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# "Firefighters" - clinical trial analysis teams

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## ABSTRACT

It is a quite typical situation for our industry when the team approaching the deadline of some reporting event experiences a lack of resources and is forced to work beyond the regular hours. The reasons for this are: underestimating during early planning of the project, unforeseen circumstances, errors in communication and many others. The consequence of all these is the constant stress for all project participants, which affects the quality of work. In this article I would like to discuss the possibility and feasibility of the developing a team of dedicated specialists that could be involved in the project work for the short term to perform as "firefighters" on the basis of CRO or biometric analytical department of pharmaceutical concern. Entering a new employee in a project at the stage close enough to deadline seems troublesome and ineffective, but is it really so? The purpose of this paper is to construct a working model for the so-called "firefighters team" so that its work is effective and it solves the problems of lack of resources on the project. There will also be an estimation of the positive and negative aspects of this type of command and the potential demand for this type of service.

## INTRODUCTION

Missing the timeline - what could be worse in the competitive world of pharma industry? The speed of delivery might be crucial at some point e.g. when the product is close enough to be approved for market. It does not matter if it is a biometric department of a pharma company or a CRO who performs the analysis. When the client/project manager approaches you, they already have a timeline in mind for the project. If the timelines are not met on your end, they will fail to meet their own, which can have a negative impact on subsequent tasks (e.g. poster or publication preparation, regulatory submissions etc.). By putting your company or client's company in this position, you hurt your professional relationship. Punctuality and meeting deadlines is critical if you want to be perceived as a reliable partner.

Quite often if a team of clinical SAS programmers turns out in such circumstances it is forced to perform at the edge of its strength by staying up late, working over weekends, foregoing breaks and meals just trying to complete the delivery on time.

But the truth is that working under pressure – even doing your best work under pressure – is an exhaust. Moreover working under constant stress might resulted in a drop in quality of the delivery that is the second crucial point of the CRO/team reputation and if you fail in both you have a good chance to completely damage your reputation.

What can be done to address these deadline issues? This article describes one of the possible ways to help you to handle the situation: a team of professionals that can step in into the project and take ownership and responsibility on some statistical outputs or tasks.

## FIREFIGHTERS MODEL

What is a 'firefighters' (FF) team? This is a team of experts that meet some requirements and can step into the project and help the project team meet the deadline so none of the teammates is overloaded with the work. In other words, it is an on demand type of group like real firefighters are.

Basically FF deals with the short-term assignments. Just because an assignment is shorter in duration does not mean that it is easier. In fact, a strong case could be made that short-term assignments are actually more fraught with potential pitfalls than longer assignments over the course of the project. With a tight timeframe in which to get the job done, short-term assignees are under pressure to hit the ground running and to accomplish a lot in a hurry. FFs do not have the time to take weeks to onboard, to get settled in a new environment, to listen and learn, to go through the trainings etc. Thus it is important to set the right requirements for individuals who will perform as the FFs and to set up the working model to make this contribution as valuable as it can be.

How many people should your company have in the FF team? This question should be answered based on analysis of your previous deliveries. From my experience, the company with about 50 statistical programmers ideally should have 2-3 "firefighters".

## REQUIREMENTS

What is actually expected from the FF individual?

- **Understanding of clinical trial analysis aspects** – individual should be familiar with CDISC standards, different ways of selecting records for the analysis (last, worst, average etc.), different approaches for selecting baseline records, visit windowing, study endpoints: primary, secondary, safety, exploratory; able to deal with different methods of imputation like LOCF, BOCF;

- **Adaptability –** ability to adjust to different working environments, in different communication models, adherence to client's SOPs - this point is relevant for CRO members as internal employees deal with internal SOPs by default;

- **Good programming/analytical skills** – this implies not only proficiency in coding from scratch but also in reading, understanding and especially updating statistical programs created by others. The means if FF takes over someone's program and has to finalize it according to new requirements, he or she must be able to adjust existing code rather than rewrite it from very beginning even if the code does not seem to be efficient in terms of time and machine resource consumption (as long as the code performs the task correctly). On the other hand, occasionally it is worthwhile to rewrite the code if its updating will require more time and efforts than creating from scratch. FF individual should keep balance on this matter and be wise when making the decision;

- **Quick in onboarding** –ability to deal efficiently with study documentation (i.e. not to spend much time on reading and understanding documentation, but rather know where to find key information and by that minimize time required ), adjust to the new working model;

- **Good communication** - ability to write clearly, succinctly and in a manner that messages can't be misinterpreted; attend team meetings and express your questions or concerns clearly and simply; negotiate in a fluid, back-and-forth manner that engages other team members, managers, etc.;

- **Flexibility** in terms of performing different tasks – FF individual feels equally comfortable performing different tasks from ADAM first line production to QC of the statistical outputs;

- **Autonomy** – FF does not require much supervision even considering that he/she is new to the project;

- **Proactivity** – FF will not be sitting quirt if he/she has completed current tasks but rather will seek for more ways to be useful on the project and communicate their own thoughts to project lead;

- **Expertise** – FF should be an expert at the given indication e.g. he/she supported studies dedicated to given disease and is aware of potential pitfalls in the analysis of clinical data;

- **Personality** – FF should have a clear concept of this type of work. FF understands he/she might not be utilized constantly for 100% of the time. Person should have passion to learn more and maintain professional skills at the top level even if hands-on practice happens occasionally.

