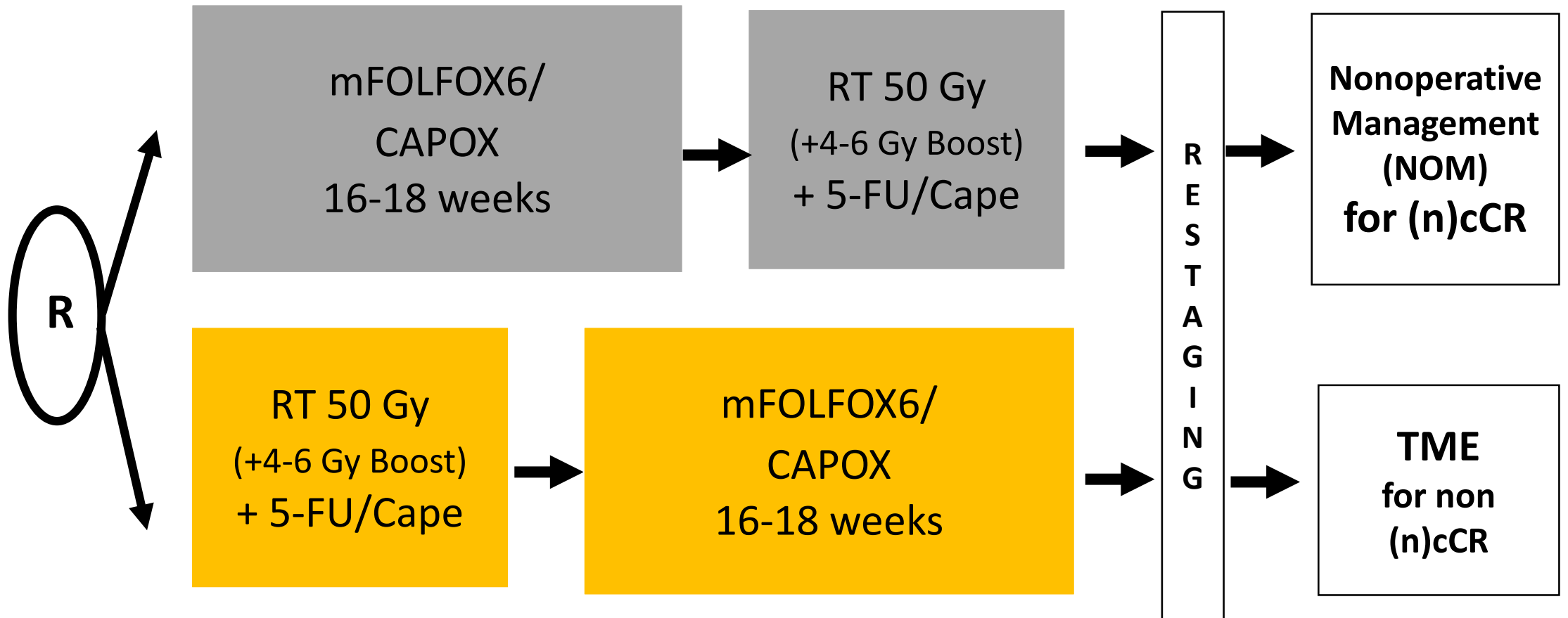


OPRA (Organ preservation in Rectal Adenocarcinoma-Trial)

UICC stage II and III, distal RC (requiring APR or coloanal anastomosis)



Primary Endpoint: **3y-DFS**: 85% compared to historical 75%; 80% Power, alpha=0.05, n=222

Secondary Endpoint: **3y-NOM** rate: 20% to 35%, n=333

OPRA: Baseline patients characteristics

	Inductionchemo - Chemoradiation N=158	Chemoradiation - Consolidation chemo N=166
Mediane age (IQR)	59 (51-68)	56 (49-67)
Female - %	35	39
cT-category – n (%)		
cT1-2	11 (7)	21 (13)
cT3	124 (78)	126 (76)
cT4	23 (15)	19 (11)
cN-category – n (%)		
cN0	47 (30)	47 (28)
cN+	111 (70)	119 (72)
Distance from AV (Median, cm)	4.3	4.5

OPRA: Treatment Adherence

	Inductionchemo - Chemoradiation N=158	Chemoradiation - Consolidation chemo N=166
Started chemotherapy – n (%)	156 (99)	156 (94)
Received FOLFOX Received 8 cycles	117 (74) 101/117 (86)	116 (70) 97/116 (84)
Received CAPEOX Received 5 cycles	33 (21) 28/33 (85)	34 (20) 30/34 (88)
Started radiotherapy	147 (93)	163 (98)
Median RT dose (IQR)	54 (50,4-54) Gy	54 (50,4-56) Gy
Median time from treatment start to restaging (IQR)	35 (33-37) wks	34 (32-37) wks

OPRA: Treatment toxicity

	Inductionchemo - Chemoradiation (n=158)		Chemoradiation - Consolidation chemo (n=166)	
	Grade 3/4	Grade 5	Grade 3/4	Grade 5
Any Adverse Event n (%)	54 (34) + 17 (11)	2 (1)	52 (31) + 11 (7)	3 (2)

OPRA: Oncological Results at 3 years (median F/u: 3 years)

	Inductionchemo - Chemoradiation N=158	Chemoradiation - Consolidation chemo N=166	p
DFS	76 %	76 %	0.63
M1-free Survival	84%	82%	0.83
TME-free survival	41%	53%	0.01

OPRA: W&W and local regrowth (median F/u: 3 years)

	Inductionchemo - Chemoradiation N=146	Chemoradiation - Consolidation chemo N=158
Recommended W&W at restaging	105 (71%)	120 (76%)
Developed local regrowth	42/105 (40%)	33/120 (27%)

OPRA: TME at restaging vs re-growth

	Inductionchemo - Chemoradiation (n=148)		Chemoradiation - Consolidation chemo (n=158)	
	TME restaging n=38	TME regrowth n=35	TME restaging N=33	TME re-growth N=27
Local recurrence	3 (8%)	4 (11%)	4 (12%)	5 (18%)
Distant recurrence	7 (18%)	6 (17%)	8 (24%)	5 (18%)
APR	16 (42%)	20 (57%)	16 (48%)	15 (56%)
LAR	22 (58%)	15 (43%)	17 (51%)	12 (44%)

Comparision OPRA vs ACO/ARO/AIO-18.1 (experimental arm)

- Inclusion Criteria: cT1-2N+, no subclassification cT3, low lying
- TNT: CRT-5-FU/Cape; consol. chemo 8 FOLFOX/5 CAPEOX vs 6/4
- Time interval from start TNT to restaging: **34-35 vs 22-24** weeks
- **W&W recommended for cCR and ncCR**

OPRA: Response and 3y-oncological outcomes

<i>Response after TNT (both arms)</i>	cCR N = 124	Near cCR N = 113	Non (n)CR N = 57
DFS (%)	84	76	52
Organ Preservation (%)	79	52	9
TME-free Survival (%)	72	44	4
OS (%)	97	93	90

International consensus recommendations on key outcome measures for organ preservation after (chemo)radiotherapy in patients with rectal cancer

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