Guidelines for

DHR-ICMR Advanced Molecular Oncology Diagnostic Services (DIAMOnDS)

Department of Health Research
Ministry of Health and Family Welfare
New Delhi
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Establishment of DHR-ICMR Advanced Molecular Oncology Diagnostic Services (DIAMOnDS)

1. INTRODUCTION:

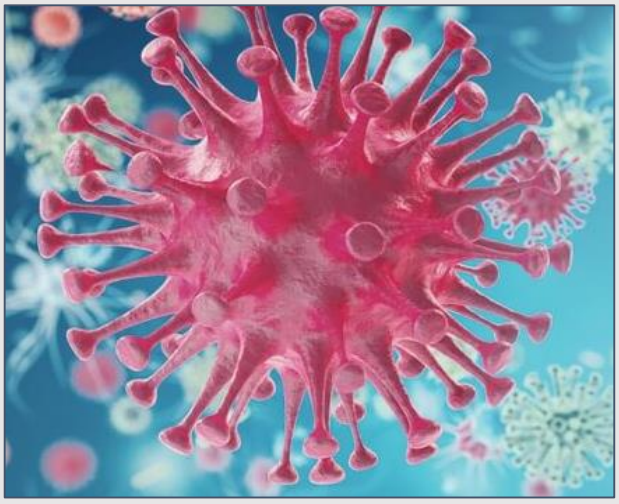
Cancer Burden in India: As per the estimates from Global burden of disease initiative 8·3% (95% uncertainty interval [UI] 7·9–8·6) of the total deaths and 5·0% (4·6–5·5) of the total DALYs in India in 2016 were due to cancer, which was double the contribution of cancer in 1990. However, the age-standardised incidence rate of cancer did not change substantially during this period. The age-standardised cancer DALY rate had a 2·6 times variation across the states of India in 2016. The ten cancers responsible for the highest proportion of cancer DALYs in India in 2016 were stomach (9·0% of the total cancer DALYs), breast (8·2%), lung (7·5%), lip and oral cavity (7·2%), pharynx other than nasopharynx (6·8%), colon and rectum (5·8%), leukaemia (5·2%), cervical (5·2%), oesophageal (4·3%), and brain and nervous system (3·5%) cancer.

In 2009, breast cancer became the most frequently diagnosed form of neoplastic disease in women in India and is now the most common cause of cancer death in the country, accounting for more than a fifth of all female cancer mortality. The age-standardised incidence rate of breast cancer increased significantly by 40·7% (95% UI 7·0–85·6) from 1990 to 2016.

Tobacco use was the leading risk factor for cancers in India to which the highest proportion (10·9%) of cancer DALYs could be attributed in 2016.Lung cancer is one of the most prevalent cancers and the leading cause of cancer-related deaths. In India, lung cancer constitutes 6.9 % of all new cancer cases and 9.3 % of all cancer-related deaths in both sexes and it is the commonest cancer and cause of cancer-related mortality in Indian men. Lung cancer comprises of two main histologic subtypes: non-small cell lung cancer (NSCLC) and small cell lung cancer (SCLC).

Cancer care services in India:

In India, most of the population does not have access to a well-organized and well-regulated cancer care system. A diagnosis of cancer often leads to catastrophic personal health expenditures. Patients with cancer generally have a poorer prognosis in India, because of relatively low cancer awareness, late diagnosis, and the lack of or inequitable access to affordable curative services compared with patients in high-income countries. The value of correct and timely reports of diagnostic and prognostic tests is paramount in selecting right treatment for cancer.



Diagnostic Research

Diagnostic Services

Rational for Establishing Zonal oncopathology Labs:

In view of the above scenario, the present proposal aims to set up zonal molecular oncopathlogy labs to provide basic as well as high-end advance diagnostic services to cancer patients and research facilities for basic, translational and clinical research. Along with the diagnosis, these labs will also be performing the research activities very actively as diagnostics and research can go hand in hand in a laboratory set-up. These labs will be named as **DHR-ICMR Advanced Molecular Oncology Diagnostic Services (DIAMOnDS).**

Aim and objectives of the DIAMOnDS project:

- Encourage and strengthen diagnostic research in the field of oncology.
- To provide free of cost oncopathology diagnostic services to cancer patients.
- Bridge the gap in the infrastructure which is inhibiting poor cancer patients in availing cancer diagnostic services by establishing DHR-ICMR Advance Molecular Oncology Diagnostic Services (DIAMOnDS) lab facilities with a view to improving the diagnostic services in the field of oncopathology.
- To ensure the geographical spread of oncopathology diagnostic services, in order to cover un-served and under-served cancer patients.
- To improve the overall health status of the population by creating evidence based application of diagnostic procedures/processes/methods through research.

