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11th Belgian Multidisciplinary Meeting on Urological Cancers

Starting your own trial – what do you need to know?

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Conflicts of interest

- I have no potential conflict of interest to report.

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Health, Innovation and Research institute

Clinical Trial Unit

- **Guide and advise** the U(Z) Gent academic researchers, i.e. submissions, project management and monitoring
- **Conduct** clinical research in accordance with all applicable (inter)national regulations
- **Safeguard** the safety, rights and well-being of U(Z) Gent study participants

Trial requests - 2023

Academic: 938 requests, 421 contracts

- Experiments: **574**
  - IMP trials: 10
  - Medical Device / IVD : 36 / 13
- Amendments: **364**

Commercial: NA requests, 1701 contracts

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Experiments

under the **law of 7 May 2004** are defined as

"Every clinical trial, study or research performed on humans,
with the intention to gain knowledge inherent to
the execution of healthcare professions as defined in
Royal Decree n ° 78 of November 10, 1967
on the execution of health professions."

Experiments

- Under the law of 7 May 2004
  - Interventional research
  - Prospective observational research

- Exceptions
  - Retrospective research
  - Research on embryos in vitro
  - Research on cadavers
  - Research on residual biological samples

IMP or MedDev

IMP

Commercially available

Obtained via pharmacy or a company

MedDev

CE marked

Obtained via hospital or a company

Regulatory pathway

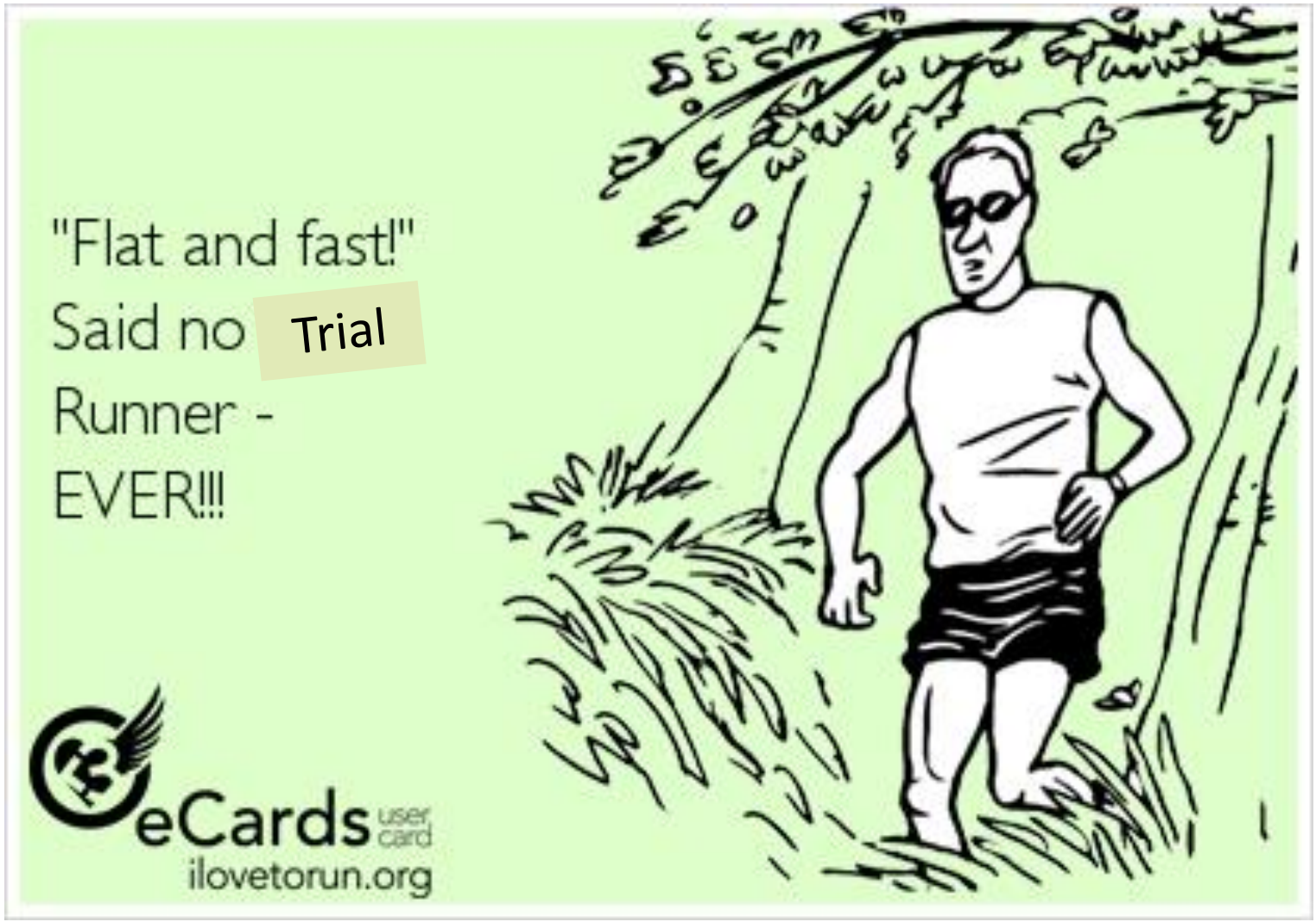
Clincial Trials Regulation

- Clinical Trials in the EU
  - Clinical Trials **Directive** (2001/20/EC) until 31 December 2024
  - Clinical Trials **Regulation** (536/2014) from 31 January 2022

- Pro
  - Harmonization
  - Consolidated opinion (EC/CA)
  - International trials

