

Flexible MBA 2007/11 (part time)
Nottingham Business School of Nottingham Trent University

Globalisation in Pharmaceutical Industry and Clinical Trials

International Consultancy Project: International Business

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I certify that this is entirely my own work and that all collaboration or material from other sources has been clearly attributed in accordance with the requirements of the module and the university regulations.

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Abstract

The assignment present evidence supporting claims that markets become more interdependent and standardised. It points to the fact that there were periods in history with high market interdependence but this era of globalisation is distinctively different from previous ones. Information technology is identified as globalisation crucial driver. Globalisation is considered economic process only secondary influencing politics or culture.

The work analyse globalisation processes in pharmaceutical industry and clinical trials. It is especially focused on Contract Research Organisations (CROs) as form of outsourcing within the industry. Clinical development is presented as significantly standardised environment.

Strategy analysis focus on one of the leading CRO. It points to the fact that rather CROs than pharmaceutical companies took advantage of globalisation and adopted some novel business concepts including flat organisational structure, extensive adoption of technology, global operations. The work also stress necessity to respect local specifics. Advantages and disadvantages of different geographical areas in conduct of global clinical trials are evaluated. On base of the analyses set of recommendations is formulated.

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Globalisation - Introduction

We all can observe that the world is somehow changing. Today it is much easier to reach people through great physical distances than it used to be 10 or 20 years ago. This is supposed to make international business easier and more efficient. While not clearly defined, easier movement of information, products, capital and people became associated with globalisation. It is also anticipated that business environment is now more dynamic as globalisation led to standardisation, increased competition and it involves changes in politics, lifestyle and culture.

This topic in general attracts attention of economists. Here are some examples how globalisation can be viewed.

Globalisation is about the growth of "worldwide interconnection and interdependence at the culture, political and economic level" (Giddens, 1999). I do not see clear evidence of rising cultural or political interdependence. In fact rise of Islamic fundamentalism or nationalism in India is often attributed to economic globalisation.

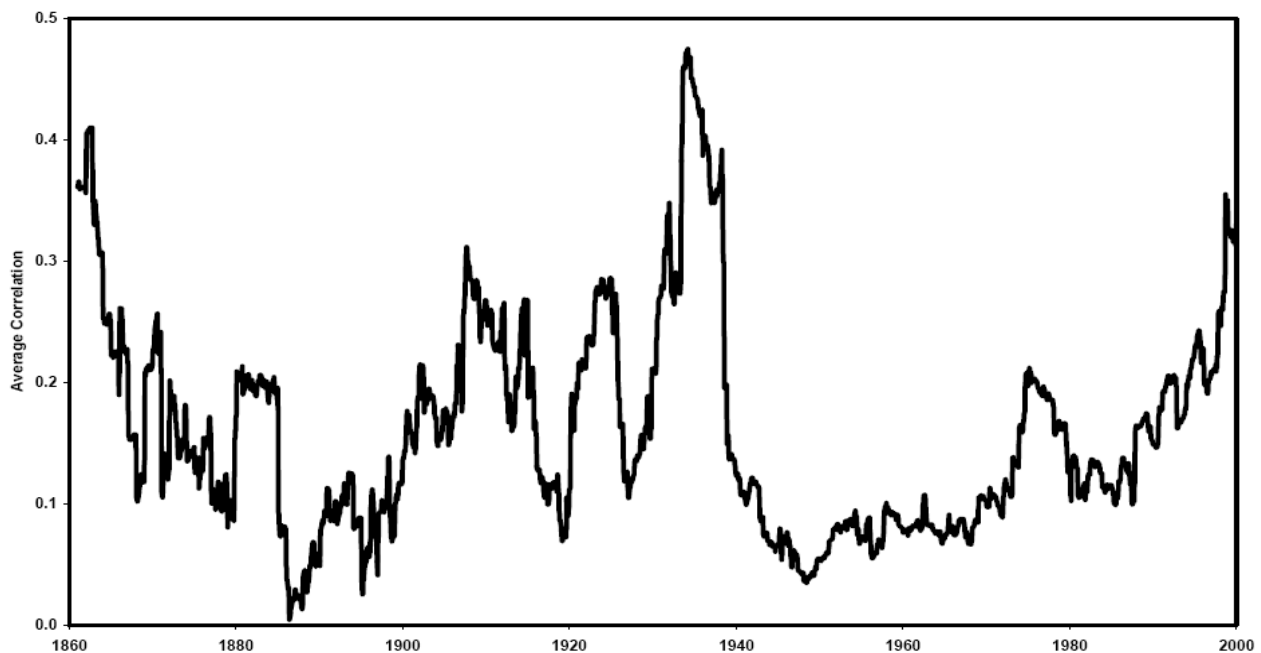
"The merging of historically distinct and separate national markets into one huge global marketplace" (Hill, 2000). I will present evidence on historically oscillating markets interdependence and challenge claim of globalisation historical singularity.

