

# NEWSLETTER | Issue No. 6

## April 2024

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

Dear ON-TRK investigators,

We are pleased to provide an update on the progress of the ON-TRK study. Since our last newsletter, we have successfully enrolled **28 new patients**, bringing our total enrollment to **123 patients**. **As we enter the final year of the enrollment period, it is crucial that we continue our efforts to identify potential patients who can be enrolled in ON-TRK.** Our goal of enrolling 300 patients is still within reach, but we need the collective efforts of all participating investigators to achieve this milestone.



\* In comparison to newsletter issue October 2023 (issue #5)

We are thrilled to announce that Spain has recently joined the list of participating countries and has already enrolled 4 patients. This is a significant achievement, and we are grateful for their contribution to the study. More generally, we extend our deepest gratitude to all investigators for their hard work and dedication.

The Argentinian team contribution marks a significant milestone in our study. In this newsletter, we are delighted to share the feedback from Dr. Cardoso, who enrolled the first patient in Argentina.

We look forward to your continued support and collaboration as we work towards our enrollment target. Thank you all for your outstanding efforts and we wish you a pleasant read.



**ON-TRK website**

*Stay updated on ON-TRK!*

Since its launch in October 2023, the ON-TRK study website has been a source of information and updates. We urge all investigators to visit the website regularly to stay informed about the latest study developments.

Your experiences and insights are invaluable. We invite you to contribute to the website by sharing your experiences, challenges, and successes related to the study. Reach out to your local project manager if you're willing to share your experiences.

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

[www.on-trk.bayer.com](http://www.on-trk.bayer.com)





## Patient enrollment

28 additional patients enrolled in 6 months!

Country	Planned FPFV	Actual FPFV	Planned total patients	Actual enrolled patients	Planned total sites	Actual active sites
Argentina	13-Dec-2023	13-Dec-2023	10	1	9	9
Australia	15-Apr-2024		3	0	2	2
Austria	12-Feb-2021	13-Sep-2023	5	1	3	3
Belgium	05-Feb-2021	09-Mar-2021	14	7	9	9
Canada	01-Jun-2020	05-Aug-2020	6	5	9	9
China	30-Apr-2023	20-Apr-2023	30	13	9	9
Finland	13-Dec-2022	03-Feb-2023	2	1	1	1
France	30-Nov-2021	23-Nov-2021	12	5	13	13
Germany	01-Nov-2021	01-Nov-2021	10	5	12	8
Italy	16-Dec-2022	12-Dec-2022	15	6	15	14
Korea	19-Jul-2022	19-Jul-2022	25	19	16	13
Luxembourg	01-Jan-2022	05-Apr-2022	3	3	2	2
Spain	31-Dec-2023	04-Jan-2024	20	4	21	16
Sweden	20-Oct-2021	21-Oct-2021	8	3	5	5
Switzerland	31-Mar-2021	22-Mar-2021	13	12	11	11
Taiwan	01-Jun-2024		10	0	6	6
United States	01-Mar-2020	03-Apr-2020	135	38	55	46
			321	123	198	176

### Gastrointestinal



7 patients

### Head and neck



17 patients

### Lung



14 patients

### Soft tissue sarcoma



8 patients

### Central nervous system



21 patients

### Melanoma



2 patients

### Pediatric



42 patients

### Other

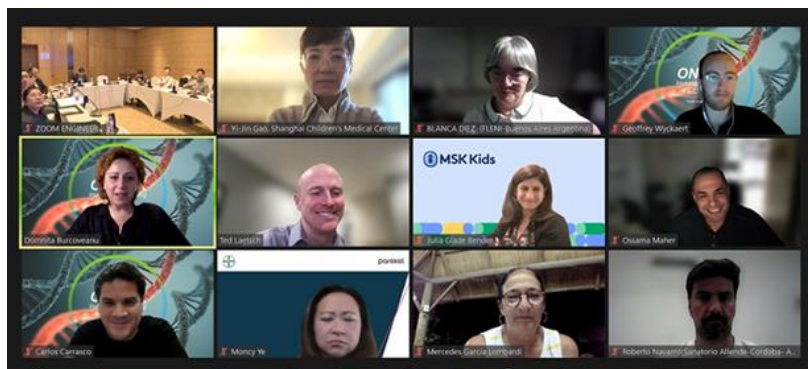


12 patients



## Investigator meeting

# Successful global investigator pediatric-focused meeting



The ON-TRK global investigator meeting, with a focus on the pediatric patients, was conducted successfully on 26<sup>th</sup> January 2024. This event brought together investigators from China, United States, Germany, Argentina, and the ON-TRK global study team. While some attendees joined in person in Beijing, others participated online.

The meeting received an overwhelmingly positive response. Dr. Domnita-Ileana Burcoveanu, medical expert and study lead, kicked off the meeting by introducing all investigators. Geoffrey Wyckaert, study manager, provided a brief overview of the study's current status. Dr. Carlos Carrasco, safety lead, shared crucial safety topics identified by ON-TRK pediatric investigators, fostering an environment of open dialogue and collaboration.

This global investigator meeting showcased a remarkable dynamic between experts from various countries, fostering an environment of collaboration and knowledge sharing. The meeting proved to be fruitful, with engaging discussions and valuable insights exchanged among the participants.

The study team is optimistic that the positive outcomes of this meeting will significantly impact the conduct of the study, particularly in patient enrollment.

With the enrollment completion foreseen by end of 2024, the collaborative spirit and shared expertise from this meeting are expected to contribute to the successful progression of the study, ultimately benefiting patients and advancing medical research.

