

EORTC 1809-STBSG

STRASS II - A randomized phase III study of neoadjuvant chemotherapy followed by surgery versus surgery alone for patients with High-Risk RetroPeritoneal Sarcoma (RPS)

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

***Study Co-Coordinator:** Winan Van Houdt, NKI-AVL, Amsterdam, The Netherlands*

Trial Scope, Design & Objectives

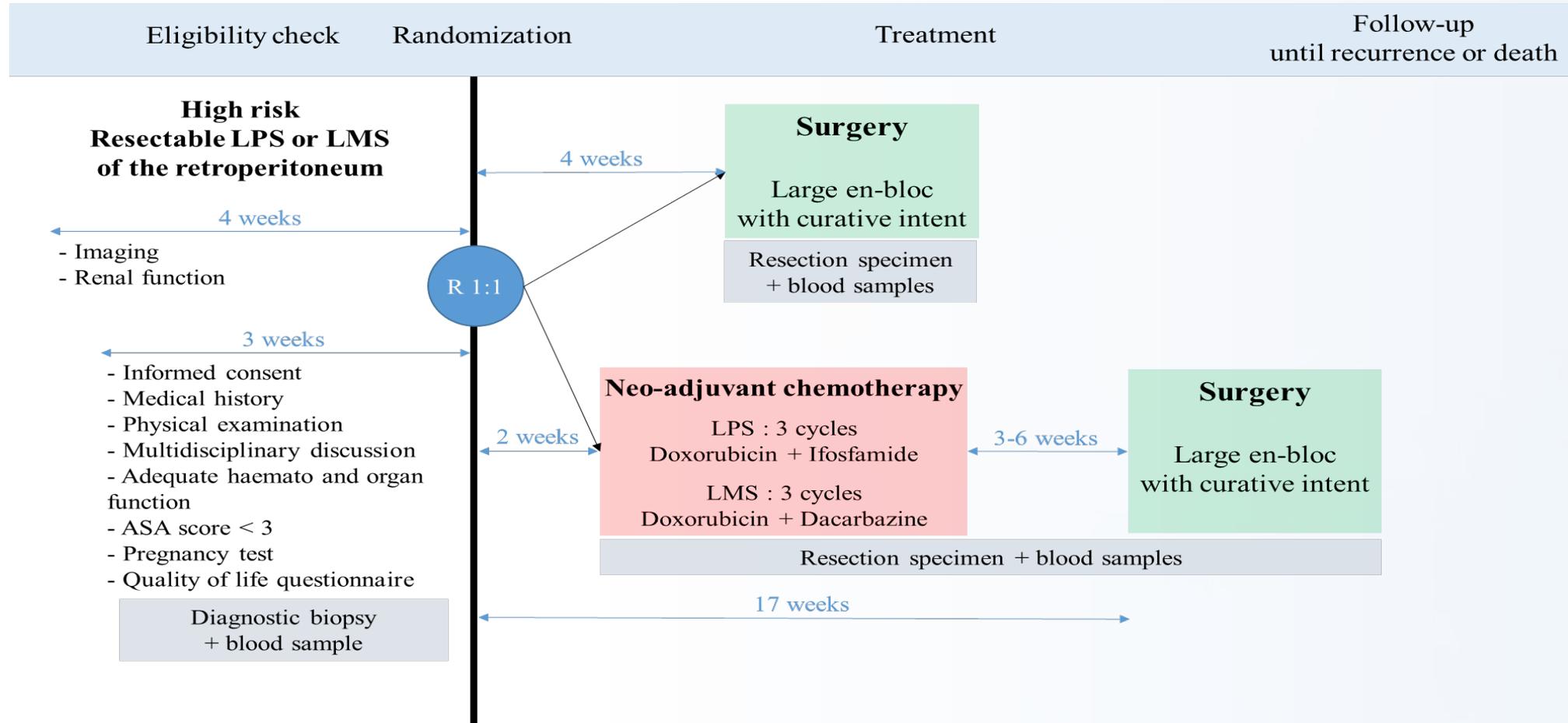
Global Study Update



Canadian
Cancer
Society



Study design



Objectives and Endpoints

Primary Objective

- to assess whether preoperative chemotherapy, as an adjunct to curative-intent surgery, improves the prognosis of G3 DD LPS and LMS patients.



