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Study of the Collaboration of the Indian Medical Devices Industry with the Academia

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Abstract

The article starts with a short introduction to the Indian medical device sector. Though the sector's growth is three times higher than the world market's growth, a critical issue is its heavy dependence on imports mainly due to a lack of focus on R&D and new product development where collaborations between the industry and academia can be of significance. In India, the industry-academia collaboration situation has not been studied well. Some of such collaborations abroad in the same sector are summarised in the article. The study was planned to deep-dive into the incidence, objectives and tactics of the medical devices industry by interviewing senior managers about the industry-academia relationship, through a descriptive study adopting both quantitative and qualitative approaches. The top executives of 64 medical device companies were interviewed for this study. Data analysis, word frequency, word cloud, and interview comments are used to study the industry's approach to industry-academia collaborations. The frequency of serious industry-academia collaborations was less than one-third for the companies interviewed across the size, the life and the types of companies. The major objectives from the industry side for such collaborations were to gain specialized knowledge and to obtain ready products as mentioned by the respondents with active collaborations. A similar pattern was revealed in Qualitative analysis also. This smaller number of companies engaged in collaboration with academia may be an area of attention for policymakers. The industry has found some innovative and ingenious models for successful collaborations. Many interview comments indicate that barriers like past experiences, trust deficit and bureaucracy in academia may be possible hindrance. The Triple Helix model addressing the barriers between the industry and academia is also discussed. The data indicates that the barriers between the industry and academia are the issues falling under the sub-theme of "Relationship" barriers as per this model. Though there is a need and good scope for industry-academia collaborations for medical device development, some course corrections may be helpful.

Keywords: Medical devices development, industry-academia collaborations, models, barriers

Introduction

India is one of the twenty largest markets in the world for medical devices and is the fourth largest in Asia (KPMG, 2022). India represents 1.65 % of the global market of devices. India has about 750 – 800 Medical Devices manufacturers as per various industry data sources (Informa Market, 2020; Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India, February 2021). The size of the medical devices sector in India is 11 bn as estimated by India Brand Equity Foundation (2023). KPMG (2022) estimated the sector size to be 12 bn USD and also mentioned that the industry is fragmented, with almost 95% of manufacturers being small or medium-level enterprises. The more significant feature of the sector is its growth rate. While the world growth rate for the sector is slightly above 5 %, the estimated growth rate for the Indian medical device industry is 16.4%, three times higher. Disposable medical devices are the major products manufactured in India, and these include complex disposables like vascular stents, intraocular lenses besides ortho implants (India Brand Equity Foundation, 2023). Population growth and higher life expectancy, along with better health awareness and higher spending on health – both public and private – are the factors driving higher growth (KPMG, 2022). The prevalence of chronic diseases also contributes to higher spending. Prevalence of CVS, respiratory diseases and cancer have been noted by the Foundation for MSME Clusters (2023).

The challenge for the Indian medical devices sector is its very high dependence on Imports. Import dependence of India is estimated to be 70 to 80 % by India Brand Equity Foundation (2023). In the Indian market, top-end high-value spaces like electronic equipment are possessed by MNCs, mainly through imports, and this may not change in the short run, and import dependence on those companies may not stop (EEPC India,2013; KPMG, 2022). In the year 2022, device imports grew by 41%, making 63,200 cr imports during 2021-22, from Rs 44,708 crore in the previous year, quoted Mr Rajiv Nath, Forum Coordinator, Association of Indian Medical Device Industry (AiMeD) based on the data of the Ministry of Commerce and Industry, India (BioSpectrum, 2022).

Literature review

R&D – A differentiator

KPMG, in its report, gave a clear insight into the possible reason of the import dependence of India for medical devices. The report stated that the value chain for medical devices has four clear activities: Research and product development, Complex manufacturing, Assembly and simple operations, and Packing & distribution. Exporting countries are involved in the first two activities, while India is at the receiving end due to a lack of new product development and research. Other countries, like Vietnam and Mexico, are also in the same situation, doing packing and distribution activities (KPMG, 2022). R&D and new product development are clear differentiators. An interesting case study of Stryker, now amongst the top ten global medical device companies proves the same point, again. John Brown took over Stryker when this company was involved in routine products, without any speciality, like emergency room stretchers and instruments for the operation theatre. From USD 17 million in sales, Stryker reached the level of USD 4.5 billion company under the leadership of John Brwon changing the focus of the company to new product development. Stryker acquired a company with research scientists and this was a turning point. Stryker then designed a unique innovative hip orthopaedic design called a UHR. This product had no competition in the market creating a niche for the company. Many more ortho implants were later developed by Stryker making it one of the largest and most important orthopaedic companies in the world. The strategy of John Brown was to bring 20 % profit growth from new products (Brown, 2007; Evans, 2016). This case study again proves the importance of R&D focus for medical device companies.

