James Wm. Forsythe, MD, HMD **Board Certified Medical Oncologist Board Certified Internal Medicine Certified in Homeopathy**

www.DrForsythe.com



info@DrForsythe.com RenoWellnessDr@yahoo.com

The Immune Protocol

The Lite LDIPT Protocol TM

Out-Come Based Investigation 1000 Patients - 70 Months From 06/2010 – 04/2016 **Chemo-Sensitivity Testing** (CST/GENOMIC)

Integrative Medical Oncology Philosophy

"In Stage IV adult cancers of any origin improvement in *quality of life* issues is directly proportional to improvement to overall response rate. Even stable disease can be tolerated and metamorphosed into a chronic livable condition."

~James W Forsythe, MD, HMD~

Alternative Cancer Treatments The Immune Protocol™ + The Lite LDIPT Protocol ™

- Top Ten Take Home Points:
- 1. Integrative cancer medicine combines conventional and alternative treatments
- 2. Hope in victory over cancer with integrative cancer therapies
- 3. Genomic Testing (CST) on whole blood isolates circulating tumor blood cells
- 4. Genomic testing offers a blue print for individual's cancer treatments
- 5. Genomic testing defines top chemo agents most effective in the treatment of one's cancer
- 6. Genomic testing isolates supplements, herbs and vitamins that are most effective in the treatment of one's cancer
- 7. Insulin Potentiated Therapy (IPT) uses insulin as its target agent
- 8. CST + IPT + Lipoic –Acid-Palladium (LAPd) Compound produces higher survivorship rates
- 9. Immune Protocol™ + Lite LDIPT Protocol™ + Lipoic –Acid-Palladium (LAPd) shows overall survivorship rate of 71% over a 70 month period in 1000 Stage IV cancer patients
- 10. Freedom to choose alternative cancer treatments is your right

Original Mission Of The Immune Protocol™/ The Lite LDIPT Protocol™

Test efficacy of CST + Lite LDIPT with the following:

- 1. Low-Dose Chemo + Immune Protocol ™
- 2. Lipoic-Acid-Palladium (LAPd) Complex, IV
- 3. Immune Protocol™ + Lite LDIPT Protocol ™ + CST
- 4. Lite LDIPT Protocol ™

Three Goals of Study

1. To prove Integrative Cancer Treatments *NOT* only work but are *SUPERIOR* to current 5 year survival statistics as reported in the Clinical Journal of Oncology as 2.1% in adult Stage IV cancers after 5 years of chemotherapy.

Three Goals of Study (continued)

2. To prove using genetic chemosensitivity testing on circulating tumor blood cells (CTCs) provides a "Blueprint" for patients by pinpointing the most effective chemotherapy drugs, targeted agents, hormonal therapies and natural supplements in order to produce lasting durable remissions and possible "cures".

Three Goals of Study (continued)

3. To prove that giving low-dose, non-toxic Insulin Potentiation Therapy (IPT) without employing the "therapeutic moment" can be equally effective without the risks of severe hypoglycemic reactions. This is called The Lite LDIPT Protocol ™.

Inquiring Cancer Patients Want to Know

Question:

What are your outcome survival statistics?

Answer:

Results of CWC's current outcome based study of 1000 patients at 70 months.

Inquiring Cancer Patients Want to Know

Questions:

What parameters are you measuring?

Answer:

The following parameters are recorded:

Inquiring Cancer Patients Want to Know (continued)

Answer:

The following parameters are recorded:

- A. Initials of patient (HIPPA rules)
- **B.** Date of Pathologic DX
- C. Start date of The Immune Protocol ™
- D. Cancer DX
- E. Prior Therapy

Inquiring Cancer Patients Want to Know (continued)

Answer:

The following parameters are recorded:

- F. Use of LAPd
- G. Whether given full-dose chemo or IPT Lite
- H. Use of CST
- I. Adverse events from therapy
- J. Current status: CR, PR, SD, EX

The Immune Protocol ™/ Lite LDIPT Protocol ™ 70 Month Report on 1000 Stage IV Adult Cancer Patients

Survival Column requirements:

- 1. Stable Remission for at least one month
- 2. Must have measurable parameters

Earlier Lipoic-Acid-palladium- (LAp) Study 2004-2006

- 225 patients with Stage IV cancers of multiple origins
- Lipoic-Acid-palladium (LAPd)-alone
- LAPd + Chemotherapy
- Study audited by FDA
 - 6 year Overall Survival (OS) rate of 32%

Lipoic-Acid Palladium- (LAPd) THE PRODUCT

- 1. A patented palladium lipoic compound (LAPd)
- 2. MVA: Minerals: molybdenum, rhodium & ruthenium Vitamins: B1, B2, B12
 Amino Acids: formyl-mcthionine, acetylcysteine
- 3. Palladium (Pd) is a rare metal often combined with platinum in jewelry. M.W. 106 found in nature alloyed with platinum, copper and nickel. Highly conductive metal.
- 4. ALA a super antioxidant and detoxifier. It is both water and fat soluble. It is an effective chelator with heavy metals.
- 5. Ongoing study of 225 patients with Stage IV cancers of multiple origins at six years shows an Overall Survival (OS) of 32% when used alone or with chemotherapy.

Past and Ongoing Clinical Outcome – Based Cancer Studies

TIME	PRODUCT	Mode of Action
2002-2003	Paw-paw NSP	Energetics
2004-2006	Lipoic-Acid- Palladium (LAPd)	Hyper-energizes Promotes Apoptosis
2010- Present	Immune Protocol [™] + CST + Lite LDIPT Protocol [™]	Immune Boosters + CST + Lite LDIPT

FINDING THE "TRIGGER" FOR CANCER

Potential Cause(s)	Tests
Heavy Metal Toxins	Hair, Blood, Urine
Chemical Toxins	Blood ELISA
Allergies: food and inhalants	Blood & Skin
Viral and Fungal Etiologies	HPV, HIV, EBV,HEP B/C
Immune Competence	Lymph Subset & NKC panels
Hormonal Imbalance	Saliva & Blood

Unique Characteristics of Cancer Cells Used in Integrative Oncology

- Simple Sugars malignant cells have increased numbers of insulin receptors to attract sugar molecules (i.e. PET Scan basis)
- Acidity A lower intracellular ph in the biological terrain is ideal for malignant cell growth – hence use the value of alkalinization – (i.e. zeolite, cesium or green powders)
- Hypoxia Malignant cells use anaerobic metabolism primarily thus the value of various O2 therapies – HBO / H2O2 / Ozone
- Low Voltage Malignant cells are low energy systems and produce only 5% ATP of normal cells – thus hyper-energizing therapy – LAPd

Conventional Oncology Examples of First, Second & Third Line Chemo Protocols used in Stage IV Cancers

Cancer Origin	Stage	1st	2nd	3rd
		Taxane	Xeloda	Navelbine
BREAST	IV	Cytoxin/ADR		
CRC	IV	FOLFOX	FOLFERI	XELODA
		+/- Avastin	+/-	+/- Erbitux
			Avastin	
H/N	IV	5FU/Carbo	Taxane	Erbitux
				+/- MTX
LUNG	IV	Carbo/Taxol	Tarceva	Nav/GEM
OVARY	IV	Carbo/Taxol	DOXIL	GEM/TOPO
PROSTATE	IV	Zoladex	KETO/HC	Taxotere/MITOX
		+/- Casodex	ZYTIGA	+ Pred

INVESTIGATION TUMOR PARAMETERS

- 1. HX & Physical Exam tumors in skin, liver, spleen lymph nodes, etc...
- 2. X-Rays: tumors detectable in CXR, bone X-Rays, mammograms, etc...
- 3. CT Scanning: tumors detectable in brain, chest, abdomen, pelvis or bones*
- 4. Ultrasounds: breasts, GB., liver, ovaries, spleen, etc...
- 5. MRI's: brain, neck, sinuses, joints, breasts, muscles, soft tissues, etc...
- 6. Pet Scans: total body scanning
- 7. Chemo-sensitivity Testing on whole blood
- 8. Hormonal balancing testing-saliva or blood
- 9. Appropriate tumor markers

*I discourage excessive use of CT/PET /BONE scanning

(Delivers 600x the radiation exposure of a CXR)

Excessive Imaging Used in Conventional Oncology

"Overuse of Imaging Adds \$500 million in healthcare costs, 500 more cancer cases a year, study finds."