Primary Endpoint

- Disease free survival (from randomization) will include as events progression on neoadjuvant treatment, non-operable tumors, distant metastases and/or local recurrence

Secondary Endpoints

- Radiological response at time of surgery (post-C3) (RECIST and Choi)
- Pathological response
- Recurrence free survival
- Overall survival

- Metastases-free survival
- Safety and toxicity of neoadjuvant chemotherapy
- Perioperative complications
- Late complications
- Health-Related QoL (QLQ-C30)

STRASS 2

Site Activation & Accrual

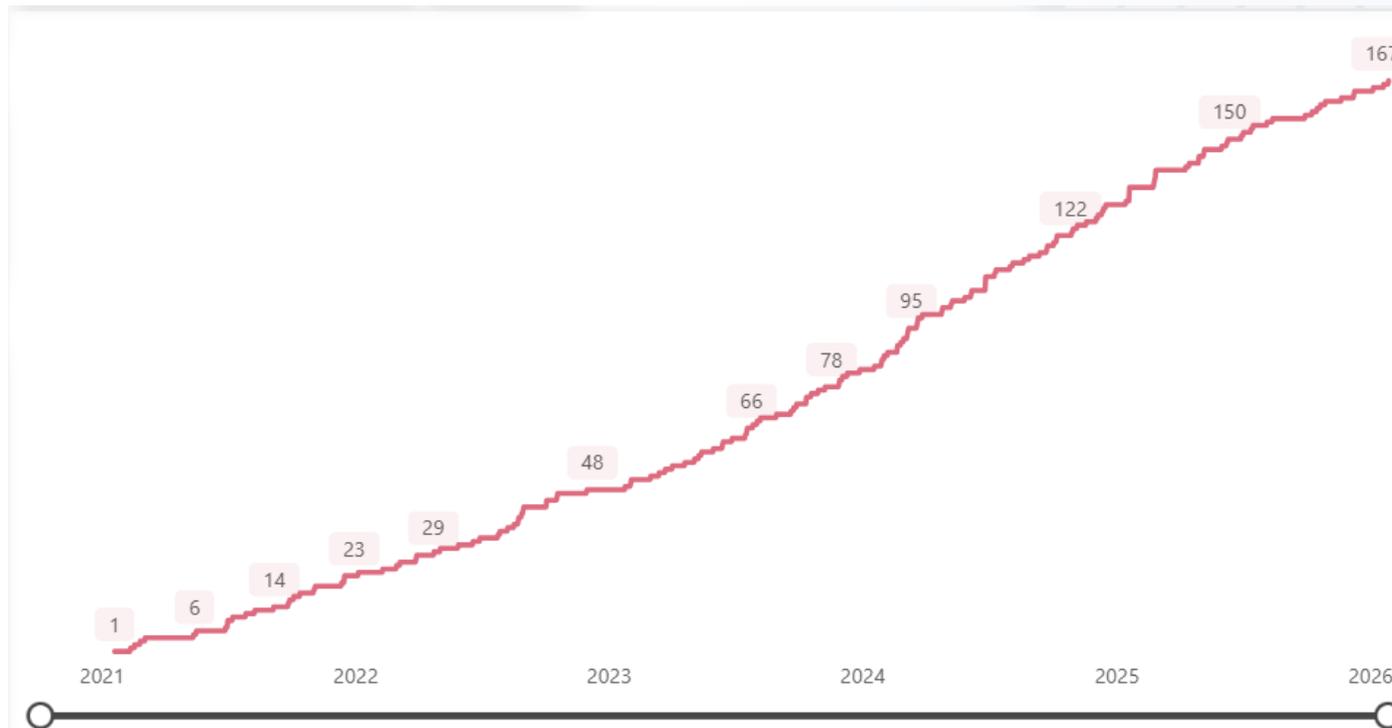
Site Activation Status

Country	# Activated sites / Total Expected	# Recruiting sites / Total Activated
Czech Republic	1 / 1	1 / 1
Denmark	2 / 2	2 / 2
France	5 / 5	3 / 5
Germany	3 / 3	2 / 3
Italy	8 / 8	7 / 8
Netherlands	3 / 3	3 / 3
Poland	1 / 1	1 / 1
Slovakia	1 / 1	1 / 1
Spain	4 / 4	3 / 4
United Kingdom	8 / 8	4 / 8
Canada	6 / 6	4 / 6
Australia	3 / 3	2 / 3
Japan	12/12	4 / 12
TOTAL	57/57	37/57

[cut off 20Feb26]

Site Activation Status

Total patients registered	Total patients enrolled (STREXIT2)	Total patients enrolled (STRASS2)	Total patients screen failed	Total patients screening
418	200	167	38	13



Accrual 167: Target 250 patients (STRASS 2) [cut off 20Feb26]

Database



Cohort status

- Randomization status [cut off 20Feb26]

# randomized patients	CT + Surgery	Surgery	Total
DDLPS	37	38	75
LMS	46	46	92
Grand Total	83	84	167

- Each cohort will be capped to 125 pts

Baseline characteristics

- Size of tumour (mm)

	CT + Surgery	Surgery	Total
Min	25	51	25
Max	302	404	404
Median	136	120	125

- Age (years)

	CT+ Surgery	Surgery	Total
Min	40	34	34
Max	81	77	81
Median	62	63	62

Baseline characteristics

- Overall diagnosis, per treatment arm and per histologic type

Histology	CT + Surgery	Surgery	Total
DDLPS	37	38	75
Grade 2	24	25	49
Grade 3	13	12	25
LMS	46	46	92
Grade 1	11	10	21
Grade 2	25	30	55
Grade 3	8	6	14
Grand Total	83	84	167

