Survey of Finnish vendors serving the pharmaceutical industry

What is required for business success?
Culminatum Innovation Oy Ltd seeks to improve the international competetiveness and attractiveness of the Helsinki Region.

The Verkkovoimaa -project supports networking and internationalization among expert service companies in the life science sector. Operations are funded by the Centre for Economic Development, Transport and the Environment for Uusimaa, the European Social Fund, the companies participating in internationalization programmes, and the cities of Helsinki, Espoo, Vantaa and Kauniainen.
This survey identified 43 pharmaceutical outsourcing vendor companies whose range of services is distributed over the entire value chain of pharmaceutical R&D. Nonclinical contract research including disease models is provided by six vendors, whereas 13 provide clinical trial services and nine companies are engaged in contract manufacturing. The rest of the companies are active in biostatistics, bioinformatics, and diverse special services. The majority of the vendors are either microenterprises or small enterprises. Only eight are medium-sized or large enterprises employing more than 50 people. The companies are often spin-offs of university groups and are characterized by a high level of know-how. The large enterprises are established companies with a longer life-span or the result of recent consolidations. The turnover of the three largest companies accounts for 58% of the entire business volume (€94 M out of €162 M).

The global pharma outsourcing business has undergone constant change during the past decade, reflecting the challenges of and trends in the pharmaceutical field. Clinical research organizations (CROs) actively form mergers and strategic partnerships with their pharma clients, becoming continuously larger and better able to offer an increasing service portfolio. Yet smaller pharma clients are best served by outsourcing vendors of equal size. In addition, there are niche markets for specialized services. In Finland, the number of clinical trials has seen a significant decrease during recent years, which is reflected in the declining turnover of CROs engaged in clinical trials.

According to the survey, the main challenges facing outsourcing companies are:

1) Credibility issues owing to their small size. Pharmaceutical companies are unwilling to take the risk of outsourcing tasks to companies where critical skills lie in the hands of only a few persons.

2) Unless the service provided by a vendor is absolutely unique, pharma clients wish to acquire a range of services from the vendors they approve. This is because the evaluation process involved is lengthy.

3) Lack of marketing power.

4) Limited resources in business management.

The interviews revealed the following keys to success:

1) A service product built on solid core competence that withstands critical assessment.

2) A product that has undergone conceptualization to deliver the intended benefits to customers.

3) Flexibility in the content of service-provision, including accessory know-how. This is particularly important when dealing with smaller customers.

3) Sufficient resources to keep up with cutting-edge know-how and the updating of products in accordance with new know-how.

4) Activities are undertaken to increase the range of services and resources through either networking or consolidations.

5) Professional business skills are in place for managing business intelligence, for understanding customer needs, the competition, risks, for providing effective marketing tools, and for winning new customers.

Successful companies have typically understood the importance of serious marketing efforts with face-to-face contacts in order to acquire international customers. Business growth has been obtained through consolidations (domestic or international), by networking with companies offering synergistic services, or through strategic partnerships. The last alternative was the strategic choice of a large renowned company manufacturing active pharmaceutical ingredients. In addition, the mindset of a successful company includes the flexibility and sensitivity needed to adjust the company’s strategy to the rapidly evolving environment.
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1. Introduction

In the first half of the past decade, the Finnish pharma-related market experienced a major recession that resulted in bankruptcies, company mergers, and diminished investments in the pharmaceutical field. A number of surveys conducted since 2005 have highlighted this market turbulence, the lack of any major recovery, and the small size of Finnish entrepreneurship in the pharma-related business. Thus, there are obvious challenges to being successful in this highly competitive field.

Clinical research organizations (CROs) typically serve pharmaceutical companies that wish to perform clinical trials in Finland, taking advantage of the high quality of the Finnish health care system. The domestic market for contract research is very limited. Success therefore depends on international customers, who are not a uniform group. Some of them are extremely large global pharma companies while others, such as biotech companies or even virtual companies, are smaller. Depending on the company type, the needs and strategies for outsourcing are different.

Vendors in Finland providing services to pharma customers have previously been surveyed by Orava and Holopainen (2008). Their study focused on creating a concept for achieving international business or for going international. The current survey focused on the formation of a holistic view of the pharma related service market in Finland and on exploration of the future prospects of the international service field, especially through potential collaboration and networks.

2. Contracting of the survey

The survey was commissioned by Culminatum Innovation Oy Ltd in 2011 as part of the Verkkovoimaa-project. The aim of the survey was to create a focused understanding of the needs and practices/action models of companies that outsource their work or functions. The goals were defined as follows:

- a. Survey the future prospects of the international service field
- b. Create an overview of the business arena and services in Finland
- c. Explore the critical success factors for continuous customer relationship (i.e., repeat business) between the customer and the service-provider
3. Definitions

According to the definition of Orava and Holopainen, the internationalization of a company means a process during which the company takes part in international efforts to an increasing extent.

The core elements of becoming international entail the specification of: 1) what is delivered; 2) the ways through which the services are made available on international markets; and 3) the target markets. The internationalization of a service-provider is grounded in the business strategy. The internationalization strategy directs the strategic choices and defines how the company aims to become international.

This can be divided into three main dimensions:
1. International service strategy
2. International operational strategy
3. International market strategy

The international service strategy defines the service offering available to the customer. The international operational strategy defines the operational modes through which the company delivers its services to customers. The international market strategy defines the solution for the target markets.

The goal of a service strategy is the capability to compile a competitive service offering for international markets. The operational mode and the target market solutions define how and where the service is delivered.
4. Strategic landscape

4.1 Global Venture Capital Funding

In the United States, venture capital (VC) funding shrank from $1.39 billion in 2007 to $688 million in 2009. The market has recovered since the financial crisis of autumn 2008, but with new rules. The 20% of US companies that were the most successful in raising funds garnered 82.6% of VC funding in 2010 — up from 78.5% the previous year and 68.7% in 2005. Conversely, the bottom 20% of companies raised only 0.4% of the VC funding — down from 0.6% in 2009 (Ernst and Young, 2012). Even though the overall funding increased, a growing share of the total was in the form of large debt financings by mature, profitable companies. While the total capital raised in the United States increased by 15% in 2010, innovation capital actually declined by 20% over the same period. “Innovation capital” means total funding minus large debt financings by mature, profitable companies. Furthermore, the amount of money truly available to companies is even lower. The widespread use of milestone-based payments may be relatively new in venture funding, but it has long been commonplace in strategic alliances. There are good reasons for the use of contingency-based payments. The practice creates a greater incentive for biotech companies to keep focused on critical milestones. Although companies have less capital available to them, they are called on to do more with diminished resources as the process of discovering and developing drugs becomes increasingly lengthy, expensive, and risky.

