

## **Appendixes**

**Appendix A:**  
**CANCER - Best-Case Series Abstraction Form**

## Appendix A: CANCER - Best-Case Series Abstraction Form

Patient's ID Code: \_\_\_\_\_

Case # \_\_\_\_\_

Description: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

CRITERIA FOR INCLUSION (check all that apply)	
1.	Diagnosis – Histological/pathology report (i.e., biopsy)
2.	Documented start point for CAM therapy
<b>If not 1 AND 2, then stop</b>	
3.	Documented previous anti-cancer therapies
4.	Exclusive CAM treatment: No other therapies used during CAM treatment
5.	Documented endpoint (tumor size, longevity, etc.) (check all that apply)
	Tumor size
	Longevity
	Other: _____
	Improved Quality of Life

## Appendix A: CANCER - Best-Case Series Abstraction Form (continued)

Patient's ID Code: \_\_\_\_\_

### A. TEAR SHEET

6. Patient's ID Code: \_\_\_\_\_

7. Date abstracted: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
mm dd yyyy

8. Patient's Medical Record #: \_\_\_\_\_

9. Patient's Social Security #: \_\_\_\_\_-\_\_\_\_\_-\_\_\_\_\_

10 Patient's Name:  
(Last)\_\_\_\_\_ (First)\_\_\_\_\_ (MI)\_\_\_\_\_

11. Patient's Date of Birth: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
mm dd yyyy



## Appendix A: CANCER - Best-Case Series Abstraction Form (continued)

Patient's ID Code: \_\_\_\_\_

### B. IDENTIFICATION DATA

12. Patient's ID Code: \_\_\_\_\_
13. Site Code: \_\_\_\_\_
14. Practitioner Code: \_\_\_\_\_
15. Abstractor Code: \_\_\_\_\_

### C. PATIENT CHARACTERISTICS

16. Date of Birth: \_\_\_\_/\_\_\_\_/\_\_\_\_  
mm dd yyyy  
(If date of birth is missing, give the patient's age at the time of the first visit and date of first visit, if available.)
- \_\_\_\_\_
- \_\_\_\_\_

17. Race/Ethnicity: (check all that apply)

American Indian/Alaskan Native ..... ☐

Asian/Pacific Islander ..... ☐

Black, not Hispanic ..... ☐

Hispanic ..... ☐

White, not Hispanic ..... ☐

Other (specify: \_\_\_\_\_) ..... ☐

Other (specify: \_\_\_\_\_) ..... ☐

Other (specify: \_\_\_\_\_) ..... ☐

No data ..... ☐

18. Sex: M / F / No Data (circle one)

19. Marital status: Married / Not married / No data (circle one)

## Appendix A: CANCER - Best-Case Series Abstraction Form (continued)

Patient's ID Code: \_\_\_\_\_

### D. PAST MEDICAL HISTORY

20.	<b>Concurrent medical problems (comorbidities):</b>
	_____
	_____
	_____
21.	Previous cancer history?    Y / N / No Data
22.	If yes, when? _____
23.	Diagnosis: _____
	Treatment: _____
	_____
	_____
	_____

24.	<b>Medications administered concurrently?</b>	Y / N / No Data	(if yes, list)	
	<u>Start Date</u> mm / dd / yyyy	<u>End Date</u> mm / dd / yyyy	<u>Name</u>	<u>Regimen</u>
A	___/___/___	___/___/___	_____	_____
B	___/___/___	___/___/___	_____	_____
C	___/___/___	___/___/___	_____	_____
D	___/___/___	___/___/___	_____	_____
E	___/___/___	___/___/___	_____	_____
F	___/___/___	___/___/___	_____	_____
G	___/___/___	___/___/___	_____	_____
H	___/___/___	___/___/___	_____	_____

## Appendix A: CANCER - Best-Case Series Abstraction Form (continued)

Patient's ID Code: \_\_\_\_\_

### E. CANCER HISTORY

25.	<b>Primary malignancy:</b> _____ (First histological confirmation)
26.	Date of first diagnosis of cancer:    ____/____/____ mm    dd    yyyy
27.	Primary site biopsy proven?    Y / N / No Data
28.	Original site of tumor location: _____
29.	Slide available?                            Y / N / No Data
30.	Type: _____
31.	Stage: _____
32.	Grade: _____
33.	<b>Other primary malignancies?</b> Y / N / No Data <i>(if no or no data, go to 54)</i>
34.	Date of diagnosis of cancer:            ____/____/____ mm    dd    yyyy
35.	Primary site biopsy proven?            Y / N / No Data
36.	Original site of tumor location: _____
37.	Type: _____
38.	Stage: _____
39.	Grade: _____
40.	<b>Other primary malignancies?</b> Y / N / No Data
41.	Date of diagnosis of cancer:            ____/____/____ mm    dd    yyyy
42.	Primary site biopsy proven?            Y / N / No Data
43.	Original site of tumor location: _____
44.	Type: _____
45.	Stage: _____
46.	Grade: _____

## Appendix A: CANCER - Best-Case Series Abstraction Form (continued)

Patient's ID Code: \_\_\_\_\_

### E. CANCER HISTORY (cont'd)

47.	<b>Other primary malignancies?</b>	Y / N / No Data
48.	Date of diagnosis of cancer:	____/____/____ mm dd yyyy
49.	Primary site biopsy proven?	Y / N / No Data
50.	Original site of tumor location:	_____
51.	Type:	_____
52.	Stage:	_____
53.	Grade:	_____
54.	<b>Family history of cancer?</b>	Y / N / No Data
55.	If yes, document family member(s), type of cancer, outcome:	_____ _____ _____
56.	Carcinogen exposure?	Y / N / No Data
57.	If yes, what kind?	Smoking      Job exposure      Other: _____
58.	<b>Metastases?</b>	Y / N / No Data (if no or no data, go to #62)
59.	Date of first metastatic diagnosis:	____/____/____ mm dd yyyy
60.	How was the diagnosis of metastatic disease made? (check all that apply)	Biopsy      Imaging      Other: _____
61.	Site(s) of first metastases:	_____ _____

## Appendix A: CANCER - Best-Case Series Abstraction Form (continued)

Patient's ID Code: \_\_\_\_\_

### E. CANCER HISTORY (cont'd)

62.	Has <b>remission</b> from the primary malignancy occurred?    Y / N / No Data
63.	If yes, how documented? _____ _____ _____
64.	If no, response to conventional therapy? _____ _____ _____
65.	Has there been recurrence of cancer?    Y / N / No Data <i>(if no or no data, go to #69)</i>
66.	Date of recurrence:    ____/____/____ mm    dd    yyyy
67.	How was the recurrence proven?    (check all that apply) Biopsy            Imaging            Other:_____
68.	Site(s) of recurrence: _____ _____ _____

Pathology	
69.	Pathology report included:                            Y / N / No Data
70.	Pathology report discussed, not included:    Y / N / No Data

**Appendix A: CANCER - Best-Case Series Abstraction Form (continued)**

Patient's ID Code: \_\_\_\_\_

**E. CANCER HISTORY (cont'd)**

71. Biopsy Table					
	Site	Date (mm/dd/yyyy)	Method	Tissue Type	Markers
A					
	Final Pathology:				
B					
	Final Pathology:				
C					
	Final Pathology:				
D					
	Final Pathology:				
E					
	Final Pathology:				
F					
	Final Pathology:				
G					
	Final Pathology:				

## Appendix A: CANCER - Best-Case Series Abstraction Form (continued)

Patient's ID Code: \_\_\_\_\_

### F. PRIOR CONVENTIONAL TREATMENT

72.	<b>Surgeries?</b>	Y / N / No Data	(if no or no data, go to #85)	(copy this sheet for additional dates)
73.	Procedure:	_____		
74.	Intent of surgery:	Cure	Palliative	Other: _____
75.	Date of surgery:	____/____/____		
		mm dd yyyy		
76.	Results:	_____ _____ _____		
77.	Procedure:	_____		
78.	Intent of surgery:	Cure	Palliative	Other: _____
79.	Date of surgery:	____/____/____		
		mm dd yyyy		
80.	Results:	_____ _____ _____		
81.	Procedure:	_____		
82.	Intent of surgery:	Cure	Palliative	Other: _____
83.	Date of surgery:	____/____/____		
		mm dd yyyy		
84.	Results:	_____ _____ _____		

# Appendix A: CANCER - Best-Case Series Abstraction Form (continued)

Patient's ID Code: \_\_\_\_\_

85. Chemotherapy? Y / N / No Data (if no or no data, go to 86)				(check all that apply)	
Drug	Dose	Start/end dates (mm/dd/yyyy)	# of cycles	Results	Complications/Reasons for discontinuation
Regimen A				Course	Adverse reaction
				Completed 1	Patient preference
				Stopped early 2	Toxicity
				Tumor response	Ineffective
				Yes 1	Other: _____
				No 2	
				Course	Adverse reaction
				Completed 1	Patient preference
			Stopped early 2	Toxicity	
			Tumor response	Ineffective	
			Yes 1	Other: _____	
			No 2		
Cycle: -----					
Regimen B				Course	Adverse reaction
				Completed 1	Patient preference
				Stopped early 2	Toxicity
				Tumor response	Ineffective
				Yes 1	Other: _____
				No 2	
				Course	Adverse reaction
				Completed 1	Patient preference
			Stopped early 2	Toxicity	
			Tumor response	Ineffective	
			Yes 1	Other: _____	
			No 2		
Cycle: -----					
Regimen C				Course	Adverse reaction
				Completed 1	Patient preference
				Stopped early 2	Toxicity
				Tumor response	Ineffective
				Yes 1	Other: _____
				No 2	
				Course	Adverse reaction
				Completed 1	Patient preference
			Stopped early 2	Toxicity	
			Tumor response	Ineffective	
			Yes 1	Other: _____	
			No 2		
Cycle: -----					



## Appendix A: CANCER - Best-Case Series Abstraction Form (continued)

Patient's ID Code: \_\_\_\_\_

### F. PRIOR CONVENTIONAL TREATMENT (cont'd)

86.	<b>Radiation?</b>	Y / N / No Data <i>(if no or no data, go to #102)</i>	
87.	Dates of radiation:	<div>____/____/____ mm dd yyyy Initiated</div>	<div>____/____/____ mm dd yyyy Completed</div>
88.	Intent of radiation:	Cure	Palliative Other: _____
89.	Area(s) radiated:	_____	
90.	Total RADS:	_____	
91.	Results of radiation therapy:	_____ _____	
92.	Adverse effects?	Y / N No Data	If yes, explain: _____ : _____
93.	Discontinue radiation early?	Y / N / No Data	If Yes, reason: _____
94.	<b>Additional Radiation?</b>	Y / N / No Data	
95.	Dates of radiation:	<div>____/____/____ mm dd yyyy Initiated</div>	<div>____/____/____ mm dd yyyy Completed</div>
96.	Intent of radiation:	Cure	Palliative Other: _____
97.	Area(s) radiated:	_____	
98.	Total RADS:	_____	
99.	Results of radiation therapy:	_____ _____	
100.	Adverse effects?	Y / N No Data	If yes, explain: _____ : _____
101.	Discontinue radiation early?	Y / N / No Data	If Yes, reason: _____

## Appendix A: CANCER - Best-Case Series Abstraction Form (continued)

Patient's ID Code: \_\_\_\_\_

### F. PRIOR CONVENTIONAL TREATMENT (cont'd)

102.	<b>Other conventional therapies?</b> Y / N / No Data <i>(if no or no data, go to #114)</i>	
103.	Bone marrow transplant? Y / N / No Data	<div style="display: flex; justify-content: space-around; align-items: center;"> <div>_____/_____/_____ mm dd yyyy</div> </div>
104.	Result: _____ _____	
105.	Hormonal cancer agents? Y / N / No Data	<div style="display: flex; justify-content: space-around; align-items: center;"> <div>_____/_____/_____ mm dd yyyy Initiated</div> <div>_____/_____/_____ mm dd yyyy Completed</div> </div>
106.	Type: _____	
107.	Regimen: _____	
108.	Other: _____	<div style="display: flex; justify-content: space-around; align-items: center;"> <div>_____/_____/_____ mm dd yyyy Initiated</div> <div>_____/_____/_____ mm dd yyyy Completed</div> </div>
109.	Regime /outcome: _____	
110.	Other: _____	<div style="display: flex; justify-content: space-around; align-items: center;"> <div>_____/_____/_____ mm dd yyyy Initiated</div> <div>_____/_____/_____ mm dd yyyy Completed</div> </div>
111.	Regime /outcome: _____	
112.	Other: _____	<div style="display: flex; justify-content: space-around; align-items: center;"> <div>_____/_____/_____ mm dd yyyy Initiated</div> <div>_____/_____/_____ mm dd yyyy Completed</div> </div>
113.	Regime /outcome: _____	

## Appendix A: CANCER - Best-Case Series Abstraction Form (continued)

Patient's ID Code: \_\_\_\_\_

### G. Tracking of Cancer Progression

114. Imaging procedures:				
	Procedure	Date mm/dd/yyyy	Area	Result
A				
B				
C				
D				
E				
F				
G				
H				
I				
J				

## Appendix A: CANCER - Best-Case Series Abstraction Form (continued)

Patient's ID Code: \_\_\_\_\_

### G. Tracking of Cancer Progression (cont'd)

115. Tumor markers? Y / N / No Data <i>List type (CEA, CA-125, PSA, e.g.)</i>			
	Type	Date	Results
A			
B			
C			
D			
E			
F			
G			
H			
I			
J			
K			
L			
M			
	Type	Date	Results
N			
O			
P			
Q			
R			
S			
T			
U			
V			
W			
X			
Y			
Z			

## Appendix A: CANCER - Best-Case Series Abstraction Form (continued)

Patient's ID Code: \_\_\_\_\_

### H. COMPLEMENTARY / ALTERNATIVE THERAPIES

#### 116. Reason(s) for pursuing CAM cancer therapy

Side-effects of conventional therapy

Failure of conventional therapy

Other: \_\_\_\_\_

No Data

#### 117. Patient in Hospice care when beginning CAM? Y / N / No Data

#### CAM Therapy

#### 118. Start Date End Date Therapy Type/ Protocol

mm dd yyyy

mm dd yyyy

A \_\_\_\_/\_\_\_\_/\_\_\_\_ \_\_\_\_/\_\_\_\_/\_\_\_\_

B \_\_\_\_/\_\_\_\_/\_\_\_\_ \_\_\_\_/\_\_\_\_/\_\_\_\_

C \_\_\_\_/\_\_\_\_/\_\_\_\_ \_\_\_\_/\_\_\_\_/\_\_\_\_

D \_\_\_\_/\_\_\_\_/\_\_\_\_ \_\_\_\_/\_\_\_\_/\_\_\_\_

E \_\_\_\_/\_\_\_\_/\_\_\_\_ \_\_\_\_/\_\_\_\_/\_\_\_\_

F \_\_\_\_/\_\_\_\_/\_\_\_\_ \_\_\_\_/\_\_\_\_/\_\_\_\_

G \_\_\_\_/\_\_\_\_/\_\_\_\_ \_\_\_\_/\_\_\_\_/\_\_\_\_

H \_\_\_\_/\_\_\_\_/\_\_\_\_ \_\_\_\_/\_\_\_\_/\_\_\_\_

I \_\_\_\_/\_\_\_\_/\_\_\_\_ \_\_\_\_/\_\_\_\_/\_\_\_\_

J \_\_\_\_/\_\_\_\_/\_\_\_\_ \_\_\_\_/\_\_\_\_/\_\_\_\_

## Appendix A: CANCER - Best-Case Series Abstraction Form (continued)

Patient's ID Code: \_\_\_\_\_

### H. COMPLEMENTARY / ALTERNATIVE THERAPIES (cont'd)

119.	<b>Other CAM therapies administered concurrently?</b> Y / N / No Data (if yes, list)	
	Start Date mm / dd / yyyy	End Date mm / dd / yyyy
A	___/___/___	___/___/___
B	___/___/___	___/___/___
C	___/___/___	___/___/___
D	___/___/___	___/___/___
E	___/___/___	___/___/___
F	___/___/___	___/___/___
G	___/___/___	___/___/___
H	___/___/___	___/___/___

## Appendix A: CANCER - Best-Case Series Abstraction Form (continued)

Patient's ID Code: \_\_\_\_\_

### H. COMPLEMENTARY / ALTERNATIVE THERAPIES (cont'd)

120.	Documented toxicity, side-effects from CAM therapies/ interventions?	Y / N / No Data (if no or no data, go to #134)
	mm / dd / yyyy	
121.	Lungs Date first documented: ____/____/____	
122.	Cardiac Date first documented: ____/____/____	
123.	Liver Date first documented: ____/____/____	
124.	Renal Date first documented: ____/____/____	
125.	Gastrointestinal Date first documented: ____/____/____	
126.	Dermatological Date first documented: ____/____/____	
127.	Endocrine Date first documented: ____/____/____	
128.	Gynecological Date first documented: ____/____/____	
129.	Bladder Date first documented: ____/____/____	
130.	Neurological Date first documented: ____/____/____	
131.	Other Date first documented: ____/____/____	
132.	Other Date first documented: ____/____/____	
133.	Other Date first documented: ____/____/____	

## Appendix A: CANCER - Best-Case Series Abstraction Form (continued)

Patient's ID Code: \_\_\_\_\_

### I. DISPOSITION

134.	<b>Is patient alive?</b>	Y / N / No Data	As of	____/____/____
				mm dd yyyy
135.	If yes, current condition: _____			
136.	If no, cause of death: _____			
137.	Pathology reports from autopsy available? Y / N / No Data			
138.	Last contact with patient: ____/____/____			
139.	Quality of life measures available? Y / N / No Data			
140.	List: _____			



## **Appendix B: Case Report Form**

## Appendix B: Case Report Form

CAM Therapy:  Case:  Condition:  Abstractor:  Interviewer:  Comments:			
		Date of Abstraction:	
		Date of Interview:	

### Criteria for inclusion: (check all that apply)

<input type="checkbox"/>	Diagnosis confirmed
<input type="checkbox"/>	Documented start date for CAM therapy
<input type="checkbox"/>	Documented previous anti-cancer therapies
<input type="checkbox"/>	No other therapies during the CAM therapy
<input type="checkbox"/>	Documented endpoint:
<input type="checkbox"/>	<input type="checkbox"/> Tumor size
	<input type="checkbox"/> Longevity
	<input type="checkbox"/> Quality of Life
	<input type="checkbox"/> Other: <input type="text"/>

### Other Relevant Information:

Sex:	<input type="text"/>
DOB:	<input type="text"/>
Diagnosis:	<input type="text"/>
Diagnosis date:	<input type="text"/>
CAM therapy dates:	<input type="text"/>
Conventional therapy dates:	<input type="text"/>
Last contact date:	<input type="text"/>
If deceased, date of death:	<input type="text"/>

Appendix B: Case Report Form (continued)

Code	Date	Date Imputed?	Dates verified?	Description of Event I

Appendix B: Case Report Form (continued)

Description of Event II	Event verified?	Retreive report?	Notes

## **Appendix C**

**IAT Patient Questionnaire**

**IAT Next-of-Kin Questionnaire**

**Naltrexone Patient Questionnaire**

**Naltrexone Next-of-Kin Questionnaire**



**PATIENT INTERVIEW FOR IMMUNOAUGMENTED THERAPY (IAT)**

**RA**

**1700 MAIN STREET  
SANTA MONICA CA 90401**

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**Appendix C: Cancer – Best-Case Series Patient Interview Form-IAT**  
**PATIENT INTERVIEW SCHEDULE**

**TEAR SHEET (to be completed prior to the interview)**

1. Patient's ID CODE: 01 \_\_\_\_\_  
Site: \_\_\_\_\_ Patient # \_\_\_\_\_
2. Patient's Name: \_\_\_\_\_  
LAST NAME FIRST NAME  
Next-of-Kin Name: \_\_\_\_\_  
LAST NAME FIRST NAME
3. STATE: \_\_\_\_\_
4. Consent Letter Received: \_\_\_\_/\_\_\_\_/\_\_\_\_
5. Doctor's Name and/ or Clinic for CAM: \_\_\_\_\_
6. Therapy Type: \_\_\_\_\_
7. Date Interviewed: \_\_\_\_/\_\_\_\_/\_\_\_\_ Interviewer: \_\_\_\_\_
8. Date Checked: \_\_\_\_/\_\_\_\_/\_\_\_\_ By: \_\_\_\_\_
9. Date Data Entered: \_\_\_\_/\_\_\_\_/\_\_\_\_

## Appendix C: Cancer – Best-Case Series Patient Interview Form-IAT (continued)

PT ID#: \_\_\_\_\_

### CALL RECORD AND FIELD CONTACT RECORD

Telephone Number: ( \_\_\_\_\_ ) \_\_\_\_\_ - \_\_\_\_\_

Contact Attempt	Date	Time of Call	Outcome Code	Interviewer
1				
2				
3				
4				

DATE & TIME FOR CALLBACK: \_\_\_\_\_

### NOTES

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### OUTCOME CODES

AM = Answering machine

BZ = Busy signal (phone, fax or modem)

CI = Completed interview

O = Other (describe)

PI = Partial interview

CB = Call back

DS = Disconnected

AP = Made an appointment

NA = No answer

WN = Wrong number

PP = Phone problem

RF = Refused

**Appendix C: Cancer – Best-Case Series Patient Interview Form-IAT (continued)**

PT ID#: \_\_\_\_\_

**PATIENT INTERVIEW SCHEDULE**

**STRICTLY CONFIDENTIAL**

*The following interview has been designed by RAND as part of a study of cancer treatment. The study has both the support and cooperation of your physician. Its purpose is to obtain, as accurately as possible, information concerning the care that you received. In order to do this, we require information about people who have used this type of care. The interview should last about 30 minutes.*

*THIS IS NOT A TEST AND THERE ARE NO RIGHT OR WRONG ANSWERS.*

*All information will be used in the strictest confidence and will be seen only by our research staff. Because the information collected is confidential there is no possibility of anyone identifying you from your answers. You may skip any questions that you feel uncomfortable answering; however, please remember that it is important that all questions be answered if we are to assess your therapy. You may stop the interview at any time.*

*The Principal Investigator is Dr. Ian Coulter from RAND who can be contacted at 310-393-0411 extension 6759 if you wish to discuss the interview with him. I am Doctor (INSERT YOUR NAME) and I will be conducting this interview. I am a member of the research staff. Do I have your permission to continue with the interview?*

Yes \_\_\_\_\_ No \_\_\_\_\_ If no, May I ask you your reason for declining?

