CHAPTER – III

Department of Biotechnology

3.1 Management of Projects under Medical Biotechnology Programme

The Department of Biotechnology did not effectively manage the execution of its Medical Biotechnology programme. Critical processes such as assessment of project proposals, ensuring compliance to mandatory safety protocols, periodic monitoring of projects and timely evaluation of all completed projects was not done. The number of publications in high impact journals was very low, indicating poor quality of the projects. Financial management needed to be improved. Even after disbursement of ₹ 1203.40 crore on projects under Medical Biotechnology Programme, only one patent has been granted with no technology transfer, indicating poor planning and outcomes of the projects for translational research in the area of improving human health and wellness.

3.1.1 Introduction

The Department of Biotechnology (Department) was set-up under Ministry of Science and Technology to achieve excellence in the promotion of biotechnology in the country with the mandate, inter alia, to promote large scale use of biotechnology, support to research and development (R&D) and manufacturing in biotechnology. Medical Biotechnology is a programme through which the Department provides grants-in-aid to various agencies for R&D projects in the areas of biomedical engineering[49]; human developmental and disease biology; human genetics and genome; infectious and non-infectious diseases; stem cell biology; vaccine research and diagnostics; RNA technology; HIV AIDS and microbicides; neuroscience and public health, food and Nutrition. Emphasis is to be placed on building a skilled workforce as well as undertaking technology-oriented research aimed at improving lives and living of millions.

During 2012-17 Department sanctioned 793 projects and disbursed total grant of ₹ 1,203.40 crore under different sub-programmes of the medical biotechnology programme. We audited 155 projects[50] under various components of the medical biotechnology programme, which were sanctioned during 2012-17 to assess the project approvals, their implementation including the outcome, financial management

[49] *Biomedical engineering* is the application of the principles and problem-solving techniques of engineering to biology and medicine.

[50] All the selected projects were considered as completed projects corresponding to their sanctioned duration. Among these projects only 1 (one) project was 'foreclosed' due to undue delay in implementation.

and monitoring. Our findings on these aspects are discussed in the following paragraphs.

3.1.2 Project approvals

A. Absence of Peer Review recommendation on project proposal

The project proposal is to be sent to external experts in related field of research for peer review. We observed that in 41 (26 per cent) projects out of 155 projects, no peer review by the external experts was done. This significant gap indicates lack of expert guidance on the usefulness and viability of these projects, before these projects were taken up.

The Department in its reply (April 2022) stated that all projects are sent for peer review but on several occasions, no comments are received. As the project review process is time-bound, the projects are subsequently discussed and recommended, based on comments of the Technical Expert Committee/ relevant Program-specific Committee.

The reply is not acceptable, as the Department had bypassed the mandatory peer review process for evaluation of the project proposal before submitting the same to Expert Committee/Task Force. As such, the department had no expert guidance on the viability/usefulness of these projects.

B. Non-obtaining of Statutory Clearances

Medical biotechnology research project involving hazardous microorganisms, experiments on animals, participation of human beings, stem cell related research activities, etc., require certain statutory approvals before commencement. We observed in many of the selected projects, these prior approvals were not submitted by the project implementing agencies, as shown in **Table-3.1.**

Table 3.1: Statutory approvals for projects

Sl. No.	Nature of approval	No of projects in which approval not obtained
1.	Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998[51] requires that an Institutional Animals Ethics Committee be constituted for the purpose of control and supervision of experiments on animals performed in an establishment[52].	13
2.	National Ethical Guidelines for Biomedical Research, 2006 requires that institution carrying out research activities involving human participants to	14

[51] Experimentation on animal in the course of medical research and education is covered under provisions of "Prevention of Cruelty of Animal Act, 1960".

[52] To secure that every experiment on animals should be performed by and under supervision of a person duly qualified in that regard and with due care and humanity. Institutional Animals Ethics Committee (IAEC) reviews and approves all types of protocols for research involving small animal experimentation before the start of research.

Sl. No.	Nature of approval	No of projects in which approval not obtained
	establish an Ethical Committee[53] for ensuring an appropriate and sustainable system for ethical reviewing and monitoring.	
3.	Rules, 1989[54] for the manufacture, use/import/export and storage of hazardous microorganisms/ genetically engineered organisms or cells requires establishing an Institutional Bio-safety Committee for ensuring all activities are compliant with these rules.	13
4.	National Guideline for Stem Cell Research, 2013 requires institutes engaged in stem cell research to establish an Institutional Committee for Stem Cell Research to ensure that review, approval, and monitoring of all research projects in the field of stem cell research is done rigorously and effectively.	3

Audit observed that the Department approved these projects without ensuring that the mandatory pre-requisites had been fulfilled by the project implementing agencies. As such, the Department had no assurance that the projects would be implemented with due regard to ethical principles for animal and human trials or safety of the researchers who would handle hazardous microorganisms.

