



# Drug Research Unit Ghent (D.R.U.G.)

The Early Phase Clinical Drug Research Unit of the University  
Hospital Ghent



# Mission statement

To contribute to the **development** of new drugs by conducting clinical trials (majority of them **early phase**) in **healthy subjects** as well as in **adult patients**.

Since 2018 the Drug Research Unit Ghent contributes also to the development of new drugs by conducting clinical trials in **pediatric patients** in close collaboration with the pediatric department of the University Hospital Ghent.

In compliance with international legislation and quality standards.

# Milestones



- ▶ 2001: Founded by Prof. dr. L. Van Bortel
- ▶ 2003: ISO 9001:2000 certified
- ▶ 2005: Contribution to development of drugs for developing countries
- ▶ 2006: Preferred partnership contract with global pharma industry
- ▶ 2009: ISO 9001:2008 certified

# Milestones



- ▶ Part of Oncology care program initially
- ▶ NOV 2008: approval of the Phase I Unit Oncology by the medical board of the hospital; ISO 9001:2008 certified
- ▶ JAN 2009: approval of the Phase I Unit Oncology by the board and the CEO of the Ghent University Hospital
- ▶ From JAN 2011 on: 4 Key Activities supported by the hospital (Oncology, Clinical Immunology, Genetics & Neuroscience)

# Milestones



- ▶ 2014: Close collaboration in between both units
- ▶ AUG 2015: New facilities on the campus
- ▶ OCT 2015: Official merging of D.R.U.G. and Phase I Oncology
- ▶ Until 2017: ISO 9001:2008
- ▶ 2018-2019: integration in hospital accreditation, NIAZ/Q-Mentum
- ▶ 2018: start of pediatric clinical trials

# Milestones



- ▶ Automatisatation of procedures
- ▶ 2024: Move to Nobel I building

# Expertise

## Healthy subjects

- ▶ First in man, SD
- ▶ First in man, MD
- ▶ Phase-0 studies (eCTA) and proof of concept
- ▶ Biomarker/surrogate marker development
- ▶ Food/Drug interaction
- ▶ Bioequivalence
- ▶ Biologicals
- ▶ Special groups (hypertensives, elderly, postmenopausal women)
- ▶ Cardiovascular: telemetry, BP, arterial function & structure

## Oncology

- ▶ First in man, dose escalation
- ▶ First in man, expansion cohorts
- ▶ Medical devices
- ▶ Interaction studies
- ▶ Biomarker studies
- ▶ QT studies
- ▶ Fresh biopsies
- ▶ Small molecules
- ▶ Immunotherapies
- ▶ CAR-T cell studies
- ▶ NGS based clinical trials
- ▶ Antibody conjugate

