

Quality Training Program

Project title: Evaluation of the inclusion rate in clinical trials of bladder cancer patients evaluated for first time in Oncology Department

Presenter`s name: Fernando Moreno

Institution: Hospital Clínico San Carlos

Date: 8 April 2019

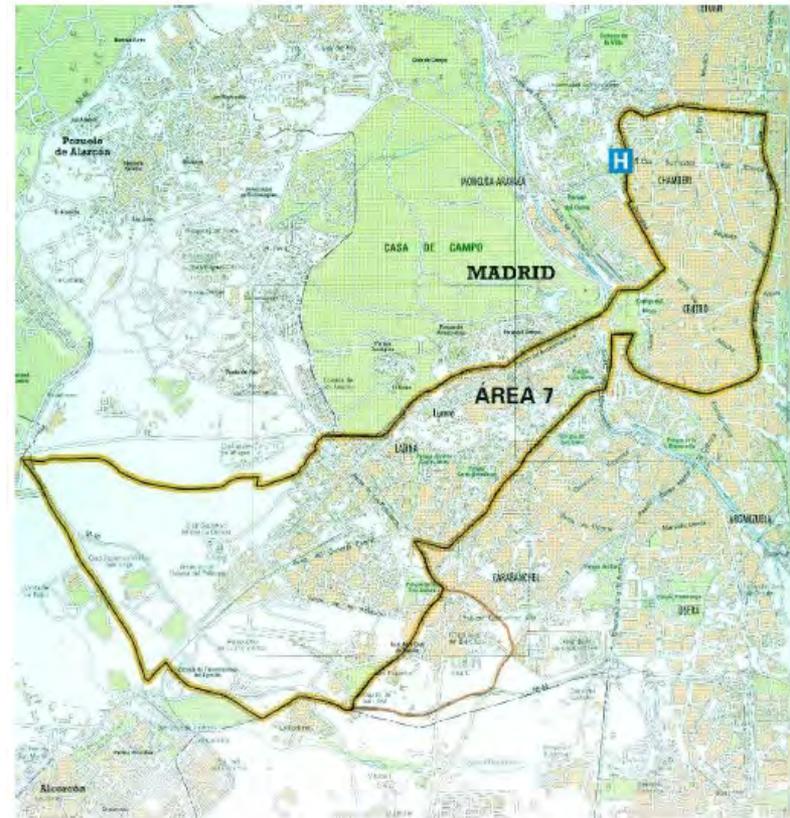
Team Members

- ✓ **Fernando Moreno:** Medical Oncologist.
- ✓ **M^a del Rosario Alfonso:** Oncologist. Coordinator of Clinical Research in Oncology Department
- ✓ **Lydia Suárez:** Study Coordinator in the Department of GU tumors
- ✓ **Javier Puente:** Medical Oncologist. Secretary of the genitourinary tumors board (GU board)
- ✓ **Pedro Pérez Segura:** Medical Oncologist. Head of Oncology Department
- ✓ **Concha Vila:** Oncology nurse
- ✓ **Marta Vígara:** Geriatrician

Institution Overview

- Public University Hospital
- Madrid. Spain.
- Population area: 364.345 habitants

Physicians	31
Head of Department	1
Head of Section	1
Physicians	14
Residents	15
Nurses	66
Administrative staff	3
Study coordinators	8
Laboratory members	8



Problem Statement

Cancer location	First visits (n)	Enrolled patients (n)	Ratio %
H&N	41	2	4.87
Brain	23	2	4.87
Gynecologic	77	17	22.07
Sarcomas & GIST	34	3	8.82
Thyroid	5	0	0
Unknown	12	3	25
Breast	290	63	21.72
Lung	152	29	19
Mesothelioma	2	0	0
Genitourinary	131	51	38.93
Melanoma	34	0	0
Colorectal	178	19	10.68
Digestive (non colorectal)	118	8	7.62
Others	16	0	0
Total	1113	197	17.68

