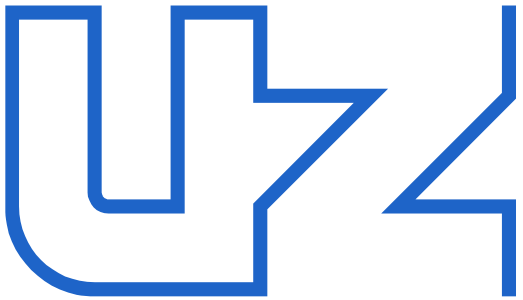

UZ
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Prof. Dr. Sylvie Rottey

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

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

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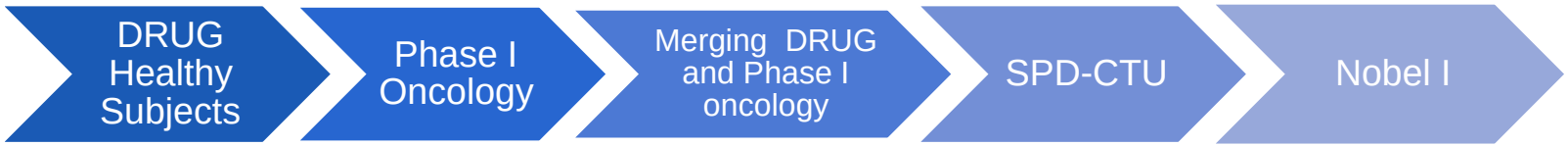
Mission Statement

- **Contribute to the development** of drugs / drug formulations by conducting clinical trials
- Offer trial **access** at national and international level
- Comply with international and national **quality standards**, legislation, GCP-ICH
- **Harmonize** trial conduct
- Improve **efficiency** and optimize **costs** of trial conduct

Milestones



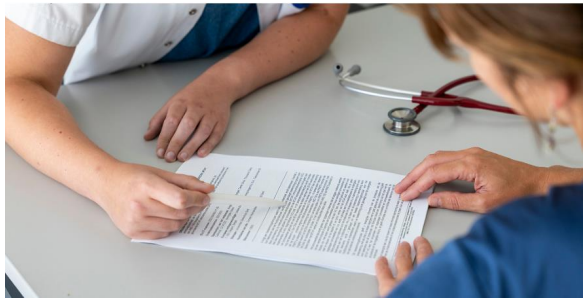
- 2001: Drug Research Unit Ghent founded by Prof. dr. L. Van Bortel
- 2008: Part of Oncology care program
- 2009: approval of the Phase I Unit Oncology by the medical board and CEO of the hospital
- 2015: official merging of DRUG and Phase I Oncology
- 2018: start of pediatric clinical trials = SafePedrug Clinical Trial Unit (SPD-CTU)
- 2024: Move to Nobel I building

Future goals

- Enhance attractiveness for industrial partners
- Broaden partnership with academic partners
- Remain trusted expert in innovative clinical trials

- Continue optimization of procedures in the unit
- Focus on digitalization
- Implementation of eSource

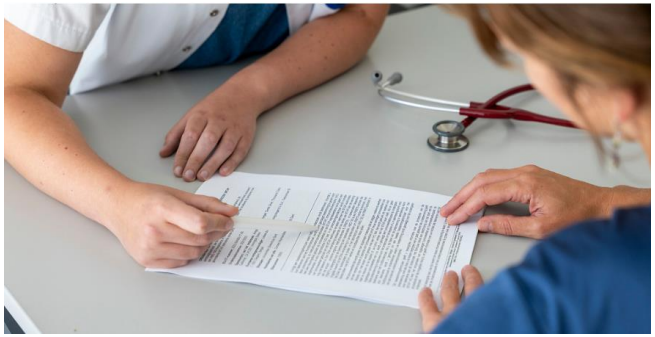
Quality Assurance



- Dedicated Quality Assurance Coordinator
- Robust Quality Management System (SOPs, STPs)
- Quality Control: internal audits + double control of key trial processes
- Infrastructure:
  - temperature management
  - calibrated devices
- Inspections
- Inspections and external audits
- Continuous training and education of employees: staff and bank personnel

