WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 8.084
Volume 9, Issue 15, 373-387. Review Article ISSN 2277– 7105

ROLE OF R&D IN PHARMACEUTICAL INDUSTRY AND HEALTH CARE SERVICES

Vishal Raghunath Nedre, Shivam Rajendra Nimbalkar, Aishwarya Avinash Shinde*, Swati Tarkase

Nandkumar Shinde College of Pharmacy, Vaijapur, Aurangabad-423701, Maharashtra, India.

Article Received on
26 Sept. 2020,

Revised on 16 October 2020,
Accepted on 06 Nov. 2020

DOI: 10.20959/wjpr202015-19228

***Corresponding Author**
Aishwarya Avinash Shinde
Nandkumar Shinde College of Pharmacy, Vaijapur, Aurangabad-423701, Maharashtra, India.

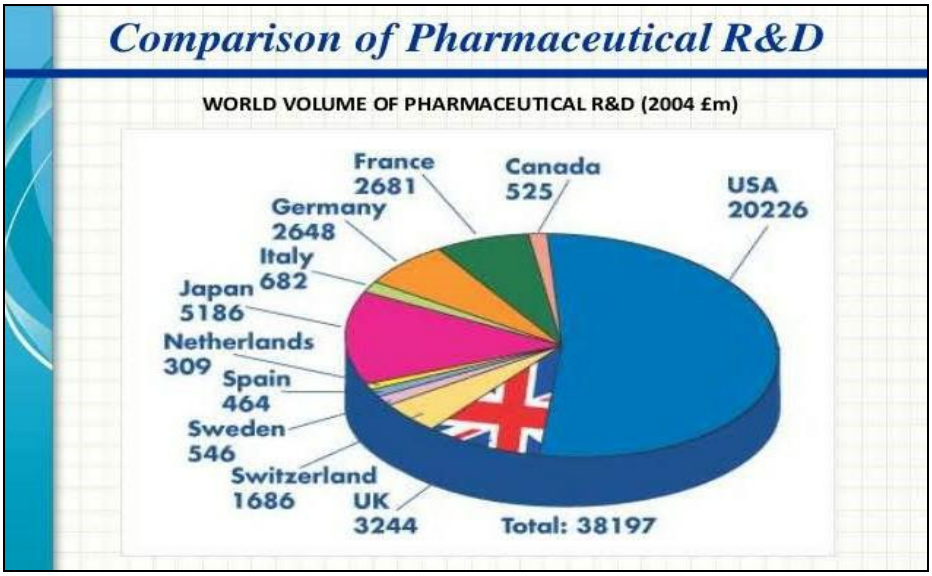
ABSTRACT

Research and Development (R&D) is the most important part of the pharmaceutical as well as biotechnological industries. R&D is work on the principle of discovery, development, manufacturing and marketing of the god quality product. R&D employs discover the new idea/drug or improve the pharmaceutical action of drug. After the discover of new drug there is many steps for development of product like synthesis compound, Preclinical studies, assay of compound, Clinical studies, Post marketing surveillance. The production cost and time reduction and quality of product/drug improvement is the main role of R&D in manufacturing department. R&D Department help to marketing department by producing proper data about product. R&D employs play a major role in health care service by discovering the new drug on any disease. R&D Department work on the basis of improvement of action of active pharmaceutical ingredient and decrease the toxicity of API. It discovers the antidote for different Poisson and produced antibodies for different types of various. R&D faces many challenges like physical barrier, language, personality and organizational responsibility etc.

KEYWORD: R&D, Discover, department, drug, new drug, pharmaceutical, product.

INTRODUCTION

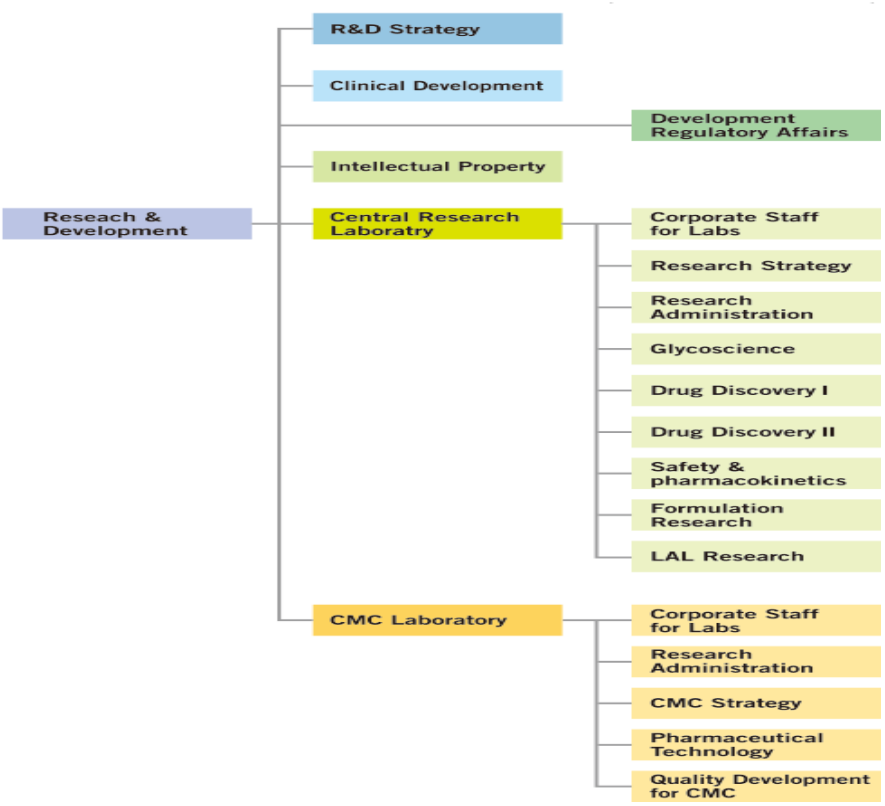
Research and Development (R&D) includes the work on which new product is introduced or improve the quality and quantity of product. R&D it is the most important department in pharma sector. Randomized clinical trial (RCT) is the one of the most important advances in today's life.[1-3] Because to improve efficacy of drug, biologics and medical devices.



