



# Wet- en regelgeving klinisch onderzoek in Nederland Anno 2007

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Drs. H. Pieterse  
Profess Medical Consultancy  
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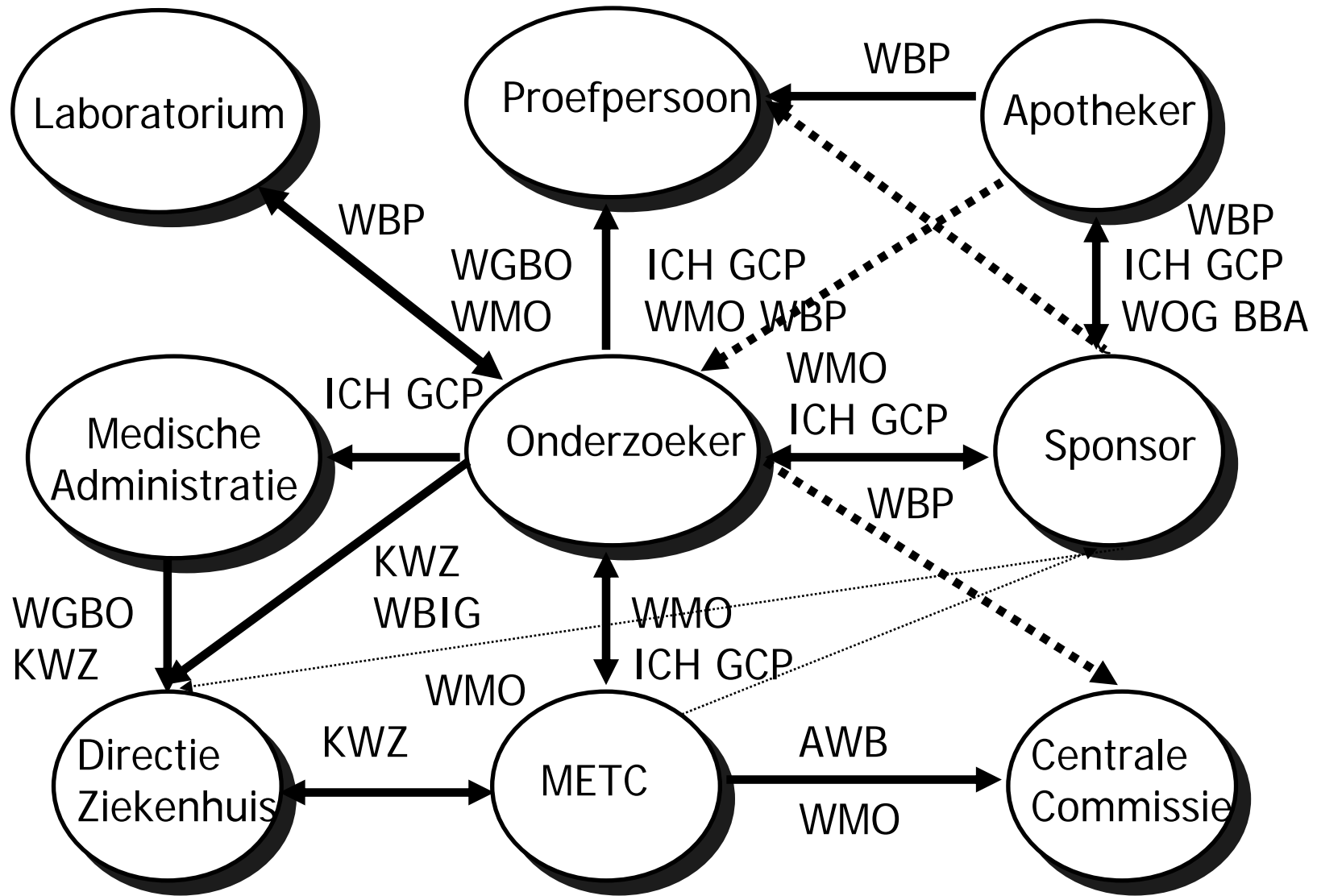


