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HIGHLIGHTS BY

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SEPTEMBER 2021

DISCLOSURES

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This content is supported by an independent educational grant from Bayer.

Disclosures: **Prof. Robert maki** has received honoraria from the following:

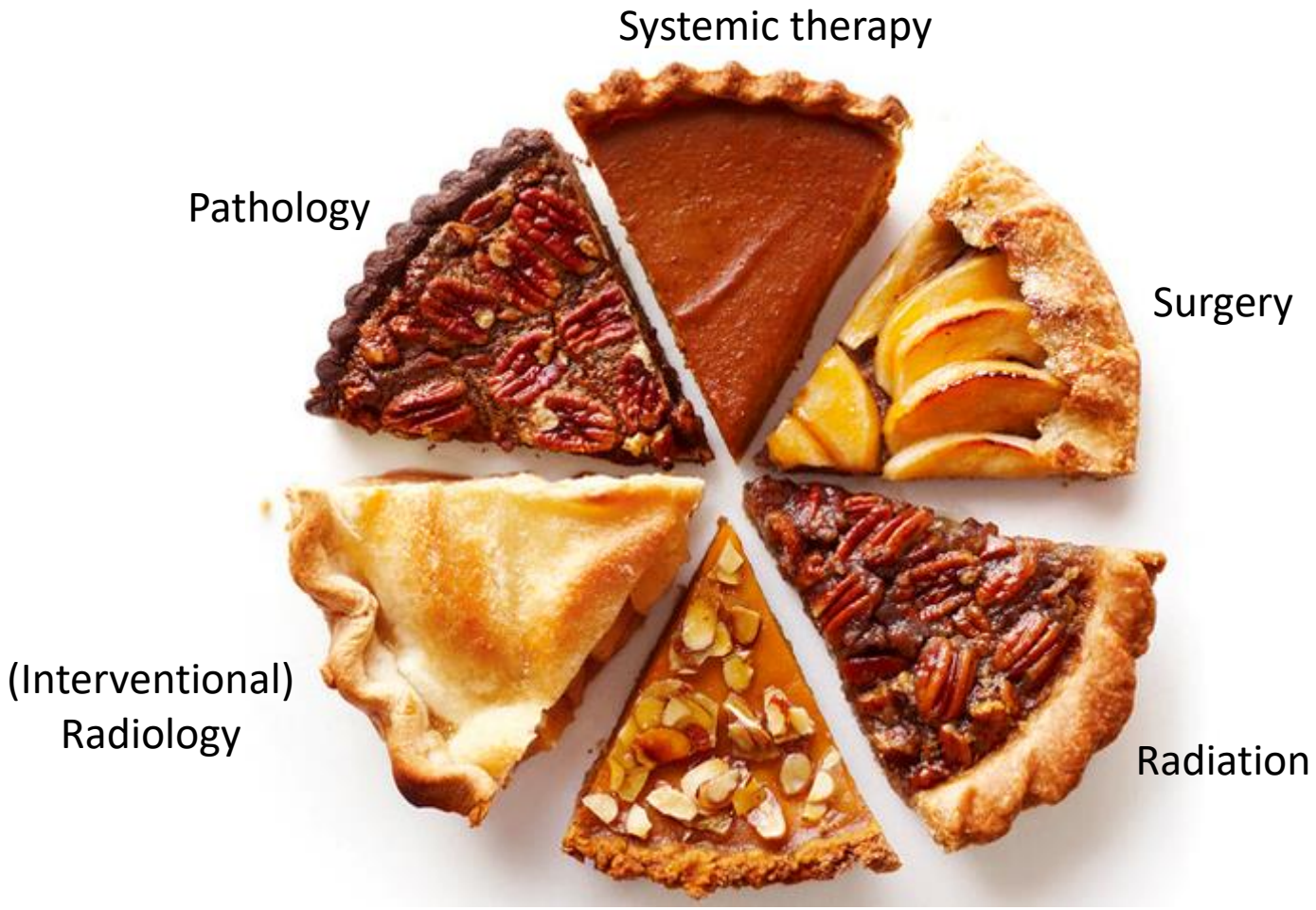
- Consulting fees/honoraria: American Board of Internal Medicine, American Society for Clinical Oncology, Bayer, Deciphera, Foundation Medicine, Immune Design, Karyopharm, Presage, Tracon
- Clinical trials support to institution: Bayer, Karyopharm, Lilly, Pfizer, Presage, Regeneron, Sarcoma Alliance for Research through Collaboration, Springworks

BACKGROUND

Multidisciplinary Tumour Board

Treatment options in Sarcoma

MULTIDISCIPLINARY MANAGEMENT OF SARCOMAS: POTLUCK – EVERYONE BRINGS SOMETHING



CHEMOTHERAPY FOR SARCOMA: TWO INTENTIONS

- **Curative intent**
  - Adjuvant chemotherapy
  - Neoadjuvant chemotherapy
- **Palliative intent**
  - Treatment of metastatic disease
    - Standard agents
    - Clinical trials

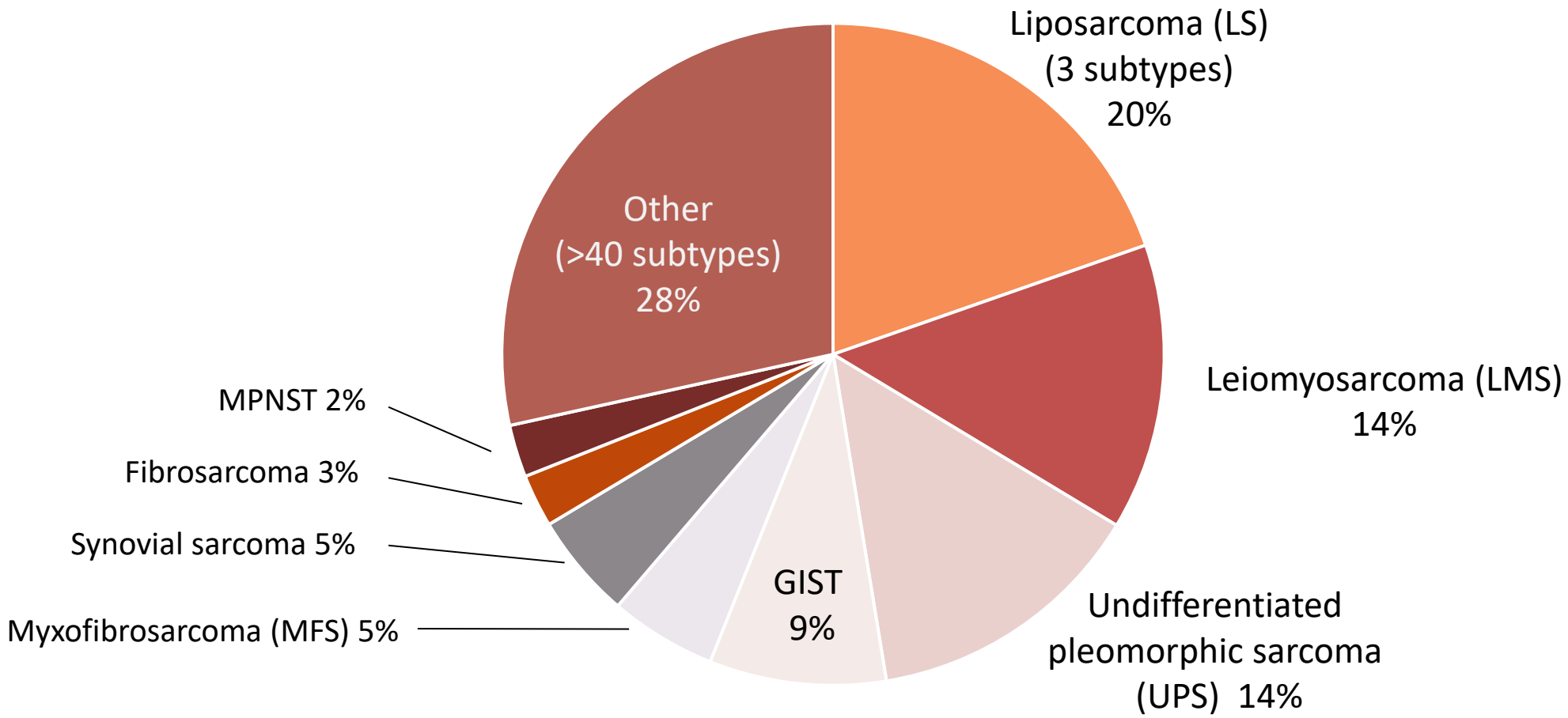
EXTREMITY SOFT TISSUE SARCOMAS

Adjuvant

neoadjuvant therapy

COMMON SOFT TISSUE SARCOMAS

13,460 CASES PER YEAR (US 2021), ~50 SUBTYPES < 1 % OF ADULT CANCER



GIST, gastrointestinal stromal tumour; LS, liposarcoma; LMS, leiomyosarcoma; MFS, myxofibrosarcoma; MPNST, malignant peripheral nerve sheath tumour; UPS, undifferentiated pleomorphic sarcoma

Brennan MF, et al. (2013). Management of Soft Tissue Sarcoma. Springer-Verlag, NY, USA

ADJUVANT CHEMOTHERAPY

- Diagnosis-dependent
- **GIST:** 3 years imatinib is standard of care (SOC) for higher-risk disease
- Paediatric sarcomas: also SOC
  - **Ewing sarcoma:** VAdrC-IE
  - **Rhabdomyosarcoma:** VDactinoC
  - **Osteosarcoma:** doxorubicin/cisplatin ± MTX
- **Extremity sarcomas** – benefit of chemoRx less clear
  - Most studies showed no benefit
  - Meta-analysis data supports its use (with ifosfamide)
  - Neoadjuvant chemoRx may be better than adjuvant chemoRx
- **Retroperitoneal sarcoma:** mostly a surgical disease

chemoRx, chemotherapy; GIST, gastrointestinal stromal tumour; MTX, methotrexate; SOC, standard of care;
VAdrC-IE, vincristine, doxorubicin, cyclophosphamide alternating with ifosfamide, etoposide; VDactinoC, VAdrC, ifosfamide, etoposide

