



# European Standards of Clinical Research in the University Hospital in Cracow

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# University Hospital potential

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- ▶ 27 Clinical and diagnostic services
- ▶ 60 Out-Patient Departments
- ▶ 9 Intensive Care Unit
- ▶ 1312 hospital beds
- ▶ 1023 doctors/1522 nurses and midwives

In 2010:

- ▶ 75 000 hospital admissions
- ▶ 380 000 visits to Out–Patient Departments

University Hospital in Cracow

- ▶ 500 one-day hospital admissions
- ▶ 2 000 000 laboratory tests
- ▶ 200 000 diagnostic imaging procedures



# Center for Innovative Therapy (CIT) Clinical Research Coordination Center

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Established in the University Hospital in 2009

## AIMS

- ▶ Establishing the trial standards
- ▶ Coordination of budgeting and contracting processes
- ▶ Clinical trials logistic support for services localised in facilities at Sniadecki Str.
- ▶ Trials supervision
- ▶ Good Clinical Practice (GCP) trainings organised for investigators and staff



# Center for Innovative Therapy Clinical Research Coordination Center

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## ► Our facilities

- \* reception area
- \* clinical rooms
- \* specimen initial preparation laboratory
- \* meeting room
- \* archive



# Standard Operating Procedures (SOP) in Clinical Trials in the University Hospital (1)

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Introduced in 2009

- developed by CIT to standardize processes
- support compliance with GCP standards as well as international and Polish regulations that govern conduct of clinical research
- provide an official way to execute required research-related activities
- improve communication among staff
- provide and improve efficiency of staff training
- improve cooperation with auditors and/or inspectors

# Clinical Trial Regulation

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- ▶ Tripartite contract: sponsor-investigator-institution
  - \* defines distribution of responsibility, rights, obligations and conditions for each contract party
  - \* provides transparent budget and clear cost categories
  - \* ensures clear information on sources of financing for all study-related procedures and for standard of care
  - \* enables easy tracking of compliance with contract requirements and predefined timelines

## Clinical study in University Hospital in Cracow

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CIT is currently involved in:

- ▶ Commercial trials (oncology, cardiology, reumatology, immunology),
- ▶ Jagiellonian University Clinical Research Trials

How to find us

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