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

Anticancer Fund

ECRF
EORTC Cancer Research Fund

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

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

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Study organization

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

STRASS-2 is an intergroup collaboration

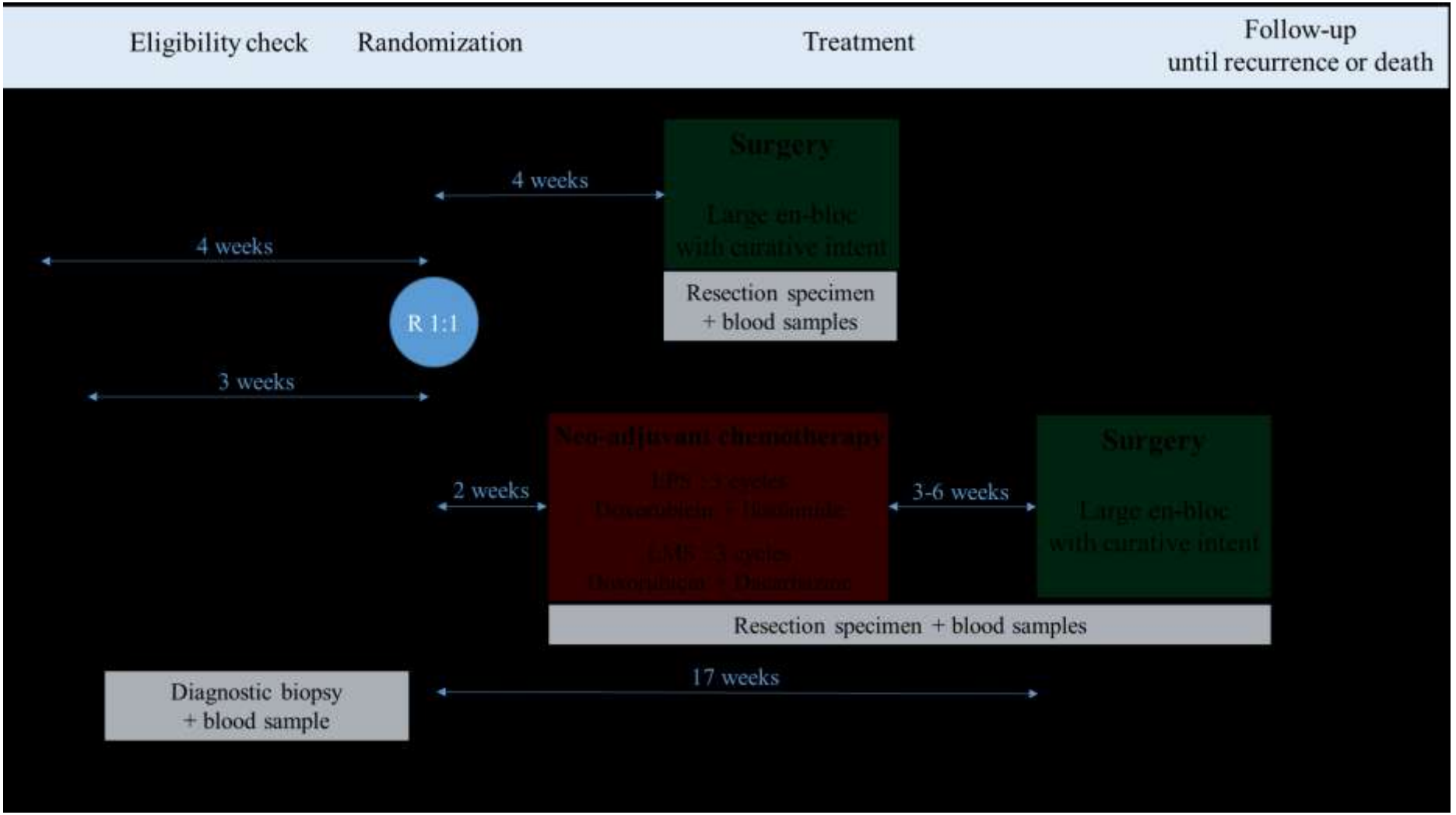
- EORTC = sponsor in Europe
- CCTG = sponsor in Canada
- ANZSA = sponsor in Australia
- ECOG/ACRIN = sponsor in US
- JCOG = sponsor in Japan