The complexity of medical device development and the need for academic collaboration

Kahn (1991), in his early notes on the comparison between medicines and medical devices, stated a point clearly that devices involve a wide variety of technologies, unlike medicines, and need collaborative efforts. Requirements of convenience, suitability of use, and ergonomics increase the complexity of device development as user convenience is an important aspect of medical devices, unlike a medicine formulation (Martin, Norris, Murphy & Crowe, 2008). Limited in-house knowledge with the medical device companies may not be sufficient for the innovation because of these complex needs bringing the importance of the role of industry-academia collaboration. Gaining knowledge through many models, mainly university-industry collaboration, is an effective method for acquiring the latest knowledge. Such industry-academia collaboration can be an effective method for innovative technologies, solutions to specific issues, newer technology acquisitions, and access to experts & specialised team members (Chung, Ko & Yoon, 2021). Chen, Pickett, Langell, Trane, Charlesworth, Loken, Lombardo, & Langell (2016) noted, from their experience of developing a technology for cervical cancer, that a well-structured academic-industry collaboration may accelerate development in the field of medical technology. WHO has also documented and suggested the members for the right national strategies for the management of health technologies with a recommendation for collaborating with people involved in technology assessment (World Health Organization, 2017).

Case studies for Industry-Academia Collaboration

A success story of industry-academia collaboration in Finland has been described in great detail by Lester & Sotarauta (2007). Known as "The Oulu Phenomenon", as the case involved a town called Oulu, the authors detailed the cases of hospital technology, telemedicine, healthcare technology and wellness medical device technology through industry-academia partnership through formal and informal meetings. A good number of managers involved said that the local university was an important academic partner in reducing the timeline for new product development and increasing competitiveness.

One more case, known as the Hamamatsu method (because of a town called Hamamatsu in south-central Japan, which was used as a testing ground) is also a success story. AMED, the Agency for Medical Research and Development in Japan, used a model involving Commercial Coordinators (CDs) for educating, matching requirements of both sides, coordinating budgets and funds, and supporting technology transfer. Success lessons and complications encountered in this model using Commercial Coordinators have been described in this case study (Yuko, 2020). Tsuruya, Kawashima, Shiozuka & Nakanishi (2018) have given a very detailed explanation of the development of academia-industry collaborations in Japan starting with such process from the 12th century till recent times. It will be clear from that detailed account that the collaborative culture is a process and not an endpoint. A simple method for initiating collaboration among industry, academia, and government is to organize a workshop involving these parties as per Linehan & Chaney (2010).

CAREFOR forum for healthcare-related industry-academia collaborations is explained in detail by Stahel, Lacombe, Cardoso, Casali, Negrouk, Marais, Hiltbrunner, Vyas, & Clinical Academic Cancer Research Forum (CAREFOR) (2020). Bench-to-bedside competition by the University of Utah, an annual program, described by Chen, et al (2016) was a simple way of encouraging the process of innovation through industry-academic

partnerships. The Balanced Scorecard (BSC), a tool for evaluating business progress, was proposed for use as a strategic success measurement tool for industry-academia collaborations by Al-Ashaab, Flores, Doultsinou & Magyar (2011). In India, Siemens Healthineers has also developed a collaboration model entering into tie-ups with academic institutes and hospitals (Press release by MeitY, 2023).

Research need

A very detailed and exhaustive work has been done by Rybnicek &Königsgruber (2019) on industry-university (that is, academia) collaboration. They mentioned that much less than expected research has happened on the subject of such collaborations. They did a fairly detailed analysis of the published work on industry-academia collaborations. Their study noted that while reasonable work has been done on this subject in the USA, UK and some other European countries, this subject is not covered much in India, and they could find only one good article worthy of covering in their study on this topic. More research work on this subject is the need of an hour due to this reason (Rybnicek &Königsgruber, 2019). The area of medical devices for such collaborations was chosen because collaborations of this type are more relevant due to the complexity of the development here, as explained earlier.

Research Questions

The study aims to find the answers to the following research questions-

- What is the extent of the industry-academia collaboration in India in the medical device sector?
- What are the primary objectives of such collaborations for the industry? What is the industry looking for, from such collaborations?
- What are the possible barriers in such relationships?

