

Pharmaceutical expectations and CRO expectations – how can we best get them to agree?

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ABSTRACT

A large number of pharmaceutical companies now use Contract Resource Organisations (CRO) for the reporting of their clinical trials, use in Data Monitoring Committees (DMC) or for consultancy work. High expectations are placed on the CRO to create the best possible results, in the fastest possible time for the least possible cost.

This paper intends to explore the expectations from both interested parties, resulting in some possible solutions / suggestions to make the working relationship easier, more efficient and with less stress on either side.

INTRODUCTION

Expectations of pharmaceutical companies for the work undertaken by a CRO are understandably very high, as are on the reverse the expectations of the Pharmaceutical companies by the employees of the CRO. Quite often, these can be found not to agree. Dependent on whether these are large or small discrepancies in expectations, the impact on the work undertaken can vary, but in many cases this can result in extra time and effort being required by both parties.

Those working in the pharmaceutical companies can surely think of an example of being inundated with questions from a CRO and thinking "But surely that is common sense / obvious!". On the reverse however, is the programmer or statistician within the CRO waiting for the response thinking "I'm not sure whether the company has a standard procedure for this" or possibly "Why haven't they replied yet – do they not realise I need to get this done!".

- How can it best be ensured that efficiency is maintained at all times and that both of the interested parties are satisfied with the working relationship?
- Are there any common issues / expectations that can be addressed and potential solutions agreed upon at the kick off / start up meeting?

By researching opinions of employees within both pharmaceutical and CRO's and categorising some of the common issues and expectations raised, this paper intends to put together a template "Action plan" that could be used to alleviate some of these issues. The following areas will be discussed: Communication, Reporting Standards, Technology, Timelines and Miscellaneous.

COMMUNICATION

Good communication between all relevant parties plays a key role in any business relationship. The frequency, method and style of communication are all crucial to achieving a good working relationship, in addition to the documentation of any decisions that have taken place. The way in which this is performed, can be influential to the outcome of the project or relationship between the pharmaceutical company/sponsor with the CRO. Communication issues can occur on both sides of the relationship, with many related and similar issues occurring.

PHARMACEUTICAL EXPECTATIONS

- 1) To be informed of all key project issues as they arise in a timely manner.

Sponsors of the CRO companies may understandably expect to be informed of major issues as they arise. For example if there is likely to be a delay in the release of study results, the sponsor can expect to be informed of this as soon as it becomes evident. All activities have an impact upon another and as per the example, the delay of the study results may impact upon key decisions for future studies or the writing and resourcing of the final study report.

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CRO EXPECTATIONS

- 1) To be provided with all of the information necessary to complete the work as contracted.

The quality of the work performed is inextricably linked to the quality of the communication of study related information such as the protocol and study analysis plan in addition to company level standards relating to study conduct and programming. The transferral of this information at the start of the project is crucial and delays to this will cause further questions being raised and potential misunderstandings.

It is also a key expectation of the CRO to be updated regularly with the progress of the study. Internal decisions can be taken that will affect the conduct of the study, it is therefore important to keep all relevant parties updated with regard to the study progress.

- 2) To feel included as part of the team.

The majority of CRO work is conducted externally to the sponsor's offices. As such, it is very easy to view the CRO as simply a service provider, as at the end of the day – it is a business partnership that has mutual benefits to either side. Reasonably or unreasonably, many employees of a CRO would like to be viewed as members of the wider project team. They are the people involved in the day to day reporting of the study so may have alternative ways of thinking / approaching a problem that has arisen. Communication between the CRO and external sponsor departments such as the data management, project management or medical writers is also key to ensure that all parts of the study reporting fit together.

- 3) To have timely resolutions to queries, with all relevant parties present.

One small issue can lead to assumptions being made and re-work being required if this is not acceptable, potentially making this small issue into a much bigger one. The CRO can understandably expect that an informed decision is made and then upheld. It is crucial [it should be noted for both parties] to have all of the relevant parties involved in the decision making to avoid the reversal of decisions, leading to rework and the potential of delays and / or cost implications through change orders.