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*Thank you for your assistance.*

## Appendix C: Cancer – Best-Case Series Patient Interview Form-IAT (continued)

PT ID#: \_\_\_\_\_

### SECTION A: DEMOGRAPHICS (To be partially completed before the interview)

*First, I would like to ask some background questions about you.*

1. What is your birth date? \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

If refused, enter REFUSED

If don't know, enter DON'T KNOW

1a. What is your age? \_\_\_\_\_

If refused, enter RF

If don't know, enter DK

2. What is your sex? (Check one)

Male \_\_\_\_\_ (1)

Female \_\_\_\_\_ (2)

3. What is your marital status? (Check one)

Single \_\_\_\_\_ (1)

Married \_\_\_\_\_ (2)

Divorced \_\_\_\_\_ (3)

Widowed \_\_\_\_\_ (4)

Refused \_\_\_\_\_ (7)

Don't know \_\_\_\_\_ (9)

4. What is your highest level of education? (Check one)

Grade school \_\_\_\_\_ (1)

High school \_\_\_\_\_ (2)

Some college \_\_\_\_\_ (3)

College degree \_\_\_\_\_ (4)

Graduate degree \_\_\_\_\_ (5)

Refused \_\_\_\_\_ (7)

Don't know \_\_\_\_\_ (9)

## Appendix C: Cancer – Best-Case Series Patient Interview Form-IAT (continued)

PT ID#: \_\_\_\_\_

5. What is your ethnic origin?

(Check all that apply)

Caucasian \_\_\_\_\_ (1)

Black/African American \_\_\_\_\_ (2)

Hispanic/Latino \_\_\_\_\_ (3)

Asian/Pacific islander \_\_\_\_\_ (4)

Other \_\_\_\_\_ (5) Please could you specify: \_\_\_\_\_

Refused \_\_\_\_\_ (7)

Don't know \_\_\_\_\_ (9)

6. What type of health insurance do you have?

(Check all that apply)

HMO \_\_\_\_\_ (1)

PPO \_\_\_\_\_ (2)

Fee for Service \_\_\_\_\_ (3)

None \_\_\_\_\_ (4)

Other \_\_\_\_\_ (5) Please could you specify: \_\_\_\_\_

Refused \_\_\_\_\_ (7)

Don't know \_\_\_\_\_ (9)

7. What insurance coverage did you have for Immunoaugmentation Therapy?

HMO \_\_\_\_\_ (1)

PPO \_\_\_\_\_ (2)

Fee for Service \_\_\_\_\_ (3)

None \_\_\_\_\_ (4)

Other \_\_\_\_\_ (5) Please could you specify: \_\_\_\_\_

Refused \_\_\_\_\_ (7)

Don't know \_\_\_\_\_ (9)

8. What is your current or most recent occupation? (ENTER VERBATIM)

\_\_\_\_\_

## Appendix C: Cancer – Best-Case Series Patient Interview Form-IAT (continued)

PT ID#: \_\_\_\_\_

### SECTION B. HEALTH STATUS

*We would like to begin by asking about your current health.*

	<u>No</u>	<u>Yes</u>	<u>RF</u>	<u>DK</u>
9. Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	7	9
10. Do you have any trouble taking a <u>long</u> walk?	1	2	7	9
11. Do you have any trouble taking a <u>short</u> walk outside of the house?	1	2	7	9
12. Do you have to stay in a bed or a chair for most of the day?	1	2	7	9
13. Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	7	9
14. Are you limited in any way in doing either your work or doing household jobs?	1	2	7	9
15. Are you completely unable to work at a job or do household jobs?	1	2	7	9

*During the past week, have any of these things happened to you not at all, a little, quite a bit, or very much?*

	<u>Not at all</u>	<u>A little</u>	<u>Quite a bit</u>	<u>Very much</u>	<u>RF</u>	<u>DK</u>
16. Were you short of breath?	1	2	3	4	7	9
17. Have you had pain?	1	2	3	4	7	9
18. Did you need to rest?	1	2	3	4	7	9
19. Have you had trouble sleeping?	1	2	3	4	7	9
20. Have you felt weak?	1	2	3	4	7	9
21. Have you lacked appetite?	1	2	3	4	7	9

## Appendix C: Cancer – Best-Case Series Patient Interview Form-IAT (continued)

PT ID#: \_\_\_\_\_

<i>(continued)</i>	<u>Not at all</u>	<u>A little</u>	<u>Quite a bit</u>	<u>Very much</u>	<u>RF</u>	<u>DK</u>
22. Have you felt nauseated?	1	2	3	4	7	9
23. Have you vomited?	1	2	3	4	7	9
24. Have you been constipated?	1	2	3	4	7	9
25. Have you had diarrhea?	1	2	3	4	7	9
26. Were you tired?	1	2	3	4	7	9
27. Did pain interfere with your daily activities?	1	2	3	4	7	9
28. Have you had difficulty in concentrating on things like reading a newspaper or watching television?	1	2	3	4	7	9
29. Did you feel tense?	1	2	3	4	7	9
30. Did you worry?	1	2	3	4	7	9
31. Did you feel irritable?	1	2	3	4	7	9
32. Did you feel depressed?	1	2	3	4	7	9
33. Have you had difficulty remembering things?	1	2	3	4	7	9
34. Has your physical condition or medical treatment interfered with your <u>family</u> life?	1	2	3	4	7	9
35. Has your physical condition or medical treatment interfered with your <u>social</u> activities?	1	2	3	4	7	9
36. Has your <u>physical</u> condition or medical treatment caused you financial difficulties?	1	2	3	4	7	9

## PT ID#: \_\_\_\_\_

37. How would you rate your overall physical condition during the past week?

38. How would you rate your overall quality of life during the past week?

(CIRCLE ONE)    1       2       3       4       5       6       7     RF     DK

Very PoorExcellent



## Appendix C: Cancer – Best-Case Series Patient Interview Form-IAT (continued)

PT ID#: \_\_\_\_\_

### SECTION C. Immunoaugmentation Therapy (IAT)

*I would now like to ask you some questions about your Immunoaugmentation (IAT) treatment.*

39. How did you learn about the Immune Augmentation Therapy center? (Check all that apply)

(Check)

Physician \_\_\_\_\_

(If checked, record the following)

Can you tell me that person's name? \_\_\_\_\_

Is this person your primary care physician or a specialist or both?

(CHECK ALL THAT APPLY)

Primary Care \_\_\_\_\_

Specialist \_\_\_\_\_

What type of specialist are they? \_\_\_\_\_

Refused \_\_\_\_\_

Don't know \_\_\_\_\_

Is this person a Complementary/Alternative Provider?

Yes \_\_\_\_\_

No \_\_\_\_\_

Refused \_\_\_\_\_

Don't know \_\_\_\_\_

CAM provider, not a physician \_\_\_\_\_

Can you tell me that person's name? \_\_\_\_\_

Do you know what is their specialty? \_\_\_\_\_

Another patient of the clinic \_\_\_\_\_

Friend / Family Member / Co-Worker  
who is not a patient of this clinic \_\_\_\_\_

Friend or relative of Doctor at the clinic \_\_\_\_\_

Local newspaper, radio, or TV \_\_\_\_\_

Advertisement \_\_\_\_\_

Where did you see or hear the advertisement? \_\_\_\_\_

## Appendix C: Cancer – Best-Case Series Patient Interview Form-IAT (continued)

PT ID#: \_\_\_\_\_

Question 39 continued... (Check)

Other \_\_\_\_\_ Specify: \_\_\_\_\_

Refused \_\_\_\_\_

Don't recall \_\_\_\_\_

40. At the time you started IAT, had your medical doctor for cancer recommended you seek complementary/alternative treatment?

Yes \_\_\_\_\_

No \_\_\_\_\_

Refused \_\_\_\_\_

Don't know \_\_\_\_\_

41. Did you inform any of your medical doctors that you were using IAT?

Yes \_\_\_\_\_

No \_\_\_\_\_

Refused \_\_\_\_\_

Don't know \_\_\_\_\_

41a. (IF YES) Does that include your oncologist?

Yes \_\_\_\_\_

No \_\_\_\_\_

Refused \_\_\_\_\_

Don't know \_\_\_\_\_

42. Did the IAT clinic request medical records from your primary doctor?

Yes \_\_\_\_\_

No \_\_\_\_\_

Refused \_\_\_\_\_

Don't know \_\_\_\_\_

42a. (IF YES) Were the records obtained?

**Appendix C: Cancer – Best-Case Series Patient Interview Form-IAT (continued)**

**PT ID#:** \_\_\_\_\_

Yes \_\_\_\_\_  
No \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

43. Did you have other forms of complementary or alternative medicine for the treatment of the cancer?

Yes \_\_\_\_\_ What were they? \_\_\_\_\_  
No \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

44. Would you take IAT if you had the chance to begin your treatment over again?

Yes \_\_\_\_\_  
No \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

45. Was there any difference between how you felt with IAT care and your other care?

Yes \_\_\_\_\_  
No \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

## Appendix C: Cancer – Best-Case Series Patient Interview Form-IAT (continued)

PT ID#: \_\_\_\_\_

45a. (IF YES) How was it different? (RECORD VERBATIM)

46. Why did you choose IAT for treatment of your cancer? (Check all that apply)

- ☐ Failure of another form of complementary/alternative medicine
- ☐ Failure of conventional therapy
- ☐ Side effects of conventional therapy
- ☐ Side effects of another form of complementary/alternative medicine
- ☐ Philosophical congruence
- ☐ Other, specify \_\_\_\_\_
- ☐ None of the above (no reason)
- ☐ Refused
- ☐ Don't know

47. Did you use conventional therapy for your cancer?

- Yes \_\_\_\_\_
- No \_\_\_\_\_
- Refused \_\_\_\_\_
- Don't know \_\_\_\_\_

## Appendix C: Cancer – Best-Case Series Patient Interview Form-IAT (continued)

PT ID#: \_\_\_\_\_

47a. (IF NO) How come? (Check all that apply)

☐ Failure of conventional therapy

☐ Side effects of conventional therapy

☐ Philosophical reasons

☐ Some other reason (specify) \_\_\_\_\_

☐ None of the above (no reason)

☐ Refused

☐ Don't know

47b. (IF YES) Did you complete conventional therapy?

Yes \_\_\_\_\_

No \_\_\_\_\_

Refused \_\_\_\_\_

Don't know \_\_\_\_\_

47b. (IF COMPLETED) Was the following statement true:

"I completed conventional therapy, but was not cured"

Yes \_\_\_\_\_

No \_\_\_\_\_

Refused \_\_\_\_\_

Don't know \_\_\_\_\_

**Appendix C: Cancer – Best-Case Series Patient Interview Form-IAT (continued)**

**PT ID#:** \_\_\_\_\_

48. What did you expect from your IAT treatment? (RECORD VERBATIM)

49. When you were being treated with IAT, did you tell your friends that an alternative medical practitioner was treating you?

Yes \_\_\_\_\_  
No \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

50. How far did you travel for IAT? (CHECK ONE)

5 miles or less \_\_\_\_\_  
6-10 miles \_\_\_\_\_  
11-20 miles \_\_\_\_\_  
21-30 miles \_\_\_\_\_  
over 30 miles \_\_\_\_\_  
over 100 miles \_\_\_\_\_  
over 500 miles \_\_\_\_\_  
over 1000 miles \_\_\_\_\_  
over 2000 miles \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

## Appendix C: Cancer – Best-Case Series Patient Interview Form-IAT (continued)

PT ID#: \_\_\_\_\_

51. Do you have a family medical doctor?

Yes \_\_\_\_\_  
No \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

51a. If yes, how often do you see this doctor?

Yearly \_\_\_\_\_  
Monthly \_\_\_\_\_  
Weekly \_\_\_\_\_  
Other \_\_\_\_\_ (specify) \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

52. The last time you went to see your family medical doctor, how satisfied were you with the care you received? Were you... (READ RESPONSES AND CHECK ONE)

Extremely satisfied \_\_\_\_\_  
Very satisfied \_\_\_\_\_  
Satisfied \_\_\_\_\_  
Somewhat satisfied \_\_\_\_\_  
Not at all satisfied \_\_\_\_\_

(DON'T READ) Refused \_\_\_\_\_  
(DON'T READ) Don't know \_\_\_\_\_

53. Did you rely primarily upon alternative medicine providers for all of your medical care?

**Appendix C: Cancer – Best-Case Series Patient Interview Form-IAT (continued)**

**PT ID#:** \_\_\_\_\_

Yes	_____
No	_____
Refused	_____
Don't know	_____



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## SECTION D: CONFIRMATION OF THE MEDICAL FILE

54. Did you receive the materials we sent?

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55. If you have the documents we sent you, can we review them with you now?

---

56. (IF NO) Would you like us to schedule another time to do it?

---

56a. (IF STILL NO) *May I ask your reason for declining?*

--

**NEXT OF KIN INTERVIEW FOR IMMUNOAUGMENTED THERAPY (IAT)**

**RA**

**1700 MAIN STREET  
SANTA MONICA CA 90401**

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**Appendix C: Cancer – Best-Case Series Patient Interview Form for Next of Kin**  
**PATIENT INTERVIEW SCHEDULE**

**TEAR SHEET (to be completed prior to the interview)**

1. Patient's ID CODE: 01 \_\_\_\_\_  
Site: \_\_\_\_\_ Patient # \_\_\_\_\_
2. Patient's Name: \_\_\_\_\_  
LAST NAME FIRST NAME  
Next-of-Kin Name: \_\_\_\_\_  
LAST NAME FIRST NAME
3. STATE: \_\_\_\_\_
4. Consent Letter Received: \_\_\_\_/\_\_\_\_/\_\_\_\_
5. Doctor's Name and/ or Clinic for CAM: \_\_\_\_\_
6. Therapy Type: \_\_\_\_\_
7. Date Interviewed: \_\_\_\_/\_\_\_\_/\_\_\_\_ Interviewer: \_\_\_\_\_
8. Date Checked: \_\_\_\_/\_\_\_\_/\_\_\_\_ By: \_\_\_\_\_
9. Date Data Entered: \_\_\_\_/\_\_\_\_/\_\_\_\_

**Appendix C: Cancer – Best-Case Series Patient Interview Form for Next of Kin (continued)**

**CALL RECORD AND FIELD CONTACT RECORD**

Telephone Number: ( \_\_\_\_\_ ) \_\_\_\_\_ - \_\_\_\_\_

Contact Attempt	Date	Time of Call	Outcome Code	Interviewer
1				
2				
3				
4				

**DATE & TIME FOR CALLBACK:** \_\_\_\_\_

**NOTES**

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**OUTCOME CODES**

- |  |                        |                          |                    |
|--|------------------------|--------------------------|--------------------|
| AM = Answering machine                 | PI = Partial interview | AP = Made an appointment | PP = Phone problem |
| BZ = Busy signal (phone, fax or modem) | CB = Call back         | NA = No answer           | RF = Refused       |
| CI = Completed interview               | DS = Disconnected      | WN = Wrong number        |                    |
| O = Other (describe)                   |                        |                          |                    |

**Appendix C: Cancer – Best-Case Series Patient Interview Form for Next of Kin (continued)**

**PATIENT INTERVIEW SCHEDULE**

**STRICTLY CONFIDENTIAL**

*The following interview has been designed by RAND as part of a study of cancer treatment. The study has both the support and cooperation of the patient's physician. Its purpose is to obtain, as accurately as possible, information concerning the care that (PATIENT) received. In order to do this, we require information about people who have used this type of care. The interview should last about 30 minutes.*

*THIS IS NOT A TEST AND THERE ARE NO RIGHT OR WRONG ANSWERS.*

*All information will be used in the strictest confidence and will be seen only by our research staff. Because the information collected is confidential there is no possibility of anyone identifying you or (PATIENT) from your answers. You may skip any questions that you feel uncomfortable answering; however, please remember that it is important that all questions be answered if we are to assess the therapy. You may stop the interview at any time.*

*The Principal Investigator is Dr. Ian Coulter from RAND who can be contacted at 310-393-0411 extension 6759 if you wish to discuss the interview with him. I am Doctor (INSERT YOUR NAME) and I will be conducting this interview. I am a member of the research staff. Do I have your permission to continue with the interview?*

Yes \_\_\_\_\_ No \_\_\_\_\_ If no, May I ask you your reason for declining?

---

---

*Thank you for your assistance.*

## Appendix C: Cancer – Best-Case Series Patient Interview Form for Next of Kin (continued)

### SECTION X: RELATIONSHIP

*What was (PATIENT'S) relationship to you? (CHECK ONE)*

Spouse \_\_\_\_\_  
Mother \_\_\_\_\_  
Father \_\_\_\_\_  
Son \_\_\_\_\_  
Daughter \_\_\_\_\_  
Brother \_\_\_\_\_  
Sister \_\_\_\_\_  
Other \_\_\_\_\_ (SPECIFY:\_\_\_\_\_)

*We realize that you may not be able to answer many of the questions we will ask about (PATIENT). We appreciate your help in answering what you can.*

## Appendix C: Cancer – Best-Case Series Patient Interview Form for Next of Kin (continued)

### SECTION A: DEMOGRAPHICS (To be partially completed before the interview)

*First, I would like to ask some background questions about (PATIENT).*

1. What was their birth date? \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
If refused, enter REFUSED  
If don't know, enter DON'T KNOW
- 1a. What was their age? \_\_\_\_\_  
If refused, enter RF  
If don't know, enter DK
2. What was their sex? (Check one)  
Male \_\_\_\_\_ (1)  
Female \_\_\_\_\_ (2)
3. What was their marital status? (Check one)  
Single \_\_\_\_\_ (1)  
Married \_\_\_\_\_ (2)  
Divorced \_\_\_\_\_ (3)  
Widowed \_\_\_\_\_ (4)  
Refused \_\_\_\_\_ (7)  
Don't know \_\_\_\_\_ (9)
4. What was their highest level of education? (Check one)  
Grade school \_\_\_\_\_ (1)  
High school \_\_\_\_\_ (2)  
Some college \_\_\_\_\_ (3)  
College degree \_\_\_\_\_ (4)  
Graduate degree \_\_\_\_\_ (5)  
Refused \_\_\_\_\_ (7)  
Don't know \_\_\_\_\_ (9)

## Appendix C: Cancer – Best-Case Series Patient Interview Form for Next of Kin (continued)

5. What was their ethnic origin?

(Check all that apply)

Caucasian \_\_\_\_\_  
Black/African American \_\_\_\_\_  
Hispanic/Latino \_\_\_\_\_  
Asian/Pacific islander \_\_\_\_\_  
Other \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

Please could you specify: \_\_\_\_\_

6. What type of health insurance did they have?

(Check all that apply)

HMO \_\_\_\_\_  
PPO \_\_\_\_\_  
Fee for Service \_\_\_\_\_  
None \_\_\_\_\_  
Other \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

Please could you specify: \_\_\_\_\_

7. What insurance coverage did they have for Immunoaugmentation Therapy? (Check all that apply)

HMO \_\_\_\_\_  
PPO \_\_\_\_\_  
Fee for Service \_\_\_\_\_  
None \_\_\_\_\_  
Other \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

Please could you specify: \_\_\_\_\_

8. What was their most recent occupation? (ENTER VERBATIM)

\_\_\_\_\_



## SECTION B. HEALTH STATUS

37. How would you rate their overall physical condition during that time?

38. How would you rate their overall quality of life during that time?

(CIRCLE ONE)      1      2      3      4      5      6      7      RF      DK

Very Poor      Excellent

## Appendix C: Cancer – Best-Case Series Patient Interview Form for Next of Kin (continued)

### SECTION C. Immunoaugmentation Therapy (IAT)

*I would now like to ask you some questions about the Immunoaugmentation (IAT) treatment.*

39. How did {PATIENT} learn about the Immune Augmentation Therapy center? (Check all that apply)

(Check)

Physician

\_\_\_\_\_ (If checked, record the following)

Can you tell me that person's name? \_\_\_\_\_

Was this person their primary care physician or a specialist or both?

