

What Makes one Project Successful and another Stressful?

Colin Andrew Brown, Hearthought Enterprises Ltd, Totnes, Devon, U.K.

ABSTRACT

In an intense 18 months experience of leading a group of e-Submission (e-Sub) specialists supporting over twenty NDA's, it became obvious which project teams worked successfully together and which were struggling to deliver and why. It had nothing to do with their ability to stick to standard procedures or the complexity of the submission taking place. This paper will reveal what was the secret of the successful teams, how projects effectively managed to deliver their NDAs, even under extreme circumstances, why it works and how you can do the same on your project. A personal viewpoint.

INTRODUCTION

The wonderful thing about e-Sub work is that it shows humanity at its best. e-Subs occur at the very last moment before a drug is submitted to the FDA for marketing approval. It is a vital process, to prepare the data and documents to a standard so the FDA can quickly review and analyze the clinical data used to support the marketing application. According to Forbes Magazine (August 14th 2013) pharmaceutical companies now spend an average of five billion dollars in drug development for every drug brought for marketing. With five billion to reap back, the pressure to make sure the drug is on the market as soon as possible and not delayed, is tremendous. Every day, quite literally, counts.

For drug development teams, performing a relatively new task, such as e-Sub, can seem like an unnecessary burden. It is a one off task, which occurs at the end of the drug development process and by its nature, it is something which not many people have experience in- not everyone has repeated experience of performing a New Drug Application to the FDA. Therefore it makes sense to have a separate team, which performs this task. This is what was setup. It covered a variety of submissions, from a few datasets to about thirty gigabytes of data and programs. The e-Sub team was based in a CRO in India and served the sites of the pharmaceutical company in U.K., Switzerland, as well as West and East coast U.S.A. From the outset, a wide mixture of working styles and cultures was the basis of the project.

WHAT WORKED WELL?

For the drug development teams working under high pressure, it can be a difficult task to have a brand new group of specialists come and work on your project at the last minute and start to look very closely at your carefully prepared documents, data and programs. In this situation and under this pressure, different teams react differently. Some are as smooth as silk, others as deadly as a kung fu team. Some are friendly, taking the attitude that the new e-Sub team is helping them out with an unwanted task, others are reluctant to engage in the necessary processes, communication and learning which a new task and team brings with it.

So who did better? After working with several teams it became quite clear that the teams which performed effectively at this critical moment, were the teams which were already functioning well together. Some of these teams were very experienced in clinical drug development, others were not. Their experience did not make any difference in how well they performed. Their ability to function well together as a team was what made the difference in coping with the high stress situation they were in.

Things go wrong all the time. And in this moment of going wrong this is where the true strength of the team lies. Do they come together and quickly cope with the issues that have arisen or do they start wasting time and energy in high emotional discussions amongst themselves?

One particular project will serve as an example to illustrate what happened. This project had a leader who had no experience in the e-Sub process and was about to do an NDA using some studies, which had serious technical problems with them. The project leader initiated the meeting with the e-Sub team asking for help, guidance and training saying that none of them had a clue what they were doing in the process. This provided clarity and openness from the first interaction onwards. At the first e-Sub training, all the relevant drug project team members were brought together and time was deliberately allowed for a discussion afterwards. This discussion between all the people involved took several hours and solved some of the biggest technical difficulties the team was likely to face. Following on from this every interaction with that team went very smoothly. A sense of trust and fair play was built between all involved. When problems did arise it was obvious that the project leader was very good at getting input from various project participants and in doing so quickly finding the best solution to the problem. At first this did not seem very efficient. Meetings went on for longer and the

Paper PD01

discussion was broader. When tasks were assigned however they were quickly and easily achieved. The majority of the stress was taken out of the situation, as there was a clear understanding that the team was quite capable of performing their respective tasks on time.

