

## **Combined NCCAM-NCI Medical Oncology-CAM Fellowship**

### ***Précis***

Complementary and Alternative Medicine (CAM) approaches are increasingly being used by cancer patients and practitioners to address the medical, psychosocial and spiritual needs resulting from cancer. Medical oncologists frequently find themselves in a position where they are asked for their expert opinion on the use, benefits and risks of CAM approaches in the treatment of cancer. In addition, there is a growing need for research into the role of CAM for cancer treatment. The combined NCCAM-NCI fellowship offers a model to train academic oncologists both in medical oncology and CAM to become experts in research in the field of CAM in oncology as well as providing them with exposure to clinical and regulatory aspects of CAM in oncology.

The duration of the fellowship training program is projected for 3 years. During the first year, fellows will fulfill the NCI Medical Oncology clinical fellowship training requirements with 6 months' rotations in medical oncology at the Clinical Center and at NNCM. The NCCAM component will encompass years two and three. It consists of four modules:

1. The CAM Research Module
2. The CAM Policy/Regulatory Affairs Module
3. The CAM Educational Module
4. The CAM Practice Module.

In addition, the fellow will have a medical oncology continuity clinic for 1/2 day per week as required to meet the ABIM requirements for board eligibility in Medical Oncology.

### **1. CAM Research Module**

The CAM Research Module is intended to focus primarily on clinical research in the area of Cancer CAM. The fellow will choose a mentor at NCCAM and a co-mentor at the NCI for a clinical research project in one of the following areas:

1. Cancer symptom management with CAM modalities
2. Biologics and botanical/drug interactions in cancer treatment
3. Mind/body interventions in cancer treatment

The CAM cancer fellowship research module will include research activities in the following areas:

1. Design, formulation and execution of an original clinical research project
2. Participation in the conduct of at least one ongoing clinical trial
3. Clinical trials data evaluation, analysis and publication

It is expected that the fellow design, write and initiate implementation of a clinical research protocol under the supervision of the mentors. This will include design of a protocol proposal and a clinical trial protocol as well as presenting and "defending" the projects in Branch review, scientific review and IRB meetings under the guidance of the mentor. In addition, the fellow will serve as study chair of an ongoing clinical trial in the NCCAM/DIR Oncology Program with primary responsibility for trial implementation and data collection.

The fellow will also have the opportunity to participate in clinical trial data analysis of available CAM cancer trials, scientific publication of results and scientific publication peer review.

After application by the fellow, extension of the duration of the fellowship into a fourth year may be granted to qualified candidates following review of fellowship performance and progress by both the NCCAM and the NCI mentor and the Director, NCCAM upon completion of year 2 of the fellowship. The fellowship is designed to allow for at least 80% of fellowship activity allocated to clinical research (see Section 5.).

## **2. CAM Policy/Regulatory Affairs Module**

The CAM Policy/Regulatory Affairs Module will address the following training objectives:

1. Cancer CAM research review/policy making (FDA/OCCAM)
2. Cancer CAM research regulatory affairs (NCCAM/FDA)
3. Cancer CAM research trial methodology (OCCAM/FDA)

The fellow will be exposed to the spectrum of cancer CAM research review, trials methodology, policy making and regulatory affairs. Rotations of one month's duration during the second year will allow the fellow to gain familiarity with CAM oncology research review and policy making issues and to meet these objectives. The FDA rotation is planned for the third year of fellowship as described in Section 5., and is outlined in Appendix 3.

## **3. CAM Educational Module**

The fellow is encouraged to participate in a variety of ongoing CAM educational activities:

- 1 CAM lecture series
- 2 Weekly LCI Journal club
- 3 Cancer CAM seminars/conferences (OCCAM)
- 4 Other NCCAM educational activities

In addition, the fellow will be expected to present a formal discussion of the clinical research proposal and give intermittent formal and informal research project updates to members of the LCI and the larger NCCAM community.

## **4. CAM Practice Module**

The CAM Practice Module is allocated to year 3 of the fellowship. As outlined in Section 5., the fellow will spend 20% of the fellowship year activity shared between this module and the FDA rotation.