**+ Patient studies** for other hospital departments and other principal investigators



# Stipulations

High Quality

Quality control - Quality assurance

Quality management system - Document management

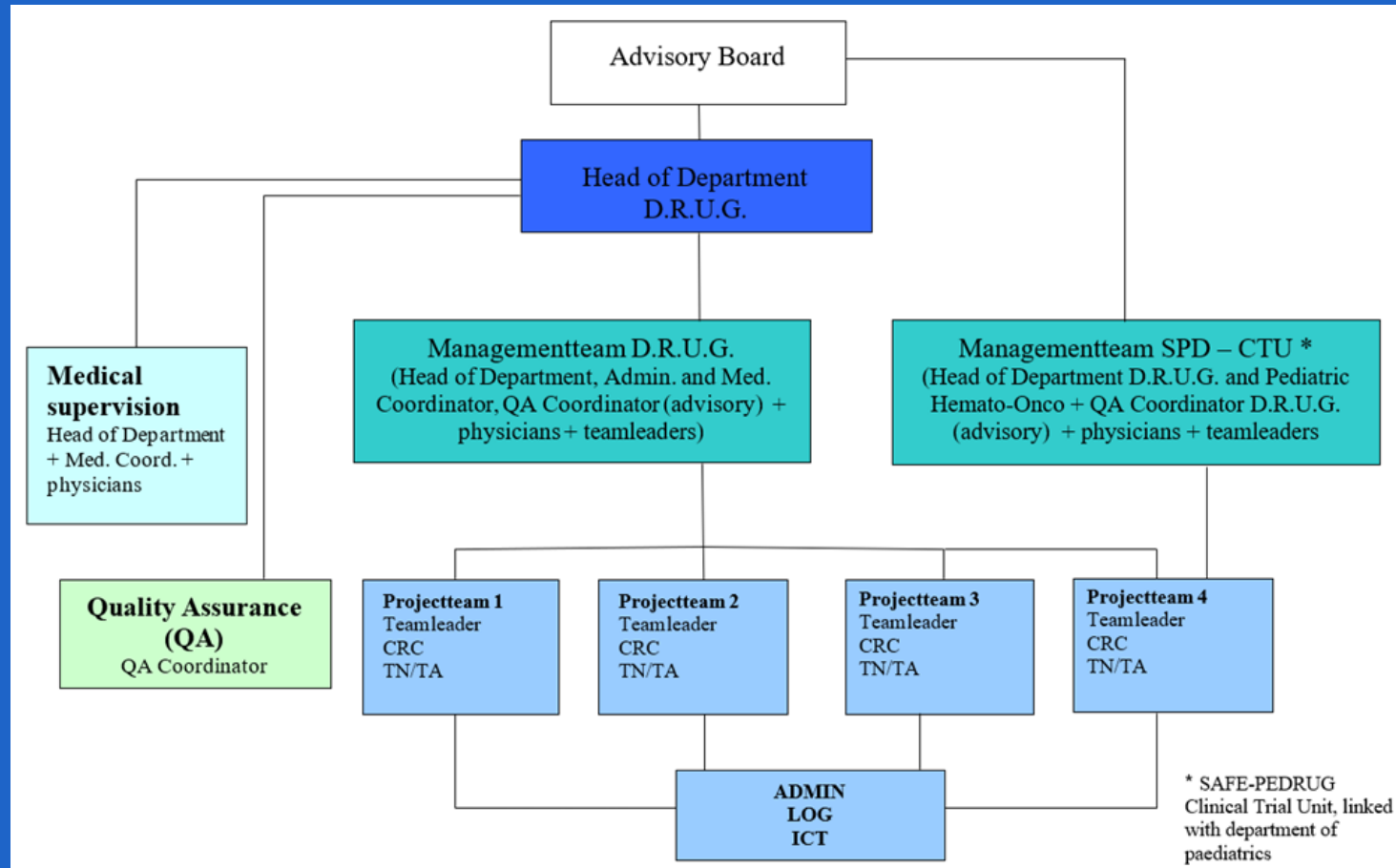
Training employees

Apparatus: temperature management and control – Calibrated devices

FDA - FAGG Inspections

Second party audits

# Flowchart department 2023



# Composition Advisory Board (University Ghent / Ghent University Hospital)

- ▶ Prof. Dr. Mortier: CEO of the Hospital
- ▶ Prof. Dr. Vermassen: Chief Physician of the Hospital
- ▶ Prof. Dr. Hoebeke: Dean of the Faculty of Medicine and Health Sciences
- ▶ Prof. Dr. De Paepe: Head of the Emergency Department
- ▶ Prof. Dr. Van Vlierberghe: Representative of the Medical Board, Director of Research
- ▶ Prof. Dr. Geboes: Head of the Cancer Center of the Hospital
- ▶ Prof. Dr. Van daele: Head of the Department of Pediatrics
- ▶ Mrs. Commeyne: Head of the Pharmacy
- ▶ Mr. Van Rompaey: Head of the Health, Innovation and Research Institute (HIRUZ)

