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EMCC case studies

Biomedical healthcare sector: Unimed, Czech Republic

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Background

Unimed s.r.o.[1] was founded in 2004 by a team of medical professionals with 10 years of experience in clinical trials and a good knowledge of Central and Eastern European healthcare systems. The company is a middle-sized Contract Research Organisation (CRO) located in Prague, Czech Republic.

Since 2004, the company has developed a range of services and is now able to offer 'the full package': monitoring, data management, medical writing, etc. Unimed performs multinational clinical trials with quality guaranteed through independent audits.

The company currently employs a total of 17 employees including 8 freelancers, management and administrative staff. According to Ales Horacek, the CEO of Unimed, one of the company's key strengths is its small and flexible organisation.

Unimed has developed close relations with a range of pharmaceutical companies that either buy the company's services or lease Unimed employees to carry out specific tasks in-house. The company is also collaborating with companies in Slovakia and CROs in other East European countries (e.g. Bulgaria, Ukraine, Russia, Macedonia and Croatia).

Outsourcing of drug development

Drug development is a complex activity that requires a broad array of medical and laboratory expertise, including toxicology, preclinical evaluation, clinical trial design and implementation. Today's drug development process is very complex and requires extensive testing and documentation. As a result, it can take up to 12 years or more and over US $800 million to bring a new therapy from discovery to market – a capital-intensive, time-consuming and resource-intensive process. In the face of this, many pharmaceutical and biotech companies look to outsourcing some or all of their drug development activities.

There are several factors driving the outsourcing of drug development:

- Pharmaceutical companies need to develop drugs faster to maximise patent protection and secure marketplace advantage.
- The emergence of biotech companies and the consequent explosion in new compounds in the early drug development pipeline.
- Sophisticated therapeutic and regulatory expertise is needed to successfully develop a compound.
- More complex, multinational clinical trials, requiring sophisticated diagnostic and laboratory testing.
- Opportunities for pharmaceutical companies to reallocate resources and strategic investments to other core competencies, such as manufacturing.

Through strategic outsourcing, biomedical companies can access additional therapeutic and regulatory expertise, extensive non-clinical and clinical drug development experience and state-of-the-art technology – without adding the associated fixed costs to their R&D overhead.

Source: *Covance website*: **http://www.covance.com/aboutcvd/industry.php**

[1] **http://www.uni-med.cz/**

Czech CRO sector

CROs search for cost-effective countries in which to carry out clinical trials. This has been to the benefit of Central and East European countries due to their relatively low cost-level compared to West European countries. For instance, in 2006, the US-based CRO Covance opened a clinical development office in Prague, Czech Republic.

Over the last decade, the number of clinical trials in the Central and Eastern Europe region has been growing at an average rate of 30% per annum and this growth is expected to continue.[2] In particular, the Czech Republic has shown dramatic growth in clinical research over the past decade due to the adoption of FDA- and EMEA-compatible regulations and a high incidence of many of the diseases most targeted by the pharmaceutical industry.

The attractiveness of the Czech Republic for CROs and pharmaceutical companies has resulted in an increase in the number of CROs in the country. In the beginning of the 1990s, the number of Czech CROs was limited, but in 2007 the number of companies had increased to 23, including some large international CROs, such as Quintiles (**http://www.quintiles.com/**). The many experienced national and international CROs in the Czech Republic and the skills and competencies of employees in the Czech CRO sector provide a strong basis for carrying out clinical trials in the country.

Strengthening sectoral collaboration – ACRO-CZ

ACRO-CZ is a professional association of Contract Research Organisations (CROs) in the Czech Republic which focuses on clinical research and the development of pharmaceuticals. The association was founded in 2005 and is a member of the European federation of CROs.

The main goals of the association are:

- To represent CROs in conceptual negotiations with state authorities and institutions, as well as internationally.
- To actively participate in discussions regarding the creation of legal and ethical norms in the area of clinical research.
- To create conditions for the further education of its members, as well as to develop cooperation in the area of clinical evaluation of pharmaceuticals.

