Chapter 3. Results

Overview of Case Review

For IAT, we reviewed, in depth, 30 cases (of the possible 60 cases) that had the potential to be included in a best-case series. Of those, nine cases are presented that we consider the most complete or appropriate in terms of the NCI criteria for a best-case series. They included the following types of cancer: Hodgkin's lymphoma, non – small cell carcinoma of the lung, nodular lymphoma (poorly differentiated), abdominal mesothelioma (two cases), ovarian adenocarcinoma, squamous cell carcinoma of vocal cord (two cases), and colon cancer.

For Naltrexone only three cases of the 21 we reviewed in depth approximated the NCI criteria. These included the following cancers: melanoma, pancreatic cancer, and endometrial adenocarcinoma with breast adenocarcinoma (single case).

However, the extent to which these cases meet the NCI criteria varied considerably. The most difficult criteria to meet are the histological/imaging confirmations, for two reasons; 1) inadequate information was provided by the file or the patient, or 2) the case was so old that the providers no longer had the specimens or files.

Whereas no institution refused to provide us with the material we requested, we had to rely in some cases on biopsy reports, radiological reports, and other such interpretations of the original material instead of the actual slides and images. Any case older than five years was unlikely to be able to meet the strict criteria of providing actual biopsy material and/or original images. However, we are still actively seeking much of this material for the cases included in this review. The status reports of the requested materials are shown below in Tables 1 and 2.

Cancer Best-Case Series

Patient #1-1
Nodular Sclerosing Lymphoma Stage 1B

Case 1-1

The patient in case 1-1 is a 46-year-old male diagnosed on 12/2/83 with nodular sclerosing lymphoma stage 1B after presenting with superior vena caval obstruction. Palliative radiation therapy was completed on 12/7/83 with a total of 800 RADS delivered to his vena cava. Chemotherapy (MOPP) was started on 12/00/83 and stopped early on 6/00/84. Four cycles of full-dose chemotherapy and two additional courses of a 25% reduced dose were given. On 7/19/94, it was recommended that the patient receive full mantle radiation, which he declined. At the termination of conventional therapy, the patient had no palpable peripheral lymphadenopathy but still had a superior mediastinal mass (CXR 7/10/84). IAT was started on 8/2/84, and 22 courses were completed as of 12/8/00 (the data of chart abstraction). The patient had sporadically taken a variety of dietary supplements in the past. Serial chest x-rays performed during IAT therapy showed a decrease in tumor mass. The most recent MRI for which we have a report (11/4/86) showed inactive disease. The most recent MRI of the chest (1995) revealed no tumor according to the patient. At the last patient contact (interview, 9/26/01), the patient reported that his overall physical condition was excellent.

Pathology

12/2/83	**Biopsy: anterior mediastinal Hodgkin's lymphoma (nodular sclerosing type)**
12/7/83	**Biopsy: bone marrow: normal**

Imaging

4/17/84	**X-ray chest: further improvement of mediastinal mass**
7/10/84	**X-ray chest: mass in chest, no change**
11/4/86	**MRI chest: complete obstruction of superior vena cava. Unchanged anteromediastinal mass suggests inactive disease at this time**
1995	**MRI chest: no evidence of disease per patient**

Conventional therapy

12/7/83	**Radiation: palliative to superior vena cava: 800 RADS: decrease in size of mass**
12/83-6/84	**Chemotherapy: MOPP: 4 cycles: followed by 2 cycles reduced by 25%: Did not complete chemotherapy due to patient preference and low blood counts.**
7/19/84	**Radiation (mantle) recommended; patient declined**

Complementary therapy

8/2/84-12/8/00	**IAT 22 courses**
11/1/84	**Benzaine E, calcium orotate, molybdenum, S.O.D., beta-carotene, glutathione, kyolic, Vitamin C, Vitamin E, lithumorate, Wobenzym, inzellonal, transmutase forte, thymus pills & injections, asterile injections, beriglobin, Vitamin D oil, selenium, carnitine (treatment recorded as provided by patient)**
Date unknown	**Live cell therapy in Germany; did not proceed with entire treatment**

Patient # 1-1						
EVENT	**PERIOD 1** **1st qtr 1983 – 4th qtr 1983**	**PERIOD 2** **1st qtr 1984 – 4th qtr 1984**	**PERIOD 3** **1st qtr 1985 – 4th qtr 1985**	**PERIOD 4** **1st qtr 1986 – 4th qtr 1986**	**PERIOD 5** **1st qtr 1995 – 4th qtr 1995**	**PERIOD 6** **1st qtr 2000 – 4th qtr 2000**
Biopsy/diagnosis	**12/83**					
Surgery						
Radiation	**12/83**					
Chemotherapy	**12/83**	**6/84**				
IAT		**8/84**				**12/00**
CAM other		**11/84**				
Imaging CXR		**3/84 4/84 7/84**				
Imaging MRI				**11/86**	**1995**	

CAM Therapy:	IAT		
Case:	1-1		
Condition:	Hodgkin's disease, nodular sclerosing type		
Abstractor:	1	**Date of Abstraction:**	6/14/01
Interviewer:	IDC	**Date of Interview:**	9/26/01
Comments:	Incomplete chemotherapy with residual tumor		

Criteria for inclusion: (check all that apply)			
x	Diagnosis confirmed		
x	Documented start date for CAM therapy		
x	Documented previous anti-cancer therapies		
	No other therapies during the CAM therapy		
x	Documented endpoint:		
	x	Tumor size	
		Longevity	
		Quality of Life	
		Other:	

Other Relevant Information:	
Sex:	male
DOB:	12/6/55
Diagnosis:	Hodgkins disease, nodular sclerosing type, involving mediastinum
Diagnosis date:	12/7/83
CAM therapy dates:	8/2/84-12/8/00: 22 courses
Conventional therapy dates:	12/83-6/84 chemo: incomplete 12/7/83 radiation: completed
Last contact date:	12/8/00
If deceased, date of death:	

Date	Description of Events	Requested	Status of requests
	Family history of lymphoma in brother		
12/2/83	Biopsy: anterior mediastinal: Hodgkin's disease (nodular sclerosing)	Slides	Not avail.
12/7/83	Biopsy: bone marrow; normal	Slides	Not avail.
12/7/83	Radiation: palliative to superior vena cava: 800 RADS: decrease in size of mass		
12/83-6/84	Chemotherapy: MOPP: 4 cycles: followed by 2 cycles reduced by 25%: Did not complete chemotherapy due to patient preference.		
4/17/84	X-ray chest: further improvement of mediastinal mass	Films	Not avail.
7/10/84	X-ray chest: mass in chest, no change	Films	Not avail.
8/2/84-12/8/00	IAT 22 courses		
11/1/84	Benzaine E, calcium ortate, molybenum, S.O.D., beta-carotene, glutathione, kyolic, Vitamin C, Vitamin E, lithumorate, wobenzym, inzellonal, tranmusase forte, thymus pills & injections, astenile injections, beriglobin, Vitamin D oil, selenium, carnitine		
11/4/86	MRI chest: complete obstruction of superior vena cava. Inactive disease at this time	Films	Not avail.
1995	MRI chest: no evidence of disease per patient	Films	Pending

Cancer Best-Case Series

Patient #1-3
Squamous Cell Carcinoma of the Right Vocal Cord and Anterior Commissure

Case 1-3

The patient in case 1-3 is a 68-year-old male who was diagnosed with squamous cell carcinoma of the right vocal cord and anterior commissure on 9/3/81. An excisional biopsy was performed at that time, but the resection was not complete. The patient was referred for radiation therapy, which he refused due to patient preference. Thus, the patient received no definitive conventional therapy. He completed 15 courses of IAT from 9/22/81 to 5/19/89. Serial examinations by his otolaryngologist revealed the persistent presence of disease without progression through 2/23/82. An otolaryngologist performed an indirect laryngoscopy on 7/20/94, which did not reveal any abnormal findings. At the last contact (interview, 9/24/01), the patient reported that his overall physical condition was very good to excellent.

Pathology

9/3/81	**Biopsy: squamous cell carcinoma, well differentiated, infiltrating: right vocal cord and anterior commissure: stage T:1 1/2 N:0 M:0**

Imaging

9/22/81	**X-ray chest: normal**
7/20/94	**ENT evaluation visual inspection via indirect laryngoscopy: normal exam**

Conventional therapy

9/3/81	**Surgery: biopsy with debulking; 80–90% bulky tumor mass removed; residual cancer remained**
9/16/81	**Referred for radiation: patient refused**

Complementary therapy

9/22/81-5/19/89	**IAT 15 courses**

Patient # 1-3						
EVENT	**PERIOD 1** **1st qtr 1981 – 4th qtr 1981**	**PERIOD 2** **1st qtr 1984 – 4th qtr 1984**	**PERIOD 3** **1st qtr 1985 – 4th qtr 1985**	**PERIOD 4** **1st qtr 1986 – 4th qtr 1986**	**PERIOD 5** **1st qtr 1989 – 4th qtr 1989**	**PERIOD 6** **1st qtr 1994 – 4th qtr 1994**
Diagnosis/ biopsy	**9/81**					
Diagnostic procedure						**7/94**
Surgery	**9/81**					
Radiation						
Chemotherapy						
IAT	**9/81**				**5/89**	
CAM other						
Imaging CXR	**9/81**					

CAM Therapy:	IAT		
Case:	1-3		
Condition:	Squamous cell carcinoma right vocal cord and anterior commisure: stage T:1 1/2 N:0 M:0		
Abstractor:	1	**Date of Abstraction:**	6/14/01
Interviewer:	JTF	**Date of Interview:**	9/24/01
Comments:	Surgical debulking, residual cancer; no other conventional therapies		

Criteria for inclusion: (check all that apply)			
x	Diagnosis confirmed		
x	Documented start date for CAM therapy		
x	Documented previous anti-cancer therapies		
x	No other therapies during the CAM therapy		
x	Documented endpoint:		
	x	Tumor size	
		Longevity	
		Quality of Life	
		Other:	