2. IMPLEMENTATION PLAN:

These laboratories may be established in Medical institutions/Government Medical Colleges that will ensure the optimum utilization of facilities available there, in terms of equipment and manpower and will also provide the much required diagnostic services to the cancer patients in those areas. A two-phase, six step - pilot development model will be followed where following activities will be performed phase wise. These may be scaled up later for the entire country in the form of a research infrastructure scheme and proposed for approval in the 15th Finance commission.

1st PHASE

Step 1: Identifying institutes in four zones of India i.e. east, west, north and south to setup oncopathology labs: In each zone of the country one institute will be selected to function as **DIAMOnDS hubs** for that region. This should be a relatively well established institutes, equipped with all basic as well as the high end onco-pathology services. Whereas the other institutes (known as **DIAMOnDS centres**) in that region would be the one where the facilities are somewhere lacking and need to be further strengthened. DIAMOnDS hubs for that region would provide mentorship and guidance to the other DIAMOnDS labs established in the zone.

Step 2: Providing facilities, infrastructure and manpower: All institutes selected under the DIAMOnDS project will be provided funds from DHR for Recurring, non-recurring, contingency, manpower and travel including overheads. In the first round of project implementation, funds will be provided to perform diagnostic and prognostic tests related to the cancer of highest prevalence in India in male (lung cancer) and female (breast cancer).

Step 3: Establishing and standardizing the tests: The nodal officers at the selected centres will be responsible for establishing and standardizing the tests related to breast and lung cancer and developing a fast and digital system for providing the test reports. The molecular tests to be established for breast cancer will be **ER, PR, HER2Neu** and **Ki67/Mib1,** and the tests to be established for lung cancer will be **ALK, EGFR, PDL1 and ROS rearrangements** in the first round.

2nd PHASE

Step 4: Creating awareness among the physicians, diagnostic service providers, primary health workers and patients about the facilities available at zonal oncopathology labs.

Once the facilities are established and ready to provide services, the nodal officers at each centre will ensure creating awareness among the physicians, diagnostic service providers, primary health workers and patients about the facilities available at zonal oncopathology labs.

Step 5: Networking between the health and wellness centres, primary and community healthcare centres, districts hospitals, and medical colleges for proper guided referral.

These established laboratories may be linked to health and wellness centres, primary and community healthcare centres, districts hospitals, and medical colleges for proper guided referral to receive samples for tests.

Step 6: Monitoring and evaluation of services for assessment and improvements.

Third party assessment of performance may be done to ensure the quality of services being provided at each centre and the feedbacks will be utilized to make further improvements.

3. PROPOSED OUTCOME:

The project will help delivering the much required diagnostic services to cancer patients which in turn will ensure timely treatment. Regional variation in cancer incidence and mortality is driven by multiple factor. As the centres are being established in four different zones of India along with a central place like New Delhi, this study may provide some indication of the proportion of cancers that could be prevented by modifying specific harmful lifestyle or environmental factors in different regions of India which can become the area of further research.