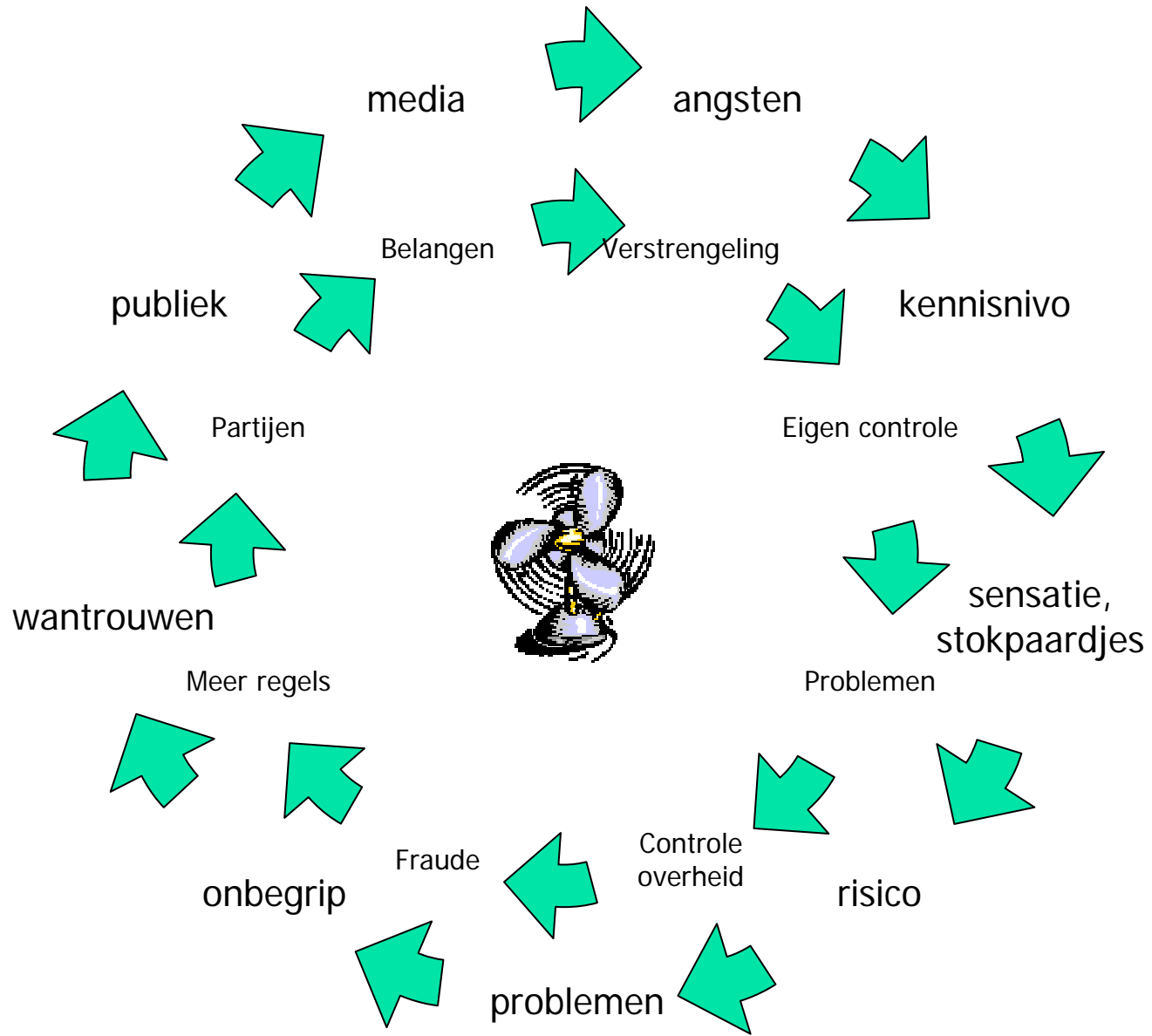
# Regels en regelgeving onderzoek

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- Nationaal:
  - Burgerlijk recht
    - WOG, WMO, WBIG, KWZ, WBP, WGBO
- Europees:
  - Directives
    - Clinical Trial Directive (geïmplementeerd in NL in de WMO)
    - Data Protection (WBP)
    - Medicine (WOG)
- Internationaal:
  - ICH Guidelines (Good Clinical Practice en 70 andere guidelines)
  - ISO standards (ISO 14155 onderzoek medische hulpmiddelen)