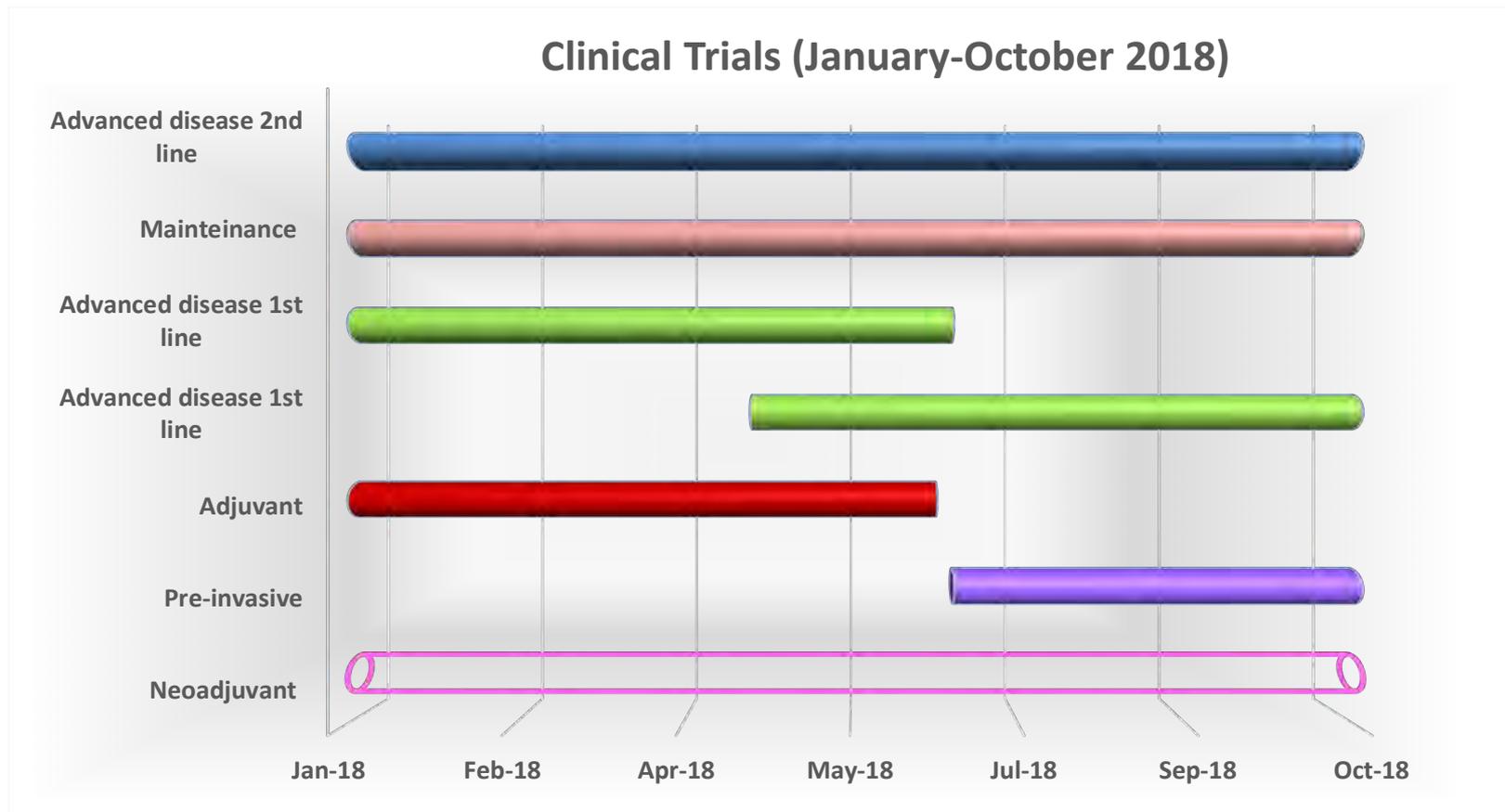
Problem Statement

- ✓ **Between January and November 2018 the percentage of patients with GU tumors enrolled in clinical trials was 39%**
- ✓ **Lower percentage of enrollment in clinical trials in Bladder cancer compared to other GU tumors.**
 - Prostate cancer 43%
 - Kidney cancer 47%
 - Bladder cancer 24%

Measures

- ✓ **Measure:** Enrollment rate in clinical trials.
- ✓ **Population:** Bladder cancer patients evaluated for the first time in the Oncology Department of HCSC
- ✓ **Methodology (metrics):**
 - Proposals of clinical trials (n)
 - Available trials (n)
 - Patients evaluated for the first time (n)
 - Patients enrolled in clinical trials (n)
 - Causes of non-enrollment & screening failures
 - Enrollment rate (patients enrolled/patients evaluated)
- ✓ **Data source:** Medical records and data base of clinical trials in the department of clinical research unit.
- ✓ **Data collection frequency:** january-october 2018.
- ✓ **Data quality:** paper medical record

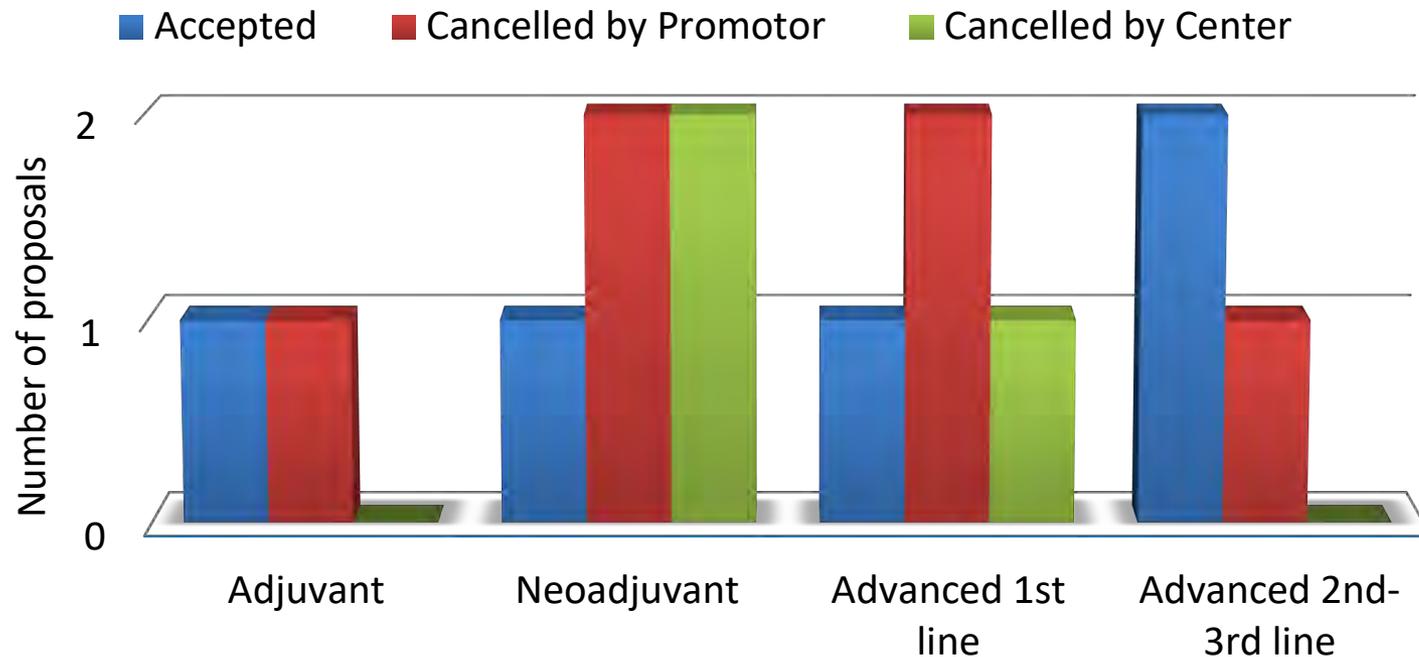
Diagnostic data: Available Clinical Trials



Diagnostic data : Clinical Trial Proposals (January-October 2018)