Research and Development are the process mostly affect the productivity and also the quality of the product. In it back up to 13 years, one of 5000 products are launched in market but only 1out of 10000 substances becomes marketable product

R & D Structure

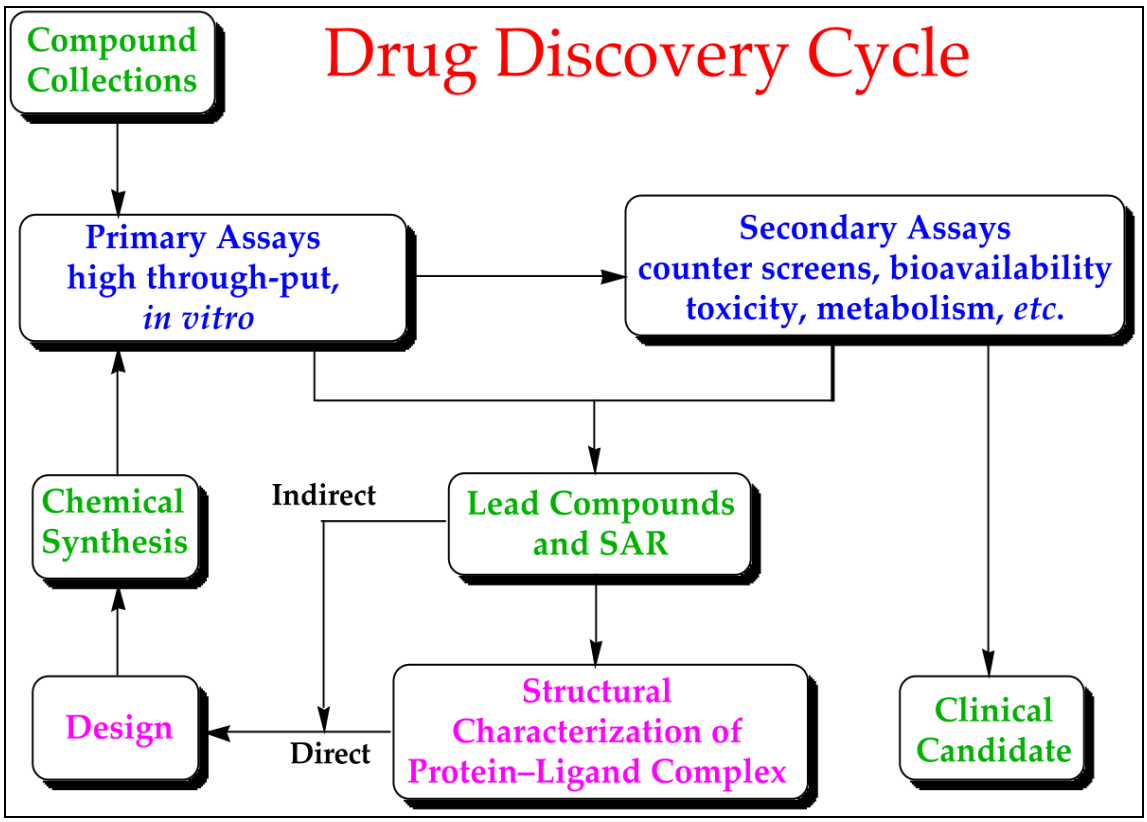
A companies R&D structure defined by its organization structure (org. chart), coordination mechanisms and culture for innovation and strategic mission for R&D activities.



R & D designed structure

We need a structure that is more effective and agile so it can match better with industrial organization.[32]

