FACULTY OF MEDICINE AND HEALTH SCIENCES

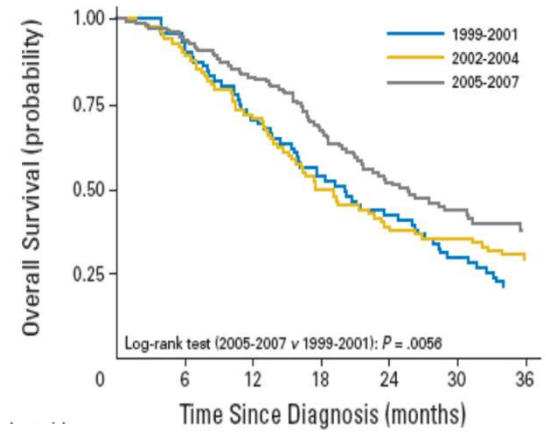
NATIONAL DATA ON SBRT.

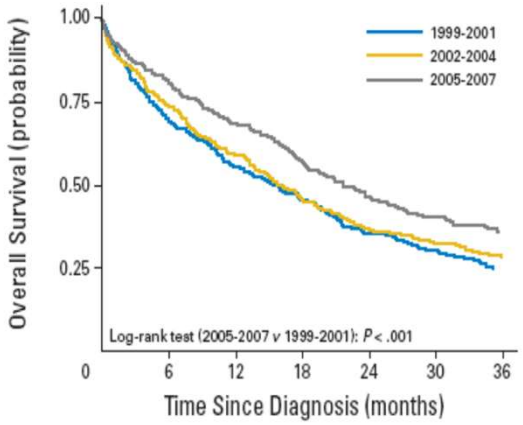
Belgian SBRT experience over the years.

Yolande Lievens, MD, PhD
Radiation Oncology Department
Ghent University Hospital & Ghent University

UZ GENT UNIVERSITEIT GENT KCE Belgian Cancer Registry INAMI-RIZIV College van Geneesheren Radiotherapie-Oncologie Collège des Médecins Radiothérapie-Oncologie EORTC

SBRT for early-stage lung cancer - patterns of care & outcome





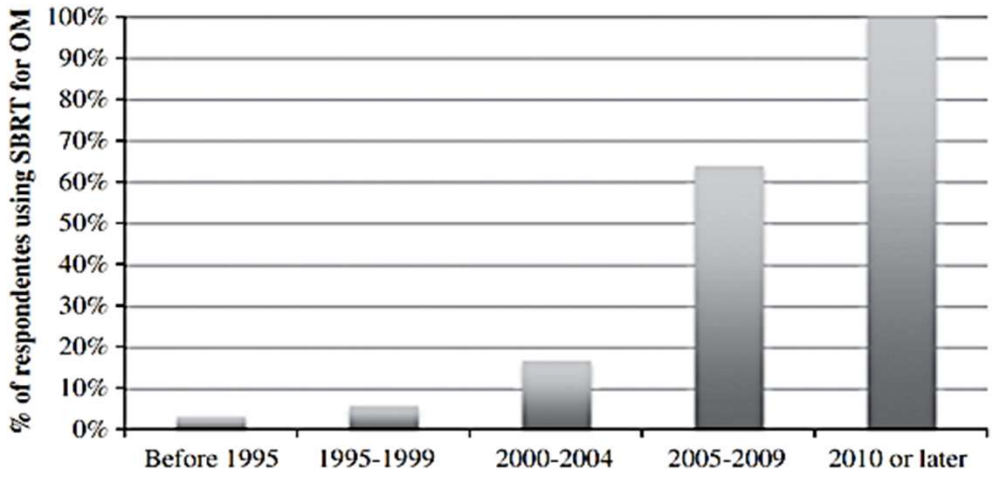
SBRT introduction ***improved RT use***, with a decline in untreated elderly patients
improved OS

2010

… no randomized evidence

Palma et al, J Clin Oncol 2010

SBRT for oligometastasis – survey in >1000 radiation oncologists



2010

… no randomized evidence

Lewis 2015 Am J Clin Oncol

SBRT in Belgium

2011

SBRT gradually implemented in Belgium
reimbursement not granted due to lack of clinical and economic data from Belgium

2013

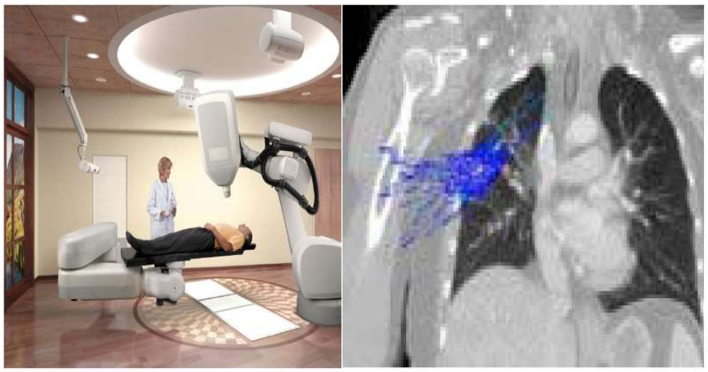
coverage with evidence development (CED) project

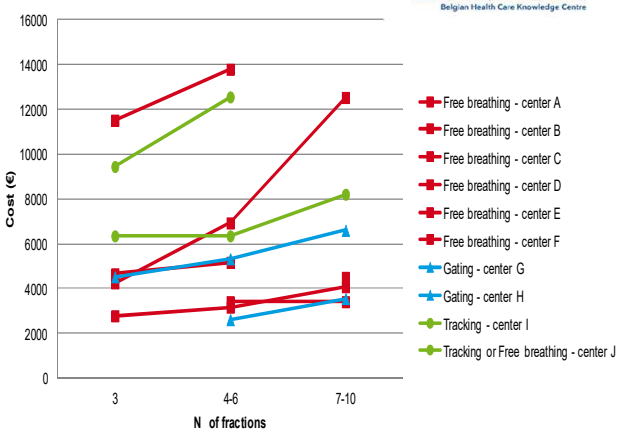
- early **access** while collecting **real-life data**
- **map** diffusion, **monitor** safety and effectiveness
- examine the conditions under which to include SBRT in the medical **nomenclature**

suggested by	Belgian Knowledge Centre (KCE)
close collaboration of	Belgian Cancer Registry (BCR)
	Belgian National Institute for Health and Disability Insurance (NIHDI)
with the professionals	Belgian College for Physicians of Radiation Oncology Centres ('the College')

determining the real-life cost of SBRT in Belgium

INNOVATIVE RADIOTHERAPY TECHNIQUES: A MULTICENTRE TIME-DRIVEN ACTIVITY-BASED COSTING STUDY





- defining the payment level for provisional financing
- real-life costing in 10 Belgian radiotherapy departments

