A Outpatient Services

A1 AMBULATORY CARE CENTRE

A1(d) Cancer Centre Clinical Trials Office

A1(d) CANCER CENTRE CLINICAL TRIALS OFFICE

A1(d).1 SERVICE DESCRIPTION

A1(d).1.1 Scope of Clinical Services

This section A1(d) sets out the requirements for the centralized facilities for the Clinical Trials office area of the Facility to be achieved or accommodated by Project Co in providing the Works and the Services. Clinical Trials study new methods of screening, prevention, diagnosis, or treatment of a disease with a specific group of patients. The objectives of Clinical Trials are to identify the most effective treatments for specific types of cancer, to improve survival rates and/or increase the comfort of patients. The various aspects of cancer care that may be studied in Clinical Trials include chemotherapy, radiation therapy, nutrition, quality of life measures, and pain management.

The range of Clinical Trials activities to be provided in this component includes:

- Initiating and encouraging promising new projects and developments
- Recruiting of potentially eligible patients
- Controlling and managing the content, flow and accuracy of trials
- Undertake patient physical assessments
- Providing patient teaching and support relevant to the trials
- Providing and promoting clinical trial awareness to health care professionals and the public
- Assisting in the coordination of oncological clinical trials
- Interpreting and utilizing complex clinical trial data
- Maintaining comprehensive files on various studies
- Monitoring the distribution of clinical trial medications

Clinical Trials staff will collect statistical data in accordance with clinical trials designed by the various groups, and will meet to discuss the treatment of different diseases. Each trial will have protocols to follow for the collection of data, the assessment of patients and the efficacy of the treatment program. It is dependent on coordinating with the caregivers, the collection of data and the assessment of patients who are participating in a trial. The Cancer Centre may also be involved in developing Phase II and III trials.

A1(d).1.1.1 *Current Trends*

In providing the Works and Services, Project Co shall take into account the following trends:

- *The success of clinical trials in identifying new agents and treatment modalities will result in an increased proportion of cancer patients participating in therapeutic trials.*

A1(d).1.2 Scope of Education Services

The Cancer Centre is responsible for:

- Ensuring that Clinical Trials staff are knowledgeable in current clinical trials procedures, national and international guidelines, regulations issued by TPD of Health Canada, Canada, FDA, ICH-GCP, EU and other institutions. Certification of staff through professional organizations (e.g., Society of Clinical Research Associates) will be ensured. In addition, the attendance of courses and seminars offered by professional organizations and public institutions will be encouraged.

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- Organizing in-services/workshops for staff and investigators to discuss clinical trials procedures/research.
- Keeping investigators up to date on current regulatory practices, such as UBC guidelines for ethics approval.

A1(d).1.3 Scope of Research Services

This component will include central facilities in support of the Cancer Centre's clinical trials protocols. The Cancer Centre will participate in regional, national and international studies.

A1(d).1.4 Specific Exclusions

This specification excludes Clinical Trials services/requirements provided elsewhere, including:

- Cancer Centre pharmacy services for Clinical Trials (see section C5 Pharmacy Services)
- Clinical Trials interview rooms in Cancer Centre General Clinics (see section A1(e) Cancer Centre General Clinic)

A1(d).2 OPERATIONAL DESCRIPTION

A1(d).2.1 Minimum Hours of Operation

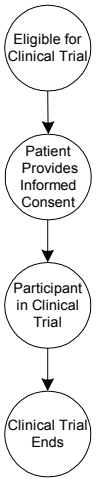
The Clinical Trials Office will typically operate from 0800h to 1630h, Monday to Friday.

A1(d).2.2 Patient Management Processes

A1(d).2.2.1 Clinical Trial Participation

Once a patient has been identified eligible to participate in a clinical trial, researchers will review key facts about the clinical trials before they decide to participate (process referred to as informed consent). Once the patient decides to participate, they will sign an informed consent form. The consent form details the study approach, the intervention given in the trial, the possible risks and benefits, and the tests that may be performed. The patient will review this information with the research doctor or nurse.