Primary Care \_\_\_\_\_

Specialist \_\_\_\_\_

What type of specialist are they? \_\_\_\_\_

Refused \_\_\_\_\_

Don't know \_\_\_\_\_

Is this person a Complementary/Alternative Provider?

Yes \_\_\_\_\_

No \_\_\_\_\_

Refused \_\_\_\_\_

Don't know \_\_\_\_\_

CAM provider, not a physician

\_\_\_\_\_ Can you tell me that person's name? \_\_\_\_\_

Do you know what is their specialty? \_\_\_\_\_

Another patient of the clinic

\_\_\_\_\_

Friend / Family Member / Co-Worker  
who is not a patient of this clinic

\_\_\_\_\_

Friend or relative of Doctor at the clinic

\_\_\_\_\_

Local newspaper, radio, or TV

\_\_\_\_\_

Advertisement

\_\_\_\_\_ Where did they see or hear the advertisement? \_\_\_\_\_

## Appendix C: Cancer – Best-Case Series Patient Interview Form for Next of Kin (continued)

.....  
Question 39 continued (Check)  
.....  
Other \_\_\_\_\_ Specify: \_\_\_\_\_  
.....  
Refused \_\_\_\_\_  
.....  
Don't recall \_\_\_\_\_  
.....

40. At the time (PATIENT) started IAT, had their medical doctor for cancer recommended they seek complementary /alternative treatment?

Yes \_\_\_\_\_  
No \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

41. Did they inform any of their medical doctors that they were using IAT?

Yes \_\_\_\_\_  
No \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

41a. (IF YES) Does that include their oncologist?

Yes \_\_\_\_\_  
No \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

42. Did the IAT clinic request medical records from their primary doctor?

Yes \_\_\_\_\_  
No \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

42a. (IF YES) Were the records obtained?

Yes \_\_\_\_\_

## Appendix C: Cancer – Best-Case Series Patient Interview Form for Next of Kin (continued)

No \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

43. Did they have other forms of complementary or alternative medicine for the treatment of the cancer?

Yes \_\_\_\_\_ What were they? \_\_\_\_\_  
No \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

44. Would you recommend IAT to someone else?

Yes \_\_\_\_\_  
No \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

45. Was there any difference between how they felt with IAT care and their other care?

Yes \_\_\_\_\_  
No \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

## Appendix C: Cancer – Best-Case Series Patient Interview Form for Next of Kin (continued)

45a. (IF YES) How was it different? (RECORD VERBATIM)

46. Why did they choose IAT for treatment of their cancer? (Check all that apply)

- ☐ Failure of another form of complementary/alternative medicine
- ☐ Failure of conventional therapy
- ☐ Side effects of conventional therapy
- ☐ Side effects of another form of complementary/alternative medicine
- ☐ Philosophical congruence
- ☐ Other, specify \_\_\_\_\_
- ☐ None of the above (no reason)
- ☐ Refused
- ☐ Don't know

47. Did they use conventional therapy for the cancer?

- Yes ☐
- No ☐
- Refused ☐
- Don't know ☐

47a. (IF NO) How come? (Check all that apply)

## Appendix C: Cancer – Best-Case Series Patient Interview Form for Next of Kin (continued)

- ☐ Failure of conventional therapy
- ☐ Side effects of conventional therapy
- ☐ Philosophical reasons
- ☐ Some other reason (specify) \_\_\_\_\_
- ☐ None of the above (no reason)
- ☐ Refused
- ☐ Don't know

47b. (IF YES) Did they complete conventional therapy?

- Yes ☐
- No ☐
- Refused ☐
- Don't know ☐

47b. (IF COMPLETED) Was the following statement true:

“(PATIENT) completed conventional therapy, but was not cured”

- Yes ☐
- No ☐
- Refused ☐
- Don't know ☐

## Appendix C: Cancer – Best-Case Series Patient Interview Form for Next of Kin (continued)

48. What did they expect from their IAT treatment? (RECORD VERBATIM)

49. When (PATIENT) was being treated with IAT, did they tell their friends that an alternative medical practitioner was treating them?

Yes \_\_\_\_\_  
No \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

50. How far did they travel for IAT? (CHECK ONE)

5 miles or less \_\_\_\_\_  
6-10 miles \_\_\_\_\_  
11-20 miles \_\_\_\_\_  
21-30 miles \_\_\_\_\_  
over 30 miles \_\_\_\_\_  
over 100 miles \_\_\_\_\_  
over 500 miles \_\_\_\_\_  
over 1000 miles \_\_\_\_\_  
over 2000 miles \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

51. Did they have a family medical doctor?

## Appendix C: Cancer – Best-Case Series Patient Interview Form for Next of Kin (continued)

Yes \_\_\_\_\_  
No \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

51a. If yes, how often do they see this doctor?

Yearly \_\_\_\_\_  
Monthly \_\_\_\_\_  
Weekly \_\_\_\_\_  
Other \_\_\_\_\_ (specify) \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

52. Were they satisfied with the care they received from the family medical doctor? Were they... (READ RESPONSES AND CHECK ONE)

Extremely satisfied \_\_\_\_\_  
Very satisfied \_\_\_\_\_  
Satisfied \_\_\_\_\_  
Somewhat satisfied \_\_\_\_\_  
Not at all satisfied \_\_\_\_\_

(DON'T READ) Refused \_\_\_\_\_  
(DON'T READ) Don't know \_\_\_\_\_



**Appendix C: Cancer – Best-Case Series Patient Interview Form for Next of Kin (continued)**

53. Did (PATIENT) rely primarily upon alternative medicine providers for all of their medical care?

Yes \_\_\_\_\_  
No \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

## SECTION D: CONFIRMATION OF THE MEDICAL FILE

54. Did you receive the materials we sent?

---

55. If you have the documents we sent you, can we review them with you now?

---

---

56. (IF NO) Would you like us to schedule another time to do it?

---

---

56a. (IF STILL NO) *May I ask your reason for declining?*

--

**PATIENT INTERVIEW FOR NALTREXONE THERAPY**

**RA**

**1700 MAIN STREET  
SANTA MONICA CA 90401**

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## Appendix C: CANCER – Best-Case Series Patient Interview Form – Naltrexone Therapy

### PATIENT INTERVIEW SCHEDULE

#### TEAR SHEET (to be completed prior to the interview)

1. Patient's ID CODE: 01 \_\_\_\_\_  
Site: \_\_\_\_\_ Patient # \_\_\_\_\_
2. Patient's Name: \_\_\_\_\_  
LAST NAME FIRST NAME  
Next-of-Kin Name: \_\_\_\_\_  
LAST NAME FIRST NAME
3. STATE: \_\_\_\_\_
4. Consent Letter Received: \_\_\_\_/\_\_\_\_/\_\_\_\_
5. Doctor's Name and/ or Clinic for CAM: \_\_\_\_\_
6. Therapy Type: \_\_\_\_\_
7. Date Interviewed: \_\_\_\_/\_\_\_\_/\_\_\_\_ Interviewer: \_\_\_\_\_
8. Date Checked: \_\_\_\_/\_\_\_\_/\_\_\_\_ By: \_\_\_\_\_
9. Date Data Entered: \_\_\_\_/\_\_\_\_/\_\_\_\_

## Appendix C: CANCER – Best-Case Series Patient Interview Form – Naltrexone Therapy (continued)

PT ID#: \_\_\_\_\_

### CALL RECORD AND FIELD CONTACT RECORD

Telephone Number: ( \_\_\_\_\_ ) \_\_\_\_\_ - \_\_\_\_\_

Contact Attempt	Date	Time of Call	Outcome Code	Interviewer
1				
2				
3				
4				

DATE & TIME FOR CALLBACK: \_\_\_\_\_

### NOTES

---

---

---

### OUTCOME CODES

AM = Answering machine  
BZ = Busy signal (phone, fax or modem)  
CI = Completed interview  
O = Other (describe)

PI = Partial interview  
CB = Call back  
DS = Disconnected

AP = Made an appointment  
NA = No answer  
WN = Wrong number

PP = Phone problem  
RF = Refused

**Appendix C: CANCER – Best-Case Series Patient Interview Form – Naltrexone Therapy (continued)**

PT ID#: \_\_\_\_\_

**PATIENT INTERVIEW SCHEDULE**

**STRICTLY CONFIDENTIAL**

*The following interview has been designed by RAND as part of a study of cancer treatment. The study has both the support and cooperation of your physician. Its purpose is to obtain, as accurately as possible, information concerning the care that you received. In order to do this, we require information about people who have used this type of care. The interview should last about 30 minutes.*

*THIS IS NOT A TEST AND THERE ARE NO RIGHT OR WRONG ANSWERS.*

*All information will be used in the strictest confidence and will be seen only by our research staff. Because the information collected is confidential there is no possibility of anyone identifying you from your answers. You may skip any questions that you feel uncomfortable answering; however, please remember that it is important that all questions be answered if we are to assess your therapy. You may stop the interview at any time.*

*The Principal Investigator is Dr. Ian Coulter from RAND who can be contacted at 310-393-0411 extension 6759 if you wish to discuss the interview with him. I am Doctor (INSERT YOUR NAME) and I will be conducting this interview. I am a member of the research staff. Do I have your permission to continue with the interview?*

Yes \_\_\_\_\_ No \_\_\_\_\_ If no, May I ask you your reason for declining?

\_\_\_\_\_  
\_\_\_\_\_

*Thank you for your assistance.*

## Appendix C: CANCER – Best-Case Series Patient Interview Form – Naltrexone Therapy (continued)

PT ID#: \_\_\_\_\_

### SECTION A: DEMOGRAPHICS (To be partially completed before the interview)

*First, I would like to ask some background questions about you.*

1. What is your birth date? \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
If refused, enter REFUSED  
If don't know, enter DON'T KNOW

1a. What is your age? \_\_\_\_\_  
If refused, enter RF  
If don't know, enter DK

2. What is your sex? (Check one)  
Male \_\_\_\_\_ (1)  
Female \_\_\_\_\_ (2)

3. What is your marital status? (Check one)  
Single \_\_\_\_\_ (1)  
Married \_\_\_\_\_ (2)  
Divorced \_\_\_\_\_ (3)  
Widowed \_\_\_\_\_ (4)  
Refused \_\_\_\_\_ (7)  
Don't know \_\_\_\_\_ (9)

4. What is your highest level of education? (Check one)  
Grade school \_\_\_\_\_ (1)  
High school \_\_\_\_\_ (2)  
Some college \_\_\_\_\_ (3)  
College degree \_\_\_\_\_ (4)  
Graduate degree \_\_\_\_\_ (5)  
Refused \_\_\_\_\_ (7)  
Don't know \_\_\_\_\_ (9)

## Appendix C: CANCER – Best-Case Series Patient Interview Form – Naltrexone Therapy (continued)

PT ID#: \_\_\_\_\_

5. What is your ethnic origin?

(Check all that apply)

Caucasian \_\_\_\_\_ (1)

Black/African American \_\_\_\_\_ (2)

Hispanic/Latino \_\_\_\_\_ (3)

Asian/Pacific islander \_\_\_\_\_ (4)

Other \_\_\_\_\_ (5) Please could you specify: \_\_\_\_\_

Refused \_\_\_\_\_ (7)

Don't know \_\_\_\_\_ (9)

6. What type of health insurance do you have?

(Check all that apply)

HMO \_\_\_\_\_ (1)

PPO \_\_\_\_\_ (2)

Fee for Service \_\_\_\_\_ (3)

None \_\_\_\_\_ (4)

Other \_\_\_\_\_ (5) Please could you specify: \_\_\_\_\_

Refused \_\_\_\_\_ (7)

Don't know \_\_\_\_\_ (9)

7. What insurance coverage did you have for Naltrexone therapy?

HMO \_\_\_\_\_ (1)

PPO \_\_\_\_\_ (2)

Fee for Service \_\_\_\_\_ (3)

None \_\_\_\_\_ (4)

Other \_\_\_\_\_ (5) Please could you specify: \_\_\_\_\_

Refused \_\_\_\_\_ (7)

Don't know \_\_\_\_\_ (9)

8. What is your current or most recent occupation? (ENTER VERBATIM)

\_\_\_\_\_



## Appendix C: CANCER – Best-Case Series Patient Interview Form – Naltrexone Therapy (continued)

PT ID#: \_\_\_\_\_

### SECTION B. HEALTH STATUS

*We would like to begin by asking about your current health.*

	<u>No</u>	<u>Yes</u>	<u>RF</u>	<u>DK</u>
9. Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	7	9
10. Do you have any trouble taking a <u>long</u> walk?	1	2	7	9
11. Do you have any trouble taking a <u>short</u> walk outside of the house?	1	2	7	9
12. Do you have to stay in a bed or a chair for most of the day?	1	2	7	9
13. Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	7	9
14. Are you limited in any way in doing either your work or doing household jobs?	1	2	7	9
15. Are you completely unable to work at a job or do household jobs?	1	2	7	9

*During the past week, have any of these things happened to you not at all, a little, quite a bit, or very much?*

	<u>Not at all</u>	<u>A little</u>	<u>Quite a bit</u>	<u>Very much</u>	<u>RF</u>	<u>DK</u>
16. Were you short of breath?	1	2	3	4	7	9
17. Have you had pain?	1	2	3	4	7	9
18. Did you need to rest?	1	2	3	4	7	9
19. Have you had trouble sleeping?	1	2	3	4	7	9
20. Have you felt weak?	1	2	3	4	7	9
21. Have you lacked appetite?	1	2	3	4	7	9

## Appendix C: CANCER – Best-Case Series Patient Interview Form – Naltrexone Therapy (continued)

PT ID#: \_\_\_\_\_

<i>(continued)</i>	<u>Not at all</u>	<u>A little</u>	<u>Quite a bit</u>	<u>Very much</u>	<u>RF</u>	<u>DK</u>
22. Have you felt nauseated?	1	2	3	4	7	9
23. Have you vomited?	1	2	3	4	7	9
24. Have you been constipated?	1	2	3	4	7	9
25. Have you had diarrhea?	1	2	3	4	7	9
26. Were you tired?	1	2	3	4	7	9
27. Did pain interfere with your daily activities?	1	2	3	4	7	9
28. Have you had difficulty in concentrating on things like reading a newspaper or watching television?	1	2	3	4	7	9
29. Did you feel tense?	1	2	3	4	7	9
30. Did you worry?	1	2	3	4	7	9
31. Did you feel irritable?	1	2	3	4	7	9
32. Did you feel depressed?	1	2	3	4	7	9
33. Have you had difficulty remembering things?	1	2	3	4	7	9
34. Has your physical condition or medical treatment interfered with your <u>family</u> life?	1	2	3	4	7	9
35. Has your physical condition or medical treatment interfered with your <u>social</u> activities?	1	2	3	4	7	9
36. Has your <u>physical</u> condition or medical treatment caused you financial difficulties?	1	2	3	4	7	9

## PT ID#: \_\_\_\_\_

37. How would you rate your overall physical condition during the past week?

38. How would you rate your overall quality of life during the past week?

(CIRCLE ONE)      1      2      3      4      5      6      7      RF      DK

Very Poor      Excellent

## Appendix C: CANCER – Best-Case Series Patient Interview Form – Naltrexone Therapy (continued)

PT ID#: \_\_\_\_\_

### SECTION C. Naltrexone Therapy

*I would now like to ask you some questions about your Naltrexone Therapy.*

39. How did you learn about Naltrexone Therapy and Dr. Bihari's clinic? (Check all that apply)

(Check)

Physician \_\_\_\_\_

(If checked, record the following)

Can you tell me that person's name? \_\_\_\_\_

Is this person your primary care physician or a specialist or both?

(CHECK ALL THAT APPLY)

Primary Care \_\_\_\_\_

Specialist \_\_\_\_\_

What type of specialist are they? \_\_\_\_\_

Refused \_\_\_\_\_

Don't know \_\_\_\_\_

Is this person a Complementary/Alternative Provider?

Yes \_\_\_\_\_

No \_\_\_\_\_

Refused \_\_\_\_\_

Don't know \_\_\_\_\_

CAM provider, not a physician \_\_\_\_\_

Can you tell me that person's name? \_\_\_\_\_

Do you know what is their specialty? \_\_\_\_\_

Another patient of the clinic \_\_\_\_\_

Friend / Family Member / Co-Worker  
who is not a patient of this clinic \_\_\_\_\_

Friend or relative of Doctor at the clinic \_\_\_\_\_

Local newspaper, radio, or TV \_\_\_\_\_

## Appendix C: CANCER – Best-Case Series Patient Interview Form – Naltrexone Therapy (continued)

PT ID#: \_\_\_\_\_

Advertisement	_____	Where did you see or hear the advertisement? _____
Question 39 continued... (Check)		
Other	_____	Specify: _____
Refused	_____	
Don't recall	_____	

40. At the time you started Naltrexone therapy, had your medical doctor for cancer recommended you seek complementary/alternative treatment?

Yes \_\_\_\_\_  
No \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

41. Did you inform any of your medical doctors that you were using Naltrexone therapy?

Yes \_\_\_\_\_  
No \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

41a. (IF YES) Does that include your oncologist?

Yes \_\_\_\_\_  
No \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

42. Did Dr. Bihari's clinic request medical records from your primary doctor?

Yes \_\_\_\_\_  
No \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

**Appendix C: CANCER – Best-Case Series Patient Interview Form – Naltrexone Therapy (continued)**

**PT ID#:** \_\_\_\_\_

42a. (IF YES) Were the records obtained?

Yes \_\_\_\_\_  
No \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

43. Did you have other forms of complementary or alternative medicine for the treatment of the cancer?

Yes \_\_\_\_\_ What were they? \_\_\_\_\_  
No \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

44. Would you use Naltrexone therapy if you had the chance to begin your treatment over again?

Yes \_\_\_\_\_  
No \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

45. Was there any difference between how you felt with Naltrexone therapy and your other care?

Yes \_\_\_\_\_  
No \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

**Appendix C: CANCER – Best-Case Series Patient Interview Form – Naltrexone Therapy (continued)**

**PT ID#:** \_\_\_\_\_

45a. (IF YES) How was it different? (RECORD VERBATIM)

46. Why did you choose Naltrexone therapy for treatment of your cancer? (Check all that apply)

- ☐ Failure of another form of complementary/alternative medicine
- ☐ Failure of conventional therapy
- ☐ Side effects of conventional therapy
- ☐ Side effects of another form of complementary/alternative medicine
- ☐ Philosophical congruence
- ☐ Other, specify \_\_\_\_\_
- ☐ None of the above (no reason)
- ☐ Refused
- ☐ Don't know

47. Did you use conventional therapy for your cancer?

- Yes \_\_\_\_\_
- No \_\_\_\_\_
- Refused \_\_\_\_\_
- Don't know \_\_\_\_\_

## Appendix C: CANCER – Best-Case Series Patient Interview Form – Naltrexone Therapy (continued)

PT ID#: \_\_\_\_\_

47a. (IF NO) How come? (Check all that apply)

☐ Failure of conventional therapy

☐ Side effects of conventional therapy

☐ Philosophical reasons

☐ Some other reason (specify) \_\_\_\_\_

☐ None of the above (no reason)

☐ Refused

☐ Don't know

47b. (IF YES) Did you complete conventional therapy?

Yes \_\_\_\_\_

No \_\_\_\_\_

Refused \_\_\_\_\_

Don't know \_\_\_\_\_

47b. (IF COMPLETED) Was the following statement true:

"I completed conventional therapy, but was not cured"

Yes \_\_\_\_\_

No \_\_\_\_\_

Refused \_\_\_\_\_

Don't know \_\_\_\_\_



**Appendix C: CANCER – Best-Case Series Patient Interview Form – Naltrexone Therapy (continued)**

**PT ID#:** \_\_\_\_\_

48. What did you expect from your Naltrexone therapy? (RECORD VERBATIM)

49. When you were being treated by Dr. Bihari, did you tell your friends that an alternative medical practitioner was treating you?

Yes \_\_\_\_\_  
No \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

50. How far did you travel to go to Dr. Bihari's clinic? (CHECK ONE)

5 miles or less \_\_\_\_\_  
6-10 miles \_\_\_\_\_  
11-20 miles \_\_\_\_\_  
21-30 miles \_\_\_\_\_  
over 30 miles \_\_\_\_\_  
over 100 miles \_\_\_\_\_  
over 500 miles \_\_\_\_\_  
over 1000 miles \_\_\_\_\_  
over 2000 miles \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

**Appendix C: CANCER – Best-Case Series Patient Interview Form – Naltrexone Therapy (continued)**

**PT ID#:** \_\_\_\_\_

51. Do you have a family medical doctor?

Yes \_\_\_\_\_  
No \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

51a. If yes, how often do you see this doctor?

