

FINAL REPORT

Specific Objectives/Aims and milestones (Years 1-3)

1. Developed infrastructure for small animal imaging research and established the KUSAIR in association with the UNM College of Pharmacy, the UNM Cancer Center, and the Los Alamos National Lab.
2. Through a Pilot Project Program – we developed novel isotopes and radiochemistry in collaboration with LANL and industrial partners for targeted radionuclide imaging and cancer therapy
 - a. Developed Ga⁶⁸ and other generator-produced radioisotope labeled compounds (Years 1-3)
3. Through a Pilot Project Program - performed preclinical small animal imaging, dosimetry, and safety/efficacy evaluation on promising new diagnostic and therapeutic agents
 - a. Testing of Ga68 or other labeled agents in animals (Year 1)
 - b. Testing of 1b agents in animal models (Year 2-3)

Purpose: The purpose of the New Mexico Center for Isotopes in Medicine (NMCIM) is to support research, education and service missions of the UNM College of Pharmacy Radiopharmaceutical Sciences Program (COP RSP) and the Cancer Research and Treatment Center (CRTC). NMCIM will develop and coordinate unique translational research in cancer radioimaging and radiotherapy agents based on novel molecules developed at UNM and elsewhere. NMCIM will be the primary interface for novel radioisotopes and radiochemistries developed at the Los Alamos National Laboratory (LANL) for SPECT/PET imaging and therapy. NMCIM will coordinate the use of the small animal imaging facility with the CRTC and will provide support services to assist investigators in their studies. NMCIM will also develop education and training programs that benefit professional, graduate, and postdoctoral students that utilize its unique facilities and technologies. In order to respond to the many novel agents that are anticipated, the UNM COP RSP must increase its critical mass of faculty. UNM COP RSP will be active in writing research and training grants, as well as supporting contract research with industrial partners. The ultimate goal of NMCIM is to bring new radiopharmaceutical imaging and therapeutic agents into clinical trials that will benefit the health and well being of cancer patients in New Mexico and the U.S.

Background: The New Mexico Center for Isotopes in Medicine (NMCIM) is based at the UNM College of Pharmacy (COP) and the UNM Cancer Research and Treatment Center (UNM CRTC). The mission of NMCIM is to develop unique medically-useful radioisotopes, in collaboration with the Los Alamos National Laboratory (LANL) Isotope Production Facility (IPF). The IPF is a beam spur off of the LANL linear accelerator (LINAC) that produces unique gamma emitting and positron emitting (PET) isotopes that have not historically been available in sufficient quantities for product development. The IPF represents a \$30M investment in infrastructure. While LANL has unique capabilities in the production of novel isotopes, it does not have the ability to formulate or test potentially useful medical products. This, NMCIM was established to develop medically useful radioisotope formulations for cancer imaging and therapy, and eventually for the detection of other diseases.

The UNM Radiopharmaceutical Sciences Program (RSP) brings its longstanding expertise in handling, formulation, research and development of medical isotopes to establish medically useful radiopharmaceuticals. The UNM RSP will work with renowned scientists and commercial sponsors to develop products and markets for the radioisotopes from LANL IPF. UNM RSP will develop radiochemical procedures and formulations, will test these novel radiopharmaceuticals in appropriate in vitro and in vivo models leading to clinical trials for diagnostic and therapeutic agents. It is anticipated that the NMCIM will contribute to the interdisciplinary research and education programs of the UNM HSC and UNM main campus and will strongly support the Cancer Center imaging and therapy program in product development and future Neuroscience imaging approaches. NMCIM will also support economic development in New Mexico by attracting new radioisotope- and radiopharmaceutical-related businesses and activities to the State. The Center also plans to be active in workforce development through the new Technology Research Consortium (TRC) State of NM initiative. For more information please visit our website located at <http://hsc.unm.edu/pharmacy/isotope>.

Relationship to Institutional Goals: NMCIM has been identified by the COP as one of its Signature Programs. Cheryl Willman, MD (Director) and the UNM CRTC have identified medical isotope imaging and therapy as one of its key areas for development. The UNM CRTC and COP currently operate and support the Keck University Small Animal Imaging Resource (KUSAIR). At the request of Governor Richardson and Governor Napolitano (Arizona) new partnerships are currently being developed between the UNM CRTC and the University of Arizona Cancer Center for preclinical and clinical imaging and therapy. Dr. Burchiel serves on the Senior Leadership team for the UNM Cancer Center. The NMCIM has been highly integrated with the Clinical Translation Science Center (CTSC).

Collaborations and Partnerships: There are over 20 members of NMCIM, 4 of whom are full-time faculty in the COP (Burchiel, Miao, Norenberg, Pieper), 2 COP staff members (Anderson, Post-Doc TBD). In addition, there are 3 LANL scientists who have graduate faculty appointments within the COP (Atcher, Peterson, Nortier). There are also several commercial partners who are members of the NMCIM, including Robert Rubin, MD, CEO Lovelace Respiratory Research Institute, and Roy Brown, Executive Director, Commission on Radiopharmaceuticals and Radionuclides (CORAR). There are also 3 key collaborators from the CRTC in Drs. Larson, Prossnitz, and Sklar working on 2 projects pursuing radiolabeled biomarkers for cancer detection and/or therapy. There are also key partners at New Mexico Highlands (Martinez), and New Mexico State (Arterburn) Universities. NMCIM is partnering with GE Healthcare on the development of a Ga⁶⁸ Generator for PET imaging.

NMCIM Progress and Accomplishments

- NMCIM (College of Pharmacy, Dr. Burchiel - Director) established a formal partnership with the UNM CRTC, the Los Alamos National Laboratory, and the Lovelace Respiratory Research Institute for examine of novel radiopharmaceuticals
- NMCIM successfully completed a contract (Dr. Robert Atcher, PI) with Los Alamos National labs for examination alpha emitter chemistry for Herceptin antibodies in a human breast cancer model
- Because of the collaboration between NMCIM and the UNM CRTC, Dr. Larry Sklar and several CRTC and College of Pharmacy and Los Alamos National Lab investigators competed successfully for a new P30 NCI Cancer Center Grant

- The imaging facility that was completed as part of this funding now forms a key small animal imaging facility known as KUSAIR that is being used by multiple investigators for preclinical imaging for cancer and non-cancer applications
- NMCIM utilized funding from this grant to complete the remodel of lab B52 in the COP which will house both the NanoSPECT/CT instrument plus the AMI MicroPET instrument; NMCIM has received the \$610K BioScan NanoSPECT/CT instrument and has already performed several studies and demonstrated its capabilities to several commercial groups; NMCIM has received a \$550K Advanced Molecular Imaging (AMI) LabPET8 Instrument, which is now operational in the KUSAIR Facility