N= 14 proposals
Average:1.5 proposals/month

Accepted Trials N= 5
Cancelled Trials N=9
Cancellation rate: 64%

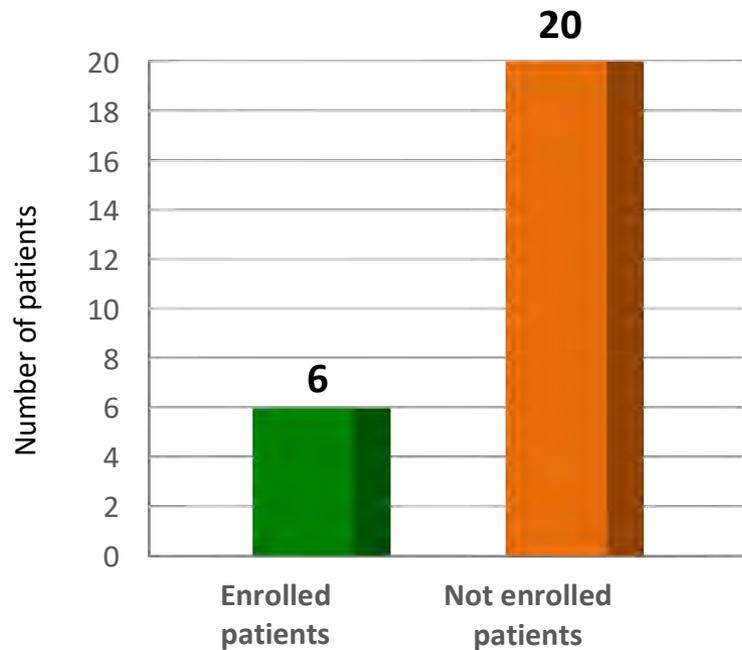


Diagnostic data: Patients Enrolled (January-October 2018)

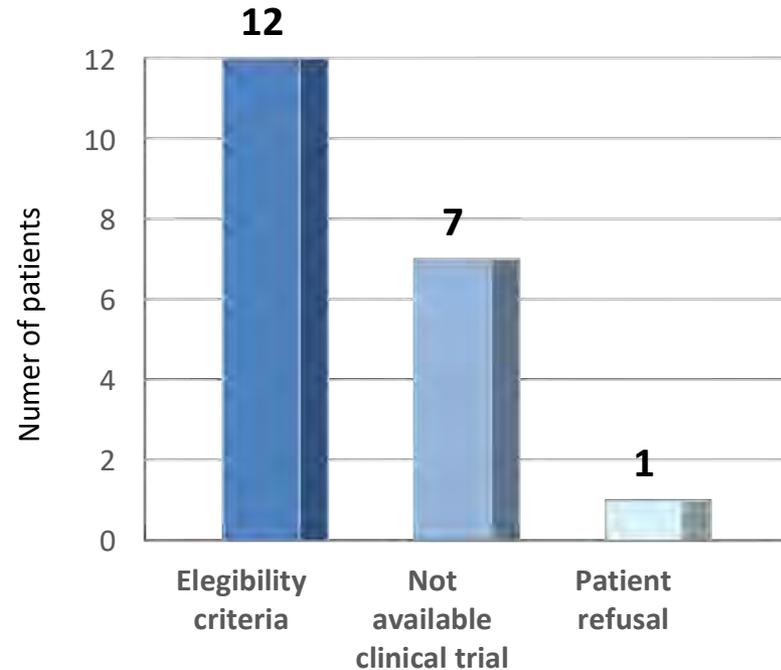
Average: 2.1 patients/month

Enrollment rate: 23%

Patients candidate for treatment
(N=26)

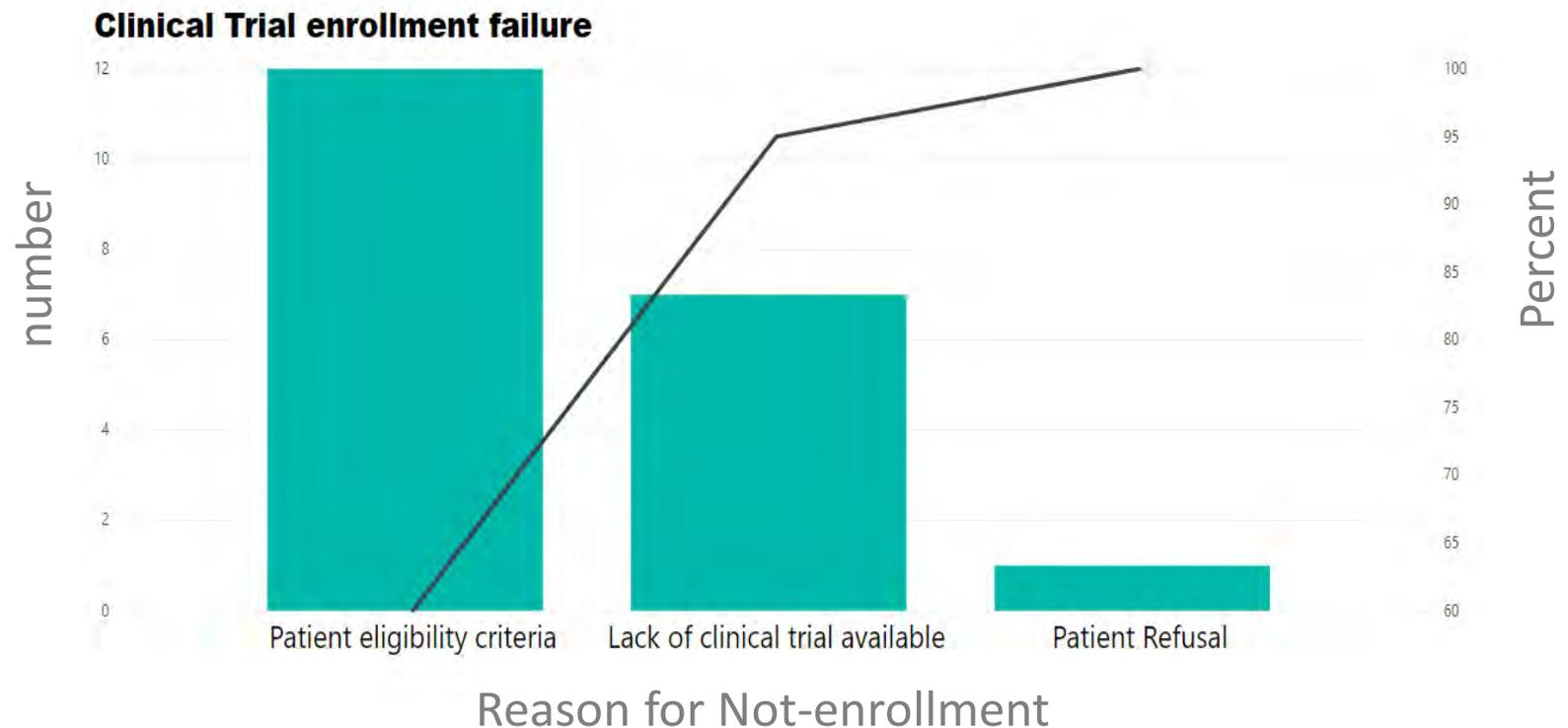


Patients not included in clinical trial
(N=20)