Yearly \_\_\_\_\_  
Monthly \_\_\_\_\_  
Weekly \_\_\_\_\_  
Other \_\_\_\_\_ (specify) \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

52. The last time you went to see your family medical doctor, how satisfied were you with the care you received? Were you... (READ RESPONSES AND CHECK ONE)

Extremely satisfied \_\_\_\_\_  
Very satisfied \_\_\_\_\_  
Satisfied \_\_\_\_\_  
Somewhat satisfied \_\_\_\_\_  
Not at all satisfied \_\_\_\_\_  
  
(DON'T READ) Refused \_\_\_\_\_  
(DON'T READ) Don't know \_\_\_\_\_

**Appendix C: CANCER – Best-Case Series Patient Interview Form – Naltrexone Therapy (continued)**

**PT ID#:** \_\_\_\_\_

53. Did you rely primarily upon alternative medicine providers for all of your medical care?

Yes	_____
No	_____
Refused	_____
Don't know	_____

## PT ID#: \_\_\_\_\_

## SECTION D: CONFIRMATION OF THE MEDICAL FILE

*Now, I would like to confirm the information we obtained from your medical files that we sent to you prior to this conversation.*

54. Did you receive the materials we sent?

Yes

---

No

\_\_\_\_\_

Arrange to resend information and/or make appointment for another phone conversation

55. If you have the documents we sent you, can we review them with you now?

Yes

---

No

\_\_\_\_\_

56. (IF NO) Would you like us to schedule another time to do it?

Yes

---

No

\_\_\_\_\_

56a. (IF STILL NO) *May I ask your reason for declining?*

--

**NEXT OF KIN INTERVIEW FOR NALTREXONE THERAPY**

**RA**

**1700 MAIN STREET  
SANTA MONICA CA 90401**

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## Appendix C: CANCER – Best-Case Series Patient Interview Form for Next of Kin – Naltrexone

### PATIENT INTERVIEW SCHEDULE

#### TEAR SHEET (to be completed prior to the interview)

1. Patient's ID CODE: 01 \_\_\_\_\_  
Site: \_\_\_\_\_ Patient # \_\_\_\_\_
2. Patient's Name: \_\_\_\_\_  
LAST NAME FIRST NAME  
Next-of-Kin Name: \_\_\_\_\_  
LAST NAME FIRST NAME
3. STATE: \_\_\_\_\_
4. Consent Letter Received: \_\_\_\_/\_\_\_\_/\_\_\_\_
5. Doctor's Name and/ or Clinic for CAM: \_\_\_\_\_
6. Therapy Type: \_\_\_\_\_
7. Date Interviewed: \_\_\_\_/\_\_\_\_/\_\_\_\_ Interviewer: \_\_\_\_\_
8. Date Checked: \_\_\_\_/\_\_\_\_/\_\_\_\_ By: \_\_\_\_\_
9. Date Data Entered: \_\_\_\_/\_\_\_\_/\_\_\_\_

## Appendix C: CANCER – Best-Case Series Patient Interview Form for Next of Kin - Naltrexone (continued)

PT ID#: \_\_\_\_\_

### CALL RECORD AND FIELD CONTACT RECORD

Telephone Number: ( \_\_\_\_\_ ) \_\_\_\_\_ - \_\_\_\_\_

Contact Attempt	Date	Time of Call	Outcome Code	Interviewer
1				
2				
3				
4				

DATE & TIME FOR CALLBACK: \_\_\_\_\_

### NOTES

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### OUTCOME CODES

AM = Answering machine  
BZ = Busy signal (phone, fax or modem)  
CI = Completed interview  
O = Other (describe)

PI = Partial interview  
CB = Call back  
DS = Disconnected

AP = Made an appointment  
NA = No answer  
WN = Wrong number

PP = Phone problem  
RF = Refused

**Appendix C: CANCER – Best-Case Series Patient Interview Form for Next of Kin - Naltrexone (continued)**

PT ID#: \_\_\_\_\_

**PATIENT INTERVIEW SCHEDULE**

**STRICTLY CONFIDENTIAL**

*The following interview has been designed by RAND as part of a study of cancer treatment. The study has both the support and cooperation of the patient's physician. Its purpose is to obtain, as accurately as possible, information concerning the care that (PATIENT) received. In order to do this, we require information about people who have used this type of care. The interview should last about 30 minutes.*

*THIS IS NOT A TEST AND THERE ARE NO RIGHT OR WRONG ANSWERS.*

*All information will be used in the strictest confidence and will be seen only by our research staff. Because the information collected is confidential there is no possibility of anyone identifying you or (PATIENT) from your answers. You may skip any questions that you feel uncomfortable answering; however, please remember that it is important that all questions be answered if we are to assess the therapy. You may stop the interview at any time.*

*The Principal Investigator is Dr. Ian Coulter from RAND who can be contacted at 310-393-0411 extension 6759 if you wish to discuss the interview with him. I am Doctor (INSERT YOUR NAME) and I will be conducting this interview. I am a member of the research staff. Do I have your permission to continue with the interview?*

Yes \_\_\_\_\_ No \_\_\_\_\_ If no, May I ask you your reason for declining?

\_\_\_\_\_  
\_\_\_\_\_

*Thank you for your assistance.*



**Appendix C: CANCER – Best-Case Series Patient Interview Form for Next of Kin - Naltrexone (continued)**

**PT ID#:** \_\_\_\_\_

**SECTION X: RELATIONSHIP**

*What was (PATIENT'S) relationship to you? (CHECK ONE)*

Spouse	_____
Mother	_____
Father	_____
Son	_____
Daughter	_____
Brother	_____
Sister	_____
Other	_____ (SPECIFY:_____)

*We realize that you may not be able to answer many of the questions we will ask about (PATIENT). We appreciate your help in answering what you can.*

## Appendix C: CANCER – Best-Case Series Patient Interview Form for Next of Kin - Naltrexone (continued)

PT ID#: \_\_\_\_\_

### SECTION A: DEMOGRAPHICS (To be partially completed before the interview)

*First, I would like to ask some background questions about (PATIENT).*

1. What was their birth date? \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
If refused, enter REFUSED  
If don't know, enter DON'T KNOW
- 1a. What was their age? \_\_\_\_\_  
If refused, enter RF  
If don't know, enter DK
2. What was their sex? (Check one)  
Male \_\_\_\_\_ (1)  
Female \_\_\_\_\_ (2)
3. What was their marital status? (Check one)  
Single \_\_\_\_\_ (1)  
Married \_\_\_\_\_ (2)  
Divorced \_\_\_\_\_ (3)  
Widowed \_\_\_\_\_ (4)  
Refused \_\_\_\_\_ (7)  
Don't know \_\_\_\_\_ (9)
4. What was their highest level of education? (Check one)  
Grade school \_\_\_\_\_ (1)  
High school \_\_\_\_\_ (2)  
Some college \_\_\_\_\_ (3)  
College degree \_\_\_\_\_ (4)  
Graduate degree \_\_\_\_\_ (5)  
Refused \_\_\_\_\_ (7)  
Don't know \_\_\_\_\_ (9)

**Appendix C: CANCER – Best-Case Series Patient Interview Form for Next of Kin - Naltrexone (continued)**

**PT ID#:** \_\_\_\_\_

5. What was their ethnic origin? (Check all that apply)
- |                        |       |                                 |
|------------------------|-------|---------------------------------|
| Caucasian              | _____ |                                 |
| Black/African American | _____ |                                 |
| Hispanic/Latino        | _____ |                                 |
| Asian/Pacific islander | _____ |                                 |
| Other                  | _____ | Please could you specify: _____ |
| Refused                | _____ |                                 |
| Don't know             | _____ |                                 |
6. What type of health insurance did they have? (Check all that apply)
- |                 |       |                                 |
|-----------------|-------|---------------------------------|
| HMO             | _____ |                                 |
| PPO             | _____ |                                 |
| Fee for Service | _____ |                                 |
| None            | _____ |                                 |
| Other           | _____ | Please could you specify: _____ |
| Refused         | _____ |                                 |
| Don't know      | _____ |                                 |
7. What insurance coverage did they have for Naltrexone therapy? (Check all that apply)
- |                 |       |                                 |
|-----------------|-------|---------------------------------|
| HMO             | _____ |                                 |
| PPO             | _____ |                                 |
| Fee for Service | _____ |                                 |
| None            | _____ |                                 |
| Other           | _____ | Please could you specify: _____ |
| Refused         | _____ |                                 |
| Don't know      | _____ |                                 |
8. What was their most recent occupation? (ENTER VERBATIM)
- \_\_\_\_\_

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## SECTION B. HEALTH STATUS

37. How would you rate their overall physical condition during that time?

38. How would you rate their overall quality of life during that time?

(CIRCLE ONE)      1      2      3      4      5      6      7      RF      DK

Very Poor      Excellent

## Appendix C: CANCER – Best-Case Series Patient Interview Form for Next of Kin - Naltrexone (continued)

PT ID#: \_\_\_\_\_

### SECTION C. Naltrexone Therapy

*I would now like to ask you some questions about the Naltrexone therapy.*

39. How did (PATIENT) learn about Naltrexone therapy and Dr. Bihari's clinic? (Check all that apply)

(Check)

Physician

\_\_\_\_\_ (If checked, record the following)

Can you tell me that person's name? \_\_\_\_\_

Was this person their primary care physician or a specialist or both?

Primary Care \_\_\_\_\_

Specialist \_\_\_\_\_

What type of specialist are they? \_\_\_\_\_

Refused \_\_\_\_\_

Don't know \_\_\_\_\_

Is this person a Complementary/Alternative Provider?

Yes \_\_\_\_\_

No \_\_\_\_\_

Refused \_\_\_\_\_

Don't know \_\_\_\_\_

CAM provider, not a physician

\_\_\_\_\_ Can you tell me that person's name? \_\_\_\_\_

Do you know what is their specialty? \_\_\_\_\_

Another patient of the clinic

\_\_\_\_\_

Friend / Family Member / Co-Worker  
who is not a patient of this clinic

\_\_\_\_\_

Friend or relative of Doctor at the clinic

\_\_\_\_\_

Local newspaper, radio, or TV

\_\_\_\_\_

Advertisement

\_\_\_\_\_ Where did they see or hear the advertisement? \_\_\_\_\_

## Appendix C: CANCER – Best-Case Series Patient Interview Form for Next of Kin - Naltrexone (continued)

PT ID#: \_\_\_\_\_

Question 39 continued (Check)

Other \_\_\_\_\_ Specify: \_\_\_\_\_

Refused \_\_\_\_\_

Don't recall \_\_\_\_\_

40. At the time (PATIENT) started Naltrexone therapy, had their medical doctor for cancer recommended they seek complementary /alternative treatment?

Yes \_\_\_\_\_

No \_\_\_\_\_

Refused \_\_\_\_\_

Don't know \_\_\_\_\_

41. Did they inform any of their medical doctors that they were using Naltrexone therapy?

Yes \_\_\_\_\_

No \_\_\_\_\_

Refused \_\_\_\_\_

Don't know \_\_\_\_\_

41a. (IF YES) Does that include their oncologist?

Yes \_\_\_\_\_

No \_\_\_\_\_

Refused \_\_\_\_\_

Don't know \_\_\_\_\_

42. Did Dr. Bihari's clinic request medical records from their primary doctor?

Yes \_\_\_\_\_

No \_\_\_\_\_

Refused \_\_\_\_\_

Don't know \_\_\_\_\_

**Appendix C: CANCER – Best-Case Series Patient Interview Form for Next of Kin - Naltrexone (continued)**

**PT ID#:** \_\_\_\_\_

42a. (IF YES) Were the records obtained?

Yes \_\_\_\_\_  
No \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

43. Did they have other forms of complementary or alternative medicine for the treatment of the cancer?

Yes \_\_\_\_\_ What were they? \_\_\_\_\_  
No \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

44. Would you recommend Naltrexone therapy to someone else?

Yes \_\_\_\_\_  
No \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

45. Was there any difference between how they felt with Naltrexone therapy and their other care?

Yes \_\_\_\_\_  
No \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

**Appendix C: CANCER – Best-Case Series Patient Interview Form for Next of Kin - Naltrexone (continued)**

**PT ID#:** \_\_\_\_\_

45a. (IF YES) How was it different? (RECORD VERBATIM)

46. Why did they choose Naltrexone therapy for treatment of their cancer? (Check all that apply)

- ☐ Failure of another form of complementary/alternative medicine
- ☐ Failure of conventional therapy
- ☐ Side effects of conventional therapy
- ☐ Side effects of another form of complementary/alternative medicine
- ☐ Philosophical congruence
- ☐ Other, specify \_\_\_\_\_
- ☐ None of the above (no reason)
- ☐ Refused
- ☐ Don't know

47. Did they use conventional therapy for the cancer?

- Yes \_\_\_\_\_
- No \_\_\_\_\_
- Refused \_\_\_\_\_
- Don't know \_\_\_\_\_



**Appendix C: CANCER – Best-Case Series Patient Interview Form for Next of Kin - Naltrexone (continued)**

**PT ID#:** \_\_\_\_\_

47a. (IF NO) How come? (Check all that apply)

- ☐ Failure of conventional therapy
- ☐ Side effects of conventional therapy
- ☐ Philosophical reasons
- ☐ Some other reason (specify) \_\_\_\_\_
- ☐ None of the above (no reason)
- ☐ Refused
- ☐ Don't know

47b. (IF YES) Did they complete conventional therapy?

- Yes \_\_\_\_\_
- No \_\_\_\_\_
- Refused \_\_\_\_\_
- Don't know \_\_\_\_\_

47b. (IF COMPLETED) Was the following statement true:

“(PATIENT) completed conventional therapy, but was not cured”

- Yes \_\_\_\_\_
- No \_\_\_\_\_
- Refused \_\_\_\_\_
- Don't know \_\_\_\_\_

48. What did they expect from their Naltrexone therapy? (RECORD VERBATIM)

**Appendix C: CANCER – Best-Case Series Patient Interview Form for Next of Kin - Naltrexone (continued)**

**PT ID#:** \_\_\_\_\_

49. When (PATIENT) was being treated by Dr. Bihari, did they tell their friends that an alternative medical practitioner was treating them?

Yes \_\_\_\_\_  
No \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

50. How far did they travel to get to Dr. Bihari's clinic? (CHECK ONE)

5 miles or less \_\_\_\_\_  
6-10 miles \_\_\_\_\_  
11-20 miles \_\_\_\_\_  
21-30 miles \_\_\_\_\_  
over 30 miles \_\_\_\_\_  
over 100 miles \_\_\_\_\_  
over 500 miles \_\_\_\_\_  
over 1000 miles \_\_\_\_\_  
over 2000 miles \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

51. Did they have a family medical doctor?

**Appendix C: CANCER – Best-Case Series Patient Interview Form for Next of Kin - Naltrexone (continued)**

**PT ID#:** \_\_\_\_\_

Yes \_\_\_\_\_  
No \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

51a. If yes, how often do they see this doctor?

Yearly \_\_\_\_\_  
Monthly \_\_\_\_\_  
Weekly \_\_\_\_\_  
Other \_\_\_\_\_ (specify) \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_

52. Were they satisfied with the care they received from the family medical doctor? Were they... (READ RESPONSES AND CHECK ONE)

Extremely satisfied \_\_\_\_\_  
Very satisfied \_\_\_\_\_  
Satisfied \_\_\_\_\_  
Somewhat satisfied \_\_\_\_\_  
Not at all satisfied \_\_\_\_\_  
  
(DON'T READ) Refused \_\_\_\_\_  
(DON'T READ) Don't know \_\_\_\_\_

53. Did (PATIENT) rely primarily upon alternative medicine providers for all of their medical care?

Yes \_\_\_\_\_

**Appendix C: CANCER – Best-Case Series Patient Interview Form for Next of Kin - Naltrexone (continued)**

**PT ID#:** \_\_\_\_\_

No \_\_\_\_\_  
Refused \_\_\_\_\_  
Don't know \_\_\_\_\_



## **Appendix D**

### **Letters to Patients Including (3) Consent Forms**



## **Appendix D: Letters to Patients Including (3) Consent Forms –Dr. Clement Patients**

June, 2001

Dear

We are currently conducting a national study of patients using alternative and complementary medicine. Dr. John Clement of the Immunology Research Centre in the Bahamas has agreed to participate in this study. As part of the study we wish to obtain the records of patients enrolled in complementary and alternative care to determine the outcomes of these treatments.

You are one of approximately 20 patients from The Centre selected to take part in this Study and your participation is very important to the validity of the results. However, you do not have to participate and your decision whether or not to take part will not affect any services you receive from any health care provider. You were selected by Dr. Clement as a patient who he feels has responded well to Immuno-Augmentive Therapy (IAT).

To complete the study we would like to have access to your files in Dr. Clement's office. In addition, if you are also being treated by any other health provider (s) for the same health problem we would like permission to obtain those records. We would also like to complete a short telephone interview (10-15 minutes) with you regarding the impact these various treatments have had on your health and on the quality of your life.

No provider will be informed by us that you are receiving other care. All the information we obtain from your files is for research purposes only. We will protect the confidentiality of this information, and will not disclose your identity or information that identifies you to anyone except as required by law. We will not identify you in any reports we write. We will destroy all personal information from our files at the end of the study or sooner if no further information is required.

We will not be asking you to take part in any experimental treatments or therapies. We will be simply reviewing your medical records and asking you some questions. There are no direct benefits to you by participating in the Study but it might benefit other patients in general by showing which types of treatment benefit which types of patients.

If you are willing to participate please complete the enclosed authorizations and return them to us. A pre-stamped, addressed envelope is enclosed for this purpose.

You can request additional information about the Study or discuss problems related to the Study by calling the Principal Investigator for the Study, Ian Coulter, Ph.D. at 310-393-0411, ext. 6759.

Yours sincerely,

Ian D. Coulter, Ph.D.  
RAND

Mary Hardy, M.D.  
RAND



**Appendix D: Letters to Patients Including (3) Consent Forms –Dr. Clement  
Patients (continued)**

*PLEASE NOTE THAT IF YOU ARE NOT THE PATIENT, YOU HAVE BEEN SENT THIS BECAUSE **IAT** HAS NOTED THAT YOU ARE THE NEXT-OF-KIN AND YOUR INPUT IS VERY IMPORTANT TO THIS NATIONAL STUDY OF ALTERNATIVE TREATMENT.*

Enclosed are the following authorization forms:

- Document A: Release for patient records from Dr. Clement (IAT)
- Document B: Allowing us (SCEPC) to call you for a short interview
- Document C: Release for patient records from any other health providers *(3 forms enclosed – feel free to copy this form if there are more than 3)*

You may consent to A, B or C, or all three.

**Appendix D: Letters to Patients Including (3) Consent Forms –Dr. Clement  
Patients (continued)**

**PATIENT AUTHORIZATION:**

To: Dr. John R. Clement  
IAT (Bahamas) Ltd.  
PO Box F-42689  
Freeport, Grand Bahamas, Bahama

I, \_\_\_\_\_ (*print your name*), authorize  
the release of a copy of my patient record to the SCEPC study of cancer.

I, \_\_\_\_\_ (*print your name*), am the legal  
next-of-kin to IAT patient \_\_\_\_\_ (*print his/her  
name*) and authorize the release of a copy of his/her patient record to the SCEPC study  
of cancer.

\_\_\_\_\_  
Patient (or legal) signature

\_\_\_\_\_  
Date

*\* You can request additional information about the Study or discuss problems related  
to the Study by calling the Study's Principal Investigator, Ian Coulter, Ph.D., at 310-  
393-0411 ext. 6759. The SCEPC will reimburse you for all reproduction costs of the  
patient's file.*

**Document A**

**Appendix D: Letters to Patients Including (3) Consent Forms –Dr. Clement  
Patients (continued)**

**PATIENT AUTHORIZATION:**

I, \_\_\_\_\_ (*print your name*), authorize  
the Southern California Evidence-Based Practice Center to call me for a short interview  
regarding \_\_\_\_\_ (*print patient's name if you are next-of-kin*).

The best time to call me during the day is: \_\_\_\_\_ (if possible, please give a 3-hour span)

\_\_\_\_\_  
(time, time zone) Phone #: (\_\_\_\_\_) \_\_\_\_\_  
Alternate phone #: (\_\_\_\_\_) \_\_\_\_\_

\_\_\_\_\_  
Patient (or legal) signature

\_\_\_\_\_  
Date

**Document B**

**Appendix D: Letters to Patients Including (3) Consent Forms –Dr. Clement  
Patients (continued)**

**PATIENT AUTHORIZATION:**

To: Dr. Mr. Ms. \_\_\_\_\_ (*insert the name of the provider*)  
[circle one]

\_\_\_\_\_ (*address*)

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_ (*telephone*)

I, \_\_\_\_\_ (*print your name*), authorize  
the release of a copy of my medical record to the SCEPC study of cancer.

I, \_\_\_\_\_ (*print your name*), am the legal  
next-of-kin to IAT patient \_\_\_\_\_ (*print  
his/her name*) and authorize the release of a copy of his/her patient record to the  
SCEPC study of cancer.

I request that the copy be sent to:

Ian Coulter Ph.D.  
Southern California Evidence Based Practice Center  
PO Box 2138  
Santa Monica, CA 90407-2138.

