

The work of the QoL-Group at EORTC

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8th SPAEN Annual Conference
February 2-4, 2018 Milan, IT

World Cancer Day 2018 (Sunday)

“Quality of Life (QoL) has been part of the EORTC’s mission from the very start and the QoL Department continues to ensure that patients’ voices are heard loud and clear in clinical and translational research on a daily basis”



A bit of history

- 1962: Groupe Européen de Chimiothérapie Anticancéreuse (GECA), founded by Henry Tagnon.
- Idea: multidisciplinary approach and international cooperation in clinical research in Europe.
- 1968: European Organisation for Research and Treatment of Cancer (EORTC)
- Network and a coordinating scientific and operational infrastructure based in Brussels.
- **1980: Quality of Life Group (QLG)**

The early years of QoL in the EORTC

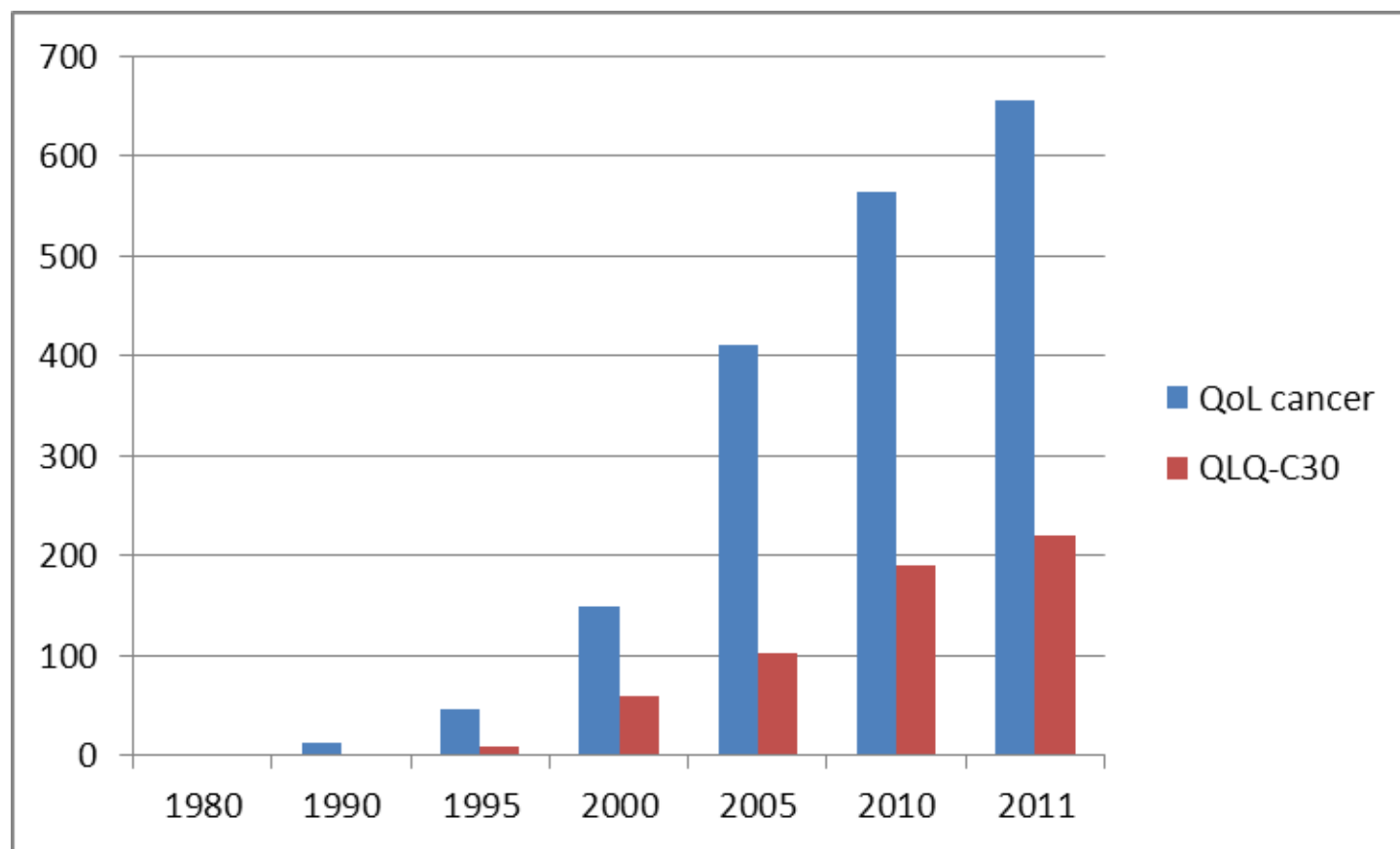
- QoL was a new concept for clinical groups
- Scepticism was high
- No robust standardized measure was available
- Only a few translations were available
- Only a few modules were available
- Investigators debated the added value of QoL
- Few studies worldwide had shown the added value of QoL
- Consequently, **QoL was a challenge**

