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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

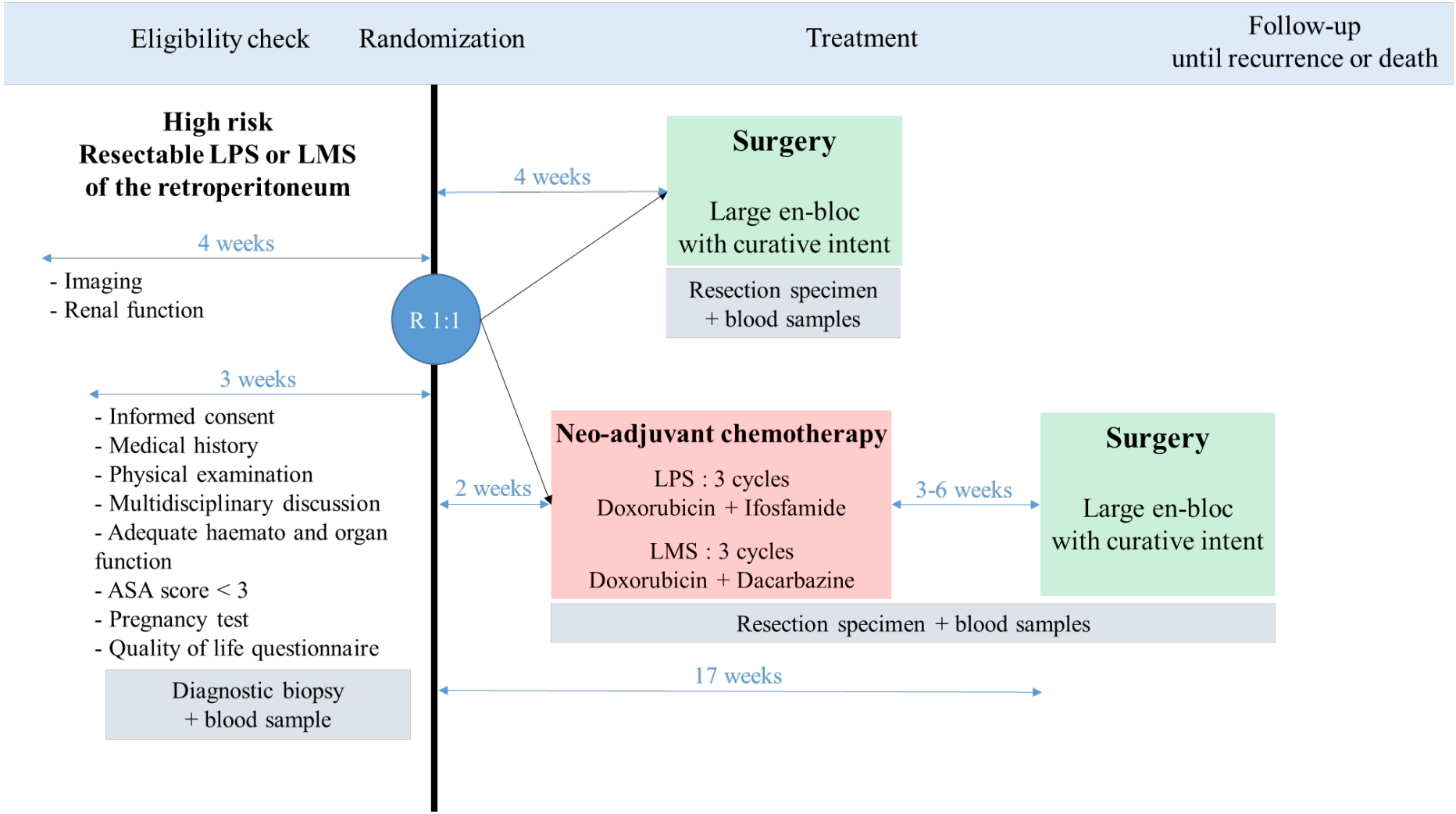
- EORTC = sponsor in Europe
- CCTG = sponsor in Canada
- ANZSA = sponsor in Australia
- ECOG/ACRIN = sponsor in US
- JCOG = sponsor in Japan

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



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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

- Upcoming amendments
  - PISIC v5.0 → updated safety language for doxorubicin
- Future amendments
  - Patient preference sub-study (for UK patients only)
  - CTR changes – migration is planned in Q2 2023

