

Name and Institution: Yuhchyou Chen, MD, PhD. University of Rochester Medical Center

Project Title: Upstate Proton Therapy Consortium at the University of Rochester Medical Center/Wilmot Cancer Institute

Background, Challenge or Opportunity:

Proton therapy is a life-saving FDA approved cancer treatment modality. It offers unique clinical advantages due to the physical characteristics of proton particles that can deliver ultra-precise radiation treatment. As positively charged protons travel, only a small amount of radiation dose is delivered along its path, and most of the dose can be delivered at a precise distance in the target tissue, called the "Bragg Peak." Consequently, much more healthy tissues can be spared of radiation, and deep cancer targets can receive a higher dose of radiation. Published work has consistently shown fewer side effects and better quality of life as the main advantages over conventional photon-based radiotherapy. In addition, because of very little scattered radiation and no exit dose of proton radiation, proton therapy can reduce delayed and long-term radiation effects, such as second malignancy, coronary artery disease, fibrosis and organ dysfunction.

The first-generation proton machines utilize a single cyclotron unit to feed 4 treatment machines costing well over \$150 to \$200 million and a football-field size space. Smaller proton systems have been developed with smaller space need with the cost of \$25 - \$30 million per machine, thus offers a unique opportunity to consider a proton center for many academic cancer centers. There are currently 45 operating proton centers in the US with 38% single room proton facilities. Sixty percent proton facilities are affiliated with academic centers, and many are under development in most academic centers.

Purpose/Objectives: The primary objective of this project has been modified from the initial ELAM proposal of 2012 due to evolving changes of proton therapy over the past decade.

Access to proton therapy in New York state has undergone new development since initial ELAM proposal. A certificate of need (CON) for a proton therapy center of 10 years operation was issued by DOH of New York and a Consortium of New York Proton Center was formed in year 2019 by Memorial Sloan Cancer Center, Montefiore Health System and Mount Sinai Health in New York City. This first CON was a demonstration project to assess the feasibility, success, and the future needs of a second proton center in New York State. The NYC proton center is a large 4 room proton center and very active with the demand exceeding access. Patients have been constantly moved to the Procure Proton Center in New Jersey to accommodate the demand.

This CON will expire in 2029, which is 4 years from 2025. A timely window of opportunity has arrived for URMW/Wilmot Cancer Institute to take the lead of the preparation to compete for the second CON through an Upstate NY Consortium of proton therapy by URMW in Rochester, SUNY Upstate in Syracuse, and Roswell Park Cancer Center in Buffalo.

There are compelling reasons why URMW should take the lead: (1) We anticipate Wilmot Cancer Institute to be awarded the NCI Designated Comprehensive Cancer Center status in year 2025. (2) Rochester is physically located in between Syracuse and Buffalo, allowing equal access from the east and the west of Rochester (3) The Department of Radiation Oncology at URMW is in the best position to lead the education and training efforts of proton therapy. Our ACGME accredited medical residency program has a long-standing history of training excellent medical residents in Radiation Oncology. In last few years, we also successfully established a CAMPEP-accredited medical physics residency program, as well as a graduate program of MS in medical physics. We are the only department in upstate NY with all three components of major education and training programs in comparison to Roswell Park and SUNY Upstate. Our objectives are the following:

1. A Consortium of Upstate Proton Center that will include URMC, SUNY Upstate and Roswell Park Cancer Center and physically located in Rochester at the center of upstate NY.
2. Being the only program with medical residency, medical physics residency, and graduate school in medical physics in upstate NY, through the consortium arrangement of the proton center, Radiation Oncology Department at URMC will lead the training and education of medical residents of all 3 institutions, medical physics residents of URMC and Roswell Park Cancer, and graduate students at URMC.
3. Through the consortium arrangement, the proton center at URMC will lead the research efforts and grant applications for proton particle therapy and FLASH therapy research, the latter is a novel technique in radiotherapy that delivers a high dose of radiation in an ultra-short time frame, typically within milliseconds. This rapid delivery is achievable using specialized equipment that generates high-energy radiation beams, such as proton beams.