Biotech investors large and small — ranging from venture capitalists to activist public investors — focus increasingly on mergers and acquisitions as the most efficient way to capitalize on their holdings. As venture capitalists have to nurture portfolio companies for ever longer periods before the companies can go public — and are seeing relatively low public market valuations when the companies do go public — many of them have concluded that exit via a trade sale is the only sensible path. Indeed, many venture capitalists now have a portion of their portfolios invested in low-burn-rate “build-to-sell” entities — which essentially are research projects.

4.2 Trends in the pharmaceutical industry affecting pharmaceutical outsourcing service-providers

The advancement of pipelines and the approval of new products are the tangible milestones of companies’ R&D efforts and expenditures. New product approvals decreased industry-wide in 2010 as compared to 2009 and remained at a distressingly low level given the aggregate amount of R&D investment and the significant unmet needs of patients. In the absence of new and better drugs, demographic changes and the increasing incidence of chronic diseases will stretch government programs and budgets around the world.

During the last decade, expiring patents have profoundly influenced the behavior of pharmaceutical companies. Even so, patents expiring in 2011-2014 will lead to a loss of $82 billion in pharmaceutical business. At the end of the last decade, major pharmaceutical companies, impacted by the financial crisis and concerned by the imminent loss of patent exclusivity on blockbuster products, revised their research and development priorities. In particular, a greater proportion of funding was allocated to products in later stages of development. Indeed, the number of FDA drug approvals has declined markedly, from an average of 36 per year between 1994 and 2004 to an average of 21 per year since 2005.

The patent cliff also prompted big pharmaceutical companies to bolster drug development pipelines and increase efficiencies through both mega-mergers and mini-mergers. These takeovers resulted in periods of outsourcing inertia as integration took place. The merger process also contributed to the trimming of development pipelines and reduced the number of pharmaceutical companies both big and small from which to win business. All these factors have impacted on service-providers in recent years. At the same time, service-providers have had to cope with the withering of biotech business once venture
capital funding had dried up. As to CROs as an investment target for VCs, many VCs typically shy away from services, the few exceptions being funds that work in the healthcare service space. The reason for this is the focus on high growth in order to increase the exit values that VCs need.

**4.3 Market for contract research organizations**

The CRO market has grown continuously for some two decades, especially in clinical services. In 2010 the market for CROs covering preclinical through to Phase I to IV clinical trial services grew 16%, to $27 billion. Similarly, the global market for contract manufacturing organizations (CMO) was valued at $22.5 billion in 2009. By 2013 it is predicted that the market will reach nearly $34 billion as biopharmaceutical companies turn to CMOs for active pharmaceutical ingredients (API), excipients, formulation services, lyophilization, and more.

Private equity firms are driving a large proportion of merger and acquisition activity among small to medium-sized CROs. At $3.9 billion, PPD was the largest equity takeover in 2011. In fact, most of the big CROs are now owned by private equity firms, which may mean that further consolidation of the CRO business will occur.

Before the dramatic shift in the biopharmaceutical landscape that occurred at the end of the decade, some preclinical CROs claim to have had six-month waiting lists for toxicology work. Recently with total global capacity at CROs and biopharmaceutical companies far exceeding demand, prices fell and service-providers faced pressures to go lower and lower. In spite of this, preclinical toxicology currently runs at 70% of capacity. Large sponsors do not implement major changes in their strategies; only a small portion of toxicology is outsourced. The return of funding for biotechs, which before the downturn were vital toxicology clients, will be a key element of any recovery.

While toxicology continues to face problems, preclinical CROs can benefit from the imminent loss of patent exclusivity on the first wave of biologics. To capitalize on this market opportunity, companies are developing two types of products: attempts at exact copies of the innovator biologic, called biosimilars; and improvements over the original molecule, known as biobetters. Biobetter development in particular requires an understanding of preclinical toxicology and assay development beyond the skill set of many pharma companies entering the market.

Drug discovery services are also expected to perform well. In 2009, Business Insights valued the market at $7.4 billion but, with the industry becoming more comfortable with the outsourcing of discovery work, the figure is expected to rise to $18.5 billion by 2015. However, continued prioritization of late-stage candidates could make these growth predictions optimistic. As it stands, chemistry services account for close to 40% of the market. Biological services make up 28% of the market and this share is expected to grow in the coming years.

Major pharmaceutical companies announced 22 alliances with CROs in the past year. The real figure is greater, as many deals are kept private. Big companies, in particular, sign strategic partnerships, such as Eli Lilly and Covance: Covance bought the Greenfield, Indiana site for $50 million. The fee paid by Covance was drafted by an outsourced business by Lilly, worth $1.6 billion over 10 years. Another case, that of Sanofi and Covance, illustrates how a CRO can secure a guaranteed amount of business, tighter links to the client, and new capabilities. Through the deal with Sanofi, Covance added chemistry capabilities and became the sole provider of central laboratory services, adding $1.2 billion to its backlog. In December 2010, Aesica (a CMO) bought three European production plants from UCB and entered into a long-term supply agreement as a sign of more strategic outsourcing relationships. Discussions around deeper, more strategic relationships are now moving into early phase development, too. Bristol-Myers Squibb signaled the trend in August by choosing Icon as one of two preferred providers in early phase clinical development.

Sponsors increasingly want to perform clinical trials in patients, as opposed to healthy volunteers. Taking this approach is one part of a strategy designed to get to proof-of-concept as quickly and efficiently as possible.
The wish to secure consistent business from key clients plays a role in the second trend – consolidation of CMOs. A report by PwC predicted that consolidation of CMOs will create service-providers with the scale and capabilities to support completely outsourced production and distribution networks, a 100% virtual supply chain (Taylor 2012).

The strategic outsourcing trend is driving large amounts of business to a small group of CROs that possess the global capabilities required to handle the late stage needs of leading pharmaceutical companies. Leading CROs are taking steps across their businesses as they seek to access the knowledge needed to be a true drug development partner to biopharmaceutical companies without burdening themselves with the overheads sponsors are shedding by outsourcing. An April 2011 report by Jefferies & Company predicted that the leading CROs, defined at the time as Quintiles, Covance, PPD, Parexel, Icon, Charles River, and Kendle, would account for close to half of the market by 2014. In 2010 these companies had 41% of the market. The trend in the pharmaceutical business is cutting the vendor networks (Taylor 2012).

Niche market players will benefit from the increased demand for specialized clinical trial services, particularly in cancer and central nervous system disorders. With big CROs signing strategic deals and niche players winning business through specialization, there is a theory that mid-tier players will be caught between two stools. The diversity of sponsor sizes is one factor underpinning mid-tier CRO business wins. Data suggest that there is a close association between the size of a sponsor company and the size of the clinical service-provider selected to perform clinical trials. Smaller sponsor companies are best served by small to medium-sized providers (Taylor, 2012).

Contract manufacturers have also had a challenging few years. Simple, low-margin ingredients and formulation work moved east, to India and China in particular, where the work can be performed more cheaply. Biologics, high potency active pharmaceutical ingredients (HPAPI) and sterile are a few of the areas in which CMOs have added capabilities. This also reflects the increasing prevalence of these products in the biopharmaceutical development pipeline. However, with regard to predictions concerning preclinical CROs, India and China have been disappointments.

