The Global Health Network

Adhering to the GCP Principles.. what does that even mean?

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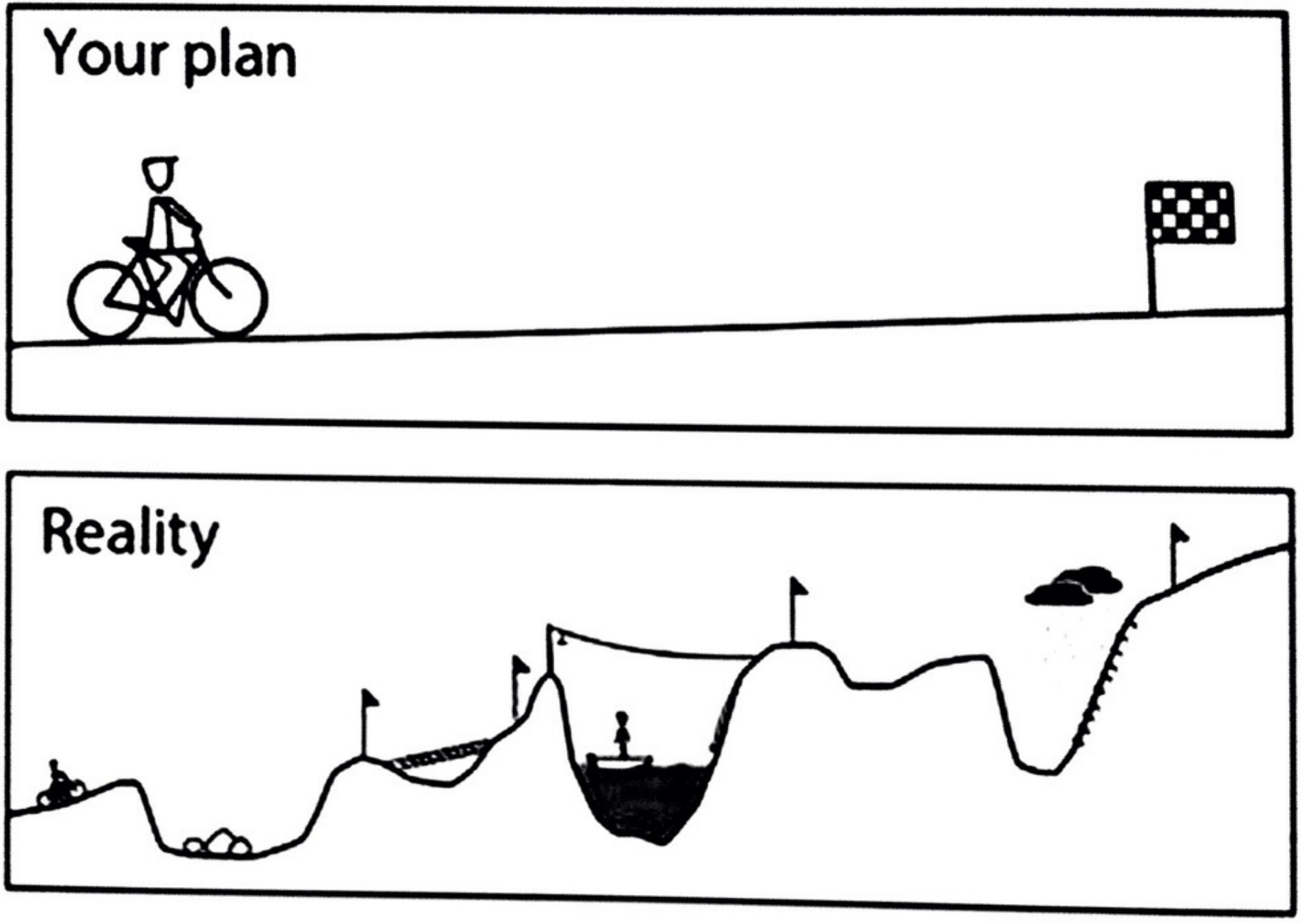
Many important things to do when executing a clinical trial but the two most important goals are to ensure:

1. Participant safety & 2. Data integrity

To introduce you to or remind you about the GCP Principles that we need to follow when conducting clinical research.


Your plan
Reality

What is Project Management?