→ **HIGH QUALITY**

Training and education



- Training in Quality Management System (SOP/STP)
- Individual training plan
- Hands-on study specific trainings for delegated staff
- Continuous education cycle (journal club, UZ speakers,…)
- Stimulate participation in the UZ Ghent learning programm
- Credentialed nurses (oncology and pediatrics)
- Investigator meetings
- Yearly symposia
- The unit is an internship location for the Master of Specialist Medicine, a postgraduate degree in Belgium for physicians specializing in Clinical Pharmacology and Pharmaceutical Medicine

Organizational structure

Advisory board

Management team
Head of DRUG
Physicians
Teamleaders
QA coordinator

Project team 1
Team Leader
CRCs
TNs

Project team 2
Team Leader
CRCs
TNs

Project team 3
Team Leader
CRCs
TNs

Project team 4
SPD-CTU
Team Leader
CRCs
TNs

IT
File managers
Data entry team

Advisory Board
(Ghent University / Ghent University Hospital)

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

Facilities

- 20 beds for overnight stay
- 2 clinical laboratories (temperature controlled)
- 1 sample handling laboratory + 1 drug storage room (temperature controlled/alarm)
- Multiple freezers (-20°C/-70°C) and refrigerators (temperature controlled/alarm)
- Telemetry monitoring for 15 subjects
- Common areas: canteen, recreation room, offices, reception, meeting room, monitor room, storage rooms and kitchen

- Biosafety level 1
- Biosafety level 2 in collaboration with the laboratory of Clinical Biology of the hospital

Drug Research Unit Ghent

Expertise (Healthy Subjects)

Trials

- First-in-human (SD, MD)
  - Safety & PK
  - PD & biomarkers
  - Complex sample handling
- Food and DDI trials
- Bioequivalence trials
- QT studies

IMP

- Small molecules
- Peptides
- Biologicals
- Vaccines
- …

Study population

- Healthy subjects
  - Male and female
  - 18 – 65 years
- Special groups
  - Elderly
  - IONCBP
  - Overweight /obese
  - Hypertensives
  - Allergic/atopic

Phase I Trials in Healthy Volunteers

Recruitment:

- Large database with +/- 4300 active subjects
- Recruitment by e-mail and (online) advertisement
- VCT (Verified Clinical Trials) prevents concurrent participation in multiple trials.

Trials in 2024:

Type	Mandator	Number of Trials	Number of Randomized Healthy Subjects
First in Humans	Industry	3	60
Other studies	Industry	4	107

Expertise (Oncology)

Trials

- First-in-human (dose-escalation)
- Expansion cohorts
- Biomarker cohorts
- DDI
- Food cohorts
- Other

IMP

- Small molecules
- Checkpoint inhibitors
- Immune agonists
- Bispecific T-cell engagers
- ADCs
- Cancer vaccines
- Oncolytic viruses
- Adoptive cell therapy (CAR-T)

Study population

- All tumor types
- Niche populations (histology/molecular)
- Pre-screening

Phase I Oncology Trials - recruitment

Internally:

- On a multidisciplinary basis (GI, Thoracic and Medical Oncology…)

Externally:

- https://www.uzgent.be/nl/geneesmiddelenonderzoek
- A quarterly **newsletter** to medical doctors involved in oncology in Flanders
- https://cancertrials.be
- Trialing app

60% referral patients

Patient waiting list

Recruitment of cancer patients 2024:

- **214** registrations (via email, phone, personal contact MD)
- **166** prescreening ICF's signed – modern trials !
- **68** subjects signed main ICF in 2024
- **12** ongoing subjects from 2023

