



## RAIDs Project Newsletter

### BioRAIDs study

Issue No 5

May 2015

Dear BioRAIDs investigators,

Your center participates in the BioRAIDs study, which is the core of the European project RAID (<http://www.raids-fp7.eu>). The main objective of the study is to identify prognostic and predictive biomarkers for standard and targeted therapy in cervical cancer patients.

Thanks to your active participation to the BioRAIDs study we have recruited **144 patients** till date. One year is remaining before the end of inclusions. Our aim is to reach 500 patients. This is possible if we can maintain the most recent accrual rates.

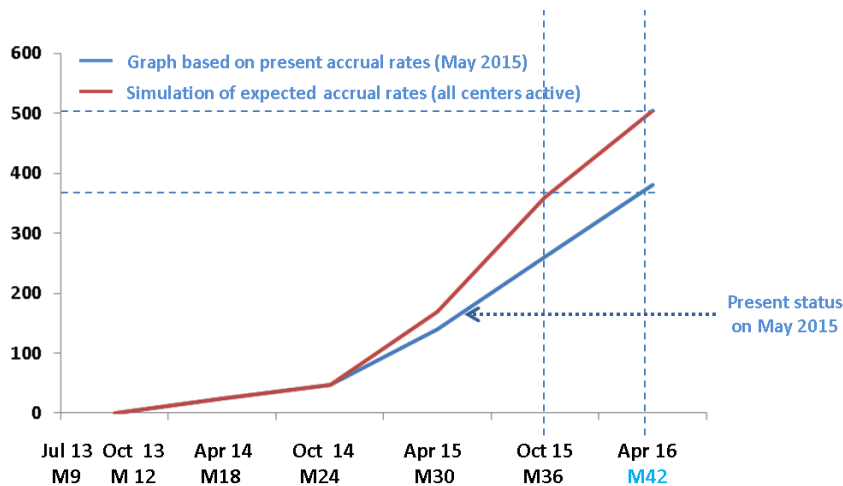
The recruitment in the BioRAIDs study is competitive!

**Countries participating in BioRAIDs clinical study: France, Germany, The Netherlands, Romania, Serbia and Moldavia.**





**Figure 1. BioRAIDs inclusion rate: actual status and expectations**



**France:** 12 centers are open, 89 patients since October 2013.

**Serbia: single center:** 24 patients have been recruited starting November 2014.

**The Netherlands:** 2 centers: 12 patients, starting November 2014.

**Germany:** single center: 9 patients, starting November 2014.

**Romania:** single center: 7 patients, starting February 2015.

**Moldavia:** single center: 3 patients, starting March 2015.

### Important note: a clarification concerning exit of study

- All the data is to be collected in the eCRF from the start of treatment till evaluation at the end of treatment for all patients included in the study (*independently* on whether the patient responds or progresses during treatment).
- A decision to exit the study can be taken only after the end of the treatment evaluation and after the collection of biological material (serum and biopsy *whenever possible*). Therefore exit of study date should be **after evaluation** at the end of treatment

### PROGRESS OF ANALYSES AND SCIENTIFIC DATA:

Exome sequencing of the first samples from 35 patients is ongoing in Hungary (SeqOmics). Quality control of samples (estimation of the percentage of tumor cells in the biopsy: 30% is needed) was already performed at Erasmus, in the Netherlands.



## QUALITY CONTROL OF RADIOTHERAPY:

The completion of the RT/BT section in the eCRF is crucial for the future analysis of the treatment efficiency.

Centralized analysis of MRI imaging will be performed in Serbia. We plan to organize a teleconference in June 2015 in order to allow discussions between radiologists from participating centers as regards the common evaluation criteria. Prof. Dr. Katarina Koprivsek from Institut of Oncology of Vojvodina (Serbia) will be in charge of this task. If the radiologists from your center are interested to participate, please let us know (you may contact Ksenia Bagrintseva and/or Prof. Dr. Katarina Koprivsek).

## DISSEMINATION

- In France, inclusion rates in the BioRAIDs study correspond to expected rates.
- In Serbia the inclusion rates are presently in line with expected rates – 5 to 8 patients per month, which is high for a single center.
- A manuscript, describing the BioRAIDs protocol and the hurdles of implementation of this type of the study in Europe has been submitted to BMC Cancer.
- Two abstracts (on the description and early results of the BioRAIDs study and on a dropbox for patients' requests) were submitted to ESGO.

*NOTE: For future publications the authors will be selected according to the inclusion rates in their centers during last 4-6 months.* If you wish to participate in other tasks, please discuss this at the planned meeting in September/October 2015.

## NEXT STEPS:

We plan to organize an investigator meeting for best recruiting centers in September/October 2015.



# RAIDS

Rational molecular  
Assessment  
Innovative Drug  
selection



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