ISSN: 0972-7566 Vol. 19 | No. 3 | November 2017

ASIAN BIOTECHNOLOGY AND DEVELOPMENT REVIEW

Asian Biotechnology and Development Review

This journal is abstracted/indexed in CAB International, Scopus, Elsevier Database and EBSCO host™ database.

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RNI Registration No. DELENG/2002/8824.

Asian Biotechnology and Development Review

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Vol. 19 No. 3 November 2017 ISSN: 0972-7566

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Research and Information System
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Asian Biotechnology and Development Review
Vol. 19 No. 3, pp 1-2

Editorial Introduction

K. Ravi Srinivas*

This issue, the third in Volume 19 of Asian Biotechnology and Development Review, has two articles and a book review.

Clinical trials are an inevitable part of development of new medicines and their approval. They have often become controversial on account of concerns over ethical issues and regulatory norms. Since a significant number of them are conducted in developing countries, questions about exploitation, prior informed consent and procedural issues are raised. Globally, the industry and the governments have realized that the credibility and acceptability of data are at stake if norms on trials are revised to ensure that ethical rules and other obligations are adhered to. Taking into account data on clinical trials in Africa and their respective developments, the paper by Swapan Kumar Patra and Mammo Muchie, provides an interesting analysis and suggests measures to make them more acceptable as well as to meet the ethical norms. Readers may be aware that even in India regulating clinical trials is an significant issue and over the years the regulatory system is getting revamped to address concerns on inter alia, prior informed consent and to move towards harmonization.

Bio economy, bioclusters, global innovation networks are buzz words in discussions on geographies of innovation. Why some locations attract biotechnology firms or for that matters firms specializing in high technology prefer some regions is a matter of study and debate. In India, Bengaluru aka Bangalore and Hyderabad are the two important centers for bioclusters. What makes Bengaluru tick as a biocluster is an interesting question and what is the role of institutions, actors, networks in making Bengaluru part of global innovation networks is another important issue. Nimita Pandey and Pranav N Desai address these in their article and present some preliminary findings, that will be of interest to policy makers.

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RIS has been studying status of biotechnology in Asia and Pacific for many years. Earlier, RIS did a study for UNESCO and based on that a publication was brought out, which is available at *http://ris.org.in/images/RIS_images/pdf/UNESCO%20Biotechnoloy%20Report-web.pdf*. Recently FAO commissioned RIS to undertake a study on status of agricultural biotechnologies in Asia Pacific. A presentation based on the initial findings was presented at the Regional Meeting held in September 2017 at Kula Lumpur. More details about the meetings, RIS presentation and other presentations is available at *http://www.fao.org/asiapacific/events/detail-events/en/c/1440/* ; RIS Presentation is at

https://www.slideshare.net/ExternalEvents/the-status-of-application-capacities-and-the-enabling-environment-for-agricultural-biotechnologies-in-the-asia-pacific-region-presentation-of-preliminary-findingssrinivas

As ABDR completes 19 volumes we take this opportunity to thank RIS for hosting ABDR and supporting it. Prof.Sachin Chaturvedi, DG, RIS has been associated with ABDR since its inception and is the guiding spirit. A journal cannot survive without continuous support from authors, referees and obviously without readers. We thank all of them for their support and appreciation. Over the years ABDR has grown with the consistent guidance of the Editorial Advisory Board. We thank the Board for the support we have received.

We look forward to your comments and suggestions.

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Asian Biotechnology and Development Review
Vol. 19 No. 3, pp 3-23

Safeguarding health and well-being of people: How Clinical Trials in Africa set for Sustainable Development Goals?

Swapan Kumar Patra*
Mammo Muchie**

Abstract: To make availabile cheap medicines for number of diseases is one of the pressing challenges in Africa. Clinical trials are the foundation for making new medicines and continuation of the existing medicine. With the diverse patient population, African continent is a fertile ground for conducting clinical trials by many pharmaceutical firms, universities or research institutes. Governments of many African countries have adopted suitable pharmaceutical policies to make these countries comparatively researcher friendly and thus attracting firms or institutes to conduct the clinical trials. Governments of these countries are considering in making them centre of excellence in pharmaceutical and healthcare research. As a result, over the past few decades, there has been a dramatic increase in the number of registered clinical trials all -over Africa. This study is an attempt to map the clinical trial activities in African continent using data from the clinical trial database (ClinicalTrials.gov) website of the United State Government. It has been observed that although there has been a growth of clinical trials all -over African continent in the recent years, it is comparatively lower to other parts of the globe. The total number of the trials have shown that they are only conducted and that too to a limited extent in a few countries of the continent having stronger science and technology (S&T) base. The study concludes with some policy recommendations, including uniform research guidelines, and ethical regulations for further improvement of clinical trial research in Africa.

Keywords: Healthcare, Africa, Clinical Trial, Internationalization, Globalization, Globalization of R&D

Introduction

In all 17 Sustainable Development Goals (SDGs) of the United Nations (UN), ensuring good health and well-being for all has been considered as an essential element. As per the UN, efforts have been made to increase

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life expectancy, control many killer diseases, and lower infant and maternal mortality rate. Since the last couple of decades, governments all -over the world have taken keen interest to meet these goals. Besides this, a major advancement has been made on increasing access to clean water and sanitation. Target has also been achieved in reducing many diseases, including malaria, tuberculosis, polio and spread of HIV/AIDS. However, many more efforts are still required to fill in gaps related to health-related issues, particularly in the developing part of the world. Clinical trials are needed globally to reduce disease burdens by developing safe-and- effective new therapies and vaccines. Till lately, African countries have been under-represented in research owing to lack of commercial viability and trained researchers. The African continent, however, possess tremendous opportunities in terms of conducting clinical trials as it has diverse population, skilled manpower available at comparatively lower cost besides availability of clinical trial volunteers at a low cost (Lang and Siribaddana, 2012).

With diversity in patient population, African continent is considered to be a fertile ground for conducting clinical trials for new medicines and renewal of existing medicines. Ambitious, governments of many African countries have adopted different policies to make Africa a comparatively research- friendly. For example, South Africa is one of the African countries that has taken many recent initiatives to develop biotechnology industry to meet persistent challenges of poverty, unemployment and inequality (Patra and Muchie, 2017). There are many countries, which have undertaken initiatives to make these countries as to be with excellent pharmaceutical and health sectors (Puppalwar *et al.,* 2015). As a result, over the past few decades, there has been dramatic increase in the number of registered clinical trials in Africa.

Generally, developing countries are under-represented in clinical research. Africa is emerging as an important destination in the recent years. Moreover, if firms and other entities conduct clinical trials in low- and middle-income countries, perhaps it would yield many positive outcomes. For example, it would generate knowledge spillovers in terms of manpower training, increase in research standards, and would bring investments in research and overall improvements in healthcare. However, conducting clinical trials in Africa has its own issues and challenges, for example,

regulatory laws and evolving guidelines vary across countries. In some countries, there is no clear regulatory framework; in some cases, regulations exist but it lacks implementation owing to inadequate infrastructure.

Providing cheap medicines to citizens for many diseases is one of the pressing challenges for many African countries. Clinical trials are the very foundation for new medicine development. In addition, in case of the existing therapies, it is an important phase for extension of licenses or patents. The time and cost to conduct a clinical trial is an essential factor. There is fierce competition in the market, so research in this area needs to be precise and done in a timely manner. With the increase in Research and Development (R&D) costs of new drug development, and limited access to larger populations for trials have led pharmaceutical firms to be global. Many big pharmaceutical firms have relocated recently their clinical trial activities to offshore locations into less developed, developing or emerging economics. Lately, Multinational firms (MNEs) from developing countries are offshoring their R&D activities to developing Asian countries, particularly, in India and China. And MNEs' foreign-based subsidiaries are increasingly playing active role in generation, use and transmission of knowledge back to the firms headquarters in developed countires (Patra, 2017).

With the present web of globalization, along with other industries, such as information and communication technologies (ICT), biotechnology, manufacturing, drug development has become highly globalized. The major reason behind offshoring of clinical trials is cost reduction and shorter product life- cycle in making new medicine (Chin, 2011). It is already mentioned that clinical trials are the foundation for new drug development processes, and also an important step for renewal of licenses for the existing therapies. For reduction in cost and owing to increased competition in global pharmaceutical market, short- life cycle of the new drugs is very crucial. In African continent, Egypt, South Africa, Kenya, Nigeria, Tanzania, Uganda and Zambia are the major countries attracting global firms for conducting clinical trials. These countries have diverse patient population, comparatively good infrastructure, research environment, skilled workers, and government's encouragement in the form of incentives. They have developed research guidelines with a span of time to give appropriate environment to firms for clinical trials (Puppalwar *et al.,* 2015).

From the host countries' prespective, the trials would benefit them by having increased capacity development and investment. It would also bring skill and expertise for better management techniques of health-related issues. Sometimes trials often do not involve a medicinal product but instead compare different options such as different types of managements for an illness in the hospital with community-based care. According to Lang and Siribaddana (2012), clinical trial might be used to assess different mechanisms to improve patient's adherence to therapy. The pragmatic disease management trials can improve public healthcare in a long run in the country (Lang and Siribaddana, 2012).

With this backdrop, the study is an exploratory research to investigate current scenario of clinical trials being conducted in African countries. The study would investigate the growth of clinical trials over years, different disease conditions for which clinical trials being conducted, the phases where maximum trials conducted, the sponsorers and actors involved.

Regulatory Issues in Clinical trials in Africa

As mentioned already that lately the scholarly researches as well as popular articles on clinical trials have significantly increased in the developing countries. There are many reasons for offshoring of clinical trials from the developed countries to less developed part of the globe. The reasons are—easy availability of clinical trial volunteers, treatment-naïve patient population, favourable government policies to attract clinical trial sponsors and diverse types of diseases.