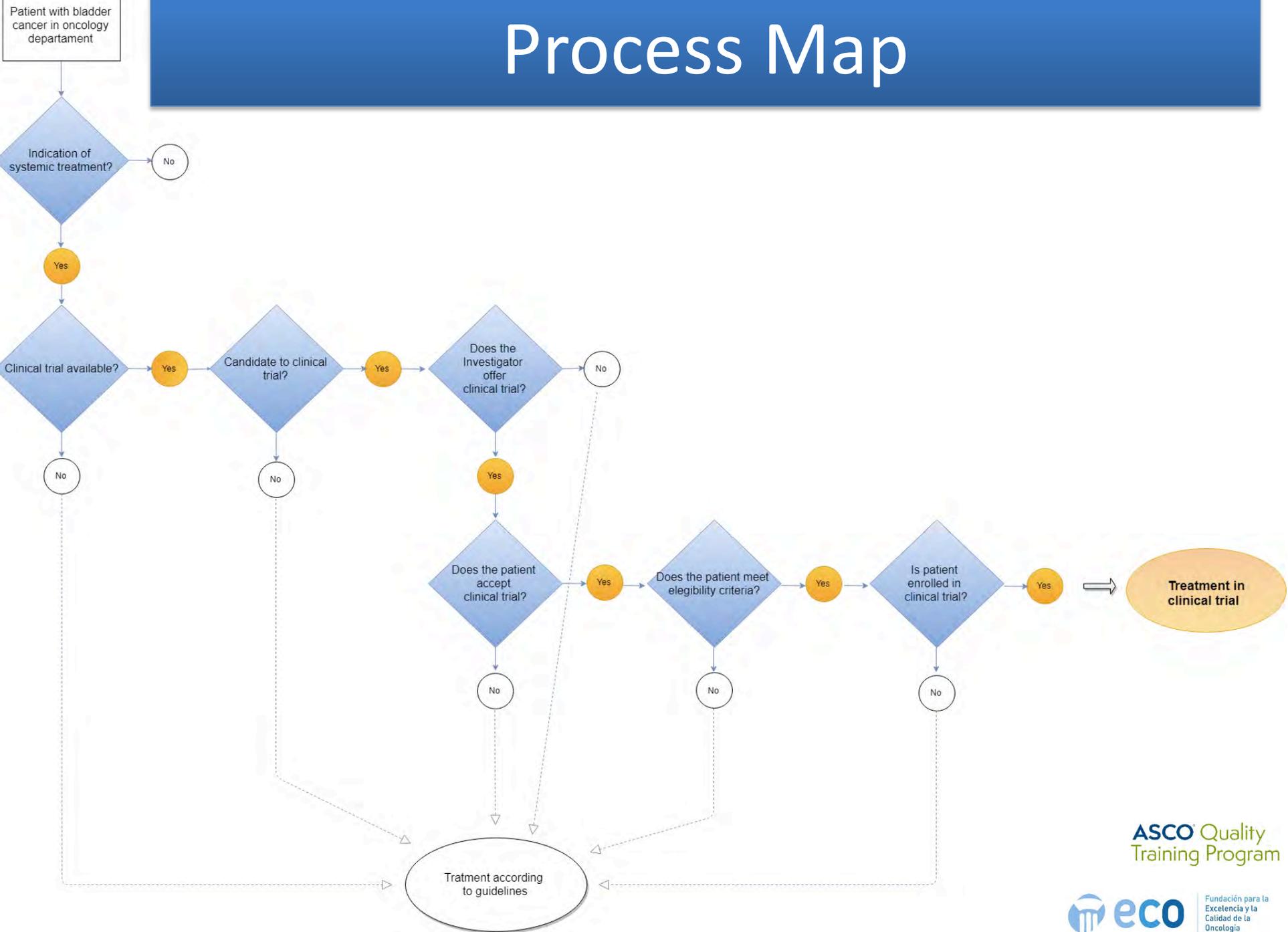


Pareto Chart

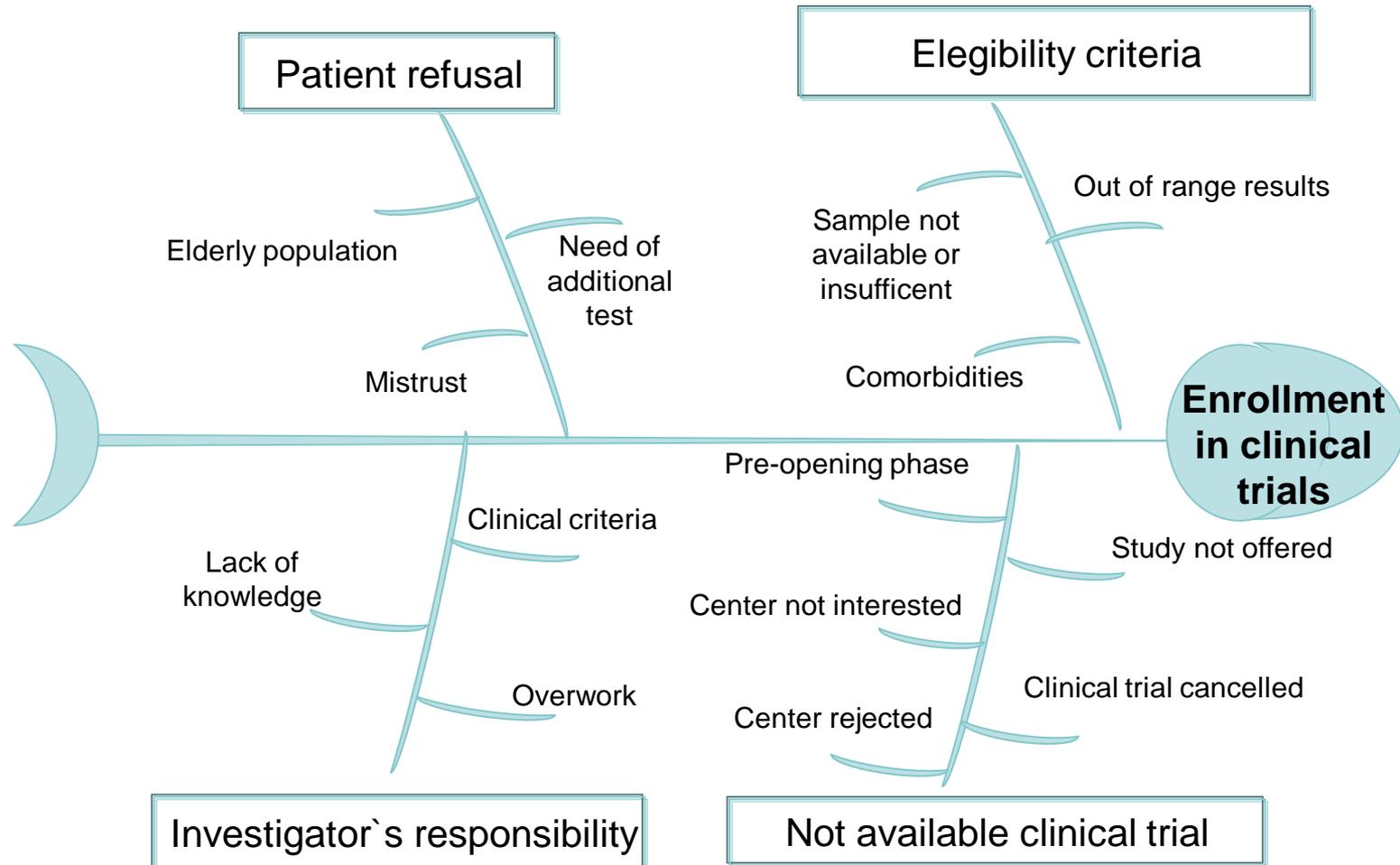
Patients Not-enrolled in clinical trials Jan-Oct 2018 (N=20)



Process Map



Cause & Effect Diagram