This list looks like a standard requirement for the position of SAS clinical programmer with experience of more than 3 years and in fact potential FF should be of this grade. Most critical skills are: quick onboarding, expertise, good programming skills in the meaning described above. If a person shows above average results in these competencies and have right personality for this type of job then he or she will perform most effectively in FF model.

## WORKING MODEL KEY POINTS TO SUCCESS

### Onboarding

Short-term assignments, with aggressive deadlines, require very clear and substantial onboarding. The best way to do this is to setup a kick-off meeting with the team. Usually one hour is enough. During this meeting the following points can be addressed:

- Setting Expectations – what the team expects from FFs in terms of work;
- Meet the team – FF should be introduced to key individuals to understand who is who. This also keeps the team in the loop that they have new person that they be closely working with. It is also beneficial to discuss the structure of the team;
- Brief project overview - The manager should focus on covering any questions that the FF might have concerning the location of documentation, data, programs, outputs etc.; upcoming timelines etc.;
- Preferred working hours;
- Preferred ways of communication along with regular team meetings, sharing some documents that store history of the project decisions etc.;
- Working assignments to the FF.

**Scope of work**

What types of tasks can be delegated to FF and what would be the most efficient approach? First of all I performed the analysis of what types of work the team will potentially deal with during the project. Typical clinical analysis can be divided in two parts: safety part and efficacy part. Each of these two sections implies several subtasks like:

- Initial programming analysis datasets along with datasets specification;
- Quality check of analysis datasets (usually it is double programming);
- Initial programming of statistical output (tables, listings, graphs);
- Initial quality checks of statistical outputs (double programming or visual review);
- Updating analysis datasets after revision or changes in analysis;
- Updating statistical outputs according to revision comments;
- Programming ad-hoc statistical outputs;
- Quality check of ad-hoc statistical outputs;

I have made a research on the projects that I have been working on and below is the table that estimates time that is usually required to complete the tasks listed above.

| Type | Safety Analysis | Efficacy Analysis |
|---|---|---|
| Initial programming analysis datasets along with datasets specification | 6% | 4% |
| Quality check of analysis datasets | 5% | 4% |
| Initial programming of statistical output | 22% | 10% |
| Initial quality checks of statistical outputs | 14% | 7% |
| Updating analysis datasets after revision or changes in analysis | 4% | 3% |
| Updating statistical outputs according to revision comments and re-qc | 10% | 4% |
| Programming ad-hoc statistical outputs | 3% | 2% |
| Quality check of ad-hoc statistical outputs | 1% | 1% |

**Table 1. Estimation of efforts needed to complete each type of clinical analysis tasks**

Assuming that the need in FF occurs close to the end of the project activities it would be correct to expect that all initial programming is completed and the project is at stage of resolving issues, performing quality checks, ad-hoc etc.

The FF can take over updating of the outputs, programming and validation ad-hocs for the safety part whilst the team could complete efficacy part and analysis datasets. In this case it allows FF to address up to 18% of the activities which is quite a good score. In the best case, FF's could be utilized on other tasks that make their contribution to the project even more valuable.

**Knowledge transferring**

After the work is completed and the short-term assignment is close to its finish it should be properly accomplished. For this purpose would be beneficial to have a wrap-up meeting with the team dedicated to updating everyone with the information of what has been done, what potential issues and work-around were found and any other stuff that could have value for the employees who will eventually replace FF.

## POSSIBLE ISSUES

What bumps could be met on this way?

- There could actually be a lack of resources. It means that all your employees are fully occupied on their projects and could not be transferred to the FF team;
- You might not find people with required qualification or expertise in the given area;
- You may find a person gets off on the wrong foot with a client or project lead or the team;
- Time for onboarding to the project might cover all the remaining time before the delivery. It can often take longer than expected to set up the VPN connection, obtain logon IDs and UNIX permissions and required documentation;
- Obvious down side of this model is that this is an on-demand resource. Although you can minimize time this team is underutilized at the stage of planning activity for your company for the upcoming year. FFs could be utilized on long term projects during the spare time; however it should be clearly communicated to stakeholders that this resource could be unavailable at some point.

## CONCLUSION

As the final point in this article I would like to summarize strengths and weaknesses of the described model:

| Positive aspects | Negative aspects |
|---|---|
| You increase chances to meet timelines regardless of circumstances | This type of resource is quite costly |
| Your team does not undergo pressure during reporting events | FF might have no assignments for a while if there is no place on the long-term projects |
| New member might bring a fresh perspective to the team and might discover some gaps that could be unnoticed | It might be quite stressful for the FF to onboard to new project in aggressively limited time |
| FF gain experience working on multiple studies | Due to lack of time on proper onboarding FF might have difficulties with understanding the 'Big Picture' of the project that might reflect on some decision making |

**Table 2. Positive and negative aspects of the firefighter model**

As all we have different personality there are always people that thrive on Firefighting. People who feel bored with the routine work as statistical programmer and do love the adrenaline rush a position like this has. It is good opportunity for them to explore different aspect of the work they do and maybe bring it closer to the ideal work they pictured in their minds.

I think this model deserves to be tried in pharma industry because, despite the fact that this type of resource is costly, this should be considered as insurance that helps to protect the reputation of your group or company.

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