Methods/Approach:

1. To conduct a market analysis of the current cancer patient population that could benefit from proton treatment in upstate NY, and to assess the challenges of planning, developing, and operating a successful single-room proton center.
2. To engage SUNY Upstate and Roswell Park Cancer Center in the discussion of forming a Consortium of Upstate Proton Center that will not only allow easy access of patients to proton therapy in Upstate New York, but also northern Pennsylvania.
3. To developing a Proforma business plan for the consortium for 3 institutions, including financial arrangements, construction, organization structure, operating costs, and reimbursement logistics of a single room proton treatment site at URMC.
4. To conduct a technology and cost assessment of current proton machine models to select the best model for the consortium.
5. To engage the New York Proton Center in NYC n supporting the upstate NY proton consortium in planning, finances, and management. I have started conversations with the Director of NY Proton Center, Dr. Charles Simone, and received support from Dr. Simone.
6. To engage the office of URMC Government Relation in this plan of consortium in the discussion with DOH of NY and in the preparation of CON applications.

Outcomes and Evaluation:

The business analysis should reveal that a single-room proton center is feasible and financially viable with the potential for further growth in Upstate NY. This is based on the fact that many academic centers have or are currently implementing the single-room proton therapy after independently assessing the current proton therapy technology and finances.

I already discussed with the Director of WCI Dr. Jonathan Friedberg who has suggested to engage in further discussions in June 2025 after NCI designation.

The engagement of SUNY Upstate and Roswell Park Cancer Center will start following further discussion with WCI and URMC leadership. On-going negotiations in the context of a consortium in finances, organization, education, and research goals will be anticipated.

The developmental plan and the Proforma will be presented to the URMC CEO Strategic Group for further evaluation.

ABSTRACT: 2013 ELAM Institutional Action Project Poster Symposium

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Name and Institution: Yuhchyan Chen, MD, PhD. University of Rochester

Collaborators: George Uschold, Eric T. Gommel, Richard Cowen, and Michael Schell

Background, Challenge or Opportunity:

Proton therapy offers unique clinical advantages due to the physical characteristics of proton particles. As protons travel, only a small amount of radiation dose is delivered along its path, and most of the dose can be delivered at a precise distance in tissue, called the "Bragg Peak." As a consequence, much more healthy tissue can be spared of radiation, and deep targets can receive a higher dose of radiation. Proponents cite fewer side effects and better quality of life as the main advantages over conventional radiotherapy. Very little scatter and no exit dose of proton radiation can reduce delayed radiation effects, such as second malignancy, coronary artery disease, fibrosis and organ dysfunction.

The first-generation proton machines utilize a single cyclotron unit to feed 4 treatment machines costing well over \$150 to \$200 million and a football-field size space. Smaller proton systems are in development with smaller space need, and the cost of \$25 - \$30 million per machine, thus offers a unique opportunity to consider a proton center. There are currently 10 operating proton centers, 14 under construction and 22 under development.

Purpose/Objectives:

The primary objective of this project is to assess the feasibility of establishing a proton therapy center at URMCM including:

1. Developing a Pro Forma business plan including the development, construction, and operating costs for treating patients in the greater Rochester region.
2. Conducting a technology and cost assessment of current proton vendors to select the right machine for our needs.
3. Developing a plan to build and operate a Center of Excellence in Proton Therapy that will be the premier destination for cancer care in upstate New York (NY). The facility will be recognized for innovative and advanced technology, clinical excellence, translational research, and outcomes research.

Methods/Approach:

1. The team attended the National Proton Conference to update the current proton therapy market place in the context of health care reform. The conference provided an overview of clinical trials, current studies, and the economics of proton therapy involving providers and insurers.
2. The team conducted a market analysis of the cancer patient population that could benefit from proton treatment in upstate NY, and assessed the challenges of planning, developing, and operating a successful proton center.
3. The team will propose a proton center plan through a regional proton center partnership. The plan will combine multi-institution proton clinical care with a research center, which will build upon the expertise of radiation biology, translational research, and cancer survivorship of the Department of Radiation Oncology at UR.