Other Relevant Information:	
Sex:	male
DOB:	7/1/33
Diagnosis:	squamous cell carcinoma right vocal cord and anterior commisure: stage T:1 1/2 N:0 M:0
Diagnosis date:	9/3/81
CAM therapy dates:	9/22/81-5/19/89
Conventional therapy dates:	9/3/81 surgery
Last contact date:	5/19/89
If deceased, date of death:	

Date	Description of Events	Requested	Status of requests
	Family history of gastric cancer in mother		
9/3/81	Biopsy: squamous cell carcinoma, well-differentiated, infiltrating: right vocal cord and anterior commisure: stage T:1 1/2 N:0 M:0	Slides	Not avail.
9/3/81	Surgery: biopsy with debulking- residual cancer remained		
9/3/81	Referred for radiation: patient refused		
9/22/81	X-ray chest: normal		
9/22/81-5/19/89	IAT: 15 courses		
7/20/94	ENT evaluation visual inspection via indirect laryngoscopy		

Cancer Best-Case Series

Patient #1-4
Metastatic Non – Small Cell Carcinoma of the Lung

Case 1-4

The patient in case 1-4 is a 67-year-old woman with a family history of cancer, diagnosed with metastatic non – small cell carcinoma of the lung in July 1992. She initially presented with swelling in the neck, an enlarged supraclavicular lymph node, and a chest mass demonstrated by CT in the area of the aortic notch. A mini-thoracotomy was performed to obtain tissue for diagnosis. Initially, the mass was identified as an anaplastic mediastinal tumor, which subsequent review at the Canadian Reference Lab for Pathology determined to be non – small cell poorly differentiated lung cancer. Subsequently, she was referred for palliative chemotherapy and radiation, which she completed. No response was demonstrated to these treatments, and no further conventional therapy was advised. She initiated IAT in February 1993 and continues on maintenance therapy today. Serial CT scans beginning in September 1994 revealed resolution of the tumor. At the last contact (interview, 12/4/01), the patient reported that her overall physical condition was good.

Pathology

7/31/92	**Surgical biopsy: mediastinum (multiple bite biopsy via mediastinotomy): discrepancy of pathological diagnosis: first diagnosis lymphoma, second diagnosis metastatic giant cell carcinoma, third diagnosis lung carcinoma poorly differentiated (9/4/92)**
7/31/92	**Biopsy: left supraclavicular lymph node final pathology revealed lung carcinoma poorly differentiated**
8/12/92	**Biopsy: bone marrow: negative for malignancy**

Imaging

July, 92	**CT scan thorax: tumor 5cm mass in the area of the aortic notch**
7/31/92	**X-ray chest: no change compared with prior**
8/4/92	**Bone scan whole body: no metastatic bone disease**
9/9/93	**CT scan thoracic: tumor decreased in size, residual tumor or post treatment fibrosis**
11/30/93	**X-ray chest/ left shoulder: right lung clear; no tumor; increase left hemi-diaphragm**
4/13/94	**X-ray chest: no significant changes compared with previous**
9/26/94	**X-ray chest: lungs clear**
9/26/94	**CT scan thoracic: no evidence of tumor; Remission based on CT scan of thorax revealing no evidence of tumor**
6/24/93	**Ultrasound abdomen: normal**
11/11/96	**CT scan thoracic: no evidence of tumor; post radiation changes in left thorax**
11/25/97	**CT scan thoracic: no evidence of tumor**
12/7/98	**CT scan thoracic: no evidence of tumor**
12/15/00	**CT scan thoracic: no evidence of tumor; no change compared with 12/7/98**

Conventional therapy

7/31/92	**Left anterior mediastinotomy; mediastinal mass biopsy**
8/00/92	**Chemotherapy: cytoxan, adriamycin, vincristine, prednisone; stopped early due to change in tissue diagnosis**
9/00/92	**Chemotherapy: VP16 190mg, cisplatinum 48 mg : 3 days every 3 weeks: completed recommended course: no tumor response**
10/21/92	**Radiation: palliative: mediastinum/ left perihilar/ supraclavicular: 4,000cGy; no tumor response**
11/92-12/92	**Chemotherapy: VP16 190mg, cisplatinum 48 mg: 3 days every 3 weeks: completed recommended course: no tumor response**

Complementary therapy

2/8/93-present	**IAT; still on maintenance therapy**

Patient # 1-4						
EVENT	**PERIOD 1** **1st qtr 1992 – 4th qtr 1992**	**PERIOD 2** **1st qtr 1993 – 4th qtr 1993**	**PERIOD 3** **1st qtr 1994 – 4th qtr 1994**	**PERIOD 4** **1st qtr 1995 – 4th qtr 1995**	**PERIOD 5** **1st qtr 1996 – 4th qtr 1996**	**PERIOD 6** **1st qtr 1997 – 4th qtr 1997**
Diagnosis/biopsy	**7/92, 8/92**					
Surgery	**7/92**					
Radiation	**10/92**					
Chemotherapy	**7/92-9/92** **12/92**					
IAT		**2/93**				
CAM other						
Imaging CXR	**7/92**	**11/93**	**4/94** **9/94**			
Imaging CT	**7/92**	**9/93**	**9/94**		**11/96**	**11/97**
Imaging bone scan	**8/92**					

EVENT	PERIOD 7 1st qtr 1998– 4th qtr 1998	PERIOD 8 1st qtr 1999 – 4th qtr 1999	PERIOD 9 1st qtr 2000 – 4th qtr 2000	PERIOD 10 1st qtr 2001 – 4th qtr 2001
Diagnosis/biopsy				
Surgery				
Radiation				
Chemotherapy				
IAT				
CAM other				
Imaging CXR				
Imaging CT	12/98		12/00	
Imaging bone scan				

CAM Therapy:	IAT		
Case:	1-4		
Condition:	Large cell lung carcinoma--metastatic		
Abstractor:	1	**Date of Abstraction:**	6/14/01
Interviewer:	IDC	**Date of Interview:**	12/4/01
Comments:	Giant cell carcinoma later diagnosed as large cell lung carcinoma, no response to chemotherapy or radiation		

Criteria for inclusion:	**(check all that apply)**		
x	Diagnosis confirmed		
x	Documented start date for CAM therapy		
x	Documented previous anti-cancer therapies		
x	No other therapies during the CAM therapy		
x	Documented endpoint:		
	x	Tumor size	
		Longevity	
		Quality of Life	
		Other:	

Other Relevant Information:	
Sex:	female
DOB:	6/15/44
Diagnosis:	Large cell lung carcinoma-metastatic
Diagnosis date:	8/12/92
CAM therapy dates:	2/8/93-still on maintenance therapy
Conventional therapy dates:	Chemotherapy: 8/00/92-1/6/92 Radiation: 10/11/92
Last contact date:	5/1/01
If deceased, date of death:	

Date	Description of Events	Requested
no date	Family history: sister lung cancer, maternal aunt breast cancer, mother urinary cancer	
7/31/92	Surgical biopsy: mediastinum (multiple bite biopsy via mediastinotomy): discrepancy of pathological diagnosis: first diagnosis lymphoma, second diagnosis metastatic giant cell carcinoma, third diagnosis lung carcinoma poorly differentiated (9/4/92)	Slides
7/31/92	Biopsy: left supraclavicular lymph node final pathology revealed lung carcinoma poorly differentiated	Slides
7/31/92	X-ray chest: no mass	
8/4/92	Bone scan whole body: no metastatic bone disease	
8/12/92	Biopsy: bone marrow: negative for malignancy	
8/00/92	Chemotherapy: cytoxan, adriamycin, vincristine, prednisone; stopped early due to change in tissue diagnosis	
9/00/92	Chemotherapy: VP16 190mg, cisplatinum 48 mg : 3 days every 3 weeks: completed recommended course: no tumor response	
10/21/92	Radiation: palliative: mediastinum/ left perihilar/ supraclavicular: 4,000cGy; no tumor response	
1/6/93	Chemotherapy: VP16 190mg, cisplatinum 48 mg : 3 days every 3 weeks: completed recommended course: no tumor response	
2/8/93-present	IAT; still on maintenance therapy	
6/24/93	Ultrasound abdomen: normal	
9/9/93	CT scan thoracic: tumor decreased in size, residual tumor or post treatment fibrosis	Films
11/30/93	X-ray chest/ left shoulder: right lung clear; no tumor; increase left hemi-diaphragm	
4/13/94	X-ray chest: no significant changes compared with previous	

Date	Description of Events	Requested	Status of requests
9/26/94	X-ray chest: lungs clear	Films	Pend.
9/26/94	CT scan thoracic: no evidence of tumor		
11/11/96	CT scan thoracic: no evidence of tumor; post radiation changes in left thorax		
11/25/97	CT scan thoracic: no evidence of tumor		
7/12/98	CT scan thoracic: no evidence of tumor	Films	Pend.
12/15/00	CT scan thoracic: no evidence of tumor; no change compared with 12/7/98	Films	Pend.

Cancer Best-Case Series

Patient #1-6
Poorly Differentiated Nodular Lymphoma

Case 1-6

The patient in case 1-6 is a 49-year-old male who was diagnosed in 1983 with poorly differentiated nodular lymphoma after presenting with an enlarged node on his chin, fever, night sweats, and generalized pruritus. Although the patient was not found to have significant demonstrable adenopathy outside of the neck at diagnosis, he was felt to represent stage II disease. Local radiation was not recommended, and chemotherapy was deferred awaiting progression of disease. By 2/1/84, he had palpable adenopathy in both axillae and demonstrated anergy in skin testing. The patient elected to try unconventional therapy. He started IAT on 2/14/84 and had completed twelve courses by 7/19/90. He is currently in remission. At last contact (interview, 11/07/01), the patient reported that is overall physical condition was excellent.

