Barriers to Industry-Academia Collaboration —– A Study With a Focus on the Indian Medical Devices Sector

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Giving a summary of the Indian medical devices industry, the article starts by highlighting the over-dependence of the medical devices sector on imports and the need for an effective industry-academia collaboration. Such collaborations are not common in India. Academicians involved with medical device research and the healthcare sector were selected to administer a questionnaire on the barriers with a five-point Likert scale and through interviews. The barriers were analyzed from the perspective of sub-themes of the Triple Helix model - Relationship, Policy, and Perceptions. Barriers falling under the subtheme of Relationships were found to be the most common barriers.

Keywords: medical devices, Indian market, industry – academia collaboration, barriers

INTRODUCTION

Before a decade ago, it was predicted that in the coming years, the medical devices and equipment sector in India could be the next sunrise sector and have a high growth potential comparable to that of the IT sector of India, which had a phenomenal boom in recent years (EEPC India, 2013). Data on this sector from multiple sources states that the size of the medical devices sector in India is about 11 bn USD (ET Healthworld, 2024; India Brand Equity Foundation, 2024). India represents a 1.65% share of the global medical devices market and is the 4th largest Asian medical devices market, after Japan, China, and South Korea markets. The more impressive part of the sector in India is its growth rate. Some very recent estimates state the growth rate at a staggering 18-20 %, while other conservative estimates mention the growth rate at 15 – 16% per year (ET Healthworld, 2024; India Brand Equity Foundation, 2024). This growth rate is impressive when compared with the world growth rate of 5% for the 2008 to 2020 period for the sector (EY, 2023). It should also be noted that despite this reasonable market size and a respectable growth rate,

India has an overall 70-80% dependence on imports for medical devices and there is a large gap between the country's demand and its internal production of medical devices (Informa Markets, April 2020). During 2022-23, imports increased to 21% as per one report (India Brand Equity Foundation, 2024). Medical device demand has seen large differences between the developed and the developing countries. A good example is cardiac procedures – about 1000 per million population in the US versus only 18 in the African subcontinent (Bergsland, Elle & Fosse, 2014). However, the Indian economy is fast catching up with good growth and this is one of the many factors contributing to the growth of medical device demand, besides population growth, increased life expectancy, increased disposable income with health awareness, rise in Government health spending and better insurance coverage, to name a few (Foundation for MSME Clusters, 2023).

To reduce this over-dependence on imports, under the "Make in India" program, the Indian Government is trying a lot to support local production. 100 % foreign direct investment under an automatic route, performance-linked incentives (PLI in short), a new medical device parks scheme, and an order for procurement of some devices from local sources (PPO) are some of the important measures (India Brand Equity Foundation, 2024). It may be noted that India generally does not take extreme measures like China to reduce import dependence. In China, Hubei, Shanxi, Anhui and Ningxia local authorities issued notices to the local hospitals limiting and restricting their use of imported medical equipment, in a way to reduce imports and force overseas companies to hand over technology to local Chinese manufacturers or to leave the market (Nikkei Asia, 2022). The absence of a strong regulatory structure until 2018 for medical devices allowed imports from all sources. The Central Drugs Standard Control Organization (CDSCO) published the 'Medical Devices Rules 2017' in the year 2017, which was implemented in 2018, giving a clear regulatory framework for devices (Ministry of Health and Family Welfare, 2017).

A very detailed report covering many aspects of the sector was published by KPMG in 2022. The report mentioned that in the value chain for the medical device sector, the US and EU regions have a coveted position at the Research and Product Development end. The US and EU have the major R&D and manufacturing activities and these regions have access to the latest technology and the right infrastructure besides workforce and are exporting countries. India and some other countries are at the opposite end of the value chain and is involved in packaging, importing and distribution (KPMG, 2022). New product development thus seems the answer to the problem of export dependence.

LITERATURE REVIEW

The Complexity of Medical Devices and the Need for Collaboration

The degree of complexity in medical devices is significantly higher when compared to their pharma peers and this complexity limits new device development. Medical device development requires an understanding of a large spectrum of technologies, like chemicals, biomaterials, metallurgy, mechanics, electronics, and fluidics, to name a few. If we compare medical devices with medicines, knowledge of very few sciences may be adequate for developing a new drug. All research is complex, including pharma research. However, the spectrum of technologies in medical device development is much larger, comparatively. Kahn, in 1991, mentioned this point, besides other complexities of medical devices like regulatory aspects. Again, convenience, suitability, and safety of the final user are important features of a device. Thus, medical device development also involves the consideration of ergonomics. Sufficient guidelines and studies are not available in this area of ergonomics (Martin, Norris, Murphy & Crowe, 2008).