# Facilities

- ▶ 20 beds for overnight stay
- ▶ Telemetry for 15 subjects
- ▶ 2 clinical laboratories (temperature controlled)
- ▶ 1 sample handling laboratory (temperature controlled)
- ▶ 1 drug storage room (temperature controlled/alarm)
- ▶ 3 freezers (-20°C) + 1 freezer (-70°C) (temperature controlled/alarm)
- ▶ 6 refrigerators
- ▶ Wifi network
- ▶ Canteen, recreation room, offices, reception, meeting room, monitor room, storage rooms and kitchen
- ▶ Biosafety level 1

# For healthy subjects / patients

- ▶ **Overnights and measurements in separate rooms**  
(2 subjects/room for the night)
- ▶ **A group of 36 staff members**  
(except for the nights which are done by Assistant Trial Nurse)
- ▶ **5 investigators close on the spot**  
(24h/24h availability)

# Sponsors

- ▶ Pharmaceutical industry (majority)
- ▶ University
- ▶ University hospital

# Recruitment

## Healthy subjects

- ▶ Database with +/- 3800 active subjects (including patient-subjects)
- ▶ VCT (Verified Clinical Trials) prevents concurrent participation in multiple trials.
- ▶ Recruitment by e-mail and (online) advertisement

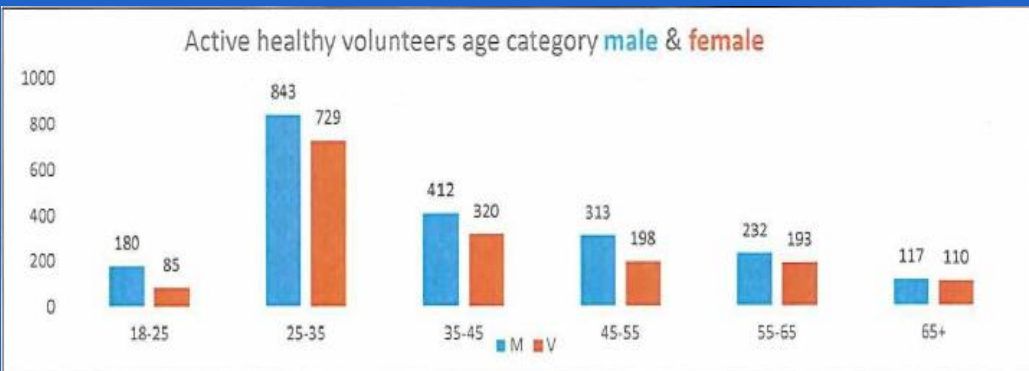
## Patients

### ▶ Internally:

Inclusion on a multidisciplinary basis, which is reflected by the composition of the Phase I working group of the hospital. Patients come from different departments: Medical oncology, GI oncology, pneumo-oncology, hematology...

### ▶ Externally:

- ▶ Patients are referred on a regular basis from > 25 different hospitals
- ▶ Newsletter of running clinical trials is sent on a regular basis to medical doctors involved in oncology in Flanders



# Embedding in University Hospital Ghent







## Phase I Oncology Working Group

- ▶ 4x/year meeting
- ▶ Discussion about trials (new and ongoing), listing side effects, recruitment issues, operation of the department,...
- ▶ Different oncology disciplines are represented next to the head of the department Prof. Dr. Rottey:
  - ▶ Cancer Centre UZ Ghent
  - ▶ Gastroenterology
  - ▶ Pneumology
  - ▶ Hematology
  - ▶ Medical Oncology
  - ▶ Radiation Oncology
  - ▶ Gynecology
  - ▶ Pathology
  - ▶ Pharmacy
  - ▶ Research physicians D.R.U.G. + 1 team leader of D.R.U.G.



## **Poli Medical Oncology**

- ▶ 1st contact with patient interested in inclusion in Phase 1 trial
- ▶ Patient is informed about Phase I trials in general
- ▶ Patient is put on waiting list if no slot for trial is available

## **Day hospital and hospitalization Medical Oncology**

- ▶ **Patient Care**
- ▶ **Day hospital**
  - ▶ **Blood transfusion**
- ▶ **Hospitalization:**
  - ▶ **Hypercalcemia**
  - ▶ **Neutropenic sepsis**
  - ▶ **Start up of parenteral nutrition**
  - ▶ **Optimization pain medication**
  - ▶ **Serious adverse events (SAE)**
  - ▶ ...



