr. Orbach, PI at Institut Curie (Paris, France)

Our site has been open in ON-TRK since 29 November 2021 with a first patient enrolled on 09 December 2021.

Due to systematic RNA sequencing in our genetic somatic unit, for all pediatric tumors, depicting these tumors with NTRK fusion transcript is nowadays easier, even if their frequency is low. The recent authorization of reimbursement for larotrectinib means that all children with sarcoma can be treated in France.

The Institut Curie SIREDO Oncology Center in Paris (Care, Innovation and Research for Children, Adolescents and Young Adults with Cancer) is the first integrated center in France for care, translational and basic research in pediatric, adolescents and young adult's oncology. Childhood cancers at Institut Curie is:



- // Daily care for children, adolescents and young adults with all types of solid tumors and lymphoma.
- // Over 380 new young patients treated each year by multi-disciplinary teams working in tandem with other regional hospitals.
- // A national leader for molecular diagnosis and characterization of pediatric cancers.
- // About 200 young patients involved in therapeutic trials (including early trials, thanks to the Clip2 pediatrics certification for early clinical-trial centers) and interventional studies.
- // The leading national center for treating children suffering from retinoblastoma.

Our main area of research are sarcomas, rhabdoid tumor, retinoblastoma, neuroblastoma and medulloblastoma with 4 basic research teams, 60 scientists, 14 people dedicated to translational research, including 2 physician-researchers and 40 clinical trials. The SIREDO center provides eight adolescent and young adult beds with 18 pediatric beds in addition to day care close to the Panthéon and the Jardin du Luxembourg, in the center of Paris, France. The « Clinical Trials Team » for our pediatric department is a small team composed of three study coordinators and one study nurse, in addition to pediatricians, and is part of a more substantial unit which supports Clinical Research throughout the hospital.

Up to now, 2 patients are included in ON-TRK.

Thank you for having read this newsletter. Next issue is due for March 2024. For any study-related questions, please reach out to your **local project manager**.

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