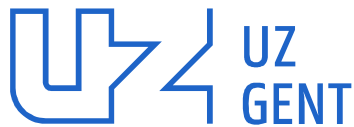




# Drug Research Unit Ghent

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 volunteers** as well as in **patients**.

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
- ▶ JAN 2018: Replacement of ISO by NIAZ/Q-Mentum applied for in the hospital

# 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/year

# 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

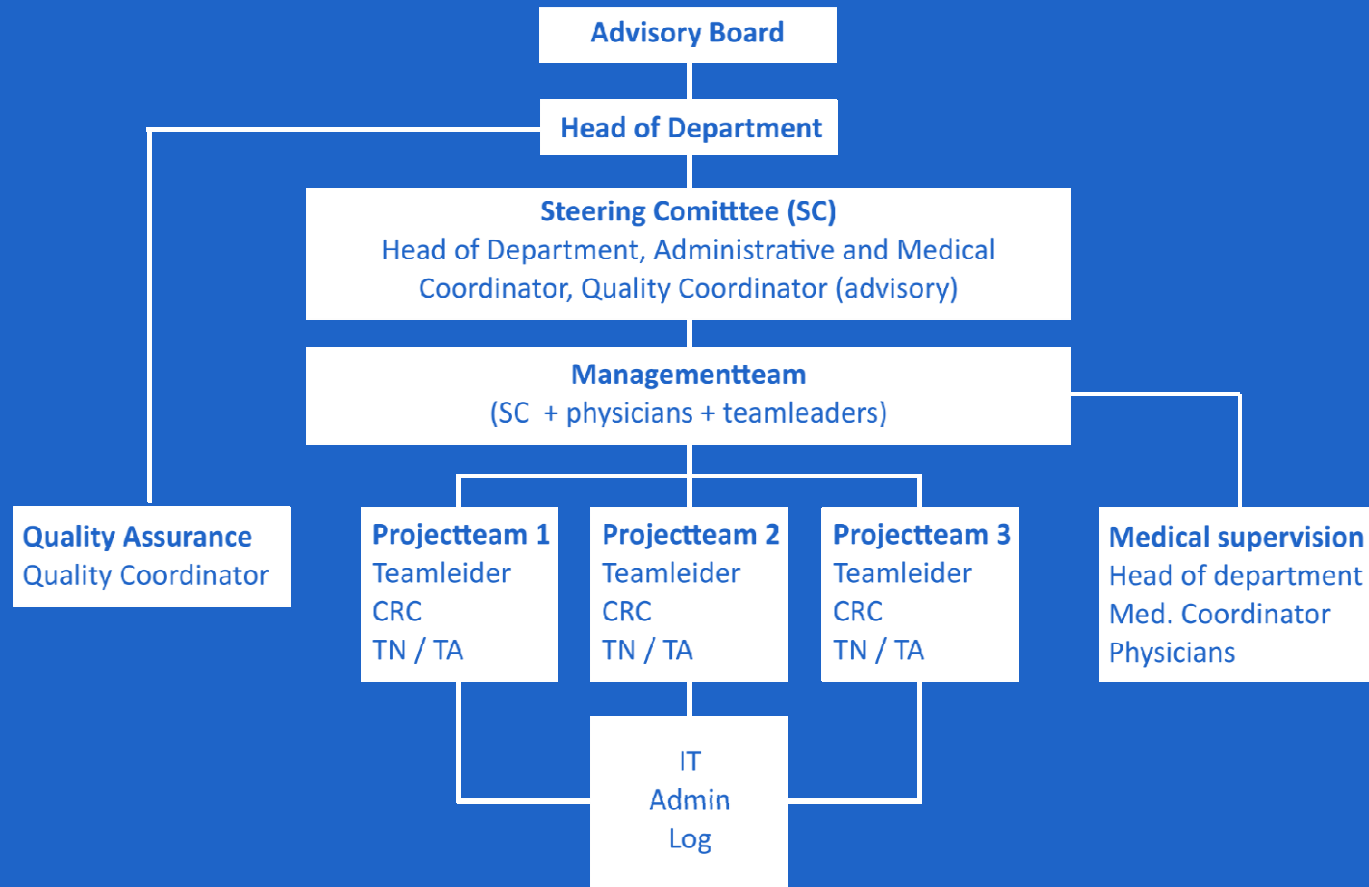
- ▶ No Form 483 issued

### FAGG Inspections

### Second party audits



# Staff



# 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 2017

Patients	Mandator	Number of Trials	PI
Cancer patients	Industry (15# sponsors)	20	S. Rottey
Head & Neck cancer patients	Academic - UCL	1	S. Rottey
NPC Patients	Academic – IWT grant UZ Gent	1	S. Rottey