POSSIBLE SOLUTIONS TO DIFFERENCES IN EXPECTATIONS

Within the discussion above, it can be seen that there are several overlapping areas and the importance that good communication plays in creating a harmonious working relationship. Consequently, there are potential actions that could be taken to avoid some of the key issues above. These include:

- Ensure that Sponsor / CRO partnership is initiated at a time suitable within the project life cycle.
- Have a kick off meeting, where key study information is communicated. If decisions have already been made, communicate these.
- Ensure that protocol, study analysis plan and any other company/study documentation are of sufficient quality for programming to be performed and these are available in a timely fashion.
- Identify the core project team who will meet regularly to discuss study progress / issues.
- Agree on frequency of meetings to satisfy everyone's needs. Cancel meetings if not required.
- Ensure all relevant parties are present at time of decision making. If these are not part of the core team, ensure they are invited to be part of discussions.
- Keep well documented minutes and potentially a decision log.
- Identify key study contacts within both companies and agree upon preferred method of communication. Always identify alternative contacts, including those for escalation of major issues.
- Identify agreed timeframe for response to queries / issues. If this cannot be kept to, ensure all parties are aware that there will be a delay.
- Always ensure open communication – do not try and 'hide' issues. Be prepared to discuss them openly.

REPORTING STANDARDS

The majority of companies will work within the guidelines as specified by the regulatory authorities, for example ICH or EMEA guidelines. However, the interpretation, tools and software may vary from company to company and are detailed in their Standard Operating Policies (SOP's), Working Practices (WP's) or Guidance documents.

A common example is the handling of missing data. Whilst within the setting of adverse events and concomitant medications, the handling of missing or partial dates is often similar across companies and different phases of the studies. The conventions used to report other study data can also vary depending on the company standards, for example the number of decimal places to be provided.

Another common example is the way to calculate percentages and the denominator to be used, considering or not considering missing data. An additional example seen on many occasions is slightly different methods for the

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derivation of Treatment Emergent Adverse Events (TEAE). Depending on the data collection and interpretation of the phrase “occurring after the first dose of medication or increasing in severity if experienced pre-first dose”, the programmatic handling of this data can vary.

All of the examples detailed above are fairly straight forward ones, but emphasize the need to be clear on the company reporting standards as differences between companies do exist.

PHARMACEUTICAL EXPECTATIONS

- 1) To work within sponsor defined SOP's, WP's and Guidance documents.

Both Pharmaceutical companies and CRO's will have SOP's, WP's and Guidance documents to ensure that good practices are always maintained and quite often these will be very similar. If the sponsor requests their own in-house SOP's to be followed, these should be clearly identified and all relevant documents provided.

- 2) Study output to be generated using sponsor / study defined algorithms.

Different companies have different methods and standards for handling study data, varying in complexity depending on the issue, which it may be expected to follow for the generation of study output. If a CRO is working within sponsor defined software, with generic code, it is possible that this is in-built within the code. It is also possible that the methods of handling data are contained within sponsor defined study guidance. These should be clearly defined within the protocol or statistical analysis plan and or any additional guidance provided.

- 3) To receive quality output in company defined standards.

Within the statistical analysis plan, there are often details provided on the format of output, for example the layout of TFL's (tables, figures and listings) including headers, footnotes and the ordering and labels to be used for treatment groups. Whilst there are widely accepted guidelines for the presentation of output [landscape, in font size 9-10], if specific layout in terms of the font size, margins or any other reporting standards are required these should be agreed prior to the starting of programming to reduce any necessary re-work and / or delays.

CRO EXPECTATIONS

- 1) To be informed of and trained in relevant Standard Operating Procedures.

Whilst all CRO's will have standard operating procedures, these may differ slightly to those of the sponsor and it can be requested that sponsor SOP's and guidance documents are used in addition or instead of internal SOP's. This should be clearly documented upfront, allowing access and sufficient time for training where necessary.

- 2) To be given any study / sponsor specific documentation in a clear and concise manner

Often the algorithms for handling data are detailed within the statistical analysis plan. It is expected that this will provide sufficient detail to program from. If not questions will arise.

Whilst it is useful to be given all of the information for guidance, unless the information is ordered in a logical manner and is clear and concise, this will not always help.

- 3) To be given a consistent methodology across studies where more than one study is reported for the same sponsor.

