

**STUDIES ON FACTORS AFFECTING BUSINESS PERFORMANCE
OF BIOTECHNOLOGY COMPANIES**

HESHAM ALI EL ENSHASY

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To the memory of my parents

To my uncle Hassan

To my wife Rania and my big boy Ali

To my sisters Hend and Hoda

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ABSTRACT

Biotechnology industries are fast growing, technology based and multibillion dollars business. Biotechnology dealt with using biomaterials to produce bioproducts or to provide service in many industrial sectors of health, food, chemical and environmental industries. Like most of high-tech business, biotechnology is long term investment business with high risk. Therefore, based on the unique nature of this business, factors affecting its performance are different from those of ordinary business. Thus, this study is focused on the determination of the current factors affecting the performance of biotechnology business by 46 worldwide experts using mixed research method (a combination between Expert Opinion Assessment EOA technique and questionnaire of closed ended questions). Two rounds of questioning were conducted to identify, categorize and prioritize these factors by mean ranks. In the first round, experts listed all factors affecting business performance. The results of the first round were grouped and returned to the experts in the second round to score the importance of each factor. The second round showed high results consensus among the experts. Based on the favorable Kendall's coefficient of consensus, it was not necessary to run the third round. Based on the results obtained from EOA study, a non-Financial Business Performance Indicator (n-FBPI) was developed for quantitative determination of performance of biotechnology companies. To evaluate the company's performance, another research instrument (questionnaire) was developed. This questionnaire composed of 97 questions to evaluate the company's external and internal environment and strength in points related to the effective factors uncovered in the first part of this study. The developed instrument was tested by 5 companies and gave quantitative measure for companies performance. Furthermore, a new website (www.biotechhorizon.com) was developed for this study for online assessment of the performance of biotechnology companies. The results of this study will help all stakeholders in biotechnology business either who are new in this type of business or who are well established by providing the current factors which have significant effect on biotechnology business performance. The n-FBPI developed will also be a useful tool for companies to evaluate their non financial performance quantitatively.

ABSTRAK

Industri bioteknologi merupakan sejenis sektor perniagaan berasaskan teknologi yang semakin berkembang pesat dan bernilai berbillion dolar yang melibatkan penghasilan bioproduct atau penawaran perkhidmatan di pelbagai sektor seperti kesihatan, makanan, kimia dan pengurusan alam sekitar. Perniagaan bioteknologi merupakan sejenis perlaburan jangka panjang yang berisiko tinggi. Oleh itu, faktor yang mempengaruhi perniagaan ini berbeza daripada perniagaan biasa. Kajian ini tertumpu kepada penentuan faktor-faktor semasa yang memberi kesan kepada prestasi perniagaan bioteknologi oleh 46 pakar dari seluruh dunia menggunakan kaedah penyelidikan bercampur (kombinasi “Expert Opinion Assessment, EOA dan borang soal selidik soalan tertutup). Soal selidik sebanyak dua kali dijalankan untuk mengenal pasti dan mengkategorikan faktor-faktor tersebut berdasarkan keutamaan. Dalam soal selidik pertama, pakar-pakar menyenaraikan semua faktor yang mempengaruhi prestasi perniagaan. Permarkahan kepentingan setiap faktor dijalankan dalam soal selidik kedua. Soal selidik kedua menunjukkan keputusan pekali konsensus Kendall yang tinggi dikalangan pakar-pakar. Oleh itu, soal selidik ketiga tidak diperlukan. Petunjuk prestasi perniagaan bukan kewangan telah dikemukakan untuk menilai prestasi syarikat-syarikat bioteknologi. Untuk tujuan ini, satu borang selidik yang terdiri daripada 97 soalan telah disediakan untuk menilai persekitaran dalaman dan luaran syarikat serta permarkahan faktor-faktor penting yang ditemui dalam langkah pertama penilaian prestasi syarikat-syarikat. Instrumen yang dihasilkan digunakan untuk menentukan prestasi 5 syarikat berlainan. Satu laman web (www.biotechhorizon.com) telah disediakan untuk menilai prestasi syarikat bioteknologi secara “online”. Hasil kajian ini dapat membantu pihak-pihak berkepentingan dalam industri bioteknologi memahami faktor semasa yang mempengaruhi prestasi perniagaan bioteknologi. Selain itu, petunjuk prestasi perniagaan bukan kewangan yang ditunjukkan dalam kajian ini dapat membantu dalam penilaian prestasi bukan kewangan syarikat-syarikat bioteknologi.

