Exploring Trust and Commitment in Inter-firm Relationships when Outsourcing R&D
A Qualitative Study of Pharmaceutical Firms and Clinical Research Organizations

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ABSTRACT
The Swedish pharmaceutical industry is going through structural changes due to the increased cost of drug development. This has led pharmaceutical firms to outsource clinical trials to Clinical Research Organisations (CRO). This thesis explores the inter-firm relationships between pharmaceutical firms and CROs in the Stockholm area, with focus on the development of trust and commitment. The empirical material gathered from nine qualitative interviews with representatives from both parties suggests that trust and commitment are both important factors. Trust is based on competence and reputation whilst commitment is developed through communication. Commitment is highly valued by the companies that wished to develop long-term relationships. The results also point to challenges in the area mainly regarding patient recruitment that due to the high competition amongst the CROs can lead to opportunism when they are overly optimistic of what they can deliver. This is an issue that needs to be addressed as it affects the whole industry.

Keywords: Outsourcing, Inter-firm Relationship, Trust, Commitment, Opportunism, Pharmaceutical industry, Clinical Research Organisations (CRO).
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Adapting to Structural Changes in the Pharmaceutical Industry

At the beginning of industrialization, control over the market was held by manufacturers in the form of supplier power. Since then the market development has lead to a shift in power, and today it lies mostly with the consumer. (Kucuk and Krishnamurthy, 2007.) This has affected companies to adjust aspects such as improving their speed to market (McNally, 2011). In order to accomplish this, companies have become more effective and often refine their core competences. This has enabled non-core activities to be outsourced, and eventually also core activities such as Research and Development (R&D) (Quinn, 1999). One industry that is affected by the changing market landscape is the pharmaceutical industry (KPMG, 2011).

The global pharmaceutical industry is characterized by constant change due to the endless need to adapt to external and internal challenges. Patents that have long been at the core of the business success for many companies are now expiring, making it possible for competing firms to manufacture almost identical drugs without having to pay the price of R&D. The anticipated loss from patents for pharmaceutical companies in 2009-2014 is estimated to USD 78 billion. Shrinking profits and increased competition coupled with growing regulatory pressure are issues that all market players deal with. (KPMG, 2011.) Developing a new drug is a long and expensive quest; it usually takes between 10-15 years and costs on average USD 1.3 billion, with no financial gain before the finalized drug reaches the market (Boehringer Ingelheim Website, 2013). Over the last 10 years there has been a 20 per cent decline in drugs reaching the market, whilst at the same time R&D expenditure has increased by 60 per cent (KPMG, 2011).

"You now get less and less drugs for a higher price"
– (Interview respondent)

These issues, together with the fact that the average period of market exclusivity for new drugs has fallen to less than two years has forced the industry to find new ways of lowering costs, increasing flexibility and speeding up time to market (Lowman, et al, 2011). The industry has responded to these changes by increased consolidation through mergers, acquisitions and joint ventures. Partnerships have increased and collaborations are now something firms deliberately focus on developing. (KPMG, 2011.) One way of collaborating is through outsourcing research and development to Clinical Research Organizations (CRO) (Lowman et al., 2012). CROs are third-party niche organizations that perform research projects at different stages of the drug discovery process (Piachaud 2002). In 2002 10 per cent of global R&D was represented by CROs (Lowman et al., 2012). In Sweden the CRO industry developed during the 1990’s and in 2011 they were involved in 60 per cent of all clinical trials (Life Science Sweden, 2013). When
cooperating with a CRO, the pharmaceutical company can outsource everything in a clinical trial except for accountability (Interview respondent).

**Cooperation Between Pharmaceutical Firms and CROs**

The CROs and pharmaceutical firms complement each other well as the pharmaceutical firms possess assets that are required to complete the pipeline for the research and development of new drugs. The CROs on the other hand, have specialized knowledge and modern technologies that the pharmaceutical companies need in order to sustain their competitive edge. This has led to a variety of inter-firm relations with outsourcing as one alternative to gain access to the external knowledge needed. (Nigro et al, 2012.) When outsourcing research in the pharmaceutical industry there are many regulatory constraints and controls that the companies by law have to take into account. The regulatory control can consists of such things as verification and traceability of research; trials and test results throughout the drug development cycle is very important. (Howell et al, 2008.) The inter-firm collaborations can come in many forms and is a phenomenon that has grown over the last few decades. The fail-rate of inter-firm collaborations is however high and it is often the lack of trust from both parties that is the cause of failure. (Nicolaou et al, 2011.) This lack of trust can arise from a partner acting opportunistically. Opportunism is defined as “One who takes advantage of opportunities with little regards for principals and consequences” (The Free Dictionary, 2013). Opportunism together with information asymmetry is in this thesis investigated to learn how they affect the creation of trust and development in the inter-firm relationship, when outsourcing R&D. These different aspects bring us to the following research question.

**Research Question**

*How is trust and commitment developed in inter-firm relationships between pharmaceutical firms and Clinical Research Organizations?*

**Previous Research**

Researchers in the field of outsourcing have claimed that more empirical research needs to be conducted on inter-firm relationships between buyers and suppliers (Espino-Rodriguez and Padron-Robiana, 2006). Previous research has primarily focused on traditional hierarchical organizations, leaving a gap dealing with inter-firm relationships characterized by asymmetry, especially from the perspective of the supplier. Researchers have also called for more research in general regarding CROs, as this phenomenon is quite unexplored. (Donada and Nogachevsky, 2006.) In our literature search we have not found much written on relationships between pharmaceutical firms and CROs in Sweden. We hope to add to the growing body of research in
this field with a Swedish perspective by looking at the Uppsala-Stockholm Life Science cluster of pharmaceutical firms and CROs. A cluster is defined as an agglomeration of related industries that can host and create industrial and societal development (Waluszewski, 2004, p. 126). The Uppsala-Stockholm Life Science cluster was chosen as appropriate for our study because it is the leading life science cluster in Scandinavia; within the cluster there are six universities, three university hospitals, more than 500 companies and 20 000 employees. (Uppsala Kommun website, 2013). Because there are many players in this limited geographic area the market is characterized by high competition which is also an interesting aspect, especially as it could place more pressure on the inter-firm relationships to be successful. By interviewing key representatives from both pharmaceutical firms and CROs that have personally been involved in an inter-firm relationship we aim to gain a deeper knowledge of the chosen phenomenon. When researching inter-firm relationships network-theory can also be an aspect of interest, however this perspective will not be discussed in this thesis.

**Purpose**

This thesis aims to explore the phenomenon of outsourcing Research and Development in the Swedish pharmaceutical industry. In particular we explore trust and commitment in the inter-firm relationship between pharmaceutical firms and Clinical Research Organisations.

**Industry Background**

We wish to give a brief background of the drug development process, in order to ease the understanding of the terminology used in this thesis.

Creating a new pharmaceutical drug is a long and complicated process. The research stage consists of identifying different drug candidates and active substances that are appropriate to help battle or prevent a certain medical condition. This initial phase is followed by preclinical development of the substance, which consists of testing how the substance affects the body, what an appropriate dosage is, and what the possible side effects are. When this preclinical phase is complete the clinical trial can begin which primarily consists of three phases and involves testing the drug on humans. Phase I consists of testing the drug on a small number of healthy volunteers during a limited time with the aim to learn how much of the drug is absorbed and if there are any major side effects. Phase II consists of testing on a larger group that suffer from the disease that the drug is developed for. This phase aims at evaluating the effect of the drug and decides on optimal dosage. Phase III involves testing the drug on an even larger group of patients, and aims at evaluating the effectiveness of the drug in comparison to an already existing drug or against a
placebo. It is the clinics that identify and contact suitable patients for the clinical trials. If positive results can be proved in phase III the drug can be submitted for registration. (Fass Website, 2013.)
Theoretical Framework

The theoretical framework is based on why R&D is outsourced and the inter-firm relationships that it implies. The framework explores the development of inter-firm relationship based on trust and commitment, as these are the two key components that build relationship capital. It also looks into the factors of opportunism and information asymmetry, which are identified as risks against the development of trust and commitment.

Outsourcing R&D

Outsourcing as a concept was to begin with seen as a way to cut costs by offshoring production (Rilla and Squicciarini, 2011). However, in the knowledge-based economy outsourcing is not seen as a short-term solution. Outsourcing yields more value for companies when it is used for longer-term knowledge-based systems or strategic benefits. (Quinn, 1999.) By allowing companies with expertise in a certain area to perform the job rather than having the work done in-house, companies are both cutting costs but also adding shareholder value by using knowledge that the company in question does not have in-house (Grimpe and Kaiser, 2010; Lowman et al., 2012). Knowledge-based outsourcing, such as R&D, presents different issues than traditional outsourcing (Quinn, 1999). The provider of the service will usually have more knowledge in the area than the buying firm, meaning that the buyer cannot give direct orders or specify exact outcomes and therefore the cost is hard to control (Howell et al., 2008).