# Regelgeving relaties bij Onderzoek







# ICH-GCP-7

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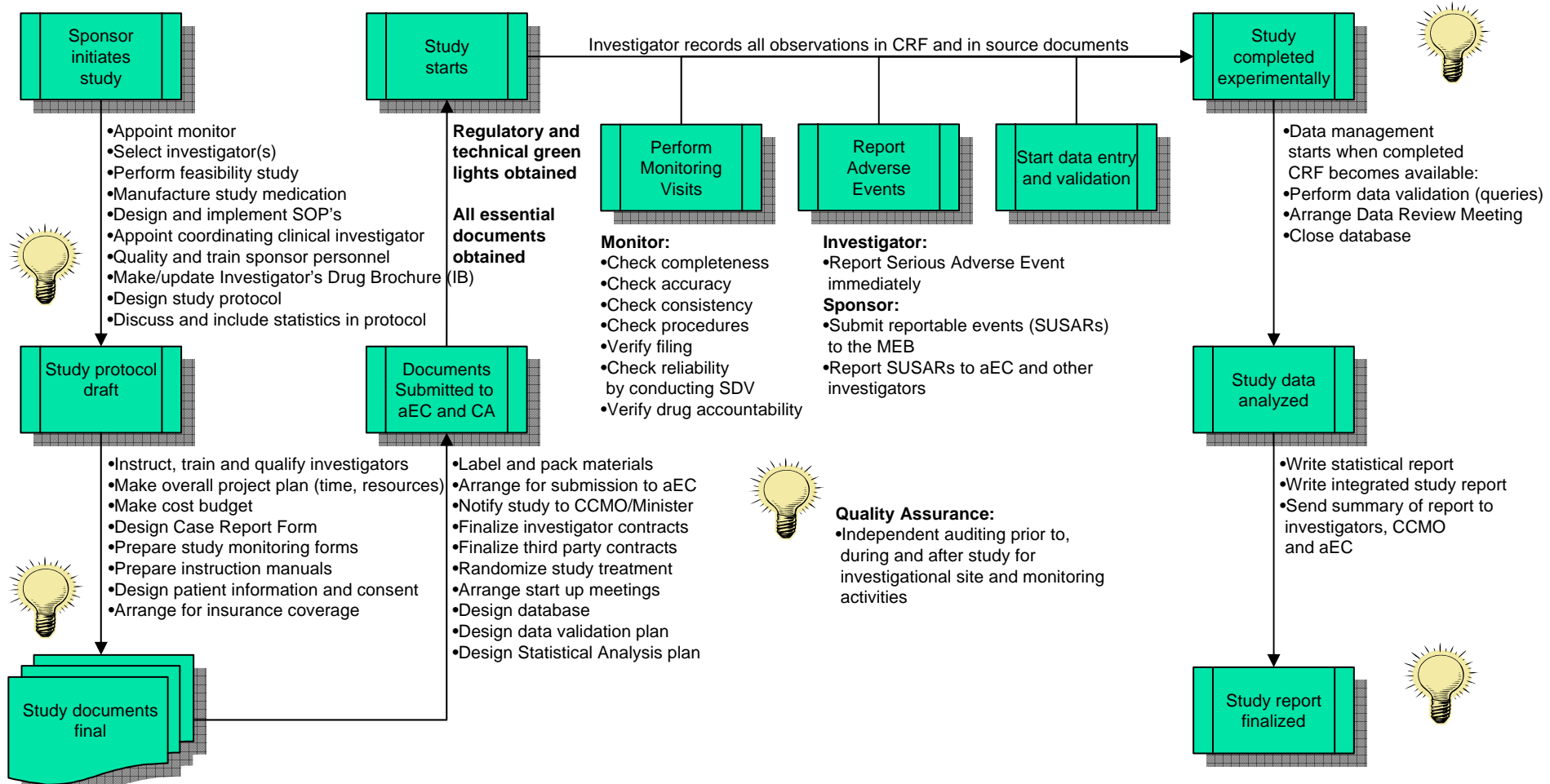
- Definities
- beginselen
- Medisch-ethische toetsingscommissie
- Onderzoeker
- Sponsor
- Klinisch onderzoeksprotocol
- Investigator's brochure
- Essentiële documenten



**Clinical Research  
with medicinal products  
in the Netherlands**

**Instruction Manual**

Ministry of Health, Welfare and Sport



**Study documents:**

- IB, study protocol
- CV's investigators
- List centres
- aEC approval
- CCMO notification
- Investigator agreement
- Insurance certificate
- Patient info, consent
- CRF
- Forms AE, ADE
- Monitor contact info

**Sponsor responsibilities:**

- Sign approved study protocol
- Ensure that all deviations from protocol are reported and accounted for
- Ensure that all AE's are reported as required
- Inform all investigators about all SAE's
- Inform investigator when study is terminated prematurely or suspended
- Inform investigators on development status drug
- Review and approve deviations from study protocol
- Collect, store, keep secured and ensure completion of essential documents

**Monitor responsibilities:**

- Verify if compliance with protocol is maintained
- Verify if drug is used according to plan
- Verify qualification of investigational staff
- Verify if investigator has access to adequate number of subjects
- Verify if informed consents are properly signed and dated
- Verify if AE have been recorded and reported adequately
- Verify drug accountability and traceability
- Verify maintenance and calibration equipment
- Verify recording subject withdrawal, non-compliance
- Report monitoring visits

**Investigator responsibilities:**

- Have resources to conduct study
- Has no conflict of interest
- Knows the drug and its properties
- Knows the study protocol
- Supports the monitor and auditor
- Communicates deviations from the protocol
- Ensures compliance with protocol for all staff
- Protects health and welfare of subjects
- Communicates with the aEC on SAE's, submission amendments
- Endeavors to ensure adequate recruitment
- Ensures that informed consent is obtained and documented
- Reports any deviation due to emergency
- Ensures drug accountability

# Hoe doe je klinisch onderzoek?

- Zorgvuldig
- Eerlijk
- Billijk
- Redelijk
- Altijd

