

Private Practice Medical Office

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Disclosure

- Siu-Fun Wong, PharmD, FASHP, FCSHP has no real or apparent conflicts of interest to report

Outline

- Common research models
- Advantages
- Barriers
- Resources and personnel
- Research opportunities

Common Research Models in Private Practice Offices

- Independent program in physician-owned private practice office
 - Single site
 - Multiple sites
- Private practice network
 - eg, US Oncology
- Affiliation to regional community hospital
 - Member or affiliate of cooperative research group
 - Cancer trial support unit (CTSU)
- Affiliation with comprehensive cancer center
 - Member of cooperative research group
 - Partnership Programs, eg, Mayo Clinic, MD Anderson, UCLA
- Community clinical oncology program (CCOP)

Community Partners With Comprehensive Cancer Centers

- Translational Oncology Research International (TORI) Program at the University of California, Los Angeles
- Partners with research institutions, companies, and health care providers across the United States in order to offer clinical trials and research studies to patients and volunteers beyond the UCLA campus

Community Clinical Oncology Program (CCOP)

- Established in 1983
- Funded by National Cancer Institute (NCI)
- Linked community cancer specialists, primary care physicians, and other health care professionals to the NCI-supported cooperative groups and cancer centers to conduct NCI-approved cancer treatment, prevention, and control clinical trials
- In 2005, 50 CCOPs and 13 minority-based CCOPs across the country received funding for participation in NCI-approved trials, including 3,645 participating physicians and 415 participating hospitals working on more than 300 active treatment trials and more than 70 active prevention and control trials
- Research bases (14 cooperative groups and cancer centers) are eligible to develop and implement cancer prevention and control clinical trials

Types of Clinical Trials

- Physician-owned private practice office
 - Phase I-IV industry-sponsored trials or Principal Investigator Initiated New Drug (PIND) trials
- Private practice network
 - Phase I-IV industry-sponsored trials or PIND trials
- Affiliation with regional community hospital
 - NCI-sponsored trials
 - Phase I-IV industry-sponsored trials or PIND trials
- Affiliation with comprehensive cancer center
 - NCI-sponsored trials
 - Phase I-IV industry-sponsored trials or PIND trials
- Community clinical oncology program (CCOP)
 - NCI-sponsored trials

Advantages of Conducting Research at a Private Practice Office

- Protocol set-up
 - Protocol screening and approval process
 - Central IRB
 - Contract process
- Protocol execution
 - Limited personnel involved
 - Communication
 - Motivation and incentives

Barriers to Conducting Research at a Private Practice Office

- Selection of clinical trials
- The value of science
- Commitment to research
 - Providers
 - Patients
- Lack of resources
 - System
 - Personnel
 - Time

Resource Availability System

- Facility
 - Research space
 - Patient care areas – evaluation, treatment
 - Trained personnel
- Clinical laboratory
- Radiology
- Pathology
- Medical records
- Hospitalization
- Others

Resource Availability Personnel

- Mandatory
 - Executive Director or Administrator
 - Physician
 - Research Nurse
 - Data Manager

- Optional
 - President
 - Board of Directors
 - Scientific Advisory Committee
 - Credentials Committee
 - Institutional Review Board
 - Research Pharmacist
 - Statistician
 - Data Abstractors
 - Community Outreach Coordinator
 - Finance Coordinator
 - Secretary

How to Get Started?

- Evaluate the site and investigators
- Prepare the site
 - Set up policies and procedures
 - Assure standards can be met
 - Look for outside resource availability if needed
- Prepare personnel
- Select protocol wisely
- Prepare itemized protocol budget
- Contact all potential collaborator units
- Contract negotiation

Protocol Execution

- Patient screening
- Informed consent process
- Preprint orders
- Patient assessment and monitoring
- Patient follow-up
- Research drug handling
- Research financial issues
 - Clear billing procedures
- Research record handling and storage

Summary

- Conducting clinical research in a private practice setting can be challenging and yet rewarding
- With proactive and thorough planning, private practice can provide a rich resource for research
- With majority of cancer patients being cared for in the private practice setting, many patients can benefit from the availability of a clinical research program