



# RAIDs

Rational molecular  
Assessment  
Innovative Drug  
selection



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HANNOVER CLINICAL TRIAL CENTER GMBH

## RAIDs Project Newsletter

### BioRAIDs study

Issue No 6

March 2016

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.

We entered the last 6 months of recruitment – so far 308 patients have been assigned to the BioRaids trial until March 23. This is a great result given all the hurdles we encountered in getting the trial started in the different countries. However, our goal must be to have 350 patients recruited at the end of April 2016. We need to have 500 patients assigned to the trial at the end of September 2016 when recruitment will stop. The follow-up period will end in September 2017, thus there will be a 12 months follow-up for the last patients recruited in September 2016.

The recruitment in the BioRAIDs study is competitive!

Countries participating in BioRAIDs clinical study: France, Germany (Hannover, Dresden), The Netherlands, Romania (Timisoara), Serbia (Novi Sad) and Moldavia (Chisinau).

We are happy to welcome Dr. Noreen Gleeson, Trinity College Dublin, Ireland, as new investigator. Dr. Gleeson will soon be able to start recruitment of patients.





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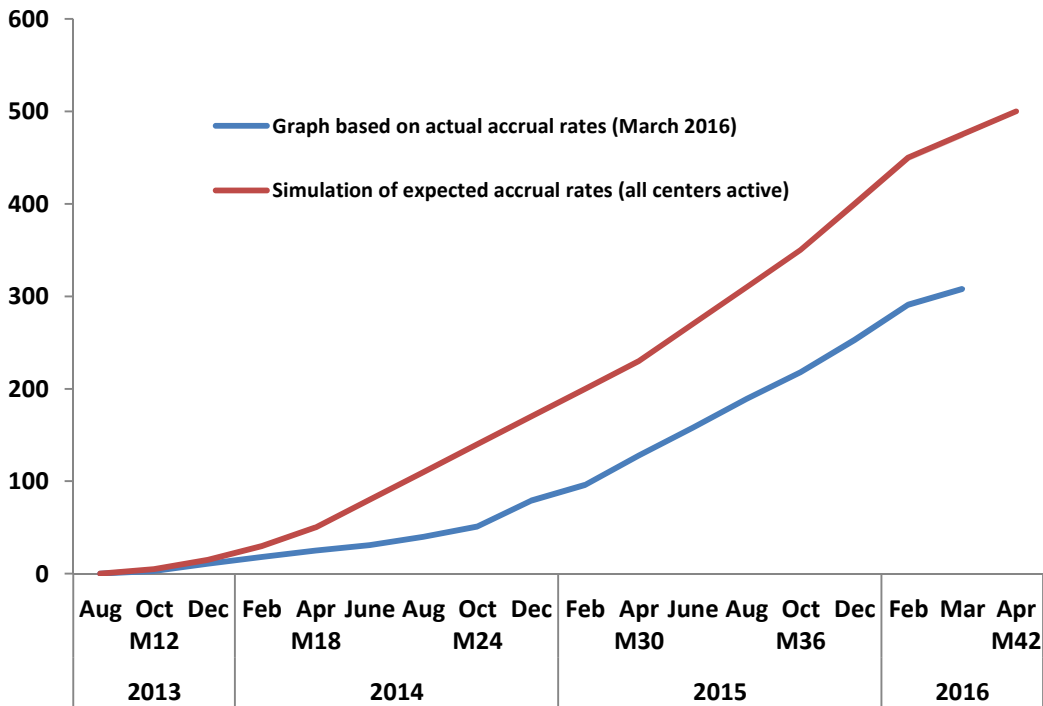


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**Figure 1. BioRAIDs inclusion rate: actual status and expectations**





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**France:** 12 centers are open, 158 patients have been recruited starting October 2013.