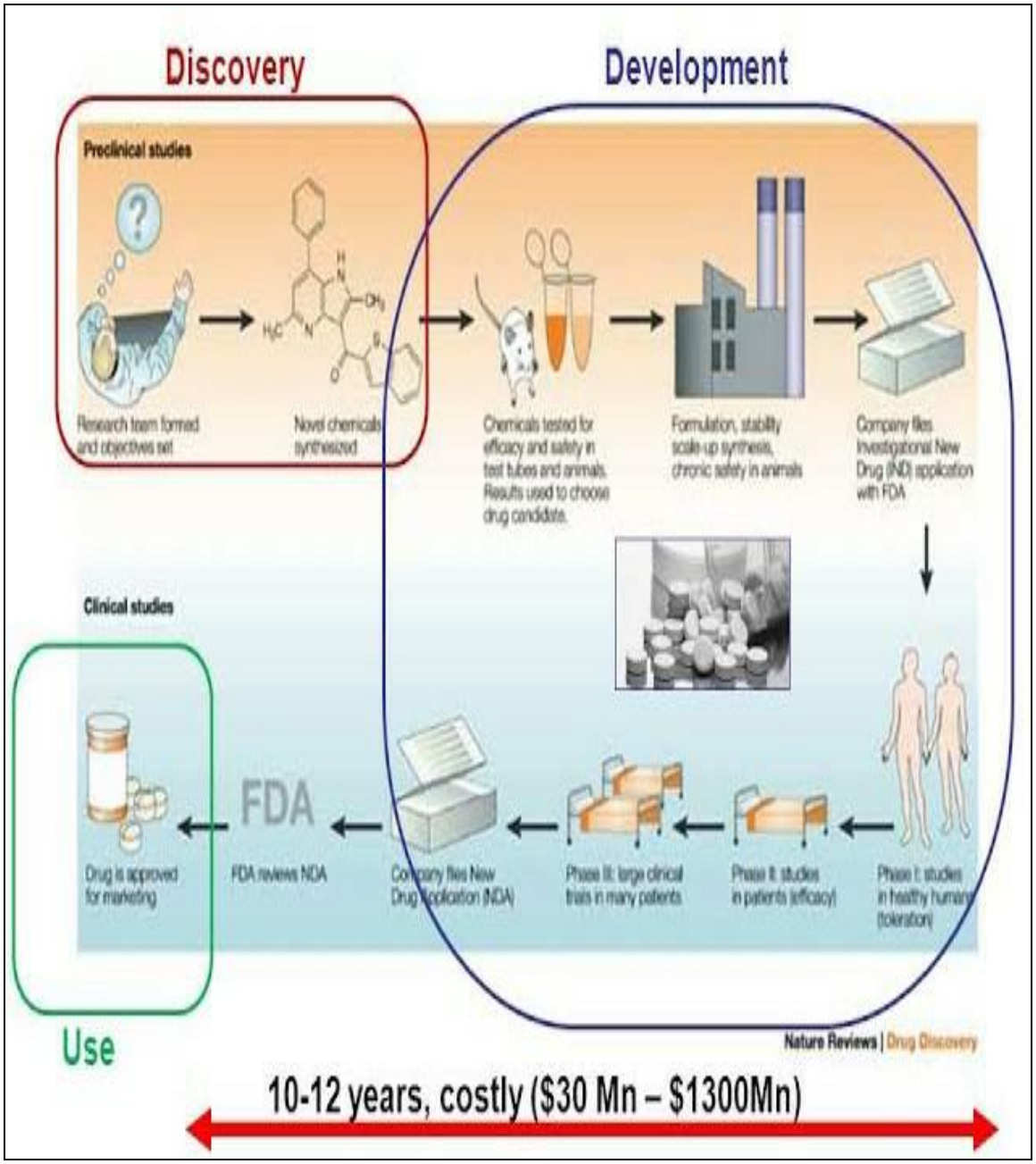
Drug discovery



Development of product/drug

In this era of increasing toxic or older medicinal use it is required to known the physicians about the development of new drug or medicine and marketed medicine. Drug development is a highly complex, competitive, costly and commercially risky process.[4]

Stages in new drug development	
Synthesis/isolation of the compound	1-2 years
Preclinical studies: screening, evaluation, pharmacokinetic and short-time toxicity testing in animals	2-4 years
Scrutiny and grant of permission for clinical trials	3-6 months
Pharmaceutical formulation' standardization of clinical/biological/immune-assay of compound	0.5-1 years
Clinical studies: phase 1, phase 2, phase 3 trials; long-term animal toxicity testing	3-10 years
Review and grant of marketing permission	0.5-2 years
Post marketing surveillance	Phase 4 studies



The pharmaceutical R & D process

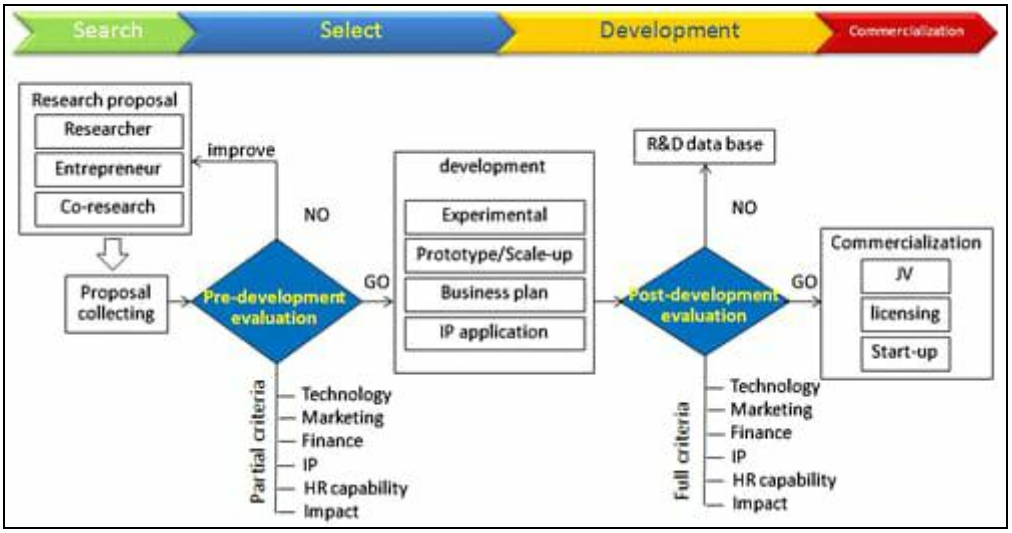
R & D Evaluation and Its benefits

R & D commercialization

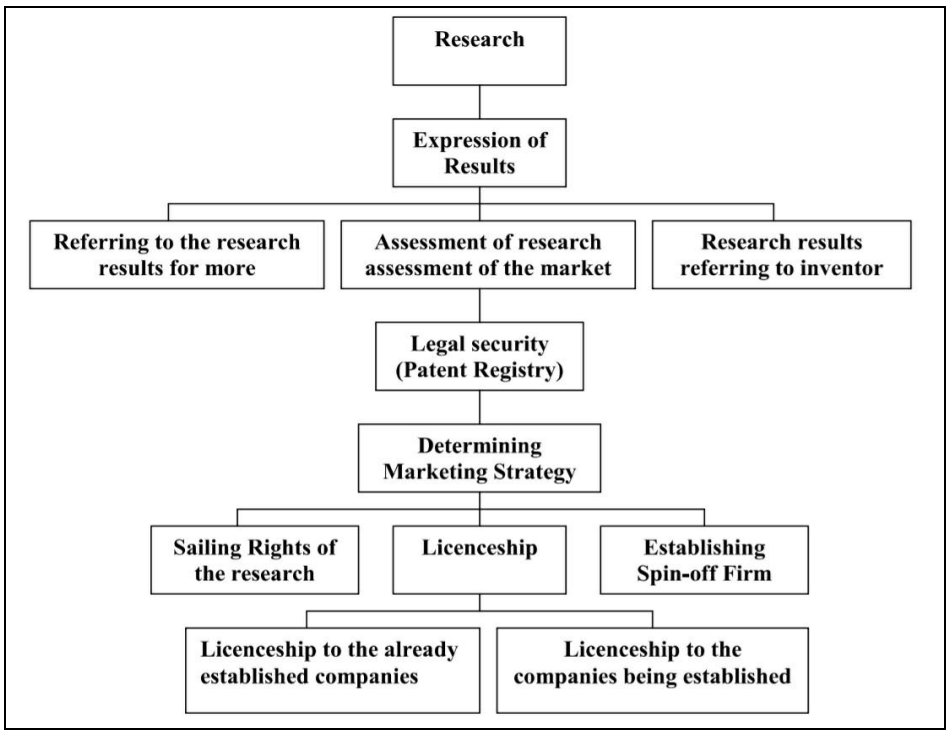
R & D and Enovation helps to increase the effectiveness, growth, quality and competitive advantage. The policy to support the R&D is done through the governmental research institute.

