CSIBER INTERNATIONAL JOURNAL OF ENVIRONMENT (CIJE)

Vol. 1, Issue No. 2, October 2024

Published By :
CSIBER Press, Central Library Building,
CSIBER Campus, University Road,
Kolhapur, Maharashtra, 416004, INDIA.

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Published By:
CSIBER Press, Central Library Building
Chhatrapati Shahu Institute of Business Education & Research (CSIBER)
University Road, Kolhapur – 416004, Maharashtra, India

CSIBER International Journal of Environment – CIJE

A Bi-Annual Double-Blind Peer Reviewed (Refereed/Juried)
Open Access International e-Journal - Included in the International Serial Directories

Editorial Note

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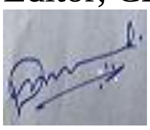
We invite authors to contribute original high-quality research on recent advancements and practices in Environment Management. We encourage theoretical, experimental (in the field or in the lab), and empirical contributions. The journal will continue to promote knowledge and publish outstanding quality of research so that everyone can benefit from it.

Er. D. S. Mali
Editor, CIJE



CSIBER International Journal of Environment (CIJE)

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Industry-Academia collaboration modelsfor the medical device development

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ABSTRACT - The article covers in detail the subject of collaboration - one of the most effectivestrategies for managing growth. Scopes of implementing collaborative models in the Indian scenario for medical devices product development are many and the relevance of these models to India needs immediate consideration. The medical devices industry is represented heavily by MSMEs. The industry overview section details that India still relies significantly on the importationof medical devices, and local manufacturing still addresses only lower-end products. The article explores the power of collaboration through examples of medical technology and the medical devices sector. The sector of medical devices especially demands collaborative efforts, mainlybetween industry and academia because of the involvement of a large spectrum of diverse technologies, like chemicals, electronics, biomaterials, metallurgy, optics, mechanics, fluidics, andcomputer programming, to name a few. Some successful case studies are described in the article involving industry-academia collaborations in developed and developing countries, and learnings from these cases are summarised. Collaboration models resulting in successful medical device development are also covered. Collaborations between countries and recommendations by bodies like WHO on collaborative models are also discussed. These collaborations are not always smooth,and the article lists the barriers encountered in such collaborations. Legal and procedural aspects to support such collaborations are also stated.

Keywords: Industry – academia collaboration, medical devices, models, barriers

Introduction - Industry Overview

During the pandemic, the market for medical devices declined by 3.7% though the pharma market had grown during the same period. With this decline, the size of the global medical devices industry was around USD 432.23 billion in 2020, with a decline on a year-on-year basis. However, in the next eight years, the value projection is USD 657.98 billion, and its growth rate would be 5.4% pa. Increase in patients, diagnostic procedures, and surgeries are projected to increase during the coming years which will support upping in demand for medical devices. Both capital equipment and consumables will be in more demand in both developed and developing countries (Fortune Business Insights, 2023). However, this 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).

India now produces many disposable medical devices, like catheters, perfusion sets, extension lines, cannulas, feeding tubes, needles, and syringes, and even implants, like cardiac stents, drug-eluting stents, intraocular lenses, and orthopaedic implants. The Medical Devices industry in India has shown significant growth during the past decade (India Brand Equity Foundation, 2020). The sector is represented by large multinationals, medium-sized companies, and smaller companies. Market size estimation for Indian medical devices is about US$ 12 billion in 2020 and is growing at an expected rate of 15%, which is significantly higher than the global growth rate for the industry. India is the 4th largest medical devices market in Asia. It should also be noted that 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).

The medical devices industry has been given the status of a focus sector by the government of India at the time of the “Make in India” campaign. Many initiatives have been suggested and implemented by the Ministry of Health and Family Welfare (MOHFW) as well as the Central Drugs Standard Control Organisation (CDSCO) to increase the export of medical devices from India (India Brand Equity Foundation, 2020). The industry is highly fragmented with about 1000 domestic operators in the device manufacturing sector with the production of generally lower end of technology products. However, a paradigm shift has been seen in recent years and the initiatives have started to produce cost-effective, medium-end medical devices (EEPC India, December 2013).

