# EORTC-STBSG
# Study **1809 (STRASS 2)**

## A randomized phase lll study of neoadjuvant chemotherapy followed by surgery versus surgery alone for patient with High Risk RetroPeritoneal Sarcoma

Study coordinator: **Alessandro Gronchi**
Fondazione IRCCS Istituto Nazionale dei Tumori, Milano, Italy

Study co-coordinator: **Winan van Houdt**
The Netherlands Cancer Institute-Antoni Van Leeuwenhoekziekenhuis, Amsterdam, the Netherlands

# Study organization

**STRASS-2 is a multicenter phase III study run in 38 EORTC sites over 11 countries**

**STRASS-2 is an intergroup collaboration**

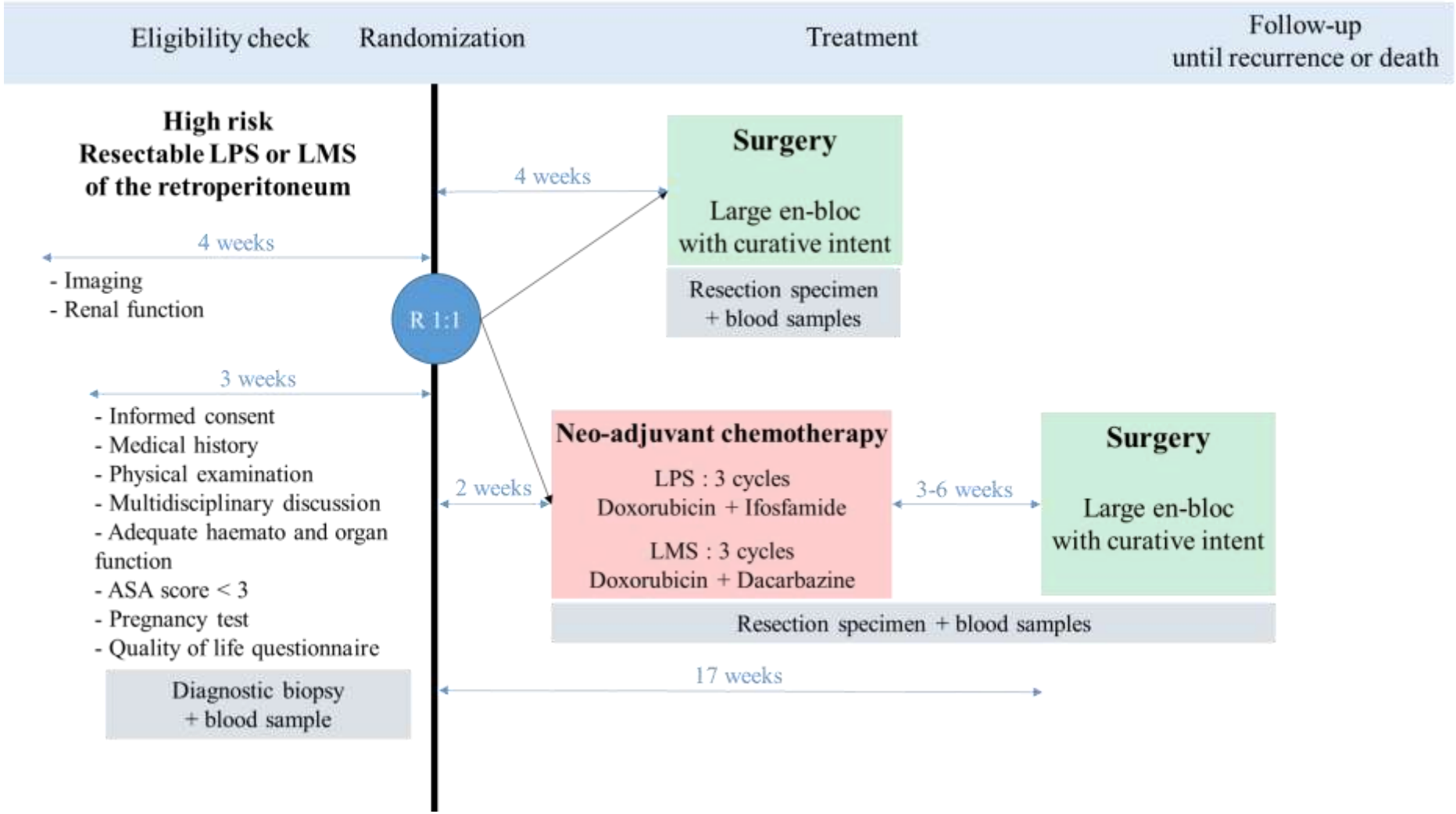
- EORTC = sponsor in Europe
- CCTG = sponsor in Canada
- ANZSA = sponsor in Australia
- ECOG/ACRIN = sponsor in US
- JCOG = sponsor in Japan

# STRASS 2 main objective

- STRASS 2 aims to investigate whether patients affected by RPS with the highest metastatic risk (G3 DDLPS and LMS) could benefit from neoadjuvant chemotherapy.

- The main objective of this study is to demonstrate that neo-adjuvant chemotherapy, as an adjunct to curative intent en-block surgery can improve the prognosis of these patients by reducing the risk of development of distant metastasis.