One strategy the firm can use is to focus on a few capabilities that add value to the customer as well as to constantly be innovative in order to stay ahead of competition. The core competence of these companies is to develop a small amount of intellectually based knowledge activities that are the most important to the customer. (Quinn, 1999.) The company must therefore analyse their value chain, determine their most valuable capability as well as integrate outsourcing to be part of the company's overall strategy (McIvor, 2000). This allows the organization to be flexible in order to deal with changing competition and is a way to leverage their resources and investments in others (Lowman et al. 2012). By using this type of outsourcing the organization can become more flat and flexible by removing fixed overhead costs (Quinn, 1999).

If a firm chooses to outsource R&D or not, is according to Steensma and Corley (2001) dependent on the managerial risk preference of the firm. If the firm can accept losing control, outsourcing can be an option according to the authors. Risk in this type of relationship commonly arises from financial risks, an opportunistic partner and information asymmetry (Lui and Ngo, 2004). A financial risk for the partners can be the fact that one firm’s problems concerning budget,
responsibilities and investments will affect the other firm as well. This leads them to be interested in all aspects of the partner firm. A firm involved in a relationship might even have their own financial position in the market affected by the partner’s financial situation. (Tomkins, 2001.) Opportunism and information asymmetry are discussed in more detail below because they can affect the development of trust and commitment between firms in a relationship.

**Building Relationship Capital**
To create a successful inter-firm relationship, relationship capital needs to be created and managed. Relationship capital can be defined as the relationship quality between two actors in a social setting and encompasses the socio-physical relationship aspects. It is expressed through the pattern of interaction between the parties and facilitates that day-to-day functions run efficiently. Relationship capital is made up of two main components, trust and commitment. (Cullen et al., 2000.) These two components encourage the partners to resist attractive short-term alternatives in favour of the long-term benefits of staying with the same partner. Partners that have these two components are also more likely to view potential high-risk actions as being sensible as they believe their partner will not act opportunistically. (Morgan and Hunt, 1994.) When the partnership has both commitment and trust it can produce outcomes that promote efficiency, productivity and effectiveness according to Morgan and Hunt (1994). They also argue that trust is seen as the cornerstone of the relationship, this because a relationship characterised by trust is so highly valued that the parties will want to develop commitment to it.

**Trust**
To trust someone allows us to act as if the uncertainty we face is reduced, without it actually being reduced. Trust implies adopting a belief without having all the information. (Tomkins, 2001.) Trusting a partner firm implies having confidence in their honesty and that they will be sensitive and responsive to the needs of the focal firm (Geyskens et al., 1996).

Trust is a concept that has been researched widely and is considered an important aspect to take into account as it is a way to reduce opportunism (Nicolaou et al, 2011), this as trust is negatively related to the calculation of perceived risk (Lui and Ngo, 2004). The definition of trust ranges from economically to socially based, where the economic view of trust is based on a cost-benefit analysis where the other party is expected to cooperate as it is in their best interest. Management literature is more focused towards socially based trust, meaning that the other party is expected not to exploit other’s vulnerabilities. (Nicolaou et al, 2011.) Das and Teng (2001) develop the definition further by separating trust in the partner’s ability to perform and the intention of performing. This means that there is a difference if you trust the other party’s competence or their
goodwill (Nicolaou et al, 2011). There are different forms of trust that will be discussed below, but common for them is that the initial cost of developing trust is high, but over time trust is more effective than contracts as they will require revision for every transaction (Lui and Ngo, 2004).

When managing outsourcing, three definitions of trust become most relevant; contractual trust, competence trust and goodwill trust. **Contractual trust** is based on the assumption that the other party will own up to what is promised and is built on moral standards of honesty (Langfield-Smith and Smith, 2003). Contractual trust can also be defined as respect for verbal or written agreements (Donada and Nogatchewsky, 2006). **Competence trust** concerns the perception or belief of another party’s skill or ability to fulfil their role and deliver to a set standard (Langfield-Smith and Smith, 2003; Donada and Nogatchewsky, 2006). In order to minimize this risk the partner’s resources or reputation is evaluated (Langfield-Smith and Smith, 2003; Lui and Ngo, 2004). Competence trust is independent from contractual safeguards, as it cannot reduce the risk of opportunism. If the competence trust is broken through the partner being incapable of completing the task, stricter contractual terms will not help solve the issue. Competence trust can also lead to an increased risk of opportunism; if a focal firm is confident in the partner’s competence they might increase the scope of the cooperation locking themselves in and thereby might become exposed to opportunistic behaviour. (Lui and Ngo, 2004.) **Goodwill trust** concerns the belief in the other parties’ intention to perform as agreed, even if there is an interest or opportunity for not living up to the agreement (Langfield-Smith and Smith, 2003; Donada and Nogatchewsky, 2006). Goodwill trust has the ability to reduce the relational risk by increasing confidence in a partner’s willingness to fulfil their responsibility. If there is no goodwill between the partners there will have to be a contractual safeguard instead that will use monitoring to reach the level of confidence that the partners need. (Lui and Ngo, 2004.)

According to Lui and Ngo (2004) trust and contractual safeguard are substitutes and will if used together cancel out the positive perception of the other partner and therefore fail to reduce opportunism. Both competence trust and goodwill trust can be developed through personal consultations and intense communications (Langfield-Smith and Smith, 2003). In a relationship with an external partner trust is needed, as a contract can never stipulate every possible uncertainty. If this is attempted the contract will often become inflexible and monitoring becomes impossible. (Lui and Ngo, 2004.) Depending on the type of trust the parties share, the focal firm will engage in different types of control that are discussed in more detail below.
Control in the Inter-firm Relationship
When a relationship is built on contractual and competence trust both behavioural and output control is used, that focus on direct intervention in the third party’s way of working. Behavioural control focuses on changing the workers behaviour whilst output control focuses on rewarding a specified outcome, however behaviour will also be a part of reaching the wanted output. (Ouchi, 1977.) To apply behavioural control the focal firm will need to have knowledge regarding the means-end relationship; when using output control supervisors must know what input will lead to a certain output. How behavioural control is used will vary depending on the situation. In the case of knowledge creation, monitoring the behaviour of the employees will not lead to the wanted output. When using output control there must be a reliable and valid measure of the desired output. For example, in a factory the managers can sample the output but ignore the behaviour of the workers. (Ouchi, 1977.) The control mechanisms in use are for example rigid performance targets, detailed rules of behaviour and detailed contracts (Langfield-Smith and Smith, 2003).

To develop competence and goodwill trust in a relationship a series of control devices can be applied such as regular personal contacts, intense communications and an attitude of commitment. The forms of control that could be used are outcome controls and social controls that would be allowed to develop over time. (Langfield-Smith and Smith, 2003.) Outcome control is appropriate to use when task programmability decreases meaning that behaviour cannot be controlled. To implement outcome control goals needs to be clearly stated to enable measurements of the control mechanism. (Eisenhardt, 1985.) Social control is defined as the enforcement of conformity upon its members either by law or social pressure (The Free Dictionary, 2013). Other control mechanisms could include broad, non-specific contracts, assessing performance through broad and evolving standards as well as a high level of information sharing and communication (Langfield-Smith and Smith, 2003).

Commitment
Commitment is the other component of relationship capital. Commitment is defined as an exchange partner believing that an on-going relationship with another is so important as to warrant maximum efforts at maintaining it, the parties believe that the relationship is worth working on to ensure that it endures. Commitment in this type of relationship can be built on both a social and economic base, (Morgan and Hunt, 1994) and is argued to be the most important factor when understanding the performance of inter-firm relationships, and that cooperative behaviour is a result of a firm’s commitment (Liu et al., 2010).
Attitudinal and Calculative Commitment

There are many forms of commitment. The two forms that this thesis will focus on are calculative commitment and attitudinal commitment. The reason for this distinction is due to previous research that have judged calculative and attitudinal commitment as seemingly most important as they appear often in the literature and are relevant when studying inter-firm relationships (Geyskens et al., 1996), which suits the purpose of this paper. Both of these forms can be described as psychological states that are founded on rather stable beliefs that both parties share about the relationship, and are developed through interaction. However, what differentiate these two forms of commitment are the motivations behind them. (Geyskens et al., 1996.)

Calculative commitment is of instrumental nature and represents the economic base. It encompasses the business intention of the relationship and is driven by the potential of future economic rewards, expectations and evaluations. (Cullen et al., 2000.) This type of commitment can also be described as the degree to which the different partners in an inter-firm relationship need each other (Geyskens et al., 1996). Calculative commitment also realizes the potential costs of leaving the relationship and entails a constant rational evaluation of the gains and costs of staying in the relationship (Liu et al., 2010), meaning that calculative commitment is directly connected to the factor termination cost. Termination costs are all the expected losses from an ended partnership, both in situations where there is a perceived lack of comparable potential alternative partners and where there is a switching cost for replacing a partner. These expected costs lead to an on-going relationship being viewed as important and therefore commitment is generated. (Morgan and Hunt, 1994.)