"The emergence of global markets and services for standardized consumer products" (Levitt, 1983). Levitt point out to technology induced market homogenization. I think there is no question that markets are much more standardized now than a decades ago and this can be largely attributed to technology. However, ignoring persisting market differences would lead to flaws in marketing strategies. There are only limited product groups with truly global markets.

There is also ongoing discussion on extent of globalisation. Contrary to claim "Globalisation is a fact standardisation is a fiction" evidence on standardization of markets will be presented.

There is convincing evidence that degree of economic interdependence varied during history. An early example can be economic integration and rise in regional trade during times of the Roman empire and subsequent fall as it declined. However, ups and downs in global economic integration were occurring since beginnings of capitalism. End of 19th century was era of free trade agreements and period of relatively unrestricted movement of products and capital. This era is sometimes mentioned as first era of globalisation. That time it was steam engine and falling transportation costs what driven that era of globalisation.

Beside international trade another strong indicator of economic interdependence is correlation of world equity markets. On turn of 19th and 20th century correlations were much higher than during most of 20th century with exception of Great Depression. We can observe this on correlation data representing 150 years of equity markets history.



International equity markets correlation (Goetzman, Li, Rouwenhorst, 2001)

Goetzman, Li, Rouwenhorst (2001) claim that “the period from 1870 to 1913 was, in some ways, the golden era of global capitalism”. What followed was World War I, hyperinflation, Great Depression, World War II, Cold War, decolonization with numerous weak protectionist states.

Recent openness of economies is not purely underlain by technology change. But understanding importance of technology in the process is crucial in defining this era of globalisation and distinguishing it from previous waves of economic integration. Therefore I define globalisation as economic processes triggered and maintained by falling communication costs. Single most important globalisation process has been introduction of internet accelerating since second half of 1990s. However, other developments leading to borderless world had already been on the track that time.

Structural changes in the US economy traced back to late 1970s paved road to more open American economy. 1980s restructuralization, free market politics and increased competition all favored international economic cooperation. Thatcher's Britain soon adopted these ideas too. But may be more unexpectedly other huge countries started to head world markets. China gradually implemented market reforms. Finally, the world changed with collapse of the Soviet Union. Just inclusion of such large markets into international trade has its inevitable consequences. Even if technological revolution had not followed world market would likely operate more efficiently then decades before. There would be place for global products, free trade agreements, no serious obstacles for movement of capital. It could be similar to free trade eras of late 19th century and post WWI in its nature.

It was emergence of disruptive information and communication technologies what set up further direction for global economy. Just to summarize, the crucial consequences are: dramatic fall of communication costs, speed up and qualitative change in communication, enabling cooperation of large groups of people without need of a hierarchical structure, simplified information processing. All changes we observe in business processes and structures are the consequences. Internet means to service industry what serial production meant to manufacturing.

Open architecture of internet is one of clues to understanding importance of technical standards in modern economy. The network is built on open protocols such as TCP/IP. Platform independence enables cooperation of large numbers of machines/people. This might had not be the case. In fact many companies forced their own standards in networking (Friedman, 2005). Open source philosophy is just next step. Unorganized individuals can now create software often credited higher then those offered by biggest world corporations. Linux, Mozilla Firefox or Open Office successfully compete Microsoft products. Another point is that standardization goes well beyond IT - International Organization for Standardization (ISO) or International Conference on Harmonization (ICH) in pharmaceuticals are good examples.

There is a direct link between IT and outsourcing. New paradigm may be anything that can be digitized can be outsourced. Other noticeable change in organizational structures is that they tend to be flatter. This could have been achieved as decentralized IT based decision making systems are capable to replace hierarchical organizational structures.

Rather controversial issue remains global marketing. As markets are supposed to be more integrated and homogenized some suggest using global marketing as only efficient strategy. This imply offering of standardized products worldwide utilizing economies of scale and leading to lower sales costs. Contrary there are opinions that customization is the trend. From my point of view in line with trends of relationship marketing customization is becoming rather focused on individuals then to broader markets segments. This is possible thanks to modern technology that power globalisation itself. In other words customization is not contradictory to globalisation or global markets.