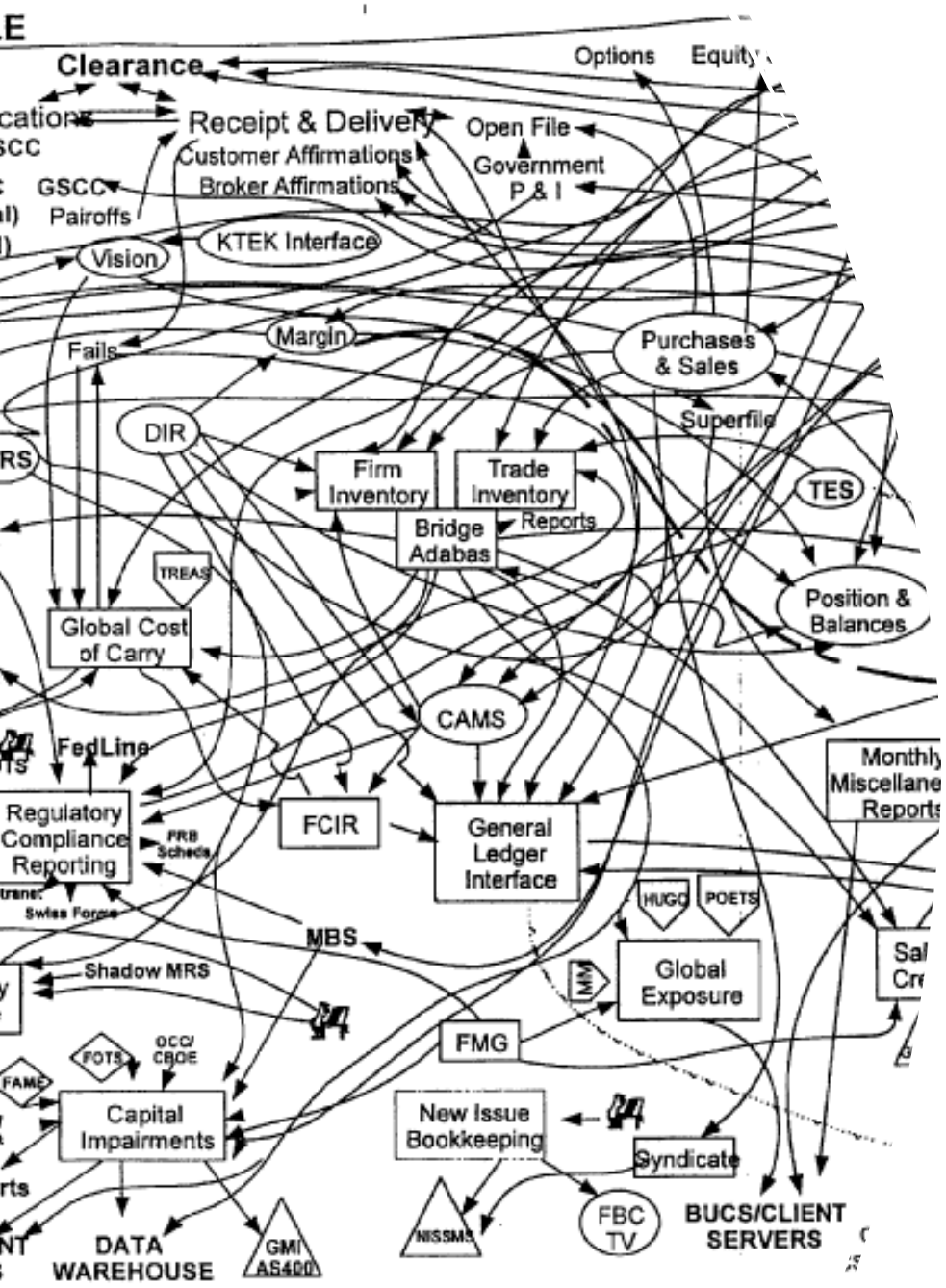
- Contra
  - Prolonged timeline

How to run a trial?



1. Research Team

- There’s no I in TEAM
  - (National) Coordinating or Principal Investigator(s)
  - Sub-investigator(s)
  - Study coordinator or nurse(s)
  - Project manager
  - Data manager



2. Trial Design

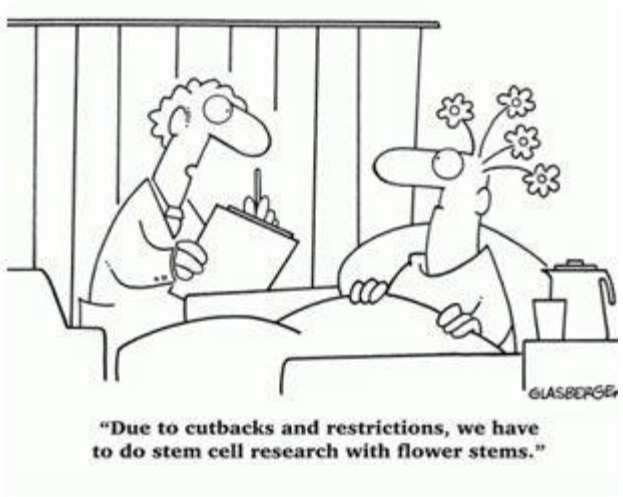
- Protocol
  - Objectives and endpoints
  - Subjects
  - Statistics
  - Trial assessments
  - Safety
- Multicenter trial
  - Feasibility checklist
  - Contracts (!)

3. Biobanking

Sample collection

Sample shipment

Biobank



- Registration
- Sample processing and storage
- Future research

4. Data management

- Electronic Data Capture system
  - REDCap
  - Greenlight Guru, Inform, CASTOR, Marvin, Alea, CACTUS, …
- eCRF design
- Data entry and cleaning

5. Risk-based monitoring

Risk assessment

Identify risks associated with the trial

Adjust the protocol to avoid risks

Monitoring

Clinical Trial Monitoring Plan

6. Budget

- Project funding
  - National: FWO, KCE, Kom Op Tegen Kanker…
  - European: Horizon Europe…
- Budget for
  - Patient fees
  - Start-up participating sites
  - Pharmacy fee
  - Monitoring, project/data management
  - …

7. Trial publication

Public registration
WHO primary registry

Approval of
Competent Authorities

Approval & registration
for publication

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Take home

- Study team
- Prepare submission
- Discuss agreements
- Budget service

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