LARGEST INDIVIDUAL ADJUVANT STUDY IN ADULTS: NO SURVIVAL ADVANTAGE FOR DOXORUBICIN + IFOSFAMIDE

- High-risk soft tissue sarcoma patients: doxorubicin/ifosfamide / lenograstim vs observation alone
  - 351 patients recruited, 1995-2003
  - 5 cycles of doxorubicin 75 mg/m^2 + ifosfamide 5 g/m^2 q3w
- Interim analysis for futility led to early study closure

	Estimated 5-yr RFS	Estimated 5-yr OS
Treatment	55%	67%
Observation	53%	68%

The hypothesis that adjuvant chemotherapy improves recurrence-free survival and overall survival was *rejected*

OS, overall survival; q3w, every 3 weeks; RFS, relapse-free survival

Woll PJ, et al. Lancet Oncol. 2012;13:1045-54

HOWEVER…2008 META-ANALYSIS SHOWED IMPROVED SURVIVAL FOR IFOSFAMIDE-BASED THERAPY

- Largest adjuvant study compiled to date
- Update to a 1997 meta-analysis
  - Greater use of ifosfamide
  - 18 trials
  - 1,953 patients
- New data are

  still needed…

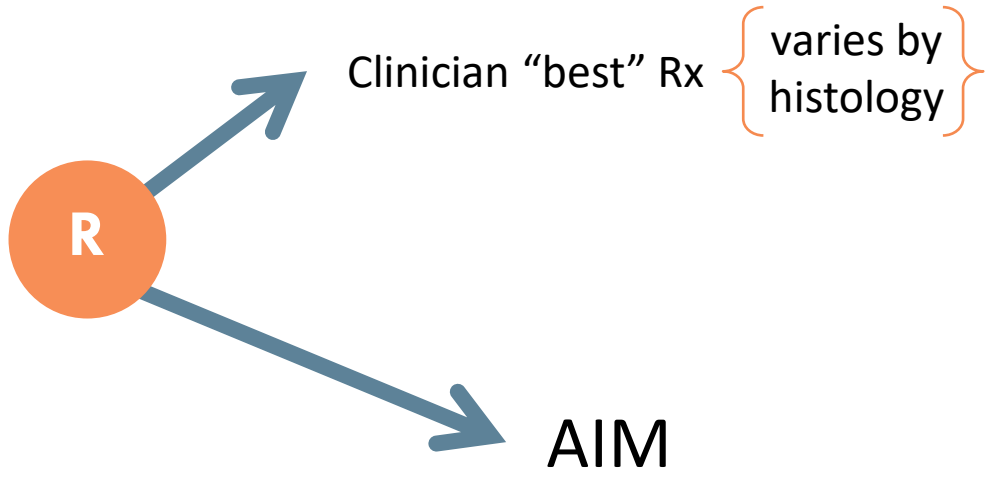
Hazard ratios	Overall survival
Any chemo	0.77 (p=0.01)
Dox only	0.84 (p=0.09)
Dox + Ifos	0.56 (p=0.01)

Dox, doxorubicin; Ifos, ifosfamide

Pervaiz N, et al. Cancer. 2008;113:573-81

NEW NEOADJUVANT DATA: TAILORED VS STANDARD RX

- Primary STS Dx:
  - UPS
  - Leiomyosarcoma
  - MPNST
  - Myxoid Liposarcoma
  - Synovial
  - Sarcoma NOS
- Outcomes
  - **Primary: DFS** (specifically if tailored > standard Rx)
  - Secondary included: OS



AIM, standard chemotherapy consisting of epirubicin plus ifosfamide; DFS, disease-free survival; Dx, diagnosis; MPNST, malignant peripheral nerve sheath tumour; NOS, not otherwise specified; OS, overall survival; Rx, chemotherapy; STS, soft tissue sarcoma; UPS, undifferentiated pleomorphic sarcoma

Gronchi A, et al. Lancet Oncol. 2017;18:812-22; Gronchi A, et al. J Clin Oncol. 2020;38:2178-86

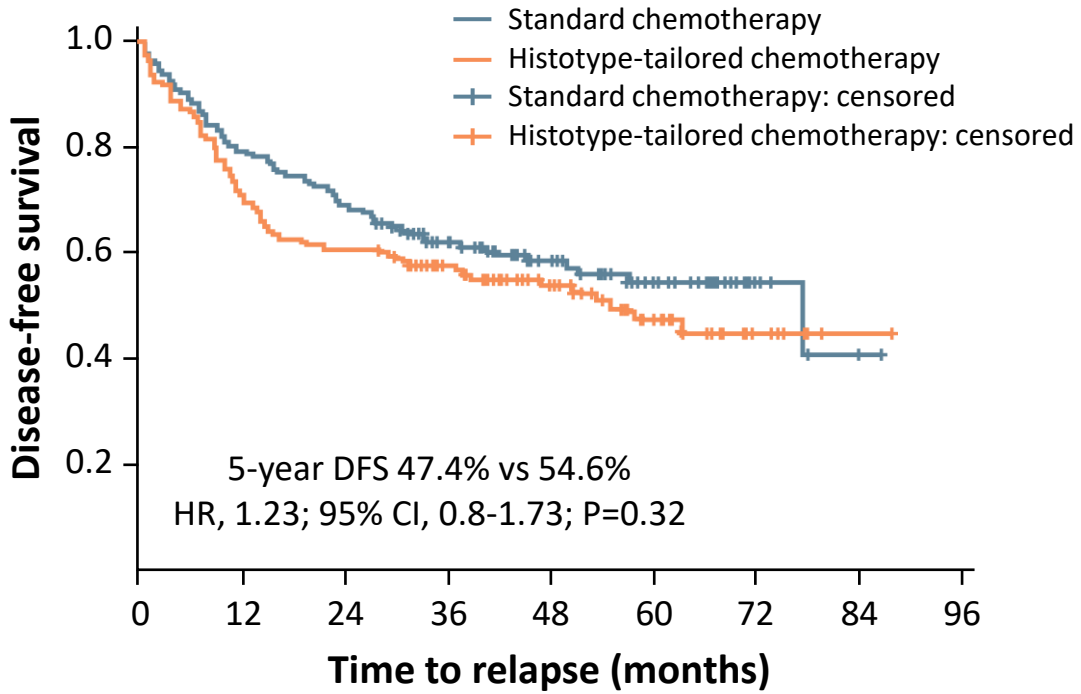
DEMOGRAPHICS

Characteristic	Standard Rx (n=145)	Tailored Rx (n=142)
Age, years, mean	48	49
Female gender	37%	40%
Tumour size, mm, mean	112	105
Histology (n, %)		
Myxoid liposarcoma	37 (26%)	28 (20%)
Synovial	36 (25%)	34 (24%)
MPNST	15 (10%)	12 (9%)
Leiomyosarcoma	12 (8%)	16 (11%)
UPS	43 (30%)	50 (35%)
Other	2 (1%)	2 (1%)
RT preop	12%	13%
RT postop	66%	67%
% R0 margin	78%	81%

MPNST, malignant peripheral nerve sheath tumour; R, resection; RT, radiation therapy; Rx, chemotherapy; UPS, undifferentiated pleomorphic sarcoma

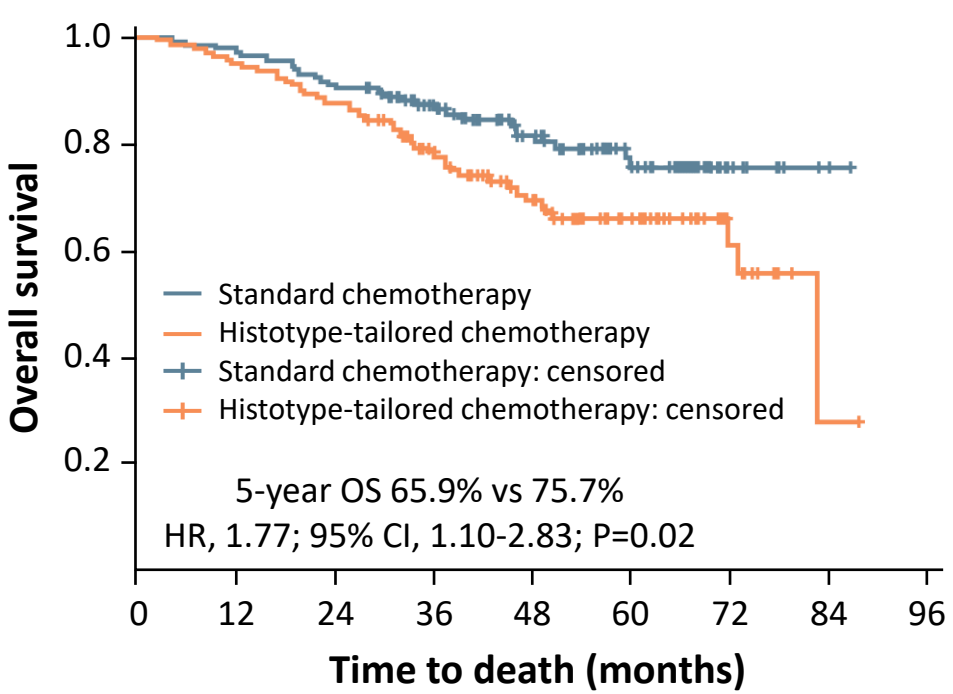
Gronchi A, et al. Lancet Oncol. 2017;18:812-22; Gronchi A, et al. J Clin Oncol. 2020;38:2178-86

DFS AND OS: STANDARD VS TAILORED THERAPY



No. at risk:									
Standard CT	145	115	100	77	55	36	8	2	0
HT CT	142	101	86	65	44	23	8	1	0