Along with the global concern on the ethical issues in clinical trial procedures, in Africa, concerns have been raised in public and professional sphere. The key ethical issue in the trials is the protection of the rights for research participants. Several ethical guidelines have been adopted internationally and are followed by developed as well as developing countries. First and foremost ethical guideline was adopted in 1947, named as 'The Nuremberg Code for research on human subjects'. In 1964, World Medical Association formulated 'Ethical principles for research on human subjects', known as the 'Helsinki Declaration'. Considering the pressing need of the time, the Helsinki Declaration is undergoing changes; it had laid down Ethical issues regarding research on human subjects (Resnik, 2017;

Bhatt, 2010). In the similar way, the Council for International Organizations of Medical Sciences (CIOMS), had laid down guidelines (adopted in 1982, revised in 1993, 2002, 2009, 2016) on health -related research ethics, safety protocols and healthcare product development[1].

Although many African countries have some guidelines related to Clinical Trials, many do not have stringent ethical rules and regulations (Table 1). Many of the African countries have weak legislation and monitoring system (due to lack of infrastructure and facilities), and it is quite easy for the clinical trial sponsors to bypass guidelines related to clinical trials. As a result, there are many reported cases of ethical violations while conducting clinical trials.

Table 1: Legislations related to clinical trials in Africa

Regions	Regulations related to clinical trials exists in the following countries	National legislation does not provide key regulatory function in clinical trials	No information
East Africa	Uganda, Tanzania, Zambia, Zimbabwe, Mozambique, Madagascar, Kenya, Mauritius, Malawi	Rwanda, Burundi, Seychelles	Ethiopia, Djibouti, Comoros, Eritrea, South Sudan
Central Africa	Congo, The Democratic Republic of theAngola		Cameroon, Gabon, Congo, Chad, Central African Republic, Equatorial Guinea, Sao Tome and Principe
Northern Africa	Egypt, Algeria, Tunisia, Morocco		Sudan, Libyan Arab Jamahiriya
Southern Africa	South Africa, Botswana Lesotho Swaziland	Namibia	
Western Africa	Ghana, Burkina Faso, Mali Nigeria, Senegal, Niger, Liberia, Togo, Cabo Verde, Sierra Leone	Gambia, Guinea-Bissau, Guinea	Benin, Côte D'Ivoire, , Mauritania

Source: Compiled from Situation Analysis Study on Medicines Registration Harmonisation in Africa: Final Report for the Southern African Development Community SADC[2] ECOWAS[3], EAC[4] and https://clinregs.niaid.nih.gov/

Material and Methods

This study used ClinicalTrials.gov data - a database maintained and updated by the United States (US) government to map dynamics of Clinical Trials conducted by various actors in Africa. The database maintains records of clinical trials conducted globally by various publicly and privately supported clinical studies of human participants. The website provides free information for patients, their family members, professionals, researchers, and the public. The publicly and privately supported clinical studies on a wide range of diseases and conditions are easily accessible. The database and the website is maintained by the National Library of Medicine (NLM) at the National Institutes of Health (NIH), US. The sponsor or the principal investigator of the clinical study generally updates information on the website. Studies are generally submitted to the website (that is, registered) when they begin, and the information on the site is updated throughout the study. In some cases, sponsorers or collaborators update the status of the study after the study ends. This web- site and the database of clinical studies are commonly referred to as a "registry and results database." (Source: https://clinicaltrials.gov/ct2/about-site/background)

Results

Globalization of Clinical Trials

The globalization of clinical research is relatively a recent phenomenon. Pharmaceutical firms are increasingly offshoring their clinical trial studies.Trial sites increased outside the United States and their number more than doubled in the last 10 years (Glickman *et al.* ,2009). On the other hand, number of clinical trials declined in the United States and Western Europe (Glickman *et al.,* 2009). Getz (2009), however, observed that clinical trials are increasingly taking place on a global scale irrespective of the national boundaries. The industrial and the government sponsors in developed countries are shifting trials to developing and less developed countries. Since 2002, Food and Drug Administration (FDA), a federal agency of the US Department of Health and Human Services, has observed that number of offshoring trials are annually growing by 15% and the number of the U.S.-based investigators have declined by 5.5% (Getz, 2009). This trend is suggestive that clinical research is undergoing the same patterns of globalization process of any other high- technology industry.

The major reason for globalization of clinical trial is the cost- related factor. Firms can save its cost substantially by having trials in offshore locations. Many firms are conducting phase 2 and phase 3 trials in many developing countries; In addition, these have shortened timeline for clinical testing (Glickman *et al.,* 2009). In 2000, the average cost to develop a new drug was about $802 million; and with the span of time, the cost of developing a prescription drug that gains market approval, reached at about $2.6 billion. It was 145 per cent increase over the estimate in 2003 (Mullin 2014). In this scenario, the large pool of potential research participants and the lower cost of research and development (R&D) in the countries of African continent, may provide tremendous opportunities to accelerate R&D in pharmaceuticals and recruitment of subjects for clinical trials.

The concept of outsourcing for development and global studies on new drugs has become widely accepted in the pharmaceutical industry (Maiti and Raghavendra, 2007). Clinical trials are increasingly being conducted at numerous sites all around the globe. Several developing countries are emerging as relevant investigative sites. Although, India and China appear as the preferred destinations, good prospects are also available in other advanced but developing economies, such as Brazil, South Africa and Mexico. In addition to the large domestic markets, those emerging economics have consolidated major regional manufacturing and export bases for foreign-owned subsidiaries as well as for some domestic firms. These emerging countries feature some country- specific conditions for example their universities and government research institutes or research centres of excellence, high technology clusters and so on. The knowledge hubs dispersed in these high technology clusters in many developing countries are shaping into attractive investigative sites (Santiago-Rodríguez, 2009).

According to the clinical trial database available (https://clinicaltrials.gov/, accessed during mid-March 2017), globally the number of international trial sites are growing. Out of the total 239,204 clinical trials listed in the database only about 5,802 (2.43 per cent) were conducted in African countries. The maximum number of trials were conducted in North America 110, 877(46.35 per cent), followed by Europe 67, 458 (28.20 per cent). North America and Europe as predominant clinical trial sites; more than any other part of the globe. Table 2 indicates globally conducted clinical trials.

Table 2: Number and the location of global clinical trials

Region	Number of Studies	percentage
Global total	239204	100
Africa	5802	2.43
Central America	2472	1.03
East Asia	24272	10.15
Japan	4479	1.87
Europe	67458	28.20
Middle East	9697	4.05
North America	110877	46.35
Canada	16586	6.93
Mexico	2737	1.14
United States	100180	41.88
North Asia	4231	1.77
Pacifica	5985	2.50
South America	7908	3.31
South Asia	3672	1.54
Southeast Asia	4819	2.01

Source: Clinical Trial registry database of US available at ClinicalTrials.gov accessed on March 2017

Number and Growth of Clinical Trials in Africa

According to the clinical trial registry of the United States (https://clinicaltrials.gov), the break-up of clinical trials conducted in African countries are shown in Table 3. From the clinical trial database (accessed in March 2017), this study observed that out of 231,055 globally conducted trials, only about 5,562 (2.41 per cent) were conducted in Africa. Among the 54 member -countries of the African Union, clinical trials were conducted in 46 countries. A good number of clinical trials were conducted only in a few countries. The maximum number of Clinical trials were conducted in South Africa (2,269 trials), and it alone constituted about 40 per cent of the trials conducted in Africa. Egypt was in second position with (1,368 trials), followed by Uganda (363 trials) Kenya (345 trial ;5.95 per cent), Tanzania (243 trials ;4.19 per cent), Tunisia (207 trials ;3.57 per cent); Malawi (160 trials ;2.76 per cent), Zambia (147 trials ;2.53 per cent); Ghana(117 trials ;2.02 per cent); Burkina Faso (112 trials ;1.93 per cent) Mali (111 trials ;1.91 per cent) and Nigeria (99 trials ;1.71 per cent). Rest of the countries had limited number of clinical trial sites.

Table 3: Number of Clinical Trials conducted in African Countries

Africa	Total number of Trials in 2016	Percentage of total
Eastern Africa		
Uganda	363	6.26
Kenya	345	5.95
Tanzania	243	4.19
Malawi	160	2.76
Zambia	147	2.53
Ethiopia	87	1.50
Zimbabwe	82	1.41
Rwanda	59	1.02
Mozambique	55	0.95
Madagascar	13	0.22
Burundi	9	0.16
Djibouti	1	0.02
Middle Africa		
Cameroon	61	1.05
Gabon	38	0.65
Congo	37	0.64
Congo, The Democratic Republic of the	32	0.55
Chad	6	0.10
Central African Republic	5	0.09
Angola	3	0.05
Equatorial Guinea	2	0.03
Northern Africa		
Egypt	1368	23.58
Tunisia	207	3.57
Morocco	86	1.48
Algeria	76	1.31
Sudan	24	0.41
Libyan Arab Jamahiriya	6	0.10
Southern Africa		
South Africa	2269	39.11

Table 3 continued...

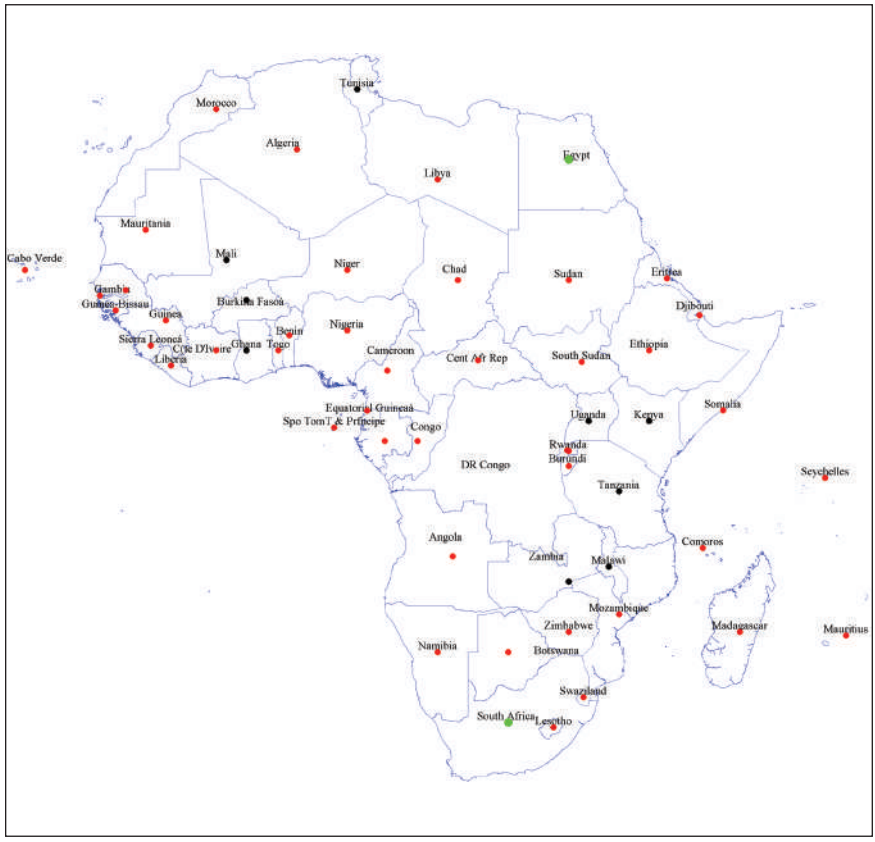
Table 3 continued...

