Trial SR.7

EORTC Protocol Number: STRASS 2/1809-STBSG

Eudra CT Number: 2019-003543-30

NCT04031677

A Randomized Phase III Study of Neoadjuvant Chemotherapy Followed by Surgery versus Surgery Alone for Patients with High Risk RetroPeritoneal Sarcoma (STRASS 2)

Canadian Study Chair: Rebecca Gladdy

CCTG Senior Investigator (SI): Janet Dancey

CCTG Study Coordinator (SC): Selene Miller

Canada SR7 update (March 15/2021):

Centrally Activated in Canada on 2021Feb02, the date the protocol, Canadian appendix and related documents were released to sites.

Virtual investigator meeting was held on 2021Feb16 where we had research staff from approximately 11 centres attend.

Thank you to EORTC for attendance at the meeting along with Study PI's: Gronchi and van Houdt

CCTG Sites Planning on Activating Trial

1. Vancouver PI: Christine Simmons
2. Winnipeg PI: Shantanu Banerji/Justin Rivard (with banking)
3. Ottawa PI: Carolyn Nessim
4. Toronto PI: Carol Swallow (with banking)
5. Montreal PI: Sinziana Dumitra/Thierry Alcindor

Central Histopathology Review

This study involves **mandatory** central review.

The histopathological diagnosis and tumour grading of all participating patients (both arms) will be reviewed and confirmed *retrospectively* by a Canadian central reference pathologist.

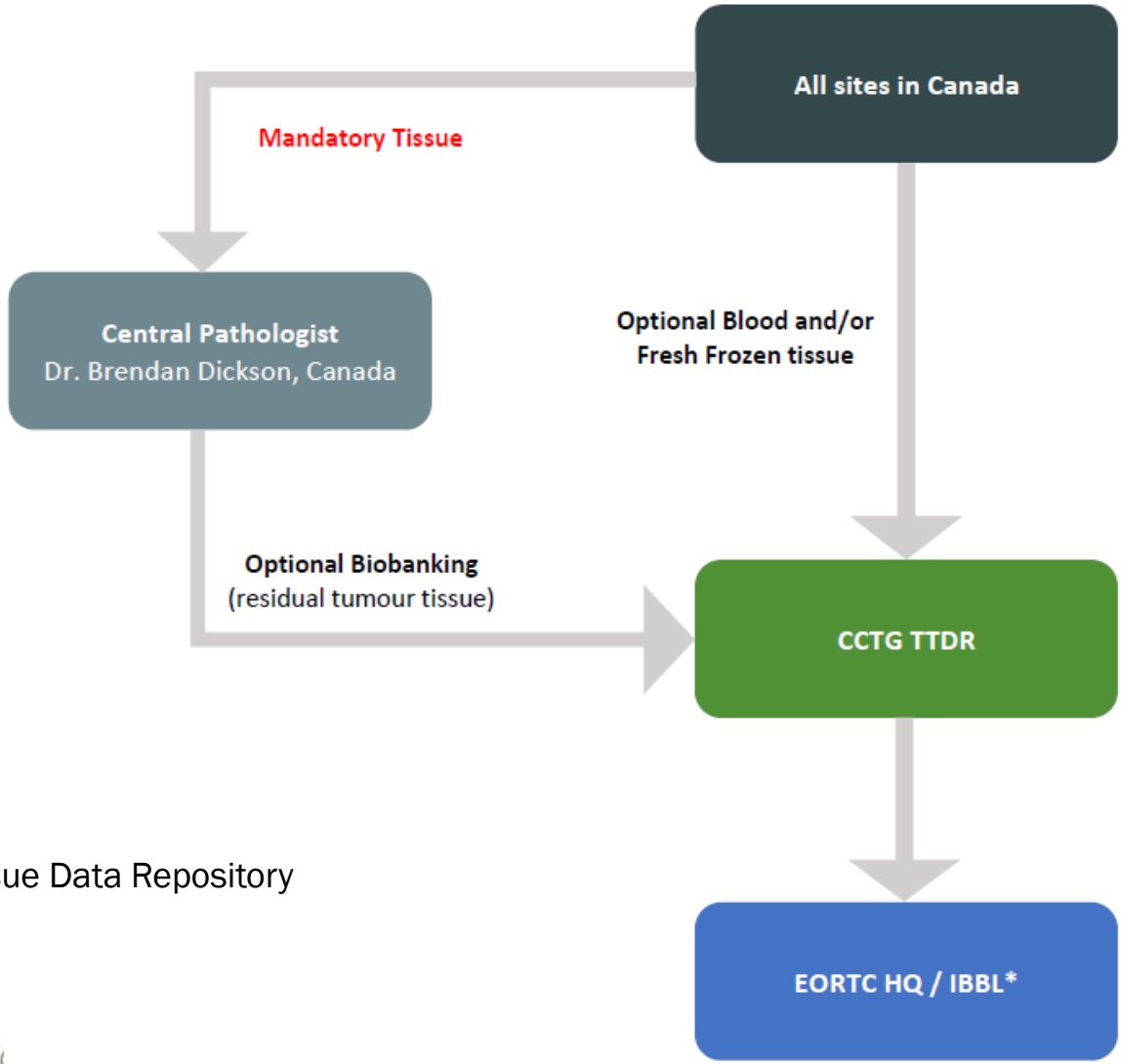
Sites will send the following to the Canadian reference pathologist (BCD):

- ✓ Tumor material at baseline (diagnosis) and during surgery (response)
- ✓ An anonymized copy of the local pathology report

Note: Histological central review is not required before treatment start.
Patient entry will be based on local diagnosis.