Quality of Life Group

- **1980: Quality of Life Group**
- Aim: to advise the EORTC Headquarters and the various cooperative groups on the design, implementation and analysis of QoL studies
- **Today**
- More than 350 active members
- More than 30 different countries
- Broad range of professionals
- <http://groups.eortc.be/qol/>



Source: PubMed



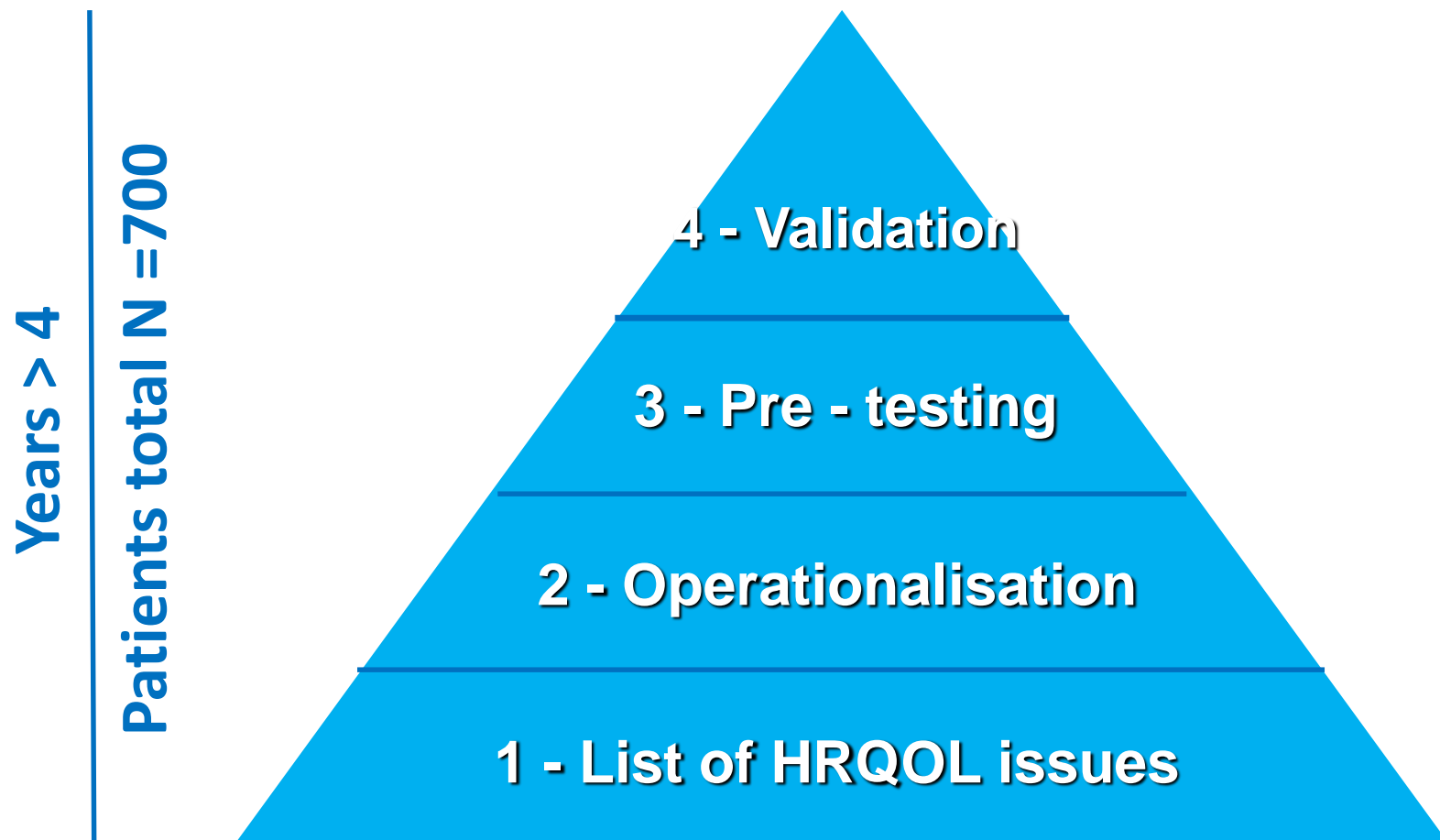
Quality of Life Department

- **1993: Quality of Life Department**
- Aims:
- to evaluate the importance of various factors that improve the QoL of cancer patients
- to supervise the evaluation of QoL in selected cancer clinical trials
- to encourage physicians to pay greater attention to quality of life factors in the treatment of cancer by stimulating, enhancing and coordinating the evaluation of quality of life in cancer clinical trials

Where are we today? Main activities of the Quality of Life Group (#1)

- **Development of questionnaires**
 - Core questionnaire: QLQ-C30
 - Disease-specific modules: QLQ-BN20, QLQ-STO22...
 - ... and not only: IN-PATSAT32, QLQ-C15-PAL, Survivorship
 - Item Library

Example of validated development (4 phases)



QLQ-C30

		Not at All	A Little	Quite a Bit	Very Much
		1	2	3	4
1.	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?				
2.	Do you have any trouble taking a long walk?				
3.	Do you have any trouble taking a short walk outside of the house?				
4.	Do you need to stay in bed or a chair during the day?				
5.	Do you need help with eating, dressing, washing yourself or using the toilet?				
During the past week:					
		Not at All	A Little	Quite a Bit	Very Much
		1	2	3	4
6.	Were you limited in doing either your work or other daily activities?				
7.	Were you limited in pursuing your hobbies or other leisure time activities?				

Available translations (more than 110)