Phase I Oncology Trials

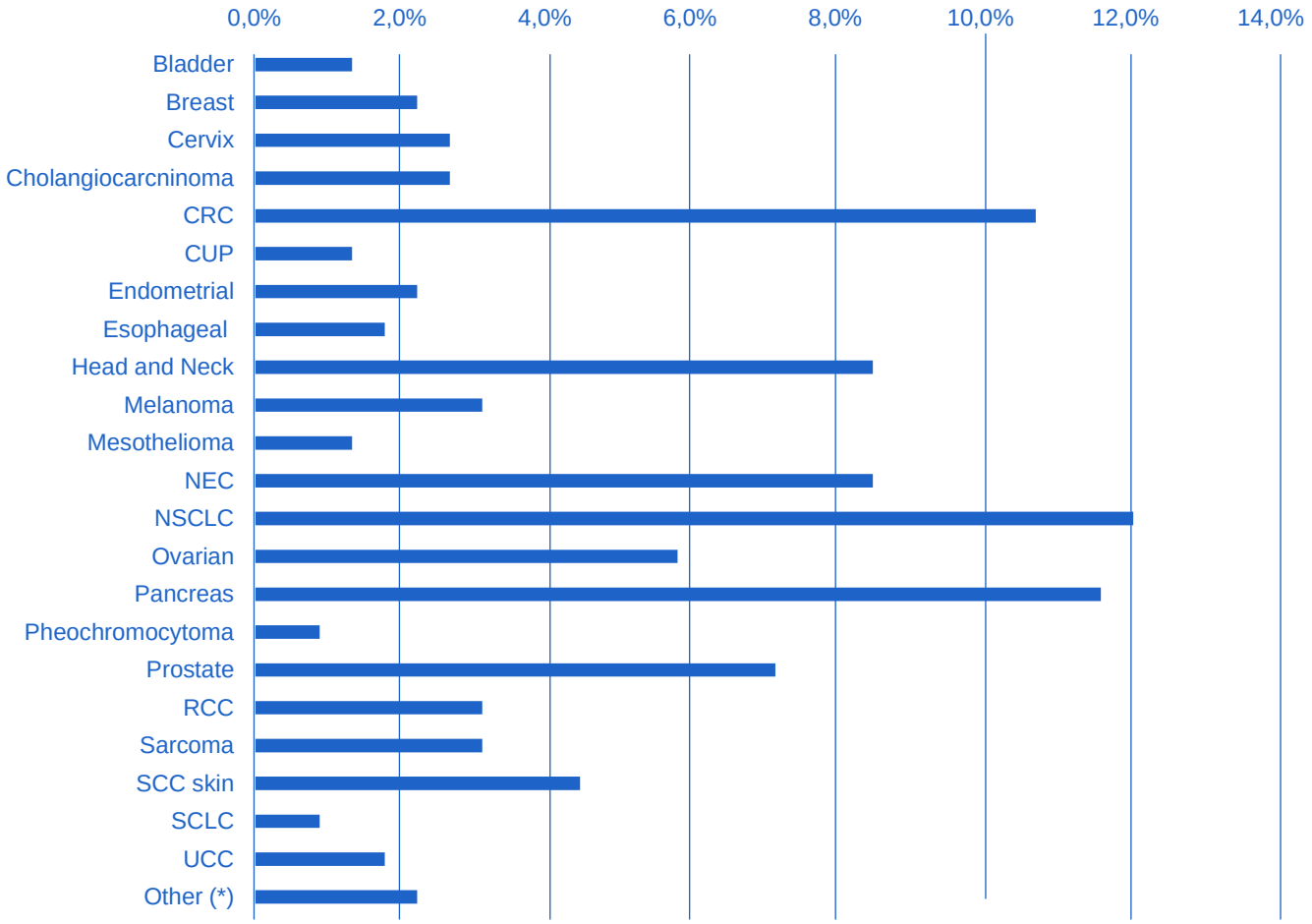
Patients	Mandator	Number of Trials in 2024
Cancer patients	Industry (2024: 20# sponsors)	42

Industrial partners

Amgen	GSK	iTeos	Servier
Bayer	Eli Lily	KlingBiotherapeutics	T-Knife
Bicycle Therapeutics	Exelixis	Merus	
Boehringer Ingelheim	Immunocore	Pyxis Oncology	
Bristol Meyers Squibb	Incyte	Roche	
Byondis	JnJ	Sairopa	
CDR-life	Immunocore	SalubrisBio	
Deuter Oncology	iOMXTherapeutics	Sanofi	

