

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

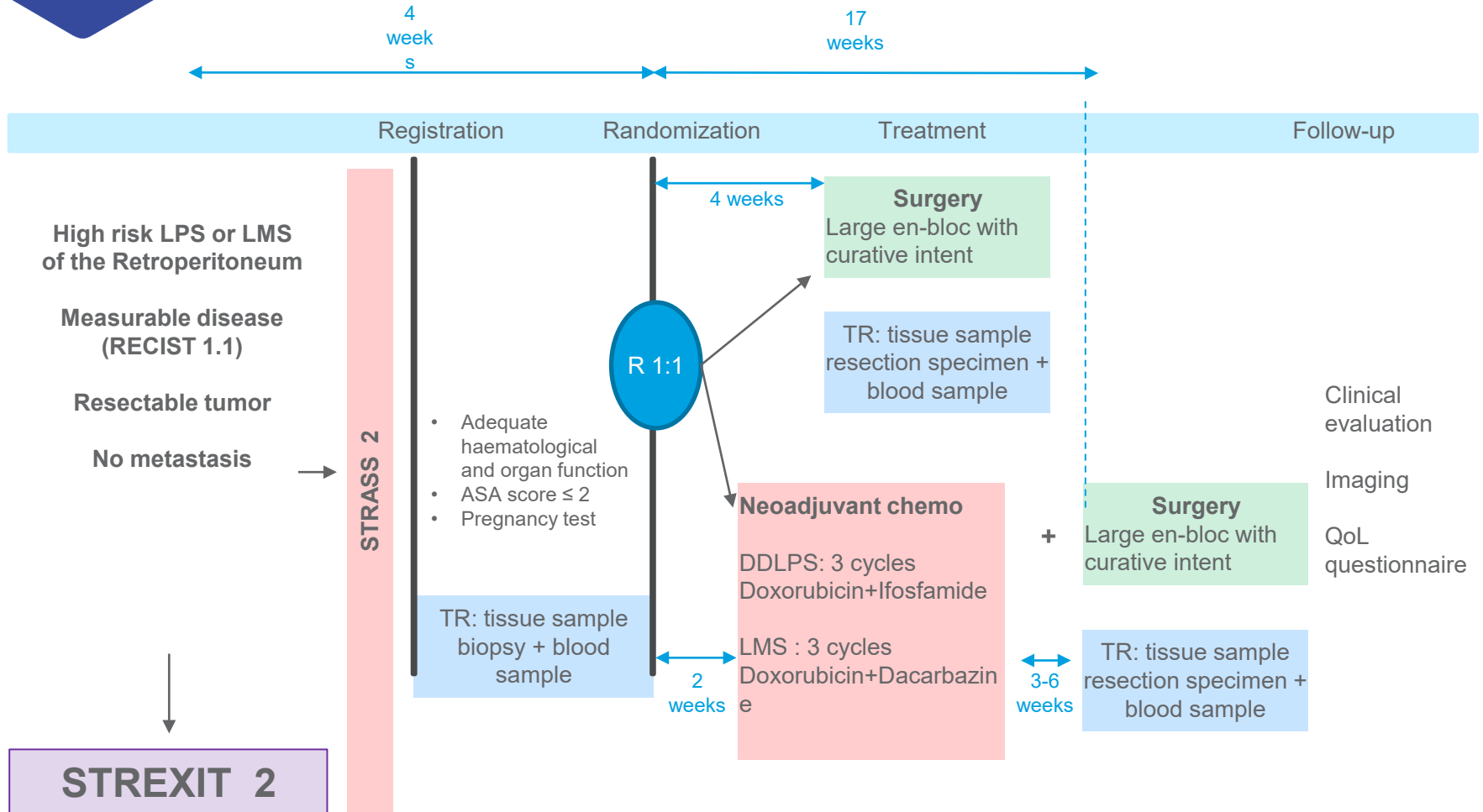


- STRASS 2 aims to investigate whether patients affected by RPS with the highest metastatic risk (G3 DDLPS and LMS) could benefit from neoadjuvant chemotherapy.
- The main objective of this study is to demonstrate that neo-adjuvant chemotherapy, as an adjunct to curative intent en-block surgery can improve the prognosis of these patients by reducing the risk of development of distant metastasis.

