CERTIFIED FELLOWSHIP IN IMMUNO-ONCOLOGY

[Syllabus Approved by Board of Studies, Medical & Health Sciences]

Programme Code	:	HLTH14A10
Programme Details	:	2-YEARS HBNI CERTIFIED FELLOWSHIP IN IMMUNO-ONCOLOGY
Programme Learning Outcomes (PLOs / PSOs)	:	MENTIONED [COMMON FOR ALL 2 YRS HBNI CERTIFIED FELLOWSHIPS OFFERED AT TMC]
Eligibility Criteria	:	DM (MEDICAL OR PEDIATRIC ONCOLOGY OR DNB (MEDICAL ONCOLOGY) OR POST MD MEDICINE / PEDIATRICS WITH POST MD EXPERIENCE OF AT LEAST 3 YEARS OF WHICH AT LEAST 2 YEARS ARE IN A STRUCTURED FELLOWSHIP / DIPLOMATE PROGRAMME IN THE FIELDS OF ONCOLOGY AND OR HAEMATO-ONCOLOGY.
Duration of the Course	:	2 YEARS
Programme Structure (Credit-Based)	:	NA
Detailed Course Syllabus	:	ATTACHED
Teaching–Learning Methodologies	:	2 YEARS PROGRAM
Examination & Evaluation System	:	ANNUAL APPRAISAL FOLLOWED BY UNIVERSITY FINAL EXAMINATION
Internship / Project / Dissertation Guidelines	:	NA
Program In Charge	:	PROF. GAURAV NARULA (***drgauravnarula@gmail.com***)

CERTIFIED FELLOWSHIP (IMMUNO-ONCOLOGY)

Programme Code: HLTH14A10

Programme Outcome:

- The HBNI Fellowship Programmes at Tata Memorial Centre are designed to develop competent, ethical, and academically oriented healthcare professionals with advanced knowledge and skills in their respective specialties and subspecialties.
- At the completion of the fellowship, candidates are expected to demonstrate excellence in clinical practice, patient-centered care, multidisciplinary teamwork, communication, professionalism, and evidence-based decision-making.
- Fellows shall acquire the ability to independently evaluate, diagnose, plan, and manage patients while adhering to institutional protocols, quality standards, patient safety practices, and ethical principles in healthcare delivery.
- The fellowship programmes also aim to foster academic growth, research aptitude, lifelong learning, and leadership qualities among trainees.
- Fellows are expected to actively participate in teaching, seminars, journal clubs, conferences, audits, and research activities, thereby contributing to the advancement of medical science and institutional development.
- Upon successful completion of the programme, the fellow should be capable of functioning independently as a skilled specialist/subspecialist with competence in clinical services, academics, research, and collaborative healthcare practice in tertiary care and oncology-focused settings.

DETAILED SYLLABUS

Two Year TMC-HBNI Fellowship in Immuno-oncology

1. Prospect of the proposed Programme, outcome and job opportunity:

- **Aims:**
  - To fulfill the growing and unmet need for medical and pediatric oncologists trained in Immuno-oncology, which is emerging as a paradigm-changing mode of cancer treatment.
  - The successes and burgeoning of immunotherapeutic agents brings its own complexities, requiring deeper understanding of immunological concepts, a change of orientation away from maximum-tolerated dose basis of traditional cytotoxic chemotherapy, and traditional imaging-based response assessments, along with a unique set of toxicities that require management with a fine balance of suppression, while not negating their efficacy.
  - The incidence of cancer in India is high and Tata Memorial Hospital is in the forefront trying to cater to the huge deficit of cancer centres across the country by establishing Cancer Centers, both under aegis of DAE as well as by philanthropic Trusts. To ensure that these centers are staffed with skilled and well trained doctors, technicians and nurses, Tata Memorial Hospital has again been in the forefront by initiating numerous training programmes and Fellowships both under aegis of TMC and HBN
  - However, it needs to be highlighted that despite the proven necessity and inclusion of immunotherapy in all the guideline of multi-disciplinary management of cancers, currently there are no trained immuno-oncologists in any of the dedicated Regional Cancer Centers for optimal immunotherapeutic management of any cancer and /or management of immunotherapy related complications in the cancer patient.
  - Due to lack of adequate exposure oncologists are hesitant in using immunotherapy and those who do, are not fully skilled to manage complications, resulting in, referral to other experts (eg endocrinologists, cardiologists etc) who are also not always attuned to the issues faced in a dedicated large Oncology.
  - Tata Memorial Hospital is the leading large public cancer hospital wherein immune-therapeutics are used for various cancers under specific disease management groups.