Phase I Oncology Trials 2024

Number of cycles in trial: **5,5 cycles in trial** (4,9 cycles without outliers)



(*) Other includes rare tumor types or tumor types presented only once:
adenoid cystic, HCC, kidney (Collectin Duct Carcinoma), malignant peripheral nerve sheath tumor (MPNST), female adnexal tumor of Wolffian origin (FATWO), adrenal cortex carcinoma, carcinoma external auditory canal (2 pts), duodenal carcinoma, pecoma, thymoma type B, testis, thyroid
(**) from 17 patients tumor type was not known at registration

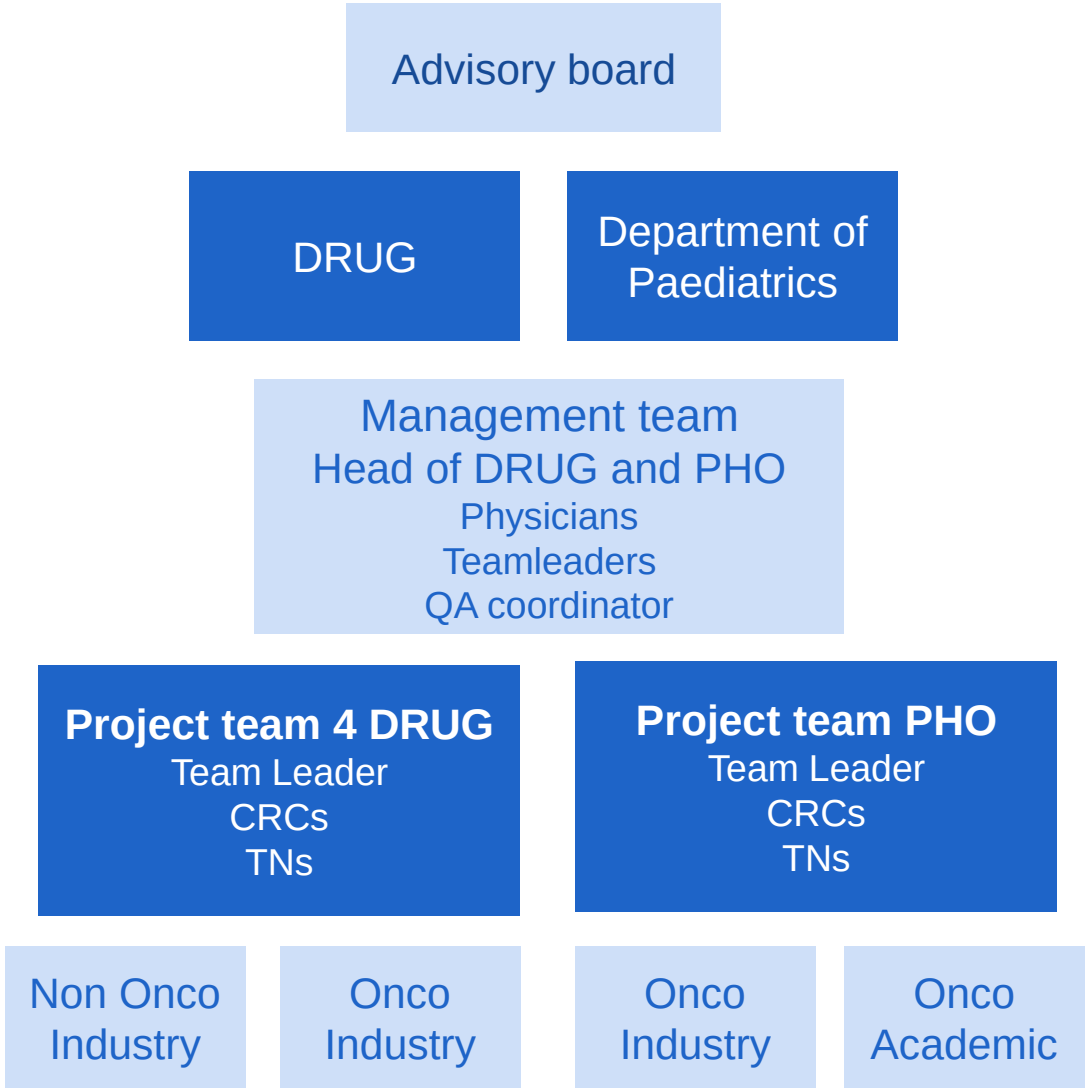
Expertise (Other patient trials)