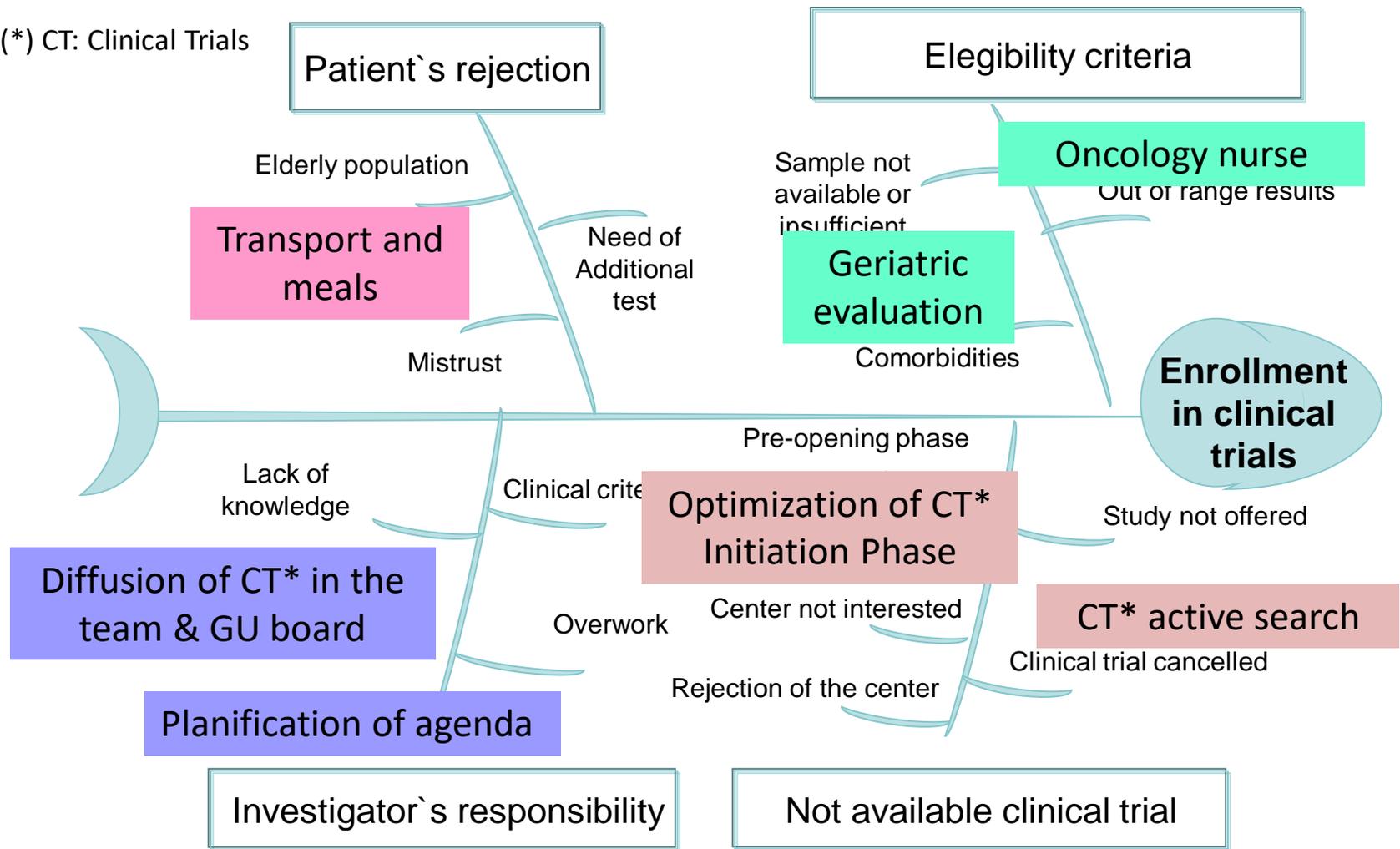


Aim Statement

To increase patients enrollment rate in bladder cancer clinical trials in Oncology Department of Hospital Clinico San Carlos, between November 2018 and March 2019 up to 30%.