Attitudinal commitment is the social base and can be defined as the emotional or affective component, meaning that both parties see the value of the relationship and are willing to nurture and care for its survival and development. (Cullen et al., 2000.) It means having confidence in the relationship, being willing to make short-term sacrifices for the long-term benefit of the relationship, and having a desire to develop a stable relationship. Attitudinal commitment can also be defined as the intention of a party to continue the relationship and also having an expectation of that continuation, and encompasses the affective dimension of the relationship. (Gilliland and Bello, 2002.) Attitudinal commitment also means giving the effort to make the relationship work and even going beyond the contractual agreement (Cullen et al., 2000).

Attitudinal commitment has been found to benefit inter-firm relationships by positively influencing cooperation and financial performance and has also been found to be negatively related to relationship termination and conflict between the parties according to Liu et al., (2010).
They also point out that if there is an imbalance between attitudinal commitment and calculative commitment where calculative is overrepresented, it can cause difficulties in the relationship between a buyer and a supplier. For example, if the supplier is overwhelmingly calculative in their decision-making they might be very short-term focused and therefore terminate the relationship as soon as the expected profits are gained. In such a situation, the buyer might perceive the relationship as being of higher risk and thus express hostility towards the supplier and also lessen the trust of the supplier. This can result in the buyer acting opportunistically when protecting the buying firms’ own interests (Liu et al., 2010). The risk of opportunism can also arise if there is a disproportion of commitment between the parties of the inter-firm relationship (Gundlach et al., 1995).

The duration of a relationship affects the level of commitment in a relationship between a buyer and a supplier and is an important factor in building closeness and stability in the inter-firm relationship. Scholars view the duration of a relationship as having a direct effect on attitudinal commitment and that control; trust and power will change over the course of the relationship. (Liu et al., 2010.)

There are other downsides to commitment that can arise from a very high level of commitment leading to for example a common identity being created (Selnes and Sallis, 2003). This identity can hinder a creative process that is found in more heterogeneous groups, also known as groupthink. The authors argue that this makes the partners less objective, reducing the capacity to question assumptions in the projects. Swink and Zsidisin (2006) argue that firms that pursue high commitment relationships are also at risk of missing opportunities to work with other suppliers that could be superior in areas of innovation and cost management, and could get too attached to a supplier that is not qualified leading to increased costs, quality problems and poor performance. The authors also state that there is a risk of moral hazard involved regarding the supplier not delivering the agreed-upon effort in the project. The risks with high commitment are heightened if the technology that the supplier provides falls outside the buying firm’s competence and also if the supplier’s product or service is critical for the buyer (Swink and Zsidisin, 2006.), two criteria that are common when outsourcing R&D (Quinn, 1999). Swink and Zsidisin (2006) continue to argue that a high level of commitment also leads to high termination costs; it may be difficult to break long-term contracts and having to develop the competence in-house, which in turn can lead to a potential opportunity cost for the buyer.
Information Asymmetry

When outsourcing knowledge information asymmetry can become an issue. The buyer does not have as much knowledge in the specific research area as the provider and is also not able to check the provider’s previous work unless that information is already disclosed. If the information is disclosed that means that other actors can use it, making the knowledge generic. The provider on the other hand does not know the full extent of how the knowledge will be used by the buyer and the value it can create for them. (Howell et al, 2008.) This leads to two problems in the technological exchange between the two parties; the superiority that the provider holds regarding the value of the innovation and the ability for the buyer to invent around the transferred knowledge (Gallini and Wright, 1990).

The asymmetric information where the buyer holds less information can lead to the buyer being reluctant to invest in the technology that the provider is delivering without first receiving some assurance of the profitability of the innovation. The buyer tends not to trust the provider in this area, as there is awareness from the buyer’s side of the tendency the provider has of being overly optimistic about the commercial significance of a licenced innovation, leading them to convey misinformation. (Gallini and Wright, 1990.) Information asymmetry together with opportunism is judged as two important issues that can hinder the development of trust and commitment.

Opportunism in the Inter-firm Relationship

Opportunism is a factor that can cause high-trust relationships to be less effective (Selnes and Sallis, 2003), implying that it is an issue that needs to be dealt with in order for trust and commitment to develop successfully. Williamson who first theorized the concept in 1975 described it as “self-interest seeking with guile” (Williamson, 1979 p. 234). Wathne and Heide (2000) describe guile as lying, stealing, distorting and in other ways misleading. In this view humans are of weak morale and can therefore not be counted on to honour contracts or fixed rules (Wathne and Heide, 2000). They continue to argue that there are two types of opportunistic behaviour, passive and active opportunism. The active opportunism is the one Williamson speaks of and is for example when the buyer exaggerates rival bids to a supplier in order to drive the price down. A passive opportunism is for example when a supplier agrees to a business offer knowing they will not be able to uphold the quality but fails to mention it. (Wathne and Heide, 2000.)

A common but contradicting norm in the relationship is according to Wathne and Heide (2000) the expectation of sharing benefits and burdens equally. There must be a norm in place concerning how the parties share expectations in order for an opportunistic behaviour to occur by
having one of the parties violating the norm (Wathne and Heide, 2000). The threat of opportunism is affected by the characteristics of the transaction, the partner and the relationship (Lui and Ngo, 2004).

Trust and commitment and their connection to opportunism are summarized in table 1 and table 2. In this thesis the factor of information asymmetry is assumed to be present in all relationships and is therefore not specifically mentioned.

**Table 1 Summary of Trust**

<table>
<thead>
<tr>
<th>Trust</th>
<th>Foundation</th>
<th>Type of Control</th>
<th>Opportunism</th>
<th>Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contractual</td>
<td>Perceived contractual trust</td>
<td>Rigid performance targets, detailed contracts, behavioural and output control</td>
<td>Contract limited effect, norms and informal agreements determine opportunism</td>
<td>Comprehensive contract can become inflexible</td>
</tr>
<tr>
<td>Competence</td>
<td>Perceived competence, reputation</td>
<td>Increased scope leading to opportunistic behaviour from the supplier</td>
<td>If competence level is not reached contracts will not solve the issue</td>
<td></td>
</tr>
<tr>
<td>Goodwill</td>
<td>Friendships, prior relations, regular contact</td>
<td>Outcome, Social</td>
<td>Passive opportunism</td>
<td>Together with contractual safeguard opportunism will not be reduced</td>
</tr>
</tbody>
</table>

**Table 2 Summary of Commitment**

<table>
<thead>
<tr>
<th>Commitment</th>
<th>Foundation</th>
<th>Expression</th>
<th>Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attitudinal</td>
<td>Socially based Of emotional nature</td>
<td>Intent to continue Going beyond agreement</td>
<td>Disproportionate commitment can lead to opportunism by the least committed party</td>
</tr>
<tr>
<td>Calculative</td>
<td>Economically based Of instrumental nature</td>
<td>Calculating potential future rewards Calculating cost of leaving</td>
<td>High calculative commitment can lead to short-term focus</td>
</tr>
</tbody>
</table>
Summary of the Theoretical Framework

Relationship capital, which is based on trust and commitment, is the quality between two actors in a social setting and concerns the socio-physical relationship aspects. Relationship capital encourages the partners to resist short-term alternatives that are attractive in favour of the long-term benefits of staying with the same partner. (Cullen, et al, 2000.) Trust and commitment are important as they can give flexibility to the relationship, as a formal contract can never be written to include all possible scenarios. Partners who do not have trust and commitment might hold back information from each other and could act opportunistically if the chance is given.

Opportunism and information asymmetry are seen as the highest risks in inter-firm relationships. There is passive and active opportunism (Wathne and Heide, 2000), the threat of opportunism in an inter-firm relationship will vary and depends on the transaction, the partner and the relationship (Lui and Ngo, 2004). Opportunism can occur either when engaging in a relationship with a short-term focused partner or when one of the firms becomes too dependent on the other.

Trust is defined as one partner believing the other party will not exploit their vulnerabilities, and can be separated into trust in the partner’s ability to perform and their intention of performing (Nicolaou et al, 2011). There are three types of trust identified in this thesis; contractual, competence and goodwill trust. The different types of trust also lead to different forms of controls being used. Commitment is defined as an exchange partner believing that an on-going relationship with another is so important as to warrant maximum efforts at maintaining it (Morgan and Hunt, 1994). There are two forms of commitment, calculative and attitudinal, but unlike trust they cannot be separated depending on the type of relationship, therefore both types of commitment are used. There are also risks involved with commitment, if a lock-in effect is created the termination cost might become too high leading to the firm being exposed to opportunity costs. When the partnership has both commitment and trust it can produce outcomes that promote efficiency, productivity and effectiveness (Morgan and Hunt, 1994). This theoretical framework builds the base for our empirical study, and the operationalization of this theory will be discussed next in our methodology chapter.
Methodology

This section will describe our methodology and research design, and motivate the choices we have made with regards to both the strengths and weaknesses of the chosen method. We will elaborate on data collection through interviewing and the sampling process. Finally, the issue of quality, validity and research ethics will be discussed.