Pathology

12/5/83	**Biopsy: pathology: lymph node: poorly differentiated lymphocytic nodular lymphoma**
12/21/83	**Biopsy: bone marrow: negative for malignancy**

Imaging

12/4/83	**Chest x-ray: within normal limits**
12/21/83	**Chest x-ray: within normal limits**
12/21/83	**Ultrasound abdomen: within normal limits**
2/14/84	**Ultrasound abdomen: within normal limits**
2/14/84	**Chest x-ray: within normal limits**
3/23/88	**Ultrasound abdomen: within normal limits**

Complementary therapy

2/14/84-7/19/90	**IAT: 12 course s**

Conventional therapy

	None

Patient # 1-6						
EVENT	**PERIOD 1** **1st qtr 1983 – 4th qtr 1983**	**PERIOD 2** **1st qtr 1984 – 4th qtr 1984**	**PERIOD 3** **1st qtr 1985 – 4th qtr 1985**	**PERIOD 4** **1st qtr 1986 – 4th qtr 1986**	**PERIOD 5** **1st qtr 1988 – 4th qtr 1988**	**PERIOD 6** **1st qtr 1990 – 4th qtr 1990**
Diagnosis/biopsy	**12/83**					
Surgery						
Radiation						
Chemotherapy						
IAT		**2/84**				**7/90**
CAM other						
Imaging CXR	**12/83, 12/83**	**2/84**				
Imaging ultrasound	**12/83**	**2/84**			**3/88**	

CAM Therapy:	IAT		
Case:	1-6		
Condition:	Lymphoma; poorly differentiated lymphocytic nodular lymphoma		
Abstractor:	1,2	**Date of Abstraction:**	6/14/01
Interviewer:	IDC	**Date of Interview:**	11/7/01
Comments:	no conventional therapy except excisional biopsy		

Criteria for inclusion: (check all that apply)			
x	Diagnosis confirmed		
x	Documented start date for CAM therapy		
x	Documented previous anti-cancer therapies		
x	No other therapies during the CAM therapy		
x	Documented endpoint:		
	x	Tumor size	
		Longevity	
		Quality of Life	
		Other:	

Other Relevant Information:	
Sex:	male
DOB:	4/7/52
Diagnosis:	lymphoma: poorly differentiated lymphocytic nodular lymphoma
Diagnosis date:	12/5/83
CAM therapy dates:	2/14/84-7/19/90
Conventional therapy dates:	none
Last contact date:	7/26/90
If deceased, date of death:	

Date	Description of Events	Requested	Status of requests
no date	Family history of cancer: mother died age 32 melanoma; father died age 57 of lung cancer		
12/5/83	Biopsy: diagnostic excisional biopsy: poorly differentiated lymphocytic nodular lymphoma	Slides	Not avail.
12/21/83	Bone marrow: negative for malignancy		
12/21/83	Ultrasound abdomen: within normal limits	Films	Not avail.
12/4/83	Chest x-ray: within normal limits	Films	Not avail.
12/21/83	Chest x-ray: within normal limits	Films	Not avail.
2/14/84	Chest x-ray: within normal limits	Films	Not avail.
2/14/84-7/19/90	IAT: 12 courses		
3/23/88	Ultrasound abdomen: within normal limits	Films	Not avail.
6/20/98	Physical exam: peripheral lymphadenopathy resolved by 1988: negative radiological studies		

Cancer Best-Case Series

Patient #1-7
Peritoneal Mesothelioma

Case 1-7

The patient in case 1-7 is a 50-year-old Caucasian female with a history of peritoneal mesothelioma. She was initially misdiagnosed with ovarian cancer on 7/1/99 after peritoneal biopsies were obtained from an exploratory laparoscopy with excision of left pelvic mass, left colectomy, colostomy, and omentectomy. Given the diagnosis of ovarian cancer, chemotherapy was initiated with taxol and carboplatin on 7/28/99. She had an anaphylactic reaction to taxol, and chemotherapy was stopped. On 8/5/99, the biopsies were again reviewed at the Armed Forces Institute of Pathology, and a diagnosis of peritoneal mesothelioma was made. No other conventional therapy was pursued due to patient preference. IAT was started on 12/1/99 and continued, with her most recent treatment on 6/6/01. Serial pelvic CT scans reveal a gradual diminution of pelvic densities, with the most recent pelvic CT scan on 5/24/01 revealing no evidence of progressive tumor or other abnormality. On 10/24/01, an attempt was made to reverse the patient's colostomy. Reversal was not possible due to adhesions, and the patient's small bowel was nicked, leading to a complicated post-operative course. However, according to the patient, the surgeon reported a decrease in the tumor bulk based on visual inspection. At last contact (interview, 9/26/01), the patient reported that her overall physical health is good.

Pathology

7/1/99	**Pathology: ovarian carcinoma vs. mesothelioma melanoma**
8/5/99	**Pathology: final diagnosis: malignant mesothelioma (same tissue specimen)**

Imaging

2/29/00	**CT scan of abdomen and pelvis: no associated definitive soft tissue mass to suggest progression or recurrence of disease, no evidence of lymphadenopathy**
5/19/00	**CT scan of abdomen and pelvis: abdomen-no recurrent mass, no definite associated soft tissue mass effect, pelvis-increase in fluid collection L>R c/w 2/29/00.**
8/10/00	**X-ray chest: normal**
8/30/99	**CT scan of pelvis: decrease in soft tissue density and fluid c/w 6/28/99**
9/12/00	**CT scan of abdomen and pelvis: small nodular densities adjacent to the spleen, fluid collection right side of pelvis not decreased, left side extension no longer identified**
11/14/00	**Bone scan whole body: prominent activity in right renal pelvis similar to 2/98**
12/15/00	**US RUQ: no abnormality, no change from prior**
1/16/01	**CT scan of abdomen and pelvis with contrast: no bowel abnormalities, fluid collection on right side has increased to 4.5x3cm, now fluid to lower pelvis left side, findings nonspecific but recurrence possible**
1/23/01	**CT scan of pelvis: increased size of 2 rounded densities in pelvis, right lateral pelvic wall 4.5x3x0.15cm**
1/23/01	**CT scan of abdomen: mild prominence of left adrenal unchanged**
3/9/01	**CT scan of abdomen and pelvis with contrast: abdomen unremarkable, pelvis with loculated fluid collection in inferior pelvis in midline and on right, slight reduction in size**
5/24/01	**CT scan of abdomen: no pathologically enlarged lymph nodes or free fluid**
5/24/01	**CT scan of pelvis: no evidence of progressive tumor or abnormality; significant interval reduction of irregularly loculated fluid collections compared with 3/9/01 consistent with response of mesothelioma**
8/15/01	**CT scan of abdomen: no upper abdominal mass compared with 5/24/01**
8/15/01	**CT scan of pelvis; further reduction in small amounts of fluid. No evidence of progressive neoplasm compared with 5/24/01**

Tumor markers

7/23/99	**CA[a] 125 = 22 (<35)**
5/16/00	**CA 125 = 13 (<35)**

[a]Cancer Antigen.

Conventional therapy

7/1/99	**Exploratory laparoscopy with excision of left pelvic mass, left colectomy, colostomy, omentectomy, and multiple peritoneal biopsies**
7/28/99	**Taxol, carboplatin (initially thought to be ovarian cancer) stopped due to anaphalaxis**
10/24/01	**Surgery: attempted reversal of colostomy: decrease of tumor bulk based on visual inspection**

Complementary therapy

12/1/99-6/6/01	**IAT 6 courses over this time interval**
12/1/99-present (intermittent)	**MGn3, noni juice, colostrum, vitamin E, green tea, vitamin C, beta carotene, cat's claw, homeopathic miasms**
1/30/01-present (intermittent)	**Homeopathic –Haelan (fermented soy product), cat's claw, lyperinol**
2/2/01-present (intermittent)	**Illumination: multiherbal combo, Universal Complex (echinacea mix), Circu-Plus (gingko, ginseng), Mg/K aspartate, alpha-oxzyme, LSK Plus (granular liver, spleen, kidney)**

Patient # 1-7						
EVENT	**PERIOD 1** **1st qtr 1999 – 4th qtr 1999**	**PERIOD 2** **1st qtr 2000 – 4th qtr 2000**	**PERIOD 3** **1st qtr 2001 – 4th qtr 2001**			
Diagnosis/biopsy	**7/99**					
Surgery	**7/99**		**10/01**			
Radiation						
Chemotherapy	**7/99**					
IAT	**12/99**		**6/01**			
CAM other	**12/99**		**1/01, 2/01**			
Imaging CT scan		**2/00 5/00 9/00**	**1/01, 3/01 5/01 8/01**			
Imaging CXR		**8/00**				
Imaging ultrasound		**12/00**				
Tumor marker		**5/00**				

CAM Therapy:	IAT		
Case:	1-7		
Condition:	Malignant peritoneal mesothelioma		
Abstractor:	1	**Date of Abstraction:**	6/14/01
Interviewer:	IDC	**Date of Interview:**	9/26/01
Comments:	Chemotherapy stopped when anaphylaxis from taxol, and second review of pathology specimen revealed malignant peritoneal mesothelioma		

Criteria for inclusion: (check all that apply)			
x	Diagnosis confirmed		
x	Documented start date for CAM therapy		
x	Documented previous anti-cancer therapies		
x	No other therapies during the CAM therapy		
x	Documented endpoint:		
	x	Tumor size	
		Longevity	
		Quality of Life	
		Other:	

Other Relevant Information:	
Sex:	female
DOB:	7/12/52
Diagnosis:	Malignant peritoneal mesothelioma
Diagnosis date:	8/6/99
CAM therapy dates:	12/1/99-6/6/01
Conventional therapy dates:	7/28/99
Last contact date:	6/11/01
If deceased, date of death:	