Where multiple studies in the same therapeutic area are reported for the same sponsor, it is often the most efficient method of reporting and programming to re-use / adapt the same methodology and code. This can lead to time and cost savings, which are likely to be agreeable to all concerned.

- 4) To be given clear guidance on company interpretation of regulatory guidance, for example CDISC.

Regulatory guidance documents are generally put in place to do as the name suggest, provide guidance on the assumptions and format that a study should take or be reported in. Often these are not hard and fast rules to be followed, but merely a recommendation and as such can be open to interpretation. A clear example of this point is the interpretation of CDISC standards and the application of these to ADAM and SDTM datasets. Whilst many of the principles of CDISC standards are straightforward, different companies may have different understandings and experiences of CDISC, sometimes in relation to their prior use of CDISC standards, which in many cases may be none.

It is very important that the sponsor communicates properly their requirements with regards to CDISC and this has been thought through prior to contract being signed. It is also important that members of either the biostatistics department and / or other relevant departments are available to review the specifications as they become available to make sure they are applicable and most importantly usable.

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POSSIBLE SOLUTIONS TO DIFFERENCES IN EXPECTATIONS

- Ensure that there is a clear and concise guidance on what SOP's should be used in the Work Order. If not, a supplemental definition of approach should be provided.
- Clear guidance on the sorts of issues that should be checked with sponsor and what can be decided within CRO.
- Try to ensure that work being outsourced is consistent in approach with other work outsourced from same company / therapeutic area. This means that processes can be re-used / modified, which will lead to potential time and cost savings.
- Clarify in the statistical analysis plan and / or protocol the procedures to be followed. Do not assume that because it is a sponsor standard, that it will be "obvious".

TECHNOLOGY

SAS® is one of the widely recognised software packages used across both pharmaceutical companies and CRO's. Differences between both companies may occur due to issues such as the version of SAS® to be used, the operating platform, or how are the results to be delivered (for example: .lst, .rtf, a single file containing all outputs or one file per output).

PHARMACEUTICAL EXPECTATIONS

- 1) In-house systems to be used in the reporting.

Where the sponsor specifies that their own reporting systems are to be used, the time and processes to get access for the CRO personnel should be built in to the overall timelines. Delays can occur when access is delayed for any reason. Delays may also occur when the connection between the CRO and Sponsor software is not stable, leading to the possibility of down time. There should be some consideration and judgement at the start up and negotiation phase as to the practicability of training the CRO in the standards and software.

CRO EXPECTATIONS

- 1) To have a clear expectation of the software requirements at the kick-off meeting.

At the kick-off meeting all expectations, not just the technology expectations, should be discussed and agreed. A key example of a software requirement is the version of SAS® that should be used. Due to the small differences in the versions of SAS®, particularly relating to the statistical analyses, the version to be used should be agreed and documented. Any changes to this should be highlighted as soon as it is required, taking into account any potential impact this may have dependent on the stage of the request.

- 2) To be granted access to systems in a timely manner and be provided with sufficient training.

As detailed in an earlier section, delays can occur when the access to systems is not available at the time of the project starting. Consideration should also be given to the timing of the training – whilst it is not always possible to have training up-front, on the job training is not the most time efficient and ultimately can lead to frustrations and questions.

- 3) To be provided with sufficient work to make the most of the training to provide quality results in a timely manner.

Linked to the expectations above (1&2), is also the impact of learning a sponsors systems and processes for a limited amount of work. It is unlikely to be in the interest of both parties if work is undertaken to train the personnel of a CRO in sponsor specific software, and then for only one or two studies to be reported using it. Consideration should therefore be given to whether it is absolutely necessary to use sponsor defined software, if an alternative can be found or whether a long term contract can be sourced to ensure benefits to both parties.

- 4) To have discussed and agreed the procedures for delivery of results.

Once the tables have been developed and validated in the required presentation, there are varying formats that displays can be delivered in. These can be delivered in separate files, in one file with all outputs present, with or without a contents page, in a zip file or in another specified format. Different sponsors can request different methods of outputs being sent to them also, via a secure portal, via email, hard copies. Consideration should be given to these methods, and where possible details provided in the analysis plan.

