

Phase I / Early Drug Development



**'Patients appreciate
our personal
approach and
oncological
specialism'**

Marjolein, Advanced Practice Nurse

No tumor is
the same, no
patient is the
same, no day
is the same.



Emile Voest,
medical director

Every day at the Netherlands Cancer Institute, we do everything we can to improve the treatment of cancer patients. From the continuous ambition to unravel the biology of cancer to the translation of these findings to new treatment opportunities.

We are a Comprehensive Cancer Center, that belongs to the top worldwide. Patients come to our institution to get access to new trials and novel treatment approaches. Every year, several thousands of our patients take part in clinical studies. The fact that 25% of our patients participates in clinical studies demonstrates our drive to advance our knowledge and the life expectancy of cancer patients.

We have an internationally renowned Phase I/Early Drug Development program with patients referred to our study team from all parts of the country and abroad. It is our ambition to have every new drug (class) available for our patients by initiating or participating in all high impact phase I/II studies.

We have been able to realize this goal for the past ten years and we will continue to do so for the benefit of our patients. We have a specialized Clinical Research Unit with a dedicated team of highly qualified medical specialists. To ensure fast-track review, dedicated phase I contract negotiators and dedicated slots for Ethics Committee review are in place. In addition, we work closely together with our pharmacy which also includes a large bio-analytical lab, drug formulation, GMP production facility and large research facilities.

With energy and enthusiasm, we are committed to our patients and the realization of our mission: through the combination of care, research and (international) exchange of knowledge, we make a significant contribution to solving the cancer problem in the 21st century.



Inge (43)

Has: lung cancer with metastases to the brain.

Is being treated with: targeted (personalized) medication.

And now: curing her is no longer possible, but she has now been living with the disease for four years now.

She was 39 when her lung cancer was discovered – metastasized and not curable. Targeted therapy has kept the cancer under control. The treatments are developing together with Inge. Every time a medicine has run its course, the doctor takes a biopsy and looks for the right new medicine. Inge herself picked up her life again after the initial shock. 'I make plans for a maximum of three months.'

‘You know that the cancer will start to grow again at some stage’

Inge: ‘I was playing tag with my niece when I noticed that I couldn’t breathe properly. At night I became short of breath when I lay on my right side. After a hiking holiday in the Alps, the persistent shortness of breath made me realize something had to be done. A week after a photo of the lungs that showed fluid behind the lungs, I heard that it was lung cancer. That first night, after hearing that news, I was shocked and terrified. Until that moment I was fit and healthy and not worried about getting sick. Now I had the feeling that I could die at any moment.

I turned out to have a DNA error in the tumor, for which targeted, inhibiting medication exists in tablet form. It was a matter of wait and see if the medication would work and for how long, but it worked for me. I was saved from the classic image I had of cancer, with chemotherapy, nausea and a bald head. It didn’t take me long to turn the fear into the full enjoyment of what I have. I really enjoy my work and wanted to get back to it three weeks after the diagnosis. My employer responded fantastically. “Tell me what you need to be able to continue working,” he said. Within a week there was a bed in the office so that I can rest when necessary. I started working a day less, so I have enough time for friends and family. I don’t have a bucket list. I make plans for a maximum of three months, I live in the here and now.

I did well on that first medication for a year. I had a scan once every three months on which you saw the tumors shrink. At one stage there was nothing left to see. Misleading, because the cancer is still there and you know that it will grow again. And yes, a year later, a new biopsy showed that the tumor had changed. It had changed to an aggressive but treatable variant, because at that time a study was open with a combination treatment of a new experimental drug with a light dose of chemotherapy. I had to go to the hospital for the administration one day

a week. I was very sleepy then, but I had enough energy the rest of the week. The treatment worked again.

Two years ago, a new biopsy showed that the tumor had shifted again and that a second mutation had developed in it. I have been taking another new medicine since then, it had been on the market for only two months when I got it. But then I got neck complaints. The MRI scan showed that my small brain was full of metastases. It took some persuasiveness from my doctor, I hoped that brain radiation was not necessary if the new medication caught on quickly, but eventually I underwent that radiation. I was scared but managed to talk about it. I am a researcher myself, so I know that there is not always one answer, but that there are considerations in choosing a certain treatment over another. Because my doctor discussed his considerations with me, gave me time, but also clearly said: it is important to do it this way, I thought: he is right, I have to do this. It worked out well. After the radiation, I had a few weeks of fatigue, but that was soon over and many metastases in my brain have disappeared.