- TMH has also taken lead at the national level to develop a cellular therapy program using immunological cells. A GMP (Good Manufacturing Practice) compliant facility will be commissioned in March 2019. Initial use of the facility is for clinical trials for at type of cellular therapy that has shown remarkable results in trials abroad and is now approved by Regulatory bodies abroad. This unit will be functional in 2019, initially for the above-mentioned technology which has been indigenously developed in collaboration with Indian Institute of Technology (IIT-B) at Mumbai, and later for several other cellular immuno-therapy indications involving modified and un-modified immune cells.
- Thus, there is a need to develop a formal training fellowship programme to train oncologists all across the country to service the large number of dedicated cancer Centers coming up across the country.
- Currently there is no such training programme in India available for the same (Fellowship in Onco-immunology) and is an unmet need.
- Our Fellowship will be under the aegis of HBNI and the National Cancer Grid (NCG). With the large number of Cancer Centres coming up across India as well as the overall rising incidence of cancers in India, we have no doubt that the experience gained at TMH in the form of the Fellowship in Immuno-oncology will supplement immunotherapy treatment and complication management related issues in all cancers where this therapy is indicated.

2. Two duration of the programme:

- Two Years

3. Detailed academic curriculum with syllabus and semester wise distribution of courses:

- **Outline of the Fellowship:**
  - The Fellowship will be conducted by the Medical Oncology department TMC under the aegis of the TMC, the National Cancer Grid (NCG) and the Homi Bhabha National Institute (HBNI)
  - Candidates will work in the department of Medical Oncology at Tata Memorial Hospital, rotate amongst the relevant Divisions within Tata Memorial Hospital and ACTREC, Kharghar and participate in Multidisciplinary cancer Tumour Boards for all the relevant cancer types.

- The post will be residential with Fellows having to attend to Immunotherapy related references on an on-call basis
- The fellow will mandatorily publish or submit for publication an original article in Immuno-oncology pertaining to cancer and final certification will be subject to completion of the same.
- The fellow will be expected to attend and participate in academic activities including clinical rounds, seminars, journal clubs, webcasts, and didactic lectures as per the Immuno-oncology teaching programme schedule.
- The Fellow will maintain a Logbook detailing all important cases handled, complications managed independently as well as all academic lectures and seminars attended.

- **Scope of the Fellowship:**
  - To understand basic and advanced concepts of the Immune system and its intersections and applications in the field of Oncology in diagnostics, therapeutics and response evaluations.
  - To gain skills and knowledge in cell based immune-therapy, including pre-clincial development, cell collection, cell-processing and manipulation, gene-modification, storage, dispensation of cell-based immunotherapy products.
  - To learn translational of cell-based products from concept to clinical trial.
  - To learn clinical management, including administration, toxicity management and follow-up of patients receiving cell-based immunotherapy.
  - To evaluate all patients referred to the Medical Oncology department for immunotherapy.
  - To diagnose and manage unique immunotherapy related complications (e.g, hematological, dermal, neurological, endocrine, cardiac, gastrointestinal etc.) in cancer patients including serious complications requiring Intensive Care.
  - Understand the indications and manage complications of immunotherapy (eg. check point inhibitors, single or double) with or without other therapies like chemotherapy, targeted therapy, radiotherapy and various techniques of delivering immunotherapy like intravenous, intralesional (eg T-VEC) and combination of both.
  - Train Fellows in the indications and interpretation of Imaging and Bio-imaging modalities with cancer immunotherapy
  - Gain an understanding of palliative and pain management of cancer patients on immunotherapy and also ethical and end of life issues.