- Commitment to support (early phase) clinical trials for other UZ Ghent investigators
- PI = organ specialist (beneficial for patient recruitment)
- DRUG involvement
  - intensive PK sampling
  - safety monitoring (CRS, ICANS, IRR,…)
  - overnight stays
  - ECGs
  - administrative support
  - …

Expertise (Other patient trials)

- Cooperations 2024/2025
  - Internal medicine: phase I HIV trial
  - Dermatology:- phase III Hidradenitis suppurativa trial
    - phase III Moderate to severe Atopic Dermatitis trial
    - phase III Nonsegmental Vitiligo trial
  - Neurology: phase Ib multiple sclerosis trial
  - Pulmonology: phase I cystic fibrosis trial
  - Reumatology: phase I Rheumatoid Arthritis trial
  - Nephrology: phase I autosomal dominant polycystic kidney disease trial

SPD-CTU: Organizational structure



SPD-CTU - Expertise

Trials

- Phase I – IV
- Observational studies

IMP

- Small molecules
- Biologicals
- Vaccines
- ATMP

Study population

- Healthy infants
- Paediatric patients 0-18yr
- Rare diseases

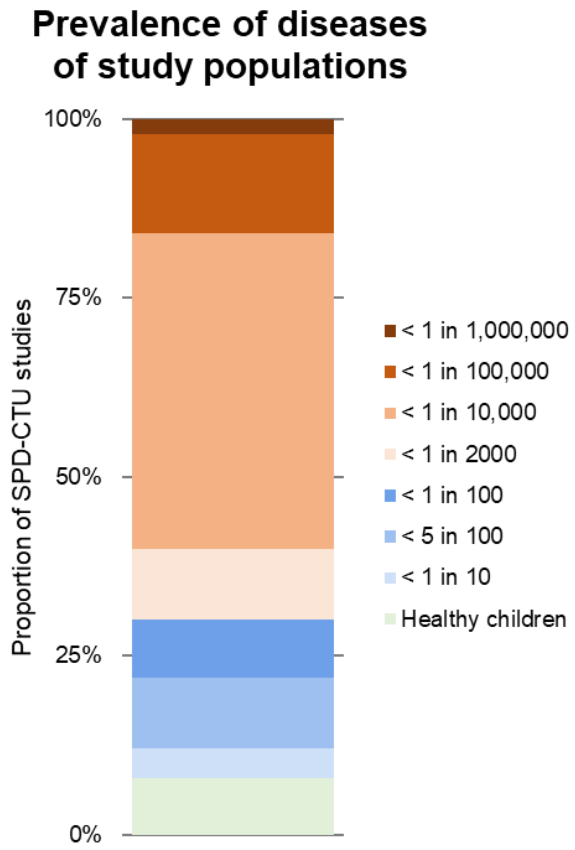
Contact: safepedrug.clinicaltrialunit@uzgent.be