POSSIBLE SOLUTIONS TO DIFFERENCES IN EXPECTATIONS

- Be clear at the start as to the software and processes that are required.
- If sponsor software is to be used, ensure sufficient access rights and adequate, timely training is available.
- Investigate whether long term contracts can be made available to ensure benefits to both parties.

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- Clarify how the results should be delivered at the beginning of the study.

TIMELINES

It is very important that timelines are set up for all major process and functions that link together to meet the requirements of the contract and that these timelines are mutually agreeable between all the relevant parties involved in the study (pharmaceutical company, CRO and any other party involved). All involved parties should be encouraged to provide information in reasonable timeframes to facilitate this.

PHARMACEUTICAL EXPECTATIONS

- 1) Changes to the timelines made by the CRO should be discussed and agreed previously with the sponsor.

Changes to timelines can occur for many reasons including the following: priorities have changed, database closure has changed, it is not reasonably possible to complete the work in the agreed timelines. All timelines should be agreed up front with all relevant parties present. As and when priorities change, these again should be discussed with all relevant parties to ensure that a mutually agreeable resolution is obtained.

- 2) To be informed if it is not possible to meet the current timelines.

Whilst on all occasions, all necessary and reasonable efforts will be made to meet the requested timelines, from time-to-time, this will not always be possible. As indicated in the communication section, this should be conveyed to the sponsor as soon as it becomes apparent and not only on the day of agreed delivery. It is possible that alternatives can be found, such as staged delivery of study outputs that do not mean enforced and unreasonable working hours for all concerned.

- 3) To receive study output in the agreed timeframe, regardless of any prior delays.

All companies have pressure put on them to meet the agreed timelines for study reporting regardless of whether previous activities have presented delays, in many cases the delay of data transferral or database lock / closure. This pressure is acknowledged to not always be from the biostatistics departments of the sponsor, but from higher level management or the clinical team in order to meet company objectives. As indicated in points 1 and 2 above, all reasonable efforts should be made to meet these timelines, but occasionally, it is not possible and this should be communicated as soon as evident.

CRO EXPECTATIONS

- 1) To have clear, achievable and complete timelines.

All of the timelines should contain all of the required activities and be maintained on an ongoing basis. It should be clear and agreed at the start up meeting, whose responsibility it will be to keep the timelines maintained and ensure that everyone is in agreement and informed of the timelines that relate to their function.

Where possible, an application such as Microsoft® Project should be used to detail the inter-dependencies between tasks so that a clear overview of the whole project is available.

- 2) To include where necessary and possible a dry-run of study outputs and receive regular transfers of data.

The inclusion of a dry-run into the timelines ensures that project focus is maintained by all concerned and ensures that the sponsor is satisfied with and can provide comments on the outputs received. The inclusion of a dry-run will also ensure that there are no nasty surprises at the final study reporting.

Regardless of whether the data management is performed by the sponsor or the CRO, it is important that regular transfers of data are received, including both CRF and external vendor data where applicable. Timelines for this should be agreed up-front and adhered to where possible. This will not only help with the up-front programming, but will also help with the identification of data cleaning issues.

- 3) To be provided with full and detailed requirements of the task requested.

The details provided by the sponsor are the only information that a CRO has to base their judgment on how long a task will take and ultimately how to produce it. It is sometimes apparent requests that may have originated from the clinical or regulatory departments have not been given sufficient consideration as to specific details. To rectify this, full consideration should be given to the exact nature of the request in relation to the data. If this is not possible, collaboration should be sought between the sponsor and CRO at the development stage, to try and identify the best procedures to be used. Ultimately, this should lead to less questions being raised and the requested results being provided more efficiently as time is better spent up-front developing clear ideas, rather than at the programming stage when there are likely to be constraints on time.

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- 4) To be given the impression that the sponsor has a clear understanding of the timing and magnitude of tasks requested.

On occasion, it can become apparent within the CRO that not all tasks completed are fully understood by the requesting sponsor. Who hasn't heard the statement about simply "pushing a button" to get the final results tables out? In reality, all heavily involved in the industry know that this simply is not true! There are other examples of where extra time is required to be fully confident in the results provided, such as

- Interim data cuts when the data cleaning is ongoing
- When the DSMB is run on dirty data
- Time spent on investigating data issues.