# Study design



# Study conduct

- 250 patients will be randomized over 66 months (5.5 years).
- Follow-up = 1.5 years

- To ensure balance between the number of patients in the two histology cohorts, accrual to each cohort will be capped to 125 patients.

- Two interim looks for futility are foreseen in this design: one after approximately 40% of events have occurred (around 4 years after first patient in) and one after approximately 66.7% of events have occurred (around 5 years after first patient in)

# Protocol versions

- The study protocol has been amended concerning the inclusion of LMS patients:

→ *Protocol v3.0:* LMS: Grades 2 and 3 LMS of minimum size 5 cm

→ *Protocol v4.0:* LMS: any grade and size > 5 cm

# Study status – regulatory submissions

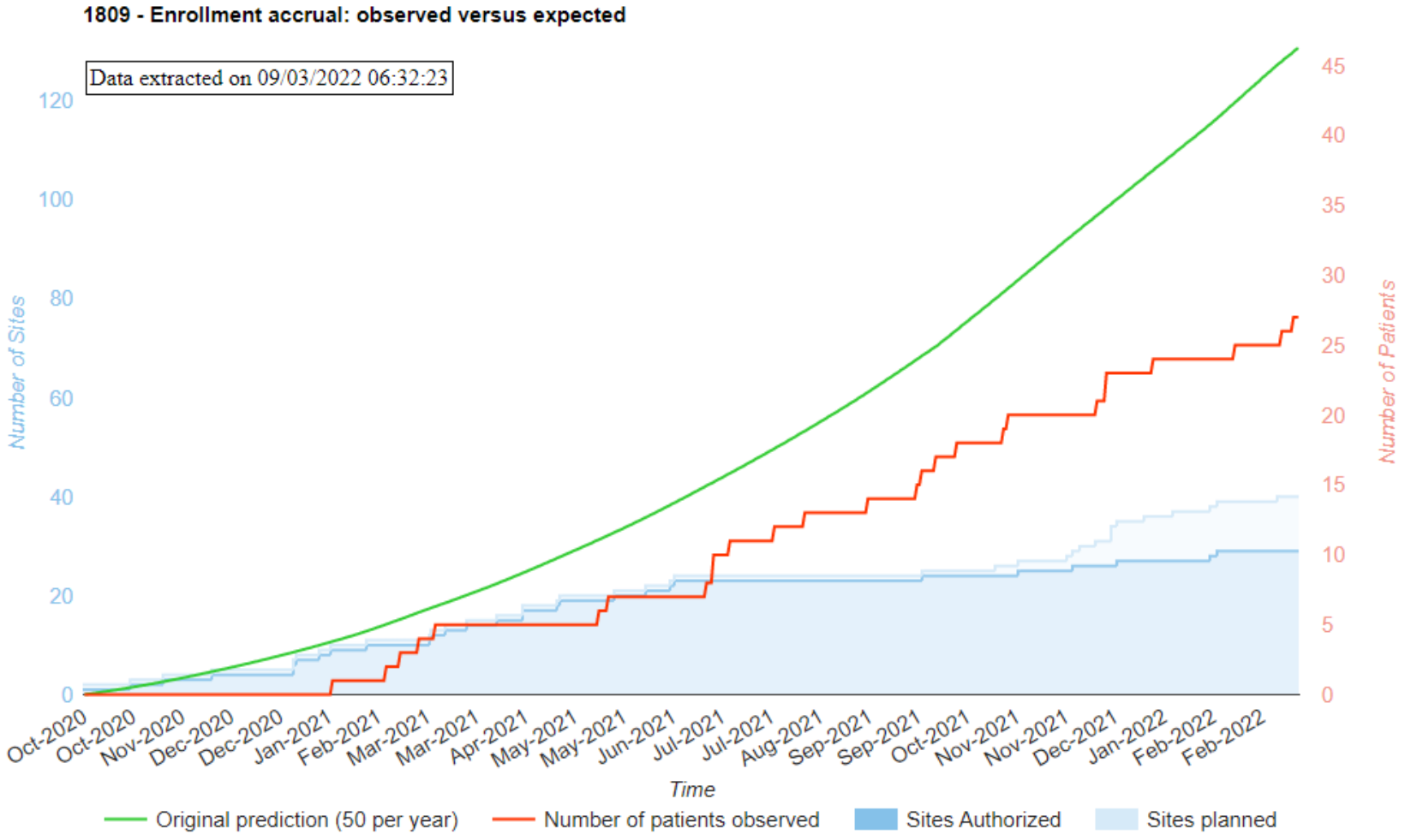
| Country | Ethics Committee | Competent Authority |
|---|---|---|
| Cyprus | **Approved** (protocol v3.0, PISIC v3.0) | **Approved** (protocol v3.0, PISIC v3.0) |
| Czech Republic | **Under review** (protocol v4.0, PISIC v4.0) | **Under review** (protocol v4.0, PISIC v4.0) |
| Denmark | **Under review** (protocol v3.0, PISIC v3.0) | **Approved** (protocol v3.0, PISIC v3.0) |
| France   | **Approved** (protocol v4.0, PISIC v4.0) | **Approved** (protocol v4.0, PISIC v4.0) |
| Germany   | **Approved** (protocol v4.0, PISIC v4.0) | **Approved** (protocol v4.0, PISIC v4.0) |
| Italy   | **Approved by central EC** (protocol v4.0, PISIC v4.0) | **Approved** (protocol v4.0, PISIC v4.0) |
| Netherlands | **Under review** (protocol v4.0, PISIC v4.0) | **Approved** (protocol v4.0, PISIC v4.0) |
| Poland   | **Approved** (protocol v4.0, PISIC v4.0) | **Approved** (protocol v4.0, PISIC v4.0) |
| Slovakia   | **Under review** (protocol v4.0, PISIC v4.0) | **Approved** (protocol v4.0, PISIC v4.0) |
| Spain   | **Under review** (protocol v4.0, PISIC v4.0) | **Under review** (protocol v4.0, PISIC v4.0) |
| United Kingdom | **Approved** | **Approved** |

