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IstvÃ¡n PetÃ¡k, co-founder and CEO of Oncompass introduces the innovative start-up and elaborates on how its solution for digital treatment planning and digital biomarkers can revolutionize not only personalized oncology treatment for patients, but also be a key tool in accelerating the clinical development of new targeted therapies.

Can you please begin by introducing Oncompass?

Our mission is to find the right targeted therapy for individual cancer patients based on the genetic alterations which exist in the genes of their cancer. We have developed a medical software that is registered as a medical device in the European Union called the RealTime Oncology Treatment Calculator. This program can be used to match 125 targeted therapies already in clinical use in addition to over 1000 compounds in clinical trials to individual genetic alterations that exist in a patientâ??s tumour. This can help oncologists in their daily medical work to select the best personalized treatment strategy for every cancer patient.

Why is this technology so valuable within todayâ??s healthcare paradigm?

The need for this technology is fueled by the unprecedented growth of new drugs registered each year in the oncology field. Within the past decade between ten and 25 new treatments have been registered each year. More than half of these drugs are registered from phase II trials and can achieve more than 50 percent response rate in a well-selected patient pool. These drugs are then identified as breakthrough therapies and given accelerated approval by regulatory bodies. This is also due to the complexity of arranging phase III trials for such small groups of patients.

This leads to the issue that doctors then do not have comparative randomized clinical data to determine which drug is better for a certain patient with a certain combination of genetic alterations. Therefore, a new type of medical device like the Treatment Calculator is necessary. The tool uses artificial intelligence (AI), a special database of 24,000 medical rules, and an algorithm that calculates the aggregated evidence score for each gene alternation and a corresponding drug. This is extremely useful for patients with extremely rare genetic alterations or multiple genetic alterations each corresponding to different therapies at the same time. This system is key to improving the efficacy and cost-effectiveness of targeted therapies. In fact, our system has received a positive assessment from the national fund through and independent technological evaluation process which has proved the feasibility of complex molecular profiling of cancer if our method was used to use its results in clinical decisions.

Around the world, everyone is excited about the prospect of personalized medicine, especially in oncology, but in practice, it is very difficult to implement and prove cost-effectiveness given the complexity of establishing patient populations. First, we developed drugs to fight cancer based on the symptoms of patient groups such as the localization of tumours. In the next phase of development treatments, it was realized that we must identify the molecular target of the drug and strategize trials based on the genetic makeup of the tumour. Now, we must take this one step further as each gene has a unique sensitivity to different drugs and most tumours have multiple mutations. Not taking these factors into account can result in a failure to predict the reaction to a drug or in selecting the best treatment overall.

How is the RealTime Oncology Treatment Calculator differentiated from technology solutions which already exist on the market?

Rather than selecting patients for clinical trials based on a single biomarker, we must take into consideration the entire molecular profile of a tumour. Once the genetic makeup is sequenced, a program like the RealTime Oncology Treatment Calculator can take all biomarkers into account and determine which patients will respond best to a certain drug based on the unique pattern of genetic alterations in each patient. Therefore, the systems and algorithms used to accomplish this will become what we call â??digital biomarkerâ?•, a kind of â??digital therapeuticsâ?• which is a fast-growing field of digital health.

Oncompassâ?? ambition is to pioneer this field of digital therapeutics and develop the first digital therapies and digital biomarkers for oncology. It is important to note that this is different from digital medicine which is a category of pharmaceuticals also within the field of digital health which combines a prescription medication with an ingestible sensor component. Digital therapeutics, on the other hand, are evidence-based therapeutic interventions driven by high-quality software programs to prevent, manage, or treat a medical disorder or disease.

Oncompass recently won an innovation competition â??GET IN THE RING!â?• â?? what does this accomplishment mean for the company?

I believe by winning this yearâ??s GET IN THE RING! V4 regional startup and innovation competition, Oncompass has proven its ability to be a leader in this emerging discipline of medicine. This competition aimed to match startups in the VisegrÃ¡d region based on their strength to find a better solution to accelerate drug development. Currently targeted drugs are being matched one by one for hundreds of tumour genes which result in the same cost of development but for a much small patient population, ultimately leading to extremely high drug prices per patient. This has created a price crisis for both the healthcare system which cannot sustain the cost and for the pharma industry which cannot gain reimbursement to make up the development cost.