The Chosen Research Design
This thesis aims to explore the phenomenon of outsourcing Research and Development in the Swedish pharmaceutical industry, and in particular we aim to explore trust and commitment in the relationship between pharmaceutical firms and their CRO suppliers. The exploratory approach was chosen mainly because the research field of inter-firm relationships is in need of more attention (Espino-Rodriguez and Padron-Robiana 2006) and especially the perspective of the supplier in these relationships (Donada and Nogachevsky, 2006). It is also appropriate because we were not certain as to what results we would find, which is in line with the recommendations of Saunders et al. (2009, p.139).

In regards to our research question and the exploratory nature of our purpose we chose to collect data through interviews, which is presented by Saunders et al., (2009, p 139) as appropriate when conducting this type of study. Semi-structured interviews were conducted with representatives from both pharmaceutical firms and CROs. Because of the risk of discussing sensitive subjects, many companies did not wish for us to speak to their partner company, so for this reason the interviews are independent of each other. This means that the pharmaceutical firms and CROs in the study have no relation to each other that we are aware of. Not interviewing both parties of the same relationship could be judged as a weakness, but for our study we instead see this as a strength because the interviewees might have spoken more freely for precisely this reason. This also enabled the interviewees to speak about several relationships they were engaged in, thus giving us a more complete picture of these relationships in general.

By adopting a qualitative, non-standardized research approach our findings cannot be generalized to the whole population of pharmaceutical firms and CROs in Sweden (Saunders et al 2009, p 328). However, the goal of qualitative data is to understand specific circumstances and situations, which is appropriate for our case. For this reason, it is not a weakness that the knowledge gained through interviewing is situational and conditional. (Dilley, 2004.) The strength of our chosen method is that we can be dynamic in our exploration of this phenomenon (Saunders et al., 2009, p 328), which will let us answer our research question in the most appropriate way.
Sampling
We decided to focus our study on pharmaceutical firms and CRO suppliers in the Stockholm area, primarily because we did not find any theory describing our chosen research topic from a Swedish perspective, and the geographic proximity from Uppsala facilitated interviewing face-to-face. The sample population was made up of a list of participants from a conference in 2010 organized by Life Science Sweden. This is an annual conference that addresses how to choose a suitable partner for successful pharmaceutical development. The participants were representatives of both pharmaceutical firms and CROs and the list contained 46 companies. We judged this as a good population, due to its large size and as the participants of this conference had expressed an interest in inter-firm relationships and outsourcing R&D by attending the conference. We organized the list by company type and omitted those that were no longer in business and organizations without a homepage, which left us with 41 companies, 25 pharmaceutical firms and 16 CROs. We contacted the participants of the conference by e-mail, presenting ourselves, the study and Uppsala University and asked them to take part in our study. We contacted the 25 pharmaceutical companies and received positive replies from three organizations. We are aware that this response rate is quite low. However, we believe that the interviewed pharmaceutical firms give a good indication of the industry in this geographic area, and that they gave us sufficient information to fulfil our exploratory purpose. When contacting the 16 CROs we received positive replies from six companies that we booked interviews with. This has lead our paper to be more focused on the CRO perspective, which as previously mentioned is an area in need of more research (Donada and Nogachevsky, 2006).

Because it was the participants themselves who chose to participate in the study the method used falls under self-selection sampling. Using this approach means that we were not in total control of who would participate, but we had a greater chance of finding participants who were motivated and committed to our research topic. (Saunders et al 2009, p 241.) We are however aware that there is a chance that the companies that wanted to participate mostly had positive accounts of their inter-firm relationships, but this remains a speculation. All interviews lasted approximately an hour.
Table 3 Interviewed Companies

<table>
<thead>
<tr>
<th>Company Name</th>
<th>Interviewee</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>PharmaAlpha</td>
<td>Country Team Manager</td>
<td>Global actor, in Sweden perform phase II-III. Uses CROs for staffing and whole projects</td>
</tr>
<tr>
<td></td>
<td>Clinical Study Unit</td>
<td></td>
</tr>
<tr>
<td>PharmaBravo</td>
<td>Section Manager</td>
<td>Global focus on rare diseases. Uses CROs for whole projects in phase I-III</td>
</tr>
<tr>
<td>PharmaCharlie</td>
<td>CEO, Founder</td>
<td>Small pharmaceutical/biotech firm. Uses CROs for whole value chain and collaborates with a large pharmaceutical company.</td>
</tr>
<tr>
<td>CRODelta</td>
<td>CEO</td>
<td>Many smaller customers in Sweden, can handle whole projects in phase II-IV</td>
</tr>
<tr>
<td>CROEcho</td>
<td>Sales and Service</td>
<td>Smaller projects towards global pharmaceutical. Unique technique in Sweden.</td>
</tr>
<tr>
<td>CROFoxtrot</td>
<td>Vice President</td>
<td>Smaller CRO with many biotech customers.</td>
</tr>
<tr>
<td>CROGolf</td>
<td>Founder</td>
<td>Mid-size Swedish CRO with all Phases for smaller projects.</td>
</tr>
<tr>
<td>CROHotel</td>
<td>Regional Sales Manager</td>
<td>Large Nordic CRO with full service for whole projects and staffing in all phases.</td>
</tr>
<tr>
<td>CROIndia</td>
<td>Project Leader</td>
<td>Independent Clinical Research Support Organization, Phase I-IV, one of two players of its kind in Sweden. The problematic situation with gaining access to patients for clinical trials has given rise to a whole new type of organization that works closely with pharmaceutical firms, CROs and the county council. These types of organizations ease the access to patients and thereby make the clinical trial process more efficient</td>
</tr>
</tbody>
</table>

*Prefix Pharma means pharmaceutical or biotech firm. Prefix CRO means CRO firm.

Data Collection Process and Operationalization of Theory
With our theoretical framework in mind we created our interview themes and questions, which ensured that all questions added value to our investigation. Prior to our interviews, we sent the interviewee information about the topics we wanted to focus on, and we also raised the question of anonymity and if we could record the meeting. By introducing the themes in advance, the interviewee had a chance to think about the topics, but without the ability to answer specific questions beforehand. The themes then lay the foundation for our interview model, which followed a chronological order (see figure 1). We also performed desktop research about the companies consisting of reading information on the company websites, looking up financial data as well as performing media searches. This was done in order to gain a more objective picture of the companies.
The semi-structured model of our interviews gave us the opportunity to probe the interviewee on certain topics that we judged as especially valuable for our study, and we were able to clarify questions that the interviewee did not understand. We also experienced that performing the interviews face-to-face gave us the added possibility of analysing the interviewees’ behaviour and body language, which for example could emphasize the importance of a point. We were aware that body language and tone of voice could also reveal if the interviewee was insecure about a certain topic or if what was said was contradictory to how it was said. Saunders et al. (2009, p 324) emphasizes these advantages as it allows the interviewer to collect very detailed data that is valuable when the aim of the research is exploratory. Through interviewing you gain someone else's perspective and increase your own understanding through their experiences (Dilley, 2004).

When conducting the interviews we used the responsive interviewing model. This approach focuses on understanding the situation of the interviewee through interpreting their experiences and learning how they view their world and their work. By using this method we had to be flexible and adaptive during the interview and analysed the information quickly in order to incorporate this into probing questions, in line with recommendations from Rubin and Rubin (1995, p. 36). Using this method the interview sometimes ended up taking a different direction than we first intended. This was positive as it led to interesting points being raised that we could not have anticipated.

The interviews began with us summarizing the information the interviewee has already received before the interview; consisting of a brief background to the study and how we would handle the information we received. We then began with some “warm-up” questions about the company and the interviewee’s background to create a more relaxed atmosphere. These were questions such as “Please tell us about your background and your role in the company”. The interview then proceeded through a chronological set of themes that were alike for all interviews, however the specific questions did differ from interview to interview as we wanted to be flexible in our questions depending on the information that was revealed.

The interviews with the pharmaceutical firms then proceeded by us asking an open-ended question, such as “Please tell us about the selection process of the CRO”. In this way the interviewee could speak freely about the entire process without us having to ask specific
questions. When appropriate, we asked follow-up questions such as “What were the most important criteria when choosing a CRO?” The questions about the selection process of the CRO and the contract aimed at understanding what factors were important in the choice of a partner company. We wanted to understand what the initial types of trust the pharmaceutical company felt for the CRO when choosing them; if the company developed a contractual, competence or goodwill trust for the CRO. When interviewing the CROs they were asked the same questions but from their perspective, we asked questions such as “which strengths do you emphasize during the selection process?”