\_\_\_\_\_  
Patient (or legal) signature

\_\_\_\_\_  
Date

*\* You can request additional information about the Study or discuss problems related to the Study by calling the Study's Principal Investigator, Ian Coulter, Ph.D., at 310-393-0411 ext. 6759. The SCEPC will reimburse you for all reproduction costs of the patient's file.*

**Document C**

## **Appendix D: Letters to Patients Including (3) Consent Forms –Dr. Bihari Patients**

June, 2001

Dear

We are currently conducting a national study of patients using alternative and complementary medicine. Dr. Bernard Bihari and his medical clinic have agreed to participate in this study. As part of the study we wish to obtain the records of patients enrolled in complementary and alternative care to determine the outcomes of these treatments.

You are one of approximately 20 patients from Dr. Bihari's practice selected to take part in this Study and your participation is very important to the validity of the results. However, you do not have to participate and your decision whether or not to take part will not affect any services you receive from any health care provider. You were selected by Dr. Bihari as a patient who he feels has responded well to Naltrexone.

To complete the study we would like to have access to your files in Dr. Bihari's office. In addition, if you are also being treated by any other health provider(s) (both conventional and alternative) for the same health problem, we would like permission to obtain those records. We would also like to complete a short telephone interview (10-15 minutes) with you regarding the impact these various treatments have had on your health and on the quality of your life.

No provider will be informed by us that you are receiving other care. All the information we obtain from your files is for research purposes only. We will protect the confidentiality of this information, and will not disclose your identity or information that identifies you to anyone except as required by law. We will not identify you in any reports we write. We will destroy all personal information from our files at the end of the study or sooner if no further information is required.

We will not be asking you to take part in any experimental treatments or therapies. We will be simply reviewing your medical records and asking you some questions. There are no direct benefits to you by participating in the Study but it might benefit other patients in general by showing which types of treatment benefit which types of patients.

If you are willing to participate please complete the enclosed authorizations and return them to us. A pre-stamped, addressed envelope is enclosed for this purpose.

You can request additional information about the Study or discuss problems related to the Study by calling the Principal Investigator for the Study, Ian Coulter, Ph.D. at 310-393-0411, ext. 6759.

Yours sincerely,

Ian D. Coulter, Ph.D.  
RAND

Mary Hardy, M.D.  
RAND

**Appendix D: Letters to Patients Including (3) Consent Forms –Dr. Bihari Patients  
(continued)**

Enclosed are the following authorization forms:

Document A: Release for your records from Dr. Bihari

Document B: Allowing us (SCEPC) to call you for a short interview

Document C: Release for your records from any other health providers  
*(3 forms enclosed – feel free to copy this form if there are more  
than 3)*

You may consent to A, B or C, or all three.

**Appendix D: Letters to Patients Including (3) Consent Forms –Dr. Bihari Patients  
(continued)**

**PATIENT AUTHORIZATION:**

To: Dr. Bernard Bihari  
29th West 15th Street  
New York, NY 10011

I, \_\_\_\_\_ (*print your name*), authorize  
the release of a copy of my patient record to the SCEPC study of cancer.

\_\_\_\_\_  
Patient signature

\_\_\_\_\_  
Date

*\* You can request additional information about the Study or discuss problems related to the Study by calling the Study's Principal Investigator, Ian Coulter, Ph.D., at 310-393-0411 ext. 6759. The SCEPC will reimburse you for all reproduction costs of the patient's file.*

**Document A**

**Appendix D: Letters to Patients Including (3) Consent Forms –Dr. Bihari Patients  
(continued)**

**PATIENT AUTHORIZATION:**

I, \_\_\_\_\_ (*print your name*), authorize  
the Southern California Evidence-Based Practice Center to call me for a short interview.

The best time to call me during the day is: \_\_\_\_\_ (if possible, please give a 3-hour span)

\_\_\_\_\_  
(time, time zone) Phone #: (\_\_\_\_\_) \_\_\_\_\_  
Alternate phone #: (\_\_\_\_\_) \_\_\_\_\_

\_\_\_\_\_  
Patient signature

\_\_\_\_\_  
Date

**Document B**



**Appendix D: Letters to Patients Including (3) Consent Forms –Dr. Bihari Patients  
(continued)**

**PATIENT AUTHORIZATION:**

To: Dr. Mr. Ms. \_\_\_\_\_ (*insert the name of the provider*)  
[circle one]

\_\_\_\_\_ (*address*)

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_ (*telephone*)

I, \_\_\_\_\_ (*print your name*), authorize  
the release of a copy of my medical record to the SCEPC study of cancer.

I request that the copy be sent to:

Ian Coulter Ph.D.  
Southern California Evidence Based Practice Center  
PO Box 2138  
Santa Monica, CA 90407-2138.

\_\_\_\_\_  
Patient signature

\_\_\_\_\_  
Date

*\* You can request additional information about the Study or discuss problems related to the Study by calling the Study's Principal Investigator, Ian Coulter, Ph.D., at 310-393-0411 ext. 6759. The SCEPC will reimburse you for all reproduction costs of the patient's file.*

**Document C**

## **Appendix E: Additional Cases Reviewed—Rejected IAT Cases (E-1)**

## Appendix E: Additional Cases Reviewed— Rejected IAT Cases (E-1)

### Rejected IAT Cases

NAME	DIAGNOSIS	REASON FOR REJECTION
1-R	Adenocarcinoma of the rectum	Definitive surgery
2-R	Carcinoma of the bladder	Care not received in North America (France)
3-R	Breast carcinoma right and left	Multiple recurrences; more than IAT for chemotherapy
4-R	Ductal carcinoma of breast	No records
5-R	Bladder cancer	Incomplete record
6-R	Large-cell lymphoma	Incomplete record
7-R	Squamous cell carcinoma, metastatic-primary unknown; possibly tongue	Poor response to therapy
8-R	Squamous cell carcinoma of chest	Progression of disease on IAT treatment
9-R	Ductal carcinoma of breast, 1 of 12 nodes positive	Probable definitive therapy (surgical excision)
10-R	Carcinoma of the right breast	Definitive surgery 1979; metastases on IAT
11-R	Carcinoma of the bladder	Definitive surgery
12-R	Adenocarcinoma of the prostate	Inadequate documentation - possible
13-R	Ductal carcinoma of breast	Long survival but possible curative surgery

## Appendix E: Additional Cases Reviewed— Rejected IAT Cases (E-1) (continued)

NAME	DIAGNOSIS	REASON FOR REJECTION
14-R	Gastroesophageal cancer	Current patient; insufficient followup
15-R	Ductal carcinoma of both breasts '87, recurrence on left 5/00	Definitive therapy (surgical), relapse, other CAM
16-R	Squamous cell carcinoma, floor of mouth	Incomplete record
17-R	Malignant sarcoma	Long survivor; eventually died of the disease
18-R	Squamous cell carcinoma of lung	Progression of disease on IAT treatment
19-R	Astrocytoma	Prolonged survival but poor functional outcome
20-R	Endometrial adenocarcinoma	Recurrence on IAT
21-R	Malignant mesothelioma of the chest	Care not received in North America (Austria)
22-R	Adenocarcinoma of the breast	Definitive surgery—node negative
23-R	Poorly differentiated squamous cell carcinoma of nasopharynx	Recent start on IAT; insufficient time for followup
24-R	Adenocarcinoma of unknown primary	Lived longer than expected time, but progressed on treatment
25-R	Adenocarcinoma of the prostate	Incomplete record
26-R	Bronchsarcoma protruberans of face	Multiple recurrences; surgery and local excision
27-R	Adenocarcinoma of the pancreas	Progression of disease on IAT treatment

## Appendix E: Additional Cases Reviewed— Rejected IAT Cases (E-1) (continued)

NAME	DIAGNOSIS	REASON FOR REJECTION
28-R	Adenocarcinoma of the caecum	Progression of disease on IAT treatment
29-R	Breast carcinoma, left	Possible curative resection; no measurable disease to follow
30-R	Carcinoma of the left breast	Confounding conventional therapy
31-R	Lymphocytic lymphoma	Progression of disease on IAT treatment
32-R	Sq. cell carcinoma left vocal cord 5/80, rectal carcinoma 10/90, liver angiosarcoma 9/00	Incomplete record
33-R	Ductal carcinoma of breast	Progression of disease on IAT treatment
34-R	Carcinoma of colon to local nodes	Long survival but possible curative surgery
35-R	Adenocarcinoma of breast	Long survival but extensive conventional therapy
36-R	Squamous cell carcinoma of anum	Definitive surgery
32-R	Small cell carcinoma of the lung	Second primary (adenocarcinoma of breast) on treatment; confounding conventional and unconventional therapy
33-R	Adenocarcinoma of the colon	Long survivor, but questionable documentation of liver metastases; second primary (prostate) developed on treatment
34-R	Metastatic malignant melanoma	Progression of disease on IAT treatment
35-R	Clear cell carcinoma of the kidney	Stabilization of metastatic disease—variable by report. Confounding CAM therapy

## **Other IAT Cases Reviewed E-2**

**Patient #1-2**

## Appendix E: Other IAT Cases Reviewed E-2 Patient #1-2

CAM Therapy:	IAT		
	Case:	1-2	
	Condition:	Adenocarcinoma of the rectum	
	Abstractor:	2	Date of Abstraction:
	Interviewer:		Date of Interview:
	Comments:	Adenocarcinoma of the rectum with incomplete resection (equivocal documentation)	

  

Criteria for inclusion: (check all that apply)	
<input checked="" type="checkbox"/>	Diagnosis confirmed
<input checked="" type="checkbox"/>	Documented start date for CAM therapy
<input checked="" type="checkbox"/>	Documented previous anti-cancer therapies
<input checked="" type="checkbox"/>	No other therapies during the CAM therapy
<input checked="" type="checkbox"/>	Documented endpoint:
	<input type="checkbox"/> Tumor size
	<input checked="" type="checkbox"/> Longevity
	<input type="checkbox"/> Quality of Life
	Other: <input type="text"/>

  

Other Relevant Information:	
Sex:	male
DOB:	7/7/29
Diagnosis:	Adenocarcinoma (infiltrating) of the rectum
Diagnosis date:	Mar-84
CAM therapy dates:	10/8/97-5/11/01
Conventional therapy dates:	Surgery 5/3/89; 8/28/89    Chemotherapy 5/22/89    Radiation 3/90
Last contact date:	5/11/01
If deceased, date of death:	

## Appendix E: Other IAT Cases Reviewed E-2 Patient #1-2 (continued)

Date	Description of Events
4/19/89	Biopsy rectum (colonoscopy): infiltrating adenocarcinoma
5/3/89	Surgery: transphincter local excision: tumor margin not clear
5/8/89	Biopsy rectum (surgery): in situ and infiltrating adenocarcinoma moderately differentiated - tumor at margin
5/22/89	Chemotherapy: 5-FU, leucovorin
6/5/89	Selenium, bioflavinoid, vitamin C, vitamin A, vitamin E
8/18/89	CT scan abdomen: thickening distal rectal wall: bilateral hydronephrosis: lucent mass 3.8cm x 2cm
8/28/89	Surgery: Abdomino-peritoneal resection with permanent colostomy
8/30/89	Biopsy ano-rectum (surgery): no residual carcinoma; margins clear; negative lymph node
11/12/89	X-ray chest: normal
11/28/89	CT scan abdomen/pelvis: irregular soft tissue mass 4.4cm; resolution of hydronephrosis
12/6/89	Biopsy: needle aspirate: malignant adenocarcinoma
3/22/90	CT scan abdomen/pelvis: mass 4.56cm x 3.35cm in rectal fossa: no change since 11/28/89
3/22/90	CEA 1.1 ( normal < 5)
3/28/90	Bone scan: whole body: normal
	Radiation: stopped early due to radiation cystitis (written in report 9/29/89)



## Appendix E: Other IAT Cases Reviewed E-2 Patient #1-2 (continued)

Date	Description of Events
9/25/90	CT scan abdomen/pelvis: decrease in sacral mass (slight) 4.2 cm x 2.7cm)
11/8/90	AMAS 213mg/ml (normal < 134)
3/6/91	AMAS 219mg/ml (normal < 134)
4/30/91	X-ray chest: normal
4/30/91	CT scan abdomen/pelvis: increase in size of mass from 9/90, tumor vs. inflammation
8/6/91	MRI pelvis: thickening of left levator ani muscle
9/17/91	AMAS 116mg/ml (normal < 134)
12/18/91	MRI pelvis: no recurrence of tumor
12/19/91	MRI abdomen: normal
3/11/92	AMAS 162mg/ml (normal < 134)
3/19/92	X-ray chest: no evidence of metastatic disease
8/18/92	AMAS 130mg/ml (normal < 134)
1/5/93	MRI pelvis: no recurrence or spread of tumor
1/5/93	MRI abdomen: no adenopathy
11/11/93	AMAS normal

## Appendix E: Other IAT Cases Reviewed E-2 Patient #1-2 (continued)

Date	Description of Events
11/19/93	MRI pelvis: no interval change
11/19/93	MRI abdomen: no change; unremarkable MRI
12/12/94	MRI abdomen: no change
5/24/95	AMAS 137 mg/ml (normal < 134)
6/8/95	MRI abdomen: bilateral renal cysts
6/8/95	MRI pelvis: no interval change; normal study
6/22/95	CEA 0.8 ( normal < 5.0)
10/17/95	AMAS 104 mg/ml (normal < 134)
12/26/95	MRI abdomen: no change
12/26/95	MRI pelvis: no change
7/2/96	AMAS normal
9/30/96	X-ray c-spine: spondylotic changes
6/28/96	MRI pelvis: no tumor recurrence
6/28/96	MRI abdomen: no adenopathy
9/17/96	MRI brain lacunar infarcts; peritrial ischemic changes

## Appendix E: Other IAT Cases Reviewed E-2 Patient #1-2 (continued)

Date	Description of Events
5/13/97	CEA 0.9 ( normal < 5.0)
5/30/97	AMAS normal
12/30/97	AMAS 104 mg/ml (normal < 134)
10/8/97- 5/11/01	IAT 8 courses



**Additional Case Reviewed**

**Patient #1-5**

## Appendix E: Other IAT Cases Reviewed E-2 Patient #1-5

<b>CAM Therapy:</b>	IAT		
<b>Case:</b>	1-5		
<b>Condition:</b>	Right renal adenocarcinoma		
<b>Abstractor:</b>	1	<b>Date of Abstraction:</b>	
<b>Interviewer:</b>		<b>Date of Interview:</b>	10/5/01
<b>Comments:</b>	IAT started after right nephrectomy for cure. Metastasis not documented, although retroperitoneal and liver masses were present on CT scan. Retroperitoneal mass not always noted on imaging studies. Endpoint not documented.		

<b>Criteria for inclusion: (check all that apply)</b>			
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Diagnosis confirmed	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Documented start date for CAM therapy	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Documented previous anti-cancer therapies	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	No other therapies during the CAM therapy	
<input type="checkbox"/>	<input type="checkbox"/>	Documented endpoint:	
<input type="checkbox"/>	<input type="checkbox"/>	Tumor size	
<input type="checkbox"/>	<input type="checkbox"/>	Longevity	
<input type="checkbox"/>	<input type="checkbox"/>	Quality of Life	
<input type="checkbox"/>	<input type="checkbox"/>	Other:	

<b>Other Relevant Information:</b>	
Sex:	female
DOB:	4/6/42
Diagnosis:	Right renal adenocarcinoma, well-differentiated
Diagnosis date:	5/17/79
CAM therapy dates:	10/28/80-12/2/98
Conventional therapy dates:	5/17/79 surgery
Last contact date:	12/2/98
If deceased, date of death:	

## Appendix E: Other IAT Cases Reviewed E-2 Patient #1-2 (continued)

Date	Description of Events
04/30/79	Renal IVP: duplicate left collecting system, dilated right upper pole collecting system, irregular bladder wall
05/09/79	Renal US: large solid mass in right kidney
05/10/79	Renal arteriogram: mass lesion at lower pole of right kidney
05/11/79	Bone scan of whole body: within normal limits
05/17/79	Right kidney biopsy: well-differentiated adenocarcinoma with focal extension through the renal capsule
05/17/79	Surgery: right nephrectomy
10/01/79	Bone scan of whole body: right kidney absent
12/07/79	CT scan of abdomen: 3.5cm low density area at posterior right lobe of liver
01/18/80	CT scan of abdomen with contrast: no change in low density area in posterior right hepatic lobe
01/18/80	X-ray chest: within normal limits
06/25/80	Bone scan of whole body: right nephrectomy
06/25/80	Renal arteriogram: s/p nephrectomy, no evidence of residual tumor at excision site
06/27/80	CT scan of abdomen: enhancing lesion in right lobe, second area seen
09/29/80	X-ray chest: within normal limits
09/29/80	Liver US: 3 solid lesions in right lobe of liver 3.6cm largest, 2cm other 2 lesions

## Appendix E: Other IAT Cases Reviewed E-2 Patient #1-2 (continued)

Date	Description of Events
10/13/80	CT scan of abdomen: retroperitoneal mass in area of right pedicle, low density areas in liver
01/08/82	CT scan of abdomen with contrast: mass at posterior of right lobe of liver decreased 3-2.4cm, 4.9cm mass in right renal pedicle decreased to 4cm
03/21/83	CT scan of abdomen with contrast: enhancing hypodense masses in liver, no change
04/09/84	CT scan of abdomen: multiple hypodense areas in right lobe of liver 2-3.5cm, recurrent mass medial and inferior to site of nephrectomy
10/24/84	CT scan of abdomen: absent right kidney
10/25/84	Bone scan of whole body: within normal limits
05/01/89	CT scan of abdomen: double collecting system on left, 3 low density lesions in right lobe of liver, no change since 1984
06/19/92	CT scan of abdomen with contrast: metastatic disease to liver, multiple masses (5-6), largest at right lobe of liver 2cm
07/13/94	CT scan of abdomen and pelvis with contrast: 4 lesions at right lobe of liver, largest 3cm presumed not metastatic
06/19/97	CT scan of abdomen 5-6 low attenuation foci within liver most consistent with metastatic disease
10/28/80-present	IAT 15 courses, then yearly injections



**Additional Case Reviewed**

**Patient #1-12**

## Appendix E: Other IAT Cases Reviewed E-2 Patient #1-12

<b>CAM Therapy:</b>	IAT		
<b>Case:</b>	1-12		
<b>Condition:</b>	Breast cancer (left breast)		
<b>Abstractor:</b>	IDC	<b>Date of Abstraction:</b>	
<b>Interviewer:</b>		<b>Date of Interview:</b>	
<b>Comments:</b>	No adjuvant therapy with the surgical excision and node dissection. Patient never achieved remission. Patient deceased from pulmonary embolism.		

