A DECENTRALIZED CLINICAL TRIAL CASE STUDY

How Fortrea Mobile Clinical Services (MCS) may improve the patient experience in oncology studies

Abstract: Fortrea MCS is a suite of solutions that aims to reduce the patient burden of studies while also providing flexibility to the investigator sites. The following case studies highlight Fortrea MCS support in global oncology trials since 2010, showcasing instances in which MCS has proven to be an invaluable aid to investigator sites and patients.

As of June 2022, Fortrea MCS—previously known as GlobalCare Clinical Trials LLC—has been awarded with more than 95 studies in oncology since 2010, most of which have been conducted in multiple regional locations. These studies are interventional Phase I, II and III or observational clinical trials, covering many types of cancers and tumors. Fortrea MCS has broad experience in supporting oncology studies in adult and pediatric populations, as well as in monotherapy and polytherapy oncology clinical trials with drugs or antibodies.

Clinical trials in oncology have varying study designs and needs that can benefit from the flexibility of Fortrea MCS. From measuring vital signs to enabling sample collection to take place at a patient's home, Fortrea MCS provides innovative solutions that strengthen patient engagement and retention, allowing studies to overcome common roadblocks and advance more easily through the drug development continuum.

Fortrea MCS has been contracted to:

- Perform, support, supervise and review intravenous, intramuscular, subcutaneous, or oral investigational product (IP) preparation and administration at the patient's home
- Measure vital signs, oxygen saturation, body weight and Eastern Cooperative Oncology Group performance status
- Perform a limited physical assessment
- Conduct 12-lead electrocardiogram
- Collect biological specimens
- Review questionnaires and dosing diaries
- Check central lines for signs of infection or extravasation and assess changes in signs and symptoms and in concomitant medications
- Provide pump training to the investigator site staff and offer 24/7 on-call pump support and emergency visits

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A consistent key to success is the partnership between investigator sites and Fortrea MCS personnel to ensure continuity of care for the patients' benefit and to comply with the sponsor's protocol.

Use of MCS for long and continuous intravenous IP infusion

Associated risks and challenges:

- Risk of infection or extravasation at the venous access
- Need to regularly change the infusion bags every few days
- Continuous need for pump support
- For patients, long infusions are cumbersome and could lead the patients to discontinue the trial

Fortrea MCS approach:

Fortrea MCS engaged services for studies for a variety of clinical indications that nonetheless had similar support needs (case studies 1 through 6 below), with long and continuous IP intravenous infusion in a matter of weeks. Local Fortrea MCS personnel were trained in trial specifics, and collaboration between MCS personnel ensured continued protocol compliance. Coordination between site pharmacies and Fortrea MCS supported IP preparation, delivery and full infusion within the stability period. Fortrea MCS also provided support to the investigator sites by conducting training on infusion pumps and provided 24/7 support to the patients by making it possible to conduct long continuous IP infusions at home.

A few examples of these studies are included below:

Case Study 1	Fortrea MCS participated in a Phase III trial conducted in pediatric patients with high-risk first-relapse B-precursor acute lymphoblastic leukemia. These patients required a four-week continuous intravenous IP infusion. Over 44 months, 83 home visits and 4 on-call support events occurred within the trial, assisting 27 patients in 6 countries.
Case Study 2	Fortrea MCS participated in a Phase III trial conducted in adult patients with relapsed/refractory B-precursor acute lymphoblastic leukemia, requiring a four-week continuous intravenous IP infusion. Over 38 months, 657 home visits occurred within the trial, assisting 78 patients in 14 countries.
Case Study 3	Fortrea MCS participated in a Phase II trial conducted in adult patients with Philadelphia-positive acute lymphoblastic leukemia that required a four-week continuous intravenous IP infusion. Over 16 months, 325 home visits occurred within the trial, assisting 25 patients in 5 countries.
Case Study 4	Fortrea MCS participated in a Phase I trial conducted in adult patients with relapsed/refractory gastrointestinal adenocarcinoma that required one- or two-week continuous intravenous infusion. Over 58 months, 1,008 home visits occurred within the trial, assisting 48 patients in 2 countries.
Case Study 5	Fortrea MCS participated in a Phase I/Ib trial conducted in adult patients with EGFRvIII-positive glioblastoma that required one- to four-week continuous intravenous IP infusion. Over 28 months, 126 home visits and 55 on-call support events occurred within the trial, assisting 13 patients in 6 countries.
Case Study 6	Fortrea MCS participated in a Phase II trial conducted in adult patients newly diagnosed with high-risk diffuse large B-cell lymphoma that required a four- or eight-week continuous intravenous IP infusion. Over 16 months, 258 home visits and 29 on-call support events occurred within the trial, assisting 14 patients in 3 countries.

