

# Common Misconceptions from Sponsor and CRO Programmers & Their Challenges

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# Overview

- + Purpose
- + Misconceptions around timelines and delivery.
- + Programmer's roles, responsibilities and challenges from both Pharma & CROs.

# Purpose

To build stronger collaboration for programmers between CROs and their sponsors leading to long-standing, shared partnerships through the shared commitment to help patients.

# Misconceptions from CRO Programmers: 1

Make deliveries way ahead of the schedule.

Author's perception

Client's team might not be available prior to the scheduled time forced to change their timelines accordingly.

Suggestion

Communicate any proposed changes to the timeline ahead of time.

## Misconceptions from CRO Programmers: 2

Expect comments from client including root cause.

Author's perception

Client's programmer won't spend more time to identify cause of discrepancies.

Suggestion

Add programs and logs in delivery.

## Misconceptions from CRO Programmers: 3

Comments from sponsor's programmers or statisticians should be blindly followed.

Author's perception

Comments might be from people with various range of knowledge.

Suggestion

CRO programmers should feel obligated to ask for clarifications and give the sponsor appropriate reference documents.

Reduce re-work by getting familiar with client's SOPs, therapeutic standards.

# Misconceptions from Sponsor's Programmers: 1

CRO programmers have unlimited time on a study.

Author's perception

CRO programmers need to work as efficiently as possible to adhere to the study scope agreed to by the sponsor and the CRO.

Suggestion

Sponsor and CRO must work collaboratively on implementing updates.

Limit excessive small changes and always consolidate comments.

Going through the proper channel to request the updates.

## Misconceptions from Sponsor's Programmers: 2

Subsequent IDMC deliveries won't need extra effort.

Author's perception

Make things right for all type of unexpected various data issues.

Suggestion

Program robustly for interim delivery ensuring data quality & integrity.

## Misconceptions from Sponsor's Programmers: 3

CRO programmers are dedicated full-time on their study.

Author's perception

Programmers are assigned based on the need of the study.

Suggestion

Please communicate the expectations.

Incorporate them in the timelines and contract.

# Programmer's Roles, Responsibilities and Challenges from Both Pharma & CROs

|                             | CRO                                                                                                                                                               | PHARMA                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|-----------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Broader view</b>         | Work with dynamic clients/standards to develop a broader skillset and flexibility.                                                                                | Get to see the full clinical study picture. Programmers have been involved in clinical trial development, e.g. review protocol, SAP & CRF, attend meetings and communicate directly with medical, regulatory and clinical teams.                                                                                                                                                                                                                                         |
| <b>Challenge</b>            | Uncollated/unconsolidated comments from a variety of sources at the sponsor, leading to challenging/aggressive timelines.                                         | Pressure of working on ad hoc reports, publications, exploratory analyses, and quick turnaround regulatory requests, while lacking programming infrastructure and deep understanding of details of the programs when studies are outsourced. Being responsible for delivery of outputs with no direct authority over CRO employees doing programming. Doing oversight without direct access to CRO programmers, maybe not even knowing who or where the programmers are. |
| <b>Standards and Tools</b>  | Exposed to a much larger variety of drugs, indications, and company standards and need to apply the CRO standards flexibly to meet sponsor requirements.          | Use the standards and tools from only one company.                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Financial Management</b> | CRO functional leads need to account directly for the financial health of their projects.                                                                         | Management of budget is often done at a higher (e.g., compound) level.                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Career path</b>          | Technical and management tracks based on skills more than degree or ability to succeed at office politics. More opportunities for advancement in technical track. | Can manage the work being done by others without management career track. More opportunities to focus on innovative solutions or solving new problems instead of using existing tools to program datasets and TLFs.                                                                                                                                                                                                                                                      |

# Conclusion

- + We all aim to achieve the same goals, working collaboratively to deliver new, effective drugs to patients. Producing high-quality outputs in a timely manner is common to both the CRO and pharma worlds.
- + To achieve these results, a common set of skills are necessary: organization and planning, agility, leadership, and use of standards.
- + Being accountable and responsible for the delivery you are leading or supporting really makes the difference. This is one of the greatest keys for success, whichever side of the sponsor/ CRO.