The Department stated (April 2022) that the host institutions are advised to follow the statutory guidelines and obtain the necessary clearances, as applicable while sanctioning the project. The sanction order incorporates clauses to that effect, to ensure compliance by the host institutions. The reply is not tenable, as mere incorporation of clauses in sanction order is not enough to monitor ethical principles by the implementing agencies. Violation of ethical principles would lead to vitiating the project result, leading to unviability of the project.

3.1.3 Project Implementation

The primary objective of the programme was technology-oriented research along with building a skilled workforce to meet the national requirements. However, we observed significant gaps in implementation of these projects against the set objectives. Some of these issues have been discussed below:

3.1.3.1 Development and Commercialization of technologies

National Biotechnology Development Strategy (2015-20) of the Department stressed on innovation for socially relevant biotech products with primary thrust on

[53] It is required for all research proposals on biomedical, social and behavioral science research for health involving human participants, their biological material and data to be reviewed and approved by the appropriately constituted EC to safeguard the dignity, rights, safety and well-being of all research participants.

[54] Rules for the manufacture, use/import/export and storage of hazardous microorganisms/ genetically engineered organisms or cells, 1989 (commonly referred as Rules, 1989) notified by the Ministry of Environment, Forest and Climate Change (MoEF&CC), Government of India under the Environment (Protection) Act (1986).

translational research[55] and commercialization of technologies. Biotechnology Patent Facilitation Cell (BPFC) was established (July 1999) by the Department to bridge the gap between the research outcome and its use for the benefit of the stakeholders by facilitating patent filing through BPFC on priority basis.

We observed that out of 107 projects in which project completion reports were submitted, 16 provisional patents were filed in 11 projects, of which only one[56] patent had been granted. Further, only two[57] patents were filed through BPFC which indicates the sub-optimal usage of the facilitation centre.

The Department stated that BPFC was set up to facilitate the patent filing process for patents and its use is not mandatory. The reply is not acceptable, as the Department established BPFC with an aim to provide a single window awareness-cum-facilitation mechanism about Intellectual Property Rights (IPRs) among the scientists and researchers. Non usage of BPFC would lead to the Department being unaware of development in the area of IPRs and thus, unable to bring important issues to the attention of policy makers, scientists, biotech industries etc.

Further, the Department was silent about the poor rate of success of patents filed from projects. Since this was a major thrust area, the Department's lack of success in this area would impact its emphasis on translational research. Non commercialisation of technologies also had a direct impact on broader objectives of the scheme for promoting technology-oriented and translational research in the area of human health and wellness.

3.1.3.2 Publications

Impact Factor (IF)[58] is generally used as an indicator to evaluate the relative importance of a journal in its field. In most of the scientific fields, impact factor of 10 or more is considered excellent.

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[55] Translational research is research aimed at translating results in basic research into results that directly benefit humans.

[56] One American patent in the project "Translational Research on root knot Nematode tolerant RNAi transgenics based on vital parasite gene targets from validation to proof-of concept to selection of event (s) in the field under confined conditions".

[57] (i) One Indian patent in the project "Translational Research on root knot Nematode tolerant RNAi transgenics based on vital parasite gene targets from validation to proof-of concept to selection of event (s) in the field under confined conditions. (ii) One American patent in the project "Translational Research on root knot Nematode tolerant RNAi transgenics based on vital parasite gene targets from validation to proof-of concept to selection of event (s) in the field under confined conditions.

[58] The **impact factor (IF)** is a measure of the frequency with which the article in a journal has been cited in a particular year. The calculation is based on a two-year period and involves dividing the number of times articles were cited by the number of articles that are citable. **Calculation of 2010 IF of a journal:** A = the number of times articles published in 2008 and 2009 were cited by indexed journals during 2010. B = the total number of "citable items" published in 2008 and 2009. A/B = 2010 impact factor

We observed that in 20 projects, no publications were made in any peer reviewed journal[59]. In 66 projects a total number of 261 publications were made in peer reviewed journals out of which IF of 242 publications were available. Analysis of the IF of these 242 publications is given in **Table-3.2**:

Table 3.2: Impact factor of publications

IF Range[60]	0-1	1-2	2-3	3-4	4-5	5-6	6-7	7-8	8-9	9-10	10-11	>11	Total
Number of Publication	16	23	46	56	43	23	15	02	06	07	00	05	242
Percentage	07	10	19	23	18	10	06	01	02	03	00	02	--

It can be seen from the table that only five publications had an IF of more than 10, whereas 75 per cent of publications were made in journal of IF less than five which indicates less quality of evaluation of research work.