What made the difference was in the small ways how people reacted together. They showed appreciation of each other. If you are already highly stressed and you just want to get the job done it can be very difficult to allow talking and discussion to meander on. The project leaders of the successful projects were very good at asking the opinions of a large variety of members of their project not just the more experienced ones. In this way the quiet introverted programmers who might not normally say much at a meeting could bring their ideas to the table, ideas, which often led to an easy solution to the issue at hand. What was also obvious is that these projects were used to working this way. The younger less experienced programmers were not surprised at being asked for their input and were clearly aware that they could achieve a big influence on the project.

At first this seemed quite astonishing to me. After over twenty years in this industry I had expected that those who had most experience and who were used to quickly structuring their work would come up with the most efficient ways of solving the task at hand. Over the years we have got used to having more and more standard operating procedures developed and evolved, so that the processes we use to create and analyze data are becoming more and more refined. Surely this leads to greatest efficiency, learning from experience and changing processes when your issues occur?

However the negative side of having so many processes carefully defined, is that the creativity needed to find new solutions can become suffocated, along with the human-human interaction. Those projects which came through the e-Sub process with the least amount of stress, where the projects that were constantly looking for creative input from all members of their teams regardless of the roles which they played. What was also clear was that this openness and creativity from the drug development team also had an effect on the e-Sub team. The e-Sub team was happier to work with the creative drug development teams and were more willing to put in the additional hours which ensured that the project timelines were kept.

So the effective drug development teams not only worked well together by their example, they also helped create a better working environment in those groups working with them. This was in strong contrast to other teams who looked very closely at the standard operating procedures (SOP) involved and if anything went wrong they would start arguing about why a standard operating procedure was not clear enough and who was to blame for the mishap. While this is understandable for teams working under such pressure, it was not effective and ensured that everyone started working defensively. The typical responses were:

- Concentrate as a group to find an interim solution to the problem, then address the SOP later
- Blame the SOP
- Blame individuals

Blaming processes or individuals is a downhill process not focused on the task in hand. Getting an interim solution in place and ensuring good ideas are later addressed in the SOP is doubly effective, working for the present as well as assisting future teams.

The conclusion I drew from working with different projects, is that those teams which work well together and have the best functioning relationships and obvious appreciation of each other was the deciding factor in being able to understand how well a team would get through the submission process. The ability to function well in a high stress situation is therefore created long before the stress situation is encountered.

The stunning factor was that the way the team worked together was more important than the technical knowledge and experience of a team in deciding how well they came through the e-Sub process and the NDA delivery.

WHAT DOES THE SCIENCE SAY?

So good friendly relationships rather than logical experienced programmers make the best teams? This was so surprising it obviously needed further investigation.