Botswana	53	0.91
Lesotho	10	0.17
Swaziland	10	0.17
Namibia	2	0.03
Western Africa		
Ghana	117	2.02
Burkina Faso	112	1.93
Mali	111	1.91
Nigeria	99	1.71
Senegal	63	1.09
Gambia	50	0.86
Guinea-Bissau	43	0.74
Benin	33	0.57
Côte D'Ivoire	29	0.50
Niger	19	0.33
Sierra Leone	14	0.24
Guinea	12	0.21
Liberia	12	0.21
Togo	7	0.12
Mauritania	1	0.02

Source: Clinical Trial registry database of US available at ClinicalTrials.gov accessed on March 2017

Egypt and South Africa were seen only as the two countries with more than 1000 studies (Figure 1). The distribution of clinical research showed that in the Eastern Africa, the maximum number of trials were concentrated among the following countries —Uganda; Kenya; Tanzania; Malawi—Zambia. In the Middle Africa not much significant activities happened. In the Southern Africa, the republic of South Africa, because of its scientific work- force and infrastructure was the only country with maximum activity. In the Western Africa, the good numbers of studies were conducted in Ghana, Burkina Faso and Mali.

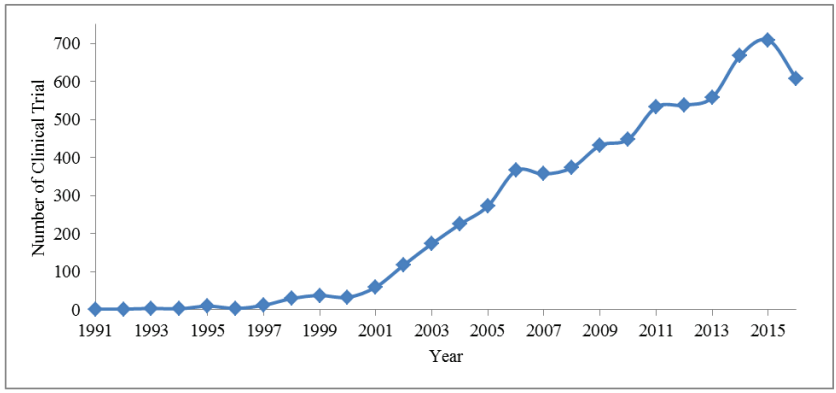
Figure 1: Location of Clinical Trials in Africa



Source: Own drawing, Legends: Green colour >1,000 studies, black colour >100 but less than 1000 studies and red colour <100 studies and no circle of any colour means no studies

From 2001 to 2015, there were about 6,581 studies conducted from Africa (one trial was conducted in many countries). In the initial years, there were very few studies were conducted; actual growth was observed after 1998 (Figure 2). After that growth momentum continued and lately about 600-700 clinical trials were cumulatively conducted in Africa. However, the numbers were lesser compared to India, China etc.

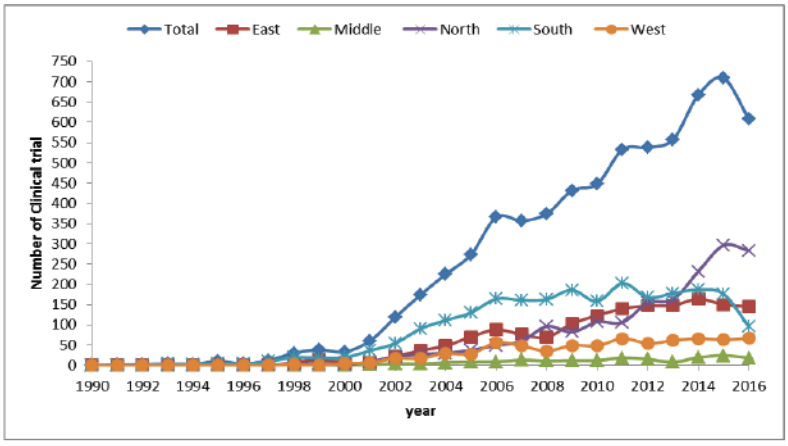
Figure 2: Growth of clinical Trial in Africa



Source: Author's compilation; Clinical Trial registry database of US available at ClinicalTrials.gov accessed on March 2017.

Although a good number of clinical trials are conducted only in a limited number of countries; South Africa and Egypt are the only two countries where maximum numbers of clinical trials are being done. The region- wise break-up of the number of trials is shown in Figure 3. The number of studies conducted in the Southern region was more than any other region. But lately, the numbers of studies conducted from the Northern regions outnumbered from other regions, and the Middle region showed the lowest in Africa

Figure 3: Region- wise growth of Clinical Trials in Africa



Source: Author's compilation; Clinical Trial registry database of US available at ClinicalTrials.gov accessed on March 2017.

Table 4: Different disease conditions of Clinical Trials conducted in African Countries

Conditions	Total Africa	Conditions	West	Conditions	South	Conditions	North	Conditions	Middle	Conditions	East
HIV Infections	654	Malaria	177	HIV Infections	275	Infertility	85	Malaria	37	HIV Infections	184
Malaria	370	HIV Infections	58	Tuberculosis	92	Diabetes Mellitus, Type 2	39	HIV	29	Malaria	179
Tuberculosis	161	Malnutrition	20	Diabetes Mellitus, Type 2	82	Breast Cancer	28	Diabetes Mellitus	4	Tuberculosis	70
Diabetes Mellitus, Type 2	109	Tuberculosis	20	Asthma	71	Diabetes	27	Dyslipidemia	4	Pregnancy	30
Infertility	85	Anaemia	18	Rheumatoid Arthritis	65	Pain	24	Fever	4	Malnutrition	29
Breast Cancer	80	Malaria, Falciparum	15	Breast Cancer	56	Postoperative Pain	24	Malnutrition	4	Anemia	21
Diabetes	79	Plasmodium Falciparum Malaria	14	Diabetes	53	Healthy	22	Plasmodium Falciparum Malaria	4	Contraception	21
Asthma	77	Pregnancy	13	Pulmonary Disease, Chronic Obstructive	40	Postpartum Hemorrhage	19	Pregnancy	4	Pneumonia	21
Rheumatoid Arthritis	72	Mortality	11	Type 2 Diabetes Mellitus	33	Polycystic Ovary Syndrome	17	Sickle Cell Disease	3	Malaria, Falciparum	19

Table 4 continued...

Table 4 continued...

Anemia	58	Anaemia	9	Schizophrenia	26	Hypertension	15	Trypanosomiasis, African	3	Human Immuno-deficiency Virus	19
Malnutrition	57	Morbidity	9	Type 2 Diabetes	25	Chronic Hepatitis C	14	Tuberculosis	3	Diarrhea	17
Pregnancy	55	Pneumonia	9	Alzheimer's Disease	23	Hepatitis C	13	Human African Trypanosomiasis (HAT)	3	Plasmodium Falciparum Malaria	17
Hypertension	42	Postpartum Hemorrhage	9	Atrial Fibrillation	23	Acute Coronary Syndrome	12	Obesity	3	Fever	14
Pulmonary Disease, Chronic Obstructive	41	Diarrhea	8	Hypertension	23	Subfertility	12	Anxiety	3	Anaemia	11
Type 2 Diabetes Mellitus	39	HIV Infection		Crohn's Disease	22	Rheumatoid Arthritis	10	Anaemia	2	Male Circumcision	11

Source: Author's compilation; Clinical Trial registry database of US available at ClinicalTrials.gov accessed on March 2017.

Disease conditions of Clinical Trials

From the clinical trial studies databases, the disease condition can be defined as "The disease, disorder, syndrome, illness, or injury that is being studied. On the ClinicalTrials.gov, conditions may also include other health-related issues, such as lifespan, quality of life, and health risks".

The cumulative and the region- wise analysis of the disease conditions show that in terms of total African clinical trial scenario, HIV/AIDS related clinical trials are at the top of the list. The most number of clinical studies are conducted in the Southern Africa. There are regional variations of clinical trials in different regions in Africa (Table 4).

Phases

The US FDA defines phases for trials involving investigational new drugs (available at https://clinicaltrials.gov/ct2/about-studies/glossary#P). These phases can be categorised into *Phase 0; Phase 1; Phase 1 & Phase 2; Phase2; Phase 2& Phase 3; Phase 3* and *Phase 4.*

Phase 0 is the first step and it involves investigative trials. The drug to be experimented with is to be involved only for a very limited human exposure, with no therapeutic or diagnostic intent. There were only 39 studies conducted in this phase.

Phase 1 is the initial phase of any clinical study. This phase requires health human volunteers to examine metabolism and pharmacologic actions of the drugs in humans. The side effects related to collective doses are also investigated in this phase. Beside this, it gives the early evidences of the effectiveness of the drug. About 262 studies were conducted in Phase I in Africa.

Phase 2 is the more advanced stage, which includes controlled clinical studies to evaluate effectiveness of the drug for specific symptom in patients with the disease or condition under the study and for determining common short-term side effects and risks.

