

How to Increase Study Profits:
The Relationship Between Study Profit and GCP Training for Investigative Sites
By Ruth Ann Nylen, PhD

About The Author

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GCP requires sponsors to select only those investigators who are qualified by training, education and experience to conduct clinical trials. (21 CFR 312.53 and ICH GCP 5.6) From a practical perspective, training includes training in the study protocol requirements, as well as training in Good Clinical Practices.

Over the years, I have met, listened to and observed many research professionals who perceive GCP training as an unnecessary evil, or an arduous, uninteresting and bothersome requirement. The belief that GCP training is an unnecessary expense with no return on investment has permeated the clinical research arena. These perceptions have often led to many research professionals seeking to get by with as little as possible, believing the requirement to be nothing more than “doing time” to get the certificate for the file.

If this is or has been your perspective, I invite you to consider evaluating the impact that GCP training, or lack thereof, has had on your study profits. This article provides a method to help investigative sites evaluate this relationship and calculate the actual impact on study profits.

Study Profit for Clinical Investigators

To determine the return on your investment in GCP training, one must understand the study results that can be directly linked to GCP training. To do this, the following points must be understood.

1. The primary purpose of Good Clinical Practice training is to enable those being trained to comply with the regulations and guidelines that apply to clinical research.
2. It is not possible to comply with GCP if one does not know what the GCP regulations and guidelines require.
3. Non-compliance with GCP is most often due to lack of knowledge of GCP requirements.
4. Non-compliance with GCP (or the study protocol requirements, which is also a GCP requirement) is the primary reason that investigators lose revenue in clinical research.

How to Calculate Real Impacts on Study Profit

Make the following calculations for each study completed during the past year

1. Determine the number of contracted subjects.

Example: 15 subjects.

2. Determine the gross amount defined in the study contract for each completed subject with usable data.

Example: \$ 6,000/subject

3. Multiply the number of subjects (item 1) by the amount of gross revenue (item 2).

Example: $15 \times \$6,000 = \$90,000$

4. Determine the number of subjects completed with fully-usable data by the sponsor.

Example: 11

5. Determine the number of enrolled subjects for which full revenue was not received and state the specific reason why the full amount was not received. (The reason is typically provided to the investigator in a report from the sponsor or CRO). Record the amount you were actually paid by the sponsor. You must be brutally honest with defining the reason why full payment was not received. You must determine if the underlying reason was within the control of the investigator/staff, or it was not in the control of the staff. For example, if a subject moves to another state and voluntarily leaves the study, the reason for leaving the study (and the investigator losing revenue) is not in control of the investigator. On the other hand, when ineligible subjects are enrolled, visits or procedures are not done in absolute compliance with the protocol, these are GCP-related issues that potentially could have been avoided by the investigator or staff. Anything that can be traced to a “mistake” made by the investigator or any member of his or her staff, is potentially a GCP-knowledge or compliance matter that has directly impacted profits.

Example:

Subject	Reason	Amount paid
# 2	Determined to be protocol-ineligible by the monitor	\$ 800
# 8	Voluntary withdrawal, after 4 months-moved too far to return for visits	\$ 2,200
# 14	Two reasons: <input type="checkbox"/> Fourth visit not scheduled within protocol-specified time period. <input type="checkbox"/> Final efficacy procedure not completed within time period specified in the protocol.	\$ 2,400

6. For each subject for which you were not paid the total contracted amount, determine if the reason is related to GCP knowledge or compliance. Calculate the amount lost due to mistakes related to GCP knowledge or non-compliance.

Subject	GCP-Related (Potentially could have been avoided by the investigator/staff) Yes or No?	Revenue lost due to mistakes in GCP knowledge or non-compliance
# 2	Yes	\$ 6,000-\$800 = \$5,200
# 8	No	0
# 14	Yes	\$ 6,000-2,400= \$3,600
NET study revenue lost due to GCP-related mistakes		\$5,200 + 3,600 = \$8,800

7. Compare the amount of lost revenue due to GCP-related mistakes to the cost of acquiring comprehensive GCP training. (Note: It is important to understand that a 60-90 minute GCP overview during an investigator's meeting should not be considered comprehensive).
8. Repeat this exercise for each study completed since your last formal GCP training.

9. Calculate the sum total of lost study profits due to GCP compliance errors. Note: This calculation only takes into account the cost related to lost revenue. In addition to this cost, the cost associated with time required for extended monitoring visits, correction of errors, repeated procedures, etc., add to the cost of not completing comprehensive GCP training. Additionally, non-compliance can lead to audit findings and potentially a 483 letter, the cost of which could be immeasurable to your site.

The Bottom Line

The cost of NOT completing comprehensive GCP training will become clear as these data are evaluated.

Increasing levels of GCP proficiency, which can be effectively measured via properly designed GCP training, has proven to lead to increasing levels of profitability. If the investigator/staff have completed GCP training and you are still experiencing substantial revenue losses due to GCP-related mistakes, it is worthwhile to consider another more comprehensive GCP training program that allows for proficiency benchmarking and tracking of individual improvement.

In conclusion, increasing your investment in GCP training is a quick and easy way to substantially increase your study revenues and profit.