Strategic decisions in industry seem to take place slowly. Proponents of outsourcing say pharmaceutical companies would make more efficient use of resources by closing in-house capacity, thereby eliminating a fixed cost, and using CROs. This strategic thinking is reflected in the predicted growth in the turnover of CRO businesses. Progress in implementing this approach, however, has been slow.

4.4 Situation on the Finnish market

Both the pharma business and the service business have been fairly turbulent in the recent years. Some 20% of vendors have ceased operations. The domestic market for the vendors has become largely nonexistent. Success therefore hinges on international customers that are by no means uniform. Some of the customers are extremely large and global while others are smaller, e.g. biotech companies or even virtual companies. The needs of and strategies in outsourcing services obviously differ depending on the company type.

Basic research in Finland has been of high quality. Many of the service-providers are spin-offs from university groups and possess some unique skills. University departments, however, continue to provide selected services that compete with those offered by commercial national service-providers.
Traditionally, Finland was a preferred location for conducting clinical trials due to the country’s well organized health care and highly trained clinical investigators. This led to the founding of several clinical CROs. In recent years, however, there has been a decreasing trend in the volume of clinical trials. The reasons for the decline are manifold and include, e.g., cost level, physicians’ lack of interest in acting as investigators, a scarcity of patients and the speed of recruiting patients for clinical trials. In all of the Nordic countries, submissions to the regulatory authorities to perform clinical trials have decreased considerably. Great drops occurred when the EU Directive on drug trials entered into force in 2004/2005 and with the economic recession in 2009. In Finland, submissions of drug trials have decreased by half in five years’ time, coming to about 200 in 2010 and further declining to 110 commercial submissions in 2011 (and a total of 141). The number of ongoing trials has diminished by more than one third, being 340 in 2011. Furthermore, more than 90% of the study subjects in trials are included in vaccine trials – which indicates the importance of unique skills and the opportunity of niche players in the marketplace. Conversely, “bulk trials” are no longer conducted in Finland.

5. SWOT analysis

SWOT analysis is presented on the following page.
<table>
<thead>
<tr>
<th>Strengths</th>
<th>Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Finnish basic science continues to be highly ranked internationally</td>
<td>Few big pharma companies have true R&amp;D activities in Finland</td>
</tr>
<tr>
<td>Research with long and sound traditions leads among other things to high-quality service business with an appreciated core competence in areas such as vaccine research, carbohydrate research, organic chemistry in connection with a pharmaceutical background, neurobiology, cardiovascular diseases, and cancer biology</td>
<td>The number of start-ups in Finland has not increased markedly during the past decade</td>
</tr>
<tr>
<td>Tekes funding is available for start-ups and successful development companies</td>
<td>The number of domestic pharma sponsors outsourcing R&amp;D activities is too small to support service business</td>
</tr>
<tr>
<td>CMOs offering biopharmaceuticals and gene transfer products are located in Finland</td>
<td>In Finland, only a few subsidiaries of international pharma companies have maintained a real medical department for interaction specifically in the case of clinical trials</td>
</tr>
<tr>
<td>Some Finnish service companies (CROs and CMOs) have been able to offer unique services attracting attention even from big companies</td>
<td>Decisions on where clinical trials take place are taken at the headquarters of pharma companies or by CROs contracted by these companies</td>
</tr>
<tr>
<td>Some service-providers (based on ingenious skills) have been set up and are beginning to prosper</td>
<td>Most non-clinical CROs are small whereas the trend is towards bigger players.</td>
</tr>
<tr>
<td>Investing in professional business skills has proved successful when in place</td>
<td>Comprehensive risk management as well as business and marketing skills are underdeveloped in small domestic companies</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Opportunities</th>
<th>Threats</th>
</tr>
</thead>
<tbody>
<tr>
<td>Results from basic science continue to produce findings that have business potential – including the potential for service business</td>
<td>Clinical trials in Finland may dry up</td>
</tr>
<tr>
<td>Networking between companies can create critical mass that will help to win business</td>
<td>CROs and service business continue to consolidate</td>
</tr>
<tr>
<td>Small sponsors are better served by small vendors</td>
<td>Big and medium-sized pharmaceutical companies deal only with companies of the same size</td>
</tr>
<tr>
<td>Flexibility in adjusting the business strategy in accordance with global trends</td>
<td>Small and start-up companies deal with local service companies</td>
</tr>
<tr>
<td>International visibility achieved through collaboration</td>
<td>Knowledge of and experience in the pharma business as well as familiarity with their preferred ways of working are limited, due to the limited history of the business in Finland</td>
</tr>
<tr>
<td>Strategic partnerships to improve the service portfolio</td>
<td>Strategic partnerships between pharmaceutical companies and vendors may narrow down the “open” CRO market</td>
</tr>
<tr>
<td>Flexible and tailored services entailing special skills to serve niche markets</td>
<td></td>
</tr>
<tr>
<td>Utilization of public sector data warehouses such as KELA</td>
<td></td>
</tr>
</tbody>
</table>

The items listed in this SWOT analysis are shown in the order of their priority.
6. Results of the survey

The survey focused on companies that have a close relationship with drug development.

6.1 Future prospects of the international service field

As a whole, both the CRO market and the CMO market will continue to grow internationally, since many large to medium-sized biopharmaceutical companies are cutting their in-house assets. The prospects are dimmed by the strategic deals made between the big CROs and pharmaceutical companies. CROs are thus ensured a guaranteed amount of business, their links to clients are tighter, and they acquire new capabilities. Only big CROs are able to make such deals. About half of the clinical trial work conducted in Finland is secured by strategic, preferred provider deals between the parent company and big pharmaceutical players (Interviews).

6.2 Overview of the services and business arena

Selected company listings and business catalogues were utilized in surveying the business arena. Furthermore, the websites of the companies identified for the survey were consulted in order to check and update the information and service profiles.

In total, 63 companies were identified for inclusion in the survey. Twenty were pharmaceutical companies and 43 were service-provision companies in seven different areas (Appendix A; Table 1).

