

Authors: Rivera F¹, Antía F², Macarulla T³, Mangues MA⁴, Muñoz A⁵, Comellas M⁶

Affiliations: ¹ Medical Oncology Service, Hospital Marqués de Valdecilla, Santander, Spain. ² Clinical Trails Unit, Hospital Universitario Marqués de Valdecilla, Santander, Spain ³ Gastrointestinal Tumors Unit, Hospital Universitario Vall d' Hebrón, Barcelona, Spain. ⁴ Hospital Pharmacy Service, Hospital de la Santa Creu i Sant Pau, Barcelona, Spain. ⁵ Medical Oncology Service, Hospital General Universitario Gregorio Marañón, Madrid, Spain. ⁶ Outcomes'10, Castellón, Spain.

INTRODUCTION

Systematic collection of patient-reported outcomes (PROs) is of increasing importance in cancer care since it improves symptom control¹ and patient-physician communication². Given the poor prognosis of pancreatic cancer, accurate monitoring of symptoms becomes critical to improve patient outcomes, health status and care.

OBJECTIVE

This project aims to reach consensus on the most significant PROs in pancreatic cancer, from both patients and healthcare professionals' perspectives, to be collected in clinical practice.

METHODS

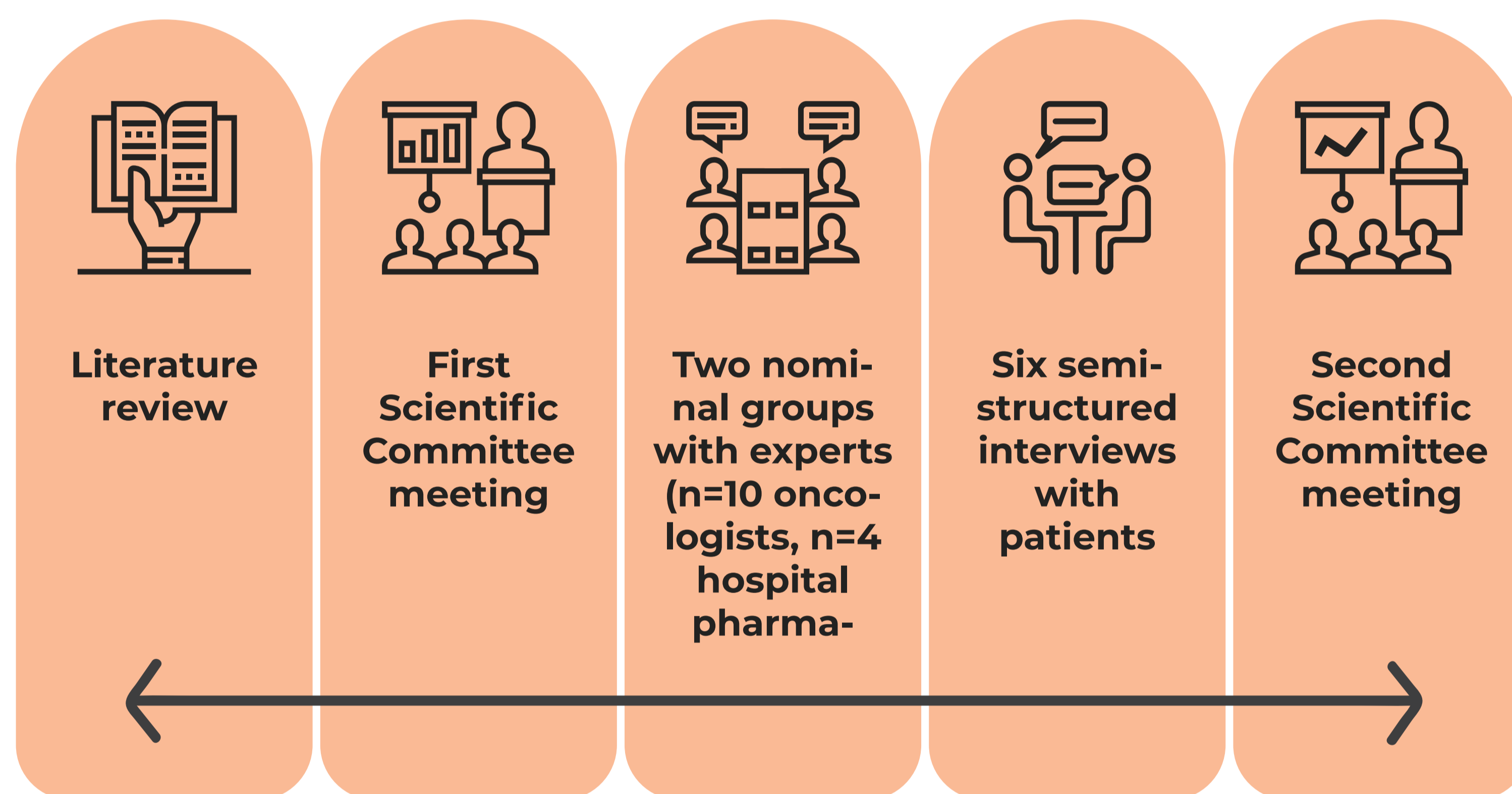
Scientific Committee

The project was led by a Scientific Committee composed by 5 experts on pancreatic cancer management (n=3 oncologists, n=1 hospital pharmacist, n=1 nurse).