Date	Description of Events	Requested	Status of requests
6/28/99	CT scan of pelvis: 3.5cm cystic left adnexal mass	Films	Rcvd.
7/1/99	Exploratory laparoscopy with excision of left pelvic mass, left colectomy, colostomy, omentectomy, multiple peritoneal biopsies.		
7/1/99	Pathology: Ovarian carcinoma vs. malignant melanoma		
7/23/99	CA 125 = 22 (<35)		
7/28/99	Taxol, carboplatin (initially diagnosed with ovarian cancer)		
7/28/99	Adverse event: anaphylaxis from taxol		
8/5/99	Pathology: final diagnosis: malignant mesothelioma (same tissue sample)	Slides	Pend.
8/30/99	CT scan of pelvis: decrease in soft tissue density and fluid c/w 6/28/99	Films	Rcvd.
9/24/99	PET scan of whole body: no specific findings to suggest residual tumor in torso, increased activity small area in neck		
2/29/00	CT scan of abdomen and pelvis: no associated definitive soft tissue mass to suggest progression or recurrence of disease, no evidence of lymphadenopathy		
5/16/00	CA 125 = 13 (<35)		
5/19/00	CT scan of abdomen and pelvis: abdomen-no recurrent mass, no definite associated soft tissue mass effect, pelvis-increase in fluid collection L>R c/w 2/29/00.		
8/10/00	X-ray chest: normal		
9/12/00	CT scan of abdomen and pelvis: small nodular densities adj. to spleen, fluid collection right side pelvis not decr., left side extension no longer identified	Films	Not avail.
11/14/00	Bone scan of whole body: no change c/w 2/98		
11/14/00	X-ray chest: within normal limits		

Date	Description of Events	Requested	Status of requests
12/15/00	US RUQ: no abnormality, no change from 6/29/99		
1/16/01	CT scan of abdomen and pelvis with contrast: no bowel abnormalities, fluid collection on right side has increased to 4.5x3cm, now fluid to lower pelvis left side, findings nonspecific but recurrence possible		
1/23/01	CT scan of pelvis: increased size of 2 rounded densities in pelvis, right lateral pelvic wall 4.5x3x0.15cm		
3/9/01	CT scan of abdomen and pelvis with contrast: abdomen unremarkable, pelvis with loculated fluid collection in inferior pelvis in midline and on right, slight reduction in size		
5/24/01	CT scan of abdomen: no pathologically enlarged lymph nodes or free fluid	Films	Rcvd.
5/24/01	CT scan of pelvis: no evidence of progressive tumor or abnormality		
12/1/1999-6/6/01	IAT 5 courses		
12/1/1999-present (intermittent)	Mgn3, noni juice, colostrum, vitamin E, green tea, vitamin C, beta carotene, cat's claw, homeopathic miasms		
1/30/2001-present (intermittent)	Homeopathic – not specified, Haelan (fermented soy product), cat's claw, lyperinol		
2/2/2001-present (intermittent)	Illumination: multiherbal combo, Universal Complex (echinacea mix), Circu-Plus (ginko, ginseng), Mg/K aspartate, alpha-oxzyme, LSK Plus (granular liver, spleen, kidney)		
8/15/01	CT scan abdomen: no upper abdominal mass compared to 5/24/01.	Films	Rcvd.
8/15/01	CT scan of pelvis; further reduction in small amounts of fluid. No evidence of progressive neoplasm compared with 5/24/01	Films	Rcvd.
10/12/01	CT scan of abdomen and CT scan of pelvis with contrast: high grade partial small bower obstruction. No discrete mass is visualized, however, there is free intraperitoneal air with an air fluid level.	Films	Rcvd.
10/17/01	CT scan of abdomen and CT scan of pelvis with contrast: small bowel dilation slightly less prominent than previously seen, otherwise basically unchanged compared to previous examination.	Films	Rcvd.
10/24/01	Surgery: attempted reversal of colostomy: decrease of tumor bulk based on visual inspection		

Cancer Best-Case Series

Patient #1-9
Ovarian Cyst Adenocarcinoma

Case 1-9

The patient in case 1-9 is a 54-year-old woman with ovarian cyst adenocarcinoma diagnosed on 5/3/80. She had a total abdominal hysterectomy with bilateral salpingo-oophorectomy with debulking at that time. Subsequently, she was referred for chemotherapy but refused due to patient preference. Her only therapy has been 34 courses of IAT from 6/3/80 to 6/12/99. In June 1987, a CT scan revealed lesions in her liver suspicious for metastatic disease. A liver biopsy was recommended, but since a needle biopsy was not possible due to adhesions, none was performed. Subsequent followup did not reveal progression of disease. A pelvic mass was noted on 8/6/00 and found to be increasing over the next year to a maximal dimension of 2.8cm x 2.8cm. An exploratory laparotomy with resection of left pelvis mass and biopsy of right pelvis was performed on 6/29/81. Pathology from the surgery was negative. Tumor markers have also been negative. Routine gynecologic care has not revealed any abnormalities. At last contact (interview, 10/09/01), the patient reported that her overall physical health was good.

Pathology

5/3/80	**Biopsy: right ovary: papillary cyst adenocarcinoma, left ovary: same diagnosis**
6/29/81	**Biopsy: excision of pelvic mass—no tumor**
6/14/90	**Pap smear cytology: negative for malignancy**
6/12/91	**Pap smear cytology: negative for malignancy**

Imaging

5/1/80	**Ultrasound: pelvis mass 9cm x 7cm**
5/21/80	**Liver scan: normal**
5/23/80	**Bone scan whole body: normal**
8/6/80	**Ultrasound: pelvis cystic left adnexal mass 2cm x 2.5cm, no fluid in pelvis**
9/24/80	**Ultrasound: pelvis cystic left adnexal mass present since 8/6/80 unchanged**
12/10/80	**Ultrasound: pelvis cystic left adnexal mass present since 8/6/80 slightly smaller**
1/28/81	**Bone scan whole body: new area of increased uptake left iliac crest since 5/23/80**
4/20/81	**Ultrasound: pelvis cystic left adnexal mass 2.3cm unchanged c/w 12/10/80**
4/22/81	**Bone scan whole body: diffuse uptake in skull; increased uptake lumbar spine consistent with osteoarthritis: no evidence of metastases**
6/8/81	**Ultrasound: pelvis cystic left adnexal mass 2.8cm x 2.8cm, increased since 4/20/81**
9/8/81	**Ultrasound: pelvis no adnexal mass present, no fluid present**
6/1/83	**Ultrasound: pelvis no adnexal mass present, no fluid present**
1/15/86	**Ultrasound: pelvis no adnexal mass present, no fluid present**
6/10/87	**CT scan abdomen: suspicious for liver metastases; focal areas of low attenuation throughout liver**
3/4/91	**X-ray chest no change c/w 8/9/89**
5/31/91	**Mammogram breast: normal**
5/27/92	**Mammogram breast: normal**
8/6/1993	**MRI thoracic spine: osteoporosis**

Tumor markers

5/30/90	**CA[a]-125: <7.5 (normal 0-35)**
5/29/91	**CA-125: 6.3 (normal 0-35)**
5/6/94	**CA-125: <8.0 (normal 0-35)**
6/10/97	**CA-125 = 5.0 (0-35); CEA[b] = 0.3 (0-3)**
6/11/01	**CA-125 = 6.0 (0-35)**

[a]CA: Cancer Antigen.
[b]CEA: Carcinoembrionic Antigen.

Conventional therapy

5/1/80	**Surgery: TAH/BSO with appendectomy**
5/3/80	**Chemotherapy recommended: never started**
6/29/81	**Surgery: exploratory laparotomy with resection of left pelvic mass and biopsy**

Complementary therapy

6/3/80-6/12/99	**IAT: 34 courses over this time period; no home maintenance after 16 courses**

Patient # 1-9						
EVENT	**PERIOD 1** **1st qtr 1980 – 4th qtr 1980**	**PERIOD 2** **1st qtr 1981 – 4th qtr 1981**	**PERIOD 3** **1st qtr 1983 – 4th qtr 1983**	**PERIOD 4** **1st qtr 1986 – 4th qtr 1986**	**PERIOD 5** **1st qtr 1987 – 4th qtr 1987**	**PERIOD 6** **1st qtr 1989 – 4th qtr 1989**
Diagnosis/biopsy	**5/80**	**6/81**				
Surgery	**5/80**	**6/81**				
Radiation						
Chemotherapy						
IAT	**6/80**					
CAM other						
Imaging CXR						
Imaging ultrasound	**5/80** **8/80, 9/80** **12/80**	**4/81, 6/81** **9/81**	**6/83**	**1/86**		
Imaging CT					**6/87**	
Tumor markers						
Bone scan	**5/80**	**1/81** **4/81**				
Pap smear						

Patient # 1-9, cont'd						
EVENT	PERIOD 7 1st qtr 1990– 4th qtr 1980	PERIOD 8 1st qtr 1991 – 4th qtr 1991	PERIOD 9 1st qtr 1994 – 4th qtr 1994	PERIOD 10 1st qtr 1997 – 4th qtr 1997	PERIOD 11 1st qtr 1999 – 4th qtr 1999	PERIOD 12 1st qtr 2001 – 4th qtr 2001
Diagnosis/biopsy						
Surgery						
Radiation						
Chemotherapy						
IAT					6/99	
CAM other						
Imaging CXR		3/91				
Imaging ultrasound						
Imaging CT						
Tumor markers	5/90	5/91	5/94	6/97		6/01
Bone Scan						
Pap smear	6/90	6/91				

CAM Therapy:	IAT		
Case:	1-9		
Condition:	Bilateral cystadenocarcinoma of the ovaries		
Abstractor:	mh	**Date of Abstraction:**	6/14/01
Interviewer:	IDC	**Date of Interview:**	10/16/01
Comments:	recurrence then disappearance of pelvic mass		

Criteria for inclusion:	**(check all that apply)**		
x	Diagnosis confirmed		
x	Documented start date for CAM therapy		
x	Documented previous anti-cancer therapies		
	No other therapies during the CAM therapy		
x	Documented endpoint:		
	x	Tumor size	
		Longevity	
		Quality of Life	
		Other:	