### **4.1 CAM Rotations at the Clinical Center**

The fellow will spend one month with the Pain/Palliative Care Service (PPCS, Appendix 2, Contact Dr. Ann Berger). The fellow will also be offered the opportunity to evaluate and follow oncology patients from a CAM/Rehabilitation Medicine perspective under the supervision of the Department of Rehabilitation Medicine staff (Appendix 1, contact Dr. Jay Shah) during the month spent with the PPCS. In addition, the fellow will be encouraged to review patients seen in the oncology continuity clinic from the CAM/Rehabilitation Medicine perspective with RMD staff. The aim for these rotations is to gain experience with the use of CAM approaches in clinical and clinical research settings emphasizing the care of cancer patients.

## **4.2 CAM Electives**

The fellow may have the opportunity for an elective rotation selected from a list of available CAM practice settings in the Washington Metropolitan Area according to individual interests. On a case-by-case basis, off-site placements within the U.S. may be possible. The fellow is expected to prepare an outline to the fellowship director under the supervision of the research mentor during the first three months of the second year of the fellowship, specifying areas of interest and goals for the CAM practice rotations. One rotation with a cumulative duration of one month will be available during fellowship years two or three.

## 5. Curriculum Outline

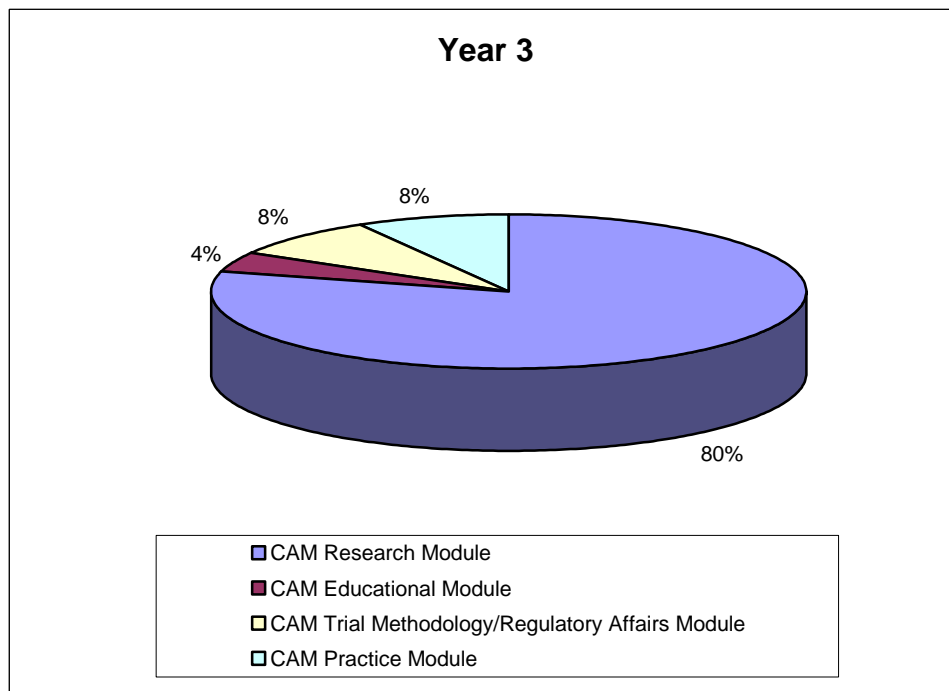
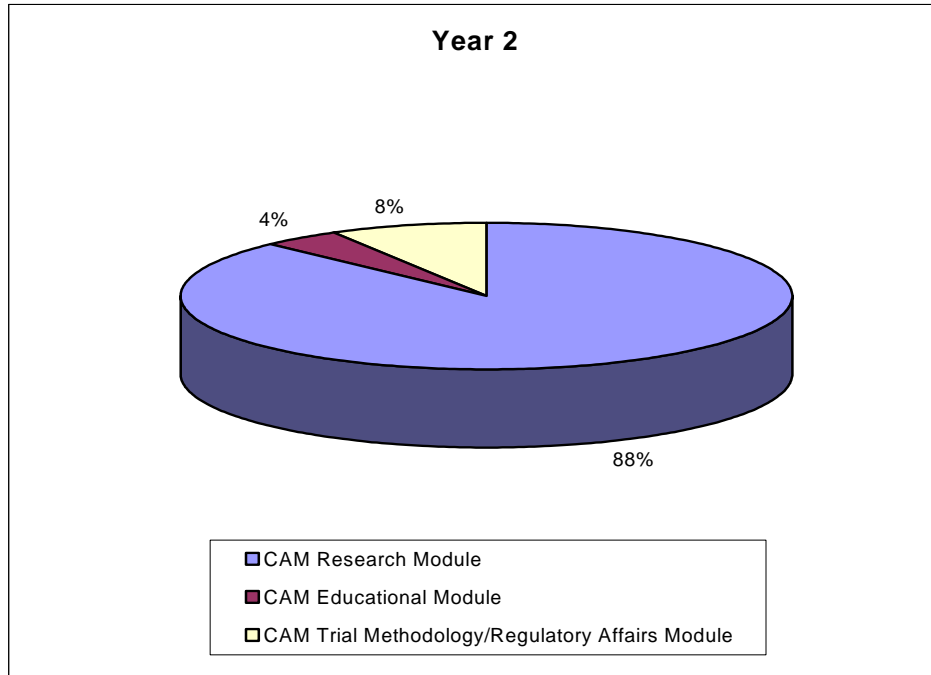
### 5.1 Overview of Fellowship Program