Collaboration of Academia With the Industry

Knowing multiple diverse sciences, academic institutes can play a key role in the medical device development process. Dosanjh (2022) has rightly mentioned, in the title of his research article, "Collaboration: The Force That Makes the Impossible Possible." Academic institutions are an important source of research and development, and collaboration of the industry with academic universities can be a model for success (Chung, Ko & Yoon, 2021). While highlighting the role of biomedical engineers, WHO (2017) also recommends "interdisciplinary collaboration" in line with the regulations of each country

involved. The document further advises that governments, professional councils, and associations need to develop the right models and inter-professional collaborations (World Health Organization, 2017).

Many success stories support an industry-academia collaboration. "The Oulu Phenomenon", described by Lester & Sotarauta (2007), in their book with a very pertinent title "Innovation, Universities, and the Competitiveness of Regions" detailed a case of Oulu City in Finland, an industrial city affected by economic slowdown which prompted the city to explore formal and informal industry-academia collaborations. Smaller companies in Oulu represented the medical devices industry. Seventy-five percent of medical devices were developed in the networks of manufacturers and potential users like hospitals, and network members included universities, research institutes, scientific foundations, government agencies, consultants, and distributors. A study of "The Oulu Phenomenon" involving 40 managers using a snowball sampling method revealed that the University of Oulu was the most important academic partner, the timeline for new product development was reduced and competitiveness had increased due to collaboration with the university (Lester & Sotarauta, 2007).

Export dependence was also a case with Japan for medical devices, like that in India, though to a lesser extent. A study in Japan documented a unique collaboration model called the Hamamatsu Method. A city called Hamamatsu was used as a study platform. A Japanese agency for medical research and development, called AMED, and Mitsubishi Research Institute, involved a model using Collaboration Coordinators for implementing successful industry-academia collaborations. These coordinators played a critical role by educating parties through seminars, matching requirements through hospital visits and consultations, funding through R&D budgets, support on the R&D front like space and equipment arrangement, and then technology transfer support (Yuko A, 2020).

Similar examples and success stories are narrated on such synergistic relationships in various journals. (Chen, Pickett, Langell, Trane, Charlesworth, Loken, Lombardo, & Langell, 2016; Chung et al, 2021; Jager, Chimhundu, Saidi & Douglas, 2017; Linehan & Chaney, 2010; Stahel, Lacombe, Cardoso, Casali, Negrouk, Marais, Hiltbrunner, Vyas, & Clinical Academic Cancer Research Forum (CAREFOR), 2020; Tsuruya, Kawashima, Shiozuka, & Nakanishi, 2018). Most of these studies have happened in the USA, Europe and Japan. Rybnicek & Königsgruber (2019) gathered all the articles on such industry-academia studies and noted that the maximum number of such studies were in the USA, UK, Italy, Spain, China, Japan and Portugal. In India, however, only one such study had happened as per these authors based on their extensive work, together with a fairly large team of researchers. Discussions with many industry representatives and academicians in the field of medical devices also revealed that a strong possible reason for the lack of such studies is probably that such collaborations are not common in India, suggesting the need to study the possible reasons for the absence of such collaborations. Though beneficial in more than one way, university-industry collaboration is challenging to implement (Austin, May, Andrade & Jones, 2020).

RESEARCH OBJECTIVES

A quick background given above will help understand the objectives mentioned here. The study aims to understand the reasons for the low extent of industry-academic collaborations in the field of medical devices in India despite the usefulness of such collaborations. The objectives of the study were-

1. To understand the barriers to industry-academia collaborations.
2. To get an insight into issues causing such industry-academia barriers by interviewing academicians.

