Health Technology Assessment in India (HTAIn)

And

DHR-ICMR Advanced Molecular Oncology Diagnostic Services (DIAMOnDS)

Guidelines

(June – 2021)

Department of Health Research
Ministry of Health & Family Welfare
Government of India

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PART 1:
HEALTH TECHNOLOGY ASSESSMENT IN INDIA (HTAIn)

1. Background of the scheme

1.1. Ensuring access to effective and equitable health care for 1.34 billion population of India, within the limited resources involving current spending of just 1% of GDP on public health expenditure (as per Ministry of Finance – Press Release Posted On: 29 JAN 2021 3:45PM by PIB Delhi - https://pib.gov.in/PressReleasePage.aspx?PRID=1693225), is a great challenge and putting India within reach of the Sustainable Development Goals. Due to heavy out-of-pocket expenses on medical treatment by large proportion of population and rising cost of healthcare without corresponding increase in the government healthcare budget, there is a strong need to have a formal and institutionalized Health Technology Assessment mechanism to prioritize national health spending.

1.2. The need to establish a Medical Technology Assessment Board (MTAB) was recommended by 12th Plan Working Group on Health Research and also by the Planning Commission (now NITI Aayog) in its 12th Plan document on Social Sector. The Standing Committee of Parliament in its 56th Report on the Examination of Demand for Grant of DHR for the year 2012-13 has emphasised early setting up of MTAB. The National Health Policy, 2017 has also highlighted the importance of HTA by stating 'One important capacity with respect to introduction of new technologies and their uptake into public health programmes is health technology assessment'

1.3. Department of Health Research, therefore, decided to establish a mechanism for Health Technology Assessment for evaluation of appropriateness and cost effectiveness of available and new health technologies in the country as part of research governance mandate of the Department. The proposal approved by Department of Expenditure, MoF (Expdr.) vide ID.No.16(25)2016-EII(A) dated 16.11.2016 (F.No. V-25011/479/2016-HR). To start with, instead of creating a separate institution/body as in NICE UK or HITAP Thailand, the, it was decided that MTAB in DHR would be constituted only as an Advisory Body comprising eminent people from relevant fields, like public and private healthcare providers, academia, researchers, representatives from the MoHFW, civil society etc.

2. Objective of The Scheme

   i. To undertake HTA studies aiming at maximizing health in the population, reducing out of pocket expenditure (OOP) and reducing inequity.

  ii. To support the process of decision-making in health care at the Central and State policy level by providing reliable information based on scientific evidence.

 iii. Develop systems and mechanisms to assess new and existing health technologies by a Transparent and inclusive processes.

 iv. To appraise health interventions and technologies based on available data on resource use, cost, clinical effectiveness, and safety.

  v. To collect and analyse evidence in a systematic and reproducible way and ensure its accessibility and usefulness to inform health policy.

 vi. Disseminate research findings and resulting policy decisions to educate and empower the public to make better informed decisions for health.

3. Definitions

i. **Health Technology or Health Intervention:** Health Technology is defined as application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives. This includes pharmaceuticals, devices, procedures, and organizational systems used in the healthcare system, as well as computer-supported information systems.

ii. **Health Technology Assessment (HTA):** HTA is a multidisciplinary process that gathers policy relevant evidence about the medical (clinical effectiveness), economic (cost effectiveness), social and ethical issues related to the use of a health technology in a systematic, inclusive, transparent and robust manner to assist policy makers in decision making while formulating policies for incorporating or excluding health interventions from the health system.

iii. **Health Technology Assessment in India (HTAIn):** is an institutional body established in 2017, under the Department of Health Research (DHR), Ministry of Health & Family Welfare (MoHFW) with the approval of the Hon'ble HFM.

4. Structure of HTAIn

a) **Board**: Board is the highest decision-making body of HTAIn that endorses/appraise the TAC approved Outcomes/ Recommendation. The Board consist of Government officials, Policy experts, Clinicians etc. If required, the Board may seek clarification on any aspect of the study through comments. The Board may also look into the gaps in evidence and instruct for further research. i.e. Board can identify the area that require further research.

b) **Technical Appraisal Committee**: Technical Appraisal Committee (TAC) is a multidisciplinary body with experts drawn from different areas viz economists, clinicians, researchers, social scientists, health policy experts etc. There may be co-opted members in the TAC depending upon the study under consideration by HTAIn. The Committee is invariably headed by an eminent person. It ensures the appraisal of the study at different stages viz. topic selection, allocation, proposal development, outcome report and recommendations. TAC does the quality assurance and provides overall stewardship to the HTAIn.

c) **Technical Partners**: Technical Partners are Institutes of the Central/ State Government which have been identified by HTAIn secretariat, with regards to their capacities, expertise and previous experience in the area of HTA/ Multi-centric/ Operational research. Technical Partners are the research conducting body for HTAIn with their existing capacity/ manpower. The outcome reports of the studies conducted by technical partners are submitted to the HTAIn Secretariat for approval from the TAC and Board.

The following institutes have been identified as Technical Partners of HTAIn, so far:

    i. All India Institute of Medical Sciences (AIIMS), New Delhi.
    ii. National Institute of Medical Statistics (NIMS), New Delhi
    iii. National Health Systems Resource Centre (NHSRC), New Delhi
    iv. Public Health Foundation of India (PHFI), New Delhi
    v. Institute of Economic Growth (IEG), New Delhi
    vi. Indian Institute of Health Management Research (IIHMR), Jaipur
    vii. Indian Institute of Technology (IIT), Mumbai
    viii. National AIDS Research Institute (NARI), Pune
    ix. Indian Institute of Public Health (IIPH), Bhubaneswar
    x. Indian Institute of Technology (IIT), Chennai
    xi. Technology (IIT), Chennai.

d) **Regional Resource Centres or Resource Centres**: Some of the technical partners are upgraded to the Resource Centres to become an extended arm of the HTAIn Secretariat. DHR will provide requisite manpower to these Centres in order to bridge the gap between Central and the State Governments, assist capacity building, support a bunch of States located in the vicinity and undertake the studies allocated to them by the Secretariat. The mentor of the Centres would liaise with the officials of the State Governments and sensitize them about a need for Health Technology Assessment (HTA) for any health intervention.