Hulstaert F, et al. KCE Report 198C. D/2013/10.273/9
Lievens et al, JTO 2015

collecting real-life data of SBRT in Belgium

- **'Innovative Radiotherapy Project'**
  prospective registration and data collection, temporary research funding
- all Belgian radiation oncology centres using SBRT in clinical practice
- **'NIHDI convention':**
  - **pre-determined target groups**: primary tumours (PT) or oligometastatic disease (OMD)
  - 'standard' vs. 'non-standard' **indications**

Safety monitoring REQ:

Belgian Cancer Registry

❍ Standard indication REQ
- ❍ Primary lung (peripheral) lesion (Complete sections: 6)
- ❍ Hepatic metastases (Complete sections: 6)
- ❍ Primary (para-) spinal lesion (Complete sections: 4, 6)
- ❍ (Para-) spinal metastases (Complete sections: 4, 6)
- ❍ Lung metastases (Complete sections: 6)

❍ Study indication REQ
- ❍ Primary lung lesion (central lesion and/or lesion >5 cm) (Complete sections: 3, 6)
- ❍ Primary prostate lesion (Complete sections: 3, 6)
- ❍ Primary renal lesion (Complete sections: 3, 6)
- ❍ Primary pancreatic lesion (Complete sections: 3, 6)
- ❍ Primary head & neck lesion (Complete sections: 3, 6)
- ❍ Primary hepatic lesion (Complete sections: 3, 6)
- ❍ Non-standard oligometastatic disease (Complete sections: 3, 5, 6)

- register **clinical and technical real-life data**, no formal restrictions (except: up to max 3 active lesions)
- dedicated **online registration module** at BCR website

http://kankerregister.org/Innovatieve%20Radiotherapie

collecting real-life data of SBRT in Belgium

- project **timeline**: 10/2013 – 12/2019
- 20/25 **centres** participated, increase over time (3 to 18 on annual basis)
- number of **courses per centre**: 284 (21 – 950)
- 6,296 SBRT registrations; 5,675 SBRT courses withheld for analysis
  - **Primary** 2,885 (51%) peripheral lung (97%); prostate (1.7%) and paraspinal (0.6%)
  - **OMD** 2,790 (49%) lung (53%); (para)spinal (19%) and liver (12%) and 'non-standard' (16%)
- data collected
  - **patient** characteristics (age, gender, WHO)
  - **tumour** characteristics (stage of primary, location OMD, number and size of lesions,…)
  - **treatment** characteristics (RT type, motion management, image guidance,…)
- outcome
  - **survival**: data by August 9th, 2021
  - **link** with other administrative data sets, obtain vital status

Belgian Cancer Registry · INAMI-RIZIV · College van Geneesheren Radiotherapie-Oncologie · Collège des Médecins Radiothérapie-Oncologie

7 years of SBRT patterns-of-care in Belgium

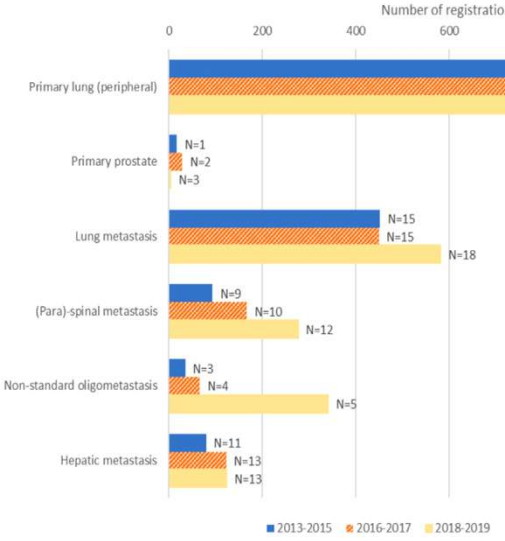
	Primary tumours				Metastatic lesions			
	Total	2013–2015	2016–2017	2018–2019	Total	2013–2015	2016–2017	2018–2019
Registrations	2885	921	838	1126	2790	660	806	1324
Patient characteristics								
Age (years): median (IQR)	72 (66–79)	73 (66–79)	72 (66–79)	72 (66–79)	68 (61–75)[a]	66 (59–74)	68 (62–75)[b]	69 (62–75)[b]
Sex: male/female (%)	66/34	69/31	67/33	63/37	63/37[a]	60/40	63/37	63/37
WHO performance: 0/1/unknown (%)	45/45/1	45/46/0	48/40/1	44/47/1	43/38/16[a]	48/37/12	45/35/16	39/41/17
Tumour characteristics								
Number of lesions treated per patient: average (range[d])	1.08 (1–3)	1.04 (1–2)	1.06 (1–2)	1.07 (1–3)	1.26 (1–5)[a]	1.20 (1–3)	1.20 (1–3)	1.23 (1–4)
Lesion size (mm): median (IQR)	19 (13–26)	20 (15–28)	18 (13–25)[b]	18 (13–25.5)[b]	19 (12–29)	17 (11–25)	20 (13–30)[b]	19 (12–30)[b]
Treatment characteristics								
Total dose (Gy): median (IQR)	54 (48–60)	55 (48–60)	55 (48–60)	54 (48–60)	48 (30–54)[a]	50 (40–55)	48 (30–50)[b]	35 (30–50)[b,c]
Number of fractions: median (IQR)	4 (4–5)	4 (4–5)	4 (3–5)	4 (3–5)	4 (3–5)[a]	5 (3–8)	4 (3–5)[b]	3 (3–5)[b,c]
Treatment duration (days): median (IQR)	10 (7–13)	10 (8–13)	10 (8–13)	9 (7–12)[b,c]	8 (6–12)[a]	10 (7–15)	9 (6–12.75)[b]	7 (5–10)[b,c]
Treatment preparation								
Imaging modalities: CT-scan/PET-CT/MRI (%)[e]	62/34/1	58/39/1	61/34/2	66/31/1	56/25/16[a]	60/27/11	56/24/17	54/25/17
Personalized immobilization (% yes)	79	84	85	69[b,c]	63[a]	72	73	52[b,c]
Identification of tumor motion (% yes)	98	97	97	99[b,c]	69[a]	84	74[b]	57[b,c]
Image fusion for target delineation (% yes)	68	64	66	73[b,c]	74[a]	70	76[b]	76[b]
Treatment delivery								
Technique: 3D-CRT/IMRT/IMRT rot (%)[e]	17/8/54	27/12/40	16/9/51	9/5/68	14/4/66[a]	28/7/42	19/3/58	4/3/84
IGRT: CBCT/stereoscopic X-rays/combination (%)[e]	70/1/5	67/2/6	65/1/8	76/0/1[b,c]	73/1/6	58/2/8	62/0/11[b]	87/0/2[b,c]
Markers (% yes)	8	9	9	7	12[a]	23	14[b]	6[b,c]
Tumor motion compensation (% yes)	60	54	63[b]	62[b]	48[a]	62	55[b]	37[b,c]