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)

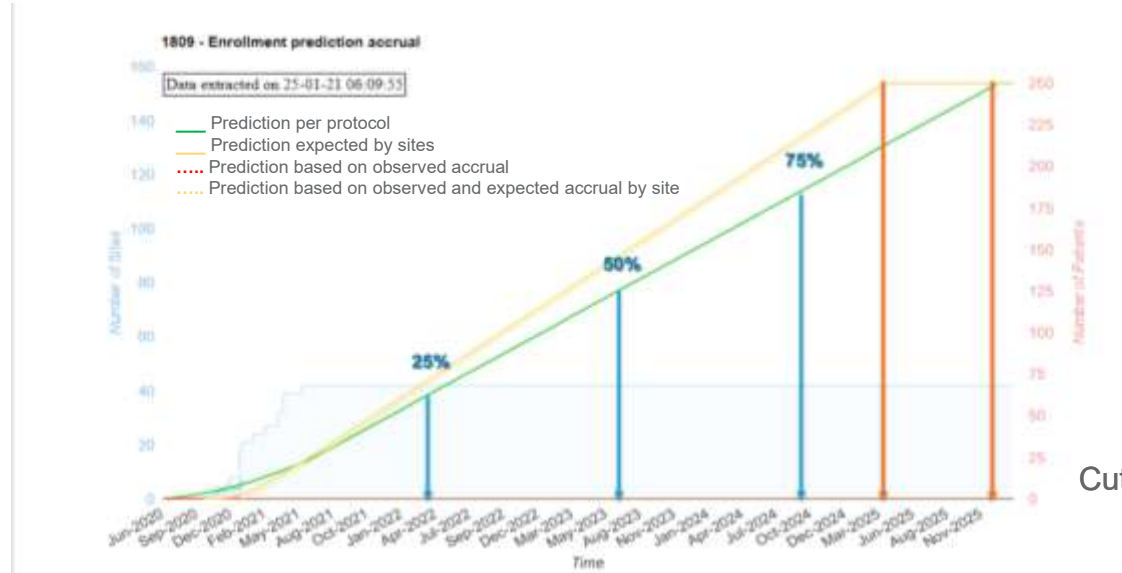
Study status – regulatory submissions

Country	Ethics Committee	Competent Authority
Cyprus	Not yet submitted	Not yet submitted
Czech Republic	Approved	Approved
Denmark	Not yet submitted	Not yet submitted
France	Approved	Approved
Germany	Submitted – under review	Approved
Italy	Approved	Approved
Netherlands	Submitted – under review	Approved
Poland	Approved	Approved
Slovakia	Approved	Approved
Spain	Approved	Approved
United Kingdom	Approved	Approved

