

Inter-Institutional Collaborations: ORIEN



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Objectives

- Describe the collaboration
- Describe how the collaboration came about and the role of the Center in developing the collaboration
- Describe the role the Cancer Center Administration plays
- How does the collaboration fits into the overall UNMCCC
- How the collaboration was highlighted in the core grant and site visit

Introducing



A National Cancer Center Alliance to integrate “Big Data” and Data Sharing For Cancer Research and Care

Mission

Accelerating cancer discovery and delivering hope through collaborative learning and partnerships



ORIEN Guiding Principles

Inclusiveness Participation by Cancer Centers AND patients in their respective communities

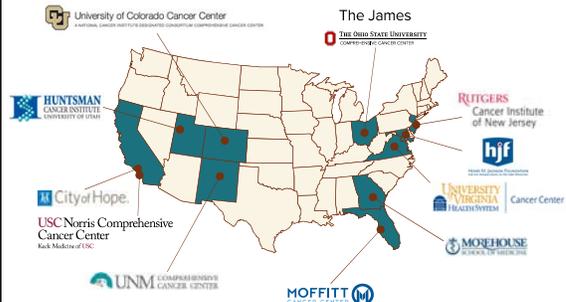
Accessibility of Data Real-time access to research data through RIE using a hybrid model of both a centralized data warehouse and a federated component: a network model

Public-Private Partnerships Establish trusted business relationships within and across sectors to achieve long-term program sustainability

Collaboration Commit to using a common protocol to ensure quality and consistency

Oncology Research Information Exchange Network (ORIEN)

Program operationalized a nation's leading cancer centers through ORIEN and collectively have annual patient volume of 50,000 new patients



ORIENT In Summary

ORIENT is an alliance of cancer centers who have contractually agreed to use a common protocol and share data, primarily for research, ultimately leading to evidence-based decision making and clinical care.

Patients consent to be followed throughout their lifetime and donate tissue, clinical and molecular data, and allow themselves to be re-contacted.

Individual members of ORIENT maintain ownership of their own data but agree to share limited data, and may choose to participate in specific projects which require extensive data sharing.

M2Gen serves as the coordinating center for member-initiated projects and commercial projects.

The TCC protocol has been in existence for over 10 years and has been approved by 26 IRBs in 18 states.

The system works, serves multiple stakeholders, (including patients) and no fees are charged to the patient.

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ORIENT Goals

- 1 Using Data science to accelerate discovery through data sharing
- 2 Anticipating Need and Tracking Patients for Biomarker-Driven Clinical Trials
- 3 Developing an Evidence-based Clinical Decision Support Tool at Point of Care

ORIENT's Members Will Utilize A Common Protocol

TOTAL CANCER CARE®

- 1 Follow the patient throughout their lifetime permitting sharing of data and information
- 2 Study the patient's tumor using molecular technology
- 3 Maintain contact with patient

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Total Cancer Care: Lessons Learned to Date

Over the course of the last decade, several "lessons learned" have identified challenges and opportunities

- Need for Scale**
 - "Scale" is multi-dimensional across the "3-V's": volume, velocity, and variety.
- Anticipate Need**
 - As opposed to being reactive, with TCC the plan is to take a pro-active approach to meeting patient need, specifically those who may benefit from a clinical trial.
- Focus on Data Utilization**
 - TCC is built with key stakeholders in mind to ensure that patients, clinicians, researchers, and administrators- can derive value from the data.
- Harmonized Approach**
 - The success of TCC to date has been a result of harmonizing all aspects of the Protocol including tissue and data SOPs across multiple sites, centralizing lab functions and utilizing a single consent.

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6 Key Steps to Implementation of Total Cancer Care

- 1 Identify Project Leadership and Key Stakeholders
- 2 Personalized Total Cancer Care Protocol to your site; Obtain IRB Approval
- 3 Communication with Faculty & Staff to Manage Change
- 4 Identify and Assess Infrastructure and Systems to Support Total Cancer Care
- 5 Define Staffing Needs
- 6 Develop Implementation Plan

Key Institutional Stakeholders

At the core of ORIENT is Total Cancer Care, which reaches across multiple stakeholders within your institution

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UNM Comprehensive Cancer Center – ORIEN Journey

- UNMCCC and ORIEN Journey
 - Dr Cheryl L. Willman, EAC for The James (OSU CCC)
 - Dr Bill Dalton, EAC for UNMCCC
- New Mexico Rich Multiethnic Population
 - Population: 1,920,000
 - 42% Hispanic
 - 10% American Indian
 - 4% Other Minorities
 - 44% Non Hispanic White

Cancer Center Administrator Role



Administrator role

- Contractual documents and initial liaison between UNMCCC and ORIEN.
- Served initially as the ORIEN Project Manager
- Identified internal stakeholders to facilitate the implementation of this collaboration.

ORIEN Program Manager Role

The Program Manager for the ORIEN member institution is a critical role for ensuring the timely and successful implementation of the ORIEN collaboration. This individual should work very closely with the Cancer Center Director and have a deep understanding of the institution's clinical research, biobanking, and overall research infrastructure. A basic understanding of the cancer center's information systems, cancer registry and LIMS is important, but also the ability to identify and bring in the organizational subject matter experts in these areas. This individual will be responsible for tailoring the TCC protocol and consent, as well as the ORIEN implementation to the new member's environment and lead in the development of a communication plan by the Cancer Center Director and/or the designated organizational leadership.

Functioning as the primary operational liaison between the Cancer Center and ORIEN, and between the Cancer Center and M2Gen, this individual should have strong communication and organizational skills, be detail oriented, and enjoy a highly collaborative working relationship that encourages sharing of best practices among all ORIEN member institutions. Based on our experience to date, individuals who have coordinated development and operations of the Total Cancer Care Protocol at their respective institutions include the following: Director of Clinical Research Operations, Director of Research Administration, Associate Director for Research Administration and Deputy Chief Administrative

ORIEN and TCCP Implementation

- UNMCCC ORIEN and TCCP implementation would report into the Clinical Research Office
- Hired a full time ORIEN Project Manager
- Established internal work groups and steering committee
 - Mirror the national ORIEN committees
 - Involve Cancer Center Director, Senior Leaders, Pathology, Informatics and Research Administration



Site Visit

- ORIEN was not included in the Core Grant submission, as membership was finalized the week of Site Visit.
- Site Visit Presentation, Director's Overview presented as future collaborations and impact on Research Programs, involvement of consortium partners and use of shared resources.

ORIEN Benefits to Cancer Centers

Contribute and have access to the largest "big data" and tissue repository to conduct collaborative research and learning

More efficient use of available research dollars to accelerate discovery and generate new intellectual property

Competitive advantage in grant applications through access to a large, diverse database and collaboration environment with other leading cancer centers

Rapid access to larger patient population for molecularly-targeted cancer therapies ecosystem

License of Total Cancer Care® Protocol

Revenue sharing model

Benefit from M2Gen's over ~10 years experience of managing Total Cancer Care® study and establishing Health & Research Informatics ecosystem

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UNMCCC ORIEN Status & Timeline

- ORIEN contract signed Feb 2015
- ORIEN Project Manager hired September 2015
- IRB Approval December 2015
- Activated Pilot GYN Oncology Clinic, January 26, 2016
- First subject enrolled January 28, 2016
- To date (March 18, 2016) 19 subjects consented