Questions regarding our fourth theme of communication and the development of the relationship aimed at understanding if the initial types of trust changed over the course of the relationship, if there were occasions of opportunistic behaviour and what type of communication the companies engaged in. We questioned the interviewees on aspects such as general forms of communication as well as the occurrence of audits and follow-ups on the work progress. We also let the interviewee talk about any problems with communication between the parties and how these issues were solved. We also posed questions on the commitment between the focal firm and the CRO and how this was expressed.

The last theme focused specifically on challenges and centred on the occurrence of opportunism and the risks associated with information asymmetry. Within this theme we also asked questions about termination costs if the relationship were to end and how this would affect the relationship and the project. We posed these questions at the end, as these were the most sensitive, hoping that the interviewee then would feel comfortable enough with us to talk about these issues. We posed open-ended questions such as “what would you describe as the biggest challenge in this relationship” and “what would be the consequences for your company if a relationship were to end?” The interview ended with wrap-up questions and the possibility of adding any additional information of choice. All interview questions can be found in Appendix A.

In an interview situation there is always the risk of the interviewee being affected by the interviewer, known as interview bias. With this in mind we attempted to be as neutral as possible in our body language, tone of voice, and avoided imposing our own beliefs on the interviewee (Saunders et al 2009, p 324). We are also aware that the data we collected was current at the time of collection and that there is a limited chance of replicability if someone were to perform the same study (Saunders et al., 2009 p. 490).
We noticed that during the course of our interviews our skills as interviewers developed, meaning that towards the end of our interview series we were more aware of which specific areas we wanted to focus on and what questions gave the most interesting answers. This led us to focus on mainly phase II in the drug development process when interviewing the CROs as this phase posed the most interesting challenges. This implies that some interviews added more data to our analysis than others. We also noticed that upon completion of our interviews we experienced saturation in information. This was due to the interviewees giving similar or identical answers to our questions. Therefore we are confident that we have collected enough data to build our analysis.

By connecting our questions directly to our theoretical framework we were able to keep discussions on-topic during our interviews and it aided our understanding of the relationships as we could directly map in our answers in our framework to facilitate our analysis. When collecting our data the information was coded and categorized in common themes, based on the theoretical framework, in order to find similarities and differences between the interviewed firms. This was a continuous process in order to secure all data as soon as possible after the interviews. Our theoretical framework was used to structure our analysis, meaning that we adopted mainly a deductive approach in order to categorize our findings (Saunders et al., 2009, p.491).

**Ethical Issues**
Throughout our data collection procedure, we did our utmost to behave ethically and honestly at all times. Already in the initial email contact with the prospect companies we were very clear as to who we were and what our reason was for contacting them. We presented ourselves, the aim of our thesis and what the requirements were for taking part in our study. It was also stated in this initial letter that both the interviewee and the company could be anonymous. Prior to the interview we sent additional information regarding the topics we aimed to discuss, asked for permission to audio record the interview and offered them to contact us beforehand with any additional questions.

At the start of each interview we presented how the data gathered from the interview would be used and when and how the thesis would be published. Because interviewing can be an intrusive experience, we avoided aggressive questioning and informed the interviewee from the start that if the interviewee did not wish to discuss certain topics we completely accepted this. It was the interviewee themselves who decided upon the date and time of the interview and the meetings were held at the company premises in a room of the interviewees’ choice. The measures taken to ensure an ethical behaviour are in line with the suggestions made by Saunders et al. (2009, p. 185-186.)
Interview Findings

The interview findings will begin by looking at the reasons for outsourcing R&D, the challenges in the relationships and then focus on how trust and commitment is developed.

Outsourcing to CROs for Financial Reasons
The pharmaceutical firms that we have interviewed have all stated that the main reason for why they outsource their R&D activities to CROs is financial. Many of our interviewees stressed the point that the industry has transformed in the last decades, making pharmaceutical development very expensive. This has according to PharmaCharlie lead to structural changes in the industry.

Today pharmaceutical firms search the market for interesting therapeutic concepts and substances that they can buy instead of trying to produce them themselves. In this way the companies can choose from a wide range of substances and stay at the forefront of research. This structure also allows flexibility as it gives the firms the possibility to change focus and direction quicker than if they still had R&D in-house, something both PharmaCharlie and CROIndia mentioned. PharmaCharlie mentioned that it was part of their business strategy to outsource everything but their core competence, which was the research and development of a unique substance. This was kept in-house, while all other aspects of the drug creation process was outsourced to CROs. PharmaBravo whose company had previously had R&D in-house agreed with most of these points, but stated that she would have preferred to retain some research, as there are still many advantages of keeping R&D within the premises. The advantage of not outsourcing to CROs was for example that small pre-studies could be made, and the entire work process was much more efficient as work could begin straight away and not be delayed by aspects such as bidding, contract negotiation and establishing new relationships.

Challenges with Patient Recruitment
An issue raised by many of our interviewees is the problem with reaching the number of patients that is required from the pharmaceutical companies side to perform an approved clinical trial in projects regarding phase II-III. According to CROFoxtrot, the problem lies mostly with the clinics. Often the CRO does not have a clear picture of how many patients will be available for the study, making it almost impossible for the CROs to make a correct quotation. This leads to the CROs estimating the number of patients they can recruit based on experience rather than having the data to back it up. CRODelta pointed out the importance of informing the client of the risks with the recruitment as early as possible. As a result of the above-mentioned uncertainties, CRODelta and CROFoxtrot stated that a common method is for the CRO to halve the estimated number of patients that the doctors say they can deliver. This is however according to
CROFoxtrot not good enough as it still leaves room for a lot of uncertainty. They felt that in order to be able to minimize the risk relating to the number of patients they can deliver, a pre-study needs to be made. The study would take time and therefore cost money for the pharmaceutical firm, and as the competition for business between the CROs is fierce CROFoxtrot and CROHotel feel that they cannot risk to add this price of the pre-study in the quotation. CROFoxtrot stated that these costs couldn’t be added to the quotations until all competitors agree to do the same.

“We almost always have to calculate and make quotations based on assumptions that are very uncertain” - CROFoxtrot

When battling this uncertainty it was pointed out by CROFoxtrot that there is a fine balance between informing the client of the risks involved with the project and being too humble as a competitor in the same situation might promise that they can deliver easily. At the same time, promising too much and not being able to deliver is worse as this would reflect badly on the company’s reputation and if the project takes longer than planned because of the CRO not being able to deliver, this cost will have to be covered by the CRO entirely.

Unforeseen Costs in the Projects
An issue raised by CROHotel is that many CROs give one price in their quotation, and then when the project starts running costs are added along the way that were not anticipated by the client. CROGolf explained that this makes the quotation and selection process of CROs even more complicated, as there is no consistency as to if companies quote an actual all-inclusive price or not.

One explanation for why there are hidden costs, as one CROs explained to us, is that the competition in the CRO market is very tough now, leading companies to have redundant staff. This leads the CROs to offer their staff at a lower price or even to a price where they are making a loss. The high competition also leads to a price war which is turn leads to the quality of the staff decreasing as the CROs will not be able to afford doctors and other professionals with as much knowledge. According to the same CRO this situation is something that the pharmaceutical companies are aware of.

One way to reduce risk is through risk sharing. Risk sharing between pharmaceutical firms and CROs is currently under debate and can according to CRODelta entail that the parties share the risk of patient recruitment and other unforeseen costs. Sharing this risk is high on the agenda, as patient recruitment has been identified by many of our interviewees as the biggest risk factor. The
smaller CROs that were interviewed were not as open to shared risks as they said it was not possible for them to share risks with such a large company as a pharmaceutical firm.

**Information Sharing not Seen as a Risk**

The contracts between the pharmaceutical firm and CROs deals with the pharmaceutical firm’s ownership of data and the non-disclosure agreement as well as all the Standard Operating Procedures (SOP), which are the written guidelines that regulate the project. The data ownership and non-disclosure agreements are rigorous in the industry but are not considered an issue as everyone has them, and it is the foundation of any collaboration. PharmaCharlie also pointed out that the industry is so regulated because in the end it is all about the patient’s safety.

When asked about sharing sensitive information the general opinion of our interviewees of all organization types was that this was not a big problem. The pharmaceutical firms felt that they only shared the information that was necessary for the CRO to be able to do their job, and any sensitive information is protected by the non-disclosure agreement. It is the pharmaceutical firm that owns all the data produced by the CRO, meaning that they report all information that is involved in the project meticulously. PharmaBravo mentioned that when they have standardized testing of secret substances the CRO does not really know anything about the study; they just deliver what they are told. When working with CROs on specialized projects more information needs to be shared and discussing the project in more detail with the CRO she saw as both a necessity but also a strength because it is through discussions and partnering that development is moved forward. Sharing information was therefore not seen as a risk but rather a condition for the partnership to work.