Study status – site activation

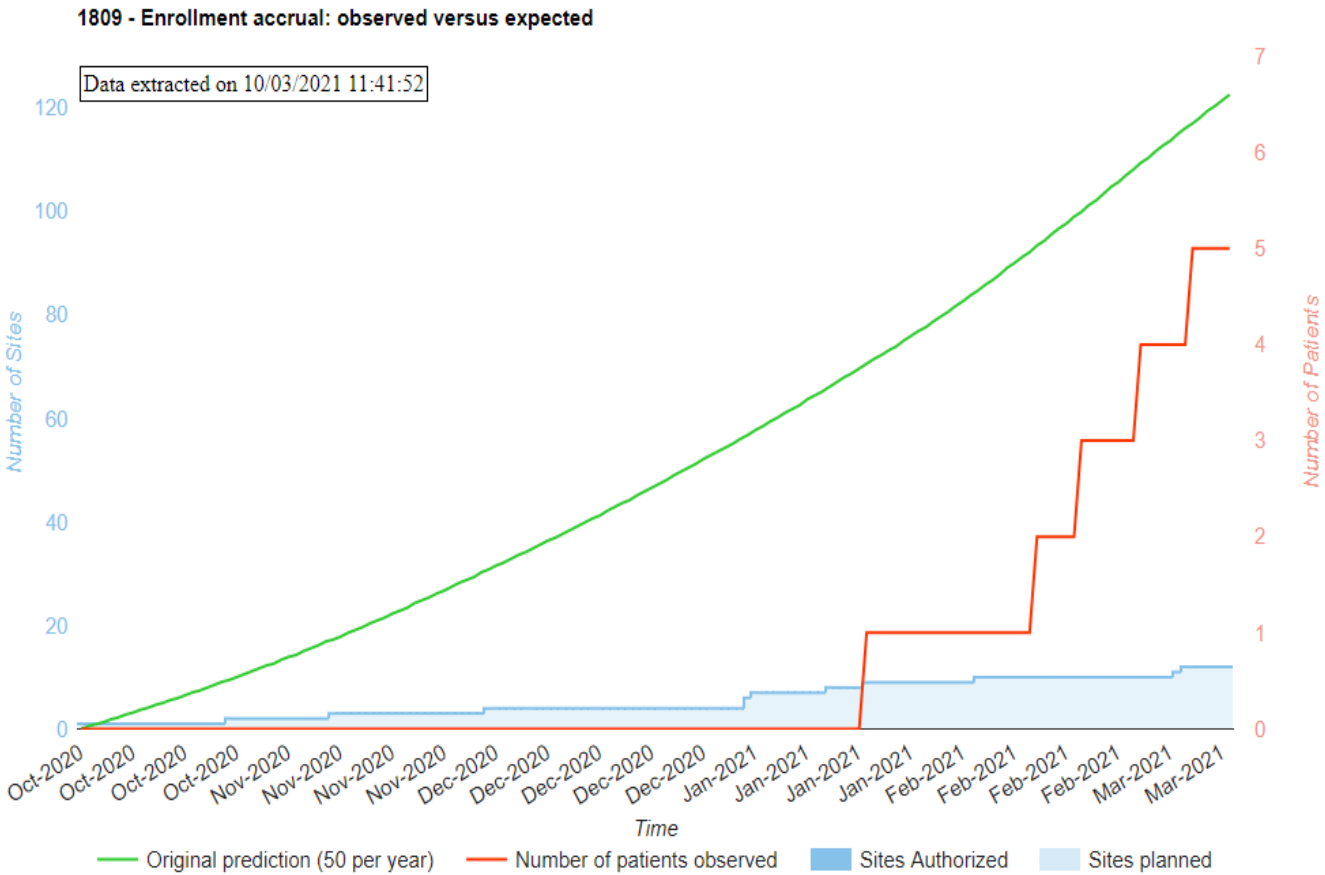
Country	# activated sites / total sites	# recruiting sites / total sites
Cyprus	0 / 1	0 / 1
Czech Republic	**1** / 1	0 / 1
Denmark	0 / 2	0 / 2
France	**5** / 5	0 / 5
Germany	0 / 3	0 / 3
Italy	**2** / 8	**1** / 8
Netherlands	0 / 4	0 / 4
Poland	**1** / 1	**1** / 1
Slovakia	**1** / 1	0 / 1
Spain	**3** /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

Recruitment planning



STRASS 2

Accrual status



The accrual of the planned 215 patients is expected in Feb 2042 based on the accrual observed in the last 6 months

Activation status non-european territories

US – ECOG/ACRIN – Ken Cardona, Chandrajit Raut

- Protocol approved by Board
- FSA expected by end of the year

Canada-CCTG - Rebecca Gladdy

- Central EC approval is received in Feb 2021
- FSA is expected in a couple of weeks

Australia – ANZSA – David Gyorki

- Contract in ROS

Japan – JCOG – Akira Kawai

- First meeting took place to initiate the collaboration
- JCOG Board still needs to approve the study
- FSA expected in 1.5 years

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: application to Sarcoma UK + CRUK
  - FR: application to INCA
  - DK: grant is received from Novo Nordisk Foundation
- Potential support from companies via sub-studies:
  - ECS Progastrin

We need your support to make this study a success!

Anouncements

- The study protocol has been amended (**protocol v 2.0 & PISIC v2.0**). Changes consist of:
  - clarifications required by regulatory bodies
  - update of the TR chapter
  - Appendix M: Specific protocol instructions during the COVID-19 pandemic

- New amendment is currently under internal review.
  Changes consist of:
  - Updated safety language in the PISIC

- Akynzeo study is cancelled due to the withdrawal of interest from the company Helsinn

The two amendments will be submitted together

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Questions?

Thank you!

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