# Study status – site activation

(cut-off 09/03/2022)

| Country | # activated sites / total sites | # recruiting sites / total sites |
|---|---|---|
| Cyprus | **1** / 1 | 0 / 1 |
| Czech Republic | **1** / 1 | **1** / 1 |
| Denmark | 0 / 2 | 0 / 2 |
| France | **5** / 5 | **3** / 5 |
| Germany | **2** / 3 | 0 / 3 |
| Italy | **8** / 8 | **3** / 8 |
| Netherlands | **2** / 4 | **1** / 4 |
| Poland | **1** / 1 | **1** / 1 |
| Slovakia | **1** / 1 | 0 / 1 |
| Spain | **3** / 3 | **2** / 3 |
| United Kingdom | **3** / 8 | **1** / 8 |
| Canada | **2** / 3 | **1** / 3 |
| **TOTAL** | 29 | 13 |

# Accrual status
(cut-off 09/03/2022)



# Study status – Collaborative groups

- **CCTG = sponsor in Canada**
  - Regulatory approvals are received
  - 2 / 3 sites are activated
  - 2 patients randomized
- **ANZSA = sponsor in Australia**
  - Regulatory approvals are received
  - Grant obtained MRFF
  - FSA expected mid-March 2022
- **ECOG-ACRIN = sponsor in US**
  - Submission to NCI performed
  - Contract between EORTC and E/A under discussion
- **JCOG = sponsor in Japan**
  - Grant submissions are ongoing
  - FSA expected in 1 year

# Study budget

| Activity/Phase | EUR |
|---|---|
| **EORTC HQ Resources** | |
| Development & Activation Phase | €628,446.00 |
| Conduct Phase | €1,331,472.62 |
| Long term follow-up and closure Phase | €108,708.10 |
| **TOTAL** | **€2,068,626.72** |
| **Network** | |
| Institution set-up | €353,050.00 |
| **TOTAL** | **€353,050.00** |
| **External Costs (to be confirmed by vendor quote)** | |
| On-site Monitoring | *€128,800.00* |
| Translational Research & HBM Management | *€28,750.00* |
| Central Imaging Review | *€28,842.00* |
| **TOTAL** | ***€186,392.00*** |
| **GRAND TOTAL** | **€2,608,068.72** |

- Study is partially covered by:
  - **Anti Cancer Funds (ACF)**
  - **ECRF**
  - **STBSG**
- Search for national grants are ongoing:
  - UK: grant is received from Sarcoma UK + CRUK
  - FR: grant is received from INCA
  - DK: grant is received from Novo Nordisk Foundation

**We need your support to make this study a success!**

# Baseline data (1)

| Tumor subtype | EXPERIMENTAL ARM | STANDARD ARM | Grand Total |
|---|---|---|---|
| DDLPS | 8 | 8 | 16 |
| LMS | 5 | 4 | 9 |
| Grand Total | 13 | 12 | 25 |

| FNCLCC grade | EXPERIMENTAL ARM | STANDARD ARM | Grand Total |
|---|---|---|---|
| Grade 2 | 9 | 10 | 19 |
| Grade 3 | 4 | 2 | 6 |
| Grand Total | 13 | 12 | 25 |

# Baseline data (2)

| Gender | EXPERIMENTAL ARM | STANDARD ARM | Grand Total |
|---|---|---|---|
| Female | 7 | 3 | 10 |
| Male | 6 | 9 | 15 |
| Grand Total | 13 | 12 | 25 |

| Age (years) | EXPERIMENTAL ARM | STANDARD ARM | Total |
|---|---|---|---|
| Minimum | 45 | 41 | 41 |
| Maximum | 77 | 77 | 77 |
| Median | 61 | 58 | 60 |

# Baseline data (3)

| Tumor size (mm) | EXPERIMENTAL ARM | STANDARD ARM | Total |
|---|---|---|---|
| Minimum | 55 | 68 | 55 |
| Maximum | 302 | 404 | 404 |
| Median | 160 | 150 | 150 |

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European Organisation for Research and Treatment of Cancer
The future of cancer therapy

*Questions?*

*Thank you!*

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