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X-act Cologne Clinical Research GmbH, based in Cologne has been successfully represented on the market as an independent contract research organization for 22 years. This privately owned company specializes in the areas of clinical data management and biostatistics in the field of clinical research. Currently, X-act's 25 employees are researching the authorization and subsequent approval of drugs, medical devices and biotechnology products. For the detailed management of research projects, the company uses Blue Ant, the multi-project management software from proventis, Berlin. We spoke with Jasmin Atarodi, Managing Director of X-act Cologne, on the use of the software.



## Case Study

**Ms Atarodi, what is your position at X-act Cologne Clinical Research GmbH and what are your areas of activity?**

As partner and director of X-act Clinical Research GmbH Cologne I have been running the company since 1994. My current responsibilities include administration, human resources and quality management. I support our organizational development with vision, values, strategies and goals.

**What is your company's focus and how would you describe your daily business/normal day?**

In the field of clinical research, the planning, implementation and evaluation of clinical trials takes up a large part of our day. Clini-

cal trials are subject to very strict requirements and regulations. A high degree of accuracy and precision is required when working in our particular area. A clinical trial always follows a clearly defined test plan, which is created or commissioned by the client, for example, a pharmaceutical company. Based on this test plan, various tasks are performed by many people in different fields; in our case very specifically clinical data management and biostatistics. Our aim is to have sound, clean, comprehensive data for statistical analysis and delivery of results. The quality requirements for our work are very high and this demands very conscientious work from our team. Ultimately, it is a matter of bringing a product to the approval phase after numerous studies. The consumer should then be able to take the medication safely.



Ms Atarodi, partner and director of X-act  
Clinical Research GmbH Cologne

The leaflet describing the side effects of the medication includes the results of these clinical trials.

### **How would you describe your project environment?**

Mainly research projects with proportionate budgets of up to €1m euros, 90-400 man days and durations of between 8-10 weeks and 8 years. The short or long terms are a result of the four different phases of a clinical trial. Although the projects follow a clear pattern, each project presents new challenges and every customer has different needs.

### **So you earn your money with external projects. Do you also work with internal projects?**

Yes, we have internal projects, too. As I already mentioned, we provide high quality work. We work for an industry that is strictly regulated by laws, guidelines and international standards. Internally, we work according to our "Standard Operating Procedures" (SOPs). We have organized the management/maintenance of these SOPs as an internal project. We have also categorized the further development of our internal procedures, optimizing processes and business development, IT and marketing, as internal projects.

### **Why did you want to introduce project management software?**

We had too much data in different systems. Absences were recorded in the payroll, working hours in an internally developed system. Then we had project overviews in Word and Excel, where we listed the most important items and tasks for the project and estimated the timelines, milestones and completion. We wanted to change this, and were looking for a system to provide an overview of as much data as possible, and create transparency for all employees. As I said, every project brings new requirements

and challenges. Different customer requirements, standards, project duration, project sizes - we wanted the software to display all these criteria better.

### **What made you decide on Blue Ant?**

We looked at a lot of systems. We decided on Blue Ant because we found the system very balanced. The software offers a lot of functions which can be gradually introduced and the appropriate number of functions can be assigned to a corresponding user group. It was important to us not to be confronted with an overloaded system straight away. Another reason for deciding on Blue Ant was the excellent advice we got from proventis. Here, the chemistry was just right.

### **How did you proceed with the introduction of the software?**

We implemented the system at the end of 2010. It has been used actively since 2011. The implementation was gradual. First, we recorded the ongoing projects, some of which had short project periods. Then we set up so-called "single-celled" projects. We created just one activity for these projects and recorded work-times on them. For the new projects we then implemented appropriate work breakdown structures for the various types of studies and phases, and recorded working hours and absences (holidays, sick days, etc.). Now we use all the functions of Blue Ant except the ticket system, travel expenses and quotes. We intend to look more into these features this year.

### **How did your employees deal with the implementation?**

In my opinion, I have an exemplary role in the company. I try to inspire the people who work with me. Of course, the use of software is also accompanied by a little more control. Greater transparency may trigger a

feeling of being more closely monitored, even if this is ultimately not the case. In our company, there are flat hierarchies and it is important to me that we change together. The employees saw the advantages of the software quickly. For example, the overview of the projects as a Gantt chart is a very popular feature.

### **When does a project start and end in the software for you?**

Currently, the project begins with the commissioning, and the Work Breakdown Structure (WBS) for the different stages of implementation is created. In recent years, we have additionally divided projects into the so-called "Start-up" phase, "Conduct" phase and "Close-out" phase. On this basis, we make our fine tuning based on budget planning. Because these are very extensive calculations, we use Excel. We load the file into the software and store the planning, the timeline the milestones and assign resources. The project is finished when the last work is completed and the final invoice has been issued. An important milestone in the data management, for example, is the "Database Lock". That is the date on which the database for this project is closed. The criteria to be evaluated are extensive and are processed using checklists. The statistical analysis is performed based on this data, which is not changed after the DB Lock. Another milestone is, for example, the "Final Medical Report." If this has been written and approved by the customer, we have successfully carried out the project to the end. And that's exactly what we want and what our customers value.

**Were there any difficulties with data management (time recording, absences, quality of the planning...) If so, how did you deal with this and do you have a recipe for success?**

I think the recipe for success is continuity and perseverance. You have to take yourself out of the daily routine and be persistent if you want to move something forward, even if things do not move as quickly as you would like. For us progress was sometimes slow due to a lack of resources and personnel changes. In addition, the change away from paper-based studies to studies conducted with electronic systems was also a factor. As a result of this change, for a long time we had the problem that the heads of department and the management were overloaded and the other staff could not keep up. So if you like, we didn't so much have growing pains with Blue Ant, but had to contend with the requirements of digitization. I learned that you have to have patience and have to carry on stubbornly, even if you cannot necessarily press on with internal projects.

**How has using the software changed your project work?**

It has changed in so far as we can now immediately access the important information we need for our project work. We know the status of the project, how busy which resources are, and how much work is going into the project. We also like to plan projects with virtual resources and look at the implications for the project. Of course, we also planned before, but we always had to laboriously gather all the information. Now we know the project status in each project phase, and so we can calculate more soundly and realistically. By using final evaluations, we know exactly whether we were right with the preliminary cost estimate. If so, we were able to make our customers

happy by providing realistic calculations. Stable budgets are of great value for every project.

**Which "Dos and Don'ts" would you recommend for the implementation?**

The employees who will operate the system in the future should be brought on board at an early stage. I would recommend a kind of brainstorming session prior to the introduction, to clarify what the plan is, what you want to achieve, and how a system could contribute to implementing the wishes and goals. For example, we talked about difficulties in their daily work (documentation, planning ...). It is important, I think, that there is an open atmosphere which allows the staff room for their own ideas, wishes and fears. You can then easily draw conclusions from the results of brainstorming. You know about the needs in the various departments and can then look at the next stage; which provider facilitates the implementation of the requirements intelligently and efficiently leading to high employee satisfaction. If the staff are not on board from the start, the best project management software is useless, regardless of what it can do. I consider being involved in the decision-making process to be a very important point.

**Many thanks for talking to us, Ms Frau Atarodi.**