DFS



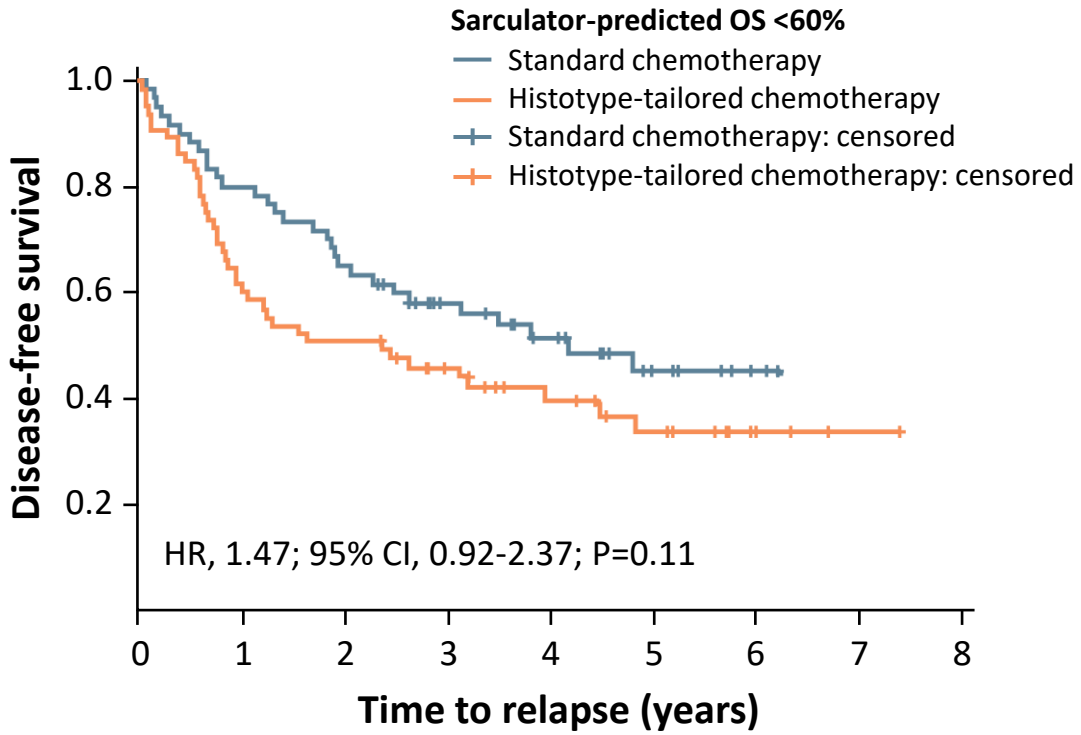
No. at risk:									
Standard CT	145	142	131	104	72	45	13	2	0
HT CT	142	135	125	92	61	35	13	1	0

OS

CI, confidence interval; CT, chemotherapy; DFS, disease-free survival; HR, hazard ratio; HT, histotype-tailored; OS, overall survival

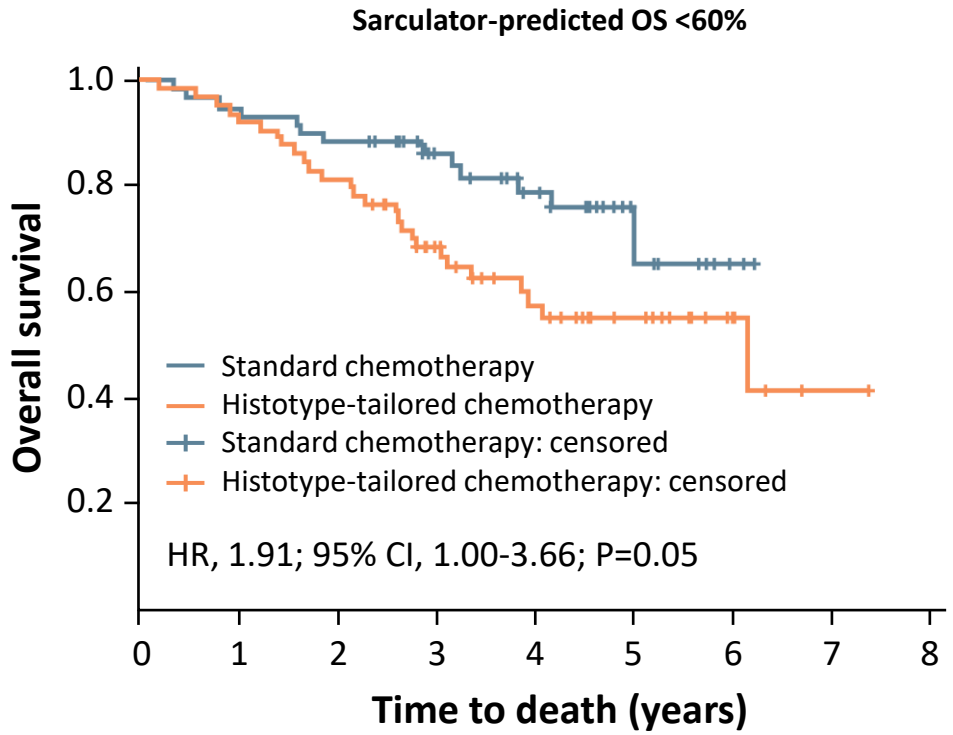
Gronchi A, et al. Lancet Oncol. 2017;18:812-22; Gronchi A, et al. J Clin Oncol. 2020;38:2178-86

WHO DID BETTER?
ONLY WHEN PREDICTED SURVIVAL <60%



No. at risk:									
Standard CT	60	48	39	28	20	11	3	0	0
HT CT	65	40	33	25	17	10	3	1	0

DFS



No. at risk:									
Standard CT	60	57	53	38	28	13	3	0	0
HT CT	65	60	53	38	24	15	4	1	0

OS

CI, confidence interval; CT, chemotherapy; DFS, disease-free survival; HR, hazard ratio; HT, histotype-tailored; OS, overall survival

Gronchi A, et al. Lancet Oncol. 2017;18:812-22; Gronchi A, et al. J Clin Oncol. 2020;38:2178-86

TAKE-HOME MESSAGES

- No placebo control – everyone got something
- RT typically given after surgery in this trial
- No study of adjuvant vs neoadjuvant therapy
  - Increasingly we give everything preoperatively
- Limitations
  - Epirubicin was the anthracycline – does that matter?
  - Hard to give ifosfamide >60 years of age
- Rule of 60s: consider therapy in patients <60 years, <60% expected survival

RT, radiotherapy

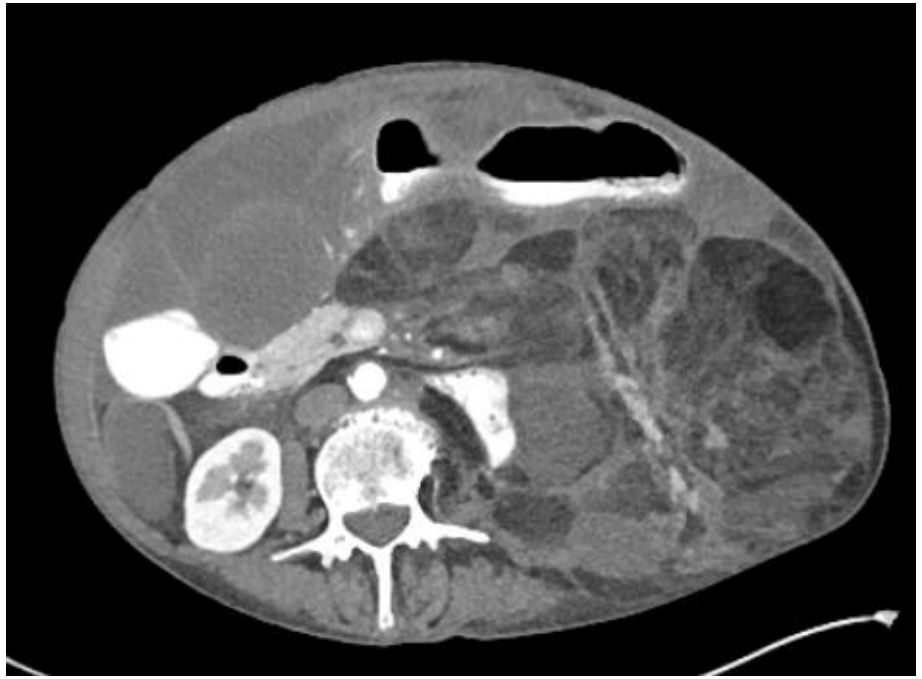
RETROPERITONEAL SARCOMAS

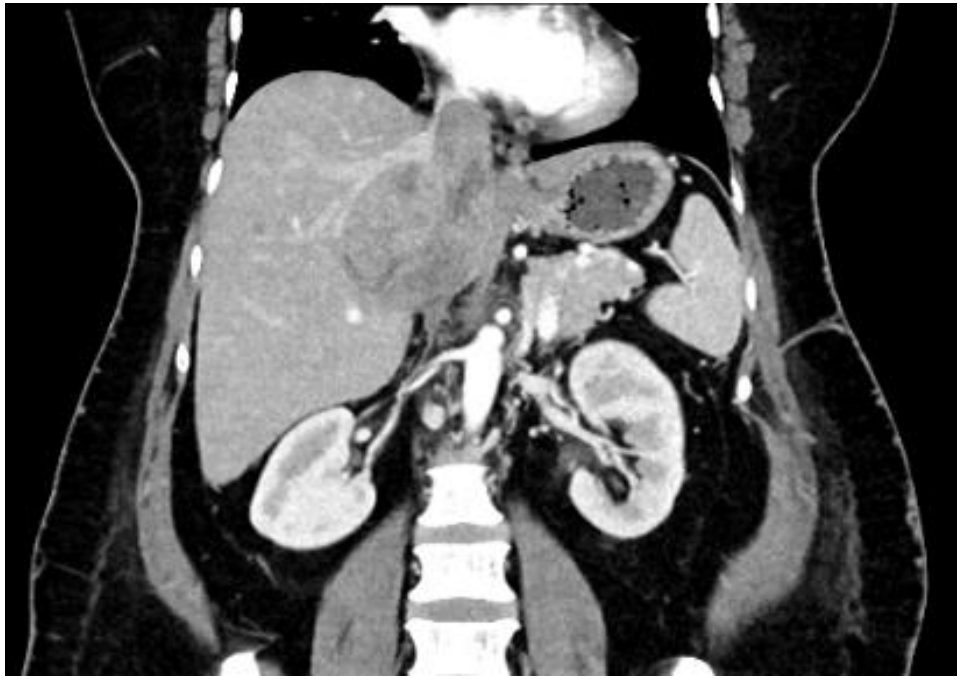
Well-differentiated / dedifferentiated liposarcoma