Phase 1/Phase 2 is a mixture of phases 1 and 2

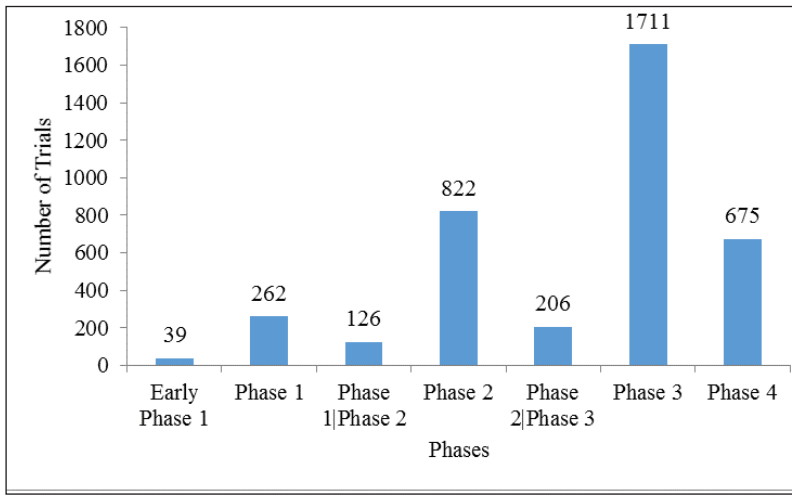
Phase 3 includes controlled and uncontrolled trials after preliminary evidence; suggesting effectiveness of the drug. This phase anticipates additional information to evaluate overall benefit-risk relationship.

Maximum trials are conducted in Phase III. About 1,711 trials are conducted in phase 3

Phase 2/Phase 3 are the combination of phase 2 and 3

Phase 4 is the final stage of the studies of FDA-approved drugs to delineate additional information including hazards of the drugs, its benefits, and the best use (Figure 4).

Figure 4: Four different phases of clinical trials conducted in Africa



Source: Author's compilation; Clinical Trial registry database of US available at ClinicalTrials.gov accessed on March 2017.

Sponsors/Collaborators

According to the US FDA definitions, collaborators are other than sponsors. They support a clinical study in various forms. The support may be financial, designing, in implementation, data analysis and reporting. The sponsors are the entities who oversee clinical study and analyze the data.

After culling duplicates, the 5753 studies were sponsored by 2,592 collaborators (Table 5). The list of collaborators included many global firms, which conducted trials in Africa; universities are prominent actors in collaboration.

Table 5: Top collaborators of the clinical studies in Africa

Rank	Sponsor	Number of Trials
1	National Institute of Allergy and Infectious Diseases (NIAID)	293
2	Cairo University	238
3	Assiut University	198
4	GlaxoSmithKline	193
5	Mansoura University	179
6	London School of Hygiene and Tropical Medicine	170
7	Pfizer	167
8	Sanofi	163
9	Ain Shams University	142
10	AstraZeneca	141
11	Novartis	140
12	Hoffmann-La Roche	130
13	Centers for Disease Control and Prevention	110
14	Makerere University	105
15	Bristol-Myers Squibb	104
16	Novartis Pharmaceuticals	104
17	University of Cape Town	99
18	Boehringer Ingelheim	95
19	National Cancer Institute (NCI)	92
20	Novo Nordisk A/S	92

Source: Author's compilation; Clinical Trial registry database of US available at ClinicalTrials.gov accessed on March 2017.

Concluding Remarks

With the increasing web of globalization, clinical trial researches for different types of medicines are also on the rise. Along with many other countries in the continent, Africa is also an important destination for conducting clinical trials by many global multinational firms and other entities. However, clinical trials conducted in Africa are comparatively lesser than other continents in the globe. This increasing web of clinical trials is fueled by numerous factors. Among the many other factors, the increasing cost of clinical trials globally is one of the important factors. Multinational firms are going offshore and conducting clinical trial research

to reduce cost of developing new medicine. It is estimated that, globally the cost is increasing at about 20 per cent per year. And cost can be reduced if the trials are conducted in developing or in less developed countries. If clinical trials are conducted in the developing or less developed countries, it can easily reduce cost by 50 per cent or more, and in some cases up to 90 per cent (Serhal, 2011). In addition, patients' enrollment process can be made quicker in many developing countries. Serhal further (2011) observed that in developing countries or less developed countries, recruitment could be increased by 100 per cent and in some cases by 500 per cent or more.

In the high technology sector, particularly, in the case of pharmaceutical development, speed of registration is an utmost requisite. Therefore, getting new volunteers for testing drugs from the developing countries can be a very strong driver for globalization. In addition, for some diseases such as oncology and rheumatology, it can be difficult to recruit patients into clinical trials who are raw to any kind of medicine in the developed countries; in the developed countries most patients with some diseases may already have been exposed to some form of drugs. On the other hand, patients from developing or lesser developed countries are not exposed to that form of drugs, and can offer a larger pool of treatment -naive patients' pools (Serhal, 2011).

To map the clinical trials studies conducted in African continent, this study uses trial register records from the United States (https://clinicaltrials.gov) database. The study observed that in the African continent, the trials conducted were comparatively lesser than other continents. The maximum numbers of trials were conducted in Southern part of Africa; South Africa is the country where maximum trials were conducted, and number is increasing. From the Northern Africa, the maximum trials were done in Egypt. The higher number of trials conducted in these countries indicate their strong knowledge base in terms of science and technology (S&T) infrastructure of these countries. Many reports have confirmed that South Africa has one of the world's highest rates of placebo-controlled trials in the recent years[5]. Due to certain advantages, 'placebo-controlled trials' conducting in South Africa has been very lucarative for many pharmaceutical firms.

There are different types of challenges while conducting clinical research in Africa. The first and the foremost thing about conducting the trial is the local research culture. Many of the African countries, particularly the less developed Sub-Saharan African countries, are quite weak in S&T. R&D culture is yet to be established among many of the African countries.

Political instability is another challenge in many African countries. The political stability certainly represents a justifiable factor in deciding to run a clinical trial in Africa. According to Serhal (2011), there are many opportunities to conduct a trial. For example, the African continent has a diverse patient population for several investigational diseases, and many governmental rules and regulations are friendlier towards firms to conduct clinical trials in Africa. Beside these, cost to conduct clinical trials are lower than the developed part of the globe. Many African countries (for example South Africa, Egypt) have good R&D infrastructure, suitable for excellent clinical research. Also, the contient is a huge reservoir of, high quality but low-cost work force for conducting R&D and clinical trials (Serhal, 2011).

From the host country's prespective, the clinical study conducted in the emerging markets of many African countries should encourage African pharmaceutical industry. The intended and unintended knowledge spillover perhaps would increase research culture, R&D infrastructure and above all the healthcare in Africa (Puppalwar *et al.,* 2015).

Along with the issues mentied above, the globalization of clinical trials has raised significant ethical and social issues. From host country's prespective it is of major concern because there are many reported cases of exploitation of research participants in developing countries, including Africa[5]. It is quite easy to by –pass ethical rules and regulations in many African countries because of less stringent monitoring or lack of appropriate legislations. In Africa, it is not only strong knowledge base but also vulnerable population plus lax regulations are the key reasons of mushrooming of clinical trials. So to ensure clinical trial participants' rights are protected and safeguarded, pharmaceutical companies must adhere to guidelines like Declaration of Helsinki or CIOMS Guidelines. From the African countries' prespective, uniform guidelines and monitoring processes must be laid down by the African Union or the other regional fora[5].

Acknowledgement: *Dr. Swapan Kumar Patra presented the earlier version of the paper in African Unity for Renaissance International Conference and Africa Day Expo, Pretoria, South Africa during 21-25th May 2017. Authors thank the participants of the conference for their valuable comments.*

Funding: *SARChI Innovation Studies through Tshwane University of Technology*

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RIS
Research and Information System
for Developing Countries
विकासशील देशों की अनुसंधान एवं सूचना प्रणाली

Asian Biotechnology and Development Review
Vol. 19 No. 3, pp 25-46

Regions, Knowledge Communities and Innovation Dynamics: A Case of Bengaluru Biocluster in India

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Abstract: Scholars from the diverse academic themes have reflected and discussed the connection between the innovation and the geographical settings. In developing countries, like India, high technology cluster development is not a new phenomenon, and has been a significant tool for policy implications. However, such clusters have emerged in certain regions, specifically southern India, endowed with diverse set of 'knowledge bases/knowledge communities', which are being utilized at different stages of the innovation. Among the clusters in southern India, Bengaluru biocluster is an important example to reflect upon various dimensions of the regional innovation system. The presence of some of the premier research institutions, Indian and foreign multinationals, skilled workforce, backed by robust policy initiatives, provides Bengaluru an edge over other clusters located in other parts of the country. With this prelude, the study attempts to explore different knowledge communities and innovation dynamics in the Bengaluru biocluster, which is influenced, inter alia, by the global waves of innovation. A mixed method is adopted along with a case study approach to examine the given cluster. Moreover, the study infers that knowledge communities enjoy linkages at the local, regional and global levels; leading to expansion of cluster. Evidently, publications and patents outputs as well as collaborating activities have an inter-relation with innovation process.

Key Words: Biocluster, Knowledge Communities, Bengaluru, Regional Innovation, Collaborations

1. Introduction

The idea of innovation and its geographical linkage has been a matter of discussion among scholars from diverse fields. Scholars of innovation studies, economic geography, business studies and other subjects, have

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The authors would like to acknowledge the support of National Research Development Council (NRDC) and the CSIR-National Institute of Science Communication and Information Resources (CSIR-NISCAIR) in enabling access to research databases and resources. The authors thank reviewers for their comments which helped in revising the article.

observed knowledge bases and innovation clusters from diverse perspectives (Asheim, 2012; Martin and Moodysson, 2011; Euyarra, 2010; Martin and Sunley, 2011). The dynamism of knowledge bases within and beyond regions, however, has remained unexplored in developing countries. The emergence of clusters in developing countries, particularly in India, is not a new phenomenon (as far as one traces introduction of the cluster in the Indian policy regime); it was first incorporated in the Abid Hussain Committee Report (1997), and was recognised in an approach paper to the 11th Five Year Plan document. Subsequently, in the last decade, there was a rapid increase in cluster development in India to encourage high-technology like Information Technology, Aerospace and Biotechnology, other than the traditional manufacturing sectors (Hashim, 2006; Dhar and Saha, 2014).

