ONCOMPASS™
Medicine

ONCOMPASS

Precision Oncology Programme

Patient Information Sheet

We believe,

that all patients have the right to state-of-the-art therapies based on the latest scientific knowledge.

that patients and their relatives have the right to do what they can to achieve this.

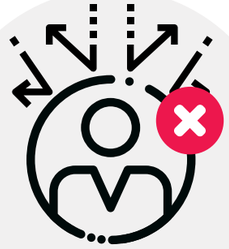
ONCOMPASS™ Medicine

Patients deserve the benefit of science, **Today.**

Our Precision Oncology Programme provides patients and their doctors with complex support to help them set up a personalised treatment plan.

WITH OUR PROGRAMME

WE ASSESS
the personalised (targeted) treatment options and immunotherapies that are likely to be effective,



WE ELIMINATE
targeted treatments that are likely to be ineffective,

WE DETERMINE
the optimal time to apply the treatments.

The dynamic nature of the programme, with a follow-up of up to several years, will ensure that the options we have identified are exploited at the optimal time. Prior to the use of targeted treatments, results are re-evaluated (updated), where appropriate, using the latest scientific evidence generated during the follow-up period.

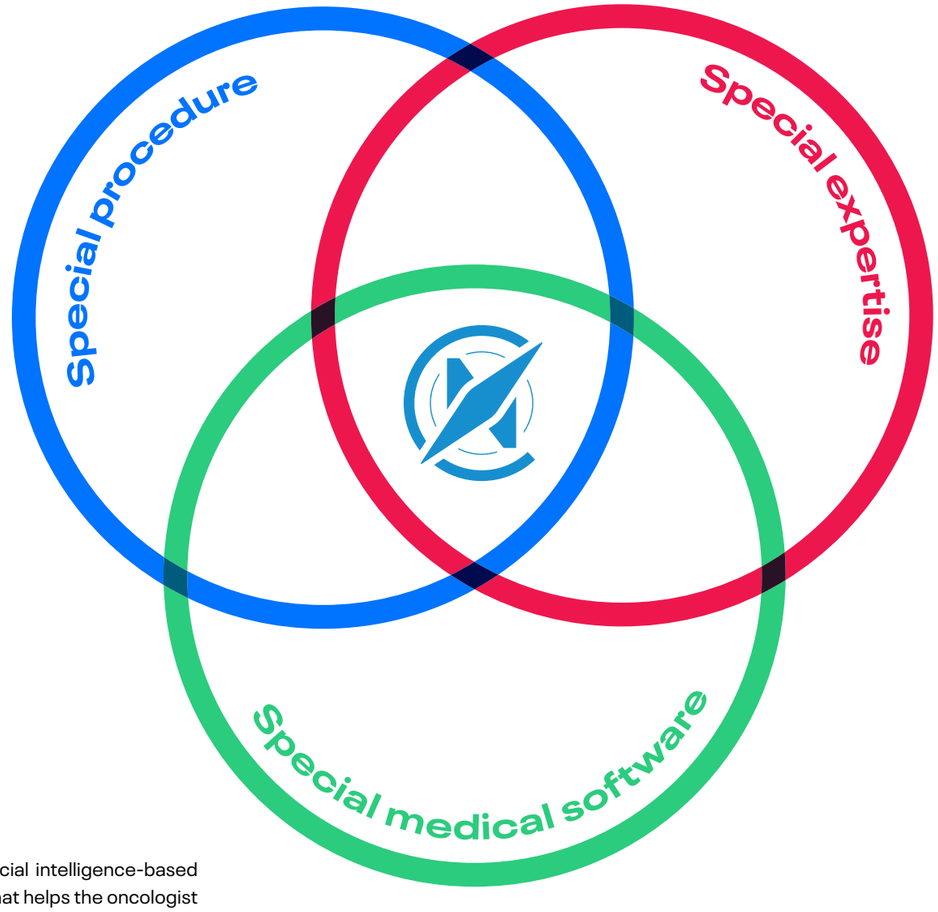
The main goal of Oncompass is to work with the doctors, tumour boards and oncology centres involved in your treatment to set up a personalised treatment plan and choose the most effective treatment.

Our research and development projects are supported by EU grants and have received approval from the appropriate ethics review boards

What makes our Precision Oncology Programme unique?

The professional philosophy of the Precision Oncology Programme is to look for a treatment for the patient instead of the current medical approach to finda patient for a special treatment. Accordingly, we do not simply assess the applicability of individual drugs by assaying a small number of genes, but also establish a detailed molecular profile, thus gaining an understanding of the biological behaviour of the patient's tumour in question and providing an opportunity to map all molecularly targeted drugs and agent.

Learn the biological behaviour of the disease, identify the target site of the tumour, find the right targeted treatment and time its application precisely.



Oncompass has created a uniquely complex decision support system, built on three pillars:

SPECIAL PROCEDURE

The personalised programme is based on a special medical procedure developed in-house. The process includes all the services needed to set up a personalised treatment plan arranged in the optimal order. This special procedure can help you and your oncologist to identify and apply personalised options.

SPECIAL MEDICAL (ONCOLOGY) SOFTWARE

Today, personalised therapy planning based on molecular information and the development of an appropriate therapeutic plan (strategy) require the combined knowledge of such massive amounts of information that even the most qualified doctor cannot absorb, process, consider and apply in an up-to-date fashion. It is impossible to know more than 30 million scientific publications, thousands of available clinical trials, the biological significance of 6 million gene defects (gene mutations) and link all of this information to more than 1900 personalised medicines already available or currently under development worldwide. Only specialised oncology software and medical decision support IT tools can do this.

Oncompass has developed its own dedicated oncology decision support tool. Artificial intelligence-based software is a registered medical device (RealTime Oncology Treatment Calculator™) that helps the oncologist make the right diagnostic and therapeutic decisions at multiple points in the procedure. More than 21,000 precision oncology rules ensure that artificial intelligence works within a framework of scientific evidence. The decision algorithm of the oncology software can be verified afterwards and continuously optimised. The therapeutic decision remains in the hands of the oncologist, but the right decision is supported by specialised oncology software and our expert panel through digital therapy planning.

SPECIAL EXPERTISE

Our staff with specialised expertise is at your service throughout the programme.

