King's Health Partners Clinical Trials Office

A Partnership for Clinical Research

Quick Reference - GCP Light

What is GCP?

Good Clinical Practice (GCP), as the name suggests, is a framework to ensure research is performed to the best possible quality standard. It is an aim for all studies but specifically regulated by law for Clinical Trials investigating drugs also known as Investigational Medicinal Products (IMPs).

Why do I need to know about GCP?

Even if you are not part of a clinical trial team, if you have contact with trial participants during the course of performing your usual role, you should be aware of GCP. This is mainly to ensure that any side effects or adverse events are picked up and reported to the trial team as soon as possible.

Why do we have to keep such detailed records for clinical trial participants?

All information needs to be carefully documented during clinical trials, particularly safety information. If this is not written down then the quality of the data is compromised.

This is not only best practice but is written into the laws governing trials with drugs. A person found guilty of any offence under the regulations is liable to a fine or prison term.

What is an SAE?

A **Serious Adverse Event (SAE)** is an event:

- that results in **death**
- is **life threatening**
- requires **hospitalisation** or prolongs existing hospitalisation
- results in persistent or significant **disability** **or** **incapacity**
- consists of a **congenital anomaly** or birth defect

An **Important Medical Event** is an event that may not be immediately life-threatening or result in death or hospitalisation but may jeopardise the patient or may require intervention to prevent one of the other outcomes listed in the SAE definition and these should also be considered serious.

What should I do if an SAE is reported to me?

If a patient participating in a clinical trial tells you about an event or illness:

- Make sure you make a written note of the event, preferably in the patient's notes.
- Record the nature of the event, the date of onset and details of any hospital admission or treatment administered.
- **Contact the PI or Trial Team** as soon as you are able to make them aware of the event and document that you have done so.

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Principles & Conditions of Good Clinical Practice

1. The rights, safety and well-being of the trial subjects shall prevail over science and society.
2. Each individual involved in conducting a trial shall be qualified by education, training and experience to perform his tasks.
3. Clinical trials shall be scientifically sound and guided by ethical principles in all their aspects.
4. The necessary procedures to secure the quality of every aspect of the trial shall be complied with.
5. The available clinical and non-clinical information on a investigational medicinal product shall be adequate to support the proposed clinical trial.
6. Clinical trials shall be conducted in accordance with the principles of the Declaration of Helsinki.
7. The protocol shall provide for the definition of inclusion and exclusion of subjects participating in a clinical trial, monitoring and publication policy.
8. The investigator and sponsor shall consider all relevant guidance with respect to commencing and conducting a clinical trial.
9. All clinical information shall be recorded, handled and stored in such a way that it can be accurately reported, interpreted and verified, while the confidentiality of records of the trial subjects remains protected.
10. Before the trial is initiated, foreseeable risks and inconveniences have been weighed against the anticipated benefit for the individual trial subject and other present and future patients. A trial should be initiated only if the anticipated benefits justify the risks.
11. The medical care given to, and medical decisions made on behalf of, subjects shall always be the responsibility of a qualified doctor or, where appropriate a qualified dentist.
12. A trial shall be initiated only if an ethics committee and the licensing authority comes to the conclusion that the anticipated therapeutic and public health benefits justify the risks and may be continued only if compliance with this requirement is permanently monitored.
13. The rights of each subject to physical and mental integrity, to privacy and to the protection of the data concerning him in accordance with the data Protection Act 1988 are safeguarded.
14. Provision has been made for insurance or indemnity to cover the liability of the investigator and sponsor which may arise in relation to the clinical trial.

For further information on GCP contact the **KHP-CTO Training Team**:

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