## HIRUZ

- ▶ HIRUZ is the Health, Innovation and Research Institute of the Hospital in collaboration with Ghent University
- ▶ HIRUZ facilitates the various individual aspects of translational biomedical research in an integrative manner



## **Intensive Care Unit and Emergency Department**

- ▶ Interested in drug development existing in our unit
- ▶ Willing to take care of our patients if needed

## **Pharmacy**

- ▶ A separate Clinical Trial Unit within the Pharmacy Department of the hospital
- ▶ Storage of study medication
- ▶ On site formulations
- ▶ Packaging of study medication
- ▶ Reconstitution of study medication
- ▶ Preparation of IV study medication
- ▶ Ordering and delivery of study medication
- ▶ Improvement of collaboration by performing audits by each other



## For study related assessments/follow up study patients

- ▶ Laboratory (safety testing)
- ▶ Radiology (CT, MRI)
- ▶ Nuclear Medicine (PET-CT, bone scan, MUGA scan, ...)
- ▶ Ophthalmology (ocular AE's)
- ▶ Dermatology (skin toxicities)
- ▶ Cardiology (echocardiography)
- ▶ Pathology (tumor tissue)
- ▶ Pneumology (lung function)
- ▶ Neurology (EEG)
- ▶ Anaesthesiology (high risk medication)
- ▶ Radiotherapy (antalgic radiotherapy)
- ▶ Interventional radiology (specific study drug administrations)
- ▶ Genetics (NGS sequencing)
- ▶ ...



## Biopsy samples (archived and fresh)

### Fresh Biopsy Sampling

- ▶ Ultrasonography (liver biopsies)
- ▶ EUS-EBUS (thoracic/mediastinal biopsies)
- ▶ Plastic surgery (skin)
- ▶ Dermatology (skin)
- ▶ Head and Neck Department (biopsies head and neck region)
- ▶ Interventional radiology (Image guided biopsies)

### Pathology Department

#### Handling of biopsy samples

- ▶ Preparing slides of archived tissue
- ▶ Handling of fresh biopsy samples following specific instructions:
- ▶ Diagnosis
- ▶ Paraffin embedding
- ▶ Preparing slides
- ▶ Freezing
- ▶ Genetic analysis
- ▶ ....

# Phase I Oncology Trials 2023

Patients	Mandator	Number of Trials	PI
Cancer patients	Industry (20# sponsors)	47	S. Rottey