Goetzman, Li, Rouwenhorst (2001) researched current correlation patterns of world equity markets and compared them to periods of high correlations in turn of 19th and 20th centuries. On base of parametric testing they rejected hypotheses that the periods have the same correlation matrices. They conclude that these patterns constitute two distinct eras in global finance. They support explanation that integration today is deeper and broader than 100 years ago as a result of less information asymmetry, reduced transaction costs, better institutional arrangements, and more complete international standards.

I consider globalisation to be economic process. It is clear that it influences politics and culture as well but I have doubts or can see only little evidence that it include politics/culture in a sense country policies/cultures becoming more interdependent. European Union is sometimes pointed out to be example of political integration. In fact there was free movement of people and products within Europe in 19th century as well. Even countries had effectively single currency as gold standard was used. May be the most important consequence of globalisation in politics is challenging nation states. They are now clearly under pressure from rising power of corporations on one hand and technology empowered individuals on the other.

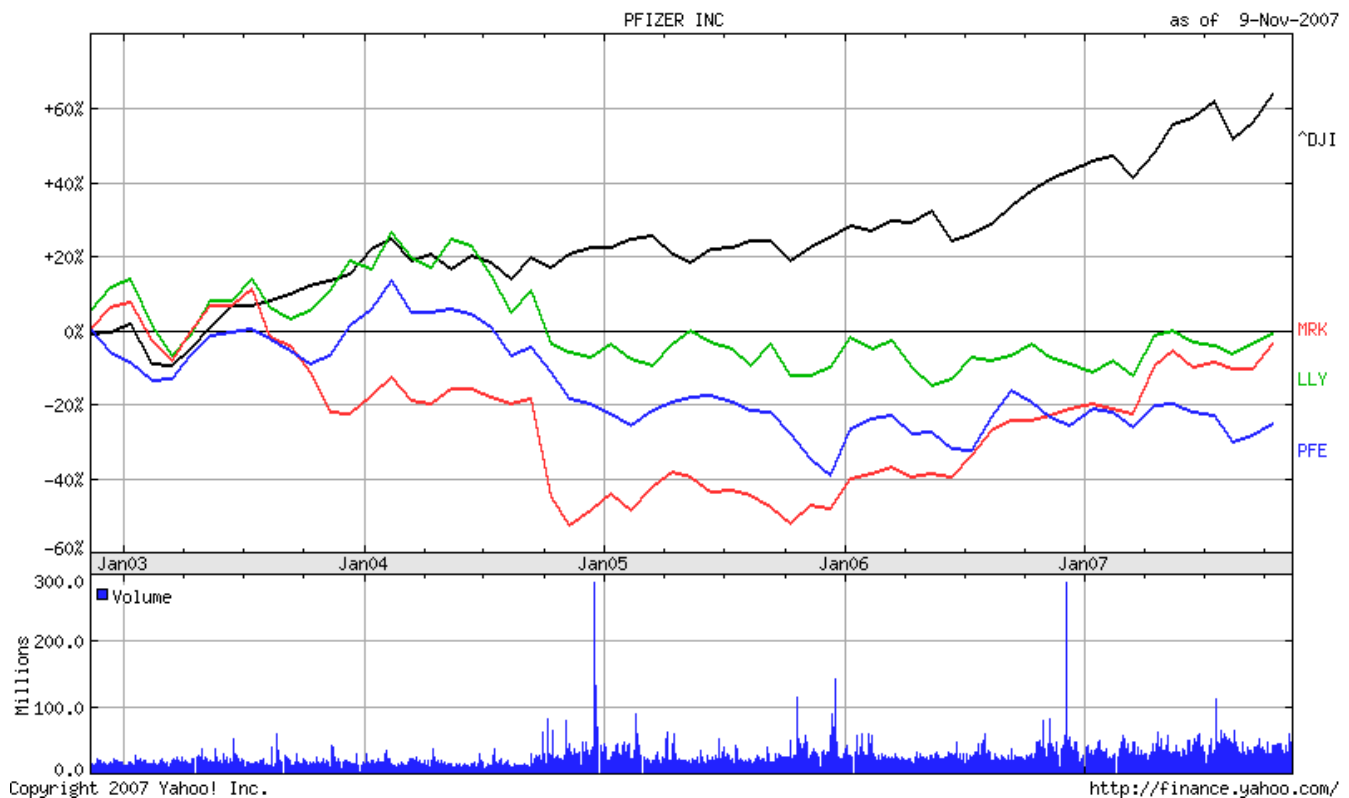
All these forces create world that we live in. We observe rise of new corporations like Google or Infosys, India call centers serving US customers, programmers working for offices in thousands of miles distance, worldwide spread of multinational corporations Not everything is visible at the first sight. Reengineered processes, modifications of supply chains, new marketing strategies. Exaggerating superficial changes without understanding of core processes leads to many misunderstandings on

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globalisation. Crucial is not to rely only on personal experience as we have not been living in previous open economies. But the point that the world is going to smaller, borderless, more efficient, dynamic. Interdependent, and standardised is accurate.