Following institutes have been identified to be the Regional Resource Centres of HTAIn, so far:

i. Postgraduate Institute of Medical Education and Research (PGIMER), Chandigarh – PGIMER liaise and coordinate with the State Govt. of Punjab, Haryana, Jammu & Kashmir and Himachal Pradesh.

ii. All India Institute of Medical Sciences, Rishikesh – AIIMS, Rishikesh coordinates with the State Government of Uttarakhand.

iii. All India Institute of Medical Science, Jodhpur – AIIMS, Jodhpur coordinates with the State Government of Rajasthan.

iv. State Cancer Institute and KGMU, Lucknow – They coordinate with the State Government of Uttar Pradesh.

v. Indian Institute of Public Health, Shillong – IIPH, Shillong coordinates with the seven sister states of North-East Region.

vi. Indian Institute of Public Health, Gandhinagar – IIPH, Gandhinagar coordinates with the State Government of Gujarat.

vii. Regional Medical Research Center, Bhubaneswar – RMRC, Bhubaneswar coordinates with the State Government of Odisha.

viii. National Institute for Research in Reproductive Health (NIRRH), Mumbai –NIRRH, Mumbai coordinates with the State Govt. of Maharashtra,

ix. National Institute of Virology (NIV), Pune – NIV, Pune also coordinates with the State Government of Maharashtra.

x. National Centre for Disease Informatics and Research (NCDIR), Bengaluru – NCDIR coordinates with the State Government of Karnataka.

xi. Kalam Institute of Health Technology (KIHT), Vizag – KIHT, Vizag coordinates with the State Government of Andhra Pradesh.

xii. Indian Institute of Public Health (IIPH), Hyderabad – IIPH, Hyderabad coordinates with the State Government of Telangana.

xiii. National Institute of Epidemiology (NIE), Chennai – NIE, Chennai coordinates with the State Government of Tamil Nadu.

xiv. National Institute for Research in Tuberculosis (NIRT), Chennai – NIRT, Chennai coordinates with the State Government of Tamil Nadu.

xv. Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Puducherry – JIPMER, Puducherry also coordinates with the State Government of Tamil Nadu.

xvi. SreeChitraTirunal Institute for Medical Sciences and Technology (SCTIMST), Trivandrum: SCTIMST, Trivandrum coordinates with the State Government of Kerala.

e) **HTAIn Secretariat or Secretariat**: Secretariat is a DHR-in-house body that coordinates between the User Department, TAC, Technical Partners and Resource Centres. Secretariat consist of Scientists, Economists, Health Policy Analyst, Financial Consultants, Project Manager, Data Entry Operators and Multi-Tasking Staffs etc. It provides necessary assistance to the TP/ Resource Centres wherever required. Secretariat may also undertake topic(s) to study in certain situations. Besides that, secretariat conducts all the TAC and Stakeholders consultation meetings in DHR and ensures transparency at all stages of the study by consultation and regular updates from the Technical Partners and Resource Centres.

5. **Process of HTAIn**
   i. The User Department will send their topic(s) to the Secretariat for assessment.
   ii. The topic will be prioritized by the Programme Division.
   iii. Approved topics are then allocated to suitable Technical Partner/ Resource Centres to conduct the study.
   iv. The respective TP/ Resource Centres then will submit the study proposal that contains the policy question(s), research question(s), objective(s), methodology, timeline, manpower required and the estimated budget.
   v. The proposal will be presented to the TAC for approval.
   vi. After the approval the TP/ Resource Centres will be allowed to conduct the HTA study and after completion of the study submit the Outcome Report to the Secretariat for TAC approval.
   vii. The report is also uploaded in the website to get comments from Stakeholders or a meeting conducted with stakeholders to get their comments.
   viii. The recommendations will be presented to the HTAIn Board for final approval and subsequently sent to the User Department for implementation.

6. **Selection, Funding Mechanism, Progress and Monitoring of Resource Centres:**
   a) **Selection**
   - The institute willing to become a Resource Centre will submit a proposal along with the required manpower and budget.
   - The Resource Centres will be selected on the basis of their capacities, expertise and previous experience in the area of HTA/ Multi-centric/ Operational research.
   - Existing technical partners may be upgraded to become a resource Centres, only if required, by the approval of the competent authority provided they have a good capacity and they have delivered at least three good quality HTA studies. They will also submit a proposal to become a Resource Centre to the Secretariat.

   b) **Funding Mechanism**
   - The Budget Proposal submitted for studies will be recommended by the Technical Appraisal Committee and approved by the Secretary, DHR.
   - The approved budget for each year will be released from the budgetary estimate provided for DHR.
   - The funds will be released on yearly basis. For the subsequent years, the funds will be released only after receipt of the annual progress report of the previous year along with Chartered Accountant (CA) and statement of expenditure (SOE) and after utilization of 70% available funds.