2. jelent-e valamilyen problémát egy hosszabb séta?	1	2	3	4
3. jelent-e valamilyen problémát egy a lakáson kívüli rövid séta?	1	2	3	4
4. szükséges-e, hogy ágyban vagy karosszékben legyen a nap folyamán?	1	2	3	4
5. segítségére szorul-e étkezésnél, öltözködséknél, mosakodásnál vagy WC-használatnál?	1	2	3	4
Az elmúlt héten:	Egáltalán nem	Egy kissé	Meglehetősen	Nagymértékben
6. korlátozva volt-e mindennapi munkájában vagy egyéb szokásos napi tevékenységében?	1	2	3	4
7. korlátozva volt-e abban, hogy szabadidős tevékenységének hódoljon?	1	2	3	4
8. volt-e légszomja?	1	2	3	4
9. fájt-e valamije?	1	2	3	4
10. szívese volt pihenésre?	1	2	3	4
11. volt alvászavara?	1	2	3	4
12. gyengeség érezte magát?	1	2	3	4
13. érzéketlen volt?	1	2	3	4
14. volt-e hányingere?	1	2	3	4
15. előfordult-e, hogy hányt?	1	2	3	4
Fordítson!				
您在戶外從事短距離步行，是否有困難？	1	2	3	4
您在白天是否需要坐在床上或椅子上？	1	2	3	4
您飲食、穿衣、洗澡或上廁所需要別人幫助嗎？	1	2	3	4
過去一個星期內（過去七天內）	1	2	3	4
您在從事工作或日常活動上是否受到限制？	1	2	3	4
您在從事嗜好或休閒活動上是否受到限制？	1	2	3	4
您呼吸會喘嗎？	1	2	3	4
您會感到疼痛嗎？	1	2	3	4
您需要休息嗎？	1	2	3	4
您睡眠會有困難嗎？	1	2	3	4
您會感到虛弱嗎？	1	2	3	4
您會缺乏胃口嗎？	1	2	3	4
您會感到作嘔嗎？	1	2	3	4
您會嘔吐嗎？	1	2	3	4
您會便秘嗎？	1	2	3	4
هل لديك صعوبة بالمشي لمسافة طويلة؟	1	2	3	4
هل لديك صعوبة بالمشي لمسافة قصيرة خارج البيت؟	1	2	3	4
هل تحتاج للبقاء في السرير أو الكرسي خلال اليوم؟	1	2	3	4
هل تحتاج للمساعدة في الأكل، ارتداء الملابس، الاغتسال أو استخدام المرحاض؟	1	2	3	4
خلال الأسبوع الماضي:				
هل كنت محدود/ مقيد عند القيام بعملك أو نشاطات يومية أخرى؟	1	2	3	4
هل كنت محدود/ مقيد في ممارسة هوايتك أو نشاطات في وقت الفراغ؟	1	2	3	4
هل شعرت بضيق بالنفَس؟	1	2	3	4
هل شعرت بألم؟	1	2	3	4
هل كنت بحاجة لتراحة؟	1	2	3	4
هل عانيت من مشاكل في النوم (أرق/ صعوبة في النوم/ نوم متقطع)؟	1	2	3	4
هل شعرت بالتعب؟	1	2	3	4
هل فقدت شهيتك للطعام (القدرة على الأكل)؟	1	2	3	4
هل شعرت بالغثاس (التعبان)؟	1	2	3	4
هل تقيأت؟	1	2	3	4
هل عانيت من إمساك؟	1	2	3	4
انتقل إلى الصفحة التالية من فضلك				
2. Avez-vous des difficultés à faire une longue promenade?	1	2	3	4
3. Avez-vous des difficultés à faire un petit tour dehors?	1	2	3	4
4. Etes-vous obligé(e) de rester au lit ou dans un fauteuil pendant la journée?	1	2	3	4