Source: *ACRO-CZ website*: **http://www.acro-cz.cz/en/index.php**

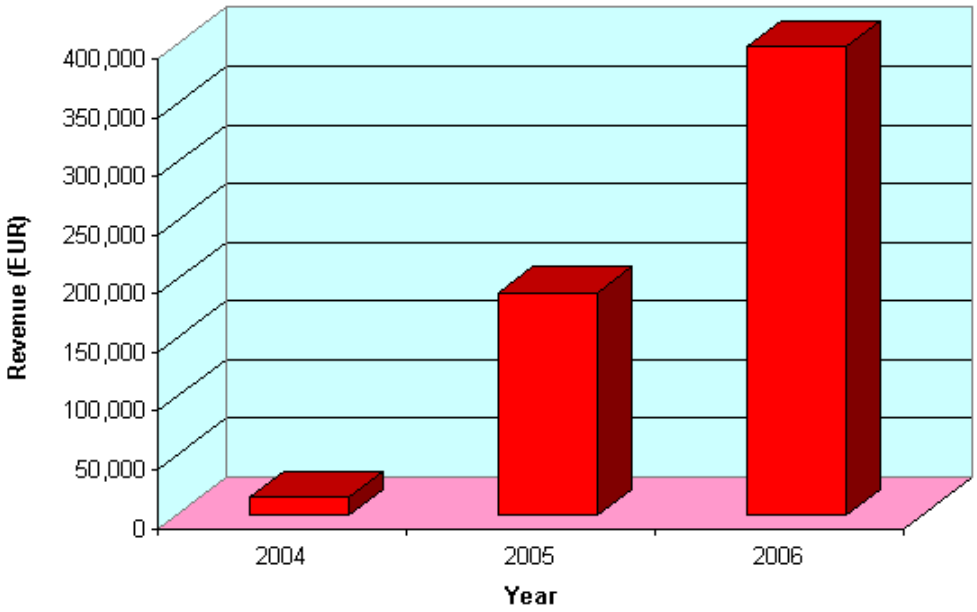
[2] DrugResearcher website, **http://www.drugresearcher.com/news/ng.asp?n=65502-synexus-covance-clinical-research-patient-recruitment-eastern-europe**

Facts about the company

Key figures

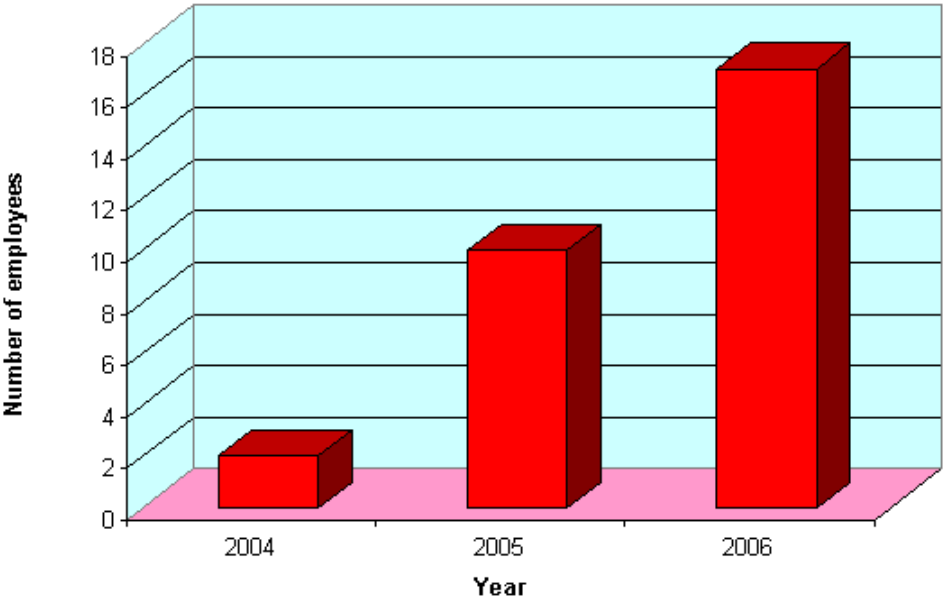
Unimed has experienced a steady increase in revenues since the company was established in 2004. In 2006, revenues reached €400,000.

Figure 1: *Revenues (2004–2006)*



Positive development is also reflected in the number of employees (see Figure 2).

Figure 2: *Number of employees*



All employees are between 31-40 years old. In terms of educational profile, 14 of the 17 employees have a university education and the remaining three have high school exams.