Other Relevant Information:	
Sex:	female
DOB:	8/11/47
Diagnosis:	bilateral cystadenocarcinoma of the ovaries
Diagnosis date:	5/3/80
CAM therapy dates:	6/3/80-6/12/99
Conventional therapy dates:	surgery 5/80; 6/81
Last contact date:	6/21/01
If deceased, date of death:	

Date	Description of Events	Requested	Status of requests
	Mother-carcinoma of the uterus, grandmother-lung cancer, grandfather-cancer of tongue, brother-leukemia		
5/1/80	Ultrasound: mass in pelvis 9cm x 7cm	Films	Not avail.
5/3/80	Surgery: TAH/BSO with appendectomy		
5/3/80	Biopsy:right ovary: papillary cystadenocarcinoma ; left ovary same diagnosis	Slides	Not avail.
5/3/80	Chemotherapy recommended: never started		
5/21/80	Liver scan: normal		
5/23/80	Bone scan whole body: normal		
6/3/80-6/12/99	IAT: 34 courses over this time period; no home maintenance after 16 courses		
8/6/80	Ultrasound: pelvis cystic left adnexal mass 2cm x 2.5cm, no fluid in pelvis	Films	Not avail.
9/24/80	Ultrasound: pelvis cystic left adnexal mass present since 8/6/80 unchanged		
12/10/80	Ultrasound: pelvis cystic left adnexal mass present since 8/6/80 slightly smaller		
1/28/81	Bone scan whole body: new area of increased uptake left iliac crest since 5/23/80		
4/20/81	Ultrasound: pelvis cystic left adnexal mass 2.3cm unchanged c/w 12/10/80	Films	Not avail.
4/22/81	Bone scan whole body: diffuse uptake in skull; increased uptake lumbar spine consistent with osteoarthritis: no evidence mets		
6/8/81	Ultrasound: pelvis cystic left adnexal mass 2.8cm x 2.8cm, increased since 4/20/81		

Date	Description of Events	Requested	Status of requests
6/29/81	Surgery: exploratory laparotomy with resection of left pelvic mass and biopsy	Slides	Rcvd.
6/29/81	Biopsy: excision of pelvic mass- no tumor		
9/8/81	Ultrasound: pelvis no adnexal mass present, no fluid present		
6/1/83	Ultrasound: pelvis no adnexal mass present, no fluid present		
1/15/86	Ultrasound: pelvis no adnexal mass present, no fluid present	Films	Not avail.
6/10/87	CT scan abdomen: suspicious for liver mets; focal areas of low attenuation throughout liver	Films	Not avail.
Jun-87	Biopsy of liver lesions recommended but not performed; needle biopsy not possible due to adhesions		
5/30/90	CA-125: <7.5 (normal 0-35)		
6/14/90	Pap smear cytology: negative for malignancy		
3/4/91	X-ray chest no change c/w 8/9/89		
5/29/91	CA-125: 6.3 (normal 0-35)		
5/31/91	Mammogram breast: normal		
6/12/91	Pap smear cytology: negative for malignancy		
5/27/92	Mammogram breast: normal		
8/6/93	MRI thoracic spine: osteoperosis		

Date	Description of Events	Requested	Status of requests
5/4/94	CA-125: <8.0 (normal 0-35)		
6/10/97	CA-125 = 5.0 (0-35); CEA = 0.3 (0-3)		
6/11/01	CA-125 = 6.0 (0-35)		
present	Routine physical exams/ serial CA-125 normal per patient during interview		

Cancer Best-Case Series

Patient #1-11
Peritoneal Mesothelioma

Case 1-11

The patient in case 1-11 is a 59-year-old male with a family history of breast cancer, diagnosed in May, 1980 with peritoneal mesothelioma after presenting with a history of right lower quadrant abdominal pain and dyspepsia. His work-up included a cholangiogram, upper GI series with a small bowel follow-through, and an intravenous pyelogram of the GU tract. After these tests returned normal, a small bowel obstruction was the leading diagnosis until an exploratory laparotomy revealed peritoneal mesothelioma. According to the operative report (5/8/80), there was widespread disease throughout the pelvic and abdominal cavities. A partial omentectomy was performed, and as much bulk disease was removed as possible. A second opinion was obtained at MD Anderson (6/16/80 – 6/23/80), and it was recommended that additional tissue be obtained to confirm the diagnosis of mesothelioma via electron microscopy, which was done on 6/25/80. Due to the lack of a definitive curative therapy, no specific recommendations for chemotherapy, radiation, or future surgery were made. The patient started IAT therapy on 7/22/80 and completed the course in 5/84. At last contact (interview, 9/19/01), the patient reported that his overall physical condition is very good.

Pathology

5/8/80	**Pathology of cysts on peritoneum: mesothelioma of peritoneum, multiple sites**
6/25/80	**Pathology: electron microscopy: multiple cystic mesothelioma of peritoneum**

Imaging

4/11/80	**IVP of GU tract: within normal limits**
4/12/80	**IV cholangiogram: within normal limits**
4/12/80	**UGI with SBF: within normal limits**
4/14/80	**Barium enema: within normal limits**
4/16/80	**CT scan of abdomen: within normal limits**
4/20/80	**X-ray chest: collapse of portion LLL, air containing structure posterior to sternum; nodular density adj. to left hilum**
4/22/80	**Tomogram of left lung: possible mass adjacent to hilum is "distorted branch of pulmonary artery"**
5/10/80	**X-ray chest: left ventricular enlargement**
5/16/80	**Bone scan of total body: within normal limits**
5/17/80	**Liver and spleen scan: within normal limits**

Conventional therapy

5/8/80	**Surgery: exploratory laparoscopy, excision of multiple cysts, subtotal omentectomy for palliative: most of peritoneal cavity lined with cysts. Debulking done. Tumor is cystic, grape-like, no ascites.**

Complementary therapy

7/22/80-7/20/84	**IAT 16 courses**

Patient # 1-11						
EVENT	PERIOD 1 1st qtr 1980 – 4th qtr 1980	PERIOD 2 1st qtr 1981 – 4th qtr 1981	PERIOD 3 1st qtr 1982 – 4th qtr 1982	PERIOD 4 1st qtr 1983 – 4th qtr 1983	PERIOD 5 1st qtr 1984 – 4th qtr 1984	PERIOD 6 1st qtr 1985 – 4th qtr 1985
Diagnosis/biopsy	5/80					
Surgery	5/80					
Radiation						
Chemotherapy						
IAT	7/80				7/84	
CAM other						
Imaging CXR	4/80					
Imaging tomogram	4/80					
Imaging CT scan abdomen	4/80					
Imaging liver spleen scan	4/80					
Imaging bone scan	5/80					

CAM Therapy:	IAT		
Case:	1-11		
Condition:	Peritoneal mesothelioma		
Abstractor:	IDC, JLG	**Date of Abstraction:**	6/14/01
Interviewer:	IDC	**Date of Interview:**	9/19/01
Comments:	Surgical debulking is only conventional care		

Criteria for inclusion:	**(check all that apply)**	
x	Diagnosis confirmed	
x	Documented start date for CAM therapy	
x	Documented previous anti-cancer therapies	
x	No other therapies during the CAM therapy	
x	Documented endpoint:	
		Tumor size
	x	Longevity
		Quality of Life
		Other:

Other Relevant Information:	
Sex:	male
DOB:	1/23/42
Diagnosis:	peritoneal mesothelioma
Diagnosis date:	5/8/80
CAM therapy dates:	7/22/80-7/20/84
Conventional therapy dates:	5/8/80
Last contact date:	7/1/87
If deceased, date of death:	

Date	Description of Events	Requested	Status of requests
4/11/80	IVP of GU tract: within normal limits		
4/12/80	IV cholangiogram: within normal limits		
4/12/80	UGI with SBF: within normal limits		
4/14/80	Barium enema: within normal limits		
4/16/80	CT scan of abdomen: within normal limits		
4/20/80	X-ray chest: collapse of portion LLL, air containing structure posterior to sternum; nodular density adj. to left hilum		
4/22/80	Tomogram of left lung: possible mass adjacent to hilum is “distorted branch of pulmonary artery”		
5/8/80	Exploratory laparoscopy, excision of multiple cysts, subtotal omentectomy for palliative: most of peritoneal cavity lined with cysts. Debulking done. Tumor is cystic, grape-like, no ascites.		
5/8/80	Pathology of cysts on peritoneum: mesothelioma of peritoneum, multiple sites	Slides	Not avail.
5/10/80	X-ray chest: left ventricular enlargement		
5/16/80	Tomogram of chest: volume loss LLL, unknown etiology		
5/16/80	Bone scan of total body: within normal limits		
5/17/80	Liver and spleen scan: within normal limits		
6/25/80	Pathology: electron microscopy: multiple cystic mesothelioma of peritoneum		
7/22/80-7/20/84	IAT 16 courses		

Cancer Best-Case Series

Patient #1-19
Sigmoid Carcinoma (Dukes Stage C2)

Case 1-19

The patient in case 1-19 is a 50-year-old male with a family history of colon cancer. He was diagnosed with sigmoid carcinoma (Dukes stage C2) in March1985 after presenting with hematochezia, lower-left quadrant abdominal pain, and a normal CEA. Biopsies obtained during colonoscopy verified the diagnosis. He underwent a sigmoid resection, and 6 of 14 nodes were positive for metastases, but no gross residual disease was left in the abdomen. No other conventional therapy was pursued. He started IAT on 5/85 and completed 11 courses by 5/91. Serial colonoscopies have remained normal, with the last exam conducted on 9/8/00. At the last contact (interview, 10/12/01), the patient reported that his overall physical condition was excellent.

