

TAK-113-5005 Privacy Statement

NHS England Application Reference Number: DARS-NIC-749150-S0M7G-v0

Effective date of this privacy notice: 08/09/2025

Background

Your privacy is important to us. Takeda recognizes and respects the privacy rights of individuals with regards to their personal data. Takeda Pharmaceuticals North America (“Takeda”, “we”, “us”, “our”) is conducting a research study called “Characteristics, Treatment Patterns and Outcomes of Patients with Refractory Metastatic Colorectal Cancer” (TAK-113-5005).

Why is Takeda conducting this Study?

The purposes of the TAK-113-5005 study are to:

- Describe demographic and clinical characteristics of patients with metastatic colorectal cancer who have received at least three lines of treatments.
- Describe patterns and sequences of anti-cancer treatments given to patients with metastatic colorectal cancer.
- Estimate overall survival and time to next treatment after third- and fourth-line treatment in patients with metastatic colorectal cancer

Who is this notice intended for?

This privacy notice is intended for patients treated and managed by the National Health Service (NHS) in England whose data is included in the TAK-113-5005 study.

Who is the data controller?

NHS England is the custodian of the national datasets (generated by health and social care services) that will be used as part of the TAK-113-5005 study. As this is a Takeda initiated study, although we will not have access to any of your personal data, we will also constitute a data controller for the purposes of the TAK-113-5005 study.

We have appointed Evidera Limited, (address: Second Floor, The Ark, 201 Talgarth Road, Hammersmith, London, W6 8BJ), as the data processors. As data processor, Evidera will be given access to the national datasets to process your data. The data that will be accessed will however be pseudonymised data which means you will not be identifiable as an individual.

Do we collect any personal data?

As set out above, the TAK-113-5005 study will access and process data already held in NHS England datasets which consist of patients’ electronic health records, which may include, but is not limited to:

- Age (or year and month of date of birth), gender, ethnicity

- Health status, diagnoses, and treatment details

We do not collect or use any additional data beyond what already exists in your electronic health record (as listed above)

How We will process your data.

Data will be processed both by manual and automatic means on a secure data server by Takeda's appointed data processor. Once each set of analyses is conducted by Takeda's appointed data processor, the output is checked for compliance with NHS England's Disclosure Control Rules. Output will consist of aggregated, summary results only with suppression of all counts under 10.

What is the Lawful basis for processing your data?

Data protection legislation (UK GDPR) requires us to have a valid legal reason to process and use pseudonymised data about you. This is called a 'legal basis'.

In the context of the TAK-113-5005 study, the lawful basis upon which we will process your information is in accordance with Article 6(1)(f) and Article 9(2)(j) of the UK GDPR, we process your data where it is within our legitimate interest to do so, and where it is necessary for reasons of public interest in the area of public health and/or is necessary for research purposes.

We will use the datasets for the purpose of carrying out the TAK-113-5005 study. We may use the results from the study for the following purposes or for purposes reasonably compatible with the ones listed in this notice such as:

- To understand demographic and clinical characteristics of patients with metastatic colorectal cancer, overall and by different treatments they received.
- To understand later line treatment use and unmet medical needs among patients with metastatic colorectal cancer.
- Data from this study will provide information for Medical Science Liaisons to share with health care providers and patient advocacy groups in UK on current treatment patterns and unmet needs.
- Data from this study will help evaluate the proportion of patients with metastatic colorectal cancer who may benefit from new therapies in later line settings such as fruquintinib.

To be clear, at no point throughout the study will Takeda itself have access to any patient-level data. All data shared with Takeda will be fully aggregated in nature with small numbers suppressed. Any results of the study will also be fully aggregated and will not include any personal level information.

With whom We may share results of the TAK-113-5005 study data.

Only your aggregated data may be shared with:

Auditors and consultants to verify Our compliance with internal and external requirements;

Statutory bodies, law enforcement agencies, legal advisors and litigants when required for a legal reporting requirement or defending or instigation a legal claim; and

Other third parties providing contracted services on Our behalf e.g. medical writers.

How long We keep your data.

Your aggregated data may be processed by manual and automatic means and stored securely for the number of years required to complete the study and no longer than 2 years per our Data sharing Agreement with NHS England. Once the study is complete, the aggregated data will be permanently deleted.

Your rights in relation to your data and how to exercise them.

NHS England patients are able to opt out from the national cancer registration data collection by contacting the opt-out team at NDRSoptout@nhs.net . This will remove any future use of your data for research or planning purposes. Further details can be found on NHS England website [Opting out of disease registration - NDRS](#)

For questions about this notice or to exercise your rights, please contact us at: Email Address: privacyoffice@takeda.com