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

What are the Sponsor responsibilities in Good Clinical Practice?

Nelle Stocquart

ICH Good Clinical Practice Definition



Compliance with this standard provides public assurance that

1. the rights, well-being and confidentiality of trial subjects are protected, and
2. that the clinical trial data are credible

What is your opinion? GCP is a legally binding document.

ICH GCP is a guideline, not a legislative document on itself, but due to regulator requirements, adherence to GCP can become a legally binding requirement.

ICH-GCP Content:

- Chapter 1: Definitions
- Chapter 2: The Principles of ICH GCP
- Chapter 3: The IRB/IEC
- Chapter 4: The Investigator
  - 13 responsibilities
- Chapter 5: The Sponsor (Monitoring)
  - **23 responsibilities**
- Chapter 6: The Clinical Trial Protocol & Amendments
- Chapter 7: The Investigator’s Brochure
- Chapter 8: The Essential Documents



SPONSOR RESPONSIBILITIES

Sponsor Responsibilities

Report expedite serious adverse drug reactions

Act on non-compliance (CAPA)*

Make the clinical study report

Have a trial insurance (& compensation) in place

Provide medical expertise

Implement a risk-base quality management system*

Ensure direct record access, verify informed consent

Select investigators

Perform audits

Manage trial, handle data, keep records, validated computerized system

Supply & handling & inventory of investigational products

Coordinate multicentre trials

Design trial

Allocate trial responsibilitie

Financial contract with the investigator/institution

Monitor the trial (risk-based approach) *

Notify/Submit to regulatory authorities

Provide & update information on investigational products

Manufacturing, packaging, labelling, and coding investigational products

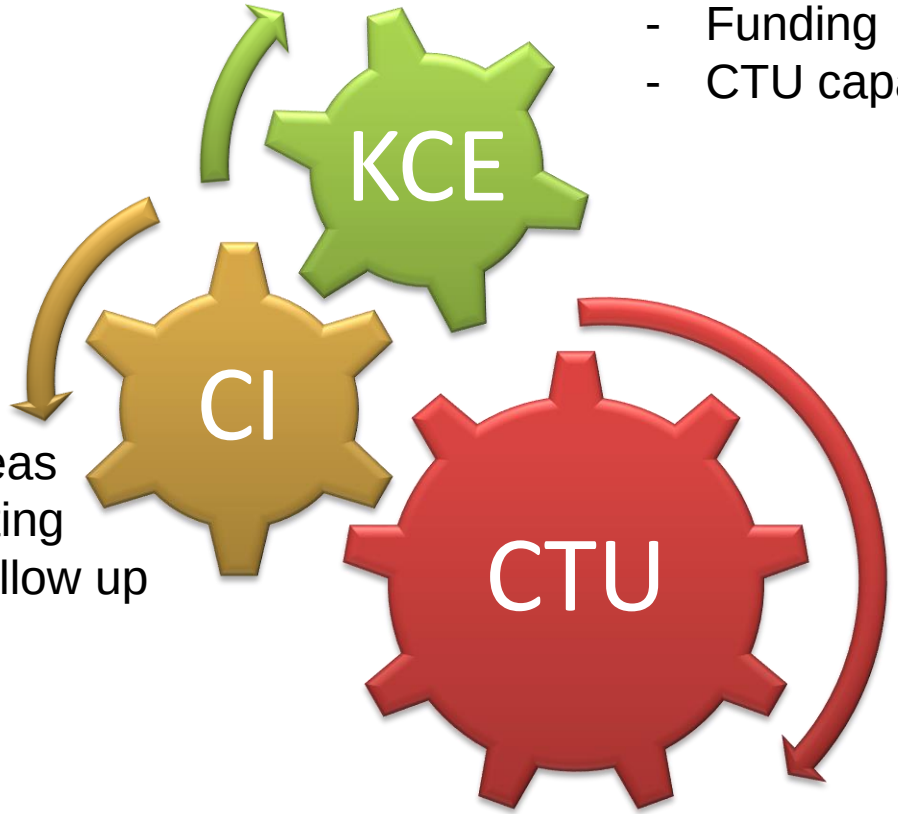
Supervise delegation of tasks to Contract Research Organization*

Inform on premature termination/suspension of a clinical trial

Evaluate & provide safety information

Ensure quality assurance and quality control

Sponsor responsibilities – How to fulfil them?
The need for structural support



- Funding
- CTU capacity building

- Scientific ideas
- Protocol writing
- Scientific Follow up

- **Sponsor**
- Project management
- Protocol writing
- Data Mgt
- Monitoring
- Safety
- Legal advice
- Insurance
- RA & EC
- Finance
- Logistics
- QA & QC
- …

