# A REGISTRY TO COLLECT CHARACTERISTICS AND OUTCOMES FROM PATIENTS WITH SOLID TUMORS PROFILED WITH A NEXT-GENERATION SEQUENCING TEST (WAYFIND-R)

**04/04/2025 05:48:24**

## Main Information

**Primary registry identifying number**
LBCTR2022105085

**Protocol number**
MX39897

**MOH registration number**

**Study registered at the country of origin**
No

**Study registered at the country of origin: Specify**
Not Applicable - The Registry will be conducted in several countries worldwide including EU countries like France

**Type of registration**
Prospective

**Type of registration: Justify**
N/A

**Date of registration in national regulatory agency**
27/08/2020

**Primary sponsor**
F. Hoffmann-La Roche Ltd

**Primary sponsor: Country of origin**
Switzerland

**Date of registration in primary registry**
09/12/2022

**Date of registration in national regulatory agency**
27/08/2020

**Public title**
A REGISTRY TO COLLECT CHARACTERISTICS AND OUTCOMES FROM PATIENTS WITH SOLID TUMORS PROFILED WITH A NEXT-GENERATION SEQUENCING TEST (WAYFIND-R)

**Acronym**
WAYFIND-R

**Scientific title**
A REGISTRY TO COLLECT CHARACTERISTICS AND OUTCOMES FROM PATIENTS WITH SOLID TUMORS PROFILED WITH A NEXT-GENERATION SEQUENCING TEST (WAYFIND-R)

**Acronym**
WAYFIND-R

**Brief summary of the study: English**

This is an observational, non-interventional, prospective, multinational and multicenter solid tumor cancers registry. Patients with any type of malignant solid tumor will be targeted for enrolment. Patients who have undergone NGS testing no more than 3 months prior to the enrolment date will be included, irrespective of the availability of test results. All medicinal products used to treat solid tumor cancers (all oncology treatments) are considered studied medicinal products for this registry.

The study has several objectives, the most prominent of which are:
-To provide a platform to support the design and conduct of clinical and epidemiological research
-To develop an evidence-generation platform to better understand health outcomes and cancer care processes
-To characterize the treatments and clinical course of solid tumor cancers in patients who have undergone NGS testing

Participants' data will be abstracted from the medical records collected by the registry treating physician or medical staff and recorded on electronic case report forms (eCRFs). Data from participant medical records and notes should be entered on the eCRFs as soon as they become available, or at regular intervals and for all visits that occurred within every 6 months from the enrolment or previous visit until participant withdrawal or discontinuation of the site or the
registry, whichever occurs first. Data on pregnancy should be reported using the paper pregnancy reporting form provided by the Sponsor.
Additionally, at the time of the patient's enrolment visit two baseline information forms will be
collected:
-A baseline physician information form on rationale/reason for ordering NGS testing and the reimbursement for the test (for each patient enrolled in the registry)
-A baseline patient information form to collect, risk factors, confounders and effect modifiers including comorbidities and sociodemographic information that may not be present or well completed in patient medical records

Due to the nature of this registry, it is currently not possible to determine the exact sample size; however, we aim to enroll around ≥15,000 patients by 2026 and beyond based on enrolment rate.

**Brief summary of the study: Arabic**

هذه الدراسة هي عبارة عن دراسة تسجيل رصدية غير تدخلية استطلاعية متعددة الجنسيات ومتعددة المراكز على الأورام السرطانية الصلبة.
سيتم استهداف المرضى ممن يعانون من أي نوع من الأورام الصلبة الخبيثة. سيتم تضمين المرضى الذين خضعوا لاختبار تسلسل الجيل التَّالي أشهر من تاريخ التسجيل، بصرف النظر عن توفر نتائج الاختبار. تعتبر جميع المنتجات الدوائية المستخدمة لعلاج الأورام3قبل ما لا يزيد عن السرطانية الصلبة (جميع علاجات الأورام) منتجات طبية خاضعة للدراسة في دراسة التسجيل.
للدراسة عدة أهداف، أبرز عناوينها هي:
-توفير منصة لدعم تصميم وإجراء البحوث السريرية والوبائية
-استحداث منصة لتوليد الأدلة لفهم النتائج الصحية وعمليات رعاية مرضى السرطان بشكل أفضل
-توصيف العلاجات والمسار السريري للأورام السرطانية الصلبة في المرضى الذين خضعوا لاختبار تسلسل الجيل التَّالي