Patients were allocated to the period based on the start date of the radiotherapy course. Abbreviations: IQR: interquartile range; WHO: World Health Organisation; Gy: Gray; CT: computed tomography; PET: positron emission tomography; MRI: magnetic resonance imaging; 3D-CRT: 3-dimensional conformal radiotherapy; IMRT: intensity modulated radiotherapy; IMRT rot: rotational IMRT; IGRT: image-guided radiotherapy; CBCT: cone beam computed tomography. [a]Significantly different from total primary tumor. [b]Significantly different from 2013 to 2015. [c]Significantly different from 2016 to 2017. [d]Range of number of registrations per patient. [e]3 most common categories.

Table 1: **Patient, tumour and treatment characteristics, primary tumours vs metastatic lesions, each for different time periods.**

Lievens et al, Lancet Reg Health Eur 2024

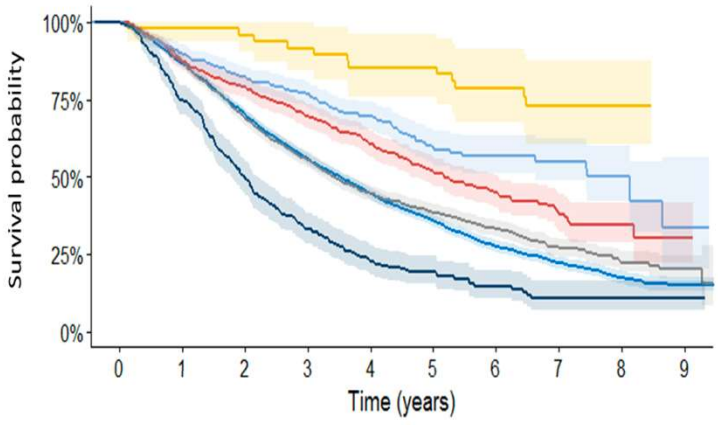
7 years of SBRT patterns-of-care in Belgium



Radiation oncology department	*1*	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	*12*	*13*	*14*	*15*	*16*	*17*	*18*	*19*	*20*	
																					Total
Cases per centre, selected indications	**110**	**677**	**41**	**285**	**621**	**168**	**22**	**350**	**107**	**38**	**421**	**21**	**313**	**132**	**43**	**168**	**867**	**41**	**487**	**401**	**5313**
Primary lung (peripheral)	79	272	34	132	223	118	18	160	33	28	215	16	122	73	19	83	536	34	350	256	**2801**
Primary prostate		1			7								41								**49**
Lung metastasis	31	144	7	151	117	28	4	136	64	10	89	4	78	59	18	54	241	7	115	127	**1484**
(Para)-spinal metastasis		70			109	22		44	5		48	1	71		6	31	90		22	18	**537**
Non-standard oligometastasis		190		2	165			10	5		69		1								**442**
Hepatic metastasis		49		29	8	14	2	27	17		19		14		4	21	72		16	35	**327**

Lievens et al, Lancet Reg Health Eur 2024

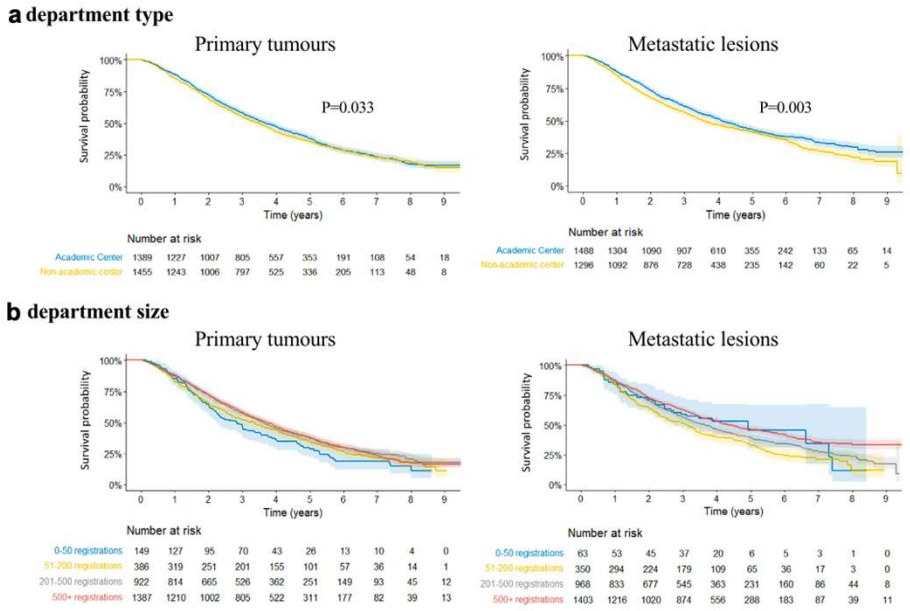
up to 7 year survival data



Primary lung (peri)	2796	2423	1967	1558	1041	648	367	206	98	26
Primary prostate	48	47	46	44	41	41	29	15	4	0
Lung meta	1482	1291	1019	821	546	339	232	122	49	11
(Para)-spinal meta	536	467	424	373	252	136	87	39	15	2
Non-standard meta	440	395	361	334	193	78	46	25	18	3
Hepatic meta	326	243	162	107	57	37	19	7	5	3

Lievens et al, Lancet Reg Health Eur 2024

explorative analysis impact type & size of department



further analyses ongoing

Lievens et al, Lancet Reg Health Eur 2024

real-life outcome data supported inclusion in nomenclature

30- and 90-days mortalities were reassuring
OS compared favourably with the available evidence in the literature