Criteria for inclusion: (check all that apply)	
<input checked="" type="checkbox"/>	Diagnosis confirmed
<input checked="" type="checkbox"/>	Documented start date for CAM therapy
<input checked="" type="checkbox"/>	Documented previous anti-cancer therapies
<input checked="" type="checkbox"/>	No other therapies during the CAM therapy
<input type="checkbox"/>	Documented endpoint:
<input type="checkbox"/>	Tumor size
<input type="checkbox"/>	Longevity
<input type="checkbox"/>	Quality of Life
<input type="checkbox"/>	Other:

Other Relevant Information:	
Sex:	female
DOB:	3/26/41
Diagnosis:	Left breast Infiltrating ductal cell carcinoma, stage 0, moderately differentiated, node positive, ER/PR positive
Diagnosis date:	12/28/84
CAM therapy dates:	5/14/85-3/3/94
Conventional therapy dates:	12/28/84
Last contact date:	3/3/94
If deceased, date of death:	pulmonary embolism 4/10/94

## Appendix E: Other IAT Cases Reviewed E-2 Patient #1-12 (continued)

Date	Description of Events
12/28/84	Biopsy: Left breast pathology: 8 mm well-differentiated ductal cell carcinoma with microcalcification and stromal infiltration with comedo-carcinoma features
12/28/84	Surgery: left partial mastectomy for diagnosis and palliation.
12/28/84	X-ray chest: within normal limits
4/18/85	X-ray chest: within normal limits
4/19/85	Surgery left axilla: moderately differentiated ductal cell carcinoma, 29/30 nodes positive
4/22/85	ERA binding sites: 13.9 fmol/mg, Estradiol receptor cytosol protein 2 mg/ml; PRA binding sites 219.3 fmol/mg; Progesterone receptor cytosol protein 4 mg/ml
4/22/85	Radiation recommended for palliation; patient refused due to personal preference
4/22/85	Liver scan: borderline hepatomegaly
4/23/85	Bone scan: within normal limits
7/8/86	Bone scan: within normal limits
7/8/86	X-ray chest: within normal limits
3/6/87	X-ray chest
12/2/87	Bone scan: within normal limits
12/2/87	X-ray chest: within normal limits
5/14/85	Vitamin C, beta carotene, vitamin E, selenium, multivitamin
5/14/85-3/3/94	IAT 18 courses



**Additional Case Reviewed**

**Patient #1-15A**

## Appendix E: Other IAT Cases Reviewed E-2 Patient #1-15A

<b>CAM Therapy:</b>	IAT		
<b>Case:</b>	1-15A		
<b>Condition:</b>			
<b>Abstractor:</b>	IDC, JLG	<b>Date of Abstraction:</b>	
<b>Interviewer:</b>	IDC	<b>Date of Interview:</b>	9/25/01
<b>Comments:</b>	Cancer excised with clean margins 10/87; second primary adenocarcinoma of the cecum excised 2/24/98 with clean margins		

Criteria for inclusion: (check all that apply)	
<input checked="" type="checkbox"/>	Diagnosis confirmed
<input checked="" type="checkbox"/>	Documented start date for CAM therapy
<input checked="" type="checkbox"/>	Documented previous anti-cancer therapies
<input checked="" type="checkbox"/>	No other therapies during the CAM therapy
<input type="checkbox"/>	Documented endpoint:
<input type="checkbox"/>	Tumor size
<input type="checkbox"/>	Longevity
<input type="checkbox"/>	Quality of Life
<input type="checkbox"/>	Other:

Other Relevant Information:	
Sex:	female
DOB:	7/27/26
Diagnosis:	Squamous cell carcinoma of the larynx, moderately differentiated 10/2/87
Diagnosis date:	10/2/87
CAM therapy dates:	4/26/88-7/3/98
Conventional therapy dates:	10/28/87
Last contact date:	7/3/98
If deceased, date of death:	

## Appendix E: Other IAT Cases Reviewed E-2 Patient #1-15A

Date	Description of Events
10/2/87	Biopsy: vocal cord pathology: moderately differentiated squamous cell carcinoma
10/10/87	CT scan of thorax: within normal limits
10/27/87	CT scan of neck: thickening of the right aryepiglottic fold compatible with exophytic mass, extends posteriorly to the pharyngeal wall
10/27/87	X-ray head and neck: single lymph node measuring <1 cm of level of vocal cords on the right
10/28/87	Anterior laryngoscopy, tracheostomy, partial laryngectomy for palliation: cancer involving posterior and superior margins;
10/28/87	Biopsy pathology: surgical excision larynx, posterior and superior margins have infiltrating squamous cell cancer; clean margins
11/5/87	X-ray chest: left pleural effusion
12/30/87	Laryngoscopy for diagnostic: no exophytic lesion inviting biopsy, but biopsy done of glandular appearing tissue near junction of right true cord and epiglottis
12/30/87	Biopsy pathology: direct laryngoscopy of right supraglottic larynx: dysplastic changes focally present
8/23/95	X-ray chest: within normal limits except mild atelectasis
5/28/97	Pelvic US: no pelvic adnexal masses nor fluid collection
2/24/98	Exploratory laparotomy with right hemicolectomy and excision of right lateral abdominal wall for diagnosis and palliation: perforation of cecal carcinoma with abscess. Intention of surgery was appendectomy. Incidentally found cancer
2/24/98	Biopsy cecum: pathology: invasive moderately differentiated adenocarcinoma arising in association with tubulovillous adenoma, invades muscularis with perforation of colonic wall, margins clear: all 12 nodes negative
2/15/99	Colonoscopy: anastomic right side of colon stable
3/2/99	X-ray lumbar spine: mild osteopenia

## Appendix E: Other IAT Cases Reviewed E-2 Patient #1-15A

Date	Description of Events
3/3/99	CT scan of abdomen and pelvis: no significant evidence of mass lesion
4/26/88- 7/3/98	IAT; 13 courses



**Additional Case Reviewed**

**Patient #1-16**

## Appendix E: Other IAT Cases Reviewed E-2 Patient #1-16

<b>CAM Therapy:</b>	IAT		
<b>Case:</b>	1-16		
<b>Condition:</b>	Hodgkin's disease		
<b>Abstractor:</b>	IDC, MH	<b>Date of Abstraction:</b>	
<b>Interviewer:</b>		<b>Date of Interview:</b>	
<b>Comments:</b>	Hodgkin's disease, local excision with no definitive conventional therapy: incomplete documentation; considered disease free in 1/98		

<b>Criteria for inclusion: (check all that apply)</b>			
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Diagnosis confirmed	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Documented start date for CAM therapy	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Documented previous anti-cancer therapies	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	No other therapies during the CAM therapy	
<input type="checkbox"/>	<input type="checkbox"/>	Documented endpoint:	
<input type="checkbox"/>	<input type="checkbox"/>	Tumor size	
<input type="checkbox"/>	<input type="checkbox"/>	Longevity	
<input type="checkbox"/>	<input type="checkbox"/>	Quality of Life	
<input type="checkbox"/>	<input type="checkbox"/>	Other:	

<b>Other Relevant Information:</b>	
Sex:	male
DOB:	6/13/62
Diagnosis:	Hodgkin's disease
Diagnosis date:	1/9/81
CAM therapy dates:	1/19/81-11/30/99
Conventional therapy dates:	none
Last contact date:	11/30/99
If deceased, date of death:	

**Appendix E: Other IAT Cases Reviewed E-2 Patient #1-16 (continued)**

Date	Description of Events
1/9/81	Surgery: tonsillectomy
1/9/81	Biopsy: tonsil : Hodgkin's lymphoma: initially, diffuse histiocytic lymphoma after reviewed at Yale felt to be Hodgkin's disease, lymphocytic and histiocystic predominant type
1/14/81	Biopsy: bone marrow: negative for Hodgkin's disease
1/14/81	Chemotherapy recommended:patient refused due to patient preference; was not followed by oncologist
1/19/81-11/30/99	IAT 19 courses



**Additional Case Reviewed**

**Patient #1-20**

## Appendix E: Other IAT Cases Reviewed E-2 Patient #1-20

<b>CAM Therapy:</b>	IAT		
<b>Case:</b>	1-20		
<b>Condition:</b>	Adenocarcinoma of the sigmoid colon		
<b>Abstractor:</b>	IDC	<b>Date of Abstraction:</b>	
<b>Interviewer:</b>		<b>Date of Interview:</b>	
<b>Comments:</b>	no radiation or chemo		

Criteria for inclusion: (check all that apply)			
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Diagnosis confirmed	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Documented start date for CAM therapy	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Documented previous anti-cancer therapies	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	No other therapies during the CAM therapy	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Documented endpoint:	
<input type="checkbox"/>	<input type="checkbox"/>	Tumor size	
	<input checked="" type="checkbox"/>	Longevity	
	<input type="checkbox"/>	Quality of Life	
	<input type="checkbox"/>	Other:	

Other Relevant Information:	
Sex:	female
DOB:	10/18/28
Diagnosis:	Adenocarcinoma of the sigmoid colon; Duke stage C
Diagnosis date:	6/9/87
CAM therapy dates:	6/7/88-5/22/01
Conventional therapy dates:	Surgery 6/9/87
Last contact date:	5/22/01
If deceased, date of death:	

## Appendix E: Other IAT Cases Reviewed E-2 Patient #1-20 (continued)

Date	Description of Events
	Smoking quit at age 28
6/8/87	Sigmoidoscopy rigid: confirm tumor presence of tumor @20-30cm
6/9/87	Surgery: resection of colon: margins free of tumor
6/9/87	Biopsy colon and nodes: moderately well differentiated adenocarcinoma of sigmoid colon: 3/8 pericolic nodes positive: 1/2 inferior mesenteric nodes positive
6/9/87	No conventional therapy offered by physician; physicians chose to follow serial markers instead
9/18/87	CEA 1.9 ng/ml (normal < 5.0)
6/7/88-5/22/01	IAT: 35 courses
6/9/89	CEA 0.8 ng/ml (normal < 5.0)
10/11/89	CEA 2.0 ng/ml (normal < 5.0)
2/8/90	CEA 3.3 ng/ml (normal < 5.0)
10/1/90	CEA 1.8ng/ml (normal < 5.0)
2/1/91	CEA 1.4 ng/ml (normal < 5.0)
7/9/92	CEA 3.5 ng/ml (normal < 5.0)
11/19/92	CEA 3.6 ng/ml (normal < 5.0)
3/21/93	CEA 4.0 ng/ml (normal < 5.0)

## Appendix E: Other IAT Cases Reviewed E-2 Patient #1-20 (continued)

Date	Description of Events
7/21/93	CEA 1.9 ng/ml (normal < 5.0)
11/1/93	CEA 3.0 ng/ml (normal < 5.0)
3/11/94	CEA 5.3 ng/ml (normal < 5.0)
7/27/94	CEA 4.9 ng/ml (normal < 5.0)
3/22/95	CEA 6.3 ng/ml (normal < 5.0)
7/26/95	CEA 4.8 ng/ml (normal < 5.0)
10/1/95	CEA 7.7 ng/ml (normal < 5.0)
4/1/96	CEA 9.5 ng/ml (normal < 5.0)
5/7/97	CEA 8.7ng/ml (normal < 5.0)
7/1/97	CEA 12 ng/ml (normal < 5.0)
5/3/90	Colonscopy: normal
5/23/96	Colonscopy: benign polyp
5/23/96	CT scan abdomen/pelvis normal
11/18/99	Colonscopy: normal



**Additional Case Reviewed**

**Patient #1-21**

## Appendix E: Other IAT Cases Reviewed E-2 Patient #1-21

<b>CAM Therapy:</b>	IAT		
<b>Case:</b>	1-21		
<b>Condition:</b>	Adenocarcinoma of the lung metastatic to mediastinum		
<b>Abstractor:</b>	IDC	<b>Date of Abstraction:</b>	
<b>Interviewer:</b>		<b>Date of Interview:</b>	
<b>Comments:</b>			

<b>Criteria for inclusion: (check all that apply)</b>			
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Diagnosis confirmed	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Documented start date for CAM therapy	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Documented previous anti-cancer therapies	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	No other therapies during the CAM therapy	
<input type="checkbox"/>	<input type="checkbox"/>	Documented endpoint:	
<input type="checkbox"/>	<input type="checkbox"/>	Tumor size	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Longevity	
<input type="checkbox"/>	<input type="checkbox"/>	Quality of Life	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Other:	non-progression of disease

<b>Other Relevant Information:</b>	
Sex:	female
DOB:	7/20/25
Diagnosis:	Adenocarcinoma of the lung, stage III T2 N3 M0. Grade IV (metastatic to mediastinum)
Diagnosis date:	6/18/85
CAM therapy dates:	5/13/86-4/23/93
Conventional therapy dates:	Surgery: 6/18/85 Radiation: 6/24/85-7/8/85
Last contact date:	4/23/93
If deceased, date of death:	4/22/99

## Appendix E: Other IAT Cases Reviewed E-2 Patient #1-21 (continued)

Date	Description of Event I
1/12/78	Biopsy stomach; normal gastric mucosa
5/16/85	X-ray chest : right upper lobe amorphous area of increased density not well delineated on lateral view
5/28/85	X-ray chest : changes consistent with a mass lesion right upper lobe; mild fibrotic changes
6/11/85	Biopsy pathology: bronchial brushings: no cancer cells
6/11/85	Bone scan full body: normal
6/11/85	CT scan mediastinum: previously noted mass: 4-5cm against mediastinum; 1 cm lymph node and several 15mm lymph nodes present
6/12/85	Surgery: fine needle aspiration right upper lung
6/12/85	Biopsy pathology: lung (fine needle aspiration) large malignant cells present
6/17/85	X-ray chest : compared to 6/12/85 right upper lung mass unchanged
6/18/85	Surgery: right minithoracotomy
6/18/85	Biopsy mediastinal lymph node: 2 parts: part 1-no evidence of malignancy: part 2- metastatic grade IV carcinoma
6/18/85	X-ray chest : no pneumothorax; slight atelectasis
6/24/85-7/8/85	Radiation right lung: 6000 RADS in 30 fractions
7/19/85	X-ray of ankle and wrist : periosteal thickening otherwise normal
12/17/85	X-ray chest : questionable nodule behind the heart on the left
1/5/86	X-ray chest : irregular 3cm mass behind the heart on the right side, only change compared with 4/10/86

## Appendix E: Other IAT Cases Reviewed E-2 Patient #1-21 (continued)

Date	Description of Event I
4/30/86	X-ray chest : post-broncoscopy - no evidence of pneumothorax
5/13/86-4/23/93	IAT: 14 courses
6/13/86	X-ray chest : post-radiation reduction in size of right hilar mass since 4/30/86. Large right apical mass also smaller
11/4/86	X-ray chest : mass-like density recurrence in right hilum cannot be excluded
3/10/87	X-ray chest : compared to 1/5/87 small density behind left border is no longer seen
4/30/88	Biopsy pathology: bronchial brushings: no cancer cells
1/23/89	X-ray chest : no evidence of associated bone erosion to suggest bone invasion of residual tumor
2/6/89	X-ray chest : no suggestion of mets
7/28/89	X-ray chest : compared with 7/26/88 significant radiation changes in apical pleural thickening
10/23/90	X-ray chest: stable chest; no recurrence
11/25/91	X-ray chest : unchanged from 4/9/91
4/24/92	X-ray chest : stable exam
9/22/92	X-ray chest : no signs of recurrence or metastasis
3/19/93	X-ray chest : unchanged from 9/22/92
4/22/99	Deceased from acute MI

**Additional Case Reviewed**

**Patient #1-24**

## Appendix E: Other IAT Cases Reviewed E-2 Patient #1-24

<b>CAM Therapy:</b>	IAT		
<b>Case:</b>	1-24		
<b>Condition:</b>	Rhabdomyosarcoma		
<b>Abstractor:</b>	IDC	<b>Date of Abstraction:</b>	
<b>Interviewer:</b>		<b>Date of Interview:</b>	
<b>Comments:</b>	Multiple local recurrences and distant mets, despite radiation and chemotherapy. No recurrences since 1997		

Criteria for inclusion: (check all that apply)			
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Diagnosis confirmed	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Documented start date for CAM therapy	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Documented previous anti-cancer therapies	
<input type="checkbox"/>	<input type="checkbox"/>	No other therapies during the CAM therapy	
<input type="checkbox"/>	<input type="checkbox"/>	Documented endpoint:	
<input type="checkbox"/>	<input type="checkbox"/>	Tumor size	
<input type="checkbox"/>	<input type="checkbox"/>	Longevity	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Quality of Life	
<input type="checkbox"/>	<input type="checkbox"/>	Other:	

Other Relevant Information:	
Sex:	male
DOB:	2/10/49
Diagnosis:	Rhabdomyosarcoma of chest wall
Diagnosis date:	6/3/93
CAM therapy dates:	3/3/97-2/23/01
Conventional therapy dates:	6/3/93-8/1/96
Last contact date:	2/23/01
If deceased, date of death:	

## Appendix E: Other IAT Cases Reviewed E-2 Patient #1-24 (continued)

Date	Description of Events
6/3/93	Surgery wedge biopsy of mass at right scapula for diagnosis and palliation
6/3/93	Biopsy pathology: 18x15x5 cm pleomorphic rhabdomyosarcoma with margins free of tumor
8/93-10/93	Radiation: 6560 cGy to right medial posterior thorax
7/24/95	Surgery wedge biopsy of RUL of lung
7/24/95	Biopsy pathology wedge biopsy of right upper lobe lung: metastatic pleomorphic rhabdomyosarcoma 3 cm, margins clear
2/16/96	Biopsy pathology: rhabdomyosarcoma: 3rd interspace, posterior chest wall; RUL lung with chest wall. Multiple biopsies of chest wall and nodes negative
3/96-8/96	Chemotherapy completed 6 cycles
1/3/97	CT scan of chest, abdomen, pelvis: since 10/8/96, internal resection of duodenal mass, otherwise no significant change, no new disease
1/3/97	CT scan of chest
2/19/97	Surgery duodenectomy of 2nd and 3rd portions for palliation
4/2/97	Surgery pancreaticoduodenectomy (pylorus sparing)--Whipple
4/14/97	CT scan of abdomen: 1 cm simple cyst unchanged, low attenuation areas in left kidney unchanged, 2.5 cm enhancing mass in duodenum
4/14/97	CT scan of chest, abdomen, pelvis: no evidence of local recurrence of tumor in right chest; new 2 cm enhancing intraluminal mass within the duodenum
4/14/97	CT scan of chest: post-surgical changes, irregular soft tissue area (post-surgical) no enlarged lymph node
4/14/97	CT scan of pelvis: unchanged
4/17/97	Biopsy pathology: recurrent pleomorphic rhabdomyosarcoma extending into peripancreatic soft tissue, all 19 nodes negative

## Appendix E: Other IAT Cases Reviewed E-2 Patient #1-24 (continued)

Date	Description of Events
4/21/97	X-ray chest: consistent with prior right lung surgery
4/22/97	X-ray chest: post surgical changes
4/22/97	Surgery Whipple procedure for palliation
4/22/97	Biopsy pathology: gall bladder within normal limits
4/22/97	X-ray abdomen: post surgical drains
4/27/97	X-ray chest
4/27/97	X-ray chest: new LLL opacification, right pleural effusion may be bigger
7/7/97	CT scan of chest, abdomen, pelvis: no evidence of metastatic disease or recurrence within the chest abdomen or pelvis
9/21/98	CT scan of chest, abdomen, pelvis: compared to 3/31/98, no new lung nodules, no significant change in abdomen and pelvis
4/19/99	CT scan of chest, abdomen, pelvis: compared to 9/21/98, no abnormally enlarged lymph nodes in abdomen and pelvis, no recurrence or metastasis in chest or pelvis
4/19/99	CT scan: post-operative changes right chest and abdomen, no evidence of recurrence or metastasis
4/19/99	CEA 2.2 (<5)
4/19/99	PSA 0.8 (<4)
3/3/97-2/23/01	IAT
	Quality of life measure: Kavaioncy 95



**Additional Case Reviewed**

**Patient #1-28**

## Appendix E: Other IAT Cases Reviewed E-2 Patient #1-28

<b>CAM Therapy:</b>	IAT		
<b>Case:</b>	1-28		
<b>Condition:</b>	Chondrosarcoma vs. cellular chondroma of the brain (right middle and posterior fossa)		
<b>Abstractor:</b>	AC	<b>Date of Abstraction:</b>	
<b>Interviewer:</b>		<b>Date of Interview:</b>	
<b>Comments:</b>	Long survival with good control of disease: eventually died of disease. Next of kin to be interviewed		

<b>Criteria for inclusion: (check all that apply)</b>	
<input checked="" type="checkbox"/>	Diagnosis confirmed
<input checked="" type="checkbox"/>	Documented start date for CAM therapy
<input type="checkbox"/>	Documented previous anti-cancer therapies
<input type="checkbox"/>	No other therapies during the CAM therapy
<input type="checkbox"/>	Documented endpoint:
	<input type="checkbox"/> Tumor size
	<input checked="" type="checkbox"/> Longevity
	<input type="checkbox"/> Quality of Life
	Other: <input type="text"/>

<b>Other Relevant Information:</b>	
Sex:	female
DOB:	7/9/36
Diagnosis:	chondrosarcome vs. cellular chondroma of the brain
Diagnosis date:	9/24/75
CAM therapy dates:	6/24/80-4/14/89: IAT 14 courses
Conventional therapy dates:	Surgery: 9/24/75
Last contact date:	
If deceased, date of death:	6/12/89 (cause unclear)

## Appendix E: Other IAT Cases Reviewed E-2 Patient #1-28 (continued)

Date	Description of Events
	Concurrently has multiple sclerosis
	Family history of cancer: father died of acute leukemia at age 45
9/22/75	Myelogram of posterior fossa: questionable mass in right cerebellum
9/23/75	Scan brain: abnormal lesion in brain stem
9/23/75	X-ray of clavus and sella turcica: no definite abnormality
9/23/75	Arteriogram cerebral: mass in right cerebellum
9/24/75	Surgery: right suboccipital craniotomy: discovered posterior fossa tumor
9/24/75	Biopsy: pathology chondromatous tumor
10/6/75	Pathology (2nd opinion on same tissue sample 9/24/75): cellular chondroma
6/24/80-4/14/89	IAT: 14 courses
6/12/89	Deceased

## **Other Naltrexone Cases Reviewed E-3**

### **Patient #2-1**

## Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-1

### Case 2-1

The patient in case 2-1 is a 71-year-old female with a history of chronic lymphocytic leukemia. She was initially diagnosed in 1988, per patient report. She started chemotherapy with chlorambucil and prednisone in August 1988 and stopped early in January 1989, secondary to bone marrow suppression. The following year she was diagnosed with pulmonary histoplasmosis and was treated with five months of amphotericin B. In the fall of 1991, she was diagnosed with a recurrence of CLL and the same chemotherapy was initiated. The chemotherapy was stopped after it was determined to have no effect, and five rounds of fludarabine (a full course) was completed by June 1992. In October 1997, she was diagnosed with a recurrence and fludarabine was started and stopped after it was determined to have no effect. In March 1998, Naltrexone was initiated. In August 1998, a bone marrow biopsy revealed histoplasmosis of the bone marrow and itraconazole was initiated. Since that time she has had intravenous immune globulin and rituxan treatments. In July 2001, her physician told her there has been no improvement in her condition. At last contact (patient interview 10/10/010, the patient reports that her general health is good.