### Table 1. Service-provision companies by area, ownership, and competitive situation

<table>
<thead>
<tr>
<th>Grouping of service-provision companies</th>
<th>Finnish</th>
<th>Subsidiary of an international owner</th>
<th>Competition within the group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bioinformatics</td>
<td>4</td>
<td>0</td>
<td>Yes</td>
</tr>
<tr>
<td>Preclinical CROs</td>
<td>3</td>
<td>1</td>
<td>Yes</td>
</tr>
<tr>
<td>Disease models</td>
<td>1</td>
<td>1</td>
<td>No</td>
</tr>
<tr>
<td>APIs/Biological</td>
<td>6</td>
<td>3</td>
<td>No</td>
</tr>
<tr>
<td>Statistical services</td>
<td>2(3)</td>
<td>(1)*</td>
<td>Yes</td>
</tr>
<tr>
<td>Clinical CROs</td>
<td>6</td>
<td>7</td>
<td>Yes</td>
</tr>
<tr>
<td>Special services</td>
<td>7</td>
<td>1</td>
<td>No</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>30</strong></td>
<td><strong>13</strong></td>
<td></td>
</tr>
</tbody>
</table>

*4Pharma
The service-provider field is heterogenous. Companies have apparently tried to specialize so that they can provide unique services. The competitive situation is the toughest for clinical CROs, where the market is declining, big international players have subsidiaries here, and the services offered are practically identical. A number of companies within the fields of bioinformatics and preclinical CROs offer at least tangential services.

The size distribution of the companies identified is presented in Table 2.

### Table 2. The size distribution of the companies identified

<table>
<thead>
<tr>
<th>Business area</th>
<th>Micro (Personnel 1-9)</th>
<th>Small (Personnel 10-49)</th>
<th>Medium (Personnel &gt; 50)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Service</td>
<td>13</td>
<td>22</td>
<td>8</td>
</tr>
<tr>
<td>Pharma</td>
<td>10</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td><strong>Summary</strong></td>
<td><strong>23</strong></td>
<td><strong>28</strong></td>
<td><strong>12</strong></td>
</tr>
</tbody>
</table>

The medium-sized service-provision companies were the Systems Biology Worldwide group (including 4Pharma, Novamass, and Toxis), Cerebricon (part of Charles River), Fermion (large; a subsidiary of Orion), Galilaeus, PCAS, Medfiles, Quintiles and Encorium. Only Orion was categorized as large, while Santen, Bayer, and the Finnish Red Cross Blood Service were medium-sized. In general, the size of the company seems to increase with the time in operation.

The companies were placed into the most appropriate locations in the value chain. The distribution of service-provision companies based on size and phase of drug development is presented in Table 3a. A more detailed view is presented in Table 3b, where the service-provision companies are grouped on the basis of their core service area.

### Table 3a. Distribution of service-provision companies by headcount and location in the value chain

<table>
<thead>
<tr>
<th>Phase of development</th>
<th>Micro (Personnel 1-9)</th>
<th>Small (Personnel 10-49)</th>
<th>Medium (Personnel &gt; 50)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discovery</td>
<td>8</td>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td>Nonclinical</td>
<td>2</td>
<td>10</td>
<td>6</td>
</tr>
<tr>
<td>Phase I</td>
<td>6</td>
<td>16</td>
<td>5</td>
</tr>
<tr>
<td>Phase II/III</td>
<td>4</td>
<td>12</td>
<td>2</td>
</tr>
<tr>
<td>Different companies*</td>
<td>13</td>
<td>22</td>
<td>8</td>
</tr>
</tbody>
</table>

*The totals for the different companies by headcount are not the column sums because many companies are active in multiple fields of drug development.
Table 3b. Service-provision companies by core service area

<table>
<thead>
<tr>
<th>Phase of development</th>
<th>Micro (Personnel 1-9)</th>
<th>Small (Personnel 10-49)</th>
<th>Medium (Personnel &gt; 50)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discovery</td>
<td>20-22, 124, 24, 30, 126</td>
<td>130, 70, 131, 41</td>
<td>40</td>
</tr>
<tr>
<td>- Biology/target</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Screening /Chem</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Disease models</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nonclinical</td>
<td>31</td>
<td></td>
<td>32 (32)</td>
</tr>
<tr>
<td>- ADME</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Toxicology</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase I</td>
<td>91</td>
<td>60, 61, 90, 122, 125, 127</td>
<td>53</td>
</tr>
<tr>
<td>Phase II/III</td>
<td>101, 103, 105, 108</td>
<td>32, 51, 62, 81, 102, 104, 109, 110, 120</td>
<td>50, 52, 100, 106, 107</td>
</tr>
<tr>
<td>Regulatory</td>
<td>121, 123</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The numbers refer to information in Appendix A. Numbers in bold represent foreign companies.

A few characteristic strongholds were identified in the Finnish service business arena. All of the successful companies have long traditions of top-quality research. Such areas include cardiovascular diseases, cancer biology, chemistry with a longstanding history in the pharmaceutical environment, unique biopharmaceutical CMOs, a vaccine research tradition starting in the 1950’s when pioneering clinical trials on the polio virus vaccine were conducted in Finland, basic research on the role of bacterial polysaccharides in disease pathogenesis and immunity conducted at the National Publich Health Institute combined with a suitable infrastructure (antenatal and well-baby clinics) and registries. These are the reasons for the success in attracting global vaccination trials to Finland, and today they account for the majority of subjects included in clinical trials in Finland. For decades, carbohydrate chemistry studies were systematically carried out by a prominent group at University of Helsinki; this work laid the basis for the success of Glykos Finland. Other high-quality research areas include neurobiology, encompassing both basic and clinical research as well as product development for a variety of imaging purposes. The above list is not conclusive but illustrates the importance of having a tradition to build on, both for continued research activity and for spin-offs such as service business.
The total turnover of service-provision companies in 2010 was €162 M, of which Fermion accounted for some €66 M. The other two service-providers with a turnover exceeding €10 M were PCAS and Encorium (together €27.7 M).

The distribution of turnover among service-provision companies is presented in Table 4 (Lith 2012).

### Table 4. Distribution of turnover among service-provision companies in 2010

<table>
<thead>
<tr>
<th>Turnover</th>
<th>Not available</th>
<th>&lt; €100000</th>
<th>€100000-1 M</th>
<th>€1-5 M</th>
<th>€5-10 M</th>
<th>&gt; €10 M</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Companies</td>
<td>8</td>
<td>7*</td>
<td>9</td>
<td>12</td>
<td>5#</td>
<td>3</td>
<td>44</td>
</tr>
</tbody>
</table>

*Of the service-providers in this category, Imanext, Genosyst and CNServices no longer exist. The other companies in this category, being start-ups in 2010, are apparently doing well. Glykos Finland has a rapidly increasing turnover; over €6 M by 2010.

The turnover of clinical CRO companies decreased by more than 25% from 2008 to 2010 (from €55 M in 2008 to €38 M in 2010). Nevertheless, some clinical CROs, e.g. Medfiles, have managed to increase their business during the same period. At the same time, the turnover of other service-provision companies increased from €19.6 M to €25.9 M, excluding the incidental increase of turnover of ARK Therapeutics in 2008.

Profitability is challenging for companies with a turnover of less than €5 M because business development, marketing, and international presence are difficult in such a situation.
6.3 Conclusions based on the interviews conducted

Interviews were carried out as follows:

Questionnaire for Pharmaceutical outsourcing vendors (Appendix B)

Questionnaire for Pharma companies as sponsors for outsourced services (Appendix C)

6.3.1. Pharma companies as sponsors for outsourced services

6.3.1.1 Potential areas for outsourcing

Outsourcing is highly dependent on the company, its size, its in-house capabilities, and company culture.