Pathology

3/18/85	**Biopsy: mucinous producing adenocarcinoma, mod well diff, associated with adenomatous polyp, sigmoid colon, 6/14 nodes positive for mets, mesocolon and mesentery of colon.**
9/8/00	**Biopsy: colon polyp: no evidence of malignancy**

Imaging

3/22/85	**Liver spleen scan: normal**
1/8/1987	**CT abdomen pelvis: no evidence of recurrent tumor**
3/27/87	**Sigmoidoscopy: normal to 25cm**
9/26/88	**Colonoscopy: colon fully visualized to the cecum**
4/13/89	**CT scan abdomen; normal exam, no change compared with 1/8/87**
10/5/89	**Colonoscopy: normal exam**
11/13/92	**Colonoscopy: no evidence of recurrent colorectal polyps or cancer**
12/2/94	**Colonoscopy: normal exam**
2/10/98	**Sigmoidoscopy: normal to 40cm, normal anastamosis**
5/7/98	**Colonoscopy: normal exam**
7/27/99	**Sigmoidoscopy: normal to 70cm**
9/8/00	**Colonoscopy: sessile polyp (3mm) near anastamotic site**

Tumor markers

3/17/85	**CEA[a] <1.0 (normal)**
2/25/86	**CEA <2.5 (normal)**
7/8/1986	**CEA 1.9 (normal<2.5)**
2/1/1987	**CEA 1.8 (normal)**
7/14/87	**CEA 1.1 (normal <2.5)**
3/9/88	**CEA 1.9 (normal<2.5)**
4/24/89	**CEA 1.2 (normal)**
10/4/89	**CEA 2.0 (normal)**
9/26/90	**CEA 1.4 (normal)**

[a]Carcinoembryonic Antigen.

Conventional therapy

3/18/85	**Surgery: sigmoid resection**

Complementary therapy

5/21/85-5/7/91	**IAT 11 courses**

Patient # 1-19						
EVENT	**PERIOD 1** **1st qtr 1985 – 4th qtr 1985**	**PERIOD 2** **1st qtr 1986 – 4th qtr 1986**	**PERIOD 3** **1st qtr 1987 – 4th qtr 1987**	**PERIOD 4** **1st qtr 1988 – 4th qtr 1988**	**PERIOD 5** **1st qtr 1989 – 4th qtr 1989**	**PERIOD 6** **1st qtr 1990 – 4th qtr 1990**
Diagnosis/biopsy	**3/85**					**9/90**
Surgery	**3/85**					
Radiation						
Chemotherapy						
IAT	**5/85**					
CAM other						
Imaging CT scan			**1/87**		**4/89**	
Colonoscopy				**9/88**	**10/89**	
Sigmoidoscopy			**3/87**			
Tumor markers	**3/85**	**2/86** **7/86**	**2/87** **7/87**	**3/88**	**4/89**	**10/89** **9/90**
Liver spleen scan	**3/85**					

Patient # 1-19, cont'd						
EVENT	**PERIOD 7** **1st qtr 1991– 4th qtr 1991**	**PERIOD 8** **1st qtr 1992 – 4th qtr 1992**	**PERIOD 9** **1st qtr 1994 – 4th qtr 1994**	**PERIOD 10** **1st qtr 1998 – 4th qtr 1998**	**PERIOD 11** **1st qtr 1999 – 4th qtr 1999**	**PERIOD 12** **1st qtr 2000 – 4th qtr 2000**
Diagnosis/biopsy						
Surgery						
Radiation						
Chemotherapy						
IAT	**5/91**					
CAM other						
Imaging CT						
Colonoscopy		**11/92**	**12/94**	**5/98**		**9/00**
Sigmoidoscopy				**2/98**	**7/99**	
Tumor markers						

CAM Therapy:	IAT		
Case:	1-19		
Condition:	Adenocarcinoma of the colon		
Abstractor:	MH, IDC	**Date of Abstraction:**	6/14/01
Interviewer:	IDC	**Date of Interview:**	9/26/01
Comments:	No other conventional therapy except surgery; serial colonoscopies normal		

Criteria for inclusion:	**(check all that apply)**	
x	Diagnosis confirmed	
x	Documented start date for CAM therapy	
x	Documented previous anti-cancer therapies	
x	No other therapies during the CAM therapy	
x	Documented endpoint:	
		Tumor size
	x	Longevity
		Quality of Life
		Other:

Other Relevant Information:	
Sex:	male
DOB:	12/2/51
Diagnosis:	Adenocarcinoma of the colon, Duke C2
Diagnosis date:	3/18/85
CAM therapy dates:	5/21/85-5/7/91
Conventional therapy dates:	Surgery 3/18/85
Last contact date:	9/8/00
If deceased, date of death:	

Date	Description of Events	Requested	Status of requests
	Family history of colon cancer in uncle		
3/17/85	CEA <1.0 (normal)		
3/18/85	Biopsy: mucinous producing adenocarcinoma, mod well diff, associated with adenomatous polyp, sigmoid colon, 6/14 nodes positive for mets, mesocolon and mesentery of colon.	Slides	Rcvd.
3/18/85	Surgery: sigmoid resection	Oper. Rpt.	Not avail.
3/22/85	Liver spleen scan: normal		
5/21/85-5/7/91	IAT 11 courses		
2/25/86	CEA <2.5 (normal)		
7/8/86	CEA 1.9 (normal<2.5)		
1/8/87	CT abdomen pelvis: no evidence of recurrent tumor	Films	Not avail.
2/1/87	CEA 1.8 (normal)		
3/27/87	Sigmoidoscopy: normal to 25cm		
7/14/87	CEA 1.1 (normal <2.5)		
3/9/88	CEA 1.9 (normal<2.5)		
9/26/88	Colonoscopy: colon fully visualized to the cecum		
4/13/89	CT scan abdomen; normal exam, no change compared with 1/8/87	Films	Not avail.

Date	Description of Events	Requested	Status of requests
4/24/89	CEA 1.2 (normal)		
10/4/89	CEA 2.0 (normal)		
10/5/89	Colonoscopy: normal exam		
9/26/90	CEA 1.4 (normal)		
11/13/92	Colonoscopy: no evidence of recurrent colorectal polyps or cancer		
12/2/94	Colonoscopy: normal exam		
2/10/98	Sigmoidoscopy: normal to 40cm, normal anastamosis		
5/7/98	Colonoscopy: normal exam		
7/27/99	Sigmoidoscopy: normal to 70cm		
9/8/00	Colonoscopy: sessile polyp (3mm) near anastamotic site		
9/8/00	Biopsy: colon polyp: no evidence of malignancy	Slides	Rcvd.

Cancer Best-Case Series

Patient #1-22
Squamous Cell Carcinoma of the Tongue

Case 1-22

The patient in case 1-22 is an 80-year-old male who was diagnosed in February 1999 with squamous cell carcinoma of the tongue accompanied by a benign parotid cyst. He subsequently completed the recommended course of radiation. Definitive surgery was recommended, but the patient refused, due to personal preference. IAT was initiated in June 1999, and he continues on maintenance therapy today. An MRI in October 2001 revealed no evidence of a discrete mass in the oropharynx and a decrease in right cervical lymph node. At the last contact (interview, 9/26/01), the patient reports that his overall physical condition is good.

Pathology

2/12/99	**Biopsy left side tongue: squamous cell carcinoma, invasive, moderately differentiated**
2/18/99	**Biopsy (fine needle) right parotid lymph node: cystic contents; inconclusive**
4/20/99	**Biopsy (fine needle) right parotid lymph node: abscess with Strep species, acute suppurative inflammation with cocci**
5/6/99	**Biopsy aspiration of cyst in right parotid lymph node: cyst contents; acute inflammation**

Imaging

2/17/99	**CT scan left neck and tongue: invasive carcinoma of tongue extends to tonsillar fossa, parapharyngeal space, and beyond inferior margin of mandible into cervical subcutaneous tissue: large contralateral node metastasis**
2/25/99	**MRI of neck: ill-defined enhancing mass at base of tongue with extension into left piriformis sinus, highly suspicious for squamous cell carcinoma; cystic structure in submandibular space/ jugulodiagastric space**
3/4/99	**MRI neck: 2.26cm x 3.60cm x 3.50cm enhancing mass base of left tongue extending into hypopharynx, to level of epiglottis piriformis sinus; no extension past midline; cystic structure 3.2cm x 6.5cm x 7.80cm in jugulodiagastric region**
12/8/99	**CT scan neck: Resolution of left tongue base/lateral pharyngeal mass; pleomorphic adenoma or necrotic lymph node (right parotid cystic mass)**
4/7/00	**X-ray chest: emphysematous changes, otherwise normal**
4/7/00	**MRI of brain: normal**
6/14/00	**CT scan abdomen: bilateral lower lobe fibrosis consistent with UIP; possible nephrolithiasis involving left kidney**
7/11/00	**CT scan thorax: linear interstitial fibrosis consistent with UIP; bilateral apical fibrosis**
7/23/00	**CT scan neck: low attenuation of lesion on along right anterior border of right parotid gland; 2.2cm x 2.3cm; suspicious for metastatic necrotic lymph node**
10/3/01	**CT scan chest: bilateral interstitial lung disease**
10/3/01	**MRI neck: no evidence of discrete mass in oropharynx or oral cavity. Diffuse enhancement in dorsal aspect of hypopharynx could represent post-radiation changes. Interval decrease in right lymph node now measures 1.2cm**

Conventional therapy

3/5/99-4/15/99	**Radiation: upper neck, total rads 7200: 30 fractions over 41 days: completed full course: residual disease present after radiation**

Complementary therapy

6/22/99-present	**IAT (5 courses); still on maintenance therapy**

Patient # 1-22						
EVENT	**PERIOD 1** **1st qtr 1999 – 4th qtr 1999**	**PERIOD 2** **1st qtr 2000 – 4th qtr 2000**	**PERIOD 3** **1st qtr 2001 – 4th qtr 2001**			
Diagnosis/biopsy	**2/99, 2/99 4/99, 5/99**					
Surgery						
Radiation	**3/99**					
Chemotherapy						
IAT	**6/99**					
CAM other						
Imaging CT scan	**2/99** **12/99**	**6/00, 7/00**	**10/01**			
Imaging CXR						
Imaging MRI	**2/99, 3/99 4/99**		**10/01**			

CAM Therapy:	IAT		
Case:	1-22		
Condition:	Squamous cell carcinoma at the base of the tongue: Stage 1, T2-3, N0		
Abstractor:	IDC, MH	**Date of Abstraction:**	6/14/01
Interviewer:	IDC	**Date of Interview:**	9/30/01
Comments:	Squamous cell carcinoma at the base of the tongue, declined surgery, experimental chemotherapy. Had aggressive radiation with residual disease.		