Industry Analysis - Global Pharmaceuticals and Clinical Trials Business

Big pharmaceutical companies are typical multinational corporations with worldwide presence. Their products are marketed in all relevant world markets. In face of still rising healthcare costs, ageing populations and changes in lifestyle globalisation was expected to be another opportunity how to utilize worldwide presence and bring revolutionary genomic based medicines into the market. Investors loved that vision and tech boom fueled pharma stocks as well. Now it is clear that there is a trouble in paradise. Blockbuster drugs are in maturity cycle phases, big pharmas pipelines are empty and some prospective molecules even failed to gain marketing authorization. Many of these problems stem from inefficient R&D. These analysis track genesis of the problems and possible solutions which seem to be outsourcing.



Comparison of Pfizer, Eli Lilly, Merck and Dow Jones (index) returns in last five years.

Pharma managers admit that the industry goes through very difficult times. It can be defined as end of blockbuster era. Companies which have represented industry once belonged to largest world multinational corporations. Pfizer may be the best example. The company was 4th largest world corporation measured by market capitalization in 2001. Since than one bad news have followed another. New drugs (new chemical entities – original drugs) are granted 10 years market exclusivity period during which no other companies are allowed to market the same substance. In recent years especially established pharmaceutical companies failed to deliver new molecules into the market and exclusivity periods for their products are expiring. There are more reasons behind weakening pipelines. Drugs today are more complex, often produced by biotechnology, targeting specific pharmacology pathways. It is more sophisticated process to design and test new drugs now. At the same time regulatory requirements on conduct of clinical trials are more stringent. High level of regulation is industry pattern as public health is very sensitive issue. Other reasons of rising R&D costs are focus on indications with smaller patient groups, maybe also problems with recruiting of good scientists as profession is becoming less attractive.

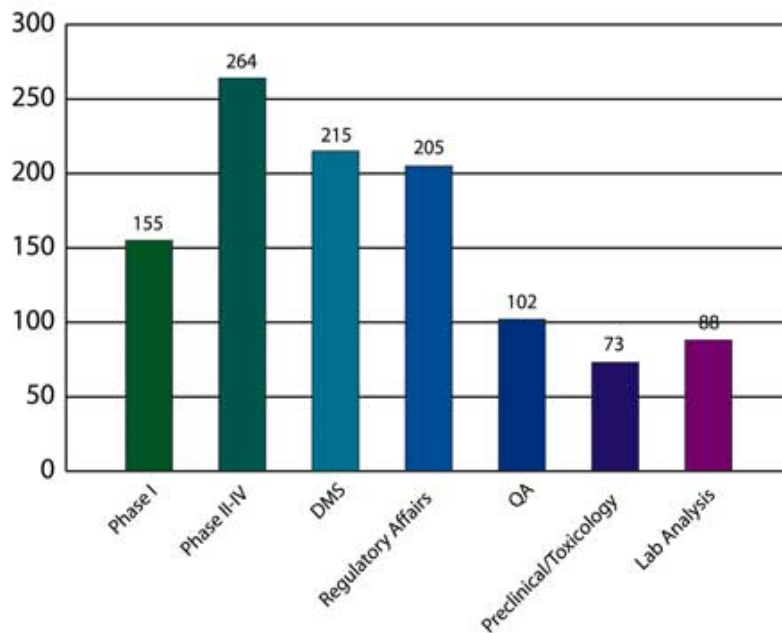
There is a link between regulatory agencies politics and consumer behavior which is often not fully recognized. The industry has traditionally been focused on healthcare professionals. Doctors have in fact played role of contractors when deciding on treatment of a patient. This is reflected in relational marketing based on large sales force practiced in pharma business. However, information availability is impacting value chain in pharmaceuticals. For internet empowered patients the doctor decisions are not unquestionable any more. And for Food and Drug Administration it is the same true. Why Vioxx market withdrawal, TGN1412 clinical trial, Elan's Tysabri brain tumor link were such an issues when there were many similar cases before? Only because now more people knew about it. Regulatory agencies are now under public attention and forced to act more cautiously. They continue to issue new safety guidelines to avoid any such incidents in future. According to some studies this approach prevent market enter of some promising medications. On the other hand also pharmaceutical marketing is shifting toward patients.