During the clinical trial, the study participant will work with members of the research team. The research team may include the principal investigator, doctors, nurse, dieticians, and other health care professionals. The participant will be required to come in at designated times for tests, completing log information, or completing questionnaires. Patients will be monitored by data managers and nurses during their participation in the study.



Patient Flow Diagram

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A1(d).2.3 Patient Information Management

Refer to Output Specifications, Section 3: Non-Clinical Services, subsection D1 Information Management; Section 5: Design and Technical, subsection 5.3.17 Technology and Communication Systems; and Section 6: IT/Tel Services.

A1(d).2.4 Staff Work Processes

A1(d).2.4.1 Recruitment of Participants for Clinical Trial

Once the researchers develop a clinical trials protocol, the research team will enrol participants based on eligibility criteria. Staff will interview patients in rooms in the General Clinic area.

A1(d).2.4.1 Conduct Clinical Trial

Members of the research team will monitor the participant's health, offer specific instruction about the study, and ensure reliability of results throughout the course of the trial. The nurse coordinator may administer tests or treatments (i.e., drugs) to the study participants at designated intervals throughout the course of the trial. An area for the storage of kits and drugs on trials and a workroom to see patients and assembly of materials for clinical trials will be provided in Cancer Centre Pharmacy area. Once the trial ends, the research team may continue to contact participants via telephone.

Process Flow Diagram

A1(d).2.5 Materiel Services

Disposal of used medical equipment and hazardous wastes will take place in a dirty utility area.

Also refer to Output Specifications, Section 4: Facility Management Services, subsection E7 Materiel Services, and Section 2: Clinical Services, subsection C8 Sterile Processing Services.

A1(d).2.6 Linen/Housekeeping Services

Refer to Output Specifications, Section 4: Facility Management Services, subsections E5 Housekeeping Services and E6 Laundry/Linen Services.

A1(d).2.7 Equipment Asset Management

Refer to Output Specifications, Section 4: Facility Management Services, subsection E2 Biomedical Engineering; and Section 7: Equipment.

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A1(d).3 ACTIVITY INDICATORS

The table below summarized the projected activity for the Clinical Trials Office services which must be addressed by Project Co in performing the Works and the Services.

A1(d).3.1 Hospital Activity *(Incl. in Cancer Centre Activity below)*

A1(d).3.2 Cancer Centre Activity

Unit	Minimum Projected Yearly Activity
Number of Patient Screened	333
Number of Patients Accrued	111

A1(d).4 PEOPLE REQUIREMENTS

This component will have a total staff complement in the range of 13 FTE, consisting of 6 clinical trials data managers, 3 nurse coordinators, 1 biostatistician, 1 clinical trials pharmacist, 1 clinical trials pharmacist technician, and 1 clerical/administrative personnel.

It is anticipated that the key functional areas in the component will need to accommodate the following maximum number of people.

Functional Areas	Patients	Staff	Visitors	Others	Total
Office Area	2-3	3-7	1-2	1-2	7-14

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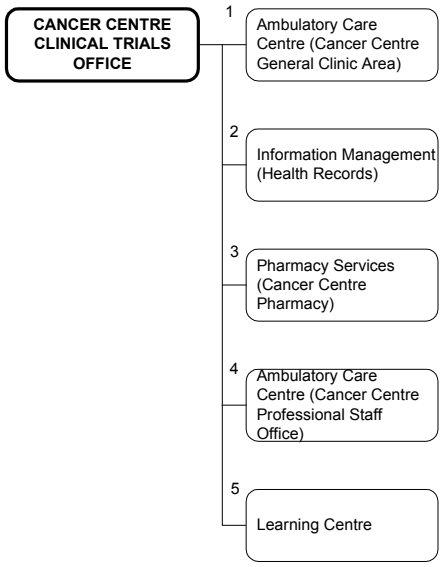
A1(d).5 DESIGN CRITERIA

A1(d).5.1 Key External Relationships

The following key relationships will be achieved in the priority order as numbered for the purposes stated:



1. Provide direct access by general circulation to Ambulatory Care Centre (Cancer Centre General Clinic Area) for visibility of patients by protocol nurses.
2. Provide convenient access by general circulation to IM (Health Records) for the movement of staff and patient records.
3. Provide direct access by general circulation to Pharmacy Services (Cancer Centre Pharmacy area) for the movement of staff.
4. Provide convenient access by general circulation to Ambulatory Care Centre (Cancer Centre Professional Staff Office area) for staff communication and interaction.
5. Provide convenient access by general circulation to Learning Centre for ease of access to conference/library resources.