2020
Cat 4bis

maximally 5 active lesions

extracranial SBRT: *primary tumour, OMD*
- 3 per year per organ
- 1 course per plan
- 1 reimbursement

cerebral SRS/SRT: *malignant & benign*
- 1 course, independent of number of plans
- 1 reimbursement

up to **6 reimbursements per year**, inclusive brain *(5 per time point)*

MOC/COM is required

→ **restrictions stipulated** in art 19, to avoid too quick increase

→ **registration necessary**, module of Belgian Cancer Registry

continued monitoring

2024

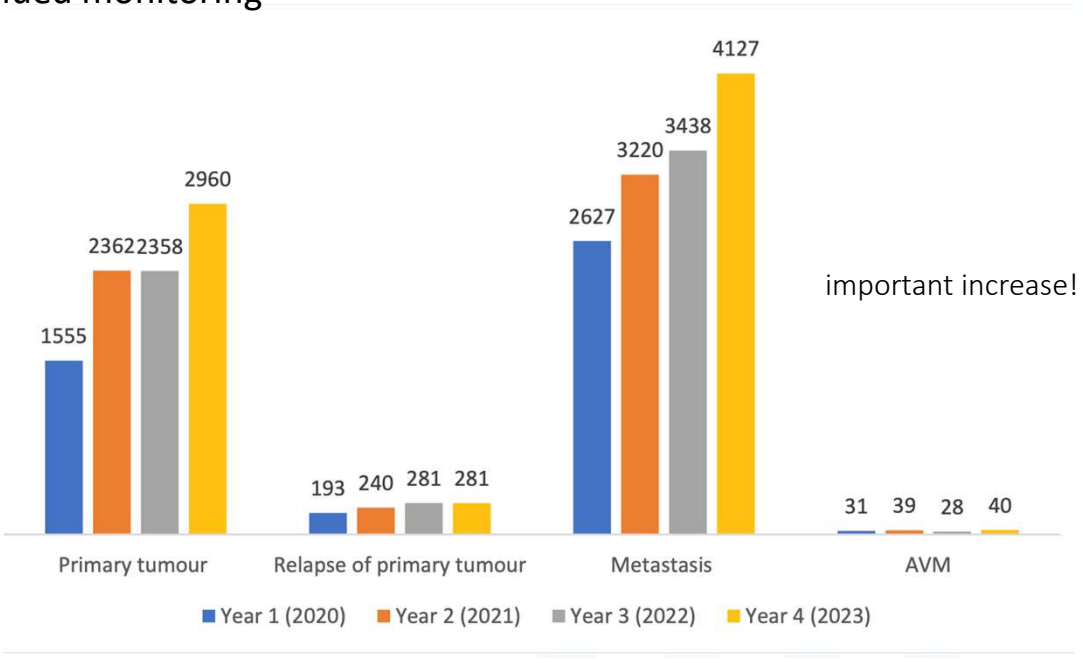
23,642 cases over 4 years (including cranial lesions)

26 hospital sites

	2020	2021	2022	2023	Total		Primary tumour		Relapse primary tumour		Metastasis	
	N	N	N	N	N	%	N	%	N	%	N	%
H01	230	361	387	333	1,311	5.5	486	5.3	45	4.5	780	5.8
H02	76	90	114	111	391	1.7	91	1.0	8	0.8	292	2.2
H03	63	100	96	138	397	1.7	160	1.7	5	0.5	232	1.7
H04	56	76	108	174	414	1.8	175	1.9	15	1.5	224	1.7
H05	70	27	0	117	214	0.9	73	0.8	4	0.4	137	1.0
H06	77	136	171	262	646	2.7	178	1.9	25	2.5	443	3.3
H07	308	325	383	400	1,416	6.0	467	5.1	59	5.9	890	6.6
H08	332	374	442	510	1,658	7.0	590	6.4	121	12.1	947	7.1
H09	97	129	184	261	671	2.8	221	2.4	38	3.8	412	3.1
H10	418	428	508	506	1,860	7.9	665	7.2	149	15.0	1046	7.8
H11	44	95	109	153	401	1.7	97	1.1	6	0.6	298	2.2
H12	1,034	1,613	1,291	1,676	5,614	23.7	3439	37.2	221	22.2	1954	14.6
H13	258	332	373	483	1,446	6.1	404	4.4	66	6.6	976	7.3
H14	24	80	74	90	268	1.1	55	0.6	8	0.8	205	1.5
H15	77	99	94	113	383	1.6	71	0.8	17	1.7	295	2.2
H16	85	120	159	210	574	2.4	175	1.9	2	0.2	397	3.0
H17	79	86	131	180	476	2.0	152	1.6	6	0.6	318	2.4
H18	218	269	231	280	998	4.2	326	3.5	17	1.7	655	4.9
H19	331	406	416	483	1,636	6.9	516	5.6	84	8.4	1036	7.7
H20	56	78	116	111	361	1.5	120	1.3	23	2.3	218	1.6
H21	76	68	103	108	355	1.5	90	1.0	20	2.0	245	1.8
H22	31	36	39	48	154	0.7	31	0.3	7	0.7	116	0.9
H23	15	37	37	53	142	0.6	89	1.0	3	0.3	50	0.4
H24	208	264	266	239	977	4.1	332	3.6	27	2.7	618	4.6
H25	85	141	158	240	624	2.6	124	1.3	16	1.6	484	3.6
H26	27	52	87	89	255	1.1	108	1.2	3	0.3	144	1.1
Total	**4,375**	**5,822**	**6,077**	**7,370**	**23,642**	**100**	**9,235**	**100**	**995**	**100**	**13,412**	**100**

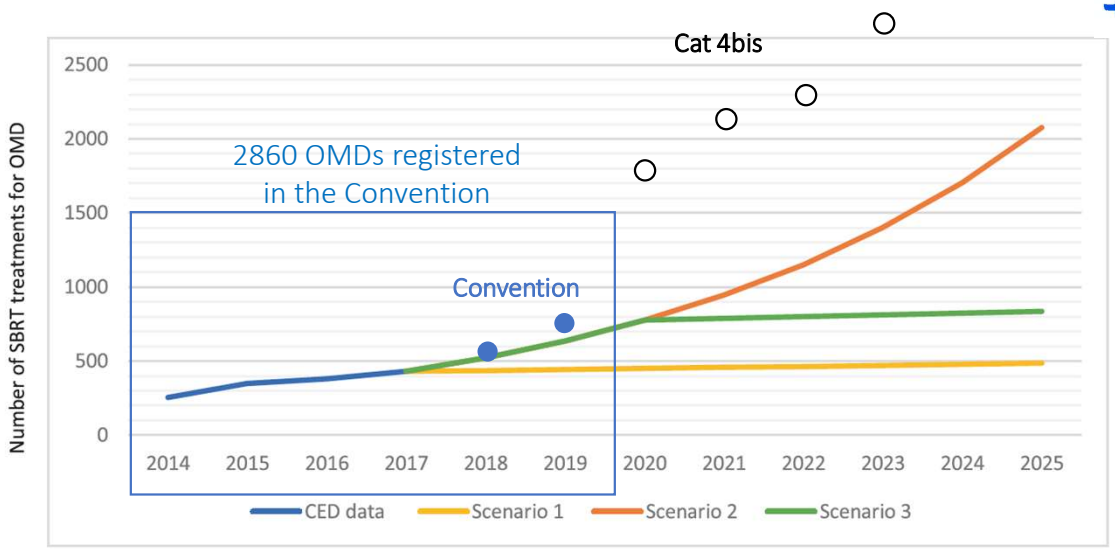
% calculated on column total

continued monitoring



important increase!

important increase, budget impact?