Expert Panel (Virtual Molecular Tumour Board)

Major medical decisions are made by the Oncompass expert panel, the Virtual Molecular Tumour Board (hereinafter: VMTB), which meets daily. The work of the expert panel is supported by a clinical oncologist, a genetic counsellor, a molecular pharmacologist, a molecular biologist, a molecular bionics engineer, a logistician and other experts. At two points, at the beginning of the process (programme design) and at the end of the process (digital therapy planning), each case is discussed in detail and the most accurate decisions can be made thanks to the wide range of expertise. If a targeted treatment is available, but is recommended later in time (not immediately), we will update the results immediately before its application and our expert panel will review them again. It is important to emphasise that the decisions of the VMTB are limited to therapeutic planning, which cannot and does not replace the therapeutic decisions of clinical oncologists and oncology teams. The advantage of VMTB is that your doctor can also join its virtual platform, allowing the planning and adoption of a treatment plan to be carried out together and at the same time. We are directly involved in the work of tumour boards in many countries and in many centres. Through our VMTB service, a management plan can be set up at the local level.

Dedicated expert

We provide a dedicated expert for each case. The expert will provide professional supervision, preparation for the decisions of the VMTB and liaise with the treating doctor. During the programme, access to the experts will be provided through the dedicated coordinator, but direct contact will not be possible.

IMPORTANT!
The experts cannot and do not replace the opinion of the treating doctor and other clinicians. In all cases, we will indicate if a question arises in the course of the programme that does not directly concern the programme and which we won't be able to answer or manage.

Dedicated coordinator

The programme requires continuous contact, and accordingly, we provide a personal contact person, a patient pathway coordinator. The coordinator helps to organise and monitor the processes and to overcome any obstacles that may arise during the programme. At specific points in the procedure, information is provided to patients or their authorised representatives both orally and in writing.

IMPORTANT!
Please, save the phone number of your coordinator!

How can our programme help you and your doctor?

The Precision Oncology Programme is a dynamic framework that ensures the fulfilment of a complex set conditions through a quality-assurance process.

CONSULTATION AND CONNECTION

For programme design we offer a face-to-face or online consultation, during which we consider a numerous factors. We will examine clinical data, evaluate the results of previous molecular diagnostic tests, assess patient needs and options, determine the legal and clinical deadlines for the service (more on this later) and collect data on existing samples. If the conditions are met, you can join the programme.

PREPARATION

Oncompass provides a dedicated expert for each patient to prepare their case for the meeting of the expert panel (VMTB). As part of the preparation, our experts and clinical oncologist partners carry out the so-called data digitization, i.e. the input of the data required for digital therapy planning into the oncology software. Once the data has been digitalized, the experts also use the software's calculation functions to make recommendations on the case.

PROGRAMME DESIGN

After the preparation provided by the dedicated expert, the VMTB will draw up the programme plan, defining the content of the dynamic programme. The expert meeting may be attended online by the treating doctor or, if the treating doctor is unable to attend, by clinical oncologists under contract to us (our consultant clinicians) to help provide clinical input.

Key issues to be discussed at the meeting of the expert panel:

ASSESSMENT

Evaluation of the available molecular diagnostic test results based on accurate knowledge of the patient's medical history

IF MOLECULAR INFORMATION IS SUFFICIENT		IF MOLECULAR INFORMATION IS INSUFFICIENT
Ordering a Digital Therapy Planning Programme (without organising diagnostic tests)		Ordering a STANDARD or SMART Precision Oncology Programme (diagnostic mix)
✓	**Setting a time limit available for the utilisation of the results (clinical deadline)**	✓
○	**Sample selection and/or ordering a new sample**	✓
✓	**Assessment of the patient's physical condition**	✓
✓	**Developing further elements of the personalised programme plan**	✓

THERAPY PLANNING

Precision oncology is now part of everyday life in many countries with advanced healthcare around the world. Molecular diagnostics can provide a detailed molecular profile of the tumour, and there has been an explosive growth in the number and availability of targeted drugs. In the age of digital oncology, it is no longer enough to identify the gene defects that led to the patient's tumour and to map the drug therapies that may be useful against them. It is also necessary to determine the order of application of the potential drugs, which is essential to making the choice between therapies.

Digital Therapy Planning (DTP) helps doctors to choose the right drug(s).

WHAT ARE THE CONDITIONS FOR SELECTING TARGETED DRUGS?

1. **Comprehensive molecular diagnostics and bioinformatics (molecular pathology report)**

   Digital therapy planning presupposes the availability of detailed molecular diagnostic results (covering preferably hundreds of genes, but at least 300). If this is not the case, Oncompass will arrange to carry out the necessary tests. After completing diagnostics, we use various bioinformatics software to screen for the gene defects that caused the tumour. The result is a molecular pathology report, which will not be sent out as a stand-alone document, but will be used exclusively in our internal processes.

2. **Functional analysis (molecular oncology report)**

   The tumour is caused by a combination of multiple gene defects. The role and significance of individual gene defects can vary. In functional analysis, we provide oncologists with knowledge about the gene defects, and we link the gene defects to drugs and active substances that can be positively or negatively associated with them. Functional interpretation does not establish a therapeutic sequence, this will be the task of digital therapy planning.

3. **Digital therapy planning**

   Digital therapy planning (DTP) is the design of personalised treatments and immunotherapies using digital tools. Our artificial intelligence-based therapy planning software determines the recommended sequence of targeted drugs and immunotherapies based on detailed molecular information and relevant clinical data. Using a special algorithm, our medical decision support tool combines human knowledge from scientific publications with the power of artificial intelligence.

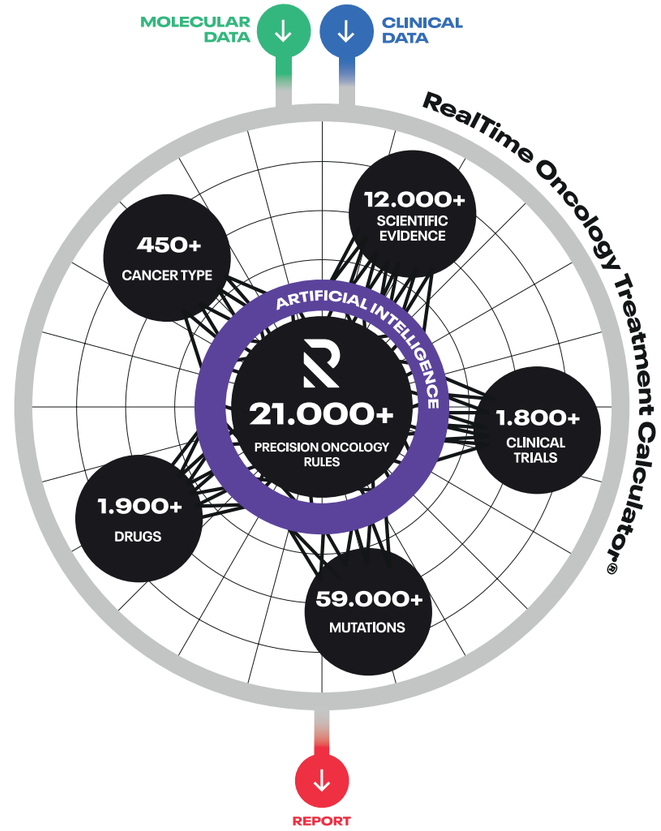
WHY IS IT NECESSARY TO INVOLVE ARTIFICIAL INTELLIGENCE?