5. Avez-vous besoin d'aide pour manger, vous habiller, faire votre toilette ou aller aux toilettes?	1	2	3	4
Au cours de la semaine passée:				
6. Avez-vous été gêné(e) pour faire votre vos activités de tous les jours?	1	2	3	4
7. Avez-vous été gêné(e) dans vos activités?	1	2	3	4
8. Avez-vous eu le souffle court?	1	2	3	4
9. Avez-vous eu besoin de repos?	1	2	3	4
10. Avez-vous eu des difficultés pour dormir?	1	2	3	4
11. Avez-vous eu des difficultés pour dormir?	1	2	3	4
12. Vous êtes-vous senti(e) faible?	1	2	3	4
13. Avez-vous manqué d'appétit?	1	2	3	4
14. Avez-vous vomie?	1	2	3	4
15. Avez-vous eu de la constipation?	1	2	3	4
2. Heeft u moeite met het maken van een wandeling buitenshuis?	1	2	3	4
3. Heeft u moeite met het maken van een wandeling buitenshuis?	1	2	3	4
4. Moet u overdag in bed of op een stoel?	1	2	3	4
5. Heeft u hulp nodig met eten, aankleden, wassen of naar het toilet gaan?	1	2	3	4
Gedurende de afgelopen week:				
6. Was u beperkt bij het doen van uw we-dagelijkse bezigheden?	1	2	3	4
7. Was u beperkt in het uitoefenen van uw bij andere bezigheden die u in uw vrije-tijd doet?	1	2	3	4
8. Had u moeite met slapen?	1	2	3	4
9. Had u moeite met slapen?	1	2	3	4
10. Had u moeite met slapen?	1	2	3	4
11. Had u moeite met slapen?	1	2	3	4
12. Had u moeite met slapen?	1	2	3	4
13. Had u moeite met slapen?	1	2	3	4
14. Had u moeite met slapen?	1	2	3	4
15. Had u moeite met slapen?	1	2	3	4
Una tatizo lolote unapontemba umbali mrefu?	1	2	3	4
Unapata shida yoyote utembeapo umbali mrefu nje ya nyumba?	1	2	3	4
Unahitaji kupumzika kitandani au kwenye kiti wakati wa mchana?	1	2	3	4
Unahitaji msada wakati wa kula, kuwaa, kuoga au kwenda msalini?	1	2	3	4
atika kipindi cha wiki moja iliyopita:				
Umekuwa ukishindwa kufanya kazi zako au shughuli za kila siku ipasavyo?	1	2	3	4
Umekuwa ukishindwa kuendelea kufanya mambo yako unayoyapenda au shughuli zako za wakati wa mapumziko?	1	2	3	4
Ulishindwa kupumua vizuri?	1	2	3	4
Ulikuwa na maumivu?	1	2	3	4
Uhitaji mapumziko?	1	2	3	4
Umekuwa na matatizo ya kupata usingizi?	1	2	3	4
Umejisikia dhahiri?	1	2	3	4
Umekosa hamu ya chakula?	1	2	3	4
Umesikia kichefuchefu?	1	2	3	4
Uhitapika?	1	2	3	4
Umekuwa na tatizo la kufunga choo?	1	2	3	4