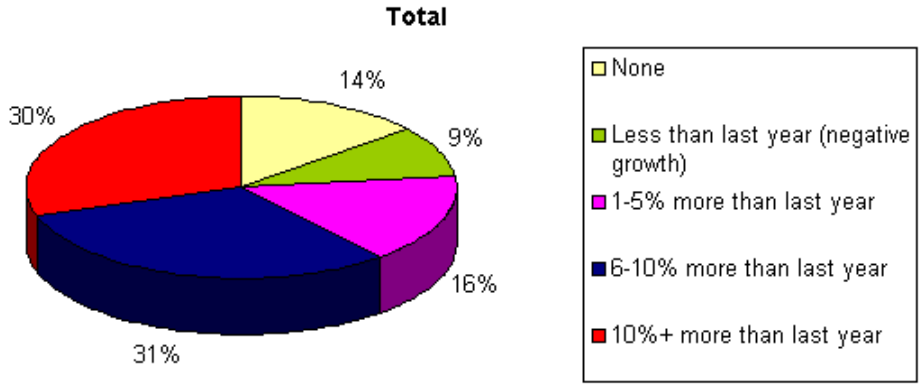
Challenges

Increasing demand for CRO services

For companies in the healthcare sector, the development of products is risky and demands many resources, which makes the efficient use of resources very important. A key strategy for companies is to focus internal efforts on core research, pipeline development, product management and marketing, while outsourcing non-core activities, such as clinical trials to CROs and contract manufacturing organisations.

In a survey of pharmaceutical and biopharmaceutical companies, 77% of the respondents answered that their outsourcing spending would probably increase the following year. This indicates that the volume of outsourced activities will also increase.

Figure 3: *Expected growth in outsourcing spending (2007)*



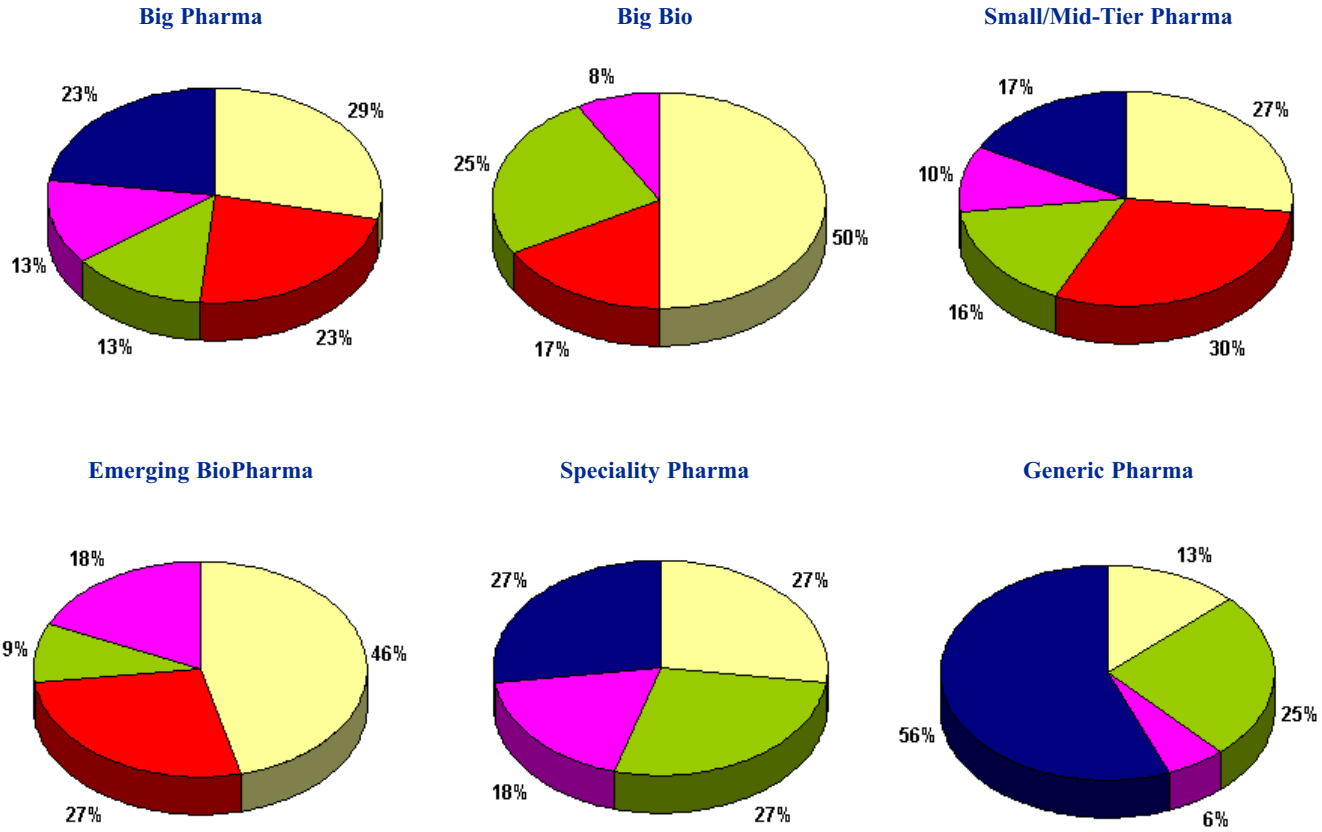
Source: *ContractPharma, Contract Pharma outsourcing survey 2007*, **http://www.contractpharma.com/articles/2007/05/2007-annual-outsourcing-survey**