^{*} Source: The American Journal of Managed Care 11/14, Vol 20

Tumor Markers

- 1. Bladder NMP-22, BTA
- 2. Breast CEA, CA 27-29, CA-15-3
- 3. Colorectal CEA, CA 19-9, 5HIAA (Carcinoids)
- 4. Esophagus CEA, CA 19-9
- 5. Gastric CEA, CA 19-9
- 6. Liver AFP, CEA, & CA19-9
- 7. Lung CEA, CA 19-9
- 8. Lymphomas ESR, LDH, Beta 2 Microglobulin, SPE
- 9. Myeloma B2MG, SPE, LDH, ESR
- **10.Pancreas CEA, CA 19-9**
- 11.Prostate PSA, Free PSA
- 12.0vary CA-125
- 13.Testes AFP, HCG

HISTORICAL CONTROLS CHEMO-RESISTANT Stage IV LITERATURE REVIEW - LONGEVITY

CANCER ORIGIN	STAGE IV HISTORICAL CONTROLS (Chemo-resistant) on Longevity
Breast	6 – 18 months
Colorectal	3 – 6 months
Head / Neck	4 – 8 months
Hematological	3 – 12 months
Lung	3 – 6 months
Prostate	6 – 18 months

THE IMMUNE PROTOCOL ™ **Proprietary Blend**

- 1. Normal Saline
- 2. B Complex
- **Pyridoxine**
- Vitamin B-12
- Vitamin C
- Magnesium Chloride 12. Selenium

- 7. L-Lysine
- 8. Zinc
- 9. DMSO
- 10. Folic Acid
- 11. L-Glutathione

THE IMMUNE PROTOCOL ™ THE LITE LDIPT PROTOCOL ™ 1000 Patient Safety Profile IV / Oral LAPd / CST / Investigation

Nausea / Vomiting	<1%
Diarrhea (oral only)	<5%
Short of Breath	<5% (40 ml only)
Skin Rash	<5%
ABN Liver Tests	<2%
Transfusion Reactions (shakes/chills)	<5%
ABN Renal Tests	<1%
Sulfa Allergies (DMSO)	<5%

Standard 3 Weeks The Immune Protocol ™The Lite LDIPT Protocol ™ (06/10-04/16)

- Monday Immune Protocol ™ + LAPd IV
- Tuesday Lite LDIPT [™] + L-Glutathione IV
- Wednesday Super "C" 50 grams + H2O2 IV
- Thursday Lite LDIPT [™] + L-Glutathione IV
- Friday Immune Protocol ™ + LAPd

DC to home on maintenance CT / Targeted treatments for 3 mos-return visits after 3 mos

Monitor appropriate X-Rays, MRIs, US's, and CXR's

RGCC TESTING LAB – GENE PROBES

TS	DNA	EGF
DHFR	M-TRANS	TGFb
TUBULIN	O6AT	MMP9
ТОРО	DNAdeam	NUC-REDUCT
SHMT	MPP	COX-2
DPD	LRP	S-lox
IP	GST	SS-r
p27	BEGF	C-erb2
p53	PDGF	ER/PR

The Greek RGCC Supplement Sample Recommendations

Artemesia	LAPd	Salvestrol	Ellagic acid
H2O2	Thalid	Uncara tom	L-Meth
Vitamin C	Quercetin	Carcitrol	NAC
Vitamin B6	Cox-2	Noni juice	Vitamin B3
Mistletoe	Cytokines	Acetogen	L-carnitine
Ukrain	Carnivora	Cesium CI	Vitamin E
Vitamin B17	COQ 10	Mitake	SOD
Coll Silver	Essiac tea	Curcumin	Selenium
DIM	Mod cit pec	Green tea	Aloe Vera
C-Statin	IP-6	Melatonin	Alpha IFN

