



**Thomayer University Hospital
Prague
&
Clinical – Pharmacology Unit**

Content

- ❖ **Thomayer University Hospital (TUH)**
 - **Organization, QA**
 - **Pharmacy, IT and Laboratory base**

- ❖ **Clinical-Pharmacology Unit (CPU)**
 - **Volunteers, Patients**
 - **Staff, Facilities, Equipment**
 - **Experience with clinical studies**
 - ❖ **Future development**

Thomayer University Hospital



Thomayer University Hospital

Organization type (and size)

- State (public) ownership number of beds: 1 400
- Number of employees: 2 132 (Y2009)
- Annual turnover in EUR: 83 mil EUR (Y2009)
- Balance total in EUR: 87 973 EUR (Y2009)

Main area: Health care

„Minor“ area: Research & Development

- Clinical studies (esp. phase II, III, IV)
- Grant & Academical projects

.....for many years

Thomayer University Hospital (TUH)

2 Departments of **Internal Medicine**

Department of **Anaesthesiology and Resuscitation**

Department of **Gynecology and Obstetrics**

Immunological Laboratory

Department of **Infectious Diseases**, Inoculation Centre

Department of **Pediatric** Surgery and Traumatology

Neurological Clinic

Department of **Ophthalmology**

Department of Child Psychiatry

Department of Transfusion

Department of Medical Genetics

Department of **Pathology** and National Reference Lab.