سيتم استخراج بيانات المشاركين من السجلات الطبية التي جمعها الطبيب المعالج أو الطاقم الطبي بدراسة التسجيل والمسجلة في نماذج تقرير الحالة الإلكترونية (eCRFs). يجب إدخال البيانات المأخوذة من السجلات الطبية والملاحظات الخاصة بالمشاركين في نماذج تقرير الحالة أشهر من وقت التسجيل أو الزيارة السابقة حتى6الإلكترونية بمجرد توفرها، أو على فترات منتظمة ولجميع الزيارات التي حدثت خلال كل انسحاب المشارك أو توقف الموقع أو دراسة التسجيل، أيهم يحدث أولا. يجب الإبلاغ عن البيانات المتعلقة بالحمل باستخدام النموذج الورقي للإبلاغ عن الحمل المُقدَّم من الشركة الرَّاعية.
بالإضافة إلى ذلك، في وقت زيارة تسجيل المريض، سيتم جمع نموذجي المعلومات الخاصين ببدء الدراسة:
-نموذج معلومات الطبيب عند بدء الدراسة حول الأساس المنطقي/سبب طلب اختبار تسلسل الجيل التَّالي وسداد تكاليف الاختبار (لكل مريض مسجل في دراسة التسجيل)
-نموذج معلومات المريض الخاص ببدء الدراسة لجمع عوامل الخطورة والعوامل المربكة ومُحَوِّرَات التأثير ومن ضمنها الأمراض المصاحبة والمعلومات الاجتماعية الديموجرافية التي قد لا تكون موجودة أو مكتملة بشكل جيد في السجلات الطبية للمريض

2026 مريض بحلول عام 15000نظرًا لطبيعة دراسة التسجيل هذه، لا يمكن حاليًّا تحديد حجم العينة بدقة؛ ومع ذلك، نهدف إلى تسجيل نحو ≤ وما بعده بناءً على معدل التسجيل.

**Health conditions/problem studied: Specify**

The registry population will include adult patients who are diagnosed with solid tumor cancers (at any anatomical location) and at any stage of the disease.

**Interventions: Specify**

Non-interventional study

**Key inclusion and exclusion criteria: Inclusion criteria**

Patients must meet the following criteria for enrolment in this registry:
- Patient is an adult (according to age of majority as defined by local regulations)
- Patient is currently diagnosed with any type of solid tumor cancer, at any stage of the disease, at the enrolment date (informed consent date)
- Patient has undergone NGS testing, no longer than 3 months prior to the enrolment date, irrespective of the availability of test results
- Informed consent has been obtained from the patient or legally authorized representative, as per local regulations

**Key inclusion and exclusion criteria: Gender**

Both

**Key inclusion and exclusion criteria: Specify gender**

**Key inclusion and exclusion criteria: Age minimum**

18

**Key inclusion and exclusion criteria: Age maximum**

100

**Key inclusion and exclusion criteria: Exclusion criteria**

Patients who meet the below exclusion criterion at the time of enrolment will not be enrolled in this registry:
- Patient has a prior or current diagnosis of hematological malignancy

**Type of study**

Observational

**Type of intervention**

N/A

**Type of intervention: Specify type**

N/A

**Trial scope**

N/A

**Trial scope: Specify scope**

N/A

**Study design: Allocation**

N/A

**Study design: Masking**

N/A

**Study design: Control**

N/A

**Study phase**

N/A

**Study design: Purpose**

N/A

**Study design: Specify purpose**

N/A

**Study design: Assignment**

N/A

**Study design: Specify assignment**

N/A

**IMP has market authorization**

**IMP has market authorization: Specify**

**Name of IMP**

**Year of authorization**

**Month of authorization**

**Type of IMP**

**Pharmaceutical class**

**Therapeutic indication**

**Therapeutic benefit**

**Study model**

**Study model: Explain model**

Other

**Study model: Specify model**

Registry

This is an observational, non-interventional, prospective, multinational and multicenter solid tumor cancers registry. As per the EMA discussion paper, a patient registry is an organized data collection system that uses observational methods to collect uniform data on a patient population that is followed over time (EMA 2018). Patients enrolled in this registry might be already enrolled in a clinical trial or might be offered participation in a clinical trial at the same time, as applicable per inclusion/exclusion criteria of the clinical trial.

This registry will not be a product registry, as it aims to collect data on patients who are undergoing a variety of treatments for diverse solid tumors that are not predefined. Instead, enrolment is subject to the prescription of NGS within clinical practice, irrespective of the availability of test results.

**Time perspective**

Prospective

**Time perspective: Explain time perspective**

Observation Period for the participant:
The term “observation period” is defined as the period spanning from the date of consent until the date of death, loss to follow-up, withdrawal of consent, registry closure by Sponsor or site withdrawal from the registry, whichever occurs first.