STREXIT 2

Site Activation & Accrual



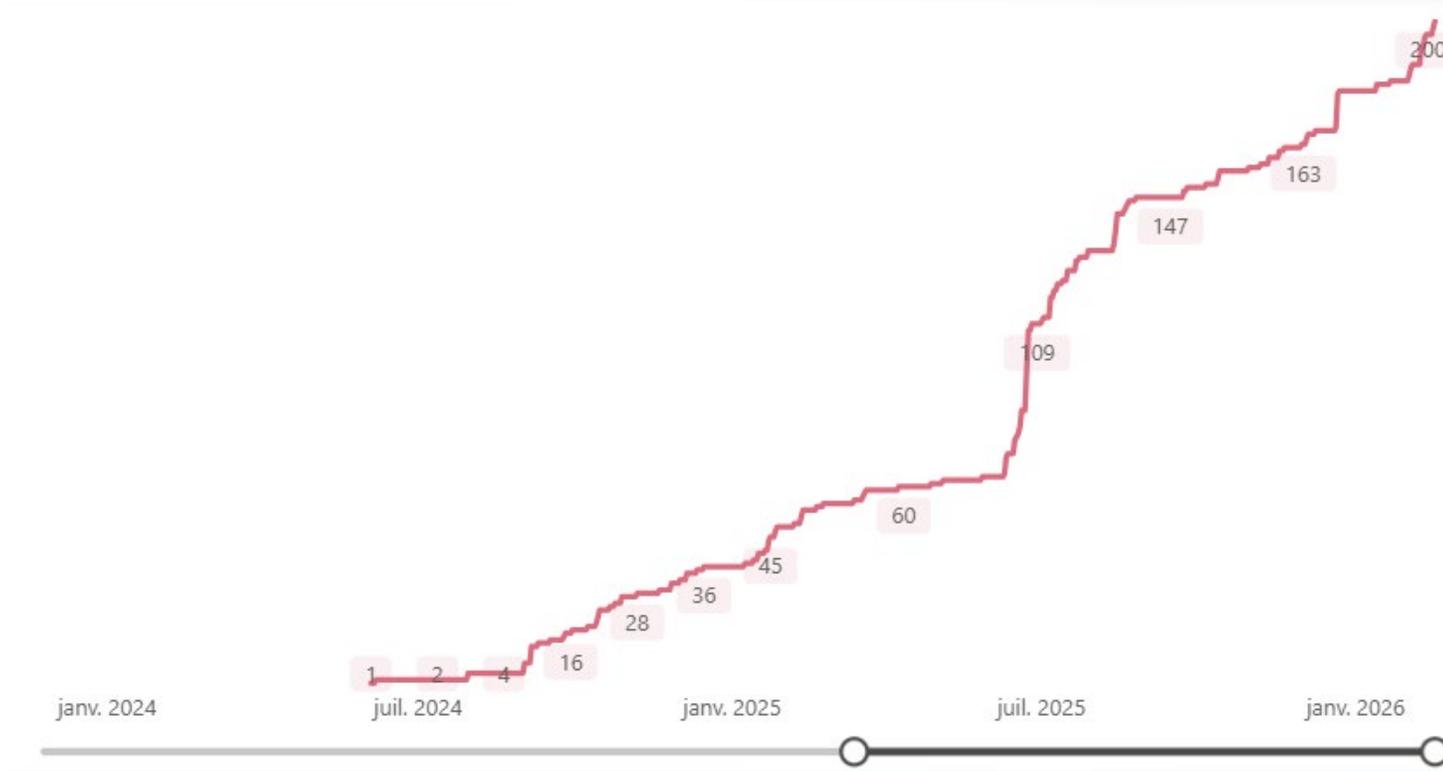
Site activation

(cut-off 20/02/2026)

Country	# Activated sites / Total Expected	# Recruiting sites / Total Activated
Czech Republic	1/1	1/1
Denmark	2/2	2/2
France	3/3	1/3
Germany	2/2	1/2
Italy	6/7	2/6
Netherlands	3/3	1/3
Poland	1/1	0/1
Slovakia	1/1	0/1
Spain	4/4	1/4
United Kingdom	6/6	0/6
Canada	2/2	0/2
Australia	3/3	2/3
Japan	12/12	1/12
TOTAL	46/47	12/46

Accrual

Total patients registered	Total patients enrolled (STREXIT2)	Total patients enrolled (STRASS2)	Total patients screen failed	Total patients screening
418	200	167	38	13



Accrual 200: Target 500 - 1000 patients (STREXIT 2) [cut off 20/02/2026]

STREXIT 2: prospective vs retrospective

Site name	Prospective	Retrospective alive	Retrospective dead	Total
IRCCS - Istituto Nazionale dei Tumori (IT)	16	52	23	91
Institut Curie- Hopital de Paris (FR)	0	22	11	33
Istituto Clinico Humanitas (IT)	0	16	0	16
Peter MacCallum Cancer Institute (AU)	3	10	0	13
Chris O'Brien Lifehouse (AU)	1	11	0	12
The Netherlands Cancer Institute-Antoni Van Leeuwenhoekziekenhuis (NL)	0	9	2	11
Universitaetsmedizin Goettingen - Georg-August Universitaet (DE)	0	7	0	7
Masaryk Memorial Cancer Institute (CZ)	0	5	1	6
Hospital De La Santa Creu I Sant Pau (ES)	1	2	0	3
National Cancer Center Hospital (JP)	0	3	0	3
Region Midtjylland - Aarhus University Hospital-Skejby (DK)	2	1	0	3
Herlev Hospital - University Copenhagen (DK)	0	1	0	1
Royal Marsden Hospital - Chelsea, London (GB)	1	0	0	1
Grand Total	24	139	37	200

