



# New York Pharma Forum

**M2Gen & Total Cancer Care  
July 21, 2011**

*The future of  
personalized  
medicine.*

# M2Gen

- ❖ M2Gen (“Moffitt 2nd Generation”)
- ❖ Moffitt Cancer Center’s wholly owned subsidiary
- ❖ Moffitt’s first “for-profit” entity; developing business to serve the pharmaceutical / biotech space
- ❖ Currently executes on projects run for Merck & Moffitt’s Total Cancer Care® (TCC) Initiative
- ❖ Operating with over \$150 million dollars of public/private funding



# Moffitt Cancer Center

- Established through legislative statute in 1981 and opened in 1986 (162 beds)
- Initiated research recruitment in 1994
- Received NCI designation in 1997, NCI CCC in 2000
- Today >4,000 staff, 326 faculty, >\$82M in grant funding

***Moffitt Cancer Center is the 3<sup>rd</sup> largest cancer center in the US***

# Moffitt Model of Personalized Medicine

Data → Information → Knowledge → Wisdom

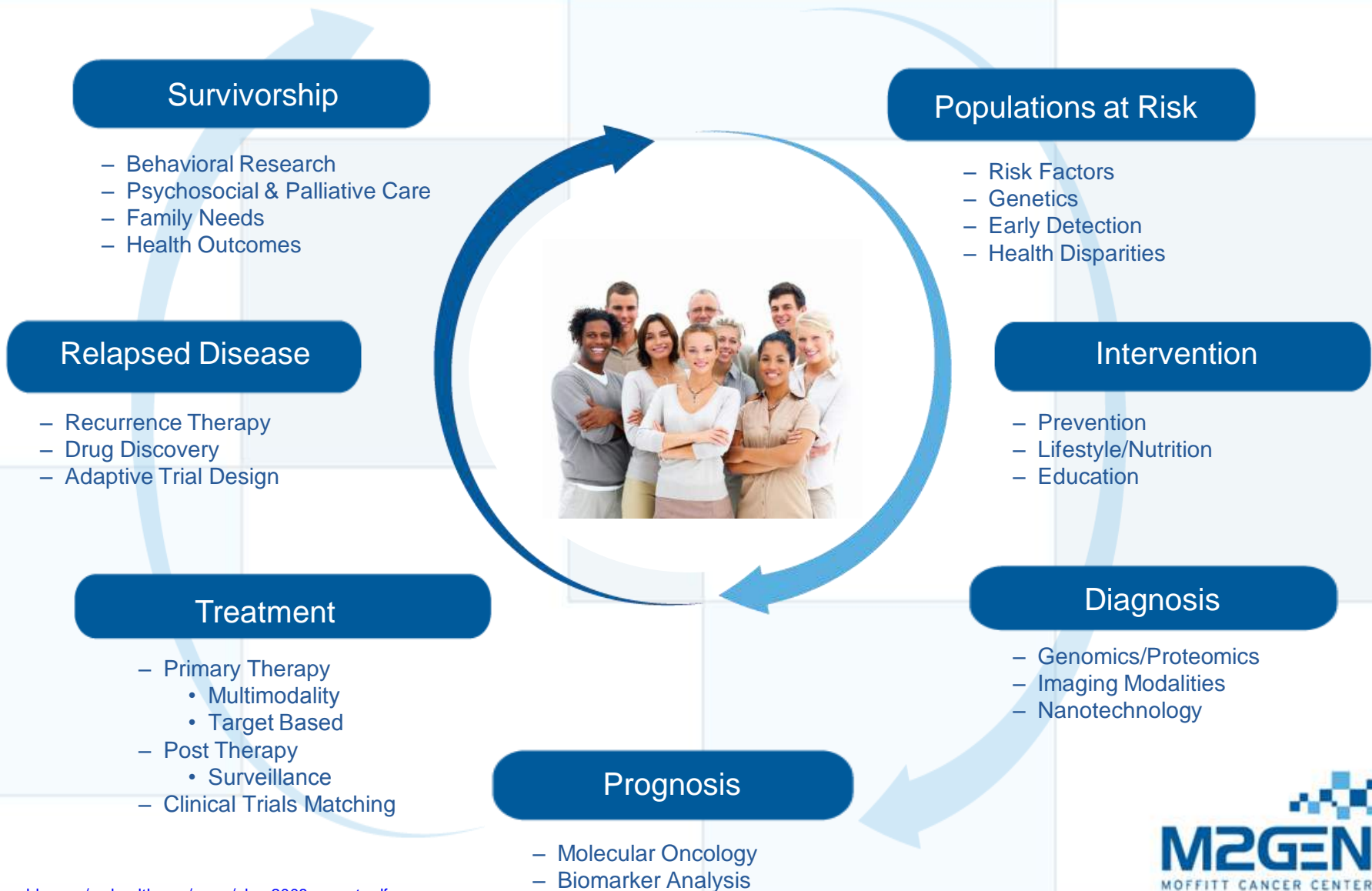
***Improved medical practice***

Create a delivery system that will integrate new technologies into the standard of care and develop evidence-based guidelines for the treatment of cancer.