Research Objectives

The research objectives for this study are to understand in some detail the level and dynamics of the industry-academia collaboration by studying the views of the industry side by interviewing the senior people heading their medical device companies. The study also aims to get an idea of the models being followed for such collaborations, by interviewing the respondents. The study also plans to get an idea of the possible reasons and possible barriers for not going for such collaborations. The study plans to cover the industry side of the processes of industry-academia collaboration by interviewing industry representatives.

General Hypothesis

H_1: There is no significant association between industry-academia collaboration and the new product developments in the medical devices sector in India.

Research methodology and sampling design

The primary focus of the study is to understand the prevalence, objectives and approach of the medical devices industry representatives towards industry-academia relationship. A descriptive research design, which allows more flexibility, was selected. Flexibility and freedom to quantify the numbers are also provided by the descriptive study design. The study used both quantitative and qualitative methods.

A convenience sampling method was used. Both Informa Market (2020) and KPMG (2022) reported that there are about 750 – 800 local Medical Devices manufacturers in India. A complete list of these companies is not available from any data source. The Interview method was selected for the study, and 60 valid interviews were planned. The final number came to 64 interviews, after deducting a few rejected interviews, where the rejection was mainly due to inconsistent data.

A fairly detailed profiles of the companies were gathered from the databases, and their web pages and also by rechecking the data with the respondents, for correlating this data with the responses. A preliminary communication was sent to all the possible respondents through mail or WhatsApp, and the purpose of the interview was explained in detail. After their initial positive response, a convenient time was fixed for a longer conversation with the right person. A very senior person or a promoter/owner-level person who can tell correct information on the R&D models or collaboration practices would be the right respondent, and so, contact with such a person was ensured. The interviews were recorded for qualitative analysis, besides noting down key data during the ongoing interview.

Results

Quantitative analysis

It was found that 31% of the companies (20 companies out of 64, or less than one-third companies) interviewed, had some meaningful and active collaboration with the academic institutes in one form or the other. This was across the size of the companies, the life of the companies and the types of products. The only observation was that such collaborations were prevalent with the companies that had an investment in R&D of more than 5% of their turnover. In other words, the companies focusing on new product development have higher tendency to do a collaboration with academia. Figure 1, below, represents these results in a graphical form.

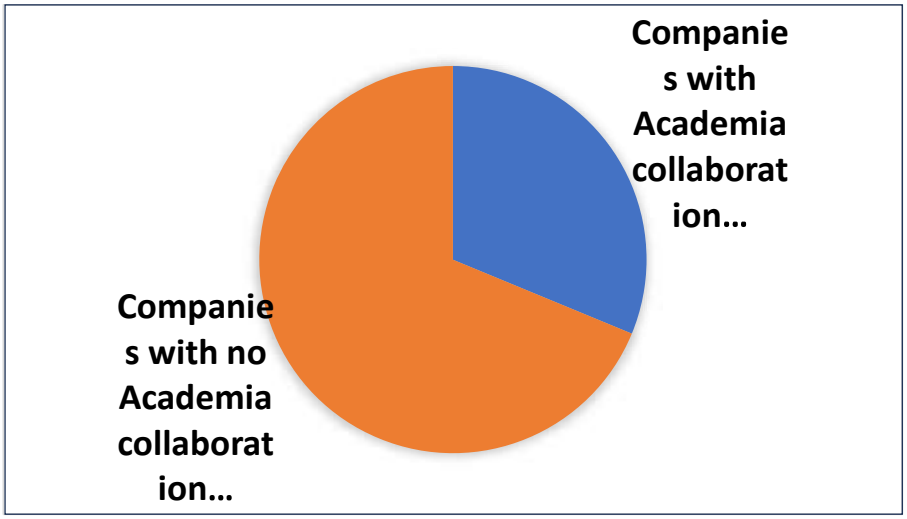

Figure 1 : Frequency of collaborations with academia among the companies (Source: Interviews)

The Tree map chart (Figure 2) represents a good total picture of "Why an Academic Collaboration" – the primary reasons stated by the respondents. The chart summarises the primary reasons behind Academic collaboration.

Seeking specialized knowledge was the number one reason for a collaboration with an academic institute. The companies are looking for specialized knowledge from academia due to the complexity and variety of the devices. Ready product (3 out of 20), Protocol testing (3 out of 20), Clinical trials (2 out of 20) and Training (1 out of 20) are other expectations from these educational institutes. "Specialized knowledge" and "Ready products" out of the total respondents as visually clearer reasons for collaborations in Figure 2.