Outcomes and Evaluation:

The business analysis reveals that a single room proton center is feasible and financially viable with the potential for further growth in upstate NY. The developmental plan and the Pro Forma will be presented to the URMCM CEO Strategic Group for further evaluation.

ELAM Fellow: Yuhchyan Chen, MD, PhD, University of Rochester **Mentor:** Mark Taubman, MD, Dean of UR SMD
Collaborators: George Uschold, D Ed, Eric T. Gommel, MBA, Richard Cowen, MBA, and Michael Schell, PhD

Background, Challenge or Opportunity

Proton therapy is a form of charged particle radiotherapy. It offers unique clinical advantages due to the physical characteristics of proton particles. As protons travel, only a small amount of radiation dose is delivered along its path, and most of the dose can be delivered at a precise distance in tissue, called the "Bragg Peak." As a consequence, much more healthy tissue can be spared of radiation, and deep targets can receive a higher dose of radiation. Proponents cite fewer side effects and better quality of life as the main advantages over conventional radiotherapy. Very little scatter and no exit dose of proton radiation can reduce delayed radiation effects, such as second malignancy, coronary artery disease, fibrosis and organ dysfunction.

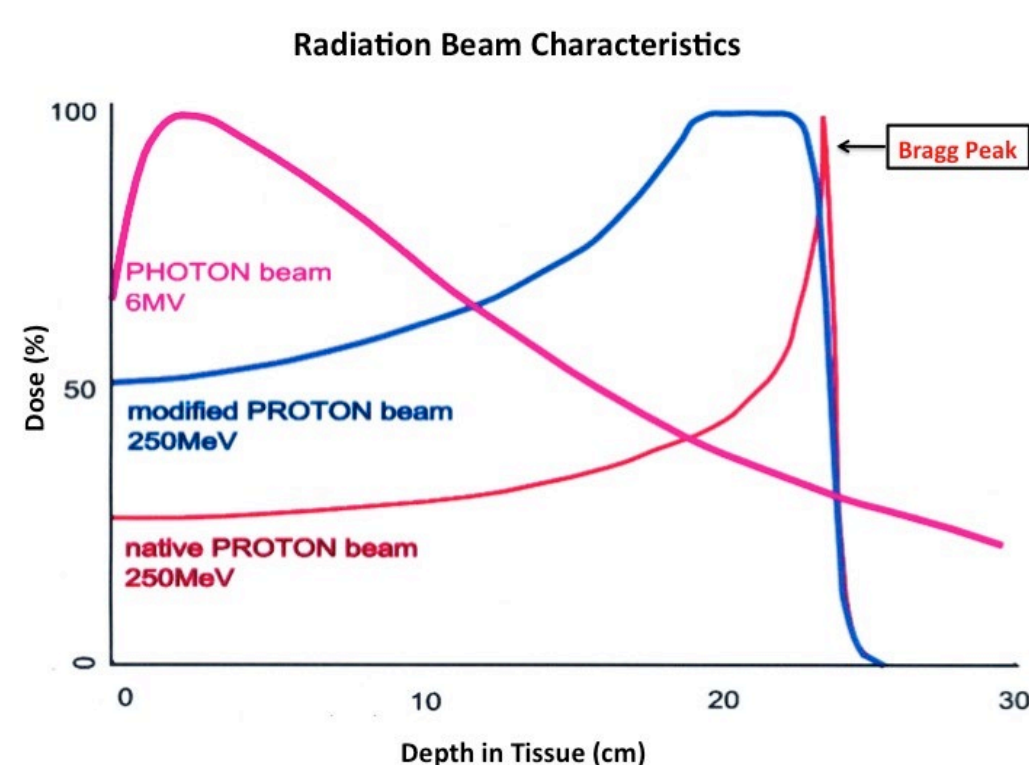


Figure 1. Beam characteristics: proton vs. photons. Proton beam Bragg Peak is shown.