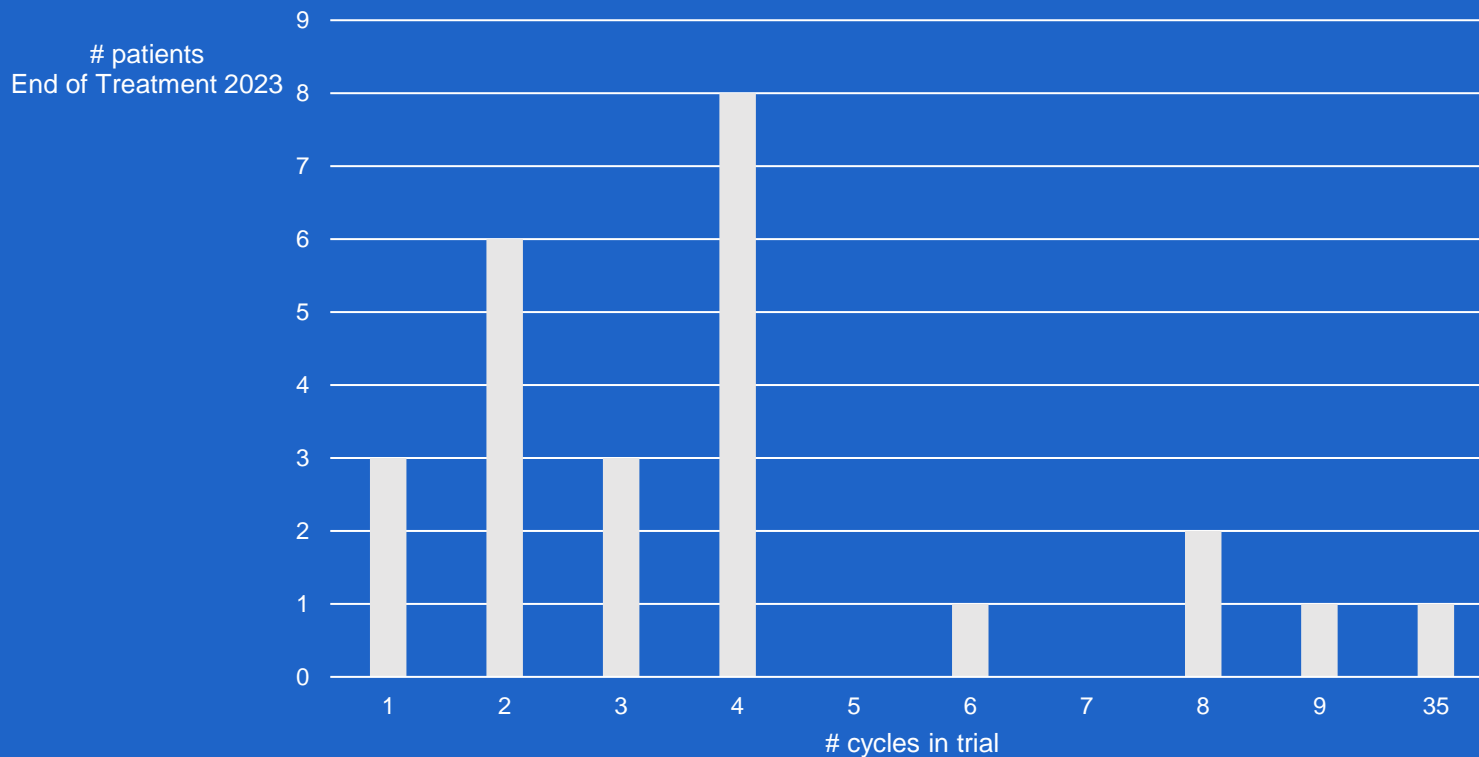
**Subjects registered for Phase I Oncology trials in 2023: 246 (via email, phone, personal contact MD)**

## **Subjects in trial in 2023:**

- ▶ Prescreenings:
  - ▶ 209 prescreening ICF's signed – modern trials !
  - ▶ Some patients were prescreened for multiple trials (2 or 3)
- ▶ 13 ongoing subjects from 2022 (excl. follow ups)
- ▶ 81 subjects signed main ICF in 2023
- ▶ Number of cycles in trial: 4,9 cycles in trial (3,6 cycles without outliers) - 1 cycle is mostly 3-4 weeks