Criteria for inclusion: (check all that apply)			
x	Diagnosis confirmed		
x	Documented start date for CAM therapy		
x	Documented previous anti-cancer therapies		
x	No other therapies during the CAM therapy		
x	Documented endpoint:		
	x	Tumor size	
		Longevity	
		Quality of Life	
		Other:	

Other Relevant Information:	
Sex:	male
DOB:	11/24/21
Diagnosis:	Squamous cell carcinoma at the base of the tongue: Stage 1, T2-3, N0
Diagnosis date:	2/12/99
CAM therapy dates:	6/22/99-5/4/01
Conventional therapy dates:	3/5/99-4/15/99
Last contact date:	5/4/01
If deceased, date of death:	

Date	Description of Events	Requested	Status of requests
2/12/99	Biopsy left side tongue: squamous cell carcinoma, invasive, moderately differentiated	Slides	Pend.
2/17/99	CT scan left neck and tongue: invasive carcinoma of tongue extends to tonsillar fossa, parapharyngeal space, and beyond inferior margin of mandible into cervical subcutaneous tissue: large contralateral node	Films	Pend.
2/18/99	Biopsy (fine needle) right parotid lymph node: cystic contents; inconclusive		
2/25/99	MRI of neck: ill-defined enhancing mass at base of tongue with extension into left piriformis sinus, highly suspicious for squamous cell carcinoma; cystic structure in submandibular space/ juglodiagastric space		
2/25/99	MRI of brain: normal		
3/4/99	MRI neck: 2.26cm x 3.60cm x 3.50cm enhancing mass base of left tongue extending into hypopharynx, to level of epiglottis piriformis sinus; no extension past midline; cystic structure 3.2cm x 6.5cm x 7.80cm in juglodiagastric region		
2/18/99	Definitive surgery recommended: patient refused		
3/4/99	MRI neck: 2.26cm x 3.60cm x 3.50cm enhancing mass base of left tongue extending into hypopharynx, to level of epiglottis piriformis sinus; no extension past midline; cystic structure 3.2cm x 6.5cm x 7.80cm in		
4/20/99	Biopsy (fine needle) right parotid lymph node: abscess with Strep species, acute suppurative inflammation with cocci		
5/6/99	Biopsy aspiration of cyst in right parotid lymph node: cyst contents; acute inflammation		
3/5/99-4/15/99	Radiation: upper neck total rads 7200: 30 fractions over 41 days: completed full course: residual disease present after radiation	Rpt. After treatment	Pend.
12/8/99	CT scan neck: Resolution of left tongue base/lateral pharyngeal mass.pleomorphic adenoma or necrotic lymph node (right parotid cystic mass)	Films	Pend.
4/7/00	X-ray chest: emphysematous changes, otherwise normal		
4/7/00	MRI of brain: normal		
6/14/00	CT scan abdomen: bilateral lower lobe fibrosis consistent with UIP; possible nephroliathiasis involving left kidney		

Date	Description of Events	Requested	Status of requests
7/11/00	CT scan thorax: linear interstitial fibrosis consistent with UIP; bilat apical fibrosis		
7/23/00	CT scan neck: low attenuation of lesion on along right anterior border of right parotid gland; 2.2cm x 2.3cm; suspicious for metastatic necrotic lymph node		
10/3/01	CT scan chest: bilateral interstitial lung disease	Films	Pend.
10/3/01	MRI neck: no evidence of discrete mass in oropharynx or oral cavity. Diffuse enhancement in dorsal aspect of hypopharynx could represent post-radiation changes. Interval decrease in right lymph node now measures 1.2cm	Films	Pend.

Cancer Best-Case Series

Patient #2-10
Pancreatic Cancer Involving the Bile Duct

Case 2-10

The patient in case 2-10 was a 55 year-old female with pancreatic cancer involving the bile duct. Her diagnosis was made in July 1999, after presenting with low back pain and a gastrointestinal bleed. No conventional therapy was pursued, as she was considered terminally ill at the time of her diagnosis and palliative drainage. Naltrexone was initiated on 11/11/99, and by July 2000, a CT scan showed a 90% reduction of her tumor mass. On August 8, 2000, she died from overwhelming septicemia, after three episodes of gram-negative sepsis secondary to loosening of her biliary stent. According to next of kin, no autopsy was performed.

Pathology

7/1/99	**Biopsy of body of pancreas; carcinoma of pancreas (per physician's notes)**

Imaging

Jul-00	**CT scan abdomen: residual pancreatic lesions <1cm: 90% reduction of tumor mass; per physician's notes**

Liver enzymes

10/22/99	**Alk Phos- 1646; ALT 93; AST 159**
10/23/99	**Alk Phos- 1471; ALT 74; AST 108**
11/21/99	**Alk Phos- 2262; ALT 126; AST 180**

Conventional therapy

7/1/99	**Laparoscopy**
Dec-99	**Metenkephalin IV**

Complementary therapy

11/11/99	**Naltrexone 3mg qHS**

Outcome:

8/5/00	**Death—due to septicemia secondary to loosened stent in bile duct**

Patient # 2-10						
EVENT	**PERIOD 1** **1st qtr 1999 – 4th qtr 1999**	**PERIOD 2** **1st qtr 2000 – 4th qtr 2000**				
Biopsy/diagnosis	**7/99**					
Surgery	**7/99**					
Radiation						
Chemotherapy						
Naltrexone						
Imaging CT scan		**7/00**				
Liver enzymes	**10/99,10/99, 11/99**					
Death		**8/00**				

CAM Therapy:	Naltrexone		
Case:	2-10		
Condition:	Pancreatic cancer with bile duct involvement stage IV		
Abstractor:	AC IC JU	**Date of Abstraction:**	7/11/01
Interviewer:		**Date of Interview:**	10/11/01
Comments:	Regression without chemo/XRT/surgery, no diagnosing pathology report		

Criteria for inclusion: (check all that apply)			
	Diagnosis confirmed		
x	Documented start date for CAM therapy		
	Documented previous anti-cancer therapies		
x	No other therapies during the CAM therapy		
x	Documented endpoint:		
		Tumor size	
	x	Longevity	
	x	Quality of Life	
		Other:	need confirmation

Other Relevant Information:	
Sex:	female
DOB:	9/14/46
Diagnosis:	Pancreatic cancer with bile duct involvement
Diagnosis date:	7/1/99
CAM therapy dates:	11/11/99- started Naltrexone
Conventional therapy dates:	surgery, date unclear
Last contact date:	8/5/00
If deceased, date of death:	8/5/00

Date	Description of Events	Requested	Status of Requests
7/1/99	Laparoscopy; diagnosis of pancreatic cancer per physician's notes	Slides	Pend.
10/22/99	Alk Phos- 1646; ALT 93; AST 159		
10/23/99	Alk Phos- 1471; ALT 74; AST 108		
11/21/99	Alk Phos- 2262; ALT 126; AST 180		
11/11/99	Naltrexone 3mg qHS		
Dec-99	Metenkephalin IV		
Jul-00	CT scan abdomen: residual pancreatic lesions <1cm: 90% reduction of tumor mass; per physician's notes	Films	Pend.
8/5/00	Death--due to septecemia secondary to loosened stent in bile duct		

Cancer Best-Case Series

Patient #2-21
Melanoma

Case 2-21

The patient in case 2-21 is a 67-year-old male who was diagnosed with melanoma in July 1996. The melanoma was resected from his right shoulder at that time, and no further therapy, other than close surveillance, was recommended. In April 1998, a lymph node dissection of his right axilla revealed metastatic disease in 1 of 15 lymph nodes. No conventional therapy was pursued. After presenting in August 1999 with proprioceptive changes in his left lower extremity, he had an MRI that showed a small brain lesion. This proved in fact to be a small bleed. During the course of 1999, the patient reported trying but not sustaining treatment with a variety of alternative therapies (see below). Also, he reported participating in a vaccine trial. Naltrexone was initiated in January 2000. At the last contact (interview, 10/10/2000), the patient reported that his overall physical condition was very good.

Pathology

7/23/96	**Pathology from excision: malignant melanoma focally filling to papillary dermis (level III), vertical thickness 0.78mm. No abnormal melanocytes at margins of specimen**
9/10/99	**Biopsy brain: revealed no evidence of malignancy (per patient report)**

Imaging

4/15/98	**CT scan brain, chest, abdomen, and pelvis: no evidence of metastasis**
8/1/99	**MRI brain: proprioceptive changes in left lower calf and foot: diagnosed with cranial metastasis (per patient report) (this proved to be incorrect as the patient was later diagnosed to have had a small bleed**

Conventional therapy

7/23/96	**Surgical excision of pigmented skin lesion on right shoulder**
8/13/96	**Surgical excision after melanoma diagnosis confirmed**
4/1/98	**Surgery: lymph nodes: 1 of 15 nodes positive for malignancy**
1999	**Clinical trial: vaccinia melanoma cell lysates (VMCL) (per patient report)**

Complementary therapy

1/00-present	**Started Naltrexone 4.5mg**
1999	**Melatonin 3mg q.d. MVI q.d.; antioxidant q.d.; green tea; ginseng; vegetarian diet; selenium; milk thistle; pancreatic enzymes**

Patient # 2-21						
EVENT	PERIOD 1 1st qtr 1996 – 4th qtr 1996	PERIOD 2 1st qtr 1997 – 4th qtr 1997	PERIOD 3 1st qtr 1998 – 4th qtr 1998	PERIOD 4 1st qtr 1999 – 4th qtr 1999	PERIOD 5 1st qtr 2000 – 4th qtr 2000	PERIOD 6 1st qtr 2001 – 4th qtr 2001
Biopsy/diagnosis	7/96			9/99		
Surgery	7/96, 8/96		4/98			
Radiation						
Chemotherapy						
Clinical trial				1999		
Naltrexone					1/00	
CAM other				1999		
Imaging-MRI brain						
Imaging-CT scan abdomen			4/98	8/99		