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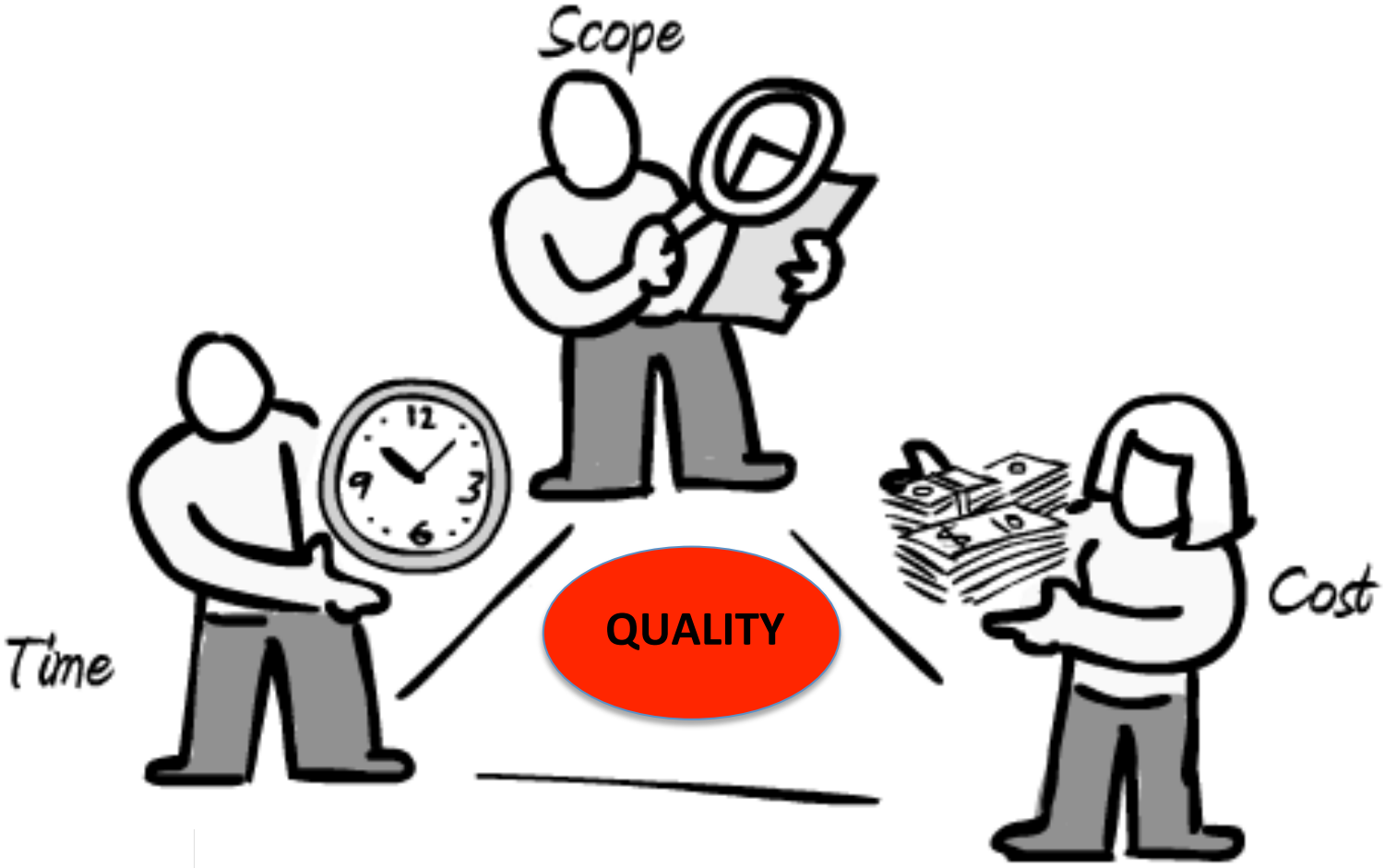

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What is GCP?

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- Set of International ethical and scientific guidelines and quality standards that must be followed when conducting a clinical trial.

- GCP provides a basis for the scientific and ethical integrity of research involving human participants and for generating valid observations and sound documentation of research findings.

13 GCP Principles for Research

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1. Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with the GCP and the applicable regulatory requirement(s).

2. Before a trial is initiated, foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual trial subject and society. A trial should be initiated and continued only if the anticipated benefits justify the risks.

3. The rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society.

4. The available non-clinical and clinical information on an investigational product should be adequate to support the proposed clinical trial.

5. Clinical trials should be scientifically sound, and described in a clear, detailed protocol.

6. A trial should be conducted in compliance with the protocol that has received prior institutional review board (IRB)/ independent ethics committee (IEC) approval/ favorable opinion.