Study 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 design



Study status – Collaborative groups

(cut-off 15/02/2024)

- **CCTG = sponsor in Canada**
 - Regulatory approvals are received
 - 6/6 sites activated and 2/4 are recruiting
 - 7 patients have been randomized
- **ANZSA = sponsor in Australia**
 - Regulatory approvals are received
 - Grant obtained MRFF
 - 3 / 3 sites are activated and 2/3 site is recruiting
 - 3 patients randomized
- **ECOG-ACRIN = sponsor in US**
 - Regulatory approvals (NCI + CIRB) have been received
 - Contract between EORTC and E/A is finalized and signed
 - 28/33 main sites have been activated
 - FPI enrolled on 29JAN2024
- **JCOG = sponsor in Japan**
 - Grant submissions are ongoing
 - Regulatory approvals have been received and setup completed
 - 12/12 sites activated
 - FPI is expected in the coming months

Protocol and Amendments

- Current protocol documents in use in EU:
 - **Protocol v4.0 dd. 19 October 2021:** LMS: any grade and size > 5 cm
 - **PISIC v5.0 dd. 13 September 2022:** Updated safety language for doxorubicin
- Ongoing amendment includes Protocols V5.0, V6.0 and V6.1:
 - Changes related to new EU regulation for clinical trial
 - STREXIT 2 registry cohort
 - Patient preference sub-study
 - Health economics component
 - Clarifications
 - Update of reference safety information for the chemotherapies

Study status – CTR transition

Country	Competent Authority	Ethics Committee	Decision
Cyprus	Part I under evaluation	Part II under evaluation	Pending
Czech Republic		Part II under evaluation	Pending
Denmark		Part II under evaluation	Pending
France		Part II under evaluation	Pending
Germany		Part II under evaluation	Pending
Italy		Part II under evaluation	Pending
Netherlands		Part II under evaluation	Pending
Poland		Part II under evaluation	Pending
Slovakia		Part II under evaluation	Pending
Spain		Part II under evaluation	Pending
United Kingdom	To be submitted upon receiving CTR Part I conclusion	To be submitted upon receiving CTR Part I conclusion	Not applicable

Study status – site activation (EU+UK)

(cut-off 15/02/2024)

Country	# Activated sites / Total Expected	# Recruiting sites / Total Activated
Cyprus	1 / 1	0 / 1
Czech Republic	1 / 1	1 / 1
Denmark	2 / 2	0 / 2
France	5 / 5	3 / 5
Germany	3 / 3	2 / 3
Italy	8 / 8	8 / 8
Netherlands	3 / 4	2 / 3
Poland	1 / 1	1 / 1
Slovakia	1 / 1	0 / 1
Spain	4 / 4	3 / 4
United Kingdom	7 / 8	3 / 7
TOTAL	36/38	23/36

Study status – site activation (Non-EU)

(cut-off 15/02/2024)

Country	# Activated sites / Total Expected	# Recruiting sites / Total Activated
Canada (CCTG)	6/6	2/6
Australia (ANZSA)	3/3	2/3
United States (ECOG-ACRIN)	28*/33	1/28
Japan (JCOG)	12/12	0/12

* Subsites not included

Study status – site activation (Non-EU)

(cut-off 15/02/2024)

Activated US sites

Site Name	Name of PI
City of Hope Comprehensive Cancer Center	William Tseng
UC Irvine Health/Chao Family Comprehensive Ca Ctr	Tran, Thuy
UCHealth University of Colorado Hospital	Maleddu, Alessandra
Yale University	Deshpande, Hari A.
Moffitt Cancer Center	John Ellis Mullinax
Mayo Clinic in Florida	Attia, Steven
Emory University Hospital Midtown	Kenneth Cardona
Northwestern University	Seth M. Pollack
University of Kansas Cancer Center	Luke Vail Selby
Our Lady of The Lake Hospital	Marshall Patrick Stagg
Johns Hopkins Univ/Sidney Kimmel Cancer Center	Meyer, Christian Frederick
University of Michigan Comprehensive Cancer Center	Schuetze, Scott Michael
Sanford Joe Lueken Cancer Center	Almquist, Daniel
Washington University School of Medicine - Siteman Cancer Center	Mia Chana Weiss