CAM Therapy:	Naltrexone		
Case:	2-21		
Condition:	Melanoma, malignant		
Abstractor:	JTF	**Date of Abstraction:**	10/5/01
Interviewer:		**Date of Interview:**	10/10/01
Comments:	Unclear if patient had conventional therapy, or dates of initiating Naltrexone		

Criteria for inclusion: (check all that apply)			
x	Diagnosis confirmed		
x	Documented start date for CAM therapy		
x	Documented previous anti-cancer therapies		
	No other therapies during the CAM therapy		
x	Documented endpoint:		
		Tumor size	
	x	Longevity	
		Quality of Life	
		Other:	

Other Relevent Information:	
Sex:	male
DOB:	12/12/38
Diagnosis:	Malignant melanoma
Diagnosis date:	7/23/96
CAM therapy dates:	1/00-present Naltrexone
Conventional therapy dates:	7/96 surgery; 4/98 surgery
Last contact date:	1/20/00
If deceased, date of death:	

Date	Description of Events	Requested	Status of Requests
7/23/96	Surgical excision of pigmented skin lesion on right shoulder		
7/23/96	Pathology from excision: malignant melanoma focally filling to papillary dermis (level III), vertical thickness 0.78mm. No abnormal melanocytes at margins of specimen	Slides	Pend.
8/13/96	Surgical excision after melanoma diagnosis confirmed		
4/1/98	Melanoma metastasized to right axilla with lymph node involvement (per patient report)	Slides	Pend.
4/15/98	CT scan brain, chest, abdomen, and pelvis: no evidence of metastasis (per patient report)	Films	Pend.
4/1/98	Surgery: lymph nodes: 1 of 15 nodes positive for malignancy		
year '99	melatonin 3mg qd; MVI qd; antioxidant qd; green tea; ginseng; vegetarian diet; selenium; milk thistle; pancreatic enzymes		
year '99	Clinical trial: vacinia melanoma cell lysates(VMCL) (per patient report)		
8/1/99	Proprioceptive changes in left lower calf and foot (per patient report)		
8/1/99	MRI brain: diagnosed with cranial metastasis (per patient report)	Films	Pend.
9/10/99	Biopsy brain: revealed no evidence of malignancy (per patient report)		
1/00-present	Started Naltrexone 4.5mg		

Cancer Best-Case Series

Patient #2-22
Adenocarcinoma of the Endometrium With Extension into the Peritoneum

Case 2-22

The patient in case 2-22 is a 58-year-old female diagnosed in May 1998 with adenocarcinoma of the endometrium with extension into the peritoneum. She completed four cycles of chemotherapy with adriamycin, cytoxan, and cisplatin. After her initial round of chemotherapy, adriamycin was withheld due to an equivocal multigated radionuclide (MUGA) scan and a past history of pericarditis. A course of radiation was completed. A CT scan (1/22/99) after chemotherapy and radiation showed a decrease in the pelvic mass. In July 1999, she was diagnosed with a second primary malignancy, intraductal carcinoma of the right breast with negative axillary nodes. Subsequent CT scans of her thorax revealed bilateral pulmonary nodules consistent with metastatic disease. She was referred to a thoracic surgeon, but a biopsy was not performed because the procedure was felt to be too difficult. She initiated Naltrexone in January 2001. In March 2001, a CT scan showed fewer abdominal and intrathoracic nodules compared to 1/3/01. A subsequent CT scan in June 2001 revealed a further reduction in peritoneal carcinomatosis. Her oncologist continues to follow her with serial CT scans. Currently, she reports her overall condition over the past week as excellent.

Pathology

5/8/98	**Biopsy endometrium: pathology- adenocarcinoma, endometroid moderately to well-differentiated with 33% invasion of the myometrium: extension into peritoneum and left pelvic sidewall**
7/29/99	**Biopsy breast (right) pathology intraductal carcinoma well differentiated**

Imaging

10/30/98	**CT scan 2.5cm mass in lymph nodes on left side of pelvis (MD's notes only-no full report)**
1/22/99	**CT scan abdomen and pelvis: improvement in pelvic mass**
4/9/99	**CT scan abdomen and pelvis: improvement in pelvic mass**
5/10/00	**CT scan chest, abdomen, and pelvis: no abdominal or pelvic lesion. No evidence of metastatic disease. 1cm inguinal node unchanged**
8/2/00	**CT scan chest compared to 5/10/00 upper lobe anterior segment nodule 10mm; 3 new nodules 5mm left apex, 5mm lingula, 7mm right middle lobe. Progression of metastatic disease**
9/29/00	**CT scan chest: no adenopathy (mediastinal)-multiple small nodules; no change c/w 8/2/00**
11/9/00	**CT scan chest, abdomen, and pelvis: bilateral pulmonary nodules some cavitated. New peritoneal carcinomatosis**
3/14/01	**CT scan chest, abdomen, and pelvis: compared to 1/3/01; abdominal and intrathoracic nodules decrease in number**
6/11/01	**CT scan chest, abdomen, and pelvis: compared to 3/14/01; no new adenopathy, interval decrease in peritoneal carcinomatosis. Small superior mediastinal lymph node unchanged**

Conventional therapy

7/15/98-9/24/98	**Chemotherapy: cisplatin and AC; adriamycin held due to equivocal MUGA scan; four cycles**
11/9/98-12/24/98	**Radiation: 5400 cGy to para-aortic lymph nodes; CT scan on 1/22/99 showed improvement of pelvic mass**
9/1/1999	**Surgery: lumpectomy with sentinel node dissection: 1.7cm with clear margins and lymph nodes: ER + PR positive**

Complementary therapy

1/9/01	**Naltrexone 4.5mg daily**

Patient # 2-22						
EVENT	**PERIOD 1** **1st qtr 1998 – 4th qtr 1998**	**PERIOD 2** **1st qtr 1999 – 4th qtr 1999**	**PERIOD 3** **1st qtr 2000 – 4th qtr 2000**	**PERIOD 4** **1st qtr 2001 – 4th qtr 2001**		
Diagnosis/biopsy	**5/98**	**7/99**				
Surgery		**9/99**				
Radiation	**11/98-12/98**					
Chemotherapy	**7/98 9/98**					
Naltrexone				**1/01**		
CAM other						
Imaging CXR						
Imaging tomogram						
Imaging CT scan	**10/98**	**1/99 4/99**	**5/00 8/00. 9/00 11/00**	**3/01 6/01**		

CAM Therapy:	Naltrexone		
Case:	2-22		
Condition:	Adenocarcinoma of endometrium stage III and right breast intraductal carcinoma		
Abstractor:	AC	**Date of Abstraction:**	11/13/01
Interviewer:	IDC	**Date of Interview:**	12/12/01
Comments:			

Criteria for inclusion: (check all that apply)			
x	Diagnosis confirmed		
x	Documented start date for CAM therapy		
x	Documented previous anti-cancer therapies		
x	No other therapies during the CAM therapy		
x	Documented endpoint:		
	x	Tumor size	
		Longevity	
		Quality of Life	
		Other:	

Other Relevant Information:	
Sex:	female
DOB:	4/6/43
Diagnosis:	adenocarcinoma of endometrium stage III and right breast intraductal carcinoma
Diagnosis date:	5/8/98 adenocarcinoma of endometrium 9/99 breast intraductal carcinoma
CAM therapy dates:	1/9/01 Naltrexone
Conventional therapy dates:	Chemotherapy: 7/15/1998-9/24/98 Radiation: 11/9/98-12/24/98
Last contact date:	
If deceased, date of death:	

Date	Description of Events	Requested	Status of Requests
5/8/98	Biopsy endometrium: pathology- adenocarcinoma, endometroid moderately to well-differentiated with 33% invasion of the myometrium: extension into peritoneum and left pelvic sidewall	Slides	Pend.
7/15/98-9/24/98	Chemotherapy: cisplatin and AC; adriamycin held due to equivocal MUGA scan		
10/30/98	CT scan 2.5cm mass in lymph nodes on on left side of pelvis (MD's notes only--no full report)	Films	Pend.
11/9/98-12/24/98	Radiation: 5400 cGy to para-artic lymph nodes; CT scan on 1/22/99 showed improvement of pelvic mass		
1/22/99	CT scan abdomen and pelvis: improvement in pelvic mass	Films	Pend.
4/9/99	CT scan abdomen and pelvis: improvement in pelvic mass	Films	Pend.
7/29/99	Biopsy breast (right) pathology intraductal carcinoma well differentiated	Slides	Pend.
9/1/99	Surgery: lumpectomy with sentinel node dissection: 1.7cm with clear margins and lymph nodes: ER + PR positive		
5/10/00	CT scan chest, abdomen, and pelvis: no abdominal or pelvic lesion. No evidence of metastatic disease. 1cm inguinal node unchanged.	Films	Pend.
8/2/00	CT scan chest compared to 5/10/00 upper lobe anterior segment nodule 10mm; 3 new nodules 5mm left apex, 5mm lingula, 7mm right middle lobe. Progression of metastatic disease		
9/29/00	CT chest: no adenopathy (mediastinal)-multiple small nodules; no change c/w 8/2/00		
11/9/00	CT chest, abdomen, and pelvis: bilateral pulmonary nodules, some cavitated. New peritoneal carcinomatosis	Films	Pend.
1/9/01	Naltrexone 4.5mg daily		
3/14/01	CT scan chest, abdomen, and pelvis: compared to 1/3/01; abdominal and intrathoracic nodules decrease in number	Films	Pend.
6/11/01	CT scan chest, abdomen, and pelvis: compared to 3/14/01; no new adenopathy, interval decrease in peritoneal carcinomatosis. Small superior mediastinal lymph node unchanged	Films	Pend.