2.1. Commercialization prosses

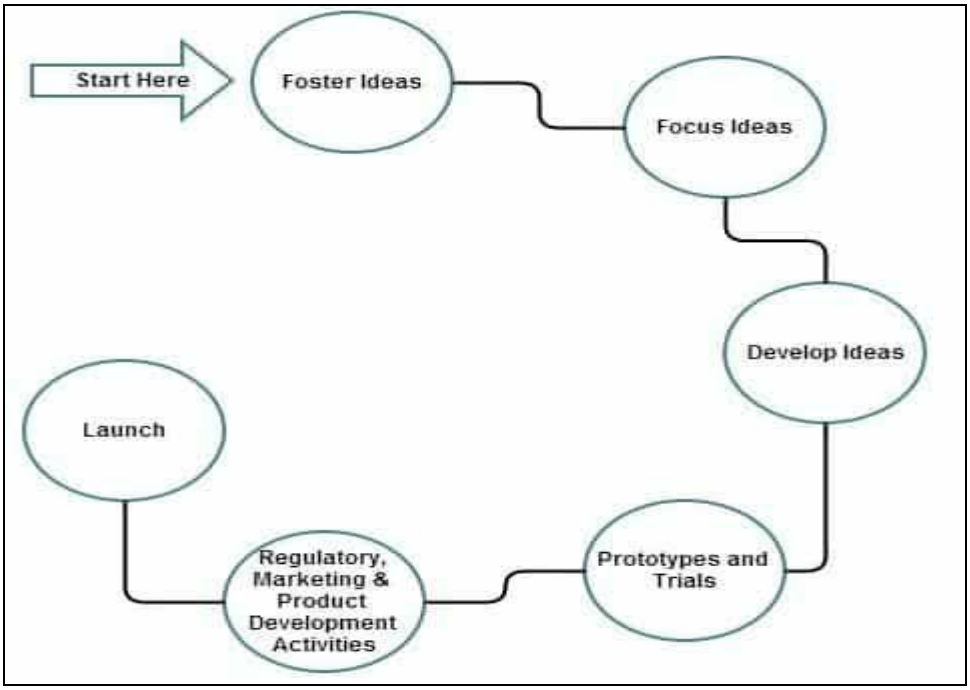
According to literature review the R&D commercialization process consist following stages;



1. **Research**



2. **Select:** The selection of potential R&D commercialization capability to create the business matching and draft of legal agreement.
3. **Development:** in its new product developed.



4. **Commercialization:** all agreements and documents are collected to negotiate the compensation, when the innovation is launched to market. The profit dividend got from research institute is used for developing the R&D of further generation.

Increasing program manager information on program performance

R&D program managers are close to the projects and activities that make up their programs. The more reliable the those responsible for research is the more likely to prove that they value money, the more reliable the issue of resources.[5]

How this booklet can help you get the information you need

This booklet is part of the planning and evaluating Health Information Outreach Project series designed to supplement measuring the difference it is the guide to planning and evaluating health information outreach.[6] This booklet provides a quick reference guide to evaluation methods for R&D managers in the U.S. Department of Energy's Technology Development programs

Why use a variety of evaluation methods?

it takes a variety of methods to answer different types of project management questions. By using these and other methods can help to the R&D program managers for better understanding and managing his program to achieve its goal.