Clinical Trials Unit

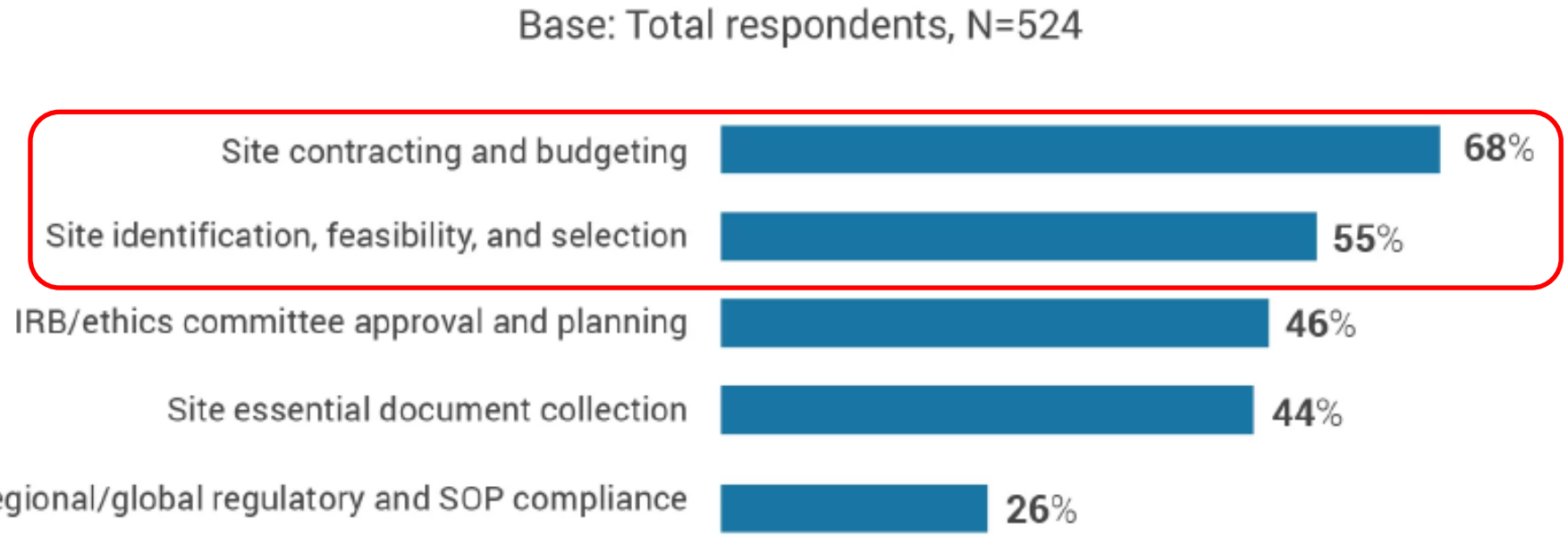
- **KCE visited CTUs that are willing to take the responsibility of being the Sponsor (https://kce.fgov.be/en/content/clinical-trial-units-ctus-in-Belgium)**

- **Certain institutions are willing to provide sponsorship &/or CTU services to CI's who are not staff: UZ Ghent, UZ Antwerp, IJB & ITM (CTU)**
  - **There may need to be a match in interests**

ICH-GCP 5.6 Select investigators

- 5.6.1 The sponsor is responsible for selecting the investigator(s)/institution(s). Each investigator should be qualified by training and experience and should have adequate resources (see 4.1, 4.2) to properly conduct the trial for which the investigator is selected. If organization of a coordinating committee and/or selection of coordinating investigator(s) are to be utilized in multicentre trials, **their organization and/or selection are the sponsor's responsibility.**

Biggest Challenges with Study Start-up Processes



Fast Tracking Study Start-Up from Site Selection to First-Patient Enrollment. November 18, 2020
Ashley Davidson; **Applied Clinical Trials**, Applied Clinical Trials-11-01-2020, Volume 29, Issue 11

ICH-GCP 5.6 Select investigators

- Having a study ready to start recruitment (SIV done) is time consuming and not easy

Company Type	Variable	N	Average Number of Weeks	P-Value
CRO	Sites Worked With Before	70	21.8	0.007
	Sites Not Worked With Before	69	28.0	<.0001
Sponsor	Sites Worked With Before	161	27.4	0.007
	Sites Not Worked With Before	163	39.0	<.0001

Tufts Center for the Study of Drug Development June 2017

- **KCE Timelines:**
  - From Funding (TB letter) confirmation to FPI ~ 67 weeks
  - From contract signed to FPI ~ 23 weeks

KCE recommendations

- All identified sites should have a feasibility either F2F (+/- 50%) or by phone
- KCE is strongly recommending to have the feasibility done with an external partner
  - KCE has contracted a CROs to support you with this
- It allows independent assessment also on well known PI colleagues and then a better budget and timelines assessment
- PI and/or PM and CTU representative should assist to the feasibility visit



Lessons learned at KCE

A good feasibility is essential to define study timelines and final budget

Multicentre trials requests contact with « unknown » PIs – feasibility exercise is focusing on this ones

Going to sites is time consuming but useful to have a better feasibility assessment, to identify study challenges, potential recruitment issues and opportunities as protocol changes

Sponsor-Investigators and CTUs have few or no experience in such exercise

↳ Advance available for feasibility (after recommendation for funding by TB)

Take home message

- Clinical Trials must follow ICH-GCP in order to ensure subject safety, data integrity and quality
- There are 23 ICH-GCP sponsor responsibilities on the top of the 13 Investigator responsibilities
- It requests a multi-disciplinary team
- CTU involvement is key for success
- Feasibility is crucial for recruitment and budget planning.

KCE

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