Literature Review – The complexity of medical devices and the need forcollaborations

The development of most medical devices needs an understanding of a large array of technologies. Some of the technologies commonly encountered for medical devicedevelopment are chemicals, electronics, biomaterials, metallurgy, optics, mechanics, fluidics, and computer programming. If we compare medical devices with their pharma peers, for the development of a new drug, knowledge of very few sciences may be adequate. Though pharma research is also complex, the spectrum of areas involved in medical device development is certainly much larger, comparatively. Even from a regulatory perspective, it is not always practical for the regulatory teamsto develop special expertise in all the fields involving a medical device. Kahn, in 1991, mentioned this point besides other complexities of medical devices in a comparison of devices with medicines. Medical device development also involves the consideration of ergonomics. Convenience, suitability, and safety of the final user are important parts for a device. A well-designed device with convenience for the user during the care of a patientis important. Sufficient guidelines and studies are not available in this area ofergonomics (Martin, Norris, Murphy& Crowe, 2008). Medical device designing considering the practical situations of developing lower-income nations is also part of the problem and the authors recommend collaboration between developing countries and advanced countries so that such situations can be adapted (Saidi, & Douglas, 2022).

The key to success in such situations is Collaboration (or Partnerships or Teamwork). The dictionary defines collaboration as the state of having shared interests or efforts (Merriam- Webster.com, 2023). Dosanjh (2022) has rightly mentioned the title of his research article as “Collaboration: The Force That Makes the Impossible Possible.”

Research Objectives

The objective of the article is to do a critical review of the processes of collaboration, mainly industry-academia collaboration, and the models being practised for the collaboration process in outside countries as well as in India, and then derive learnings from this analysis, with the focus on medical technologies and medical devices. One more objective is to understand success factors as well as barriers to industry-academia collaborations. Thus, the article aims to cover-
Case studies of successful industry-academia collaborations abroad pertaining to medical technology
Learning points from these case studies
Barriers in these collaborations and care to be taken for successful outcomes.

Research Methodology

Some of the advanced countries that spend more amount on research and development have used collaboration models effectively for research. The critical analysis of the literature review describing these models and processes is the methodology adopted here.
Industry-Academia Collaboration

Cases, models and methods

Academic institutions are an important resource for research. Collaboration of the industry with academic universities can therefore be a good model for success (Chung, Ko & Yoon, 2021). Academic institutes thrive on innovations and discoveries while companies being process-driven, often struggle with their ability to innovate. (Chen, Pickett, Langell, Trane, Charlesworth, Loken, Lombardo & Langell, 2016). The partnership between academics and the industry – an alliance that is important for both sides, helps in technology transfer and completion of the innovation cycle. Both academia and the industry have different missions, and different skill sets, and their cultures also differ, however (Pantanowitz, Bui, Chauhan, ElGabry, Hassell, Li, Parwani, Salama, Sebastian, Tulman, Vepa & Becich, 2022). WHO, in their document, requests members to formulate the right national strategies for the assessment,planning, procurement, and management of health technologies and also recommends that this should be done by collaborating with people involved in technology assessment. Though the document highlights the role of biomedical engineers, it also recommends “interdisciplinary collaboration” as per the regulations of each country involved. The document further recommends that Governments, professional councils, and associations need to develop the right models and inter-professional collaborations. Documentation of associations (national as well as international) involved in promoting collaboration between individuals, governing bodies, and academic institutions is also recommended. Further data is also given on the WHO website including international collaborative work (World Health Organization, 2017).

Lester & Sotarauta (2007), in their book titled “Innovation, Universities, and the Competitiveness of Regions” (the title is self-explanatory) has detailed a case study, now known as “The Oulu Phenomenon”. Oulu City in Finland, an industrial city located in the center-west of Finland, has a population of above 130,000 people. This city was struggling due to economic slowdown and this struggle created, or forced, trust and solidarity among the population. This was the main force behind their collaborations, both formal and informal. This collaboration story is described as the Oulu Phenomenon, triggering a series of positive situations. The Government of Finland, the city itself, and the local companies made supportive strategic investments, and a science park was created there in the city with further support from the University of Oulu and a European foundation. The relevant chapter in the book stated above covers cases for medical device technology including hospital technology, telemedicine, healthcare technology, and wellness devices. The medical devices industry is represented by smaller companies. In this city, the science park, the University Hospital, the Oulu Polytechnic,the medical department of the University of Oulu, and companies are situated in close vicinity to each other since the size of the town is relatively small. This closeness prompted and eased face-to-face meetings – both formal and informal. These networks were found to be important for technology transfer. Organizations related to each other through formal ties in organized networks, while individuals were connected through informal networks. Seventy-five percent of medical devices were developed in the networks of manufacturers and potential users like hospitals and also involved network members like universities and research institutes, scientific foundations, government agencies, consultants, and distributors. The authors note that trust between the parties involved makes them willing to share knowledge related to their core competence without apprehensions. The authors conducted a study with the objective of exploring the role of university-industry collaboration in medical device development and how the perception of collaborations in the Oulu region, with a snowball sampling method. The snowball sampling method was used because it would easily locate people connected informally in these networks ("n" was 40). Most of the managers stated that the University of Oulu was the most important academic partner. Few also collaborated with universities other than the University of Oulu. The timeline for new product development was shortened because of such collaboration with the university, and competitiveness was increased. It may be worth noting that the research found that despite this positive effect on the universities, the managers felt that the University could do more to collaborate.