Tumour-causing gene mutations are gradually created during the development of tumours according to biological laws and algorithms. Cancer is caused by millions of combinations of millions of possible mutations in hundreds of genes. Our specialised oncology software uses a proprietary algorithm and knowledge base to understand the biological underpinnings ("rules" or "laws") of the tumour, analyse the molecular code used by the tumour and thus identify the target for intervention (molecular target). Additionally, the molecular target is linked to available targeted treatment options using the software.

„Cancer is caused by millions of combinations of millions of possible mutations in hundreds of genes."

As a registered medical device, the Realtime Oncology Treatment Calculator™ can link more than 320 drugs already on the market and more than 1900 drugs in development to gene defects in a patient's tumour.

To accomplish this, the mathematical algorithm takes into account more than 21,000 evidence-based relationships (precision oncology rules). These rules help the software to collect and organise therapeutically relevant correlations in milliseconds, and then link the gene mutations in the tumour to targeted therapeutic options.



The digital health revolution in oncology has accelerated the development and application of IT solutions required for therapy planning, as it has in many other disciplines. The volume of information that needs to be analysed and organised is increasing exponentially, while the time available for medical decision-making has not increased.

There is a wealth of scientific evidence showing that a mutant gene can be associated with multiple targeted drugs, and that a single drug can be effective against multiple mutations within the same tumour. The final order of the proposed targeted drugs and active substances will be determined by which drug has the most evidence linking it to the mutations in the patient's tumour.

It would take the human brain hundreds of hours to read all the scientific literature on a particular case, weigh the available evidence and use it to plan a therapy. Oncology software does all this in a fraction of a second. Our programme also aims to help the doctors planning precision oncology treatments and the so-called molecular tumour boards make therapeutic decisions.

IMPORTANT!

The choice of the right therapy remains the responsibility of doctors, clinicians and tumour boards. We want to help you make better therapeutic decisions by gathering and organising scientific information.

MOLECULAR DIAGNOSTICS

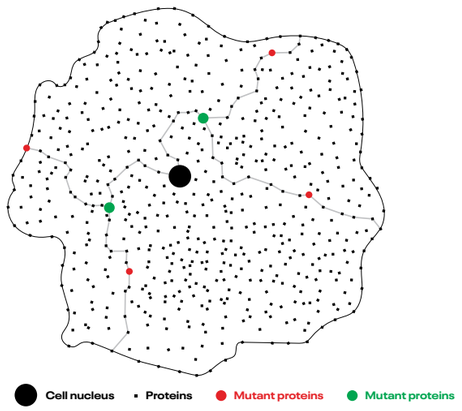
A detailed genetic profile of the tumour is needed for digital therapy planning. It helps us to understand which genetic alterations have initiated cancer and where the false signal causing uncontrolled cell proliferation originates. Molecular diagnostics will help us to understand the behaviour of the tumour at the molecular level. To do this, the detailed genetic profile of the tumour and the biological "rules" specific to the particular tumour must be identified. Therefore, molecular diagnostics is the process of understanding tumour cells at the molecular level to identify the underlying cause(s) of the cancer.

HOW ARE GENE DEFECTS DETECTED?

The division of healthy cells is ruled by strict biological control. However, genetic defects (mutations) can occur during division, which can lead to uncontrolled proliferation. This is how cancer develops. Molecular diagnostic tests are used to identify gene defects and determine the target (targets at the molecular level) necessary for personalised treatment. The definition of the target is a priority, as it may be different from the identified gene defects.

Target diagnosis is now performed using artificial intelligence with our oncology software.

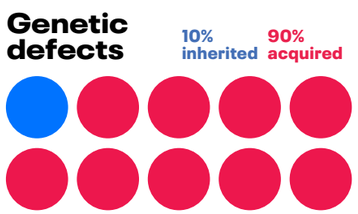
TARGET DIAGNOSTICS



All tumours are genetic in origin. In 10% of cases the disease is hereditary (we are born with a specific gene defect) and in 90% of cases it is caused by a genetic defect acquired during our lifetime. From the standpoint of precision oncology, it is less important where a gene defect develops (e.g. in the lungs or the breasts) and more important which gene defects cause the disease. The same gene defect can cause cancer in different organs, but in different percentages, meaning that some mutations are more common in some organs and less common in others. Various gene defects can be therapeutically associated with over 2,000 active substances in the form of medicines already on the market and active substances under development (in so-called clinical trials).

THE PHILOSOPHY OF HUNDREDS OF GENES

Out of 25,000 human genes, about 700 genes can cause cancer. On average, 4 to 5 different gene defects are responsible for abnormal cell division within a tumour. Consequently, a detailed genetic map of the tumour is needed to make the right therapeutic decision. The more gene defects present in a particular tumour, the more difficult it is to select the molecular target of the drug therapy. One gene defect can sensitise the tumour to a particular therapy, while another can cause resistance to the same therapy, thus the different gene defects need to be analysed together. Targeted treatment can only be safely based on a detailed genetic profile of the tumour. This is the only way to understand the behaviour of the tumour at the molecular level.



WHAT TESTING METHODS DOES ONCOMPASS USE?