## Save the date!

### Investigator meeting (virtual)

Thursday 16<sup>th</sup> May, 2024

From 1:00 to 2:30 pm CET

The upcoming investigator meeting is set for **16<sup>th</sup> May 2024** and will focus on adult patients.

If your site is treating adult patients and that larotrectinib is accessible for these adult patients, you should have already received the invitation. We are eager to meet with you at this event!



## Study team

### Celebrating success: recent achievements in Spain

We are pleased to share the significant progress made by the ON-TRK study in Spain, led by Anna Maria Vallverdú, Local Project Manager. Following the approval of larotrectinib without restrictions last July, 16 sites have been initiated, with 5 more scheduled to begin in the coming weeks. Notably, 4 patients have already been enrolled!

We acknowledge the dedication and perseverance of the entire ON-TRK team for their efforts. The effective communication and continuous work by the team have been crucial in achieving these milestones. Last but not least, we recognize the contributions of the Spanish investigators, whose dedication and hard work have been essential in ensuring the success of the ON-TRK study. We are grateful for their outstanding efforts.



**Left picture:**

From left to right:  
Joan Rico Lledo,  
OS LPM Trainee,  
Anna Maria Vallverdú,  
OS LPM,  
Aina Torres Florit,  
OS LPM Trainee

**Right picture:**

Julio Pozueta Larios,  
Medical Advisor



## ON-TRK faces

### Testimony from Buenos Aires' FLENI Institute



From left to right: Dr. Blanca Diez, Juliet Saba (study coordinator) and Dr. Agustín Cardoso

“ The neuro-oncology department at Buenos Aires' FLENI Institute sets the standard for brain, spinal, and peripheral nervous system tumor care in the region. With cutting-edge technology, an experienced interdisciplinary team, and patient-centered values, we deliver unmatched individualized treatment.

The medical team is spearheaded by Dr. Blanca Diez, a neuro-oncologist with a career spanning over four decades. She is supported by two oncologists dedicated to pediatric patients and four others specializing in adult care, all of whom have received training from nationally and internationally recognized centers of excellence. For each case, we complement their expertise with input across specialties – neurosurgery, radiation oncology, palliative care, pathology and more.

Our dedication to patients reaches beyond the clinical practice. An energetic clinical research program, directed by Dr. Agustín Cardoso and staffed across medical roles, drives the development of pioneering treatments. By participating in clinical trials alongside esteemed global centers, we are progressing science.

We have recently joined the ON-TRK study as a participating center, aligning our expertise with all the other prestigious international sites. We have proudly recruited the first Argentinian patient for this study, a 9-year-old girl with a low-grade glioma and NTRK gene fusion and we are enthusiastically continuing our efforts to enlist new participants, furthering our collective fight against cancer.

At FLENI, our ambition transcends merely treating cancer; we are dedicated to forging new pathways of hope.






## Data entry best practices and updates

### CRF updates

#### 'Additional tumor assessment' form

**Only one method** of tumor assessment should be selected per visit (initial visit, treatment visit and follow-up visit). If there are additional imaging assessments performed up to 8 weeks prior to first dose of larotrectinib and after larotrectinib start, but within the timeframe of 1<sup>st</sup> larotrectinib cycle (28 days), the **additional imaging assessments should be recorded on the independent form 'Additional tumor assessments'**.

Method of assessment prior to or at study entry  ☐ FDG-PET/CT

Please select **only one** method of assessment.


☐ CT Scan

☐ MRI

☐ Ultrasound

☐ Other, please specify

For questions on uploading relevant scans images and radiology reports, please go to the [Imaging](#) page.

Patient: 160200006 Site: 16020 - ON-TRK Demo Site FR 16020 (FR)  [HOME](#) [PATIENTS](#) [X LOGOUT](#)

Status | Screening | Eligibility | **Initial Visit** | End of Treatment | End of Observation


[Add Treatment](#) → | Treatment 1


[Add Follow-up](#) → |


Sexual Dev. | Cancer-rel. Surg. Procs. | Radiother. | Larotrectinib Treat. | AEs | Medication | **Add. Tumor Asmt.** | [Add. Lab.](#)

#### 'Additional laboratory' form

The most recent laboratory data before the visit (initial visit, treatment visit and follow-up visit) must be documented in the visit itself. The additional laboratory tests should be recorded on the independent form 'Additional laboratory tests'.

 Please enter only the most recent collection date before the visit. Any Additional lab tests done prior should be recorded on page [Add. Laboratory](#).

Any lab test performed?  ☐ Yes ☐ No

Patient: 160200006 Site: 16020 - ON-TRK Demo Site FR 16020 (FR)  [HOME](#) [PATIENTS](#) [X LOGOUT](#)

Status | Screening | Eligibility | **Initial Visit** | End of Treatment | End of Observation

[Add Treatment](#) → | Treatment 1

[Add Follow-up](#) → |

Sexual Dev. | Cancer-rel. Surg. Procs. | Radiother. | Larotrectinib Treat. | AEs | Medication | Add. Tumor Asmt. | **Add. Lab.**



## Data entry best practices and updates

### How to capture larotrectinib discontinuation in CRF?

If larotrectinib is discontinued and then re-initiated at a later time, two scenarios must be considered:

#### If no systemic anti-cancer therapy was administered in between:

1. Record dose interruption and restart in the 'Larotrectinib treatment' form.
2. Capture data in the 'Treatment' form.

#### If a systemic anti-cancer therapy was administered in between:

1. Document dose interruption in the 'Larotrectinib treatment' form.
2. Complete the 'End of Treatment' form.
3. Record data in the 'Follow-up' form.
4. Consider larotrectinib as subsequent therapy.

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

**Geoffrey Wyckaert**  
Global OS Project Manager



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Global Medical Expert



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