Department of **Oncology**

Pneumological Clinic

Department of **Radiodiagnostics**

Department of Stomatology

Pediatric Clinic

Department of **Surgery**

Department of **Urology**

Long-term Patients Departments

Ntl Centre for Breastfeeding

Department of Neonatology

Dept of Child Neurology

Dept of **Clin.Biochemistry**

Dept of **Clin.Hematology**

Dept of **Clin.Microbiology**

Dept of Otorhinolaryngology

Dept of Hygiene and Epidemiology

Department of Psychology

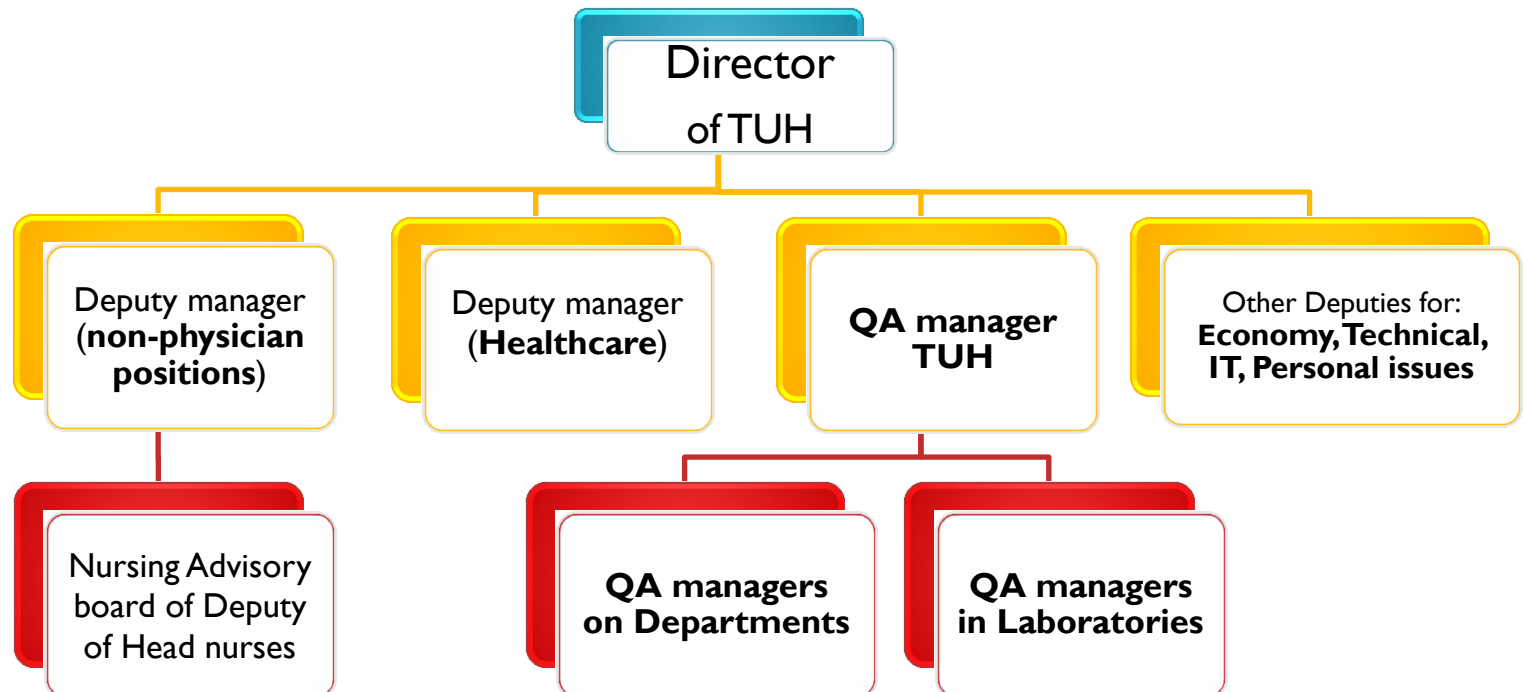
Dept of **Rheumatology and Rehab.**

Clinical – Pharmacology Unit (CPU)

Quality management system in TUH

General Requirements:

- ✓ demonstrates its ability to consistently provide product that meets customer (patients, volunteers,...) & applicable statutory and regulatory requirements
- ✓ aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system & the assurance of conformity to customer & applicable statutory & regulatory requirements.



QA system status in TUH

ISO 9001:2008 Accredited departments:

- ✓ Department of Biochemistry
- ✓ Department of Heamatology
- ✓ Department of Microbiology
- ✓ Department of Pathology and molecular biology
- ✓ Clinical-Pharmacology Unit (CPU) since 2010

ISO 15189 Accredited department:

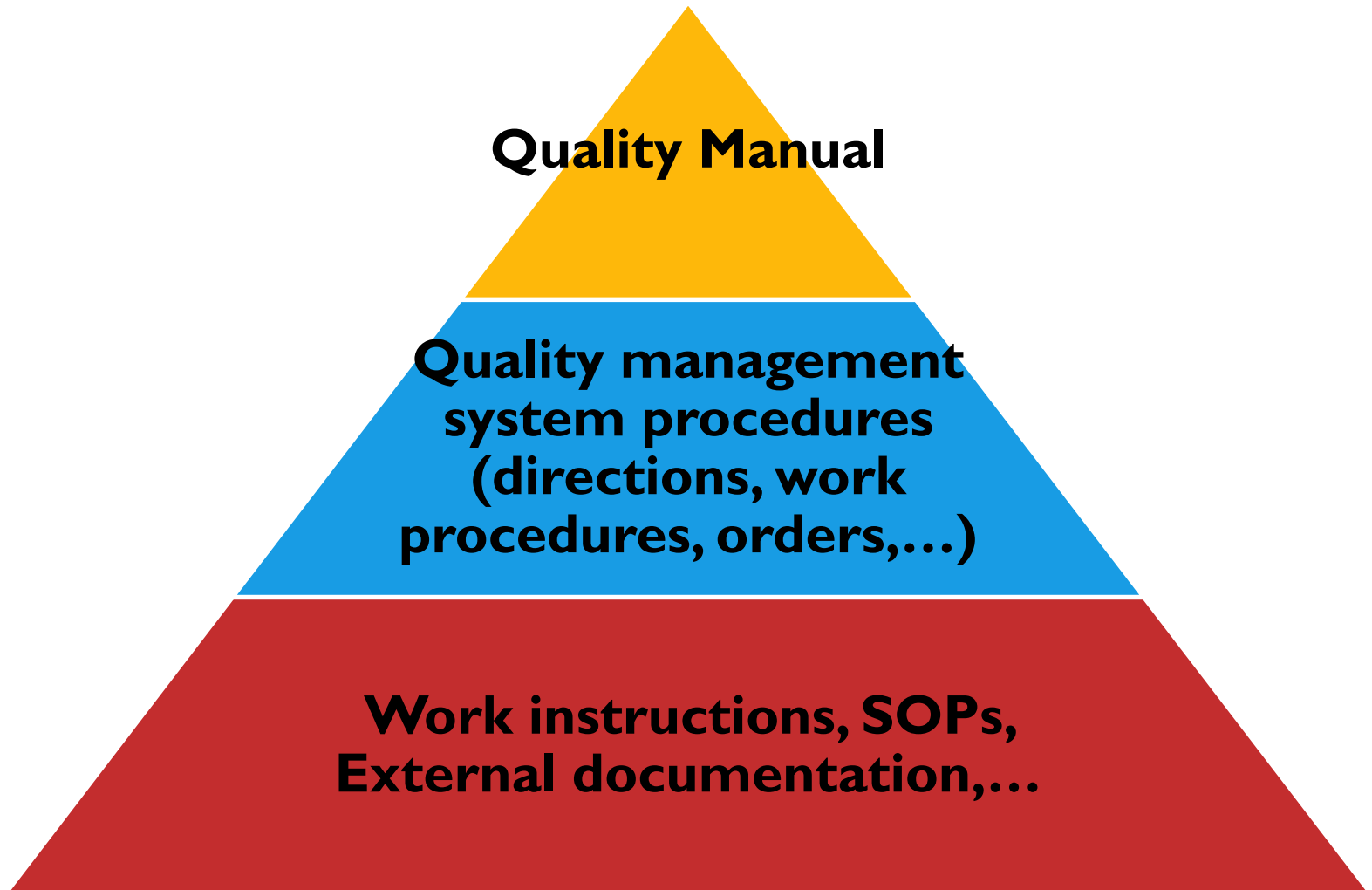
- ✓ Department of Immunology

RA (SUKL), EC requirements are being implemented as they come...

Quality management system Clinical – Pharmacology Unit (CPU)

- **ICH GCP**
- **SOPs**
- **Work instructions CPU** (*Czech language*)
- **Quality Manual & Quality management system procedures ISO 9001**
- **Internal Quality management system procedures Thomayer University Hospital**
- **External documents (legislation,...)**