***Moffitt/M2Gen have created “best in class” knowledge services for personalized medicine.***

# Moffitt Total Cancer Care<sup>®</sup>

## A Patient's Personalized Health Journey



# Total Cancer Care Protocol

CONFIDENTIAL

001-000  
MCC-001

**Title:** Total Cancer Care Protocol: A Partnership with M2Gen and the Progress of Cancer Patients (TCCP)

**Principal Investigator:** Timothy J. Travers, M.D.

**Sub-Investigator:** William S. Barlow, Ph.D., M.D.

**Sponsor:** Moffitt Cancer Center and Research Institute

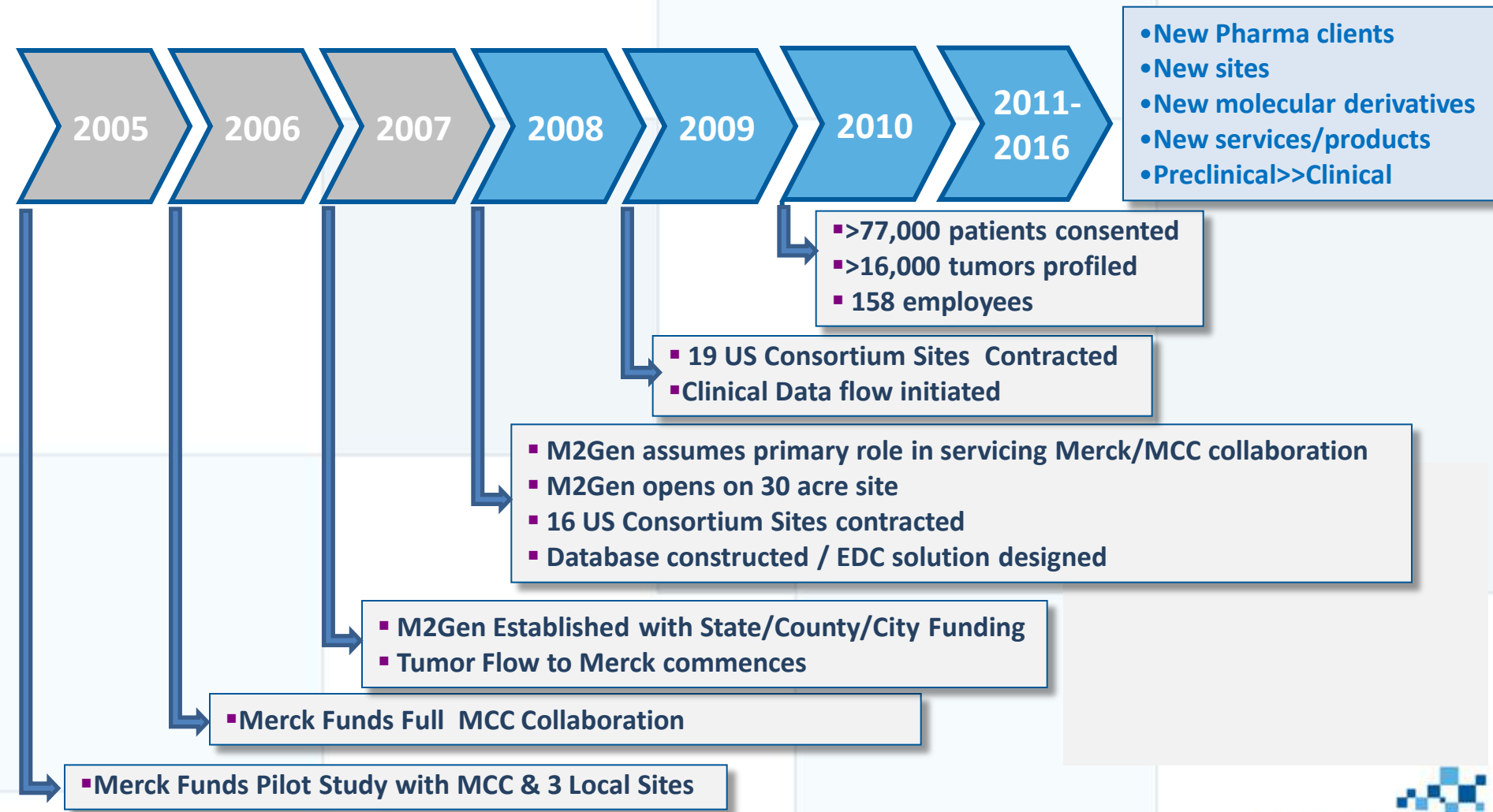
\_\_\_\_\_  
Principal Investigator

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Sponsor

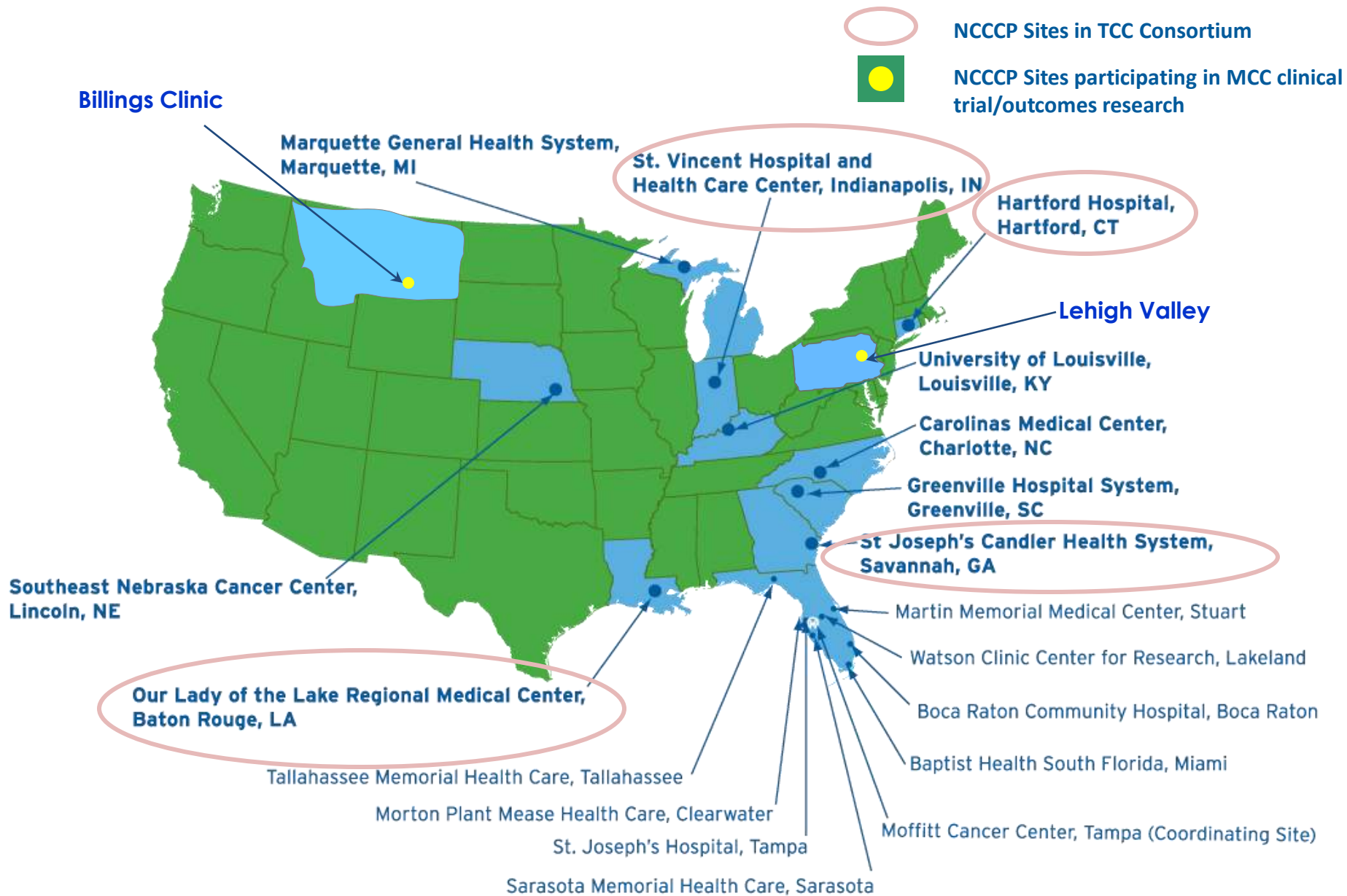
- ❖ *Can we follow you throughout your lifetime?*
- ❖ *Can we study your tumor using molecular technology?*
- ❖ *Can we re-contact you?*