Site Name	Name of PI
Duke University Medical Center	Richard F. Riedel
University of Nebraska Medical Center	Mammen, Joshua Matthew Varghis
Roswell Park Cancer Institute	Gupta, Ajay
University of Rochester	Barr, Paul Michael
Ohio State University Comprehensive Cancer Center	Valerie Grignol
University of Oklahoma Health Sciences Center	Phan, Minh
Oregon Health and Science University	Lara Davis
UPMC Hillman Cancer Center	Burgess, Melissa Amber (Moidel)
Fox Chase Cancer Center	Lee, Teresa
M D Anderson Cancer Center	Roland, Christina L.
Virginia Commonwealth Univ/Massey Cancer Center	Poklepovic, Andrew
University of Washington Medical Center - Montlake	Sharib, Jeremy Matthew
Medical College of Wisconsin	Charlson, John A.
Huntsman Cancer Institute/University of Utah	Asare, Elliot Amponsah

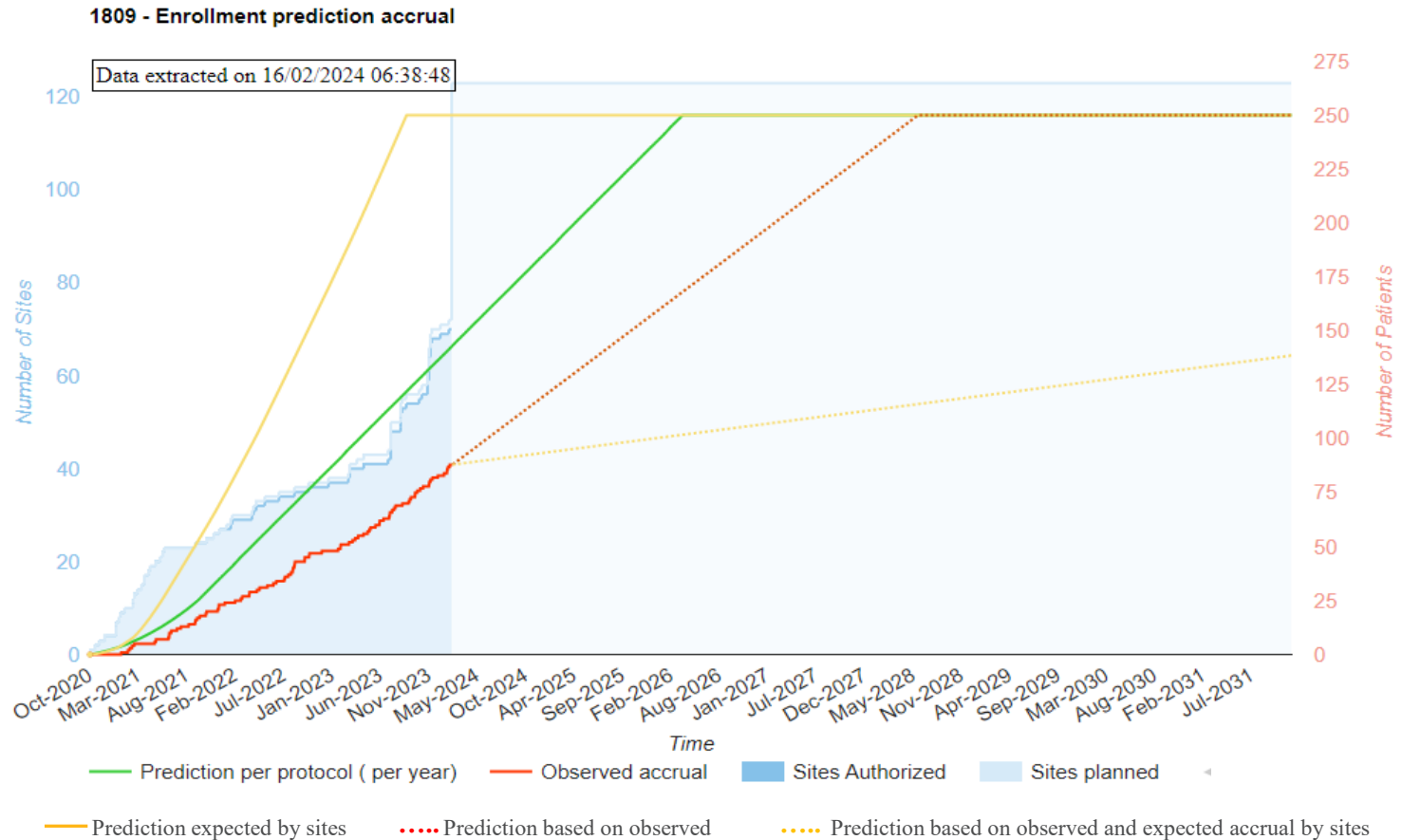
Study status – site activation (Non-EU)