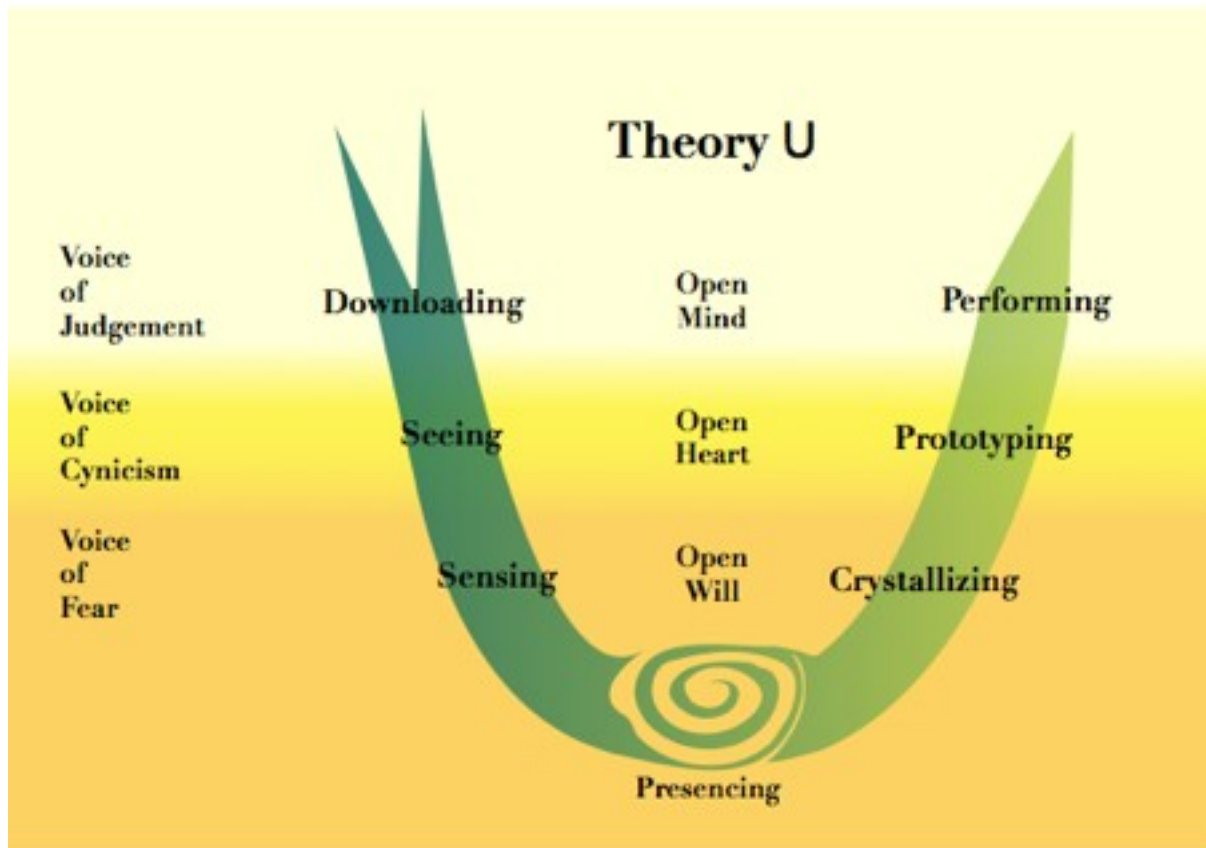
There is plenty of evidence that good relationships and appreciation have a direct positive physiological effect¹. Not only are vital signs improved (lowering of heart rate, systolic and diastolic blood pressures) but increasing amounts of oxytocin are measured in an appreciated environment. This hormone helps in creating a more social environment. Positive relationships also healthily affect immune system response².

In this work place this can also be seen. Positive relationships help people get back up from negative experiences³.

It is this creation of an appreciated environment, which has a direct effect on physical well-being and obviously mental and emotional wellbeing as well.

THEORY U

What also is enabled, is a more creative working environment. By lowering the fear of failure in the project and creating a better, more co-operative working environment, some of the fundamental requirements for creating an innovative working group are achieved⁴. Theory U gives three stages to getting a project to a place of intense creativity. One of these is called Sensing, creating a fine cohesive group-working atmosphere. It was this, which the successful projects were clearly demonstrating, overcoming the fear of failure and delay in the submission situation.



To recap the basics from a previous PhUSE paper (see link below), Theory U has three points leading to a creative environment:

- "Downloading"- know your area of expertise.
- "Seeing"- be open to something new.
- "Sensing"- be willing to sacrifice your expectations for the good of the project.

It is this third part which is addressed in this paper. Often it is the hardest part of the U-process to establish, as there are no easy guidelines for deciding right and wrong ways of the process.

WHEN THINGS DO NOT GO WELL, HOW DO YOU REACT?

So when things go wrong, how do you react? Your reaction is not just in the things you do and the actions you bring into motion but also your manner. Are you showing stress, or are you showing optimism, despite whatever negative noise is playing in your head. An air of optimism under stress can make the difference between success and hardship.

WHAT CAN YOU DO?

INFLUENCING YOUR ENVIRONMENT

What the e-Sub project demonstrated was that the culture of a project clearly affected the other groups they worked with. If a drug project team functioned well, it was easy for the e-Sub team to function well with them, and vice versa, if a project

Paper PD01

team functioned badly, the e-Sub team would have difficulty interacting positively with them. So how a project team functions affects not only them but all the other groups who interact with them.