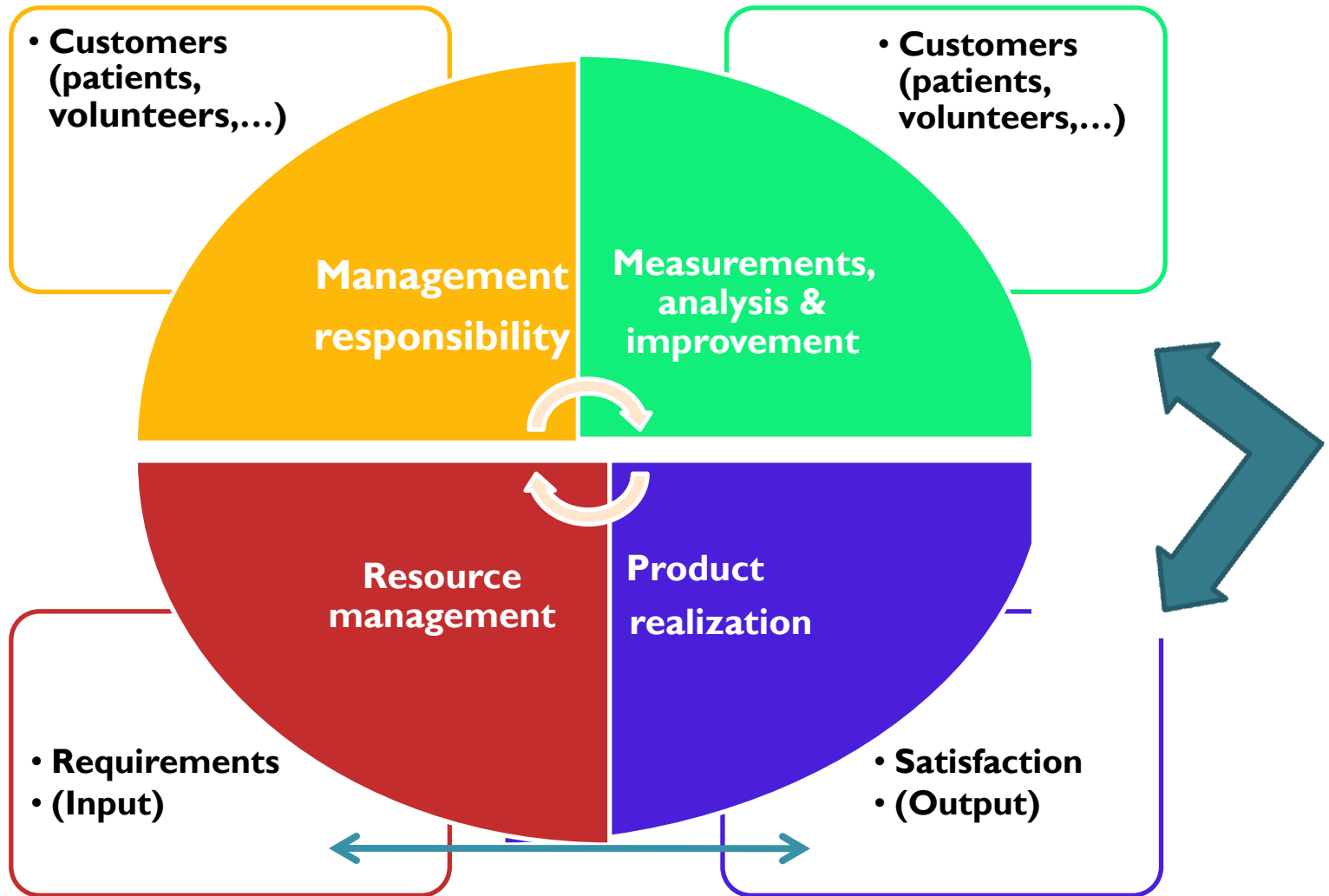
Quality management system documentation hierarchy



QA System at CPU..

- 👍 **Evaluation of service for CROs & pharma-companies**
as well as Volunteers (questionnaires,..)
- 👍 **Management review**
- 👍 **Staff (periodic education/trainings)**
- 👍 **Control of documents**
- 👍 **Control of devices/measures**
- 👍 **Evaluation of suppliers**

Continual improvement



External Quality management system

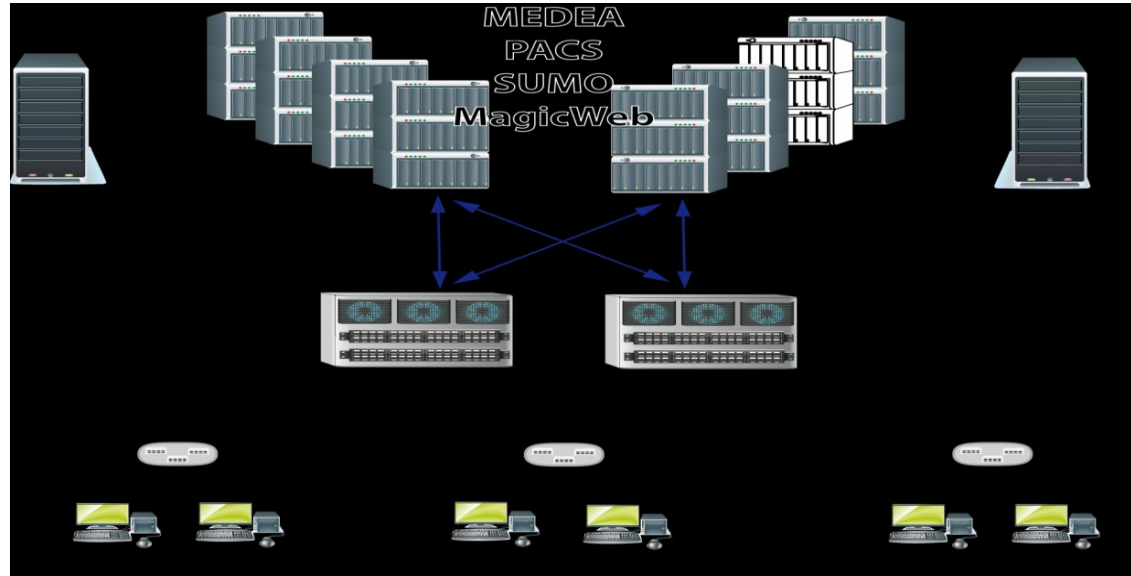
- **Audit & monitoring:**
 1. **External auditor (ICH GCP, ISO 9001)**
 2. **External Monitoring**
 3. **State regulatory authorities, ECs**