Nevens et al, Radiother Oncol 2019

patient characteristics

	Primary tumour (N=9,235)	Relapse of primary tumour (N=995)	Metastasis (N=13,412)	AVM (N=138)
Sex				
Female	4,469 (48.4%)	399 (40.1%)	5,375 (40.1%)	67 (48.6%)
Male	4,766 (51.6%)	596 (59.9%)	8,037 (59.9%)	71 (51.4%)
Age at SRT treatment (years)				
Median (IQR)	70 (61-77)	70 (62-77)	68 (60-74)	43 (26-55)
Mean (SD)	68 (12)	69 (13)	67 (11)	41 (18)
Min age	4	13	17	2
Max age	99	98	97	80
WHO score at SRT treatment *				
0 – Asymptomatic, normal activity	4,432 (48.0%)	349 (35.1%)	4,687 (34.9%)	41 (29.7%)
1 – Symptomatic, but ambulant	4,000 (43.3%)	561 (56.4%)	7,418 (55.3%)	93 (67.4%)
2 – Symptomatic, bedbound <50% of the day	523 (5.7%)	61 (6.1%)	775 (5.8%)	3 (2.2%)
3 – Symptomatic, bedbound >50% of the day	74 (0.8%)	11 (1.1%)	114 (0.8%)	0
4 – Completely dependent, 100% bedbound	3 (0.03%)	1 (0.1%)	16 (0.1%)	1 (0.7%)
Unknown	203 (2.2%)	12 (1.2%)	402 (3.0%)	0

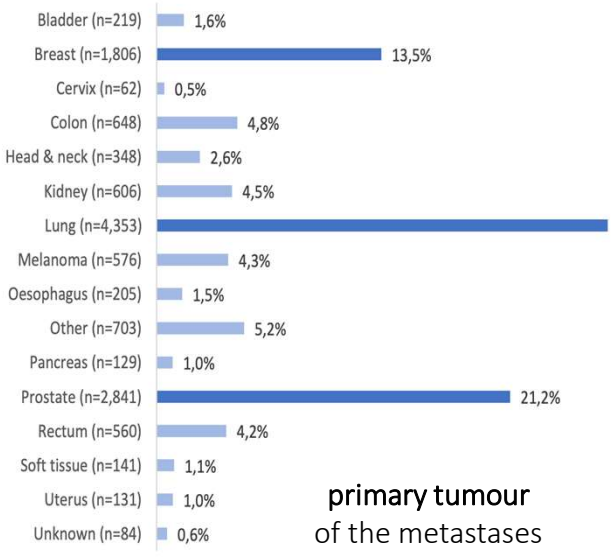
** WHO 0 – asymptomatic, normal activity: fully active, able to carry out all activities, such as before the disease; WHO 1 – symptomatic, but ambulant: limited in heavy physical activity but ambulatory and able to perform light or sedentary work (e.g. small house chores, office job); WHO 2 – symptomatic, bedbound <50% of the day: ambulatory and able to take care of themselves, but impossible to*

tumour characteristics, *primary*

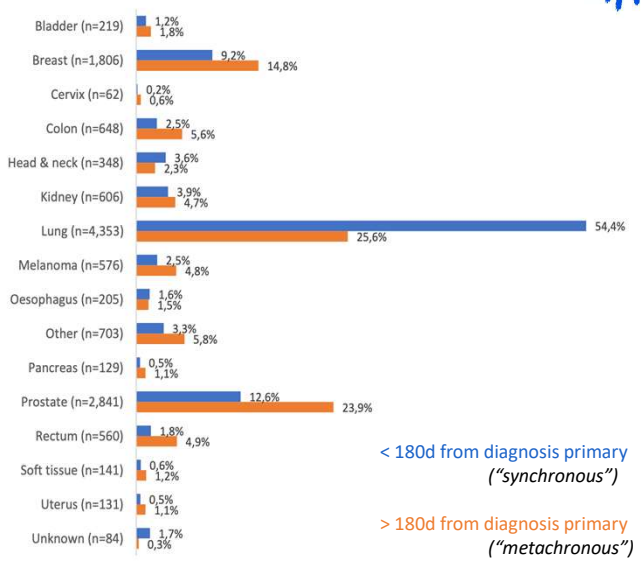
localisation of **primary tumour**

RT centre	Total		Brain		Breast		Head & Neck		Liver		Lung (peripheral)		Lung (central and/or >5cm)		Pancreas		Prostate		Kidney		(Para) spinal and other primary	
	N	%*	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
H01	486	5.3	33	6.8	7	1.4			<5		231	47.5	9	1.9	<5		125	25.7	<5		77	15.8
H02	91	1.0	<5						<5		79	86.8	6	6.6								
H03	160	1.7									144	90.0	14	8.8					<5			
H04	175	1.9	<5								98	56.0	<5		<5		62	35.4	<5		8	4.6
H05	73	0.8							<5		37	50.7	33	45.2								
H06	178	1.9	20	11.2					<5		144	80.9	<5						8	4.5	<5	
H07	467	5.1	23	4.9			8	1.7	<5		142	30.4	35	7.5			215	46.0			43	9.2
H08	590	6.4	30	5.1			<5		17	2.9	518	87.8	10	1.7	<5		<5				8	1.4
H09	221	2.4	18	8.1					29	13.1	126	57.0	20	9.0	10	4.5	10	4.5	<5		<5	
H10	665	7.2	287	43.2	34	5.1	<5		7	1.1	140	21.1	24	3.6	98	14.7	59	8.9			12	1.8
H11	97	1.1	<5				<5				44	45.4	<5				38	39.2			8	8.2
H12	3,439	37.2	74	2.2	2.103	61.2	<5		9	0.3	518	15.1	45	1.3	9	0.3	502	14.6	12	0.3	163	4.7
H13	404	4.4	18	4.5					<5		360	89.1	15	3.7	6	1.5					<5	
H14	55	0.6	<5				<5				49	89.1			<5		<5					
H15	71	0.8							<5		66	93.0					<5				<5	
H16	175	1.9	<5						<5		72	41.1	<5		<5		94	53.7	<5			
H17	152	1.6					<5				101	66.4	9	5.9	<5		37	24.3	<5		<5	
H18	326	3.5	7	2.1							144	44.2	<5		<5		101	31.0	9	2.8	60	18.4
H19	516	5.6	89	17.2	7	1.4	<5				238	46.1	43	8.3	6	1.2	120	23.3	9	1.7	<5	
H20	120	1.3					5	4.2			100	83.3	6	5.0			7	5.8			<5	
H21	90	1.0	<5						<5		73	81.1	<5		5	5.6	7	7.8				
H22	31	0.3									28	90.3	<5									
H23	89	1.0									88	98.9	<5									
H24	332	3.6	52	15.7	12	3.6			6	1.8	209	63.0	30	9.0	<5		9	2.7	<5		12	3.6
H25	124	1.3	17	13.7					<5		81	65.3	<5		12	9.7	5	4.0	<5		<5	
H26	108	1.2															108	100.0				
Total	9,235	100	681	7.4	2,163	23.4	29	0.3	90	1.0	3,830	41.5	321	3.5	161	1.7	1,502	16.3	52	0.6	404	4.4