RESEARCH DESIGN AND METHODOLOGY

A descriptive research design was selected for this study to understand the barriers. The purpose was to deep-dive into what academicians think about the issue of collaboration, and not to study cause-and-effect relationships or project a future scenario. This objective fits with the descriptive research design. This design also gives freedom to quantify the numbers, reveal certain clear patterns and suggest the next study topics. Both quantitative methods as well as qualitative approaches were used for the study. Since the

numbers of academicians related to the healthcare sector and those having exposure to the industry-academia collaboration were not recorded anywhere, a list of such academicians in the closer vicinity of the city of Ahmedabad in West India was prepared. 30 people from this list agreed to respond to the questionnaire and many also agreed for the personal interviews. A sample size of 30 was decided based on the experts' opinions for the study. Previous work of Mirza, Al-Senawi, Al Balushi, Al Alawi & Panchatcharam (2020) on barriers to university-industry collaboration in the UK was also taken as the basis for this study. Their work was then given a slightly different angle from the Triple Helix model, which was studied well for the dynamics of the industry-academia relationships. The Triple Helix model of Etzkowitz and Leydesdorff (1998) was used to analyze possible barriers in such industry-academia collaborations. Based on this concept, Abd Razak and White (2015) have discussed three themes for grouping the barriers. These themes are:

- Relationships issues
- Perception issues
- Policy issues

Their studies were based on the studies on the same subject in the developing countries (Rivera, 2010; Irawati, 2010; Ranga and Etzkowitz, 2010). These authors also wrote that these three themes are not mutually exclusive and may overlap. The concepts of barriers and the Triple Helix framework, as well as the Indian context along with possible barriers, were discussed with a small group of experts with exposure to both industry and academia. The questionnaire developed by Mirza, et al (2020) was also shared with these members and based on their suggestions, this questionnaire was modified. The purpose was to make it more suitable for the study because the original work by Mirza, et al (2020) covered clinical trials for medicines rather than medical devices, and was also for a study in the UK. This whole process helped in generating a good questionnaire relevant to the Indian context and to the medical devices industry. A pilot study with this questionnaire followed to confirm that the questionnaire served the planned purpose. The questionnaire used a five-scale Likert scale (Strongly agree to Strongly disagree) to get responses from the academicians on these questions so that a neutral point is also available for selection. (The original questionnaire by Mirza, et al (2020) used a four-point scale.) Some Examples will clarify the outcome-

Questions on the relationship between the industry and academia

- Industry will develop your ideas and results without giving credit to you or your institute.
- The industry has less concern for patients than for its own gains.

These questions are designed around the relationship of the academic institutes with the industry. The remarks mentioned talked about what the industry may do which is not desirable or is not right in the opinion of academicians for a conducive industry-academia relationship. Relationships work on trust and the points covered under this head reflect a trust gap. These were the main principles for designing these questions.

Questions about the policy at academic institutes

- There are very few projects in our field that can be useful to the industry.
- We do not understand the details of the legalities of industry-academia collaboration.

These questions cover the internal policies, constraints or restrictions of an academic institute of a respondent. If the barriers are of these types, they may be addressed by the institution with better policies, but they are still barriers.

Questions regarding the perception of academicians about the industry

- The healthcare industry is biased towards their product though less effective sometimes.
- Basic science research should not be commercialised.

As the word “perception” says, these points reflect perceived (and not necessarily real) issues, typically without data to back up their perceptions. For example, a perception-related point on Collaboration of the industry mainly with well-known institutes can be countered by a logical thought that better or cost-effective output is what an industry representative will look for, rather than the fame or name of an institute.

These questions are not exclusive to the themes they represent, as mentioned earlier, it must be noted. These questions were then sequenced so that questions on each theme were evenly mixed up. Other rules of questionnaire design were also checked, like starting with positive questions, not negative ones. Barring

one case, a telephonic or personal preamble preceded the questionnaire. External Validity for the Questionnaire was also followed by contacting two experts. Mean scores for each of the 20 questions were calculated by tabulating all the responses for a particular question, giving weightage for each response and taking a mean. The standard deviation was calculated for each response. Both these parameters were analysed. Most of the faculty members selected were from the Engineering colleges. The second largest number was from the medical devices technology division of NIPER (National Institute of Pharmaceutical Education and Research, a major institute receiving the highest device-related research funding from the Government). There were also professors from IITs - the education institutes at the forefront of industrial research and development in India, head of a device development incubation Center and other academicians who were exposed to and actively involved with medical device research and development including some doctors. Their distribution is mentioned below in Table 1.

TABLE 1
DESCRIPTION OF RESPONDENTS

SPECIALITY WISE DISTRIBUTION	
Name of the institute	**No. of academicians from those institutes**
Engineering Colleges	10
NIPER	4
Pharmacy Colleges	3
Medical Colleges	3
Other institutes	6
Indian Inst of Technology	3
Biotech Institute	1

RESULTS

The study involved administering 20-question questionnaires with a five-point Likert scale for data collection on possible barriers. The list of questions in the questionnaire and their classification on three themes, Relationship, Policy and Perception based on the Triple Helix model, is mentioned in Table 2, below. An almost equal number of questions were designed to represent each of these three themes, giving equal weightage to each theme. Mean Scores on individual questions and SD are also mentioned for each question in Table 2.