So how do you influence those other teams in a positive fashion? From the e-Sub experience several guidelines can be extracted:

- Do you know how the person delivering to you works? Do you know what is difficult for them and what is easy? A key to being able to be highly productive in a complex environment is to take the time to understand those around you. Do you have an understanding of the processes the person who is delivering an input to you has? You do not need to know the full complexities of what they do, but a rough overview can work wonders.
- Can you adjust your requirements accordingly? If not, can you warn them when the difficult requirements are needed?
Here is where your knowledge can really help. If you have an understanding of the complexities involved, can you adjust your requirements to make it easier for those working close to you? If you still need full requirements, can you at least warn them?
- Can you show appreciation for their efforts? Such attitudes work wonders- changing an “us” and “them” situation in to a “we”.
- Can you “Step In” to their shoes? Can you look at the world for a moment from someone else’s perspective and appreciate their situation?
- Can the people you deliver to do the same for you, can they also step into your shoes? Have you got into the situation where the people working closest to you can also appreciate your position?

APPRECIATION

There are many ways of demonstrating appreciation for someone’s skills and bearing. The simplest is to thank people, either privately, in groups or in a more public environment, such as a large departmental meeting. Be aware of what people like- some hate to be mentioned in public and would much prefer a quiet word in private. Also be prepared to show appreciation at non-goal moments, so that appreciation is not just felt at success points. Your fellow workers also will appreciate you spending time with them, freely, for lunch and coffee breaks. At one company I worked for the cafeteria area was always full of managers having discussions, one-on-one with their employees in an informal atmosphere. What can also help but is not so easy in a modern international atmosphere, are small gifts and the huge value of touch. A simple coffee or snack at the right time can be really effective.

CONCLUSIONS

As I began this paper I thought I only had a personal viewpoint of a small set of projects that I had worked with. I did not expect that my observations had also been scientifically researched.

Appreciation of your colleagues makes a great deal of difference as to how you get through the most crucial and important parts of your project. A further important aspect as shown in Theory U, is to be willing to make sacrifices to make things work and put the project ahead of your own personal goals. Creating a positive, appreciative, resilient work atmosphere is critical to performing successfully at the key points of the drug delivery process.

REFERENCES

- ¹ Positive Leadership, Kim Cameron, Berrett-Kohler Publishing 2012, P45 – 58.
- ² Sheldon Cohen, William J. Doyle, David P. Skoner, Bruce S. Rabin, Jack M. Gwaltney, Jr (1997) Social Ties and Susceptibility to the Common Cold Journal of the American Medical Association, 277, 1940-1944
- ³ Dutton and Heaphy, The power of high quality connections in Cameron, Dutton and Quinn, Positive Organizational Scholarship, Berrett-Koehler
- ⁴ Theory U- Social Technology for Innovation, PhUSE 2010

ACKNOWLEDGMENTS

Many thanks to Petra Auclair, Christian Mueller, Kiran Bonda and Ryan Finch at Roche, Basel, Nutley and Welwyn, Phuong Dang at Genentech, California and Veena Terekar and Trupti Kadgaonkar TCS Mumbai, India for their support.

RELATED PAPERS

[Theory U- Social Technology for Innovation, PhUSE 2010](#)

[Create Innovation Now, PhUSE 2012.](#)

RECOMMENDED READING

Theory U Leading from the Future as it Emerges The Social Technology of Presencing by Otto Scharmer, SoL, the Society for Organizational Learning.

Positive Leadership: Strategies for extraordinary performance by Kim Cameron, Berrett-Koehler Publishers Inc.

Practicing Positive Leadership: Tools and Techniques which create extraordinary results by Kim Cameron, Berrett-Koehler Publishers Inc.

The 5 Languages of Appreciation in the Workplace by Gary Chapman and Paul White, Northfield Publishing.

CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the author at:

Author Colin Andrew Brown

Company Hearthought Enterprises Ltd

Totnes, Devon, U.K.

Email: colin@hearthought.com

Web: www.hearthought.com