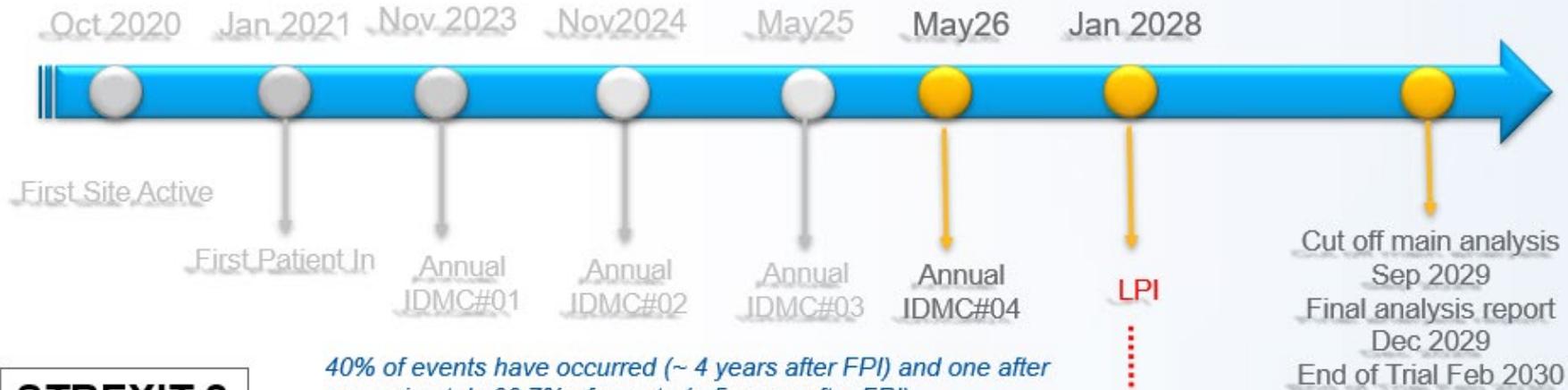
[cut off 20/02/2026]

Trial Timelines



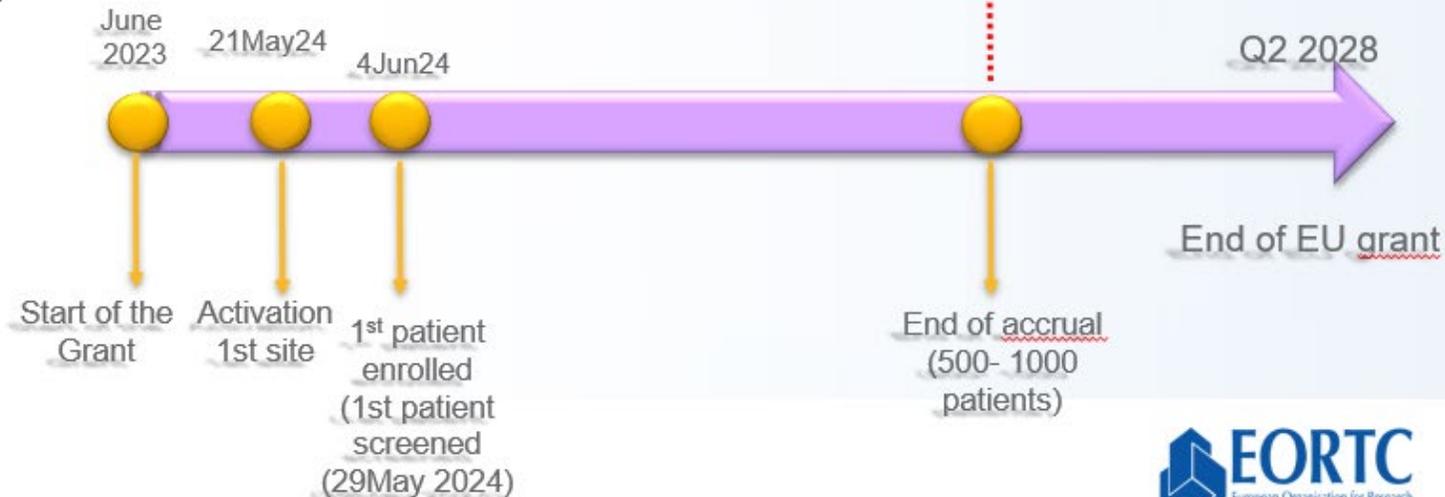
Global Timelines

STRASS 2



STREXIT 2

40% of events have occurred (~ 4 years after FPI) and one after approximately 66.7% of events (~ 5 years after FPI)



THANK YOU

Find out more : eortc.org