

John Paul II Medical Research Institute

Personalized Cancer Medicine

May, 2014

About Us



- The John Paul II Medical Research Institute (JP2MRI) seeks to find cures and therapies exclusively using a variety of adult stem cells and cancer cells.
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- No embryonic stem cell research.
- Developing research technologies that advance drug discovery and regenerative and personalized medicine for chronic disease, rare diseases and cancer.
- Engaged in educational outreach to increase number of scientists and medical practitioners that will work with adult stem cells.
- Emphasis on medical bioethics that is consistent with the dignity of human life.

Cancer Overview



- **Focus:** Reduce the bottlenecks and streamline drug development for therapeutic areas underdeveloped and underperformed by pharmaceutical industry (e.g. neurological and pulmonary disease, rare disease and cancer).
- **Technology:** Created a clinical research operation to provide personalized medicine for cancer patients.
- **Proof of concept:** With partnership with CET, an Iowa Biotech company (co-founded by Dr. Moy), the Institute has created a first of its kind integrated program in cancer diagnosis, treatment and drug development.

Cancer Challenge Overview



- ◆ 0.65% of patient population but consume 10% costs.
- ◆ Chemotherapy given empirically based on limited diagnostics.
- ◆ 22 percent of cancer patients receive chemotherapy – increases the 5-year survival by 2% (If increase survival by 1% -> 30K lives saved / yr).
- ◆ Chemotherapy patients generate 4x more cost (110k) than non-chemotherapy patients (10% drop cost -> \$31 billion annual savings).
- ◆ 95% drug development failure rate – (5% improvement -> 60-120 million dollars savings).



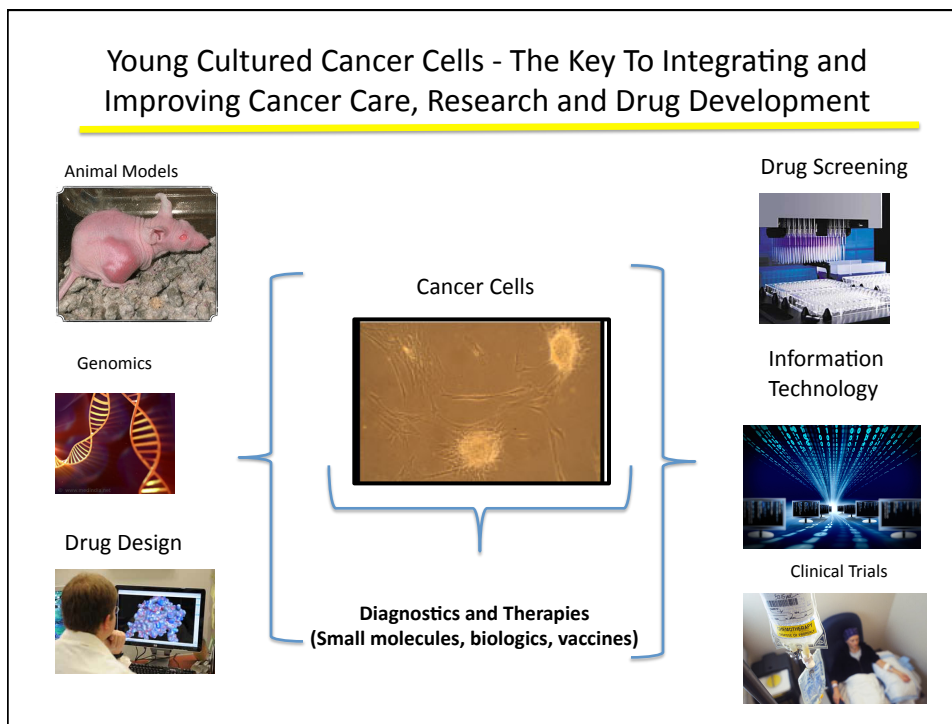
Unsustainable Pharmaceutical Cancer Drug Development Costs

- 1970 – 140 million 7 years to approval
- 1980 – 320 million
- 1990 - 800 million
- 2000 – 1.2 billion 12.5 years to approval
- 20 year patent life of a drug.
- Cancer drug development failure rate is 95 percent.
- Number of annual FDA approved drugs declined since 1970.
- Increasingly more difficult to achieve ROI within the patent protection period.
- Costs are not sustainable and drug makers are risk averse to cure disease.

Outcome of Society Investment Towards Cancer Research

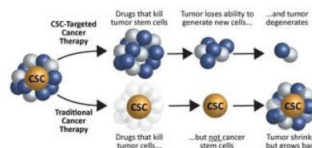
- Since President Nixon declared war on cancer, trillions of dollars spent on medical research achieving modest outcomes.
- It is time do things fundamentally different.
- What fundamental technical advancement is needed to dramatically improve cancer care and drug development?
- **Answer: We need more innovative, accurate and capital efficient ways to predict patient outcomes and develop more superior diagnostics and therapeutics at lower cost to society.**
- **To achieve that end – cancer care, medical research and drug development has to be integrated – presently fragmented.**

Young Cultured Cancer Cells - The Key To Integrating and Improving Cancer Care, Research and Drug Development