Pharmacy service in TUH



Presentation of the Head of Pharmacy

IT systems in TUH



MEDEA ... A Clinical Information System (Lab. results, patients charts, insurance codes,..)

SUMO ... A **managerial and economic informatics system** including the economic agenda.

AMIS*PACS ... A **Picture Archiving and Communication System** (X – ray images, CT, NMR).

FAMA+ ... one module of a modern CAFM (Computer Aided Facility Management) system

KIS ... A clinical information system that provides doctors with timely, accurate, and comprehensive patient information.

APOTHEKE, INFOLAB ...

Maintenance Service for all departments, employees

Laboratory base for TUH

- ✓ Department of Biochemistry (and Immunology)
- ✓ Department of Hematology
- ✓ Department of Pathology and molecular biology (genetics)
- ✓ Department of Microbiology
- ✓ Pharmacology lab , I. Internal Medicine Department

Active participation in clinical studies, introduction of new examinations and evaluations.

Department of Biochemistry

- **Specificity of the lab:**
- Provides basic and special assessments of biological material, consultations concerning indications and interpretations of assessments (1000 samples/day, 24/7)
- **Statim lab (86 methods), routine lab (179 methods), Urine lab, Immunochemical lab (cancer, thyroid markers, bone metabolism, hepatitis,..), liquor and morphology lab, electrophoresis lab and analyzers on other departments ...**
- From 2007 – accredited for teaching in the field of specialized educational practice.
- From 2009 – certified according to ISO 9001:2008.
- System of external quality evaluation - 2x year (EHK) SEKK.
- [Manual of methods of Biochemistry dept.](#)
- [Manual of Immunochemical methods](#)

Department of Hematology

- **Specificity of the lab:**
- Part of the lab complement TUH
- Provides hematological (morphology) and coagulation assessments
 - Examinations allowing to diagnose hypo-hyper coagulation situations
- From 2006 – accredited for teaching in the field of specialized educational practice.
- From 2009 – certified according to ISO 9001:2008, Lab norm. 15189
- System of external quality evaluation - 2x year (EHK) SEKK.

Equipment:

- 5 automatic hematological analyzers to analyze blood counts, differential counts of leukocytes (Coulter LH755, Coulter Gen-S, Celltac F MEK8222, Celltac MEK6400J/K). Coagulation lab. Is equipped with automatic multi-test coagulation analyzer (STA Compact).
- [Manual of methods of Hematology dept.](#)

Department of Pathology and molecular biology

1. **Autopsy part**
2. **Laboratories**
 - **bioptic**
 - **necroptic**
 - **National referential lab of prion diseases**
 - neuropathology lab, immunological lab, molecular-genetic lab

Equipment:

Sequenator, PCR real time, PCR cyclers, centrifuges, freezers(-20 C, -80 C), paraffin unit, biohazards, coloring automat, microtomes, electrophoresis, bio-imaging system, spectrophotometer, microscopes, thermostats, water , scales, pH meter, cryostat, tissue processor-autotechnikon, ..)

Service:

- * Diagnostic activity, teaching activities for physicians, lab. assistants (pathological anatomy),
 - * Differential diagnostics of prion and neuro-degenerative diseases for the whole Czech R.
 - * Bioptic and cytology diagnostics done in a short time, using also the contracted labs (lymphoma specification, bone or soft tissue cancer specification).
-
- International certificate ISO 9001:2001 (since 05/2008) and 9001:2008 (since 2009)
 - Manual – Pathology and molecular biology.