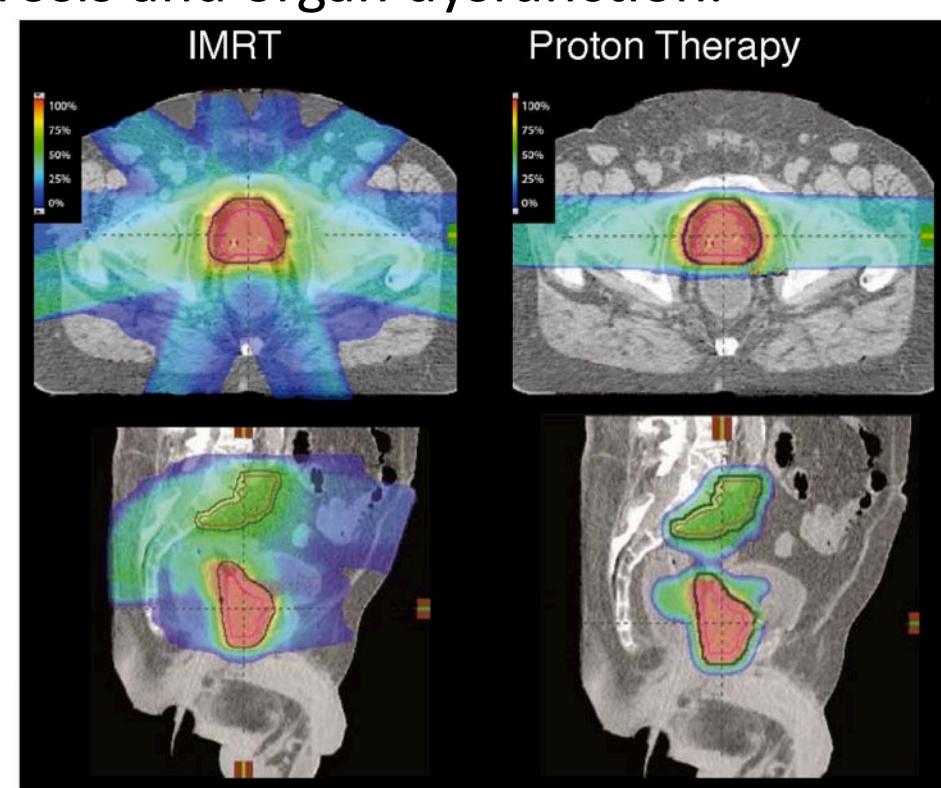