1) Anything can be outsourced. Certain functions are always outsourced because of a lack of in-house capability. Other entities are outsourced depending on the in-house resources that are available.

2) In general, early R&D on proprietary molecules is carried out in-house rather than outsourced, although this is not an absolute rule. Protection of intellectual property rights influences the outsourcing policy and may rule out the use of outsourced services.

3) There are big global players that tend not to outsource any research activities before phase I because they do not want to reveal the targets they are working on. Such companies are self-sufficient with regard to most of the technologies necessary for conducting drug research, e.g. genomics and bioinformatics. However, research activities are carried out with academic institutions, which are the preferred collaborators simply because scientific excellence is the only thing that matters.

4) Precompetitive research often carried out through public-private consortia involves joint activities of academic institutions and industry. This form of “outsourcing” is under constant growth (Cain 2012).

6.3.1.3 Vendor selection process

Preferred provider agreements

About half of the clinical trial business conducted by big international CROs is based on preferred provider agreements. Basically all business that is directed to Finland takes place by decision of the parent company. Possible strategic partnerships or risk sharing issues are not reflected in the operational activities practiced in Finland.

Strategic partnerships are really strategic issues

Contrary to published information, strategic partnerships are not really practiced by some big pharmaceutical companies. On the other hand, medium-sized pharmaceutical companies are eager to enter into such agreements.

Risk sharing

Shared responsibility is challenging and is therefore avoided by players big enough to do so.

6.3.1.2 Outsourcing strategies

Preferred provider agreements

In general, companies wish to restrict the number of CROs to collaborate with. This means that the vendors they select tend to be larger rather than smaller in size and are therefore able to provide an array of services. The reliability and quality of services, including the economic stability of the company, are assessed through a lengthy process involving on-site visits and interviews. The sponsor wants to see references, thereby making sure that they are not the only customer. Overly small vendors are considered a risk. A need for truly exceptional expertise may prove to be a reason for diverging from both of the usual requirements, namely size and previous experience.

Companies seek vendors with unique skills and excellence. Mutual trust is the most important criterion for a continued relationship. Personal contacts are pivotal to business!

Price plays a role but may not be decisive. Overall costs count, i.e. the total costs of the outsourced service and the internal work required to accomplish the task. CROs are assessed regularly and tendering takes place in order to ensure that the price level remains at an acceptable level.

A new vendor is seldom selected to provide all of the required services because of the risk involved when prior experience of quality, speed, etc. is lacking. When a new vendor is considered, due diligence is conducted, including the financial status of the vendor. In most cases, the sponsor team visits the vendor and the due diligence can be very thorough, going down to inspecting lab notebooks.
A commercial company as a vendor may be a better service-provider option than an academic group, because universities today are difficult in terms of getting an agreement. Furthermore, there may be conflicting interests between internal research activities and service-provision needs. Companies of one or two persons are seldom chosen as a service-provider because the deal entails the risk that a person with critical skills may leave the company, thereby endangering the whole task.

Requirements for making a new or a small company a credible vendor:

- Documentation of the product established (validated to ensure that the results can be relied on)
- Certainty for the client that the service will be delivered as agreed (an established quality management system is a prerequisite for confidence)
- Prior personal contacts increase credibility (applies, e.g. to biostatistics services).
- The selected company is recognized as representing excellence in its field (quality scientific publications, cross references by other known clients, unique and novel features of the service that make the service more attractive than the standard service)
- References about the service-provider(s)
- Previous positive experience

6.3.1.4 Gaining information about potential service-providers

- Register of service-providers. It is difficult for a new vendor to get on the list. The change of vendor should result in tangible benefits for the client that make it worth starting the evaluation process.
- Congresses and exhibitions are the main forum for new contacts. In other words, the vendor must engage in marketing efforts in order to be considered as a potential service-provider. Many vendors pre-arrange a contact with the appropriate person at the potential client organization. All interviewed service vendors stressed both the importance of being present at commercial congresses and exhibitions and the need of being very active even when hunting for potential customers.
- Publications attract the interest of sponsors, especially when dealing with cutting-edge research services. Again, it is scientific excellence that is decisive.
- Personal contact(s) are helpful in establishing initial interest.

6.3.1.5 Services acquired from Finland

Reasons for selecting a Finnish service-provider

- Local and therefore handy
- Good previous experience
- Skills in the Finnish language are required
- Tekes projects may require collaboration with a defined Finnish vendor

6.3.1.6 Opinion of service-provider networks

Services offered to pharmaceutical company through a network of vendors are not considered attractive because of unclear responsibility issues and the quantity of legal work. Subcontracting by a service-provider is acceptable provided that one of the vendors bears the responsibility for the services of all vendors (legal, quality, delivery time). Nevertheless, networking can be the key to success. Emerging information indicates that smaller CROs benefit and win business to Finland through integration into networks (Medfiles).

6.3.1.7 Recommendations of the interviewees to CROs wishing to acquire international business

1) Share experience and standards of operation between experienced and inexperienced vendors

- The clinical CROs in Finland, e.g. Medfiles, have established a quality system in their company and have sufficient know-how of the quality requirements of the pharmaceutical industry. Therefore, their eventual contribution as a partner of an inexperienced vendor (e.g. one providing discovery research services) could speed up the vendor’s capability to go global.
- Sharing experience, e.g. by entering into a partnership, needs to be justified by sound business (Fermion).
2) Make sure that the business is built on solid core competence and that the competitive edge is maintained
- There are plenty of CROs selling standard services. The competitive edge depends on company size and especially on solid core competence(s) and a unique company and service portfolio. Niche markets for specialized skills!

3) Networking with other companies providing synergistic services may be essential for the success of small companies
- A dynamic network; the service portfolio should be designed as a collaborative activity, and it should be synergistic and mutually beneficial to all parties
- Agreement as to who in the network takes responsibility for the service range acquired by the customer (service sales, delivery conditions, quality, and financial transactions). The consortium needs to speak with only one voice.

4) Gain marketing muscle one way or another
- Strategic partnership with a suitable international network may be a solution for gaining business (Medfiles' approach)

6.3.2 Pharmaceutical service-provision companies

There are some 43 service-provision companies (a small representation of international CRO companies was not included). Thirteen (2 medium-sized, 6 small and 5 micro companies) of the 43 companies were clinical CROs. Size, personnel, or history is not necessarily reflected in the maturity of operations and the level of professionalism (Tables 3a & 3b).