- Expenditure should not exceed above the prescribed budget. For re- appropriation of the expenditure and for unspent balance, a request may be sent to DHR and the competent authority may take the appropriate decision.
- Contingency grant is meant for recurring expenditures. The contingency grant can be utilized for purposes it was sanctioned but not limited to – Stationary, Printing, Computer Utilities, Official Travels etc.
- Contingency grants should not exceed 3-5% of the total budget. For contingency grant exceeding Rs. 25000/- per annum, detailed breakdown should be given.
- All expendable and non-expendable articles acquired for work of the project should be purchased in accordance with GFR and with the procedure in vogue in the host institutions. For permanent and semi-permanent assets acquired solely or mainly out of the grant, a separate audited record in the form of register in prescribed Performa enclosed shall be maintained by the Institute. The term moveable property where the value exceeds Rs. 1000/-, separate assets register for items costing more than Rs. 20,000/- and less than Rs. 20,000/- may be maintained.
- Overhead expenses will be restricted to maximum ceiling of 3% or 5% of the total cost of the project depending upon the type of host Institution. Overhead expenditure will not be granted on equipment and travel allowances.

c) **Progress**
- The Resource Centres will submit a quarterly progress report to the Secretariat regarding the activities of Resource Centres, progress of the studies allocated and also a justification for the continuation/ discontinuation of recruited staffs.
- The timeline of various activities including the study should be followed strictly.

d) **Monitoring/ Evaluation**
- The coordinating person of the Resource Centres will respond to the Secretariat regarding any query or update besides the progress report mentioned above and submit a quarterly report as mentioned above prescribed by DHR.
- Resource Centres will be visited by the officials from DHR/ Secretariat to monitor their progress.
- The Utilization Certificate or Statement of expenditure should be in a proper format and may reflect the justified usage of the budget.
- If the performance of the Resource Centres is not satisfactory then the Resource Centres will be discontinued from being an HTAIn Resource Centres.

7. **Type of HTA Projects, Funding Mechanism, Progress and Monitoring**
   a) **Types of projects**

   HTAIn may undertake following type of Research studies/ projects related to HTA:
   i. Monocentric Studies (HTA)
   ii. Multi-centric Project (HTA/ Validation study/Operational study etc.)
   iii. Any other project/ study requested by the Central and the State Government.

   b) **Funding Mechanism**

   i. The budget for a multicentric study may vary between Rs.1-15 crores based on the proposal submitted by the PI of the study.
   ii. The budget proposal will be recommended by the TAC to DHR, which will be approved by the Secretary, DHR.
   iii. The approved budget for each year will be released from the budgetary provision of DHR under the scheme.
   iv. The funds will be released on yearly basis till the project is completed. For the subsequent years, the funds will be released only after receipt of the annual progress report of the previous year along with Chartered Accountant (CA) or standard auditor certified utilization certificate (UC) and statement of expenditure (SOE).
   v. Expenditure should not ordinarily exceed the prescribed budget. Any inter-se variations under various components will be permissible only with the specific recommendation of TAC and approval of Secretary, DHR.
   vi. Contingency grant is restricted below 5% of the budget proposed. The contingency grant can be utilized for purposes it was sanctioned but not limited to – Stationary, Printing, Computer Utilities, Official Travels etc.
   vii. Overhead charges should be between 3-5% of the proposed budget.
   viii. The budget will cover, Manpower, recurring, travel, contingency and overhead.

   Note: The studies will be undertaken within the allocated budget. However, in exceptional cases where additional budget is will be decided on case to case basis with the recommendations of TAC and approval of Secretary DHR in consultation with AS & FA.

   c) **Progress**

   i. The Principle Investigator (PI) will provide updates regarding the progress of the study on quarterly/ half-yearly basis.
   ii. PI may respond to all inquiry/ update from the Secretariat.
   iii. The PI/ research team may visit HTAIn Secretariat if there is a need of further clarification regarding the research question or methodology.

   d) **Monitoring**
   i. The resource Centres or technical partner undertaking the study may be called to the Technical Appraisal Committee meeting at DHR headquarters for a review presentation or update quarterly.
   ii. Officials from DHR may also visit the respective institute for monitoring purpose.

8. **Travel Grants and Accommodation**

   The travel grants provided for a project may be utilized for the following:
   i. Visiting the DHR Office for meeting(s) related to the project.
   ii. Attending a training course/ workshop conducted by DHR/HTAIn Sec./ Resource Centres/ Technical Partners.
   iii. Travel for collection of data related to the study undertaken
   iv. The travel entitlement would be as per Govt. of India guidelines or, at par with the entitlement of the regular employees holding similar/ equivalent positions in the respective institutes.
   v. Accommodation during the travel is also included in the Travel Grants and may be as per Govt. of India guidelines at par with the entitlement of the regular employees holding similar/ equivalent positions in the respective institutes.

9. **Capacity Building / Support for Sustained Quality Research.**

   i. DHR will provide the necessary capacity building in the form of Training Workshops/ Conferences in the DHR.
   ii. If a Resource Hub or Technical Partner requires to conduct such capacity building the respective institutes they need to submit a proposal along with the Agenda, name of the Participants/ Speakers, required budget etc. to the Secretariat for the same. The funds will be released only after the recommendation of the proposal by the TAC and the approval of Secretary, DHR.

10. **Physical Targets - For 2021-22 To 2025-26**

Components	2021-22	2022-23	2023-24	2024-25	2025-26	Total
HTA studies	15	20	25	30	35	**125**
New resource Centres	2	2	2	3	3	**12**
Resource centres (Cumulative)	16	18	20	23	26	**29**
New DIAMOnDS centres	3	3	3	3	3	**15**
DIAMOnDS centres (Cumulative)	9	12	15	18	21	**24**

11. **Financial Outlay For 2021-22 To 2025-26**   **(Rupees in Crore)**

S. No.	Description	2021-22	2022-23	2023-24	2024-25	2025-26	Total for 5 years
	Financial Targets in crores						
1	Cost for New Resource Centers and Committed Liabilities for Existing Centres	12.00	12.50	13.00	13.50	14.00	**65.00**

2	Cost for New Oncopathology DIAMOnDS Centres and committed Liabilities for existing centres.	10.00	10.00	10.00	10.00	10.00	**50.00**
3.	HTAIn Secretariat Staff salaries	1.00	1.00	1.05	1.05	1.10	**5.20**
4.	HTAIn Secretariat Administrative expenses	0.15	0.15	0.15	0.15	0.15	0.75
5.	**Total**	23.10	23.65	24.20	24.75	25.30	**121.00**