TABLE 2
QUESTIONNAIRE, MEAN SCORE AND STANDARD DEVIATION (SD)

Q. No.	**Questions**	**Sub-theme**	**Mean**	**SD**
1	Industry will develop your ideas and results without giving credit to you or your institute	Relationship	2.33	0.87
2	There are very few projects in our field that can be useful to the industry	Policy	2.73	1.44
3	The industry has less concern for patients than its own gains	Relationship	2.93	1.24
4	The healthcare industry is biased towards their product though less effective sometimes	Perception	3.37	0.93
5	We do not understand the details of legalities for industry-academia collaboration	Policy	2.87	0.99

6	Industry sometimes lacks knowledge in some special areas of development	Relationship	3.7	1.10
7	Basic science research should not be commercialized	Perception	2.43	1.43
8	The industry is over-interested in its financial gain	Relationship	3.93	0.93
9	Patients are not always the industry's primary concern	Perception	2.9	1.11
10	The industry has a record of presenting favourable results rather than factual results.	Relationship	3.23	0.99
11	Industry uses academia as a testing lab, and not a research partner	Relationship	3.43	1.17
12	Industry might use the name of my institute's reputation in their marketing	Perception	3.3	0.94
13	We do not want to become over-dependent on industry funding	Policy	3.3	1.10
14	We do not have enough information on how to collaborate with the industry	Policy	2.92	1.21
15	We do not have the time to meet industry representatives	Policy	2.47	1.20
16	Industry only collaborates with well-known academics	Perception	3.77	0.99
17	We are concerned about protecting our IP and know-how from the industry	Relationship	3.63	1.38
18	Interaction with industry is not well facilitated by my institute	Policy	2.67	1.30
19	My reputation may be affected negatively if I enter into an industry collaboration	Perception	1.9	0.94
20	Industry reputation as a partner is not reliable	Perception	2.13	1.06

The summary, an average score for each theme, is mentioned in Table 3, below-

TABLE 3
AVERAGE SCORE FOR EACH SUBTHEME

SUBTHEME	**Average Score**
Relationship barriers	3.31
Policy barriers	2.83
Perception barriers	2.81

DISCUSSIONS

The results strongly indicate that a major barrier between academia and the industry in the medical device sector is the Relationship barrier. The mean score for this theme is 3.31, much higher than the scores for other themes. A good relationship depends on trust, while trust seems lacking here. Amongst statements reflecting this barrier, "The industry is over-interested in its financial gain" got the highest score, with a low SD. The orientation of the academicians is always research, non-finance, and education, while that of the industry is profit. A lack of trust arising from the over-orientation for profit motive may need information-sharing and involvement from the industry side. The Triple Helix model also states that an ideal state of affairs is a hybrid model where industry representatives understand and consider the research needs of academicians and also, an academic institute appreciates and negotiates the money motive of a partner industry. Statements from the academicians interviewed (below), like "Industry uses academia as a testing lab, and not a research partner" or "The industry has less concern for patients than its gains"

reflecting Relationship barriers and low trust also highlight the same issues. Communication is the remedy for relationship-building or trust-building and the lack of communication on both sides may keep this barrier intact. Inactive relations between actors, lack of interaction and lack of collaborative arrangements mentioned in the Triple Helix model description seem to be playing here.

