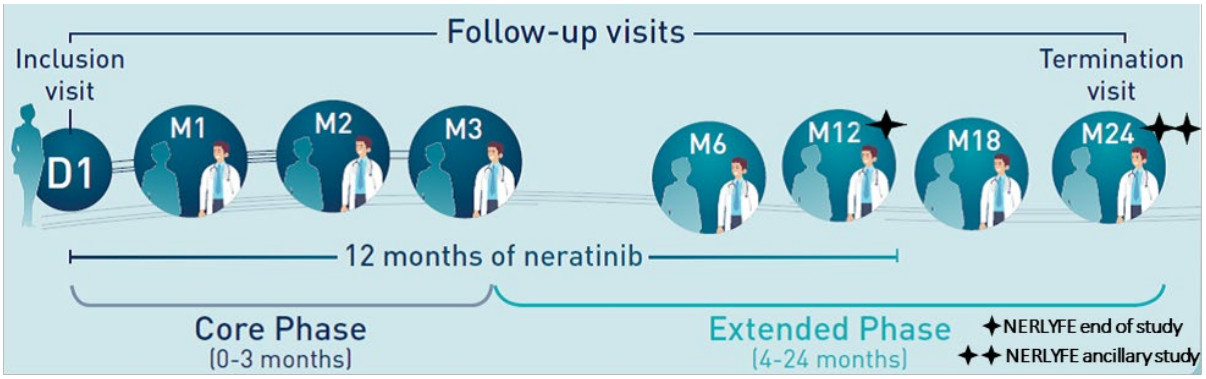
Study title	An observational safety study to describe the diarrhoea related discontinuations of extended adjuvant neratinib in HER2+ early breast cancer.
Disease 	Breast cancer.
Treatment(s) observed 	Neratinib (Nerlynx®).
Participants 	Adult patients with HER2+ breast cancer treated with extended adjuvant neratinib.
Study dates 	From 09 May 2022 to Jan 2026.
Study Locations 	Germany, Austria, United Kingdom, Czech Republic and extended to additional European countries depending on the reimbursement status in those countries.
We do research to improve patient care. By participating in an observational study, one helps to answer important scientific questions for the benefit of all.	

This document is a brief summary of a clinical study protocol. It is written in plain language for the general public, providing answers to the following questions:

- What is the purpose of the study?
- What are the objectives of the study and how are they evaluated?
- How is the study conducted?
- Who can take part in the study?

What is the purpose of the study?	HER2+ breast cancer is a subtype of breast cancer which represents approximately 15% to 25% of breast cancer worldwide. In patients with early-stage HER2+ breast cancer, a pivotal clinical study demonstrated that the use of neratinib (Nerlynx®), following (neo)adjuvant trastuzumab based therapy improves clinical outcomes of patients. However, neratinib is known to induce diarrhoea, its' primary side effect. As a consequence, pharmacovigilance activity is performed to better characterise and minimise the risks of diarrhoea associated with the neratinib administration. In this context, the purpose of this observational, prospective study is to describe the diarrhoea related discontinuations during the use of extended adjuvant neratinib in the real-world setting.
What are the objectives of the study and how are they evaluated?	The primary objective of the study is to describe the incidence of permanent discontinuation due to diarrhoea in the first 3 months of neratinib treatment. The key secondary objectives of the study are: • Description of diarrhoea patterns (e.g. severity, duration, ...). • Assessment of educational material effectiveness (accessibility, knowledge and adherence). • Impact of treatment-related diarrhoea on quality of life assessed by a questionnaire.

How is the study conducted?	The schema summarizes the study visits:



NERLYFE ancillary study will observe patients for 2 years to describe effectiveness outcomes. Patients participating to NERLYFE PASS are part of the NERLYFE ancillary study.

The core phase covers the first 3 months of neratinib treatment whereas the extended phase lasts up to 24 months of neratinib treatment.

No specific medical procedures or in-person clinical visits beyond routine care will be required for this study.

Who can take part in the study?	To be eligible for the study, participant must fulfill several conditions including the following: • Adult patient assigned to receive extended adjuvant neratinib as indicated in the summary of product characteristics (SmPC). • Adult patient having received the educational materials (EM). • Adult patient having provided consent.

Clinical Study identification	
Protocol Number	NIS12501
Protocol version	3.0 dated 25 May 2022.
Full study title	Multicentre, multi-country, prospective, observational, post-authorisation safety study to describe the incidence of discontinuation due to diarrhoea within the first 3 months of treatment with neratinib, in adult breast cancer patients treated in extended adjuvant in a real-world setting: the NERLYFE study.
Registry ID	EUPAS41584.

Who sponsors this study?	
Name and contact details of the sponsor	Pierre Fabre Médicament Les Cauquillous 81500 Lavaur-France .

Additional Information	
	EMA neratinib SmPC: neratinib NERLYNX PSUSA-10712-20210-EN PI-annotated (europea.eu)

Glossary	
HER2+ breast cancer	Breast cancer that expresses a protein called human epidermal growth factor receptor 2 (HER2)
Adjuvant	A treatment whose objective it is to prevent or stop the spread of cancer to other parts of the body. Often used after surgical removal of the primary lesion. These can include chemotherapy, immunotherapy, radiation, and vaccine therapy. An Extended adjuvant therapy is provided following another adjuvant. A Neo-adjuvant therapy is provided before primary treatment.
Pivotal clinical study	Clinical study intended to demonstrate and confirm the safety and efficacy of a treatment.
Pharmacovigilance	Science and activities relating to the detection, assessment, understanding and prevention of side effects or any other medicine-related problem
Side effects	Side effects are unwanted medical events (such as headache) that happen during the trial and that are related or possibly related to trial treatment.
Prospective study	Study where researchers will follow and observe a group of subjects over a period of time to gather information and record the development of outcomes
Ancillary study:	Study that uses samples or data from a previous study to extend knowledge beyond the original scope of the previous study.
Post-authorisation safety study	Any study relating to an authorised medicinal product conducted with the aim of identifying, characterising or quantifying a safety hazard, confirming the safety profile of the medicinal product, or of measuring the effectiveness of risk management measures.