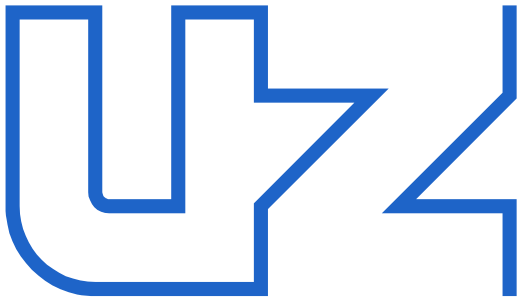

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Drug Research Unit Ghent

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

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Mission statement

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

Since 2018 the Drug Research Unit Ghent will contribute 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

Landmarks

D.R.U.G. Healthy subjects

- 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 a top 10 global pharma industry
- 2009: ISO 9001:2008 certified

Phase I Oncology

- 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)

- 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
- Since 2018: integration in hospital accreditation, NIAZ/Q-Mentum
- Quality system developed under ISO9001 remains applicable
- National accreditation Phase I pending

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

+ Patient studies for other hospital departments and other principal investigators

Preconditions

High Quality

Quality control

- First party (internal) audits
- Qualified internal auditors (4)
  - Scheduled on main procedures
  - Ad hoc for (near) errors
- Training in SOP (all SOPs revised within 2 years)
- Close feedback on the spot / approval system

Quality assurance

- 1 GCP-ICH third party audit/ 2 years

Preconditions

High Quality

Quality management system

- Quality manual
- Standard Operating Procedures (SOPs)
- Standard Technical Procedures (STPs)
- Forms
- Examples
- Documents

Training employees

- SOP trainings (min. 7/year)
- Training + test in GCP and national and international legislation
- BLS/AED
- Study-specific trainings
- Individual trainings in SOP’s and STP’s
- In the framework of patient trials: training in oncology topics, training by psychologists, …

Preconditions

High Quality

Document management

Infrastructure

- Apparatus: temperature management and control
- Calibrated devices

Involvement of management !

Involvement of team !