7. The medical care given to, and medical decisions made on behalf of, subjects should always be the responsibility of a qualified physician or, when appropriate, of a qualified dentist.

8. Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).

9. Freely given informed consent should be obtained from every subject prior to clinical trial participation.

10. All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.

11. The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).

12. Investigational products should be manufactured, handled, and stored in accordance with applicable good manufacturing practice (GMP). They should be used in accordance with approved protocol.

13. Systems with procedures that assure the quality of every aspect of the trial should be implemented.

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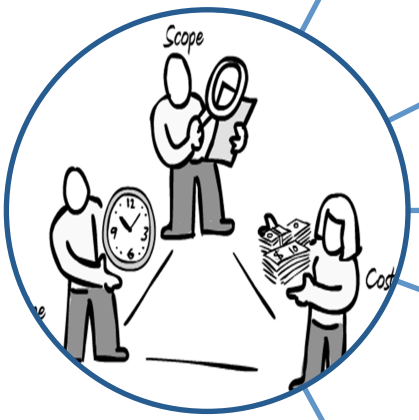
What om a Planning Perspective?

Conduct clinical trials from an ethical perspective



Participant protection is a priority

Have a well defined plan, and stick to it

Select qualified staff

Documentation is essential

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1. Conduct Clinical Trials from an Ethical Perspective

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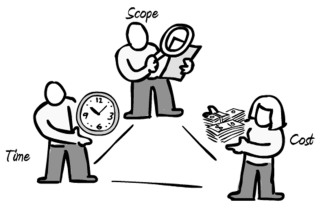
1: DOH

2: Benefits & Risks

3: Rights and safety of participants over the interest of science/ society

6: Approvals from IRB



"It doesn't *matter* that you never got caught!"

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2. Participant Protection is a Priority

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4: Available information of IP