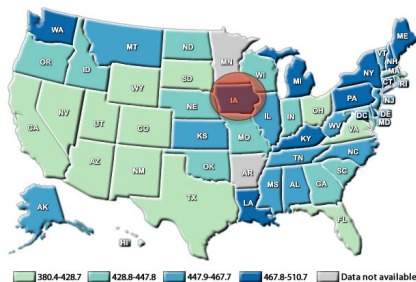


The Diagnostic and Therapeutic Problem in Cancer

- Cancer diagnosed by pathologist based on microscopic description.
- Routine cancer pathology has poor predictive value: prognosis and response to chemotherapy.
- Genetic testing used but major flaws remains.
- Animal models used but major flaws exist.
- Cancer stem cell phenomena.
- Need an approach in cancer diagnosis and treatment like what's available in the field of microbiology – bacterial culture and antibiotic susceptibility.
- If cancer cells can be isolated from tumors and grown artificially and tested against chemotherapy, rather than blindly exposing patients to unnecessary drugs, this would represent a major breakthrough in care and drug development.



Cancer Diagnosis – Scope of the Problem



Data From the Center for Disease Control

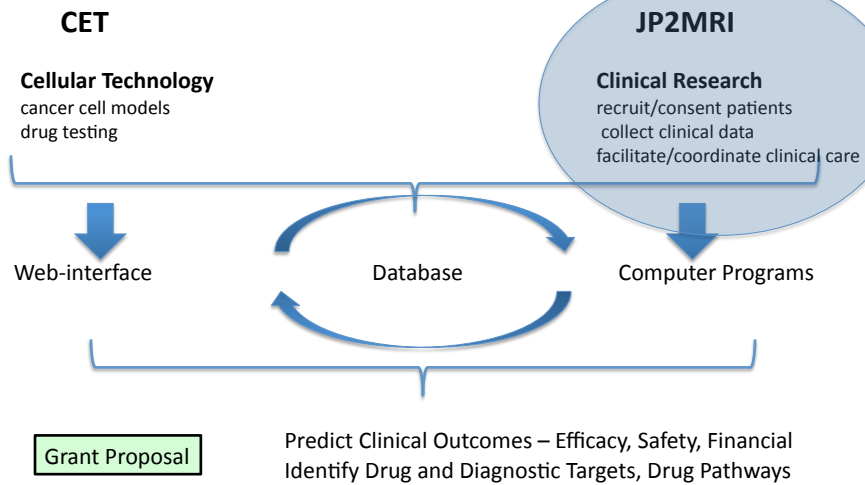
- Incidence: > 14,000 new cases/yr in IA (1.6 mil. in US).
- Prevalence: (150k in IA, 13 mil. in US).
- Possible to process samples in continental US.

Management Team

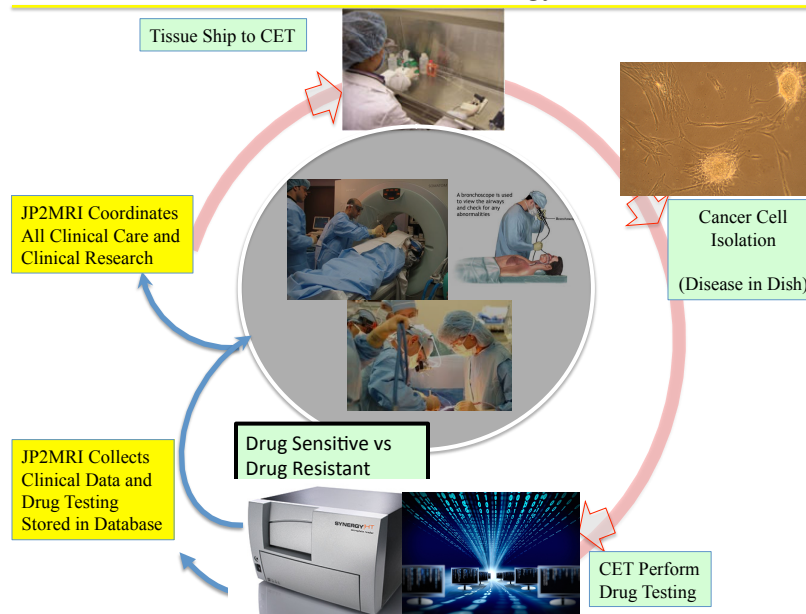


- Jay Kamath, BA, JD - CEO
Non-profit management experience.
Graduate of University of Iowa
- Alan Moy, MD – Scientific Director & Founder
Over ten years in industrial stem cell manufacturing human cells & clinical regenerative medicine and lung cancer experience, computer science
UC-Davis, Creighton U & U of Iowa, JP2MRI
- Board of Directors

CET-JP2MRI Partnership

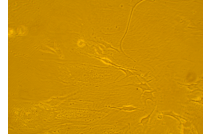


Cancer Diagnostics/Drug Discovery Through Information Technology

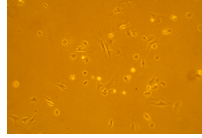


Proof of Concept

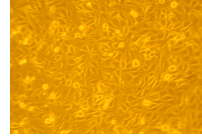
JOHN PAUL II
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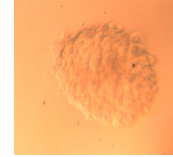
Brain Cancer Clone 3859