tumour characteristics, *metastases*



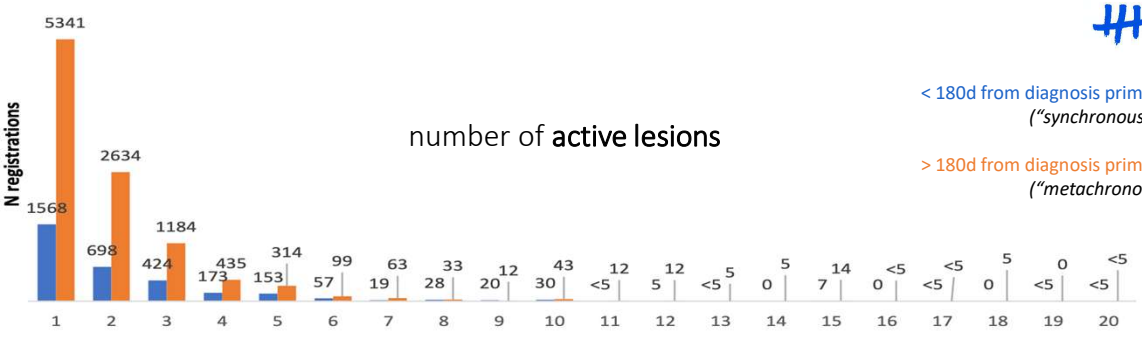
primary tumour
of the metastases



< 180d from diagnosis primary
("synchronous")

> 180d from diagnosis primary
("metachronous")

tumour characteristics, *metastases*

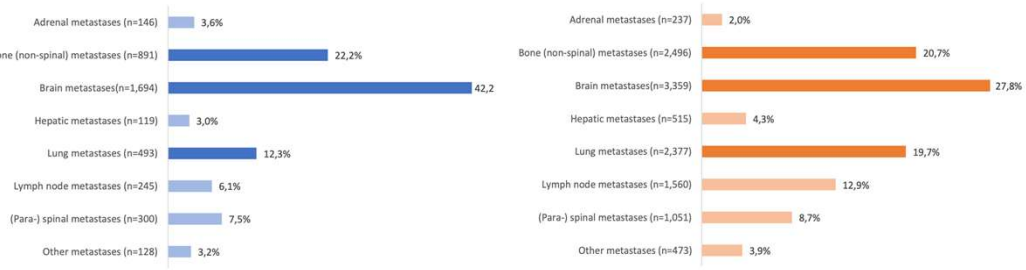


number of **active lesions**

< 180d from diagnosis primary
("synchronous")

> 180d from diagnosis primary
("metachronous")

localisation of the **metastases**



treatment characteristics, *primary & metastases*

	Brain (N=681)	Breast (N=2,163)	H&N (N=29)	Liver (N=90)	Lung (peri) (N=3,830)	Lung (central) (N=321)	Pancreas (N=161)	Prostate (N=1,502)	Kidney (N=52)	Other primary (N=404)
Total dose delivered (Gy)										
Minimum	10	6	12	8	6	8	8	8	8	6
Maximum	85	35	42	60	70	60	60	60	60	85
Mean	16.1	6.6	27.0	45.1	52.1	50.4	43.3	37.0	35.0	22.4
Median	14	6	30	45	51	55	45	36	40	18
Number of fractions delivered										
Minimum	1	1	1	1	1	1	1	1	1	1
Maximum	29	5	6	8	15	12	5	16	8	10
Mean	1.9	1.1	4.1	4.6	4.7	5.8	4.9	5.2	3.4	3.2
Median	1	1	5	5	4	5	5	5	3	3
Treatment duration (days)										
Minimum	1	1	1	1	1	1	1	1	1	1
Maximum	43	22	23	18	73	31	30	46	18	43
Mean	2.8	1.1	10.9	9.6	10.0	11.5	6.8	17.1	7.3	7.9
Median	1	1	13	10	9	10	5	14	7	5

Gy: Gray; H&N: Head & Neck; There were only 2 registrations for a primary (para-) spinal lesion (for 1 patient 1 fraction of 16Gy and for 1 patient 3 fractions of 8Gy), these registrations are not mentioned in the table.