Overview of questionnaires (September 2017)

VALIDATED	24
Completed phase 4, paper pending for review	2
In phase 4	11
Completed phase 3 with phase 4 pending	4
In phase 3	3
In phase 1-2	4
TOTAL OF MODULES IN ACTIVE DEVELOPMENT	24

Item Library

- Online platform comprised of more than 900 individual items from over 60 EORTC questionnaires, some of which have been translated into up to 110 languages
- Aims:
 - to facilitate the development and use of existing EORTC instruments
 - to provide users with the possibility to create custom-made ad hoc item lists
- From STATIC to DYNAMIC approach
- <http://www.eortc.be/itemlibrary/>

Where are we today? Main activities of the Quality of Life Group (#2)

- **Development of *projects***
 - Computerized Adaptive Testing (CAT)
 - Computer-based Health Evaluation System (CHES)
 - Support for QLQ-C30
 - Support for CAT
 - Utility measures
 - Long-term follow-up / Survivors
 - Reviews / Meta-analyses

Support for QLQ-C30 and CAT

- Confirming content validity of the EORTC QLQ-C30
- The anchor-based approach to determine minimal important differences with the EORTC Quality of Life Group measures
- Development of thresholds for the EORTC QLQ-C30 and the EORTC CAT measures to enable their use for symptom screening in daily clinical practice
- Collection of normative data for the EORTC-CAT

Utility measures

- Determination of European utility weights for a cancer-specific preference-based Quality of Life measure derived from the EORTC QLQ-C30
- Comparison of the EORTC QLU-C10D with generic utility instruments and development of a comprehensive manual for its use