Study status – regulatory submissions

Country	Ethics Committee	Competent Authority
Cyprus NEW	**Approved** (protocol v4.0, PISIC v4.0)	**Approved** (protocol v4.0, PISIC v4.0)
Czech Republic NEW	**Approved** (protocol v4.0, PISIC v4.0)	**Approved** (protocol v4.0, PISIC v4.0)
Denmark	**Approved** (protocol v3.0, PISIC v3.0)	**Approved** (protocol v3.0, PISIC v3.0)
France NEW	**Approved** (protocol v4.0, PISIC v4.0)	**Approved** (protocol v4.0)
Germany NEW	**Approved** (protocol v4.0, PISIC v4.0)	**Approved** (protocol v4.0)
Italy NEW	**Approved by central EC and most local ECs** (protocol v4.0, PISIC v4.0)	**Approved** (protocol v4.0)
Netherlands NEW	**Approved** (protocol v4.0, PISIC v4.0)	**Approved** (protocol v4.0, PISIC v4.0)
Poland NEW	**Approved** (protocol v4.0, PISIC v4.0)	**Approved** (protocol v4.0, PISIC v4.0)
Slovakia NEW	**Approved** (protocol v4.0, PISIC v4.0)	**Approved** (protocol v4.0, PISIC v4.0)
Spain NEW	**Approved** (protocol v4.0, PISIC v4.0)	**Approved** (protocol v4.0)
United Kingdom NEW	**Approved**	**Approved**

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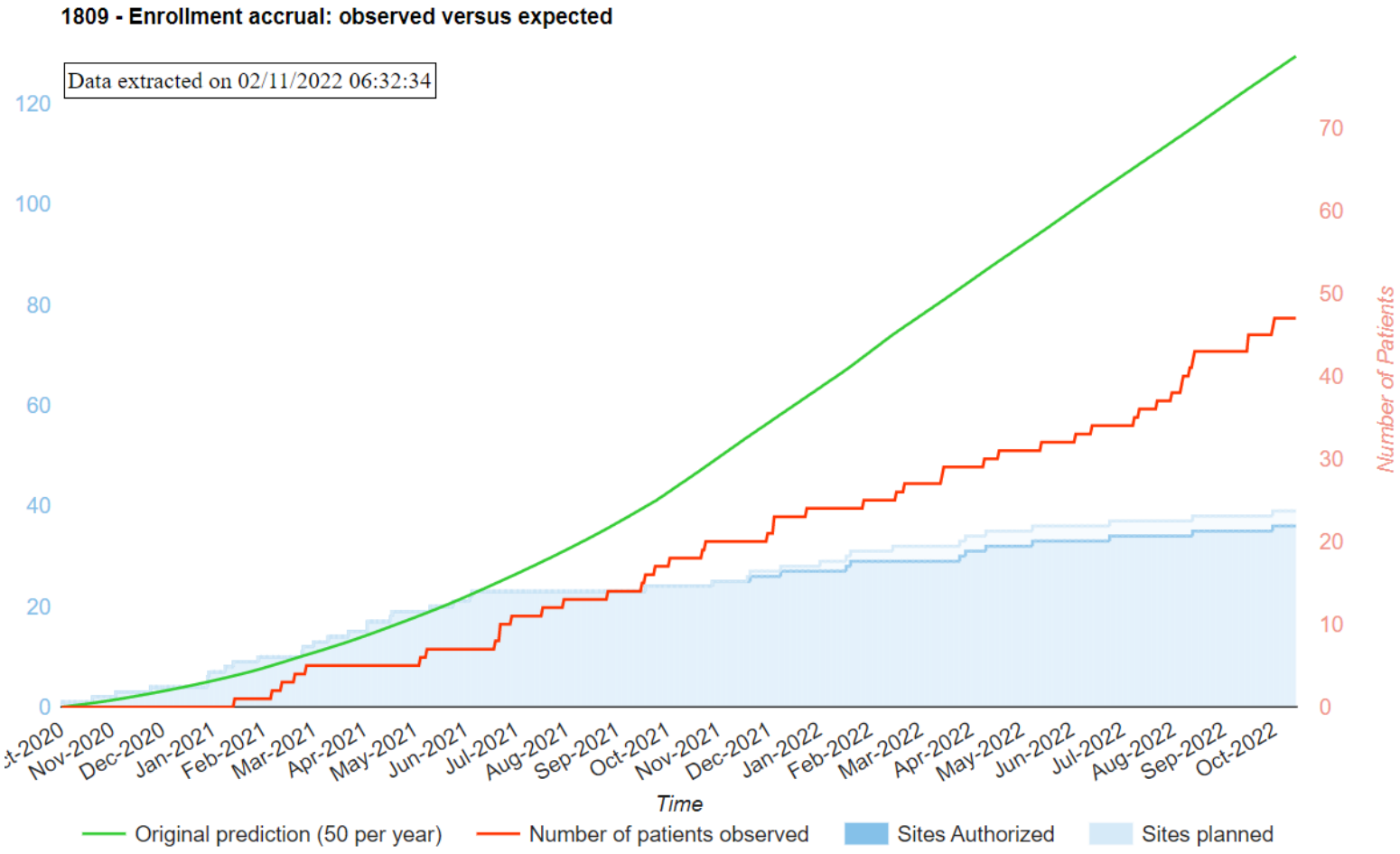
Study status – site activation

