EORTC 1335 - SPECTAlung

Screening Patients with thoracic tumors for Efficient Clinical Trial Access

Phase : Sans

Type d'essai : Observationnel

Etat de l'essai : Ouvert

Objectif principal

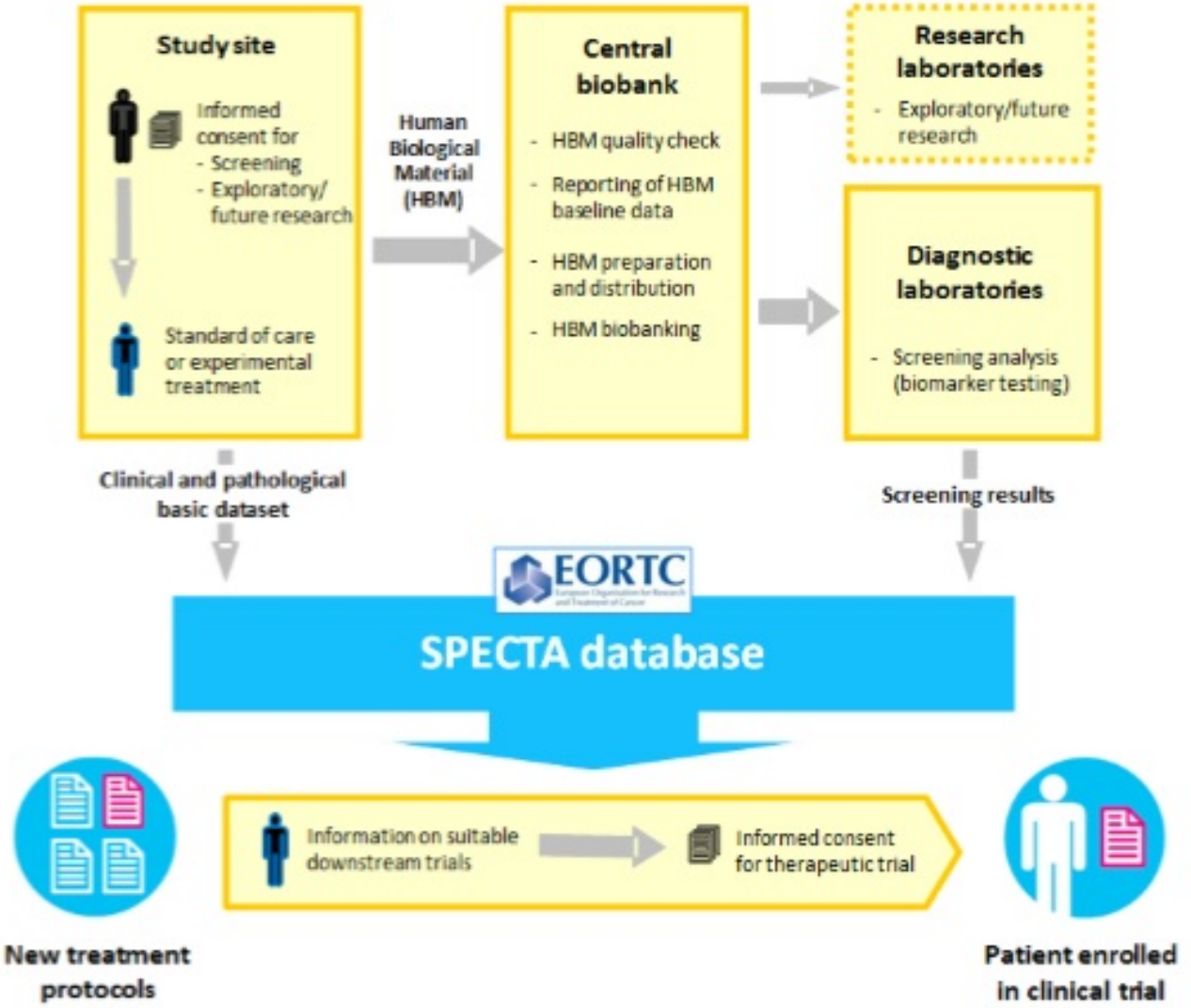
Establish a platform for screening patients with thoracic malignancy (lung cancer, MPM and thymic malignancies) and efficiently allocate them to biomarker-driven clinical trials.

Objectifs secondaires

Identify or validate new molecularly defined subgroups of tumors.
Investigate the prevalence and the predictive prognostic value of novel biomarkers to plan future clinical trials.
Correlate the identified biomarkers and the tested samples with clinical and demographical patient characteristics.
Perform exploratory/future research.
Facilitate the establishment of quality-assured and validated tests for thoracic cancer (lung cancer, MPM and thymic malignancies) biomarkers.

Résumé / Schéma de l'étude

Description of the processes :



Critères d'inclusion

Patient enrollment will follow a 2-step procedure. Subjects must meet all of the following criteria to be enrolled. Both steps must be completed in order for the patient to be considered as eligible.

The following criteria are a prerequisite for step 1 registration :

1 Pathologically confirmed lung cancer, malignant pleural mesothelioma, thymoma or thymic carcinoma at any stage.

2 Mandatory availability of adequate human biological material (HBM): FFPE tissue sample from the primary tumor, recurrent tumor, metastasis, obtained at the time of primary surgery/biopsy; minimal amount requested is detailed in the HBM guidelines; if feasible, inclusion of samples taken at any recurrence diagnosed during followup is strongly encouraged but optional.

3 Age ≥ 18 years.

4 At least three months life-expectancy.

5 Written informed consent according to ICH/GCP and national/local regulations.

6 Absence of any active malignancy, except pT1-2 prostatic cancer Gleason score < 6, non melanomatous skin cancer or carcinoma in situ of the cervix, in the 5 years before study entry.

7 Absence of exclusion criteria like active hepatitis B/C or HIV, second malignancies, no severe organ dysfunction or other comorbidities that may prevent inclusion into clinical trials.

Central confirmation of human biological material (HBM) adequacy for step 2 :

1 Centrally performed confirmation of tumor tissue adequacy in terms of quality/ quantity for central screening.

Calendrier prévisionnel

Lancement de l'étude : Mai 2015
Fin estimée des inclusions : Janvier 2019
Nombre de patients à inclure : 3500

Etablissement(s) participant(s)

> AP-HM - Centre Hospitalier Universitaire Nord

(13) BOUCHES-DU-RHÔNE

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Promoteur(s)

European Organisation for Research and Treatment of Cancer - (EORTC)

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