12. Details of Posts for HTAIn Secretariat and Salary Structure

S. No.	Name of the Post Existing	No. of Posts sanctioned (All contractual)	Salary
1	Junior Health Economist	2	60000-70000
2	Health Policy Analyst	1	70000-80000
3	Programme Manager/Project Manager	1	80000-90,000
4	Scientist D	1	78000/-+HRA
5	Scientist C	2	67,000/-+HRA
6	Administrative Officer	1	40,000
7	Consultant (Finance & Accounts)	1	60,000--
8	Data Entry Operator (Graduate)	3	20,000
9	MTS	2	18,000
Total		**14**	

Annual increase will be 5% every two years for technical positions as per DST Norms.
DEO/MTS salary will be subject to minimum payable under the Minimum Wages Act.

PART 2

DHR-ICMR Advanced Molecular Oncology Diagnostic Services (DIAMOnDS)

1. **Background**

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. The expert panel for DHR-ICMR Advanced Molecular Oncology Diagnostic Services (DIAMOnDS) has been approved by Hon'ble HFM (F.No. T.11012/02/2019-HR dated 13.09.2019)

2. **Objective**

DIAMOnDS project aims to set up zonal 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. These laboratories will be established in 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.

3. **Process**

A two-phase pilot development model has been established for 9 centers. The process followed is as below:

Phase 1:
Step 1: Identifying institutes in four zones of India i.e. east, west, north and south to setup oncopathology labs.
Step 2: Providing facilities, infrastructure and manpower 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 related to Breast and lung cancer and developing a fast, digital system for reporting.

Phase 2:
Step 4: 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.
Step 6: Monitoring and evaluation of services for assessment and improvements.

4. DIAMOnDS Regional Hubs and Centres:

The following institutes have been established, so far, as DIAMOnDS Oncopathology lab.

	Zone	DIAMOnDS Regional Hub	DIAMONDS Centre
1	North	AIIMS (New Delhi)	State Cancer Institute- Lucknow
2	South	CMC (Vellore)	JIPMER- Pondicherry
3	North East	TMC (Kolkata)	Cachar Cancer Hospital and Research Centre (CCHRC)- Silchar RIMS, Imphal
4	West	TMH (Mumbai)	AIIMS-Jodhpur, Rajasthan

5. Funding Norms

S.No	Component	Amount (Rs.)
1	**Equipment/Non recurring**	**50,00,000**
2	**Manpower** **Manpower Details** **Scientist-C** – 1 post **Research assistant** - 1 post **Lab Technician III** – 2 posts **Data Entry Operator** - 1 post **Multi-tasking staff-1**	67,000/-+HRA 35000/- 20000/-+HRA 20000/- 18000/-
3	**Recurring including workshops/training**	25,00,000
4	**Travel/Meeting/Training/workshop**	2,00,000
5	**Contingency**	50,000
6	**Overhead**	360,480

Note: Variation up to 10% in the above cost norms will be allowed, in exceptional cases, with the recommendations of the Technical Committee and approval of Secretary, DHR in consultation with AS & FA.

6. The proposed strategy to establish zonal onco-pathology lab

a. The process of screening/evaluation and final approval will be as follows:

The proposals will be screened/ evaluated by the HTAin Secretariat and the proposals fulfilling the criteria will be presented before the Technical Committee and finally approved by the Secretary, DHR.

Phase 1:

Step 1: Identifying institutes in four zones of India i.e. east, west, north and south to setup oncopathology labs: which has been completed

Step 2: Providing facilities, infrastructure and manpower to perform diagnostic and prognostic tests related to the cancer of highest prevalence in India in male (lung cancer) and female (breast cancer).

- A comprehensive list of all the basic and advance tests required for breast and lung cancer has been compiled in consultation with the experts (Table 1 and 2).

Table 1: List of all the basic and advance tests required for lung cancer

Diagnostic tests for Lung Cancer		
S no.	Test Name	Test Methods
1	Basic	Histo/Cyto
2	IHC	TTF-1, Napsin A
		P63, P40 (Sq. Vs Adeno)
		EGFR (Adeno & EGFR)
		ALKD5F3 (for TKI)
		Synatophysin/chromogranin
3	Biochem	CEA, CA (CyFRA 21-1)
4	FISH	ALK-1 Break-apart (Gold standard)
		ROS 1 Rearrangement
		MET amplification
		RET rearrangement

Table 2: List of all the basic and advance tests required for breast cancer

Diagnostic tests for Breast Cancer		
S no.	Test Name	Test Methods
1	Basic	Histo/Cyto, IHC.ER, PR, Her2neu, Ki67
2	Cytogenetics	FISH-Her2neu
3	Biochem	CA 27.29
		CA 15.3 (Monitoring response and recurrence)
4	Mol. Biopsy	BRCA1 & BRCA2

- A list of test methods, equipment and manpower required to perform the tests mentioned in Table 1 and 2 has been populated in consultation with the experts (Annexure VI and VII).

Step 3: Establishing and standardizing the tests related to Breast and lung cancer and developing a fast, digital system for reporting:

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.

<u>**Phase 2:**</u>

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

7. **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.

8. **Funding Mechanism**

- The budget proposal will be recommended by the DIAMOnDS Technical Committee to DHR, which will be approved by the Secretary, DHR.
- The approved budget for each year will be released from the budgetary provision of DHR under the scheme.
- The funds will be released on yearly basis. For the subsequent years, the funds will be released only after receipt of the annual progress report of the previous year along with Chartered Accountant (CA) or standard auditor certified utilization certificate (UC) and statement of expenditure (SOE) and after utilization of 70% of available funds.