TABLE OF CONTENTS

CHAPTER	TITLE	PAGE
	TITLE PAGE	i
	DECLARATION	ii
	DEDICATION	iv
	ACKNOWLEDGEMENTS	v
	ABSTRACT	vi
	ABSTRAKT	vii
	TABLE OF CONTENT	viii
	LIST OF TABLES	xiii
	LIST OF FIGURES	xv
	LIST OF APPENDICES	xvii
	LIST OF ABBREVIATIONS	xviii
1	INTRODUCTION 1.1 Research background 1.2 Statement of the problem 1.3 Purpose of the study 1.4 Objectives of the study 1.5 Research questions 1.6 Operational definition 1.6.1 Biotechnology 1.6.2 Business performance 1.6.2. Delphi method (EOA method)	1 1 3 4 5 5 6 6 7 8

1.7	Scope of the study	9
1.8	Importance and significance of the study	9
1.9	Limitation of the study	10
1.10	Plan of the thesis	10
2	LITERATURE REVIEW	12
2.1	Business performance and measures	12
2.2	Business performance measurement of network	15
2.3	Biotechnology business	16
2.4	Factors affecting business performance in biotechnology sector	17
2.4.1	Fund availability	20
2.4.2	Innovation capability	22
2.4.3	Marketing ability	24
2.4.4	Technology availability	26
2.4.5	Public acceptance	26
2.4.6	Political factors	28
2.4.7	Networking	30
2.4.8	Regulatory issues	32
2.4.9	Human capital capacity	33
2.4.10	Business location and related issues	34
2.5	Relations between factors affecting business performance	35
2.6	Research framework	35
2.7	Summary	37
3	MEHODOLOGY	38
3.1	Research design	39
3.2	Research tool for data collection (Mixed Methods Research)	41
3.2.1	Delphi/Expert Opinion Assessment (EOA) method of research	42

	3.2.1.1 Criticism for Delphi method	44
	3.2.1.2 Methods to overcome the disadvantages/ limitations of EOA Method	46
	3.3 Development of EOA instrument	48
	3.3.1 Identification and selection of the expert panel	48
	3.3.2 Preparation of question	50
	3.3.3 Running EOA method	51
	3.3.4 Hypothesis testing and analysis using Kendall's Coefficient of concordance	55
	3.4 Development of general and specific non-Financial Business Performance Indicator (n-FBPI) for Biotech. companies	56
	3.5 Data collection process	57
	3.6 Summary	58
4	FINDINGS	60
	4.1 Introduction	60
	4.2 Determination of factors affecting business performance of biotech. companies (first round of EOA)	62
	4.2.1 RQ1. What factors are deemed As important for business performance of biotech. companies	62
	4.2.1.1 Profile of respondents in EOA research (first round of EOA)	63
	4.2.1.2 Feedback and responses from the first round of EOA	64
	4.3 Determination of weight of factors affecting business performance of biotech. companies (second round of EOA)	79
	4.3.1 RQ2: How are the aforementioned factors ranked?	79
	4.3.2 Profile of respondent in EOA research (second round)	80

4.3.3	Determination of weight of factors affecting the business performance	83
4.3.4	Determination of weight of individual factor based on geographic and demographic information of the Experts	105
4.4	Determination of weight of factors affecting business performance of biotech. companies (second round of EOA)	115
4.4.1	RQ3:How the non-financial performance of Biotech companies could be determined quantitatively?	115
4.4.2	Development of different n-FBP Indexes	116
4.4.2.1.	Non-specific n-FBP Index (1 Index)	116
4.4.2.2.	specific n-FBP Index (6 Indexes)	117
4.4.3.	Empirical quantitative determination of n-FBP of biotech. companies	118
4.5	Design of dedicated web-based research instrument for online measurement of n-FBP of biotech. companies	131
4.5.1	RQ4: How best can a dedicated instrument be developed to measure non-financial performance of biotechnology companies taking in consideration the factors uncovered in this study?	131