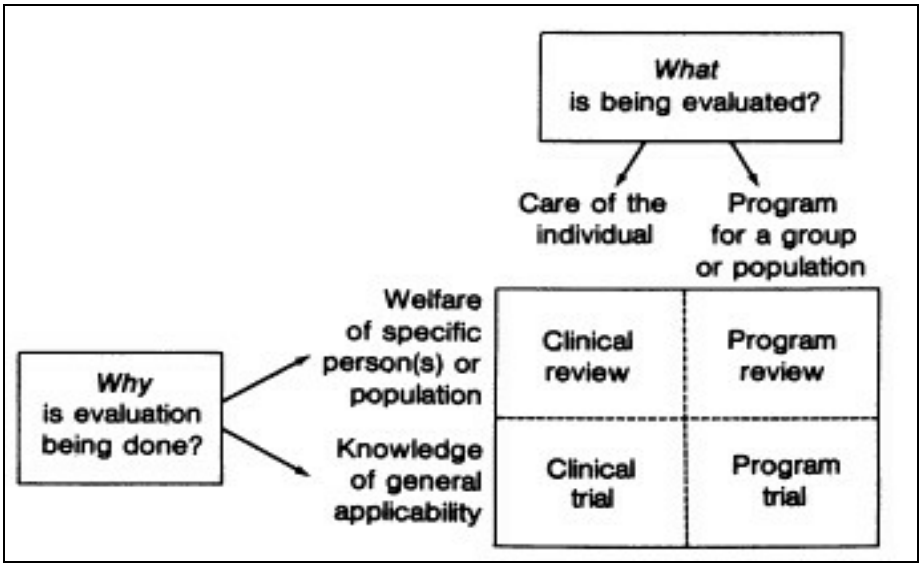


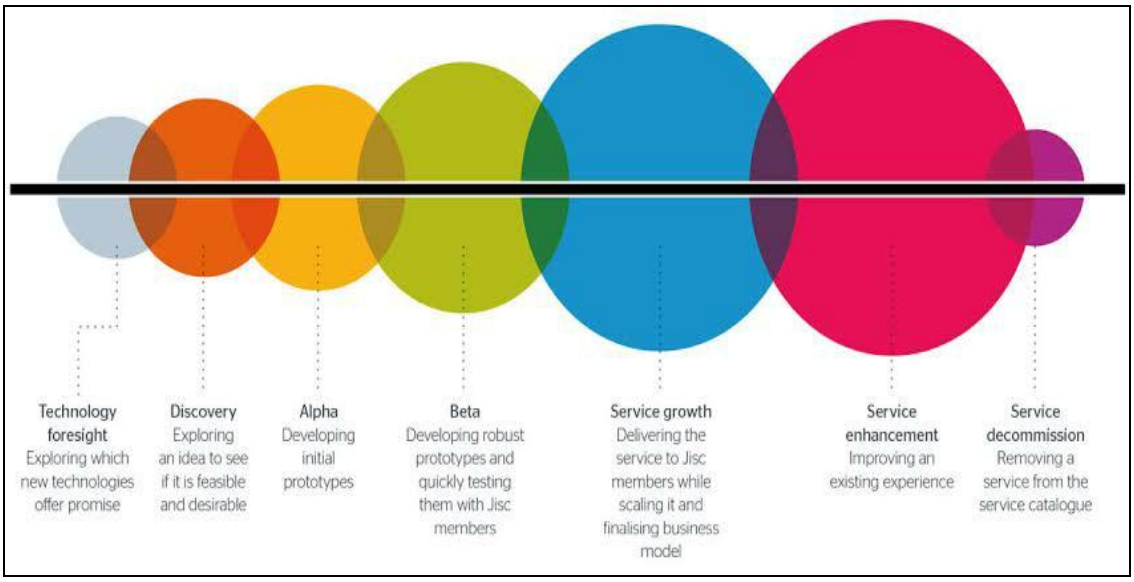
Fig: Type of evaluation.

Manufacturing

Today day by day increase the widespread of the research on technological innovation.

The relationship between learning, R & D and manufacturing Capabilities and Technological learning

TICs are assets which facilitate the development of new products application of new process technologies, and the ability to appropriately adapt to unexpected technological uncertainties. TICs are suggested throughout the literature a common view highlights that these resources e.g. knowledge, skills, products, processes, technology, experience, and organization not only incorporate internal elements of the firm.



Manufacturing and R&D haw a capability to build the basis for systemic innovation strategy by establishing appropriate routine, accumulating skill internally and by developing the ability to learn selectively, their effect n technological learning is investigated. TIM is dimensions namely; i-) learning. ii-) R&D and iii-) manufacturing capabilities which have a common function of screening the external environment, adapting to internal process accordingly and concurrent feedback mechanism which enables to continuous improvement / development, act in strengthening technological learning.[30-31]

The ability of firm's production system by increasing cost efficiency, flexibility, delivery and quality to compete in market. Manufacturing capability which is embedded in the technological systems of firms is often regarded as the ability to convert R&D outcome to commercialized products and services.