The main motivation for outsourcing activities is 'to focus on core competences' (40%), followed by 'company is virtual' (27%) and 'temporary lack of capacity' (24%).

The respondents were also asked to consider the opportunity of outsourcing to Asia. While 20% of the respondents answered that they would definitely outsource to Asia the following year, a total of 32% of the respondents indicated that they would definitely not outsource activities to Asia.

When it comes to outsourcing, there are huge differences between the different types of companies (see Figure 4).

Figure 4: *Outsourcing of activities to Asia (by type of company)*



Source: *ContractPharma, Contract Pharma outsourcing survey 2007*,
http://www.contractpharma.com/articles/2007/05/2007-annual-outsourcing-survey

According to the survey, pharma companies (in particular generic pharma companies) are most inclined to outsource to Asia, while biopharma companies are less inclined to outsource to Asia.

This outsourcing trend translates into an increase in the demand for service, for instance managing trials. But meeting the demand requires more people, and according to Petr Janda the shortage of skilled staff is a serious threat to the sector's growth opportunities.

Consolidation and growth of the company's market position

A key challenge for Unimed is to consolidate its market position – getting a 'name' in the industry. The quality of the company's services (e.g. speed and reliability) is key to the future success of the company.

Increasing competition

The Czech CRO sector is facing increasing competition from other countries; competition from West European CROs is currently very tough. According to Ales Horacek, CEO of Unimed, competition from India and China is not that visible at the moment. However, there are some indications that competition is growing, mainly in relation to phase 1 trials. In addition, non-European actors are increasingly entering the European market, as illustrated by recent buy-ups of Polish CROs by Indian companies. This has emphasised the need to put effort into ensuring the high quality of services offered.

Rising costs and stricter regulation

The approval and monitoring of products is very complex and commands many resources. Furthermore, the legal ramifications of clinical research efforts can be astonishing, even years after a product has received regulatory approval.[3] According to Ales Horacek, the Czech CRO sector has been experiencing rising costs and stricter regulation of clinical trials in recent years. This makes clinical trials more expensive and more burdensome for companies operating in the country and could result in pharmaceutical companies moving their clinical trials to Asia.

Demand for full service packages

The Czech CRO sector specialises in monitoring clinical trials. According to Petr Janda, head of ACRO-CZ, biomedical companies are increasingly looking for full service packages. In order to meet this demand, the CRO industry is evolving toward a full-service model, which makes it possible for the companies to offer a complete range of services that can be harnessed from the earliest stages of development through post-approval research.[4] As a result, CROs must either expand their activities to other areas, merge with other CROs or enter strategic partnerships.

Internationalisation of the CRO sector

CROs increasingly operate on an international scale, conducting trials in multiple countries at once, under the supervision of multiple regulatory bodies.