RGCC Chemosensitivity Testing Commonly Recorded Supplements

Quercetin	LAPd
Artemesia	Salvestrol
Vitamin C	Ukrain
C-Statin	DIM
Vitamin D3	Paw-Paw
Mistletoe	Curcumin

Total Survivors on The Immune and Lite LDIPT Protocols + CST 1000 Patients 70 Months Study

Survivors: 710/1000
Percent Survivors = 71%

The Immune Protocol ™ CST + The Lite LDIPT Protocol ™

Response Rates at 70 months 1000 patients with Stage IV Cancers

Cancer Origin	Total #	% Survivors
Bladder	21	71
Brain	23	69
Breast	295	85
Colorectal	85	70
Gastric/Esop	20	60
Head/Neck	51	62
Lung	90	52
Myeloma	39	87

The Immune Protocol ™

CST + The Lite LDIPT Protocol™

Response Rates at 70 months 1000 patients with Stage IV Cancers

Cancer Origin	Total #	% Survivors
NHL/CLL	25	83
Ovary	45	78
PAN/GB	35	57
Prostate	90	82
Renal Cell	20	70
Sarcomas	24	58
Thyroid	7	100
UT/CX	50	63

Overview

The Contribution of Cytotoxic Chemotherapy to 5-year Survival in Adult Malignancies

Graeme Morgan*, Robyn Ward†, Michael Barton!

*Department of Radiation Oncology, Northern Sydney Cancer Centre, Royal North Shore Hospital, Sydney, NSW; †Department of Medical Oncology, St Vincent's Hospital, Sydney, NSW; ‡Collaboration for Cancer Outcomes Research and Evaluation, Liverpool Health Service, Sydney, NSW, Australia

ABSTRACT:

Aims: The debate on the funding and availability of cytotoxic drugs raises questions about the contribution of curative or adjuvant cytotoxic chemotherapy to survival in adult cancer patients.

Materials and methods: We undertook a literature search for randomised clinical trials reporting a 5-year survival benefit attributable solely to cytotoxic chemotherapy in adult malignancies. The total number of newly diagnosed cancer patients for 22 major adult malignancies was determined from cancer registry data in Australia and from the Surveillance Epidemiology and End Results data in the USA for 1998. For each malignancy, the absolute number to benefit was the product of (a) the total number of persons with that malignancy; (b) the proportion or subgroup(s) of that malignancy showing a benefit; and (c) the percentage increase in 5-year survival due solely to cytotoxic chemotherapy. The overall contribution was the sum total of the absolute numbers showing a 5-year survival benefit expressed as a percentage of the total number for the 22 malignancies.

Results: The overall contribution of curative and adjuvant cytotoxic chemotherapy to 5-year survival in adults was estimated to be 2.3% in Australia and 2.1% in the USA.

Conclusion: As the 5-year relative survival rate for cancer in Australia is now over 60%, it is clear that cytotoxic obemotherapy only makes a minor contribution to cancer survival. To justify the continued funding and availability of drugs used in cytotoxic chemotherapy, a rigorous evaluation of the cost-effectiveness and impact on quality of life is urgently required. Morgan, G. et al. (2004). Clinical Oncology 16, 549-560

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Key words: Chemotherapy, combined modality treatment, palliarion, quality of life, radiotherapy, survival

Stage IV Cancer Case Histories The Immune Protocol ™ CST + Lite LDIPT Protocol ™

Patient	Age	R/G	Cancer	Mets
R.T.	57	WF	Left Breast	Chest Wall
I.D.	58	BF	Ovarian	Pulmonary
C.C.	73	WF	Esophageal	Lung
E.U.	64	WF	Ovarian	Lung
E.D.	77	WM	ST Sarcoma	Testes
P.N.	48	WM	Appendix	Pseudomyxoma Peritoneii
J.S.	27	WF	Hodgkin	chest

Stage IV Cancer Case Histories The Immune Protocol ™ CST + Lite LDIPT Protocol ™

Patient	Age	R/G	Cancer	Mets
G.T.	69	WM	Prostate	L-S Spine
W.G.	77	WM	Prostate	Bones
R.W.	66	WF	Breast	Bones
A.A.	27	WF	NHL	Spinal
J.T.	28	WM	CRC	Peritoneal
M.N.	48	WF	Thyroid	Lungs
A.S.	51	WF	ACC	Lungs