With the advent of the globalization and in the post-TRIPS era, the sector has been witnessing proliferation of biotechnology clusters across the country. Cluster development has been considered important for the Indian biotechnology sector in providing support to domestic firms and SMEs working in the area of biotechnology. Cluster formation would aid in better infrastructural development, in conducive research collaborations, and would result in competitive edge and effective sharing of resources. As the sector has undergone different stages since 1980s, the present growth at a CAGR of 20.33%, valued at INR 149.23 billion for the year 2015-16 (Make in India, 2018), narrates the story of its unprecedented growth.

As per the estimates of 2016, nearly 1,070 units operated in biotechnology, and 58% of which were engaged in healthcare biotechnology (BIRAC, 2016). Through policies, Central and State Governments, have stressed the importance of clusters (e.g. 'Biotechnology Policy, 2001'; Biotechnology policy 2013; Biotechnology Policy, 2015),[1]that led to the development of many technology parks and bioclusters to erect a robust regional system of innovations for biopharmaceutics (Vaidhyanathan, 2008; Patra, 2014). Some of the emerging as well as established biotech clusters are located in the Western (Maharashtra, Gujarat and Goa), Northern (Delhi, Haryana, Uttar Pradesh) and Southern (Andhra Pradesh, Karnataka and Tamil Nadu) regions of India (Biospectrum, 2009). The Southern part of India, particularly Hyderabad and Bengaluru, has emerged as a potent site for biopharmaceutical research and innovation. These regions have nurtured scientific research and innovative activities through institutional

mechanisms. The clusters envisage various actors — firms, public research labs and academic institutions, funding agencies, incubation centres— involved at different stages of the innovation process. For the study, the actors are termed as 'knowledge bases'[2] or 'knowledge communities' with distinct characteristics in terms of their organizational structure, innovation capabilities, regional settings and other factors, conducive for innovations in biopharmaceuticals.

Among Southern India, Bengaluru biocluster is an important example to reflect upon various dimensions of the regional innovation system. The presence of some of the premier research institutions, Indian and foreign multinationals, skilled workforce, backed by robust policy initiatives, gives Bengaluru an edge over other clusters located in the other parts of the country. Many studies were done on the IT cluster in Bengaluru but biotechnology cluster did not receive the attention it deserved. This paper is a preliminary exploration on the innovation dynamics of the Bengaluru biocluster, which is influenced, inter alia, by global waves of innovation.

2. Literature Review: Regions and Knowledge Communities

Regions, agglomerations, clusters have been carefully examined by many scholars (Marshall, 1920; Weber and Friedrich, 1929; Porter; 1998) to analyse local-level innovations (Krugman 1991; Porter 1998; Rosenfeld 1997). Michael Porter (1990) conceptualized the notion of cluster in his celebrated work, 'Comparative Advantage of Nations' and defined cluster as "a geographically proximate group of interconnected companies and associated institutions in a specific field, based on commonalities and complementarities" (Porter, 1991). However, this definition, due to its complex ontological vagueness, became a matter of debate in the later decades. Besides the monumental definition by Porter, many theorists have revisited and retranslated the definition, respectively.

As defined by Rosenfeld (1997), the notion of clusters can be considered as the concentration of enterprises, capable to create strong linkages from exchange, due to their spatial proximity and mutual dependence. And Roelandt *et al.* (1999) attributed clustering to linkages of interdependent business enterprises, which are a part of the larger global value- chain. On observing the cluster, the definition of Baptista and Swann (1998) ,which incorporates spatial and technological perspectives, one may see cluster

as a large group of interrelated firms, situated at a particular geography, involved in the process of innovation. Some of the prominent examples of innovation clusters, particularly in biotechnology, have been: the Boston Bay Area (US); Medicon Valley (Sweden); HealthBio Cluster (Finland); and in countries like Japan, Germany, Singapore and Italy.

Reflecting on different innovation clusters, scholars realised that regional innovation is not merely confined to firm-level activities at a given geography, it involves other non-firm entities like public research organisations, academic institutions and government initiatives for creating and disseminating knowledge. With a systemic approach, the concept of Regional Innovation System (RIS) found its way in visualizing innovation as an outcome of interactive process (Lunvall, 1992). As reflected by Coenen *et al.* (2004), *a system in which firms and other organisations are systematically engaged in interactive learning through an institutional milieu characterised by local embeddedness*, can be termed as a RIS. Innovation is, therefore, seen as a socially embedded process (Moodysson, 2008), where firms and organisations located within a short proximity share network relations, predominantly of a tacit and informal nature crucial for innovation (Bathelt *et al.,* 2004).

The RIS concept reaffirms that geographical proximity among actors may help in the creating relations to foster innovation in a better way, through face-to-face interactions, and reinforces natural embeddedness of economic ties in specific institutional settings[3] (Steiner, 2011), which in turn support firm and regional competitive advantage (Asheim *et al.,* 2007). By studying dynamics of the regional development through analysis of the local interactions, RIS has become an important part of conceptualisation of geography of the innovation field. The very idea of the RIS also reformed the notion of clusters; according to the best-known taxonomy of innovating firms, clusters can be categorized as science-based, scale-intensive, supplier dominated and/or specialized suppliers (Pavitt, 1984). A degree of openness is a key part of the comparative advantage that clusters offer over non-clustered locations (Oakey, 2013). A more evolved definition of cluster is "a geographical concentration of actors in vertical and horizontal relationships, showing clear tendency of cooperating and sharing their competencies, all involved in a localized infrastructure of support" (Zechendorf, 2011).

With respect to knowledge generation and diffusion subsystem, higher education institutions, research centres and other intermediaries, which the OECD (2011) refers to as *knowledge hubs*, have a significant role to play. Intensive interactions between subsystems in terms of scientific and applied knowledge and human resources flows, include links with other regional, national and international institutions; high-quality infrastructures and institutional setting, including sufficient regional autonomy; regional policy actors.

There was emergence of clusters in Brazil, China, India and South Africa (OECD, 2010), due to the presence of different public R&D organizations, science- education institutions and research centres, which acted as a 'pull-factor' for various foreign firms and also aided in strengthening domestic counterparts. With this context, the given study reviews innovation activities of knowledge bases of prominent academic institutions, public R&D organizations as well as some firms existing in the Bengaluru Biocluster, which are engaged in biopharmaceutical innovation. The paper also reflects upon different government initiatives and policies that led to the formation of Bengaluru biocluster and accelerated regional innovation process.

3. Knowledge Communities in Bengaluru Biocluster

The Government of Karnataka was the first to announce a state biotechnology policy in 2001. Later, state-level biotechnology policies were adopted by Andhra Pradesh, Maharashtra, and other states (Patra, 2014). Bengaluru is seen as a super-cluster of high technology firms and institutions, across sectors, like Information Technology, aerospace, machine tools, pharmaceuticals and biotechnology (Rao and Balasubrahmanya, 2017).

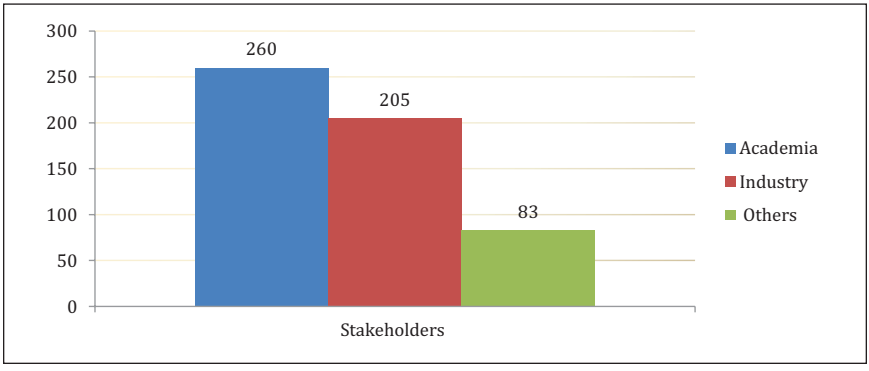
It is one of the largest urban agglomerations, with a population density of 4,381 per sq. km (Government of Karnataka, 2014); well connected through rail, road and air,and with government policies encouraging foreign as well as domestic firms to be located in the given cluster. As per the Karnataka Biotech Policy – III (2017-2022), the Biotechnology market of Karnataka would be worth USD 18.6 Billion, accounting for 35% of India's biotechnology revenue and would house nearly 60% of biotech companies across the country. As per the ABLE (2015) estimates, the state accounts for more than 7, 500 biotechnology graduates every year. The ecosystem is synergized further with the presence of Association of Biotechnology

Led Enterprises (ABLE), a not-for-profit pan-India forum, representing the Indian Biotechnology sector. The ABLE works towards engaging different stakeholders of the sector, within and beyond the region, for facilitating innovation processes. The cluster is largely influenced by different government agencies at the state and national levels, including Department of Biotechnology (DBT), Government of India. At the state level, most of the interventions are carried by the Department of Information Technology, Biotechnology and Science &Technology (IT&BT), Government of Karnataka.

The MNCs had started their operations in this region from 70s, leading to translation of a huge wealth of knowledge and talent pool into applied and interdisciplinary areas. Biocon has been credited for vibrant biotech industry in Bengaluru. The city also has a large pool of service providers and contract research / outsourcing companies, making it one of the most sought after innovation clusters in India.

As per the BIRAC –IKP report (2016), the academic fraternity is significantly higher in Bengaluru as compared to firms, making it a fundamental case to reflect on knowledge communities (Figure 1). The city envisages many stakeholders, namely academia, industry, funding agencies, etc. The category 'others' includes, funding agencies, incubation centres, biotechnology fora, medical colleges and other enablers of knowledge production and dissemination.

