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### Evaluation of a digital treatment assignment system on whole-exome sequencing data of pediatric cancer patients

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#### Background

The utility of extensive molecular profiling like whole-exome sequencing (WES) of pediatric tumors in routine clinical practice is a matter of debate and the interpretation of the results is time-consuming. RealTime Oncology Treatment Calculator® (RTO) is a medical software system using rule-based artificial intelligence, that recently showed promising clinical activity improving molecular profile-based drug-assignment in the retrospective analysis of the SHIVA01 precision oncology trial in adults (ASCO 2020, abstract 3642, DOI: 10.1200/JCO.2020.38.15\_suppl.3642). In this study, we assessed the potential clinical utility of RTO in the precision oncology of high-risk pediatric malignancies.

#### Methods

Between 2017 and 2020, 90 patients (< 21y) were included in the precision oncology program of our clinical practice with the following tumor types: central nervous system tumors: 36%, sarcomas: 28%, neuroblastomas: 19%, other solid tumors: 12%, hematological malignancies: 5%. Tissue samples were tested by whole-exome sequencing (WES), targeted sequencing, IHC, MSI and FISH. Molecular profiles were evaluated by the RTO system. Next, a Molecular Tumor Board (MTB) reviewed the results to provide final therapy recommendations.

#### Results

85 samples yielded detailed molecular diagnostic data, 81 had WES. After bioinformatic filtering, on average 52 variants were identified for further interpretation. The average driver count was 3. RTO identified matching registered targeted treatment options in 68%, while 75% had at least one driver associated with drug resistance. The actionability rate of the RTO has reached 90% by 2020 due to the continuous real-time updates of the evidence database. Between 2018-20, MTB approved the clinical use of an RTO top-listed treatment in 70% out of the 53 cases with registered targeted treatment options.

#### Conclusions

Our results indicate that computer-assisted, semi-automated drug assignment with RTO can be a promising solution to introduce precision oncology based on WES and other complex molecular profiling into the routine care of high-risk pediatric cancers. Based on these results, clinical studies evaluating also the clinical efficacy of treatment recommended by RTO are warranted.

#### Legal entity responsible for the study

The authors.

#### Funding

Hungarian Innovation Agency, WESPED project (KFI\_16-1-2016-0048).

#### Disclosure

All authors have declared no conflicts of interest.