# Phase I Oncology Trials 2023

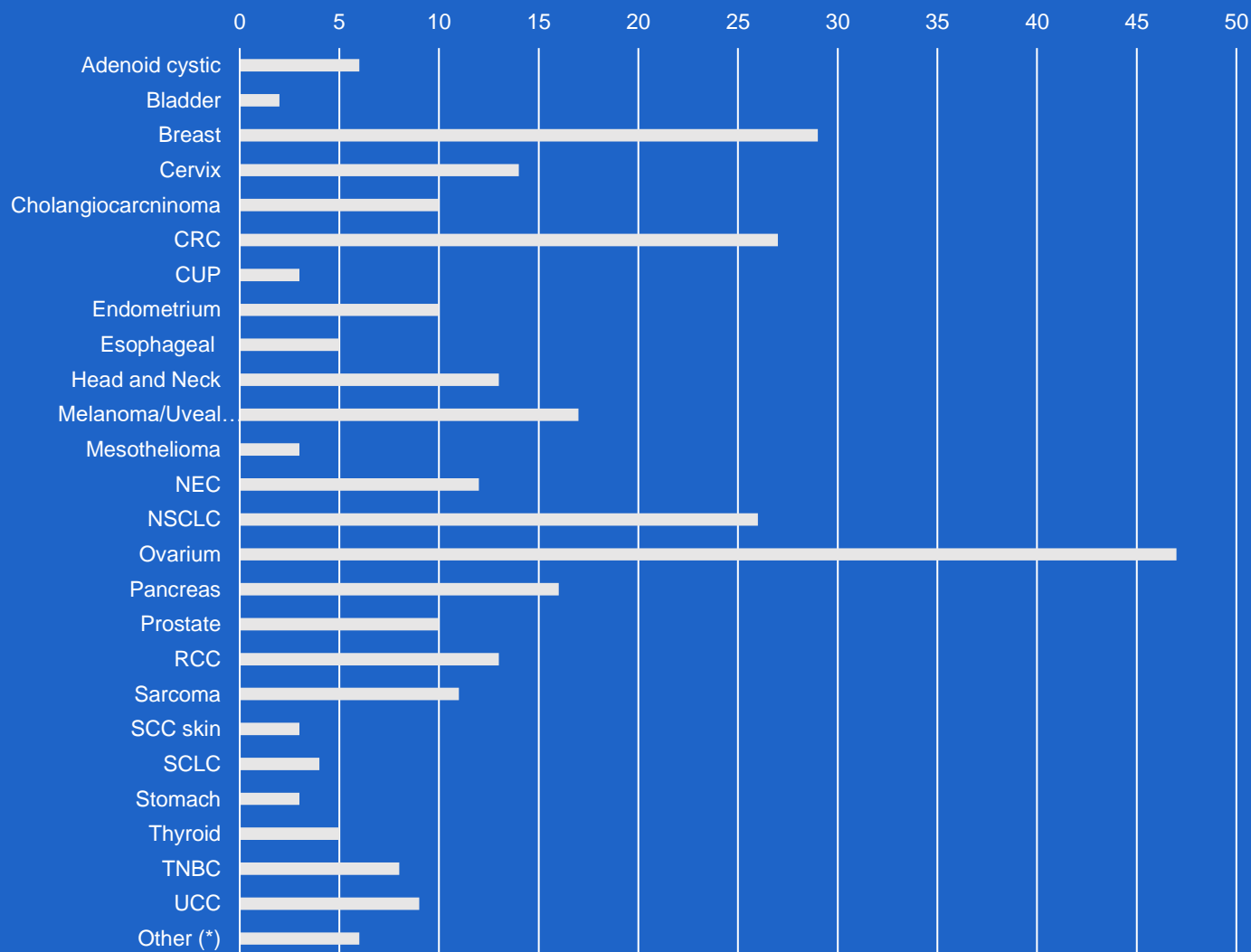
**Number of cycles per patient** in trial (based on end of treatments 2023)





# Phase I Oncology Trials 2023

## Diagnoses subjects registered for/included in Phase I Oncology trials in 2023



(\*) Other includes rare tumor types or which presented only once:

Atypic carcinoid of the mediastinum, hemangiopericytoma, NET atypic carcinoid, small cell carcinoma of the ovary hypercalcemic (SCCOHT), malignant peripheral nerve sheath tumor (MPNST, 2 patients)

# Referral of patients for Phase I Oncology Trials : analysis of 22 patients in MAY 2024 in our Phase I unit treated

UZGent Medonc	7
UZGent Longziekten	1
Mouscron	1
Terneuzen Nederland	1
Bonheiden	1
St Lucas Brugge	1
AZ Jan Palfijn Gent	1
UZBrussel	2
OLV Aalst	1
AZ St Lucas Gent	1
Izegem	1
AZ Groeninge Kortrijk	2
AZ St Jan Brugge Medonc	2
	8/22 UZGent