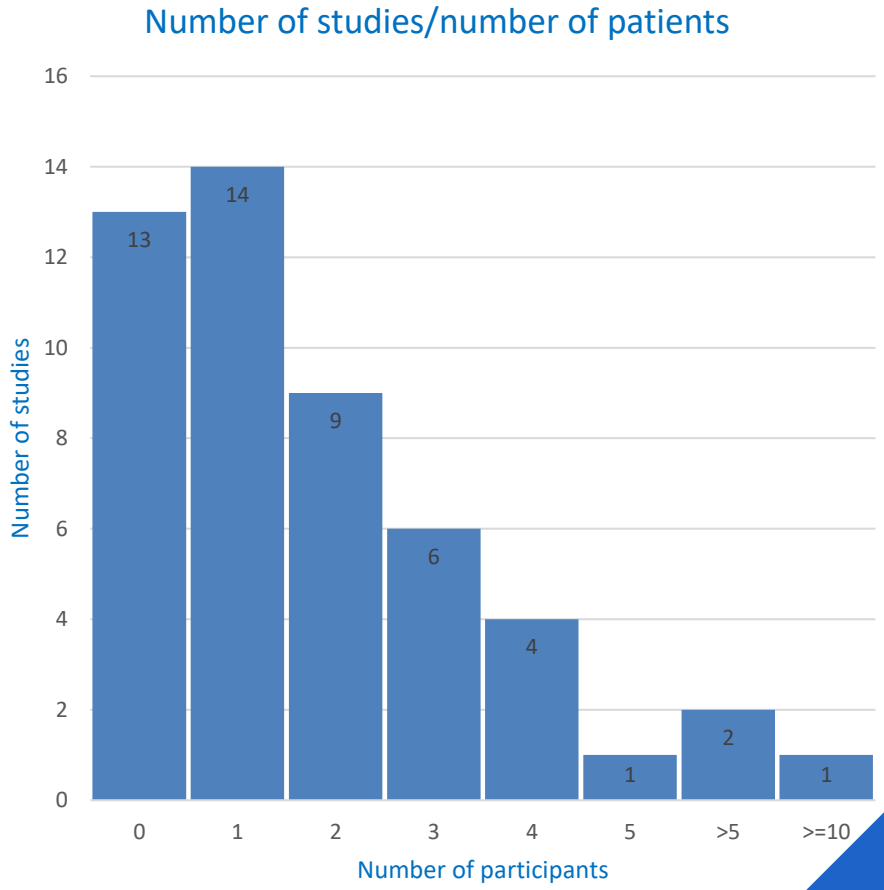
SPD-CTU - Recruitment

- Challenges of (ultra) rare disease trials in paediatrics:

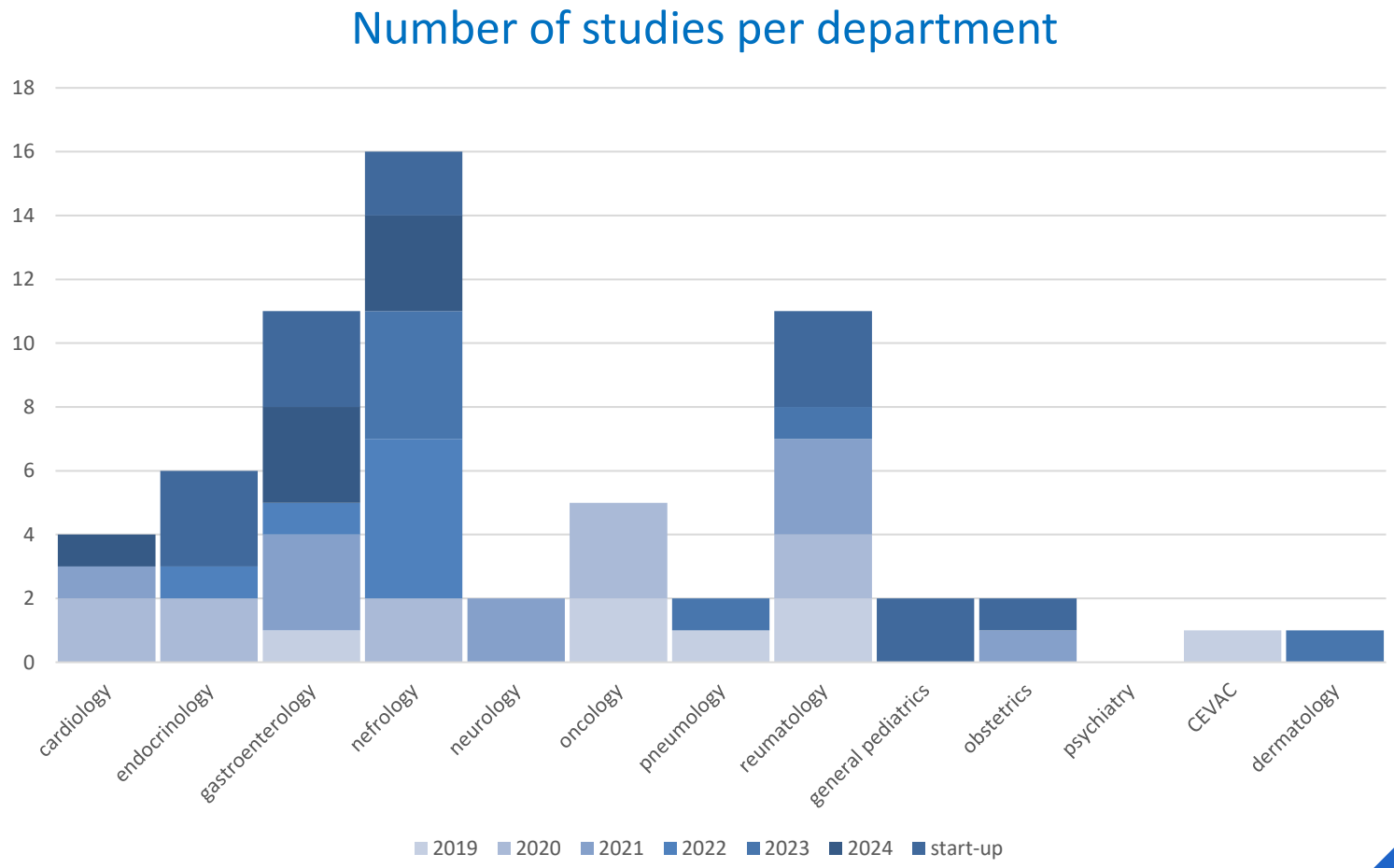
In 50% of the open studies, the current maximum enrollment is one patient.