RETROPERITONEAL SARCOMAS

- **Two major subtypes**
  - Both usually present with large tumours >10 cm
- **Well-differentiated / dedifferentiated liposarcoma**
  - Local-regional recurrence common (70%)
  - Uncommon metastatic disease (20%)
- **Leiomyosarcoma**
  - Local-regional recurrence uncommon (20%)
  - Metastatic disease common (>50%)
- Principal therapy
  - Surgery
  - Chemotherapy for unresectable disease
  - Radiation for unresectable leiomyosarcoma, usually not liposarcoma

RETROPERITONEAL SARCOMAS





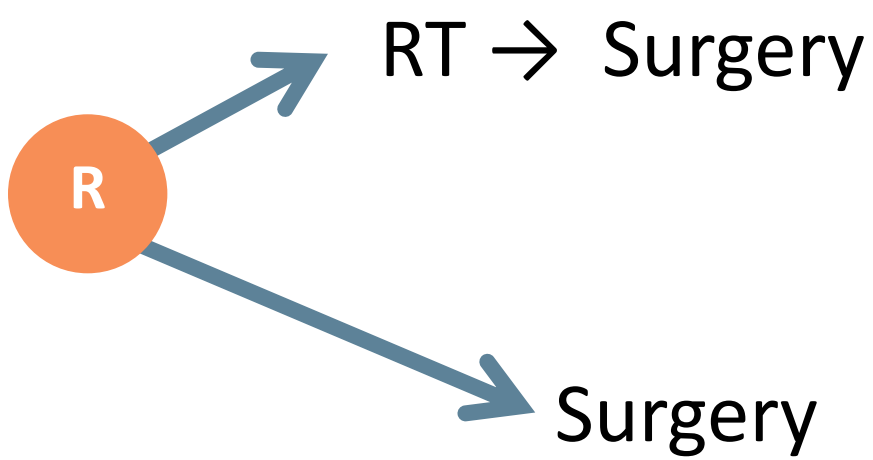
WDDDLS

Leiomyosarcoma

WDDDLS, well-differentiated and dedifferentiated liposarcoma

STRASS TRIAL (EORTC-62092): IS RADIATION USEFUL BEFORE SURGERY FOR RETROPERITONEAL SARCOMAS?

- Primary STS Dx:
  - WDDDLS
  - Leiomyosarcoma
  - Other
- Outcomes
  - Primary: **Abdominal RFS**
  - Secondary included: RFS, OS



RT: 3DCRT or IMRT
50.4 Gy, 1.8 Gy/fraction,
28 fractions, 5.5 weeks

3DCRT, 3D conformal radiotherapy; Dx, diagnosis; IMRT, intensity modulated radiotherapy; OS, overall survival; RFS, recurrence-free survival; RT, radiotherapy; STS, soft tissue sarcoma; WDDDLS, well-differentiated and dedifferentiated liposarcoma

Bonvalot S, et al. Lancet Oncol. 2020;21:1366-77

DEMOGRAPHICS (N=266)

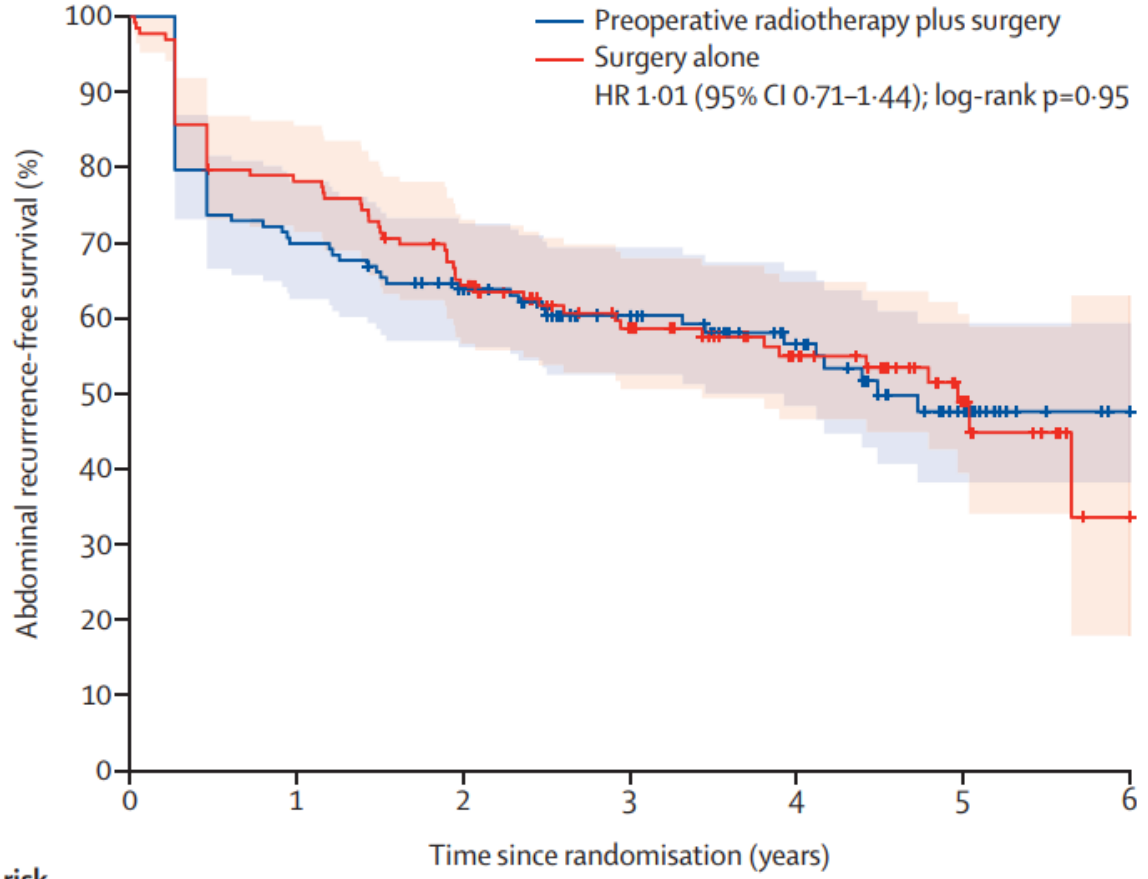
Characteristic	Surgery (n=133)	Surgery + RT (n=133)
Age, years, median	61	61
Female gender	50%	47%
Tumour size, mm, median	167	160
Histology (n, %)		
WDDDLS	96 (72%)	97 (73%)
Leiomyosarcoma	22 (17%)	16 (12%)
Other/data missing	11 (8%)	19 (14%)
WHO PS 0	75%	83%
Tumour Grade at Bx (1: low / 2: intermediate / 3: high)	32%/29%/14%	33%/35%/9%

Table simplified for readability

Bx, biopsy; RT, radiotherapy; WDDDLS, well-differentiated and dedifferentiated liposarcoma; WHO, World Health Organization

Bonvalot S, et al. Lancet Oncol. 2020;21:1366-77

ABDOMINAL RFS

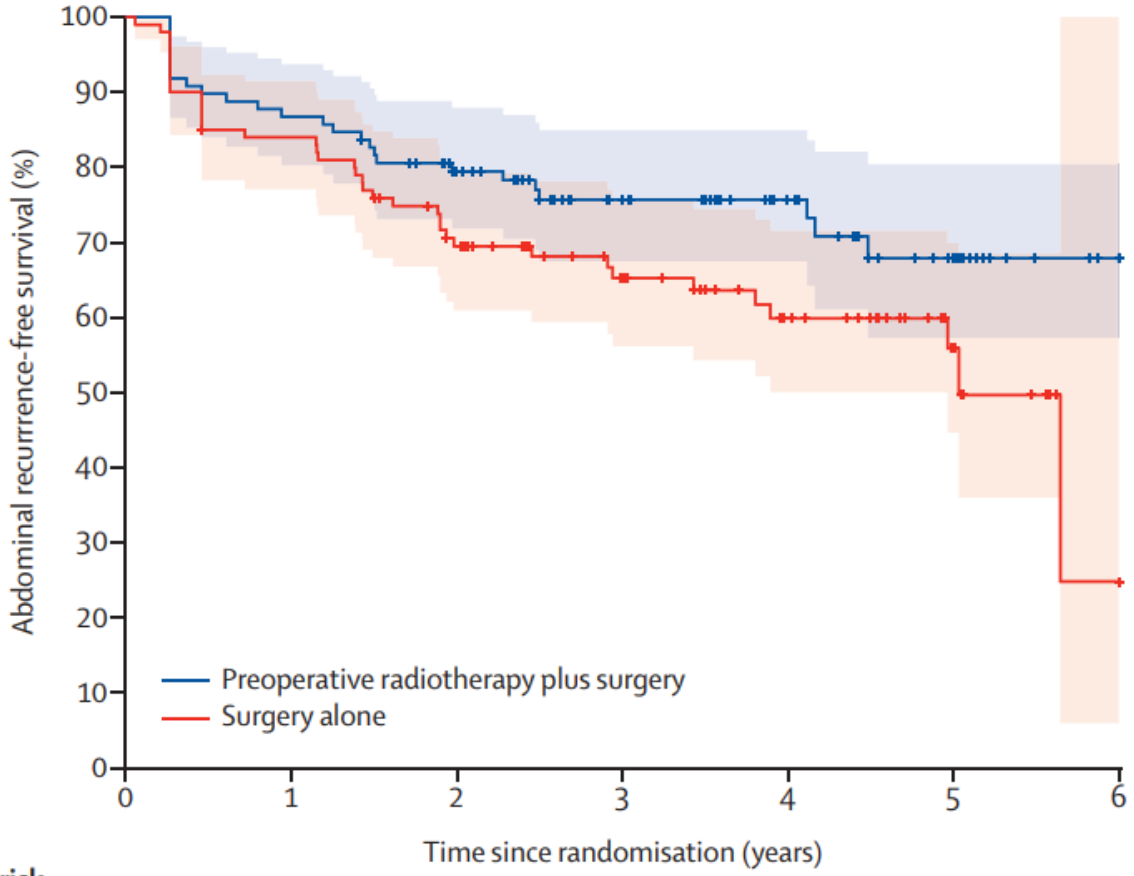


Number at risk (number censored)							
Preoperative radiotherapy plus surgery	133 (0)	93 (0)	78 (7)	57 (24)	38 (40)	17 (56)	3 (70)
Surgery alone	133 (0)	103 (1)	82 (4)	57 (23)	40 (37)	17 (57)	2 (70)