The reasons for this could be due, in addition to other reasons, to the lack of statisticians and / or programmers with the sponsor company or lack of experience / understanding. Always be up front in the procedures that will be used so that all have a clear understanding of the time required.

POSSIBLE SOLUTIONS TO DIFFERENCES IN EXPECTATIONS

- When things don't go as planned, engage in discussions to explore options for the best solution rather than just shifting the timelines.
- Identify potential areas for delays and put in place alternatives as soon as reasonably possible, preferably having suggestions available early on.
- Ensure that all relevant parties are available for comment when deciding timelines, and ensure they are reviewed often to make sure they are still relevant
- Timelines are essential to ensure that activities take place when they are intended to. All parties need to stick to timelines agreed as much as possible, but be open if there is a problem, no matter where it stems from.
- Agree key responsibilities at the outset of the project both within and between companies. If not kept to, may require change orders throughout the study.
- Use an application such as Microsoft® Project to keep a detailed overview of timelines and make available to all concerned.
- Ensure sufficient test data is available for programming in advance.
- Be sure of what you are asking for and have a full understanding of what is involved. If unsure, use time to discuss and ask for clarification.
- Set up timelines as X days after Database lock at the beginning of the study. The number X should not be reduced if database lock is being delayed.

MISCELLANEOUS

Throughout the research for this paper, it became evident that not all of the points and expectations fitted into the four categories above. There is below a brief discussion of some important points for consideration, discussed below as a whole, rather than breaking down into the expectation of pharmaceutical companies and CRO's.

OBJECTIVES

- 1) Consideration of differences in objectives and ways of working

The short term objectives involved within a sponsor / CRO collaboration will ultimately be the same, to fulfil the requirements of the project as specified within the contract. However in terms of long term objectives, differences will inevitably occur. Within a sponsor company, often the objectives will be linked to a compound and employees will stay with that compound throughout its life cycle, hence building up knowledge and experience. However due to the differences in the nature of companies, a CRO will have different long term objectives with the project teams moving from one therapeutic area to another. Whilst this leads to the employees of a CRO developing wider experiences which will be beneficial to all, this is another example of where the transferral of key study information in concise and quality documentation is a necessity.

PLANNING

- 1) Planning is performed in sufficient time

The planning of a study doesn't just mean that timelines are discussed, it means that quality information and documentation is available at the various stages of the partnership, contract sign off, project kick off, during the study in addition to post study and is the responsibility of both companies. This will ultimately ensure that the quality levels determined in the contract are achieved. The quality of any output can only be as good as the information received so planning of any documentation to be transferred is key to this.

2) Reason for outsourcing

The decision to outsource is obviously one that is taken by the sponsor in collaboration with the various internal departments of their company. The possible reasons for outsourcing may include the lack of internal resource, need for independent biostatistics input, need for specialist input or ultimately cost savings. The reasons for outsourcing need to be considered by both parties as this will help in most of the areas discussed in this paper.

If the reason for outsourcing is in relation to cost, it should be considered that the lowest cost and quickest output is not always better. Time should be taken at the planning stage by the sponsor company when choosing the CRO to consider which one will actually provide the best quality in relation to the cost.

If the reason is for access to specialised input, then the expectations of the CRO are likely to be higher, but at the same time the communication will have to be adapted as it is likely the sponsor may not have experience in that specific area. In addition, if the reason is for independent analyses, the documentation will need to be completed to the highest possible standard to ensure that it is possible to complete all contracted activities. The same is also true if the reason for outsourcing is the lack of internal resource, as in these cases, it is often desired by the sponsor that minimal input is required throughout the conduct of the trial.

3) Consideration of the appropriate experience needed for the study

The responsibility of the choice of employees working on the projects should be equally considered to be important to both the sponsor and CRO. Whilst the CRO will be contracted to provide adequately qualified employees, a similar consideration could / should also be made within the sponsor company.

As the number of collaborations between sponsors and CRO increases, more and more statisticians and programmers within sponsor companies are taking on management / oversight roles. This can lead to several consequences, a) they are taking a step back from the day to day activities of the running of the studies so may forget about the detailed aspects of the project and b) sponsors often give junior members of the team the responsibility to work with CRO's. Both of these can cause delays in decision making and communication of these decisions if not appropriately managed.