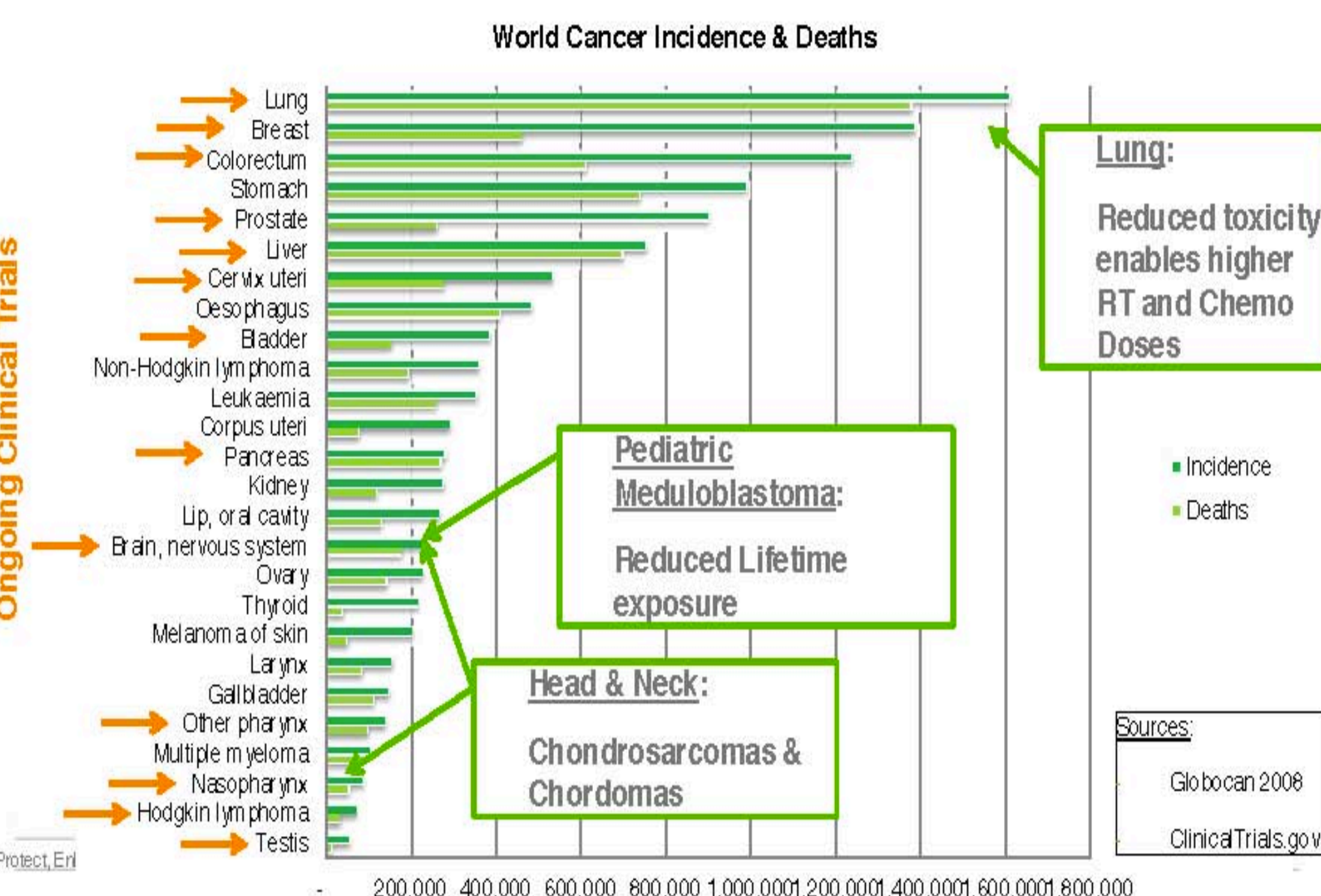