CI, confidence interval; HR, hazard ratio; RFS, recurrence-free survival

Bonvalot S, et al. Lancet Oncol. 2020;21:1366-77

ABDOMINAL RFS: LIPOSARCOMA ONLY



Number at risk (number censored)							
Preoperative radiotherapy plus surgery	98 (0)	85 (0)	69 (9)	50 (25)	34 (41)	18 (54)	4 (68)
Surgery alone	100 (0)	83 (1)	64 (6)	44 (23)	30 (34)	13 (50	1 (60)

RFS, recurrence-free survival

Bonvalot S, et al. Lancet Oncol. 2020;21:1366-77

TAKE-HOME MESSAGES

- No difference in overall survival with use of RT, but follow up is short as of 2021
- Liposarcoma patients are the only subgroup that may benefit from radiation since local control is the most problematic issue. Study needs longer follow up
- Leads to next study: Neoadjuvant chemotherapy before surgery – AIM for WDDDLS, doxorubicin/dacarbazine for leiomyosarcoma (NCT04031677)
- Both this and prior study are great examples of expert centres cooperating to study rare cancers

AIM, standard chemotherapy consisting of epirubicin plus ifosfamide; RT, radiotherapy; WDDDLS, well-differentiated and dedifferentiated liposarcoma

IMMUNOTHERAPY AND KINASE-TARGETED THERAPIES

TREATMENT FOR METASTATIC SARCOMA

- Are there symptoms from advanced disease?
  - If **yes**, combination regimens have a better chance of alleviating symptoms
  - If **no** symptoms, single agents are reasonable
- Consider disease sensitivity based on histopathology
- Agents
  - doxorubicin
  - ifosfamide (synovial sarcoma, myxoid liposarcoma)
  - pazopanib (synovial sarcoma, leiomyosarcoma)
  - gemcitabine / docetaxel (UPS, leiomyosarcoma)
  - trabectedin, eribulin, dacarbazine
  - some subtype specific drugs
    - Angiosarcoma: taxanes
    - Epithelioid sarcoma: tazemetostat

UPS, undifferentiated pleomorphic sarcoma

BUT WHO CARES ABOUT ANYTHING EXCEPT IMMUNOTHERAPY?

- Today: focus on **immune checkpoint inhibitors – ICI –** no special handling needed

- **Cellular therapies** against NY-ESO-1 **are** active against **synovial sarcoma** and **myxoid liposarcoma**

ICI, immune checkpoint inhibitors; NY-ESO-1, New York esophageal squamous cell carcinoma-1

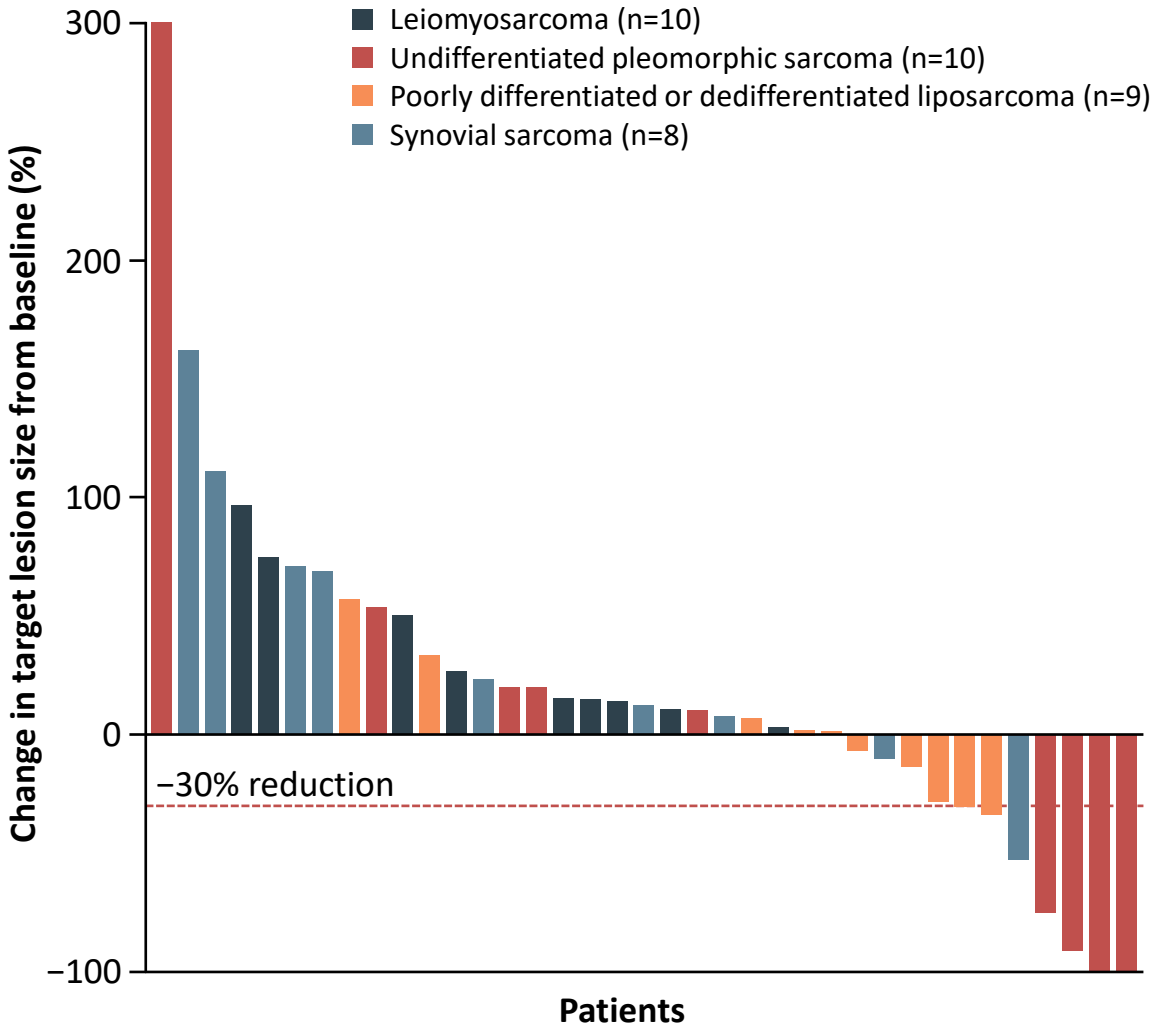
FIRST ICI TRIALS IN ADVANCED SARCOMAS

Year (published)	Drug(s)	N	Diagnosis	RR (%)
2013[1]	ipilimumab	6	synovial sarcoma	0
2017[2]	pembrolizumab	86	bone sarcoma STS	5 18
2017[3]	nivolumab	12	uterine LMS	0
2018[4]	nivolumab nivolumab + ipilimumab	43 42	bone & STS	5 16
2018[5]	pembrolizumab + metronomic cyclophosphamide	57	STS (incl GIST)	2
2019	nivolumab	21	STS	0
2019[6]	axitinib + pembrolizumab	33	bone & STS	25

GIST, gastrointestinal stromal tumour; ICI, immune checkpoint inhibitors; LMS, leiomyosarcoma; RR, response rate; STS, soft tissue sarcoma

1. Maki RG, et al. Sarcoma. 2013;2013:168145; 2. Tawbi HA, et al. Lancet Oncol. 2017;18:1493-1501; 3. Ben-Ami E, et al. Cancer. 2017;123:3285-90;
4. D'Angelo SP, et al. Lancet Oncol. 2018;19:416-26; 5. Toulmonde M, et al. JAMA Oncol. 2018;4:93-7; 6. Wilky BA, et al. Lancet Oncol. 2019;20:837-48

SARC028: PEMBROLIZUMAB



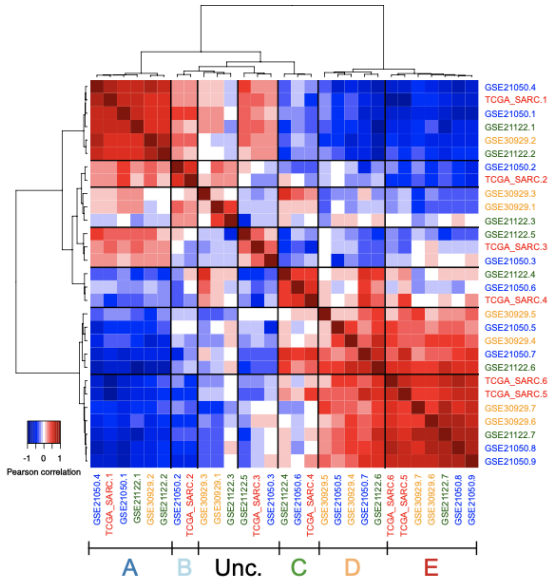
Histology subtype-specific responses (n=40)

- UPS: 4/10
- Dedifferentiated LPS: 2/10
- Synovial sarcoma: 1/10
- Leiomyosarcoma: 0/10
- Median PFS for all patients: 18 weeks