Phases of the project

Phases of the project are shown in Figure 1.

Figure 1. Phases of the project.

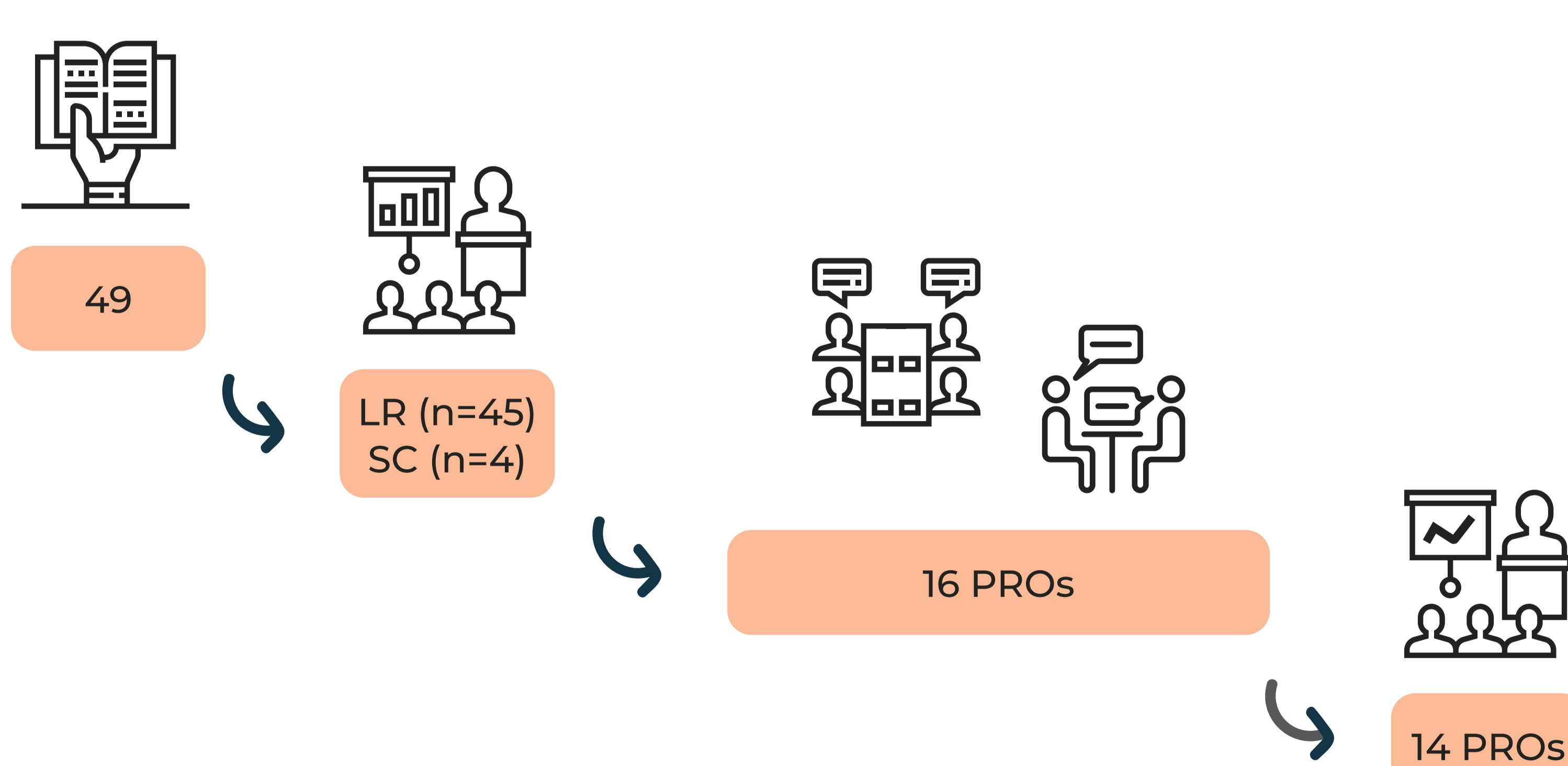


- Initially, a **literature review** was performed to identify PROs in pancreatic cancer.
- Based on the results of the literature review and their clinical expertise, the **Scientific Committee** elaborated a list of PROs that was subsequently presented to healthcare professionals and patients.
- Two **nominal groups** with healthcare professionals (n=10 oncologists, n=4 hospital pharmacists, n=2 nurses) and 6 **semi-structured interviews** with patients were conducted to establish the most valuable PROs (consensus $\geq 75\%$ participants agree).
- Finally, the **Scientific Committee** determined the inclusion or did not of those PROs that not achieve consensus among nominal groups and semi-structured interviews (Figure 1).