The major reasons for not having collaboration was "No Need" or "Past Experience". This needs to be noted.

Figure 2 : Primary reasons of an academic collaboration (Source: Respondents' comments)

Qualitative analysis

Table 1: Word frequency table from the interviews (Source: Interviews)

Word Frequency Analyser		
Word	**% of text**	**Occurrence**
collaboration	2.77 %	67
academia	1.45 %	35
industry	1.28 %	31
institute	0.62 %	15
university	0.54 %	13
academic	0.45 %	11
research	0.45 %	11
development	0.45 %	11
medical	0.41 %	10
professors	0.33 %	8
collaborations	0.33 %	8
college	0.33 %	8
products	0.33 %	8
product	0.33 %	8
knowledge	0.29 %	7
colleges	0.25 %	6
universities	0.21 %	5
institutes	0.21 %	5
instruments	0.17 %	4
hospitals	0.17 %	4
specialized	0.12 %	3
complexity	0.12 %	3
technology	0.12 %	3

The Word Frequency table (Table 1) through the analysis of the scripts recorded showed that the words "academia, industry, institute, university, college.." were the top words captured during the interviews, and this is natural since these words represent the subject of our interview. The next words were "research, development, medical, products, knowledge, instruments, hospitals, specialized, complexity, and technology". These are more important giving insight into the objectives of collaborations. The words "Knowledge, Instruments, Hospitals, Specialized, Complexity and Technology" are in line with the objectives of specialized knowledge and ready product/technology objectives.

The same results can also be seen in the word – cloud below (Figure 3). The transcripts were also subjected to the Word Cloud formation programs. The word Cloud captures the same essence effectively where these particular words are represented by proportionate sizes for these keywords. Since this format of the Word Cloud shows a relative proportion of the frequency of words, this style was chosen.

Figure 3: Word Cloud from the scripts (Source: Table 1)

Comments from the interviews

Interview comments relevant to the subject but are critical responses are covered here, to understand the barriers and constraints.

Respondent A - an x-ray machine manufacturer in the line for 30 years

We do not have a collaboration with any college. (Q:Why?) We have been working for 30 years. We have gathered sufficient knowledge in this line. Therefore it is not necessary to have any collaboration. It is a management decision. (The respondent was a senior-most manager, not part of the owner's family.)

Respondent B - a 5 years old company of small size

I mean, actually, we have collaborations but they are not with institutions or academic universities. They are with independent professors. These professors are associated with some good universities and academic institutes. This way of relationship is easier to manage instead of managing a relationship through a college because of institutional bureaucracy.

Respondent C -a wound care products startup

Industry-academia collaboration is important for our line. What we do is, we give our free products for trials to hospitals under collaboration, they do trials and then we collect the data and we publish the data, we include the hospital name as well as the doctor's names. So they feel motivated and they always feel involved, and they start using the final products when introduced to them. It is more like a win-win collaboration because we are a small company, we can't afford big money to be paid.

Respondent D- a fairly large operation theatre accessories manufacturer

My experience of such collaborations is not very positive. Most of the colleges lack infrastructure for our type of products like electrical or electromagnetic products. The ecosystem of these colleges or institutes is not conducive. I really do not feel very comfortable dealing with them here.

Respondent E - a large disposable products manufacturer

I had actually initiated this (industry-academia collaboration) process, but it did not work out, unfortunately. And I understand and appreciate your points that we can always get specialized knowledge or technological know-how, the latest know-how, but this does not work. And right now, we do not have any collaboration. (When probed about his experience) Better not to speak about our past experiences. The past is gone.

Respondent F - A diagnostic products and machine manufacturer

We were working with BARC long ago, and it was a good working arrangement, but now we do not need BARC because there are private players in radiation technology with good service.

Respondent G - a very old diagnostic company

There were lot many dynamics. We are in business, we don't want to enter into their internal politics. Why should we? It is very complicated. Now we have just stopped that as a policy. In India, the problem is the syllabus of universities and colleges is not appropriate. It is more towards the academic side. Instruments, for example, their own instruments are very old. Universities in India are not investing in newer developments. They are laggards. Education should be at the forefront while these people are lagging. So, not worth entering into collaboration.

Respondent H - a textile manufacturer who diverted to collagen sheet manufacturing

You see, IITs in India have the newest or the best instruments. However, after a year or so, these machines or instruments become dormant, and nobody uses them. When they order, probably there is some project in their hand. But then after some time, the project is over or the project gets abandoned and the machine becomes dormant and the machine just lies, and nobody knows, nobody cares or nobody maintains that machine.