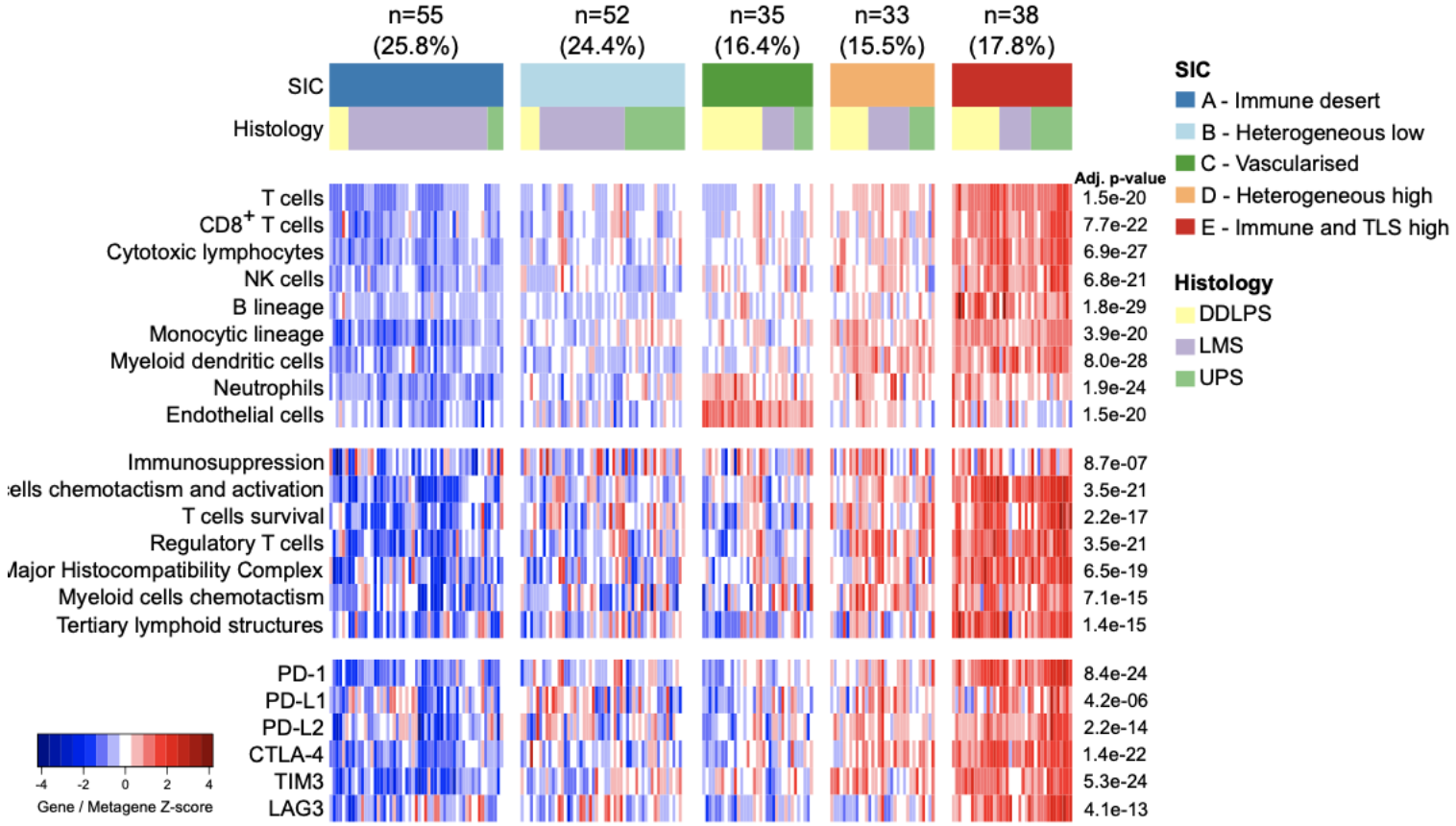
LPS, liposarcoma; PFS, progression-free survival; UPS, undifferentiated pleomorphic sarcoma

Tawbi HA, et al. Lancet Oncol. 2017;18:1493-1501

SARCOMA GENE EXPRESSION SIGNATURES FROM PUBLIC DATABASES



Heat map of the Pearson correlation of centroids from each SIC class of discovery cohorts (TCGA SARC, GSE21050, GSE21122 and GSE30929, n=608), with five immune classes and two groups of unclassified samples.

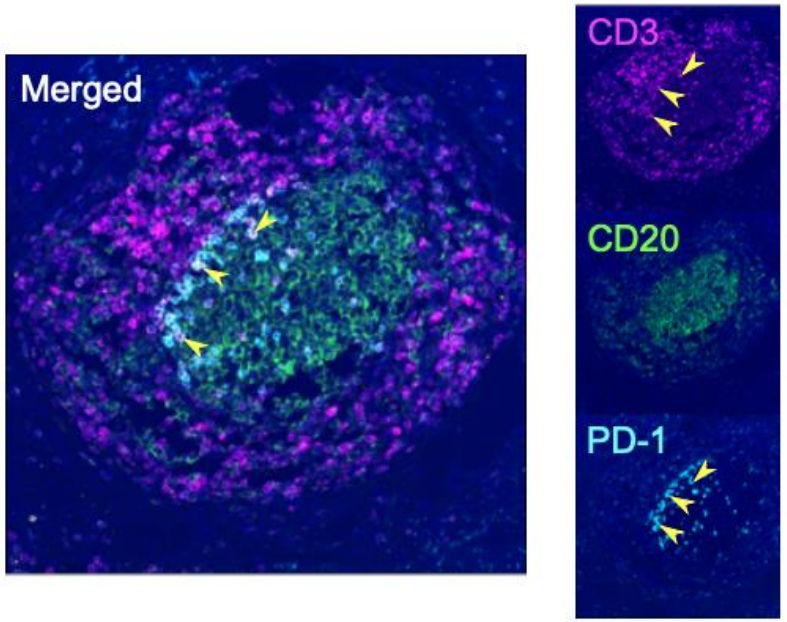


The Sarcoma Immune Class (SIC) exhibit strongly different TMEs

CTLA-4, cytotoxic T lymphocyte antigen 4; DDLPS, dedifferentiated liposarcoma; LAG3, lymphocyte activating 3; LMS, leiomyosarcoma; NK, natural killer; PD-1, programmed death 1; PD-L1, programmed death ligand 1; PD-L2, programmed death ligand 2; SIC, sarcoma immune class; TIM3, T cell immunoglobulin and mucin-domain containing 3; TLS, tertiary lymphoid structures; TME, tumour microenvironment; UPS, undifferentiated pleomorphic sarcoma

Petiprez F, et al. Nature. 2020;577:556-60

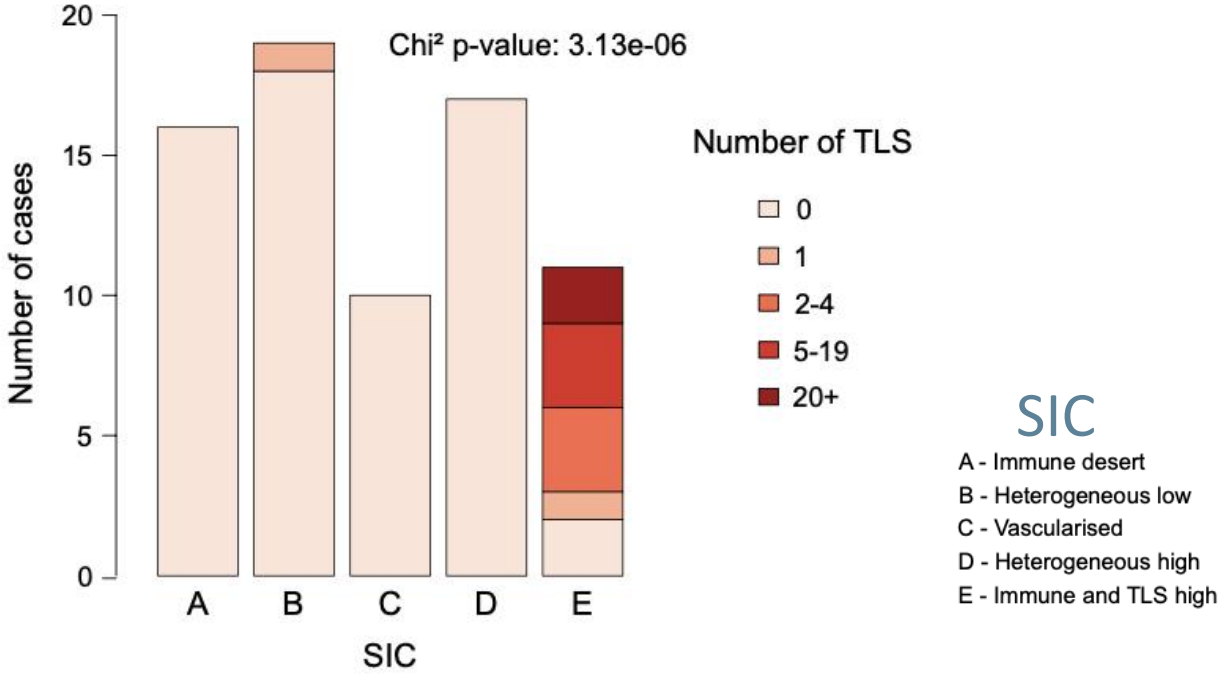
PEMBROLIZUMAB RESPONDERS HAD SIGNS OF TERTIARY LYMPHOID STRUCTURES (TLS)



Representative immunofluorescence staining of a TLS for CD3 (magenta), CD20 (green) and PD1 (cyan)

DAPI staining is shown in blue

The merged image shows CD3+PD1+ double-positive cells (yellow arrows)



Number of TLS among 5 SICs of 73 tumours of NTUH cohort (n=73)

Overall SIC E tumours were associated with the highest response rate to pembrolizumab vs tumours from other SICs (P=0.026)

I/O, immuno-oncology; SIC, sarcoma immune class; TLS, tertiary lymphoid structures