5 DISCUSSION, CONCLUSIONS, AND RECOMMENDATIONS

5.1	Introduction	135
5.2	Discussion of the findings	136
5.2.1	Profile of the experts involved in this study	136
5.2.2	Factors affecting n-FBP in biotech. business	137
5.2.3	Evaluation of the importance of individual facto in biotech. business performance	139
5.2.4	Quantitative determination of n-FBP of biotech. companies	142

5.3	Conclusions	143
5.4	Recommendations for further research	145

REFERENCES	147
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APPENDIXES	160
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Appendix A	160
Appendix B	174
Appendix C	190
Appendix D	230

LIST OF TABLES

TABLE NO.	TITLE	PAGE
4.1	Feedback of the biotechnology business expert panel for EOA study (first round).	65
4.2	Complete factors affecting the business performance of biotechnology business according to the first round of EOA	77
4.3	Experts involved in the second round of EOA	81
4.4	Second round survey results of EOA	89
4.5	Expert opinion of the second round of EOA sorted by weight of factors (All experts) n=40	102
4.6	Experts opinion of the second round of EOA ranked by factor`s weight (Regional vs. International)	112
4.7	Experts opinion of the second round of EOA ranked by factor`s weight (Non-medical vs. Medical)	113
4.8	Basic data of biotechnology companies evaluated using n-FBP Index	119
4.9	Determination of n-FBP index of company A based on non-specific ranking system.	121

4.10	Determination of n-FBP index of company B based on non-specific ranking system.	123
4.11	Determination of n-FBP index of company C based on non-specific ranking system.	125
4.12	Determination of n-FBP index of company D based on non-specific ranking system.	127
4.13	Determination of n-FBP index of company E based on non-specific ranking system.	129
4.14	The values of specific and non-specific n-FBP of the biotech. Companies involved in this study.	131
5.1	The top ten factors affecting business performance based on Expert`s geographic and demographic background	141

LIST OF FIGURES

FIGURE NO.	TITLE	PAGE
2.1	Dimensions of ENBSC	15
2.2	Axis of product-based (sectors) in biotechnology: A combination of 'core biotechnology' and sectors	17
2.3	Networks of key factors influencing innovation	24
2.4	Proposed Research Framework of the study	36
3.1	Flowchart for the research method	40
4.1	Geographic, demographic and field of expertise for experts who involved in the first round of EOA.	64
4.2	Geographic, demographic and field of expertise for experts who involved in the second round of EOA.	82
4.3	The weight of factors affecting the n-FBP according to all experts opinion (n=40)	101
4.4	The weight of factors affecting the n-FBP according to regional experts opinions (n=18)	108

4.5	The weight of factors affecting the n-FBP according to international experts opinions (n=22)	108
4.6	The weight of factors affecting the n-FBP according to non-medical biotech. experts opinions (n=18)'	109
4.7	The weight of factors affecting the n-FBP according to medical experts opinions. (n=22)	109
4.8	The weight of factors affecting the n-FBP according to the opinions of experts from universities, government and consultants (n=19).	110
4.9.	The weight of factors affecting the n-FBP according to the responses of experts from industries (n=21).	110
4.10	Flowchart for determination of n-FBP for biotech. companies using non-specific n-FBP Index.	133
4.11	Flowchart for determination of n-FBP of biotech. companies using specific n-FBP Indexes.	134

LIST OF APPENDICES

APPENDIX	TITLE	PAGE
A	Expert opinion assessment documentation	144
B	Questionnaire for evaluation of non Financial Business Performance Indicator (n-FBPI) for Biotechnology Business	158
C	The differences in factors weights based on geography, demography and type of industry of expert involved in the second round of EOA	174
D	n-FBP Indexes developed in this study	214

LIST OF ABBREVIATIONS

BINGOs	Business Interest non-Governmental Organizations
BPM	Business Performance Management
CEO	Chief Executive Officer
COO	Chief Operating Officer
CRO	Contract Research Organization
EOA	Expert Opinion Assessment
FDA	Food and Drug Administration
GLP	Good Laboratory Practice
GM	Genetically Modified
GMO	Genetically Modified Organism
cGMP	current Good Manufacturing Practice
IPR	Intellectual Property Rights
KAADM	Knowledge Assets Value Dynamic Map
MENA	Middle East and North Africa
n-FBP	non-Financial Business Performance
n-FBPI	non-Financial Business Performance Indicator
NTBFs	New Technology Based Firms
OECD	Organization for Economic Co-operation and Development
PINGOs	Public Interest non-Governmental Organizations
PMS	Performance Measurement Systems
POH	Pecking Order Hypothesis
R&D	Research and Development
RTD	Research and Technology Development
TT	Technology Transfer
VC:	Venture Capital