- ❖ Captures longitudinal clinical data and matched tissue samples (along with derivative molecular data) to support research and development
- ❖ Nationwide network of 18 hospitals, including MCC
- ❖ Bio-repository and database managed by M2Gen

# Evolution of M2Gen



# Total Cancer Care Consortium





# M2Gen

- ❖ World's largest cancer-focused biorepository linking cancer tumor tissue and non-tumor specimens to longitudinal clinical data and derived molecular data
- ❖ Serves Pharma/Biotech R&D needs to facilitate biomarker and drug development as a resource to translational research and development
- ❖ Rigorous collection and processing procedures result in consistently high quality tissue samples with high tumor concentration
- ❖ M2Gen offices, laboratory, biorepository, data warehouse – 100K sq ft, Tampa, FL



# M2Gen Biorepository Nexus System



- ❖ **Capacity** of 2.5 Million samples
- ❖ **Stores** its samples in a  $-80^{\circ}\text{C}$  environment
- ❖ **Handles** its samples in a  $-20^{\circ}\text{C}$  environment
- ❖ **Retrieves** its samples using NEXUS proprietary '**Cool Transition**' technology
- ❖ **Accommodates** a variety of sample vessel types:

# Total Cancer Care To Date



**Patients Consented**  
77,354

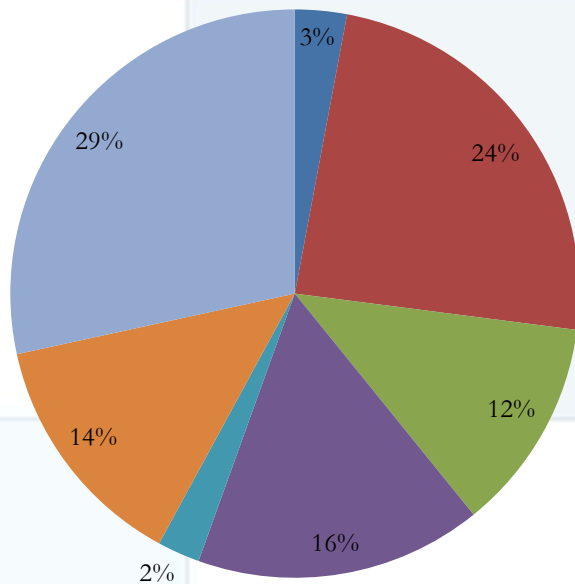
**Tumors Collected**  
38,942

**Tumors Profiled**  
16,393

As of July 17, 2011

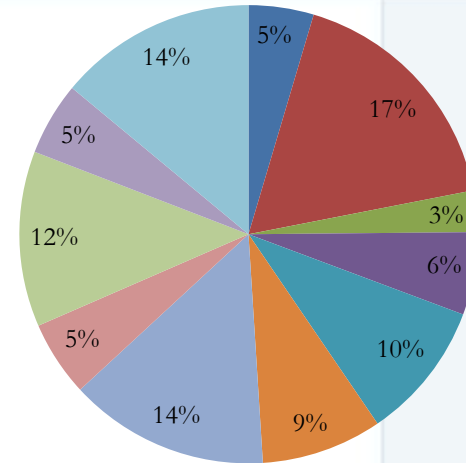
# Scope of Tumor Collection

## Top Six + Other



- Brain
- Breast
- Colorectal
- Lung
- Pancreas
- Prostate
- Other

## Other Tumor



- Bladder
- Kidney
- Liver
- Other Gastrointestinal
- Ovary
- Other Gynecological
- Head & Neck
- Non-Melanotic Skin
- Soft Tissue & Bone
- Other Miscellaneous
- Skin