Preconditions

High Quality

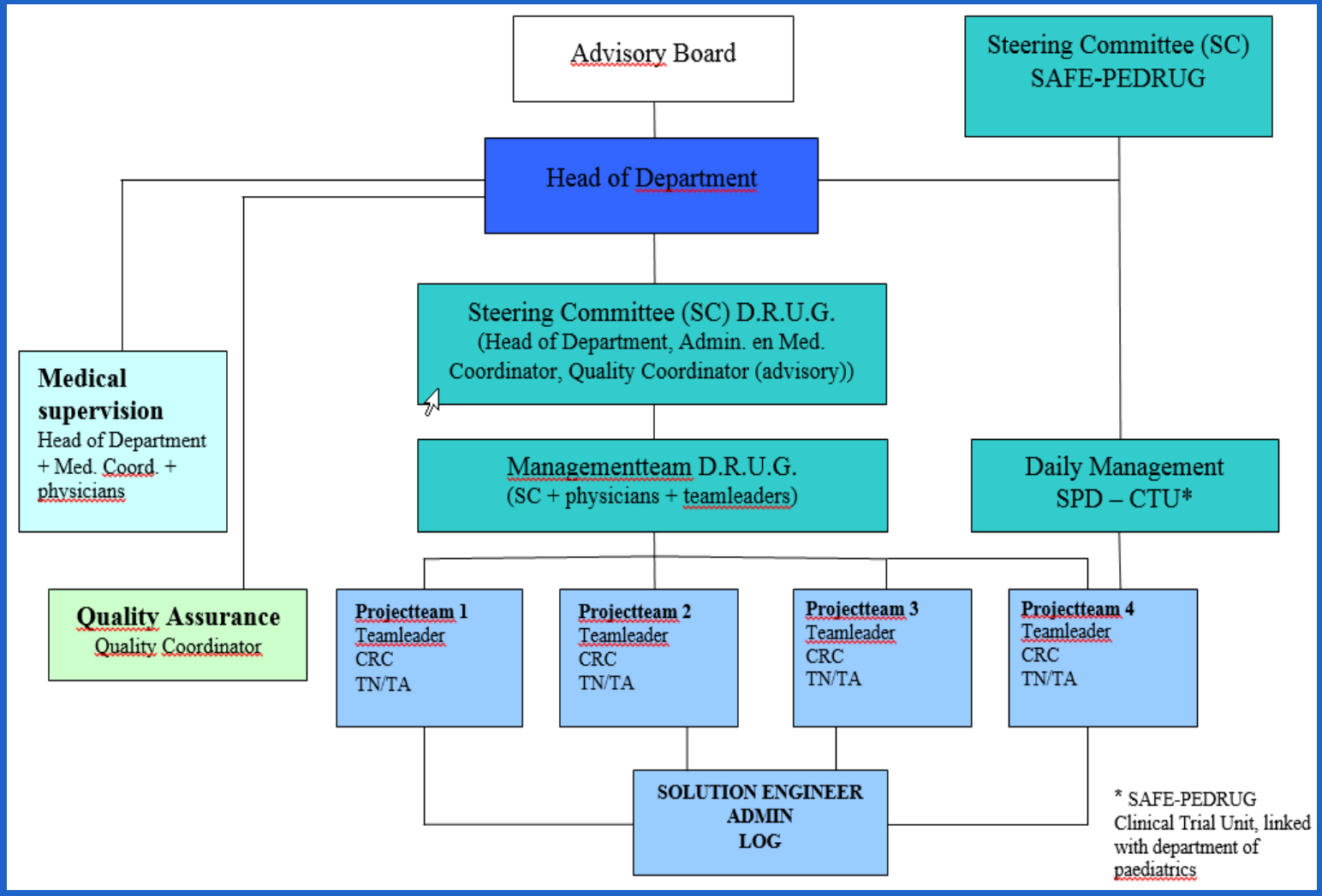
FDA inspection June 2015

- No Form 483 issued

FAGG Inspections

Second party audits

Staff


Advisory Board
Steering Committee (SC)
SAFE-PEDRUG
Head of Department
Steering Committee (SC) D.R.U.G.
(Head of Department, Admin. en Med. Coordinator, Quality Coordinator (advisory))
Medical supervision
Head of Department + Med. Coord. + physicians
Managementteam D.R.U.G.
(SC + physicians + teamleaders)
Daily Management
SPD – CTU*
Quality Assurance
Quality Coordinator
Projectteam 1
Teamleader
CRC
TN/TA
Projectteam 2
Teamleader
CRC
TN/TA
Projectteam 3
Teamleader
CRC
TN/TA
Projectteam 4
Teamleader
CRC
TN/TA
SOLUTION ENGINEER
ADMIN
LOG
* SAFE-PEDRUG Clinical Trial Unit, linked with department of paediatrics

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)
- 5 freezers (-20°C) + 1 freezer (-70°C) (temperature controlled/alarm)
- 5 refrigerators
- 1 biohazard case
- Wifi network
- Canteen, recreation room, offices, reception, meeting room, monitor room, storage rooms and kitchen
- Biosafety level 1

Key processes

- Trial initiation
- Recruitment
- Conduction of the trial
- Data entry
- Archiving

Phase I Oncology Trials 2018

Patients	Mandator	Number of Trials	PI
Cancer patients	Industry (**15# sponsors**)	25	S. Rottey
Head & Neck cancer patients	Academic - UCL	1	S. Rottey
NPC Patients	Acamedic – IWT grant UZ Gent	1	S. Rottey