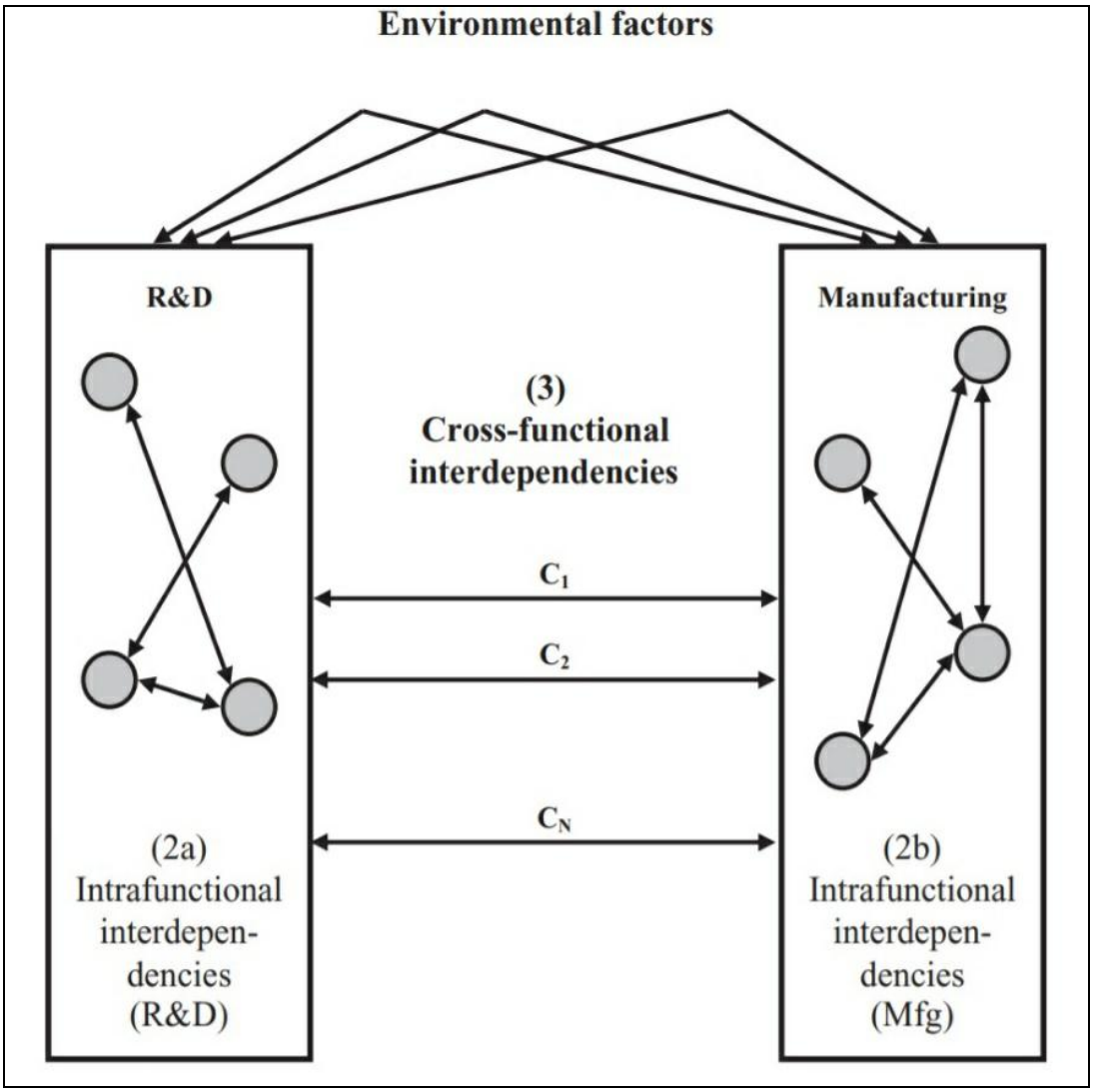


Fig: Different views on location decisions.

Technological learning positively influences firm performance

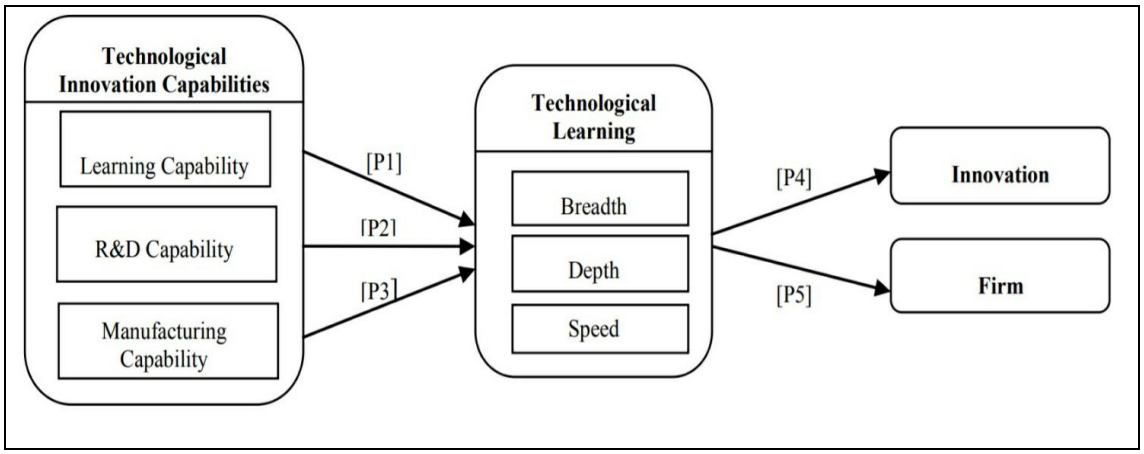
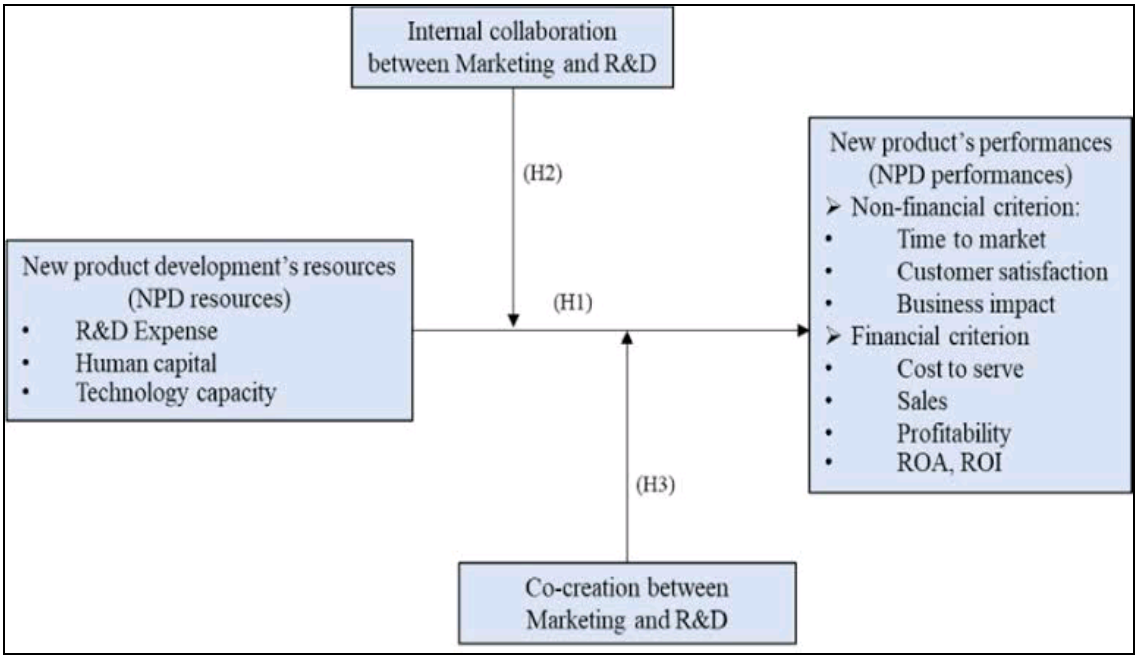


Fig: Conceptual model.

Relationship between R & D and marketing

To achieve the success in todays marketplace most of the corporations or industry's helps to the marketing and R&D functions. For the long-term profitability, it required the repeated renewal of product. Wealth, materials, information and technical expertise flow across the borders between functional areas to continue developing product.[7-8] The first and foremost step taken to establish a better working relationship between marketing and r & d is to assure general management of the importance of scientific, market and sustained.