	Year 1	Year 2	Year 3
<b>Medical Oncology Clinical Fellowship</b>			
<b>CAM Research Module</b>			
<b>CAM Educational Module</b>			
<b>CAM Trial Methodology/ Regulatory Affairs Module</b>		Cancer CAM research trial methodology*	Cancer CAM research regulatory affairs (FDA)# Appendix 3
<b>CAM Practice Module</b>			Pain/Palliative Care* Appendix 2 Rehabilitation Medicine Appendix 1
			Elective*

\*Duration: 1 month

# Duration: 4-6 weeks

## 5.2 Time Allocation (%) per Module by Year



### **5.3 Research/Clinical Activity Break Down (%) by Year**

<b>Fellowship Year</b>	<b>1</b>	<b>2</b>	<b>3</b>
<b>Research</b>	0	90	80
<b>Clinical</b>	100	10	20

## **6. Appendices**

**Appendix 1: CAM Oncology-Rehabilitation Medicine Rotation**

**Appendix 2: CAM Oncology-Pain and Palliative Care Rotation**

**Appendix 3: CAM Oncology Fellowship FDA Regulatory Module**

## **CAM Oncology-Rehabilitation Medicine Rotation**

### ***Précis***

The exposure to the role of CAM in cancer rehabilitation forms an integral part of the CAM Practice Module and the CAM Educational Module within the NCCAM/NCI CAM Oncology Fellowship program. The fellow will be offered the opportunity to learn about the role and benefit of CAM modalities in the rehabilitation of cancer patients and will gain hands-on experience in the practice of some of these CAM modalities within the causality-and functionality-oriented framework of rehabilitation medicine.

### ***Educational Goals***

1. Increase understanding of functional problems of cancer patients and increase skills in the evaluation and treatment of problems pertaining to function.
2. Increase skills in the evaluation and treatment of dysfunction in the neuromusculoskeletal system.
3. Increase competencies in the ability to prescribe and evaluate efficacy of the following modalities: guided imagery, relaxation, biofeed back training, massage, acupuncture for musculoskeletal problems, yoga, t'ai chi.
4. Develop skills in evaluating and treating myofascial problems including use of trigger point injections.

### ***Curriculum Outline***

#### **1. Educational activities**

Each fellow will attend Rehabilitation Medicine Grand Rounds lectures covering the role of CAM modalities in rehabilitation medicine, and attend seminars and lectures offered through RMD on specific CAM modality practices and applications, as well as topics offered within rehabilitation medicine pertinent to the understanding of the discipline as it relates to the role and practice of CAM modalities.