DECISION MAKING

1) What level of independent decision making is appropriate?

This has been discussed briefly within previous sections of the paper. Resolution of issues that arise fall broadly into two categories, those that need to be discussed by both the sponsor and the CRO and those that a resolution can be sought without needing to involve the sponsor or CRO as applicable. As per the introduction of the paper, these issues can lead to delays if not resolved efficiently and effectively. Some sponsors wish to be informed of all of the decisions that are made, whilst others are happy for reasonable assumptions to be made without sponsor approval. The level of sponsor involvement in decision making should be agreed up front, and the preferred method of communication for these – for example should a document of the assumptions made be kept in order that these can be reviewed?

CONCLUSION

The intention of this paper was to investigate the expectations raised by both sides of a pharmaceutical / contract research organisation collaboration with the intention to create a template action plan for area to consider helping expectations of both the pharmaceutical sponsor and CRO to agree. This is detailed below, broken into the suggested time frame for the action.

Whilst some of the expectations may be deemed as fairly obvious, during the research for this paper, issues have been raised that whilst extremely valid, may not have initially been evident and therefore may not be evident during a project collaboration. There seems to be one main area that if ignored can lead to an inefficient and un-satisfactory working relationship and that is in relation to good and timely planning (including timelines).

The planning of a project and setting of timelines helps to ensure that project runs smoothly and meets the requirements of the contract. Planning to allow access to the systems and software should be considered and completed at appropriate times, whilst the documentation of timelines should be done in consultation with all appropriate functions at the start of the project. Changes to timelines should only be done in full consultation with all affected persons and when all other options have been explored. For both involved parties, the planning process should consider the levels of experience and contributions required of team members to ensure adequate resource is available. This in turn will also help to ensure that sufficiently detailed [again balance is crucial here] project information is available when required.

All of the other issues raised within this paper will also play part in the working relationship, particularly the need to have no barriers to communication and having a communication plan in place to ensure the right balance is obtained.

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TEMPLATE STUDY ACTION PLAN

At Contract Sign-off	
Identify and document key responsibilities	☐
Identify software / operating procedure requirements • Arrange Training as required • Ensure access is possible and request accounts as necessary	☐ ☐
Identify if similar studies have been reported previously and ensure information is available at time of project start.	☐
At Start of Project	
Arrange a kick off meeting, preferably Face-to-Face	☐
Ensure that all required documentation as applicable before project start is available, clear and approved. Possible list: • Protocol • Statistical analysis plan (SAP) • Data transfer specifications • Standard operating procedures • Reporting requirements	☐ ☐ ☐ ☐ ☐
Document "core" team members from all functions • Clinical • Study / Project Management • Data Management • Biostatistics	☐ ☐ ☐ ☐
Identify key points of contact. • Agree preferred method of communication • Agree guidelines for time taken to respond where appropriate	☐ ☐ ☐
Agree on frequency of study meetings and on required attendee list	☐
Agree on timelines for all major study milestones (dependent on stage of CRO involvement) and document. Link events as applicable based on previous activities. • Final Protocol • Study initiation • Final SAP approval • Data transfer dates • Interim Analysis • Last Patient Last Visit • Database Close / Lock • Final TFL Delivery	☐
Identify preferred method of TFL presentation and transfer,	☐
Discuss / agree types of issues to be checked and level of decision making that is appropriate / expected.	☐
During project	
Core team meets regularly and includes wider team members as applicable.	☐
Ensure all applicable functions are included in decision making necessary to ensure all applicable options are considered	☐
Keep minutes and as necessary a decision log.	☐
Identify possible barriers to open communication and remove where possible.	☐
Maintain timelines document and ensure changes are communicated to all.	☐
If requirements change, ensure all are informed and provided with new, clear requirements, including resources and timelines required.	☐
Both parties to remain realistic in expectations!	☐
After project completion	
Conduct a lesson's learnt meeting (preferably jointly) to identify • What went well? • What could be improved?	☐

Whilst in many cases the working relationship between pharmaceutical and Contract Research Organisations does work well, hopefully by taking into consideration some or all of the points in this paper will help the relationship to be more effective and efficient.

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