CHAPTER 1

INTRODUCTION

1.1 Research background

Biotechnology is one of the high-tech and knowledge based industry and considered as the most dynamic and diverse business sector in the 21st century. Biotechnology based products are usually innovative and come as a result of long time intensive research. The products of biotechnology industries are covering a wide range of our daily used products from agriculture biofertilizers to recombinant insulin and vaccine. Thus, studying the factors affecting the performance of biotechnology business is an interesting topic for research.

The success of any organization is usually affected by many factors which govern the success and sustainability of business. Thus, business performance measurement is a critical process to ensure the healthy and sustainable growth of any organization. Therefore, determination of the proper method of business performance measurement is a matter of interest for many researchers (Neely, 2007; Taticchi, 2010). Measures of business performance can be used as indicators and factors affecting these measures can be considered as drivers and key factors for organization success. These factors are usually linked directly to nature and

activities of the organization. However, factors affecting business performance are not standard and dependent on business sector. Moreover, those factors are dynamic and the weight of each factor is changeable based on external business environment.

Based on the uniqueness feature of biotechnology business, success measures and factors affecting business performance in biotechnology industry may differ from those of other types of business. For example, innovation is usually the main success factor in biotech industry and used as large measure and indicator for firm's success and sustainability (Chen, 2004). Innovativeness is heavily dependent on the company's long term Research and Technology Development (RTD) efforts. In other sectors like the car industries, business performance is highly affected by marketing, technology availability and supply chain effect. Moreover, biotechnology is also subject to more security issues and debate than other new technologies. This based on the fact that genetically modified organisms, especially those used in the food supply chain, many have a negative effect on human health and the risk of genetically modified crops may persist in the soil and affect the environment in general (Traore and Rose, 2003). Therefore, customer acceptance and regulatory effect on business performance are critical factors in case of the biotechnology industry. Moreover, biotechnology industry include also ethical concern when they use issues of high debates and uncertain acceptance regarding to moral and religious perspective such as using embryonic stem cells and cloning.

The present work will focus on the determination of the critical factors which can affect the business performance of Biotechnology companies. This research will provide suggestions for biotechnology companies to increase their business performance.

1.2 Statement of the problem

Biotechnology business is multibillions high-tech and innovation based. Biotechnology is huge multi-billion dollar industries. This business sector generated total revenues of \$171.8 billion in 2007, representing a compound annual growth rate (CAGR) of 10.7% for the period spanning 2003-2007 (Tan, 2009). However, market share of each sector are not equally. According to the biotechnology market report done by Tan (2009), the medical/healthcare segment is the most important sector and share about 69.4% of the market's overall value followed by service provider segment which contribute to 14.7% of the market's aggregate revenues. Agriculture/environmental biotechnology sector comes in the third stage followed by industrial biotechnology (non-medical) industries.

However, this type of industry is relatively new compared to other known and well established business like steel, car manufacturing and electronic industries. Based on previously published reports, factors affecting this type of business are highly diversified.

Many research papers investigated the effect of particular factor on biotechnology business growth and performance such as innovation ability (Hall and Bagchi-Sen, 2002; Hult *et al.*, 2004), networking and cooperation (Audretsch, 2001; Festel *et al.*, 2010) fund availability (Lee and Dibner, 2005; Chen and Marchioni (2008), and business location (van Geenhuizen and Reyes-Gonzales, 2007). Few others studied the effects of the co relatedness of two or more factors and investigated this combined relation on biotechnology business. For example, the combined effect of location and knowledge collaboration showed positive effect on the performance of Swedish biotechnology companies working in pharmaceutical sector (McKelvey *et al.*, 2003). However, few researchers studied those factors as a group and discussed their integrated effects on the overall biotechnology firm's performance. These studies were limited to particular country such as Canada

(Woiceshyn and Hartel, 1996). Another study conducted by Hsu *et al.*, (2005) was focused on the effects of those factors related to governmental policies on new biotechnology firm's performance in Taiwan. To the researcher's knowledge, no research was conducted before using Delphi/EOA method to determine and rank the factors affecting business performance of biotechnology companies in global market. Moreover, as biotechnology is highly dynamic and fast growing industries, those factors affecting this business as well as their ranking can change very rapidly. Thus, the results published a couple of years ago may be less valid since many new factors may be raised and others may not exist anymore. Moreover, the level of importance of those factors is changeable very fast.