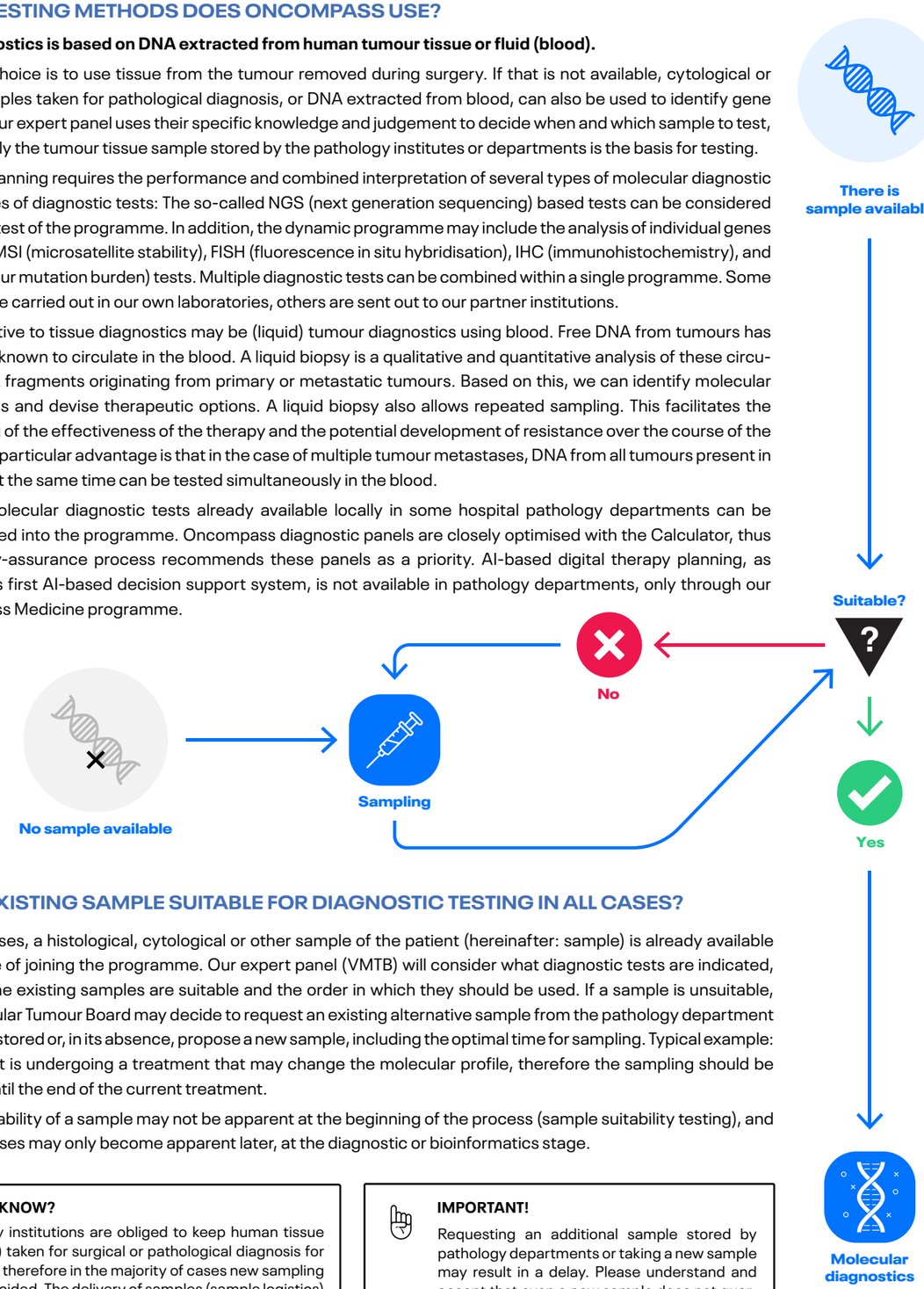
The diagnostics is based on DNA extracted from human tumour tissue or fluid (blood).

The best choice is to use tissue from the tumour removed during surgery. If that is not available, cytological or tissue samples taken for pathological diagnosis, or DNA extracted from blood, can also be used to identify gene defects. Our expert panel uses their specific knowledge and judgement to decide when and which sample to test, but typically the tumour tissue sample stored by the pathology institutes or departments is the basis for testing.

Therapy planning requires the performance and combined interpretation of several types of molecular diagnostic tests. Types of diagnostic tests: The so-called NGS (next generation sequencing) based tests can be considered as the key test of the programme. In addition, the dynamic programme may include the analysis of individual genes as well as MSI (microsatellite stability), FISH (fluorescence in situ hybridisation), IHC (immunohistochemistry), and TMB (tumour mutation burden) tests. Multiple diagnostic tests can be combined within a single programme. Some of these are carried out in our own laboratories, others are sent out to our partner institutions.

An alternative to tissue diagnostics may be (liquid) tumour diagnostics using blood. Free DNA from tumours has long been known to circulate in the blood. A liquid biopsy is a qualitative and quantitative analysis of these circulating DNA fragments originating from primary or metastatic tumours. Based on this, we can identify molecular correlations and devise therapeutic options. A liquid biopsy also allows repeated sampling. This facilitates the monitoring of the effectiveness of the therapy and the potential development of resistance over the course of the disease. A particular advantage is that in the case of multiple tumour metastases, DNA from all tumours present in the body at the same time can be tested simultaneously in the blood.

Certain molecular diagnostic tests already available locally in some hospital pathology departments can be incorporated into the programme. Oncompass diagnostic panels are closely optimised with the Calculator, thus our quality-assurance process recommends these panels as a priority. AI-based digital therapy planning, as the world's first AI-based decision support system, is not available in pathology departments, only through our Oncompass Medicine programme.



IS THE EXISTING SAMPLE SUITABLE FOR DIAGNOSTIC TESTING IN ALL CASES?

In most cases, a histological, cytological or other sample of the patient (hereinafter: sample) is already available at the time of joining the programme. Our expert panel (VMTB) will consider what diagnostic tests are indicated, whether the existing samples are suitable and the order in which they should be used. If a sample is unsuitable, the Molecular Tumour Board may decide to request an existing alternative sample from the pathology department where it is stored or, in its absence, propose a new sample, including the optimal time for sampling. Typical example: The patient is undergoing a treatment that may change the molecular profile, therefore the sampling should be delayed until the end of the current treatment.

The unsuitability of a sample may not be apparent at the beginning of the process (sample suitability testing), and in many cases may only become apparent later, at the diagnostic or bioinformatics stage.

DID YOU KNOW?

Pathology institutions are obliged to keep human tissue (samples) taken for surgical or pathological diagnosis for 30 years, therefore in the majority of cases new sampling can be avoided. The delivery of samples (sample logistics) will be provided by Oncompass by courier or post, or if so desired the patient (or his/her representative) can arrange transportation after scheduling with the institution.

IMPORTANT!

Requesting an additional sample stored by pathology departments or taking a new sample may result in a delay. Please understand and accept that even a new sample does not guarantee the suitability of the new sample (this may be influenced by various clinical and other circumstances beyond our control).

DIGITAL THERAPY PLANNING

The aim of digital therapy planning is to analyse the complete molecular profile in order to prioritise targeted oncology drugs and immunotherapies based on their expected efficacy. The Calculator is a specialised oncology software that weights and combines scientific evidence according to a predefined algorithm. The therapy planning software therefore organises the body of human knowledge available in scientific publications. It generates a specific value or number for each active substance (Aggregated Evidence Level - AEL*) to determine the relative order of the applicable targeted drugs. The order of drugs and active substances depends on the magnitude of the AEL value.

PRECISION ONCOLOGY REPORT

Molecular diagnostics filters out genes that potentially cause disease, and Oncompass uses various bioinformatics filters to do this. The role of individual genes in tumour development and growth maintenance is then determined by the Calculator interpretation software. Digital therapy planning helps to select the right treatment options.