The maturity (size, age, and personnel) of a company is partly reflected in its age (Table 5).
Many of the companies are successors to a previous company, e.g.
- Encorium is the successor to Remedium (trade sale)
- Euformatics is the successor to Medicel (Medici had ceased operations)
- Admescope is the successor to Novamass (a new company established on a knowledge base)
- Systems Biology Worldwide is the successor to Toxis, Novamass, and 4Pharma (acquisitions)
- Pharmatest is the successor to Dermagene/Clinitixion, Orthotopix, and Genolyze (merger/fusion)
- Spin-offs from university groups (Pharmatest, Orthotopix, Novamass, Genolyze) or industry (Remedium, 4Pharma, Statfinn, Cyncron, Crown CRO, Premedic, Syrinx)
- Some of the companies seemed to have ceased operations during some 6-month period of the survey; this is a sign of the volatility of the field (GCP tutkimuspalvelu, Imanext, CNServices, Genosyst, Fatman Biodesign).

6.3.2.1 Customers, marketing, and markets

Type of customers
The need for services depends on the customer’s experience and size.
- Big pharmaceutical companies need outsourcing vendors in situations involving lack of resources, whereas smaller companies are dependent on the overall know-how a vendor can provide in addition to the acquired specific service. This is perceived as an opportunity by vendors highly skilled in their area of expertise (e.g. ADME studies).
- The customers of Finnish vendors are mainly virtual drug development companies, phytopharma, biotech and medium-sized European pharmaceutical companies. However, the largest vendors and those providing very specialized services have been successful in gaining big pharmaceutical companies as customers. A larger vendor with sufficient service capacity is required when dealing with a large customer.

Gaining customers
References from big customers that are satisfied with the services received are important when dealing with smaller customers having scarce knowledge of the field. Pilot projects are a functional but not a guaranteed way, even if successful, of obtaining a customer for repeated business. The pilot, if run smoothly, is intended to convince the customer of the entire service process from purchase to final report.

Identification of the real decision-makers in the customer companies is an issue and remains a great challenge.

Universities or university groups usually are not customers. They are often perceived as competitors.

Marketing muscle is badly needed. Usually this is a challenge for a small company, especially when in the initial phase.

Ways for overcoming the issue include:
• Consolidation (the trade sale of Remedium to Encorium; the creation of Systems Biology Worldwide with strategic acquisition to serve customers especially in the preclinical arena; Pharmatest; Cerebricon with the acquisition of special know-how by Charles River, thereby gaining access to global distribution channels)

• With the exception of the contract manufacturing business, we are not aware of real examples of partnering with a pharma client, a phenomenon that is increasingly common in the US.

Dedicated full-time sales personnel and agents for promoting business are available thus far only in the largest vendor companies, but smaller vendors are currently investing in dedicated marketing and sales personnel.

6.3.2.2 Defined and conceptualized service product
The extent to which the company has conceptualized the service product is a key issue for success irrespective of the service area. Here, the vendor needs to possess: 1) a high level of acknowledged expertise in a narrow area; 2) special skills (plus resources) and dedication to improve or develop the next generation product extremely quickly; 3) service-mindedness, entailing flexibility in service-provision with timely delivery as well as the capability to offer custom tailored services to customers who need know-how and support.

The basic issues are a clearly defined product or service (fact sheet available) and a quality system in place to ensure the repeatability of the quality of the service product. Furthermore, using a healthy critical attitude, the vendor company needs to fully understand its core competence(s), its competitive edge, and the unique selling points of its service or product:

• the customer benefits must be formulated
• a unique selling proposition must be formulated

The more mature the vendor was, or the more industrial experience its key personnel had, the better the product was standardized and the better the other requirements were in place.

• Room for improvement with some of the vendors!

Customized products based on a technology platform

An example of a highly specialized product is the custom tailored R&D collaboration of Glykos with its pharma clients. Firstly, Glykos Finland represents exceptional skills in carbohydrate chemistry, with expertise that has accumulated over 40 years. Secondly, it is pursuing an aggressive IP policy possessing more than 45 patent families, and it is actively protecting any new innovations. Thus, their product is a conceptualized R&D package based on their proprietary technology.

In return, customers are requested to pay royalties on any product entering the market in which the IP protected technology of Glykos Finland is utilized. The business model differs from that of a service-provider because the revenues are not linearly dependent on the amount of work needed for producing the service.
6.3.2.3 Strategy for obtaining international customers
There is virtually no market for pharma services in Finland. Therefore, international customers are a prerequisite for business. Many of the service companies are small and provide diverse services. However, the possibility of forming strategic partnerships should be considered so it would be possible to offer more competitive and comprehensive service packages to international customers. The partnering company obviously does not need to be Finnish.

Customers are obtained through active marketing and sales efforts as the product or service has been conceptualized and fulfills the quality requirements. The success of these activities is closely related to the strategic choices of the company and its understanding or creation of its core competencies.

All outsourcing vendors agreed that successive commercial exhibitions (expensive!) are essential for developing international business. In some cases, scientific publications or congresses are helpful. Decision-makers regularly visit commercial conferences.
- The active search for customers (electronic searches; a network of companies revealing potential customers to one another) may help as preparatory work for conferences
- Try to arrange face-to-face contacts with decision-makers. As an initial contact, this is seldom successful since decision-makers are efficiently protected from these kind of contacts because all service providers are trying to make contact. Even dedicated consultants have not been able to make contact.

The following are important additions when securing business
- Web page
- Mass emailing
- Electronic news and letters to customers
- References of important customers
- Repeat business deals obtained through quality; flexibility and appropriate pricing when tied up with longer-term business deals
- Time is needed: 2–3 years of marketing efforts

6.3.2.4 Networks and strategic partnerships
Networking with companies providing complementary services are becoming highly important for business also in Finland. Services are sold by one of the network participants, who takes responsibility for the entire purchase (legal aspects, quality, delivery terms). A university is not part of such network because companies are usually reluctant to buy services from a university. Universities seldom provide timely deliver with sufficient quality and quantity.

Main challenges
- Small vendors face economic challenges in two critical issues

Partnerships to increase business
Fermion is partnering with an established clinical research organization providing the active pharmaceutical ingredient (API) for clinical trials managed by the CRO. The partner’s share is in providing the API for preclinical and phase I studies, whereas Fermion’s share is in phase 2 to phase 3 trials. Fermion’s strength is to produce the API in sufficient quantity and with sufficient quality to continue as the API provider when the experimental product has eventually obtained marketing approval. Acting as a CMO was a strategic decision taken in 2008.

Medfiles is part of a regulanetR network, with members in over 80 CROs throughout the world, providing life science services. This allows the establishment of new service packages, e.g. including health economic analyses in the service. Altogether Medfiles is a good example of a company that continuously develops its business strategy to reflect the global trends of the field in order to be successful.

Via strategic partnering, the scope of services can be widened (as above). This was mentioned as a strategic aim by several of the vendors interviewed.
• Marketing efforts remain modest and insufficient to gain the bulk of new customers
• Development resources are inadequate to keep up with cutting-edge technology and thereby to remain competitive
• Change in the global environment (the number of clinical trials has decreased in Finland)
• Opportunities to find strategic companions within the service field are perhaps underutilized
• Comprehensive business skills may be lacking, which impacts on risk management, IP strategy, skills in compiling agreements, sales strategy, understanding customer needs, and thus also impacting on the sales package formulated to meet the needs of each individual customer.