Please ship all mandatory samples above to the Canadian central reviewer per *CCTG SR.7 HBM Guidelines.*

HBM Flowchart



TTDR – Tumour Tissue Data Repository

Optional TR and Biobanking

Translational Research (TR)

- If Canadian site opts-in to **blood sample** collection, it is mandatory for the patient. Sites will collect/process blood per CCTG *SR.7 HBM Guidelines* and ship to the CCTG Tumour Bank in for storage.
- Collection of **fresh frozen tissue** is optional for *both* sites and patients. If collected by the site, it is optional for the patient. Sites will ship directly to the CCTG Tumour Bank for storage.

Biobanking

- If the patient consents to optional banking, **residual tissue and blood** (including leftover mandatory tissue from central review) will be shipped to the CCTG Tumour Bank for storage.

Please ship all biospecimens above to CCTG Tumour Bank per *CCTG SR.7 HBM Guidelines* & send a shipment notification to **tissue@ctg.queensu.ca**.

Human Biologic Material Collection

Please refer to the **CCTG *SR.7 Human Biologic Material (HBM) Guidelines*** for a summary of all Canadian-specific protocol adaptations.

Specimen	*Quantity*	*Collection time point(s)*	*Optional for sites?*	*Patient choice?*
FFPE tissue	4 cores biopsies (14-18gauge)	diagnosis (archival)	Required	No
FFPE tissue	- 3 blocks of tumour tissue - 1 slide of each block of resected specimen - Normal tissue (if available)	Surgery	Required	No
Fresh Frozen Tissue	mirror of collected FFPE samples	diagnosis and surgery	Optional	yes
whole blood (for plasma and buffy coat)	1 EDTA tube (10 ml)	- baseline - before C2 of chemotherapy - pre-surgery & D15 after surgery - at recurrence	Optional	No - YES
whole blood (for ctDNA)	1 STRECK tube (10 ml)	- baseline - before C2 of chemotherapy - pre-surgery & D15 after surgery - at recurrence	Optional	No -YES

Canadian sites MUST collect FFPE tissue for site participation. Collection of fresh frozen tissue and whole blood is highly encouraged, but not required for site participation on SR.7 in Canada.

Site Requirements for Local Activation

A brief list of items below that must be submitted to CCTG prior to local activation of SR.7 at your site:

1) Local REB approval for protocol and protocol-related documents

2) Approved Participants List in RIPPLE

- All required tasks delegated (QI, PCRA, ECRA)
- Individuals must have valid CCTG account and have completed/submitted the following:
  - Study Acknowledgement/ Disclosure Form
  - Investigator CV
  - Training (GCP and Division 5, SR.7 STU slides)

3) Trial Lab Use form

4) List of study personnel requiring EDC access

Refer to the *Notice of Central Activation Letter on the SR.7 webpage* for all details.

Registration/Randomization Procedures

STEP 1 - CCTG registration and obtain CCTG ID

- Fax a copy of the signature page(s) of the patient consent forms (main and optional) and **SR7 Patient Enrollment Transmittal form** to CCTG
- Site and investigator credentialing checks
- Relay CCTG patient ID to the site

STEP 2 – EORTC registration and randomization confirmation

- Sites must complete the patient registration form in the *EORTC Medidata RaveEDC* system and enter the corresponding CCTG ID
- Once randomization is confirmed, submit a **SR.7 Randomization Confirmation form** to the CCTG SR.7 trial team

All patients must be enrolled with CCTG first and then subsequently registered in the EORTC Medidata RaveEDC system before any treatment is given.

Canadian-Specific Process (all sites)

LOCAL SITE ACTIVATION

- Local REB approval of protocol and documents
- RIPPLE parts list approval
- Trial Lab Use form
- EORTC EDC data access

CCTG PATIENT ENROLLMENT

- Informed consent obtained
- Site sends CCTG signature pages + enrollment form
- CCTG verifies site and investigator credentialling
- CCTG ID assigned

EORTC PATIENT ENROLLMENT

- Sites complete registration form in EORTC database
- EORTC confirms randomization
- Return **Randomization Confirmation form** to CCTG

Queries

The EORTC HQ will perform extensive consistency checks on the received data.

Queries will be issued in order to resolve other inconsistent data.

Queries for the electronic forms will appear in the ***EORTC RaveEDC system*** and must be answered there directly.

The CCTG will forward relevant correspondence between the lead group and Canadian centres.

Trial Contacts

Please contact EORTC directly for clinical & general protocol issues (copy CCTG on all correspondence):

Clinical protocol questions (i.e. eligibility or treatment-related)	EORTC 1809-STBSG **Study (Physician) Coordinator**, *Alessandro Gronchi* alessandro.gronchi@istitutotumori.mi.it
Non-clinical protocol questions (i.e., unrelated to patient eligibility, treatment, or clinical data submission)	EORTC 1809-STBSG **Clinical Operations Coordinator**, *Laura De Meulemeester* laura.demeulemeester@eortc.org
Data Management (i.e. related to eCRFs or EDC data reporting or submission)	EORTC 1809-STBSG **Clinical Data Manager**, *Axelle Nzokirantevye* axelle.nzokirantevye@eortc.org
CCTG Study Coordinator	*Selene Miller* smiller@ctg.queensu.ca
CCTG Study Chair	*Rebecca Gladdy* Rebecca.gladdy@sinaihealth.ca

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