+ 1 observational trial

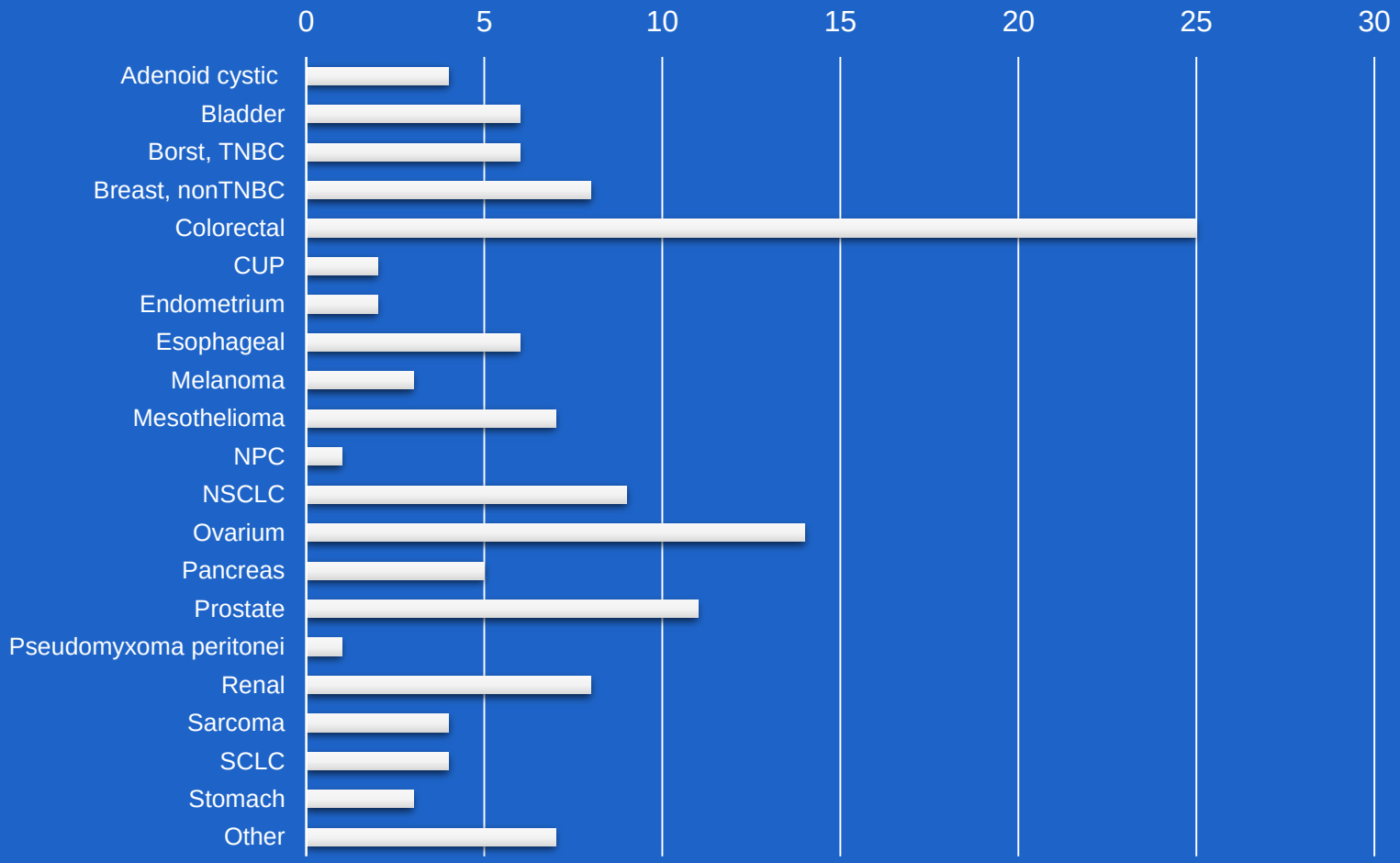
Subjects registered for Phase I Oncology trials in 2018: 134

Subjects in trial in 2018:

- 5 patients were prescreend
- 14 ongoing subjects from 2017
- 39 subjects signed main ICF