(cut-off 21/10/2022)

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	**3** / 3	2 / 3
Italy	**8** / 8	**3** / 8
Netherlands	**3** / 4	**1** / 4
Poland	**1** / 1	**1** / 1
Slovakia	**1** / 1	0 / 1
Spain	**3** / 4	**3** / 4
United Kingdom	**5** / 8	**2** / 8
Canada	**2** / 3	**1** / 3
Australia	**3** / 3	**1** / 3
TOTAL	36/44	18/44

Accrual status
(cut-off 02/11/2022)



The accrual of the planned 250 patients is expected in Oct 2031 based on the accrual observed in the last 6 months

Study status – Collaborative groups

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

Baseline data (1)

	EXPERIMENTAL ARM	STANDARD ARM	Grand Total
DDLPS	**14**	**14**	**28**
Grade 2	10	10	20
Grade 3	4	4	8
LMS	**10**	**9**	**19**
Grade 1	1	2	3
Grade 2	6	7	13
Grade 3	3		3
Grand Total	**24**	**23**	**47**

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Baseline data (2)

Gender	EXPERIMENTAL ARM	STANDARD ARM	Grand Total
Female	15	11	26
Male	9	12	21
Grand Total	24	23	47

Age (years)	EXPERIMENTAL ARM	STANDARD ARM	Total
Minimum	45	34	34
Maximum	77	77	77
Median	68	58	62

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Baseline data (3)

Tumor size (mm)	EXPERIMENTAL ARM	STANDARD ARM	Total
Minimum	55	68	55
Maximum	302	404	404
Median	153	130	130

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Missing data overview

Site	Present		Missing		Due		Overdue		Total
301	68	98.6%	1	1.4%	0	0 %	1	1.4%	69
381	17	94.4%	1	5.6%	0	0 %	1	5.6%	18
3919	56	96.6%	2	3.4%	1	1.7%	1	1.7%	58
227	69	93.2%	5	6.8%	1	1.4%	4	5.4%	74
527	26	76.5%	8	23.5%	8	23.5%	0	0 %	34
550	244	68.7%	111	31.3%	69	19.4%	42	11.8%	355
613	70	62.5%	42	37.5%	19	17%	23	20.5%	112
888	63	46.3%	73	53.7%	35	25.7%	38	27.9%	136
3908	138	61.6%	86	38.4%	50	22.3%	36	16.1%	224
379	13	48.1%	14	51.9%	10	37%	4	14.8%	27
259	69	66.3%	35	33.7%	16	15.4%	19	18.3%	104
1054	32	88.9%	4	11.1%	3	8.3%	1	2.8%	36
876	11	68.8%	5	31.3%	5	31.3%	0	0 %	16
9848	2	100%	0	0 %	0	0 %	0	0 %	2
6998	11	61.1%	7	38.9%	7	38.9%	0	0 %	18
520	29	85.3%	5	14.7%	5	14.7%	0	0 %	34
3901	1	100%	0	0 %	0	0 %	0	0 %	1
225	40	60.6%	26	39.4%	22	33.3%	4	6.1%	66
240	1	100%	0	0 %	0	0 %	0	0 %	1
704	651	90.2%	71	9.8%	60	8.3%	11	1.5%	722
962	133	89.9%	15	10.1%	10	6.8%	5	3.4%	148
429	2	100%	0	0 %	0	0 %	0	0 %	2
366	61	91%	6	9%	2	3%	4	6%	67
	1807	**78%**	**517**	**22%**	**323**	**14%**	**194**	**8%**	**2324**

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**

Confirmed grants:

- Study is partially covered by:
  - Anti Cancer Funds (ACF)
  - ECRF Cancer Research fund
  - STBSG
- National grants are received:
  - UK: Sarcoma UK + CRUK+UK climbers against cancer
  - FR: INCA (not covered all activities): no feedback?
  - DK: Novo Nordisk Foundation
- Potential support from companies via sub-studies:
  - ECS Progastrin

Pending grants:

- Spanish funding: 14 k €
- EU grant (Horizon-Miss-2022-CANCER-01-03):
  - STRASS 2: 1,096,812 €
  - STREXIT 2: 1,347,708 €

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Questions?

Thank you!

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