4. EXPERT PANEL FOR DIAMONDS:

A high level panel of experts, consisting of Medical Oncologists, Pathologists, Molecular Biologists, epidemiologists and policy makers has been set up to oversee the functioning of DIAMOnDS. Composition of the expert panel as approved by Hon'ble HFM is as given below:

1. Prof. Balram Bhargava, Secretary-DHR and DG-ICMR (Chairperson)
2. Dr. Lalit Kumar, Prof & HoD, Dept. of Medical Oncology, AIIMS- (Vice Chairperson)
3. Dr. C.S. Pramesh, Director, TATA Memorial Hospital, Mumbai, (Member)
4. Dr. Sudeep Gupta, ACTREC, Mumbai, (Member)
5. Dr Dharmendra Singh Gangwar, AS & FA, IFD, New Delhi (Member)
6. Dr. Chitra Sarkar, Prof. Dept. of Pathology, AIIMS, (Member)
7. Dr. Usha Agarwal, Scientist, NIOP-ICMR, New Delhi, (Member)
8. Dr. Prashant Mathur, Director, NCDIR, Bengaluru. (Member)
9. Dr. Tanvir Kaur, Scientist, ICMR, New Delhi, (Member)

6. FUND RELEASE:

Funds would be released to the concerned institutes/organizations annually through DHR for three years.

7. PROJECT MANAGEMENT:

DIAMOnDS project will be managed by a team at DHR to be manned by contractual staff supervised by concerned Joint Secretary with overall command under Secretary DHR.

8. MONITORING MECHANSISM:

The nodal in charge of DIAMOnDS lab as appointed by the head of the institute/medical college will be responsible for taking care of all DIAMOnDS lab at that institute/medical college with the overall command under the head of the institute/medical college. All institutes funded under the DIAMOnDS project would be required to present their progress annually/biannually to the expert committee of DIAMOnDS. Funds for the next year will be released only after the progress of the previous year was found satisfactory. DHR team can also make visit to the funded institutes for monitoring if required. The 2nd instalment of the year would be released based on the submission of duly certified Utilization Certificate (UC), along with the item-wise statement of expenditure, for at least 70% of the previously released grant, by the nodal in charge of the DIAMOnDS lab.

9. TERMS & CONDITIONS OF FUNDING UNDER THE DIAMONDS PROJECT:

9.1 Selection of institute/medical college: Selection of institutes for establishment of DIAMOnDS lab will be made based upon the following criteria

- Institutes from each zones of the country will be recommended by the Expert committee of DIAMOnDS.

- Capacity, expertise and infrastructure available at the institute as well as the burden of cancer patients and requirement of oncopathology diagnostic services will be the criteria for consideration while making the recommendations for selecting institutes.

- In order to assess the requirements, willingness and responsiveness of the institutes recommended by the expert panel, a formal letter will be sent from DHR to seek their consent within a given timeframe.

- Final selection of the institutes to be funded under the DIAMOnDS project will be made upon receiving a consent from the institutes on first come first serve basis for that round of institute selection.

- All institutes identified to develop DIAMOnDS lab from where the consents are received late will not be considered for funding in that round but may be considered in the next round. Expert committee of DIAMOnDS will take a decision in this regard.

9.2 The grant should be utilized for the purpose for which it is intended and a utilization certificate in the prescribed proforma together with an audited statement of accounts (annexure-) should be submitted to this Ministry. All these documents should be signed by the head of the institution and countersigned by the Chartered Accountant and the original ones should be sent to the Ministry.

9.3. The grantee institution will execute a bond in the prescribed proforma with two sureties to the effect that the institution will abide by all the conditions of the grant. In the event of any failure to comply with these conditions or committing any breach of the bond, the grantee along with sureties individually and jointly will be liable to refunded to the Government the entire amount of the grant together with interest thereon. The bond should be signed on behalf of the institution by a person who is authorized to operate upon the Bank accounts and to bind the institution in accordance with its rules/ regulations for this purpose. The requirement of furnishing sureties will not be necessary if the grantee institution/ organization is a society, registered under the Societies Registration Act, 1860. The requirement of furnishing sureties will not be necessary for central and state govt. run institutions.

9.4 Conditions for NGOs: Conditions applicable to the NGOs selected for establishment of DIAMONDS labs are as follows:

- It should be a Society registered under the Indian Societies Registration Act, 1860 (Act XXI of 1860 or any such act resolved by the State) or a charitable public trust registered under any law for the time being in force.
- Private Institutions/NGO (Registered with the Department of Scientific and Industrial Research (DSIR), Govt. of India)/ recognized by DHR as a health research institute.
- Track record of having experience in providing cancer care services over a minimum period of 5 years.
- Properly constituted managing body with its powers duties and responsibilities clearly defined and laid down in a written constitution.
- Services open to all without distinction of caste, creed, religion or language.
- Having available well trained staff, infrastructure and the required managerial expertise to organize and carry out various activities under the scheme; and agreeing to abide by the guidelines and the norms of the project.