- Expenditure should not ordinarily exceed the prescribed budget. Any inter-se variations under various components will be permissible only with the specific recommendation of Technical Committee and approval of Secretary, DHR.
- Contingency grant is restricted below 5% of the budget proposed. The contingency grant can be utilized for purposes it was sanctioned but not limited to – Stationary, Printing, Computer Utilities, Official Travels etc.
- Overhead charges should be between 3-5% of the proposed budget.
- The budget will cover, Manpower, recurring, travel, contingency and overhead.

9. Progress

- The Principle Investigator (PI) will provide updates regarding the progress of the study on quarterly/ half-yearly basis.
- PI may respond to all inquiry/ update from the Secretariat.
- The PI/ research team may visit HTAIn Secretariat if there is a need of further clarification regarding the research question or methodology.

10. Monitoring

- The resource Centres or technical partner undertaking the study may be called to the Technical Appraisal Committee meeting at DHR headquarters for a review presentation or update quarterly.
- Officials from DHR may also visit the respective institute for monitoring purpose.

11. Travel Grants and Accommodation

The travel grants provided for a project may be utilized for the following:
  i. Visiting the DHR Office for meeting(s) related to the project.
  ii. Attending a training course/ workshop conducted by DHR/HTAIn Sec./ Resource Centres/ Technical Partners.
  iii. Travel for collection of data related to the study undertaken

Note:
1. The travel entitlement would be as per Govt. of India guidelines or, at par with the entitlement of the regular employees holding similar/ equivalent positions in the respective institutes.
2. Accommodation during the travel is also included in the Travel Grants and may be as per Govt. of India guidelines at par with the entitlement of the regular employees holding similar/ equivalent positions in the respective institutes.

12. Capacity Building / Support for Sustained Quality Research.

- DHR will provide the necessary capacity building in the form of Training Workshops/ Conferences in the DHR.
- If a Resource Hub or Technical Partner requires to conduct such capacity building the respective institutes they need to submit a proposal along with the Agenda, name of the Participants/ Speakers, required budget etc. to the Secretariat for the same. The funds will be released only after the recommendation of the proposal by the TAC and the approval of Secretary, DHR.

Salary Structure of HTAIn Secretariat Staff

S.No.	Designation	Salary structure
1.	Project Manager	**Rs.80,000-90,000/-**
2.	Finance Manager/Consultant Finance & Accounts	**60,000/- p.m**
3.	**Scientist 'B' (In Labs only)**	
i	Medical	**Rs. 56,000/-+HRA as per city rate**
Ii	Non- Medical	**Rs.56,100+HRA as per city rate**
3.	**Scientist 'C' [Pay level (11) 67,700-Minimum]**	
	Medical	**67,000/-+ HRA as per rate**
	Non-Medical	**Rs. 67,700/- +HRA as per city rate**
4.	**Scientist 'D'**	
	Medical	**Rs. 78,000/- +HRA as per city rate**
	Non –Medical	**Rs. 78,000/- +HRA as per city rate**
5.	Administrative Officer	**40,000/-**
6.	Section Officer	**40,000/-**
7.	Assistant	**35,000/-**
8.	DEO	**Rs.20,000/- p.m.**
9.	MTS	Rs.18,000/-p.m.
SPECIFIC POSTS FOR HTA		
i	Junior Health Economist	60000-70000
ii	**Health Policy Analyst**	**70000-80000**
Other Lab Staff (specific to Labs)		
I	**Lab Technician Grade –C**	**Rs. 20,000+HRA**
ii	**Research Assistant**	**35,000/-**
iii	**Technical Assistant (Statistics)**	**35,000/-**
iv	**Technical Assistant (Research)**	**Rs. 20,000+HRA**
v	**Lab Assistant Gr.A**	**Rs. 18,000+HRA**

- Annual increase will be 5% every two years for technical positions as per DST Norms.
- DEO/MTS salary will not be less than minimum pay under the Minimum Wages Act.
- If due to revised structure, any official gets less than what is being paid currently due to any reason, the existing pay will be protected till he/she reaches the same level under the revised structure.
- HRA will be admissible as per the classification of the city.

Component-wise breakup of cost per Resource Centre

S. No.	Component	Unit	Cost
1	Equipment/Non recurring		NA
2	Manpower 1. Health Economist (level of Scientist B	01 (One)	Rs. 65,000-70,000
	2. Scientist D (Medical/Non Medical)/Senior Research Officer	01	Rs. 78000+HRA
	3. Scientist C (Medical/non-Medical)	01	Rs. 67000/-+HRA
	4. Administrative Assistant	01	Rs.25,000-35000
	5. Field Officer	01	Rs.25000-30000
	6. Field Investigator	01	Rs. 30,000-32000
3	Recurring		
4	Travel/Meeting/Training/workshop		
5	Contingency		3-5%
6	Overhead		3-5 %
	Total		

Note:
3. Procurement of laptops, field data collection, publication charges, stationary may be done from the contingency and the overhead budget
4. Recurring budget can be utilized for software procurement for statistical data analysis and for journal subscriptions for review of literatures
5. Hiring of manpower may vary according to the study undertaken but within the aforesaid budget. In exceptional cases, 10% variation will be permitted with the recommendation of the approval of Joint Secretary.
6. Annual increase will be 5% every two years for technical positions as per DST Norms.
7. HRA will be at the rate of applicable in the city.
8. DEO/MTS salary will not be less than the minimum pay under the Minimum Wages Act.
9. If due to revised structure, any official gets less than what is being paid currently due to any reason, the existing pay will be protected till he/she reaches the same level under the revised structure.