Stage IV Cancer Case Histories The Immune Protocol ™ CST + Lite LDIPT Protocol ™

Patient	Age	R/G	Cancer	Mets
K.P.	65	WF	Renal	Lung
C.S.	75	WM	Prostate	Bones
J.J.	52	WF	NHL	Lung
C.M.	54	WM	Myeloma	Bones
C.C.	69	WM	Prostate	Spine & Pelvic
M.C.	73	WF	NSC Lung	Liver

Case # 1 R.T.

A 57 y.o. postmenopausal, white female with Stage IV left Breast CA with chest wall mets. DX 2008. Tumor ER/PR (+) and HER-2 (-). Tumor makers normal at time of dx. Mets when came to clinic in 2009 and started treatment in 2010 with The Immune Protocol ™ using LAPd following chemosensitivity genomic testing on CTC's. Following the gene testing she was offered The Lite LDIPT Protocol ™, to be given over a three week period, twice weekly, with The Immune Protocol ™ on Monday, Wednesday and Friday. The Immune Protocol ™ consisted of LAPd, hydrogen peroxide, high dose Vit C, The Immune Protocol™ I.V., and the L-glut-I.V. The patient is seen at yearly intervals. She continues free of disease and with no evidence of residual disease in her chest wall or elsewhere. Her performance status is 100% after five years.

Case # 2 I.D.

A 58 y.o. postmenopausal, black female dx with Stage IV adenocarcinoma of the ovaries with mets to her lungs and mediastinum in 2008. Her initial conventional tx was that of standard protocol chemo with carboplatin plus Taxol. First seen by me in 2010 and offered genomic testing. This was done and she was treated with The Immune Protocol ™ + LAPd using the two best drugs offered by the gene report. Drugs given twice weekly with The Lite LDIPT Protocol ™, and on Mondays, Wednesdays and Fridays of each week she was given the various immune therapies as listed above. CT scan of abdomen and chest showed no disease. Her cancer maker CA 125 is normal has been off all chemo and hormonal therapies for the past five years.

Case # 3 C.C.

74 y.o. widowed white female dx with Stage IV adenocarcinoma of the gastroesophageal junction in 2006. Refused chemo as she had mets to her lungs, given six months to one year prognosis. First seen by me in 2008 for second opinion offered genomic testing and IPT. Returned started tx in 2010 with The Immune Protocol ™ consisting of three days per week of immune-stimulating therapy plus, LAPd and two days per week of The Lite LDIPT Protocol ™. The patient has been in a prolonged, complete remission showing disappearance of all chest wall metastases and no new lesions in her mediastinum, liver, lungs or bones. Her tumor markers, CEA and CA 19-9 remain normal and she has a 90% performance status for five years.

Case # 4 E.D.

A 77-year-old, divorced, white male who was dx in 2009 as having liposarcoma with mets into the right testes, right inguinal canal, and the right groin. Started tx in 2010 with The Immune Protocol ™ three days per week, The Lite LDIPT Protocol ™ two days per week for a three-week period, and then he was discharged on oral chemo and followed at threemonth intervals until this date. He continues to survive and has a 100% performance status. As no tumor markers are available for sarcomas, no lab confirmations of his complete remission are available other than the follow-up scans, pelvic x-rays and ultrasounds of this area. He remains stable after five years.

Case # 5 P.N.

A 48-year-old, white, single male who was diagnosed with adenocarcinoma of the appendix complicated by massive ascites and a condition called "pseudomyxoma peritonei". The patient was first dx in 2008 with exploratory laparotomy. He refused all conventional therapies, including aggressive surgery, radiation and chemo. He came to see me in 2009, and after agreeing to CST started tx in 2010 given The Immune Protocol [™] + LAPd three days per week, The Lite LDIPT Protocol [™] two days per week for a three-week period, and then discharged on oral-effective chemo agents at a 50% dosage. The patient has required no paracentesis, as the ascites fluid is very thick, mucoid and gelatinous, and it is possible to drain through a standard paracentesis procedure. The patient is wellcontrolled, has some ascites, but functional and maintains a part-time employment in a stable remission and has not used any ambulatory-assistive devices. He remains stable after five Years.