Petiprez F, et al. Nature. 2020;577:556-60

ASCO 2021: TLS IHC SCREENING FOR I/O THERAPY

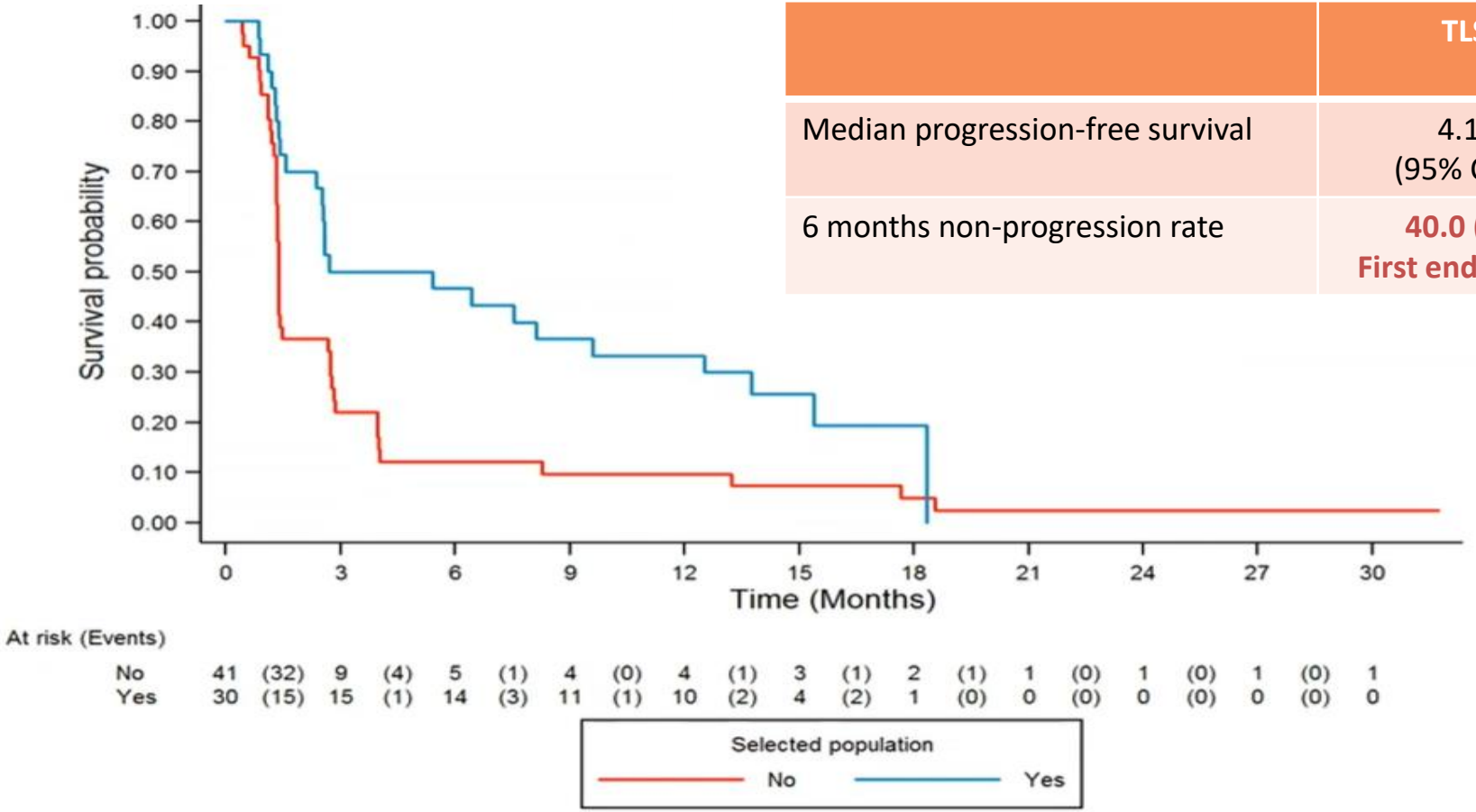
- Unselected patients Rx PD-1 antagonist – median PFS
  - 4.1 months – SARC028 – 4 cohorts of 10 patients each[1]
  - 1.4 months – PEMBROSARC trial, unselected n=57[2]

- PEMBROSARC trial, response by TLS status[3]
  - Screened 240 patients for TLS(+)
  - 48 were (+) by central review (20%), 35 included on trial: WDDDLS, UPS, leiomyosarcoma
  - Therapy: pembrolizumab IV q3w and oral cyclophosphamide

IHC, immunohistochemistry; I/O, immuno-oncology; IV, intravenous; PD-1, programmed death 1; PFS, progression-free survival; q3w, every 3 weeks; Rx, chemoatherapy; TLS, tertiary lymphoid structures; UPS, undifferentiated pleomorphic sarcoma; WDDDLS, well-differentiated and dedifferentiated liposarcoma

1. Tawbi HA, et al. Lancet Oncol. 2017;18:1493-1501; 2. Toulmonde M, et al. JAMA Oncol. 2018;4:93-7; 3. Italiano A, et al. J Clin Oncol. 2021;39(15_suppl):11507

COMPARISON OF SELECTED PATIENTS VS UNSELECTED PATIENTS OF PRIOR STUDY



	TLS cohort N=35	Previous cohorts N=41
Median progression-free survival	4.1 months (95% CI: 2.4-12.5)	1.4 months* (95% CI: 1.3-2.7)
6 months non-progression rate	**40.0 (22.7-59.4) First endpoint reached**	4.9% (0.6-16.5)

CI, confidence interval; TLS, tertiary lymphoid structures

*Toulmonde et al. Jama Oncol. 2017

Italiano A, et al. J Clin Oncol. 2021;39(15_suppl):11507 (ASCO 2021 abstract #11507)

ASCO 2021: TLS IHC SCREENING FOR I/O THERAPY

- Primary endpoint: 6 month non-progression rate
- 8/30 (27%) had RECIST PR
- 13/30 (43%) had tumour shrinking of any sort
- Median PFS 4.1 months, median OS 14.5 months
- Compare to prior response rate in French trial of 2%
- Raises the question of how we can best screen patients

IHC, immunohistochemistry; I/O, immuno-oncology; OS, overall survival; PFS, progression-free survival; PR, partial response; RECIST, Response Evaluation Criteria in Solid Tumours; TLS, tertiary lymphoid structures

Italiano A, et al. J Clin Oncol. 2021;39(15_suppl):11507

IMMUNOTHERAPY: TAKE-HOME MESSAGES

- Cellular therapeutics (NY-ESO-1, MAGE-A4) are active in myxoid liposarcoma, synovial sarcoma
- PD-1, (PD-L1) inhibitors are active in specific diagnoses amongst the 70 or so sarcoma subtypes
  - UPS, angiosarcoma, dedifferentiated liposarcoma and others (e.g. ASPS) have supportive trials data
- Biomarker screening increases the odds of success
- As with other cancers, combination immunotherapy trials are underway

ASPS, alveolar soft part sarcoma; MAGE-A4, melanoma-associated antigen 4; NY-ESO-1, New York esophageal squamous cell carcinoma 1; PD-1, programmed death 1; PD-L1, programmed death ligand 1; UPS, undifferentiated pleomorphic sarcoma

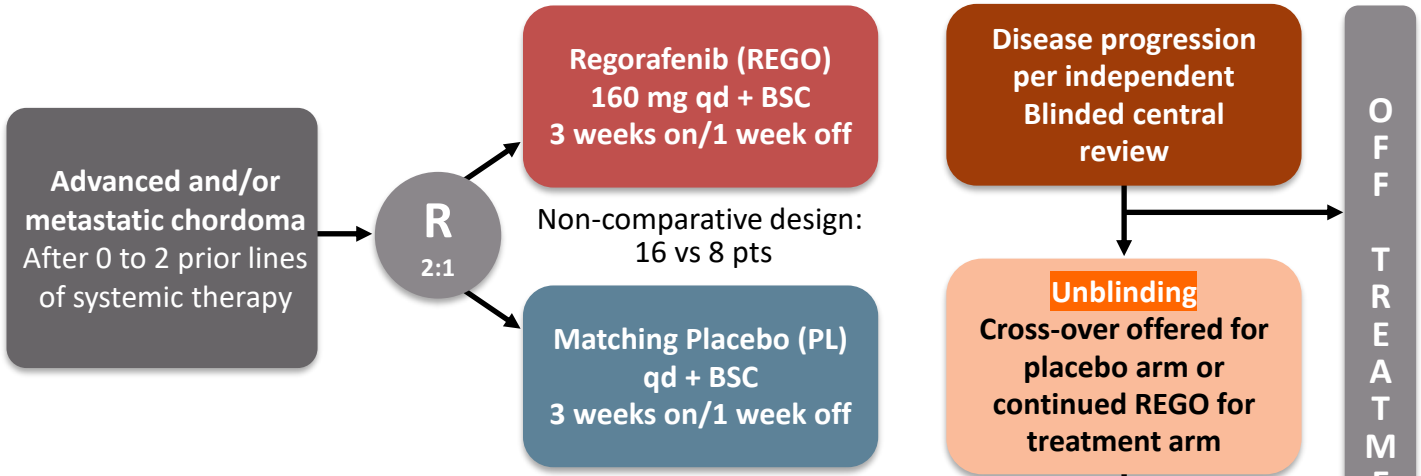
LATE-BREAKING ABSTRACTS FROM ESMO 2021

CHORDOMA IN REGOBONE: STUDY DESIGN

Background:

REGOBONE (NCT02389244) = investigator-initiated study to explore the activity of regorafenib in patients with relapsed advanced and/or metastatic chordoma as well as cohorts of other primary bone sarcomas in separate parallel cohorts

REGOBONE has shown prior signals of regorafenib activity in **osteosarcoma, chondrosarcoma and Ewing sarcoma cohorts**



- Treatment duration: until objective progression, unacceptable toxicity, or patient withdrawal
- Disease staging at baseline and repeated at months 1, 2, 3, 4, then every 8 weeks until end of study drug dosing
- After cross-over disease restaging with the original schedule