RESULTS

A total of 49 disease-related signs and symptoms and/or its treatment that could be self-reported by the patient were identified during the Literature review (n=45) and by the Scientific Committee (n=4). During nominal groups and semi-structured interviews 16 PROs were identified as the most significant. Of them, 6 reached consensus in both nominal groups and 9 were also considered valuable by patients. Finally, the Scientific Committee selected 14 PROs (Figure 2 and Figure 3).

Figure 2. Identification and selection of most relevant PROs.



LR: Literature Review; SC: Scientific Committee; PROs: Patient Reported Outcomes

Figure 3. Agreed PROs selected to be systematically collected

Fever	Do you have a fever (over 38°C)?	<input type="radio"/> YES <input type="radio"/> NO
	Have you been receiving chemotherapy in the last three weeks?	<input type="radio"/> YES <input type="radio"/> NO
Gastro-intestinal/bleeding	Have you had vomiting with bright red blood or a blackish appearance ("coffee grounds type")?	<input type="radio"/> YES <input type="radio"/> NO
	Have you had black, doughy, foul-smelling stools?	<input type="radio"/> YES <input type="radio"/> NO
Pain	0 1 2 3 4 5 6 7 8 9 10	0 = no pain; 10 = worst possible pain
Edema	Is the swelling asymmetrical? (Appears only in one side of the body)	<input type="radio"/> YES <input type="radio"/> NO
	Was the onset of swelling abrupt?	<input type="radio"/> YES <input type="radio"/> NO
	Is the swelling associated with redness of the skin or warmth?	<input type="radio"/> YES <input type="radio"/> NO
Weight/Apetite	0 I haven't lost weight or appetite	<input type="radio"/>
	1 I haven't lost some weight or appetite	<input type="radio"/>
	2 I've lost quite a lot of weight or my appetite	<input type="radio"/>
	3 I've lost a lot of weight or appetite	<input type="radio"/>
Diarrhea/Constipation	What is the maximum number of loose or liquid stools you have had during the last week?	—
	Have you been more than 3 days without a bowel movement?	<input type="radio"/> YES <input type="radio"/> NO
Nausea and vomiting	Have you had nausea?	<input type="radio"/> YES <input type="radio"/> NO
	Have nausea changed your eating habits?	<input type="radio"/> YES <input type="radio"/> NO
	Have you vomiting more than 3 times or more in 24 hours?	<input type="radio"/> YES <input type="radio"/> NO
	Have you been vomiting for more than 3 days?	<input type="radio"/> YES <input type="radio"/> NO
Asthenia/fatigue	0 1 2 3 4 5 6 7 8 9 10	0=no asthenia/fatigue 10=worst possible asthenia/fatigue
Dyspnea	0 I haven't had difficulty breathing	<input type="radio"/>
	1 I've had difficulty breathing with little efforts	<input type="radio"/>
	2 I have had difficulty breathing with moderate efforts	<input type="radio"/>
	3 I have had difficulty breathing with small efforts	<input type="radio"/>
Emotional Wellbeing	4 I have had shortness of breath that has been disabling	<input type="radio"/>
	Has the shortness of breath or choking sensation appeared suddenly?	<input type="radio"/> YES <input type="radio"/> NO
Neuropathy	0 I have not had loss of sensation or strenght	<input type="radio"/>
	1 I have had a slight loss os sensation or strenght, which has not interested with my daily life	<input type="radio"/>
	2 I have had a loss of sensation or strenght that has meant extra efforts to perform my daily activities	<input type="radio"/>
	3 I have had a loss of sensation or strenght that causes thigns to fall off my hands	<input type="radio"/>
Ascites	4 I have had loss of sensation or strength that has been disabling	<input type="radio"/>
	In the last week, have you experienced a progressive increase in abdominal perimeter?	<input type="radio"/> YES <input type="radio"/> NO
Change in the color of urine/stools and/or skin/eyes	Has the increment of abdominal perimeter caused you significant pain or discomfort?	<input type="radio"/> YES <input type="radio"/> NO
	In the past week, have you experienced a change in the color of your stool (light) or urine (dark) for more than 2 days?	<input type="radio"/> YES <input type="radio"/> NO
Swallowing problems	Your skin or your eyes are yellow?	<input type="radio"/> YES <input type="radio"/> NO
	Have you had mouth sores or discomfort from swallowing?	<input type="radio"/> YES <input type="radio"/> NO

CONCLUSIONS

The findings of the present project are the first step to implement the systematic collection of PROs that may enhance patient care and patient-physician communication in clinical practice.

REFERENCES

- Basch et al. 2016. J Clin Oncol 34:557-565.
- Yang et al. 2018 Support Care Cancer. 26(1):41-60.