Big pharmas are most in risk. On the other hand generic market is growing. Teva and Ranbaxy are pointed out as winners. They utilize both expiration of market exclusivity of originals and manufacturing in low cost territories. It should be stressed that that many pharmaceutical companies in emerging countries do not have many problems with market exclusivity of original products as local

governments do not actively enforce the protection. Ranbaxy, one of miracles of new Indian economy, is fast expanding in both Europe and USA.

There is also substantial group of small biotechnology companies with their own problems. Their number exploded in late 1990s during the tech bubble when it was easy to find financing for this kind of projects. In fact this group is main source of innovative molecules and their business models seem to be superior in R&D productivity. This apply to preclinical development but there is no way how to bypass clinical trials with its stellar costs and many biotechs face financial problems. Acquisitions and alliances with established pharmas is often solution.

Consequence of this development is rising competition but compared to other industries there is not substantial pressure on restructuralization. Big pharmas did little to improve their R&D productivity and they seem to be rather focusing on future where they will be engaged mostly in marketing and other services will be outsourced. Outsourcing involve both manufacturing and clinical development. This connection lead to increasing role of Contract Research Organizations (CRO). CROs are contracted to conduct part or all clinical trial for a particular new substance. Some CROs are also increasingly involved in preclinical research, regulatory services and marketing focused research. While CROs clients were previously mostly biotechnology companies importance of big pharmas is increasing fast. Value of market served by CROs is estimated to be \$ 17.8 B (Shuchman, 2007).



Services offered by Contract Research Organisations (Brooks, 2006)

Aim of clinical trial is to prove safety and efficacy of a new chemical entity. Results of clinical trial are included in application for marketing authorization for new drug. Technical standards for conduct of clinical trials are harmonized throughout developed countries. Clinical trials are most expensive part of new drug development. They may include thousands of patients usually in many countries.

Contract Research can be considered emerging industry. It did not exist independently before and clinical development only separates from operations of pharmaceutical companies now. CRO number is estimated to be over 1000 worldwide. Currently number of acquisitions and mergers is under way. Leading group of CROs has profiled which include Pharmaceutical Product Development (PPD), Quintiles, Parexel, Kende, Covance. Research conduct in cost effective way is only one of reasons why pharmaceutical companies contract research. Others are core competencies and experience. Established CROs have built relationships toward local investigators, patient allocation databases and substantial experience in regulatory affairs. CROs are considered to be much more innovative in applying new business concepts and technology with Electronic Data Capture (EDC) as a good example. EDC is use of electronic devices in collecting biological data and their online integration through web interfaces.

There are also local CROs which operate on limited territory but these small companies are often not competitive and are even often subcontracted by larger CROs in case they have not presence on the place. Each established CRO build its global presence. It is specific of the industry that not only lower costs push the companies into new territories. Current trends in drug development lead to more specific therapies focused on smaller patient groups. This is also endorsed by regulations on orphan drugs by both Food and Drug Administration (FDA) and European Medicines Agency (EMA). Boom in pharmacogenetics which aim to produce individualized therapies is another reason to reach heterogenic populations. As a consequence of these new patient pools are inevitable. Today lack of patients for trials is at least the same important as cost on trials conduct. After boom in Eastern Europe in late 1990s and early 2000s another location with currently fast growth in clinical trials are now India and Latin America. However, barriers of conduct clinical trials in those territories are also recognized. They may include different standards of care, less developed healthcare infrastructure, inexperience of local physicians with clinical trials conduct and Good Clinical Practice (GCP) guidelines.

Future business models in pharmaceutical industry will likely rely more on outsourcing. There are complex reasons behind low research productivity of largest pharmaceutical companies and using

contract research may be solution. CROs rather than pharmaceutical companies were able to take advantage of globalisation. As relatively small companies with flat organizational structures they are able to manage clinical trials that often include all continents. They utilize their global presence in selecting suitable combination of patients, conduct costs and healthcare infrastructure best fitting particular study. Extensive IT use is requisite in flat global organizations and on the other hand this leads to further innovations like electronic data capture or advanced systems of electronic data management and reporting.

Strategic Analysis

Position of leading CRO – Kendle will be analysed. It is good example for company in contract research. Actions and basis for its global strategy are sketched in following chapter.

Kende was founded in 1981. It claims to operate in 80 countries, has currently approx. 3000 employees and is headquartered from Cincinnati, OH, USA. Clinical development is Kendle main business. It means mostly III (IIIb) trials. Company is involved also in regulatory affairs (consulting, marketing authorisations) and plan to expand into IV phases and postmarketing research. By sales it is fourth largest CRO. Kendle is public company listed on Nasdaq stock exchange. Recently Kendle presented somehow satisfactory results with financial performance on rise. However, the company is traded at P/E of 80.5 what corresponds to 2006 profit of \$ 8.5 M. Kendle competitors are other global CROs – most notably PPD, Quantiles. Service offering is similar to competitors and there is not distinct distinguishing feature.