6.4 Critical success factors for a continuous customer relationship

If the service is based on scientific achievements, those need to be of top class. Mechanisms need to be in place to stay level with, or preferably ahead of, scientific development in the global field.
• Ability to produce or provide unique services or services of extremely high quality
• Ability to create or change the market
• Let the customer know that you are committed to achieving the common goal
• Be a trustworthy vendor. If the customer is on its way to making a mistake, you must have the courage to advise the customer even if it jeopardizes the deal
• You have the financial capability to be visible
• Ability to continuously produce value to the customer without fail.

7. Conclusions

Internationally and in Finland, investment markets are in a downturn, making the acquisition of funding extremely difficult, especially in Finland. The pharmaceutical industry as well as the service-provision market is consolidating both horizontally and vertically, making the competition ever tougher. Both of these main trends make the international commercialization of services by Finnish vendors a challenging task. International commercialization is, however, a necessity since the home market is unable to support service-providers.

Based on the experience obtained in their project, Orava & Holopainen (2008) divided the internationalization process of service companies into three phases: (i) development of the knowledge base; (ii) international commercialization; and (iii) accelerated growth. The phases were in relation to the maturity of the products (development of services, definition and formalization of service products and marketing communication) and preparedness to go international (especially the capabilities in and knowledge of international marketing, resources, and the level of detailed market information). In general, the later the phase in which the company was, the higher the level of the capabilities seems to be.
Table 6. The internationalization process of service-provision companies of Finnish origin as defined by Orava & Holopainen (2008)

<table>
<thead>
<tr>
<th>Grouping of service-providers of Finnish origin</th>
<th>N</th>
<th>Development of the knowledge base</th>
<th>International commercialization</th>
<th>Accelerated growth or established international business</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bioinformatics</td>
<td>4</td>
<td>Euformatics, Genevia</td>
<td>Xemet</td>
<td>Medisapiens</td>
</tr>
<tr>
<td>Preclinical CROs</td>
<td>3</td>
<td>Neurotar, Plexpress</td>
<td></td>
<td>Admescope</td>
</tr>
<tr>
<td>Disease models</td>
<td>1</td>
<td></td>
<td></td>
<td>Pharma test</td>
</tr>
<tr>
<td>APIs/Biological</td>
<td>6</td>
<td>Galilaeus Macrocrystal</td>
<td>Biovian</td>
<td>Fermion, Pharmatory, Glykos Finland</td>
</tr>
<tr>
<td>Statistical services</td>
<td>2(3)</td>
<td></td>
<td>EPID Research, Statfinn</td>
<td></td>
</tr>
<tr>
<td>Clinical CROs</td>
<td>5</td>
<td>CRST, Secret files, Premedic Clinical Research</td>
<td>Medfiles, Crown CRO</td>
<td></td>
</tr>
<tr>
<td>Special services</td>
<td>6</td>
<td>Galena, DRA consulting</td>
<td>DelSiTech, Syrinx</td>
<td>Zora, CRF Health</td>
</tr>
<tr>
<td>Total</td>
<td>28</td>
<td>2</td>
<td>11</td>
<td>10</td>
</tr>
</tbody>
</table>

The international companies operating in Finland can be considered to be either in the advanced international commercialization phase or the accelerated growth phase, meaning that they are in direct competition with the corresponding Finnish companies (Table 1).

In terms of products, the suggested means for becoming international and for reaching accelerated growth include
- ensuring that your perceived competitive edge is true from a global perspective. Be critical and honest
- making sure that your skills remain up-to-date and your service product remains competitive, being preferrably unique
  - The product or service (fact sheet available) should be clearly defined and a quality system should be in place to ensure the repeatability of the quality of the delivered service product. Furthermore, using a healthy critical attitude, the vendor company needs to fully understand its core competence(s), its competitive edge, and the unique selling points of its service or product:
    - Customer benefits formulated
    - Unique selling proposition formulated
- In terms of business skills, invest in comprehensive business planning. Researchers are usually not the best persons for sales or for planning a business strategy. Use professionals for the purpose.
- be flexible and alert in modifying your business strategy to reflect domestic and global trends
marketing muscle is required to make yourself visible. The most important is to participate repeatedly in commercial congresses and exhibitions and even to hunt for customers. One has to be prepared that this phase may last at least 2–3 years.

- Being content with websites, e-mailings and newsletters is not the most efficient way to gain sales. Rather, you should attempt to understand any customer’s needs individually and to tailor your sales package accordingly. Business intelligence is a prerequisite for achieving the above.

Finnish-based companies should aim at a preferred provider status and, in some cases, at strategic partnerships, but risk sharing is almost beyond the arsenal of Finnish companies (Point 6.3.1.2).

Strategic partnerships may be an efficient way of widening your service portfolio to meet customer needs in a competitive way. During recent years, much consolidation has already taken place to achieve the needed operative and financial objectives from development of the knowledge base to commercialization (Table 6). In any case, the general critical success factors need to be taken into account (Point 6.4). Internationally, strategic partnerships seem to be the preferred way to gain growth.

Yet, the interviews indicate that many companies seem to appreciate independence and tend to keep customer contacts as an “intellectual property” of the company. This may mean that the companies should be more open to cooperation to be able jointly to utilize the knowledge and capabilities of a number of companies instead of wasting energy on mutual competition (Table 1).

It seems that the companies which are able to form or participate in networks are successful. This is supported by the current international trends in use even by big companies. The resources of small companies are always limited; this together with the current findings may lead to the general conclusion that collaboration even to the extent of losing independence may be the preferred approach to growth and going international. Another model some smaller companies are employing and moving forward in their internationalization is to provide really unique services (Medisapiens, Epid Research and Glykos Finland).