The Department stated (April 2022) that publications in high Impact Factor journals, although desirable, is not essential as the same is dependent on a number of variables and IF is just one of the measures to assess the quality of the journal and may not necessarily be indicative of the quality of the work. The reply should be viewed in the light of the fact that major achievements of a scientific research organisation are reflected in its research publications. High impact factor journals are usually considered more prestigious than lower-impact journals, subsequently**,** Impact factor indicates standing of the journal in the world and is indicative of the quality of research outputs.

3.1.4 Financial management of projects

3.1.4.1 Non-adherence of timeline for final settlement of account

The norms for Extramural research Projects funded by the Department stipulate (July 2015) that on acceptance of the Project Completion Report, the Final Settlement of Accounts (FSA) of the project is to be completed within nine months from the completion of project. Further, terms and conditions of grants stipulated that in case the whole or a part of the amount of grants-in-aid is being refunded, an interest at the rate of 10 per cent per annum thereon shall be recovered.

In 142 projects, the final settlement of accounts was either not done or had been done after nine months from completion of project. In 91 percent of projects, the Department could not adhere to stipulated timeline for final settlement of accounts. Thus, the Department did not assess total amount remained unspent, if any, with the implementing agencies, which should be recovered with interest.

[59] A peer-reviewed publication is also sometimes referred to as a scholarly publication. The peer-review process subjects an author's scholarly work, research, or ideas to the scrutiny of others who are experts in the same field (peers) and is considered necessary to ensure academic scientific quality.

[60] Impact factor of 10 or greater is considered as 'excellent'. Similarly, score of 3 is flagged as 'good' and score of less than 1 is considered as 'average' (source: https://manuscriptedit.com/scholar-hangout/good-impact-factor-journal)

The Department stated (April 2022) that the final settlement of accounts (FSA) is a financial process which is often delayed for want of documents such as Utilization Certificate, Statement of Expenditure, Manpower Statement, Asset Acquired Certificate etc. from host institutes. Audit is of the view that total amount remained unspent, if any, after completion of project must be assessed in time and recovery of such amount should be made as per terms and conditions of grants.

3.1.4.2 Re-appropriation between Revenue and Capital

According to the provisions of GoI's decision (4) below Rule 10 of the Delegation of Financial Power Rules (DFPR), 1978, in the same Demand for Grants, savings in the funds provided in Revenue Section are not available for re-appropriation to meet additional requirements in the Capital Section or vice versa.

In 55 projects, re-appropriation from Capital Head to Revenue Head was done by the Department in violation of above said Rules as shown in **Table-3.3**.

Table 3.3: Re-appropriation from Capital Head to Revenue Head

Year	No. of Re-appropriation	Amount. (₹ in lakh)
2013-14	05	01.628
2014-15	11	05.539
2015-16	11	16.027
2016-17	15	41.759
2017-18	10	08.022
2018-19	03	09.965
Total	**55**	**82.94**

Thus, the sanction and expenditure of ₹ 82.94 lakh was irregular, and no action was taken to regularize these re-appropriations by the Department.

The Department stated (April 2022) that re-appropriation of funds was done with the concurrence of Department's - Integrated Finance Division (IFD). The reply is not tenable, as approval of Ministry of Finance is required for re-appropriation of funds from Capital to Revenue Heads.

3.1.5 Project Monitoring

3.1.5.1 Non monitoring of project at required intervals

The Task Force/Project monitoring Committee[61] of the Department was to monitor the project at least once in a year. The Department was also to designate experts to visit the implementing agencies periodically for reviewing the progress and for suggesting

[61] The Task Force/Project monitoring Committee/TEC had been constituted with a composition of one chairperson, one co-chairperson, having 8-10 members of the respective field and a member secretary from Department. Generally, TEC evaluate the proposal for taking them to next stage i.e., short listing of proposal for presentation, recommending projects to STAG committee for consideration. It also review /monitor ongoing, completed projects with total sanctioned budget up to ₹ 5.00 crore.

measures for early realisation of project objectives. We observed that these conditions were not fulfilled in many projects, as discussed below.