9.5 The accounts of institution receiving the grant should be open for inspection by person authorized by the Central Government and C & A.G.

9.6 The assets created out of Government grants by autonomous bodies are neither to be disposed off without the specific sanction of the Government nor likewise encumbered not utilized for an object other than the intended one. If, and when such body is dissolved the assets are to be reverted to the Government.

9.7. The grantee institution should furnish a certificate to the effect that the organisation was not/ has not been sanctioned grant-in-aid for the same purpose by another Department of Central Government during the period to which the grant relates.

9.8 Annual audited Statements of expenditure incurred by institute are to be submitted and the activity wise amount spent against allocation vis-à-vis the technical performance of the activity be analysed for timely corrective measures, as and when required.

10. MEMORANDUM OF AGREEMENT: An appropriate MOA with all the institute/NGO will be signed to ensure that the interest of the DHR and public interest is protected.

Responsibilities of institutes having a DIAMOnDS Labs (applicable to DIAMOnDS Hubs as well as Centres):

- **Memorandum of Agreement (MoA):** A bilateral Memorandum of Agreement (MOA) will be signed by Institution and Government of India before the release of financial assistance.
- **User charges:** All patients are to receive tests free of charge.
- All DIAMOnDS labs will participate in the **cancer registry programme.**
  - **Entering the data into dedicated software.**
  - **Submitting data to our data management unit.**
- All DIAMOnDS labs will **participate and promote research activities for cancer.**

Deliverables of DIAMOnDS Hubs:

- To provide mentorship and guidance for diagnosis and research to the DIAMOnDs Centres chosen in that zone.
- Should be equipped with all basic as well as the high end onco-pathology services.
- To provide the testing for referred samples for the facilities which are currently not available in their respective zones like for sequencing and FISH, as and when required.
- To start a one-year specialization course/fellowship in molecular pathology to generate skilled manpower in this field.
- To provide the observership and hands on training to the staff recruited at the DIAMOnDs Centres chosen in that zone.
- Therefore, curriculum design will be also a part of this initiative.

Deliverables of DIAMOnDS Centres:

- To have reasonable capacity in pathology to establish DIAMOnDS lab for research as well as for diagnostic services.
- To provide the required space and existing equipment for the lab services. The approximate area required for a basic molecular pathology lab should be around 2000 sq ft.
- To establish immunohistochemistry, biochemical tests and molecular pathology tests.
- DIAMOnDS Centre will be established in the existing pathology/lab medicine Department and will be directly linked with Department of medical/surgical oncology of the institute.

Data Management Centre:

National Centre for Disease Informatics and Research, (NCDIR) Bengaluru will perform as data management institute for the DIAMOnDS project with the financial assistance from Department of Health research, Ministry of Health and family welfare Govt. of India.

Role of NCDIR are defined as under:

a) To assist each DIAMOnDS lab in linking with the existing cancer registries to gather the data on cancer epidemiology.

b) To assist each DIAMOnDS lab by providing the software and training required to enter the data for cancer registries for an initial period of three years.

c) To assist in collecting, collating, and analyzing the data at regular interval.

Deliverables of NCDIR: With a view to achieving the objectives of DIAMOnDS project, the NCDIR will be having following responsibilities to discharge:

- To provide training to DIAMOnDS project staff for cancer registry data entry in to the dedicated software.
- To provide access to cancer registry software.
- To collect, collate, analyses and share the final data with DHR at regular interval.
- To help implementing the project as per the guidelines provided by the DHR.
- To constitute Local Research team, which would deliver the responsibilities of DIAMOnDS labs in consultation with the DHR.
- To submit the Utilization Certificate of NCDIR in the prescribed format as per the General Financial Rules for the funds received under the proposal.
- DHR in collaboration with the NCDIR shall regularly monitor the implementation of the activities undertaken and the output under this project.