One more case of Japan can also be quoted here. A unique collaboration model called Hamamatsu Method for medical devices has been presented by Yuko (2020). Japanese medical devices market has a situation of export dependence like that in India but to a lesser degree. The author states that the local requirements for medical devices are growing year after year and importations are increasing, while exports have not increased proportionately, and this creates an imbalance between import and export. A network was created between AMED, an agency for medical research and development, and Mitsubishi Research Institute, Inc. with the objective of promoting collaborations and support. Hamamatsu, a local city in south-central Japan, was used as the platform for hypothesis testing of a new model where Commercial Coordinators (CDs) were involved in the successful implementation of collaborations. The role of Commercial Coordinators was multifaceted – education through methods like 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. The article, in the form of small summary cases, discusses success stories with examples as well as complications encountered in some cases. The role of Commercial Coordinators here appears to be critical and the same model, with local adaptations, can be used in more places, as the author concludes.

Tsuruya, Kawashima, Shiozuka & Nakanishi (2018) have also given a fairly detailed outline of the progress of academia-industry collaborations in Japan in the medical field including medical devices. This article mentions a historical perspective of how a humble beginning of collaboration started as early as the 12th century, and how it has progressed so far.This historical outline also describes how the universities started in Japan (in the 12th century), the influence of the Western styles and culture, parallels between industry-academia models in the US and Japan, how some Japanese professors started their companies, and then the current scenario. It also gives a vivid description of collaboration platforms like DSANJ, and AMED,a national agency stated above, and also a case study of the Kyushu University hospital centre.It will clearly appear to the readers that 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 (Clinical Academic Cancer Research Forum) is one more platform created for improving the industry-academia collaborative interface. Barriers hindering broader collaboration in Europe in the field of academia-industry cancer research were seen, prompting to form CAREFOR platform. Industry representatives were joined by academic professionals who had good experience. These team members had joint discussions about various aspects (related to clinical trials) and put forth collaborative success stories. Legal points and contracts pertaining to the subject were also discussed, and broad principles of interaction and access to data were also addressed by Stahel, Lacombe, Cardoso, Casali, Negrouk, Marais, Hiltbrunner,Vyas & Clinical Academic Cancer Research Forum (CAREFOR) (2020). (on behalf of the Clinical Academic Cancer Research Forum (CAREFOR)). Though dealing with the subject of cancer research, this model appears to be relevant for the industry-academia collaboration for medical devices, deserving its mention here.

The case of the University of Utah's annual Bench-to-Bedside competition will also be relevant here. This was a simple way of accelerating the innovation process through industry- academic partnerships, mainly because The Centre for Medical Innovation gathered a team of students, surgical residents, and clinical faculty at the University of Utah's annual Bench-to- Bedside competition. All participants gathered on a voluntary basis. This university program, the Bench-to-Bedside medical program, had an objective of medical innovation. In this program, the industry partner acted in the role of a business mentor. This group of volunteers studied the therapeutic landscape as well as environmental constraints. Later, to facilitate the usage of a device, the group took the help of a simulation to understand human factors like usage requirements and design. First, a digital image was created, and later, the image was converted into a physical object using a 3D printer. In the final stage, clinicians (here, obstetricians and gynaecologists) were informed about how to use a device and were asked to use the device (Chen, et al., 2016). A successful model of industry-academic partnership!!

Selection of the right partners in such projects is important, and Chung, et al., (2021) have described this step of the process in detail. Their study presents a partner identification approach that is based on innovations selecting the right university inventor groups for academic-industry collaborations. Their approach suggests four steps in the process – 1. Patent data collection and institution identification, 2. Grouping the inventors of the universities, 3. Screening these groups against the needs of the industrial firms, and, 4. Partner group identification based on competence, concentration, and size of the inventor group.

An interesting study on collaborations in South Africa for medical device development among four sectors namely academia, healthcare sector, Industry, and science & support drew collaboration networks, and after that, the links between institutions were studied. The results of the study may be useful to recommend strategies and policies for medical device development. (Jager, Chimhundu, Saidi, & Douglas, 2017).