In the researcher's opinion, determination of these factors with proper ranking of their influence on business performance is a research topic of high demand for all stakeholders of biotechnology businesses. As such, this research is timely as biotechnology is now revered as a powerful engine for industrial and technological growth of a nation.

1.3 Purpose of the study

The purpose of this study is to determine the factors that currently affecting the business performance of biotechnology companies based on expert opinion assessment method. In addition, the study aims to identify the weight of each factor and its degree of influence on biotechnology business. It is hoped that the outcomes of this research will provide better awareness about the real and current practical factors which are affecting biotechnology business performance. This study will also serve as guidelines for new biotechnology investors to have proper start up for their business and help also those companies who already in the market to perform better and enjoy healthy sustainable business growth. The outcomes of this research will also help as guidance for governmental bodies to understand what are required to

improve in term of business and investment environment to attract biotechnology companies and to support them for sustainable growth.

1.4 Objectives of the study

The objectives of the current research are as follows:

- 1- To identify the factors affecting the business performance of biotechnology companies based on expert opinion.
- 2- To evaluate the importance of each factor and how it affect the business performance.
- 3- To develop non-financial business performance indicator for biotechnology companies.
- 4- To design a dedicated web-based research instrument for online measurement of non financial business performance of biotechnology companies

1.5 Research Questions

This study addresses the following research questions:

1. What factors are deemed as important for business performance of biotechnology companies?
2. How are the aforementioned factors ranked?
3. How could the non-financial performance of biotechnology companies be determined quantitatively?

4. How best can a dedicated instrument be developed to measure non-financial performance of biotechnology companies taking in consideration the factors uncovered in this study?

1.6 Operational definitions

Key terminologies which will be used consistently throughout this study are defined as follows:

1.6.1 Biotechnology

Many definitions for the word biotechnology exist in literature to describe this modern science. It was defined as the field of applied biology that involves the use of living organisms and bioprocess in engineering, technology, medicine and other fields requiring bioproducts (Biotechnology:Wikipedia, 2011). However, the most acceptable definition for biotechnology is “the application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services” (OECD, 2006:7).

1.6.2 Business performance

Performance shows a diversity of meaning. The usable definition in business was presented in the study of Lebas and Euske (2007) by the following three definitions:

1. To accomplish something with a specific intention (e.g. create value)
2. The result of action (the value created, however measured)
3. The ability to accomplish or the potential for creating a result (e.g. customer satisfaction, seen as measure of the potential of the organization for future sale).

According to Choe *et al.* (1997), business performance is evaluated as combined measure of the three major aspects of business performance: profitability, growth and manufacturing performance. In many research, Return of Assets (ROA) and growth are the most common indicators of business performance. Manufacturing performance is directly related to the four competitive priorities in manufacturing: cost efficiency, product quality, manufacturing flexibility, and dependability. According to the recent research of Tseng *et al.* (2009), five dimensions of business performance were identified. These are: competition performance, financial performance, manufacturing capability, innovation capability and supply chain relationship.

1.6.3 Delphi method (EOA method)

This technique was named after the ancient Greek oracle at Delphi from which prophecies were given (Koontz and O'Donnel, 1976). This research method was first developed by Dalkey and Helmer in the early 1950s to perform forecasting study for RAND Corporation to improve the technology of Douglas aircraft. The Delphi method was conceived as a group technique whose aim was to obtain the most reliable consensus of opinion of a group of experts by means of a series of intensive questionnaires with controlled opinion feedback (Dalkey and Helmer, 1963). This technique was also identified by Skutsch and Hall (1973) as follows: A method for gaining judgments on complex matters where precise information is unavailable. However, one of the basic definition in literature was provided by Linstone and Turoff, (1975) as follows: "Delphi is a method for structuring a group communication process so that the process is effective in allowing a group of individuals, as a whole, to deal with a complex problem". Based on the initial forecasting application of this technique it was also defined as "a medium-term qualitative forecasting method that is based on building a consensus amongst a group of experts (Bonnemaizon *et al.*, 2007).