Most CROs stated that they knew what the anticipated final result of the drug development process would be as they understood what type of medication their project was a part of creating. They also stated that they were aware of the anticipated market value of the final drug if it were to reach the market. On the other hand, PharmaAlpha told us that they did not share such information with the CROs, as it was not necessary for them to perform their work. It is not seen as an ethical problem by the CROs that they are not 100 per cent informed about the substance they are testing. The CROs interviewed are of the opinion that they have enough information in order to make ethical decisions about the drug they are working on, and this is also secured by an ethical committee that all drugs need to be approved by before testing.
Trust in the Inter-firm Relationship is Crucial

In the selection process between the CRO and the pharmaceutical company the reputation regarding the competence of the CRO is the reason most frequently mentioned. The information regarding the reputation can be gathered from contacts within the industry or through samples that the CRO has of previous work performed. Another reason for selecting a CRO can be that they are the only one with a particular competence that the pharmaceutical company needs. For example, CROEcho offered a standardized data analysis service that is unique for them and one other company, and they have clients from all over the world that send them substances that they in turn produce reports about. In the case of PharmaCharlie, they had discovered a unique substance that attracted investments from a large pharmaceutical company.

In all cases the selection process is a very time consuming activity as there are many visits and documentations to be dealt with. In this process the CROs emphasized the importance of quickly answering any questions the client might have and presenting and matching appropriate project leaders both professionally and personality-wise to the client projects. In general the CROs stressed the importance of giving a trustworthy impression.

Many CROs pointed out that the quotation process is very extensive and can sometimes take up to or over a year according to CROGolf, a period during which the CRO will get paid nothing for their time spent. Common for the majority of CROs is the desire for a paragraph in the contract that allows for the CRO to be flexible in the delivery if something unforeseen were to happen. The contract also controls how and when communication will occur, CROFoxtrot stated that this is often based on a risk assessment that the pharmaceutical company will perform regarding the project.

The challenge with pharmaceutical firms is, according to the CROs, mainly that they have not yet learned that the contracts cannot be as strict as they are today. In clinical trials there is much uncertainty regarding the outcome of the projects, so it would be appropriate if the contracts were a little bit more flexible and realistic according to some of the CROs interviewed. One interviewee said that they often had to "educate" smaller biotech firms that projects rarely proceed exactly as in the contract, and stated that open communication and honesty is the best way to solve these issues. CRODelta also pointed to the fact that all details of the project cannot be foreseen and included in the contract. It is therefore important that the pharmaceutical firm trusts the CROs ability to solve problems when they arise.
“To be able to trust the CRO’s work is very important for the pharmaceutical company as they alone are responsible for the result of the study” – CROHotel

CROEcho spoke of the importance of building up a “goodwill account” with the pharmaceutical companies by for example doing more than what is asked of them. The CRO views goodwill in the relationship as crucial when building long-term relationships that will secure their future income. Goodwill will according to the same interviewee also protect them from the customer leaving if something in the future would go wrong in a project.

Communication Builds Relationships
All interviewees spoke of the importance of good communication to make a relationship work. PharmaCharlie stressed the importance of solid communication not only to make the projects work well, but because it was an absolute necessity in order to secure the safety of the project and the quality of the results. This, he explained is a matter of scientific principle.

“In the end it’s about people’s safety and our image, that we deliver credible results, we will gain from that in the long run” – PharmaCharlie

All interviewees emphasized the importance of having one contact person in each organization to make communication smooth and quick. One risk associated with this was explained by a majority of interviewees that if the organization were to change their contact person it would result in a lot of extra work in training this person to understand the processes in place which takes time and focus from the project.

“It’s very difficult with the CROs, they often change personnel. Then someone new comes along and makes a fuss about everything. And we have to explain everything again” – CROIndia

If the CRO did not know exactly how to do something, the interviewee at PharmaAlpha preferred them informing her of this upfront. She pointed out the importance of honesty from her organization as well; honest two-way communication was the recipe for success according to her. She also stressed communication as one of the main points of evaluation when the project is done, and how the CRO communicated if something unforeseen occurs. Another company, CRODelta, pointed out that when evaluating a project that had not been successful the reason behind it was almost always communication.

According to the CROIndia the most important challenges with the partnership is that the entire process of clinical trials and the cooperation between different parties in these processes is very
rigid. Her opinion is that there are often delays and miscommunications as well as blaming between the parties as to who is responsible for the delay. According to her, the CROs make matters worse as their decision-making processes are usually centralized and individual representatives often do not have the mandate or competence to take decisions quickly.

“There is so much talk about problems at the clinics. But all along, we are ready to go and wondering what you are up to?” - CROIndia

Commitment Builds Long-term Relationships
The CROs speak of both their own commitment and the commitment from the pharmaceutical companies. It is very important for the CROs to show commitment towards the pharmaceutical company, as they want to build long-term relationships. Their view of their own commitment is based on communication and how fast they reply to the customer. They also try to act proactively so that the customer is never surprised, as well as advise them in matters they need help in. They do this as the projects are worth more than just the price, as they want to build long-term relationships with the pharmaceutical companies to improve the chances of future business. CROEcho also mentioned that if they saw something interesting or important during their work that the client had not asked for, they could sometimes investigate it without compensation.

Commitment from the pharmaceutical companies side is shown in the intensity of the communication and how much communication they wish to have with the CRO. Many of the six CROs also point out the higher level of commitment from the smaller biotech companies, as the projects are usually more important for them. They often reply faster and get more involved in the CROs work. At the smaller biotech firms it is often the CEO or some other senior person who is the contact person, which reflects the level of commitment and speeds up the decisions making process according to CROFoxtrot.

The relationship that PharmaCharlie had with their partner company was mutually beneficial; therefore they were both very committed to the relationship. The partner bought the rights to the substance and PharmaCharlie could not have continued the drug development process without the funding from them. This is a big risk-taking for the partner firm, according to him, because they will not earn any money until the finalized drug researches the market. PharmaCharlie were paid based on milestones that were controlled based on them reaching certain predetermined goals.

Another mentioned benefit for the CRO is the knowledge they can obtain through working with the pharmaceutical companies. An example of this is CROFoxtrot that had developed a device for their client. The device was something they had not produced before and the process was
therefore developing for CROFoxtrot. They saw this as a win-win situation for them and the pharmaceutical company as they charged less for developing it because they saw the knowledge as an investment for the future.

If a relationship were to end, the CRO is the partner it affects the most and the termination costs are for example the loss of income and redundancy for the staff. This was exemplified in the interview with CROIndia; she spoke of great termination costs for a competing CRO firm that had become dependent on one large pharmaceutical firm as they were guaranteed all their clinical trials. When the number of outsourced clinical trials dropped dramatically, the CRO had a difficult time gaining new business as they had not been forced to compete before and therefore did not have the experience of maintaining more than one customer.

For the pharmaceutical firms, a termination will mean a delay in the project, as they will have to find a new CRO. However, for the smaller pharmaceutical and biotech firms it can even mean the end as they might have only secured funding for one project. As PharmaCharlie pointed out they are dependent on a series of CROs that all perform one-step each in the supply chain, if one relationship were to break down the whole process would fall apart for the company. They are therefore very committed to the relationship and have built personal relationships to maintain it.

Professional networks is something all of the CROs mentioned as crucial for them to bring in business as everyone in the industry seems to know each other and will ask for recommendations. These professional relationships turned personal for many or our interviewees. People in the industry also tend to change jobs often, especially within the biotech companies as they are often sold to the pharmaceutical companies when their projects reach phase two or three. CROFoxtrot mentioned that they are very keen on building professional and personal relationships because you never know where that person will work next.

The above-presented empirical material will together with our theoretical framework lay the foundation for our analysis in the following chapter.
Analysis

The Development of Outsourcing
The pharmaceutical industry is today very much dependent on the services of CROs, as it has become too expensive to keep all aspects of R&D in-house according to the pharmaceutical firm interviewees. This could mean that today, the decision of outsourcing is not based on managers’ risk preference as suggested by Steensma and Corley (2001), but on a fundamental willingness to survive financially in an industry that through structural development is adapting to a new competitive landscape. Outsourcing as a business strategy mentioned by McIvor (2000) was confirmed in the case of PharmaCharlie, as this company focused solely on the research and development of their unique substance and outsourced all other activities to CROs. This was confirmed by our CRO interviewees as common for smaller pharmaceutical firms and biotech companies. PharmaBravo on the other hand, would prefer to have some R&D in-house, as it is more efficient for them to be able to do certain pre-studies before starting a large project. The tendency to outsource can in our case companies therefore be suggested to be based on a combination of financial factors as well as the specificity of the R&D project in question.