Innovation and new technologies

The CRO industry is adopting a complete electronic information environment, gathering and reporting data through secure online channels. Besides reducing errors, electronic tools speed up information gathering and reduce the need for paper documentation.[5]

Patient recruitment

The CRO sector as a whole needs to consider suitable patient recruitment and retaining strategies and understand patient motivation in Central and Eastern Europe in order to further develop their business.

Workforce

For the sector as a whole, there is a shortage of monitors. According to Petr Janda, companies in the sector have been able to recruit new employees via personal contacts, but it is getting more difficult and companies often have to advertise for potential employees. Currently, all Czech CROs have a shortage of skilled staff. The shortage is primarily explained by the increase in the number of projects that Czech CROs are carrying out.

In addition, there are currently no requirements or formal certifications for monitors/people working in clinical trials. This makes it very difficult for companies to assess the quality of potential employees.

[3] Association of Clinical Research Organisations, **http://www.acrohealth.org/trends.php**

[4] Ibid.

[5] Ibid.

Recruiting new employees is also one of Unimed's main challenges. The pool of qualified employees in the Czech Republic is simply too small and Ales Horacek characterises the recruitment situation as being very difficult. In particular, the company needs people that have knowledge of IT and databases. In order to get the right people with the right skills, Unimed is implementing a new system of training which makes it possible for employees to work for the company while they receive training. The share of working hours that an employee uses for training ranges from 30% to 50% of total working hours. Employees usually receive training at the European Pharma School or via ACRO-CZ.

The European Pharma School

The European Pharma School was established in 2005 by Czech professionals from clinical research, namely Dr Petr Janda (ACRO-CZ), Dr Ales Horacek (Unimed) and Dr Stivinova. The objective of the school is to provide integrated education, certified by significant Czech and foreign institutions, to all those that operate in the field of pharmaceutical medicine and pharmaceutical marketing.

The European Pharma School (EPS) intends to satisfy the following criteria:

- It will be a representative, postgraduate educational centre covering all fields of pharmaceutical medicine, from molecule to marketplace.
- The European Pharma School will be organised on a yearly basis, in the same manner as other postgraduate education.
- The diploma awarded by the European Pharma School will have Europe-wide input thanks to endorsement by Czech as well as foreign institutions.

A professional endorsement has been secured from the following institutions:

- Cardiff University/BrAPP Postgraduate Course in Pharmaceutical Medicine, UK.
- 3rd School of Medicine of the Charles University, Prague, Czech Republic.
- EUCROF, European Association of CROs, Amsterdam, Holland.

In addition to professionals from these institutions, specialists in the field of pharmaceutical medicine and pharmaceutical marketing in the Czech Republic are participating in the project. The European Agency for the Evaluation of Medicinal Products (EMEA) is also contributing by providing lecturers for some of the educational programmes and by assisting with professional advice in the preparation of the programme.

Source: **http://www.eps-eu.com/en/introduction/**

The school is an important initiative for the Czech CRO sector, making it possible to meet staff shortages and bridge skills gaps.

Unimed has benefited from close personal relations with its employees, but as the company grows, the need for new human resource initiatives is growing. The management is currently focusing on providing training for its employees. In the future, the management of Unimed will be working on different measures in order to get people to stay at the company.

Conclusion

Pharmaceutical companies are increasingly outsourcing non-core activities, such as clinical trials, and CROs are benefiting from this trend. The Czech CRO sector is growing and companies such as Unimed are now providing a full range of clinical services to companies. However, Unimed is facing a range of challenges, such as increasing competition, stricter regulation and rising costs. Moreover, the company is finding it difficult to recruit skilled employees, making it necessary to rethink the company's approach to training.

SWOT analysis

The company's main strengths, weaknesses, opportunities and threats are identified below.

Strengths	Weaknesses	Opportunities	Threats
• High standards for clinical research • Small and flexible organisation	• Lack of qualified employees • No official certification of people working with clinical trials	• Increasing demand for clinical services (companies are outsourcing non-core activities)	• Rising costs • Increasing competition • Increasing regulatory demands concerning clinical trials (more complex and more expensive)

Sources

Interviews

Dr Ales Horacek, CEO of Unimed s.r.o.

Dr Petr Janda, Head of ACRO-CZ

Reports

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Henrik Noes Piester, Danish Technological Institute

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