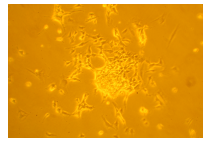
Colon Cancer Clone 1995



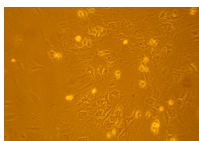
Gastric Carcinoma line 2183



3-D gastric carcinoma spheroid



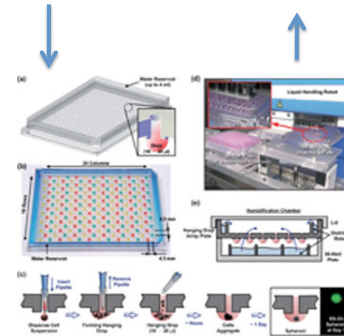
Glioblastoma Clone 1448



Glioblastoma Clone 3454

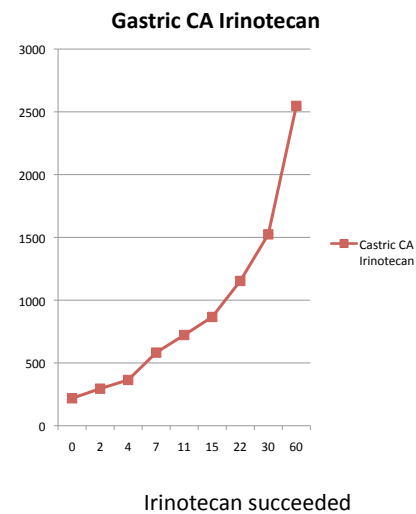
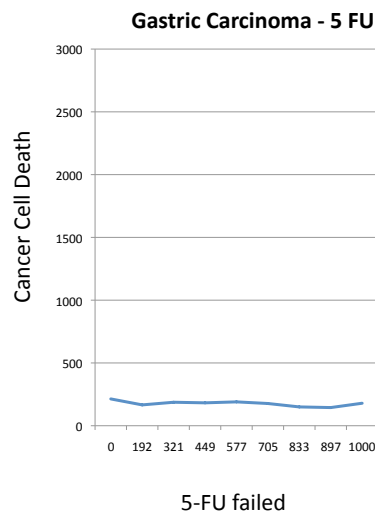
BREAST Colon HEAD/NECK LUNG Bladder
FROM PATIENTS

**55 PERCENT OF CANCER PATIENTS CAN
BE EVALUATED THUS FAR**



Time Comparison
Cell -2 weeks Animals 4-8 weeks

Gastric Carcinoma Treated With Different Chemotherapy



Cost and Use of JP2MRI Seed Funds

- CET will put up \$300,000 to conduct cancer testing as proof of concept.
- Dr. Moy's medical practice will provide \$216,000 of in-kind support to provide a medical office infrastructure for clinical care and clinical research for first 2 years.
- **Private gap funding sought: \$250,000 to cover 2 years of clinical research support.**
- Anticipate competing for formal external funding to create self-sustaining operation by year 2.
- Expenditures include:
 - Personnel: Partial costs for CEO, Scientific Director, RN Clinical Research Coordinator, Computer programmer.
 - Computer and office supplies.
 - Advertisement and Marketing.

Comparison Between JP2MRI Against Other Non-Profit Cancer Foundations Research Expenditures

- American Cancer Society (spends 16 percent on research)
 - CEO paid \$2.4 million in 2012.
 - Raised 934 million in 2012.
- Susan G Komen (spends 20 percent on research).
 - President paid \$606,461 in 2012.
 - Raised 360 million in 2010.
- JP2MRI (spent 55 percent on research in 2013).
 - Expenditures spent on Alzheimer's and cancer.
 - Dr. Moy received ~\$1,000 in compensation and spent 40 hrs/week on research program.
 - JP2MRI works towards helping current and future cancer patients.
- ACS and SGK work towards helping future cancer patients.
 - Not clear how 1.2 billion of ACS and SGK addresses major cancer problems - decrease healthcare cost, better diagnostics, new and safer drugs or approaches in pipeline, decrease drug failure rate.

Summary



- Clinical program addresses huge need for cancer patients.
- Anticipated outcomes:
 - More accurate and personalized information for cancer patients.
 - Lower costs for treating cancer patients.
 - Better tools available for cancer patients and doctors.
 - Streamline and more efficient drug development.

What You Can Do To Help



- Send donations.
- Organize fundraising events in your local community.
- Organize efforts in your local community to set up a cancer tissue collection research program.
 - Educate your community on due diligence of private foundations that advocate for cancer patients – i.e. (1) What percent of their budget is devoted towards research?; and (2) What metrics do they use to define success? (increase survival, decrease drug failure rate, find treatments, ect or simply publishing papers, helping faculty get tenure, ect.).
 - Educate and recruit your local surgeons and pathologists to help obtain tissue.
 - Help facilitate getting program established through an Institutional Review Board at your local hospital.
 - Organize media attention to your program and connection to the Institute.