Component wise breakup of cost per DIAMOnD Lab

S.No	Component	Amount (Rs.)
1	**Equipment/Non recurring**	**50,00,000**
2	**Manpower** **Manpower Details** **Scientist-C** – 1 post **Research assistant** - 1 post **Lab Technician III** – 2 posts **Data Entry Operator** - 1 post **Multi-tasking staff-1**	67,000/-+HRA 35000/- 20000/-+HRA 20000/- 18000/-
3	**Recurring including workshops/training**	25,00,000
4	**Travel/Meeting/Training/workshop**	2,00,000
5	**Contingency**	50,000
6	**Overhead**	360,480

Eligibility Criteria for Various Positions Mentioned

S.No.	Nomenclature of Post	Qualification	Upper age-limit for fresh recruits
		Research Personnel	
1.	Scientist D (Medical)	**Essential:** • Post Graduate Degree (MD/MS/DNB/MPH) after MBBS with 6 year research experience in the relevant field. Or • MBBS degree with 8 years' experience or Post Graduate Diploma in medical subjects after MBBS with 5 years' experience in the relevant subject. Or • Ph. D in the relevant subject (Community Medicine/ Preventive & Social Medicine/ Paediatrics/ Medicine/ Tropical Medicine/ Community Health Administration/Health Administration/ Family Medicine/ Epidemiology/ Public Health) from a recognized university with 5 years' experience in the relevant field Plus • 2 years' experience in the management of R & D projects in a team effectively. **Desirable:** • Additional Post-doctoral research/teaching experience in relevant subjects in recognized institute(s). • Knowledge of Computer Applications/Data Management.	45 Yrs.
2.	Scientist D (Non-Medical)	**Essential:** • Ph.D degree in Microbiology/ Biochemistry/ Biotechnology subject from a recognized University with 5 years R&D/Teaching experience in the relevant subject after Ph.D. or • First class MPH/ Pharm D (Doctor of Pharmacy)/Master's degree in the relevant subjects from a recognized university with 8 years R&D/teaching experience in the relevant subject after 1st Class Master's Degree. Or • Second class M.Sc/MPH + Ph.D degree in the relevant subject from a recognized University with 8 years R&D/teaching experience in the relevant subject post qualification. Plus • 2 years experience in the management of R & D projects	45 Yrs

		in a team effectively. **Desirable:** • Post-doctoral research/teaching experience in relevant subjects in recognized Institute(s). • Knowledge of Computer Applications or Business Intelligence tools/Data Management	
3.	Scientist C (Medical)	**Essential:** • MBBS degree with 6 years' experience or Post Graduate Diploma in medical subjects after MBBS with 5 years' experience in the relevant subject. Or • Post Graduate Degree (MD/ MS/ DNB/ MPH) after MBBS with 4-year research experience in the relevant field. **Desirable**: • Doctorate (Ph.D.) in the relevant subject (Community Medicine/ Preventive & Social Medicine/ Pediatrics/ Medicine/ Tropical Medicine/ Community Health Administration/Health Administration/ Family Medicine/ Epidemiology/ Public Health) from a recognized university. • Additional Post-doctoral research/teaching experience in relevant subjects in recognized institute(s). • Knowledge of Computer Applications/Data Management.	40 Yrs
4.	Scientist C (Non-Medical)	**Essential:** • M.Sc. Life science/ MPH/MHA/ M. Pharma (Masters of Pharmacy) /Pharm. D (Doctor of Pharmacy) with 4 year of experience in relevant area. **Desirable:** • Ph.D. degree Microbiology/ Biochemistry / Biotechnology subject from a recognized University with 2 years R&D/Teaching experience in the relevant subject. • Knowledge of Computer Applications or Business Intelligence tools/ Data Management.	40 Yrs
5.	Health Policy Analyst	**Essentials** • Post-Graduation in Science/ Life Science/ Health & Allied Science Such as Public Health/ Clinical Research/ Health Information Management/ Health Management. • 2 Years of Experience in The Relevant Field. **Desirable** • Ph.D. In the Related Field. • Knowledge of HTA. • Good communication and interpersonal skills. • Proficiency In Various Computer Applications (MS Office/ Mendeley/ End Note/ Coral etc.)	40 Yrs

		Essentials	
6.	Junior Health Economist	**Essentials** • Masters in Health Economics/ Economics/ Public Health/ Community Medicine with specialization in Healthcare Costing, Economic Evaluation. • 2 years of experience in the field of health economics for Junior Staff and 6 years for Seniors **Desirable** • Ph.D. in the related field. • Proficiency in MS Office, VBA and TreeAge.	40 Yrs
Administrative Staff			
7.	Programme Manager/ Project Manager	**Essential:** • MBA/ Master's Degree in any discipline from Government recognized institute with 3-5 years working experience in Government Sector / PSU. • Exposure in social sector schemes at national, state and district level. • Knowledge of MS Office, MS Word, MS Power Point, MS Excel. • Preference will be given to persons having experience of working in Health sector, AYUSH, NRHM, NACO, etc. or in the Scientific Departments/Organizations with experience in coordination of health programmes or projects. **Desirable:** • Excellent interpersonal, communication (written and verbal) and organizational skills. • Knowledge of project management tools and techniques. • High proficiency in the English language, both verbal and written.	Not less than 35 years but not exceeding 60 years
8.	Consultant (Finance & Accounts)	• Bachelor degree in any discipline and having 10 years of work experience in the administration, finance and accounts matters.	50-70 Yrs.
9.	Administrative Officer	•	
10.	Administrative Assistant	• Graduate from a recognized institution with computer knowledge	35-40 Yrs.
Technical Staff			
11.	Senior Project Officer/ Senior Research Officer	• Graduate in Science/ relevant subjects from a recognized university with 5 years of work experience from a recognized institution or master's degree in the relevant subject or Pharm D (Doctor of Pharmacy) from a recognized institution	45 Yrs
12.	Research Officer	• Graduate in Science/ relevant subjects from a recognized university with 4 years of work experience from a recognized institution or master's degree in the relevant	40 Yrs