	Adrenal meta	Bone (non-spinal) meta	Brain meta	Hepatic meta	Lung meta	LN meta	(Para-) spinal meta	Other (oligo) meta
Total dose delivered (Gy)								
Minimum	16	6	5	8	8	6	8	6
Maximum	60	60	60	70	63	60	60	75
Mean	35.1	27.9	25.2	46.2	49.4	30.7	27.4	29.2
Median	33	30	25	45	48	30	30	30
Number of fractions delivered								
Minimum	2	1	1	1	1	1	1	1
Maximum	15	15	10	10	15	10	10	15
Mean	4.6	3.2	2.6	4.8	4.6	3.8	3.2	3.6
Median	5	3	3	5	4	3	3	3
Treatment duration (days)								
Minimum	5	1	1	1	1	1	1	1
Maximum	32	45	38	30	41	36	37	41
Mean	9.6	6.3	4.6	10.2	9.5	7.7	6.1	7.2
Median	10	6	5	10	9	7	6	7

Gy: Gray; LN: lymph node

outcome, *survival data metastases*

	Lesion type	All patients			Died within 90 days		Died within 180 days		Died within 1 year		Died within 2 years		Died within 3 years		
		N total	N died	%	N total	N died	N total	N died	N total	N died	N total	N died	N total	N died	
	Total of metastatic lesions	9,435	4,301	45.6	9,435	717	9,435	1,400	8,985	2,440	7,256	3,621	5,948	4,063	32% alive
"syn-chronous"	**Metastatic lesions *within 6 months****	2,446	1,250	51.1	2,446	291	2,446	526	2,350	806	1,952	1,105	1,638	1,196	27% alive
	Adrenal meta	30	19	63.3	30	0	30	<5	30	7	28	15	23	19	
	Bone (non-spinal) meta	518	143	27.6	518	17	518	37	489	71	366	113	256	132	
	Brain meta	1,318	861	65.3	1,318	247	1,318	427	1,280	612	1,123	785	1,009	834	
	Hepatic meta	36	18	50.0	36	0	36	<5	32	10	27	18	23	18	
	Lung meta	240	96	40.0	240	9	240	24	233	45	185	80	145	90	
	LN meta	68	33	48.5	68	7	68	11	66	20	56	27	44	31	
	(Para-) spinal meta	194	54	27.8	194	5	194	12	181	26	134	45	108	47	
	Other (oligo) meta	42	26	61.9	42	6	42	9	39	15	33	22	30	25	
"meta-chronous"	**Metastatic lesions *after 6 months****	6,989	3,051	43.7	6,989	426	6,989	874	6,635	1,634	5,304	2,516	4,310	2,867	34% alive
	Adrenal meta	105	49	46.7	105	<5	105	10	99	26	81	42	67	44	
	Bone (non-spinal) meta	1,371	368	26.8	1,371	31	1,371	73	1,292	135	948	263	676	330	
	Brain meta	2,217	1,526	68.8	2,217	325	2,217	604	2,149	1,019	1,914	1,395	1,756	1,490	
	Hepatic meta	267	145	54.3	267	10	267	30	255	63	209	109	176	135	
	Lung meta	1,377	516	37.5	1,377	21	1,377	73	1,293	202	1,001	376	784	465	
	LN meta	869	182	20.9	869	15	869	39	816	79	617	132	427	165	
	(Para-) spinal meta	539	156	28.9	539	8	539	23	498	56	355	110	274	136	
	Other (oligo) meta	244	109	44.7	244	12	244	22	233	54	179	89	150	102	
	TOTAL	18,948	6,496	34.3	18,948	916	18,948	1,862	17,949	3,438	13,801	5,305	10,558	6,090	

* *current SRT-treated metastases diagnosed within or later than 6 months after the primary tumour diagnosis*

E²-RADIatE: EORTC-ESTRO RADIotherapy Infrastructure for Europe

Collaboration EORTC – ESTRO

- Observational prospective **multi-cohort**
- Collects **real-world data** of cancer patients treated with radiotherapy
- **Overarching infrastructure** with 1 database; 1 protocol and 1 PIS-IC
- Links clinical data with diagnostic and radiotherapy treatment imaging, PROMs and health economic data

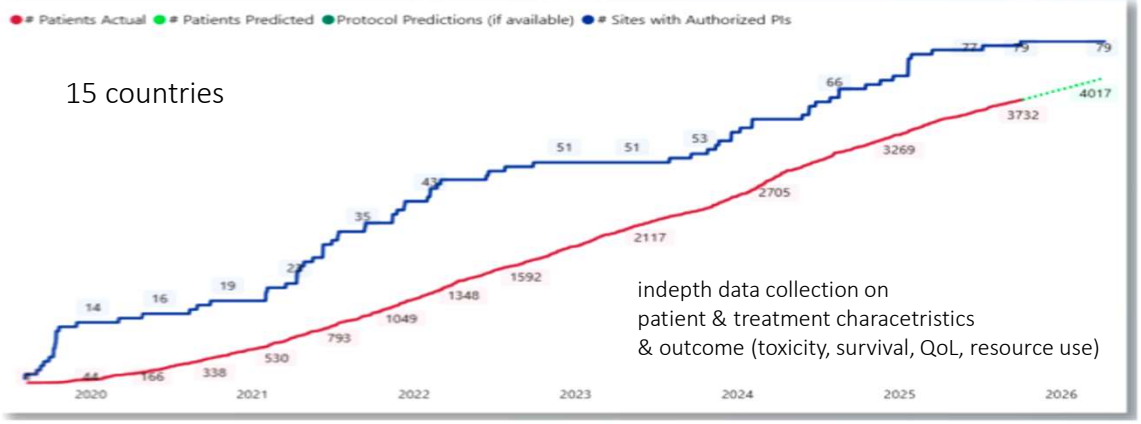
https://project.eortc.org/e2-radiate/

support radiotherapy research
provide **evidence** of the role of radiotherapy in a multidisciplinary approach
generate hypotheses for future clinical trials

OligoCARE

OligoCare, the E²-RADIatE cohort on oligometastases

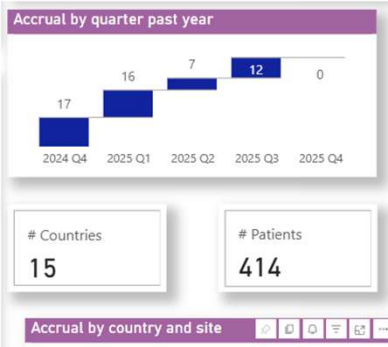
# Total patients in studies open for recruitment in Rave as of today (blue line):	3732	# Total patients predicted in 6 months from today, based on last 3 months average recruitment:	4017
# Sites with Authorized PIs in Rave as of today (red line):	79	# Predicted netto new patients (in 6 month from today):	285



15 countries

indepth data collection on
patient & treatment characetristics
& outcome (toxicity, survival, QoL, resource use)

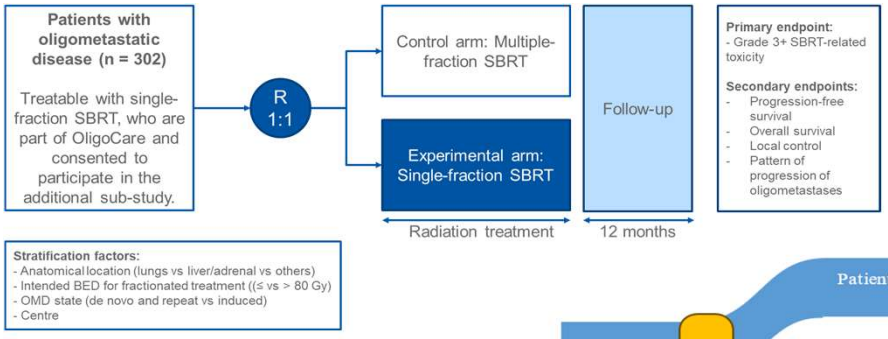
OligoCare, the E²-RADIatE cohort on oligometastases