Figure 2. Radiation dose intensity map of proton vs. IMRT photon for the treatment of prostate cancer. Note much less radiation to the surrounding normal structures by proton therapy.

The first-generation proton machines utilize a single cyclotron unit to feed 4 treatment machines costing well over \$150 to \$200 million and a football-field size space. Smaller proton systems are in development with smaller space need, and the cost of \$25 - \$30 million per machine, thus offers a unique opportunity to consider a proton treatment center.

Figure 3. Ongoing Proton Clinical Trials (in orange arrows)



Purpose/Objectives

The primary objective of this project is to assess the feasibility of establishing a proton therapy center at the James P. Wilmot Cancer Center at URM including the following:

- Conducting market analyses, insurance and provider analyses, and the impact of health care reform to develop a Pro Forma Business Plan, that will include the development, construction, and operating costs for treating patients in the greater Rochester region.
- Conducting a technology and cost assessment of current proton vendors to select the right technology and machine for our needs.
- Developing a plan to build and operate a Center of Excellence in Proton Therapy that will be the premier destination for cancer care in upstate New York (NY). The facility will be recognized for innovative and advanced technology, clinical excellence, translational research, and outcomes research.

Outcomes and Interpretation of Results

1. There are currently many operating charged particle (including protons) radiotherapy centers worldwide, and an increasing global interest in developing more centers. There are 10 operating proton centers, 14 under construction and 22 under development in U.S. (Fig. 4)

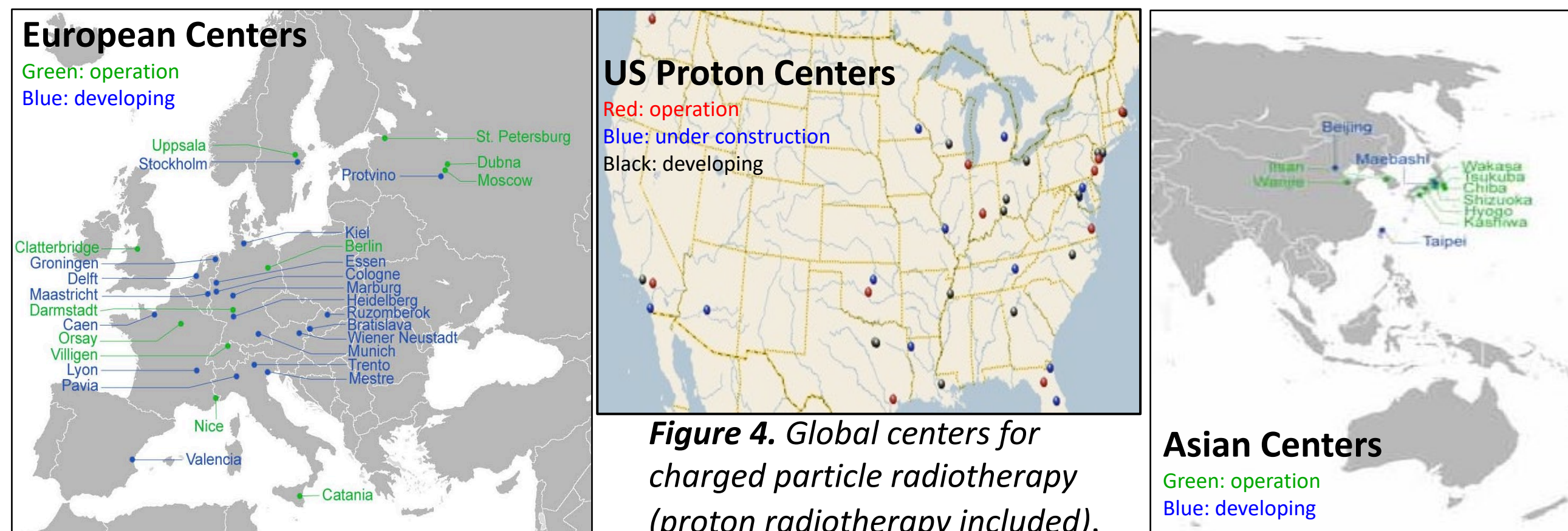


Figure 4. Global centers for charged particle radiotherapy (proton radiotherapy included).

- There are many ongoing clinical trials assessing efficacy and cost-effectiveness of proton (and other charged particle) radiotherapy (Fig. 3).
- Market analyses (population data and URM radiation treatment database, 2012) of potential patient population for proton therapy in the Rochester & 16 county regions reveal an estimated 300-400 patients/year for the proposed upstate proton center (Figs. 5 & 6).
- Technology assessment reveals that 'pencil beam scanning' proton offers higher conformity than the classical 'passive scattering' proton. It does not require patient-specific and field-specific hardware and the risk of generating harmful neutron is greatly reduced. A built-in Cone-Beam CT will reduce the sensitivity to organ motion for 'pencil beam scanning' protons.
- The Pro Forma business plan reveals that the single room design (either one or two rooms, pending capital investment) of a proton facility centered at Rochester is feasible and financially viable with a potential for further growth in upstate NY. A developmental plan (Fig.7) and the Pro Forma will be presented to the URM CEO Strategic Group for an evaluation.

Impact: The Upstate Proton Center at URM will provide the leading edge cancer treatment technology to serve patients in upstate NY and to increase the economy of NY state.