(cut-off 15/02/2024)

Activated Japanese Sites

Site name	Name of PI
Tohoku University Hospital	Shinichiro Yoshida
Saitama Medical Center, Jichi Medical University	Toru Akiyama
National Cancer Center Hospital	Shintaro Iwata
Cancer Institute Hospital of JFCR	Keisuke Ae
Yokohama City University Hospital	Masanobu Takeyama
Kanagawa Cancer Center	Toru Hiruma
Niigata University Medical and Dental Hospital	Hiroyuki Kawashima
Aichi Cancer Center	Satoshi Tsukushi
Nagoya University Hospital	Yoshihiro Nishida
Osaka International Cancer Institute	Satoshi Takenaka
Kyushu University Hospital	Makoto Endo
Okayama University Hospital	Toshifumi Ozaki

Accrual status (cut-off 16/02/2024)



Risk:

Additional 2 years delay (LPI March 2026 --> March2028) in accrual if we keep the current enrolment pace

Total patients registered	=	112
Total patients enrolled	=	88
Total patients screen failed	=	20
Total patients screening	=	4

Accrual per site

(Cut-off 16/02/2024)

Country	Site Name	Number of enrolled patients
Italy	IRCCS - Istituto Nazionale dei Tumori	26
Poland	Maria Skłodowska Curie - Curie's National Institute of Oncology	10
Czech Republic	Masaryk Memorial Cancer Institute	7
Italy	Istituto Oncologico Veneto IRCCS	6
Canada	Mount Sinai Hospital	5
Netherlands	The Netherlands Cancer Institute-Antoni Van Leeuwenhoekziekenhuis	4
Spain	Hospital De La Santa Creu I Sant Pau	2
France	Institut Curie- Hopital de Paris	3
Australia	Peter Maccallum Cancer Institute	2
Canada	The Ottawa Hospital - General Campus	2
United Kingdom	Royal Marsden Hospital - Chelsea, London	2
Italy	Istituto Clinico Humanitas	2
Germany	Universitaetsmedizin Goettingen - Georg-August Universitaet	2
United Kingdom	Leeds Teaching Hospitals NHS Trust - St. James's University Hospital	2
Germany	UniversitaetsMedizin Mannheim	1
France	Gustave Roussy	1
France	Centre Leon Berard	1
Spain	Hospital Universitario San Carlos	1
Spain	ICO Badalona - Hospital Germans Trias i Pujol	1
Italy	IRCCS - Fondazione Piemonte Inst di Candiolo	1
United Kingdom	Nottingham University Hospitals NHS Trust - City Hospital	1
Italy	Istituto Scientifico Romagnolo per lo Studio e la Cura dei Tumori	1
Netherlands	Leiden University Medical Centre	1
Australia	Chris O'Brien Lifehouse	1
Italy	Policlinico Universitario Campus Bio-Medico- Oncology Center	1
United States	Mayo Clinic Florida	1
Italy	Istituto Europeo di Oncologia	1
TOTAL		88

Tumour Board Meeting TCs

Take home messages:

- Investigators are encouraged to include patients that are fit for the trial as per protocol
- Investigators are reminded on the possibility of dose modification and reductions as per protocol.
- Regular case discussion TCs (failures and successes) will be set-up to support each other and to boost recruitment.

Upcoming dates:

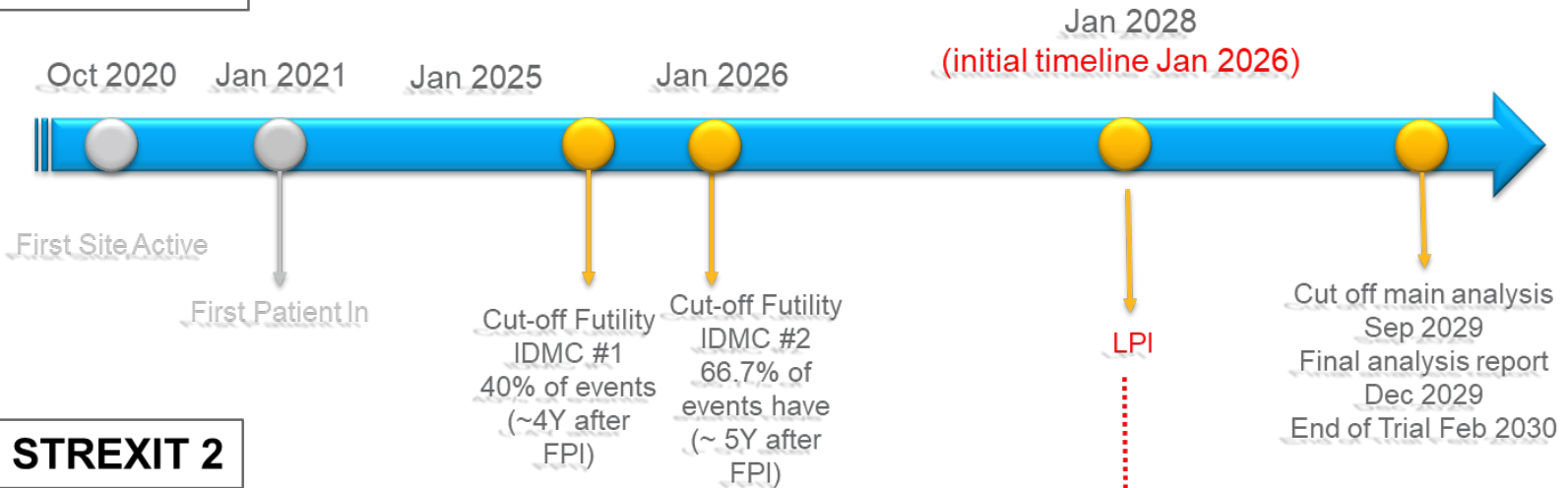
- 28FEB2024, 2pm CET
- 27MAR2024, 2pm CET
- 24APR2024, 2pm CET
- 26JUN2024, 2pm CET

STREXIT 2

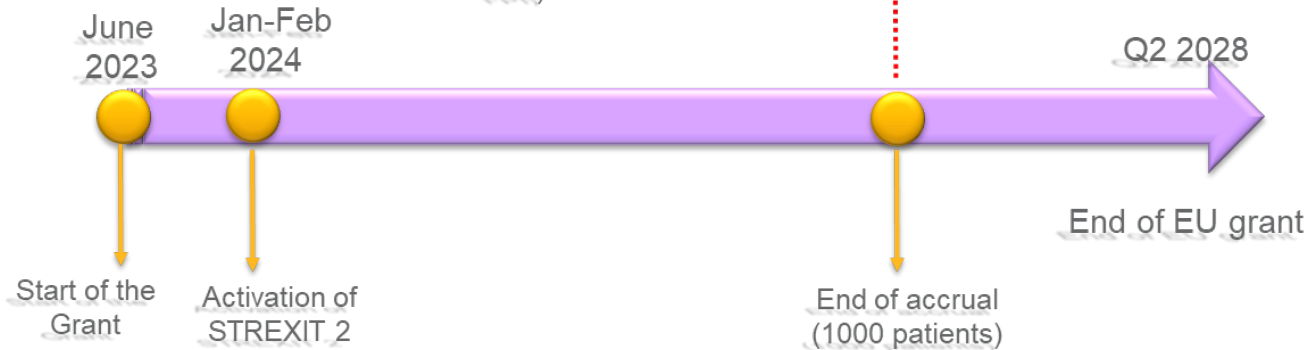
- EU commission has approved STREXIT 2 “*A Pragmatic Clinical Study of Neoadjuvant Chemotherapy Followed by Surgery Versus Surgery Alone for Patients with High Risk Retroperitoneal Sarcoma*” proposal in the frame of the **Horizon Europe (HORIZON) program**
- Total budget: + 4.2 M€ starting for 5 years (June 2023→ June 2028)
included STRASS 2 work and also STREXIT 2
- Start: Activation of STREXIT 2 sites mid Q2 2024
- Participation: All groups can participate
Only EU site can benefit from EU grant

Overall study milestones

STRASS 2



STREXIT 2



Baseline data (1)

(Cut-off 16/02/2024)