CRO market is well defined and extensively regulated. Clients are pharmaceutical and biotechnology companies wishing to market new molecules. There are many regulations and standards how to conduct clinical trials aimed to protect study subjects and drug efficacy data integrity. Important are also relationships with investigators (physicians) and patients who play role of suppliers. In case of Kendle most contracts are given by biotechnology companies – approximately 70 % vs. 30 % from big pharmas. However, in recent time there is clear tendency of rising portion of larger companies.

Data integrity is the first market winning condition. For contracting companies it is crucially important to receive reliable scientific data collected in accordance with all applicable standards. Otherwise they would be in risk of rejecting of marketing authorization when submitted for regulatory approval. Another point is that study design should produce data pointing to superiority to potentially competing drugs what is important from marketing point of view and this have to be in framework of accepted scientific and regulatory standards. Probably sensitivity of this issue is reason why pharmaceutical companies set up study design by themselves and usually contract only its conduct. It is clear that adherence to standards and legislation is important also to avoid any potential harm to subjects what would spark negative publicity. Secondary importance of costs can be partially explained by value chain in healthcare as costs are often paid by third parties and after all price sensitivity is low. Naturally pharmaceutical companies include trial costs in projected product price when it is marketed.

There is not substantial price competition in original drugs.

Other point is data protection. There is large amount of data in this business and almost all of them shall be handled as strictly confidential. These include patients data, data on physicians, data obtained in research and data provided by pharmaceutical companies on drugs in development. All these require not only secure IT systems but in the main reliable system of handling with confidential data.

As regulation is important issue in pharmaceutical industry and clinical trials, regulatory competencies may be one of critical competitive advantages. Currently Kendle has one office specialized in regulatory affairs (RA) in Ely, UK.

Electronic systems are considered strength of Kendle. They include many areas of operations – reporting project status, investigator databases, electronic research data capture, electronic document libraries. There is concern on less integration of these systems and also missing system for regulatory intelligence. All procedures are written down in SOPs and easily available. There is also educational system for associates (“Kendle College”) which comprise several hundreds of electronic lectures covering all areas of company operations.

One of rather problematic aspects of project management is extent of client involvement. Pharmaceutical company contract part of work on trial but is not otherwise usually directly involved in project management or partial services related to the trial. This approach is not always flexible and results are not necessarily satisfying for the contractor.

Kendle rose through series of acquisitions what is in line of consolidations within contract research industry. In 2006 Kendle bought European part of Charles River Laboratories (CRL). About half of European Kendle offices were previously CRL. It may be too early to assess success of the acquisition. However, there are important transition issues. Kendle exercise its system of operations (Kendle Performance System - KPS) into new offices. There are not substantial differences as also former CRL were using some formally written down regulations. More problematic is incompatibility of electronic systems and data exports. Also some cultural issues arised. As company is headquartered from the US local European managers are sometimes afraid that the Americans do not understand how things works in Europe and force their own concepts.

In global trials specifics of each region should be considered. Advantages of Central and Eastern Europe are availability of patients, GCP compliance, motivated investigators and lower costs. On the other hand less developed healthcare infrastructure, standards of care may differ in some cases,

logistics, language, lower experience with clinical trials can bring some problems (Witte, 2003).

Kendle has offices in more CEE countries and also contract other clinical services providers in some countries where it does not have own offices. However, only offices in Poland and Romania has larger staff. For example in Russia local office consist only of 6 people. In general interest of companies to conduct trials in CEE is still high and rising. Another geographical are with weak presence is Asia Pacific as Kendle has one small office in India and currently opened office in Beijing. There are also two established offices in Australia.

Conclusions and Recommendations

Kendle asserts its position between world leading CROs and continues to build its global presence. After CRL acquisition it plans to expand in Asia Pacific. Company seems to be winning more contracts recently and delivers satisfactory financial results. However, its net profit is low compared to employed capital. As contract research market is fast growing, rise in sales is expected.

Market in which Kendle operates can be considered to be much globalised in many ways. It cooperates with global acting pharmaceutical companies. It operates on market that is subject of extensive standardization. There are agreed international standards, harmonized legislation, and extensive use of technology is also factor of market standardization. There are many unifying principles of local markets as healthcare has some similar patterns worldwide. However, differences should also be considered as there is different diseases/patients distribution, differences in organization of healthcare. Anyway, most of clients originate from the US as most pharmaceutical and biotechnology companies are headquartered from there. Rest of them are from Europe. On the other hand conduct of trials is really global. All offices have roughly same core capabilities and determining is the external environment.