**Time perspective: Specify perspective**

N/A

**Target follow-up duration**

2

**Target follow-up duration: Unit**

years

**Number of groups/cohorts**

1

**Biospecimen retention**

None retained

**Biospecimen description**

NA

**Target sample size**

15000

**Actual enrollment target size**

**Date of first enrollment: Type**

Anticipated

**Date of first enrollment: Date**

15/11/2022

**Date of study closure: Type**

Anticipated

**Date of study closure: Date**

31/12/2024

**Recruitment status**

Pending

**Recruitment status: Specify**

**Date of completion**

31/12/2024

**IPD sharing statement plan**

Yes

**IPD sharing statement description**

The Sponsor maintains confidentiality standards by coding each participant enrolled in the registry through assignment of a unique participant identification number. This means that participant names or other direct identifiers are not included in datasets that are transmitted to any Sponsor location. Data protection and privacy regulations will be followed in capturing, processing, storing and sharing participant data, in accordance with local applicable privacy and confidentiality requirements. An external anonymized data sharing plan that aligns with national regulations and EU GDPR (2016) (General Data Protection Regulation) will be developed. This will outline the mechanism of data sharing with relevant research parties who are interested in utilizing the data collected in this registry for conducting SDU studies. The data will be stored in a data warehouse after closing the registry. Participant medical information obtained by this registry is confidential and may be disclosed to third parties only as permitted by the ICF (or separate authorization for use and disclosure of personal health information) signed by the participant, unless permitted or required by law. Medical information may be given to a participant's personal treating physician or other appropriate medical personnel responsible for the subject's welfare, for treatment purposes.
Data collected by this registry must be available for inspection upon request by representatives of national and local health authorities, Sponsor monitors, representatives, collaborators and the IRB/EC for each registry site, as appropriate.

**Additional data URL**

**Admin comments**

**Trial status**

Approved

## Secondary Identifying Numbers

No Numbers

## Sources of Monetary or Material Support

| Name |
| --- |
| F. HOFFMANN-LA ROCHE LTD |

## Secondary Sponsors

No Sponsors

## Contact for Public/Scientific Queries

| Contact type | Contact full name | Address | Country | Telephone | Email | Affiliation |
|---|---|---|---|---|---|---|
| Public | Hampig Kourie | Hotel Dieu De France - ALFRED NACCACHE STREET 20631111 Beirut | Lebanon | 01604000 | hampig.kourie@hotmail.com | Hotel Dieu De France |
| Scientific | Hampig Kourie | Hotel Dieu De France - ALFRED NACCACHE STREET 20631111 Beirut | Lebanon | 01604000 | hampig.kourie@hotmail.com | Hotel Dieu De France |

## Centers/Hospitals Involved in the Study

| Center/Hospital name | Name of principles investigator | Principles investigator speciality | Ethical approval |
|---|---|---|---|
| Hotel Dieu De France | Dr. Hamig Kourie | Hematologist-Oncologist & Oncogeneticist | Approved |

## Ethics Review

| Ethics approval obtained | Approval date | Contact name | Contact email | Contact phone |
|---|---|---|---|---|
| Hotel Dieu de France | 31/05/2022 | Professor Sami Richa | cue@usj.edu.lb | +961-1-421 229 |

## Countries of Recruitment

| Name |
|---|
| Lebanon |
| Argentina |
| Austria |
| Brazil |
| Canada |
| Colombia |
| France |
| Greece |
| Hungary |
| Ireland |
| Mexico |

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|---|
| Portugal |
| Spain |
| Thailand |
| Turkey |
| United Kingdom |
| Germany |
| Estonia |
| Philippines |
| Republic of Serbia |
| Slovenia |
| Viet Nam |
| Taiwan |
| Chile |
| Slovakia |
| India |
| South Africa |
| Poland |
| Egypt |
| United Arab Emirates |
| Saudi Arabia |

## Health Conditions or Problems Studied

| Condition | Code | Keyword |
|---|---|---|
| Solid Tumors | Neoplasm of uncertain or unknown behaviour, unspecified (D48.9) | ALL SOLID TUMORS |

## Interventions

| Intervention | Description | Keyword |
|---|---|---|
| Non-Interventional Study (Registry) | NA | NA |

## Primary Outcomes

| Name | Time Points | Measure |
|---|---|---|
| To provide a platform to support the design and conduct of clinical and epidemiological research | NA being that it's a registry | - Collect data that can inform future trial design and facilitate identification of potential trial populations - Provide a resource to identify, develop and qualify biomarkers, novel assessment tools and clinical endpoints - Provide a resource to support the conduct of disease-modeling studies |
| To develop an evidence-generation platform to better understand health outcomes and cancer care processes | NA being that it's a registry | - Provide a resource to inform how precision medicine tools are used and how they affect patient care in the real world - Provide a resource to generate evidence that can support clinical, regulatory and access decision-making - Provide a resource to identify and assess clinical practices that can improve the healthcare of affected individuals |
| To characterize the treatments and clinical course of solid tumor cancers in patients who have undergone NGS testing | NA being that it's a registry | - Collect data that describes the history of patients undergoing NGS testing - Collect data that can help identify the complex genomic landscape affecting the diagnosis and prognosis of solid tumor cancers and deepen the understanding of underlying biologic pathways - Collect data that can help identify sub-populations that may best benefit from precision medicine tools |

## Key Secondary Outcomes

| Name | Time Points | Measure |
|---|---|---|
| NA - It's a registry | NA | NA |

## Trial Results

**Summary results**

**Study results globally**

**Date of posting of results summaries**

**Date of first journal publication of results**

**Results URL link**

**Baseline characteristics**

**Participant flow**

**Adverse events**

**Outcome measures**

**URL to protocol files**