*Some patients entered the unit via second opinion in UZGent at another department.*

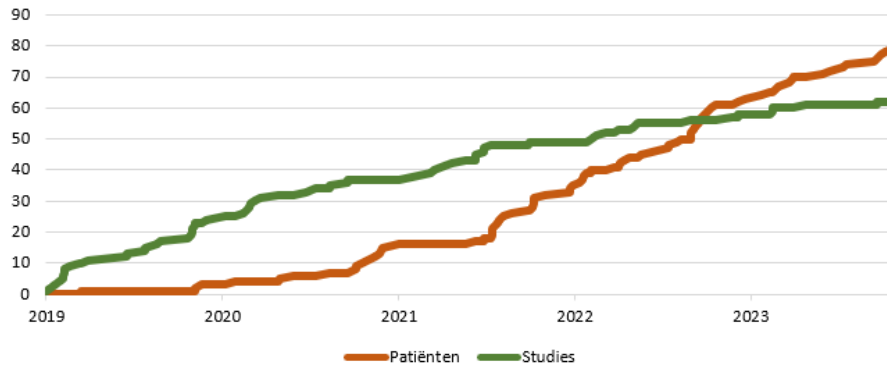
*A newsletter of running clinical trials is sent on a regular basis to medical doctors involved in oncology in Flanders*

# Phase I Trials in Healthy Subjects 2023

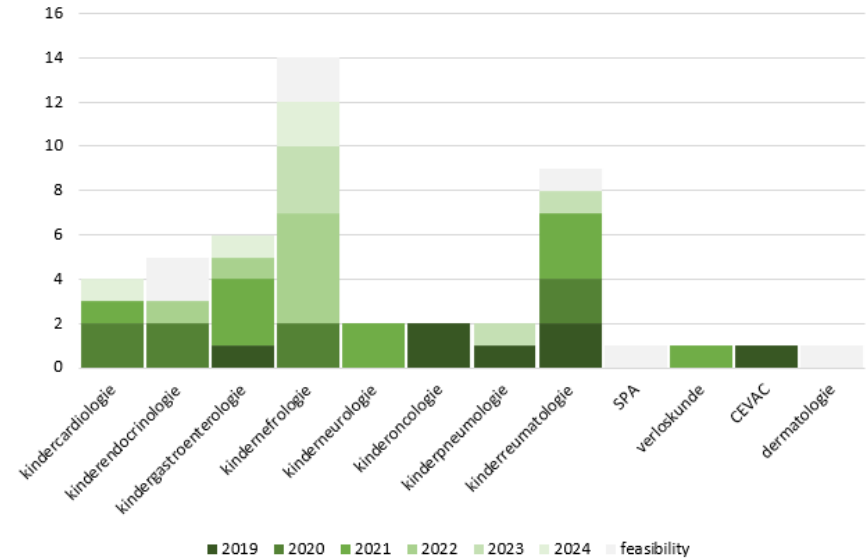
Type	Mandator	Number of Trials	Number of Randomized Healthy Subjects	PI
First in Humans	Industry	6	84	S. Rottey
Other studies	Industry	2	67	S. Rottey

# SPD-CTU- team 4 – collaboration with many Principal Investigators of the department of Paediatrics

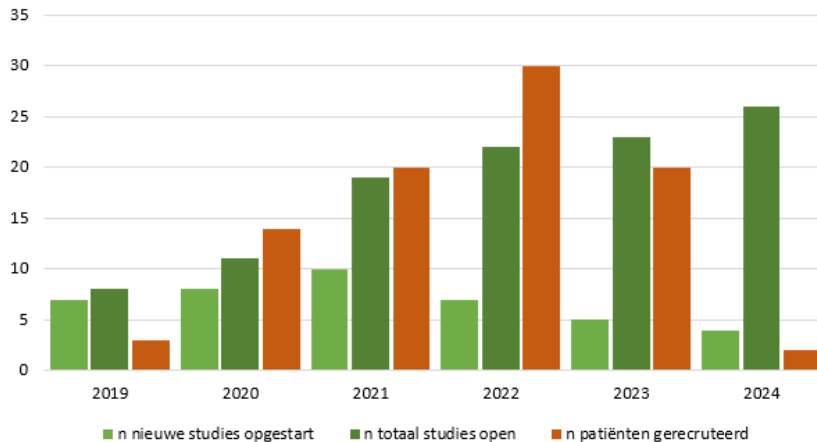
Cumulatief aantal studies en patiënten ifv tijd