Long-term follow-up / survivorship

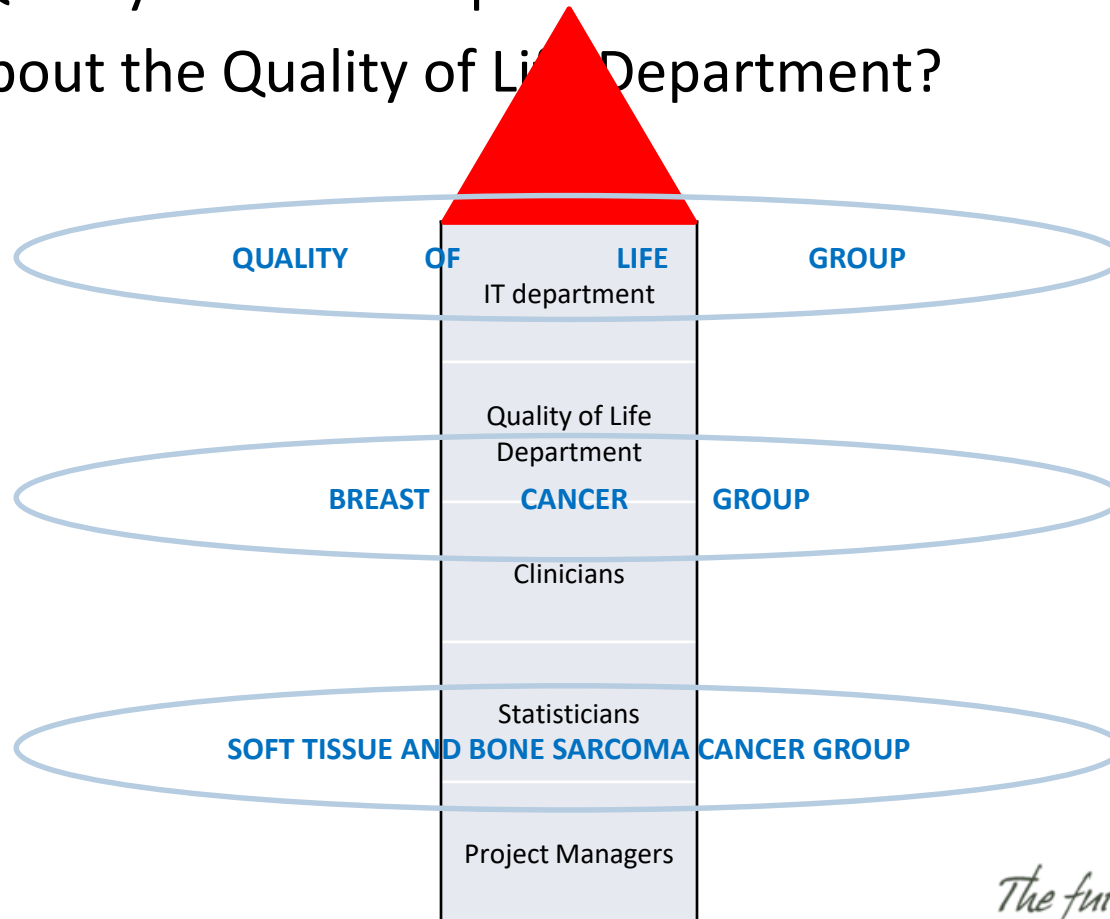
- Follow-up in early and locally advanced breast cancer patients: an EORTC QLQ-BCG-ROG protocol
- Routine follow-up of gynecological cancer patients: a joint EORTC QLQ-GCG protocol
- Assessment of the Quality of Life of childhood acute lymphoblastic leukemia patients enrolled in EORTC Children Leukemia Group trials between 1971 and 1998
- Late toxicity and long-term Quality of Life in head and neck cancer survivors
- Long-term Quality of Life in acute myeloid leukemia survivors treated in randomized controlled trials and in real-life settings

Reviews and meta-analysis

- Combining clinical trial datasets in glioma patients: the added value of health-related QOL assessment

... and the Quality of Life Department?

- This was a brief and not exhaustive summary of the activities of the Quality of Life Group.
- What about the Quality of Life Department?





Clinical trials reality (#1)

- 1321 ALT-GIST: A randomised phase II trial of imatinib alternating with regorafenib compared to imatinib alone for the first line treatment of advanced gastrointestinal stromal tumour (GIST)
- 1402 EE2012: International randomised controlled trial for the treatment of newly diagnosed Ewing's sarcoma family of tumours – Euro Ewing 2012
- 1506 ANITA: A phase II multicenter study comparing the efficacy of the oral angiogenesis inhibitor nintedanib with the intravenous cytotoxic compound ifosfamide for treatment of patients with advanced metastatic soft tissue sarcoma after failure of systemic non-oxazaphosphorine-based first line chemotherapy for inoperable disease – "ANITA"

Clinical trials reality (#2)

- 62091 TRUSTS: TRUSTS: A phase IIb/III multicenter study comparing the efficacy of trabectedin administered as a 3-hour or 24 hour infusion to doxorubicin in patients with advanced or metastatic untreated soft tissue sarcoma
- 62092 STRASS: A phase III randomized study of preoperative radiotherapy plus surgery versus surgery alone for patients with retroperitoneal sarcomas (RPS) – STRASS
- 62113: A randomized double-blind phase II study evaluating the role of maintenance therapy with cabozantinib in high grade uterine sarcoma (HGUtS) after stabilization or response to doxorubicin +/- ifosfamide following surgery or in metastatic first line treatment

Questions?

Got a research idea?

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