Discussion

Little less than one-third of companies involved in serious industry-academia collaboration for new product development is an area of attention for policymakers, especially when new product development is the way to reduce import dependence. Good R&D investments in the pharma sector, a similar area in the healthcare arena,

and its excellent export contribution to India is a situation worth comparing. This lack of collaboration was across the size of the companies, the life of the companies and the types of products. However, there was a correlation between the companies with 5% or more R&D expenditure and academic collaboration. This, along with more frequent words mentioned like "research, development" are indicators that the role of academic collaborations for new product research and development is the main objective of the industry players. Looking for specialized knowledge was the most common reason for seeking a collaboration with an academic institute. This is also in line with this new product development need. As discussed earlier in the article, the complexity of medical devices does prompt a medical device company for such collaborations because a company may not always have specialized knowledge of all the areas which are needed for new product development.

Why no collaboration? A large majority, 35 out of 44 respondents said that there is no need for any such collaboration. There is a strong possibility that most of these respondent companies do not have serious R&D plans. Some comments in the interview (respondent A, for example) also indicate less inclination of these companies towards R&D. This is in line with what KPMG (2022) has also reported for the whole sector. Some unique ingenious models found by these entrepreneurs, like using hospitals for trials as well as future launch platforms, and connecting with individual professors bypassing the bureaucracy of institutes were also captured in the comments mentioned. Two responses mentioned that there is no specialized knowledge available for their types of products or technologies in the colleges and one response mentioned that he does not know whom to approach. It may be worth noting here, that a study conducted by the Entrepreneurship Development Institute of India for the Department of Pharmaceuticals (DoP), "Bridging the academia-industry gap to achieve self-reliance for NIPER institutions in India", The National Institutes of Pharmaceutical Education and Research (NIPERs) need to establish a more comprehensive ecosystem that includes mentorship, support for incubation, funding methods, and industrial alliances to promote entrepreneurship in the pharmaceutical sector. National Institutes of Pharmaceutical Education and Research (NIPERs) should focus on multidisciplinary research to bridge the gap between academic education and the needs of the country's health industry (PharmaBiz, 2024).

The comments of respondents regarding their complicated and negative past experience of such collaborations is somewhat alarming. If we park aside the reason of "No Need", the next most significant reason for not entering into a relationship with academic institutes was such experience. Some companies did the efforts but did not get conducive responses in the past and so, now they are averse to such collaborations. Internal politics and bureaucracy of academic institutions were stated clearly by some respondents. In a very well-discussed and highly quoted theoretical model called the Triple Helix model, Etzkowitz and Leydesdorff (1998) have touched upon the barriers of the industry-academia relationship. Abd Razak and White (2015) have elaborated further on the barriers based on this Triple Helix model for innovation, stating that there are three types of barriers - Relationship issues; Perception issues; and Policy issues. The data in the current study suggests that the issues present are the "Relationship" issues. The issues are not "perceived barriers" as they are based on actual experience rather than perception. The problems are not issues of internal "Policies" of the companies also. In other words, "Trust", *materia prima* for a successful "Relationship" seems to be missing. The Hamamatsu models discussed in the article using volunteer commercial coordinators may be highly effective in this situation (Yuko, 2020). These Commercial Coordinators may facilitate the meetings and work as the coordinators as their name suggests. The study also reveals that there exist successful collaborations in the industry. Therefore, it is right to assume that the collaborative models are workable if nurtured carefully and sensitively.

Conclusions and Recommendations

To answer the first objective, the extent of industry-academia collaboration is 31%, which appears low. For a successful new product development culture for the medical device sector in India, this should go up. The major objectives of such collaborations from the industry side are to gain specialised knowledge and to adopt readily developed products by the universities. The major barrier is under the sub-theme of "Relationship" or trust deficit. It is recommended that there be more trust-building and interactive processes between both sides. These can build a bridge between industry and academia for such collaboration. The policymakers may need to look into collaboration-enhancing models, which will help in more innovative culture and will ultimately help in reducing import dependence of the sector.

Limitations and further scopes of the study

A similar study to understand the views from the academicians' side may be a very interesting possibility. This part is not covered in the current study and this is a limitation as well as a future opportunity. One more limitation was that this study was restricted to the medical devices field, and similar studies with some other healthcare-related fields like pharma or nutraceuticals may also reveal some interesting possibilities. This also provides a possible scope for future study.

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