+ 1 observational trial

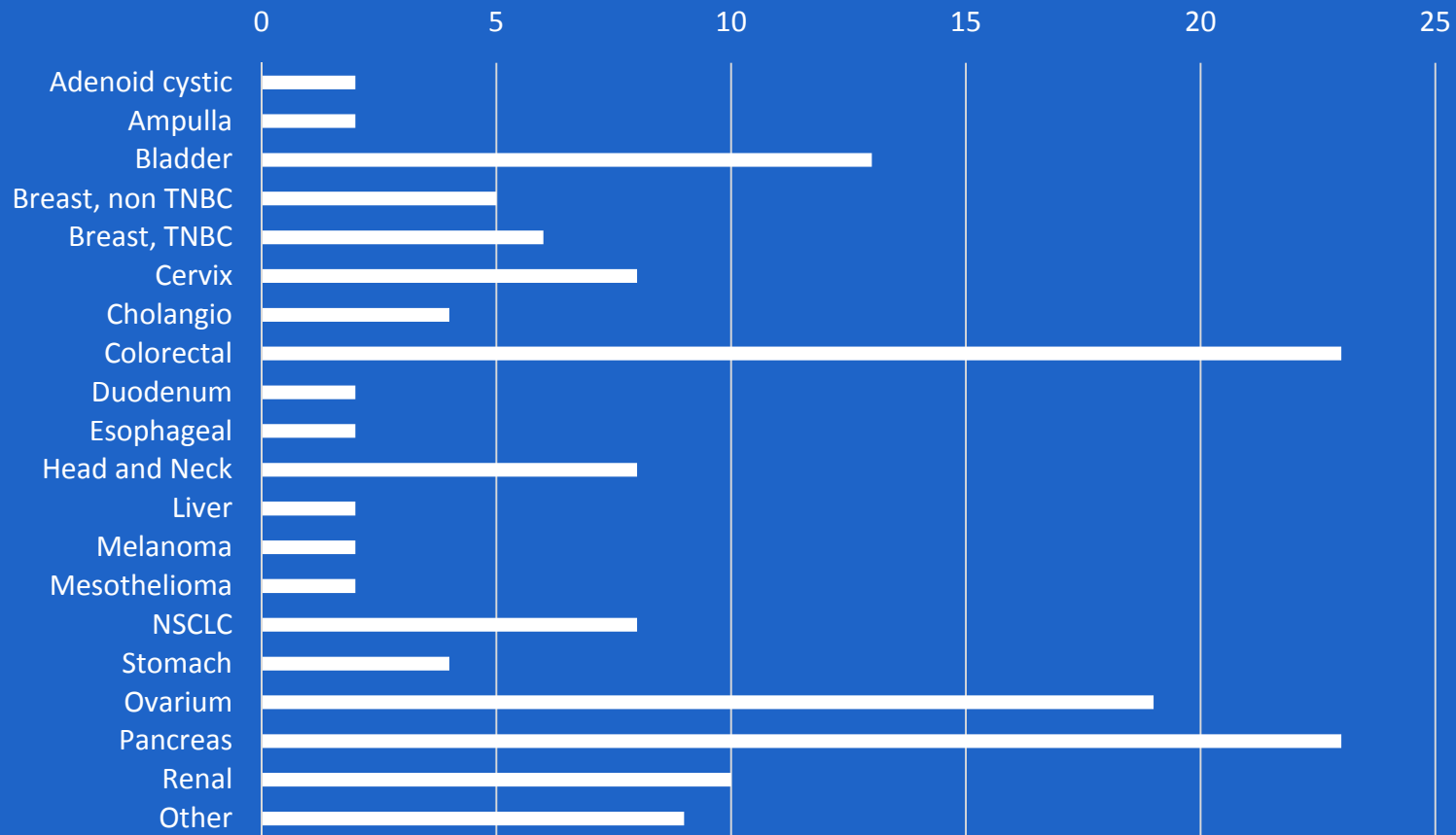
**Subjects registered for Phase I Oncology trials in 2017: 159**

**Subjects in trial in 2017:**

- ▶ 20 ongoing subjects from 2016
- ▶ 48 subjects signed main ICF

# Phase I Oncology Trials 2017

Diagnoses subjects registered for Phase I Oncology trials in 2017 (154 subjects)