Delphi was initially developed as a qualitative, long-range forecasting technique that elicits, refines, and draws upon the collective opinion and expertise of a panel of experts (van Zolinge and Klaassen, 2003). However, Delphi technique is not only limited to forecasting research but also was successfully used in many other studies such as strategy formulation through analyzing current problems related to setting objectives, generating alternatives, and evaluating potential strategies (Wedley, 1977; White *et al.*, 2007). Therefore, this technique was recently defined as "Delphi is a group process involving an interaction between the researcher and a group of identified experts on a specified topic, usually through a series of questionnaires" (Yousuf 2007). Based on this definition, Delphi could be considered as wide scope technique for Expert Opinion Assessment (EOA) method for both current problem assessment and forecasting applications.

1.7 Scope of the study

This study is focused on only one type of industry: biotechnology industry. This will involve all stakeholders related directly or indirectly of this business. This includes experts who have knowledge, strong background and market information about this type of business. Delphi (Expert Opinion Assessment) method will be applied in this research in three rounds as the main research tool in this research. The results will be measured by number and presented through statistical analysis. The results obtained were used to develop a non-Financial Business Performance (n-FBP) Index for quantitative measure of company's performance in biotechnology sector using simple research instrument (questionnaire).

1.8 Importance and significance of the study

Determination of factors affecting the business performance of biotechnology companies became important issues to understand the unique feature of this type of business. Therefore, this study will be of significant values for all stakeholders involved in biotechnology business such as (researchers, investors, companies, regulatory bodies and governmental agencies). However, the importance of this study could be summarized in the following points:

1. This study will give full determination of the main factors affecting business performance in biotechnology field based on the current expert's opinion.
2. This research will identify the divergence and convergence in the opinion of expert about those factors

3. This research will help in the determination of the weight of each factor to understand the main driving factors in this type of business.

Thus, this study will give clear view of the factors which are critical for sustainable business performance in this type of industry.

1.9 Limitation of the study

There are some limitations that need to be acknowledged and addressed for the present study. This study will be conducted with help of a panel of experts in form of 40 persons who have deep knowledge of biotechnology industries. The first limitation is the availability of experts in this field who would like to share his/her knowledge in this type of business. Second, finding experts who have enough time and willing to spend time in these 3 rounds based research. Third, the time frame of this study is limited. Fourth, this study is limited in scope and the results obtained are highly specific to biotechnology industries and cannot be generalized to other business sector. Moreover, this research is mainly based on expert opinion; therefore the accuracy and reliability of our finding will be dependent on the degree of sincerity and truthfulness of the experts.

1.10 Plan of the thesis

The introduction chapter of this thesis represents an overview about the biotechnology business sector, statement of the problem, purpose and objective of this study, research questions, operational definition, scope of this study,

significance and limitation of the study. This outcomes of this research will help biotechnology based firms to understand the culture of this business through understanding the factors affecting the non-financial business performance of biotechnology companies. Furthermore, this will help also government policy makers to put new strategy to attract and to promote biotechnology based firms as key drivers in knowledge based economy. Furthermore, as this study ended by the development of non-Financial Business Performance Indicator (n-FBPI) Index, it will help biotech. companies to do proper assessment for their non-financial performance and to understand their strengths and weaknesses based on experts opinion.

CHAPTER 2

LITERATURE REVIEW

This section of thesis started by giving information about methods applied for measurement of business performance. Knowing these measures in the first step is important to understand the factors affecting business performance of this business. Following this, factors affecting business performance in biotechnology companies were determined based on previously published scientific papers, industrial organizations and governmental agencies. These factors were classified under 10 categories. However, most of these factors are interrelated and it is generally difficult to evaluate some of these factors independently.

2.1 Business performance and measures

Measuring performance is important to evaluate the success, progress and competitiveness for all types of organization. Performance measurement system (PMS) has different definitions in literatures. In our opinion, the most proper definition was set by Neely *et al.* (1995:81) as “the set of metrics used to quantify both the efficiency and effectiveness of actions.”

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