Case # 6 M.N.

A 49-year-old, white, married female, college professor, who was diagnosed with Stage IV papillary thyroid carcinoma with pulmonary metastases in 2008. She was first seen by me in 2010 and received CST, following which she was treated with The Immune Protocol ™ + LAPd three days per week and The Lite LDIPT Protocol [™] two days per week. This resulted in a complete remission with disappearance of all lung metastases and the development of a 100% performance status. The patient has been off all chemotherapy treatments for the past four years.

Case # 7 T.M.

A 44-year-old, white, married male with Stage IV adenocarcinoma of the pancreas with liver mets, dx via needle biopsy for liver mets in 2010. This patient was initially seen by me shortly after his dx and underwent CST, which was followed by tx with The Lite LDIPT Protocol ™ given twice weekly for three weeks, with the other three days per week being occupied by treatment with The Immune Protocol ™ plus LAPd. Following three weeks of I.V. therapy the patient was sent home on oral Tarceva, to be taken once daily. The patient has been in a stable remission for the past five years and he has not required other systemic, low-dose chemo.

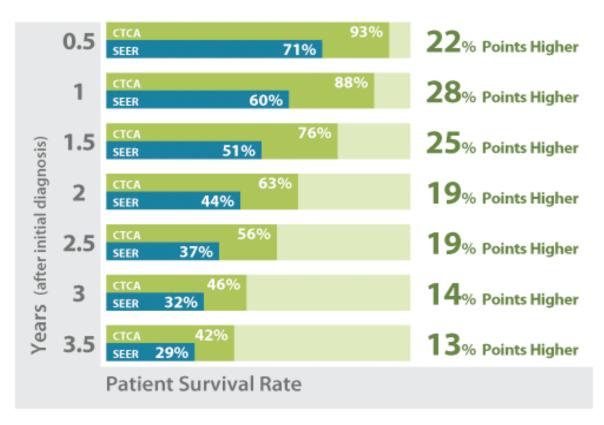
Case # 8 C.M.

A 54-year-old, white, married male, doctor of chiropractic's, who was dx with multiple myeloma in 2005. He received conventional therapies for the next several years. He first saw me in 2010 with Stage IV disease, with extensive bony mets. He underwent CST followed by treatment with The Immune Protocol ™ and LAPd. The Lite LDIPT Protocol ™ was given two days per week with The Immune Protocol ™ and other therapies given on Mondays, Wednesdays and Fridays for a three-week period. He was discharged on oral medications, according to genetic sensitivity testing. He has been in a prolonged durable remission for the past four years and has, in fact, written a book about his excellent progress.

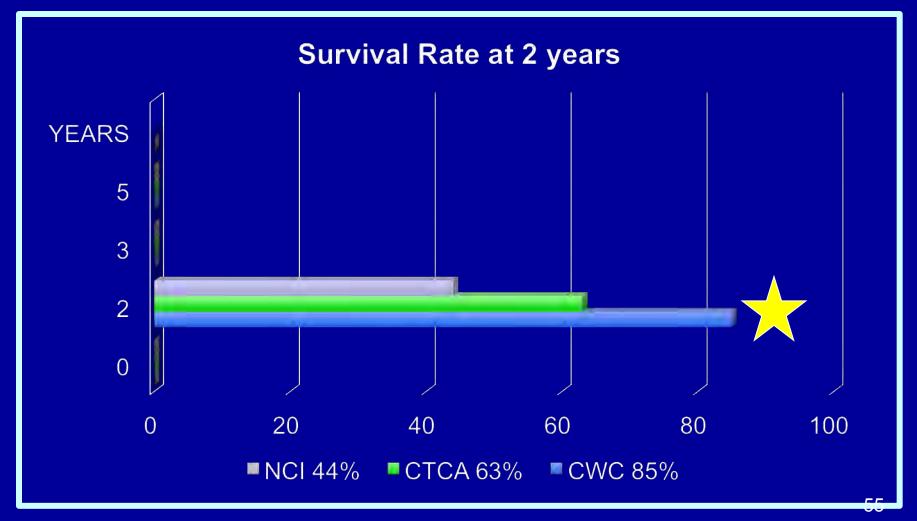
Case # 9 K.P.