Phase I Oncology Trials 2018

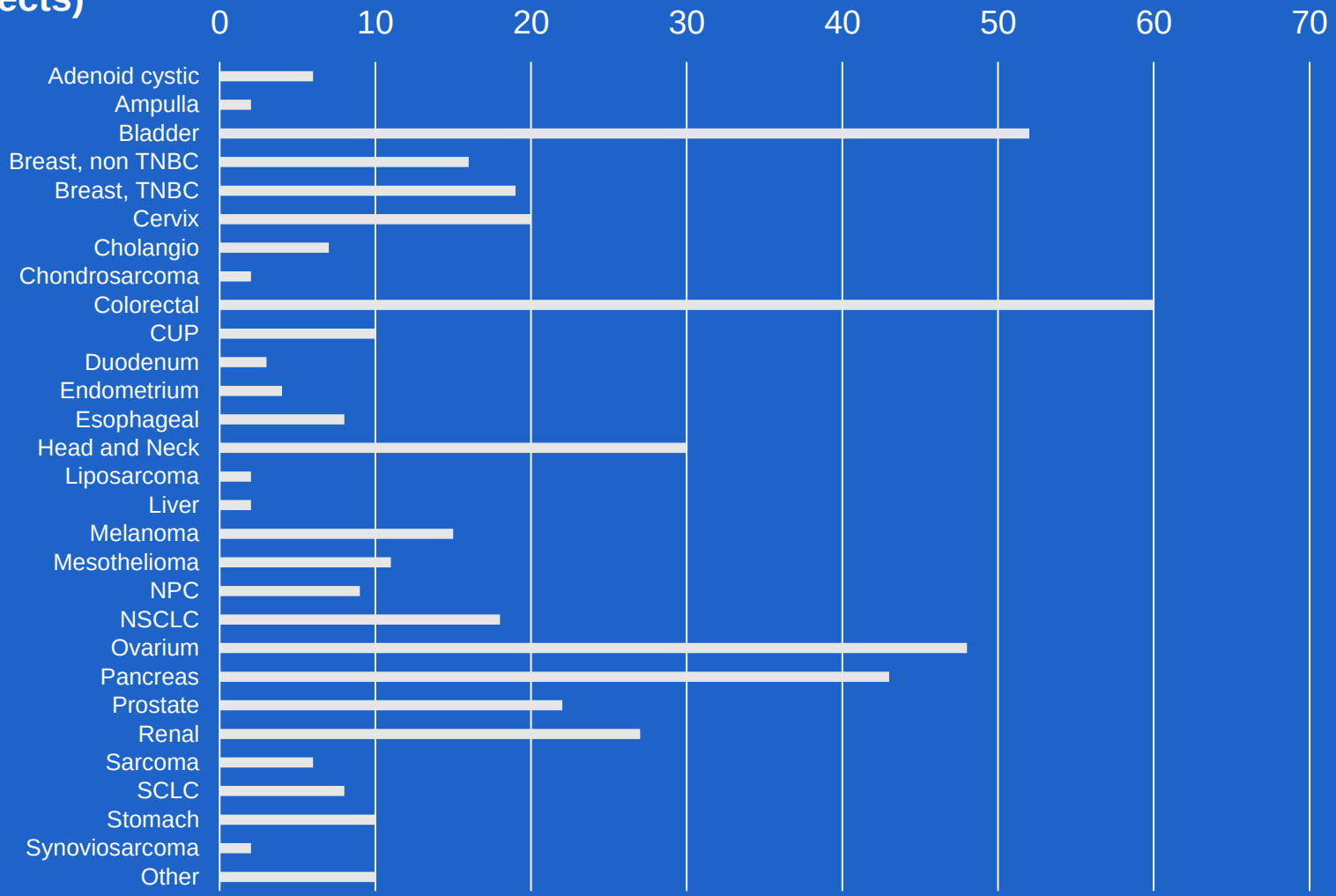
Diagnoses subjects registered for Phase I Oncology trials in 2018 (134 subjects)



Other includes tumor types which presented only once (cervix, cholangiocarcinoma, duodenum, NPC, pseudomyxoma peritonei, uterus, vulva).

Phase I Oncology Trials 2018

Diagnoses subjects registered for Phase I Oncology trials in 2016-2018 (472 subjects)



Other includes tumor types which presented only once (appendix, epitheloïd hemangioendthelioma, malignant solitary fibrous tumour, pseudomyxoma peritonei, soft tissue pyo-epithelioma, thymic, uterine leiomyosarcoma, uterus, vaginal, vulva).

Phase I Trials in Healthy Subjects 2018

Type	Mandator	Number of Trials	Number of Randomized Healthy Subjects	PI
First in Humans	Industry (**2# sponsors**)	3	104	S. Rottey
Other studies	Industry	3	88	S. Rottey

Summary

Centre of Excellence:

- Qualified staff
- Approval system – double control
- External audits
- NIAZ/Q-Mentum
- Accreditation phase I unit pending

Short timelines

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

Memberships

Prof. Rottey is Board Member of Eufemed
President of BSMO
President of BAPU
President of BMUC

Prof. Dr. Sylvie Rottey – Head of the Department
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