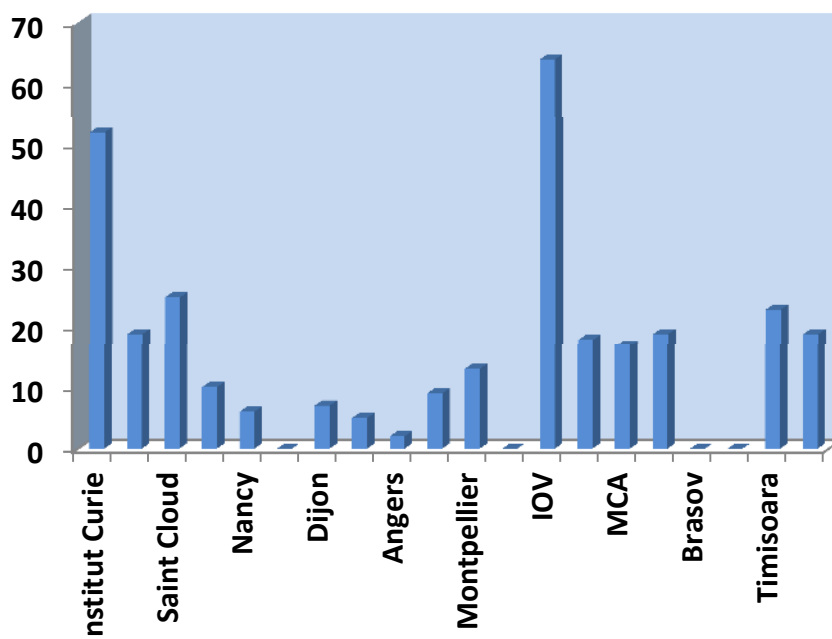
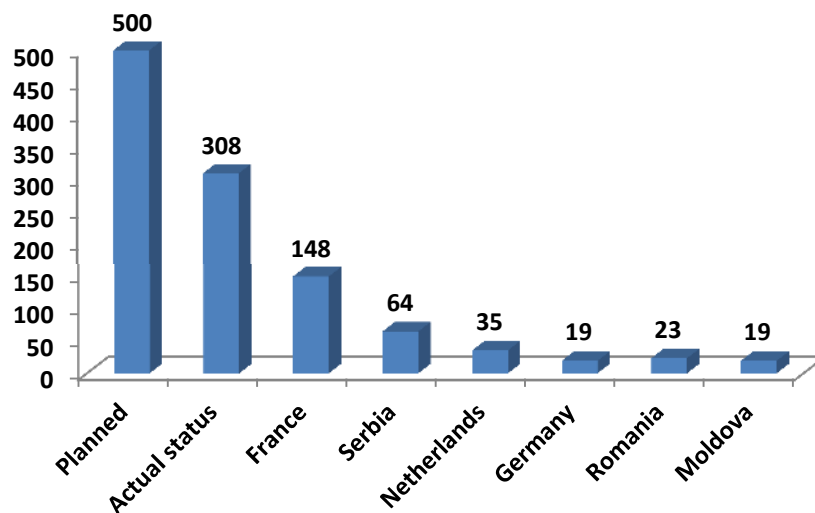
**Serbia:** 64 patients have been recruited starting November 2014.

**The Netherlands:** 25 patients starting November 2014.

**Germany:** 19 patients starting November 2014.

**Romania:** 23 patients starting February 2015.

**Moldavia:** 19 patients starting from March 2015.





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

- ➔ All the data should be collected in the eCRF from the start of treatment until evaluation at the end of treatment for all the patients included in the study (independently from the treatment response or disease evaluation during the treatment).
- ➔ A decision to exit the study can be taken only after end of treatment evaluation and collection of biological material (serum, and if possible - biopsy). Therefore exit of study date = after evaluation at the end of treatment even in case of relapse or progression during the treatment.

### **Important issues to be reminded are:**

1. Patient data need to be entered and monitored until End of May 2016
2. All queries must be resolved before End of June 2016

### **Logistics**

The next shipments of samples will be organized in June 2016.

### **PROGRESS OF ANALYSES AND SCIENTIFIC DATA :**

Exome sequencing of the first samples from 55 patients is ongoing in Hungary (SeqOmics). Quality control of samples (estimation of the percentage of tumor cells) was performed at Erasmus, in the Netherlands. SeqOmics with the help of the bioinformatics' team at Institut Curie is working on an optimal list of genes for a targeted sequencing panel design to be validated in the frame of the RAIDs project. This panel will include the genes of interest in cervical cancer and will allow analyses of DNA samples from tumor with less than 30% of tumor content.



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## 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 images will be performed in Serbia. We plan to organize in June 2015 a teleconference in order to allow to the radiologists from participating centers to discuss common evaluation criteria. Prof. Dr. Katarina Koprivsek from Institut of Oncology of Vojvodina (Serbia) will be in charge of this task. A first of CDs for the centralized imaging review will be sent to Serbia End of April 2016.

## DISSEMINATION

- A paper describing the BioRAIDs study design has been accepted by BMC Cancer
  - Ngo Ch, Samuels S, Bagrintseva K, Slocker A, Hupé Ph, Kenter G, Popovic M, Samet N, Tresca P, von der Leyen H, Deutsch E, Rouzier R, Belin L, Kamal M, Scholl S, RAIDs Consortium (2015) From prospective biobanking to precision medicine: BIO-RAIDs - an EU study protocol in cervical cancer. BMC Cancer 15: 842 doi:10.1186/s12885-015-1801-0
- A paper describing the BioRAIDs hurdles for the implementation of this type of the study in Europe is in progress
  -

*For further publications the authors will be selected according to the inclusion rates in their centers during last 4-6 months.*

## NEXT STEPS:

Steering committee meeting in Paris in April 2016



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