Cause & Effect Diagram

(*) CT: Clinical Trials



Prioritized List of Changes (Priority/Pay –Off Matrix)

Impact	High	<p>Supportive care (nurses)</p> <p>Improvements in GU board</p>	<p>Geriatric assesment</p> <p>Active search of CT</p>
	Low	<p>Diffusion of Clinical Trials (other units, other centers)</p> <p>Diffusion of CT (Oncology Department)</p>	<p>Optimization of CT Initiation Phase</p> <p>Planification of Agenda</p> <p>Logistics: transport and meals</p>
		Easy	Difficult
		Ease of Implementation	

List of Changes: Support Program for cancer patients

Supportive care (nurses)

First visit:

- ✓ Evaluation
 - Symptoms
 - Comorbidities
 - Nutrition
 - Pain
 - Emotional situation
 - Medication
 - Family support
 - Social needs
- ✓ Treatment Plan

Follow-up visits

- ✓ Revision and update

Geriatric Oncology

Criteria:

- ✓ Age > 75 years
- ✓ Advanced disease
- ✓ Functional status ECOG ≤ 2
- ✓ Barthel Index >60
- ✓ Caregiver

First Visit

- ✓ Full Geriatric assessment
- ✓ Inform
 - Robust patient
 - pre-frail patient
 - Frail patient
- ✓ Improvement plan

Follow-up visits

PDSA Plan

Improvement in Performance Status of patients

Supportive care (nurses)

Geriatric Oncology

Date of PDSA Cycle	Description of Intervention	Results	Action Steps
From 01-11-2018 to 31-03-2019	Oncology nurse support	18 patients submitted	Maintain
From 08-01-2019 to 31-03-2019	Geriatric evaluation	4 patients submitted	Maintain

PDSA Plan

Increment available candidates

Diffusion of Clinical Trials

Date of PDSA Cycle	Description of Intervention	Results	Action Steps
01-11-2018 to 31-03-2019	<p>Review of clinical trials in the Investigation Unit</p> <p>Indicators: Active CT *, Follow-up CT*, New CT*, Proposals</p> <p>Tools: Data base of Clinical Research Unit</p>	<ul style="list-style-type: none"> ✓ Active CT*: 4 ✓ Follow-up CT*: 2 ✓ New CT*: 2 ✓ Proposals: 14 	Maintain
22-11-2018 to 31-03-2019	<p>Presentation of CT* in GU** board</p> <p>Indicators: Updates of CT*, new CT*</p> <p>Tools: Monthly report of GU** board</p>	<ul style="list-style-type: none"> ✓ Updates CT*: 5 ✓ New CT*: 2 ✓ Proposals (localized disease) : 2 	Maintain