Primary endpoint (PFS rate at 6 months) not achieved

Source: Duffaud F. et al. ESMO 2021 LBA58

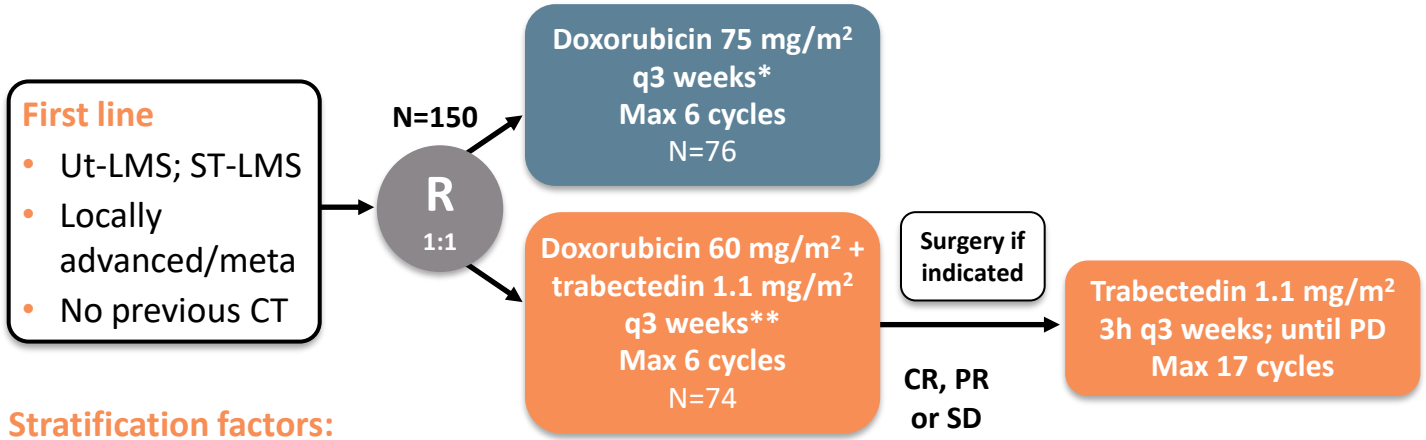
BSC, best standard of care; PFS; progression-free survival; qd, once a day; REGO, regorafenib

LMS-04: STUDY DESIGN

Background:

LMS-04 (NCT02997358) = Randomised Phase III multicentric study comparing efficacy of doxorubicin with trabectedin followed by trabectedin in non-progressive patients versus doxorubicin alone as first-line therapy in patients with metastatic or unresectable leiomyosarcoma (uterine or soft tissue)

LMS 04: Ph-III first-line therapy for locally advanced/metastatic LMS



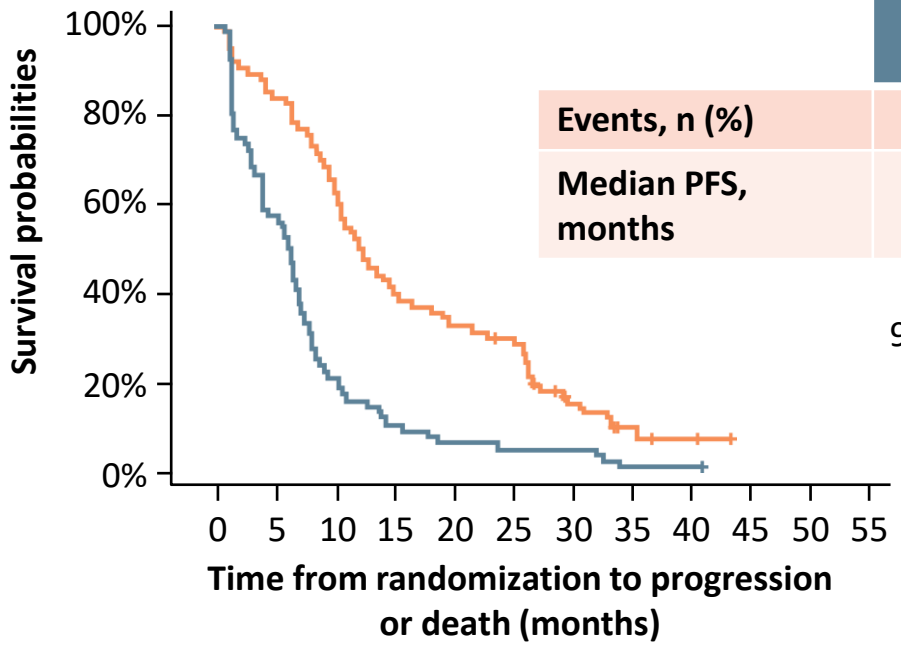
Stratification factors:

- Uterus vs soft tissue
- Locally advanced vs metastatic

* + Lenograstim 150 µg/m²/day s.c. d3-9; ** + Pegfilgrastim 6 mg s.c. day 2
CT, chemotherapy; PFS, progression-free survival; RX, radiological; CBR, clinical benefice rate; LMS, leiomyosarcoma; PFS inv, investigator-assessed PFS; ST-LMS, soft tissue leiomyosarcoma; Ut-LMS, Uterine leiomyosarcoma
Source: Pautier P, et al. ESMO 2021 LBA59

LMS-04: PFS BY BICR, ITT POPULATION

Progression-free survival



	Doxo N=76	Doxo + Trab N=74
Events, n (%)	74 (97%)	65 (88%)
Median PFS, months	6.2	12.2

HR 0.41
95% CI 0.29-0.58; P<0.0001

1: Arm A: doxorubicin	75	43	16	8	5	4	4	1	1	0
2: Arm B: doxorubicin + trabectedin	74	61	46	29	24	21	9	4	2	0

Conclusion:

- Safety profile of doxorubicin + trabectedin = consistent and manageable toxicity
- Doxorubicin + Trabectedin should be a new standard of care for 1L treatment of metastatic LMS

1L, first-line; BICR, blinded independent central review; CI, confidence interval; Doxo, doxorubicin; HR, hazard ratio; ITT, intent to treat; LMS, leiomyosarcoma; PFS, progression-free survival; Trab, trabectedin
Median follow-up was 37 months
Source: Pautier P, et al. ESMO 2021 LBA59

SARCOMA TREATMENT: SUMMARY

- First, get the diagnosis right – expert pathology
- Primary therapy – increasingly **neoadjuvant** Rx, just like other cancers
  - Osteosarcoma is a prime example (since the 1970s!)
- Metastatic disease
  - Increasingly Rx is a function of primary diagnosis
    - **The LMS-04 study indicates a possible new standard of care for 1st line therapy for metastatic leiomyosarcoma patients**
  - Clinical trials for later stage disease now often focussed on specific histologies or groups of them
  - Rare, so need multicentre trials
- Act locally (patient level), think globally (collaborative, diagnosis-specific trials)

Rx, chemotherapy

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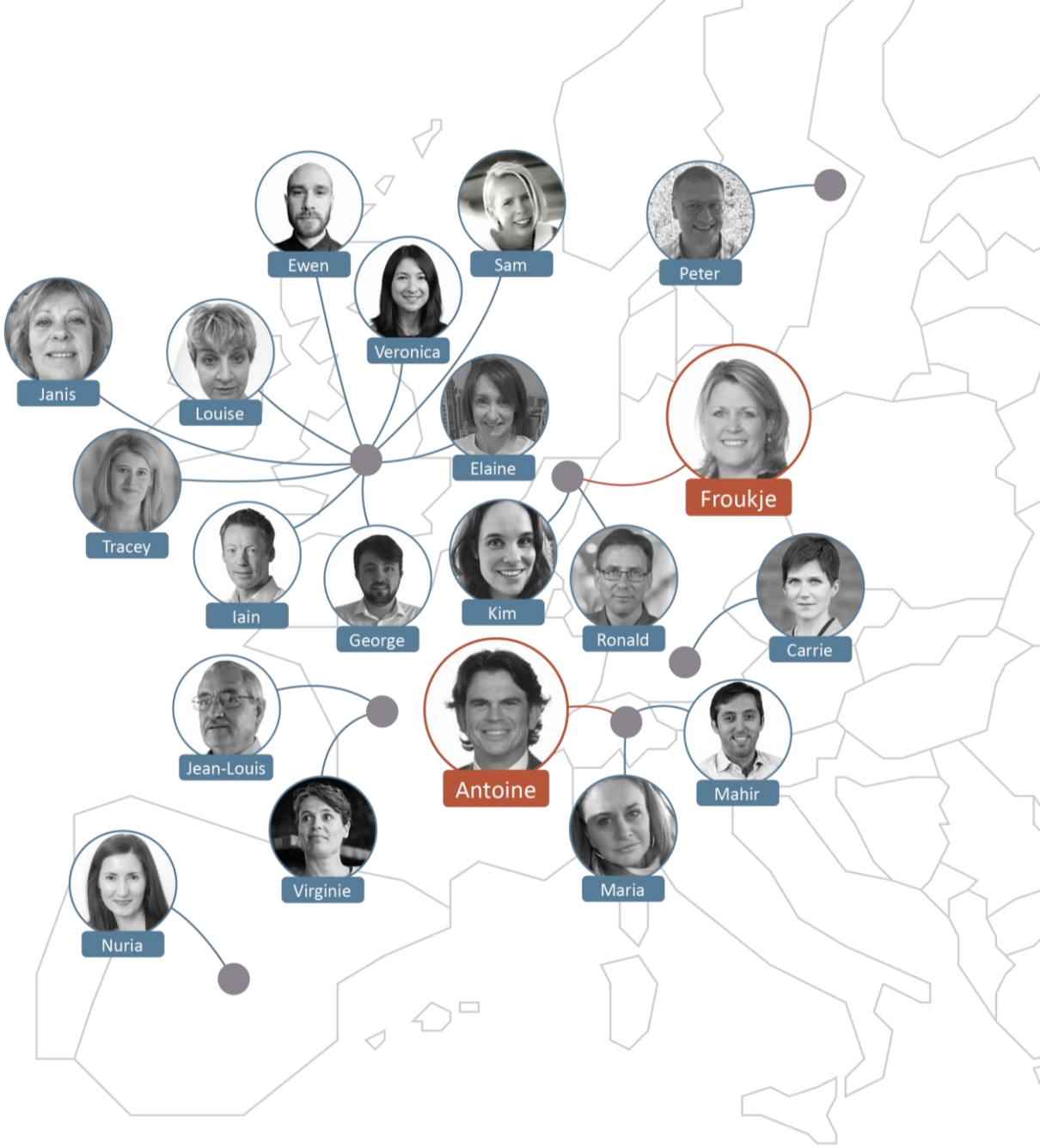

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