#### **2. CAM/RMD patient evaluation**

The fellow will via direct contact from the Rehabilitation Medicine Department, perform new and follow-up evaluations of cancer patients on a case-by case basis. The fellow will assess the role of CAM in the rehabilitation medicine needs of each consult patient under supervision of a trained physiatrist and will assist in the development of CAM aspects of a rehabilitation medicine plan. The fellow will have the opportunity to observe and learn the basics of practice of the CAM modalities included in the respective management plan and will gain experience and understanding of the role and efficacy of CAM modalities as part of the general rehabilitation medicine management plan. The CAM/RMD patient evaluation process will be available to the fellow as part of the ongoing clinical activities during the third year of fellowship. In addition the fellow will be encouraged to develop,

as indicated, rehabilitation concepts to include CAM approaches for patients being followed in the medical oncology continuity clinic.



## **CAM Oncology-Pain and Palliative Care Rotation**

### ***Précis***

The Pain and Palliative Care (PPC) Rotation forms an integral part of the CAM Practice Module and the CAM Educational Module within the NCCAM/NCI CAM Oncology Fellowship program. The fellow will be offered the opportunity to learn about the role and benefit of CAM modalities as part of the pain and symptom management of cancer patients. The fellow will gain hands-on experience in the practice of some of these CAM modalities with the goal of quality of life improvement and reduction of suffering in cancer patients.

### ***Educational Goals***

1. Use of CAM modalities in cancer PPC management.
2. Exposure to and opportunity to practice the basics of CAM modalities such as:
  - Hypnosis
  - Guided imagery
  - Relaxation
  - Massage/ Reiki
  - Acupuncture
1. Attendance of the PPC clinic for evaluation and management of cancer patients emphasizing incorporation of CAM modalities for pain and symptom management.

### ***Curriculum Outline***

#### **1. Educational activities**

Each fellow will attend PPC lectures and seminars covering the role and practice of CAM modalities in PPC, and attend seminars and lectures offered through PPC on specific CAM modality practices and applications, as well as topics within the PPC Service pertinent to the basic understanding of the discipline.

#### **2. PPC clinic**

One rotation of a month's duration will be offered during the third year of fellowship. During that time, the fellow will attend the regular PPC clinic. New and follow-up evaluations of cancer patients will be scheduled. The fellow will assess the PPC needs of each cancer patient under supervision of a trained member of the PPC team and will develop a PPC plan with emphasis on the role and indication of CAM modalities in the management plan. The fellow will have the opportunity to observe and learn the basics of practice of the CAM modalities included in the respective management plan and follow the patient for PPC and CAM modality treatment outcome.

#### **3. PPC Consult Service**

The fellow will also become an active member of the inpatient PPC consult service. This participation will include answering to PPC inpatient consult requests, evaluation of consult patients, formulation of a consult plan including applicable CAM modalities, and follow-up for response.

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## **CAM Oncology Fellowship FDA Rotation**

### ***Précis***

The fellow will be exposed to the spectrum of cancer CAM research review, trials methodology, policy making and regulatory affairs. Rotations will allow the fellow to gain familiarity with the issues and to meet these objectives. These rotations will be spread out over the second and third year of the fellowship and may be expanded according to the individual fellow's interests.

### ***Educational Goals***

- Basic understanding of General drug development, review and approval process with emphasis on cancer therapeutics
- Exposure to and understanding of botanical guidance, regulatory issues and rational of provisions

### ***Curriculum Outline***

The FDA rotation specifically will provide the fellow with an initial period of 1-2 weeks of full time general introduction and training pertinent to CAM/ botanical and cancer therapy related regulatory issues, such as:

- General drug development, review and approval process with emphasis on cancer therapeutics
- Botanical guidance, regulatory issues and rational of provisions

This introductory period will be followed by a period of 3-6 months during which the fellow will be assigned a mentor at the FDA to pursue the following areas:

- Participation in review discussions/meetings of botanical applications
- Review of available information on literature/trials of the therapeutic use of botanicals with particular emphasis on the regulatory perspective
- Review of existing botanical applications with emphasis on cancer therapy and clinical trial design

The fellow will be assigned to the Botanical Review Team in the FDA's Center for Drug Evaluation and Research and will be participating in the outlined activities at least one day per week or according to the schedule of meetings and review sessions during the 3-6-months period.