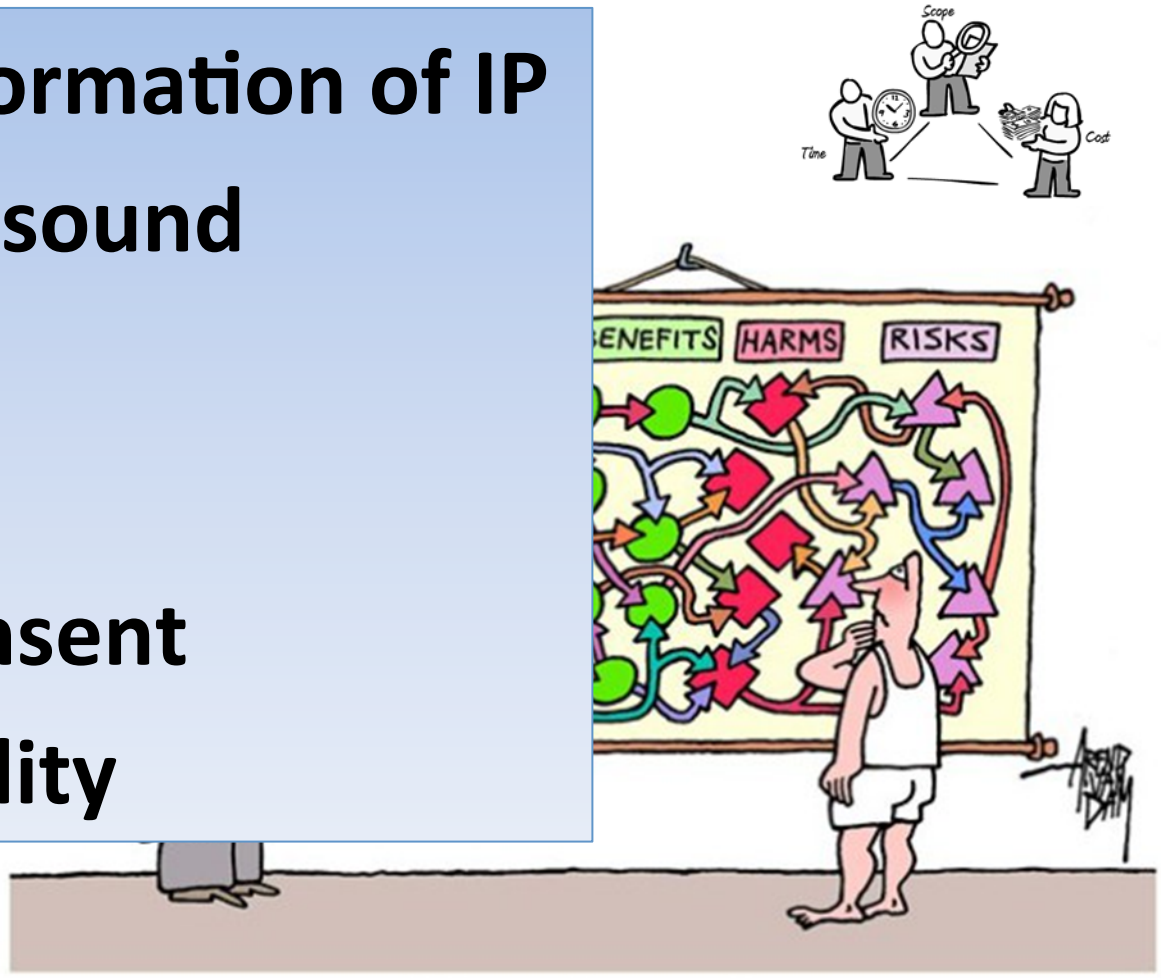
5: Scientifically sound

6: Approval

7: Care

9: Informed consent

11: Confidentiality



informed consent

3. Well Defined Plan and Stick to it.

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5: Protocol

6: Approvals

12: IP

13: Systems

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4. Select Qualified Staff

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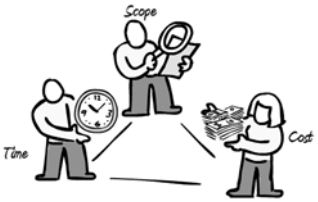
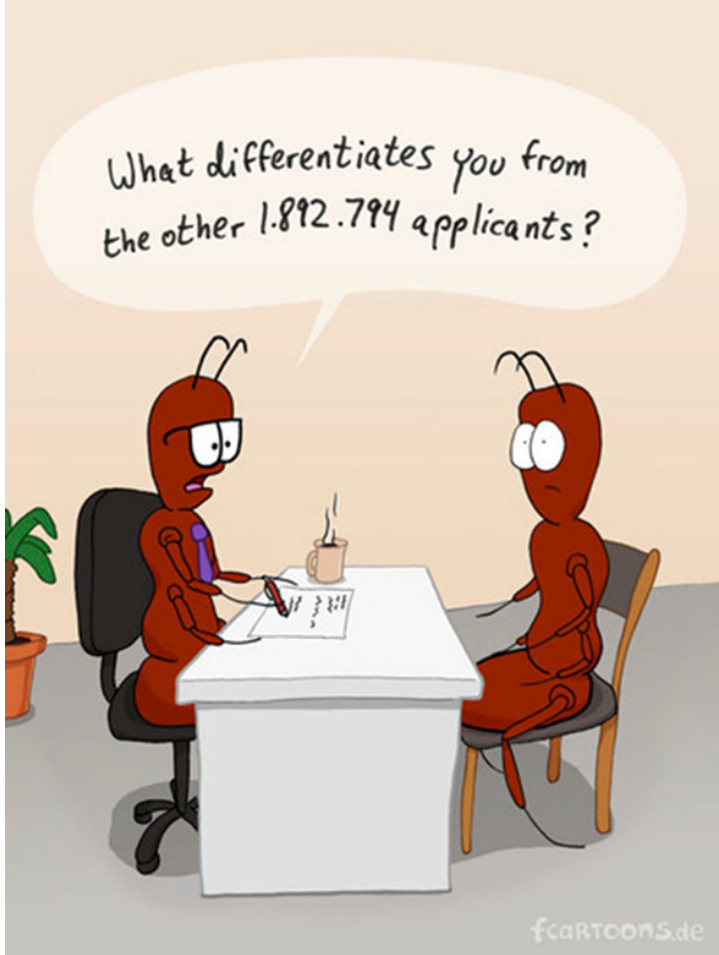


7: Medical care

8: Education, training and experience



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5. Documentation

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10: Accurate reporting, interpretation and verification

11: Confidentiality

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Summary

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13 Principles into 5 categories :

1. Ethics :1,2,3,6,13
2. Participant Protection:4,7,9,11,13
3. Clear Plan *aka*- PROTOCOL: 5,12,13
4. Staff: 7,8,13
5. Documentation: 10,11,13

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"You'd be surprised the headaches you can avoid by addressing these 4 simple questions before beginning a project."

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Thank you.

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