MOLECULAR TUMOUR BOARD OPINION

On the basis of the precision oncology report, the dedicated expert of the particular case prepares the recommendations for the expert panel meeting (VMTB). The VMTB will give its opinion on the drugs ranked according to the AEL and furthermore, other therapeutic options will be compared through the participation of the clinical oncologist. The Board's decision is the Molecular Tumour Board opinion. In case the treating oncologist is present at the panel meeting and a common position is reached, the treating doctor should still bring the proposal to the tumour board and then use it once approved. In partner centres where the Oncompass expert team participates directly in the tumour board meetings (molecular tumour board), the results of the discussion are immediately used and recorded in the tumour board minutes. Thus the aim of Oncompass is to be able to discuss the results with the treating physician and the tumour board.

The medical team, unlike a traditional tumour board, should also include a molecular biologist and other specialists. The Oncompass Molecular Tumour Board, i.e. its expert panel, provides this specialist knowledge to doctors, tumour boards and oncology centres.

TREATMENT STRATEGY

The treatment plan, or in other words the treatment strategy is always the responsibility and option of the treating doctor and the tumour board. That is why Oncompass aims to work closely with them and some – specifically professional – information is only sent to the doctor and the tumour board. In several countries we share a molecular tumour board with several tumour boards, so that the agreed treatment strategy can be immediately used in the treatment centre. In the absence of a molecular tumour board, a joint expert consultation (VMTB) with the treating doctor is carried out. If for any reason this is not possible, the opinion of our precision oncology network and partner clinics can prevail, and all patients have the right to a second opinion. In this case, the patient can ask for a second opinion from any tumour board where the Oncompass procedure is known and used.

* The aggregate evidence level (AEL) of an active substance is a numerical value used for ranking and it is proportional to its presumed efficacy based on scientific information linking it to molecular abnormalities detected in the tumour.

PRECISION ONCOLOGY OPINION

Oncompass is not a therapy centre. We do not provide treatments. Our internal competence is medical decision support (interpretation) and digital therapy planning based on artificial intelligence, which helps us to rank targeted treatment options based on expected effectiveness. Our results are used by the treating physician and the tumour boards.

The basic document of our service is the Precision Oncology Report, which presents detailed molecular information and its therapeutic implications in written form. The report also includes a summary opinion, which provides clinical oncologists and tumour boards with a summary of the therapeutic options available according the report.

IMPORTANT!

The interpretation of molecular information is narrower than an assessment based on different clinical information (e.g. the side effect profile of a given drug or the physical condition of a given patient should also be evaluated when making a therapeutic decision). This is why only clinical oncologists (tumour boards) can make the therapeutic decision on the therapeutic options set by our centre, but naturally it does matter what information they base this decision on.

The report and its summary opinion are intended for doctors, but it is very important for ONCOMPASS that patients joining the Programme understand the identified therapeutic options in the necessary detail. The clinical interpretation of the results will appear in the so-called Precision Oncology Opinion (hereinafter: Opinion). In all cases, the Opinion is provided by an external private clinic, with the involvement of a clinical oncologist, using a precision oncology approach.

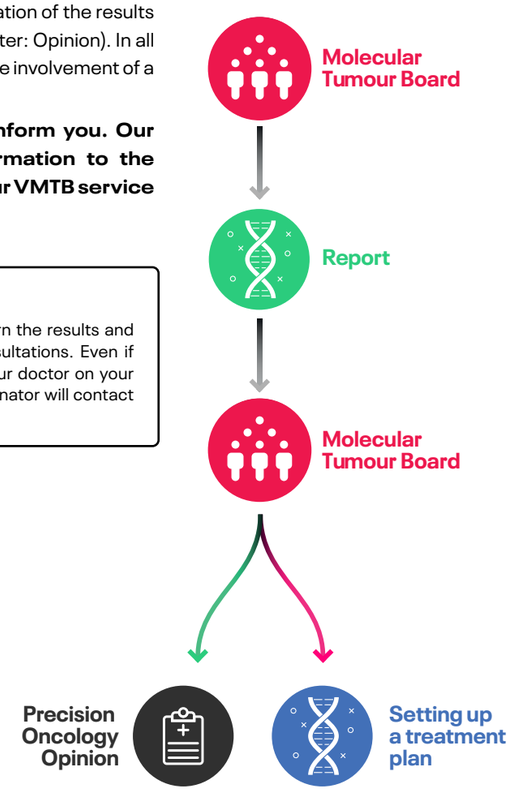
The primary purpose of the Opinion is therefore to inform you. Our procedures pay special attention to providing information to the centre and doctors managing the treatment through our VMTB service and the involvement of expert colleagues.

IMPORTANT!

Partner clinics provide a relaxed environment in which to learn the results and answer questions in the form of face-to-face or online consultations. Even if there is full agreement between our panel of experts and your doctor on your treatment plan, we advise you to use this service. Your coordinator will contact you to make an appointment.

Please note that patient satisfaction is a priority for us. If you have any complaints or comments, please contact us. We would be grateful if you could share your experience to help us continuously improve the quality of our services.

Optimally, when the results are presented (in the form of the consultation), the position already agreed with the treating doctor is conveyed, or if the level of partnership does not allow it, the opinion of the invited clinical oncologist/private clinic is presented. Considering that we support the molecular tumour boards of many oncology centres with our specialised knowledge, patients can also request tumour board second opinions in these centres. Patient rights allow for this, but the request must be initiated by the patient.



Managing datelines

In the Precision Oncology Programme, multiple services are delivered according to a defined logic. In the dynamic programme, we distinguish between legal and clinical deadlines. The legal deadline is primarily the deadline for the establishment of the Tumour Board opinion, while the clinical deadline focuses on the first possible date of clinical applicability of the results, which is independent of the legal deadline.

LEGAL DEADLINE

During the programme, we commit to a legal deadline that cannot be affected by external factors.

The AI-based Digital Therapy Planning Programme does not require molecular diagnostic tests, therefore the legal deadline starts from the day of joining the programme, provided that we have the necessary information and documents to comply with it.

In AI-based Standard – or other – Precision Oncology Programmes (where molecular diagnostic testing is required), the legal deadline starts after successful sample suitability testing (starting date of the sequencing). The legal deadline therefore starts from the date of availability of the DNA for the designated diagnostic test.

As the time of completion depends on factors beyond our control (e.g. when the test sample arrives at our laboratory or the categories of sample suitability), Oncompass assumes a duty of care, i.e. it will do its utmost to ensure that the condition for completion is met as soon as possible.

