**Birmingham Children's Hospital (BCH) and the Clinical Trials Unit (CRCTU) at the University of Birmingham (UoB) offer a unique opportunity for an ITCC Fellow to train within one of the largest children's cancer centers in the UK and Europe's leading paediatric cancer clinical trials unit. This program is ideal for individuals looking to combine clinical training with gaining in-depth experience in the processes involved in designing and executing clinical trials, spanning from early-phase development to later-stage implementation.**

**Program Overview**

The ITCC Fellow training integrates clinical trial expertise between:

- **Clinical Trials Unit (CRCTU)** at the University of Birmingham (UoB).
- **Birmingham Children's Hospital (BCH)**, part of the Birmingham Women's and Children's NHS Foundation Trust.

**Training Components**

**Clinical Exposure at BCH**

1. **Paediatric Oncology Department**:
    - One of the UK's largest, managing ~250 new cases annually.
    - Early-phase clinical trials (Phase I/II) for solid tumors (intracranial/extracranial) and haematological malignancies.
    - Trial management from patient screening to safety reporting (SAE/SUSAR) and efficacy evaluations (RECIST 1.1/RANO/INRG).
    - Responsibilities include:
        - Multi-Disciplinary Team (MDT) involvement.
        - Patient consent processes.
        - Documenting study visits and sponsor reporting.
        - Regular sponsor communication (virtual).
    - Exposure to the national **therapeutic drug monitoring program** (collaboration with the University of Newcastle) for standard chemotherapy in specific patient subgroups (e.g., low weight, single kidney, adiposity).
2. **Ethics and Palliative Care**:
    - Understanding trial-related ethical aspects:
        - Informed consent (clinical and development perspectives).
        - Designing eligibility criteria ensuring safety while maintaining accessibility.
    - Collaborating with the **specialist Palliative Care team** for symptom management and family support in the early-phase trial setting.

**Research Opportunities at CRCTU**

1. **Comprehensive Trial Management**:
    - Experience across the trial lifecycle:
        - Protocol writing, regulatory applications, trial setup, monitoring, and closure.
        - Interim assessments, dose escalation meetings, and management group participation.
    - Exposure to **large platform trials**:
        - **FaR-RMS**: Rhabdomyosarcoma platform trial.
        - **GLO-B-NHL**: Innovative Phase I/II trial for relapsed/refractory B-NHL with multiple treatment arms.
2. **Statistical and Translational Expertise**:
    - Working with a large statistical team to learn about trial design approaches (e.g., Bayesian designs).
    - Involvement in biomarker studies and pharmacokinetic (PK)/pharmacodynamic (PD) assessments.
3. **Translational Research**:
    - Collaboration with UoB labs focusing on:
        - Target identification.
        - Research into sarcoma, brain tumours, and lymphoma.
    - Opportunities to participate in lab meetings, journal clubs, and observe modern cancer biology research.

**Education and Development**

1. **MSc/PGDip Clinical Trials Program (UoB)**:
    - Access to modules/lectures on:
        - Early-phase clinical trials.
        - Statistical trial design.
    - Optional enrollment in full MSc program (fees apply).
2. **Skill Development**:
    - Ethical considerations in trial development and execution.
    - Patient data confidentiality and monitoring procedures.