The subtle interchange of communication between marketing and research Marketing - r & d communication should not be introduced when a new product is coming up at the time of market introduction but instead when a research programme is planned to create a market kit. The need to manage the flow in marketing and R&D borders was recognized as interface.[7,9,10] At a more detailed level, combining retrospective interviews and project paper trail analysis, a study of nine pairs of successful and failed new product projects in industrial, consumer and service firms has been undertaken.[11]



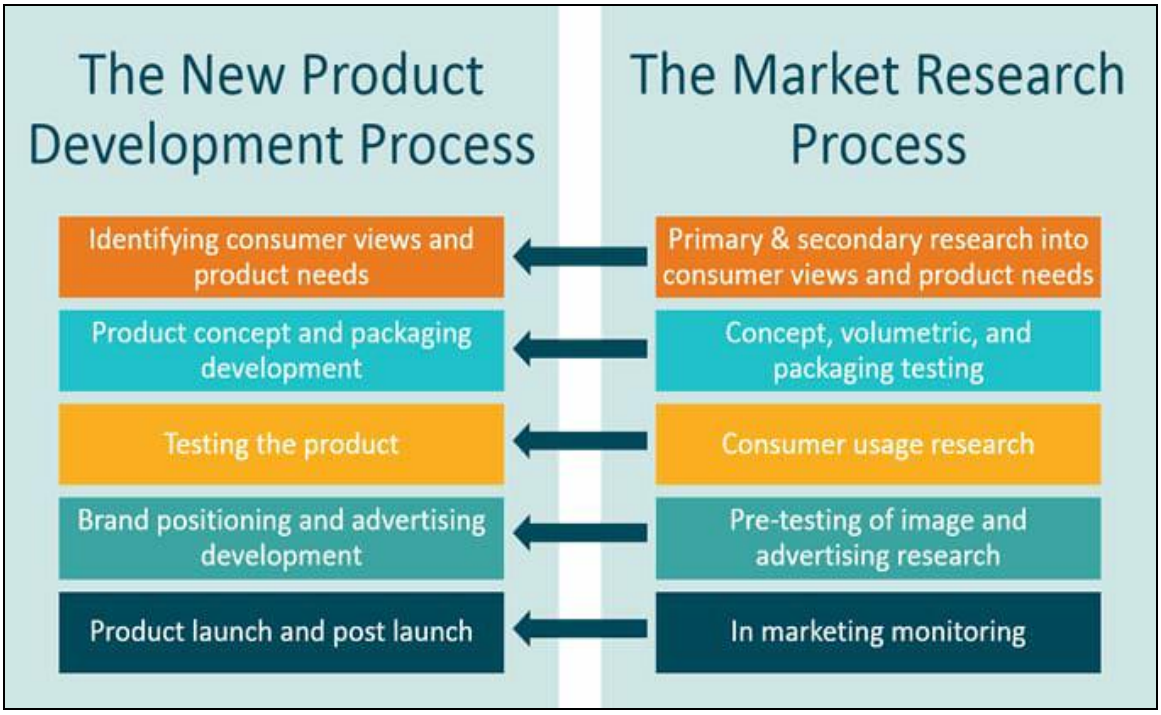
When marketing R&D focused on understanding and work on customer needs, then it produced more perfect or good product and also make their job easier. R&D employs work on the data provided by the marketer (MR), this data is most useful in developing and launching new product or idea and in the development of safety, quality, productivity and reduction of the production cost of the existent molecule or product.

R & D-Marketing integration

After the 1990s, many scholars, well-informed and enterprises focused on the work to the integration of the organizational structure.[12-15] If the different specializations in the enterprises are work separately then it will be not sufficient for high performance, therefore specialized department should be integrated or combinedly work to complete overall target.[16] It is showing the effect on social performance of the business. Today day by day new product introduced in market with notable result and also technical level of industry is increase Therefore, marketing competition will be change and enterprises can get well chances to develop well.[17] R & D employs are helps to enterprises in this development proses.

within the Rothwell's five generation of innovation model in the third generation, interaction within the different element or department such as R&D, marketing, manufacturing and quality control is recognized and importance of "feedback loops" is highlighted. The four different segments in the innovation proses represent divisions of finance, marketing and

sales, research and development. This thesis will investigate and analyze basic factor in order to plane and provide comprehensive conclusion for R & D companies with lagging factors in marketing and Seles.[18]



Barriers to Communication and Cooperation:

There are many barriers to achieving cooperation and communication between marketing and R & D.[19-20]

Lack of reliability of published data.[22]

Suboptimal PK is the biopharmaceutical issues.[23]

Concept of target-based drug discovery with related advanced complexity of target selection, a competition for ownership goal and complex process of target verification.[24-28]

1. **Personality**
2. **Cultural Thought-Worlds**
3. **Language**
4. **Organizational Responsibilities**
5. **Physical Barriers**

Changing R & D models in research based pharmaceutical companies

The cumulative investment in R&D in this sector it is the evidence of the importance of research and development for pharmaceutical industry. The total worldwide in

pharmaceutical companies and biotechnology companies R&D spend is increased by 33 billion (2006-2015).[21] The reduced R&D efficiency makes it necessary for pharma companies to change or make the R&D concept clear.

Research alliance concepts are applicable for organizations that are more open to fundamental changes in their R&D models Gyan leveraged shire's strategy recommends that the r & d concept can be converted into improved performance.[29]

CONCLUSION

R&D is the most important part in health care service. We are observed that the day by day we introduced with new disease, we did not haw any treatment at a time R&D department play a major role in health care service. R&D have a important role in pharma sector for improvement of action of API and introduce the new drug/API.

R&D is work on the basis of decrease the toxicity and increase the therapeutic effect of API/drug/medicine.