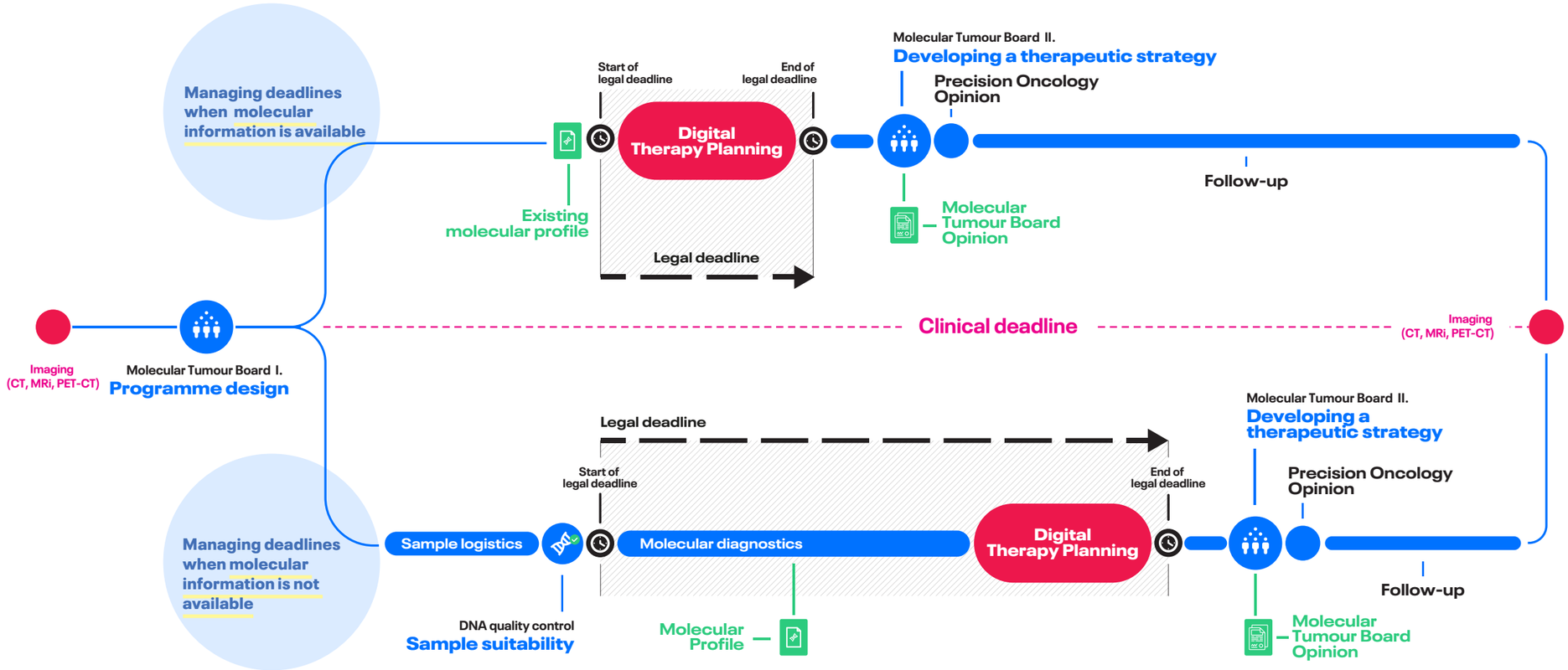
The legal deadline is the completion of the expert proposal based on the precision oncology report. The timing of the subsequent expert meeting (VMTB) depends on the availability of the treating doctor or the timing of the tumour board meeting, over which Oncompass has no direct control and therefore only assumes a duty of care.

CLINICAL DEADLINE

Optimally, the digital therapy planning is completed before the tumour board makes its therapeutic decisions. When planning the Programme, we assess how much time is available to set up a Tumour Board opinion and treatment strategy. During the phase before therapy change or the start of the therapy, the time until the planned treatment is started is taken as the time available, and for patients already receiving therapy, the clinical deadline is the date of the next imaging study (CT, PET-CT, MR, etc.) constitutes the clinical deadline.

We tailor our diagnostic and decision support services to the clinical deadlines. This ensures for our patients that we can adapt our activities to the treatment regimen and schedule of the oncology centre where they are treated. The clinical deadline conveys the clinical approach required for the optimal timing of the proposed targeted treatments and immunotherapies (timing).

Of course, the clinical deadline may be too short to perform all diagnostic tests and therapeutic decision support. In such a case, our expert panel will plan which tests can be performed and evaluated within the clinical deadline and for which we will set a different clinical deadline (it usually means the time when the next imaging test should be available).



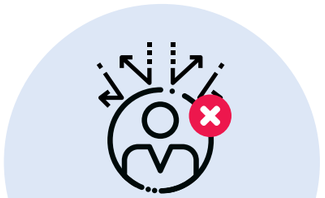
Additional things to discuss...

WHAT THERAPEUTIC OPTIONS MIGHT YOUR SERVICES OPEN UP FOR ME?

The age of molecular oncology has made it possible to treat tumours with targeted drugs in addition to or instead of traditional chemotherapy. These drugs are called targeted because they act on a specific type of molecule found in the tumour, i.e. malfunctioning proteins whose synthesis or action can be inhibited to prevent the „grow and divide" commands approaching the cell's control centres from ever reaching the nucleus. This means that the growth of the tumour can be stopped.

Understanding the behaviour of the patient's tumour at the molecular level is necessary to map personalised therapeutic options. Based on the evaluation of hundreds of active substances, our special software classifies the therapeutic options into two broad categories:

Recommended therapeutic options



Not recommended (contraindicated) therapeutic options

It is extremely important for the patient to understand that molecular information will always help to define a therapeutic plan as accurately as possible, regardless of its specific content. In other words, even if our report does not reveal a new targeted therapy option, the results are still useful, because in this case we confirm that the originally proposed targeted therapy or another non-targeted therapy, such as protocol-based chemotherapy, is the best choice. Moreover, in cases when our report does not recommend a targeted treatment that could be given according to the protocol, one of the key benefits is that our oncology software indicates the ineffectiveness of that particular agent. In such cases, our decision-support AI-based software provides an assessment based on a much more precise gene map, which may differ significantly from the options based on more narrow molecular diagnostic tests. Our programme can therefore reveal molecular connections that can protect you from ineffective treatments.

The results can therefore be used in the following ways:

1. Recommendation and confirmation of a targeted treatment according to protocol
2. Recommendation and confirmation of a non-targeted treatment according to protocol
3. Contraindication to a targeted treatment according to protocol
4. Contraindication to a non-targeted treatment according to the protocol
5. Recommendation of a targeted treatment outside of protocol or a combination therapy

It is very important to stress that the recommendation or contraindication of a treatment does not guarantee that it will be effective or ineffective, respectively. The method helps to increase the chances of making a good decision based on the molecular information available. The right therapeutic decision is ensured by our artificial intelligence (AI) based software algorithm. Specific drugs are assigned specific mathematical weights (values) and their relationship to each other determines the ranking of recommended or contraindicated treatments (AEL). The dynamic decision support of Oncompass is provided by the software's computational method.

