

# [A case study on biotech management essay](https://assignbuster.com/a-case-study-on-biotech-management-essay/)

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## Introduction

Biotech is a biopharmaceutical company developing human monoclonal antibody therapeutics independently and in collaboration with partners. It is a public company based in US with around 600 employees with net assets exceeding $500 million. The company also licenses its technologies for others to develop new medicines. However, the company’s major revenue is from ‘ royalties’ received from a developed drug licensed to large pharmaceutical firms. With reference to the case, Biotech’s expertises mainly in preclinical development and its R&D activities are funded from revenues ensuring self-financing until the demonstration of the effectiveness of the new drug in relative terms.

Biotech 123 (the focal innovation project) is a therapeutic aimed at handling an acute respiratory disease and a potential ‘ blockbuster’ conditional to its success in development. This is a radical new treatment for the inflammatory disease that can change the current practice used in clinics for the treatment of this disease.

## Problems

The problems with Biotech are manifold. But, these problems in the case can be mainly categorized as problems associated with managing knowledge, managing innovation and knowledge sharing. However, when going through the case, I realized that there were more problems in managing knowledge than in managing innovation. The problems in knowledge sharing also seemed to be linked with managing knowledge. Hence, managing knowledge for Biotech was a big challenge that the firm did not think would cause such delays, setback and failure in the innovation of the process and in collaboration with potential partners.

## Managing Innovation

The product is radical although innovative but the whole process and approach for treatment is new. As it was a new product, particles were found in the suspension which indicated that there were problems even at the earlier stage. With reference to the case, Biotech had little experience of conducting and managing clinical trials. So, not surprisingly many doubts and questions were raised as what could be the appropriate number of patients. This reflected Biotech’s lack of experience in Phase 2 clinical trials. With reference to the case, the project manager commented “ you might as well stick your finger in the air as to how many patients you need”. Further, there were difficulties in recruiting sufficient patients which partly linked to the problems in managing innovation and partly with managing knowledge. The chemists took a long time and still could not come to an agreement in identifying the cause of formation of particles. Innovation is rarely an individual activity which implies that for innovation to take place workers should be willing to collaborate with others to create, share and apply knowledge. This willingness is influenced by many contextual factors and is shaped by trust and power relations between workers.

Innovation may be facilitated within communities of practice but radical innovations occur at the interstices across communities and communities of practice play a significant role in the innovation process together with communication (Swan et al., 2002). Communication clearly plays a role in managing innovation and knowledge with the will to bring effective project management, knowledge sharing and management, team management and scientific innovation.

## Managing Knowledge

Biotech faced miscommunication with FDA (Food and Drug Administration), the US regulatory agency which could lead to future problems in managing knowledge, knowledge sharing and interpretation. There were even differences in prioritisation of goals and objectives between chemists and clinical trial teams because chemists did not have the sense of urgency as that of clinicians. So, this clearly showed that there were some knowledge management issues and knowledge gap among teams. The different proposal plans by 4 partners seemed to be at odds with Biotech’s methodology and the plans were not very well developed. With reference to the case, Biotech’s past experience of partners was really bad when the “ partner screwed even after taking a year to get things sorted out” which in consequence led to delays in acquiring a future partner. The deal with a future partner should be finalized before trial and it seemed obvious that risk management sharing was not considered. The partners and project teams were unaware of financial terms of the project and similarly with reference to the case, the tension created due to particles and identifying partners simultaneously drew a chaos. These problems in management of knowledge were also because of lack of trust within Biotech and as well as with its partners. As a result, time was consumed and the clinical trial team was becoming desperate as ‘ a day saved in development was worth $1 million’. There was even lack of information as hospital was not permitted as it did not have the license to carry out the labelling processes. FDA did not give the approval and labelled Biotech as ‘ external’ which again caused delays.

## Knowledge Sharing

There were even problems in knowledge sharing which can be somewhat correlated with issues in knowledge management. The knowledge of partners was limited which consequently led to misinterpretation of data and with reference to the case was solved through the formation of new ‘ satellite’ teams which enabled a better understanding of Biotech product development process. If knowledge is not shared then innovative practical feedback and ideas are not drawn from teams which in turn can lead to a failure of the product or process. In case of a failure, any process or product is subject to end up just like the Sinclair C5 shown in Figure 1 (See Appendix) which became an object of media and popular ridicule leading to a commercial disaster in Britain during 1980s.