The companies interviewed stated that the reason for outsourcing was mostly due to financial benefits, which is in line with the arguments by Gripme and Kaiser (2010). The organization also has to be flexible to deal with changing competition (Lowman et al 2012), which was exemplified by our interviewees. By outsourcing, the companies are able to search the whole market for a suitable substance rather than having to develop it in-house. This gives the firms the possibility to change focus and direction quicker than if they still had R&D in-house, and at the same time removes fixed overhead costs. (Quinn, 1999)

Opportunism
According to all interviews the competition is intense among the actors present on the Swedish market, resulting in some companies promising more than they can deliver in order to win contracts in long and complicated bidding processes. The opportunism we discovered through our interviews can appropriately be described as the passive kind of opportunism that was defined by Wathne and Heide (2000), which entailed making a business offering when knowing that they will not be able to reach the standards of quality. From our interviews we realized that the biggest risk of this passive opportunism was when the CROs promised a certain number of patients for the clinical trials without a pre-study to support it, as well as presented a budget so low they could not keep it. This confirms Gallini and Wright’s (1990) argument of the tendency the provider has of being overly optimistic, leading them to convey misinformation. Most of our CRO
interviewees said that they themselves always informed the client of the uncertainties with the patient recruitment. However, many said that other CROs in the industry knowingly promise more than they could deliver, and CROGolf pointed out two CROs in our study specifically. Lui and Ngo (2004) state that when the buying company can feel the partner’s short-term behaviour they will in turn tend to act opportunistically when protecting their own interests. CROGolf pointed out that the pharmaceutical firms are aware of this behaviour when it comes to promising too much. However, it has yet not affected the pharmaceutical firms behaviour toward the CROs.

A risk for a lock-in effect was found in one of PharmaCharlie’s relationships. They sold the rights to their unique substance to a large pharmaceutical firm that in return invested money in more research on the substance, which was necessary for PharmaCharlie’s survival. This lock-in effect creates according to Lui and Ngo (2004) a risk of opportunism, as they will become dependent on each other. The interviewee stated that this was the only way for them to get to market with this drug and that both firms were committed for the long run and need each other for the entire drug development process. It can be argued that PharmaCharlie was not at risk of opportunism as the two parties were equally dependent on each other and neither company would benefit from this kind of behaviour. However, the relationship that PharmaCharlie was engaged in was quite rare which could explain the low risks, as overly committed parties are otherwise at risk for opportunism according to Swink and Zsidisin (2006).

Another risk with the lock-in effect as presented by Lui and Ngo (2004), was exemplified in our interview with CROIndia where the dependency between a CRO and a pharmaceutical firm became a liability when the number of projects outsourced decreased radically. The CRO had over the years become passive in building other inter-firm relationships, making it difficult for them to bring in new business.

**Information Asymmetry**

All interviewees do share the same opinion that the non-disclosure agreements and ownership of data is not a problem. The CROs also did not have an issue with not being given all the information from the pharmaceutical firm; in fact they sometimes preferred it. These values go against Howell et al. (2008) who state that knowledge-based outsourcing have problems with the fact that the buyer and provider hold different information. Also Gallini and Wright (1990), argue that there is a risk of conflict or problem between the buyer and supplier in terms of technological exchange, because the supplier knows more about the value of the innovation than the buyer does. Our pharmaceutical firm interviewees did not identify with these risks, and explained that they chose to outsource to the selected firms because they had this specific competence that they
themselves did not. This is therefore not in line with the above mentioned authors, but could be explained by the general uncertainty in the pharmaceutical industry and that investing in uncertain projects is the only way for research to develop successfully, as suggested by PharmaBravo.

To minimize the risks in the relationships and thereby allowing for more cooperation between the CROs and pharmaceuticals, risk sharing is a subject under discussion. This could make Tomkins’s (2001) theory of one firm’s financial position being affected by a partner firm even more relevant. To share risks is something that the CROs react differently towards and the size of the CRO seemed to be the determining reason for this, where bigger companies could share risks and small ones like CROGolf could not.

Another risk in the asymmetric relationship between the buyer and the supplier is the buyer’s ability to invent around the results of the supplier’s work (Gallini and Wright, 1990). However, the interviewees did not see this as a risk as allowing it was a condition for the partnership. Instead the opposite seemed to exist in our cases; the CROs were given to ability to invent around the knowledge obtained from the partnership. This was exemplified by CROFoxtrot, as the technology they had used for one client could be adapted to suit another client’s needs. This might be one way for the industry as a whole to continue developing. By allowing knowledge and learning to be free-flowing, but protecting information and data, the pharmaceutical firms might feel safe to invest as they know that the knowledge created in the process will only be used by others once their project is complete.

**Relationship Capital**
Building relationship capital is according to Cullen et al., (2000) just as important as finding a partner that matches the firm financially, legally and operationally. These calculative factors were judged as fundamental by our interviewees, but just as important was the development of the actual relationship. Trusting the partner firm to own up to their end of the bargain and committing fully to the relationship was important to the pharmaceutical firms, and in the same way almost all the CROs mentioned these aspects as important in order to gain trust from their clients.

When looking at the socio-physical aspects of the relationships (Cullen et al., 2000) we found that all the interviewees engage in inter-firm interaction during the course of a project, and that the quality of this interaction was judged as very important for the success for the projects as a whole. Just as Cullen et al. (2000), many of our interviewees pointed to the fact that a contract cannot be written to predict or encompass all possible scenarios, and therefore especially our CRO interviewees appreciated some flexibility in the contracts and the ability to solve problems along
the way. This was a flexibility given to the CROs based on competence and previous experiences. The nature of the relationships with classified information and high knowledge sharing (Cullen et al., 2000) together with the small size of the industry in Sweden also led the partner to want to develop long-term relationships, where good communication played a major role.

**Trust**

Trusting a partner firm implies having confidence in their honesty and that they will be sensitive and responsive to the needs of the firm (Geyskens et al., 1996), and it allows them to act as if uncertainty is reduced even if it actually is not (Tomkins 2001). All interviewed firms in our study spoke of the importance of trust and honesty towards their partner firm in projects. The interviewed pharmaceutical firms mentioned it as an important factor when choosing a partner and CRO firms spoke of the importance of giving a trustworthy impression based on competence and personality when bidding for contracts to the pharmaceutical firms.

In the relationships between CROs and pharmaceutical firms, competence trust, contractual trust and goodwill trust were all present, but to different extents in each case. Competence trust as the belief in another party’s skill and ability to deliver (Langfield-Smith and Smith, 2003) was often stated by the pharmaceutical firms as the most important factor when choosing a CRO partner. The risks in relation to competence trust were by the pharmaceutical firms minimized by having previously worked with the CRO, looking up previous work references, and having knowledge of the general reputation of the firm, which are in line with the suggestions of Langfield-Smith and Smith (2003) and Lui and Ngo (2004). In the case of CROEcho and CROIndia, these CROs were the only possible partners because they offered a unique service, making this decision based on the expected competence. Four of six CRO interviewees stressed the importance of doing a good job in order to upkeep a good reputation in the industry to be an attractive future partner.

All interviewed companies shared contractual trust between them. It was taken for granted that these contracts were respected and that the parties would own up to what was promised (Langfield-Smith and Smith, 2003; Donada and Nogatchewsky, 2006). Many CROs suggested more flexibility in the contracts to make them more reflective of the reality found in the industry. This would entail a bigger reliance on goodwill trust, which is developed through personal consultations and intense communication (Langfield-Smith and Smith, 2003). Lui and Ngo (2004) explain that contracts and goodwill trust cancel each other out if used together. According to our interviews, because of the sensitivity of the information in the projects that pharmaceutical firms and CROs engage in, the information shared between them needs to be regulated by NDA’s and rigorous and detailed contracts. This is due to the fact that the industry is very conservative; in the
end they are dealing with patient health and safety. They also used goodwill trust in particular to solve unforeseen problems along the way. Therefore the above-mentioned argument by Lui and Ngo (2004) cannot be applied in these relationships.

**Control in the Inter-firm Relationship**
According to Langfield-Smith and Smith (2003), inter-firm relationships can be controlled through rigid performance targets, detailed rules of behaviour, and detailed contracts. These were exemplified through our interviews, and the types of control used by the client firm to safeguard the quality of the work done were dependant on the type of project. In clinical trial studies it was usually not known exactly what the outcome would be and the client owned all the data the CRO produced along the way. As the pharmaceutical firms were usually interested in the progress and design of the project they engaged in behavioural control by having close contact with the CROs and following up on their work. They were able to do this as some pharmaceutical firms, for example PharmaBravo, had means-end knowledge of the work that was being done as they had previously performed these projects in-house or were experts in the area. According to Ouchi (1977), applying behavioural control to knowledge creation processes will not lead to the desired output. In the clinical trial projects the pharmaceutical firms used a combination of output and behavioural control, because even though they did not know exactly what the end result would be, it was decided beforehand what types of tests and how they would be done which would fall under output control. If the projects were highly standardized the pharmaceutical firms mostly engaged in output control, making sure that the end result was according to contract (Ouchi 1977). This was exemplified by CROEcho who received substances from their clients and produced standardized analyses and reports according to their clients’ needs. The opposite was true for PharmaCharlie where only behavioural control could be used, as the results of the research could not be promised when the partnership was first established. The task programmability of this research is very low, making it appropriate for the pharmaceutical partner to instead use outcome control. Goals and milestones were set up in this relationship rather than controls of PharmaCharlie’s behaviour, in accordance with Eisenhardt (1985).