Tumor subtype	EXPERIMENTAL ARM	STANDARD ARM	Grand Total
DDLPS	22	21	43
LMS	22	23	45
Grand Total	42	44	88

Each cohort will be capped to 125 pts

Histology	EXPERIMENTAL ARM	STANDARD ARM	TOTAL
DDLPS	22	21	43
Grade 2	16	15	31
Grade 3	6	6	12
LMS	22	23	45
Grade 1	4	4	8
Grade 2	14	12	26
Grade 3	4	6	10
Data missing		1	
Grand Total	44	44	88

Baseline data (2)

(Cut-off 16/02/2024)

Gender	EXPERIMENTAL ARM	STANDARD ARM	Grand Total
Female	26	23	49
Male	18	21	39
Grand Total	44	44	88

Age (years)	EXPERIMENTAL ARM	STANDARD ARM	Total
Minimum	45	34	34
Maximum	81	77	81
Median	65.5	62	63

Baseline data (3)

(Cut-off 16/02/2024)

Tumor size (mm)	EXPERIMENTAL ARM	STANDARD ARM	Total
Minimum	49	52	49
Maximum	302	404	404
Median	149	124	136

Missing data overview

(Cut-off 15/02/2024)

Site	Country	Present	%	Missing	%	Due	%	Overdue	%	Total
225	France	77	92.8%	6	7.2%	1	1.2%	5	6%	83
227	France	70	88.6%	9	11.4%	3	3.8%	6	7.6%	79
240	France	1	100%	0	0 %	0	0 %	0	0 %	1
259	France	129	89%	16	11%	8	5.5%	8	5.5%	145
301	Netherlands	220	84.6%	40	15.4%	30	11.5%	10	3.8%	260
310	Netherlands	54	100%	0	0 %	0	0 %	0	0 %	54
366	Spain	88	100%	0	0 %	0	0 %	0	0 %	88
379	Spain	118	84.3%	22	15.7%	18	12.9%	4	2.9%	140
381	Spain	18	100%	0	0 %	0	0 %	0	0 %	18
429	France	2	100%	0	0 %	0	0 %	0	0 %	2
520	Germany	114	95%	6	5%	5	4.2%	1	0.8%	120
527	Germany	59	98.3%	1	1.7%	0	0 %	1	1.7%	60
550	Poland	573	91.4%	54	8.6%	42	6.7%	12	1.9%	627
601	United Kingdom	71	88.8%	9	11.3%	9	11.3%	0	0 %	80
613	United Kingdom	107	80.5%	26	19.5%	17	12.8%	9	6.8%	133
629	United Kingdom	2	100%	0	0 %	0	0 %	0	0 %	2
704	Italy	1533	96.8%	50	3.2%	42	2.7%	8	0.5%	1583
876	Canada	120	87.6%	17	12.4%	12	8.8%	5	3.6%	137
888	Canada	309	84.4%	57	15.6%	23	6.3%	34	9.3%	366
962	Czech Republic	365	98.1%	7	1.9%	7	1.9%	0	0 %	372
1054	Australia	81	91%	8	9%	2	2.2%	6	6.7%	89
3039	Germany	2	100%	0	0 %	0	0 %	0	0 %	2
3869	Italy	12	75%	4	25%	4	25%	0	0 %	16
3901	Italy	92	78%	26	22%	13	11%	13	11%	118
3903	Italy	24	85.7%	4	14.3%	4	14.3%	0	0 %	28
3908	Italy	334	74.9%	112	25.1%	63	14.1%	49	11%	446
3919	Italy	58	90.6%	6	9.4%	6	9.4%	0	0 %	64
6998	United Kingdom	50	76.9%	15	23.1%	13	20%	2	3.1%	65
9074	Italy	44	80%	11	20%	11	20%	0	0 %	55
9368	United States of America	15	68.2%	7	31.8%	7	31.8%	0	0 %	22
9848	Australia	40	95.2%	2	4.8%	1	2.4%	1	2.4%	42
		4782	90.3%	515	9.7%	341	6.4%	174	3.3%	5297

Next Steps

1) Activation of remaining 2 sites in Europe

- Universitair Medisch Centrum Groningen – The Netherlands
- Newcastle Hospitals NHS Trust - UK

2) Activation of STREXIT 2 across EU, UK and non-EU territories.

Questions?

Thank you!



Back up slides