For the lunching of new drug/medicine it is required the R&D will be prove that the drug is safe for use for consumption.

R&D department helps to the many department in pharma sector by providing many helpful information.

ACKNOWLEDGEMENT

Authors are thankful to Hon Shri. Padmatai Shinde, President Shriram Dhyan Shikshan Prasarak Mandal, Vaijapur.

MS India for Providing the necessary facilities in the Institute and for their constant support and encouragement.

REFERENCES

1. Fisher LD. Advances in clinical trials in the twentieth century. Annual Review of Public Health, 1999; 20: 109 – 124.
2. Harrington DP. The randomized clinical trial. Journal of the American Statistical Association, 2000; 95: 312–315.

3. Smith R. Fifty years of randomized controlled trials. British Medical Journal, 1998; 317: 1166.
4. Essential of medical pharmacology, eighth edition, KD Tripathi, 2019: 87-91.
2. David Austin and Molly Macauley, “A Quality-Adjusted Cost Index for Estimating Future Consumer Surplus from Innovation,” Resources for the Future, Discussion Paper, 1998; 98-45.
3. Burroughs C. Measuring the difference: Guide to planning and evaluating health information outreach [Internet]. Seattle, WA: Network of the National Library of Medicine, Pacific Northwest Region, 2000; 28: 2012.
4. Rubenstein, A.H., A.K. Chakrabarti, R.D. O'Keefe, W.E. Souder and H.C. Young, "Factors Influencing Innovation Success at the Project Level," Research Management, 1976; XX:3: 15-20.
5. Ruekert, Robert W., and Orville C. Walker "Marketing's Interaction with Other Functional Units: A Conceptual Framework and Empirical Evidence," Journal of Marketing, 1987; 51: 1-19.
6. "An Exploratory Study of the Coordinating Mechanisms Between R&D and Marketing as an Influence on the Innovation Process," National Science Foundation Final Report #, 1977; 26: 75-17195.
7. Managing New Product Innovations, Lexington MA: Lexington Books, and Elko Kleinschmidt (1987), "New Products: What Separates Winners from Losers?," Journal of Product Innovation Management, 1987; 4: 169-184.
8. dyer and X. M. Song, “The Impact of Strategy on Conflict: A Cross-National Comparative Study of US and Japanese Firms,” Journal of International Business Studies, 1997; 28(3): 467-493. http://dx.doi.org/10.1057/palgrave.jibs.8490108.
9. X. M. Song, M. M. Montoya-Weiss and J. B. Schmidt, “Antecedents andConsequences of Cross-Functional Cooperation: A Comparison of R&D, Manufacturing, and Marketing Perspectives,” The Journal of Product Innovation Management, 1997; 14(1): 35-47. http://dx.doi.org/10.1111/1540-5885.1410035 [Citation Time(s):2].
10. X. M. Song, R. J. Thieme and J. H. Xie, “The Impact of Cross-Functional Joint Involvement across Product Development Stages: An Exploratory Study,” The Journal of Product Innovation Management, 1998; 15(4): 289-304. http://dx.doi.org/10.1016/S0737-6782 (97)00108-2.

11. M. G. Enz and D. M. Lambert, “Using Cross-Functional, Cross-Firm Teams to Co-Create Value: The Role of Financial Measures,” Industrial Marketing Management, 2012; 41(3): 495-507. http://dx.doi.org/10.1016/j.indmarman.2011.06.041.
12. S. Sarin and C. McDermott, “The Effect of Team Leader Characteristics on Learning, Knowledge Application, and Performance of Cross-Functional New Product Development Teams,” Decision Sciences, 2003; 34(4): 707-739. http://dx.doi.org/10.1111/j.1540-5414.2003.02350.
13. Rothwell, R. Towards the Fifth-generation Innovation Process. International Marketing Review, 1994; 11: 1. [Online] Available at: [Last accessed 2014-03-14].
14. "Disharmony Between R&D and Marketing," Industrial Marketing Management, 1981; 10(1): 67-73. (January-February).
15. and Alok K. Chakrabarti "The R&D/Marketing Interface: Results from an Empirical Study of Innovation Projects," IEEE Transactions on Engineering Management, EM, 1978; 25(4): 88-93.
16. Prinz F, et al. Believe it or not: how much can we rely on published data on potential drug targets? Nat Rev Drug Discov, 2011; 10: 712–3.
17. Kola I, Landis J. Can the pharmaceutical industry reduce attrition rates? Nat Rev Drug Discov, 2004; 3: 711–6.
18. Bergren R, et al. Outlook for the next 5 years in drug innovation. Nat Rev Drug Discov, 2012; 11: 435–6.
19. Agarwal P. Novelty in the target landscape of the pharmaceutical industry. Nat Rev Drug Discov, 2013; 12: 575–6.
20. Sams-Dodd F. Target-based drug discovery: is something wrong? Drug Discov Today, 2005; 10: 139–47.
21. Swinney DC, Anthony J. How were new medicines discovered? Nat Rev Drug Discov, 2011; 11: 507–19.
22. Scannell JW, et al. Diagnosing the decline in pharmaceutical R&D efficiency. Nat Rev Drug Discov, 2012; 11: 191–200.
23. Schuhmacher A, et al. Models for open innovation in the pharmaceutical industry. Drug Discov Today, 2013; 18: 1133–7.
24. European Union. Report on the EU’s R&D deficit and innovation policy. Knowledge for Growth Group. Ferdows, K. (1989). Mapping international factory networks. In K. Ferdows (Ed.), Managing international manufacturing Amsterdam: Elsevier Science Publishers, 2007; 3–21.

25. Breznitz, D. Innovation and the state: Political choice and strategies for growth in Israel, Taiwan and Ireland. New Haven: Yale University Press, 2007.
26. Semerjian, Hratch G., Deputy Director, National Institute of Standards and Technology. IRI ROR 04-03 Subcommittee Meeting, 2004.