***The TCC database is tremendously diverse, reflecting tumor tissue for research from many different populations of patients***

# Clinical Data Capture

Elements Captured	Frequency
<p>Demographic Data</p> <p>Consortium Name, Gender, first 3 digit Zip Code, Ethnicity, DOB (mo/yr), Consent information, TCC Short Survey</p>	<p>Time of consent</p>
<p>Pathology Data</p> <p>Specimen-ID, RS-Barcode, Project-Name, tumor type, anatomic site, laterality for site of collection and site of origin, primary /metastatic, histology type, TNM stage, % malignancy, % necrosis, % cellularity</p>	<p>Receipt of tissue</p>
<p>Baseline Clinical Data</p> <p>Date of visit, Date of Dx, ECOG Status, Clinical Staging, Disease status [Initial], Assessment Methods, Patient Treatment, Tumor Markers, Mortality</p>	<p>After pathological confirmation of malignant tumor</p>
<p>Longitudinal Clinical Data</p> <p>Date of visit, ECOG Status, Disease status [Recurrence, Regression, Stable, Progression, NED], Assessment Methods, Patient Treatment, Tumor Markers, Surgical Procedure/Date, Recurrence Site/Date, Mortality</p>	<p>Collected based on the following:</p> <ul style="list-style-type: none"> <li>◦ Clinical Stage 1 and 2 – Annually</li> <li>◦ Clinical Stage 3 and 4 – 6 month intervals</li> </ul>

# 2011: Patient-Matched Clinical Trials

- ❖ M2Gen VRO – ‘Virtual Research Organization’
- ❖ Goal is to accelerate drug development and delivery
- ❖ M2Gen trial matching capabilities through leveraging patient’s individual molecular/genetic data
  - Consortium network for clinical trials (practices and hospitals)
  - Obtain molecular data on patients’ tumors
  - Maintain real-time clinical data on patients
  - Match drugs to patients using molecular and clinical data
  - Faster and smaller trials with increased response rates

