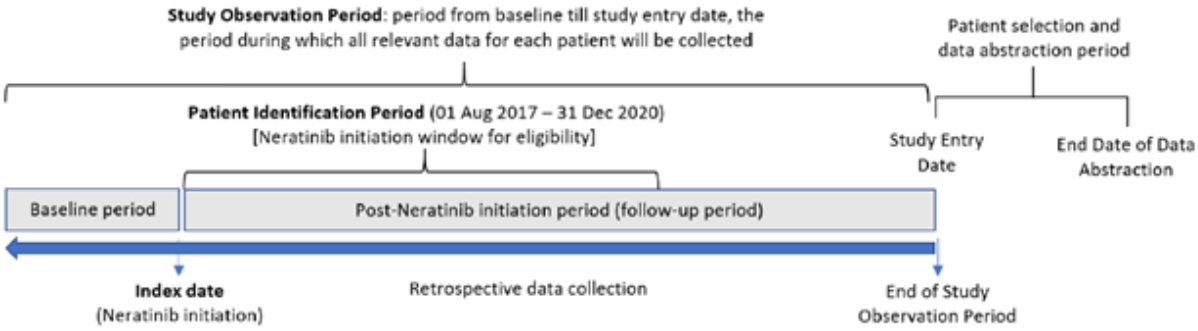
Study title	An observational study to describe the population of patients treated with extended adjuvant neratinib.
Disease 	Breast cancer.
Treatment(s) observed 	Neratinib (Nerlynx®).
Participants 	Adult patients with HER2+ early breast cancer who have been treated in the Early Access Program (EAP) with extended adjuvant neratinib in Europe from August 01, 2017 until December 31, 2020.
Study dates 	Collection of data takes place from July 2022 to July 2023.
Study Locations 	Belgium, Croatia, France, Italy, and Spain.
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 neratinib (Nerlynx®), following (neo)adjuvant trastuzumab based therapy, improves clinical outcomes of patients. In this context, the purpose of this observational retrospective study is to describe the population of patients in Europe who were treated with extended adjuvant neratinib after having received a trastuzumab based therapy*. *Trastuzumab based therapy = treatment with trastuzumab combined with chemotherapy, with or without pertuzumab, or treatment with trastuzumab emtansine and being part of the reference treatment for adjuvant (= post surgery) therapy of HER2+ breast cancer.
What are the objectives of the study and how are they evaluated?	The primary objective of the study is to describe demographic and clinical characteristics of patients with HER2+ breast cancer treated with neratinib by collecting information such as age, gender, history of disease, … The secondary objectives of NEAR are: • To describe neratinib treatment patterns (e.g. dose, treatment duration, discontinuation …).

	• To describe breast cancer treatment history before neratinib initiation. • To describe the side effects in patients with breast cancer using neratinib.
How is the study conducted?	The schema depicted below summarizes the study flow:
	
Who can take part in the study?	To be eligible for the study, participant must fulfill several conditions including the following: • Patient aged over 18 years at neratinib treatment initiation. • Patient having received at least one dose of extended adjuvant neratinib in the European EAP between August 01, 2017 and December 31, 2020. • Patient (or next of kin/legal representative, if applicable) who provides written informed consent or non-opposition.

Clinical Study identification	
Protocol Number	NIS12501
Protocol version	1.0 dated 22 September 2021
Full study title	Retrospective observational study of adult patients with early-stage HER-2 positive breast cancer, treated with neratinib as extended adjuvant therapy in the context of the European Early Access Program.
Registry ID	NCT05599334.

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 (europa.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.
Early Access Program (EAP)	program that gives access to investigational drugs outside of the clinical trial space and before the commercial launch of the drug, to patients with life-threatening diseases having no treatment options available. EAP offer ethical, compliant and controlled mechanisms.
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.
Retrospective study	Study in which participants with known outcomes are assessed based on data collected before the 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.