A 65-year-old, white, married female with renal cell carcinoma with mets to her lungs, and diagnosed with Stage IV disease at the time of diagnosis in 2007. The patient first saw me in 2010 and underwent chemosensitivity genomic testing. She was treated with The Immune Protocol ™ plus LAPd three days per week and The Lite LDIPT Protocol ™ two days per week. She was then discharged on oral medications and has been followed by myself and other physicians since that time. She currently remains in excellent remission for five years.

Advanced Stage Breast Cancer Survival Rate Patients Diagnosed Between 2000-2005 Cancer Treatment Centers of America



Immune Protocol ™ / Lite LDIPT Protocol ™ + CST Comparing Stage IV Breast Cancers



Stage IV Breast Cancer Survival 1000 Patients 70 Months Study

Cases	Patients Survival	Percent Survival
295	245	83

Stage IV Lung Cancer Survival 1000 Patients 70 Months Study

Cases	Patients Survival	Percent Survival
88	47	52

Stage IV Prostate Cancer Survival 1000 Patients 70 Months Study

Cases	Patients Survival	Percent Survival
90	73	82

Stage IV Colorectal Cancer Survival 1000 Patients 70 Months Study

Cases	Patients Survival	Percent Survival
80	55	68

Conclusions: Conventional Chemotherapy Results

* Five year Overall Survival Rate (OS) Stage IV Cancers	Adjuvant Cytotoxic Chemotherapy for 22 major adult malignancies
United States	2.1%
Australia	2.3%

^{*}Reported from the Journal of Clinical Oncology (2004) 16:549-560

The Immune Protocol ™/ CST + Lite LDIPT Protocol ™ Summary 1000 Patients over 70 months

- Integrative Oncology attempts to treat the whole patient-not just an organ i.e. prostate, lung, etc...
- CWC patients undergo a thorough hx and physical exam and complete review of pathological, radiological and lab data similar to conventional oncology.
- More than the above CWC studies patients' emotional health, underlying toxicities, toxic heavy metals, allergies, chemicals, dental health and infections.

The Immune Protocol ™/ CST + Lite LDIPT Protocol ™ Summary 1000 Patients over 70 months

- The most important new addition to The Immune Protocol ™
 program is the addition of chemo-sensitivity testing different
 families of chemotherapy agents along with 50 separate
 supplements performed on whole blood genetic decoding.
- The chemo-sensitivity labs internationally are:
 Germany Biofocus; Greece-Research Genetic Cancer Centre.
- The <u>70 month</u> results on <u>1000</u> patients shows a survivorship of <u>71%</u> – aiming for results for 10 years with 1000 patients counted.
- The Immune Protocol ™ / Lite LDIPT Protocol ™ program offers patients a full spectrum menu which is based on their own choices guided by chemo-sensitivity and supplement sensitivity testing.

Integrative Medical Oncology Philosophy (continued)

This is true provided that this improvement is not gained at the expense of toxic chemotherapy or radiation therapy leaving the patient with many of the following adverse side effects:

- Chemo Brain Syndrome
- Painful Neuropathies
- Cardiomyopathies
- Renal Failure / Platinum toxicities /Hepatic Failure
- Severe Pancytopenias
- Pulmonary Fibrosis
- Devastating Fatigue, Anorexia and Wasting Syndromes
- Osteoarthritis, myalgias, osteoporosis
- Severe dermatoses
- Death

This study shows that the "cure or kill" approach to advanced cancer treatment is not the only answer.

Freedom of Healing Is Your Right

"The Constitution of this Republic should make provisions for healing freedom as well as religious freedom. To restrict the art of healing to one class of men and deny equal privileges to others will constitute the bastille of medical science. Such restrictions are fragments of monarchy and have no place in a republic."

~Benjamin Rush, MD~