Department of Microbiology

Complex diagnostics of bacterial, myco-bacterial diseases.

Variety of virologic, parasitological and serological examinations.

Providing **culture medium and liquidation of infected material.**

Antibiotic centre – detection of resistances to antibiotics, confirmation of use of bind antibiotics, cooperation in development of positive list of antibiotics in TUH and provides antibiotic consultations.

Treatment and monitoring of hospital infections (in cooperation)

Equipment:

2 automatic **hemo-cultivation** analyzer (bact/Alert, Bactec - diagnostics of septic statuses, thermostats for cultivation in different temperatures and higher tension of CO₂,

Anaerobic station for cultivation of highly difficult anaerobic bacteria, modern autoclaves.

Aparatus GeneXpert - direct diagnostic of pathogens using multiplex real time PCR.

Service:

- basic microbiological examinations
- special examinations – hem culture, mycological and myko-bacterial examination
- automatically – sensitivity to antibiotics using disc semi-quantitative methods or quantitative method
- consultations in the field of clinical microbiology

Manual – Microbioloby

Dpt. of Clinical Pharmacology, Ist Internal Medicine Department

- ***Specificity of the lab:***
- Therapeutic drug monitoring (TDM) – analysis and PK interpretation of the drug levels in serum, plasma, urine. **The goal is to assure the best dose – regime for a patient, e.g. to choose the dose and dose intervals.**
- The interpretation is a crucial part to help the patient. to optimize the therapeutic effect and minimize the risk of toxicity.
- Methods and spectrum of analyses

Clinical – Pharmacology Unit (CPU)

Review;

- **One of the Hospital departments**
- **New clinical research Unit to provide:**
phase I & III studies, as well as later stages
 - **Healthy volunteers & patients studies**
 - **Medical drugs & medical device development**

Database of healthy volunteers

Recruitment

1. **Previous studies**
 2. **Advertising (newspaper, magazines etc.)**
 3. **Recommendation from subjects...**
 4. **Web registration gate**
- **Electronic Database of healthy volunteers in our CPU (quickly searchable)**