Implementing agencies of all the 155 projects did not submit half-yearly project progress reports to the Department. Instead, the progress reports were submitted annually, which was not in accordance with the terms and conditions of the grants. The Department stated (November 2019) that as per normal practice, progress of almost all projects were monitored on yearly basis. The reply is not acceptable, as the terms and conditions of the grants required that progress reports be submitted on half yearly basis, which were to be reviewed by the Department at least once in a year. Delayed monitoring has consequential effect in achieving the project outcome and does not leave any scope for course correction.

We further observed that Department did not conduct site visits in any of these 155 projects. Department stated (in April 2022) that site visits are also carried out based on the specific recommendations of the Expert Committee during review of the progress of the projects. However, the Department could not provide any documents in support of site visits carried out. As such, due to lack of timely monitoring, the department was unable to undertake course corrections, or provide feedback to the working of the projects.

3.1.5.2 Evaluation of completed projects

The norms for Individual Centric Extramural Research Projects (July 2015)[62] funded by the Department stipulate that on conclusion of project, Project Completion Report (PCR) is to be submitted by Project Investigator (PI) within six months from the completion of the project. Task Force or Expert Committee is required to complete the evaluation of the PCR within nine months from the completion of project. We observed that:

(i) In 47[63] projects PCRs were not submitted by the implementing agencies after completion of project due to which the final outcome of project was not evaluated.
(ii) Of the 107 projects in which PCRs were submitted to the Department, no evaluation was carried out by the Task Force/Expert Committee in 34 projects. Consequently, performance of these projects was not assessed.
(iii) The Task Force or Project Monitoring Committee of the Department is required to evaluate the PCRs received from the implementing agencies[64] and assign grading in five categories on the basis of performance of the projects. For 107 projects, PCRs were received by the Department. Of these, Department evaluated the performance of 73

[62] Department OM No. BT/2/2015-IFD dated 14.07.2015 sl. no. (XII)(d)
[63] Excluding one project titled "Cluster randomised controlled trial of home-based modified existent practices vs home based Ready to Use Therapeutic Food (RUTF) for management of uncomplicated Severe Acute Malnutrition in Indian urban" was foreclosed. Total duration of the project was 3 years and the project was foreclosed after 2 year of commencement due to undue delay in implementation of the project.
[64] As per terms of reference of the Technical Expert Committee.

projects but assigned grading in 62 projects only. The grading assigned by task force on the performance of these projects is shown in **Table-3.4**.

Table 3.4: Evaluation of projects by Department

Grading	No. of Projects	Percentage
Outstanding/Excellent	08	05
Very Good	12	07
Good	13	08
Satisfactory	28	18
Not satisfactory	01	01

From the table it can be seen that only five percent of projects were outstanding while almost 18 percent of the total 155 projects performed satisfactorily and in 15 per cent projects (i.e., 11 projects out of 73 evaluated projects) the quality of project output could not be ascertained.

The Department stated (April 2022) that in some cases, the compilation and interpretation of the findings take time which may result in delay in submission of the completion report. The reply is not tenable as the Department should ensure timely submission of PCRs from implementing agencies to avoid delay for evaluation of the completion report. Lack of PCRs would inhibit the department from assessing the quality of the research projects.

3.1.6 Conclusion

Department of Biotechnology undertakes the Medical Biotechnology Programme with the aim of promoting technology-oriented/translational research in the area of human health and wellness. Audit observed deficiencies in the management of projects sanctioned by the Department under this programme. Many projects were sanctioned for implementation without ensuring compliance to prescribed procedures such as review of project proposals by experts and observance of mandatory protocols for undertaking such research. The progress of projects was not monitored half yearly, as stipulated. Of the 154 completed projects sampled in audit, completion reports were received for only 107 projects, of which the department was able to assess only 73 projects.

The overall outcomes of the projects were also not found to be commensurate with the envisaged objective of the programme. From the 155 sampled projects, only 1 patent was obtained. By the Department's own assessment, only 12 per cent (of the project assessed by the Department) were graded as outstanding/very good. In this scenario, achievement under the Medical Biotechnology programme fell short of the objective of fostering technology-oriented/translational research in the area of human health and wellness.

Audit also observed deficiencies in financial management of the sanctioned projects. There were delay in final settlement of the accounts of completed projects and irregular re-appropriation of project grants to the extent of ₹ 82.94 lakh.

Incomplete assessment of project proposals and irregular monitoring of ongoing projects vitiated the responsibility of the Department towards ensuring that only the most viable projects having a potential for significant outputs were sanctioned and implemented. Lapses in these key processes led to adverse impact on the outcomes from the projects.

Due to deficiencies in project management and poor monitoring, despite incurring ₹ 1203.40 crore on projects under the scheme, the broader objectives related to improvement of human health and wellness through translational research could not be achieved.