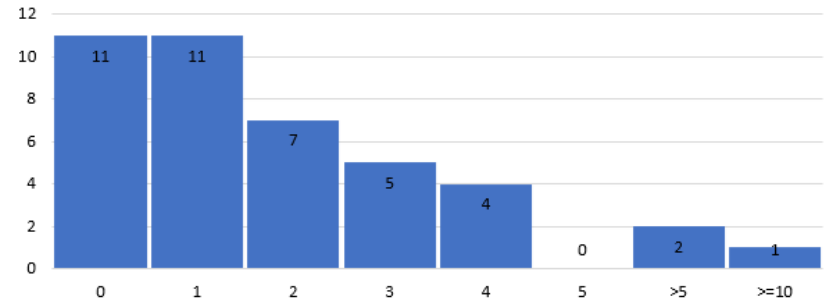
Aantal studies per discipline



Aantal studies en inclusies per jaar



Aantal studies met n aantal patiënten



# Summary

## **Centre of Excellence:**

- ▶ Qualified staff
- ▶ Approval system – double control
- ▶ Internal / External audits

## **Short timelines**

**Takes advantage of University Knowledge Centre / embedding in a University Hospital environment**

# Clinical Research Centers on UZ Campus

## Center for Vaccinology (CEVAC)

- ▶ Mission: Contribute to the development of new vaccines and the improvement of existing vaccines for the prevention or treatment of infectious diseases
- ▶ Conduct of Clinical Vaccine Trials (Phase I, II, III) in dedicated Clinical Unit and Immuno-Monitoring Lab (CEVAC CORE lab)  
(University Hospital Ghent and University Ghent)
- ▶ Founded in 1986 and gained experience since then in over 200 clinical vaccine trials.
- ▶ Experienced, GC(L)P trained team of MD's (4), coordinators (2), project managers (2), study nurses (5), lab technicians (15) and a QUA-team (2)
- ▶ Large database of > 11000 healthy volunteers (adolescents, adults, elderly)

# CANCER RESEARCH INSTITUTE GHENT (CRIG)

CRIG's mission is to unite, stimulate and enhance the impact of cancer research at Ghent University, Ghent University Hospital and VIB-UGent. Hereby, CRIG have six different objectives:

- ▶ Stimulating top research
- ▶ Collaborating and sharing knowledge and technology, across different expertise domains
- ▶ Interaction between the lab and the clinic
- ▶ Communicating and interacting with the outside world
- ▶ Education and networking for young researchers
- ▶ Valorization of research

<https://www.crig.ugent.be/nl>

# VLAAMS INSTITUUT voor BIOTECHNOLOGIE (VIB)

Scientists at VIB conduct pioneering research across a wide spectrum of disciplines ranging from cancer, inflammation and neuroscience to plant biology. Their scientists are world leaders in their fields, and this is one of their greatest strengths.

- ▶ Center for Cancer Biology
- ▶ Center for Inflammation Research
- ▶ Center for Plant Systems Biology
- ▶ Center for Medical Biotechnology
- ▶ Center for Brain & Disease Research
- ▶ Center for Microbiology
- ▶ Center for Structural Biology
- ▶ Center for Molecular Neurology
- ▶ NeuroElectronics Flanders (NERF)



# Memberships investigator



Prof. Rottey is Past President of BSMO  
Board Member of Haelixia  
Board member of BMUC

Prof. Dr. Sylvie Rottey – Head of the Department

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