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Out-Come Based 60 Month Clinical Trial
The Forsythe Immune Therapy (FIT)
500 Cancer Stage IV Adult Patients
June 2005 – June 2010

Mission of the Forsythe Immune Therapy (FIT) Study

- **Efficacy of Glyco-Benzaldehyde with:**
 - 1. Low-Dose Chemotherapy**
 - 2. Poly MVA**
 - 3. Glyco-Benzaldehyde alone**

FIT 60 Month Report on 500 Stage IV Adult Cancer Patients

- **Survival Column requirements:**

- 1. Stable Remission for at least one month**
- 2. All patients counted even if expired**
- 3. Must have measurable parameters**

Initial Study with Poly-MVA

- 225 patients with Stage IV cancers of multiple origins
- Poly MVA alone
- Poly MVA + Chemotherapy

Current 6 year Overall Survival (OS) rate of 32%

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

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

FIT / POLY-MVA INVESTIGATION TUMOR PARAMETERS

- 1. 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**

FIT / POLY-MVA

INVESTIGATION 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**
- 9. Pancreas – CEA, CA 19-9**
- 10. Prostate – PSA, Free PSA**
- 11. Ovary – CA-125**
- 12. Testes – AFP, HCG**

HISTORICAL CONTROLS CHEMO-RESISTANT LITERATURE REVIEW - LONGEVITY

CANCER ORIGIN	STAGE IV HISTORICAL CONTROLS (Chemo-resistant) on Longevity
Breast	6 – 12 months
Colorectal	3 – 6 months
Head / Neck	4 – 8 months
Hematological	6 – 8 months
Lung	3 – 6 months
Prostate	6 – 9 months

5 YEAR – 500 PATIENT FIT STUDY

CANCER ORIGIN	TOTAL CASES	OS	% SURVIVORS
ALL	2	0	0
AML	7	1	14
APPY	3	2	67
BLADDER	4	3	75
BRAIN	9	3	33
BREAST	110	68	61
CLL	2	2	100
CRC	62	26	41
ESOPH	8	2	25

CANCER ORIGIN	TOTAL CASES	OS	% SURVIVORS
GASTRIC	6	1	17
H/N	20	7	35
HEP/GB	8	1	12
HOD DIS	5	3	60
LUNG	65	19	29
MEL	15	6	40
MESO	2	1	50
MYEL	4	3	75
NE PAN	2	1	50
NHL	15	12	80
OVARY	22	7	31

CANCER ORIGIN	TOTAL CASES	OS	% SURVIVORS
PAN	20	6	30
PROST	55	35	63
RENAL	11	2	18
SARC	14	6	42
TESTES	3	2	67
THYROID	6	6	100
UTER	19	7	36
WALD	1	1	100
TOTAL	500		

Safety Profile

IV / Oral Poly-MVA / FIT Investigation

Nausea / Vomiting	0%
Diarrhea (oral only)	<5%
Short of Breath	<5% (40 ml only)
Skin Rash	0%
ABN Liver Tests	0%
Transfusion Reactions (shakes/chills)	<5%
ABN Renal Tests	0%
Sulfa Allergies (DMSO)	<5% 12

5 Year – 500 Patient FIT Study Survival Statistics 223/500

Remission Parameters	CR	PR	SD
TOTAL	38	65	120
FRACTION	38/500	65/500	120/500
%	8	13	24

**TOTAL SURVIVORS ON
Glyco-Benzaldehyde ALONE**

5 YEAR - 500 PATIENT FIT STUDY

$$20/223 = 9\%$$

TOTAL SURVIVORS ON

Glyco-Benzaldehyde +PolyMVA

5 YEAR - 500 PATIENT FIT STUDY

$$87/223 = 39\%$$

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 5 year results on 500 patients show results that are 22 times superior to those reported in 2004.**

Forsythe Immune Therapy (FIT)

500 Patients over 60 months

- **Integrative Oncology attempts to treat the whole patient-not just an organ i.e. prostate, lung, etc...**
- **Patients undergo a thorough history and physical exam and complete review of pathological, radiological and lab data similar to conventional oncology.**
- **More extensive and many times more importantly studies patients' emotional health, underlying toxicities, toxic heavy metals, allergies, chemicals, dental health and other concerns are discussed, reviewed and investigated.**

Forsythe Immune Therapy (FIT) 500 Patients over 60 months data.

- The best responders in our ongoing FIT study were:

Cancer	%
Appendix	67
Bladder	75
Breast	61
Hodgkin's Disease	60
Myeloma	75
NHL	80
Prostate	63
Thyroid	100

Integrative 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 transformed into a chronic livable condition.

Integrative Oncology Philosophy

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

This investigation further supports that the “*cure or kill*” approach through chemo and radio therapy especially in advanced cancer treatment is not the best solution and we need to further investigate other options like palladium lipoic complex’s.