Projectid	Country	Siteid	Investigator	Authorisation Date	Date planned	Removal Date	# Patients
1811	Belgium	104	Lievens	8/8/2019			109
1811	Belgium	1253	Stellamans	8/7/2019			84
1811	Belgium	1234	Dirix	6/11/2021			81
1811	Belgium	1234	Machiels	11/15/2023			81
1811	Belgium	150	Bral	9/19/2019			58
1811	Belgium	150	Roelstraete	10/31/2023		12/20/2024	58
1811	Belgium	101	Van den Begin	12/20/2023			29
1811	Belgium	121	Geets	9/3/2019			24
1811	Belgium	151	Geboers	2/2/2021			14
1811	Belgium	147	Daisne	4/14/2021		12/20/2024	11
1811	Belgium	147	Lambrecht				11
1811	Belgium	1201	Remouchamps	2/2/2021		12/19/2024	4
1811	Austria	1101	Geinitz	2/24/2022			0
1811	Austria	1455	Brunner	12/13/2021			0
1811	Austria	906	Widder	4/29/2021			0
1811	Belgium	1248	Van de Voorde	11/22/2023			0
1811	Belgium	1248	Vanhoutte				0
1811	Belgium	155	Lamande	12/20/2023		12/20/2024	0
1811	Czech Republic	1907	Sirak	4/13/2021			0
1811	France	1174	Hasbini	6/11/2021		12/20/2024	0
1811	Germany	1288	Nestle	2/9/2022			0
1811	Germany	3039	Lohaus	11/25/2021			0
1811	Germany	3039	Seidlitz	5/28/2025			0
1811	Germany	3226	Willner	9/29/2022		12/20/2024	0
1811	Germany	510	Corradini	10/27/2023			0
1811	Germany	531	Eble	7/14/2021		12/20/2024	0
1811	Ireland	2106	Mihai	2/5/2024			0
1811	Ireland	6002	Duane	2/5/2024			0

Belgium
11%, of the cases
9 active centres

SPRINT, integration of randomised comparison into OligoCare



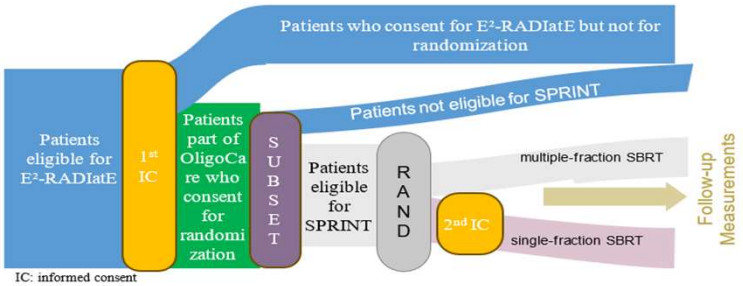
randomized, multicentre, phase II non inferiority study

- Research question:

comparing the clinical results of single-fraction SBRT with those of multiple fractions, with a focus on grade 3+ toxicity within 12 months following radiotherapy.

- Trial within Cohorts (TwiCs) design:

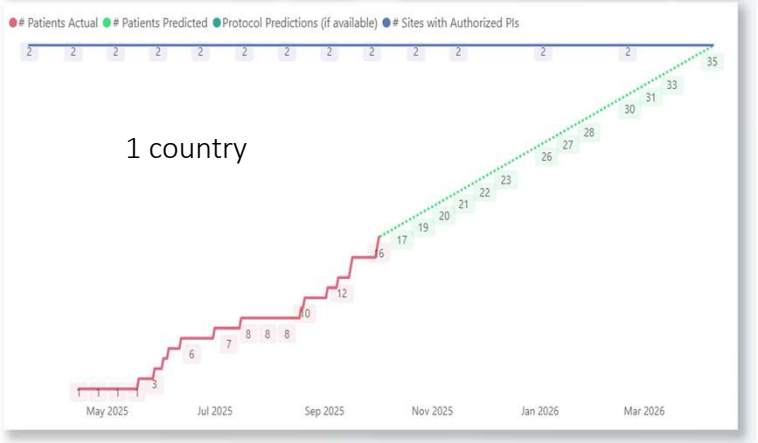
embedded within the OligoCare cohort of the E²RADIatE platform, the first pan-European TwiCs.



IC: informed consent
Rand: Randomized
* Patients who are randomized to receive single fraction but refuse or are unable to receive single fraction will remain in the single fraction arm for the ITT analysis but will receive multiple fractions (control arm).

SPRINT, integration of randomised comparison into OligoCare

# Total patients in studies open for recruitment in Rave as of today (blue line):	16	# Total patients predicted in 6 months from today, based on last 3 months average recruitment:	35
# Sites with Authorized PIs in Rave as of today (red line):	2	# Predicted netto new patients (in 6 month from today):	19



1 country

- Being the first pan European TwiCs, it will be a great success to have SPRINT up and running across multiple European countries and sites
- A subsequential success would be the activation of more TwiCs research questions within the E²RADIatE Cohort.

10 Belgian sites will be participating

start pending (central) EC approval

financial support is being searched through KOTK

take home messages

- SBRT has become a standard treatment in a large proportion of our patients, in primary as in metastatic cancer
- together with the RIZIV-INAMI and the BCR, the Belgian radiation oncology community has succeeded in collecting the largest national population-based registry of SBRT
- survival data, obtained by linking with administrative data and patient's the vital status, have shown that Belgian patients have a similar outcome as reported in the literature
- this has supported introduction of SBRT in the Belgian reimbursement system, Cat 4bis
- continuous monitoring needed to better understand the evolution in uptake and outcome of this treatment approach, and – unfortunately – has also uncovered inappropriate use of the reimbursement code
- there is a further very substantial increase of SBRT utilisation in Belgium, of which the budgetary impact should also be monitored
- in addition to real-life population-based data, collaboration with international research organisations on the use of SBRT in OMD helps in further deepening our knowledge about this very heterogeneous disease entity
- participation in the upcoming SPRINT study will support taking the next step towards implementation of single-fraction SBRT in clinical practice