RAIDs Rational molecular Assessment Innovative Drug selection

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RAIDs Project Newsletter

Clinical study BioRAIDs

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Cervical cancer is the second most common cause of cancer death in women worldwide. There are great disparities across Europe in incidence and mortality rates, which can be twelve times higher in Eastern Europe than in Northern Europe. In the last decades the screening, prevention and treatment of cervical cancer has improved considerably. However, despite the progress, the standard treatment strategy of cervical cancer still consists of surgery, radiotherapy and chemotherapy.

The project **RAIDs** « Rational molecular Assessment Innovative Drug selection » is a multidisciplinary co-operation between academic clinical centers, SMEs and translational research platforms. The main objective of the study is to identify prognostic and predictive biomarkers for standard and targeted therapy in cervical cancer patients using high throughput genomic and proteomic approaches in order to improve treatment response for the individual patient.

BioRaids clinical study is the part of the European project RAIDs (http://www.raids-fp7.eu), coordinated by Institut Curie and funded from the European Union's Seventh Programme for research, technological development and demonstration under grant agreement No 304810. BioRAIDs aims to collect the biological material from 700 patients for further analysis in order to identify dominant genomic and protein signaling pathway alterations, enabling the identification of prognostic and predictive biomarkers for standard or targeted therapy in CC.

CLINICAL STUDY BIORAIDS (WP4)

Participating countries: France, Germany, Netherlands, Romania, Moldova and Serbia.

The study **BioRAIDs** was open in France at Institut Curie (Sponsor of the study) on July 24th, 2013. The first patient was recruited in October 2013.

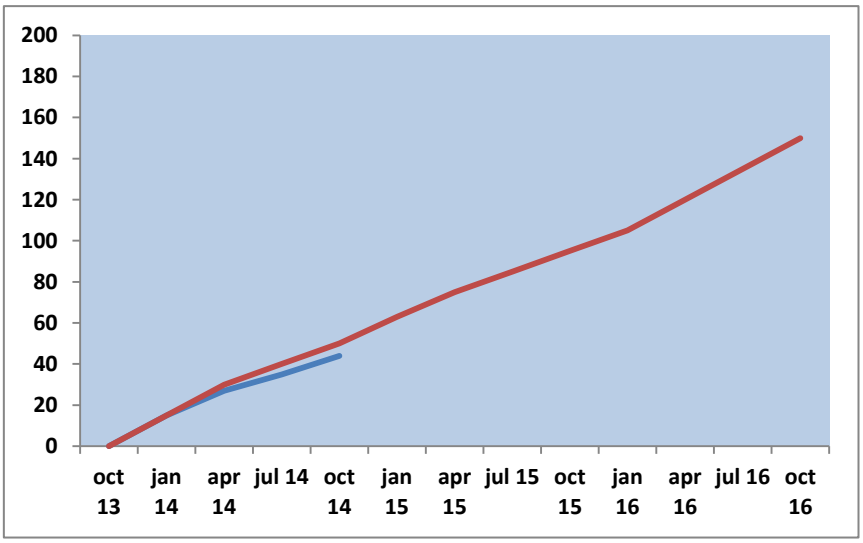
FRANCE:

The BioRAIDs study has been opened in France since one year.

Bilan on October 14th, 2014:

Nb of patients included in France: 49 Nb of centers opened in France: 10 Nb of recruiting centers: 7	**Centre to be opened**: Hospital Bichat

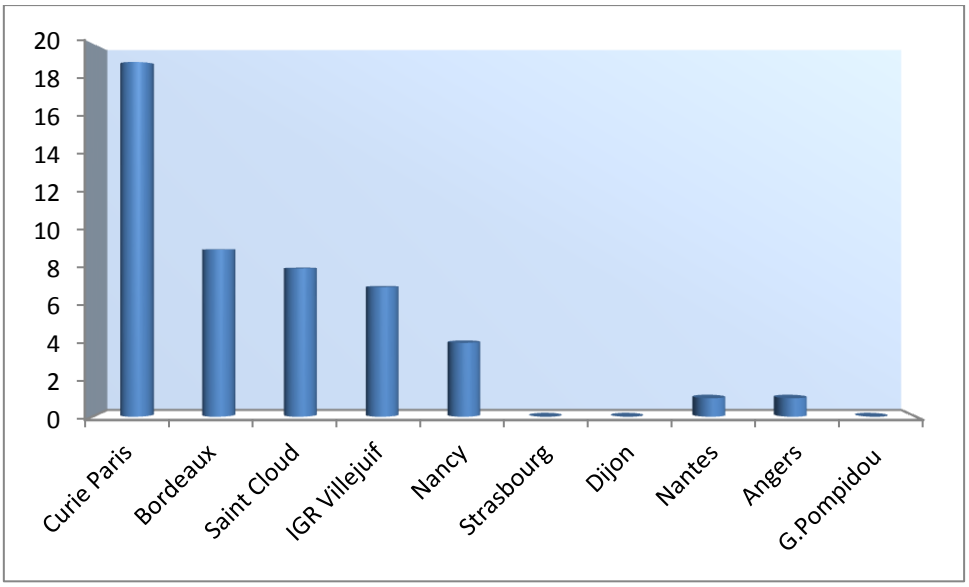
Figure 1. Patients accrual in BioRAIDs study in France: expectation and reality