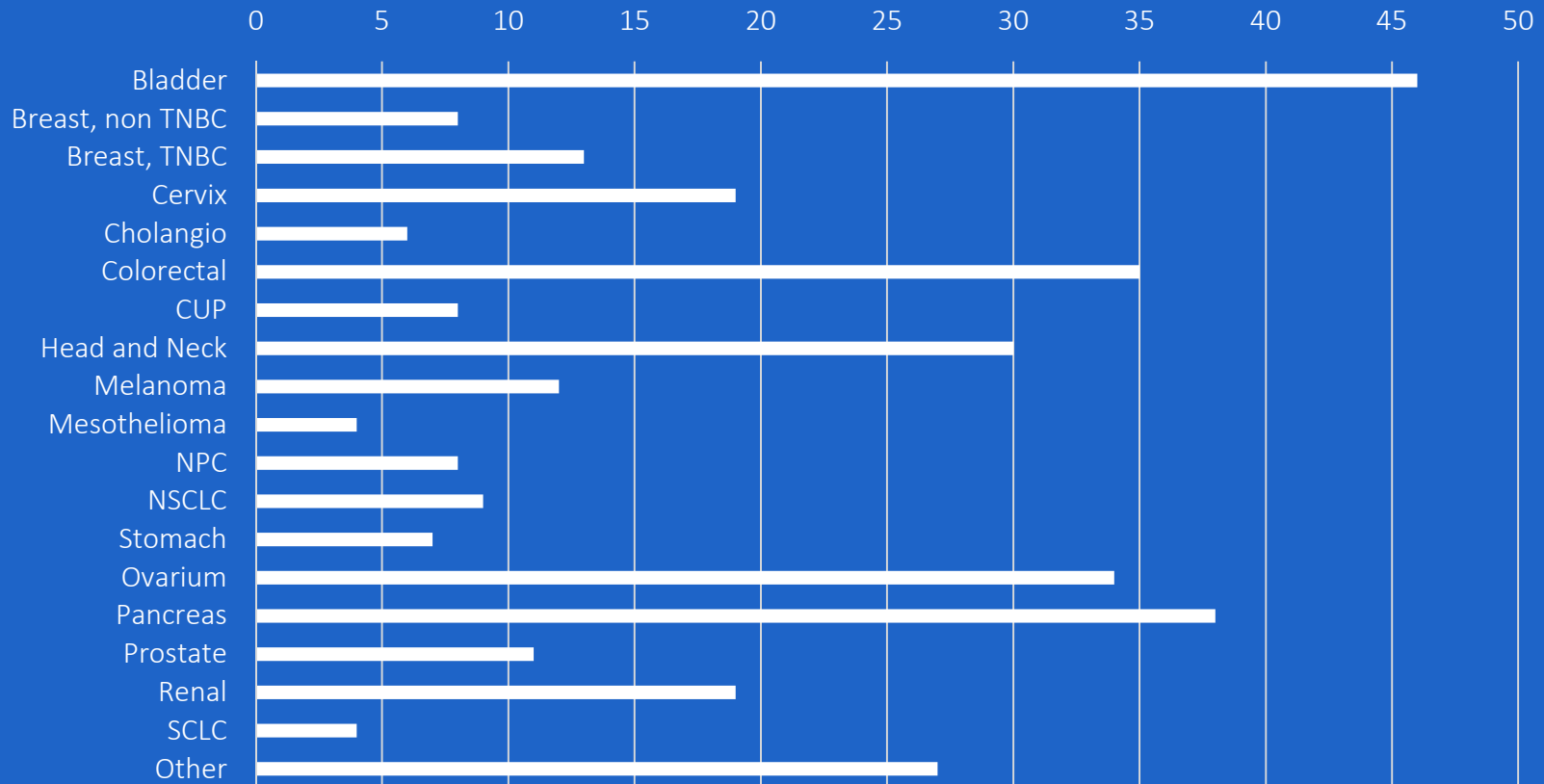


Other includes tumor types which presented only once (appendix, chondrosarcoma, CUP, endometrium, liposarcoma, SCLC, soft tissue pyo-epithelioma, uterine leiomyosarcoma and vaginal).

# Phase I Oncology Trials 2017

Diagnoses subjects registered for Phase I Oncology trials in 2016 – 2017

(338 subjects)



Other includes tumor types which presented only once (appendix, epitheloïd hemangioendothelioma malignant solitary fibrous tumour, soft tissue pyo-epithelioma, thymic, uterine leiomyosarcoma, vaginal) or twice (adenoic cystic, ampulla, chondrosarcoma, duodenum, endometrium, esophageal, liposarcoma, liver, sarcoma and synoviosarcoma).

# Phase I Trials in Healthy Subjects 2017

Type	Mandator	Number of Trials	PI
First in Humans	Industry (1# sponsors)	4	S. Rottey
Other studies	Industry	2	S. Rottey



# Summary

## Centre of Excellence:

- ▶ Qualified staff
- ▶ Approval system – double control
- ▶ External audits
- ▶ NIAZ/Q-Mentum
- ▶ Accreditation phase I unit pending (should be possible as from august 2018)

## Short timelines

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



# Memberships



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

Prof. Dr. Sylvie Rottey – Head of the Department

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