Figure 1: Different Stakeholders of Knowledge Production in Bengaluru cluster



Source: BIRAC - IKP (2016).

Emergence of Bengaluru as a biotechnology hub dates back to 2000 when the state government formed a Vision group on Biotechnology, chaired by the biotech entrepreneur, Kiran Muzumdar-Shaw, the CEO of a Bengaluru -based company, Biocon; and in April 2001, the vision group announced creation of a biotech development corridor, linking a range of public science institutions and providing space for private investment, granting tax concession for importing inputs and capital goods along the lines already offered to the IT sector (Scoones, 2003). Subsequently, the idea of cluster came into existence in millennium biotech policy –II (2011) as well as in the Industrial policy (2014-2019).

Surrounded by prominent academic institutions, research organizations, firms and translational facilities, the Bengaluru Biocluster has been divided into two different sub-clusters – (1) The Bangalore Helix in the Southern region, and (2) Northern Bangalore's Biocluster, which envisages NCBS, InStem and C-CAMP. The dynamism in and across these sub-clusters has transformed Bengaluru as a prominent hub for R&D and manufacturing of biopharmaceutical products in India. Some of the renowned Institutions are enlisted in Table 1.

Table 1: Major Research Institutions in Bengaluru

Research Centres	**Medical Colleges/ Hospitals**	**Incubation Centres**
1) Indian Institute of Science (IISc)	1) Bangalore Medical College and Research Institute (BMCRI)	1)Bangalore Bioinnovation Centre (BBC)
2) Jawaharlal Nehru Centre for Advanced Scientific Research (JNCASR)	2) St. John's Medical College (SJMC)	2) Centre for Cellular and Molecular Platforms (C-CAMP)
3) National Centre for Biological Science (NCBS)	3) Indira Gandhi Institute of Child Health (IGICH)	
4) Stem Cell Institute (SCI)	4) National Institute of Mental Health and Neurosciences (NIMHANS)	

Table 1 continued...

Table 1 continued...

5) Institute for Stem Cell Biology and Regenerative Medicine (INSTEM)	5) Rajiv Gandhi University of Health Sciences (RGUHS)	
6) Institute of Bioinformatics and Applied Biotechnology (IBAB)	6) Kidwai Memorial Institute of Oncology (KMIO)	
7) Centre for Human Genetics (CHG)		

Source: Author from different sources.

The inception of Bangalore Helix was announced in 2008, as a joint initiative of Department of IT, BT, S&T, Government of Karnataka and Alexandria Real Estate Equities, USA. It covers 86 acres of land, forming a significant part of the entire Bengaluru biocluster. The Bangalore Helix Cluster is distinctively divided into three following areas.

1. **Institutional Area**: Comprises Institute of Bioinformatics and Applied Biotechnology (IBAB) and Centre for Human Genetics (CHG) (20 Acres)
2. **Innovation Area**: The Bangalore Bio-innovation Centre (BBC) (10 Acres)
3. **Industrial Area**: Alexandria Biotech Park (56 Acres)

The institutional area, comprising two prominent institutions, IBAB and CHG, are devoted in basic as well as translational research in different domains. The IBAB has been rigorously working on different domains like bioinformatics tools, genome sequencing, computational biology and other allied themes. The institution was set- up by the Department of IT, BT and S&T, Government of Karnataka, and entertains to PhD, M.Sc, undergraduate and diploma courses affiliated to Manipal University, Manipal, Karnataka (IBAB, 2018). For research and development, the institution collaborates with regional, national and global entities for different research projects. Similarly, being nested in the same cluster, CHG has developed a niche in human disease genetics, pediatrics genetics as well as clinical and molecular cytogenetics. It also provides M.Sc, Ph.D and diploma courses in the aforementioned domains. The campus is equipped with laboratories, fly lab, sequencing and clinical facilities, which facilitate infrastructural support for experiment and research (CHG, 2018).

Besides IBAB and CHG, Bangalore Helix houses different firms, including start-ups and small-scale enterprises. Presence of a considerable number of start-up firms affirms that the state policies are motivating new bio-entrepreneurs in the region. As per the estimates of the Department of Industries and Commerce, Karnataka (2015), the direct employment generated in the cluster is nearly 7000 scientists and 2100 technicians, along with 560 individuals working on varied areas within the cluster. The incubator, Bangalore Bioinnovation Centre (BBC), was initiated by Karnataka Biotechnology and Information Technology Services (KBITS), Dept of IT, BT and S&T, Government of Karnataka, with the financial support of the Department of Biotechnology (DBT), Government of India. The Centre is a world class Incubation Centre with Central Instrumentation Facility in a 10 Acre campus with total built -up area of above 50,000 sq ft (BBC, 2018). The centre caters to broad areas of Life Sciences — Healthcare (MedTech/ Pharma/Bio-Pharma), Agriculture, Industrial Biotechnology and Environmental Biotechnology (Table 2). Through BBC, the state government encourages start-ups in healthcare biotechnology. The incubation centre provides infrastructural facilities and mentoring avenues as well as conduct periodic assessment of incubatees' performance.

On the other hand, there are significant biotechnological activities happening in the Northern Part of the city, involving a well-established triode of following three inter-related institutions.

- National Centre for Biological Sciences (NCBS),
- Institute for Stem Cell Biology and Regenerative medicines (InStem) and
- Centre for Cellular And Molecular Platforms (C-CAMP),

Together these three institutions are called as the *Bangalore Life Science Cluster (BLiSc*), excelling in the domain of biological research in India. The National Centre for Biological Sciences (NCBS) is a premier centre for cutting -edge biological research and training in India under the Tata Institute of Fundamental Research. It was conceived under the guidance of Abraham Flexner, noted American educationist. Presently, the campus offers Postdoctoral, doctoral, M.Sc courses in different biology-related subjects — Biochemistry, biophysics and bioinformatics; Genetic Development, modeling of biological systems; Cellular organization and signaling and

others. The campus is equipped with research and technical facilities with the state-of-the-art infrastructure.

Table 2: Incubatees in BBC

S. No.	Present Incubatees	Graduated Incubatees
1	Indoor Biotechnologies	Preksha Ecotech Pvt.
2	Jubelin Lifesciences	Novo Catalyz
3	Omix Labs	Oleome Biosolutions
4	Lab4Life Bio Research Pvt. Ltd.	Axio Biosolutions
5	String Bio Pvt. Ltd.	
6	TerraBlue XT (P) Ltd.	
7	Jana care Solutions Private Limited	
8	Innov4Sight	
9	E2E Biotech	
10	Tojo Vikas	
11	Aprus	
12	AINDRA SYSTEMS	
13	Bendflex	
14	Atrimed Biotech LLP	
15	Next Big Innovation Labs Pvt. Ltd	
16	Mercuri Biotechnologies Pvt. Ltd	
17	Yostra Labs Pvt. Ltd	
18	IOSYNTH Labs Pvt. Ltd	
19	Isense Innovations	
20	Ameliorate biotech Pvt. Ltd.	
21	Vnir Biotechnologies Pvt. Ltd	
22	Glogene Biosciences LLP	
23	Leucine med tech Pvt. Ltd	
24	Cellagility Biomed Pvt. Ltd.	

Source: Author from different sources, Bangalore Bioinnovation Centre (2018).

The second institution, InStem, is a translational research institution, dedicated to study stem cell and regenerative biology. The Department of Biotechnology, Government of India, significantly funds this institution to narrow down the divide between clinical and laboratory research in the arena of stem cell biology. It works closely with NCBS and C-CAMP for basic research expertise and industry interface, respectively. The third crucial wing of this cluster is an incubator, C-CAMP, initiated by the Department of Biotechnology, Government of India, and supported by the BIRAC. It

has incubated over 30 innovative start-ups and entrepreneurs working in different areas of Life Sciences and Biotechnology, including drug discovery, molecular biology, transgenic model systems, biomaterials, synthetic biology, upstream and downstream processing, agricultural sciences, nutraceuticals, etc (C-Camp, 2018). An illustrative list of incubates (present and graduated) is given in table 3. There are some individual entrepreneurs working at C-CAMP.

Table 3: Incubatees in C-CAMP

S. No.	Present Incubatees	Graduated Incubatees
1	The Avestagenome Project	Strand Life Sciences
2	Jiva Sciences Pvt. Ltd	Thermanyt Novobiologics Pvt. Ltd
3	NextGen Invitro Diagnostics Pvt. Ltd	Cellworks Research India Ltd.
4	The Pandorum	KInome Pharma Pvt. Ltd
5	Bugworks	
6	Biomoneta	
7	Cleanergis Biosciences	
8	Spotsense	
9	Viravecs Labs	
10	Luxmatra Solutions Pvt. Ltd	
11	Snaayu Lifesciences Pvt. Ltd	
12	Df3d	
13	InnAccel	
14	Coeo Labs	
15	Senssivision Health Technologies Pvt. Ltd.	

Source: Author from different sources.

The three institutions collectively work in trans-disciplinary, breakthrough research in life sciences to translate basic research outputs into innovation.

4. Methodology: Data Collection and Analysis

Case study approach (Yin, 1994), has been undertaken to reflect on the innovation dynamics among different knowledge bases. A combination of both primary and secondary data has been incorporated in the study. Primary data was collected with the help of an array of tools like in-depth interviews,

semi-structured discussions, and reports and policy documents, press releases were considered as the secondary data sources. The study,however, is predominantly dependent on the primary data, collected in the course of in-depth personal interviews of the respondents, who were employees of concerned firms, working at the strategic level; scientists and academicians of the respective research and academic institutions as well as the officials of government departments; the interviews were based on a semi-structured questionnaire.

Unit of analysis involved 13 firms present in the biocluster, which were a mix of start-ups, foreign and Indian Multinationals as well as domestic firms. Besides firms, personal interviews were conducted in three prominent research institutions — IISc, NCBS and IBAB and two incubators— C-CAMP and BBC. For the given study, patent and publication outputs were analysed with the help of ORBIT and Web of Science Databases, respectively. [4]. This should be considered as a preliminary exploration and not as a final word.