**Commitment**
The interviewees mentioned open and honest communication as vital and that projects that had turned out to be unsuccessful were often due to a failure in communication. Both sides appreciated fast, accurate and transparent communication from their partner in order to make the relationship work in the long run. This is supported by Paulraj et al. (2008); they state that open and frequent communication is essential for the maintenance of these inter-firm relationships. This long-term perspective is one of the cornerstones of attitudinal commitment; that the parties
have the intention to stay in the relationship and do what they can to nurture and build a stable relationship (Gilliland and Bello, 2002). Our CRO interviewees pointed out the importance of building a good relationship and owning up to what was expected from the relationship as the project is worth more than the project budget. A happy customer will return, and because the industry is very competitive, a bad reputation could be detrimental for their business according to two of the CROs. CROEcho also mentioned going beyond their obligations of the contract in order to satisfy their client, which is an act identified by Cullen et al. (2000) as a good way of expressing attitudinal commitment.

The economic side of commitment as expressed through calculative commitment was present in all our interviewee’s relationships. There was always a financial intention with the inter-firm relationships our interviewees engaged in, and were driven by present and potential future rewards and expectations (Cullen et al., 2000). Especially when one party had a unique service or competence is was clear that the two firms needed each other in order to continue their drug development process, as discussed by Geyskens et al., (1996).

Termination costs as discussed by Morgan and Hunt (1994), were the highest for the CROs and the biotech companies. Apart from the immediate termination cost that would affect these companies if a project were to end, the largest risk would be the potential loss of a future partnership as the long-term relationships are valued the highest. This is especially a big risk for the biotech companies, because they often only have one or two projects running at the same time. This means that whilst the CRO might lose income the biotech firm might go bankrupt, as they often do not have the funding to start over if a project fails. As they have the highest termination cost they also have the highest commitment according to several CROs. One way for the biotech firms to express their commitment was having the CEO or another senior person that handled the communication. According to Hagedoorn and Duysters (2002) the performance of the relationship will improve if a person with a high status in the company plays an important role. In parallel to safeguarding their financial interests these firms also engaged in intense communication and commitment building of the attitudinal kind. There was no visible evidence in the study of an imbalance between calculative and attitudinal commitment in these relationships, that could according to Liu et al., (2010) lead to opportunistic behaviour.

According to Liu et al. (2010), the inter-firm relationship will change over the course of time. Most interviewees specifically brought up the aspect of time as an important factor in building commitment. The longer the companies had worked together, the more they knew about the other firms’ internal processes and created an understanding for their way of working. To foster this
Inter-organisational learning that the interviewees spoke of is according to Paulraj et al. (2008) crucial for the competitive success, something we feel was also reflected by the interviewees. Liu et al., (2010) also point to the aspect of time as having a direct effect on attitudinal commitment. All interviewees stressed the importance of having one contact person at both companies in order to make communication as efficient as possible, and that the personality of this contact person was very important for a well-functioning project and often developed to a more informal communication. This argument is in line with Hagedoorn and Duysters (2002), who argue that it will benefit the company to get access to information through a limited number of diverse contacts. Also Langfield-Smith and Smith, (2003) argue that maintaining a high level of communication and information sharing can be efficient ways of controlling the supplier. Through this analyses different aspects of the inter-firm relationship have been discussed, the main point of interest can be found and have enabled the drawing of conclusions.
Concluding Discussion

In this thesis, we have explored the research question “How is trust and commitment developed in an inter-firm relationship between pharmaceutical firms and Clinical Research Organizations?”

All participants in our study spoke of the importance of both trust and commitment to build a successful relationship, which suggests that relationship capital has been created between them. Trust was initially built on competence trust, which was either established through a good reputation in the industry, or if a supplier had a unique competence that could not be found elsewhere. Through our interview findings we could not find any evidence to support the idea that goodwill and contractual trust cancel each other out. Instead we found that these two types of trust complement each other; contracts were seen as a prerequisite for any transaction and goodwill trust builds successful long-term relationships. Flexibility in the contracts was appreciated by the CROs, but a privilege only given to them if the pharmaceutical firm trusted their goodwill and competence. During the course of the projects we found examples of behavioural, output and outcome control. The type of control used varied and was directly dependent on how much knowledge the buyer held about the different aspects of the project. The more knowledge the buyer had, the more they could control the behaviour of the CRO. If they did not have enough knowledge to control the behaviour, they instead had to trust their competence and ability to deliver.

Commitment was expressed through goodwill trust, such as CROs doing more than what was dictated by the contract. This was done in order to nurture the relationship and thereby build a platform for future relationships. Commitment was created through high-quality communication and interaction between the partners. All interviewees appreciated accurate and transparent communication in order to build long-term relationships, which were seen as the highest valued. However, a too high level of commitment could be damaging as a lock-in effect can develop. Poor communication was seen as the foremost reason for project failure, which the interviewees wanted to avoid at all costs as a bad reputation in the industry could be detrimental. The projects are worth more then the project budget as a good relationship could be a future source of income. This implies that the CROs have a high termination cost as they are more dependent on their relationships and cannot afford this potential loss of a future business partner. However, there are important benefits for the CROs besides the purely financial ones. By performing clinical trials and other R&D projects, the CROs engage in a learning process, which creates knowledge within their firm that can be applied to future projects with other clients. We see this as a way for the industry as a whole to move forward by exchanging knowledge and learning from each other.
Through our study we found a threat against the development of trust and commitment in passive opportunism on the part of CROs in the process of patient recruitment. Knowingly promising more than they could guarantee to deliver was a result of the high competition in the industry. In accordance with Liu et al., (2010) we believe that this behaviour could in the future affect the pharmaceutical firms to in turn act opportunistically towards the CROs in order to safeguard their interests. The issue of information asymmetry that is common for knowledge outsourcing, was not judged as a problem by neither the pharmaceutical firms nor the CROs, it was rather seen as a condition general to the industry. The pharmaceutical industry in Sweden is very conservative with tough regulations as well as long and rigid bidding processes. This leads to a lot of time being spent on research design and Standard Operation Procedures rather than focusing on improving the uncertainty regarding patient recruitment. All parties see this as a problem but neither the pharmaceutical firms nor the CROs take the responsibility to improve the situation. It is of utmost importance to address this issue in order for Sweden to remain an attractive destination for clinical trials and to sustain the inflow of foreign business.

**Future Research and Limitations**

Many companies brought up similar issues in our study; it could therefore be of interest to conduct a larger scale study in order to validate our findings and also to investigate inter-firm relationships with both perspectives of the same relationship. Other subjects for future research that could be of interest include looking deeper into the patient recruitment process to determine the drivers and barriers of change in this area with the aspect of the high competition as a factor. We also feel that the potential development of opportunism from the pharmaceutical side towards the CROs as a result of their issues with budget and patient recruitment are of interest. Another perspective from which to analyse inter-firm relationships could be through network-theory, as the companies of the industry are connected to each other through a large-scale network.

The main limitation of our study is that our results cannot be generalized to the whole population of pharmaceutical firms and CROs, mainly because our sample is limited and also as we cannot guarantee that other researchers could replicate our study. To validate our results a larger study would need to be performed. However, we believe our results to be an important indication as to how trust and commitment is built in inter-firm relationships between pharmaceutical firms and CROs.

**Implications for Practitioners**

Because our interviewees identified patient recruitment as the greatest challenge in the drug development process, practitioners could benefit from a better understanding of this area. An
investigation as to what responsibility all involved parties have in this issue needs to be done in order to facilitate the development of a more efficient and fair system. Pharmaceutical firms, CROs, the regulatory units (Läkemedelsverket) and other involved actors need to address this issue together. The system would benefit from allowing the parties to more easily identify and locate patients, which could benefit the industry as a whole, and by extension also the patients.
References


Websites


Appendix A

Interview Guide

1. Background
Please tell us about your company?
Please tell us about your role at the company?
Could you please tell us in short about the CRO’s/Pharmaceutical firms you collaborate with?
How long have you worked together?

2. Selection process
Please tell us about the selection process?

• What did you know about the CRO/pharmaceutical firm from before?

What do you think are the main reasons that you chose them/were chosen?
How long did the selection process take from first contact to signed contract?

3. Contract
Could you tell us about the contract?
How much do you use it, do you revisit it during the project?
Have you made any investments in the CRO/ Have the pharmaceutical firm invested anything in your business?

4. Communication and Development of the Relationship
Which type of communication do you have during the projects?
Which type of information do you share with each other?
How do you/the pharmaceutical company follow up on the progress of the project?
How long do you see yourselves working together?
How would you describe the pharmaceutical firms’/CRO’s commitment to your relationship?
How would you describe your commitment for the relationship?

5. Challenges
What would you describe as the biggest challenge in your relationship?
Do you have different levels of knowledge in certain areas? If so, how is this handled?
How would it affect you if the relationship were to end?

6. Wrap-up questions
Is there anything you would like to add?