A1(d).5.2 Key Internal Relationships/Environmental Considerations

The following will be achieved:

A1(d).5.2.1 Acoustic Control

Provide acoustic privacy in all office areas for confidentiality.

Also refer to Output Specifications, Section 1: Key Site and Building Design Criteria, subsection 1.2.5.4 Acoustics.

A1(d).5.2.2 Patient Privacy

Provide visual and acoustic privacy for patients/study participants in all consultation spaces.

A1(d).5.2.3 Ergonomics Considerations

Refer to Output Specifications, Section 1: Key Site and Building Design Criteria, subsection 1.2.4.6 Ergonomics.

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A1(d).5.2.4 Flexibility/Open Office

Provide sufficient open wall space for hanging of charts, wall displays.

Also refer to Output Specifications, Section 1: Key Site and Building Design Criteria, subsection 1.2.3.3 Flexibility and Expandability.

A1(d).5.2.5 Security

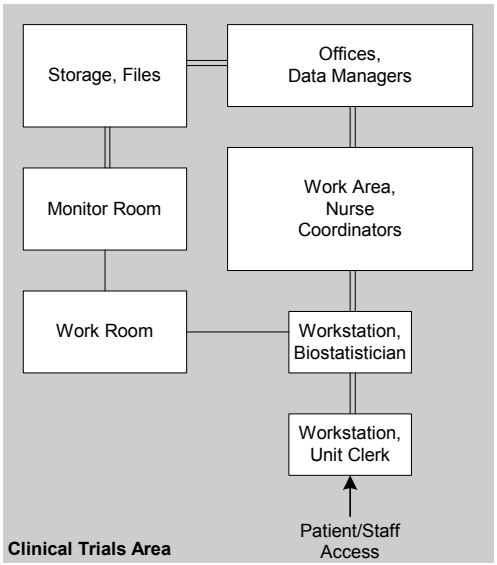
Provide secure storage of confidential documents in a locked area. Documents in lockable file cabinets will be under the visual supervision of all clinical trials staff. Ensure other clinical trials staff and public do not walk through this component to access other areas of the Clinical Trials Office.

Also refer to Output Specifications, Section 1: Key Site and Building Design Criteria, subsection 1.2.2.3 Security and Personal Safety.

A1(d).5.2.6 Component Functional Diagram

The spatial organization of this component will be generally as shown in the diagram below.

A1(d).5.2.6.1 *Micro Relationship Diagram*



Legend

- Immediately Adjacent
- Direct Access
- Reasonably Close Access
- Direct Visual Supervision

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A1(d).5.3 Schedule of Accommodation *(Note: Spaces listed in parentheses ( ) are spaces supporting services provided by Project Co and are included in the total net square metres.)*

Ref	Space	Area Requirements units	nsm/unit	nsm
	Office Area			
01	Office, Data Managers	6	6.5	39.0
02	Storage, Files	1		13.0
03	Monitor Room	1		11.5
04	Work Area, Nurse Coordinator	1		19.5
05	Workstation, Biostatistician	1		6.0
06	Workstation, Unit Clerk	1		7.5
	Storage, Kits	1		(12.0) [1]
07	Workroom	1		10.0
	Total			**106.5**

A1(d).6 DESIGN GUIDANCE

None

A1(d).7 OTHER SPECIFICATIONS

Clinical trial activity are primarily based in the Clinical Trials Offices, however, other specifications that will be consulted are:

A1(e) Cancer Centre General Clinic
C5 Pharmacy Services

[1] *Located in C5 Pharmacy Services.*

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