I feel very good now, which of course is crazy because I know that ‘it’ is always there. There are still metastases in my head which will be biopsied soon. I am really nervous about that but I have found a way to deal with it. I see it as an adventure. I used to do sports climbing. Sometimes a chosen route turned out to be difficult half way. You don’t know if you’ll stick or fall at the next grip. Is my knot good, is the person below holding me properly? The doubt and uncertainty do not help you further. If you have started the route with the goal of completing it, you will have to push away your fear and continue climbing. This is how I now treat my disease process. Sometimes adventures go wrong and are painful. But every adventure is also an opportunity. I focus on the opportunity, not on what could go wrong.’



The Phase I team



From start-up specialists, contract negotiators, datamanagers, research coordinators, quality assurance officers, planners, nurses, research nurses, advanced practice nurses, pharmacists, trial physicians to principal investigators and sub investigators.

Many different disciplines work together at the Phase I / Early Drug Development Department. The head of the department, an advanced practice nurse and oncology nurse tell.

Marjolein van Mil
MSc, Advanced
Practice Nurse



‘I am the main contact person for patients who participate in phase 1 studies. We discuss patients in our multidisciplinary consultation every week. In addition to seeing patients by appointment, I can be reached by telephone for questions or physical complaints. I notice that patients appreciate our personal approach and oncological expertise. Each time, the relationship of trust we build with patients during the period that they participate in a trial is unique.’

Neeltje Steeghs
MD PhD Medical
Oncologist Clinical
Pharmacologist
Head of Clinical
Research Unit
Director of Phase I
studies



‘Working in Phase I and clinical pharmacology is truly inspiring. The innovations that come with new drugs, with new mechanisms of action and the search for the right treatment dose and scheme keeps me on my toes. It is a continuous balance between doing right for the individual patient in my examination room and improving treatment options for future cancer patients. And it works. There are now more effective treatments that have come from such studies.’

Tom Weerts
Oncology nurse



‘My heart lies with patient care. In a rollercoaster of emotions and uncertainties, I hope to create peace with my profession and expertise. Together with my colleagues at the Clinical Research Unit, I strive to deliver the best possible care. The development of new drugs in oncology is extremely important and I contribute with a lot of love.’



Principal Investigators

The Netherlands Cancer Institute has been conducting Phase I and early drug development research for more than 20 years at a high level. The closeness of so many internationally renowned pre-clinical researchers and our top pharmacy (research) facilities makes us unique as collaboration partners for Pharmaceutical Companies. Furthermore we design and initiate many investigator initiated pharmacology studies ourselves.

Neeltje Steeghs, Medical Oncologist, Clinical Pharmacologist & Head of Clinical Research Unit & Director of Phase I studies

‘It is my role to ensure that everything concerning the research is well organized and according to the regulations and study protocol. I also ensure that all parties involved, such as the ethics committee and sponsors, are aware of the developments in the studies. Because I combine the research with my work as a doctor, I am able to inform patients properly, and advise pharmaceutical companies on the design of their studies.’

Frans Opdam, Internist & Clinical Pharmacologist

‘I mainly see patients at the outpatient clinic for making a proposal for a treatment in a study context. I do this from my ambition to improve cancer care and to offer new possibilities to treat cancer. We can only do this because we can provide truly appropriate care with our multidisciplinary team.’

Emile Voest, Medical Oncologist & Medical Director

‘I consider myself a translational oncologist with the ambition to bring new preclinical biological or predictive findings to the clinic. As a Principal Investigator I am responsible for various biomarker guided studies within pharmacology. In order to develop new successful treatments, a strong integration of all necessary disciplines is

required, so that we can treat patients ever more successfully.’

