

Confucius on Clinical Research

By Norman M. Goldfarb

Mr. Confucius, sir, I am so honored that you have risen from your grave to join me for this interview. Being dead for over 2,500 years has given you a lot of time to refine your thinking about clinical research. May I ask why you have so kindly agreed to an interview at this time?

If all were right with the world, I should have no call to set it straight.

What advice do you have for investigators?

Breadth of reading and the ties of courtesy will keep a man from error's path. A gentleman is warm in manner, dignified in bearing, faithful of speech, and painstaking at work.

How long does it take to become a competent investigator?

A man to whom three years of study have borne no fruit would be hard to find.

Is study enough, or is experience also required?

Though a man has studied three hundred poems, if he stands helpless when put to govern, what have they done for him? To learn their trade, apprentices work in a shop.

Are study and experience enough?

Could Tzu-chien have grown to be such a gentleman were there no gentlemen in Lu?

Is three years enough to become an expert in clinical research?

As I gaze it grows higher, as I dig, more remote.

How should a sponsor evaluate an investigator for a study?

Look at a man's acts. Watch his motives. Find out what pleases him. Can the man evade you?

How particular should a study sponsor be when selecting research sites?

I do not eat a dish with the wrong sauce. If the mat is not straight, I do not sit.

If the investigator is excited about a complex study but does not have a lot of experience, what should the sponsor do?

No man ready to fly unarmed at a tiger should be with me, but, rather, who is wary before a move and gains his end by well-laid plans.

Is the investigator or the study coordinator more important?

Can I herd with birds and beasts?

Is it never correct for a sponsor to compromise in selecting sites?

To pierce through the target does not score in archery.

A lot of sponsors seem to forget which investigators performed well and which performed poorly on past studies. Could this be intentional?

Po-yi and Shu-ch'i never recalled past wickedness. The foes they made were few.

But isn't it better to invest in long-term relationships with good investigators?

If a gentleman does not forsake old friends, they will not be selfish.

How open should the sponsor be with potential investigators about a study's challenges?

If thy words not be faithful and true, wilt thou get on, though in thine own home?

When responding to a site questionnaire, should an investigator reply quickly or completely?

When summoned by the king, I walked, without waiting for my carriage.

If a site has issues with a protocol, should it join the study anyway?

Rotten wood cannot be carved, nor are dung walls plastered.

Should a site take a study outside its therapeutic area?

Has a gentleman skill in many things? No, in few things.

Should a site take a study without being confident of its performance?

If the tongue have not fear, words are hard to make good in deeds.

Should a site take a good study from a bad sponsor?

In the land that is thy home, serve the best men in power, and get thee friends who love.

Should a site join an ongoing study that is having a lot of difficulties?

A man who loves learning with a simple faith will not enter a tottering kingdom.

How important is it for the sponsor to get the protocol right?

To give careless orders, and be strict when the day comes is robbery. When words are misused, affairs go wrong. A gentleman is nowise careless of words.

But what if management has given the study team a deadline?

That which is hard to do, can it be lightly spoken?

How extensive should the eligibility criteria be in a protocol?

A man and his faults are of a piece.

Should a sponsor create a budget template with low prices, knowing that inexperienced sites will not know they can negotiate?

To be stingy in rewarding men is littleness. A gentleman considers what is right. The vulgar consider what will pay.

How hard should a site negotiate the study budget?

A gentleman takes what is right to take, so none weary of his taking.

Is it better for a site to take a bad study or a study that pays badly?

A servant of the king honors work and rates pay last.

How much responsibility does the sponsor have to train investigators?

To take untaught men into battle is to cast them away.

Are in-person investigator meetings really necessary?

Mingle not in projects with men whose ways are not thine.

Must they always include a session on GCP?

Only for those stammering do I find the word.

Should the site have any say in the agenda of the site initiation visit?

A workman bent on work will first sharpen his tools.

How should a research site recruit subjects?

To know mankind is wisdom.

Does informed consent help or impede subject recruiting?

When K'ang gave a gift of medicine I did not know, I dared not taste it.

Who should write the informed consent form?

Who does not study poetry has no hold on words.

How much effort would you put into making the informed consent form understandable?

The whole end of speech is to be understood. Commend a man for plain speaking.

How much information should we put in an informed consent form?

Too far is no better than not far enough.

How should the site handle the discussion?

To men above the common we may speak of things above the common. To men below the common we must not speak of things above the common.

What role should the investigator play in the informed consent process?

No gentleman has ever come here, whom I have failed to see.

How important is the relationship between the study coordinator and the subject?

At hearing lawsuits I am no better than another. What is needed is to stay lawsuits.

What advice do you have for site monitors?

If sent to the four corners of the earth, a gentleman must not disgrace the king's commands. A good prince asks perfection of no man. When thou dost get at the heart of a crime, be moved to pity, not be puffed with joy.

Should an investigator ask the study monitor questions, even it reveals ignorance?

A gentleman asks when in doubt. Be not ashamed to mend thy faults.

Should an investigator be concerned if the study monitor seems to be learning on the job?

Who would choose as guide one that is no prop in danger, who cannot lift him when fallen?

Should an investigator complain about a bad site monitor to the study manager?

It is better if the good men of the neighborhood like him and the bad men of the neighborhood hate him. Good is no hermit. It has ever neighbors.

What makes a good study coordinator?

Whilst peace reigned in the land, Ning Wu showed understanding. When troubles came, he turned simpleton.

What should an investigator do with a study that is not enrolling subjects?

The days and months glide by. The years do not tarry for us.

What should the sponsor do with a site that is not enrolling subjects?

When wrong prevails, be fearless in deed but soft of speech.

Should a sponsor expect key opinion leaders to enroll a lot of subjects?

Why use an ox-knife to kill a fowl?

If a site keeps making the same errors, how forgiving should the sponsor be?

From him who cannot turn the whole when I lift a corner I desist.

How tough should the study manager be?

Who lacks strength faints by the way.

How important is accurate data?

To learn the truth at daybreak and die at eve is enough.

How important is GCP?

When walking, Yan-t'ai will not take a shortcut.

Given the time pressures sites are under, is it really necessary to keep study drug in a locked cabinet in a locked room?

If tortoiseshell or jade be broken the case, who is to blame?

How much warning should the sponsor give the sites before data lock?

To ask full tale without warning is tyranny.

How should a sponsor manage investigators in the developing world?

If far off tribes will not bend, win them by encouraging worth and learning.

With so many laws, regulations and guidances, how can an investigator even remember them all?

A heart set on love will do no wrong.

What if the FDA comes for an inspection?

When right prevails below heaven, power does not lie with ministers.

This question is a bit awkward, but do you recommend a study "post mortem" to learn from what went right and what went wrong?

To leave untaught and then kill is cruelty.

What do you think about the recent trend in which some companies are trying to become the "sponsor of choice?"

In governing, cleave to good. The North Star holds his place and the multitude of stars revolve around him.

Mr. Confucius, thank you again so much for your time. I know your next appointment is waiting.

Who can go out except by the door?

Reference

"The Analects of Confucius", Digireads.com Books, 2005

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