# Revolutionary Paradigm Shift

TODAY

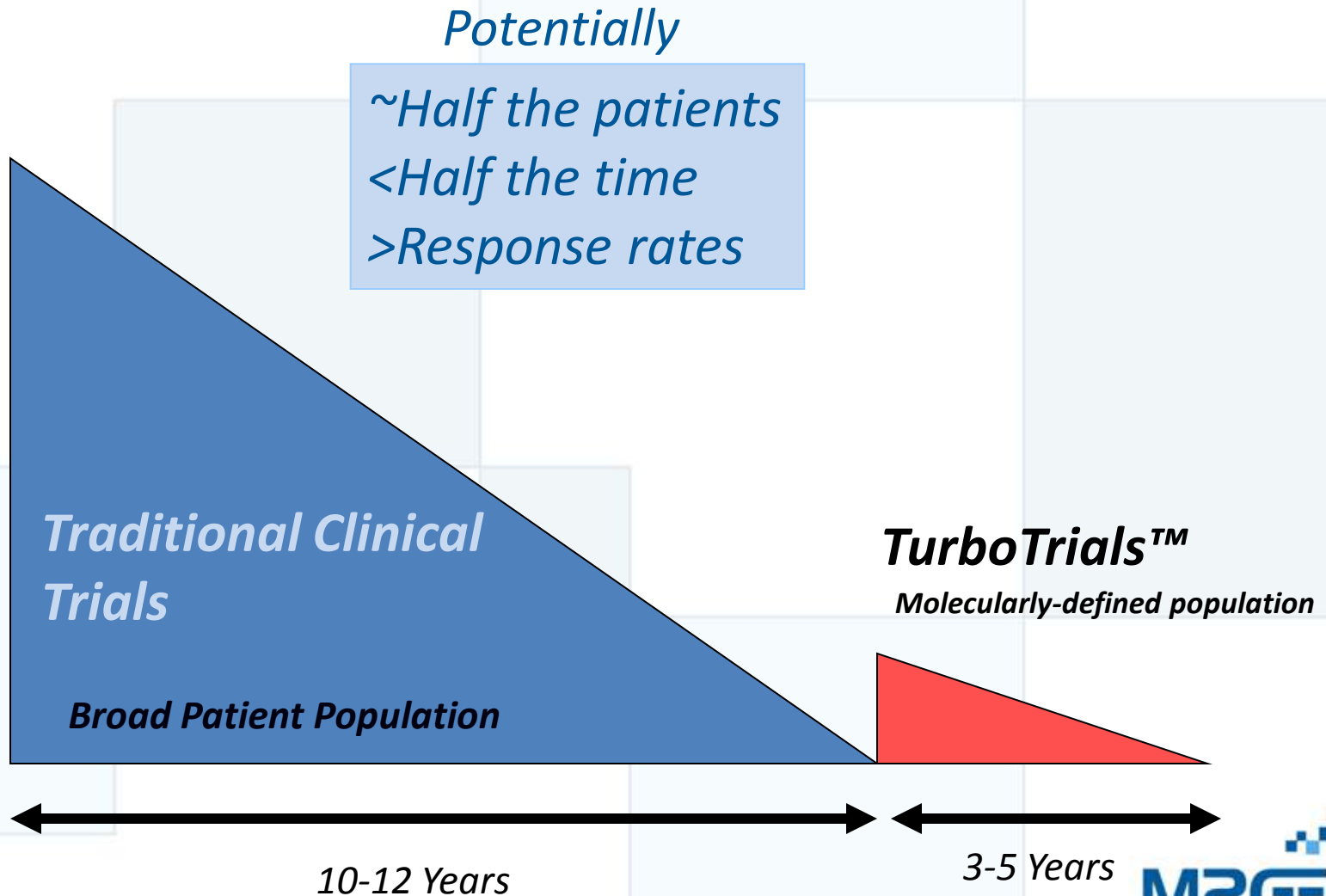
**Trials searching for patients**



TOMORROW

**Trials designed for and directed to patients**

# M2Gen Goal: Streamline Clinical Trials





# M2Gen Business

## Tissue & Data

### Translational Research / Early Development

- 77K+ consented patients
- >38K+ FF tumors
- >16K+ RNA samples
- Longitudinal Clinical Data



## Gene-Based Trial Matching

### Rapid Clinical Development to Speed New Drugs to Market

- CLIA Lab
- Oncology Trials Network
- DNA/RNA/Protein platforms
- Molecularly mapped patients

*...contributing to the prevention and cure of cancer.*