



RAIDs

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RAIDs Project Newsletter

BioRAIDs study

Issue No 7

August 2016

Dear BioRAIDs investigators,

Your center participates in the BioRAIDs study, which is the core of the European project RAIDs (<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 2 months of recruitment – so far 396 patients have been assigned to the BioRaids trial until July 31. This is a great result given all the hurdles we encountered in getting the trial started in the different countries. **The goal was to have 500 patients assigned to the trial. Thus, we all need to do our best to reach this number at the end of September 2016 when recruitment will stop.** The follow-up period will end in September 2017, thus there will be an 18 months follow-up for the last patients recruited in September 2016.

End of recruitment: 30 September 2016

End of follow-up: 30 April 2018*

(* for the last patients recruited in Sept. 2016)

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





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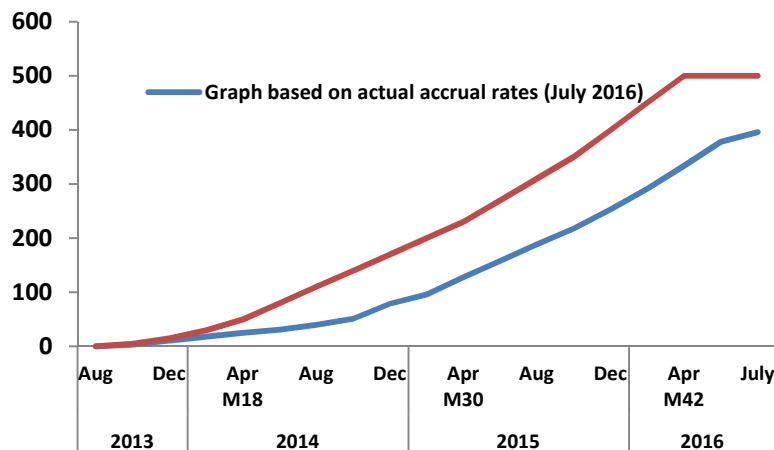
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Welcome to Dr. Noreen Gleeson, Trinity College Dublin, Ireland! Noreen will start recruitment of patients at the end of August.



Figure 1. BioRAIDs inclusion rate: actual status and expectations





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France: 12 centers are open, 173 patients have been recruited starting October 2013.

Serbia: 96 patients have been recruited starting November 2014.

The Netherlands: 52 patients have been recruited starting November 2014.

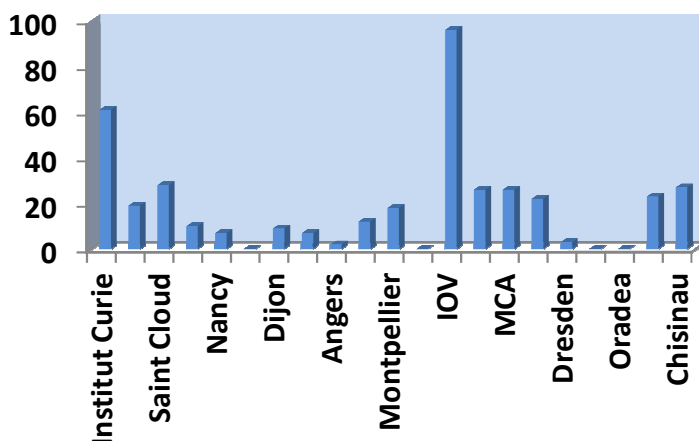
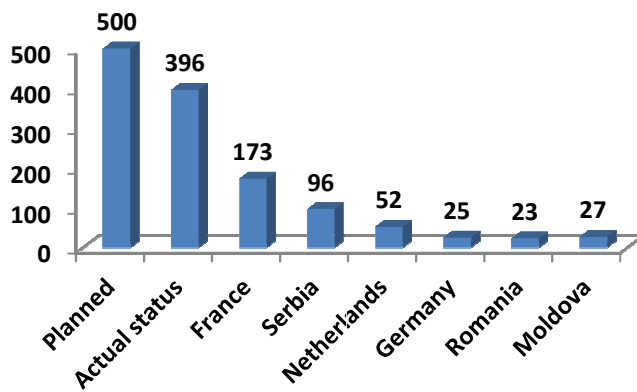
Germany: 25 patients have been recruited starting November 2014.

Romania: 23 patients have been recruited starting February 2015.

Moldavia: 27 patients have been recruited starting from March 2015.

Ireland: starting soon

Congratulations to our recruitment champions in Novi Sad, in particular to Dr. Marina Popovic !!!



Public - FP7/2007-2013 - GA n° 304810

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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. Please record the patient data in a timely manner – within 2 weeks after the visit!
2. All queries must be resolved before September 15th 2016 to be able to continue with the correlation of the molecular data to patients' characteristics and response.

PROGRESS OF ANALYSES AND SCIENTIFIC DATA :

Exome sequencing of tumor samples from 89 patients is finalized in Hungary (SeqOmics). Exome sequencing of 11 tumor samples are currently ongoing. All exome data are expected to arrive at Institut Curie End of September 2016 to the latest for the bioinformatics analyses.

Quality control of samples (estimation of the percentage of tumor cells) is being performed at Erasmus University, in the Netherlands.

SeqOmics with the help of the bioinformatics' team at Institut Curie finalized an optimal list of genes for a targeted sequencing panel design to be validated in the frame of the RAIDs project. This panel includes the genes of interest in



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cervical cancer and will allow analyses of DNA samples from tumor with less than 30% of tumor content.

The panel will likely be useful also for HNSCC.

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 is being ongoing in Serbia. An investigator meeting with participants from Serbia and Romania will be held in Timisoara in September 2016. Prof. Dr. Katarina Koprivsek from Institut of Oncology of Vojvodina (Serbia) and several radiologists will attend the meeting to prepare the centralized analysis. CDs for the centralized imaging review were already sent to Serbia.

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 has been submitted to the British Journal of Cancer and is currently under review;
 - "Precision medicine in cancer: challenges and recommendations from an EU-funded cancer biobanking study" – (<https://www.myndsphere.com/gm/folder-1.11.290273>)

Please be reminded that for further publications the authors will be selected according to the inclusion rates in their centers during the last 4-6 months.



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NEXT EVENTS:

- Meeting in Timisoara: 20th/21st September 2016 (Hotel Savoy, Timisoara)
 - centralized analysis of MRIs
 - Discussion session: “Keys to building a successful clinical research site”, agenda topics planned so far:
 - General issues
 - general topics regarding organization of clinical trials
 - basic GCP requirements
 - Study conduct : what is required, necessary and advisable
 - Current situation for (academic) clinical research in Romania and Serbia

- Steering committee meeting in Budapest: 13th/14th October 2016. Agenda and info has been sent around by Maud (further info on myndsphere).



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