It is not so easy to distinguish from competition when market is so much standardized. Some traditional company strengths should be used. Kendle have some advantage as its electronic systems are considered to be more advanced compared to competition. Further development is also part of official corporate strategy. It is clear all the players invest heavily into IT and technology advantage may disappear fast. I think this should be further developed as core Kendle competency. The company should focus on integration of systems that work independently, full integration of EDC and also to develop more project management tools not just data stores. Opening up systems for clients to facilitate project work flow is one of options but this must be in line with strategy of relationships with clients.

Part of official company strategy is to expend into “late phases” - IV and postmarketing studies. Beside reaching another segment this may support building relationships with pharmaceutical companies as they usually follow up their products and conduct further studies aimed on marketing optimization after gaining regulatory approval. Strategic intent may be to utilize these relationships in contracting of clinical development. It should be stressed that late phases are not big nor financially much interesting segment. However, this market is also in growth phase. In this respect remark may be made on organizational structure. There are specific divisions and clinical development and late phases

divisions are independent on each other. It is understandable as nature of clinical research is different to marketing research. Therefore it is not possible to utilize economy of scale in this case. Link to company marketing and building relationships may be reasonable. Move into late phases would rather distinguish Kendle from other CROs as their focus is rather on preclinical phases. This move has its pitfalls but there seems to be reasonable motives behind.

Concept of contract research is relatively new and still evolving. It can be expected that there is a place for strategic innovations, similarly to other project management areas of service sector. It is also clear that this kind of innovations are usually crucial in gaining competitive advantage.. On the other hand adoption of new concepts is risky as there is always political opposition against changes and no guarantee that the concept will work. If I were to suggest how to innovate operations in contract research I would be searching also in other areas of service sector. One of examples may be extreme programming (XP) paradigm in software engineering. XP aims to incorporate principles of communication, simplicity, feedback, courage and respect into software development. In fact this model has quite revolutionised that industry. Concepts such as Just in Time, Six Sigma, Lean Production are still more often applied in service sector but it seems their impact in clinical development is limited until now. One of often highlighted issues in modern project management is to include clients in projects. This not only make project work more smooth but also boost trust between both parties. I am not sure at the moment to suggest how to rearrange operations in clinical development but I would strongly suggest to constantly assess impact of new technologies on value chain, measure clients satisfaction and hear to them proposals, research and reengineer processes accordingly.

Kendle the same as other CROs conduct routinely one trial on more or maybe even all continents. This is challenge for both logistics and project management. However, there are not substantial problems with running global trials. It is logical that local specifics are considered. It is requirement (as the study protocol must be approved by regulatory body) that study design is the same in each location where conducted (some local amendments are acceptable). The conclusion is that the approach to run trials global is right but local specifics shall be considered as well.

Organizational structure of Kendle is quite similar to other CROs. It has some weaker presence in CEE and AP and is stronger in the US on the other hand. As there is much higher interest to conduct studies in CEE than Kendle is even capable to manage it would be appropriate to both expand local

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offices and cover countries where the company is not present now. Flat structure is bet fit for a company where hierarchical structures are often replaced by vertical IT enabled decision making systems. However, question may arise whether when this company is flat is also decentralized and whether it should be. There is some but not significant tension created likely by mixing of different national cultures as technology brings people so close one to another. As company is headquartered from the US it applies its standards in HR on its overseas (European) employees. These are also issues for management attention.

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Appendices



Comparison of stock returns and Return On Equity of Kendle (green) compared to Parexel (magenta) (www.morningstar.com, 2007)

Strengths	Weaknesses
<ul style="list-style-type: none"> - Electronic data management systems - Strong position on the US market - Knowledge management 	<ul style="list-style-type: none"> - Limited presence in some crucial territories – CEE, AP - Internal consolidation following acquisitions (CRL)
Opportunities	Threats
<ul style="list-style-type: none"> - Effort of big pharmaceutical companies to outsource clinical development - Diversification into new areas (late phases) 	<ul style="list-style-type: none"> - Rising competition - Technological change