A common strategy to transfer knowledge from projects is for teams to capture ‘ lessons learned’ and store these on a database which could easily be accessed. This strategy is widely adopted but such databases are not widely used. But, even with the use of such databases knowledge captured from one project is typically not used as a ‘ tool of knowing’ by others. The knowledge captured may not be useful and project teams could lack awareness of vital knowledge that could be useful to help them improve their processes (Newell et al., 2006). Similarly, in the case of Biotech, problems were faced with ‘ Target’- the knowledge management system because of incompatibility of data with the system. True knowledge management occurs when radical new ways are established to capture, share and leverage the knowledge of the firm’s processes and employees within an organisation, as illustrated in the knowledge sharing lifecycle (Figure 6) .

## Discussion

In my discussion, I am going to focus mainly on the lack of trust, project management and knowledge sharing issues in the case. Trust between partners is central to the effective operation of networks (Newell and Swann, 2000). For example, with reference to the case, Biotech’s chemists decided to solve the particle problem themselves as quoted in the case “ to solve the problem quickly and internally”. Here, internally means within Biotech so that knowledge is not made available to others and consequently not shared because of absence of trust. This lack of trust eliminates collective performance and any ‘ synergy’ that might have brought positive effects. As a result, lack of trust led to lack of co-operation which finally meant absence of control. Considering the classical view which is more of a management position as opposed to Marxist’s view perspective on control, absence of trust and control results in teams having chaos, disorder and uncertainty. With reference to the case, Biotech referred to its initial partner by a codename ‘ Stallion’ to keep the status, deal and name of partner confidential internally and externally so even majority workforce within Biotech did not know the actual identity of ‘ Stallion’ and the financial deals. Although, the project team had significant involvement in negotiations with potential partners, but they themselves knew absolutely nothing about the financial details of the negotiations. This again is a replication of lack of trust within Biotech. Trust binds parties in a relation and there is a belief in the competencies of those involved because of this belief there is a good will among the parties (Sako, 1992). This ensures that the other partner will behave in a ‘ mutually acceptable manner’ (Sako, 1992). The three central mechanisms of trust production are process based, characteristics based and institutional based (Zucker, 1986). In case of institutional based trust, it will allow collaborative work in a healthy environment.

Multi-disciplinary and inter-institutional collaboration is highly desirable as specified by major research funding bodies, especially when innovation is important (Newell and Swann, 2000). Processes and mechanisms that can integrate are vital because they are required for the development of trust between a diverse range of workforce. In case of Biotech, networking among different teams was absent. It can be more helpful to transfer process knowledge about effective ways to create knowledge of current practice which in future could be seen as starting point in attempting to change practice that is being used for past years (Newell et al., 2003). Networking with other organizations is seen to be crucial for the development of new processes, knowledge sharing and for innovation. It was quite possible that Biotech did not have all the relevant expertise inside the firm so in that case developing a network that draws in other pharmaceutical and innovative firms could fill in the gap of knowledge because some knowledge clearly seemed missing (‘ knowledge gap’) that was significant in developing the new radical process and hence, there was a knowing-doing gap seen among the teams of Biotech. This indicates Biotech’s unwillingness to trust other firms or partners. But, at the same time, Biotech being predominantly a knowledge intensive firm not sharing the knowledge with its partners and with reference to the case was not willing to trust its partners to whom future collaboration could mean a lot in terms of profits and sales. Surprisingly, there was even lack of trust within teams as with reference to the literature the project team was completely blank about the financial terms and deals with potential partners and which of these partners was going to be further contacted. If knowledge is shared, knowledge integration is possible and this may be reformulated into a dynamic perspective, recognizing the intergenerational learning benefits that accrue (Lindkvist, 2005). There were even problems with ‘ Target’- the knowledge management system because of incompatibility of data with the system. Although, the introduction of “ Target’ system seemed as an attempt in making knowledge sharing possible and effective, but clinical research organisations had problems relating to inputting information.