(*)CT: Clinical Trials

(**) GU board: Genitourinary tumors board

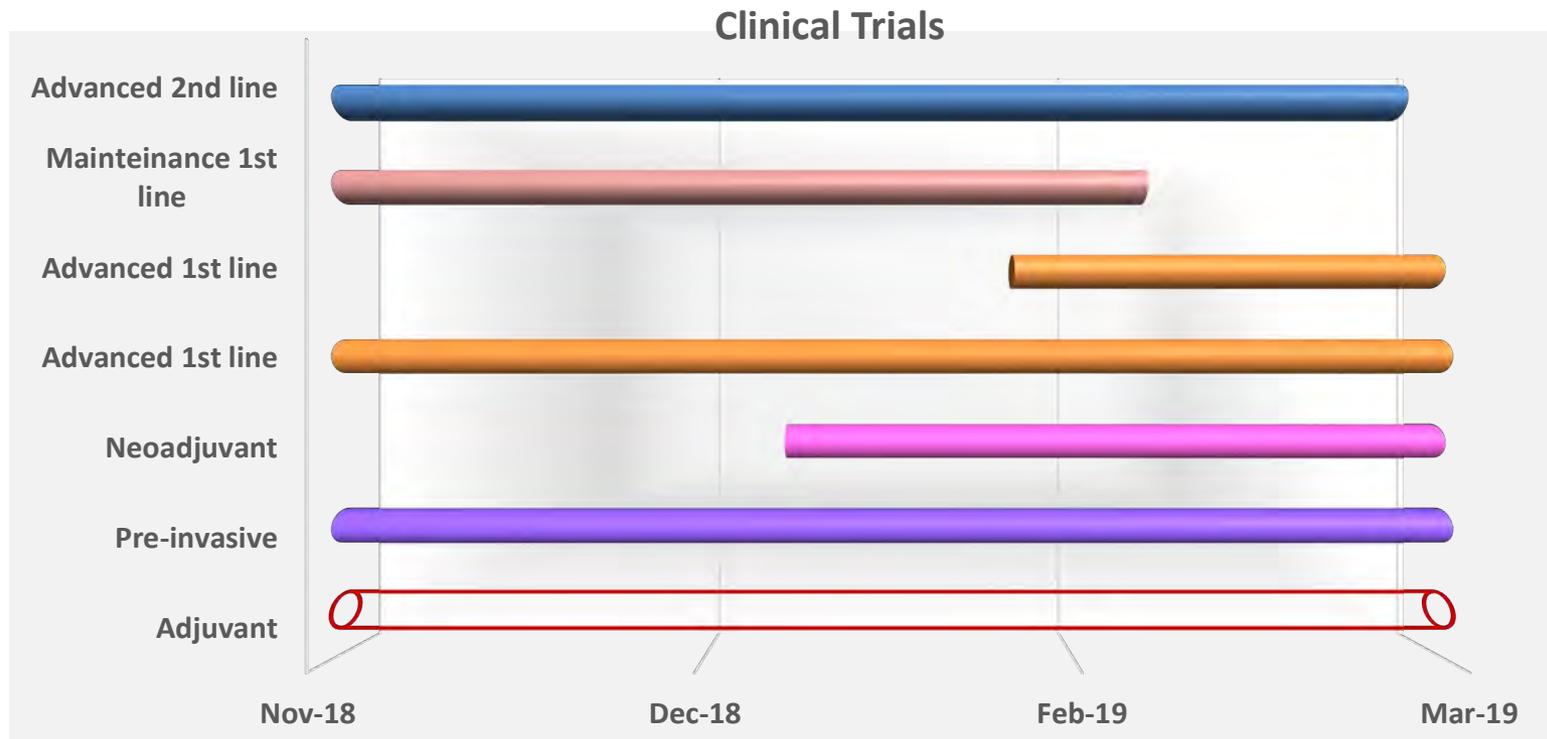
PDSA Plan

Increment available candidates

Improvements in GU board

Date of PDSA Cycle	Description of Intervention	Results	Action Steps
From 01-12-2018 to 27-03-2019	Indicator: number of patients with bladder cancer. Tools: Review of pathology report (weekly)	✓ 16 weekly reviews of pathology reports ✓ 26 patients with bladder cancer	Maintain
From 22-11-2018 to 28-03-2019	Indicator: number of patients with bladder cancer. Tools: Review GU board* minutes	✓ 17 weekly minutes ✓ 21 patients with bladder cancer	Maintain
From 22-11-2018 to 28-03-2019	Indicator: number of patients with bladder cancer candidates to Clinical trial Tools: Review of GU board* minutes	✓ 17 weekly minutes ✓ 14 patients candidates to clinical trial	Maintain

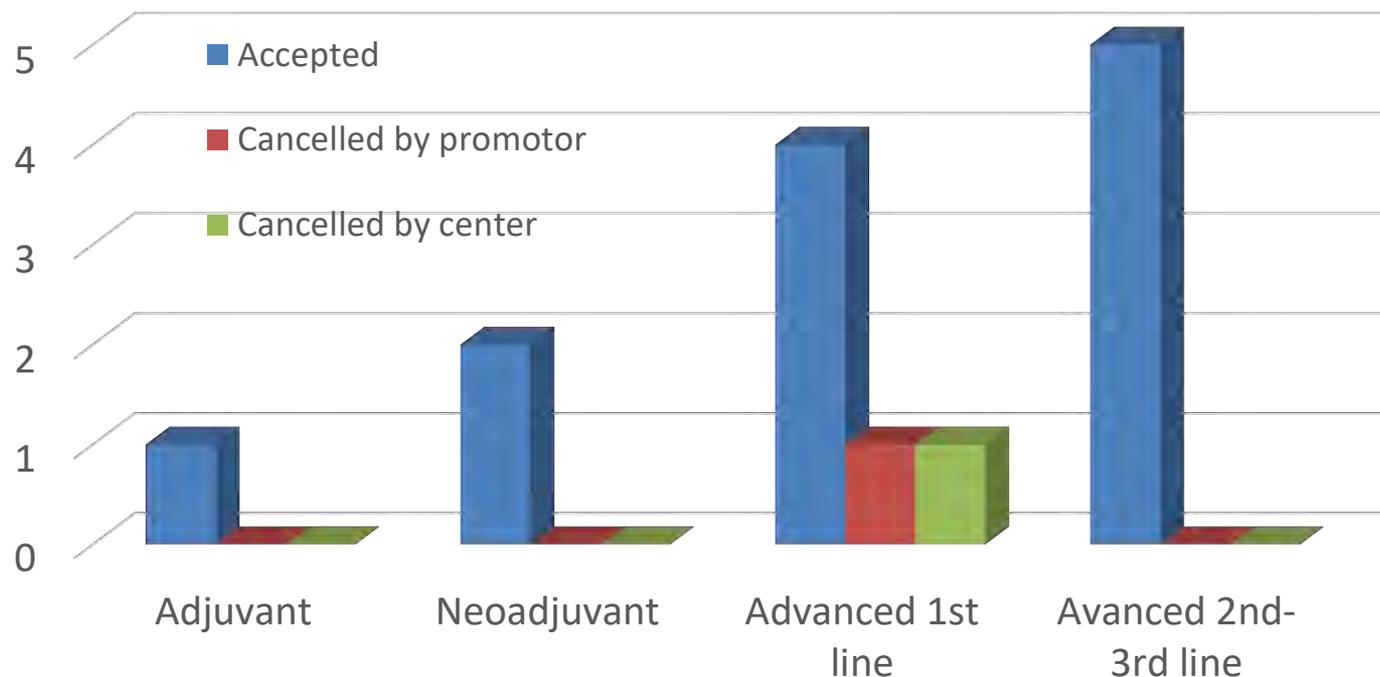
Indicators: Active clinical trials (November 2018-March 2019)



Indicators: Clinical Trials proposals (November 2018-march 2019)

N= 14 proposals
Average: 2,8 proposals/month

Accepted Trials N=12
Cancelled Trails N=2
Cancelation rate: 14%

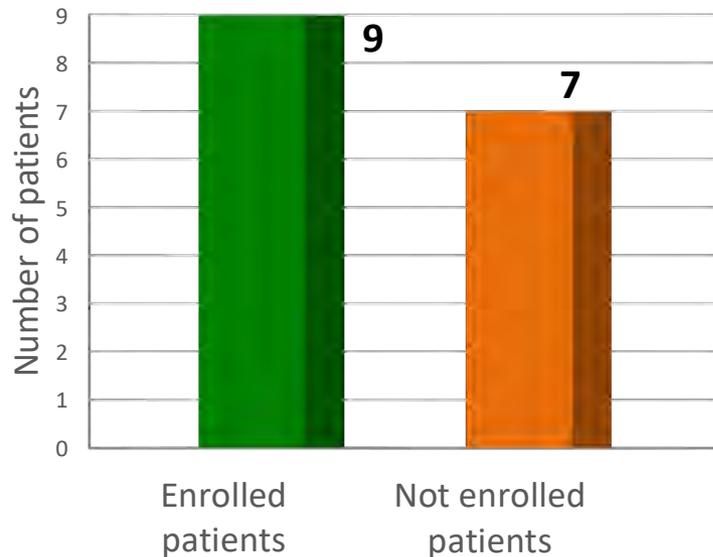


Change data (march 2019)