Orava & Holopainen 2008 proposed the following five internationalization models based on networking. Examples are presented below:

1. Virtual Hub Organization Model (Medfiles)
2. Co-exporting Alliance Model (Fermion)
3. International Integration Model (Systems Biology Worldwide)
4. Global Integration Model (Cerebricon)
5. Sub-contractor Model (Ark)
8. Selected references


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The Swedish Drug Development Pipeline. The Swedish Life Science Industry Organization. 2010

Taylor N. Optimism returns to pharmaceutical outsourcing sector. Nature Biotech 2012
9. List of Appendices

Appendix A: List of service-providing companies and pharmaceutical companies
Appendix B: Interview questionnaire, Pharma
Appendix C: Interview questionnaire, Service providers

**Appendix A. Company listing**

**Bioinformatics**
- 20 Euformatics Oy
- 21 MediSapiens Oy
- 22 Genevia Technologies Oy
- 23 Xemet Oy

**Preclinical CROs**
- 30 PlexPress Oy
- 31 Admescope Oy
- 32 Systems Biology Worldwide Oy, Toxis Ltd Oy
- 33 Novamass Oy
- 34 Neurotar Oy

**Disease models**
- 40 Charles River Discovery Research Services Finland Oy
- 41 Pharmatest Services Oy

**APIs / Biologicals**
- 50 Fermion Oy
- 51 Pharmatory Oy
- 52 PCAS Finland Oy
- 53 Galilaeus Oy
- 54 Biovian Oy
- 55 Medipolis GMP Oy
- 56 Ark Therapeutics Oy
- 57 Glykos Finland Oy
- 58 Macrocrystal Oy

**Statistical services**
- 80 EPID Research Oy
- 81 StatFinn Oy
- 82 Oy 4Pharma Ltd

**Clinical CROs**
- 90 Clinical Research Services Turku CRST (Turun yliopisto)
- 91 GCP Tutkimuspalvelut Oy
- 100 Quintiles Oy
- 101 Secret Files Oy
- 102 TFS Trial Form Support Oy
- 103 Oy Premedic Clinical Research Ltd
- 104 Crown CRO Oy
- 105 Cyncron Oy
- 106 Encorium Oy
- 107 Oy Medfiles Ltd
- 108 NORMA ApS filial i Finland
- 109 Covance Clinical and Periapproval Services Limited
- 110 PAREXEL Finland Oy

**Special Services**
- 120 CRF Box Oy
- 121 DRA Consulting Oy
- 122 SYRINX Bioanalytics Oy
- 123 Galena Oy
- 125 DelSiTech Oy
- 127 ValiRx Finland Oy
- 130 Zora Biosciences Oy
- 131 Computational Medicine Research Group (Oulun yliopisto)

**Vaccine companies - Start up**
- 150 FIT Biotech Oy
- 151 Vactech Oy
- 152 Desentum Oy

**Pharma companies - Start up**
- 160 Aurealis Oy
- 161 Faron Pharmaceuticals Oy
- 162 Hermo Pharma Oy
- 163 Hormos Medical Oy
- 164 Meedia Therapeutics Oy
- 165 Novobion Oy
- 166 Oy Fennopharma Ltd
- 170 Biotie Therapies Oyj
- 171 Laurantis Pharma Oy
- 172 Vegenics/Circadian

**Big Pharma**
- 180 Orion Oy
- 181 Bayer Oy
- 182 Santen Oy
- 183 Sanquin Oy
- 184 Finnish Red Cross Blood Service

**Viral Therapeutics - Start up**
- 190 Oncos Therapeutics Oy
- 191 FKD Therapies Oy
Appendix B.

Items to be discussed

Potential areas for outsourcing
- areas where outsourcing is never practiced?
- Outsourcing strategies
- Role of Strategic partnerships
- Risk sharing

General criteria for decision making with regard to services and service providers
- Common vs Unique Skills
- Personal contacts/Mutual respect/Distance/Cultural aspects

Gaining information of potential service providers
- Personal contacts/selling efforts/other

Who is responsible for decision making & Process in terms of which service provider to choose?
- Opinion on network by services providers.

Appendix C.

Kysymykset

1. Yrityksen luonnehdinta
   - Yrityksen historia/ ikä
   - Toimintaympäristö: suomi; kansainvälinen
   - Suuruus (liikevaihto?)/henkilöstö
   - Rahoitustilanne/ kokemus rahoituksesta/ ongelmat

2. Palvelutuote ja tuotteistus
   - miten tuotteistus on tehty?

3. Yrityksen vahvuudet?
   - Ydinosaaminen
   - Tuotteen Unique selling point / proposition
   - Toiminnan laatutekijät (toiminta-ohjeet)

4. Ketkä ovat asiakkaita?
   - tutkimusryhmät; yritykset?
   - kotimaiset
   - ulkomaiset

5. Yrityksen päämarkkinointi/myyntikeinot?
   - Miten viimeiset asiakkaat on saatu?

6. Onnistumiset/ epäonnistumiset liiketoiminnan luomisessa/markkinointi fokuksessa
   - Halukkuus, mahdollisuudet Strategic partnerships/Risk sharing
   - Kun sopimusta ei syntynyt, mikä mielikuva on miksi ei?
   - markkinapenetraation vaatimat resurssit, kuten osaaminen ja rahoitus
7. Markkinat (Mitä ja mille markkinalle yritys suuntaa toimintaansa & kansainvälistymisstrategia)

Onko kansainvälistymisstrategia tehty?
- Suunnittelu
- Markkinatutkimusten tekeminen sisäisesti tai ulkoisena palveluna
- Ulkoisten asiantuntijapalveluiden käyttö
- Tuotteistamiseen liittyvät toimenpiteet
- Markkina- ja asiakaskartoitustööt
- Osallistuminen messu- ja partneri- ja kilpailukohdissa
- Osallistuminen markkina- ja asiakaskartoituksesta

Osaaminen; resurssit
Vahvuuksien ja heikkouksien analysointi
- Palveluprosessin arviointi
- Palvelutuotteiden luominen/täsmentäminen
- Palveluiden hinnoittelu
- Palvelutuotannon tehostaminen
- Uusien näkökulmien löytäminen
- Brandin vahvistaminen

Yhteistyömuotoihin perustuvaa vai yritysten integraatioon perustuvaa?

8. Kilpailutilanne

9. Verkostot (yliopisto/yritykset) keiden kanssa yhteistyötä ja kestä olisi selkeää hyötyä

Kokemus yliopistoyhteistyöstä
- mitä tehty; tulos?
- halu jatkaa yhteistyötä/ aloittaa yhteishankkeita? Mieltä?

Kokemus yhteistoiminnasta muiden yritysten kanssa

Dynaaminen verkosto (itsenäisten yritysten liitto, jossa tehdään yhteistyötä valittujen projektien ja tavoitteiden kautta) vaatii onnistumiseen seuraavia asioita:
- Olemassa oleva tarve (market opportunity)
- Yhteiset tavoitteet
- Strateginen synergia (ml. palveluportfoliot ja toimintatavat)
- Yhteistyövalmiudet ja –kyvyt
- Sitoutuminen

Tuotteiden pitäisi muodostaa toisiaan täydentävää palvelujen ketju, jossa eri yritysten tarjoamat
- palvelutuotekokonaisuudet voidaan muokata yhteiseksi palveluportfolioksi
- Markkinanläpäiset ja operaatio-muotovalinnat täytyy saattaa yhden
- Mukaan kuuluvien yritysten kaltaiset sydänteet
- Rahoitus ja voitonjakoprosessin määritys

Kotimaisia yrityksiä
Kansainvalisia yrityksiä

Kuinka helppo on asiakkaan päättäjän identifiointi

10. Mitä muuta asiaan liittyvä mitä en ole osannut käsitellä?