Analysing the time, quality and cost model as shown in Figure 2 (See Appendix), we see that a trade off has to be made between the three factors as the triangle works on the principle that as more emphasis is placed on one element, less is placed on the others. So, in the Biotech case, speeding up the development and decreasing time may decrease costs but could damage the quality of the work as evident with reference to case “ less patients meant less costs to Biotech”. On the other hand, with reference to the literature, Biotech was searching for a future partner which should have all the capabilities (financial, legal, tax, market, environment, labour / commercial situation) and enforcing ‘ due diligence’ on its partners which did not seem to go well. In the past, line managers took extra responsibility for their projects (‘ their babies’- as used in case) which led to insufficient delegation. Power for decision making was even given to those in ‘ satellite teams’. Innovation projects involve a range of organisations entering or leaving the project during different stages so psychologically individuals does not see themselves as part of a team / group goals (Newell et al., 2009). Project management has developed as a body of knowledge and practice with organisational change and learning as the ‘ hands and legs’ of the body (Bresnen, 2006). But decentralization with short-term emphasis on project performance and distributed work practices can be important in understanding the shaping and embedding of new management practice (Bresnen et al., 2004).

In the case of biopharmaceutical innovation, it is not simply plan, implement, monitor, control, complete and review. Resources should be controlled within the project parameters and should follow some formal project management process. To cut time and with reference to the case following the motto of a day being saved in development was worth $1 million, Project Management tools could have been used in assisting with planning and managing the project. The WBS (Work Breakdown Structure) or Gantt Charts which can be made either using ‘ Microsoft Excel 2007’ or ‘ Microsoft Office Project 2007’ (See Appendix) are some examples of tools that are ideally used in Project Management. If tasks would have been divided into subtasks, with reference to the literature the problems such as the hospital licensing and the chaos of identifying partner would have been eliminated or would have been solved quickly saving time. Ishikawa ‘ fish-bone diagram’ (See Appendix) is able to illustrate some cause effect relationship so that causes of certain events / problems can be known. Most project management methodologies include practices aimed at exploiting knowledge that was created within a project and consequently organisations have recognized the importance of cross project learning (Newell et al., 2009). But, Biotech did not seem to learn from previous projects and mistakes made in past were repeated and this process of continuing previous mistakes gave almost a look of an ‘ iterative process’.

With reference to the case, the particles problem could have solved quickly by bringing together scientists, clinicians, academics, legal and social scientists just like GKP (Genetic Knowledge Parks) in UK so as to exploit knowledge where the aim is to improve medical practice, even if knowledge needs to be shared (Robertson, 2007). Gradually projects are being deployed as an important form of work organisation, especially where the focus is on developing innovation (Newell et al., 2008).

## Analysis

The only thing that Biotech seemed to do well was an establishment of the sense of urgency in the clinicians which can again be criticized to be linked with monetary returns. With reference to the literature, the senior management introduced a more co-ordinated project team structure to handle all decisions on product development which included the formation of ‘ satellite teams’ and a strategy team called Development Project Team (DPT). Later, with the help of consultant, finally changing the project matrix structure brought better results for Biotech. An overall analysis of Biotech’s ability to manage knowledge and innovation shows that the two are not mutually exclusive. In layman terms, two events are mutually exclusive if they cannot occur at the same time. That is if knowledge cannot be managed so as innovation or if knowledge can be managed so as innovation. But, an underlying assumption that if firms are going to successfully innovate then they need to manage knowledge effectively goes side by side in Biotech’s case when innovation has occurred but is not successful (particle problem) because knowledge was not handled effectively. My discussion and analysis showed Biotech had more problems in managing knowledge than in managing innovation. Even the problems associated with knowledge sharing were fully or partly linked with knowledge management issues in the case. The issues of trust, knowledge sharing and project management can be said to form a chain such that with reference to the case there was lack of trust among partners and teams at the early stage of the project. The problems got aggravated and even worse when knowledge was kept within the firm (Biotech) and knowledge was not shared among project teams and partners. This eventually led to delays in managing the project and formation of teams was even ambiguous with no clear roles. It was just like a ‘ chain reaction’ as when one end was triggered or lit, the fire spread drastically and quickly as the problem increased gradually. The fire (in this case the problem) was finally sorted out with the formation of ‘ satellite teams’ with the introduction of new co-ordinated project matrix structure which was brought about by external consultant, the chair of DPT (Development Project Team).

## Conclusion

The knowledge is tacit as the knowledge of Biotech cannot be codified and developed as a result of experience because had it been explicit for any reason, it would have been readily codified and communicated to others. From the case, we see that the assumption if firms are going to successfully innovate then they need to manage and share knowledge effectively holds true.

Biotech had to pay a significant price for this mistake as the particle problem was although solved at the end of research, but negotiations with the partner were cancelled. This in future could mean a potential licensing problem for the therapeutic or in the worst case if favourable results were not obtained in continuation of the trial.

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