Centers opened in France (10):

Institut Curie (Paris), Institut Curie (St-Cloud), Institut Gustave Roussy (Villejuif), Institut Bergonié (Bordeaux), ICL (Nancy), ICO site René Gauducheau (Saint-Herblain), Centre Paul Strauss (Strasbourg), Centre Georges François Leclerc (Dijon), ICO Paul Papin (Angers), Hospital European Georges Pompidou AP-HP (Paris).

Figure 2. Patients accrual in BioRAIDs study in France: per centre



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EUROPE:

Serbia : The center was opened 4th of June, the inclusion of first patient is expected in October 2014.

The Netherlands: The center is open; the inclusion of first patient is expected in October 2014.

Hanover Clinical Trial Center (HCTC) directed by Heiko von der Leyen will be Sponsor Delegate in Germany, Romania and Moldova.

Germany : An approval of Ethics Committee was obtained by HCTC for the investigational center in Hanover in September. The initiation visit was done in October by RAIDs Coordinator Dr. Suzy Scholl. After the training on eCRF the patients' accrual can start in November.

Romania: BioRAIDs was qualified as an observational study by Romanian competent authorities. Submissions to National Ethics Committee are ongoing.

Moldova : The investigators, especially Dr. Nina Samet, have done the submissions to regulatory authorities. Answer from Ministry of Health has been obtained. The study documents were submitted to National Ethics Committee. After the obtaining of written decision from National Ethics Committee and purchase of insurance the opening of the center is expected in November-December 2014.

PROGRESS OF ANALYSES AND SCIENTIFIC DATA :

First samples from 25 patients were sent from France to The Netherlands in order to be analyzed. DNA was successfully extracted and analysis of molecular alterations will follow soon.

QUALITY CONTROL OF RADIOTHERAPY : The workshops in radiotherapy were organized by IGR (Christine Haie-Meder, Eric Deutsch, Eleonor Rivin Del Campo and Andrea Slocker Escarpa). 14 centers from 21 has participated (11 french centers). This interaction has allowed to compare the different practices in European centers in order to standardize them.

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DISSEMINATION and NETWORKING

- In France the patient accrual corresponds to foreseen inclusion rate.
- BioRAIDs study was presented during various meetings, including to EORTC/ENGOT. The last presentation of BioRAIDs poster was done during WIN symposium in June 2014. The next presentation will be done in Melbourne, Australia at IGCS meeting.
- A manuscript describing the protocol of the study is in preparation.

IMPACT:

The results of this study will allow to define a set of stratification criteria which will be based on molecular profiling. These results will give a deeper insight into the dominant genomic and protein alterations enabling the identification of prognostic and predictive biomarkers for standard and/or targeted therapy in cervical cancer.

Next planned steps:

France :

- November 2014: Opening of the study in Hospital Bichat

Europe:

- Regulatory submissions in Romania – October/November.
- Moldova: Written decision of National Ethics Committee is expected in November. Than the center can be opened in November/December.
- Activation of centers by inclusion of first patients in Serbia, Netherlands and Germany.

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CONTACTS:

Coordinator of project RAIDS http://www.raids-fp7.eu
Dr Suzy SCHOLL, Institut Curie
e-mail: suzy.scholl@curie.fr

Project manager BioRAIDs - RAIDs Coordination Team
Dr. Ksenia Bagrintseva, Institut Curie
e-mail: ksenia.bagrintseva@curie.fr/ tel: 01.56.24.55.75

Project manager RAIDS
Maud Kamal, Institut Curie
e-mail: maud.kamal@curie.fr

PI France:
Dr Charlotte NGO, Hôpital Européen Georges Pompidou
e-mail: charlotte.ngo@egp.aphp.fr

Project manager BioRAIDs
Vanessa Moulinier**,** Institut Curie - DRCI- UGEC " cellule promotion"
e-mail: vanessa.moulinier@curie.fr / tel: 01.72.38.93.26

Sponsor Delegate in Germany, Romania and Moldova
Hanover Clinical Trial Center (HCTC)
Prof. Heiko von der Leyen
e-mail: vdleyen@clinical-trial-center.de