		subject or Pharm D (Doctor of Pharmacy) from a recognized institution	
13.	Research Associate	• Graduate in Science/ relevant subjects from a recognized university with 3 years of work experience from a recognized institution or master's degree in the relevant subject or Pharm D (Doctor of Pharmacy) from a recognized institution	40 Yrs
14.	Field Supervisor	• Graduate in Science/ relevant subjects from a recognized university with 3 years of work experience from a recognized institution or master's degree in the relevant subject or Pharm D (Doctor of Pharmacy) from a recognized institution	40 Yrs
15.	Field investigator/ Field Officer	• Graduate in Science/ relevant subjects from a recognized university with 3 years of work experience from a recognized institution or master's degree in the relevant subject or Pharm D (Doctor of Pharmacy) from a recognized institution.	35 Yrs
16.	Project Technician	• Intermediate or 12th pass in science subjects and 2 years diploma in medical laboratory technician or PMW or radiology/radiography or related field from a recognized board Or, • One year DMLT plus one year work experience in a recognized organization Or, Two years field experience. *B.Sc. degree shall be treated as 3 years' experience	30 Yrs
IT support staff			
17.	Data Entry Operator	**Essential:** • Intermediate or 12th pass from a recognized board. A speed test of not less than 15000 key depressions per hour through speed test on computer. **Desirable:** • 2 years' experience in EDP work in government, Autonomous, PSU or any other recognized organization.	30-40 Yrs
18.	Multi-Tasking Staff	• High school or equivalent from recognized institute.	30Yrs (may be relaxed in deserving cases).

٭ Ph.D. shall be treated as three years' experience.

٭ The eligibility criteria and the Age limit may be relaxed for exceptional candidates only with the approval of the TAC/ Secretary, DHR.

Job roles and responsibilities

1. **Scientists**
   - To support & execute the on-going & new programs of DHR and to provide leadership and managerial strength in the R&D projects in the area of HTA research.
   - Responsible for the scientific, and/or technical aspects of the implementation of HTA projects of DHR.
   - Senior Scientific Staff will be coordinating the Activities of HTAIn and Junior staff will be providing supportive role for all the HTAIn work
   - Invitation of applications/proposals from the States/Medical Colleges/Institutions for HTA studies
   - Getting the requisite MoU signed with the States/Medical Colleges/Resource Centre
   - Submission of the proposals for recommendations of the Technical Appraisal Committee
   - Seeking any clarifications from the States/applicants on various issues/points.
   - Submission of proposal along with the recommendations of the expert committees.
   - Maintaining effective working relationships with colleagues at DHR, ICMR, Government Ministries (i.e. NRHM, MHFW), NHSRC, DGHS, and international partner organisations
   - Supporting the HTA advisory group, secretariat, International partners, and team members in developing and maintaining effective working relationships with relevant national partners and stakeholders.
   - Regularly liaising with international partners to ensure satisfactory progress and quality of the HTAIn secretariat outputs
   - Contribute to drafting official reports from the secretariat, including summaries of workshops and events.
   - Conducting of Workshops/seminars/TAC meetings/Board Meetings/Stakeholders meeting etc
   - Any other work assigned by the Department of Health Research

2. **Programme Manager/ Project Manager**
   - To provide efficient and effective daily operational management of all activities relating to HTA project.
   - To support the communication and coordination activities between the Board, Technical Appraisal Committee, DHR, Central and State Government and nongovernment partners and International advisors.
   - To provide efficient and effective administrative and secretarial support to the HTA programme, including preparing correspondence and papers, collating, copying and distributing papers.
   - To organize meetings, teleconferences, videoconferences and other events, which may include coordinating the attendance of invitees, assisting in travel arrangements, etc.
   - To prepare agenda and other meeting papers, their distribution and preparing record of discussions of meetings.
   - To manage and operate information management systems, including filing system.
   - To develop and manage databases and other records, such as mailing lists, budget monitoring spread sheets.
   - To deal with day to day enquiries by other Departments / agencies, etc.

3. **Health economist (Junior/Senior):**
   - Contribute to technical and organizational planning of Health Technology Assessment (HTA) project.
   - To undertake HTA studies approved under concerned institute.
   - Contribute to the writing, editing and publishing of reports and journal articles related to HTA studies.
   - Taking advocacy initiatives on behalf of institute to publicize the work of HTA project including working with the media and other sources of information dissemination, such as circulars.
   - Respecting the confidentiality of work of the HTAIn Secretariat and Technical Appraisal Committee/Board.
   - Adhering to DHR policies and procedures.
   - Any other work as may be assigned by project heads.

4. **Health Policy Analyst:**
   - The Health Policy Analyst is required for performing following activities:
   - Supporting the HTA Advisory Group, team members at DHR, Senior Health Economist and to work on the day to day activities of the HTAIn secretariat.
   - Assist in drafting key documents for the HTAIn secretariat, including: Terms of reference (TORs), Standard operating procedures (SOPs), HTA Methods manuals, process documents
   - Contribute to technical and organizational planning of the HTAIn
     Contributing to identifying and communicating with technical partners in the field of HTA in India
   - Providing progress updates on the work of the HTAIn secretariat to the Secretary, DHR/ DG, ICMR
   - Providing progress updates on the work of the HTAIn.
   - Providing updates on the progress of the HTAIn secretariat outputs to the HTA advisory group.
   - Supporting the HTA advisory group, HTAIn secretariat, International partners, and team members in developing and maintaining effective working relationships with relevant national partners and stakeholders
   - Contribute to drafting official reports from the HTAIn secretariat, including summaries of workshops and events.
   - Contributing to the writing, editing and publishing of reports and journal articles
   - Contribute to initiatives to publicise the work of HTAIn, including working with the media and other sources of information dissemination, such as circulars and newsletters
   - Develop health policies by collecting and analyzing statistical data.
   - Respecting the confidentiality of work of the HTAIn Secretariat and Technical Appraisal Committee/Board.
   - Adhering to DHR policies and procedures.