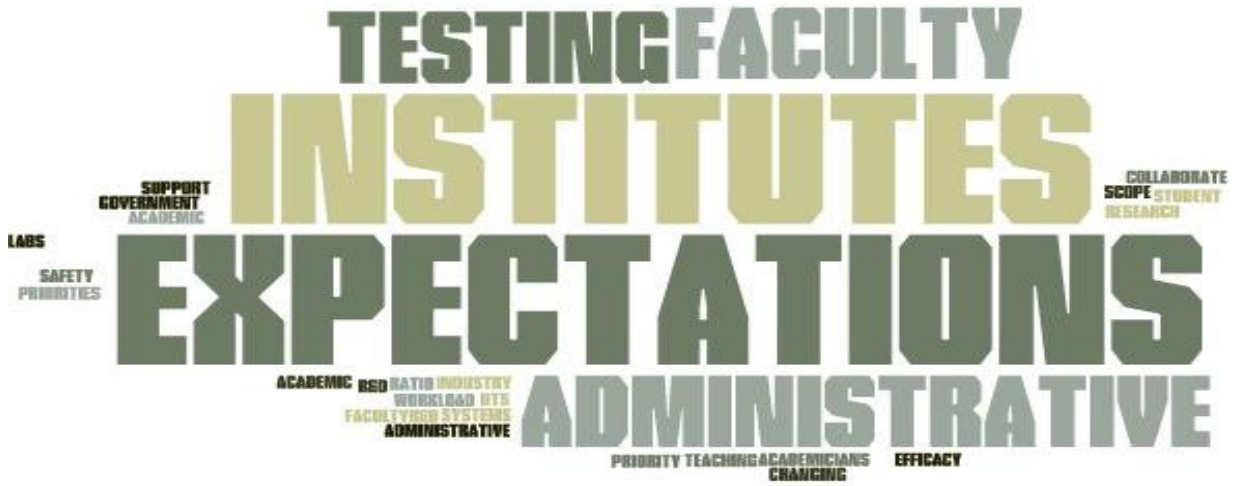
The perception barrier, on the other side, was the least affecting barrier, with a minimum score. The gap is not "perceived", it seems, meaning, the gap is not just perception-based or a "thought" gap, it is probably experienced at some level or at some time. Similarly, Policy barriers, or the policies of academic institutes do not appear to be major barriers.

Some qualitative statements taken from interviews also highlight some clear points. These comments are grouped for easier comprehension, below.

- The industry is interested in safety and efficacy testing from institutes. They need testing services from Academic institutes where academia is not interested. We are not testing labs, we are research institutes.
- The industry approaches only large institutes like IITs in the first instance and colleges like our college get lesser priority by the industry.
- In the engineering field, an internship for students in the industry is quite easy to arrange. However, this is not common with pharmacy colleges. Even arranging industry visits for the students is difficult here in the Pharma sector.

Figure 1, below, represents a word map based on the interview scripts.

FIGURE 1
WORD MAP BASED ON UNSTRUCTURED INTERVIEWS



Interviews with some academicians also indicate other possible barriers, namely workload, student-faculty ratio, prioritisation, absence of administrative support involving faculty members' time in administrative issues, and preference for IITs by the industry. The word map captures some of the words indicating these causes also. These statements show that the academic faculty members might be occupied with responsibilities other than research. Not only these comments, but researchers' observations during the process of interviews also confirmed this. When an interview was in progress, the respondent suddenly received telephonic queries about administrative issues, like progress on the exam paper analysis or rescheduling some lectures to complete the coursework, to quote examples.

Are the things changing? It appears that they are, from some comments received during the interviews-

- *Regarding industry-academia collaboration, the situation has been changing slowly during the last 10 years.*

- *During the last 30 years, the R&D mindset has changed and now the institutions are asked "What did you invent?"*
- *Until the '90s, institutes were doing teaching only. R&D was done in only two institutes. There were no R&D expectations from the institutions. However, there were high expectations from IITs.*

RECOMMENDATIONS

As stated, trust-building and confidence-building between industry and academia need more attention. Hamamatsu method (Yuko, A. 2020) stated earlier used a model of volunteers as Coordinators to connect industry representatives with Academicians. This may be a practical way of building relationships. What can substitute face-to-face meetings for building relationships? Such a model for India is recommended.

One more recommendation is to initiate a virtual platform where academicians and industry representatives can interact, share and exchange their capabilities, requirements and projects. Covid-19 already has made many academicians well-conversant with online modes of communication (Verma, Panigrahi & Alok, 2021). This skill can be useful here. Adding successful industry-academia projects in the performance areas for academic institutes may also prompt to look at these possibilities more seriously by the members of academic institutes. An active involvement of the policymakers in facilitating such collaborations between the industry and academia by prescribing directions and financial assistance is also recommended. After all, the third part of the helix is the government policymakers.

LIMITATIONS AND FURTHER SCOPES OF THE STUDY

The study was done with academicians related to the field of healthcare and medical devices. A similar study with other fields like engineering or management may also be interesting, providing great future industry-academia collaboration possibilities in other fields. A similar study to understand the concerns and comments from the industry side may also be very interesting since we must hear the other side and understand industry concerns. This offers a good possibility for future study and will complete the picture also. Two separate studies, one with IITs and one with other colleges and comparing the dynamics between these two sets may also be an interesting future possibility to have cross-learning between the academic institutes.

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