The study encompasses use of Web of Science, an abstract and citation database, which possesses nearly 22, 800+ peer-reviewed journals, to assess knowledge output of the institutions in this study. A time- frame of 2010-2018 is considered for mapping contemporary subject areas, collaboration patterns and affiliating institutions.

5. Innovation Dynamics in Bengaluru Biocluster

As discussed in the earlier sections, the Bengaluru Biocluster nests various knowledge communitiesthat generate different types of knowledge— basic, translational and applied. Moreover, the knowledge gets further synthesized into innovative outcomes in the forms of biopharmaceutical products and services. To understand innovation dynamics of the biocluster, the study assesses these knowledge hubs on the following dimensions 151 (1) global outreach, (2) Innovativeness – extent of novelty in research and/or innovation, and (3) collaboration/Networking Activities.

Global Outreach

It is important to understand that firms and non-firm entities have different orientations and objectives to go global. In case of firms in Bengaluru,

majority of the respondents represented foreign multinationals and Indian companies with global outreach.. It signifies 'stickiness'[5] of firms in selecting their clientele in the home- country. Firms are developing interest in Brazil, Venezuela, Japan, Australia, China and some other South-Asian countries to expand their markets. These countries have shown high potential in terms of the consistent demand of the biopharmaceutical goods, steady manufacturing set-ups, corporate friendly policies and trade relations. Nonetheless, firms are engaged in collaborating with clients, suppliers, competitors, consultancies, academic institutions, research labs, etc., in the home -country. But most of these firms are foreign Multinationals. Respondents stated that the focus was on strengthening local clientele (country for business), which goes beyond establishing a market for the goods; to build trust and brand image in the given location, which acts as a platform to reach other locations in the vicinity.

For six out of 13 firms, the home- country is India, and there are four foreign multinationals companies (MNCs) from the United States (North America) and Switzerland (Europe). It is interesting to note that majority of the firms collaborate with entities in the home- country, whether it is an informal or a formal linkage. However, formalized collaborations are more evident across borders. In terms of collaborations with academic institutions and universities, Indian firms are collaborating more with universities and research labs in distant geographies for R&D and basic research as compare to their counterparts in India.

Apart from firms, it is important to discuss other knowledge communities, in relation to their global outreach and research output. The interviews conducted in the IISc, NCBS and IBAB have an interesting narrative; their idea of 'going global' is entwined with the objective of building knowledge networks and tap sources for funding. These arrangements are significantly evident in joint publications, patents and research projects. It is reflective in the BIRAC-IKP report (2016), which states:

> '[..] 11 academic institutions located in Bangalore, nests nearly 1466 scientists are nested, who possess 11105 collaborators. Out of the total collaborations, 68% are located in foreign locations – United States, United Kingdom, Japan, Australia, Canada, South Korea and others. These institutions have regional as well as national collaborations'. (BIRAC-IKP, 2016)

IISc's global reach incorporates Memoranda of Understanding (MoUs) with different universities and institutions in the USA, UK, Australia, Canada, Denmark, Egypt, Ethiopia, France, Germany, Japan, Korea, New Zealand, Sweden, the Netherlands and others with a fundamental purpose to deepen mutual interest in teaching and research activities though education programmes and joint research projects (IISc, 2015). Also some of the countries/institutions provide funding opportunities through bilateral programmes. Some examples are: UK- India Education and Research (UKEIRI); DBT-Australia Biotechnology Fund; Indo-US S&T forum (IUSSTF); DST-Sweden (VR) Joint call, Indo-German Science@ Technology Centre (IGSTC) and Indo-French Centre for Promotion of Advanced Research (IFCPAR/CEFIPRA) (IISc, 2015). Likewise, NCBS has strong global collaborations in the USA, Canada, UK, Ireland, Germany, Denmark, France, Spain, Italy, Switzerland, Japan and Singapore on varied research themes and student exchange programmes (NCBS, 2016).

In case of the IBAB, the global outreach is very minimal, limited to Florida University, Lund University, Montana universities and a few others. To some extent, it collaborates with MNCs and foreign firms. However, there are strong regional collaborations with the IISc, KMIO, Central Drug Research Institute, Satya Sai Institute of High Learning, to name a few (IBAB, 2018).

C-CAMP and BBC, being incubation centres, have showcased global outreach in terms of incubating spin -off start-ups from foreign multinationals and universities. Nonetheless, there is a strong push to nurture local firms and enterprises; hence global reach is not very high.

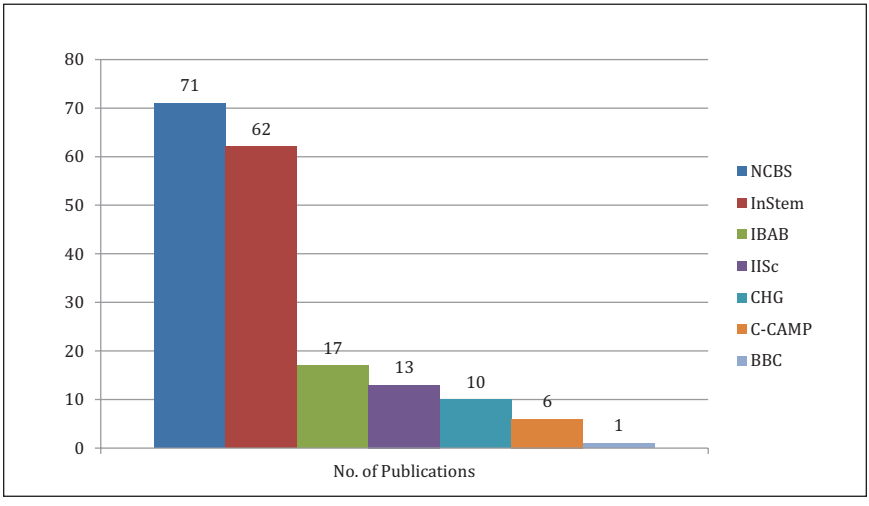
Innovativeness

Questions were asked to the respondents pertaining to activities in five categories. These categories are measured on three different levels of innovation, ranging from 'new to the firm', 'new to the industry' to 'new to the world'.[6] It was observed that products/ services developed by the firms were mostly new to the firm (80%), followed by being new to the industry (10%) and new to the world (10%). In the case of new services, innovative activities were restricted to being new to firm and new to industry. For the other novel practices and processes, the firms acquired 'best practices' from

the industry, which were new to firms. Different measures of innovation are required to create cutting-edge technologies for development of novel drugs, vaccines and other products. In doing so, the quest for capabilities, financial resources and markets in different geographies is inevitable. Even the novelty of research topics and trans-disciplinary character is considered for assessing innovativeness.

In terms of Publications, firms as knowledge community, publish more translational research than basic research. Universities and academic institutions are more involved in the latter. However, Institutions like the IISc, NCBS, IBAB and others are also going beyond basic research, towards translational studies. As per the study conducted by the BIRAC-IKP (2016), it was observed that very few scientists' accounted for a larger number of publications in institutions like IISc and NCBS (WoB, 2018). The knowledge output of most of the institutions in Bengaluru Biocluster, as per the Scopus database, is given below in Table 3. The search was done for the institutions under study. The search was limited to two research areas— 'Biotechnology and Applied Microbiology' and 'Biochemistry and Microbiology'.

Figure 2: Publication Output of Institutions in Bangalore Biocluster (2010-2018)



Source: Web of Science (2018).

It was observed that newer institutions showed increase in publications. The NCBS, In-stem, IBAB are emerging as potent research avenues and sites of knowledge generation. Even incubation centres are evidently focusing on knowledge generation, other than mentoring and counseling. In fact, 6 publications of C-CAMP and one of BBC, were result of the regional as well as international linkages with research institutions. Nonetheless, Prominent Institutions like IISc have increased number of patents from 52 patents in biotechnology related areas in 2015 to 80 patents in 2017 (ORBIT database, 2018).

Collaborations/Networking

Networks are a crucial dimension of research and innovation activities to leverage expertise and encourage sharing of resources of equipment and infrastructure. Collaborative networks are highly impactful particularly in interdisciplinary work or co-development projects. Co-patenting activities, as observed in the ORBIT database (2018), have revealed that Bengaluru has a larger number of collaborators outside India than within the country; with an average of about 38% of the collaborations within India. Most of the collaborating agencies are located in the US, UK, Japan, Australia, Germany, Switzerland, etc. Out of the 13 firms interviewed, it was realised that formal collaborations were more conducive in the form of patents, strategic alliances, joint ventures with foreign institutions and companies. It has been inferred from the ORBIT database that MNCs are inherently collaborating with entities in other countries; however there is a trend that SMEs and Stand Alone firms are upgrading themselves, sharing technological 'know-how' and patenting with the institutions abroad. The patenting culture is far too less, due to a constant push for publications in research and academic institutions. However, as per the Orbit Database, Institutes like NIMHANS, NCBS, C-CAMP, InSTEM and BBC are associated with several multicentre trials and translational research; therefore, they have a greater tendency to collaborate with institutions outside the Country. In terms of other forms of collaborations, largest fraction constituted collaborations within the state, followed by collaboration across states, and lastly within the institute.

Academic institutions at the local level qualify for having formal as well as informal linkages. Some of the institutions like Indian Institute of Sciences and National Centre for Biological Sciences (NCBS) are hubs for basic research in biomedicine, therapeutics and life sciences. Such

collaborations aim for basic research expertise, and in turn the firms invite scholars, students for internships and sponsored research programmes. Though conversations with scientists of the IISc, NCBS and IBAB, it was observed that these interfaces are occasional, and efforts should be made to create proximity between academia and industries. On the other hand, some firms are 'skeptical' to deepen relationships with academic institutions, due to lack of confidence in their capabilities. This skepticism, however, is fading out if networking achieved with academic bodies in foreign locations. Firms believe that students are not trained to have risk-taking aptitude, they lack training in translational research and are unable to work in corporate settings. However, both firms and non-firms entities possess linkages across borders for research and development. This deserves further focus, and only through in-depth research meaningful conclusions can be achieved.