The RealTime Oncology Treatment Calculator is a solution that can match even a group of compounds in a pharma companyâ??s pipeline to the right patients with our digital biomarker solution that should be included in a given clinical trial. We are currently looking for industry partners to co-development as we help to accelerate the clinical development of their pipeline and ultimately register the product simultaneously with our system. Once the efficacy of a compound is proven during trials and approved, oncologists, can then use the treatment calculator to determine whether their patient can benefit from the drug or not.

How can Oncompassâ?? solutions make personalized medicine more efficient and accessible to wider patient populations?

Effective implementation is a barrier because while the number of patients, oncologists, and original workload remains the same, there is now an extra step to understand the genetics behind personalized medicine while determining which of the 125 therapies or thousands of clinical trials are most appropriate. This is why Oncompassâ?? solution is so valuable.

We are able to provide full support to community oncologists. Eighty percent of patients treated by community oncologists in the US and EU have no access to molecular tumour board, which makes it impossible to practice precision oncology. Therefore, we integrated our special AI module into a workflow management software through which Oncompass can provide virtual molecular tumour board access. An oncologist only has to upload the clinical history data and our experts will provide a recommendation of treatment.

Each patient requires two molecular tumour boards. The first is the diagnostic board which requires a deep understanding of genetics to determine how should patients be tested, and the second is the tumour board to match the patient with potential treatments and/or therapies. Oncompass can manage the whole decision support process for our partner doctors and partner oncology clinics, and if requested Oncompass can also organize the necessary molecular diagnostic tests with its partner diagnostic companies.

When it comes to personalized medicine, how challenging is it to convince not only health professionals but regulators to understand the value of genetic profiling and molecular diagnostic solutions?

There is a lot of scepticism and ambiguity surrounding precision oncology because many doctors and regulators were concerned about the idea of making individual decisions on a patient by patient basis based on preclinical evidence from doctors on the internet. However, Oncompass can develop standardized, reproducible methods for how we make these decisions that can be tested in clinical trials, it becomes very interesting for stakeholders. With digital therapeutics, once an algorithm and software can be validated, the software will always do the same.

My vision is to conduct phase III trials again, not between drugs, but between methods of how decisions are made to determine which drugs are best for patients. Testing algorithms against each other as treatment methods is the next era of modern medicine.

Ultimately, who will be the payer of precision medicine in the long run?

We are not only looking for pharma partners for drug development but also health insurance partners. We must be able to deliver the message of how Oncompass can increase the cost efficacy of targeted therapy treatments and also make the growth of new pharmaceutical developments sustainable. Health funds are under pressure to make quick reimbursement decisions, therefore, Oncompass can help by working together to identify patients who will benefit from treatments the most and determine which populations should be reimbursed. This is closely linked to the implementation of outcome-based financing. Between the pharma companies, health payers, and us, we can sit down and identify new financing solutions that will make such treatments accessible and sustainable because, in the end, the biggest beneficiary of personalized medicine and digital therapeutics is the patient.

What is your assessment of the competitive landscape in this emerging field of digital therapeutics?

Of course, we are in competition with other big IT organizations. However, I had the opportunity to present Oncompassâ?? solution as the 2019 Global Entrepreneurship Summit in Hague, the Netherlands on the same stage as IBM Watson. Together we explained that IBM has the capabilities to perform extreme data mining from the literature of the sequencing, but Oncompass has the algorithm to make sense of this data and translate it to a medical decision. Therefore, we have different positions and roles when it comes to digital health.

What is your internationalization strategy?

Thus far we have already processed 6000 cases in Hungary with our system and are now aiming to expand to other countries. We have established a strong collaboration with Institute Marie Curie in France, UNICANCER, the European Institute of Oncology in Milan, and the Integrated Biobank of Luxembourg among others in a EU funded project.

Being an online tool, our solution is easy to implement in other countries as we grow. We are looking for molecular diagnostic laboratory partners locally to reach as many patients as possible in new markets. As a visiting professor at the University of Illinois in Chicago and having worked at the St. Judeâ??s Hospital, I have a strong network in the US. Therefore, we are interested in participating in more clinical trials there to become not just a decision-support system but a decision-making system.

What are the strategic objectives you are aiming to achieve in the upcoming five years?

We want to receive FDA approval as a decision-making machine for certain indications of treatment and also gain reimbursement in at least five markets. We hope to achieve all of these goals as an international organization while keeping our main R&D operations here in Hungary. There are many skilled scientists coming from the universities in Hungary, but of course, we also welcome young

scientists from around the world to join Oncompass.

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