The decision of the treating doctor and the tumour board is determined by multiple (among them clinical) criteria. It is possible that there are treatments recommended based on the molecular profile, but the tumour board may recommend a different type of treatment (e.g. chemotherapy or radiotherapy) based on its assessment. In such cases, the proposed targeted treatment may eventually be considered as a future therapeutic option. If there are no better treatment options available, the medical team may choose a treatment that is contraindicated based on the molecular profile.

IMPORTANT!

As a result of digital therapy planning, combined targeted treatment, i.e. the indication for the combined use of several drugs may be prioritised.

Personalised (targeted) medicines for oncology care may also fall into different categories, depending on the stage of drug development, the financing available for the active substance and its geographical availability. These categories are:

1. **Drugs already on the market and covered by health insurance for the condition in question**
2. **Drugs already on the market but not covered by health insurance for the condition in question**

IMPORTANT!

Precision oncology means that it is no longer the location (localisation) of the tumour that determines the treatment, but the genetic defect that causes the disease. This opens the way to the use of drugs that are not authorised for your cancer type ("off label"), but act on the genetic mutation you have. If this is the case, these drugs are not considered to be authorised for your cancer type, and you may also need to apply to the national authority responsible for drug licensing and drug safety.

3. **Active substances available in clinical trials conducted in your country**

We also want to provide a solution for gene defects for which there are no commercially available drugs, but which, as active substances under development, could become available with our help (or we can organise access to them). Drug development is a very long process. It can take many years from the testing of a promising drug candidate molecule to its registration as a medicine. There are currently nearly 2,000 clinical trials of targeted active substances in progress worldwide. Our advanced decision support software can screen clinical trials based on different criteria, such as the category of the active substance, its geographical availability, the stage of development or other aspects. The domestic programme will explore the potential of clinical trials conducted in Hungary.

Participation in a clinical trial also means access to medicines that cannot be financed in any other way. Participation in clinical trials depends on many different conditions that may vary from trial to trial, but a common feature is that patients in good general health are expected to apply.

4. **Active substances available in clinical trials conducted in other countries**

You have the opportunity to look beyond therapeutic alternatives available in your country to international trials. If you want to explore both in-country and international clinical trial opportunities at the same time, we recommend that you join our international programme straight away, as the in-country programme only covers opportunities in your country. Please let our colleagues know your intentions and you will then have the opportunity to join the Oncompass international programme.

„Do I need to change my doctor or will my oncologist and you work together on the programme?"

HOW WILL YOU WORK WITH THE DOCTORS MANAGING MY TREATMENT?

Oncompass has signed cooperation agreements with numerous oncology centres to provide professional support for precision oncology care. The aim of the collaboration is to translate the molecular information discovered in clinical trials into everyday clinical practice. Thus, in the ideal case the practical implementation of the therapeutic plan is ensured in oncology centres.

Throughout the programme, we aim to maintain continuous interaction with the clinicians. In line with the challenges of the modern age, this can be done via video conference or by telephone, e-mail or even face-to-face. Professional coordination is carried out by your dedicated expert, who at the end of the process will consult with your doctors to set up or modify your treatment plan. In the event that the specific results do not allow a deviation from the therapeutic regimen set in the current or previously planned protocol, the expert will inform your doctor by e-mail, forwarding the result of the digital therapy planning. If the results indicate the possibility of a personalised therapy, a joint therapy planning session, typically by video conference, is carried out according to the level of cooperation previously assessed. The agreed management strategy will then be translated into a written plan.

During the consultation (programme planning), we will let you know how and when we would like to contact your doctor, based on our previous experience of cooperation. In our general experience, the key to successful professional cooperation is professional contact, i.e. if you authorise our centre to contact your doctor, we will ensure the necessary professional support. You can, of course, decide otherwise, by sending us a consent form setting out whether and how you want us to contact your doctor. Whatever you decide, your decision will be fully respected.

It's important to know that we provide general and ad hoc training for doctors on the use of our IT methods and software. In addition to decision support, our dedicated software also offers an up-to-date way to stay in touch. One of our priorities is to familiarise oncologists and other clinicians with our procedure, so that we can collaborate at a higher professional level from time to time.

We have designed our programme so that if your doctor is not familiar with or has not used our decision support, you are not at a disadvantage in getting the desired benefits from the results. If the translation of the results of the report into benefits is not supported by your treating doctor, Oncompass recommends the use of one of our partner oncologists, even if just in the form of a second opinion supplied by the tumour board (our partners are oncologists who develop the treatment plans based on the results). All patients have the right to freely choose their doctor. Respect and enforcement of patients' rights are at the heart of our Centre's overall operation.

Oncompass fulfils its obligations under the General Terms and Conditions (GTC) by agreeing on a treatment plan. The reason is that our report allows for the planning of practical steps for the entire duration of your health care, but its fulfilment is linked to the treatment centres. Once a strategy has been agreed, the resulting activities (e.g. preparation of an application for an individual drug authorisation, organisation of clinical trials, etc.) are carried out by agreement with the centre providing your care or at the request of your doctor.

HOW LONG DOES THE PROGRAMME LAST?

The programme lasts until the Molecular Tumour Board opinion based on the Digital therapy planning is completed and the opinion of the clinical oncologist or partner clinic presenting and evaluating the results is issued.

Depending on the results and in consultation with clinicians, the programme may include follow-up. By default, the programme will include a single therapeutic decision support, unless the therapeutic options agreed between the VMTB and the doctor can be used at a future point in time if a future condition is fulfilled. In such cases, repeated therapy decision support is also provided for our patients (without diagnostic tests).

Any additional therapeutic decision support will be subject to a fee (under the Digital Therapy Tracking Programme).

THE PROGRAMME WILL ANSWER TWO IMPORTANT QUESTIONS:

WHAT?

Which targeted treatment can be effective or ineffective?

WHEN?

Under what conditions should the therapy be used?

Oncompass not only identifies effective targeted treatment options, but also suggests the timing of the treatments, which in the vast majority of cases can be delayed until the time of therapy change. Our case tracking team will follow up the implementation of the treatment plan in cases where targeted treatment is a realistic possibility.

THE PROGRAMME HAS THREE POSSIBLE ENDPOINTS:

SUPPORT FOR ACCESS TO THERAPY

If the treatment strategy suggests a specific targeted treatment or immunotherapy, we will provide follow up until the next agreed personalised treatment and do our best to ensure that the identified option is put into practice.