Limitation of the Study

Besides some of the inevitable limitations of time, space and human ability, this study is also subjected to methodological limitations in terms of generalisation of research outcomes owing to small size of the sample; leading to biased conclusions. The study does not incorporate any quantitative method and depends largely on the qualitative research. This allows the researcher to analyse the data on her own understanding, and may not give a neutral and more just analysis.

As the research was predominantly dependent on the primary data, various issues pertaining to access to enterprises and respondents' fatigue were encountered during the field trips. Due to such limitations, only a small number of firms and non-firm entities could be studied. Lastly, the study is a part of on-going research; hence the conclusion may be subjected to further in-depth outcomes and has a scope of revision.

Conclusion

Different knowledge communities have respective interests, orientations and roles in the innovation process. Where firms are involved in innovations, incremental and are radical in nature, academic institutions are exploring trans-disciplinary research themes in collaboration with research partners at the regional and global landscapes. The industry-academia linkages are very primitive and yet to achieve optimal levels.

On comparing the status of the biopharmaceutical sector in Karnataka before and after the state intervention, the cluster envisages skilled pool of talent and institutional settings as resources of knowledge creation (universities, public research organisations, and government agencies), production (producers, suppliers) and dissemination (clients and consumers). Apart from regulatory regimes, infrastructural support and funding avenues, the success of the cluster would be highly dependent on the entrepreneurial efforts and political will to meet local as well as global needs. Bengaluru possesses easy connectivity to the rest of the world, conducive policy environment, English speaking knowledge workforce, infrastructural facilities and others. Attempts are being made to elevate the essentials for a successful cluster through adequate training in biotechnology education, incentivizing innovation activities, attracting foreign enterprises to the region.

Endnotes

[1] The Department of Biotechnology has designed schemes/programmes to facilitate cluster development in this field: *"The Biotechnology Parks and Biotech Incubation Centres....provide a good template for the promotion of Biotech startup companies and the promotion of Public Private Partnerships. Biotech Parks and Incubation Centres have been established in Lucknow(Uttar Pradesh) and Shapoorji Pallonji Biotech Park, Genome Valley, Hyderabad (Andhra Pradesh). The other projects approved for Himachal Pradesh, Karnataka and Kerala for setting- up of biotech incubation/pilot plant facilities are at different stages of development".*

[2] Asheim and Gertler (2005) have described industrial settings where these two different types of knowledge bases differ in their relative importance and discuss characteristics of innovation processes in such settings. Analytical knowledge prevails in science-based industries, where innovation comes from basic and applied researches. In industries, relying on synthetic knowledge, new applications or combinations of existing knowledge are more important for innovation than development of completely new knowledge as such. While, the original theory distinguished between these two knowledge bases only. Asheim *et al.* (2007) added a third: symbolic knowledge, referring to industries in which aesthetic attributes, symbols, images and narratives are important – in short, symbolic or sign value of the product (Fitjar and Jøsendal, 2016).

[3] An institutional setting can be defined as a context of shared institutions such as values, customs, habits, legal and regulatory aspects, etc.

[4] Orbit is a web-based commercial searchable patent database made available by Questel, with full-text coverage of the PCT, Chinese, European (EP), Japanese, and US collections as well as a number of other regional coverage (WIPO, 2011); Web Of Science (WoS) is subscription based citation indexing database, with a coverage of 12, 000 Journals and 90 million records (Thomson Reuters, 2016).

[5] Stickiness is used in context to the generation of knowledge, which is partly embedded in the regional patterns of interactions and mutual learning (Malmberg, 1997); the idea of 'sticky' has also been used in relation to coherence of culture, language, values and institutional thickness (Asheim and Isaksen, 2002).

[6] As discussed by Henry Edison, Nauman bin Ali and Richard Torkar (2013), *New to the firm* refers to the minimum level of novelty of innovation is that it must be new to firm. It is defined as the adoption of an idea, practice or behaviour whether a system, policy, program, device, process, product, technology or administrative practice that is new to the adopting organisation (Parashar and Singh, 2005; Carmona-Lavado et al., 2010).; *New to the industry* describes all the aforementioned innovations which are new to the firm's industry sector (Garcia and Calantone, 2002; Beugelsdijk, 2008); and *New to the world* infers that these innovations imply a greater degree of novelty than new to the market/firm/sector and include innovations first introduced by the firm to all markets and industries, domestic and international (OECD, 2005; Berger and Revilla Diez, 2006).

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Asian Biotechnology and Development Review
Vol. 19 No. 3, pp 47-49

Book Review

Policy Perspective on Innovation and Sustainable Development

Editors: Sujit Bhattacharya, Yogesh Suman and Tabassum Jamal
Publisher: CSIR-NISTADS
Year: 2017
ISBN No.: 978-1-64204-740-0
Price: INR 1500.00

Innovation and Sustainable Development is a theme that has attracted much attention in the recent decade. Innovation can contribute to sustainable development, particularly, in the context of climate change and sustainable development goals (SDG). Hence, it has lately become the topic of much research and debate. Unless sustainable development is discussed in terms of specific issues, linkage between innovation and sustainable development cannot be clearly understood. In theory and practice, there is a need for context -specific analysis and policies connecting innovation with sustainable development.

The edited book titled "Policy Perspective on Innovation and Sustainable Development" is the fourth volume in the 'India S&T Book Series'; brought out by CSIR-NISTADS under its project "Indian S&T and Innovation Policy (ISTIP)" ,and the first volume under the newly launched NISTADS Tracks in Policy Research (NTPR).

The book is divided into five broad parts, each representing a sub-theme —. Part 1: Regional Innovation System; Part 2: Industrial and Sustainable Innovation; Part 3: Traditional Knowledge, IPR and Informal Innovation; Part 4: New Opportunities: Policy and Perspective; and Part 5: MSME: New Opportunities and Challenges. But all the parts are not connected, and nor all of them deal with innovation and sustainable development. As a result, there is no narrative that unites parts or chapters within a specific domain. Some chapters have no mention of sustainable development and innovation. Even discussion is missing in the case studies/themes covered in the context of innovation and sustainable development ;take Part I as an example.

Part 1 on Regional Innovation System reflects upon the importance of regional innovation system and the underlying institutional networks in varied regional contexts such as textile cluster in Surat, dairy industry in Anand, start-ups in Bengaluru, horticulture sector in Jammu and Kashmir and Bamboo industry in the North-Eastern region. Chapter 1 by Tabassum *et al* highlights dynamics of textile cluster of Surat and discusses reasons for its lacking global competition, despite there is a comparative advantage in terms of labour. The authors argue that lack of product as well as organizational innovation culture in the region are the main reasons behind the below par export performance. Rais and Kuruvilla in Chapter 2 discuss important role played by Amul in the transition of Indian dairy industry and factors behind the success. They highlighted the importance of the institutional innovation along with the product and process innovations in bringing about this transformation. Chapter 3 by Bala Subhramanya provides an in-depth analysis of the factors behind emergence of Bengaluru as an entrepreneurial hub and the role played by innovation ecosystem in that. Chapter 4 by Sheeraz Ahmed highlights potential of horticulture sector in J&K and steps required thereof. The author emphasized the importance of forging connectivity among actors and ensuring forward and backward linkages. Yogesh Suman *et al* in Chapter 5 discussed regarding Bamboo industry in the North-East and pointed out challenges and suggested ways to promote it by making entrepreneurs to access available technologies and skills for producing quality products not only for domestic markets but also to capture international markets.

But in the absence of a conclusive summary, which on the basis of the case studies could link Regional Innovation System with sustainable development or with innovation and sustainable development, Part I reads more of a collection of case studies lumped together under some rubric. In fact the editors could have used available literature on the Regional Innovation System and sustainable development to argue that Regional Innovation System(s) in India can contribute to sustainable development and could have suggested policy measures to facilitate their contribution. They could have drawn on the policy suggestions listed in each chapter.

To cut a long story short, this is equally applicable for the other parts as well.

The final Chapter 23 'Perspective ' even though gives some general conclusions but does not add much value to theory or practice.

This edited Volume has a collection of different sectoral case studies but in the absence of an overarching and unifying theme, they remain just case studies and hence are of lesser relevance for policy- making. As a result the publication fails to provide a coherent set of policy perspectives on the themes/issues discussed in the chapters. There are at least two chapters related to traditional knowledge but offers nothing as a policy perspective on traditional knowledge. So is the case with agriculture, MSME and textiles. Thus in terms of value addition to the debate on innovation and sustainable development, it contributes very little to the already available literature.

The volume can be a good reference reading for policy- makers, academic, researchers, who are searching for case studies to have some ideas regarding them.

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3. Use 's' in '-ise' '-isation' words; e.g., 'civilise', 'organisation'. Use British spellings rather than American spellings. Thus, 'labour' not 'labor'.
4. Use figures (rather than word) for quantities and exact measurements including percentages (2 per cent, 3 km, 36 years old, etc.). In general descriptions, numbers below 10 should be spelt out in words. Use thousands, millions, billions, not lakhs and crores. Use fuller forms for numbers and dates— for example 1980-88, pp. 200-202 and pp. 178-84.
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Shand, Ric (ed.). 1999. *Economic Liberalisation in South Asia.* Delhi: Macmillan.

(c) Articles from edited volumes:

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Asian Biotechnology and Development Review (ABDR) is a peer reviewed, international journal on socio-economic development, public policy, ethical and regulatory aspects of biotechnology, with a focus on developing countries. ABDR is published three times a year with support of Department of Biotechnology, Government of India and UNESCO by Research and Information System for Developing Countries (RIS), a New Delhi based autonomous think-tank, envisioned as a forum for fostering effective policy dialogue among developing countries on international economic issues.

This issue has two articles and a book review. An article on clinical trials provides a critical perspective on the status of clinical trials in Africa and the challenges in that sector. It suggests policy measures to enhance the credibility and acceptability of clinical trials in Africa. The second article explores the factors that have enabled Bangalore Biocluster to emerge as a success story. Using the concept of Regional Innovation System and ideas like global innovation networks it highlights the linkages among various actors and highlights the factors that are critical for success of a biocluster. The book review discusses a volume on innovation and sustainable development.

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