Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
Belgian Health Care Knowledge Centre

Capacity Assessments

GAP - analysis

KCE

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Due Diligence Visits

Rationale

- **If we invest € from the government, there is a due diligence to check that this € will be invested in a robust clinical trial**
- **Last 20 years, the clinical trial requirements have become more stringent**
- **The outcome of the KCE Pragmatic Clinical Trials Programme must be based on data that are obtained within a GCP and regulatory compliant context as they might be practice-changing**

Modus operandi

- **KCE has published a public tender for CROs to make a GAP-analysis of the clinical trial capacity at Belgian research centres**
- **Harmony CR in collaboration with ACQAS has been selected to perform this task**
- **2-day site visit by CRO and KCE**

Objectives

- **Obtain an overview of the landscape of academic clinical trial units in Belgium**
- **Make an inventory of the capacity at candidate sponsor sites**
- **Identify areas to build the capacity**

The landscape of academic trial units in Belgium

- **Belgium is well-known for its high-quality research**
- **No overview available how the academic research is organized in the different universities (but research is not limited to university hospitals)**
- **Starting with 7 university hospitals**

Inventory of the capacity at candidate sponsor sites

- **During a 2-day visit: gain insight into the clinical research organization**
- **Centralized vs scattered capacity**
- **Evaluate according to GCP & regulatory requirements for multi-site pragmatic clinical trials**

Inventory of the capacity at candidate sponsor sites

- **Focus on**
  - → **Expertise, continuity, stability**
    Organisation, Management Oversight, QMS, Document Management, Staff and Training, Regulatory knowledge
  - → **Infrastructure for Clinical Research**
    Multicentre Trials, Protocol, Insurance, Site selection and oversight, Vendor Management, Recruitment Strategy, TMF, Data Management, PV, Statistics, Reporting, Submissions, Clinical Supplies, Central Laboratory
  - → **Quality**
    Document Management, Quality Assurance, Non-compliance, CAPA
  - → **Information Systems**

Identify areas to build the capacity

- **Not all requirements are centrally available**
- **Lack of knowledge versus lack of resources**
- **Mono-centric versus multi-site studies**
- **Requirements for participation to KCE Trials Programme**
  - → **possibility/willingness to centralize**
  - → **central oversight and quality guarantee (inspection readiness?)**

Identify areas to build the capacity

- **Risk management approach when identifying the gaps = areas for improvement**
- **Risks identified as major and critical will need a CAPA-plan**

What can the due diligence visits mean to your organisation?

- **Opportunity to have a centralized view on the way clinical research is conducted at your hospital**
- **Opportunity to build capacity by moving towards the concept of a full-service clinical trial unit**

THANK YOU!

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