

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

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Main		

Primary registry identifying number

LBCTR2022105085

MOH registration number

Study registered at the country of origin

Type of registration

Prospective

Date of registration in national regulatory agency

27/08/2020

Primary sponsor

F. Hoffmann-La Roche Ltd

Date of registration in primary registry

09/12/2022

Public title

A REGISTRY TO COLLECT CHARACTERISTICS AND **OUTCOMES FROM PATIENTS WITH SOLID TUMORS** PROFILED WITH A NEXT-GENERATION SEQUENCING TEST

(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)

Brief summary of the study: English

Protocol number

MX39897

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: Justify

N/A

Primary sponsor: Country of origin

Switzerland

Date of registration in national regulatory agency

27/08/2020

Acronym

WAYFIND-R

Acronym

WAYFIND-R



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 المرضي ممن يعانون من أي نوع من الأورام الصلبة الخبيثة. سيتم تضمين المرضى الذين خُضُعوا لاختبار تسلسل الجَيل الثّالي أشهر من تاريخ التسجيل، بصرف النظر عن توفّر نتائج الاختبار . تعتبر جميع المنتجات الدوائية المستخدمة لعلاج الأورام3قبل ما لا يزيد عنّ السرطانية الصلبة (جميع علاجات الأورام) منتجات طبية خاضعة للدراسة في دراسة التس .. للدراسة عدة أهداف، أبرز عناوينها هي

توفير منصة لدعم تصميم وإجراء البحوث السريرية والوبائية ــ

استحداث منصة لتوليد الأدلة لفهم النتائج الصحية وعمليات رعاية مرضى السرطان بشكل أفضل-توصيف العلاجات والمسار السريري للأورام السرطانية الصلبة في المرضى الذين خضعوا الاختبار تسلسل الجيل الثالي-

سيتم استخراج بيانات المشاركين من السجلات الطبية التي جمعها الطبيب المعالج أو الطاقم الطبي بدراسة التسجيل والمسجلة في نماذج تقرير يُجب إدخال البيانات المأخوذة من السجلات الطبية والملاحظات الخاصة بالمشاركين في نماذج تقرير الحالة .(eCRFs) الحالة الإلكترونية 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 على المعلومات الخاصين ببدء الدراسة نموذج معلومات الطبيب عند بدء الدراسة حول الأساس المنطقي/سبب طلب اختبار تسلسل الجيل الثّالي وسداد تكاليف الاختبار (لكل مريض-(مسجل في در اسة التسجيل

نموذج معلومات المريض الخاص ببدء الدراسة لجمع عوامل الخطورة والعوامل المربكة ومُحَوّرَات التأثير ومن ضمُنها الأمرّاض 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 Key inclusion and exclusion criteria: Specify gender

Both

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

18 100

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 Type of intervention: Specify type

N/A N/A

Trial scope Trial scope: Specify scope

N/A N/A

Study design: Allocation Study design: Masking

N/A N/A

Study design: Control Study phase

N/A N/A

Study design: Purpose Study design: Specify purpose

N/A N

Study design: Assignment Study design: Specify assignment

N/A 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

Time perspective

Prospective

Time perspective: Specify perspective

N/A

Target follow-up duration

2

Number of groups/cohorts

1

Biospecimen retention

None retained

Target sample size

15000

Date of first enrollment: Type

Anticipated

Date of study closure: Type

Anticipated

Recruitment status

Pending

Date of completion

31/12/2024

IPD sharing statement plan

Yes

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: 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.

Target follow-up duration: Unit

years

Biospecimen description

NA

Actual enrollment target size

Date of first enrollment: Date

15/11/2022

Date of study closure: Date

31/12/2024

Recruitment status: Specify

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



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		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 subpopulations 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	