5. **Project Coordinator:**
   - The Project Coordinator is required for performing following activities:
   - Lead the strategic planning in designing, conducting and coordinating the study.
   - Establishing coordination among partner institutes of the project.
   - Supervising the collection, cleaning and storage of project data.
   - Analysis of data.

- Lead in drafting key documents like annual and final report of the study, summaries of meetings/ events, research publications etc.
- Organizing workshops and training programs.

6. **Research Officer:**
   - The Research Officer is required for performing following activities;
   - Conduct of structured literature search.
   - Assisting in cleaning and storage of data.
   - Analysis of data.
   - Analysis of weekly reports of interviewers' compliance of the partner institutes.
   - Contribute in drafting key documents of the project and in organizing workshops and training programs.

7. **Research Associate:**
   Research Associate will perform following duties:
   - Providing scientific and technical support in conduct of study.
   - Coordinating among the project staff at the partner institutes.
   - Monitoring the effective conduct of data collection process.
   - To organize data quality review meetings.
   - Assist in data cleaning and storage.
   - Preparation of reports of partner institute related to utilization of project resources.
   - Regular liaising to ensure satisfactory progress of project activities.

8. **Administrative Assistant:**
   Administrative Assistant will perform following duties:
   - Effective conduct of routine administrative/ operational activities of the project
   - Liaising with partner institutes
   - Arranging meetings/ workshops
   - Manage and operate information system, including filing system.
   - Develop and manage project databases and record systems including attendance lists, mailing lists and budget monitoring spreadsheets.
   - Send out and process salary requisitions and expense claim forms of project staff to accounts department of DHR.
   - Preparation of reports related to utilization of project resources.

9. **Field Supervisor:**
   - Field Supervisor will perform following duties:
   - Monitoring of the data collection process by field investigators
   - Ensuring compliance of field investigators
   - Produce weekly report of interviewers' compliance of the partner institute

10. **Field Investigator/ Field Officer:**
    - Field Investigators will be appointed at every partner institute during the period of data collection. They will perform following duties:
    - House listing
    - Perform interviews for data collection in accordance with Research topic.

11. **Project Technician:**
    - Perform study specific laboratory diagnostic procedures including molecular tests and other lab procedures;

- entry of patients' details results in lab registers;
- maintenance of consent and lab related documents;
- any other lab related activities as deemed fit by the PI.

12. Data Entry Operator:
- Data Entry of Primary/Secondary data received as soft / hard copies from the field and all other related works.

13. Multi-Tasking Staff:
- Photocopying, Making Sets, Stapling, Sending Fax, Receiving Phone Calls, providing support in No-clerical work, assisting in routine official work.

Leave entitlement:
As per the terms of engagement/ norms of the institute.

Indicative list of test methods, equipment and manpower required to perform tests for Lung Cancer

S no.	Test Name	Equipment	Consumables
span: Diagnostic tests for Lung Cancer			
1	Basic (Histo/Cyto)	Camera for gross photography	Slides
		Cutting board	Cover slips
		Weighing machine	Haematoxylin & Eosin
		BP blades (2)	DPX
		Long blade/knife (2)	IHC secondary kit
		Scissors	Primary Antibodies (panel)
		Forceps toothed (1)	Paraffin wax
		Forceps pointed (1)	Tissue chucks (metal/plastic)
		Forceps blunt (1)	Coplin Jars
		Microscope with camera	Beakers.
		Refrigerator 4'c (for storing Antibodies)	Screw-Capped flat bottomed bottles
		Tissue processor	Xylene
		Embedding station	Acetone
		Microphone	Isopropranolol
		Hot plate	Formalin
		Tissue floatation bath	Alcohol
		Distilled water plant (MilliQ)	Nacl

			Sodium bicarbonate
			Disodium carbonate
			DW
			ISH kits
2	IHC	TTF-1, Napsin A	
		P63, P40 (Sq. Vs Adeno)	
		EGFR (Adeno & EGFR)	
		ALKD5F3 (for TKI)	
		Synatophysin/chromogranin	
3	Biochem	CEA, CA (CyFRA 21-1)	
4	FISH	ALK-1 Break-apart (Gold standard)	
		ROS 1 Rearrangement	
		MET amplification	
		RET rearrangement	

Indicative list of test methods, equipment and manpower required to perform tests for Breast Cancer

S no.	Test Name	Methods/Equipments	Consumables	Manpower
Diagnostic tests for Breast Cancer				
1	Basic (Histo/Cyto, IHC.ER, PR, Her2neu, Ki67)	Camera for gross photography	Slides	Pathologist, Scientist, Technician
		Cutting board	Cover slips	
		Weighing machine	Haematoxylin & Eosin	
		BP blades (2)	DPX	
		Long blade/knife (2)	IHC secondary kit	
		Scissors	Primary Antibodies (panel)	
		Forceps toothed (1)	Paraffin wax	
		Forceps pointed (1)	Tissue chucks (metal/plastic)	
		Forceps blunt (1)	Coplin Jars	
		Microscope with camera	Beakers.	
		Refrigerator 4'c (for storing Antibodies)	Screw-Capped flat bottomed bottles	
		Tissue processor	Xylene	
		Embedding station	Acetone	
		Microphone	Isopropranolol	
		Hot plate	Formalin	
		Tissue floatation bath	Alcohol	
		Distilled water plant (MilliQ)	Nacl	
			Sodium bicarbonate	
			Disodium carbonate	
			DW	
			ISH kits	

2	Cytogenetics	FISH-Her2neu		
3	Biochem	CA 27.29		
		CA 15.3 (Monitoring response and recurrence)		
4	Mol. Biopsy	BRCA1 & BRCA2		