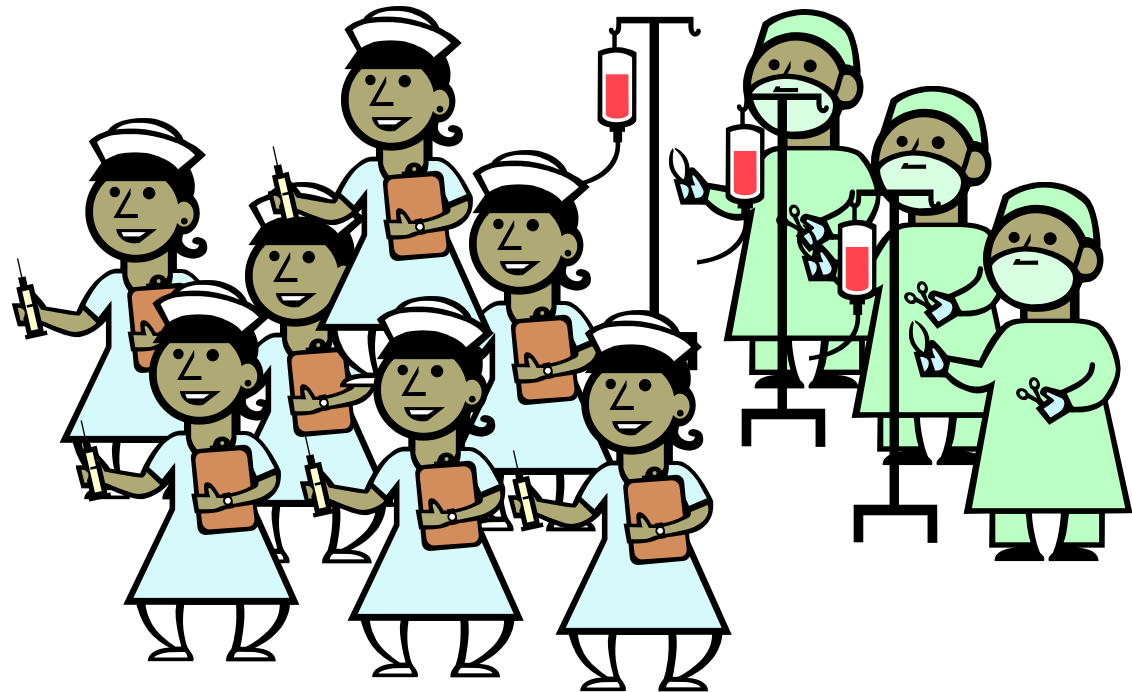
Database of Patients

Recruitment

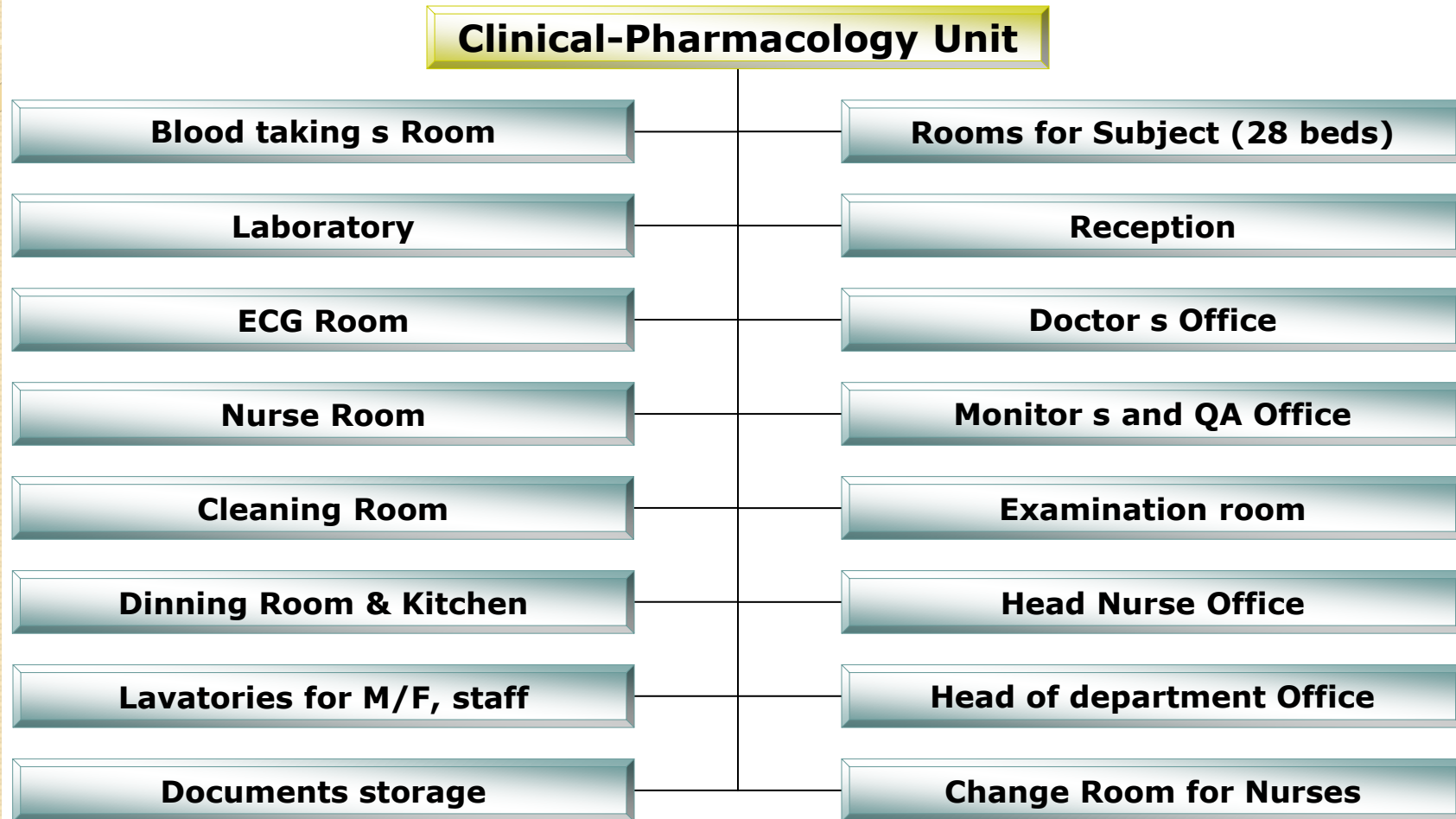
1. **Previous studies (diabetics, obese patients)**
2. **Departments in TUH (.....)**
3. **Recommendation from external docs (...)**
4. **Through GP/specialist although internal list of patients previously involved in studies exists !**

