



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

22/11/2024 03:43:20

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

15/04/2024

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



**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
American University of Beirut	Dr. Hazem Assi	Oncologist	Approved
Hammoud University Hospital	Dr. Fadi Farhat	Oncologist	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
American University of Beirut Medical Center	06/03/2023	American University of Beirut IRB	irb@aub.edu.lb	+961 1 35 00 00 – Ext 5445
Hammoud Hospital University Medical Center	11/09/2023	Hammoud Hospital IRB	info@hhumc.org.lb	+961 7 723111

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
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