- This Fellowship Programme does not meet requirements for a Certification in any other department apart from Medical Oncology

- **Proposed Syllabus and Curriculum:**
  - General principles of Immunology as applicable to Oncology:
    - ❖ Tumor immunology
    - ❖ Tumor microenvironments
    - ❖ Selection of Immunological targets
    - ❖ Immune-escape mechanisms and counter-strategies
  - Etiology and epidemiology
    - ❖ Epidemiology of various cancers, global and in context with Indian subcontinent
    - ❖ Host Immune system and cancer development
    - ❖ Tumour microenvironment and cancer development
  - Pathology of various tumours
    - ❖ Cytological and biopsy specimens for pathology/molecular analysis
    - ❖ Immune Bio-markers
    - ❖ Pathological classification and molecular pathology of relevant cancers wherein immunotherapy is indicated
    - ❖ Interpretation of pathological reports and immunological bio-markers
    - ❖ Microsatellite Instability and its testing
  - Clinical Management of patients on immunotherapy
    - ❖ Signs and symptoms
    - ❖ Performance status
    - ❖ Cytokine Release Syndrome
    - ❖ Other Syndromes and symptoms of relevant cancers with immunotherapy indications
    - ❖ Metástasis and manifestations
    - ❖ Co-existing / contributing diseases
    - ❖ Symptom complex associated with complications

- **Skills and Procedures:**

Skills to be acquired Mandatory	Skills to be acquired Preferable	Skills to be acquired Observed
• Handling of Immunotherapeutic drugs alone or in combination with chemotherapy/targeted therapy/radiation therapy • Diagnosis and Management of unique immunotherapy related complications • To gain skills and knowledge in cell based immune-therapy, including pre-clincial development, cell collection, cell-processing and manipulation, gene-modification, storage, dispensation of cell-based immunotherapy products. • To learn translational of cell-based products from concept to clinical trial. • To learn clinical management, including administration, toxicity management and follow-up of patients receiving cell-based immunotherapy	• Biomarker and their role in planning and monitoring immunotherapy • Intralesional therapy administration (T-VEC)	• Exposure to other international centers like MD Anderson Cancer Center, for enhanced exposure to Immunotherapy clinics and research labs under the mentorship of lead experts like - Dr Naval Daver (Immunotherapy in hematolymphoid malignancies) - Dr. Aung Naing, (Immunotherapy in solid malignancies) - Dr. Terry Fry (Cell based immunotherapies) - Dr Sanjeev Agarwala, St. Luke's C.ancer Center & Temple University (Melanoma)

- **Imaging and bio-imaging/ nuclear medicine:**
  - Interpretation of Chest radiograph, Computed tomography, PET and PET-CT, Ultrasound, Bone scanning, Magnetic resonance imaging

- **Clinical and pathological staging**
  - TNM description
  - T description
  - N description
  - M description
  - Stage grouping

- **Functional and pre-immunotherapy evaluation**
  - Blood work up including CBC, liver and renal function tests
  - Cardiac status
  - Endocrine workup including thyroid profile, and Serum cortisol and ACTH levels
  - Autoimmune disease workup as appropriate

- **Prognostic factors /predictive markers**
  - Clinical and staging
  - Histopathological factors
  - Molecular markers
  - Co-morbidities

- **Principles of Immunotherapy**
  - Basis and principles of immunotherapy for cancers
  - Indications and contraindications for Immunotherapy
  - Chemotherapy and immuno / targeted therapy for cancers

- **Principles of systemic therapy**
  - Basis and principles of cytotoxic and biological therapy for cancers
  - Indications and contraindications for systemic therapy including chemotherapy & targeted agents
  - Management of side-effects of radiation therapy