And here is an Indian story. Siemens Healtineers, India, is working on these lines recently.With an eye on the fast-growing Indian medical devices market, Siemens Healthineers has scaled up R&D and has emphasized tie-ups with academic institutes along with hospitals and local firms (Press release by MeitY, 2023).

Clinicians - Engineering Collaboration models

Engineering is of prime importance in device development, mainly because of the familiarity of this faculty with precision medicine and artificial intelligence which applies to many devices. Nursing faculty becomes equally important in the field, and this demands collaboration between these two disciplines. Zhou, Li & Li (2021) have explained a case study of collaboration between these teams. The authors also note that such collaborations have not been explained well, which was the reason why they have studied this collaboration between engineering and nursing in healthcare. Their study uses a scoping review using the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Extension. An interdisciplinary collaboration model was used to visualize the results in 60 studies which were found to be suitable as per the inclusion criteria selected after extensive literature study. An interdisciplinary collaboration model was constructed for the results. The findings of the study were, i) These collaborations are in their early stages and have not emerged fully; ii) Involvement of nurses should be more and should be at an early stage in the future. iii) The design phase and requirement analysis stage involvement for nurses is important.

For complex devices, involvement by clinicians is important for research sustainability. A research model addressing this issue was proposed by The University of Rochester Cardiovascular Device Design Program through a multidisciplinary solution. This program works through a collaboration between the Schools of Medicine and Engineering (Chandra, 2012). The author notes a gap between the users, that is clinicians, and the engineers who design these devices, and recommends collaboration among the medical device industry, engineering department, and clinical faculty. This university has started a one-year master’s program (The University of Rochester Cardiovascular Device Design Program) with the aim of a new paradigm in the device designing area.

A novel collaborative process for design optimization and production for face-visors used regularly during the Covid pandemic is described by Din, Althoefer, Farkhatdinov, Brown, Morgan & Shahdad (2021). This is a classical case of collaboration journey between an academic group and medical clinicians. The article elaborates on how unmet needs for this product led to the process of innovation and also details timelines and steps followed in the process. The face-visor thus developed by the collaborative team satisfied many important criteria like reusability, convenience in the form of adjustability, local production feasibility, and high utility with a controlled price and a possible scale-up for the production. This single team delivered more than 15,000 face visors through this collaborative journey. The authors also note that CAD-trained engineers were involved in the collaborative process and that facilitated the process of product development by decreasing the innovation time. This Barts and Queen Marry University of London collaborative project for Visors (The Barts and QMULVisor™) is a typical success story of collaboration.

Intercountry collaboration models

Uchida, Ikeno, Ikeda, Suzuki, Todaka, Yokoi, Thompson, Krucoff, Saito & Harmonizationby Doing Program Working Group (2013) mention a successful collaboration between Japan and the USA for developing new medical devices. Harmonization by Doing program (HBD),was started with the background that financial budget limitations affect efficient device development, and repetitive spending in different geographies for device development is not practical. Global networking is needed in such a situation. The HBD program has fourworking groups each addressing different requirements like global trials, post-market registration, infrastructure, methodology, and clinical trials. Such programs are important for efficiently delivering newer medical device ideas with better financial efficiency.

To facilitate collaborative efforts of multilingual groups, the European Federation for Medical Informatics (EFMI) Association has created a collaboration tool called MIMO (Medical Informatics and Digital Health Multilingual Ontology). EFMI is the Working Group on Health Informatics for Inter-regional Cooperation. MIMO hasuploaded about 1,000concepts and above 300 newly created concepts and this platform is regularly updated. Thistool provides a medical informatics multilingual thesaurus where the medical terms can be translated into more than 30 languages to facilitate better understanding and collaboration among multilingual groups or countries (Benis, Grosjean, Billey, Montanha Dornauer, Crișan-Vida, Werner O Hackl, Stoicu-Tivadar & Darmoni, 2022).

Barriers Affecting industry-academia Collaborations

These collaborative relationships are not as rosy as they sound, and some authors have explored complications, dispassionately studying difficulties, hurdles, issues, and suggestions to resolve them. This section will describe success stories and some models with suggestions and the next section of the article will describe difficulties noted by some authors in such relationships. We will now see some studies describing barriers encountered and care to be taken for successful outcomes from collaborations.