Figure 5. Radiation Oncology Patients By Zip Code (2012 data)

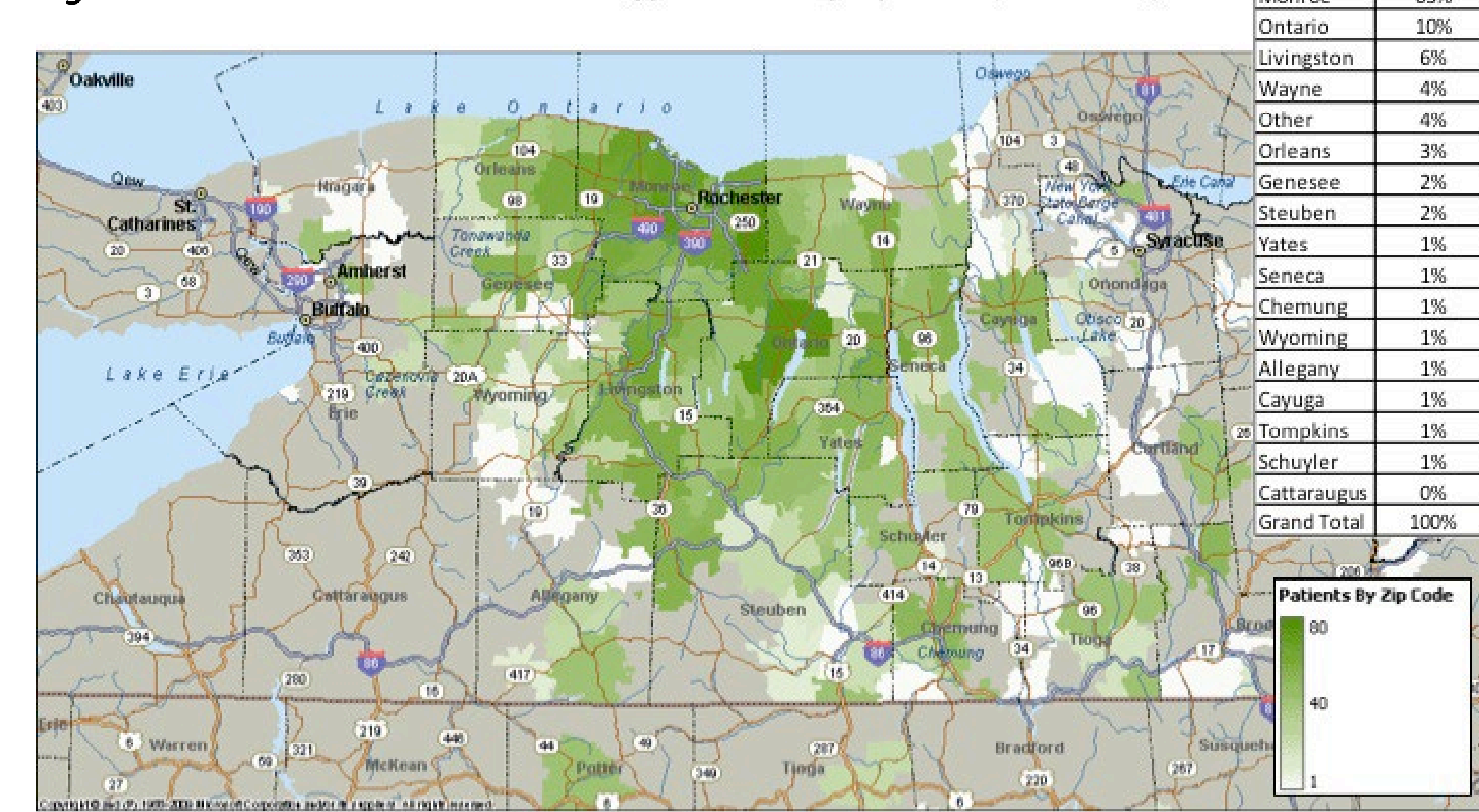
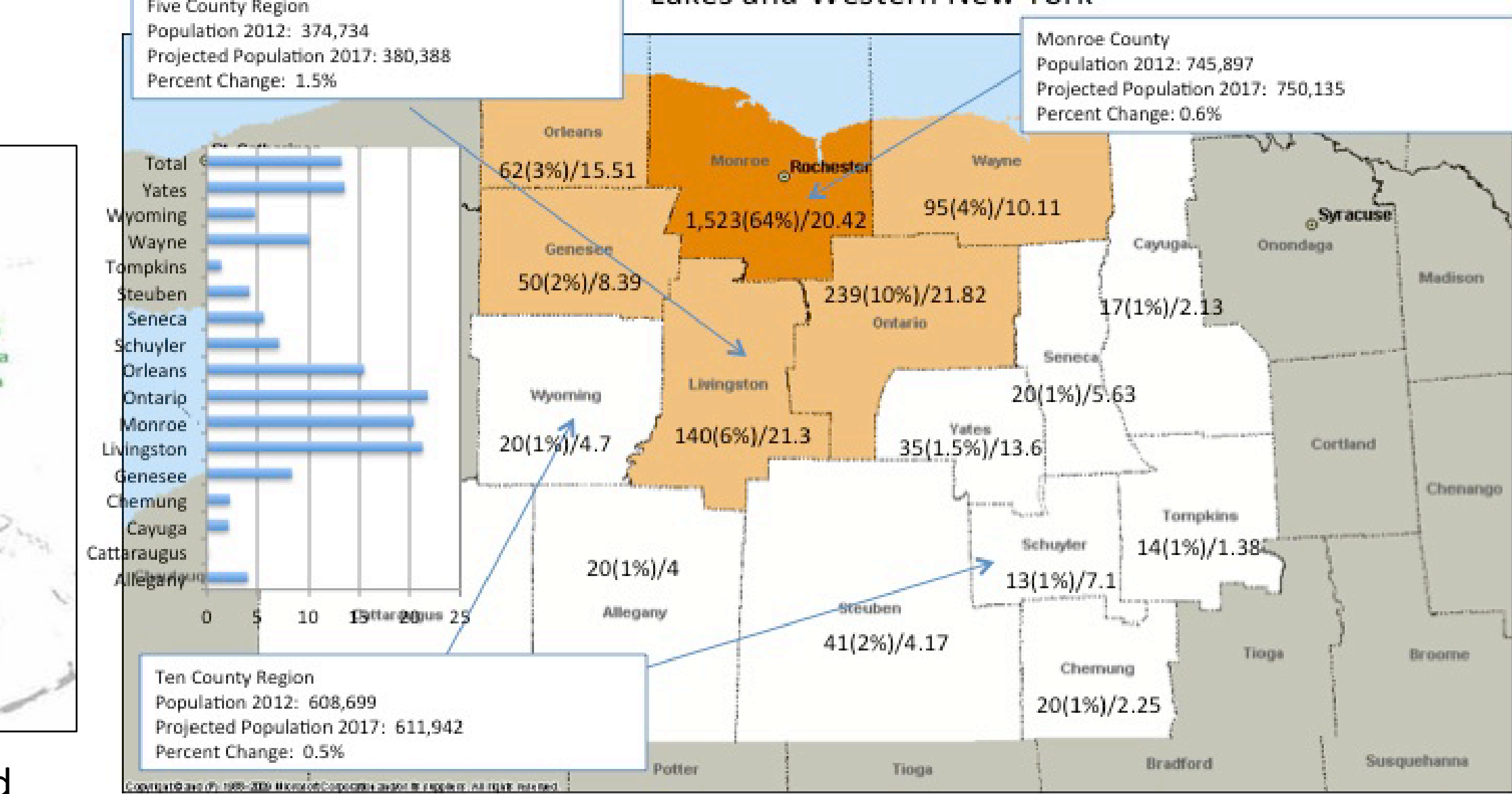


Figure 6. Population Projections Monroe County, Five County and Ten County Region of Finger Lakes and Western New York



Growth in the five county region is three times that of Monroe County and the ten county region fueled by out migration of residents to Ontario and Livingston counties.

Pts treated at UR Rad Onc/yr (% of UR Rad Onc excluding 200 Pluta patients)/ Pts per 10,000 population in each county----> "410" potential proton patients from all 16 counties/year

Figure 7. A Gantt Chart showing the timeline for the development, construction, and operation of either one-room or two-room, single room proton center at JPWCC