#### Pathology

1988	Diagnosed with CLL (per patient report)
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#### Imaging

None

## Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-1 (continued)

### Conventional therapy

8/88-1/89	Chemotherapy: chlorambucil and prednisone; stopped early due to bone marrow suppression
Jan-90	Diagnosed with pulmonary histoplasmosis: amphotericin B (5 month treatment)
fall/91	Diagnosed with CLL recurrence
fall/91	Chemotherapy: chlorambucil and prednisone; stopped early due to no effect
fall/91-6/92	Chemotherapy: fludarabine completed 5 courses
Oct-97	Diagnosed with CLL recurrence
Oct-97	Chemotherapy: fludarabine; stopped early due to no effect
Aug-98	Bone marrow biopsy: positive for CLL and histoplasmosis
Sep-98	Started traconazole
9/1/1998-9/1/00	Started rituxan weekly for four weeks over 2 years: completed treatment
2/00-present	Intravenous immune globulin treatments monthly
March 1,2001-present	Rituxan restarted
2001, July	No improvement in disease per patient's physician

### Complementary therapy

1998, March	Started Naltrexone 3mg qhs
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## Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-1 (continued)

Patient # 2-1						
EVENT	PERIOD 1 1 <sup>st</sup> qtr 1988 – 4 <sup>th</sup> qtr 1988	PERIOD 2 1 <sup>st</sup> qtr 1991 – 4 <sup>th</sup> qtr 1992	PERIOD 3 1 <sup>st</sup> qtr 1997 – 4 <sup>th</sup> qtr 1997	PERIOD 4 1 <sup>st</sup> qtr 1998 – 4 <sup>th</sup> qtr 1998	PERIOD 5 1 <sup>st</sup> qtr 2000– 4 <sup>th</sup> qtr 2000	PERIOD 6 1 <sup>st</sup> qtr 2001 – 4 <sup>th</sup> qtr 2001
Diagnosis/biopsy	1998					
Surgery						
Radiation						
Chemotherapy	8/88	6/92	10/97			
Rituxan				1998		
Ivlg				1998		
Naltrexone	3/98					

# Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-1 (continued)

<b>CAM Therapy:</b>	Naltrexone		
<b>Case:</b>	2-1		
<b>Condition:</b>	Chronic lymphocytic leukemia		
<b>Abstractor:</b>	IC	AC	JU
<b>Interviewer:</b>		<b>Date of Abstraction:</b>	7/12/01
<b>Comments:</b>		<b>Date of Interview:</b>	10/10/01

Criteria for inclusion: (check all that apply)	
<input type="checkbox"/>	Diagnosis confirmed
<input checked="" type="checkbox"/>	Documented start date for CAM therapy
<input type="checkbox"/>	Documented previous anti-cancer therapies
<input type="checkbox"/>	No other therapies during the CAM therapy
<input type="checkbox"/>	Documented endpoint:
<input type="checkbox"/>	<input type="checkbox"/> Tumor size
<input type="checkbox"/>	<input type="checkbox"/> Longevity
<input type="checkbox"/>	<input type="checkbox"/> Quality of Life
<input type="checkbox"/>	Other: <input type="text"/>

Other Relevant Information:	
Sex:	female
DOB:	2/23/30
Diagnosis:	Lymphocytic leukemia
Diagnosis date:	8/1/88
CAM therapy dates:	3/1/2001-present
Conventional therapy dates:	8/88-2/97
Last contact date:	6/11/01
If deceased, date of death:	



## Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-1 (continued)

Date	Description of Events
	Comorbidities: hepatitis
1998	Diagnosed with CLL
8/88-1/89	Chemotherapy: chlorambucil and prednisone; stopped early due to bone marrow suppression
Jan-90	Diagnised with pulmonary histoplasmosis: amphotericin B (5 month treatment)
fall/91	Diagnosed with CLL recurrence
fall/91	Chemotherapy: chlorambucil and prednisone; stopped early due to no effect
fall/91-6/92	Chemotherapy: fludarabine completed 5 courses
Oct-97	Diagnosed with CLL recurrence
Oct-97	Chemotherapy: fludarabine; stopped early due to no effect
Aug-98	Bone marrow biopsy: positive for CLL and histoplasmosis
Sep-98	Started traconazole
9/1/98-9/1/00	Started rituxan weekly for four weeks over 2 years: completed treatment
2/00-present	Ivlg threathments monthly
Mar-98	Started Natrexone 3mg qhs
Mar 01-present	Rituxan
Jul-98	No improvement in disease per patient's physician

**Additional Case Reviewed**

**Patient #2-6**

## Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-6

### Case 2-6

The patient in case 2-6 is a 56-year-old female with a history of ovarian carcinoma. She was initially diagnosed in August 1995 after a total abdominal hysterectomy with a bilateral salpingo-oophorectomy. She started chemotherapy with taxol, cisplatin, and asplax in August 1995 and six rounds were completed by December 1995. The cancer persisted and by 1998 or 1999 chemotherapy was started with doxil and topotecan, and a full course was completed. Naltrexone was initiated in September 2000. Since that time, chemotherapy was again started after metastatic disease was found in her liver. Throughout the course of her treatment, she has tried several unconventional therapies to treat her cancer, including full body hyperthermia and mistletoe. At last contact (interview on 10/09/01), the patient reports that her overall condition is very good.

#### Pathology

<b>Aug-95</b>	<b>Biopsy: Diagnosis of ovarian cancer in pelvis (patient reports)</b>
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#### Imaging

<b>8/28/00</b>	<b>CT scan abdomen compared with 9/11/98: 3.5cm cyst in posterior medial left hepatic lobe anterior to portal vein, unchanged, no sign of metastatic disease</b>
<b>8/28/00</b>	<b>CT scan pelvis: no sign of recurrent metastatic disease</b>
<b>4/19/01</b>	<b>CT scan chest abdomen pelvis: few tiny nodular densities bilateral axilla, 1cm nodularity right lower lobe lung (new); few tiny cysts in liver; multiple soft tissue densities in liver; pelvic cyst 3.8cm</b>

#### Conventional therapy

<b>Aug-95</b>	<b>Surgery: ovariectomy and hysterectomy</b>
<b>8/95-12/95</b>	<b>Chemotherapy: Taxol, cisplatin; and asplax 6 rounds completed</b>
<b>1998 or 1999</b>	<b>Chemotherapy: Doxil, topotecan:11 months - completed therapy; followed by doxil 12 months-completed therapy</b>
<b>10/3/00</b>	<b>Chemotherapy: erythrotecan and low dose taxol</b>
<b>2/1/01</b>	<b>Surgery: laparoscopy: reportedly did not reveal anything</b>
<b>4/19/01</b>	<b>Chemotherapy: initiated due to lesions on liver presumably metastatic disease: camptothecin/cisplatin</b>

## Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-6 (continued)

### Tumor markers

Aug-95	CA-125: 65
Aug-95	CA-125: <35
1998	CA-125: 200
1998	CA-125: 110
Aug-99	CA-125: 100
Aug-99	CA-125: 30
7/20/01	CA-125: 765
8/14/01	CA-125: 135

### Complementary therapy

10/97-5/98	Acupuncture
1998	Vitamin C and mistletoe, full body hyperthermia
9/19/00	Naltrexone 3mg qhs up to 6.5mg qhs
12/00-4/01	Went to Mexico had alternative cancer treatment with vaccine

# Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-6 (continued)

Patient # 2-6						
EVENT	PERIOD 1 1 <sup>st</sup> qtr 1995 – 4 <sup>th</sup> qtr 1995	PERIOD 2 1 <sup>st</sup> qtr 1998 – 4 <sup>th</sup> qtr 1998	PERIOD 3 1 <sup>st</sup> qtr 1999 – 4 <sup>th</sup> qtr 1999	PERIOD 4 1 <sup>st</sup> qtr 2000– 4 <sup>th</sup> qtr 2000	PERIOD 5 1 <sup>st</sup> qtr 2001 – 4 <sup>th</sup> qtr 2001	
Diagnosis/biopsy	8/95					
Surgery	8/95				2/01	
Radiation						
Chemotherapy	8/95 12/95	1998		10/01	1/01 4/01	
Naltrexone				9/00		
CT scan				8/00	4/01	
Tumor markers	8/95	1998	8/99	2000	7/01 8/01	
CAM other		1998		12/00	4/01	

# Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-6 (continued)

<b>CAM Therapy:</b>	Naltrexone		
<b>Case:</b>	2-6		
<b>Condition:</b>	Ovarian cancer		
<b>Abstractor:</b>		<b>Date of Abstraction:</b>	7/12/01
<b>Interviewer:</b>	AC	JU	<b>Date of Interview:</b> 10/9/01
<b>Comments:</b>	Fair case: patient increased pelvic thickening after 7 months of Naltrexone, per patient. Also on chemo		

Criteria for inclusion: (check all that apply)	
<input type="checkbox"/>	Diagnosis confirmed
<input checked="" type="checkbox"/>	Documented start date for CAM therapy
<input checked="" type="checkbox"/>	Documented previous anti-cancer therapies
<input type="checkbox"/>	No other therapies during the CAM therapy
<input type="checkbox"/>	Documented endpoint:
<input type="checkbox"/>	<input type="checkbox"/> Tumor size
<input type="checkbox"/>	<input type="checkbox"/> Longevity
<input type="checkbox"/>	<input type="checkbox"/> Quality of Life
<input type="checkbox"/>	Other: <input type="text"/>

Other Relevant Information:	
Sex:	female
DOB:	7/28/45
Diagnosis:	Ovarian cancer
Diagnosis date:	8/1/95
CAM therapy dates:	9/19/00
Conventional therapy dates:	8/95- surgery 8/95-1/96 chemotherapy
Last contact date:	8/14//2001
If deceased, date of death:	

## Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-6 (continued)

Date	Description of Events
	History of migraines, GERD
Aug-95	Surgery: ovariectomy and hysterectomy
Aug-95	Biopsy: Diagnosis of ovarian cancer in pelvis
Aug-95	CA-125: 65
Aug-95	CA-125: <35
8/95-12/95	Chemotherapy: taxol, cisplatin; 6 rounds completed
10/97-5/98	Acupuncture
1998	Vitamin C and mistletoe, full body hyperthermia
1998	CA-125: 200
1998	CA-125: 110
1998 or 1999	Chemotherapy: doxil, topotecan: 11 month- completed therapy; followed by doxil 12 months-completed therapy
Aug-99	CA-125: 100
Aug-99	CA-125: 30
8/28/00	CT scan abdomen compared with 9/11/98: 3.5cm cyst in posterior medial left hepatic lobe anterior to portal vein, unchanged, no sign of metastatic disease
8/28/00	CT scan pelvis: no sign of recurrent metastatic disease

## Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-6 (continued)

Date	Description of Events
9/19/00	Naltrexone 3mg qhs up to 6.5mg qhs
10/3/00	Chemotherapy: erythrotenecan and low dose taxol
12/00-4/01	Went to Mexico had alternative cancer treatment with vaccine
2/1/01	Surgery: laparoscopy: reportedly did not reveal anything
4/19/01	CT scan chest abdomen pelvis: few tiny nodular densities bilateral axilla, 1cm nodularity right lower lobe lung (new); few tiny cysts in liver; multiple soft tissue densities in liver; pelvic cyst 3.8cm
4/19/01	Chemotherapy: initiated due to lesions on liver presumably metastatic disease : camptothecin/cisplatin
7/20/01	CA-125: 765
8/14/01	CA-125: 135



**Additional Case Reviewed**

**Patient #2-14**

## Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-14

### Case 2-14

The patient in case 2-14 is an 11-year-old female with a history of metastatic neuroblastoma of the right adrenal gland. She was initially diagnosed in February 1996. She had surgery and palliative chemotherapy from March 1996 to December 1996. Response was inadequate and the patient had a stem cell transplant in February 1997. She also received one year of therapy at the Burzinski Clinic starting in August 1997. Recurrent disease was identified in the bone marrow in February 1999. [Naltrexone was initiated in July 1999.] A second course of chemotherapy (topotecan) was initiated in August 1999 but stopped early (February 2000) due to side effects. Currently, she is paralyzed in both lower extremities due to metastatic disease and her prognosis is poor according to the next of kin (interview 10/9/01).

#### Pathology

11/1/97	Biopsy: bone marrow- partial replacement of hematopoietic elements with sheets of aggregate malignant cells consistent with recurrent neuroblastoma
2/22/99	Biopsy: bone marrow- neuroblastoma
4/5/99	Biopsy: bone marrow- neuroblastoma
8/5/99	Biopsy: bone marrow- partial replacement by malignant cells
8/30/99	Biopsy: bone marrow-neuroblastoma
8/30/99	Biopsy: bone marrow- residual, recurrent neuroblastoma
11/16/99	Biopsy: bone marrow- residual, recurrent neuroblastoma
12/16/99	Biopsy: bone marrow- marked decrease of platelets, trilineage hematopoiesis with maturation, clusters of aggregates of malignant cells were not identified, but clot sections showed some irregular areas of fibrosis with aggregates of malignant cells consistent with metastatic neuroblastoma
2/23/00	Biopsy: bone marrow- hypercellular for patient's age

## Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-14 (continued)

### Imaging

7/29/97	CT scan: abdomen
3/12/99	CT scan: chest abdomen pelvis: lesions in L2 suspicious for metastatic disease
4/5/99	Bone scan: multiple foci of abnormal accumulation of the tracer in the sternum, thoracic spine, lumbar spine, both sacroiliac joints, and the left superior acetabular region and left anterior 11th rib
6/21/99	Bone scan: increased uptake in right humerus, sternum, T/L spine, left SI joint
6/24/99	CT scan abdomen/pelvis: new crural lymph node 1cm; 13mc paracaval lymph node minimally change in size with necrosis; 12mm x 11mm soft tissue density in gastric antrum which may represent a lymph node or lesion; new sclerotic lesion at T7
8/30/99	Bone scan: whole body- stable osseous lesions
11/18/99	Bone scans: no new lesions: T10 lesion improved: resolution of left tibial lesions
1/12/00	CT scan: eyes: normal
1/14/00	CT scan: abdomen/pelvis: no interval change T7, L2 vertebral lesions
2/22/00	Bone scans: no new lesions: improved but persistent bony changes

### Conventional therapy

3/1/96	Surgery: s/p right adrenalectomy
3/1/96	Chemotherapy- topotecan, anti-neoplasmen
2/97	Stem cell transplant
Jun-99	Platelet infusions-weekly
8/13/99	Surgery: central catheter placement
8/99 – 2/00	Chemotherapy – topotecan, stopped early due to side effects

### Complementary therapy

8/97 - 98	Burzinski clinic – anti-neoplastin therapy
7/21/99	Naltrexone 1.5mg qhs

# Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-14 (continued)

Patient # 2-14						
EVENT	PERIOD 1 1 <sup>st</sup> qtr 1996 – 4 <sup>th</sup> qtr 1996	PERIOD 2 1 <sup>st</sup> qtr 1997 – 4 <sup>th</sup> qtr 1997	PERIOD 3 1 <sup>st</sup> qtr 1998 – 4 <sup>th</sup> qtr 1998	PERIOD 4 1 <sup>st</sup> qtr 1999– 4 <sup>th</sup> qtr 1999	PERIOD 5 1 <sup>st</sup> qtr 2000 – 4 <sup>th</sup> qtr 2000	PERIOD 6 1 <sup>st</sup> qtr 2001 – 4 <sup>th</sup> qtr 2001
Diagnosis/biopsy	3/96	11/97		2/99 4/99 8/99 11/99, 12/99	2/00	
Surgery	3/96					
Radiation						
Chemotherapy	3/96					
CT scan		7/97		3/99 4/99 6/99, 8/99 11/99	1/00, 2/00	
Naltrexone				7/99		

## Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-14 (continued)

<b>CAM Therapy:</b>	Naltrexone		
<b>Case:</b>	2-14		
<b>Condition:</b>	Neuroblastoma of right adrenal		
<b>Abstractor:</b>	AC	IC	JU
<b>Date of Abstraction:</b>	9/15/01		
<b>Interviewer:</b>		<b>Date of Interview:</b>	10/9/01
<b>Comments:</b>	Good documentation of bone marrow biopsies, blood counts, CT's and bone scans, since starting naltrexone. However, pt has been receiving anti-neoplastin concurrently. Blood counts improved, but biopsies remain full of malignancy.		

Criteria for inclusion: (check all that apply)	
<input type="checkbox"/>	Diagnosis confirmed
<input type="checkbox"/>	Documented start date for CAM therapy
<input type="checkbox"/>	Documented previous anti-cancer therapies
<input type="checkbox"/>	No other therapies during the CAM therapy
<input type="checkbox"/>	Documented endpoint:
<input type="checkbox"/>	Tumor size
<input type="checkbox"/>	Longevity
<input type="checkbox"/>	Quality of Life
<input type="checkbox"/>	Other:

Other Relevant Information:	
Sex:	female
DOB:	9/27/90
Diagnosis:	Neuroblastoma of right adrenal stage IV
Diagnosis date:	9/1/97
CAM therapy dates:	7/21/99 Naltrexone started
Conventional therapy dates:	chemotherapy (dates unclear)
Last contact date:	6/01
If deceased, date of death:	

## Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-14 (continued)

Date	Description of Events
3/1/96	Surgery: s/p right adrenalectomy
3/1/96	Chemotherapy- topotecan, anti-neoplasmen
7/29/97	CT scan: abdomen
11/1/97	Biopsy: bone marrow- partial replacement of hematopoietic elements with sheets of aggregate malignant cells consistent with recurrent neuroblastoma
2/22/99	Biopsy: bone marrow- (results ?)
3/12/99	CT scan:chest abdome pelvis: lesions in L2 suspicious for metastatic disease
4/5/99	Biopsy: bone marrow- (results ?)
4/5/99	Bone scan: multiple foci of abnormal accumulation of the tracer in the sternum, thoracic spine, lumbar spine, both sacroiliac joints, and the left superior acetabular region and left anterior 11th rib
Jun-99	Platelet infusions-weekly
6/21/99	Bone scan: increased uptake in right humerus, sternum, T/L spine, left SI joint
6/24/99	CT scan abdomen/pelvis: new crural lymph node 1cm ; 13mc paracaval lymph node minimally change in size with necrosis; 12mm x 11mm soft tissue density in gastric antrum which may represent a lymph node or lesion; new sclerotic lesion at T7
7/21/99	Naltrexone 1.5mg qhs
8/5/99	X-ray: chest- no acute cardio-pulmonary process
8/5/99	Biopsy: bone marrow- partial replacement by malignant cells
8/13/99	Surgery: central catheter placement

## Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-14 (continued)

Date	Description of Events
8/13/99	X-ray: chest- no complications evident for previously described antral and porta hepatitis lymph nodes
8/30/99	Biopsy: bone marrow-neuroblastoma
8/30/99	Bone scan: whole body- stable osseous lesions
8/30/99	Biopsy: bone marrow- residual, recurrent neuroblastoma
11/16/99	Biopsy: bone marrow- residual, recurrent neuroblastoma
11/18/99	Bone scans: no new lesions: T10 lesion improved: resolution of left tibial lesions
12/16/99	Biopsy: bone marrow- marked decrease of platelets, trilineage hematopoiesis with maturation, clusters of aggregates of malignant cells were not identified, but clot sections showed some irregular areas of fibrosis with aggregates of malignant cells consistent with metastatic neuroblastoma
1/12/00	CT scan: eyes: normal
1/14/00	CT scan: abdomen/pelvis: no interval change T7, L2 vertebral lesions
2/22/00	Bone scans: no new lesions: improved but persistent bony changes
2/23/00	Biopsy: bone marrow- hypercellular for patient's age
2/17/00- 7/11/00	Serial CBC's: improving

**Additional Case Reviewed**

**Patient #2-16**



## Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-16

### Case 2-16

The patient in case 2-16 is a 62-year-old male with a history of squamous cell carcinoma of the lung with level 4 cervical lymph node involvement. He was diagnosed on 3/00. He declined conventional therapy. In June 2001, he was diagnosed with ascend primary melanoma. Naltrexone was initiated in June 2001. The cancer has continued to spread, and currently the patient has left-sided hemiparesis. His prognosis is poor but the patient reported at his interview (10/16/01) that his physical condition is very good.