- **Principles of radiation therapy as an adjunct to immunotherapy**
  - Radiotherapy planning and techniques
  - Indications and contraindications for radiotherapy
  - Palliative radiotherapy for metastatic sites
  - Management of side-effects of radiation therapy

- **Side-effects of Immunotherapy and their management**
  - Side- effects profile of Immunotherapeutic as single modality in various cancers
  - Side effects of immunotherapy combination with chemotherapy or targeted agents
  - Quantification of side –effects and their management

- Diagnosis and management of cancer site specific complications in patients with cancers

- **Opportunistic infections**
  - Symptomatology and clinical and radiological presentations of opportunistic infections especially post steroids or other immunosuppressant treatment in the setting of immunotherapy related complications.
  - Performance and interpretation of diagnostic tests for opportunistic respiratory infections
  - Treatment and management of respiratory infections in lung and other cancer patients

- **Combined modality treatments**
  - Combination of immunotherapy with chemotherapy and targeted therapy

- **Management of particular groups of patients**
  - Elderly
  - Children
  - Poor Performance Status
  - Co-Orbidities
  - Co-Existent Infection
  - Co-Existing Autoimmune Conditions

- **Treatment evaluation and follow up**
  - Survival/progression-free survival
  - Response assessment
  - Quality of life/symptom improvement
  - Follow up protocols

- **Management of specific conditions**
  - Immunotherapy at Extremes of ages
  - Immunotherapy with Comorbid conditions
  - Immunotherapy with Autoimmune conditions

- **Supportive care**
  - Pain management
  - Nutritional support

- Indications and management of intravascular stent and catheters
- Psychological support for the patient and family
- Rehabilitation
- End-of-life care
- Communicating with the patient
- Patient education

- **Intensive care**
  - Management of the critically ill cancer patient on immunotherapy
  - Assessment, diagnosis and management of conditions requiring critical care support in cancer patients on immunotherapy

- **Methodologies for clinical practice and research**
  - Study design and phases
  - Statistical analysis
  - Evidence based decision
  - Guidelines assessment and application

- **Ethics**
  - Ethical issues and conflicts of interest

- **Economic considerations in cancer treatment**
  - Quality-adjusted life-year (QALY)
  - Rational for using novel, Low cost protocols for immunotherapy use in cancers especially in developing countries
  - Cancer Registries to collect data on immunotherapy use in various cancers

4. Meeting of credit requirements (if applicable):

- Two Years

5. Students selection procedure:

- Minimum Eligibility Criteria: Indian National with Post graduate degree D.M. (Medical or Pediatric Oncology, or DNB (Medical oncology), or post MD Medicine / Pediatrics with post MD experience of at least 3 years of which at least 2 years are in a structured

fellowship/diplomate programme in the fields of oncology and/ or hemato-oncology. Candidates awaiting their results may also apply, however shortlisting would be subject to successful completion of the Postgraduate qualifying exam.

- After an advertisement, a written examination will be conducted as already ongoing for all HBNI Fellowship programmes followed by an interview. Candidates will be graded and a merit list prepared. The list would detail the selected candidate as well as a waiting list

Application form:

Personal details: contact details, date of birth, country

- Details about home and host institutes
- CV details: work experience, education, personal skills and competences, publication lists (max 5 peer-reviewed articles, max 5 abstracts)
- Recommendation letter from your home institute: Letter of recommendation from the candidate's department head/mentor or supervisor
- Maximum 1 page, preferably pdf format
- Must be written in English, on the institute's letter head paper and duly signed and dated
- Must include the following: − attest the applicant's proficiency in the English

6. Total intake per year

- Two fellows per year initially. Depending on the demand and requirement

7. Availability of faculty members for the programme at the CI/OCC:

The faculty for the 2 Year Fellowship in immuno-oncology will be sourced from existing faculty (currently various faculty members within the Medical Oncology Department) and across various Departments of TMC and invited faculty delivering lectures from across India and abroad. Notably, from MD Anderson Cancer Center immunotherapy lead Dr. Naval Daver (hematolymphoid malignancies) and Dr. Aung Naing (solid malignancies) and from St Luke's Cancer Center & Temple University, Dr. Sanjiv Agarwala (melanoma expert), and Dr Terry Fry (Cell based Immuno-therapies) are willing to be permanent international experts and mentors on board. Dr Rahul Purwar (expert on CAR T-cell development from IIT-B, Mumbai) is willing to be permanent national expert from an Indian Institution.

