

Overview of CRAFT Implementation Sites & Trials

| Primary Site | Eastern Health Regional Authority | BC Cancer - Prince George | Health Sciences North | Centre hospitalier universitaire de Sainte-Justine |
|--------------------------------|---|---|--|--|
| Trial | CUOG) PRIME | (BCC) SABR-COMET-3 | (ROCHE) GO41854 \ Skyscraper 3 | (SJCRH) SJMB12 |
| CT.gov link | https://clinicaltrials.gov/ct2/show/NCT03031821 | https://clinicaltrials.gov/ct2/show/study/NCT03862911 | https://clinicaltrials.gov/ct2/show/study/NCT04513925 | https://clinicaltrials.gov/ct2/show/study/NCT01878617 |
| 3CTN Portfolio Trial | Yes | Yes | No | Yes |
| Phase | III | III | III | II |
| Trial Notes | Minimal risk, high recruitment potential | Comparing SOC vs. SABR for patients with oligometastatic cancer. Rural patients hesitant to enroll due to travel requirements related to follow up physical exam at BC Cancer | Industry sponsored interventional trial | To enroll a young adult (19-39) at an adult site in a pediatric study |
| CRAFT Proof of Concept? | Yes | Yes | Yes | No |
| Satellite Site Initiated | Grand-Falls Windsor | Mills Memorial Hospital (Terrace) | Timmins and District Hospital | Centre Hospitalier de l'Université de Montréal (CHUM) |
| Previous Trial Experience | None | None | None | Yes - Primary Oncology Site |
| Responsibilities | IP Administration, lab based tests, follow up assessments | Follow up assessments | IP Administration, follow up assessments | Patient Visits/Exams, Collecting test results/reports |
| Satellite Site Resources (New) | Nurse Practioner | | Virtual Coordinator | |
| REB | Amendment for Satellite Site | Amendment for Satellite Site | Board of Record between OCREB - Timmins | |
| Patient Recruitment | 1 | 1 | 0 (closed to recruitment before satellite site initiated) | 1 |
| Challenges | Staffing at satellite site - NP needs to complete additional CT work; engagement of satellite site and competing priorities | Competing priorities of satellite sites, changes in personnel | Recruitment | Satellite Site REB, availability of PI/Sub-I, satellite site's capacity/capability to follow CT requirements |
| Lessons Learned | Start engagement of stakeholders early, start small and build capacity | Focus on communication (i.e., monthly meetings), create a project culture (keep on key personnel's radar), expect delays - select trial with long accrual period | Dedicated point-person (i.e., PM or Virtual Coordinator), good communication plan, use of a electronic document sharing system, streamline processes as best you can throughout the project, plan for delays, start with a trial with high recruitment potential, consider complexity of initial CRAFT trial | Possibility to have Sub-I at satellite site, funds to cover cost for satellite sites |
| Comments | IP distributed to primary site (responsible for overall accountability & shipment to satellite site). Blood draws at satellite site, storage in -80 freezer. Lab supplies sent from sponsor to satellite site. June 19, 2024 update: satellite site building/infrastructure considered for a COVID study to see remote patients in the area - however at time of report, did not open yet. | Collaboration between BC Cancer and Northern Health. Follow up physical examination at satellite sites (GPs with oncology training), Collection of patient reported outcomes (PRO) at home using REDCap | Shared EMR; Roche very supportive. Roche to distribute IP to satellite site | Challenge of adult site being able to obtain tests within study timeframe due to existing load of patients, limited funding of academic studies. |