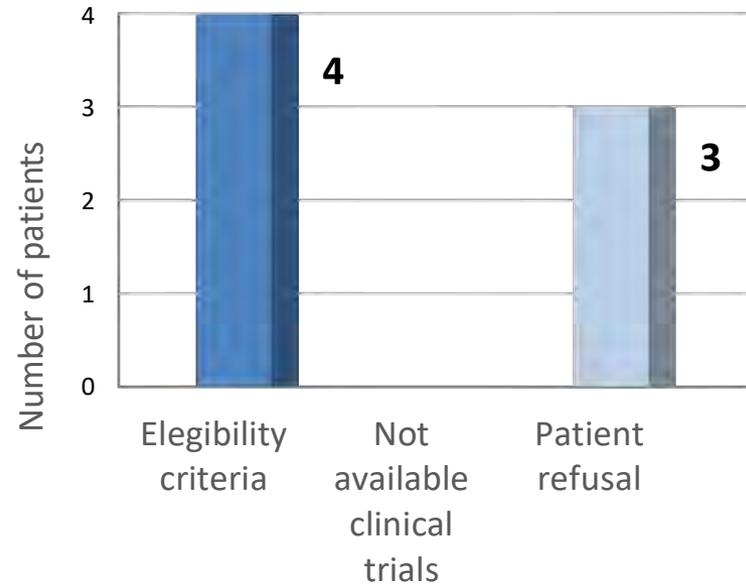
Average: 3.2 patients/month

Enrollment rate 43,75%

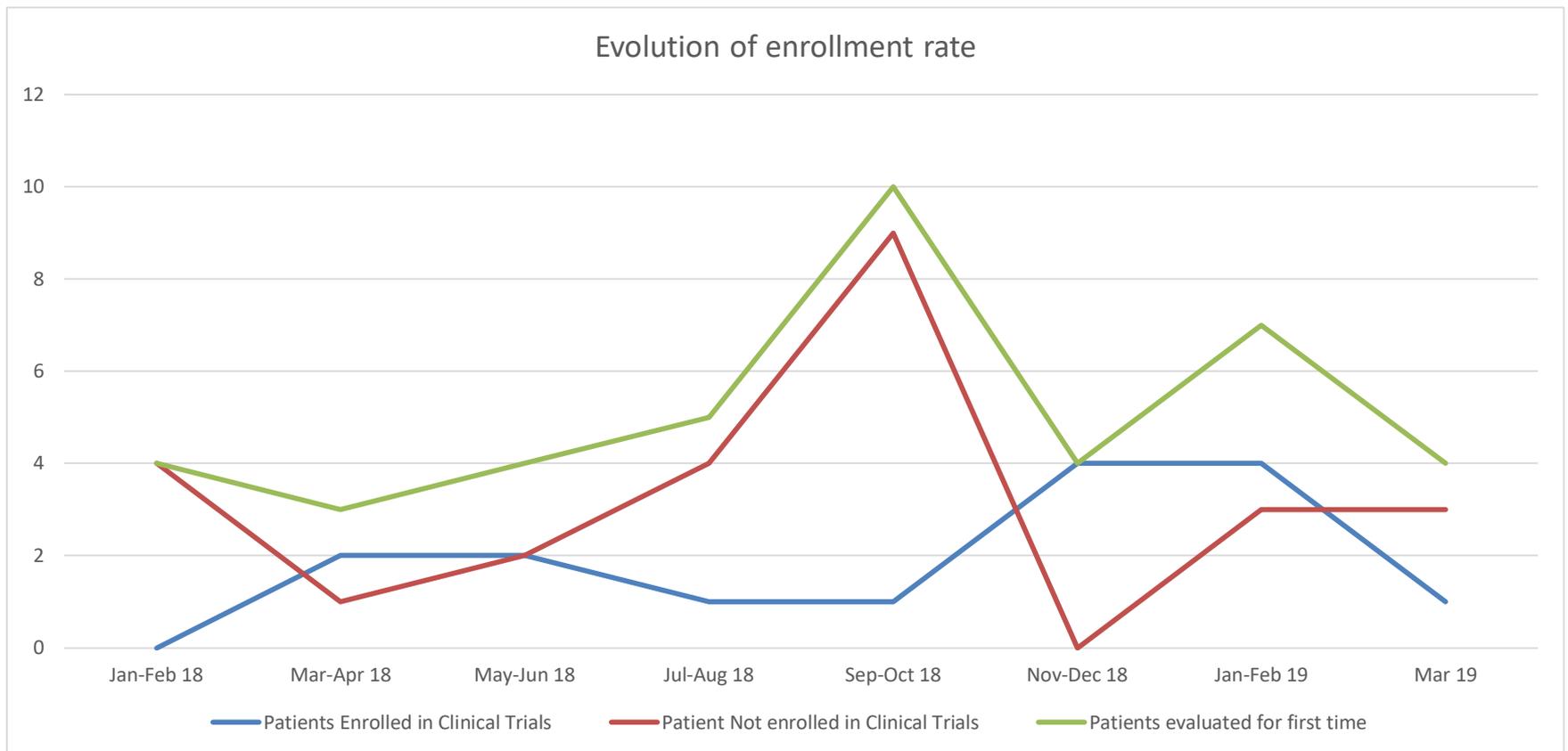
Patients candidate for
treatment n= 16



Patients not included in
clinical trials (n=7)



Evolution of enrollment rate (Jan 2018-march 2019)



Conclusions

After the introduction of changes we have observed:

- ✓ An increase of clinical trials monthly proposal rate **1.4 vs 2.8**
- ✓ A decrease of clinical trials cancellation rate **64% vs 14%**
- ✓ An increase in the number of first time evaluated patients with indication of systemic treatment **2.6 vs 3.2**
- ✓ A decrease in the percentage of not eligible patients **60% vs 25%**
- ✓ An increase in the percentage of patient`s rejection **5% vs 18%**
- ✓ An increase in the enrollment rate **23% vs 43.75%**