Egbert Smit, Pulmonologist Oncologist

‘With current treatments, only a minority of patients with lung cancer can cure. In addition to the efficient use of current treatments, new treatments and treatment modalities are desperately needed. Because specific knowledge of the disease and the medicines must be bundled for this, cooperation between various sub-specialties is indicated.’

Marloes van Dongen, Medical Oncologist & Clinical Pharmacologist

‘As Principal Investigator of several Phase I studies and medical oncologist in the breast cancer team, my ambition is to be able to treat patients in a more tailored and targeted way. The contact with and care for patients is intensive, impressive and motivating. It is great to be part of a hugely motivated team of start-up specialists, data managers, nurses, nursing specialists and the trial office.’

Christian Blank, Medical Oncologist & Immunologist

‘I am an expert in tumor immunotherapies. It is my ambition to give patients access to new promising therapies. Basket trials, the early line of treatment, are a challenge, but also very exciting because they provide structured data for different malignancies early on.’

NKI is unique as collaboration partner for pharmaceutical companies

OBJECTIVES EARLY PHASE ONCOLOGY DEPARTMENT

Improving opportunities for and access
to clinical & translational research for
clinical & translational researchers

Improving efficacy of this research by
implementing one well equipped unit for
all research groups and researchers

Improving quality of clinical &
translational research by implementing
one quality system for all groups and
researchers, fully ICH-GCP compliant

Creating a fertile soil and interactive
environment for this research

Increasing patient participation in clinical
trials

SCOPE EARLY PHASE ONCOLOGY DEPARTMENT

Early clinical trials with drug intervention

Mass balance studies

Drug-drug interaction studies

Drug imaging studies

Combined modality studies (medication
and radiotherapy)

Both patient and healthy volunteer
studies

Studies with low, intermediate, or high
intensity monitoring

Short timeline through contract with
medical ethics review committee

Dedicated unit, pharmacist, contract
negotiator/budget handler

Possibility of preferred partnerships

2017



36,648
PATIENTS
TREATED

OF WHICH
11,222
NEW PATIENTS

200
MEDICAL
SPECIALIST

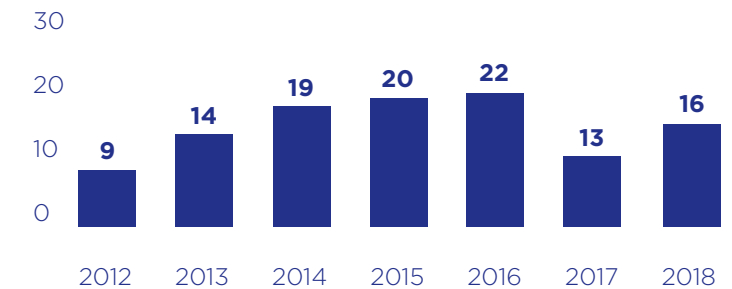


3,925
PATIENTS TOOK
PART IN AN
EXPERIMENTAL
TREATMENT



790
PUBLICATIONS
IN SCIENTIFIC
MAGAZINES

New Phase I studies

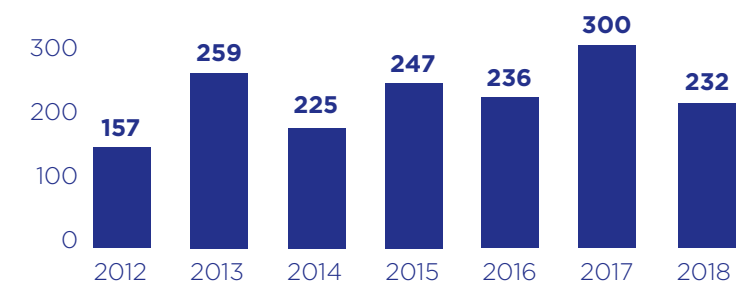


RESEARCH INSTITUTE
(THE NETHERLANDS CANCER INSTITUTE)
+
SPECIALIZED CLINIC
(ANTONI VAN LEEUWENHOEK HOSPITAL)
=
ANTONI VAN LEEUWENHOEK
COMPREHENSIVE CANCER CENTER



Treatment of patients with all tumour types,
except pediatric patients and patients with
hematological malignancies.

New patients in Phase I studies



*For more information about
industry partnership or to set
up a trial, please contact:*

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