PROPOSALS FOR A FOLLOW-UP DIGITAL THERAPY PLAN (REPORT UPDATE)

If the agreed treatment plan does not include a targeted treatment or immunotherapy, but the molecular target(s) identified justify that, based on new evidence, the Calculator should run the options assessment again after a certain time or if a certain condition is met. Report updates are carried out at the initiative of the patient or his/her doctor, and in both cases the approval of the VMTB and/or the treating doctor is required. Follow-up for report updates will not be provided.

TERMINATION OR SUSPENSION

In the event of programme termination, Oncompass sees no realistic possibility of targeted treatment or immunotherapy, either at the time of reporting the results or subsequently. This may be due to a number of reasons, such as the physical condition of the patient or the lack of an appropriate molecular target, or the low level of evidence for AEL for the identified therapies, which reinforces support for the use of conventional treatments. In the case of termination, digital therapy planning may not be justified even at a later point.

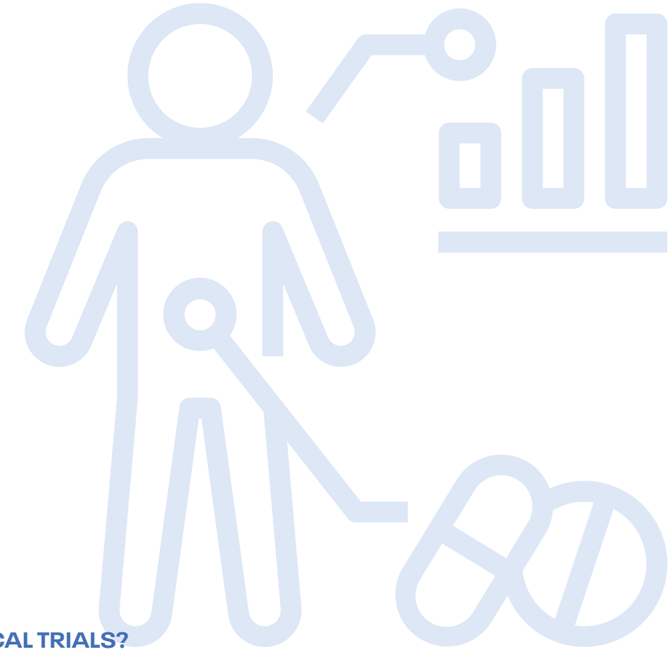
A special case of termination is when the available samples are unsuitable and the possibility of obtaining a sample is not expected within a year. In this case, the programme will be terminated with an individual settlement, and the programme fee paid will be refunded after deduction of the costs incurred up to that point.

The programme will be suspended if no sample is available, but the possibility of obtaining a sample is expected within a year. In this case, we will provide the following services (from the paid programme fee):

- Follow-up to organise sampling at the optimal time
- Helping to organise sampling
- In the case of self-administered sampling, providing assistance with sample analysis and a pathology second opinion
- Updating the programme plan (expert panel)
- Initiation of a diagnostic test out of sequence in case of suitability

IMPORTANT!

It is also possible to rejoin after the programme has been terminated. In this case, the rules for new entrants apply, with full payment of the programme fee required.



WHAT DO I NEED TO KNOW ABOUT CLINICAL TRIALS?

Active substances under development will become the medicines of the future. Our mission is to promote access to the most effective therapies available today, shortening the path of access to cutting edge oncology drugs and active substances. For many patients, investigational medicinal products tested in clinical trials may be the solution if it is not realistic for them to wait for the authorisation and marketing of a particular active substance. You have a free choice to decide whether you wish to participate in clinical trials.

Different oncology centres offer different clinical trials for patients, but the opportunities to participate in the testing of new drugs at a particular centre are a tiny fraction of the real possibilities. It is common practice for oncology centres to consider and offer only the options available to them and to have minimal information about clinical trials available at other centres. In the same way that trials assaying a small number of genes can only assess suitability for a single drug (drug-to-patient concept), clinical trials only assess suitability for clinical trials at a given centre (clinical trial-to-patient concept). Oncompass searches for the drug for the particular patient and searches for clinical trials for the particular patient.

Learn more about clinical trials

Researchers and doctors are constantly looking for ways to cure various types of cancer. Clinical trials could include new treatment options – targeted drugs, chemotherapy agents, possibly radiotherapy and combinations of these. To determine whether a new development is more effective than the old one and whether the side effect profile has been adequately assessed during the benefit/risk assessment, data collection, close monitoring, documentation and analysis of results are needed. To this end, appropriate specialists will draw up a protocol for the study and submit it for regulatory approval. Patients are thoroughly screened and assessed before they enter the trial, and new therapies are administered under strictly controlled conditions under medical supervision.

Our programme will help you identify clinical trial opportunities in your country, or abroad in our international programme. At the request of the treating doctor or partner oncologist, we will contact the trial centre to start the assessment of whether you can be included in their clinical trial. Each trial has its own Patient Information Leaflet with information specific to that trial, and a dedicated Consent Form can be used to indicate the intention to join. In addition to the Patient Information Leaflet, you will have the opportunity to clarify any important questions and receive the fullest possible information in a meeting with the doctor who will be conducting the clinical trial, in accordance with the legislation in force. This Patient Information Leaflet does not and cannot provide a complete picture of clinical trials, its sole purpose is to help add this modern and widely available option to the therapeutic regimen.

Phases of clinical trials

In Phase I trials, the new treatment/active substance is used for the first time in humans under specific test site conditions. Only a few patients receive treatment at this stage. A series of tests will be carried out to study the absorption, distribution and elimination of the new drug. Phase I studies will also determine the safe dose of the drug.

Phase II trials test the effectiveness of the drug in a small group of patients, usually in a single centre.

In Phase III, large groups of patients are tested, usually at several sites in several countries, using the known (standard of care) method to compare the effectiveness of the new medicine and to investigate adverse events. In this phase, patients are usually randomly allocated to different treatment groups (so-called treatment arms) of the trial, after the so-called randomisation step, to eliminate the possibility that either the patient or the treating doctor can influence who is assigned to the new treatment group or who receives the so-called standard of care therapy. This gives doctors and researchers the opportunity to compare the new agent/procedure with the standard of care.

In a phase I trial, all participants are treated with the active substance. In phase II-III trials, it is possible that some of the participants will receive a placebo, but they will always receive the best treatment available today as well. Of course, the patient who wishes to participate in a clinical trial will be informed of this.

The Precision Oncology Program developed by Oncompass Medicine is a unique way to take control of your life and offer you or your loved one the most advanced treatment options available today through our specialized medical procedures, advanced software and specialized expertise.

Patients deserve the benefit of science, **Today.**

ONCOMPASS™ Medicine

Oncompass GmbH.

Oncompass GmbH.
Einsiedlerstrasse 21, 8834 Schindellegi, Switzerland
EMAIL info@oncompassmedicine.com
WEB www.oncompassmedicine.com