A small but data-based study provides good insight into the extent of industry and academic participants' collaborations. Publications with industry affiliations and participants at an international conference were coded and analysed for industry collaborations. The data indicated that in 2018, such collaborations were to the extent of less than 5%. Though a rough estimate, this is a good way of having a quick analysis of the situation. The authors also studied the barriers in collaboration and listed these as motivational differences (actual or perceived), challenges in publications, and outcomes (Blanch-Hartigan, Yule, Cummings, Smith & SchmidMast, 2019). The rules of these partnerships need to be clear from the beginning and Pantanowitz, et al.,(2022) not only highlight these divergences but give a detailed outline of these rules, including legalities. Their article discusses the advantages as well as disadvantages of such partnerships, details areas of conflict of interest, and describes recommendations for success. They note that for an academic institution, a high priority area is education while for an industry, their high priority area is innovation which, for an academic institution, is the least priority area. Sponsored Research Agreement (SRA), Technology Transfer Agreement (TTA), and Consulting Agreement are discussed in the article. Overview of some other relevant agreements like Confidential Disclosure Agreement or Non-Disclosure Agreement (CDA or NDA), Material Transfer Agreement (MTA), Data Use/Transfer Agreement (DUA), and Clinical Trial Agreement (CTA) are also outlined. Some important recommendations for a successful collaboration, according to them are - building trust, compatibility of values, creating boundaries, financial reviews, governance review, transparency, full disclosures, geographical considerations (for international partnerships), and engagement of academicians.

One more study by Mirza, Al Sinawi, Al-Balushi, Al-Alawi & Panchatcharam (2020) touches on this subject of academic-industry collaboration and discusses the difficulties and barriers in such a collaboration. The authors have studied collaboration in some major academic institutes in London, UK. The study explores attitudes, beliefs, perceptions, and opinions of clinicians and academicians towards collaboration with the industry through an online questionnaire involving a four-point Likert scale and responses from researchers followed by interviews with some of them (a mini-focus group). The reputation of the industry was comingout as the major barrier perceived by the academicians. Academic people involved believed that bias for the products rather than caring for the patients, primary concerns not being patients, publication bias, and major interest being financial gains are important issues against the industry. though this study is not related to the field of medical devices, the premises being industry-academia collaboration, these issues mentioned in their work may be highly relevant. One more study on critical issues for effective academia-industry collaboration conducted in Japan by Tsubouchi, Morishita, Tabata, Matsui & Kawakami (2008) in the field of medicine covered nine representatives of Japanese companies. The study noted that the industry representatives encountered inappropriate systems in academic institutes, a deficit of understanding of industry issues by academic institutes, insufficient support system by the government, and a critical view of such alliances in the public eye as the major barriers. The institutes always have scholars, researchers, and specialists of knowledge, and one suggestion by the authors was to create academic seats in the industry or systems whereby people can move easily between industry and academics.

Austin, May, Andrade & Jones (2020) have described five case studies and discussed issues hindering university-industry collaborations and facilitators for such collaborations. They note that successful networking, higher expectations, idea evaluations, and technical support from universities were the most desired contributors to a successful relationship. Unrealistic expectations on time and fund involvement were the hurdles. One point worth noting here is that most of the participants in the study expected exchange of knowledge, and not cooperative research or technology transfer. Networking with others was one of the major advantages notedhere.

Discussions

Industry overview for the medical devices sector gives clear indications that the situation of over-dependence on imports by India needs deeper answers and the answer may be in new product development. The complexity of medical technology asks for multifaceted expertise and therefore, collaboration, for new product development. The success stories of Japan and Finland indicate the importance of cultural factors in successful collaborations, as well as initial involvement by the academic side. Facilitators connecting various agencies, as in the case of Japan, may suggest a simple and effective way of handling sensitivities. Models like CAREFOR and bench-to-bedside are quite creative and seem fairly simple to implement. In all the situations discussed, initiation or take-off appears to be the most critical stage. This has parallels in forming teams for tasks, and experienced readers will appreciate that the most difficult stage in team formation is the first stage. This stage will be achieved after the stakeholders have developed a common understanding, and after this stage, the journey seems less troublesome, though not smooth. Definitely, the scopes for implementing models which are described in this article are many, in the Indian context.

Limitations and further scopes of the study

One limitation of this study is that almost all the cases and situations are from different parts of the world. The readers would appreciate that there are many differences across borders, like culture, regulatory framework, economic background, and also, languages. These differences do affect the processes when planned for implementation, and some of the learnings may not be reproducible without the required adaptations. Analysing the possible influence of such factors on selected models may be an interesting area to study further in this regard which will help better implementations.

Conclusions

Parking barriers aside, many learnings appear to be practical and possible to implement. The success stories of these collaborations clearly indicate that in today's turbulent scenario, collaborations can be a strong possibility to lead the research and development of newer products more efficiently. To conclude, with some modifications, balancing, and adjustments, these models can very well be used in the Indian scenario.

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