And still: at study closure, 87% of the studies reach expected number of participants





SPD-CTU
Collaboration with many investigators of the department of Paediatrics



Phase I Oncology Working Group

- Quarterly meeting
- Discussion about trials (new and ongoing), listing side effects, recruitment issues, operation of the department,…
- Representatives:
  - Cancer Centre UZ Ghent
  - Digestive Oncology
  - Thoracic Oncology
  - Hematology
  - Medical Oncology
  - Radiotherapy
  - Gynaecology
  - Pathology
  - Pharmacy
  - Research physicians DRUG + 1 team leader of DRUG

Collaboration – Oncology working group

Collaboration – Department of Medical Oncology

Collaboration –HIRUZ

Collaboration – ICU / Pharmacy

Collaboration – Other departments UZ Ghent

Phase I consultations: first patient contact:

- At Drug Research Unit Ghent
- At the department of medical oncology

Day hospital Medical Oncology:

- Blood transfusion
- Pre- and post-hydration for CT scans
- Administration of bisphosphonates (zometa®)

Hospitalization Medical Oncology:

- Hypercalcemia
- CRS, ICANS, immune related adverse events (irAE)…
- Optimization of pain medication
- Fever and infections
- Other serious adverse events (drug related and not drug related)

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
- Support of academic research

Intensive Care Unit and Emergency Department

- Professional care of our patients if needed
- Close to the unit
- Service Level Agreement

Pharmacy

- A separate Clinical Trial Unit within the Pharmacy Department of the hospital
- Cleanroom
- Storage, packaging, reconstitution, preparation of study medication
- On site formulations
- Improvement of collaboration by performing audits at each others department
- Close to the unit
- Service Level Agreement

Collaboration – Oncology working group

Collaboration – Department of Medical Oncology

Collaboration – HIRUZ

Collaboration – ICU / Pharmacy

Collaboration – Other departments UZ Ghent

- Laboratory (safety testing…)
- Radiology (CT, MRI, ultrasound-guided biopsies, paracentesis, thoracentesis,…)
- Nuclear Medicine (PET-CT, bone scan, MUGA scan, …)
- Ophthalmology (ocular AE's)
- Dermatology (skin toxicities, biopsies)
- Cardiology (echocardiography)
- Pathology (handling fresh/archival tumor tissue)
- Pneumology (lung function tests, EBUS, thoracentesis,…)
- Neurology (ICANS, NE, EEG…)
- Anaesthesiology (high risk medication)
- Radiotherapy (antalgic radiotherapy)
- Interventional radiology (intra-tumoral study drug administrations, CT-guided biopsies)
- Genetics (NGS sequencing)
- …