Use of MCS for supervision of subcutaneous IP preparation and administration

Associated risks and challenges:

- The need for administering IP on a daily basis during each cycle treatment
- Multiple steps required to prepare the IP could cause disruptions leading patients to discontinue the trial

Fortrea MCS approach:

Fortrea MCS engaged the supervision of subcutaneous IP preparation and administration at home for three studies with similar needs (case studies 7-9) in a matter of weeks, enhancing the patients' engagement and confidence in the IP administration procedures.

Local Fortrea MCS personnel were trained in trial specifics, and collaboration between MCS personnel ensured continued protocol compliance.

A few examples of these studies are included below:

Case Study 7	Fortrea MCS participated in a Phase Ib trial in adult patients with advanced multiple myeloma that required a daily supervision of IP preparation and administration during each treatment cycle. Over 15 months, 203 home visits occurred within the trial, assisting 10 patients in 2 countries.
Case Study 8	Fortrea MCS participated in a Phase Ib trial in adult patients with relapsed/ refractory diffuse large B-cell lymphoma that required a daily supervision on IP preparation and administration during each treatment cycle. Over 13 months, 123 home visits occurred within the trial, assisting 9 patients in 4 countries.
Case Study 9	Fortrea MCS participated in a Phase Ib trial in adult patients with advanced ovarian cancer or triple-negative breast cancer that required a daily supervision on preparation and administration during each treatment cycle. Over 21 months, 251 home visits occurred within the trial, assisting 14 patients in 3 countries.

Use of MCS for recurrent specimen collection

Associated risks and challenges:

- The need for multiple collection time points during the trial could lead the patients to discontinue the trial

Fortrea MCS approach:

To bolster patient engagement and maximize patient comfort and convenience in the trial, Fortrea MCS facilitated home visits that made it possible for specimen collection to occur at different time points within the patients' own homes. Fortrea MCS engaged at-home specimen collection visits, including labeling, processing, packaging and shipping to the designated laboratory, in a matter of weeks. Case studies 10-15, below, all required recurrent sample collection methods.

Local Fortrea MCS personnel were trained in trial specifics, and collaboration between MCS personnel ensured continued protocol compliance. Coordination among designated laboratories, specialty couriers and Fortrea MCS allowed for specimen collection during home visits, which minimized patient burden and allowed more patients to remain in the trial. In most of these case studies, samples collected were sent to Labcorp CLS as our preferred central laboratory for testing.

A few examples of these studies are included below:

Case Study 10	Fortrea MCS participated in a Phase III trial conducted in adult patients with locally advanced, unresectable stage III non-small cell lung cancer. The cancer had not progressed after concurrent platinum-based chemoradiation, so biweekly blood collections in each treatment cycle were required. Over 16 months, 221 home visits occurred within the trial, assisting 42 patients in 9 countries.
Case Study 11	Fortrea MCS participated in a Phase I trial in adult patients with unresectable locally advanced or metastatic breast cancer that required blood collection at different time points in each treatment cycle. Over 84 months, 549 home visits occurred within the trial, assisting 440 patients in the U.S.
Case Study 12	Fortrea MCS participated in a Phase II trial in adult patients with locally advanced or metastatic urothelial cancer who previously received immune checkpoint inhibitor therapy that required blood collection at different time points in each treatment cycle. Over 29 months, 350 home visits occurred within the trial, assisting 82 patients in the U.S.
Case Study 13	Fortrea MCS participated in a Phase I trial in pediatric and adult patients with B-lineage acute lymphoblastic leukemia and highly aggressive lymphomas that required blood collection at different time points in each treatment cycle. Over 51 months, 140 home visits occurred within the trial, assisting 30 patients in the U.S.
Case Study 14	Fortrea MCS participated in a Phase I trial in pediatric and adult patients with relapsed or refractory B-lineage non-Hodgkin lymphoma that required blood collection at different time points in each treatment cycle. Over 42 months, 291 home visits occurred within the trial, assisting 42 patients in the U.S.
Case Study 15	Fortrea MCS participated in a Phase II trial in adult patients with unresected, stage IIIB to IVM1c melanoma that required the collection of oral, genital and lesion swabs at different points of the study. Over 34 months, 300 home visits occurred within the trial, assisting 33 patients in the U.S.

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