Notable Labs Protocol N-01: An Observational Study to Collect and Assess Tissue Samples from Subjects With Documented Hematologic Malignancy (ANSWer)

First published: 27/01/2021

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Study Ongoing

Administrative details

EU PAS number

EUPAS39233

Study ID

39234

DARWIN EU® study

No

Study countries

Greece

Spain

United States

Study description

This is a prospective, multicenter observational study to collect clinically annotated biospecimens in order to assess the correlation between ex vivo data generated by the Notable assay platform and clinical outcome.

Study status

Ongoing

Research institutions and networks

Institutions

Notable Labs

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Wagner Joseph

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/01/2019

Actual: 01/01/2019

Study start date
Planned: 03/12/2019

Actual: 13/12/2019

Date of final study report
Planned: 20/12/2023

Sources of funding

- Other

More details on funding

Notable Labs

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Creation of tumor registry

Main study objective:

This is a prospective, multicenter observational study to collect clinically annotated biospecimens in order to assess the correlation between ex vivo data generated by the Notable assay platform and clinical outcome.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Acute leukaemia

Myelodysplastic syndrome

Myeloproliferative neoplasm

Chronic leukaemia

Population studied

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

1.000

Study design details

Outcomes

Establish a tumor registry with annotated clinical specimens. 1) assess whether or not correlation exists between ex vivo drug sensitivity data generated by the Notable assay platform and clinical outcome, and 2) determine whether there are genotype and/or phenotype correlations between ex vivo and clinical responses with somatic tumor mutations.

Data analysis plan

There will be Minimal Risk to subjects who elect to donate specimens. Bone marrow aspirate samples are collected as part of routine medical care. Per FDA 21 CFR Part 812, blood and other remainder samples such as bone marrow may be collected as part of routine Standard Of Care (SOC). Blood samples collected via a non-SOC study-only blood draw are considered minimal risk as they will be collected from adult subjects and will not exceed 550 mL in an 8-week period and will not occur more than 2 times per week. Subjects will be properly informed of the risks of the procedure as part of the consent process. No known psychological risks will be involved as all subject identifiers will be encoded and inaccessible to any researchers except the Principal Investigator and personnel under their direct supervision.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No