Summary

Centre of Excellence:

- Expertise
- Qualified dedicated staff
- Extensive quality system

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

Clinical Research Centers on UZ Campus

- Center for Vaccinology (CEVAC) https://www.uzgent.be/nl/centrum-voor-vaccinologie
- Cancer Research Institute Ghent (CRIG)
  https://www.crig.ugent.be/en
- Vlaams Instituut voor Biotechnologie (VIB)
  https://vib.be

New MD specialist title in Belgium: Clinical Pharmacology and Pharmaceutical Medicine

ERAL SANTE PUBLIQUE,
HAINE ALIMENTAIRE
ONNEMENT

[C − 2022/45300]

royal modifiant l'arrêté royal du la liste des titres professionnels ens de l'art médical, en ce compris

s.

FEDERALE OVERHEIDSDIENST VOLKSGEZONDHEID, VEILIGHEID VAN DE VOEDSELKETEN EN LEEFMILIEU

[C − 2022/45300]

4 SEPTEMBER 2023. — Koninklijk besluit tot wijziging van het koninklijk besluit van 25 november 1991 houdende de lijst van bijzondere beroepstitels voorbehouden aan de beoefenaars van de geneeskunde, met inbegrip van de tandheelkunde

FILIP, Koning der Belgen,

Hebben Wij besloten en besluiten Wij :

Artikel 1. Artikel 1 van het koninklijk besluit van 25 november 1991 houdende de lijst van bijzondere beroepstitels voorbehouden aan de beoefenaars van de geneeskunde, met inbegrip van de tandheelkunde, laatst gewijzigd bij de wet van 18 mei 2022, wordt aangevuld als volgt:

"- arts-specialist in de klinische farmacologie en farmaceutische geneeskunde".

Art. 2. De minister bevoegd voor Volksgezondheid is belast met de uitvoering van dit besluit.

Brussel, 4 september 2023.

Acta Clinica Belgica

New MD specialist title in Belgium: Clinical Pharmacology and Pharmaceutical Medicine

Internship UGent - Sequence can change

1 year hospital	Internal medicine, paediatrics, emergency medicine, clinical trial unit
1 year hospital	Internal medicine, paediatrics, emergency medicine, clinical trial unit
1 year	FAGG or RIZIV (min. 3 mths/max. 9mths); Industry (min. 1 year); clinical trial unit
1 year	FAGG or RIZIV (min. 3 mths/max. 9mths); Industry (min. 1 year); clinical trial unit

Website: MSG UGent

New MD specialist title in Belgium: Clinical Pharmacology and Pharmaceutical Medicine

- Prof. Dr. S. Rottey
  - Coordinating internship supervisor for Ghent University
  - Member of the recognition committee
- DRUG = recognized internship department

- Recognized MD specialists in Clinical Pharmacology and Pharmaceutical Medicine working in UZ Ghent:
  - Prof. dr. Sylvie Rottey (medical oncology, DRUG)
  - Prof. dr. Mirko Petrovic (geriatrics, chairman of the commission for medical ethics)
  - Dr. Ellen Van Leeuwen (general practitioner, pharmacotherapy teacher UGent)
  - Prof. dr. Tine De Backer (cardiology)
  - Prof. dr. Peter De Paepe (emergency medicine, chief physician UZ Ghent)
  - Dr. Brant Delafontaine (DRUG)
  - Dr. Griet Van Lancker (DRUG)
  - Prof. Dr. Isabelle Leroux-Roels (CEVAC)
  - Prof. Dr. Pauline De Bruyne (Paediatrics)

Memberships Prof. Dr. S. Rottey

Past President of BSMO
Board Member of Healixia
Board member of BMUC

Trainer for the NVKFB (clinical pharmacologists)

Trainer Eufemed

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