CPU staff

- **Head of the CPU (managment, Investigator)**
- **Head nurse (clinical and QA responsibilities)**
- **Physicians (highly qualified)**
- **Study nurses (highly qualified)**



CPU, facility ...



CPU Equipment

- **Refrigerated Drug Storage**
- **Refrigerated Centrifuge**
- **Programmable Deep Freezer (-86°C) and freezer (-30°C)**
- **Back-up Generator (UPS)**
- **High Speed Internet**
- **ECG, Vital signs devices**
- **Blood Draw Stations**
- **Defibrillator/oxygen**
- **Simple monitoring system of subjects**
- **Flood, fire alarm system**
- **Other equipment: X-Ray, MRI, CT & DEXA Scanners linked to PACS, etc. are available within the Hospital**
- **Trend: fully monitored beds, professional subjects monitoring on ward, medical device equipment**

Experience in Clinical Research

TUH

Academical projects (grant system)

Phase II, III, IV

TUH studies in 2009: 41 Med.drug, 19 Grants, 1 Med.device

CPU

- In 2008 3 Pilot clinical studies (8,16,24 subjects)
- In 2009 Medical device Phase I. Clinical study,
Phase IV study
- In 2010 2 Diabetic Studies, phase II. and III. (running),
phase I. medical device study –done (Nov 2010)
phase III. Study – together with surgery dpt. (running)
- Plan 2011
Phase III. study – RA patients (initiation Visit 4/2011)
Phase III. study – COPD patients (Initiation 4-5/2011)
Phase I. study -Vaccination (420 volunteers, Initiation 7/2011)
Phase III. study – Fibrosis (Intiation Visit 5-6/2011)
Phase II. study – DM Type2 (Initiation Visit 9/2011)
- Plan 2011 – no dates set, in negotiation process
Phase II-III.: Use of Opioids+constipation, 2 Infectious diseases, 2 RA Studies
2x Phase I. study – PK+PD studies (36 and 62 subjects)

Why to choose our Unit..?

- **Quality**
 - QA system fully developed and maintained (SOP, QM).
 - Audits from independent Auditors (P. Guelen), regular internal auditing, sponsor auditing
 - RA (SUKL) GCP audit in 2009 (CPU)
 - ISO 9001:2008 certification in 2010 (CPU)
- **Flexible, professional cooperating teams**
- **Pool of subjects (healthy, patients)**
- **Commitment to timelines**
- **Cost effectiveness**
- **Stability – public University Hospital**
- **Future development**

Future development

- **Willing to increase R&D activities**
 - Early stages as well as later stages of drug and medical device development
 - Approach Academic field (grants)
- **Willing to maintain „strong points“ and to enhance „weaker points“**
 - To be a „wanted“ partner with the highest level of systems, tools, procedures, administration support ...
- **Willing to continue to collaborate with „strategic“ partners to induce long-term relationship**
 - to use an expertise and support to deliver the best product
 - To be a clinical base to increase efficacy and speed of drug and device development

Clinical study activities...

- Assistance to Essential docs development
- Help with Submission to RA/EC *(if required)*
- Clinical study conduction
- Safety laboratory, examinations
- Drug accountability, reliable pharmacy
- Data management, statistics *(CRO)*
- PK/PD analyses (Analytical report) *(CRO, TBD)*
- Internal monitoring, auditing
- Writing (Clinical report) *(CRO or TBD)*