**Dear Colleagues,**

With our newsletter November 2016 we would like to inform you about updates regarding clinical trials at the NCT. Topics for this newsletter are:

- **CTLA-4 NY-ESO-1,** a phase II trial of ipilimumab in patients with advanced melanoma and spontaneous preexisting immune response to NY-ESO-1
- **IVAC-ALL,** a prospective phase I/II study: Patient-individualized peptide vaccination based on whole exome sequencing with adjuvant GM-CSF in children with relapsed acute lymphoblastic leukemia
- **Vorinostat,** a phase I/II intra-patient dose escalation study of vorinostat in children with relapsed solid tumor, lymphoma or leukemia

For the latest news you can also visit our homepage.

Do you plan to perform a clinical study or do you have questions about services of the NCT Trial Center or the contents of this newsletter?
Please contact us!

We hope you will enjoy the reading,

**Your NCT Trial Center**

Your partner for clinical trials of the NCT and DKFZ

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## Clinical TrialsCTLA-4 NY-ESO-1 successfully completed clinical phase

The CTLA-4 NY-ESO-1 study included 25 patients with metastatic melanoma and pre-existing immune response against NY-ESO-1 with the anti-CTLA-4 antibody. They were treated for 12 weeks with Ipilimumab and followed afterwards for 36 weeks. This monocentric study was supported by Bristol-Myers Squibb and carried out at the Department of Medical Oncology of the NCT Heidelberg under the direction of Prof. Dr. Jäger. After the successful completion in June 2016 the NCT trial center is currently validating the last datasets which will then be statistically analyzed. The final report, which will be created by the NCT Trial Center, as well as the subsequent publications will report if the disease control rate could be improved through therapy. For current details please visit the Clinical Trials Portal CTIS or NCT.

## iVAC-ALL

iVAC-ALL, a prospective, multicenter phase I/II study, is designed to evaluate the safety, clinical toxicity and in vivo immunological effects of a patient-individualized peptide vaccination based on whole exome sequencing with adjuvant GM-CSF in children with relapsed acute lymphoblastic leukemia. Exome sequencing is performed at DKFZ in case patients who are also enrolled in the INFORM Registry or at the Institute of Human Genetics, Tübingen. The peptide cocktail is produced in Tübingen under GMP conditions. The leading investigator is Prof. Dr. Peter Lang at the University Children's Hospital Tübingen and the Principle Investigator of the Heidelberg site is Prof. Dr. Olaf Witt (Dept. Pediatric Oncology, Heidelberg University Hospital). The NCT Trial Center performs the project management of the study at the Heidelberg site. The study was initiated in Heidelberg in October 2016. Financial support is granted by the Joint Funding Program of the German Cancer Consortium (DKTK). Participating centers are Tübingen, Heidelberg, Essen/Düsseldorf, Munich and Berlin.

## Vorinostat – Last patient recruited

Since March, 2012 children and young people aged 3-18 years, living with a progressive or relapsed solid tumor, leukemia or lymphoma after standard therapy, could be included in the Vorinostat study throughout Germany. The dosage of Vorinostat (HDAC inhibitor) for a pediatric oncology patient population was defined by intra individual dose escalation. In addition, pharmacokinetic data were collected and response rates, tolerability and feasibility determined. In the meantime, all 50 patients have been included in the study in the 10 participating oncological centers for children. The recruitment phase has ended. The study is financially supported by the German Children's Cancer Foundation. The NCT Trial Center performs biometrics, data management and project management of the study.

For further information please contact Olaf Witt (coordinating investigator) or Ruth Witt (project management).

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http://www.nct-heidelberg.de/forschung/nct-core-services/nct-trial-center.html