Kendle SWOT Analysis

Income Statement

Annual Data 	All numbers in thousands		
PERIOD ENDING	31-Dec-06	31-Dec-05	31-Dec-04
Total Revenue	373,936	250,639	215,868
Cost of Revenue	243,291	157,189	139,889
Gross Profit	130,645	93,450	75,979
Operating Expenses			
Research Development	-	-	-
Selling General and Administrative	91,796	68,216	59,797
Non Recurring	8,436	-	302
Others	10,403	7,991	9,175
Total Operating Expenses	-	-	-
Operating Income or Loss	20,010	17,243	6,705
Income from Continuing Operations			
Total Other Income/Expenses Net	144	1,032	124
Earnings Before Interest And Taxes	20,154	18,275	6,829
Interest Expense	6,781	460	776
Income Before Tax	13,373	17,815	6,053
Income Tax Expense	4,843	7,141	2,481
Minority Interest	-	-	-
Net Income From Continuing Ops	8,530	10,674	3,572
Non-recurring Events			
Discontinued Operations	-	-	-
Extraordinary Items	-	-	-
Effect Of Accounting Changes	-	-	-
Other Items	-	-	-
Net Income	8,530	10,674	3,572
Preferred Stock And Other Adjustments	-	-	-
Net Income Applicable To Common Shares	\$8,530	\$10,674	\$3,572

Kendle income statement (<http://finance.yahoo.com>, 2007)

New Entrants

- It is difficult to set up CRO with global operations
- There is large number of small CROs and pharmaceutical companies perform their own clinical development
- Lobbying and relationship toward regulatory bodies is important – pharmaceutical companies are in advantage
- Global presence and technology is crucial in distribution channels access

Supplier power

- Crucial suppliers are physicians and patients
- Payments to physicians present substantial cost
- Associated with special physicians skills in a particular therapeutic area – market can be considered highly segmented
- They are not organised and CROs are relatively strong in bargaining
- Many regulations apply

Competition within industry

- Is strong, consolidation phase
- Market is still rising
- Strategic stakes are extremely high
- Product differentiation is low
- Companies try to be dynamic, marginating fixed costs
- Alliances and subcontracting apply

Buyer power

- Very strong – many of them have own clinical development departments and outsource only when it is cheaper
- Buyers have excellent knowledge of market
- There is no strong differentiation between leading CROs

Substitute products

- There is no other way how to gain marketing authorisation for a new chemical entity in developed countries
- Bioequivalence studies for generic drugs
- Basic toxicological testing for nutritional supplements with therapeutical claims

Porter`s five forces model applied on contract research industry

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Assignment Submission and Tutor Feedback to Students Form

Students must attach a copy of the form to each piece of submitted work after completing Sections A and C: Sections B and D to be completed by University Staff.

Section A	For office use only
Student ID Number: <i>No. 166764</i>	

Degree Programme: <i>Flexible MBA</i>	Level
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Module Title: *International Consultancy Project*

Assignment Title: *Globalisation is a fact, standardisation is a fiction*

Tutor's Name: <i>Vladimír Laššák</i>	Date Due:	Seminar Group
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Please refer to your module documentation for details of the criteria for this assessment.

Section B Tutor's Comments

Criterion 1 – Critical Literature review related to theory and industry

General issues of globalisation (reasons and consequences) are described properly in the assignment, but there is a lack of appropriate academic sources compared with author's opinions of topic (p. 6-8). There were given more effort to question of economic independence of equity market than globalisation and industry/product standardisation issues as expected. This part of the assignment cover various questions related to globalisation – history, equity markets, ITC technological development, international trade, etc. It would be better to concentrate it more to given topics and chosen sector, offering reach literature review and critical thoughts.

Criterion 2 – Critical Review of business environment

Chosen business environment cover global pharmaceuticals and clinical trials business. Industry analysis is provided well and fully justified review of macro and micro environment, including relations of CRO's and global pharmaceutical companies, industry cycle phases, stock indexes development, R&D relations, regulations, marketing and sales issues, etc. Globalisation issues related to pharma and CROs companies are explained well, regardless the lack of using appropriate theoretical models describing the business environment of the industry.

Criterion 3 – Critical Evaluation of Selected Company Strategies

Author of the assignment analysed Kendle company strategy in contract research organisation CRO business. The strategy of the company is well described and evaluated, and concerns results of the company, staff development issues, geographical and market coverage, business practices, some strengths and weaknesses of the company, etc. Strategy of the company was related with previous industry analyses appropriately, but also here there is a lack of links to suitable theoretical concepts.

Criterion 4 – Conclusions and Recommendations

Conclusions offer excellent response to issues described above. Environmental factors were well and cogently summarised, mentioned strengths and weaknesses were considered on future needed competencies of the company. Recommendations are appropriate and fully justified in terms of preceding analysis including thoughts of IT system integration, services expansions, innovation of operations, project management issues and organisational structures all realised on global base.

Criterion 5 - Format, writing style and referencing

Excellent written style with few errors. Structure of the assignment is clear and readable well, wrote with required format and corrects Harvard referencing.

Assessed by: *Vladimír Laššák*

Date: *December, 12-th, 2007*

Mark (%)