#### Pathology

3/00	Chest biopsy: fine needle aspiration: squamous cell carcinoma
5/5/00	Lymph node biopsy: right neck non-small cell carcinoma
5/15/00	Chest biopsy aspiration: pathology: metastatic non-small cell carcinoma
6/15/00	Physical exam: 3cm x4cm hard node in right neck
10/27/00	Physical exam: 1.75cm x 2.5cm hard node in right neck
6/14/01	Biopsy, mid-back: pathology: melanoma in situ, closely approaching the margins
6/26/01	Physical exam: 3cm x4cm hard node in right neck
	Bronchoscopy: pathology: washings and brushing; negative for tumor

#### Imaging

2/29/00	CT scan chest: primary tumor in RML of lung; increased hilar/peritracheal nodes
3/15/00	CT scan: abdomen/pelvis: enlarged prostate: no evidence of metastatic disease
4/26/00	PET scan: whole body: right-sided cervical and right mediastinal malignant adenopathy
7/28/00	CT scan chest: extensive mediastinal lymphadenopathy: nodular densities in both lungs
11/10/00	CT scan chest: primary tumor in RML of lung (no change); hilar/peritracheal nodes (no change)

Conventional therapy  
none

#### Complementary therapy

6/1/01	Naltrexone 4.5 mg QHs
	Supplements: multiple nutritional supplements, MGN3, shitake mushroom, wheat grass

# Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-16 (continued)

Patient # 2-16						
EVENT				PERIOD 1 1 <sup>st</sup> qtr 1999– 4 <sup>th</sup> qtr 1999	PERIOD 2 1 <sup>st</sup> qtr 2000 – 4 <sup>th</sup> qtr 2000	PERIOD 3 1 <sup>st</sup> qtr 2001 – 4 <sup>th</sup> qtr 2001
Diagnosis/biopsy					3/00 5/00	6/01
Surgery						
Radiation						
Chemotherapy						
CT scan					2/00, 3/00 4/00 7/00 11/00	
Naltrexone						6/01

## Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-16 (continued)

<b>CAM Therapy:</b>	Naltrexone		
<b>Case:</b>	2-16		
<b>Condition:</b>	Lung squamous cell carcinoma with level 4 cervical lymph node		
<b>Abstractor:</b>	AC	IC	Ju
<b>Interviewer:</b>			
<b>Comments:</b>	Good documentation of improved quality of life, but decrease in neck node only documented on physical exam		

Criteria for inclusion: (check all that apply)	
<input type="checkbox"/>	Diagnosis confirmed
<input type="checkbox"/>	Documented start date for CAM therapy
<input type="checkbox"/>	Documented previous anti-cancer therapies
<input type="checkbox"/>	No other therapies during the CAM therapy
<input type="checkbox"/>	Documented endpoint:
<input type="checkbox"/>	<input type="checkbox"/> Tumor size
<input type="checkbox"/>	<input type="checkbox"/> Longevity
<input type="checkbox"/>	<input type="checkbox"/> Quality of Life
<input type="checkbox"/>	<input type="checkbox"/> Other: <input type="text"/>

Other Relevant Information:	
Sex:	male
DOB:	7/10/39
Diagnosis:	Lung squamous cell cancer, level 4 cervical lymph node
Diagnosis date:	3/1/00
CAM therapy dates:	6/15/00 Naltrexone
Conventional therapy dates:	none
Last contact date:	6/26/01
If deceased, date of death:	

## Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-16 (continued)

Date	Description of Events
	Brother died of stomach cancer
2/29/00	CT scan of lungs: reveals tumor and enlarged lymph nodes
	Biopsy done: results unknown
3/15/00	CT scan of abdomen (belly) and pelvis reveals enlarged prostate
4/26/00	PET scan reveals enlarged lymph nodes in chest
5/5/00	Biopsy done: reveals lung cancer
5/15/00	Biopsy done: reveals lung cancer
6/15/00	Physical exam: hard lymph node in right neck
6/15/00	Started Naltrexone
7/28/00	CT scan of lungs: reveals tumor and enlarged lymph nodes
	Started supplements: multiple nutritional supplements, MGN3, shitake mushroom, wheat grass
10/27/00	Physical exam: hard lymph node in right neck smaller compared with prior exam
11/10/00	CT scan of lungs: reveals tumor and enlarged lymph nodes, unchanged
6/1/01	Increased dose of Naltrexone
6/14/01	Biopsy done on mid-back: reveals melanoma

## Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-16 (continued)

Date	Description of Events
6/26/01	Physical exam: hard lymph node in right neck
	Exam whereby a small camera inserted into airway: Cells from exam do not reveal any cancer

**Additional Case Reviewed**

**Patient #2-17**

## Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-17

### Case 2-17

The patient in case 2-17 is a 68-year-old male with a history of multiple myeloma. He was diagnosed in September 1998. He has completed his first course of chemotherapy from August 1998 to October 1999. He initiated Naltrexone in January 1999. His immune globulin levels were followed closely, and showed an increase in June 2001. At that time he resumed chemotherapy with biacin, thalidomide, and decadron. Since that time his IgG levels have decreased and at his interview (10/8/01), the patient rated his overall physical condition as good.

#### Pathology

9/2/98	Biopsy bone marrow: marrow infiltrated by plasma cell c/w plasma cell myeloma
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#### Imaging

2/15/99	MRI: lumbar spine: nodule within cauda equina at L2; presumed to be small neuroma; chronic compression fractures in L1 and L5
6/1/99	X-ray: pathological fracture in 4 vertebrae in 2 ribs
1/3/00	MRI: lumbar spine: nodule at L2 unchanged: numerous punctate focal bony lesions throughout lumbar spine; presumed to represent tiny multiple myeloma deposits
6/22/00	Bone scan: whole body: increase uptake in regions T6, T8-T10

#### IgG levels

12/2/98	IgG 9290
4/14/99	IgG 5310
5/6/99	IgG 4130
6/3/99	IgG 4130
6/4/99	IgG 4180
7/14/99	IgG 2780
8/4/99	IgG 3100
8/30/99	IgG 2290
10/22/99	IgG 1260
12/5/99	IgG 1260
1/20/00	IgG 1400
2/17/00	IgG 1380
3/16/00	IgG 1500
4/11/00	IgG 1320
5/9/00	IgG 1280

**Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-17 (continued)**

6/8/00	IgG 1230
7/5/00	IgG 1240
8/2/00	IgG 1030
9/27/00	IgG 1550
10/26/00	IgG 1840
11/30/00	IgG 2030
1/2/01	IgG 2290
1/30/01	IgG 3110
2/21/01	IgG 3200
3/29/01	IgG 4520
8/1/01	IgG 649

**Conventional therapy**

9/98-10/99	Chemotherapy: AB/CM
2/99-10/99	Chemotherapy: cytoxan, melphalan, decadron, zofran q 3weeks
6/1/01	Chemotherapy: thalodimide, biaxin, decradron

**Complementary therapy**

1/29/99	Naltrexone 4.5 mg QHs
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## Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-17 (continued)

Patient # 2-17						
EVENT	PERIOD 1 1 <sup>st</sup> qtr 1995 – 4 <sup>th</sup> qtr 1995	PERIOD 2 1 <sup>st</sup> qtr 1998 – 4 <sup>th</sup> qtr 1998	PERIOD 3 1 <sup>st</sup> qtr 1999 – 4 <sup>th</sup> qtr 1999	PERIOD 4 1 <sup>st</sup> qtr 2000– 4 <sup>th</sup> qtr 2000	PERIOD 5 1 <sup>st</sup> qtr 2001 – 4 <sup>th</sup> qtr 2001	
Diagnosis/biopsy						
Surgery						
Radiation						
Chemotherapy		9/98	10/99		6/01	
Naltrexone			1/99			
Imaging			2/99 6/99	1/00 6/00		
CAM other						

## Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-17 (continued)

<b>CAM Therapy:</b>	Naltrexone		
<b>Case:</b>	2-17		
<b>Condition:</b>	Multiple-myeloma stage 3B		
<b>Abstractor:</b>		<b>Date of Abstraction:</b>	7/13/01
<b>Interviewer:</b>	AC	IC	JU
<b>Comments:</b>	Well-documented decrease in IgG with subsequent rise in IgG to pretreatment levels		

<b>Criteria for inclusion: (check all that apply)</b>	
<input type="checkbox"/>	Diagnosis confirmed
<input type="checkbox"/>	Documented start date for CAM therapy
<input type="checkbox"/>	Documented previous anti-cancer therapies
<input type="checkbox"/>	No other therapies during the CAM therapy
<input type="checkbox"/>	Documented endpoint:
<input type="checkbox"/>	<input type="checkbox"/> Tumor size
<input type="checkbox"/>	<input type="checkbox"/> Longevity
<input type="checkbox"/>	<input type="checkbox"/> Quality of Life
<input type="checkbox"/>	<input type="checkbox"/> Other: <input type="text"/>

<b>Other Relevant Information:</b>	
Sex:	male
DOB:	4/30/32
Diagnosis:	Multiple myeloma stage 3b
Diagnosis date:	9/2/98
CAM therapy dates:	1/29/99 Naltrexone
Conventional therapy dates:	
Last contact date:	
If deceased, date of death:	

## Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-17 (continued)

Date	Description of Events
9/2/98	Biopsy bone marrow: marrow infiltrated by plasma cell c/w plasma cell myeloma
9/98-10/99	Chemotherapy: AB/CM
12/2/98	IgG 9290
2/15/99	MRI: lumbar spine: nodule within cauda equina at L2; presumed to be small neuroma; chronic compression fractures in L1 and L5
2/99-10/99	Chemotherapy: cytoxan, melphalan, decadron, zofran q 3weeks
4/14/99	IgG 5310
5/6/99	IgG 4130
6/1/99	X-ray: pathological fracture in 4 vertebrae in 2 ribs
6/3/99	IgG 4130
6/4/99	IgG 4180
7/14/99	IgG 2780
8/4/99	IgG 3100
8/30/99	IgG 2290
10/22/99	IgG 1260
12/5/99	IgG 1260
1/3/00	MRI: lumbar spine: nodule at L2 unchanged: numerous punctate focal bony lesions throughout lumbar spine; presumed to represent tiny multiple myeloma deposits

## Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-17 (continued)

Date	Description of Events
1/20/00	IgG 1400
2/17/00	IgG 1380
3/16/00	IgG 1500
4/11/00	IgG 1320
5/9/00	IgG 1280
6/8/00	IgG 1230
6/22/00	Bone scan: whole body: increase uptake in regions T6, T8-T10
7/5/00	IgG 1240
8/2/00	IgG 1030
9/27/00	IgG 1550
10/26/00	IgG 1840
11/30/00	IgG 2030
1/2/01	IgG 2290
1/30/01	IgG 3110
2/21/01	IgG 3200
3/29/01	IgG 4520

## Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-17 (continued)

Date	Description of Events
6/1/01	Chemotherapy: thalodimide, biaxin, decradron
8/1/01	IgG 649

**Additional Case Reviewed**

**Patient #2-18**

## Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-18

### Case 2-18

The patient in case 2-18 is a 43-year-old woman with a history of breast cancer in her mother, who was diagnosed with breast cancer in November 1997. Axillary lymph nodes at the time of diagnosis were negative. She subsequently underwent a lumpectomy and radiation. In March 2000, an MRI of the right hip revealed bone metastases. Radiation to the affected hip was completed. She was started on tamoxifen and aridia in March 2000. Naltrexone was initiated in May 2000. During her interview (10/10/01), she rated her overall condition as very good, although results of a followup scan are mixed.

#### Pathology

11/1/97	Biopsy: breast cancer estrogen sensitive, nodes negative
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#### Imaging

12/1/99	X-ray right hip: normal
3/1/00	MRI: brain: questionable abnormality-repeated in 8 weeks
3/1/00	MRI hip—right femoral neck and mid-femur; right acetabulum; scattered throughout osseous of pelvis
May-00	CT chest: normal
5/1/00	MRI: brain: normal
9/1/00	CT chest: negative
9/6/00	MRI: hip - extensive metastatic involvement of right femur; patchy metastatic involvement of left femur head and neck
6/1/01	CT scan liver had small lesions
6/1/2001-8/01	Chemotherapy: AC completed
8/1/01	Liver lesions remain: oncologist monitoring
10/22/01	CT scan of chest abdomen and pelvis. Decrease nodularity at anterior mediastinum. Probable improvement in hepatic lesions, probable healing and improvement in some bony metastases with exacerbation of others

## Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-18 (continued)

### Tumor markers

<b>Mar-00</b>	CA 2729: 650
<b>5/11/00</b>	CEA 3.6 (0-5)
<b>12/1/00</b>	CA 2729: 79

### Conventional therapy

<b>11/1/97</b>	Surgery: lumpectomy breast
<b>6/1/98</b>	Radiation: right breast and right axilla: adverse effects—radiation edema
<b>Mar-00</b>	Radiation: pelvis: adverse effects—on crutches since 4/1/00
<b>3/15/00</b>	Started tamoxifen 10mg bid and aridia

### Complementary therapy

<b>5/13/2000-present</b>	Naltrexone
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# Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-18 (continued)

Patient # 2-18						
EVENT	PERIOD 1 1 <sup>st</sup> qtr 1997 – 4 <sup>th</sup> qtr 1997	PERIOD 2 1 <sup>st</sup> qtr 1998 – 4 <sup>th</sup> qtr 1998	PERIOD 3 1 <sup>st</sup> qtr 1999 – 4 <sup>th</sup> qtr 1999	PERIOD 4 1 <sup>st</sup> qtr 2000– 4 <sup>th</sup> qtr 2000	PERIOD 5 1 <sup>st</sup> qtr 2001 – 4 <sup>th</sup> qtr 2001	
Biopsy/diagnosis	11/97					
Surgery	11/97					
Radiation		6/98		4/00		
Chemotherapy						
Tamoxifen				3/00		
Naltrexone				5/00		
CAM other						
X-ray			12/99			
Imaging-MRI				3/00 5/00 9/00		
Imaging-CT scan				5/00 9/00	6/01 8/01	
Tumor markers				3/00 5/00		

# Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-18 (continued)

CAM Therapy:	Naltrexone		
	Case: 2-18		
	Condition: Breast carcinoma metastatic to femur and pelvis		
	Abstractor:	AC      IC      JU	Date of Abstraction: 7/13/01
	Interviewer:		Date of Interview: 10/10/01
Comments:			

Criteria for inclusion: (check all that apply)	
<input type="checkbox"/>	Diagnosis confirmed
<input type="checkbox"/>	Documented start date for CAM therapy
<input type="checkbox"/>	Documented previous anti-cancer therapies
<input type="checkbox"/>	No other therapies during the CAM therapy
<input type="checkbox"/>	Documented endpoint:
<input type="checkbox"/>	<input type="checkbox"/> Tumor size
	<input type="checkbox"/> Longevity
	<input type="checkbox"/> Quality of Life
	<input type="checkbox"/> Other: <input type="text"/>

Other Relevant Information:	
Sex:	female
DOB:	3/3/58
Diagnosis:	Breast cancer; metastatic to femur and pelvis
Diagnosis date:	11/1/97
CAM therapy dates:	5/13/00 Started Naltrexone
Conventional therapy dates:	9/98-10/00 - radiation
Last contact date:	5/1/01
If deceased, date of death:	

## Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-18 (continued)

Date	Description of Events
	History of breast cancer in mother-currently in remission
11/1/97	Surgery: lumpectomy breast
11/1/97	Biopsy: breast cancer estrogen sensitive, nodes negative
6/1/98	Radiation: right breast and right axilla: adverse effects- radiation edema
12/1/99	X-ray right hip: no tumor present
3/1/00	X-ray right pelvis: positive for mets to pelvis/spine
3/1/00	MRI: brain: questionable abnormality-repeated in 8 weeks
3/1/00	MRI hip--right femoral neck and mid-femur; right acetabulum; scattered throughout osseous of pelvis
Mar-00	Radiation: pelvis: adverse effects- on crutches since 4/1/00
3/15/00	Started tamoxifen 10mg bid and aridia
Mar-00	CA 2729: 650
May-00	CT chest: normal
5/1/00	MRI: brain: normal
5/11/00	CEA 3.6 (0-5)
5/13/00-present	Naltrexone
9/1/00	CT chest: negative

## Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-18 (continued)

Date	Description of Events
9/6/00	MRI: hip - extensive metastatic involvement of right femur; patchy metastatic involvement of left femur head and neck
12/1/00	CA 2729: 79
6/1/01	CT scan liver had small lesions
6/1/2001-8/01	Chemotherapy: AC completed
8/1/01	Liver lesions remain: oncologist monitoring

**Additional Case Reviewed**

**Patient #2-19**

## Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-19

### Case 2-19

The patient in case 2-19 is a 51-year-old male diagnosed with non-Hodgkin's lymphoma, small-cleaved cell type on 9/13/99. He declined conventional therapy and has pursued various unconventional therapies for cancer treatment, including Naltrexone (11/99). He has not been followed by any allopathic physician for over a year. While no recent imaging scans have been performed, he reports a submandibular lymph node that has grown to greater than 3cm over the past year. At his interview (10/18/01), the patient reported that his overall physical condition was good to very good.

#### Pathology

9/13/99	Biopsy: lymph node (iliac): Malignant lymphoma non-Hodgkin's, small cleaved cell type predominately follicular and focally infiltrative: working formulation low grade
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#### Imaging/labs

5/14/99	CT scan abdomen: significant mesenteric adenopathy with multiple enlarged nodes 6cm. Multiple retroperitoneal prominent lymph nodes 2cm
1/5/00	CT scan abdomen: nodes are generally smaller, less dense c/w 5/14/99. Largest retro-peritoneal node 1.5cm instead of 2cm. No additional adenopathy
7/10/00	CT scan abdomen: mesenteric adenopathy, smaller nodes and less dense/w prior exam. Scattered, small retroperitoneal also appear smaller measuring 1cm or less. No additional adenopathy. Improved mesenteric and retroperitoneal nodes.
1/19/01	NK cell function 79 (43-100)
1/19/01	Heavy metal screen: Mercury: 8.2 Nickel:11 Aluminum:12 Arsenic:53

#### Conventional therapy

None

#### Complementary therapy

11/22/99	Naltrexone 3mg Qhs
10/00-3/01	Removed mercury amalgam fillings; chelation therapy to remove mercury in blood, high dose vitamin C IV therapy
10/00-3/01	CoQ10; pancreatic enzymes, essential fatty acids; vitamin E; milk thistle; turmeric; DHEA; selenium; N-acetyl cysteine, pro biotics
4/01-8/01	PolyMVA
8/01-present	thymic protein; cereal grass (wheat, barley), digestive enzymes

# Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-19 (continued)

Patient # 2-19						
EVENT			PERIOD 1 1 <sup>st</sup> qtr 1999 – 4 <sup>th</sup> qtr 1999	PERIOD 2 1 <sup>st</sup> qtr 2000– 4 <sup>th</sup> qtr 2000	PERIOD 3 1 <sup>st</sup> qtr 2001 – 4 <sup>th</sup> qtr 2001	
Diagnosis/biopsy			9/99			
Surgery						
Radiation						
Chemotherapy						
Naltrexone				11/99		
Imaging			5/99	1/00 7/00		
CAM other			8/99			

## Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-19 (continued)

<b>CAM Therapy:</b>	Naltrexone		
<b>Case:</b>	2-19		
<b>Condition:</b>	Non-Hodgkin's lymphoma		
<b>Abstractor:</b>	AC	IC	JU
<b>Interviewer:</b>		<b>Date of Abstraction:</b>	7/11/01
<b>Comments:</b>		<b>Date of Interview:</b>	10/18/01
Excellent care of NHL with Naltrexone + acyclovir. CT documented regression			

Criteria for inclusion: (check all that apply)	
<input checked="" type="checkbox"/>	Diagnosis confirmed
<input checked="" type="checkbox"/>	Documented start date for CAM therapy
<input checked="" type="checkbox"/>	Documented previous anti-cancer therapies
<input checked="" type="checkbox"/>	No other therapies during the CAM therapy
<input checked="" type="checkbox"/>	Documented endpoint:
<input checked="" type="checkbox"/>	Tumor size
<input type="checkbox"/>	Longevity
<input type="checkbox"/>	Quality of Life
<input type="checkbox"/>	Other:

Other Relevant Information:	
Sex:	male
DOB:	12/28/50
Diagnosis:	Non-Hodgkin's lymphoma: well-differentiated follicular lymphocyte lymphoma; monoclonal B-cell
Diagnosis date:	9/13/99
CAM therapy dates:	10/22/99 Naltrexone
Conventional therapy dates:	none
Last contact date:	6/1/01
If deceased, date of death:	



## Appendix E: Other Naltrexone Cases Reviewed E-3 Patient #2-19 (continued)

Date	Description of Events
5/14/99	CT scan abdomen: significant mesenteric adenopathy with multiple enlarged nodes 6cm. Multiple retroperitoneal prominent lymph nodes 2cm
9/13/99	Biopsy: lymph node (iliac): Malignant lymphoma non-Hodgkin's, small cleaved cell type predominately follicular and focally infiltrative: working formulation low grade
9/13/99	Radiation recommended: patient refused due to patient preference
11/22/99	Naltrexone 3mg Qhs
1/5/00	CT scan abdomen: nodes are generally smaller, less dense c/w 5/14/99. Largest retro-peritoneal node 1.5cm instead of 2cm. No additional adenopathy
7/10/00	CT scan abdomen: mesenteric adenopathy, smaller nodes and less dense/w prior exam. Scattered, small retroperitoneal also appear smaller measuring 1cm or less. No additional adenopathy. Improved mesenteric and retroperitoneal nodes
1/19/01	NK cell function 79 (43-100)
1/19/01	Heavy metal screen: Mercury: 8.2 Nickel:11 Aluminum:12 Arsenic:53
10/00-3/01	Removed mercury amalgam fillings; chelation therapy to remove mercury in blood, high dose vitamin C IV therapy
10/00-3/01	CoQ10; pancreatic enzymes, essential fatty acids; vitamin E; milk thistle; turmeric; DHEA; selenium; N-acetyl cysteine, probiotics
4/01-8/01	PolyMVA
8/01-present	Thymic protein; cereal grass (wheat, barley), digestive enzymes
10/1/00-present	Submandibular node>3cm on physical exam (progressive); patient not followed by physician >1year