- We hope to also incorporate the already available means of Video-conferencing/Skype to gain knowledge from a wider selection of faculty across regional, national and international boundaries.

- We hope to expand and share this knowledge venture in future depending on availability, scalability and demand by beaming across all Centers of the National Cancer Grid as well as open the (tentatively weekly) lectures to postgraduates across medical colleges and teaching hospitals in Mumbai.
- The faculty will be sourced from various Departments as below:
  - Medical Oncology Department, Tata Memorial Hospital (TMH), including Adult and Pediatrics Solid Tumors, and Adult and Pediatrics Hemato-lymphoid Groups
  - Radiology and Interventional Radiology, TMH
  - Department of Nuclear Medicine, TMH
  - Department of Radiotherapy, TMH
  - Department of Anesthesia, Critical Care and Pain, TMH
  - Department of Pathology, TMH
  - Clinical Research Secretariat, TMC
  - Department of Palliative Medicine, TMH
  - Invited field-specific national and international expert faculty National:
  - Indian Institute of Technology-B, Mumbai International:
  - MD Anderson Cancer Center
  - St Luke's Cancer Center & Temple University

8. Availability of stipend/scholarship for the students (copy of DAE approval, if any)

- As laid down by Tata Memorial Centre for all HBNI 2 Year Fellowships

9. Annual tuition fees:

- As laid down by Tata Memorial Centre-HBNI for all other two-year fellowships.

10. Examination pattern:

- Every 3 months, there will be a review of student progress in the form of Student-Medical Oncology representative interaction to ascertain if the quarterly Fellowship teaching and learning goals have been achieved to satisfaction.
- Every 6 months there will be a formal assessment in the form of case discussions and a viva will be conducted by TMC faculty to assess student academic progress and logbook scrutinized. A formal evaluation and grading will be done.
- At the end of the first year a written examination with a Viva would be conducted by

TMC faculty for progress assessment.

- These 6 monthly evaluations will be considered as internal assessment and will be proportionately incorporated in the final grading at the exit exam constituting 20 % of the same.
- The final fellowship certification will be issued after the successful completion of a theory and practical exit exam conducted at the end of 2 years and final scores would carry 80% weightage and remaining 20% would be internal assessment based as mentioned above. A minimum score of 50% in the theory paper as well as a minimum 50% in the viva/practical would be essential to be declared successful in the examination. External examiner (s) would be invited for the assessment.

11.Declaration of results:

- As laid down by Tata Memorial Centre-HBNI for all other two-year fellowships

12. Draft ordinance:

- As laid down by Tata Memorial Centre-HBNI for all other two-year fellowships

Practical Rotation in Solid Tumors: one year

1 month, Radiodiagnosis and Nuclear medicine

2 months Lung cancer

2 months Melanoma

1 month Sarcomas

2 months Head and Neck cancers

1 month Genitourinary cancers

1 month Gastrointestinal cancers

1 month Breast cancers

1 month Gynecological cancers

Practical Rotation in Hemato-oncology- One year

1 month for Basic sciences-

2 weeks at Immunology Laboratories in ACTREC

2 weeks in Department of Biosciences and Bio-engineering at IIT-B, Mumbai

3 months at Cell Therapy Center, ACTREC

2 months at Stem Cell Transplant Unit, ACTREC

3 months at Pediatric Hemato-lymphoid DMG, TMH

3 months at Adult Hemato-lymphoid DMG, TMH